Prostheses List
Post-Listing Review

Review of surgical guides and biomodels currently listed on the Prostheses List

Report to the Department of Health and Aged Care

FINAL REPORT

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Abbreviations

Abbreviation	Definition
AGR	annual growth rate
AHA	Australian Healthcare Associates
ANZAOMS	Australian and New Zealand Association of Oral and Maxillofacial Surgeons
APRA	Australian Prudential Regulation Authority
CMF	craniomaxillofacial
department	Australian Government Department of Health and Aged Care
DRG	diagnosis related group
HCP	hospital casemix protocol
ICD	International Classification of Disease
LOS	length of stay
MBS	Medicare Benefits Schedule
MDHTAC	Medical Devices and Human Tissue Advisory Committee
NHMRC	National Health and Medical Research Council
PBS	Pharmaceutical Benefits Scheme
PICO	population, intervention, comparator, outcome
PL	Prostheses List
PLAC	Prostheses List Advisory Committee
PSI	patient-specific implant
RCT	Randomised controlled trial
RoB	risk of bias
SGB	surgical guides and biomodels
TGA	Therapeutic Goods Administration
TMJ	temporomandibular joint
the review	review of surgical guides and biomodels (this review)
ToR	term of reference
VSP	virtual surgical planning

Glossary

Term	Meaning
Additive manufacturing	Additive manufacturing or 3-dimensional (3D) printing is the process by which 3D objects are created, layer by layer, from raw materials guided by a digital file. Although there is some disagreement in 3D printing terminology, generally, additive manufacturing describes large-scale, industrial-grade printers used to print at a commercial scale, whereas 3D printing describes smaller printing, using consumer-grade printers (e.g. for rapid prototyping or models) (e.g. De Maesschalck et al. 2017; Mason et al. 2019; Wang, Zhang, et al. 2016; Zhang et al. 2016).
Alveolar ridge augmentation	Surgical procedure to adjust the alveolar ridge (i.e. the bony ridge of the upper and lower jaws), to help improve the size and shape of the ridge in preparation for a dental implant (International Congress of Oral Implantologists n.d.).
Biomodel	Derived from patient imaging data to replicate the geometry or morphology (i.e. the form or shape) of a biological structure (Lohfeld et al. 2005). Biomodels are used to replicate a patient's anatomical structures which, in a clinical setting, can aid in visualising abnormal or disturbed anatomy, diagnosis, surgical treatment planning and simulation, patient education, designing and fabricating patient-specific prostheses, and can serve as an intra-operative anatomical reference, including for surgeries involving the placement of an implant or prosthesis. They can be either digital representations, or physical 3D-printed models.
Computer-assisted surgery	The use of computers for planning, performing or assessing surgery. This can include intraoperative navigation, the production of cutting and drill guides and 3D-printed models, as well as patient-specific implants (Schramm et al. n.d.).
Cutting guide	A surgical guide which is customised to a patient's anatomy to enable 'intra-operative reproduction of pre-planned osteotomy cuts' (Mcallister et al. 2018).
Hospital Casemix Protocol 1 Data	The Hospital Casemix Protocol 1 specified the financial, clinical and demographic data that hospitals must provide private health insurers and private health insurers must provide the Department, in respect of each episode of admitted hospital treatment for which a benefit has been paid.
Hospital separation	The administrative process by which a hospital records the cessation of an episode of care for a patient within one hospital stay (Australian Institute of Health and Welfare n.d.).
International Classification of Disease	ICD provides a method of classifying diseases, injuries and causes of death. It is the main basis for health recording and statistics in primary, secondary and tertiary care.

Term	Meaning
Orthognathic surgery	Corrective jaw surgery to 'realign disproportioned jaw bones to enable the best possible bite for mastication, speech and to balance the facial profile' (Australian and New Zealand Association of Oral and Maxillofacial Surgeons n.d.) Can be single or double jaw surgery.
Physical model	Models which are in solid physical form. These models often originate from virtual models and are produced through engineering technologies such as rapid prototyping (Lohfeld et al. 2005).
Rapid prototyping	Rapid prototyping is the "fast fabrication of a physical part, model or assembly using 3D computer-aided design (CAD). The part, model or assembly is usually completed using additive manufacturing, or more commonly known as 3D printing. Where the design closely matches the proposed finished product it is said to be a high fidelity prototype, as opposed to a low fidelity prototype, where there is a marked difference between the prototype and the final product" (TWI n.d.).
Stereolithography	An industrial 3D printing process that "uses a bath of photosensitive liquid which is solidified layer-by-layer using a computer-controlled ultra violet (UV) light" (TWI n.d.).
Surgical guide	Patient-specific tools that are designed to transfer the planned surgical and prosthetic components of a procedure to the actual surgery (Poitros and Pena 2016). They are used to guide the precise cutting of bone or drilling of holes as needed for implantation (Francoisse et al. 2020). They include surgical templates, pilot guides, cutting and drilling guides, splints and jigs.
Surgical splint	Orthognathic surgical splints are surgical guides used in single or double jaw surgery to guide the mobile jaw segments into their virtually planned dental occlusion. These may be used to implant patient-matched implants or standard plates (definition supplied by the MTAA).
Virtual model	A computer-based model developed 'for the purpose of visualisation of biological structures, for example a 3D based image of a skeletal structure generated from computed topography (CT) scans' (Lohfeld et al. 2005).
Virtual surgical planning	A planning procedure 'which uses digital clinical data for diagnostic, procedure selection and treatment planning purposes, including the forecast of potential outcomes' (Singh and Singh 2021). Surgical guides and biomodels may be produced as part of this process. Virtual surgical planning can be used in combination with other techniques such as 3-D printing, in order to produce implants and patient-specific surgical tools (Singh and Singh 2021) such as surgical guides or biomodels.

Consumer summary

In the context of this review, surgical guides and biomodels are devices – designed and manufactured according to a patient's own individual anatomy – that guide or support the implantation of a prosthesis (something that is surgically implanted to replace a body part or treat a medical condition or disease).

A number of different brands and types of surgical guides and biomodels are listed on the Prostheses List (PL). This listing means that when they are used in prosthesis implant surgeries for Australians with private health insurance, the insurance providers are required to pay a specified amount for them.

Since surgical guides and biomodels were first listed on the PL, their use has grown substantially. While they were originally listed for use in procedures involving the head and face (e.g. jaw surgeries and facial reconstructions), they are increasingly being used for procedures involving prostheses in other areas of the body. Their use across all categories has risen substantially over recent years. This means that private health insurers have had to pay more for these devices year by year, which could affect private health insurance premiums.

As part of a raft of changes and reforms to the PL, the Australian Government Department of Health and Aged Care (the department) asked Australian Healthcare Associates (AHA) to:

- analyse the current role and trends in use of the surgical guides and biomodels on the PL
- review the evidence that supports their use
- describe how they are currently used
- advise whether they meet the current eligibility criteria for listing on the PL.

AHA reviewed available evidence and spoke to key stakeholders to answer these questions. We found that:

- Surgical guides are frequently and appropriately used in complex surgeries involving prosthetic implants in difficult jaw surgeries and facial reconstructions.
- Biomodels are, overall, seen as less useful, but still play an important role in some circumstances.
- The use of surgical guides and biomodels has, on average, doubled each year since 2013-14.
- The available evidence generally supports the use of surgical guides and biomodels in a range of situations, but there have not been many high-quality studies that directly compare the results of surgeries performed with them to those performed without them.

- The use of surgical guides and biomodels is expected to continue and broaden as the technology improves and manufacturing costs reduce.
- The wording of some PL eligibility criteria is open to interpretation, making it hard to know if they are met or not met. For other criteria, we were able to say if they were met or not met by the surgical guides or biomodels listed on the PL, and under what conditions.

In this report, we discuss these issues and provide some suggestions to the department to consider.

Executive summary

In September 2022, the Department of Health and Aged Care (the department) commissioned Australian Healthcare Associates (AHA) to undertake a review of surgical guides and biomodels currently listed on the Prostheses List (PL).

This review was undertaken to inform the department whether the listed surgical guides and biomodels are eligible for PL listing, and if a further cost-effectiveness review is required.

This review considers the role of surgical guides and biomodels in clinical practice, utilisation patterns, and the evidence for their clinical benefits and clinical effectiveness, predominantly within craniomaxillofacial (CMF) and oral surgery.

There are currently 32 surgical guides and biomodels listed on the PL. All are listed in the 'plastic and reconstructive' product category, under 3 specific groupings:

- 07.02.02.04 Cranium – surgical guides
- 07.02.05.07 Mandible, Maxilla and Temporomandibular Joint (TMJ) – surgical guides
- 07.02.09 Anatomical biomodels.

Background and context

The PL lists the prostheses and related products that private health insurers must pay a benefit for and outlines the circumstances under which this benefit must be paid, and the amount of the benefit.

In the 2021-22 Budget, the Australian Government allocated $22 million over 4 years to improve the PL through a number of measures, including:

- clarifying the 'scope of the PL by defining which prostheses are eligible for inclusion and removing ineligible items'
- regularly reviewing products listed on the PL to address any post-listing issues (Department of Health and Aged Care 2022b).

As part of this reform, the Prostheses List Advisory Committee (PLAC) supported 4 device types to trial the newly-developed post-listing review framework. One of these device types was surgical guides and biomodels, which are the subject of this review.

Surgical guides and biomodels are "non-implantable, single-use devices used in planning and decision making both pre- and intra-operatively" (Department of Health and Aged Care 2022b).

Surgical guides are used to guide the precise cutting of bone or drilling of holes as needed for implantation (Francoisse et al. 2020). They include surgical templates, pilot guides, cutting and drilling guides, splints and jigs.

Biomodels are derived from patient imaging data to replicate the geometry or morphology (i.e. the form or shape) of a biological structure (Lohfeld et al. 2005). Biomodels can help clinicians to visualise abnormal or disturbed anatomy, and can therefore be useful for diagnosis, surgical treatment planning and simulation, patient education, and designing and fabricating patient-specific prostheses. They can also be used for reference while the surgery is being performed.

While surgical guides and biomodels are listed on the PL under the craniomaxillofacial (CMF) implants subcategory, they are used across a wide range of surgeries including oral, maxillofacial, cranial, neurological, orthopaedic, cardiovascular, urological, renal, and ear nose and throat (ENT) surgery. Their use is rapidly increasing across all categories, contributing to growing expenditure on prostheses.

Terms of reference

The terms of reference (ToR) for the review are:

1. Analyse the role in clinical practice of surgical guides and biomodels currently listed on the PL, including future trends in clinical use.
2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and clinical benefits.
3. Consider the current utilisation of surgical guides and biomodels listed on the PL.
4. Based on the findings of ToR 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.

Methodology

The methods and data sources used in this review are outlined below.

Desktop review

We conducted a desktop review of synthesised peer-reviewed literature (limited to systematic reviews and meta-analyses), publicly available and supplied grey literature, and other relevant documents (including product and clinical information) provided by the department, product sponsors and other stakeholders.

Stakeholder consultations

We interviewed a total of 38 individuals and accepted 9 written submissions. This included:

- 6 department representatives (via a group meeting).
- 13 oral and maxillofacial surgeons and 1 head and neck reconstructive surgeon (13 via interview or group meetings, and 1 via a written submission).
- 11 representatives from surgical and private health insurance peak bodies and technical organisations (via interview).
- 8 written submissions from 9 product sponsors. In addition, all sponsors were invited to an interview, with 8 representatives from 3 sponsors participating. One sponsor declined to participate in the review.

Submissions from sponsors

Sponsors were asked to provide evidence regarding the comparative clinical benefits and clinical effectiveness of their PL-listed surgical guides and biomodels; information on whether (and if so, why) surgical guides and biomodels are essential as an integral single-use aid for implanting a medical device, and whether the product has a unique and direct connection to the implantation of a prosthesis. We also sought information on the Australian Register of Therapeutic Goods registration status for each product.

All stakeholders consulted were given the opportunity to review and provide written feedback on the draft of this report. We received a total of 10 submissions and relevant feedback was incorporated into this final report.

Analysis of utilisation data

We analysed Hospital Casemix Protocol 1 (HCP1) data, publicly available Australian Prudential Regulation Authority (APRA) data and Medicare Item Reports data.

Systematic review

We conducted a systematic review to identify evidence on the comparative clinical effectiveness of the in-scope surgical guides and biomodels.

Key review findings

Information from review data sources was analysed and synthesised to produce this report. The key findings for each ToR are summarised below.

ToR 1: Role in clinical practice

1. Analyse the role of surgical guides and biomodels currently listed on the PL in clinical practice, including future trends in clinical use.

- Surgical guides are frequently used in complex CMF surgeries and have a range of benefits. While there are currently no clinical practice guidelines supporting their use, most stakeholders, including surgeons, considered surgical guides and biomodels part of the standard of care for complex CMF surgeries.
- Surgical guides are also used in less complex surgeries; however, surgeons and peak body representatives reported that they provide minimal clinical benefit in simpler procedures and questioned if their use was justified, especially in relation to cost.
- Overall, surgeons saw biomodels as less useful except in certain categories of CMF surgery, such as TMJ, trauma and oncology procedures where visibility of anatomical structures is hindered, when resection or reconstructive assistance is needed, or when adapting off-the-shelf plates for implantation.
- Stakeholders expect that the use of surgical guides and biomodels will continue to grow and broaden as the technology improves and manufacturing costs reduce.
- Surgeons also suggested that the recent growth in the use of surgical guides and biomodels is driven by improved patient outcomes, and the inclusion of surgical guides and biomodels as a core part of surgical training.

ToR 2: Evidence base

2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and clinical benefits.

- All studies identified in the **systematic review** related to only one of the in-scope products (ProPlan, now known as TruMatch). The majority of studies related to surgery in the oral and maxillofacial region. Various outcome measures were assessed in these studies. These include, but are not limited to, operative time, ischaemia time, complications and accuracy. Generally, the findings indicate improved or comparable outcomes for virtual surgical planning groups where surgical guides and/or biomodels had been used, when compared to the comparator group (e.g. surgery conducted with a freehand surgical technique).

- There are **limitations** in the included studies in the systematic review, for example, the sample sizes were generally small, there were no randomised controlled trials and 9 of the 13 studies were retrospective in design. Studies were also often confounded by interventions that included a 'bundling' of virtual surgical planning and various 3D-printed products, including surgical guides and biomodels but sometimes also patient-specific implants.

- The literature identified through the **desktop review** generally supports the use of surgical guides and biomodels across a range of contexts including oral and CMF applications (primarily dental implants), orthopaedics, cardiovascular surgery and ENT surgery, but almost invariably notes the paucity of randomised controlled trials and other comparative studies and other data quality limitations. The literature frequently suggests that the use of 3D technologies, including surgical guides and biomodels, produces results that are not inferior to 'conventional' techniques, and may facilitate potential improvements in accuracy of implant placement, decreased operative and/or ischaemic time, reduced intraoperative fluoroscopy and reduced complication rates.

ToR 3: Utilisation patterns

3. Consider the current utilisation of surgical guides and biomodels listed on the PL.

- When surgical guides and biomodels were initially listed on the PL in 2013–14, a total of s 47 items were used. This utilisation has, on average, doubled each year, and in 2020–21 a total of 7,488 items were used (67% of which were surgical guides).

- In 2020–21, the average number of surgical guides and biomodels per patient was 1.8 and 2.1 respectively. This has increased over time, driven in part by high numbers of items being used per patient in a small but growing number of cases.

- Surgical guides and biomodels are listed under the plastic and reconstructive product category, and were used solely in this category in 2013-14 and 2014-15. Since 2015-16, there has been increasing utilisation in other categories –for example, in 2020–21, 28% of total utilisation was outside the plastic and reconstructive category; more than half of this (15% of total utilisation) was attributable to orthopaedic procedures.

- While the PL benefit amount has not changed, the increase in utilisation has seen annual expenditure grow from s 47G in 2013–14 to $17,680,000 in 2020–21. Overall, biomodels account for 26% of expenditure and surgical guides for 74% for the 2013-14 to 2020-21 period.

ToR 4: Eligibility criteria

4. Based on the findings of ToR 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.

We used information from ToR 1, 2 and 3 to inform whether the listed surgical guides and biomodels meet the eligibility criteria for listing on the PL (Department of Health 2017). In relation to the 5 eligibility criteria, we made the following findings.

Criterion 1: The product must be entered and current on the Australian Register of Therapeutic Goods

Of the 32 products in scope for this review, 30 products are entered and current on the ARTG and the remaining 2 products are registered under transition arrangements. This criterion is therefore **met**.

Criterion 2: The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment

Based on the data we have reviewed, we understand all products have been provided to a person as part of an episode of hospital treatment or hospital-substitute treatment. This criterion is therefore **met**.

Criterion 3: A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)

Based on the data available, we understand that Medicare benefits were payable for all instances where benefits for the listed surgical guides and biomodels were paid. This criterion is therefore **met**.

However, it is difficult to determine the extent to which PL benefits paid for listed surgical guides and biomodels may be attributed to 'inappropriate' MBS item numbers (i.e. where the item number is not specific to the procedure in which the prosthesis is delivered), and this issue warrants further investigation.

Criterion 4: Essential to and specifically designed as an integral single-use aid for implanting a product

The clinical uses of listed surgical guides and biomodels was found to vary considerably, which, combined with a lack of clarity in the definition of several key terms (particularly 'essential' and 'integral') makes assessment of this criterion difficult.

Based on analysis, we have found that this criterion is:

- **not met** for surgical guides or biomodels when used in *procedures that do not involve implantation* of a prosthesis
- **met** for surgical guides and biomodels used for *complex CMF procedures*
- **not met** for surgical guides or biomodels for *simpler procedures*.

Examples of procedures that surgeons generally considered complex or simple are provided in Section 1.2 and Section 4.2. However, surgeons cautioned against blanket assumptions about the complexity of a given procedure type (as this depends on individual clinical circumstances), and highlighted the need for appropriate definitions of 'simple' and complex' procedures.

Criterion 5: The product has been compared to alternative products on the Prostheses List or alternative treatments and (i) assessed as being, at least, of similar clinical effectiveness; and (ii) the cost of the product is relative to its clinical effectiveness.

There is a paucity of high-quality evidence on the comparative clinical effectiveness or the cost effectiveness of the in-scope products. However, while the broader literature notes similar limitations, this review found support for the clinical effectiveness of surgical guides and biomodels *in general*, at least in the context of complex CMF surgeries.

As such, there is currently **insufficient evidence** to determine if criterion 5(i) or 5(ii) is met.

Stakeholder suggestions

Stakeholders suggested a number of **improvements to the PL** with respect to surgical guides and biomodels. These included: clarifying eligibility criteria; reviewing and revising PL sub-categories and product groups; restricting circumstances in which benefits are payable; reviewing benefits and claims arrangements; reviewing costs; considering the need for further and stronger evidence; and reviewing governance arrangements.

Conclusions

In our conclusion, we suggest that the department consider:

- Clarifying PL eligibility criteria (and giving examples of eligible and ineligible types and usage of surgical guides and biomodels). This could include the development of regularly updated guidelines driven by expert clinicians.
- Addressing some of the eligibility issues raised in the context of concurrent work, to reorganise or recategorise products currently listed on the PL.
- Clarifying the role of and pricing structures for surgical guides and biomodels supplied as individual products and as elements of 'kits' or bundles currently listed on the PL.
- Considering alternative funding structures for virtual surgical planning.
- In consultation with relevant clinical experts, placing limits on the benefits payable through the PL, for example:
  - specifying the MBS categories or items for which surgical guides and biomodels are eligible for benefits through the PL mechanism
  - limiting the number of surgical guides and biomodels for which a PL benefit is paid per separation
  - considering alternative approaches to listing of benefits, such as stratified or tiered approaches.
- Investigating, and taking actions to address, areas where benefits may be claimed inappropriately (e.g. in the absence of a prosthesis, or where the procedure could be performed outside of a hospital or hospital-substitute setting).
- Conducting an economic analysis (e.g. IHACPA review) to:
  - review the benefit amounts specified on the PL for the listed surgical guides and biomodels, for example to determine if the benefits listed on the PL are consistent with the cost of manufacture
  - explore whether the benefits paid are proportionate to other costs associated with implantation of prostheses (including other items supplied as part of kits)
  - determine whether the costs of products are comparable to the minimum prices available in the public sector and overseas.
- Exploring options for future consultation and governance arrangements to ensure any changes and guidance to the sector are appropriately informed by stakeholder input.

Report structure

This report is presented in 6 separate parts, as briefly outlined below. The report has been structured in this way to address the terms of reference (ToR) of the review.

Background: The background provides the context for the review and background information on surgical guides and biomodels currently listed on the Prostheses List.

Section 1 – ToR 1: Analyse the role in clinical practice of surgical guides and biomodels currently listed on the PL, including future trends in clinical use.

Section 2 – ToR 2: Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and clinical benefits.

Section 3 – ToR 3: Consider the current utilisation of surgical guides and biomodels listed on the PL.

Section 4 – **ToR 4:** Based on the findings of ToR 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.

Section 5 – **Conclusions:** Outlines a range of suggestions for the department.

Background

The review report is informed by a wide range of sources including scientific literature, data analysis and stakeholder input. Where stakeholders have provided confidential information, this information has been marked and redacted in this report.

B.1 The Prostheses List

The Prostheses List (PL) was first established in 1985 to regulate the price that privately insured patients paid for prostheses, and to reduce hospital waiting lists for surgical procedures involving implanted prostheses (Parliament of Australia 2017).[1]

The PL lists the prostheses and related products that private health insurers must pay a benefit for, the circumstances under which this benefit must be paid, and the amount of the benefit.

Since its inception, the PL has been subject to a number of reforms. Most recently, the 2021-22 Budget allocated $22 million over 4 years to improve the PL through a number of measures, including:

- clarifying the 'scope of the PL by defining which prostheses are eligible for inclusion and removing ineligible items' (Department of Health and Aged Care 2022b)
- regularly reviewing products on the PL to address any post-listing issues.

As part of implementing these measures, the Department of Health and Aged Care (the department) developed a framework detailing the processes for conducting post-listing reviews (Department of Health and Aged Care 2022b). The Prostheses List Advisory Committee (PLAC) supported 4 device types to trial the post-listing review framework. One of these device types was surgical guides and biomodels, which are the subject of this review.

[1] The PL is the schedule to the *Private Health Insurance (Prostheses) Rules*, which is the legislative instrument made under the *Private Health Insurance Act 2007* (Department of Health and Aged Care 2022a). In line with Section 72-1 of this Act, private health insurers must pay a benefit for the products listed on the PL.

Surgical guides and biomodels

Surgical guides and biomodels are 'non-implantable, single-use devices used in planning and decision making both pre- and intraoperatively' (Department of Health and Aged Care 2022b).[2] They are used across a wide range of surgeries including oral, maxillofacial, cranial, neurological, orthopaedic, cardiovascular, plastic and reconstructive, urology and renal, and ear nose and throat (ENT) surgery.

Surgical guides are tools designed to transfer the planned surgical and prosthetic components of a procedure to the actual surgery (Poitros and Pena 2016). They are contoured to each patient's specific anatomy and are designed to avoid critical structures. This enables precise cutting of bone or drilling of holes as needed for the accurate placement of an implant in a pre-planned location (Francoisse et al. 2020). Surgical guides include surgical templates, pilot guides, cutting and drilling guides, splints and jigs.[3]

Biomodels are derived from patient imaging data to replicate the geometry or morphology (i.e. the form or shape) of a biological structure (Lohfeld et al. 2005). They can help clinicians to visualise abnormal or disturbed anatomy and are used for diagnosis, surgical treatment planning and simulation, patient education, and designing and fabricating patient-specific prostheses. They can also serve as an intraoperative anatomical reference, including for surgeries involving the placement of an implant or prosthesis.

Biomodels can be either digital representations (virtual models) or physical models; however, the only biomodels listed on the PL – and therefore in scope for this review – are physical models.

[2] While this definition groups surgical guides and biomodels together, they are separate products with different applications, and this review therefore considers them separately where appropriate.

[3] While generally not 'implanted', surgical guides are often temporarily fixed to a patient's anatomy during surgery to guide the procedure. Stakeholders reported that, in some cases, surgical guides may remain in position after surgery.

Criteria for listing

The process and criteria for listing products on the PL, and for setting the benefit, are outlined in *Prostheses List: Guide to listing and setting benefits for prostheses* (PL guide) (Department of Health 2017). For a product to be listed on the PL, or for a listing to be modified, a product sponsor (typically the supplier) must submit an application to the department. Applications are assessed by the PLAC, who makes recommendations about which products should be included on the PL.[4] The PL is updated 3 times a year (in March, July and November); at the time this review was conducted, the latest version was 1 November 2022.

The PL is currently separated into 4 parts (A, B, C and D), which collectively contain more than 11,000 products.[5] Part A lists products that are surgically implanted, and associated products such as surgical guides and biomodels. Surgical guides and biomodels were first added to the PL in 2013-14, and there were 32 in-scope products listed at the time of this review.

The criteria for listing in Part A are detailed below. Criteria 1 to 3 are mandated by legislation, and criteria 4 and 5, while not legislatively based, need to be fulfilled in order for a product to be listed, as agreed by PLAC.

1. The product must be entered and current on the Australian Register of Therapeutic Goods
2. The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment
3. A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)
4. A prosthesis should:
   (a) be surgically implanted in the patient and be purposely designed in order to
      (i) replace an anatomical body part; or
      (ii) combat a pathological process; or
      (iii) modulate a physiological process;

   Or

   (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted
5) The product has been compared to alternative products on the Prostheses List or alternative treatments and
   (i) assessed as being, at least, of similar clinical effectiveness; and
   (ii) the cost of the product is relative to its clinical effectiveness.

[4] The decision to grant or not grant an application is made by the Australian Government Minister for Health.

[5] Part D lists general use items from Part A to be removed from the Prostheses List on 1 July 2023.

Product categories, groupings and benefits

The PL is divided into product categories, subcategories, groups and sub-groups, based on clinical use and effectiveness.

All surgical guides and biomodels currently on the PL are listed in Part A under the same product category (07 – Plastic and reconstructive) and sub-category (07.02 – CMF implants).

- Biomodels are listed in their own product group: 07.02.09 – Anatomical biomodels.
- Surgical guides are listed in their own subgroups under the relevant anatomical product groups:
  - 07.02.02 – Cranium
    (subgroup 07.02.02.04 – surgical guides, suffix 'biomodelled')
  - 07.02.05 – Mandible, Maxilla and Temporomandibular Joint (TMJ)
    (subgroup 07.02.05.07 – surgical guides, suffix 'biomodelled').[6]

The maximum benefit amount for each product is determined by the product grouping (including the subgroup and suffix, if applicable). While every product is given a unique billing code, each product grouping has a single group benefit – though sponsors can choose to list at a lower benefit.

Because they are based on clinical use, the PL product categories and groupings have some relationship to the MBS clinical categories; however, the PL guide acknowledges that 'some products may fit into more than one category' (Department of Health 2017, p. 49).

Increased usage

In recent years, prostheses have become one of the fastest growing areas of private health expenditure (Harris and Lim 2021). There are concerns that this growth could have wider impacts on the health care system: for example, a report from Private Healthcare Australia suggests that it could result in increased private health insurance premiums, which could consequently lead people to opt out of private health insurance, reducing healthcare funding availability and exacerbating pressure on the public health system (Harris and Lim 2021).

The use of surgical guides and biomodels is also rapidly increasing, contributing to the growing expenditure on prostheses mentioned above. Between 2016–17 and 2020–21, the total annual benefit paid for surgical guides and biomodels increased from $1.9 million to $17.2 million (Department of Health and Aged Care 2022b).

[6] Three surgical guides in scope for this review are also listed in other anatomical groups: 1 product under 07.02.06 – Nose and Zygoma (subgroup 07.02.06.06 – surgical guide) and 2 products under 07.02.07 – Orbit (subgroup 07.02.07.05 – surgical guide).

B.1 About this review

The department commissioned Australian Healthcare Associates (AHA) to undertake a review of surgical guides and biomodels currently listed on the PL.

The review was undertaken to inform the department whether the listed surgical guides and biomodels are eligible for PL listing, and if a further cost-effectiveness review is required.

This review considers the role of surgical guides and biomodels in clinical practice, utilisation patterns, and the evidence for their clinical benefits and clinical effectiveness.

B.1.1 Products covered by this review

This review covers all 32 surgical guides and biomodels on the PL as of November 2022. A full list of these products is provided in Appendix B.

B.1.2 Terms of reference

1. Analyse the role in clinical practice of surgical guides and biomodels currently listed on the PL, including future trends in clinical use.
2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and clinical benefits.
3. Consider the current utilisation of surgical guides and biomodels listed on the PL.
4. Based on the findings of ToR 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.

B.1.3 Methodology

An overview of the methodology and data sources for addressing each of the terms of reference are outlined in Table 1 and described in more detail below.

Table 1: Methodology and data sources

Method	Data sources	ToR
Desktop review	• Documents provided by the department • Publicly available and supplied academic and grey literature, including study reports, product information, clinical guidance and other relevant documents	1, 2, 3, 4
Stakeholder consultations and submissions	• Interviews with surgeons and relevant organisations • Additional documentation provided by stakeholders • Submissions from sponsors • Stakeholder feedback on draft report	1, 3, 4
Systematic review	• Peer-reviewed literature (identified through a MEDLINE search and stakeholder submissions and meeting pre-defined inclusion criteria)	2, 4
Analysis of utilisation data	• Utilisation data provided by the department (an extract of Hospital Casemix Protocol 1 data) • Utilisation data publicly available through Australian Prudential Regulation Authority • Medicare Item Reports publicly available through Services Australia • Publicly available supplied grey literature on utilisation	3, 4
Synthesis and triangulation	• All data sources and analysis for ToR 1, 2 3 and 4	4

B.1.3.1 Desktop review

We undertook a desktop review to inform all ToRs. The purpose of this review was to:

- develop a deeper understanding of the clinical role of surgical guides and biomodels in general
- gain insight into the application of the in-scope surgical guides and biomodels in particular
- explore the extent to which the surgical guides and biomodels currently listed on the PL align with the eligibility criteria outlined in the PL guide.

This review considered a range of documents and data, including:

- documents provided by the department, sponsors and stakeholders
- utilisation data provided by the department
- publicly available and supplied grey literature
- synthesised, peer-reviewed literature.

B.1.3.2 Stakeholder consultations

Interviews explored stakeholders' perspectives on:

- the clinical circumstances in which surgical guides and biomodels are used
- the benefits of surgical guides and biomodels
- patterns of use and anticipated future trends
- the extent to which surgical guides and biomodels fulfil the criteria for inclusion on the PL
- the evidence that supports the use of surgical guides and biomodels
- what surgical guides and biomodels should be included/excluded from the PL.

The department provided AHA with a list of stakeholders to approach for participation in this review. We interviewed a total of 38 stakeholders (see Appendix A), including:

- 6 department representatives (via a group meeting)
- 14 surgeons (we also received a written submission from one additional surgeon)
- 11 representatives from 8 peak bodies (surgical, medical technology, private hospital and private health insurance) and technical organisations
- 8 representatives from 3 product sponsors who took up the opportunity of an interview in addition to providing written submissions (see below).

All stakeholders consulted were given the opportunity to review and provide written feedback on the draft of this report. We received a total of 10 submissions and relevant feedback was incorporated into this final report.

B.1.3.3 Submissions from sponsors

Submissions were received from 8 of the 9 sponsors. Sponsors were asked to provide:

- Evidence regarding the comparative clinical benefits and clinical effectiveness of surgical guides and biomodels, when compared to 'standard care' or surgery without their use, for consideration in our systematic and desktop reviews.
- Information on the current role of surgical guides and biomodels in clinical practice, including whether (and if so, why) they are essential as an integral single-use aid for implanting a device and have a unique and direct connection to the implant.
- The ARTG identification number for each product, or advice as to where the product is in the medical device inclusion process.

Sponsors were also asked to identify any commercial-in-confidence information, which has been redacted in this report.

B.1.3.4 Systematic review

We conducted a rapid and targeted systematic review to inform both ToR 2 and 4. The purpose of this review was to identify evidence on the comparative clinical effectiveness of the in-scope surgical guides and biomodels. See Section 2 for details.

B.1.3.5 Analysis of utilisation data

We analysed Hospital Casemix Protocol (HCP1) data, Australian Prudential Regulation Authority (APRA) data and Medicare Item Reports to inform ToR 3 and 4. See Section 3 for details of the data used.

Section 1: ToR 1 – Role of surgical guides and biomodels in clinical practice

1. Analyse the role of surgical guides and biomodels currently listed on the PL in clinical practice, including future trends in clinical use.

1.1 Key findings for ToR 1

- Surgical guides are frequently used in complex CMF surgeries and have a range of benefits. While there are currently no clinical practice guidelines supporting their use, most stakeholders, including surgeons, considered surgical guides and biomodels part of the standard of care for complex CMF surgeries.
- Surgical guides are also used in less complex surgeries; however, surgeons and peak body representatives reported that they provide minimal clinical benefit in simple procedures and questioned if their use was justified, especially in relation to cost.
- Overall, surgeons saw biomodels as less useful than surgical guides, except in certain categories of CMF surgery such as TMJ, trauma and oncology procedures where visibility of anatomical structures is hindered; when resection or reconstructive assistance is needed; or when adapting off-the-shelf plates for implantation.
- Stakeholders expect that the use of surgical guides and biomodels will continue to grow and broaden as the technology improves and manufacturing costs reduce. Surgeons also suggested that increased use of surgical guides and biomodels is driven by improved patient outcomes, and the inclusion of surgical guides and biomodels as a core part of surgical training.

1.2 Clinical use

Surgical guides and biomodels are used in guided implant surgery, which makes use of a range of digital technologies and incorporates **virtual surgical planning**. Guided implant surgery uses digital imaging to create a virtual biomodel of a patient's anatomy. This model is then used in virtual surgical planning to prepare and test treatment options, design a precise surgical plan and create customised implants and patient-specific tools such as surgical guides or physical biomodels used during surgery (Singh and Singh 2021). While the details can vary between surgeons, manufacturers and products, Figure 1 outlines the general process.

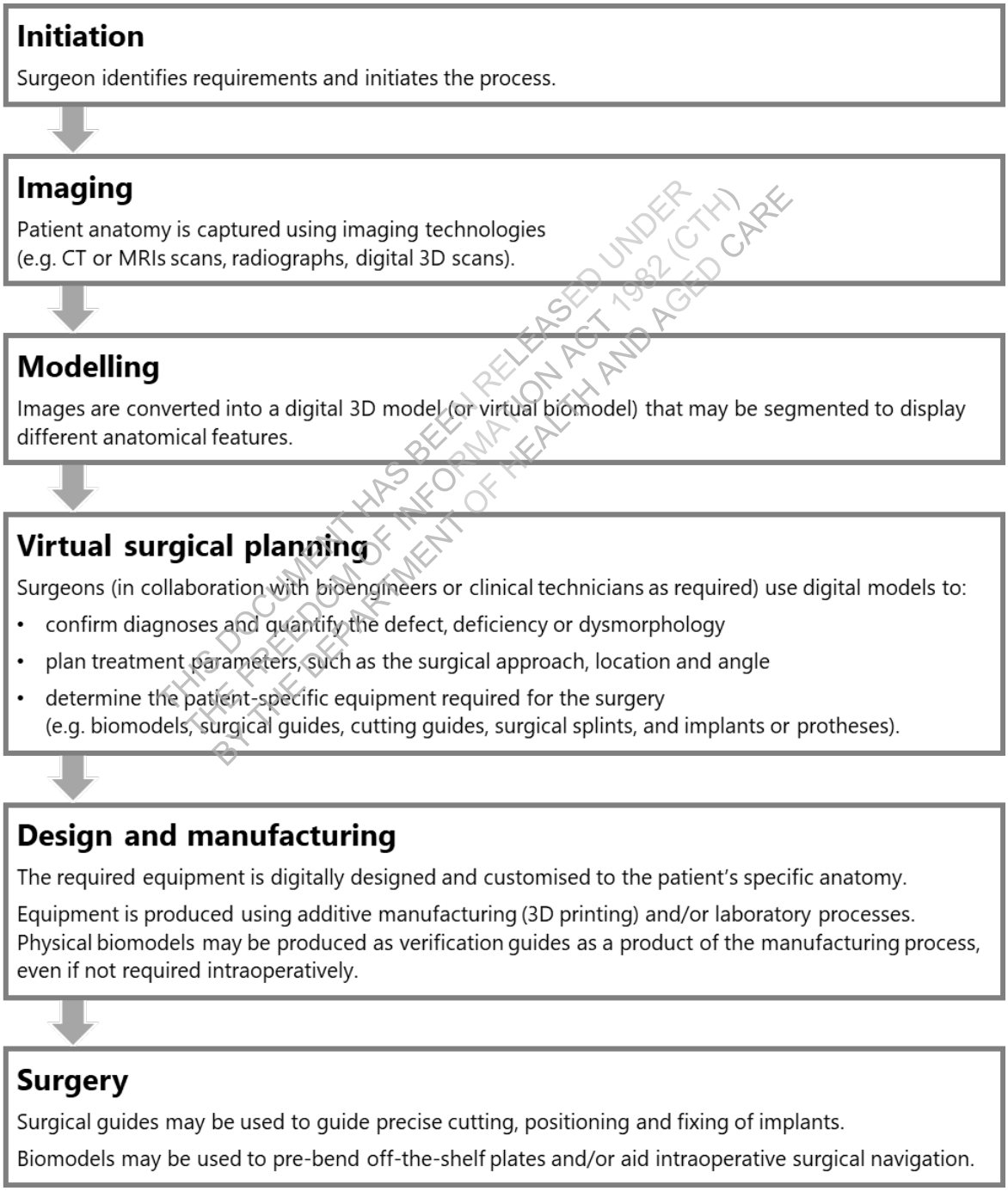

Figure 1: Process for guided implant surgery (incorporating virtual surgical planning)
Adapted from Ghantous et al. (2020)

Surgeons told us that the development of guided implant surgery and virtual surgical planning has improved the way they plan and undertake complex surgeries.[7] Before these technologies were available, surgeons would examine X-ray images and, in some instances, create plaster models to visualise anatomy prior to and during surgery. They then relied on their freehand skill to position implants. The use of virtual planning processes, surgical guides and biomodels has helped to improve surgical processes and clinical outcomes, as described below.

Benefits of surgical guides and biomodels

The use and perceived benefit of surgical guides and biomodels depend on multiple factors, including the clinical circumstances, the surgeon's experience and clinical judgement, and the products themselves.

In general, stakeholders reported that surgical guides and biomodels simplify complex procedures, taking the 'guess work' out of surgery by enabling visualisation of internal structures, leading to improved accuracy and fewer errors. Key benefits are outlined below.[8]

More efficient and effective surgical procedures:

- Avoid disturbing anatomic structures
- Guide the placement and angles of implants in difficult-to-reach places
- Minimise tissue manipulation or opening flaps (in most procedures)
- Facilitate faster surgery
- Reduce the overall number of surgeries (because of the ability to combine complex surgeries within the one procedure without the need for multiple admissions)

Improved clinical outcomes:

- Reduce incidence of revision surgery
- Optimise aesthetics and functional outcomes (such as chewing)
- Reduce complication rates

Reduced burden on hospitals and the health system:

- Achieve cost savings due to reduced theatre time and bed days saved
- Reduce the time needed for surgeons to develop the required skills and knowledge to perform implant surgeries[9]

[7] Product sponsors forwarded a total of 23 letters from surgeons supporting the use of surgical guides and outlining a range of benefits for both patients and surgeons.

[8] Conflicts of interest were reported by 3 surgeons and did not appear to influence their responses given the overall consistency in feedback across stakeholders.

[9] One surgeon suggested that the skills required for guided implant surgery could be developed in just one year of on-the-job clinical experience, as opposed to 10 years to perform the same surgeries freehand.

Broadly, stakeholders' views on the benefits of surgical guides and biomodels align with the benefits identified in the literature (see Section 2).Key benefits of the in-scope products (identified by sponsors) are provided in Appendix F.

Disadvantages of surgical guides and biomodels

Consultations identified several potential disadvantages of using surgical guides and biomodels. These disadvantages generally align with findings in the literature (see Section 2) and are described below.

Guide placement can increase risk for some procedures

We heard that, for some procedures, the use of surgical guides can have the opposite effect of the benefits described above. For example, 2 surgeons told us that using surgical guides in mandibular reconstruction often requires greater exposure of the jaw, extending the operating time and increasing the risk of bleeding compared to freehand surgery.

Quality control issues can reduce accuracy

The quality of equipment, software and the manufacturing processes all affect the accuracy of biomodels, surgical guides and customised implants. This includes the quality of the information going into the digital model (e.g. when converting analogue scans into digital formats), the preciseness of the design software, and the types of manufacturing processes used (e.g. lower quality 3D printers generate thicker – and therefore less accurate – slices, while higher-quality printers can produce more accurate products).

It is also worth highlighting that surgical guides cannot always be used intraoperatively as planned due to manufacturing errors, breakage or unsuitability.

Over-reliance on surgical guides may reduce surgical skill

Several surgeons expressed concern that the growing reliance on surgical guides may have a detrimental effect on freehand surgical skills.

They highlighted the need for surgeons to be able to recognise and respond to errors and changes during the surgery. Potential issues include manufacturing errors that make the surgical guide or biomodel unsuitable, or changes to the patient's anatomy since the surgical guide or biomodel was produced (due, for example, to increased tumour size).

Surgeons felt it was important to understand when use of a surgical guide or biomodel is clinically necessary. One surgeon suggested that limiting the use of surgical guides and biomodels to complex surgeries may help to maintain a baseline level of freehand surgical skills.

Costs may outweigh benefits for simple procedures

The use of surgical guides and biomodels can significantly increase the cost of some procedures.

Medical technology peak bodies, sponsors and other surgeons (as well as published literature – see Section 2) suggested that the costs of surgical guides and biomodels may be offset by savings from reduced theatre time and reduced need for multiple procedures, especially in complex surgeries. However, some stakeholders – including surgeons and private health insurance representatives – reported that use of surgical guides and biomodels does not represent value for money in low-complexity procedures.

We heard that the cost of using surgical guides and biomodels is not always visible to surgeons and other stakeholders, as insurers typically pay the PL benefit directly to sponsors. As a result, costs are not always considered in surgical planning and decision-making. However, some surgeons advised that they do consider the cost implications and relative value of certain products – for example, when deciding whether to use off-the-shelf implants that can be adapted using a physical biomodel or more expensive patient-specific implants.

Most stakeholders suggested that further cost analyses, including examination of manufacturing costs, are needed to clarify these cost considerations.

Growth in use of PL-listed surgical guides and biomodels

Many stakeholders, but particularly representatives of private health insurers, were conscious of the growth in benefits paid for surgical guides and biomodels on the PL. The perceived reasons for this growth are summarised below, and are consistent with the utilisation data in Section 3.

Increased utilisation in simpler procedures

Stakeholders reported that when surgical guides and biomodels were first added to the PL, they were used mainly for complex CMF procedures. Over time, their use has expanded to simpler procedures, particularly high-volume but low-complexity dental procedures (see 'Scope of use of surgical guides and biomodels', below).

Increased number of products per procedure

Stakeholders noted that the number of surgical guides and/or biomodels supplied (and billed) for a single procedure had increased over time.[10] We heard multiple reasons for this increase, including:

- Surgeons are able to combine multiple surgeries in a single admission (as noted above).
- Sponsors sometimes split biomodels into multiple parts with each billed as a separate item.
- Surgeons sometimes order multiple surgical guides so they can select the one most appropriate to the circumstances.
- Sponsors sometimes provide (and charge for) multiple biomodels, in excess of those ordered by the surgeon.

We asked stakeholders how many surgical guides and biomodels were typically needed for various procedures, and whether there should be a limit on the number of items that could be claimed through the PL mechanisms. We heard a wide range of responses – from one surgical guide and one biomodel per plate up to 10 per procedure.

Some surgeons suggested that, in most circumstances, a maximum of 2 or 3 surgical guides and 2 or 3 biomodels would be required for a complex CMF procedure; additional products were unlikely to confer any additional benefit and would only add to the overall cost of the procedure. Others said that the appropriate number of surgical guides and biomodels used is dependent on the individual circumstances of the given procedure, patient and the surgical plan.

Some surgeons suggested that further consultation may be required to identify the appropriate number(s) if limits to PL eligibility were to be considered. They also highlighted the need for an exception process to enable claims for items above the limit in appropriate clinical circumstances (see Section 4.2 for further discussion).

Increase in claims not related to prostheses

Stakeholders reported an increase in claims for uses of surgical guides and biomodels that are clearly inconsistent with PL criteria (e.g. for surgeries that did not involve implant of a prosthesis); see Section 4 for detailed analysis of product eligibility in relation to the PL criteria.

[10] We heard from private health insurer representatives of an instance where 29 biomodels were billed for a single separation.

Scope of use of surgical guides and biomodels

Historically, surgical guides and biomodels were primarily used for complex CMF procedures. Over time, their use has expanded to a broad range of procedures, including orthopaedic and dental surgery. Table 2 lists examples of procedures where surgical guides and biomodels are typically used.

Despite the increased use of surgical guides and biomodels, we did not identify any clinical practice guidelines for their use.[11]

Table 2: Typical procedures where surgical guides and biomodels are used

Type of surgery	Example procedures
CMF	• Orthognathic (jaw) surgery, including TMJ surgery • Facial trauma surgery • Cancer resection and reconstruction • Orbital surgery • Procedures for cleft and craniofacial deformities (e.g. craniosynostosis conditions) • Cranial vault reconstruction and cranioplasties • Procedures for rare conditions (e.g. fibrous dysplasia, anodontia)
Other	• Pre-prosthetic surgery (e.g. alveolar ridge augmentation) • Dental implant surgery • Sleep apnoea surgery • Orthopaedic surgery • Neurosurgery • Cardiovascular surgery

Some surgeons highlighted that, historically, they performed these surgeries without the use of surgical guides and biomodels, and many continue to do so. In fact, we heard that that some surgeons do not use surgical guides or biomodels at all (these were mostly older, more experienced surgeons who are confident in their freehand surgical skills).

Most surgeons we spoke to told us that they consider a range of factors to determine whether and what surgical guides and biomodels are required for a given surgical procedure. These include the type and complexity of the surgery; the surgeon's preferences and skills; the patient's treatment plan, including whether there is sufficient time to manufacture surgical guides and biomodels; and, for some, the relative costs and benefits of guided and freehand surgeries.

[11] None of the surgeons we spoke to was aware of clinical practice guidelines relating to the use of surgical guides and biomodels in CMF surgery.

While surgeons and peak bodies saw benefits in using surgical guides and biomodels in complex surgeries, most held the view that they were not needed for 'simpler' procedures such as:

- simple dental implant surgery or minor oral surgery
- alveolar ridge augmentation
- simple single jaw surgery.

However, surgeons reported that it was not always possible to categorise a type of procedure as 'simple' or 'complex', as complexity depends on individual clinical circumstances. For example, some single jaw surgeries were considered complex (e.g. custom genioplasty and procedures where the jaw is segmented).[12] Patient characteristics, including age and anatomy, can also influence the complexity of the procedure.

Some surgeons noted that surgical guides and biomodels could still be clinically useful – although perhaps not essential – in 'simpler' procedures (e.g. a biomodel may be useful to confirm proper positioning of a custom implant in an alveolar ridge augmentation).

In addition, input from product sponsors did not necessarily align with the view that surgical guides and biomodels were not needed in simple procedures. For example, some stated that the use of surgical guides is recognised as the standard of care in dental implantology in Australia, and it is now more common for dental implants to be placed with the use of a surgical guide than without one.

Surgical guides

Surgeons considered the use of surgical guides to be the standard of care for complex CMF surgeries including:

- complex orthognathic surgery
- TMJ surgery
- reconstruction of cranial defects
- cancer resections
- some trauma indications, such as comminuted fractures.

In addition, surgical guides were often considered necessary for implanting patient-specific implants.

[12] One peak body representative noted that even simple, single jaw surgery requires a 'surgical stent'.

Biomodels

The use and perceived benefits of biomodels varied more widely among surgeons, with some reporting that they do not use biomodels at all in their surgery, or only rarely.

Where biomodels are used, surgeons reported using physical biomodels, although stakeholders reported that dynamic virtual biomodels are also used during surgery.

Similar to surgical guides, surgeons indicated that physical biomodels are generally only required for complex surgeries, such as cranial, trauma and oncology cases to:

- visualise anatomy that cannot otherwise be visualised in surgery
- verify the fit of the surgical guide (or custom implant) and positioning on the patient
- aid in the harvesting and reconstruction of bone grafting intraoperatively
- assist the reconstruction team to understand the soft tissue requirements
- reconstruct the orbit/midface based on the mirror image of the non-affected side, enabling bending of a plate to apply to the fractured side
- adapt or pre-bend an off-the-shelf plate to fit the patient's anatomy.

However, one product sponsor indicated the wide application of biomodels, reporting that 'biomodels are used in the planning phase regardless of the surgery complexity as this is a fail-safe mechanism to verify that it is what it needs to be'.

Some other stakeholders viewed biomodels to have no clinical benefit over conventional surgery and suggested they simply increase the cost of the procedure.

Importantly, many stakeholders considered that biomodels are aids to surgical planning, or the by-product of the process for manufacturing surgical guides (that can be used for verification of guides) rather than tools used for the implantation of a prosthesis. This has implications for whether biomodels meet the criteria for the PL, as discussed in Section 4.

Influence of PL listing on patterns of use

Surgeons noted that while uptake of virtual surgical planning, including use of surgical guides and biomodels, was initially slower in the public system, the technology is available in both public and private settings.

Most surgeons we spoke to reported that their use of surgical guides and biomodels is consistent across both the public and private sectors. However, some surgeons considered that

a listing on the PL influences their use for privately insured patients, with one surgeon commenting that:

> If it's not listed, it won't be used as they are very costly things. These are the sort of surgeries that really only get done with patients who have private health insurance – you will use products that are able to be rebated as opposed to being out of pocket significantly. (Surgeon)

1.3 Trends in the use of surgical guides and biomodels

This review found that the use of surgical guides and biomodels is likely to continue to grow and broaden in the future, driven by the same factors influencing recent growth.

Surgical guides and biomodels have become a standard part of clinical practice and will continue to be used in a growing range of simple and complex procedures. The use of surgical guides and biomodels is now incorporated into surgical training: we heard that trainee oral and maxillofacial surgeons are assessed in the use of surgical guides and biomodels in clinical exams. In addition, sponsors reportedly host education and training events to upskill registrars in the use of their products. As a result, growth in the use of surgical guides and biomodels is expected to continue, particularly among younger surgeons.

Coupled with the positive outcomes experienced by surgeons, the use of surgical guides and biomodels, as well as patient-specific implants, has accelerated across a range of surgical contexts. Trends in the growth of the use of surgical guides and biomodels are also observed in utilisation data (see Section 3 for a detailed analysis) and in grey and peer-reviewed literature (Ansari et al. 2019; Chepelev et al. 2017; Meglioli et al. 2020; Royal College of Surgeons of England 2018; Tack et al. 2016).

Emerging technologies

This review also identified emerging technologies that are likely to influence future trends in the use of surgical guides and biomodels.

There was widespread acknowledgment among stakeholders that there is an increasing trend in the use of digital health and custom-made devices in surgery, aided by advances in virtual surgical planning, custom computer-aided design and manufacturing (CAD/CAM) and 3D printing technologies, particularly over the past 5 years.

Surgical guides and physical biomodels are printed using additive manufacturing' processes (more commonly known as '3D printing'). The most common types of processes used in additive manufacturing are 'rapid prototyping', and 'stereolithography' processes. Recent advances include bioprinting techniques that combine living cells with supportive biomaterials as patient-specific implants (Chepelev et al. 2017; Mason et al. 2019).

In addition to changing the way that surgeons work, stakeholders also explained that the growing market for virtual surgical planning (including surgical guides and biomodels) has created a new medical technology job stream involving sponsors, biomedical engineers and technicians working with surgeons and registrars.

Point-of-care manufacturing

Advances in 3D printing technologies have led to the emergence of point-of-care manufacturing of medical technology in public hospital settings, both in Australia and internationally. This trend was highlighted by several stakeholders, as well as in the literature.

> 3D planning and printing technologies are likely to become widely available in major hospitals, reaching more medical specialties. The field of 3D printing is expected to grow exponentially, with the healthcare sector projected to be the fastest growing segment of the market. (Royal College of Surgeons of England 2018, p. 42)

The potential benefits of point-of-care manufacturing were highlighted in a report on an in-house medical 3D printing laboratory in a university hospital in Madrid, Spain. The authors reported that point-of-care manufacturing enabled 'complete control and monitoring of the process from the indication to the manufacture of a customised medical-surgical solution'. They also reported that their experience as a manufacturing hospital had increased their capacity to work with different commercial companies in the sector, participate in the co-design of personalised implants and collaborate with external research groups in bioprinting (Calvo-Haro et al. 2021).

One study noted that hospital 3D printing hubs, with centralised digital access and applications across surgical fields, will likely improve the cost-benefit ratio of surgical guides and biomodels. However, evidence that quantifies point-of-care manufacturing costs and benefits is not available (Ansari et al. 2019).

Supporters of this approach argued that investment is needed to sustain and improve access to technology and develop point-of-care manufacturing hubs in Australia. They argued that investment in software, 3D printing equipment, and engineers will lead to improved efficiencies and cost savings, which will ultimately impact on the cost of products listed on the PL. Without investment in local manufacturing infrastructure, the cost of surgical guides and biomodels (and other custom products) will continue to grow. Stakeholders suggested that further investment in point-of-care manufacturing warrants government consideration (see Section 4.3).

Section 2: ToR 2 – Evidence base

2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and their clinical benefits.

2.1 Key findings for ToR 2

- All studies identified in the **systematic review** related to only one of the in-scope products (ProPlan). The majority of studies related to surgery in the oral and maxillofacial region. Various outcome measures were assessed in these studies. These include, but are not limited to, operative time, ischaemia time, complications and accuracy. Generally, the findings indicate improved or comparable outcomes for virtual surgical planning groups where surgical guides and/or biomodels had been used, when compared to the comparator group (e.g. surgery conducted with a freehand surgical technique).
- There are **limitations** in the included studies in the systematic review, for example, the sample sizes were generally small, there were no randomised controlled trials and 9 of the 13 studies were retrospective in design. Studies were also often confounded by interventions that included a 'bundling' of virtual surgical planning and various 3D-printed products, including surgical guides and biomodels but sometimes also patient-specific implants.
- The literature identified through the **desktop review** generally supports the use of surgical guides and biomodels across a range of contexts including oral and CMF applications (primarily dental implants), orthopaedics, cardiovascular surgery and ENT surgery, but almost invariably notes the paucity of randomised controlled trials and other comparative studies and other data quality limitations. The literature frequently suggests that the use of 3D technologies, including surgical guides and biomodels, produces results that are not inferior to 'conventional' techniques, and may facilitate potential improvements in accuracy of implant placement, decreased operative and/or ischaemic time, reduced intraoperative fluoroscopy and reduced complication rates.

2.2 Introduction

To address ToR 2, we took a 2-pronged approach to identifying relevant evidence:

- a rapid and targeted **systematic review** of published literature on the surgical guides and biomodels currently listed on the PL
- a **desktop review** of the broader evidence for surgical guides and biomodels.

As the systematic review aimed to examine the clinical evidence for the surgical guides and biomodels currently listed on the PL, the eligibility criteria and search terms used were specific to these products. This yielded a total of 13 studies.

To address this paucity of evidence, we conducted a desktop review of recent, synthesised, high-quality and peer-reviewed evidence relevant to the broader category of surgical guides and biomodels in the context of prosthesis implantation (i.e. not limited to specific products on the PL). This yielded a total of 23 articles.

Despite this dual approach, we found that the current evidence base has a number of limitations, particularly in relation to the comparative clinical effectiveness of specific products. The findings and limitations of each approach are discussed in more detail in the following sections.

2.3 Systematic review of products listed on the PL

To address ToR 2, we undertook a rapid and targeted systematic review of published literature to capture the evidence for the surgical guides and biomodels currently listed on the PL. This systematic review aimed to identify and analyse evidence regarding the clinical effectiveness of currently listed products against an appropriate comparator, and to identify the circumstances in which they provide clinical benefit. We used sponsor and product names to search MEDLINE for relevant studies.

We identified a total of 13 articles for inclusion in the systematic review (see Appendix C for detail on the search strategy, inclusion and exclusion criteria, search syntax and article selection and data extraction methods). All of the included studies related to just one of the 32 in-scope products (ProPlan/TruMatch).

Most studies assessed guided implant surgery (see Figure 1) that included the use of virtual surgical planning, surgical guides and/or biomodels (as well as, in some cases, patient-specific implants and other confounding variables).[13] As such, outcomes cannot be solely attributed to the listed product, limiting our ability to draw conclusions about their comparative benefits and effectiveness.

[13] The literature commonly uses 'virtual surgical planning' to refer to the entire process of guided implant surgery. We have generally retained this wording to reflect the language of the articles discussed.

This was further complicated by the inherent role of virtual surgical planning in the production of surgical guides and biomodels, and the various protocols and software products used. For example, in the included studies, 'ProPlan' refers to the *software* used to conduct virtual surgical planning and design surgical guides, biomodels, and implants, while in the context of the PL, 'ProPlan' refers to the *physical items* (a kit including screws, custom-made surgical guides, anatomical models and/or implants) produced using this software.

Data was extracted from these articles using a PICO (population, intervention, comparator, outcomes) framework. An overview of synthesised findings is provided below. A summary of each study is provided in Table 3, followed by and discussion of the quality and limitations of the available evidence. More detailed information on each study is available in Appendix C.

Systematic review findings

Population

In the majority of studies, the population was patients undergoing CMF surgery – specifically maxillary or mandibular reconstruction surgery. Only one study outside of the CMF context was identified, with Silva et al. (2020) instead focusing on reconstructive knee surgery (total knee arthroplasty).

Intervention

All identified studies were case-control studies (9 were retrospective in design, 2 were prospective and one was unclear). The 'case' (or intervention) group typically involved surgery assisted by virtual surgical planning/computer-assisted planning (where surgical guides and/or biomodels had been used) – that is guided implant surgery.

While some degree of preoperative virtual surgical planning is inherent in the production of surgical guides and, in some cases, biomodels (i.e. where they represent planned, reconstructed anatomy), the identified studies often included additional and confounding components associated with the technology. For example, there were 3 studies (De Maesschalck et al. 2017; Johal et al. 2022; Mazzola et al. 2020) where patient-specific implants were used for the intervention group and 2 studies where intraoperative surgical navigation was used (Zhang et al. 2015; Zhang et al. 2016). Furthermore, 6 studies (Seruya et al. 2013; Zhang et al. 2016; Zweifel et al. 2015; Zhang et al. 2015; Wang, Zhang, et al. 2016; Wang, Fan, et al. 2016) used pre-bent plates in the virtual surgical planning (i.e. intervention) groups. However, given that these were pre-bent on the biomodel, we consider them to be a variable attributable to the biomodel.

Five studies (Weitz et al. 2016; Seruya et al. 2013; Wang, Zhang, et al. 2016; Wang, Fan, et al. 2016; Silva et al. 2020) were somewhat clearer in comparing surgery with the use of surgical guides and biomodels to surgery without. However, there were still confounding factors in these studies (see 'Limitations', p. 50).

Comparators

In all but 2 studies, the comparator was conventional freehand surgery where no virtual surgical planning (and no surgical guide or biomodel) was used. The exceptions were one study where the comparator group used an alternative surgical planning method (in-house virtual surgical planning) (Johal et al. 2022), and one study in which biomodels were fabricated using an alternative 3D printing system and cutting guides and drilling templates were subsequently made by hand using synthetic composite (Rommel et al. 2017).

Outcomes

A range of outcome measures were assessed across the identified studies. Synthesised findings for the most common measures reported are summarised below; less-common measures are included in Appendix C.

Operative time

Operative time was most frequently investigated. Generally, most of the CMF studies that reported on this outcome found that virtual surgical planning using ProPlan (including the use of surgical guides and/or biomodels) was associated with shorter operative time than conventional freehand surgery. For example, Wang, Fan, et al. (2016) found that for maxillary reconstruction with vascularised graft after tumour ablation, the total operative time was 5.8 hours (± 1.1 hours) for the intervention group compared to 7.1 hours (± 1.4 hours; p = 0.007) for the comparator group. Similarly, Zweifel et al. (2015) found that for patients undergoing mandibular resections with fibular reconstructions, virtually planned and guided surgery was a mean of 67.4 minutes shorter than freehand surgery. Mazzola et al. (2020) found a lower mean procedure time in their non-matched cohort, but no significant difference in their matched cohort. Two further studies comparing guided and freehand implant surgeries reported reductions in operating times that did not reach statistical significance (Seruya et al. 2013; Weitz et al. 2016).

One study (Silva et al. 2020) compared operative times for knee reconstruction surgeries but found no significant difference between the intervention and comparator groups.

Finally, one study (Rommel et al. 2017), compared CMF surgery assisted by virtual surgical planning using ProPlan CMF to an alternative method where models, cutting guides and templates were 3D printed or hand made in an in-house laboratory. This study and found no difference in operative time between the 2 techniques. While further evidence is required, this may suggest that lab-based techniques for creating surgical guides and biomodels could achieve similar operative time savings as commercially designed and printed products when compared to freehand alternatives.

Accuracy

Accuracy was measured in a variety of different ways, and while this lack of uniformity makes it difficult to make comparisons or draw definitive conclusions, most studies indicated that virtual surgical planning was associated with improved accuracy compared to conventional surgery in the CMF region.

For example, Wang and colleagues (Wang, Fan, et al. 2016; Wang, Zhang, et al. 2016) looked at the precision of the bone-to-bone contact between either the maxilla or mandible and the fibular segments used for reconstruction. Both studies found that contact was more precise in the virtual surgical planning group (which included the use of models and pre-fabricated guides) than the conventional surgery group.

Other methods of measuring accuracy included comparing the mean difference from the angle to the midline (defined by the anterior nasal spine) before and after surgery and the difference in the angle of the mandible before and after surgery (Weitz et al. 2016), mandibular contour and condyle position (Zhang et al. 2016), the difference between the vertical distance at the canine and the first molar between the operated and non-operated sides and the horizontal fibular position (Zhang et al. 2015) and the length of bone segments, angle between adjacent segments and intercondylar and intergonial angle distances on the preoperative digital plan compared to the postoperative CT scan (Johal et al. 2022).

One study (De Maesschalck et al. 2017) found no differences in the overall accuracy of fibular free flap mandibular reconstruction using a computer-assisted technique that included the use of surgical cutting guides, and a conventional surgical technique. In this study, accuracy was assessed by comparing the difference in linear and angular parameters between pre- and postoperative scans.

Johal et al. (2022) found similar results with respect to accuracy using commercial (ProPlan/TruMatch) or in-house virtual surgical planning.

Ischaemia time

Three studies reported that virtual surgical planning (including the use of surgical guides and biomodels), was associated with reduced ischaemia time compared to conventional surgical techniques (Seruya et al. 2013; Wang, Fan, et al. 2016; Wang, Zhang, et al. 2016).

Postoperative complications

Studies investigated a range of postoperative complications (including superficial wound infection, loss of flap, failure of osteosynthesis, dehiscence, orocutaneous fistula and the rate of soft tissue and bony tissue revisions) and found that the incidence of these complications did not differ significantly between the virtual surgical planning groups and the conventional freehand surgery groups.

Similarly, Rommel et al. (2017) also found no statistically significant differences in dehiscence, plate fracture or flap loss after virtual surgical planning using ProPlan compared to alternative planning method using a different 3D printing system and hand-made cutting guides and drilling templates.

Facial appearance

Facial appearance was considered in 3 studies,. Wang, Fan, et al. (2016) and Wang, Zhang, et al. (2016) found that patients in the virtual planning group were more satisfied with their postoperative mid-face appearance than those in the conventional surgery group.

Likewise, Zhang et al. (2016) found that all patients in the computer-assisted group (which included the use of a biomodel) indicated positive results with regards to post-surgical appearance, while only half of the group who underwent conventional surgery did so ($p = 0.028$).

Other clinical outcomes

A number of other clinical outcome measures were assessed infrequently, including functional mandibular range, occlusion, speech differences and regular diet post-surgery, and bony consolidation rate. These are further detailed in Appendix C.

Cost

A total of 4 studies identified economic outcomes. All of these suggested that virtual surgical planning was a financially viable option, linking the financial benefits to reduced planning or operative times which offset the additional material costs associated with this planning method.

Resnick et al. (2016) found that virtual surgical planning takes significantly less time and is significantly less expensive than conventional planning. However, they did highlight that this was specific to the types of cases included in their study (patients undergoing bimaxillary orthognathic surgery – see Section C.6.3 for further details), and that further research is required to understand the cost implications for other surgeries.

An Australian study by Mazzola et al. (2020) compared the costs associated with virtual surgical planning with a conventional surgical approach. The study included patients undergoing reconstruction of the mandible or maxilla and compared costs for both matched and non-matched cohorts. For the non-matched cohort, the reduced operative time associated with virtual surgical planning resulted in lower costs compared to conventional surgery, despite the greater complexity of the virtual surgical planning cases and h gher material costs. The same pattern emerged for the matched cohort, but the difference was not statistically significant. Nevertheless, the study concluded that, for complex head and neck reconstructions, guided implant surgery can reduce operative time without impacting on the overall cost of the surgery.

Similarly, Zweifel et al. (2015) found that the time saved through the use of virtual surgical planning (which included the use of cutting guides) offset the additional costs associated with this method. Specifically, they identified a saving of 67.4 minutes and US$3,866 (AU$5,745) for virtual surgical planning but highlighted that, while this approach may be a financially viable option, their findings do not indicate 'complete auto-financing of such a procedure'.

Finally, Rommel et al. (2017) indicated that the cost of the virtual surgical planning method was €2,250 (AU$3,541) more expensive than the individual preoperative planning technique (where surgical guides were hand made in house). They acknowledge that other studies suggested the additional costs associated with virtual surgical planning may be offset by reduced operative time but did not observe this in their own data.

It is worth noting that virtual surgical planning technology is rapidly evolving which means that some studies may be outdated with regards to current costs. For example, Mazzola et al. (2020) indicated that then-current technology allowed production of a printed titanium plate with a lower production cost than that reported in the Zweifel et al. (2015) study.

Table 3: Summarised findings of studies included in systematic review by PICO

Citation	Study type	Population	Intervention	Comparator	Outcomes
De Maesschalck et al. (2017)	Retrospective case-control	18 patients who underwent mandibular reconstruction with fibular free flap	Mandibular reconstruction with fibular free flap via computer-assisted surgery (using ProPlan software), including the use of patient-specific plates and surgical cutting guides. n = 7	Conventional surgery (freehand technique). n = 11	There were no statistically significant differences in the morphometric accuracy between both groups, except for the axial angle on the nonaffected side. As such, it was concluded that the computer-assisted technique is comparable in its ability to provide 'satisfactory morphological fibular free flap mandibular reconstruction' when compared to conventional freehand technique. It should be noted that the results relate to computer-assisted surgical planning overall (which included the use of surgical cutting guides as well as patient-specific plates) and therefore the results cannot be solely attributed to surgical guides.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Johal et al. (2022)	Retrospective case-control	44 patients who had undergone maxillomandibular reconstruction with virtual surgical planning (VSP)	Commercial VSP involving Synthes ProPlan using Materialise software. This included patient-specific fixation plates that were either machined or 3D printed. n = 32	In-house VSP with 3D Slicer 4.0, Materialise InPrint and Autodesk 3dsMax 2016–2020 software. Stock (non-custom) fixation plates were used and contoured to a 3D printed model. n = 12	The differences in error for intergonial distance, segment length or the angle between segments were not statistically significant when comparing in-house VSP to commercial VSP (using ProPlan). The accuracy of commercial VSP and in-house VSP in this cohort is similar; therefore, it was concluded that VSP is an accurate method of maxillary and mandibular reconstruction. In-house VSP may be similar in accuracy to commercial VSP options' (p. 1400). It should be noted that the results relate to VSP (including commercial VSP using ProPlan, which included the use of patient-specific plates; as well as in-house VSP, which used stock fixation plates). Therefore, the results cannot be solely attributed to surgical guides and/or biomodels.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Mazzola et al. (2020)	Retrospective case-control	138 patients who underwent osseous free flap reconstruction of the mandible or maxilla	Proprietary virtual surgical planning approach (P-VSP). This approach was provided by DePuy Synthes with each case including a reconstructive 3D model, cutting guides for the donor and ablative sites, customised titanium plate (milled or 3D-printed) which were produced using ProPlan. Note: The use of ProPlan as part of the P-VSP group was confirmed with the authors. n = 29	A traditional non-VSP reconstructive approach where a freehand technique was used to contour the bone graft to the intraoperative defect. A pre-formed plate was used in this group. n = 99	For a non-matched cohort, P-VSP (which included the use of a 3D model, cutting guides and customised titanium plate) was associated with shorter median length of stay, a lower mean procedure time and a similar median total cost when compared to traditional non-VSP surgery and these differences were statistically significant. For the matched cohort, P-VSP had a similar median length of hospital stay, a lower mean procedure time, a lower mean total cost and a higher median total cost when compared to non-VSP. However, these differences were not statistically significant. It was concluded VSP technology is a helpful tool for reducing operative time and the length of hospital stay, without affecting the final cost of the procedure. It should be noted that the results relate to VSP (which included the use of a reconstructive model, cutting guide and customised plate) and therefore the results cannot be solely attributed to surgical guides and biomodels.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Resnick et al. (2016)	Retrospective case-control	43 patients planned for bimaxillary surgery	VSP (using ProPlan CMF software) and 3D splint fabrication.	Standard surgical planning involving 2D planning, model surgery and manual splint fabrication.	For bimaxillary orthognathic surgery, VSP (including 3D splint fabrication) is significantly less expensive and takes less time than standard planning (with manual splint fabrication).
Rommel et al. (2017)	Retrospective case-control	31 patients who underwent mandibular reconstruction with microvascular free fibular flap	A complete VSP program which included a virtual planning session and the production of VSP ProPlan cutting guides. n = 13	Individual planning method with stereolithographic models (3D printed using Projet 160), and hand-made cutting guides and drilling templates fabricated in-house. n = 18	Between the two groups, there were no significant differences in terms of the intraoperative time, duration of hospitalisation or postoperative complications. It was concluded that operative efficiency and surgical outcomes were comparable between the individual planning method and the VSP method (which included ProPlan cutting guides), and that the former was more cost-effective.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Seruya et al. (2013)	Retrospective case-control	68 patients who had undergone fibula free flap surgery for craniofacial reconstruction	Computer-aided surgical technique which included virtual surgical planning using ProPlan CMF, the fabrication of cutting guides and production of a biomodel which was used to prebend plates and as an intraoperative reference for frontal bone or maxillary reconstruction. For mandibular reconstructions, a pre-bent titanium plate was produced. n = 10	Conventional reconstructive surgical technique which was based on a process for mandibular reconstruction which does not use surgical guides and biomodels and includes the use of miniplates for fixation. n = 58	The ischaemia time for the computer-aided surgical technique was significantly shorter compared to the conventional method. Perioperative and long-term outcomes were comparable between computer-aided and conventional surgical techniques.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Silva et al. (2020)	Prospective case-control	88 patients undergoing primary total knee arthroplasty for osteoarthritis of the knee	Primary total knee arthroplasty for osteoarthritis of the knee using ProPlan Personal Solutions total knee replacement surgery which involved a 3D digital model of the knee and the fabrication of patient-specific templates which had cutting guides embedded. n = 44	Conventional primary total knee arthroplasty surgery n = 44	The authors found no difference in the operative time, recovery time, alignment and incidence of infection with the use of patient-specific instrumentation for total knee arthroplasty surgery. Furthermore, they found that there was a significantly greater decrease in haemoglobin in the intervention group. While more of these patients required transfusions, the difference was not statistically significant.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Wang, Fan, et al. (2016)	Retrospective case-control	33 patients undergoing maxillary reconstruction surgery	Surgery assisted by virtual surgical planning using ProPlan CMF software (including the production of reconstruction models, osteotomy guides and reconstruction templates. Prefabricated cutting guides and titanium miniplates which were pre-bent on the reconstruction model were used during surgery). n = 18	Conventional surgery based on the surgeon's experience. n = 15	Virtual surgical planning through ProPlan showed improved results in terms of ischaemia time, total operative time, precision and facial appearance, when compared to conventional surgery. There were comparable results in terms of intelligible speech or consuming a regular diet postoperatively between groups. It was concluded that the use of prefabricated cutting guides and plates helps fibular flap moulding and placement and supports maxillary reconstruction with improved accuracy.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Wang, Zhang, et al. (2016)	Prospective case-control	56 patients undergoing mandibular reconstruction	Surgery assisted by virtual surgical planning using ProPlan CMF software including the creation of 3D virtual models from CT scan data, the production of stereomodels comprising of a reconstruction model, osteotomy guide and reconstruction template and the use of prefabricated guides during surgery. Titanium plates were also used, and these were pre-bent using the reconstruction model and the aid of a laser. n = 21	Conventional surgery based on the surgeon's experience. n = 35	Virtual surgical planning using ProPlan CMF showed improved clinical outcomes in terms of shorter ischaemia time and total operative time, higher precision and good facial appearance when compared to the conventional surgical group. There were comparable results between groups in terms of regular diet and intelligible speech postoperatively. It was concluded that the use of prefabricated cutting guides and plates facilitates easier fibular flap moulding and placement, reduces operative time and enhances clinical outcomes.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Weitz et al. (2016)	Retrospective case-control	50 patients who had undergone mandibular reconstruction after segmental mandibulectomy	Surgery which was virtually planned using ProPlan CMF software and which included the production of cutting guides and reconstruction guides for the mandible and fibula. n = 24	Conventionally planned surgery, i.e. freehand surgery performed without cutting guides or any other appliances. n = 26	The bony consolidation rate was significantly better for virtual group when compared to the conventional group. The differences between the preoperative and postoperative angle of the mandible (a measure which can impact on the aesthetic outcomes of the lower and side face) was significantly smaller for the virtual group. Overall, there were no significant differences in complications between the two groups. The authors concluded that virtual surgical planning (which included the use of cutting and reconstruction guides) is beneficial for improving accuracy, consolidation of bony segments and operating time. It also enhances the predictability of results for the clinician.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Zhang et al. (2015)	Case-control (unclear if prospective or retrospective)	27 patients with maxillary tumours who underwent maxillectomy and free fibula flap reconstruction	Computer-assisted surgical planning and surgical navigation.[14] ProPlan was used to perform a virtual maxillectomy and for printing a resin biomodel which was used to pre-bend the titanium mesh for restoring the maxillary contour. n = 8	Traditional surgery without preoperative virtual planning. n = 19	The accuracy of positioning of fibular segments in maxillary reconstructions with free fibular flaps is significantly improved by computer-assisted techniques such as virtual planning and surgical navigation when compared to conventional reconstructions. Clinical outcomes are significantly improved with the application of computer-assisted techniques. For example, this procedure can enhance functional and aesthetic outcomes. It should be noted that the results relate to computer-assisted surgical planning (including the use of a biomodel) as well as surgical navigation, and therefore the results cannot be solely attributed to biomodels.

[14] Surgical navigation is different to surgical planning and provides 'real-time and three-dimensional visualisation during surgery' (Zhang et al. 2015).

Citation	Study type	Population	Intervention	Comparator	Outcomes
Zhang et al. (2016)	Retrospective case-control	45 patients with mandibular tumour who underwent mandibulectomy and reconstruction with vascularised crest flap	Surgery which involved virtual surgical planning via ProPlan CMF software, the production of a biomodel of the reconstructed mandible, a reconstruction plate which was pre-bent on the biomodel, and a cutting template. Intraoperatively, a computerised navigation system was used to guide the tumour resection and mandibulectomy. n = 15	Conventional surgical treatment based on the surgeon's experience without virtual planning n = 30	Computer-assisted surgical techniques including virtual planning, rapid prototyping (of surgical aids such as surgical guides and biomodels) and surgical navigation can significantly improve the accuracy of a mandibular reconstruction surgery when compared to conventional techniques. Computer-assisted techniques can improve the clinical outcomes of mandibular reconstructions with vascularised iliac crest. For example, combined with individual reconstruction plates, such surgery could improve functional and aesthetic outcomes. It should be noted that the results relate to computer-assisted surgical planning (including the use of a biomodel) as well as surgical navigation, and therefore the results cannot be solely attributed to surgical guides and biomodels.

Citation	Study type	Population	Intervention	Comparator	Outcomes
Zweifel et al. (2015)	Prospective case-control	20 patients undergoing mandibular resections with fibular reconstructions	Virtual planning and guided surgery where ProPlan CMF software was used along with Synthes software for the preoperative planning. As part of this virtual planning technique, biomodels were used to fabricate cutting guides for both the mandible and fibula. A biomodel of the mandible was also used to adapt the reconstruction plate. Milled plates cut from titanium blocks were used for the fibula. n = 9	Freehand surgery where no virtual planning was conducted and the reconstruction plates were either pre-adapted to the mandible where possible or bent freehand. The osteotomies of the fibula were conducted freehand. n = 11	The operative time was found to be shorter for virtually planned cases compared to freehand reconstructions, with an average time gain of 67.4 minutes. Relative to the time saved, the additional cost of virtual surgical planning reduced from USD$5,098 to USD$1,231.50 for a pre-bent plate and US$6,980 to US$3,113.50 for a milled plate. From the results, it was concluded that virtual planning and guided surgery, are financially feasible even in 'capped' health systems (where services or clinicians are paid a lump sum for the case or illness). It should be noted that software other than ProPlan was used to simulate both fibular and mandibular surgeries and the resulting models were used to construct cutting guides. These models were also used in early cases to produce biomodels on which reconstruction plates were adapted and, in later cases, to produce patient-specific, milled plates.

Strength of the evidence and risk of bias

The included studies were assessed for the strength of their evidence, as well as their risk of bias. A detailed description of the methods and outcomes of these assessments is provided in Section C.4.

All studies were graded as level III-2 according to the NHMRC evidence hierarchy (i.e. we did not identify any systematic reviews, randomised controlled trials or pseudo-randomised controlled trials), and all but 2 studies had at least a moderate risk of bias as assessed using the Newcastle-Ottawa Scale (NOS) (Wells et al. 2021). The main sources of potential bias were the lack of comparability between patients in the intervention and comparator groups and the failure to adjust for important potential confounders, especially surgical complexity.

Some stakeholders expressed the view that, in the assessment of new technologies in surgical practice, the classic hierarchy of evidence may be less practical or applicable than in other contexts, as evidence is generated from the 'bottom to top' – i.e. from case reports to randomised controlled trials to systematic reviews and meta-analyses – and that substantial surgical experience is needed before randomised controlled trials are contemplated (Kumar 2019). Other stakeholders suggested that the applicability of randomised controlled trials in reviewing surgical guides and biomodels is limited because of the personalised nature of each device, the potential for selection and detection bias, and the unsuitability of patients undergoing complex CMF procedures for randomisation.

Limitations

In addition to the sources of bias described above, authors of many of the included studies identified limitations such as small sample sizes, retrospective study design, the potential for selection bias, and virtual planning being 'subjective and experience-based' (Zhang et al. 2016, p. 1826) meaning the results may not be generalisable to other surgeons. Other authors did not acknowledge any limitations to their research, making it difficult to place findings 'within their proper context to ensure readers are fully able to discern the credibility of a study's conclusions, and generalise findings appropriately' (Ross and Bibler Zaidi 2019, p. 261-262). Further details on the author-identified limitations of their studies are provided in Section C.6.3.

In terms of future research, some authors identified the need for more prospective studies (including randomised controlled trials) in order to draw more definitive conclusions, and for follow-up to investigate the long-term outcomes of the interventions.

Most studies assessed virtual surgical planning or computer-assisted planning that included the use of surgical guides and/or biomodels (as well as, in some cases, patient-specific implants), rather than looking at the impacts of surgical guides and biomodels specifically. As such, outcomes cannot be solely attributed to surgical guides and biomodels, limiting our ability to

make definitive conclusions about their comparative benefits and effectiveness in the absence of these other factors.

As this review aimed to examine the comparable clinical evidence for in-scope products listed on the PL, the eligibility criteria and search terms used were specific to these products. However, the inherent role of virtual surgical planning in the production of surgical guides and biomodels, the various protocols and software products used and the extent to which these are explicitly reported in the literature make it difficult to 'match' the available evidence with products listed on the PL. For example, one study identified through the systematic review was excluded because, while ProPlan CMF was used as part of the workflow described, a different software package was used to conduct the virtual surgical planning (Jones et al. 2022). Another study used ProPlan software for the virtual surgical planning but then another software product for the design of the surgical guide (Ayoub et al. 2014).

Conversely, some stakeholders argued that there is no need to differentiate evidence for the specific products listed on the PL from the broader evidence for surgical guides and biomodels, as many utilise the same or similar back-end software for virtual surgical planning, design and production. To address this, we conducted a desktop review of the broader evidence (see Section 2.4).

Conclusions

Overall, the findings of this systematic review indicate that, in the CMF context, guided implant surgery – including the use of surgical guides and biomodels – is associated with comparable or better clinical outcomes than the relevant comparators.

These findings only relate to ProPlan. There were no studies identified for the other products listed on the PL that met the inclusion criteria for the systematic review. As such, there is insufficient evidence to comment on their comparative clinical effectiveness and benefits.

In addition, the 2 studies where ProPlan virtual surgical planning was compared to alternative methods found no meaningful difference between ProPlan and these other approaches.

Importantly, these findings should be considered in light of the strength of the evidence, including the potential for bias.

2.4 Desktop review of broader evidence for surgical guides and biomodels

To supplement the evidence presented in Section 2.2 above, we conducted a desktop review to identify recent, synthesised, high-quality and peer-reviewed evidence relevant to the broader category of surgical guides and biomodels in the context of prosthesis implantation (i.e. not limited to specific products on the PL). This review was designed to provide a snapshot of current knowledge and trends in the evidence for surgical guides and biomodels, including the contexts in which they are used and the outcomes commonly reported in the evidence base. It was not intended to be a systematic review of published literature and does not represent a complete or comprehensive summary of the literature available.

We searched for systematic reviews and meta-analyses that met specific inclusion criteria, and identified 23 articles that reviewed surgical guides and biomodels in the following contexts:

- dental implants
- oral and CMF surgeries
- orthopaedic surgery
- cardiovascular surgery

A brief summary of the key fundings is provided below, with full details in Appendix C.

Findings

The literature generally supports guided implant surgery (including the use of surgical guides and biomodels) for implanting prostheses in a range of surgical contexts.

The systematic reviews we identified highlighted the large number of current and emerging applications of 3D-printing technologies in implant procedures.

Overall, the literature suggests that guided implant surgery produces results that are not inferior to conventional techniques, and may increase accuracy of implant placement, decrease operative and/or ischaemic time, reduce interoperative fluoroscopy and reduce complication rates.

Despite these findings, the outcomes depended on a number of factors, including the choice of software and manufacturing technique (Chen et al. 2021; Putra et al. 2022; Walker-Finch and Ucer 2020). It is important to note, therefore, that while the literature supplements our own systematic review, the findings cannot necessarily be generalised to the products currently listed on the PL.

> The advantages and disadvantages of different 3D virtual software systems on the market should be further explored…the comparative advantages of different software programs have not been clarified (Chen et al. 2021, p. e17)

A number of studies noted that surgical guides may not always be used intraoperatively as planned. In some cases, surgical guides were unsuitable or broken, and planned protocols had to be abandoned (Eftekhar Ashtiani et al. 2021; Omari et al. 2022; Romandini et al. 2022; Tattan et al. 2020; Walker-Finch and Ucer 2020).

> The template-derived surgical plans are frequently abandoned, putting their utility into question. (Omari et al. 2022, p. 3284)

A number of studies looked at the cost of guided implant surgery and how this might be offset by benefits such as surgical time savings. However, there were too many variables (including the costs and cost structures in any given healthcare setting) to reach a definitive conclusion.

> Expenses related to the operating room and inpatient services vary among different centres and countries. Health insurance coverage also varies in different areas. Therefore, the economic viability of computer-assisted mandibular reconstruction remains an open question. (Powcharoen et al. 2019, p. 1426)

One study modelling the cost of point-of-care manufacturing (see Section 1.3) estimated that, in the context of oral and maxillofacial and orthopaedic surgeries in the United States, a hospital would need to produce at least 63 models or guides per year to offset the annual fixed costs of maintaining a 3D printing lab (Ballard et al. 2020).

Limitations

The authors of the systematic reviews and meta-analyses included in this desktop review identified a number of limitations, such as:

- the limited number of studies identified for inclusion in the reviews
- the small sample sizes used in the included studies, and the inclusion of case reports
- a paucity of randomised controlled trials, other comparative studies and prospective studies, and the significant risk of bias in included studies
- heterogenous methodologies, including patient cohort, follow-up and measuring/reporting of outcomes
- presence of confounding factors – including surgeon experience, types of defects and surgeries – not well controlled and variation in bundling of 3D technologies

(e.g. interventions often included any/all of virtual surgical planning, use of 3D-printed biomodels and/or surgical guides, other 3D-printed tools and patient-specific implants).

Many authors suggested that clinical outcomes can be improved, but their findings were not supported by any control group. (Meglioli et al. 2020, pp. 7-10)

Irrespective of specialty, the true effectiveness of 3D-printed interventions [in otology and auricular management] remains largely undetermined due to few large trials, use of non-randomized designs, and lack of quantitative outcomes. (Omari et al. 2022, p. 3285)

Many authors highlighted the need for further and better research on the comparative benefits of guided implant surgery with respect to conventional methods, including randomised controlled trials – or, at least, prospective, clinical and comparative data, standardised methodologies, long-term data and data regarding costs.

The findings of this review (including limitations of the evidence base) are consistent with those of our systematic review of in-scope PL products, as described in Section 2.3.

Section 3: ToR 3 – Utilisation patterns

3. Consider the current utilisation patterns of surgical guides and biomodels listed on the PL

3.1 Key findings for ToR 3

- When surgical guides and biomodels were initially listed on the PL in 2013–14, a total of s 47 items were used. This utilisation has, on average, doubled each year, and in 2020–21 a total of 7,488 items were used (67% of which were surgical guides).

- In 2020–21, the average number of surgical guides and biomodels per patient was 1.8 and 2.1 respectively. This has increased over time, driven in part by high numbers of items being used per patient in a small but growing number of cases.

- Surgical guides and biomodels are listed under the plastic and reconstructive product category and were used solely in this category in 2013-14 and 2014-15. Since 2015-16, there has been increasing utilisation in other categories –for example, in 2020–21, 28% of total utilisation was outside the plastic and reconstructive category, more than half of this (15% of total utilisation) was attributable to orthopaedic procedures.

- While the PL benefit amount has not changed, the increase in utilisation has seen annual expenditure grow from s 47G in 2013–14 to $17,680,000 in 2020–21. Overall, biomodels account for 26% of expenditure and surgical guides for 74% for the 2013-14 to 2020-21 period.

3.2 Data sources

Findings presented in this section are drawn from the following 3 data sources:

- **Hospital Casemix Protocol 1** (HCP1) data provided by the department. This data spans the 2013–14 to 2021–22 financial years and includes device volumes, financial benefits paid, patient numbers, separation numbers, MBS clinical categories, MBS item numbers and product sponsors. Public and private hospitals submit HCP1 data for each episode of admitted hospital treatment for which health insurers have paid a benefit.
- **Australian Prudential Regulation Authority** (APRA) data, which is publicly available. We looked at data related specifically to the plastic and reconstructive MBS clinical category to ascertain the overall growth of surgery in the category.
- **Medicare Item Reports** accessed through Services Australia. These reports cover services qualifying for a Medicare benefit for which a claim has been processed. They do not cover services provided to public patients in public hospitals, or services provided through the Department of Veterans' Affairs. We therefore deemed this dataset to be comparable to the HCP1 dataset and used it to further explore the number of surgical guides and biomodels used for specific MBS item numbers.

Unless otherwise specified, the following analysis is based on HCP1 data provided by the department.

3.3 Trends in utilisation

To address ToR 3, we considered the utilisation patterns for surgical guides and biomodels since their initial listing in 2013, including how utilisation relates to hospital patient and separation numbers, MBS clinical categories, and diagnostic data. We then explored expenditure in terms of benefits paid for surgical guides and biomodels overall and by MBS item number and product sponsor.

Growth in utilisation

Since 2013, the number of sponsors with surgical guides and biomodels listed on the PL has increased from one to 9. As the number of listed products has increased, so too has their utilisation. Overall, 7,488 items were used in 2020–21, including 5,043 surgical guides (67%) and 2,445 biomodels (33%). This equates to utilisation s 47G times greater than that seen in 2013–14 when a total of just s 47 items were used (Figure 2).

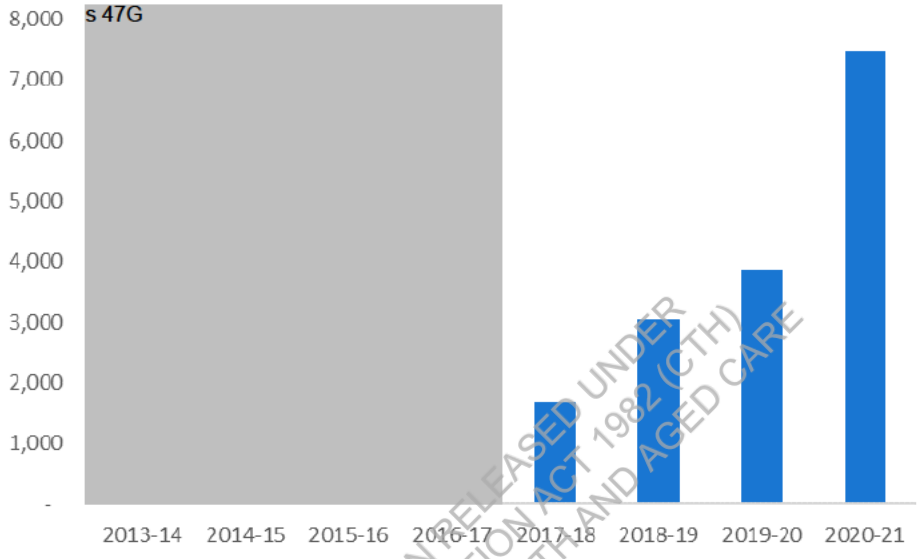

Figure 2: Total number of surgical guides and biomodels used, by financial year

In addition to looking at the number of items used, we calculated the annual growth rate (AGR) for surgical guides and biomodels. An AGR greater than zero indicates that more items were used in that year than the previous year, and an AGR of 100% equates to a 2-fold increase in utilisation.

Biomodels had an average AGR of 185% between 2015-16 and 2020-21, indicating that on average, the number of items used almost tripled each year (Table 4).

Table 4: Biomodels annual growth rate, by financial year

Measure	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
Number of items	s 47G				494	947	1,290	2,445
AGR					229%	92%	36%	90%

Surgical guides had an average ARG of 114% between 2015-16 and 2020-21, indicating that on average, the number of items used almost double each year (Table 5).

Table 5: Surgical guide annual growth rate, by financial year

Measure	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
Number of items	s 47G				1,207	2,094	2,577	5,043
AGR					133%	73%	23%	96%

The AGRs for both surgical guides and biomodels peaked in 2016-17. Lower AGRs in recent years may be at least partially attributable to the cancellation of elective surgeries due to COVID-19.

Utilisation by patients and separations

Table 6 and Table 7 show that on average, patients had a single hospital separation but more than one biomodel or surgical guide used, with a marked variability in the average number of items to patients and separations over time. Where patient and hospital separation numbers differ, this may be due to planned or unplanned readmissions and/or patients changing insurer (in which case they would be allocated a new patient identification number that is not linked to their previous records).

Table 6: Biomodel utilisation by financial year

Measure	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
Number of items	s 47G				494	947	1,290	2,445
Number of patients					265	429	664	1,337
Average items per patient					**1.9**	**2.2**	**1.9**	**1.8**
Number of separations					267	442	672	1,357
Average items per separations					**1.9**	**2.1**	**1.9**	**1.8**

Table 7: Surgical guide utilisation by financial year

Measure	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
Number of items	s 47G				1,207	2,094	2,577	5,043
Number of patients					513	810	1,087	2,409
Average items per patient					**2.4**	**2.6**	**2.4**	**2.1**
Number of separations					518	830	1,100	2,460
Average items per separation					**2.3**	**2.5**	**2.3**	**2.1**

Table 8 and Table 9 explore the number of items to separations in more detail. While the vast majority of hospital separations involved just one or 2 items, recent years have seen large numbers of items used in a small but growing number of separations. In 2020–21, 5 or more surgical guides and biomodels were used in 5% and 8% of separations, respectively.

Table 8: Number of biomodels used per separation, by financial year

Number	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
1	s 47G	s 47G		s 47G	92	125	289	703
2					150	241	291	469
3					n.p.	12	17	46
4					18	44	46	76
5 or more					n.p.	20	29	63

Cells annotated with n.p. indicate that there were fewer than 10 datapoints available and that the data was suppressed in files supplied by the department.

Table 9: Number of surgical guides used per separation, by financial year

Number	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
1	s 47G	s 47G	s 47G	s 47G	166	267	449	1308
2					185	217	256	535
3					67	142	176	246
4					50	97	114	185
5					35	70	56	113
6					n.p.	n.p.	27	36
7 or more					n.p.	n.p.	22	37

Cells annotated with n.p. indicate that there were fewer than 10 datapoints available and that the data was suppressed in files supplied by the department.

Utilisation by MBS clinical categories and item numbers

In 2013-14 and 2014-15, 100% of surgical guides and biomodels were used for CMF procedures within the MBS clinical category of plastic and reconstructive surgery. Over time, they have been increasingly used in other clinical categories (Table 10). In 2020–21, 28% of total utilisation was outside of the plastic and reconstructive clinical category; more than half of this (15% of total utilisation) was attributable to orthopaedic procedures (under the bone, joint and muscle and joint replacement clinical categories).

We note that MBS clinical category is a non-mandatory field in the HCP1 dataset and there are instances where this field is left blank as part of the hospital separation. As shown in Table 10, 'MBS category not supplied' accounted for 7% of the of products used in 2020-21.

Table 10: Proportion of products used in each financial year, by MBS clinical category

Year	Plastic and reconstructive (includes CMF)	Ear nose and throat	Bone, joint and muscle	*MBS category not supplied*	Brain and nervous system	Joint replacement	Support list
2013–14	100%						
2014–15	100%						
2015–16	92%	8%					
2016–17	83%	9%	6%	*2%*			
2017–18	81%	6%	8%	*4%*	1%		
2018–19	88%	1%	8%	*2%*	1%		
2019–20	78%	1%	12%	*6%*	1%	1%	1%
2020–21	72%	2%	11%	*7%*	1%	4%	2%

Next, we explored the relationship between MBS items and surgical guides and biomodels in more detail, using the number of admissions in the *Medicare Item Report for 2019–20* (Services Australia 2022) and HCP1 data on the aggregate number of surgical guides and biomodels for the same reporting period. While the data provided by the department only included the top MBS items, this nevertheless provides an indication of how surgical guide and biomodel use compares to MBS billing patterns.

Table 11 shows the most common MBS items linked with the use of surgical guides and biomodels. The data shows that alveolar ridge augmentation was by far the most common MBS item number where surgical guides and biomodels were used, accounting for 7,712 (72%) of the 10,682 admissions included in the analysis. Interestingly, it accounted for 15% of the total number of surgical guides and biomodels utilised despite having the lowest utilisation rate (0.07). This low utilisation rate aligns with surgeons' view that this is a less complex procedure that rarely requires the use of surgical guides and biomodels (see Section 1.2).

Unsurprisingly, the MBS item numbers with the highest utilisation rates were associated with more complex procedures. For example, complex bilateral osteotomies or ostectomies of mandible or maxilla accounted for 1% of admissions but 11% to 27% of surgical guides and biomodels. The utilisation rate for these procedures indicates that on average, between 2.5 and 6.4 products were used per hospital admission. These findings suggest that current practice aligns with most surgeons' opinion that products should be reserved for complex CMF cases (see Section 1.2).

Table 11: Utilisation of surgical guides and biomodels by MBS item, 2020-21

MBS item number	MBS item description	MBS item description detail	Surgical guides and biomodels utilised	MBS item reported admissions	Utilisation rate
45841	Alveolar ridge augmentation	n/a	592	7,712	**0.07**
45849	Sinus lift procedure	n/a	158	1,484	**0.10**
45729	Bilateral osteotomy or ostectomy of mandible or maxilla	Single jaw with 1 to 2 procedures	407	268	**1.50**
45857	TMJ arthroscopy	n/a	86	237	**0.30**
45732	Bilateral osteotomies or ostectomies of mandible or maxilla	Single jaw with 3 or more procedures	427	229	**1.90**
45752	Complex bilateral osteotomies or ostectomies of mandible or maxilla	Double jaw with 3 or more procedures on each jaw	436	172	**2.50**
52357	Osteotomies or osteectomies of the mandible or maxilla	Single jaw with 3 or more procedures	101	160	**0.60**
45738	Bilateral osteotomies or ostectomies of mandible or maxilla	Double jaw with 2 or more procedures on each jaw	480	148	**3.20**
52375	Complex bilateral osteotomies or ostectomies of mandible or maxilla	Double jaw with 3 or more procedures on each jaw	650	102	**6.40**
52363	Complex bilateral osteotomies or ostectomies of mandible or maxilla	Double jaw with 2 procedures on each jaw	346	89	**3.90**
45744	Complex bilateral osteotomies or ostectomies of mandible or maxilla	Double jaw with 3 procedures on one jaw and 2 on the other jaw	226	81	**2.80**
Total			**3,909**	**10,682**	

Utilisation by ICD classification

The vast majority of surgical guide and biomodel use was associated with dentofacial anomalies (including malocclusion) (M26). Between 2016–17 and 2018–19, anomalies of jaw-cranial base relationship (M26.10) was most common, accounting for around one-third of surgical guide and biomodel use (Table 12). Unspecified dentofacial anomalies (M26.5) have since gained prominence and were the primary classification recorded in 2021–22, accounting for 14% of surgical guide and biomodel use.

Table 12: Combined surgical guides and biomodels utilisation by ICD codes, by financial year

ICD classification	2016–17	2017–18	2018–19	2019–20	2020–21
Dentofacial anomaly, unspecified (M26.5)	s 47G	258	443	633	1,066
Anomalies of jaw-cranial base relationship (M26.10)		462	743	625	881
Temporomandibular joint disorders (M26.6)		74	140	347	532
Loss of teeth due to accident, extraction or local periodontal disease (K.08.419)		n.p.		145	463
Malocclusion, unspecified (M26.4)		133	300	313	383
Hypoplasia of maxilla (M26.02)		157	304	234	337
Other dentofacial anomalies (M26.9)		102	175	145	301
Anodontia (K00.0)				35	273
Disorder of teeth and supporting structures, unspecified (K08.9)		27	15	61	230
Hypoplasia of mandible (M26.04)		87	221	134	202
Other major anomalies of jaw size (M26.00)		n.p.	14	52	113
Other primary coxarthrosis (M16)				22	80

Note: Data subset used from 2016–17 due to minimal comparable reporting prior to the 2016–17 financial year.

Cells annotated with n.p. indicate that there were fewer than 10 datapoints available and that the data was suppressed in files supplied by the department.

Utilisation by diagnosis related group (DRG)

Table 13 shows biomodel utilisation by DRG. Major complexity maxillofacial surgery accounted for 53% of the total utilisation of biomodels in 2020–21. Minor complexity maxillofacial surgery accounted for 9% of biomodel use. Orthopaedic DRGs (hip replacement; humerus, tibia and fibula and ankle; and other hip and femur procedures) account for a combined 2% of biomodel use in 2019-20, growing to 9.5% in 2020–21.

Table 13: Biomodels by diagnosis related groupings, by financial year

DRG	2018–19	2019–20	2020–21
Maxillofacial Surgery, Major Complexity	800	829	1307
Maxillofacial Surgery, Minor Complexity	18	110	217
Other Ear, Nose, Mouth and Throat Procedures, Minor complexity	16	73	94
Hip Replacement, Minor Complexity		21	72
Humerus, Tibia, Fibula and Ankle Procedures, Minor Complexity			72
Mouth and Salivary Gland Procedures, Major Complexity		27	69
Head and Neck Procedures, Minor Complexity		28	45
Other Hip and Femur Procedures, Minor Complexity			42
Tracheostomy and/or Ventilation >=96 hours		13	42

Note: Data subset used from 2018 due to minimal comparable reporting prior to the 2017–18 financial year.

The pattern of results for biomodels was echoed for surgical guides, with major complexity maxillofacial surgery accounting for 64% of total utilisation in 2020–21(Table 14). Each of the last 2 years has seen utilisation of surgical guides expand into new DRG categories, including mouth and salivary gland procedures (major and minor complexity), which together accounted for 9% of utilisation in 2020–21.

Table 14: Surgical guides by diagnosis related groupings, by financial year

DRG	2018–19	2019–20	2020–21
Maxillofacial Surgery, Major Complexity	1775	1876	2866
Maxillofacial Surgery, Minor Complexity	58	200	708
Mouth and Salivary Gland Procedures, Major Complexity		52	319
Head and Neck Procedures, Minor Complexity	32	79	114
Mouth and Salivary Gland Procedures, Minor Complexity			112
Humerus, Tibia, Fibula and Ankle Procedures, Minor Complexity		14	108
Other Ear, Nose, Mouth and Throat Procedures, Minor complexity	92	104	107
Hip Replacement, Minor Complexity		21	78
Other Hip and Femur Procedures, Minor Complexity			47

Note: data subset used from 2018 due to minimal comparable reporting prior to the 2017–18 financial year.

3.4 Expenditure

Since 2013, $40.77 million in benefits have been paid for surgical guides ($30.26 million; 74%) and biomodels ($10.51 million; 26%) (Table 15). Expenditure has increased by 116% per year on average, with the greatest increase (274%) seen in 2016–17 and the smallest (27%) in 2019–20. Importantly, the growth in expenditure does not reflect a rise in the benefits paid per claim (this figure having remained unchanged since 2013). Rather, it can be attributed solely to the increase in number of products used. Note all expenditure amounts are rounded to the nearest thousand dollars.

Table 15: Biomodel and surgical guide expenditure, by financial year

Year	Number of sponsors with listings	Biomodels	Surgical guides	Total	Biomodels %	Surgical guides %
2013–14	1	s 47G			16%	84%
2014–15	1				27%	73%
2015–16	2				12%	88%
2016–17	4				18%	82%
2017–18	6	$979,000	$3,157,000	$4,136,000	24%	76%
2018–19	6	$1,839,000	$5,402,000	$7,241,000	25%	75%
2019–20	8	$2,514,000	$6,656,000	$9,170,000	27%	73%
2020–21	9	$4,726,000	$12,954,000	$17,680,000	27%	73%
Total		**$10,510,000**	**$30,260,000**	**$40,770,000**	**26%**	**74%**

Expenditure on biomodels, while lower than surgical guide expenditure, experienced a proportionally larger increase (170% annually on average, compared to 109%). Figure 3 shows growth in annual expenditure on both surgical guides and biomodels.

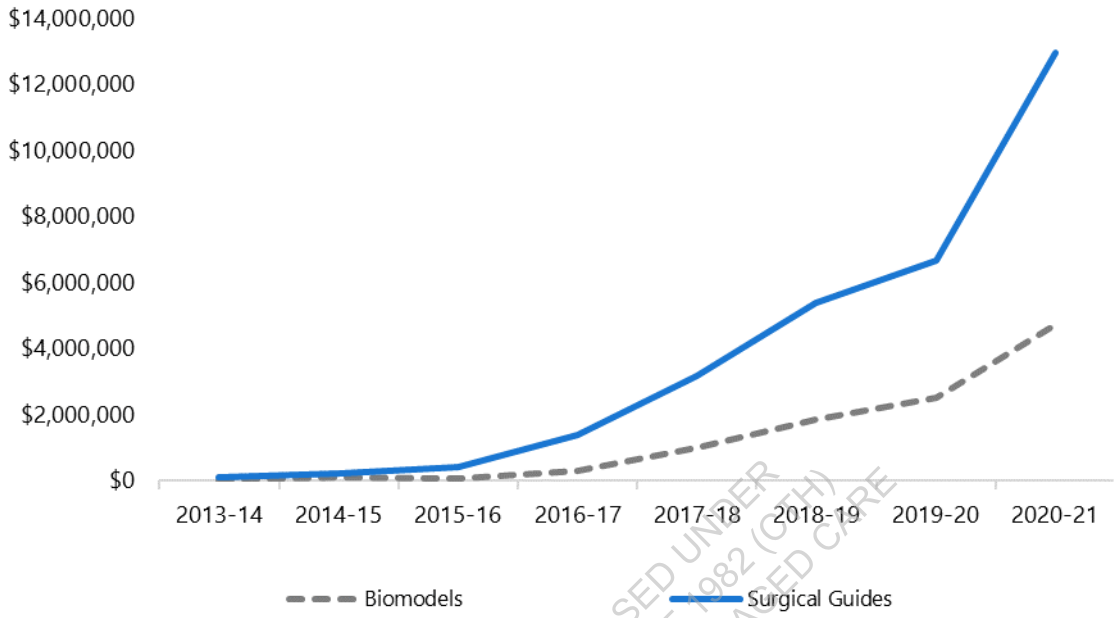

Figure 3: Benefits paid for surgical guides and biomodels, by financial year

Interestingly, the growth in expenditure on surgical guides and biomodels has not been accompanied by an increase in plastic and reconstructive surgeries, the MBS clinical category for which these items were initially listed. For example, in the 5 years to 2020–21, annual average growth in expenditure on surgical guides and biomodels was 123%. APRA data show that over the same time period, annual growth in plastic and reconstructive surgeries undertaken in private hospital facilities averaged 2.8%. This side-by-side comparison indicates that the growth in expenditure may be attributed to growth in utilisation rather than growth in surgical procedures.

Expenditure by MBS item numbers

HCP1 data on the benefits paid for the 10 most common MBS item numbers for surgical guides and biomodels suggests that there are both similarities and differences in utilisation patterns. Item numbers 52375 and 45841 account for the largest expenditure for both types of products (albeit in mirror order), and item numbers 45732, 45729, 45752, 45738 are also common in both.

In addition, hospital separations where the MBS item number was not supplied have become increasingly prevalent. In 2020–21, $1,181,000 in surgical guide and biomodel benefits could not be attributed to specific MBS items.

As shown in Table 16, there has been sustained growth in biomodel expenditure over the past 5 years for item numbers which relate to CMF procedures (52375, 45732, 45729, 45752, 52357, 52363 and 45738). Two MBS item numbers significantly increased in the 2020-21 dataset: 45857 which is for a joint arthroscopy and is not associated with a prosthesis, and 45841 which is for an alveolar ridge augmentation.

Table 16: Biomodels benefit paid, by MBS item and financial year

MBS item number	MBS item description	2016–17	2017–18	2018–19	2019–20	2020–21
52375	Complex bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$134,000	$283,000	$240,000	$404,000
45841	Alveolar ridge augmentation		n.p.		$94,000	$269,000
45732	Bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$65,000	$144,000	$135,000	$259,000
45729	Bilateral osteotomy or ostectomy of mandible or maxilla	s 47G	$62,000	$123,000	$88,000	$254,000
Unspecified			$47,000	$27,000	$162,000	$248,000
52363	Complex bilateral osteotomies or ostectomies of mandible or maxilla		$26,000	$139,000	$156,000	$248,000
45752	Complex bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$89,000	$125,000	$203,000	$215,000
52357	Osteotomies or osteectomies of the mandible or maxilla	s 47G	$36,000	$226,000	$220,000	$197,000
45738	Bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$91,000	$94,000	$78,000	$179,000
45857	TMJ arthroscopy			n.p.	$133,000	$153,000

Note: Data subset used from 2016 due to minimal comparable reporting prior to the 2016–17 financial year.
Cells annotated with n.p. indicate that there were fewer than 10 datapoints available and that the data was suppressed in files supplied by the department.

Like biomodels, surgical guide expenditure has steadily increased in MBS item numbers relating to CMF surgeries (52375, 45738, 45752, 45729, 45744 and 52353), as shown in Table 17. Notably, the 2 MBS item numbers appearing for the first time in the 2019–20 dataset (45841 and 45849) are not classified by surgeons as complex CMF procedures. In addition, hospital separations where MBS item numbers were not supplied have become increasingly prevalent, equating to $933,000 in 2020-21.

Table 17: Surgical guides benefits paid, by MBS item number and financial year

MBS item	MBS item description	2016–17	2017–18	2018–19	2019–20	2020–21
45841	Alveolar ridge augmentation				$287,000	$1,170,000
52375	Complex bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$423,000	$884,000	$685,000	$1,155,000
45738	Bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$505,000	$742,000	$674,000	$1,003,000
Unspecified		s 47G	$128,000	$80,000	$339,000	$933,000
45752	Complex bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$426,000	$476,000	$677,000	$842,000
45732	Bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$242,000	$336,000	$416,000	$760,000
45729	Bilateral osteotomy or ostectomy of mandible or maxilla	s 47G	$295,000	$421,000	$377,000	$716,000
45744	Complex bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$134,000	$393,000	$452,000	$581,000
52363	Complex bilateral osteotomies or ostectomies of mandible or maxilla	s 47G	$71,000	$331,000	$419,000	$566,000
45849	Sinus lift procedure				$98,000	$408,000

Note: Data subset used from 2016 due to minimal comparable reporting prior to the 2016–17 financial year.

Expenditure by sponsor

Some sponsors have seen sustained growth since their initial product listing on the PL; however, others have experienced exponential growth in a short period of time. s 47G

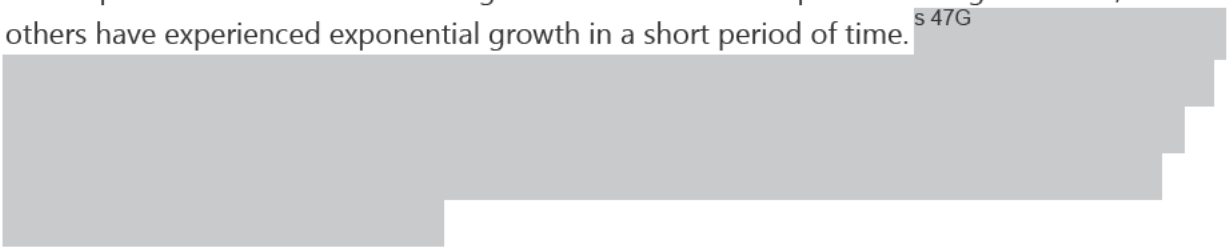

Table 18: Biomodel benefits paid by sponsor, by financial year

Sponsor	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
s 47G								

Table 19: Surgical guide benefits paid by sponsor, by financial year

Sponsor	2013–14	2014–15	2015–16	2016–17	2017–18	2018–19	2019–20	2020–21
s 47G								

Section 4: ToR 4 – Product eligibility for PL listing

4. Based on the findings of ToR 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.

4.1 Key findings for ToR 4

We used information from ToR 1, 2 and 3 to inform whether the listed surgical guides and biomodels meet the eligibility criteria. In relation to the 5 eligibility criteria, we made the following findings.

Criterion 1: The product must be entered and current on the Australian Register of Therapeutic Goods

Of the 32 products in scope for this review, 30 products are entered and current on the ARTG and the remaining 2 products are registered under transition arrangements. This criterion is therefore **met**.

Criterion 2: The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment

Based on the data we have reviewed, we understand all products have been provided to a person as part of an episode of hospital treatment or hospital-substitute treatment. This criterion is therefore **met**.

Criterion 3: A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)

Based on the data available, we understand that Medicare benefits were payable for all instances where benefits for the listed surgical guides and biomodels were paid. This criterion is therefore **met**.

However, it is difficult to determine the extent to which PL benefits paid for listed surgical guides and biomodels may be attributed to 'inappropriate' MBS item numbers (i.e. where the item number is not specific to the procedure in which the prosthesis is delivered), and this issue warrants further investigation.

Criterion 4: Essential to, and specifically designed as an integral single-use aid for implanting a product

The clinical uses of listed surgical guides and biomodels was found to vary considerably, which, combined with a lack of clarity in the definition of several key terms (particularly 'essential' and 'integral') makes assessment of this criterion difficult.

Based on analysis, we have found that this criterion is:

- **not met** for surgical guides or biomodels when used in *procedures that do not involve implantation* of a prosthesis
- **met** for surgical guides and biomodels used for *complex CMF procedures*
- **not met** for surgical guides or biomodels for *simpler procedures*.

Examples of procedures that surgeons generally considered complex or simple are provided in Section 1.2 and Section 4.2. However, surgeons cautioned against blanket assumptions about the complexity of a given procedure type (as this depends on individual clinical circumstances), and highlighted the need for appropriate definitions of 'simple' and complex' procedures.

Criterion 5: Clinical effectiveness and costs

There is a paucity of high-quality evidence on the comparative clinical effectiveness or the cost effectiveness of the in-scope products. However, while the broader literature notes similar limitations, this review found support for the clinical effectiveness of surgical guides and biomodels *in general*, at least in the context of complex CMF surgeries.

As such, there is currently **insufficient evidence** to determine if criterion 5(i) or 5(ii) is met.

Stakeholder suggestions

Stakeholders suggested a number of **improvements to the PL** with respect to surgical guides and biomodels. These included: clarifying eligibility criteria; reviewing and revising PL sub-categories and product groups; restricting circumstances in which benefits are payable; reviewing benefits and claims arrangements; reviewing costs; considering the need for further and stronger evidence; and reviewing governance arrangements.

4.2 Product alignment with PL criteria

The PL guide outlines 5 criteria that products must meet in order to be added to PL (detailed in Appendix G). Many of the listed products cannot be categorised as only a surgical guide or biomodel, as they form part of a kit that includes biomodels, surgical guides, and other items such as fixation plates, screws and implants. In the following discussion, we consider whether the surgical guides and biomodel components of the listed products meet each criterion.

Criterion 1: Australian Register of Therapeutic Goods

> 1. The product must be entered and current on the Australian Register of Therapeutic Goods (ARTG).

Of the 32 products in this review, 30 products are listed on the ARTG and the remaining 2 products are registered under transition arrangements. This criterion is therefore **met**.

The 2 products under transition arrangements are both sponsored by KLS Martin (UNIQOS Patient Specific Surgical Guides and the UNIQOS Patient Specific Anatomical Biomodel).[15] Should approval not be provided by the TGA, these products will not be eligible for the PL.

Appendix B details the ARTG status for each product, along with the identification numbers, intended purpose, whether implants are included, and the benefits payable.

[15] The TGA has established transition processes for product sponsors supplying personal medical devices (PMDs) that are not included on the ARTG. Registered sponsors were required to register for transition arrangements by 25 August 2022. Sponsor products have until November 2024 to be listed on the ARTG.

Criterion 2: Hospital or hospital-substitute treatment

2. The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment.

Based on the data we have reviewed, we understand all products for which benefits have been paid have been used during an episode of hospital treatment or hospital-substitute treatment. This this criterion is therefore **met**.

However, private health insurers reported that they are seeing low-complexity surgical procedures – such as dental procedures which can be undertaken in an ambulatory or non-hospital setting – occurring in higher-cost settings such as day hospitals. This enables PL benefits for use of surgical guides and biomodels to be claimed, which would not be possible if the procedure was undertaken in general dental surgeries. We recommend the department investigates this issue.

Criterion 3: MBS eligibility

3. A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist).

Based on the data available, we understand that Medicare benefits were payable for all instances where PL benefits for the listed surgical guides and biomodels were paid. This criterion is therefore **met**.

However, explanatory notes on the rationale for criterion 3 stipulate that the Medicare benefit should be payable under an item that is specific to the procedure in which the product is 'delivered' (Department of Health 2017, p. 14). Conversely, private health insurers are required by law (under the *Private Health Insurance (Prostheses) Rules*) to pay benefits for PL products *regardless* of the type of procedures they are used for.

Stakeholders – including private health insurers and sponsors – reported a number of instances where MBS item numbers may be inappropriately used to enable payment of benefits through the PL. For example, we note from utilisation data that benefits have been paid for surgical guides and biomodels for TMJ arthroscopies (MBS item number 45857), a procedure where the surgery does not appear to involve implantation of a device (therefore does not meet Criterion 4).

We also heard that the MBS item number for **alveolar ridge augmentation** (45841) may be used to enable PL benefits to be claimed for surgical guides and biomodels for dental implants, which would not otherwise be possible because dental procedures are not covered by the MBS.[16]

> Alveolar ridge augmentation is done essentially only for dental implants. So surgical guides and biomodels are being used in undertaking dental implant surgery (which can occur concurrently with an alveolar ridge augmentation). As dental implants do not qualify for the MBS, then the use of surgical guides or biomodels is being linked to the only other part of the procedure which attracts an MBS item number, which is the alveolar augmentation code 45841. (Surgeon)

As noted in Section 3, there has been increasing use of surgical guides and biomodels for MBS items outside the plastic and reconstructive category and where no MBS item is recorded (see Table 16 in Section 3). It is therefore difficult to determine the extent to which PL benefits paid for listed surgical guides and biomodels may be attributed to 'inappropriate' MBS item numbers. Further investigation is required to examine PL claims associated with MBS items for TMJ arthroscopies, alveolar ridge augmentation (where PL benefits are claimed for surgical guides and biomodels for dental implants), items outside the plastic and reconstructive categories, and where no MBS item is recorded, to ensure they are appropriately associated with the provision of surgical guides and biomodels to support implantation of prostheses. Interpretation of this aspect of Criterion 3 may affect the eligibility of the listed surgical guides and biomodels in some instances.

[16] Surgeons advised that some dental procedures that occur as part of complex CMF surgery – for example, where teeth need to be replaced due to cancer or trauma, or in paediatric surgery – may be appropriately claimed through the MBS.

Criterion 4: Essential, integral, single use, patient specific and related to implantation

4. A prosthesis should:

(a) be surgically implanted in the patient and be purposely designed in order to

(i) replace an anatomical body part; or

(ii) combat a pathological process; or

(iii) modulate a physiological process;

or

(b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted

or

(c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted.

Part (a) does not directly apply to surgical guides and biomodels as it relates to the implant itself, while part (c) does not apply as surgical guides and biomodels are not critical to the ongoing operation of the implant. Thus, part (b) is the only part of criterion 4 which is directly applicable to surgical guides and biomodels.[17]

We note from utilisation data (see Section 3.3) that benefits have been paid for surgical guides and biomodels in instances where the surgery does not appear to involve implantation of a prosthesis, such as TMJ arthroscopies. This is a clear example of where criterion 4(b) is not met.

In other circumstances this criterion is less clear-cut. In order to assess whether or not it is met, we therefore examine each element of 4(b) in turn – that is, whether the surgical guide or biomodel is:

- essential to implanting a prosthesis which meets criterion 4(a)
- specifically designed as an integral single-use aid to implanting a prosthesis
- only suitable for use with the patient in whom the prosthesis is implanted.

[17] Many surgical guides and biomodels listed on the PL are provided as part of a kit. In assessing this criterion, we consider surgical guides and biomodels separately from other items supplied as part of a kit.

Essential to implanting the prosthesis

The PL guide does not define the term 'essential'. As a result, this criterion is interpreted differently by surgeons, sponsors and private health insurance representatives. As discussed in Section 1, we heard that surgical guides and biomodels are currently used for many procedures that were historically (and often still are) conducted without them.

Surgeons suggested that surgical guides and biomodels are essential in procedures where their use confers better outcomes, such as improved surgical accuracy, reduced operative time and reduced incidence of revision surgery. If the surgery can be conducted accurately and effectively without the use of the surgical guide or biomodel, then the products cannot be considered essential.

Further, the surgical guide or biomodel must not only be essential to conducting the surgery, but also essential to the act of implanting the prosthesis. This means that surgical guides and biomodels that serve a different purpose in the surgical process do not meet this criterion. In particular, in instances where biomodels are used for purposes such as manufacture or verification of surgical guides or implants, surgical planning, rehearsal or education, these cannot be considered 'essential to implanting the prosthesis'. This does not mean that they do not serve an important role in surgical practice; indeed, we heard that biomodels are increasingly used, and considered useful or even essential, for a growing range of procedures. Rather, it means that such uses do not meet this element of criterion 4(b).

CMF procedures

The surgeons we consulted were unanimous in their view that surgical guides may be considered essential for implantation of a device in complex CMF procedures such as:

- orthognathic surgery (double jaw and complex single jaw – e.g. with segmentation)
- facial trauma surgery[18]
- TMJ disorder surgery
- cancer resection and reconstruction
- correction of cleft and craniofacial deformities (e.g. craniosynostosis conditions)
- cranial vault reconstruction and cranioplasties
- surgery for rare conditions (e.g. fibrous dysplasia, anodontia)
- dental surgery where it is part of a CMF procedure (for example, where multiple teeth are replaced as a result of trauma, cancer resection, cleft and palate procedures).

Biomodels may be considered essential for implanting a device in the complex CMF procedures listed above provided that they are used intraoperatively to support implantation of a prosthesis (e.g. to shape plates).

[18] In some cases, the timeframe for manufacturing products may be longer than the window of surgical opportunity.

While useful for some patients, surgeons considered that surgical guides and biomodels were not essential for implanting a device in simpler procedures, such as:

- simple single jaw orthognathic surgery
- simple orbital surgery
- sinus lift procedures
- alveolar ridge augmentation
- dental implants (e.g. following tooth extraction).[19]

However, surgeons cautioned against blanket assumptions about the complexity of a given procedure type (as this depends on individual clinical circumstances), and highlighted the need for appropriate definitions of 'simple' and complex' procedures.

Dental procedures

Most surgeons and some sponsors did not consider the use of surgical guides and biomodels in dental procedures to be essential to implantation. This was especially the case in routine dental implants, which are low-complexity procedures frequently performed in a general dental surgery.

Surgeons suggested that neither surgical guides nor biomodels are essential for alveolar ridge augmentation, which is a preparatory procedure for dental implant surgery. One surgeon argued that biomodels could be 'very useful' as a planning and visualisation aid in cases where custom mesh was used to support the graft, rather than being essential to the implantation of the mesh or graft.

Orthopaedic procedures

Surgical guides and biomodels are increasingly used in orthopaedic surgery as part of virtual surgical planning, with mixed evidence regarding their effectiveness based on the literature (see Appendix D, Section D.3.3). Our own systematic review (Appendix C) identified only one orthopaedic study (in the context of primary total knee arthroplasty), which found no difference in most outcomes investigated between the intervention and control groups, but a bigger drop in haemoglobin in the group utilising a surgical template.

In addition, as we consulted with experts in oral and maxillofacial and head and neck reconstructive surgery rather than orthopaedics, we cannot draw any conclusions on whether and when surgical guides and biomodels are essential to implanting prostheses in orthopaedic surgery.

[19] Excluding circumstances where dental implants are placed at the same time as a more complex CMF procedure.

Specifically designed as an integral single-use aid for implanting a prosthesis

The second component of criterion 4(b) is that the product must be specifically designed as an integral single-use aid to implanting a prosthesis. The explanatory note to this criterion specifies that such aids 'are only for use once in a patient, and have unique and direct connection to the product [implant] and are integral to implanting the product into the patient'. Below we consider the 3 components of this explanatory statement in turn.

Single use

All surgical guides and biomodels on the PL are single use.

Unique and direct connection

As shown in Appendix B, 18 of the 32 listed products are provided as part of a kit or system that also includes implants, and can therefore be considered to be specifically designed and to have a unique and direct connection to the implant.

Similarly, if the manufacturer of the surgical guide or biomodel is accredited or endorsed by a third-party implant manufacturer, then their products can also be considered to have a unique and direct connection to the implant.

Finally, if a biomodel is used to pre-bend an off-the-shelf plate intraoperatively, prior to implantation, then this requirement is also met.

Integral to implanting a product

We interpret the term 'integral to implanting a product' to mean 'essential to implanting the prosthesis', as discussed above.

Only suitable for use by the patient in whom that product is implanted

All surgical guides and biomodels are, by definition, based on an individual's presurgical (or planned postsurgical) anatomy and designed to support a specific surgical procedure. Therefore, they cannot be used in another patient.

Summary of assessment of criterion 4

The clinical uses of listed surgical guides and biomodels was found to vary considerably, which, combined with a lack of clarity in the definition of key terms (particularly 'essential' and 'integral'), makes assessment of this criterion difficult.

Based on the analysis provided above, we have found that this criterion is:

- **not met** for surgical guides or biomodels when used in *procedures that do not involve implantation* of a prosthesis
- **met** for surgical guides and biomodels used for *complex CMF procedures*
- **not met** for surgical guides or biomodels for *simpler procedures*.

Examples of procedures that surgeons generally considered complex or simple are provided in Section 1.2 and Section 4.2. However, surgeons cautioned against blanket assumptions about the complexity of a given procedure type (as this depends on individual clinical circumstances), and highlighted the need for appropriate definitions of 'simple' and complex' procedures.

Criterion 5: Clinical effectiveness and costs

5. The product has been compared to alternative products on the Prostheses List or alternative treatments and

   (i) assessed as being, at least, of similar clinical effectiveness; and

   (ii) the cost of the product is relative to its clinical effectiveness.

5(i) Clinical effectiveness

As discussed under criterion 1, all products have been registered by the TGA (with the exception of 2 products in the transition process). Some stakeholders considered that TGA and PLAC approval of the currently listed products meant that this criterion had already been considered and determined to have been met by these groups. However, the TGA advised us that, as low-risk medical devices, surgical guides and biomodels would likely have been approved on the basis of international listings and manufacturing control data (rather than clinical effectiveness). Where surgical guides and biomodels are listed as part of a kit including patient-specific implants, these would have been the focus of most scrutiny.

We do not have access to TGA data, and sponsors did not provide any further (i.e. unpublished) data to support the clinical effectiveness of products.

Our systematic review (Section 2.3) found limited evidence for the effectiveness of surgical guides and biomodels relative to standard treatment. The published evidence available was for only one product (ProPlan); no other product studies were found in our systematic review and we do not have sufficient information to assess the clinical effectiveness of the remaining products.

In addition, we noted significant limitations in the evidence base: sample sizes were small, there were no randomised controlled trials, most studies were retrospective in design and studies were sometimes confounded by the inclusion of patient-specific implants in intervention groups. Most studies had at least a moderate risk of bias.

However, despite this paucity of high-quality evidence on the comparative clinical effectiveness of the in-scope products (see Section 2.3), and the noted limitations of the broader evidence base (see Section 2.4), this review found support for the clinical effectiveness of surgical guides and biomodels *in general*, at least in the context of complex CMF surgeries. Both the literature and our consultations with clinical experts indicated that, in this context, surgical guides and biomodels are associated with better clinical outcomes than conventional surgery and are (at least in some clinical circumstances) considered the standard of care.

In light of these findings, this review found there is currently **insufficient evidence** to determine if criterion 5(i) is met.

5(ii) Costs relative to clinical effectiveness

> There are certainly instances in complex surgery where these items are needed, and the PL should be there to pay for it. But we need to work out restrictions or containment on making it affordable and sustainable. (Peak body representative)

Measures of cost were included in 4 studies identified in our systematic review (see Section 2.2), all of which related to ProPlan. These studies came to different conclusions in relation to cost effectiveness:

- **Cost neutral:** Mazzola et al. (2020) concluded that for osseous free flap reconstruction of the mandible or maxilla, virtual surgical planning technology is helpful in reducing operative time and the length of hospital stay, without affecting the final cost of the procedure.
- **More cost effective:**
  - Resnick et.al. (2016) found that for bimaxillary orthognathic surgery, virtual surgical planning is significantly less expensive and takes less time than standard planning.
  - Zweifel et al. (2015) found that the time saved through the use of virtual surgical planning (which included the use of cutting guides) reduced the additional costs associated with this method.
- **Less cost effective:** Rommel et.al (2017) found that for mandibular reconstruction with microvascular free fibular flap after segmental mandibulectomy, individual planning and virtual surgical planning had comparable operative efficiency and surgical outcomes, but that the individual planning method was more cost-effective.

Given these mixed results, and the absence of studies on the other in-scope products, there is insufficient evidence to determine the costs relative to their effectiveness of the surgical guides and biomodels currently on the PL. Further, the lack of high-quality, comparative evidence of clinical effectiveness for surgical guides and biomodels would appear to make a cost-effectiveness study infeasible at this stage.

Stakeholders also identified that the following issues may influence whether surgical guides and biomodels represent value for money:

- **The PL benefit may not accurately reflect the cost of the items** – for example, products may be supplied to public hospitals or overseas at a cheaper rate than the PL benefit amount. In addition, the PL benefit does not reflect differences in the cost of producing more complex, compared with simpler, surgical guides and biomodels.
- The costs of using surgical guides and biomodels may be, in some instances, **disproportionate to the cost of the implant, or the cost of the surgery.** This is more likely to be the case in low-complexity (and therefore lower cost) procedures. This mismatch is exacerbated by the growing trend to claim benefits for multiple surgical guides and biomodels in a single separation.
- The growth in point-of-care (in-hospital) manufacturing of surgical guides and biomodels was seen as a promising development (see Section 1.3). Further investigation of the costs and benefits of such approaches is encouraged.

There is currently **insufficient evidence** to determine if criterion 5(i) or 5(ii) is met.

We suggest further economic analyses are required. This is discussed in Section 5.

4.3 Stakeholder suggestions for improvements to the PL listing of surgical guides and biomodels

Stakeholders suggested a range of improvements to the PL with respect to surgical guides and biomodels, including clarification and guidance regarding eligibility, re-categorisation of products into new subcategories and product groups, restricting the circumstances under which benefits are payable, considering current benefits and alternative claiming arrangements for products, and conducting a cost review.

Specific suggestions within these categories are summarised below. We note that there were varying levels of support among stakeholders, and that a number of suggestions fall outside the scope of the review and may not be feasible under current PL mechanisms.

Clarification of eligibility criteria:

- Amending the PL criteria to **include a definition of essential** in Criterion 4(b) and clarify the **meaning of integral** for the purposes of surgical guides and biomodels.
- Providing **guidance, including examples and images,** of the surgical guides and biomodels listed and the circumstances under which they are considered eligible.
- Adding clear **definitions of relevant terms**, including diagnostic tools and surgical tools and the difference between these and biomodels and surgical guides considered eligible for listing on the PL.

Review and re-categorisation of PL sub-categories and product groups:

- **Separating dental implant guides from CMF surgical guides** and re-categorising the former to the subcategory 07.03 Dental Implants and 07.03.03 Endosseous Implants product group.
- Redefining subgroups for surgical guides to **separate out splint guides,** which could be more suitably reimbursed at a lower benefit than other surgical guides, because they are less costly to produce.
- Considering whether surgical guides and biomodels should be **moved** to Part C of the PL or be **required to be packaged** with biomodelled implants.
- **Collaborating** with surgeons, industry representatives and sponsors when considering future changes.

Restriction of circumstances in which benefits are payable:

- Limiting benefits to MBS items in specific categories (e.g. plastic and reconstructive).
- Limiting benefits for surgical guides and biomodels to only those used in complex CMF surgeries. Mechanisms could include **linking eligibility to specific MBS item numbers** where use is considered essential. While there was significant in-principle support for this approach from some stakeholders, it was not unanimous and not without significant caveats. Further consultation with clinical experts would be needed to inform such limits.
- Pending clarification of the PL eligibility criteria, considering limiting benefits for **biomodels** to only include instances **where they are used intraoperatively to support the implantation of a prosthesis** (e.g. to bend an off-the-shelf plate).
- **Limiting the number of surgical guides and biomodels per procedure/separation** for which a benefit is payable under the PL. Suggestions for limits, however, ranged from one surgical guide and one biomodel per plate to 10 surgical guides/biomodels per procedure. If more than the prescribed limit are required, then individual case discussions could occur though an 'exceptional requests' process (e.g. requiring surgeons to provide the rationale for approval by an independent body) and/or by negotiation with private health insurers.

As noted previously, some stakeholders cautioned that linking benefits to MBS items was an oversimplification, as it is not always possible to characterise procedure types (as indicated by MBS item numbers) as 'simple' or 'complex' without understanding individual clinical circumstances. One peak body suggested that this approach was 'arbitrary and restrictive', and inappropriate particularly in the context of rapidly evolving technology.

Others argued that *any* of the suggested restrictions may impact inappropriately on clinicians' choice, is likely to have unintended consequences (e.g. shifting of the cost burden, splitting of single procedures into multiple ones), or that any such limits should at least be informed by further consultation to identify appropriate limits in different clinical circumstances.

Review of benefits and claiming arrangements:

- Introducing **a stratified approach to benefits payable**, such as funding 100% of the first product, 75% of the second, and so on.
- Considering **a tiered approach**, where benefits payable may be higher for more complex surgeries.
- Listing surgical guides and biomodels only as part of **kits** and defining a benefit for the kit (noting, however, that this may produce wastage through unused items in the kit).
- Capping benefits for surgical guides and biomodels as a percentage of implant cost or relative to MBS benefits.
- Requiring that kits that do not include implants be **accredited or endorsed** by relevant implant manufacturers.
- Providing a separate funding mechanism for virtual surgical planning (and virtual biomodels) either through the PL or via the MBS. Virtual surgical planning is currently 'absorbed' in the benefit for surgical guides and biomodels (as well as patient-specific implants) listed on the PL, meaning that it may be effectively funded multiple times for a single procedure.

- **Reviewing costs** to ensure that:
  - the PL benefits listed are in line with manufacturing costs
  - the PL benefits paid for surgical guides and biomodels are proportionate to the cost of the surgery and the cost of the implants
  - the costs of products are comparable to the minimum prices available in the public sector and overseas.

Further and stronger evidence

Some stakeholders noted the need for more and/or higher-quality evidence for both the clinical effectiveness and relative costs of surgical guides and biomodels to inform funding decisions.[20] However, others suggested that these products already represented the standard of care in some instances, and that the need for economic evaluation should be balanced with the need to invest in innovation and development.

> Post-listing reviews need to find the balance in acknowledging that that early stages of developing medical innovation can cost more but can also deliver increased efficiency and/or improved clinical outcomes into the future…This is a developing area of prostheses use and should be supported unless there is more definitive evidence of reduced clinical outcomes or excessive costs. (Peak body)

Many stakeholders noted the clinical importance of surgical guides and biomodels, regardless of the question of PL eligibility, and highlighted the need for alternative funding models to be in place should they be removed from the PL (or limited to certain circumstances). They highlighted that failure to consider this is likely to have unintended consequences, as the funding burden would be shifted, for example, to the public sector or to patients.

While outside the scope of this review, surgeons suggested that the costs and benefits of point-of-care manufacturing hubs be further explored, noting that such facilities are currently operating both in Australia and overseas.

[20] For example, an Independent Health and Aged Care Pricing Authority (IHACPA) review to ensure consistency with concurrent reforms.

Review of governance arrangements

Some stakeholders suggested that the PL may benefit from more **robust governance arrangements** that include a fit-for-purpose clinical advisory group and mechanisms for ongoing consultation and engagement with clinical experts, industry representatives and sponsors.

One stakeholder suggested that PLAC – or the new Medical Devices and Human Tissue Advisory Committee (MDHTAC) – may be appropriately placed to provide and/or facilitate such consultation and governance mechanisms.[21] However, this (i.e. consideration of broader eligibility and restriction issues) may represent an expansion of the currently defined role of these committees.

[21] The PLAC will be replaced by a new Medical Devices and Human Tissue Advisory Committee (MDHTAC) from 1 July 2023 (Butler 2023).

Section 5: Conclusions

As noted in Section 4, the terms used in the PL guide to define the eligibility of surgical guides and biomodels are open to interpretation. Based on our review, we have given some context and clarity to each of these terms and discussed the extent to which the in-scope surgical guides and biomodels meet these criteria. We have found that eligibility likely depends on a number of factors, including clinical circumstances (such as type and complexity of implant surgery).

We suggest that the department consider:

- Clarifying PL eligibility criteria (and giving examples of eligible and ineligible types and usage of surgical guides and biomodels). This could include the development of regularly updated guidelines driven by expert clinicians.
- Addressing some of these issues in the context of concurrent work to reorganise or recategorise products currently listed on the PL.
- Clarifying the role of and pricing structures for surgical guides and biomodels supplied as individual products and as elements of 'kits' or bundles currently listed on the PL.
- Considering alternative funding structures for virtual surgical planning.
- In consultation with relevant clinical experts, placing limits on the benefits payable through the PL, for example:
  - specifying the MBS category or items for which surgical guides and biomodels are eligible for benefits through the PL mechanism
  - limiting the number of surgical guides and biomodels for which a PL benefit is paid per separation
  - considering alternative approaches to listing of benefits, such as stratified or tiered approaches.
- Investigating, and taking actions to address, areas where benefits may be claimed inappropriately (e.g. in the absence of a prosthesis, or where the procedure could be performed outside of a hospital or hospital-substitute setting).
- Conducting an economic analysis (e.g. IHACPA review) to:
  - review the benefit amounts specified on the PL for the listed surgical guides and biomodels, for example to determine if the benefits listed on the PL are consistent with the cost of manufacture
  - explore whether the benefits paid are proportionate to other costs associated with implantation of prostheses (including other items supplied as part of kits)
  - determine whether the costs of products are comparable to the minimum prices available in the public sector and overseas.
- Exploring options for future consultation and governance arrangements to ensure any changes and guidance to the sector are appropriately informed by stakeholder input.

5.1 Limitations

Data limitations: We were unable to ascertain the extent to which PL-listed products are currently being used in complex CMF surgeries. HCP1 data was often limited to the top items in a category. We were unable to explore individual product use by MBS item number, or the split of overnight cases versus day cases from hospital separation data, which may have been a useful marker for complexity. Further, the data included a significant proportion of admissions for which MBS items were unspecified.

Consultation limitations: The views of the surgeons consulted may not necessarily reflect the views of other surgeons with varying levels of expertise, experience and training, or of those in other surgical fields (e.g. orthopaedic surgery). Reported conflicts of interest by 3 surgeons did not appear to influence their responses given the overall consistency in feedback across the stakeholder category.

Evidence limitations: Our systematic review found evidence for only one product listed on the PL, and most included studies had at least a moderate risk of bias. While the synthesised literature included support for the use of surgical guides and biomodels in a range of surgical contexts, authors of these systematic reviews and meta-analyses similarly reflected on limitations of the evidence base, including the small number of studies identified, a paucity of randomised controlled trials, small sample sizes and the presence of confounding factors. The applicability of the broader evidence to specific products listed on the PL is also unclear.

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Appendix A List of stakeholders consulted

The department provided AHA with a list of stakeholders to approach for participation in this review. This appendix lists the stakeholders invited to contribute and who participated in individual and group interviews and/or provided written submissions.

Surgeons

We consulted with 13 oral and maxillofacial surgeons (12 via interview and one via written submission) and one head and neck reconstructive surgeon.[22]

Peak bodies

We invited 11 peak bodies, with interviews conducted with 8 organisations:

- Neurosurgical Society of Australasia
- Day Hospitals Australia
- Medical Technology Association of Australia
- Private Healthcare Australia
- The Australian and New Zealand Association of Oral and Maxillofacial Surgeons
- Royal Australasian College of Surgeons
- Australian Health Services Alliance
- Members Health Fund Alliance

Other organisations

We invited 2 technical and consumer representative organisations, with one interview conducted with the CSIRO.

Department representatives

We interviewed 6 representatives of the Prostheses List Reform Taskforce and Prostheses List Advisory Committee as advised by the Department of Health and Aged Care.

[22] Conflicts of interest were reported by 3 surgeons and did not appear to influence their responses given the overall consistency in feedback across stakeholders.

Sponsors

All sponsors were invited to provide a written submission and offered the opportunity for an interview. Eight of the 9 sponsors provided written submissions:

- Digital Dental Network Pty Ltd
- Maxoniq
- Anatomics Pty Ltd
- Stryker Australia Pty Ltd
- Johnson & Johnson Medical Pty Ltd
- KLS Martin Australia Pty Ltd
- Specific Pty Ltd
- More Group Pty Ltd

AA-Med did not provide a written submission in the first consultation round, but provided feedback on the draft report.

Representatives from 3 of the 9 sponsors opted to take part in an interview:

- Digital Dental Network Pty Ltd
- Johnson & Johnson Pty Limited
- KLS Martin Australia Pty Limited

Appendix B In-scope products

The tables below describe the 32 surgical guides and biomodels that are listed on the PL and in scope for this review. This lists the product name, ARTG identification number, ARTG intended purpose, whether the product includes an implant or prostheses (as specified in the ARTG) and the PL benefit amount.

Table 20: Cranium surgical guides (07.02.02.04)

Sponsor	Product name	ARTG Identification Number	ARTG intended purpose	Includes prostheses as part of kit/system?	Benefit
Anatomics Pty Ltd	Anatomics Surgical Guide	288564	Intended for the replacement or augmentation of bony defects in the craniofacial skeleton. This kit includes a customised craniofacial implant, **customised anatomical biomodel**, fixation plates and screws.	Yes	$1,950
Johnson & Johnson Pty Ltd	ProPlan	276733	A pack that includes a combination of screws, **custom-made surgical guides, anatomical models** or implants for bone reconstruction, augmentation and fixation in the craniofacial region (e.g. craniofacial reconstruction, stabilise fractured bone, endobrow fixation, or craniotomy flap fixation).	Yes	$1,950
Johnson & Johnson Pty Ltd	Surgical Guide for OBL PSI System – Cranium	276733	A pack that includes a combination of screws, **custom-made surgical guides, anatomical models** or implants for bone reconstruction, augmentation and fixation in the craniofacial region (e.g. craniofacial reconstruction, stabilise fractured bone, endobrow fixation, or craniotomy flap fixation).	Yes	$1,950

Table 21: Mandible, Maxilla and Temporomandibular Joint surgical guides (07.02.05.07)

Sponsor	Product name	ARTG Identification Number	ARTG intended purpose	Includes prostheses as part of kit/ system?	Benefit
Anatomics Pty Ltd	Anatomics Patient Specific Surgical Guide	288564	Intended for the replacement or augmentation of bony defects in the craniofacial skeleton. This kit includes a customised craniofacial implant, **customised anatomical biomodel**, fixation plates and screws.	Yes	$2,011
Digital Dental Network	DDN Guide	336209	Custom-made **patient-specific and single-use surgical guides and biomodels** manufactured by 3D printing, intended to be used by a dental surgeon to assist in anatomical visualisation and/or surgical treatment planning, to guide drilling in the jawbone of a patient during guided dental implantation procedure for dental implant placement/fixation.	No	$1,163
Stryker Australia Pty Ltd	VSP Orthognathics Bundle (Surgical Guide and Implants)	200615	Intended for the reconstruction, stabilisation and/or rigid fixation of non-load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and over).	Yes	$2,011
Stryker Australia Pty Ltd	VSP Reconstructio n Mandibular/ Maxillary Bundle	200615	Intended for the reconstruction, stabilisation and/or rigid fixation of non-load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and over).	No	$2,011
KLS Martin Australia Pty Ltd	UNIQOS Patient Specific Surgical Guides	200232	Currently in transition arrangements. No intended purpose listed on the ARTG.	Not known	$2,011
More Group Pty Ltd	MGuide	348196	**Custom-made guides** and **biomodels** manufactured by 3D printers intended to be used in surgical procedures, surgical treatment planning, anatomical visualisations, CMF surgical procedures and intraoperative procedures.	No	$2,011
Maxoniq	OMX Solutions Patient Optimized Guide system	276176	Intended to reconstruct a damaged or diseased temporomandibular joint that cannot be salvaged. The system consists of fixation screws, custom-made mandibular ramus metal alloy condyle, custom-made polymer based glenoid fossa component and **custom-made surgical guides**.	Yes	$2,011

Sponsor	Product name	ARTG Identification Number	ARTG intended purpose	Includes prostheses as part of kit/ system?	Benefit
Johnson & Johnson Pty Ltd	ProPlan	276733	A pack that includes a combination of screws, **custom-made surgical guides, anatomical models** or implants for bone reconstruction, augmentation and fixation in the craniofacial region (e.g. craniofacial reconstruction, stabilise fractured bone, endobrow fixation, or craniotomy flap fixation).	Yes	$2,011
Johnson & Johnson Pty Ltd	SynpliciTi System – Surgical guides	276733	A pack that includes a combination of screws, **custom-made surgical guides, anatomical models** or implants for bone reconstruction, augmentation and fixation in the craniofacial region (e.g. craniofacial reconstruction, stabilise fractured bone, endobrow fixation, or craniotomy flap fixation).	Yes	$2,011
Johnson & Johnson Pty Ltd	Custom-made plates (including Megaplates) – Surgical Guides	276733	A pack that includes a combination of screws, **custom-made surgical guides, anatomical models** or implants for bone reconstruction, augmentation and fixation in the craniofacial region (e.g. craniofacial reconstruction, stabilise fractured bone, endobrow fixation, or craniotomy flap fixation).	Yes	$2,011
Johnson & Johnson Pty Ltd	Surgical guide for OBL PorousiTi PSI System – Mandible and Maxilla	276733	A pack that includes a combination of screws, **custom-made surgical guides, anatomical models** or implants for bone reconstruction, augmentation and fixation in the craniofacial region (e.g. craniofacial reconstruction, stabilise fractured bone, endobrow fixation, or craniotomy flap fixation).	Yes	$2,011
SPECIFICA PTY LTD	OsGuide	292759	A non-sterile, **custom-made** surgical instrument intended to be used in an orthopaedic and/or CMF procedure (e.g. osteotomy, arthroplasty, tumour resection, distraction osteogenesis, cranial vault reconstruction) to assist in the **intraoperative orientation** of implant components, outlining the desired cut-line, and/or guiding of surgical instruments (e.g. surgical drill, oscillating cutting saw). It is made of synthetic polymer materials and is typically manufactured by 3D printing and CAD/CAM techniques to match the patient-specific contours of the target anatomical site. This is a **single-use device** intended to be sterilised prior to use.	No	$2,011

Sponsor	Product name	ARTG Identification Number	ARTG intended purpose	Includes prostheses as part of kit/ system?	Benefit
SPECIFICA PTY LTD	DGUIDE	322576	**Guides** and **biomodels** manufactured by 3D printing intended to assist in anatomical visualisation and/or surgical treatment planning, for intraoperative dental and CMF surgical procedures.	No	$2,011
AA-Med Pty Ltd	OrthoTin Surgical Guide	293845	Intended for reconstruction of painful and/or severely disabled temporomandibular joints. The system consists of fixation screws, fixation plate, custom-made fossa component, custom-made fossa bearing component, custom-made condylar ramus component, custom-made plate, **custom-made surgical guides** and **custom-made biomodel**.	Yes	$2,011
AA-Med Pty Ltd	Lyka Smith Patient Specific Guides	293845	Intended for reconstruction of painful and/or severely disabled temporomandibular joints. The system consists of fixation screws, fixation plate, custom-made fossa component, custom-made fossa bearing component, custom-made condylar ramus component, custom-made plate, custom-made surgical guides and custom-made biomodel.	Yes	$2,011

Table 22: Anatomical biomodels (07.02.09)

Sponsor	Product name	ARTG Identification Number	ARTG intended purpose	Includes prostheses as part of kit/system?	Benefit
Anatomics Pty Ltd	Anatomics Biomodel	288564	Intended for the replacement or augmentation of bony defects in the craniofacial skeleton. This kit includes a customised craniofacial implant, **customised anatomical biomodel**, fixation plates and screws.	Yes	$1,829
Digital Dental Network PTY LTD	DDN Biomodel	336209	Custom-made **patient-specific and single-use guides** and **biomodels** manufactured by 3D printing, intended to be used by a dental surgeon to assist in anatomical visualisation and/or surgical treatment planning, to guide drilling in the jawbone of a patient during guided dental implantation procedure for dental implant placement/fixation.	No	$1,829

Sponsor	Product name	ARTG Identification Number	ARTG intended purpose	Includes prostheses as part of kit/system?	Benefit
Stryker Australia Pty Ltd	Stryker anatomical biomodel for mandible	218563	Intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.	No	$1,829
Stryker Australia Pty Ltd	Stryker anatomical biomodel for PEEK	225792	The PEEK customised cranial implants kit is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in the cranial and craniofacial skeleton.	No	$1,829
Stryker Australia Pty Ltd	VSP Orthognathics Bundle (Custom Biomodel and Implants)	200615	Intended for reconstruction, stabilisation and/or rigid fixation of non-load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and over).	Yes	$1,829
Stryker Australia Pty Ltd	VSP Reconstruction Maxillofacial Case Bundle	200615	Intended for reconstruction, stabilisation and/or rigid fixation of non-load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and over).	No	$1,829
KLS Martin Australia Pty Ltd	UNIQOS Patient Specific Anatomical Biomodel	200232	Currently in transition arrangements. No intended purpose listed on the ARTG.	Not known	$1,829
Maxoniq	The OMX Solutions Biomodel	276753	Intended to improve and simplify the performance of surgical interventions by acting as an aid or reference to transfer a preoperative plan to surgery.	No	$1,829
Johnson & Johnson Pty Ltd	PSI	276733	A pack that includes a combination of screws, **custom-made surgical guides, anatomical models** or implants for bone reconstruction, augmentation and fixation in the craniofacial region (e.g craniofacial reconstruction, stabilise fractured bone, endobrow fixation, or craniotomy flap fixation).	Yes	$1,829

Sponsor	Product name	ARTG Identification Number	ARTG intended purpose	Includes prostheses as part of kit/system?	Benefit
Johnson & Johnson Pty Ltd	ProPlan	276733	A pack that includes a combination of screws, **custom-made surgical guides, anatomical models** or implants for bone reconstruction, augmentation and fixation in the craniofacial region (e.g. craniofacial reconstruction, stabilise fractured bone, endobrow fixation, or craniotomy flap fixation).	Yes	$1,829
SPECIFICA PTY LTD	**BIOMODEL**	292561	Intended to improve and simplify the performance of surgical interventions by acting as an aid or reference to: elaborate a preoperative surgical plan; transfer the plan to surgery; and determine the correct sizing of the fixture(s) eventually required as part of the surgical procedure.	No	$1,829
SPECIFICA PTY LTD	OMF Model	322576	**Guides** and **biomodels** manufactured by 3D printing intended to assist in anatomical visualisation and/or surgical treatment planning, for intraoperative dental and CMF surgical procedures.	No	$1,829
AA-Med Pty Ltd	OrthoTin Anatomic Biomodel	293845	Intended for reconstruction of painful and/or severely disabled temporomandibular joints. The system consists of fixation screws, fixation plate, custom-made fossa component, custom-made fossa bearing component, custom-made condylar ramus component, custom-made plate, **custom-made surgical guides** and **custom-made biomodel**.	Yes	$1,829
AA-Med Pty Ltd	Lyka Smith Anatomical Biomodel	293845	Intended for reconstruction of painful and/or severely disabled temporomandibular joints. The system consists of fixation screws, fixation plate, custom-made fossa component, custom-made fossa bearing component, custom-made condylar ramus component, custom-made plate, **custom-made surgical guides** and **custom-made biomodel**.	Yes	$1,829

Appendix C Systematic review

C.1 Methods

To capture the evidence for the surgical guides and biomodels currently listed on the PL, we undertook a rapid and targeted systematic review of relevant literature. The aim of this review was to:

- identify evidence regarding the comparative clinical benefits and clinical effectiveness of the surgical guides and biomodels (the appropriate comparator may be standard care, or no guide or biomodel)
- clearly identify and analyse the benefit/s of surgical guides and biomodels compared to the comparator, including clinical outcomes and surrogate outcomes (such as time in surgery)
- analyse the comparative clinical effectiveness of different types of surgical guides and biomodels
- identify the circumstances in which surgical guides and biomodels provide clinical benefit, for comparison, to the extent possible, with the PL utilisation of surgical guides and biomodels in Australia and overseas.

The review question was: What is the comparative evidence on the clinical benefits and clinical effectiveness of the listed surgical guides and biomodels?

The recommendations of the Cochrane Rapid Reviews Methods Group and the World Health Organization's guide to rapid reviews provided a broad framework for the methodology (Garritty et al. 2021; Tricco et al. 2017), with practical adjustments to ensure the timeliness of the review.

The systematic review was based on a PICO (population, intervention, comparator, outcomes) framework as outlined below.

Population: Patients who have undergone implant or prosthesis placement.

Intervention(s), exposure(s): Implant placement utilising the surgical guides and/or biomodels listed in Appendix B.

Comparator(s)/control: Implant or prosthesis placement that:

- does not use surgical guides or biomodels
- uses alternative surgical guides or biomodels
- uses software models instead of surgical guides and biomodels.

Outcome(s):

- comparative clinical benefits
- comparative clinical effectiveness
- other relevant outcomes (e.g. surrogate outcomes, economic outcomes).

C.2 Search strategy

We performed 3 types of searches to identify relevant articles published in English between January 2013 and September 2022:

- electronic database searching: MEDLINE (via PubMed)
- manual hand searching: the reference lists of included full text articles were scanned to identify eligible articles that were missed in the database search
- search of information provided by sponsors and stakeholders relating to the surgical guides and biomodels of interest.

C.2.1 Inclusion and exclusion criteria

Table 23 outlines the inclusion and exclusion criteria used to determine which articles were included in the review.

Table 23: Criteria for inclusion/exclusion of studies

Category	Inclusion criteria	Exclusion criteria
Study type	• Randomised clinical trials or, where experimental evidence is not available, observational studies (e.g. cohort or case-control studies) may be considered	• Qualitative studies
Publication type	• Written in English • Published (or conducted, in the case of sponsor-provided data) between January 2013 and September 2022	• Not written in English • Published (or conducted) before January 2013 • Opinion articles • Conference and poster presentations • Books and book chapters • Dissertations • Full text not available
Population	• Patients who have undergone implant/prosthesis placement where the surgeon used a surgical guide • Patients who have undergone implant/prosthesis placement where the surgeon used a biomodel	• Animal studies • Cadaver studies • In vitro studies • Studies that describe software development/manufacturing processes
Intervention	• Surgical guides listed on the PL under subgroups 07.02.02.04 and 07.02.05.07 • Biomodels listed on the PL under group 07.02.09	• Surgical guides and biomodels not listed in these PL subgroups/group • Implantable devices (in the absence of surgical guides and biomodels)

Category	Inclusion criteria	Exclusion criteria
Comparators	The study must include at least one of the following groups: • Patients who have undergone implant/prosthesis placement where the surgeon did not use a surgical guide • Patients who have undergone implant/prosthesis placement where the surgeon did not use a biomodel • Patients who have undergone implant/prosthesis placement where the surgeon used an alternative surgical guide or biomodel	• Studies without a relevant comparator
Outcomes	To be included, articles must: • discuss the use of surgical guides or biomodels as a tool for surgical planning AND contain sufficient information on at least one of the following: • benefits • comparative effectiveness	Articles will be excluded if they do not: • discuss the use of surgical guides or biomodels as a tool for surgical planning OR do not include sufficient information on any of the following: • benefits • comparative effectiveness

C.2.2 Search syntax

Because this review aimed to examine evidence specific to in-scope products on the PL, the terms used to search the database were specific to those products. Table 25 lists the search terms used in MEDLINE (via PubMed).

C.2.3 Article selection

The data selection and extraction process for this rapid review was based on the Cochrane Rapid Review Group's guidance (Garritty et al. 2021).

One researcher conducted the database search. Citations identified in the search were saved locally and 2 reviewers screened the titles and abstracts of 20% of the retrieved citations for eligibility using the inclusion/exclusion criteria. Disagreements were resolved through discussion. A single reviewer then screened the remaining titles/abstracts and the second reviewer screened all titles/abstracts excluded by the first reviewer to identify any articles that were excluded by mistake. A single reviewer scanned the reference lists of included articles to identify additional relevant articles.

C.3 Data extraction

A single reviewer extracted relevant data from included articles using a standardised Microsoft Excel form. Data extraction was limited to the set of data items required to answer the research questions, with information retrieved from the articles including:

- reference information (i.e. citation details)
- product information (i.e. name of surgical guide or biomodel, where provided)
- article type (e.g. systematic review, randomised controlled trial, sponsor-provided data)
- study information (i.e. patient characteristics, study design, study methods)
- country or countries where the study took place
- data on comparative clinical benefits
- data on comparative clinical effectiveness
- other outcomes data reported (e.g. surrogate and/or economic outcomes)
- limitations of studies (as articulated by authors)
- conflicts of interest, declared or inherent (e.g. sponsor-provided information that has not been peer-reviewed).

C.4 Quality assessment

Articles included in the review were assessed for quality using the NHMRC levels of evidence (NHMRC 2009) outlined in Table 24.

Table 24: NHMRC levels of evidence

Level of evidence	Study design
I	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls (i.e. non-randomised experimental trials, cohort studies, case-control studies, interrupted time series studies with a control group)
III-3	A comparative study without concurrent controls (i.e. historical control study, two or more single arm studies, interrupted time series studies without a parallel control group)
IV	Case series with either post-test or pre-test/post-test outcomes

The quality of evidence within these level III-2 studies was assessed using the Newcastle-Ottawa Quality Assessment Scale (NOS) (Wells et al. 2021). The NOS assesses the risk of bias in a study

by considering how well it was conducted across three domains: 1) selection of the sample, 2) comparability of groups, and 3) exposure or outcome variables. A maximum of four points can be awarded in the selection domain, a maximum of two points can be awarded in the comparability domain and a maximum of three points can be awarded in the exposure/outcome domain. The maximum total score for a study is nine. Higher scores indicated a lower risk of bias, while lower scores indicate a higher risk of bias. To date, threshold scores have not been established to distinguish between good and poor quality studies.

C.5 Data synthesis

One researcher used the extracted data to answer the research questions using a narrative synthesis.

C.6 Findings

C.6.1 MEDLINE search

The MEDLINE searches for product-specific information returned a total of 153 results. Table 25 shows the number of results for each search term used, the number of included and excluded studies, and the main reason for exclusion.

Table 25: Product-specific search terms and results

Search term/s	Number of results	Number of included studies	Number of excluded studies	Reasons for exclusion
Anatomics	12	0	12	Not relevant to SGBs (n = 7) No relevant comparator (n = 5)
ProPlan	60	4	56	Not relevant to SGBs (n = 21) No relevant comparator (n = 12) Study type (n = 7) No relevant comparator (n = 2) No clinical outcomes (n = 4)
TruMatch	2	0	2	Study type (n = 2)
"Surgical Guide OBL"	1	0	1	No relevant comparator (n = 1)
"DDN Guide", "DDN surgical guide"	10	0	10	Not relevant to SGBs (n = 10)
"Digital Dental Network" Guide	12	0	12	Not relevant to SGBs (n = 11) No relevant comparator (n = 1)
Stryker VSP	1	0	1	Study type (n = 1)
KLS Martin surgical guide	7	0	7	Not relevant to SGBs (n = 5) Study type (n = 1) Not product specific (n = 1)

Search term/s	Number of results	Number of included studies	Number of excluded studies	Reasons for exclusion
Mguide	2	0	2	No relevant comparator (n = 2)
Maxoniq	0	0	0	N/A
"OMX Solutions"	2	0	2	Not about SGBs (n = 1) No relevant comparator (n = 1)
SynpliciTi	2	0	2	No relevant comparator (n =2)
"Custom made plates"	8	0	8	No relevant comparator (n = 4) Not relevant to SGBs (n = 3) Study type (n = 1)
Megaplate	2	0	2	Not relevant to SGBs (n = 2)
Surgical Guide OBL	1	0	1	Not product specific (n = 1)
OsGuide	0	0	0	N/A
DGUIDE	0	0	0	N/A
OrthoTin	0	0	0	N/A
PorousiTi	1	0	1	Not relevant to SGBs (n = 1)
"Lyka Smith"	0	0	0	N/A
"Anatomics biomodel"	4	0	4	No relevant comparator (n = 4)
DDN Biomodel	0	0	0	N/A
Stryker biomodel	0	0	0	N/A
Stryker PEEK	17	0	17	Not relevant to SGBs (n = 15) No relevant comparator (n = 2)
Stryker virtual surgical planning	6	0	6	No relevant comparator (n = 3) Study type (n = 3)
UNIQOS	0	0	0	N/A
KLS Martin biomodel	0	0	0	N/A
OMX biomodel	0	0	0	N/A
PSI Biomodel	3	0	3	Study type (n = 2) Not relevant to SGBs (n = 1)
SPECIFICA biomodel	0	0	0	N/A
SPECIFICA OMF	0	0	0	N/A
Total	**153**	**4**	**149**	

Note: SGB = surgical guides and biomodels. ProPlan is now known as TruMatch; both terms were included in our search. There may be multiple reasons for exclusion for a study however, only the first identified reason by study was recorded. The exclusion criterion of 'not product specific' means that the study did not specifically identify the products listed in the PL and in scope for this review as interventions.

C.6.2 Search of reference list of studies identified for inclusion from electronic database search

A scan of the reference lists of included articles was conducted to identify additional relevant articles. A total of 281 titles were scanned and 254 were excluded based on the citation details (many were excluded based on publication prior to 2013). The full text of 27 articles was reviewed, from which 3 articles were identified for inclusion. The main reasons for excluding the other 24 articles were that there was no relevant comparator, or they did not identify the specific products listed on the PL.

Search of information provided by sponsors or other stakeholders

From the initial consultation with stakeholders, a total of 164 articles provided by sponsors and another 14 provided by other stakeholders were screened. From review of these articles, 4 articles from the sponsor-provided material, and 2 articles from other stakeholders, were identified for inclusion.

In the second round of consultations, an additional 24 articles which had not already been considered were referenced in stakeholder feedback submissions on the draft report. Upon review, none of these additional studies met the criteria for inclusion in the systematic review. Overall, a total of 202 articles provided by stakeholders were screened.

C.6.3 Study descriptions

A total of 13 studies met the inclusion criteria and were included in this review (Figure 4). These studies were published between 2013 and 2021 and came from China (4 studies), Australia (2 studies), Germany (2 studies), USA (2 studies) Belgium, Switzerland and Singapore. Only one of the products listed on the PL – ProPlan – was included in any studies.

The extracted data from the 13 studies is presented below. A narrative synthesis of the results is presented in Section 2.

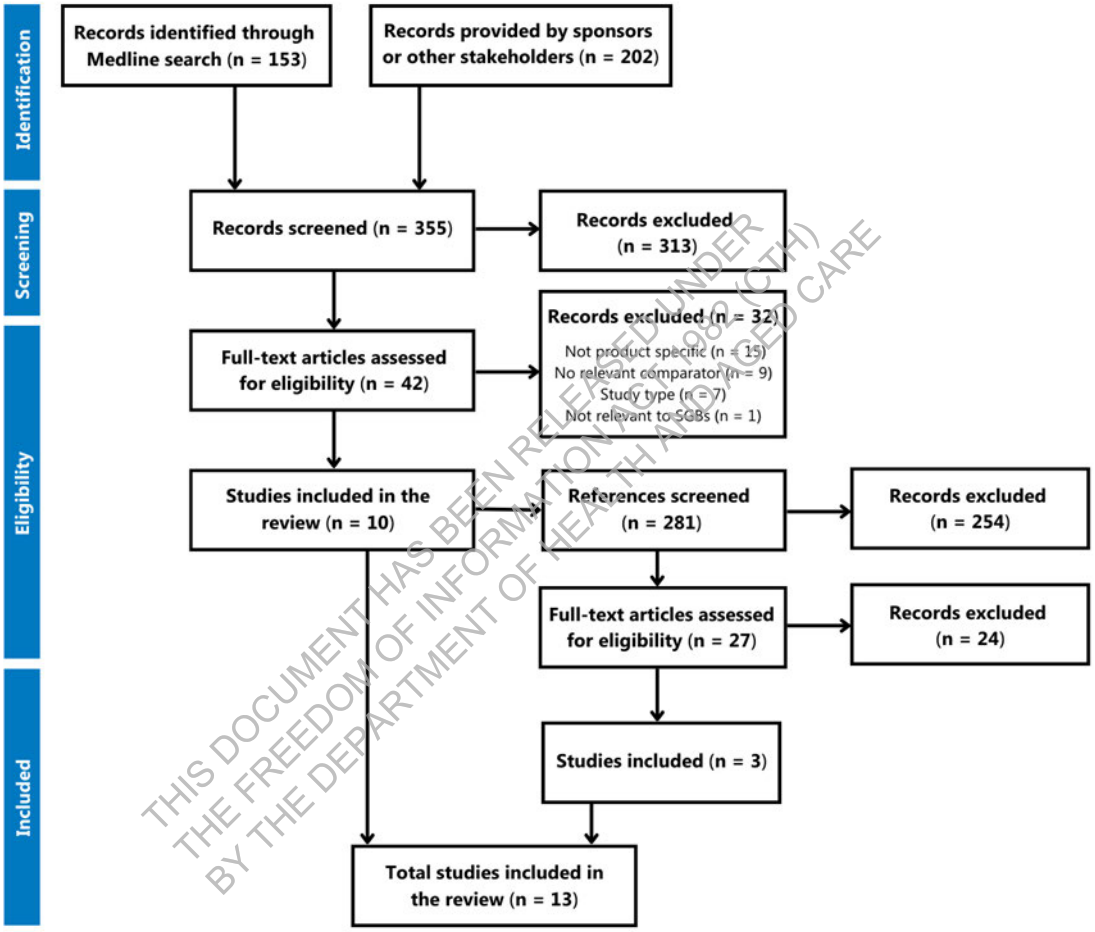

Figure 4: Selection process for studies for inclusion in the systematic review

De Maesschalck et al. (2017)

Study type (level of evidence)

Retrospective case-control (III-2)

Country

Switzerland

Study information

The study included 18 patients who had undergone mandibular reconstruction with fibular free flap following segmental mandibulectomy between 2012 and 2014 at a hospital in Switzerland. Seven of these patients underwent mandibular reconstruction with fibular free flap with virtual surgical planning using ProPlan CMF which included custom patient-specific plates and surgical cutting guides. The control group, consisting of 11 patients, was treated through conventional surgery (i.e. a freehand technique).

Outcomes

Morphometric accuracy was assessed for both groups by calculating differences in linear and angular parameters from the pre- and postoperative scans to determine the difference between planned and actual osteotomy. Five anatomical landmarks on the affected and nonaffected side were used for measurements: mandibular ramus length, 2 measures of mandibular body length, axial mandibular angle and sagittal mandibular angle. Superimposition of the planned and postoperative images of the 3D mandible was also used to assess the accuracy of the reconstruction plate positioning.

Findings

The axial mandibular angle on the nonaffected side was significantly lower in the intervention group (mean difference of 1.0° between pre- and postoperative measurement) than the control group (2.9°; p = 0.03). There were no other statistically significant differences between the pre- and postoperative measurements in either group, and no differences in overall accuracy.

Limitations

The limited number of patients and the retrospective nature of the study were identified as limitations by the authors, who noted that prospective studies comparing the 2 surgical techniques are required to draw definitive conclusions.

Conflicts of interest

Not reported.

Johal et al. (2022)

Study type (level of evidence)

Retrospective case-control (III-2)

Country

Australia

Study information

The study sample included 44 patients who had undergone virtually planned maxillomandibular reconstruction between January 2012 and July 2020. Thirty-two of these patients underwent commercial virtual surgical planning through Synthes Proplan or Trumatch using Materialise software. For the other 12 patients, in-house virtual surgical planning was conducted using 3D Slicer 4.0, Materialise InPrint and Autodesk 3dsMax 2016–2020 software.

Outcomes

Accuracy was measured by comparing the length of bone segments, angle between adjacent segments and intercondylar and intergonial angle distances on the preoperative digital plan compared to the postoperative CT scan. Predictors of reconstruction errors were also investigated.

Findings

There was no significant differences in accuracy between the intervention and control group in relation to bone segment length ($p = 0.1$), angle between segments ($p = 0.92$) or intercondylar and intergonial distance ($p = 0.76$). Predictors of error were factors related to complexity, including indication for surgery, timing or number of reconstructions, and number of segments.

Limitations

The sample size was small and there was selection bias towards patients who had undergone recent CT scanning which led to 42% attrition from the total cohort of those who had undergone virtual surgical planning. The results may therefore not be generalisable to other virtual surgical planning methods or other surgeons.

Conflicts of interest

Nil reported.

Mazzola et al. (2020)

Study type (level of evidence)

Retrospective case-control (III-2)

Country

Australia

Study information

The study sample included 138 patients who underwent osseous free flap reconstruction of the mandible or maxilla between January 2010 and March 2018. Of these patients, 29 underwent reconstruction with a proprietary virtual surgical planning approach (P-VSP) provided by DePuy Synthes. This approach included use of a reconstructive 3D model, cutting guides for the donor and ablative sites and customised titanium plates produced by ProPlan. The other 99 patients underwent surgery through a traditional non-virtual surgical planning reconstructive approach (non-VSP). A cost-analysis was conducted with a subgroup of 16 patients in each group (total n = 32), matched on site, indication, bone flap, complexity and age.

Outcomes

Complications, length of stay (LOS) on specialised or intensive care ward, total days in hospitalisation, operating time, ward cost, hospitalisation cost and operating cost.

Findings

For the non-matched cohort, there were no statistically significant differences in the total number of complications between the 2 groups. The P-VSP group had a shorter median LOS on a specialised or intensive care ward than the non-VSP group (8.0 vs 10.0 days; p = 0.037), and a shorter overall LOS in hospital (10.0 vs 13.0 days, p = 0.009). The mean operating time was also shorter for the P-VSP group (507.38 vs 561.75, p = 0.042). This led to lower costs for the P-VSP group compared to the non-VSP group, in terms of the median ward cost ($2,960 vs $3700, p = 0.037), median hospitalisation cost ($7.892 vs $11,283, p = 0.014), and operating cost ($18,623 vs $19,882, p = 0.042). This was despite P-VSP cases being more complex (median complexity score 2 vs 1) and having higher material costs ($7,864 v $3,442, p < 0.001) than the non-VSP group.

For the subgroup of 32 matched patients, the only significant difference was a higher median instrument cost in the P-VSP group ($8,124 v $3,649; p < 0.001).

Limitations

Results represent the experience of one surgeon and may not generalise to others. There were differences in case selection between groups which could bias against P-VSP. The complexity score used has not been validated. Costs were based on previous data rather instead of a micro-costing method. The cost for the surgeon for preoperative planning was not considered (because in Australia, surgeons are not paid for digital planning).

Conflicts of interest

Nil reported.

Resnick et al. (2016)

Study type (level of evidence)

Retrospective case-control

Country

USA

Study information

The study sample included 43 patients undergoing bimaxillary orthognathic surgery between January 2014 to January 2015, divided into three groups according to case complexity:

1. Symmetric, non-segmental: patients with facial symmetry undergoing single-segment Lefort 1 osteotomy and bilateral sagittal split osteotomy with or without genioplasty (n =19)
2. Asymmetric: patients with facial asymmetries planned for correction with single-segment Lefort 1 osteotomy and bilateral split osteotomy with or without genioplasty (n =17)
3. Segmental: patients requiring multi-segment Lefort 1 osteotomy and bilateral split osteotomy with or without a genioplasty (n = 7).

All patients underwent virtual surgical planning as well as standard planning, each conducted independently. Virtual surgical planning was conducted using ProPlan software and involved the preparation of cases, occlusal adjustment and a web planning session. Splints were 3D printed following plan approval.

Outcomes

Surgery planning time and cost

Findings

Virtual surgical planning was significantly faster and less costly than standard planning, overall and in all 3 groups ($p < 0.001$). Overall, average virtual surgical planning time was 194 minutes and cost was $2,765.94, compared to 540.9 minutes and $3,519.18 for standard planning. There were no significant differences between the 3 groups:

For the symmetric, nonsegmental group, average virtual surgical planning time was 188 minutes and cost was $2,700.52, compared to 524.4 minutes and $3,380.17 for standard planning.

For the asymmetric group, average virtual surgical planning time was 187.4 and cost was $3,640.00, compared to 556.1 minutes and $2,713.69 for standard planning.

For the segmental group, average virtual surgical planning time was 208.8 minutes and cost was $2,883.62, compared to 542.3 minutes and $3,537.37 for standard planning.

Limitations

The results may not be generalisable to all oral and maxillofacial practices as assumptions were made in time and cost estimates, and practices and processes may differ across settings.

More experienced surgeons may be able to perform the planning more quickly which could alter costings. Further, not all components of the planning process were timed. The cost of materials used in standard planning were included in overhead costs for all calculations; the findings could therefore underestimate the cost difference between the techniques.

Conflicts of interest

Not reported.

Rommel et al. (2017)

Study type (level of evidence)

Retrospective case-control (III-2)

Country

Germany

Study information

Thirty-one patients who underwent mandibular reconstruction with microvascular free fibular flap after segmental mandibulectomy were divided into 2 groups based on how their surgery was planned. One group underwent individual planning, with a stereolithographic model and fibular bone model produced using a 3D printer (Projet 160). Cutting guides and drilling templates were subsequently hand made in house using synthetic composite. The second group received a complete virtual surgical planning program, including virtual planning with ProPlan CMF and the fabrication of cutting and reconstruction guides.

Outcomes

Intraoperative time, postoperative hospitalisation duration, and postoperative complications including plate fracture, dehiscence and flap loss.

Findings

There was no statistically significant difference in intraoperative time (p = 0.332) or duration of hospitalisation (p = 0.312) between the individual planning group and the virtual surgical planning group. There were small but not statistically significant differences between groups in terms of postoperative complications: a slightly higher occurrence of wound dehiscence in the individual planning group (33.3% compared to 23.1%in the virtual surgical planning group) and more plate fractures (23.1%) and plate loss (15.4%) for the virtual surgical planning group than the individual planned group (11.1% and 9.7% respectively).

Limitations

The clinical examinations took place one year after surgery. Longer follow-up periods are better for detecting potential postoperative complications, and for assessing the healing process and patients' health. The effectiveness and efficiency of the planning technique outlined the study is dependent on a surgeon's experience.

Conflicts of interest

Nil reported.

Seruya et al. (2013)

Study type (level of evidence)

Retrospective case-control (III-2)

Country

USA

Study information

Charts were reviewed for 68 patients across 2 centres who had undergone fibula free flap surgery for craniofacial reconstruction; 58 who had surgery via a conventional reconstructive technique between 2003 and 2009, and 10 who had undergone surgery between 2010 and 2012 where computer-aided design/computer-aided manufacturing was used. This included virtual reconstruction performed using ProPlan CMF, the fabrication of cutting guides and production of a stereolithographic model which was used to prebend miniplates and as an intraoperative reference.

Outcomes

Intraoperative factors and outcomes included indications for surgery, skin paddle surface area, bone flap length, number of osteotomies, ischaemia time, and operative time. Perioperative and long-term outcomes included hospital LOS, length of follow-up, infection, skin, bone, or flap loss, skin or bone graft, repeated osteotomy, second bone or soft tissue free flap.

Findings

The computer-aided technique was associated with a significantly higher median number of osteotomies (2.0 versus 1.0, p = 0.002) and significantly shorter median ischaemia time (120 minutes versus 170 minutes, p = 0.004) than the conventional technique. There were no significant differences in intraoperative, perioperative, or long-term outcomes.

Limitations

The surgical techniques were conducted at different times and therefore findings could have been influenced by the learning curve for the surgeon rather than the surgical technique. There were significant differences in the comorbidity profile of the 2 groups, with patients in the computer-aided group being older and having a higher prevalence of radiotherapy exposure. Additionally, the small sample size may have resulted in a lack of statistical power to detect differences between the groups.

Conflicts of interest

Nil reported.

Silva et al. (2020)

Study type (level of evidence)

Prospective case-control (III-2)

Country

Singapore

Study information

The intervention group was all patients (n = 44) who underwent primary total knee arthroplasty for osteoarthritis of the knee using ProPlan Personal Solutions total knee replacement surgery from September 2010 to August 2012 at a single institution and by a single surgeon. The procedure involved formulating a 3D digital model from CT data, from which customised patient-specific templates (including cutting guides) were produced. The comparison group was an age, gender, side (of the surgery), diagnosis and surgeon-matched cohort (n = 44) who underwent conventional surgery.

Outcomes

Accuracy and reliability were measured by comparing intraoperative bone cuts with the preoperative planned cuts. Other outcomes included planned and actual implant sizes, mechanical and anatomical alignments, perioperative blood loss, total operative time and intraoperative complications or difficulties.

Findings

Predicted and actual cuts were significantly different for the distal medial femur ($p < .001$), distal lateral femur ($p < .001$), posteromedial femur ($p < .001$), posterolateral femur ($p < .001$), and medial tibial ($p < .001$), but not the lateral tibial ($p = .12$). There were no significant differences between the intervention and comparison groups in terms of operative time ($p = 0.26$), mechanical alignment ($p = 0.96$) or anatomical alignment ($p = 0.26$), changes in mechanical ($p = 0.06$) or anatomical ($p = 0.39$) alignment, incidence of post-operative wound infection ($p = 1.00$), length of inpatient stay ($p = 0.66$), or incidence of postoperative superficial wound infection ($p = 1.00$). There was a greater drop in haemoglobin levels ($p = 0.02$) for the ProPlan Personal Solutions group, and 5 patients requiring transfusions compared to one patient in the conventional group ($p = 0.09$).

Limitations

While the authors did not explicitly discuss the limitations of the study, they did indicate the need for large-scale randomised controlled trials to further evaluate the technology. They also suggested that further long-term follow-up is required to investigate long-term benefits as well as implant survival and revision rate.

Conflicts of interest

Nil reported.

Wang, Fan, et al. (2016)

Study type (level of evidence):

Retrospective case-control (III-2)

Country

China

Study information

The sample comprised 33 patients who underwent maxillary reconstruction with vascularised fibular graft after tumour ablation between March 2013 and 2015. Of these patients, 18 underwent the reconstruction using the virtual surgical planning software ProPlan CMF. For this virtual planning group, stereomodels including a reconstruction model, maxillary osteotomy guide, fibular osteotomy guide and reconstruction template were made. The surgery was then performed using the prefabricated guides and the titanium miniplates were pre-bent on the reconstruction model. The other 15 patients underwent conventional surgery without virtual surgical planning.

Outcomes

Precision of the cutting guides and templates was assessed through the position of the fibular flaps, precise bone-to-bone contact between the maxilla and fibular segments and the contour of the fibular flap segments. Other outcomes included operative time, post-operative facial appearance, occlusal function, ischaemia time, intelligible speech, regular diet. Postoperative photos and CT scans were taken to evaluate the surgery 6 months postoperatively.

Findings

Total operative time was significantly shorter (p = .007) for the virtual planning group (5.8 hours ±1.1) than for the conventional planning group (7.1 hours ±1.4). The virtual planning group also experienced slightly shorter ischaemia time on average, at 62 minutes (±12) compared to 79 (±16) for the conventional surgery group (p = 0.012). Accuracy was higher in the virtual planning group, evidence by a higher proportion of patients with precise bone-to-bone contact between the maxilla and fibular segments (94% vs 20%; p = 0.001) and lower rates of horizontal and vertical overextension of fibular segments (p = 0.001). Patients in the virtual planning group were slightly more likely to report good postoperative midfacial appearance (p = 0.043). There were no differences in functional mandibular range, occlusion, intelligible speech, or return to regular diet between the groups.

Limitations

The authors did not identify limitations to the study, nor make recommendations for further research.

Conflicts of interest

Nil reported.

Wang, Zhang, et al. (2016)

Study type (level of evidence)

Prospective case-control (III-2)

Country

China

Study information

Twenty-one patients underwent mandibular reconstruction with vascularised fibula grafts using ProPlan CMF between February 2013 and February 2015. Stereomodels comprising a reconstruction model, osteotomy guide and reconstruction template were produced, and the surgery was then performed using the prefabricated guides. In the same time period, another 35 patients underwent conventional surgery, performed based on the surgeon's experience.

Outcomes

Operative time, postoperative computed tomography scans, facial appearance and occlusal function were the main outcome measures. Ischaemia time and precision were also assessed, with precision being evaluated through bone-to-bone contact, condyle position and the position among plate, mandible and fibula segment. Postoperative facial appearance, regular diet and intelligible speech were also assessed. Outcomes at 6 months were assessed using CT scans and patient evaluation.

Findings

Both the operation time (p = 0.011) and ischaemia time (p = 0.021) were shorter for the virtual planning group than the conventional surgery group. The virtual planning group were also more likely to have precise condyle positioning (p = 0.007), bone-to-bone contact between the mandible and fibular segments (p = 0.013), and positioning among pre-bent plate, mandible and fibula segments (p = 0.009). Compared to conventional surgery, virtual planning group was associated with a greater likelihood of good facial appearance (95% vs 77%, p = 0.041). A high and comparable proportion of patients in both groups demonstrated excellent functional mandibular range, intelligible speech, and a regular diet at follow-up.

Limitations

The authors did not identify limitations to the study, nor did they make recommendations for further research.

Conflicts of interest

Nil reported.

Weitz et al. (2016)

Study type (level of evidence)

Retrospective case-control (III-2)

Country

Germany

Study information

The sample comprised 50 patients who had undergone mandibular reconstruction after segmental mandibulectomy between 2012 and 2014. This included 24 patients who underwent surgery that was virtually planned between using ProPlan CMF. For this group, cutting guides and reconstruction guides were created to transfer the virtual plan to the clinical setting. The comparison group included 26 patients who received conventional surgical planning.

Outcomes

Accuracy, bony consolidation, complications, and operating time.

Findings

The change the angle of the mandible from pre- to postoperation was significantly different between groups, with a median of 11.5° in the conventional group and 4.5° in the virtually planned group (p = .001). However, there was no significant difference between the two groups in change in distance from the mandible to the anterior nasal spine (p = 0.095). There was a significantly higher rate of bony consolidation rate for the virtual group (84%) compared to the conventional group (62%) (p = 0.002). There were no significant differences in the number of comorbidities, postoperative complications, or total operating time.

Limitations

The number of patients who required 2 or more osteotomies was higher in the virtually planned group, making it difficult to compare average operating time. Accuracy was analysed solely by a 2-dimensional radiograph. Not all operations were done by the same surgeon which could potentially introduce bias based on variations in experience or skills. Finally, the costs of the different techniques were not considered.

Conflicts of interest

Nil reported.

Zhang et al. (2015)

Study type (level of evidence)

Case-control (III-2)

Country

China

Study information

The study sampled included 27 patients with maxillary tumours who underwent maxillectomy and free fibula flap reconstruction between January 2011 and May 2013. These patients were divided into two groups. The first (n = 8) had undergone surgery with computer-assisted surgical planning and surgical navigation. This included the use of ProPlan to perform a virtual maxillectomy and for printing a resin stereomodel which was used to pre-bend the titanium mesh for restoring the maxillary contour. The comparator group (n = 19) underwent traditional surgery without preoperative virtual surgical planning.

Outcomes

Vertical distance between the maxilla and mandible, horizontal shift of the fibula segments and position of its posterior end. All outcomes were assessed via CT at 6-month follow-up.

Findings

The difference in the vertical distance from the canine to the first molar between the operated side and unoperated sides was significantly smaller in the virtual surgical planning group (2.82mm ±1.22) than in the conventional surgical group (6.13 ±3.12; p = 0.013). The virtual surgical planning group also had lower rates of horizontal shift (25% vs 74%; p = 0.019) and fibular overextension (13% vs 53%; p = 0.041).

Limitations

The computer-assisted techniques used in the virtual planning group were also employed for outcome evaluation, and there is the potential for systematic and cumulative error. For example, the authors note that the virtual plans (and outcome measures) were based on bony tissues in CT scans; however, soft tissues also need to be considered during surgery.

Conflicts of interest

Nil reported.

Zhang et al. (2016)

Study type (level of evidence)

Retrospective case-control (III-2)

Country

China

Study information

Forty-five patients who underwent mandibulectomy and simultaneous reconstruction with free iliac crest flaps between January 2008 and June 2015 were divided into two groups: those who had undergone reconstruction through conventional surgery based on the surgeon's experience (n = 30) and those who received virtual surgical planning (n = 15). The virtual surgical planning technique involved a virtual plan, stereomodel, pre-bending of an individual reconstruction plate and surgical navigation.

Outcomes

Condyle position, reconstructed mandible contour and complications, receipt of dental restoration, and post-surgery facial symmetry and appearance.

Findings

Overall success was high (95.6%) and there were no differences in the incidence of failure or complications between groups. Patients in the virtual planning group had a smaller average condyle shift (2.0mm vs 2.5mm; $p = 0.026$) and smaller average difference in lower mandible border (3.7mm vs 5.1mm; $p < 0.01$) than those in the conventional surgical group, although there was no difference in the average length of defects. At follow-up, 80% of patients in the virtual planning group had received dental restoration compared to 40% of the conventional surgery group ($p = 0.011$). All of the patients in the computer-assisted group indicated satisfaction with their post-surgical appearance and symmetry, while only half in the conventional surgery group did so ($p = 0.028$).

Limitations

The computer-assisted techniques used in the virtual planning group were also employed for outcome evaluation, and there is the potential for systematic and cumulative error. For example, the authors note that the virtual plans (and outcome measures) were based on bony tissues in CT scans; however, soft tissues also need to be considered during surgery.

Conflicts of interest

Nil reported.

Zweifel et al. (2015)

Study type (level of evidence)

Prospective case-control (III-2)

Country

Switzerland

Study information

Twenty patients undergoing mandibular resections with fibular reconstructions between 2012 and 2013 were included in the study. Nine of these had virtual planning and guided surgery, and 11 underwent freehand surgery. The virtual planning involved the use of 3D models to construct cutting guides, and pre-bent or milled plates.

Outcomes

Total operative time and cost.

Findings

The virtual planning group experienced a total operative time of 67.4 minutes less than the freehand surgery group (20.8 minutes vs 88.2 minutes). One minute of operative time was costed at US$47.50; multiplying this by the difference in operative time resulted in an average saving of US$3,201.50 on average. Deducting this saving from the total cost of planning and materials, procedures using a pre-bent plate reduced from US$5,098 to US$1,232 on average, and those using a milled plate reduced from $6,980 to US$3,114.

Limitations

The authors did not identify limitations to the study, nor did they make recommendations for further research.

Conflicts of interest

One of the authors participate on the speaker's bureau for DePuy Synthes. There were no other relevant conflicts to declare.

C.7 Quality of evidence and risk of bias

All 13 studies included in the systematic review were non-randomised, case-control studies. Case-control designs for intervention studies are classified as level III-2 evidence.

For the 13 studies in this review, total scores on the NOS ranged from 5 to 9 (Table 26). Just over three-quarters (10/13) of studies received a score of 6 or 7. Only the cost-analysis study by Resnick et al. (2016) received the highest possible score of 9, while the study by Silva et al. (2020) received a score of 8. The higher scores achieved by these studies reflect the fact that patients in the intervention group (i.e. the group that underwent virtually planned surgery) were matched with patients in the comparison (i.e. traditional surgery) group on key variables, thus increasing the comparability between groups. Silva et al. (2020) matched patients on age, gender and surgical complexity, while Resnick et al. (2016) matched each patient with themselves. There was one study (Johal et al. 2022) which received a score of 5.

Table 26: Newcastle-Ottawa Scale scores assessing the quality of included studies

Citation	Selection score (max 4)	Comparability score (max 2)	Exposure score (max 3)	Total score (max 9)
De Maesschalk et al. (2017)	3	0	3	**6**
Johal et al. (2022)	2	0	3	**5**
Mazzola et al. (2020)	2	2	3	**7**
Resnick et al. (2016)	4	2	3	**9**
Rommel et al. (2017)	2	2	3	**7**
Seruya et al. (2013)	3	1	3	**7**
Silva et al. (2020)	3	2	3	**8**
Wang, Fan, et al. (2016)	3	1	3	**7**
Wang, Zhang, et al. (2016)	2	1	3	**6**
Weitz et al. (2016)	3	1	3	**7**
Zhang et al. (2015)	3	0	3	**6**
Zhang et al. (2016)	3	0	3	**6**
Zweifel et al. (2015)	3	1	3	**7**

None of the studies randomised patients to the different surgical groups and only 2 studies provided any explanation of why patients received virtual surgical planning rather than traditional surgery (Seruya et al. 2013; Wang, Fan, et al. 2016). In the study by Seruya et al. (2013) patients who underwent their operation between 2003 and 2009 underwent traditional surgery and patients who were operated on from 2010 onward underwent a virtual planning procedure. The same surgeon performed all operations, yet no adjustment was made in the analysis to control for the surgeon's increased experience over two decades. The significantly shorter ischaemia times recorded in the virtual planning group compared to the traditional surgery group must be interpreted cautiously given the risk of bias associated with changes in the surgeon's experience and skill overtime, in addition to the potential for broader

improvements in surgical processes. In the study by Wang, Fan, et al. (2016), inclusion in the virtual surgical planning group was based on the patient's acceptance of this new surgical program and their economic conditions. Although not explicitly stated nor accounted for in the analysis, it is likely that patients in the virtual surgical planning group had a higher socioeconomic status and access to superior pre- and/or postoperative care, which could have influenced the results. None of the remaining studies provided any explanation as to why patients received virtual surgical planning or traditional surgery. The fact that in half of the studies, a much larger number of patients were in the comparison group than the intervention group suggests the potential for systematic bias in group allocation.

Another substantial risk of bias observed across most studies was the absence of adjustment for patient comorbidity, additional treatments and surgical complexity. Among studies that described the level of surgical complexity, some reported that higher levels of complexity were present in the traditional surgery group (e.g. De Maesschalck et al. 2017; Wang, Zhang et al. 2016; Zhang et al. 2016) while others reported greater complexity in the virtual surgical planning group (e.g. Seruya et al. 2013; Weitz et al. 2016). When Mazzola et al. (2020) performed a subgroup analysis that matched patients on complexity they found no statistically significant differences in outcomes.

The study by Rommel et al. (2017) was the only one to describe patient comorbidities in both cases and controls, finding no statistical difference between groups. They did, however, report a significant between-group difference in the proportion of patients who received preoperative radiotherapy (72% in controls compared to 17% in cases, p = 0.011). Despite the significant statistical difference in preoperative radiology exposure between the two groups, the authors did not control for this confounder in the statistical analysis. Instead, they reported the unadjusted statistics and discussed the implications of radiotherapy. Specifically, they argued that 'impaired microcirculation, fibrosis and a high increase of cytokines in radiated tissue contribute significantly to a disturbed and prolonged wound healing process. Therefore, the higher rate of dehiscences combined with a longer hospitalisation seems not to be attributable to the preoperative planning concept but rather to the preoperative radiotherapy' (Rommel et al. 2017, p. 1250). This statement highlights the potential risk of bias present in all studies that failed to report and test for patient comorbidities, preoperative treatment and surgical complexity.

In summary, all studies in this review were graded as level III-2 and, with the exception of 2 studies, had at least a moderate risk of bias. The main source of bias was the lack of comparability between patients in the intervention and control groups and the failure to adjust for important potential confounders, especially surgical complexity.

Appendix D Summary of evidence from recent synthesised literature

D.1 Introduction

Surgical guides and biomodels represent a subset of 3D printing technologies gaining traction in medical and surgical uses around the world. Accordingly, over recent years there has been rapid growth in the literature describing and evaluating the use of these technologies (Chepelev et al. 2017; Meglioli et al. 2020; Tack et al. 2016). Much of the published literature comes from the USA, China and Germany (Chepelev et al. 2017).

This desktop review was conducted to inform AHA's review of surgical guides and biomodels currently listed on the Prostheses List. It represents a limited literature search for recent, synthesised, high-quality and peer-reviewed evidence.

It is designed to provide a snapshot of current knowledge and trends in the evidence for surgical guides and biomodels, including the contexts in which they are used and the outcomes commonly reported in the evidence base. It is intended to be considered alongside our product-specific systematic review (Appendix C), particularly as no product-specific information was identified for most of the PL products in scope.

It is not intended to be, of itself, a systematic review of published literature, and does not represent a complete or comprehensive summary of the literature available.

D.2 Methods

The following search terms were used in PubMed (via MEDLINE) to retrieve relevant studies:

> (biomodel OR "surgical guide" OR "additive manufacturing" OR "3D print*" OR "three dimensional print*" OR "rapid prototyping" OR "patient-specific guide")
> AND
> (implant OR prosth*)

The results were limited to systematic reviews and meta-analyses published in the 5 years prior to 30 September 2022, written in English and with full text available.

We selected papers that met the following criteria (as per AMSTAR 2) for consideration:

- The research questions and inclusion criteria include the components of PICO (Population, Intervention, Comparator, Outcomes).
- The review used (and described) a comprehensive literature search strategy.
- At least 2 researchers were involved in determining study eligibility and performing data extraction.
- The paper described the included studies in adequate detail.
- The review used a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review.
- The article included a discussion of strengths and limitations such as assessment of bias, heterogeneity.
- Authors reported any conflicts of interest, including any funding received for the review (Shea et al. 2017).

The results of the search strategy described above were supplemented by systematic reviews and meta-analyses sourced by another method – for example, provided by sponsors and other stakeholders – that also met the criteria above.

Some studies not meeting all criteria were included where they provided relevant information, particularly in contexts where information was lacking and/or where findings were descriptive in nature (e.g. identifying situations in which the use of surgical guides and biomodels have been reported).

D.3 Key findings

Our search identified 23systematic reviews and meta-analyses in a range of clinical contexts for consideration (14 through the MedLine search, with the remainder from other sources). The highest proportion of studies related to surgery in the oral and maxillofacial region, with the use of surgical guides and/or biomodels for the placement of dental implants most common among these.

A summary of key findings from the review of synthesised literature is presented below by anatomical and/or clinical context.

D.3.1 Dental implants

For studies about dental implants, clinical performance associated with the used of surgical guides was assessed through implant survival rates, marginal bone loss and complications. Accuracy of implant placement was also frequently investigated. Other outcomes reported include morbidity, patient satisfaction and costs.

Accuracy of implant placement was measured through angle deviation, coronal deviation, apical deviation and depth deviation. Seo and Juodzbalys (2018) compared only planned and actual implant placement data (rather than a comparison with, for example, freehand techniques). Similarly, Walker-Finch and Ucer (2020) found that there are several systematic reviews which indicate that digitally designed surgical guides reproduce the digitally planned position of the implant with adequate levels of accuracy.

Gargallo-Albiol et al. (2020) found that half-guided surgery was more accurate than freehand implant placement, and that fully-guided placement was more accurate again. Similarly Tattan et al. (2020) found that static computer-aided implant placement resulted in better accuracy than freehand techniques.

Putra et al. (2022) found a significant difference in mean angular deviation between groups using computer-aided designed and manufactured surgical guides and those using conventional surgical guides, but not in coronal and apical deviations. The authors also found significant differences in accuracy (mean angular deviation, coronal deviation, and apical deviation) between pilot-drill (where a surgical guide was used only in the initial drill of the osteotomy) and fully-guided surgery protocols (with the surgical guide used to guide osteotomy and implant placement).

It should be noted that the reviews highlighted a number of factors which can impact on the accuracy of implant placement including bone density, mucosal thickness, surgical techniques (e.g. use of use of screws to fix the surgical template), type of jaw, smoking habits, implant length (Seo and Juodzbalys 2018), the edentulous space, surgical guide manufacturing procedure and the guided surgery protocol (Putra et al. 2022), the quality and resolution of the

CT scan, the impression technique, software used, the support available for the guide (e.g. tooth, mucosa or bone) and the position of the guide intraorally (Walker-Finch and Ucer 2020).

There were similar non-inferior or positive findings between studies for the survival rates of implants placed using surgical guides. A systematic review by Eftekhar Ashtiani et al. (2021) identified a study which found that the 5-year survival rate for implants placed with surgical guides is comparable to the survival rate for all implants (94.5%–100% guided implants compared to 95.6% survival rate for all implants), while other studies also indicated that the use of surgical guides does not negatively impact implant survival rates (Tattan et al. 2020; Walker-Finch and Ucer 2020). In contrast to the findings of the studies described above, Abdelhay et al. (2021) reported that – while low across both groups – failure rates were almost 3 times higher in freehand implant placement compared with guided placement.

Complications were also explored as an outcome measure in several studies. While not directly assessing complications as an outcome, reviews by Walker-Finch and Ucer (2020) and Ashtiani et al. (2021) cited a published complication rate of 7% for dental implant placement using static surgical guides, with the most common complications being limited access and fracture of the surgical guide. However, no comparator was provided to define the complication rate for dental implant surgery without surgical guides or via other methods. Of the studies included in the systematic review by Walker-Finch and Ucer (2020), none reported any complications from the use of a guide. Abdelhay et al. (2021) reported reduced postoperative swelling, pain, and bleeding with guided compared to freehand implant placement. Tattan et al. (2020) suggested that, although the quality of evidence was low, there were no tangible differences in patient perception of intra- or postoperative discomfort between static computer-aided implant placement (sCAIP), partially guided implant placement and freehand techniques. The authors concluded that 'patient perception of treatment in terms of reported intra- or postoperative discomfort seems to be highly dependent on procedural events associated with implant placement (i.e. raising a flap, utilising guide fixation screws, multiple surgical sites and concomitant ridge augmentation, among others) as opposed to the modality of placement itself' (p. 913).

Two studies specifically compared the use of flapped and flapless techniques for dental implants, with the latter usually associated with the use of surgical guides. Romandini et al. (2022) found that while flapless sCAIP was more accurate than flapped implant placement, there were still inaccuracies in comparison to the planned implant position, and 'flapless sCAIP presented a 12% group-specific intraoperative complication rate, resulting in an inability to place the implant with this protocol in 7% of cases' (p. 16). Despite this, the authors noted a 100% survival rate in one study across flapped implant placement (with or without the use of cast-based surgical guides) and flapless static computer-aided implant placement. A similar review by Cai et al. (2020) found that there was no statistically significant difference in implant survival rates, implant complication rates or marginal bone loss between flapless (either guided or freehand) and conventional surgical techniques. Although the primary aim of these studies

was to compare different surgical approaches (i.e. flapped versus flapless), Cai et al.'s finding that 'guided or freehand implant insertion did not affect the long-term effects of flapless surgery when compared to the conventional approach' (p. 1099) is relevant.

D.3.2 Orthognathic and other CMF surgery

In the context of **orthognathic surgery**, Van de Bempt et al. (2018) sought to evaluate the use of intraoperative computer navigation, surgical guides and/or customised osteosynthesis plates. The authors found that while the included studies indicated accuracy of the transfer of the virtual plan to the patient for the 3 surgical methods, variability in accuracy assessment and reported outcomes between studies meant that comparison of the techniques was not possible.

Chen et al. (2021) compared virtual orthognathic surgical planning techniques with traditional surgical planning and found that accuracy was comparable or better with the use of virtual planning. With one exception, the virtual planning technique included the use of computer-designed and manufactured splints, while the traditional technique used acrylic splints. Both techniques yielded better accuracy with respect to maxilla surgery than mandible. Virtual planning was associated with better symmetry in the frontal view, but similar quality of life outcomes. While there may be some differences in *how* time is spent in preoperative planning, the authors suggested there was no significant difference in total preoperative planning time between approaches. In addition, the use of an accurate computer-aided splint could reduce the operative time. Not considering the initial investment to purchase software and hardware, costs of virtual surgical planning were found to be similar to traditional planning (Chen et al. 2021).

In mandibular reconstruction, Powcharoen et al. (2019) found the accuracy of computer-assisted surgery to be equal to or better than conventional freehand reconstruction, although the diversity of measurements reported precluded the authors from performing a quantitative meta-analysis regarding this outcome. The nature of the computer-aided interventions variably included simulation of mandibular and fibular osteotomies and orientation of the fibular segment in the reconstruction, as well as the manufacture of mandibular and fibular cutting guides (in 10/12 and 9/12 studies respectively), fibular shaping guides, and a biomodel with pre-bent plates (6/12). One-third included the use of patient-specific surgical plates, and so the authors' conclusions are not specific to the use of surgical guides and biomodels in the absence of these patient-specific implants. The authors also note the lack of quality evidence informing their review. Despite these caveats, this review found that computer-assisted procedures were associated with shorter ischaemic, reconstructive and total operative times, as well as length of stay, with no significant difference in reconstruction outcomes or postoperative complication rates. Two identified studies considered economic viability of the technology, with mixed results (Powcharoen et al. 2019).

Also in mandibular reconstruction, Barr et al. (2020) found, in fibula free flap surgery, that virtual surgical planning (including mandibular and fibular cutting guides, stereolithographic models,

prefabricated reconstruction templates and/or pre-bent plates) was associated with a significant reduction in operative time and trends towards shorter hospital stays and more complex fibula flaps. They found no difference in major or minor complication rates, or preoperative radiation exposure.

In reviewing the use of virtual surgical planning in head and neck reconstructions involving fibula free flaps, Tang et al. (2019) found that VSP was associated with superior accuracy, ischaemic times and intraoperative times, and that complication rates were similar between VSP and 'conventional' techniques. Again, while the authors introduced their review by stating that virtual surgical planning 'results in creation of a stereolithic model of the new mandible, a customised pre-bent plate as well as a patient-specific osteotomy guide', the type of and extent to which surgical guides and biomodels were used in individual studies is unclear.

A review by Meglioli et al. (2020) explored bone biomodels in the context of surgical domains in the head and neck including dentistry and oral surgery, maxillofacial surgery, ear-nose-throat surgery and cranial surgery. They found that oral and maxillofacial surgery made up the largest proportion (43%) of articles which described models made through additive manufacturing processes. The most frequent use of models in this surgical domain was for planning or simulating a bone reconstruction or a tumour removal. While this review did not use a PICO approach nor an ideal technique for assessing risk of bias in quantitative studies (and the majority of evidence included was assessed to be of average or low quality), it suggested that surgical treatment times can be reduced by up to 20% and that failure rates tend to decrease with the use of biomodels. Over one-third of the articles identified suggested that clinical outcomes could potentially be improved, due to better planning and understanding of the case. In one included study, functional and aesthetic outcomes were higher when a biomodel was used. Only 4 (7%) of the included studies suggested that the method they described was not cost-effective (Meglioli et al. 2020).

Two reviews considered the applications and basic principles of 3D printing in **otolaryngology/ otology and auricular management**. Hong et al. (2019) identified applications relevant to this review including:

- preoperative planning and simulation (3D models can enhance tactile sensory input and improve understanding of complex anatomy and pathology and/or delicate nearby structures such as nerves and vessels)
- customised surgical templates and equipment (e.g. allowing pre-bending of reconstruction plates or titanium mesh or to guide positioning of implants)
- prosthesis sizing.

The review also notes the applications of 3D models in medical education, surgical training and informed consent (Hong et al. 2019).

Similarly, Omari et al. (2022) found that 3D-printed models were used as guides, templates, implants and devices in otology and auricular management. 3D-printed guides were most

commonly reported in the context of reconstructive surgery for microtia, where they were usually used as a cutting guide for rib cartilage to create a framework for an auricle prosthesis. In this application, the guide was found to accurately mirror the other auricle and decrease surgical time (compared with the use of 2-dimensional guides). In other contexts 3D-printed products were variously used as positioning or sculpting guides, cutting guides or drill guides. The authors concluded that 'it remains unclear whether these interventions actually improve patient outcomes due to lack of comparison with conventional methods and low levels of evidence' (p. 3284), and cited an example where conventional manufacturing techniques provided better auricle resemblance than the 3D-printed comparator.

Canzi et al. (2018) described 'new frontiers and emerging applications' of 3D printed technologies in the ear nose and throat (ENT) field, including otology, rhinology and head and neck surgery. The authors divided uses into 3 categories: surgical and pre-clinical educations, customised surgical planning, and tissue engineering and implantable prostheses. Customised head and neck surgical planning was the most frequent application reported, and the context of the vast majority of these studies was surgical management of tumours requiring mandibular resection and/or reconstruction.

Finally, review of costs associated with medical 3D-printing applications found that the use of biomodels saved a mean of 66 operative minutes in the setting of **oral and maxillofacial surgery** ($p = 0.003$). The use of surgical guides resulted in a mean operative time saving of 83 minutes that approached significance ($p = 0.05$) (Ballard et al. 2020).

D.3.3 Orthopaedic surgery

Aman et al. (2022) evaluated the use of 3D-printed cutting guides or spacers in **knee osteotomy** procedures. Their review found that such 'patient-specific instrumentation' was associated with high accuracy of coronal plate alignment. While only 6 studies identified were comparative in nature, the majority of these (5) reported superior accuracy using 3D-printed cutting guides or wedges over 'comparative techniques' – however, 3D printed cutting guides were the only patient-specific instrumentation in only 3 of these. Within the latter studies, 2 found better accuracy with use of the 3D cutting guide compared with the conventional group, while another found these guides superior to a navigation protocol, but not conventional surgery. One of these reported no significant differences in functional outcome scores, postoperative active flexion, or recurvatum between 3D-printed cutting guides and conventional techniques at 1 year follow-up. The authors noted that 'future randomised control trials evaluating efficacy on clinical outcomes and overall effect on total radiation exposure are needed before 3D-printed [patient-specific instruments] can be regarded as an essential device for these procedures' (Aman et al. 2022. p. 2753).

Kizaki et al. (2019) found that the use of patient-specific cutting block guides in **total knee arthroplasty** does not result in better patient-reported outcome measures, shorter surgery time

or lower complication rates compared with standard procedures. While blood loss was found to be slightly lower, the effect was too small to affect transfusion rates. In a review of literature pertaining to **revision total hip and knee arthroplasty** procedures assisted by 3D printing techniques, the authors noted that the technology was primarily used to produce customised prostheses and articulating spacers (Zhang et al. 2021).

Papotto et al. (2022) reviewed the use of 3D printing of biomodels to enable pre-bending of plates to repair **acetabular fractures**, compared with traditional intraoperative modelling. The authors noted that the anatomical complexity of the acetabulum, and lack of surgical access, renders the treatment of acetabular fractures particularly challenging. The studies they identified demonstrated (variably) reductions in surgical time, decreased intraoperative fluoroscopy, decreased blood loss, improved quality of reduction and lower complication rates.

A review of costs associated with medical 3D-printing applications found that the use of biomodels saved a mean 53 operative minutes in the setting of orthopaedic surgery ($p = 0.04$). The use of surgical guides resulted in a mean operative time saving of 12 minutes ($p = 0.004$) (Ballard et al. 2020).

D.3.4 Cardiovascular applications

A systematic review by Boll et al. (2019) returned 13 articles that collectively reported on a total of 34 subjects identified in the literature. The review suggested that 3D-printed models of the heart can assist in planning for valve surgery, for example by enabling the planning and selection of valve material, size, format, and thickness. Despite the small number of studies and subjects included, the authors conclude that 'this results in a reduction in surgery time, lower exposure of the operative field, reduced risk of infection and earlier rehabilitation' (Boll et al. 2019, p. 823).

A review by Croix et al. (2020) compared CT-derived 3D modelling with 2-dimensional transesophageal echocardiography (TEE) for left atrial appendage occluder device planning in the treatment of atrial fibrillation. Based on 4 clinical studies identified (with 166 subjects), the review found that the use of 3D-printed models was associated with reduced fluoroscopy time and lower risk of complications (specifically occluder device peri-prosthetic leak). There were non-significant reductions in the number of devices per procedure and total procedure time, and no difference in rates of procedure failure.

D.4 Conclusions

Generally, there is support for the use of surgical guides and biomodels in a range of surgical contexts relevant to the placement of prostheses. The systematic reviews identified highlighted the large number of current and emerging applications of 3D-printing technologies in implant procedures.

In terms of outcomes, the literature frequently suggests that the use of these technologies produces results that are not inferior to 'conventional' techniques, and may facilitate potential improvements in accuracy of implant placement, decreased operative and/or ischaemic time, reduced interoperative fluoroscopy and complication rates.

Despite these findings, the outcomes associated with 3D-printing technologies are dependent on a number of factors which include the choice of software and manufacturing technique (Chen et al. 2021; Putra et al. 2022; Walker-Finch and Ucer 2020). It is important to note, therefore, that while this summary supplements our systematic review focused on surgical guides and biomodels listed on the PL, the findings described here cannot necessarily be attributed to those products.

> The advantages and disadvantages of different 3D virtual software systems on the market should be further explored…the comparative advantages of different software programs have not been clarified. (Chen et al. 2021, p. e17)

It is also worth highlighting that a number of studies noted that a pre-fabricated surgical guide cannot always be used intraoperatively as planned. In some cases, surgical guides are unsuitable or break, and planned protocols have to be abandoned. They are subject to manufacturing errors and do not eliminate surgical errors, and therefore should not replace surgical skill (Eftekhar Ashtiani et al. 2021; Omari et al. 2022; Romandini et al. 2022; Tattan et al. 2020; Walker-Finch and Ucer 2020).

> The template-derived surgical plans are frequently abandoned, putting their utility into question. (Omari et al. 2022, p. 3284)

> Surgeons must therefore have the skills and experience to revert to freehand placement, or face the prospect of abandoning the procedure altogether. Inexperienced surgeons should not consider guided procedures a means by which they can attempt complex treatments that are beyond their skill set. (Walker-Finch and Ucer 2020, p. 274)

While a number of studies of 3D-printed technologies, including surgical guides and biomodels, mentioned cost (often considered in the context of surgical time savings), economic viability remains an 'open question' (Powcharoen et al. 2019, p. 1426), and dependent on costs and cost structures present in any given healthcare setting.

> Expenses related to the operating room and inpatient services vary among different centres and countries. Health insurance coverage also varies in different areas. Therefore, the economic viability of computer-assisted mandibular reconstruction remains an open question. (Powcharoen et al. 2019, p. 1426).

As an example of modelling, however, Ballard et al. (2020) estimated that, in the context of oral and maxillofacial and orthopaedic surgeries in the United States, the production of at least 63 models or guides per year would be needed to offset annual fixed costs of maintaining a 3D printing lab.

Another key finding is the limitations of the existing literature, as articulated by the authors of the systematic reviews and meta-analyses described here. These commonly included:

- the limited number of studies identified for inclusion in the reviews (Abdelhay et al. 2021; Omari et al. 2022; Powcharoen et al. 2019; Putra et al. 2022; Seo and Juodzbalys 2018; Walker-Finch and Ucer 2020)
- the small sample sizes in included studies and inclusion of case reports (Boll et al. 2019; Croix et al. 2020; Omari et al. 2022; Zhang et al. 2021)
- a paucity of randomised controlled trials, other comparative studies and prospective studies and the significant risk of bias in included studies (Abdelhay et al. 2021; Barr et al. 2020; Chen et al. 2021; Croix et al. 2020; Omari et al. 2022; Powcharoen et al. 2019; Putra et al. 2022; Romandini et al. 2022; Walker-Finch and Ucer 2020)
- heterogenous methodology, including patient cohort, follow-up and measuring/reporting of outcomes (Aman et al. 2022; Van den Bempt et al. 2018; Croix et al. 2020; Eftekhar Ashtiani et al. 2021; Gargallo-Albiol et al. 2020; Meglioli et al. 2020; Omari et al. 2022; Papotto et al. 2022; Powcharoen et al. 2019; Putra et al. 2022; Romandini et al. 2022; Zhang et al. 2021)
- presence of confounding factors – for example, surgeon experience, types of defects and surgeries not well controlled (Abdelhay et al. 2021; Barr et al. 2020; Powcharoen et al. 2019), and variation in bundling of 3D technologies (e.g. included interventions often involved any/all of virtual surgical planning and simulation, use of 3D-printed biomodels and/or surgical guides, other 3D-printed tools and patient-specific implants).

> Many authors suggested that clinical outcomes can be improved, but their findings were not supported by any control group. (Meglioli et al. 2020, pp. 7-10)

> Irrespective of specialty, the true effectiveness of 3D-printed interventions [in otology and auricular management] remains largely undetermined due to few large trials, use of non-randomized designs, and lack of quantitative outcomes. (Omari et al. 2022, p. 3285)

Subsequently, many authors highlighted the need for further and better research on the comparative benefits of 3D-printing technologies, including randomised controlled trials or, at least, prospective, clinical and comparative data (Abdelhay et al. 2021; Chen et al. 2021; Eftekhar Ashtiani et al. 2021; Kizaki et al. 2019; Putra et al. 2022; Romandini et al. 2022; Tang et al. 2019), standardised methodologies (Meglioli et al. 2020), long-term data (Kizaki et al. 2019; Romandini et al. 2022) and data regarding costs (Kizaki et al. 2019; Romandini et al. 2022).

Publication bias should also be considered, given the low frequency of reporting of unsatisfactory results (Barr et al. 2020), and bias may also be introduced by unblinded postoperative evaluation (Yen et al. 2021). There is also the potential for industry bias within the literature (Aman et al. 2022), although almost all systematic review authors declared having no conflicts of interest.

Appendix E MBS clinical categories

Clinical category	Scope of cover
Bone, joint and muscle	Hospital treatment for the investigation and treatment of diseases, disorders and injuries of the musculoskeletal system. For example: carpal tunnel, fractures, hand surgery, joint fusion, bone spurs, osteomyelitis and bone cancer.
Brain and nervous system	Hospital treatment for the investigation and treatment of the brain, brain-related conditions, spinal cord and peripheral nervous system. For example: stroke, brain or spinal cord tumours, head injuries, epilepsy and Parkinson's disease.
Ear, nose and throat	Hospital treatment for the investigation and treatment of the ear, nose, throat, middle ear, thyroid, parathyroid, larynx, lymph nodes and related areas of the head and neck. For example: damaged ear drum, sinus surgery, removal of foreign bodies, stapedectomy and throat cancer.
Heart and vascular system	Hospital treatment for the investigation and treatment of the heart, heart-related conditions and vascular system. For example: heart failure and heart attack, monitoring of heart conditions, varicose veins and removal of plaque from arterial walls.
Joint reconstructions	Hospital treatment for surgery for joint reconstructions. For example: torn tendons, rotator cuff tears and damaged ligaments.
Joint replacements	Hospital treatment for surgery for joint replacements, including revisions, resurfacing, partial replacements and removal of prostheses. For example: replacement of shoulder, wrist, finger, hip, knee, ankle, or toe joint.
Plastic and reconstructive surgery	Hospital treatment which is medically necessary for the investigation and treatment of any physical deformity, whether acquired as a result of illness or accident, or congenital. For example: burns requiring a graft, cleft palate, club foot and angioma.

Appendix F Sponsor product description and utilisation

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Appendix G PL criteria and rationale

This appendix lists the 5 PL eligibility criteria and rationale, sourced from the PL guide.

Criterion	Rationale
Legislatively based criteria	
1 The product must be entered and current on the Australian Register of Therapeutic Goods	All therapeutic products must be included on the Australian Register of Therapeutic Goods before they can be lawfully supplied in Australia
2 The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment	This is a requirement of item 4 of the table in subsection 72-1(2) of the *Private Health Insurance Act 2007*
3 A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)	This is a requirement of item 4 of the table in subsection 72-1(2) of the *Private Health Insurance Act 2007*. An exception to this rule is where the provision of the prosthesis is associated with podiatric treatment by an accredited podiatrist. It is intended that a Medicare benefit should be payable under an item that is specific to the procedure in which the product is 'delivered'
Other criteria	
4 The product should: (a) be surgically implanted in the patient and be purposely designed in order to (i) replace an anatomical body part; or (ii) combat a pathological process; or (iii) modulate a physiological process;	The word 'surgically' has been chosen to convey the intention that the product be provided through an interventional process, and 'implanted' has been chosen to convey that the interventional process breaches the interface (or integument) between the body and the outside world (i.e. the skin or other epithelial surfaces, such as the rectal mucosa). This is to distinguish Prostheses List products from those that are externally attached to the body, such as artificial limbs (which meet the ordinary dictionary meaning of prosthesis but are not items that are considered in the context of the Prostheses List). The term 'surgically' is not intended to limit the performance of the intervention to surgeons, but is meant in the broader sense of performance of an interventional procedure by a suitably qualified medical, dental or podiatrist practitioner.

Criterion	Rationale
	Based on the ordinary dictionary meaning of implant, 'implanted' includes the implantation of tissues into the body, or an organ of the body, by grafting. Examples of tissues are harvested bone, heart valves and corneas. A product that is implanted for the purpose of replacing an anatomical body part is considered to be a prosthesis. This includes products such as knee and hip replacements. If an implanted product does not replace an anatomical body part, its principal function should be to either combat a pathological process or modulate a physiological process. 'Combating a pathological process' may include averting, repairing or correcting a pathological process; examples include cardiac and vascular stents, and cardiac defibrillators. 'Modulating a physiological process' can mean either blocking or facilitating a process. Examples are pacemakers (to regulate heartbeat) and nerve stimulators for pain management (modulates a physiological process and prevents a pathological process)
or (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted	This criterion is for associated products that are essential and manufactured specifically to enable the delivery of a product that meets the criteria above. Associated products (as opposed to equipment) are only for use once in a patient, have a unique and direct connection to the product and are integral to implanting the product into the patient. This does not include products whose use is of a more general nature (e.g. sutures, scalpels, trocars). 'Only for use once' means that, once used, the associated product is of no further use. That is, it is incapable of further use, and may only be discarded. It does not have a general-purpose use. An example is a preloaded coronary stent that is supplied fixed on a balloon catheter that is needed for positioning and implanting the stent. Without the balloon catheter, the stent is unable to be satisfactorily implanted. The catheter is specific and integral to the particular stent.

Criterion	Rationale
	Neither the packaging of the associated product with the subject product nor its labelling as 'single use only' will be sufficient to determine compliance with this criterion. That is, even if the product has a manufacturer's stamp of 'single use only', if the product can be reused for a practical purpose or has a purpose that is not specific to the implanted product (e.g. a screwdriver is of a general nature and not specific, even where a screw is to be implanted), then the criterion is not met
or (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and	This criterion is for associated products that can only be used by the patient for whom they are provided because of their connection to the product that has been implanted in the patient. These products are critical to the continuing function of the implanted prosthesis and remain with the patient, as part of the prosthesis, after the episode of hospital treatment or hospital-substitute treatment. On their own, these products would not otherwise meet the criteria for listing on the Prostheses List. Examples are processors that are a critical element of the functioning of the implanted product, such as cochlear speech processors and patient-controlled products for pacemakers. Under this criterion, the associated product must have an ongoing role in the function of the implanted product and not be a generic disposable or consumable item. Batteries, catheters, cannulas and similar accessories whose association with the implanted product is not ongoing are considered to be disposable products under this criterion. The product's use is also restricted to an individual patient; the product cannot be one that may be used by more than one patient. For example, office-based equipment to read and download information from implanted ECG loop recorders, which is used in multiple patients, would not meet this criterion

Criterion	Rationale
5 The product has been compared to alternative products on the Prostheses List or alternative treatments and (i) assessed as being, at least, non-inferior in terms of clinical effectiveness; and (ii) the cost of the product is relative to its clinical effectiveness.	This criterion is included with the intention that clinical effectiveness and relative cost be considered. The term 'alternative treatments' is included to allow for entirely new products or technology to be compared with current treatments for the same clinical condition, as it is anticipated that not all products to be considered will have an existing counterpart on the Prostheses List. For example, when cochlear implants were first introduced, the comparator would have been a conventional hearing aid or no hearing assistance at all; when pins and plates were introduced to treat fractured femurs, the comparator would have been use of an external splint and bed rest for 10 weeks. The word 'similar' is used because it is impossible to state that one product is exactly 'equal' to another product when considering clinical effectiveness. The assessment procedure for consideration of products for inclusion on the Prostheses List does not involve analysis of cost effectiveness; therefore, the term 'cost-effective' is not used. However, a product's cost should be considered relative to alternative products or treatments, and relative to its clinical effectiveness compared with those alternative products or treatments

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From: s47F @ahaconsulting.com.au>
Sent: Friday, 17 March 2023 6:16 PM
To: s22
Cc: s22 ; s22 ; s22 ; s22 ; s47E(d) s47E(d) ; s22 ; s47F
Subject: Surgical Guides and Biomodels Review Final Report and Executive Summary
Attachments: PL review final report.pdf; PL review final report_Redacted.pdf; PL review final report_summary and background.pdf

Hi s22
We are delighted to provide you with a copy of the full Final Report and a redacted version of the Final Report. We have made a few minor changes, principally bringing forward summary findings into the Executive summary.
I have also attached a separate accessible Executive Summary, which you may choose to publish. We have revised the table of contents to match the Executive Summary and removed the reference to the report structure. Please let us know if you prefer the table of contents from the full report or the inclusion of the report structure. This can be easily changed if you need.
If there are no further changes we will take these deliverables to mean that we have fulfilled your requirements for this project.
It has been a pleasure to work with you all and we would be keen to be notified when you decide to publish the summary report.
We do have a standard feedback form which we ask all clients to complete at the end of any project. I will send this through in the near future and would appreciate if you provide some brief feedback on the conduct of this project.
Best wishes with the next stage of the review process and thanks once again.
Kind regards,
s47F

From: s22 @Health.gov.au>
Sent: Wednesday, 15 March 2023 3:57 PM
To: s47F @ahaconsulting.com.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Subject: RE: A couple of quick of quick questions regarding the Surgical Guides and Biomodels Review Final Report [SEC=OFFICIAL]
s47F
Thank you for your email. We are happy for you to do the final checks and re-issue the final report to us before the end of this week.
We are currently working through the handling of the final report. I am expecting that we would likely publish the Executive summary up to page 17 to capture the approach to the review as well as the findings.
If you want to make this section of the report accessible, that would be a great help to us. We are not likely to be ready to publish for at least another week or so.
Regards
s22
Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au

M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders past and present.

From: s47F @ahaconsulting.com.au>
Sent: Wednesday, 15 March 2023 3:53 PM
To: s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Subject: A couple of quick of quick questions regarding the Surgical Guides and Biomodels Review Final Report

Hi s22

I am just tying up some loose ends with this project and have a couple of questions:

- In the final report, we noticed that a summary point did not carry through into the Executive Summary. We would like to do some final checks and send you a final version of the report before the end of this week. Would this work for you?
- We'd also like to check with you whether you are planning to publish the report as we have not yet made the document accessible. We would be grateful if you could you let us know whether you require the report (or its parts) to be made accessible, and if so, by when.

We are happy to chat to you about this if required.

Thanks once again,

Kind regards,

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M: s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

s22

From: s47E(d)
Sent: Tuesday, 15 August 2023 8:48 PM
To: FLYNN, Elizabeth
Subject: FW: Surgical Guides and Biomodels Review Final Report and Executive Summary [SEC=OFFICIAL]
Attachments: Official Order - Australian Healthcare Associates - Executed 5 September 2022.PDF; Australian Healthcare Associates(100102)-2318-0322-1403 [SEC=OFFICIAL]

Hi Elizabeth

Is this what you were after? This one is for the surgical guides and biomodels. I'll see what else I can find in the folders.

Cheers

s22

From: s47E(d) @health.gov.au>
Sent: Monday, 17 April 2023 10:07 AM
To: s47E(d) @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: FW: Surgical Guides and Biomodels Review Final Report and Executive Summary [SEC=OFFICIAL]

Hi s22

s47G

s47E(d)

Thanks,
s22

s22
Post-market Review Section
Technology Assessment and Access Division | Health Resourcing Group
Office of Health and Technology Assessment Policy and Programs Branch
Australian Government Department of Health and Aged Care
☎ (02) 6289 s22 | s22 @health.gov.au
Location: s22 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: s47F @ahaconsulting.com.au>
Sent: Friday, 31 March 2023 3:09 PM
To: s22 @health.gov.au>; s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>
Subject: RE: Surgical Guides and Biomodels Review Final Report and Executive Summary [SEC=OFFICIAL]

Hi s22 and s22

We are pleased to provide you with the final accessible copies of both the redacted Final Report and the Executive Summary as promised.

Thanks once again for the opportunity to contribute to this important work.

Best wishes with the project,

Kind regards,

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: s47F
M: s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

SCHEDULE 6
OFFICIAL ORDER

Australian Government

Department of Health

Official Order/Contract details for Review of surgical guides and biomodels (SGBs) currently listed in the Prostheses List (PL)

Under Deed of Standing Offer – Standing Offer Notice SON3676958
Reference ID: Health/ E22-200107

Customer details	**Contractor details**
Commonwealth of Australia As represented by the Department of Health and Aged Care ABN: 83 605 426 759 MDP 910, GPO Box 9848 Canberra ACT 2601	Australian Healthcare Associates (AHA) ABN 82 072 790 848 Level 6, 140 Bourke St, Melbourne VIC 3000 Locked Bag 32005, Collins Street East, VIC 8006
Customer Contract Liaison Officer: Assistant Director, Post-market Review Section, s22 Telephone: s22 Email: s22 @health.gov.au	**Contractor Contract Liaison Officer:** Director: currently s47F Telephone: s47F Email: s47F @ahaconsulting.com.au

This Official Order is placed pursuant to and subject to the terms and conditions of the Deed of Standing Offer (Head Agreement for Services) between the ***Commonwealth of Australia as represented by the Department of Health and Aged Care*** and ***Australian Healthcare Associates*** dated ***31 March 2020.***

Note to Contractor: If you wish to provide the Services to the Customer, please sign this Official Order and send it to the Customer. If the Customer wishes to accept your offer to provide the Services, it will execute the Official Order and return a copy of the executed Official Order to you. You must not supply the Services until after you have received the copy of the executed Official Order from the Customer.

Service	Detail
Service Description	As per Item 1 of the Official Order
Cost	s47G
Date services to commence on	Countersigning by the Department of Health and Aged Care
Date services to be completed by	30 March 2023
Extension Option	An extension option may be available for a further period not exceeding 30 June 2023.

Invoices are to be issued to s47E(d) **@health.gov.au with attention to the Customer Contract Liaison Officer named above.**

1. The Services and subcontractors

The evaluator is to undertake a systematic literature review and clinical review of surgical guides and biomodels currently listed on the Prostheses List (PL). The review aims to inform whether they are eligible for PL listing, and if further cost-effectiveness review is required.

The Surgical Guides and Biomodels under the following PL groups and subgroups are to be included:

- 07.02.02.04 Cranium;
- 07.02.05.07 Mandible, Maxilla and Temperomandibular Joint (TMJ); and
- 07.02.09 Craniomaxillofacial.

The review will consider their role in clinical practice, utilisation patterns and the evidence for their comparative safety, clinical benefits and clinical effectiveness. The review will provide the department with the research evidence and clinical advice necessary to answer Terms of Reference 1 – 4 and support decision-making on eligibility.

Four phases have been planned to answer the key review questions and their sub-questions as follows:

- Phase 1: Plan the review
- Phase 2: Review the PL surgical guides and biomodels place in clinical practice (Q1)
- Phase 3: Conduct a rapid, targeted systematic review (Q2)
- Phase 4: Prepare reports on information and evidence (Q3)

Stakeholders may include sponsors, other medical device industry representatives, private health insurance representatives, private hospital representatives, consumer representatives and clinicians (including clinical experts).

The outcome of this research should include:

- Analyses of the products in the above PL groupings and whether they are considered eligible for PL listing according to the 'criteria for listing' in the Prosthesis List Guide (including but not limited to whether they are 'essential' to the implanted device). Finding regarding eligibility may differ between products and clinical circumstances.
- Identify policy issues that may arise from these findings.

The services include:

Conduct research activities to address Terms of Reference 1-4 listed below:

Terms of Reference:

Stage One

1. Analyse the role in clinical practice of surgical guides and biomodels currently listed on the Prostheses List (PL), including future trends in clinical use.
2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and their clinical benefits.
3. Consider the current utilisation of surgical guides and biomodels listed on the PL.
4. Based on the findings of Terms of Reference 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL, which may differ between products and clinical circumstances.

Stage Two

5. Subject to the findings of Terms of Reference 4, review the cost-effectiveness of surgical guides and biomodels currently listed on the PL.

Questions to be addressed:

Q1: Review the role in clinical practice of surgical guides and biomodels currently listed on the PL. In undertaking this work, the Contractor will consider the following areas of interest to the department, but will not be limited by them:

- Review guidance documents (Australian and international).
- Seek input from relevant organisations and experts using qualitative research methodology.
- Invite sponsors and stakeholders to provide relevant information and evidence and review and incorporate this correspondence in the Report where applicable.

Q2: Conduct a targeted, systematic literature review of the clinical evidence of surgical guides and biomodels currently listed on the PL. In undertaking this work, the Contractor will consider the following areas of interest to the department, but will not be limited by them:

- Undertake a systematic literature review to identify evidence regarding the comparative safety, clinical benefits and clinical effectiveness of surgical guides and biomodels (the appropriate comparator may be standard of care, or no guide).
- Clearly identify and analyse the benefit/s of surgical guides and biomodels compared to the comparator, including clinical outcomes and surrogate outcomes (such as time in surgery).
- Analyse the safety and comparable clinical effectiveness of different types of surgical guides and biomodels and identify the circumstances in which surgical guides and biomodels provide clinical benefit. Compare this to the PL utilisation of surgical guides and biomodels.
- Include a quality assessment and description of the limitations of included trials or observational studies.
- Compare Australian surgical outcomes in maxillofacial surgeries to those of countries where surgical guides and biomodels are not used or have different utilisation patterns.

Q3: Based on the information and evidence in questions 1 and 2, compile information to support the Department to assess whether surgical guides and biomodels meet the PL guide criteria. This includes specific advice on whether they are a device essential for implantation. This may vary between devices and clinical circumstances.

The Contractor will provide the following deliverables:

1. Research protocol

The contractor will be required to prepare a systematic review protocol describing the timelines of the work plan and intended methodology, including:

- inclusion/exclusion criteria
- outcomes of interest
- timeframes
- quality assessment of included studies

- qualitative research proposal to seek expert advice

The protocol must be approved by the Department prior to the contractor progressing with the remaining aspects of the work.

2. Draft Report

The Contractor will collate the review findings and discussion into a written report. This will include:

- an index and glossary with definitions for key clinical terms
- an executive summary
- a technical written report outlining:
  - the methodology used in searching for relevant literature, and identifying relevant literature from sponsor and stakeholder submissions
  - the methodology used for the desktop/ qualitative research (ie key document analysis, stakeholder submissions, and analysis of expert opinion).
  - quality assessment of the evidence used in the report
  - results and conclusions from all evidence considered
- reference list and appendices

3. Final report

The Contractor will submit a final report that incorporates feedback provided by the Department, sponsors, and other stakeholders. The final report is to be accepted by the Department prior to the completion of the project. This report should include identification of Commercial in Confidence (CIC) information for redaction.

2. Time frame

The contractor is required to provide the Services in accordance with the timeframes specified in the table below. The Contractor may supply the deliverable earlier than the previous negotiated time frame. The Final Document for any deliverable must be of a standard acceptable to the Department.

If the Contractor cannot resolve or come to an agreement the Department may at its discretion enforce its rights under the Deed of Standing Offer including Schedule 2 Clause 3.

(Annexure 1)

Deliverable	**Date Due**	**Payment** (GST Inclusive)
Research Protocol	16 September 2022	s47G
Draft report	14 November 2022	
Final report	22 December 2022	

On Signing the Official Order, the Contractor has agreed to meet all timeframes / deliverables listed above. If for any reason the Contractor cannot fulfil their contractual obligation then they must, as soon as possible:

a) advise the Department in writing their non-compliance with the agreed deliverables in the Official Order
b) identify the reasons for not meeting the agreed deliverables

c) identify the component/s that cannot be delivered within the agreed timeframes
d) advise the Post-Market Review team in writing identifying the risk and seek a resolution agreeable to both the Department and the Contractor.

If agreed by both parties, this Official Order may be extended for a further period not exceeding 30 June 2023.

3. Fees, allowances and costs

The total fee for the Services is s47G payable by the following instalments:

- s47G following delivery of the research protocol report (as described in Item 8 [Contract Material]); and
- s47G following delivery of a draft report (as described in Item 8 [Contract Material]).
- s47G following delivery of a final report (as described in Item 8 [Contract Material]) and following customer evaluation and acceptance of final report.

The due date for payment is 30 days after delivery of a correctly rendered invoice to the Customer.

4. Specified Personnel

The personnel who will work on this project are:

s47F	
	Project Director
	Project Manager
	Senior consultant
	Senior consultant
	Consultant
	Consultant
	Consultant
	Expert advisor

The Specified Personnel must produce to the relevant contract manager from the Department of Health and Aged Care a current National Police Certificate, which is no greater than 6 months old, by the contract commencement date. If any disclosable outcomes are mentioned in the certificate, the Department may delay proceeding with the Work Order until an assessment can be conducted.

5. Customer Material to be provided by Customer

The Department will provide the Contractor with the relevant documentation and material required to deliver the Services after the countersigning of the Official Order or as soon as available thereafter.

All contract materials provided to the contractor being relevant data, existing information or any other materials will be regarded as Confidential Information, and appropriate facilities must be available on site to store that material securely and to comply with all reasonable requirements.

The following existing data and information will be made available to the contractor

- Departmental utilisation Review of surgical guides and biomodels presented to the May 2022 Prosthesis List Advisory Committee (PLAC) meeting.
- Deidentified and summarised Hospital Case Mix data
- Deidentified and summarised Medicare Benefits Schedule (MBS) data
- Correspondence (including evidence) from sponsors and stakeholders.

6. Existing Material

The Department will provide the contractor with any existing material required to undertake the work including background documents for desktop review and analysis.

7. Contract Material

Deliverables

1. Research protocol
2. Draft Report
3. Final report

The Contractor must ensure that any Contract Material which is to be placed on a Departmental website or the intranet complies with the:

Level AA accessibility requirements in the Web Content Accessibility Guidelines 2.0 (available at Web Content Accessibility Guidelines); and

World Wide Web Access: Disability Discrimination Act Advisory Notes, version 4.0 (2010), released by the Australian Human Rights Commission (available at Human Rights Commission website).

The report deliverables are to be provided in .doc or .docx format and:

- use default styles and structural headings
- use true numbered and bulleted lists by using the formatting tool
- use tables rather than tab stops or carriage returns
- provide alternative text for images and graphics
- link all hyperlinks and provide meaningful hyperlink text
- include an automatically generated table of contents
- not use colour as the only way to convey meaning
- comply with the Level AA accessibility requirements in the Web Content Accessibility Guidelines 2.0 (available at Web Content Accessibility Guidelines)
- Comply with World Wide Web Access: Disability Discrimination Act Advisory Notes, version 4.0 (2010), released by the Australian Human Rights Commission (available at Human Rights Commission website).

8. Confidential Information

All contract material provided to the Contractor shall be regarded as Confidential Information and appropriate facilities must be available on site to store that material securely and to comply with all reasonable requirements.

9. Customer facilities and assistance

The contractor will liaise with the Customer on a fortnightly basis, either by telephone or workshops or videoconference or by email, and seek guidance as required. Meetings are offered to answer emerging questions as needed. Initial meeting to be scheduled around 5th September 2022.

10. Invoice procedures

- all in voices to be submitted in PDF to s47E(d) [redacted]@concursoluations.com
- and CC: s22 [redacted]@health.gov.au
- valid billing name: Department of Health and Aged Care
- valid biller: name must appear on ABR website as entity/business or trading name
- valid ABN (if applicable)
- valid 10-digit Purchase Order Number (e.g. 45xxxxxxxx). This will be provided by the Contract Liaison Officer after the Official Order has been executed
- a written statement signed by the Contractor, or where the Contractor is a body corporate, by a representative of the Contractor authorised to sign on behalf of the body corporate, verifying that no wages are due and owing by the Contractor in respect of the performance of the Services at the time the claim for payment is made.

11. Other Terms and Conditions

A Police Check is required if the specified personnel accessing confidential information.

This Contract/Official Order is **SIGNED** as a Contract.

SIGNED for and on behalf of the **COMMONWEALTH OF AUSTRALIA** as represented by the Department of Health and Aged Care ABN 83 605 426 759 on:

5TH SEPT 2022
Date

by:

ELIZABETH FLYNN
Printed name of signatory

s22
Signature

ASSISTANT SECRETARY
Position of signatory

in the presence of:

s22
Printed name of witness

s22
Signature

SIGNED for and on behalf of **Australian Healthcare Associates (AHA),** ABN 82 072 790 848 ***[insert Contractor's ABN]***, in accordance with section 127 of the *Corporations Act 2001* on: ***[You will need to insert the appropriate signature block according to the type of legal entity – see the Guide to the Standard Contract for Services. This signature block is only appropriate when the Contractor is a company incorporated under the Corporations Act with several directors or a director and secretary who are separate persons. Also please seek further advice if you are dealing with an individual person (i.e. sole trader) or a trustee]***

5 September 2022
Date

by:

s47F
Printed name of Director

s47F
Signature of Director

and:

s47F
Printed name of Director/Secretary

s47F
Signature of Director/Secretary

s22

From: s22
Sent: Monday, 3 April 2023 3:33 PM
To: Finance Helpdesk
Cc: s22 ; s22 ; s22
Subject: Australian Healthcare Associates s22 [SEC=OFFICIAL]
Attachments: Snip.png; Invoice 3 - final report.pdf

Hello,

I am unable able to match the attached invoice in SAP concur. I have spoken to our finance business partner who has confirmed there should be enough left on the PO to pay the invoice and the correct line item is 30.

The only issue I can see is that the SAP line item is for s47E(d)

Are you able to help with this please? Would appreciate your assistance so we can close of this contract. Please note I will not be the one to submit the invoice, but will be assigned to s22 for approval once this issue is resolved.

Kind regards,

s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group
Genomic and Health Technology Assessment Policy Branch
Australian Government Department of Health and Aged Care
☎ s22 | s22 @health.gov.au
Location: s22 , 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

Australian Healthcare Associates
Australia's largest health & human services consulting firm

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
(03) 9663 1950 aha@ahaconsulting.com.au
(03) 9639 4459 www.ahaconsulting.com.au
ABN: 82 072 790 848

ABN 82 072 790 848

14 March 2023

s22

Assistant Director
Post-market Review Section
Department of Health and Aged Care
MDP 910
GPO Box 9848
Canberra ACT 2601

TAX INVOICE 2318-0322-1403

Review of Surgical Guides and Biomodels currently listed in the Prostheses List

To Fees payable in relation to the abovementioned project, in accordance with the Deed of Standing Offer (number SON3676958) with the Department of Health dated 31 March 2020 and the Official Order dated 5 September 2022.

Purchase Order Number: 4500149437

s47G

Banking Details:

s47G

Please email a copy of payment advice to s47G @ahaconsulting.com.au

All Enquiries: s47F

Australian Healthcare Associates
Australia's largest health & human services consulting firm

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
(03) 9663 1950 aha@ahaconsulting.com.au
(03) 9639 4459 www.ahaconsulting.com.au
ABN: 82 072 790 848

14 March 2023

s22
Assistant Director
Post-market Review Section
Department of Health and Aged Care
MDP 910
GPO Box 9848
Canberra ACT 2601

Dear s22

Re: Review of Surgical Guides and Biomodels currently listed in the Prostheses List

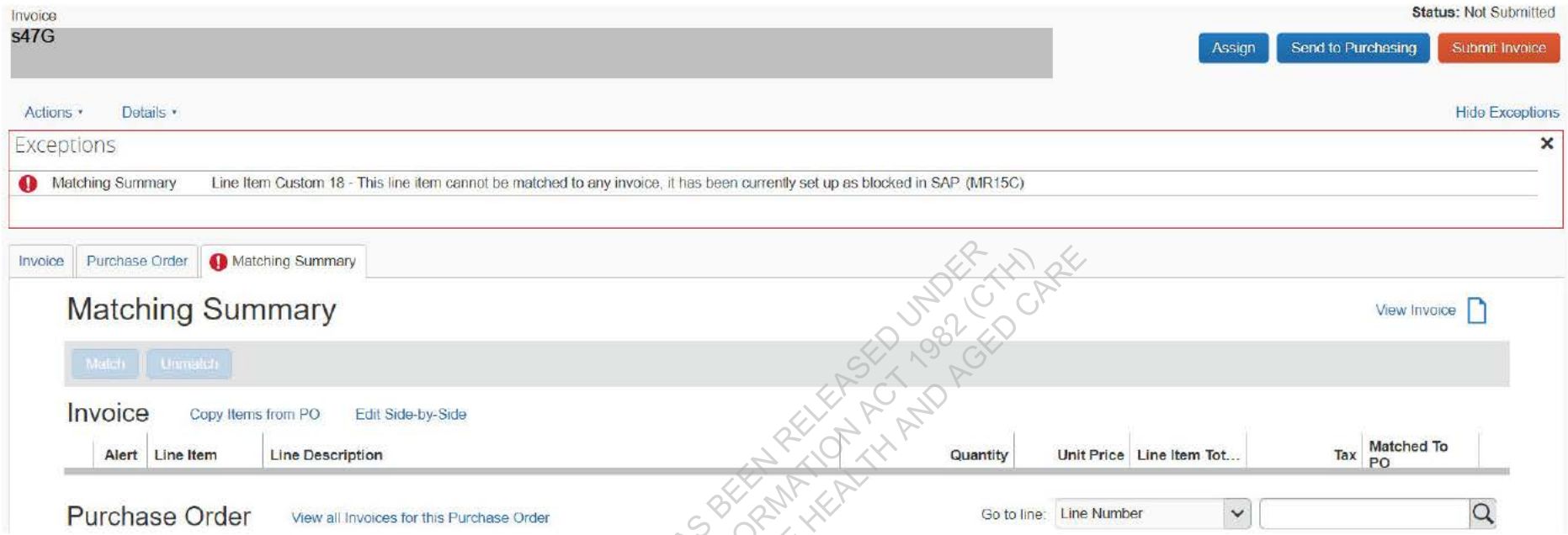
As required under our contract (Item 10), we provide the following statement.

I, s47F, Director of Australian Healthcare Associates Pty Ltd, declare that no wages, fees or other amounts payable, are currently due or owing to relevant employees, agent or subcontractors in relation to the above project.

Yours sincerely
AUSTRALIAN HEALTHCARE ASSOCIATES

s47F

s47F
Director



s22

From: s22 @health.gov.au>
Sent: Thursday, 26 October 2023 1:24 PM
To: s22
Subject: FW: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL:Sensitive]

FYI

Any spelling mistakes are credit to the Dragon voice recognition program

s22
Director, Prostheses List Administration
Prostheses List Reform Taskforce
Location Sirius Building, s22

From: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>
Sent: Thursday, 26 October 2023 1:14 PM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi s22 and s22
I had a discussion with Adriana and she agrees with the Min Sub approach.
We will need to give the Minister the option of

- Delay (suggest till 1 February 2024) or a date of Minister approval.
- Continue
- Stop all together

I think for implementation of any different decision we will need to do a PHI Circular.
The timeframe for decision will be ASAP so we will need to get a waiver from the MO.

Let me know concerns and clarification required and timeframe it may take.
I'll email s47F and let him know we are putting together a Min Sub.

Kind regards

Andrew

Andrew Rintoul
A/g Assistant Secretary

Protheses List Reform Taskforce | Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: s22 | M: s22 E: andrew.rintoul@health.gov.au
Location: Sirius s22

PO Box 9848, Canberra ACT 2601, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 @health.gov.au>
Sent: Thursday, 26 October 2023 11:47 AM
To: s22 @health.gov.au>

Cc: s22 @Health.gov.au>; RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; s22 @health.gov.au>
Subject: FW: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi s22

Andrew has asked that we start drafting a Min Sub on the below – in s22 absence can you start drafting and we can get some input from s22 (and s22 if needed) on possible ways forward.

Happy to chat

s22

Director, Prostheses Reform Policy Section

Prostheses List Reform Taskforce Branch | Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: s22
E: s22 @health.gov.au
Location: Sirius Building, s22
GPO Box 9848, Canberra ACT 2601, Australia

Please note: I do not work Fridays

I do not expect you to respond to my email outside your working hours. At the Department of Health and Aged Care we value and encourage flexible working. Feel free to read, act on or respond at a time that works for you.

From: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>
Sent: Thursday, 26 October 2023 11:41 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>
Subject: FW: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

This is the latest from the MO It is going to be difficult to discuss with Adriana in the short term, but we may need a Min Sub on this decision to get the Minister to sign off on this action.

Andrew Rintoul
A/g Assistant Secretary

Protheses List Reform Taskforce | Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: s22 | M: s22 E: andrew.rintoul@health.gov.au
Location: Sirius s22

PO Box 9848, Canberra ACT 2601, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s47F @Health.gov.au>
Sent: Thursday, 26 October 2023 11:23 AM
To: PLATONA, Adriana <Adriana.Platona@health.gov.au>

Cc: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; s22 @health.gov.au>
Subject: FW: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi Adriana,

We have concerns about the implementation timeframes on the changes for surgical guides and biomodels that were announced on 18 October, with further clarification issued on 20 October. There still appears to be a lack of clarity around the impact of the changes and how they will be implemented. We also understand that a number of surgeries will now be cancelled. To ensure a smooth implementation and minimal impact on patients, we ask that this change is delayed while further detail and clear communications about the change is worked through with hospitals.

Happy to discuss further.

s47F

From: s22 @Health.gov.au>
Sent: Tuesday, 24 October 2023 12:16 PM
To: s47F @Health.gov.au>
Cc: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22 @health.gov.au>
Subject: RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear s47F

Some background and detail about the new condition for surgical guides and biomodels that was announced on 18 October 2023 and effective 1 November 2023 for your information.

- The outcome of the post-listing review into surgical guides and biomodels was presented to the MDHTAC for consideration and advice at the September 2023 meeting. The key points considered were:
    - The post-listing review of surgical guides and biomodels was triggered by many concerns raised by stakeholders (including private health insurers, some sponsors and clinicians) regarding the questions about whether these devices meet the PL Part A criteria for listing.
    - The review report (that was undertaken by an external reviewer) concluded that surgical guides and biomodels have an established role in clinical practice predominantly in craniomaxillofacial (CMF) and oral surgery, and achieve comparable or improved outcomes by improving accuracy of implant placement, decreased operative and/or ischaemic time, reduced intraoperative fluoroscopy and reduced complication rates.
    - The review further advised that surgical guides and biomodels are considered eligible for listing on PL Part A, but their eligibility depends on the clinical circumstances in which they are used.
    - The department undertook additional targeted consultation with some clinical societies after the review report was received – specifically in the orthopaedic and spinal categories.
    - Formulating conditions that could be imposed to restrict PL reimbursement for billing codes under certain clinical scenarios is difficult.
- The MDHTAC members discussed the findings of the review and the types of clinical categories that are relevant for reimbursement of these devices. The key points were:
    - The MDHTAC advice to the delegate was that for these devices that are already listed on the PL and used in CMF and oral surgery to remain on the PL. There was no evidence to support listing of these devices on the PL in any other category at this point
    - The listings for these devices needs to be restricted to reimbursement when the device is used for CMF procedures, the implants for which the surgical guides or biomodels listed under the billing code may be used for the purposes of PL reimbursement need to be specified
    - Additional conditions may also include capping the number of devices that may be claimed per procedure or the total amount of benefits payable.
    - Finally, for any other type of surgery (eg. Orthopaedic), sponsors will be required to apply for listing of the device in that specific category and provide the satisfactory data to demonstrate that the

devices are both essential for implantation of an implantable device and lead to improved clinical outcomes.
    - If clinicians determine additional numbers of devices are required in a single procedure, the hospital and insurer are able to negotiate reimbursement for the additional devices.
- The PHI Circular 66/23 released on 18 October 2023 provided information about the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No.2) 2023 that will be effective 1 November 2023 and included:
    - A range of changes to be applied to the PL based on the outcome of applications and considerations by the Expert Clinical Advisory Groups (ECAGs) and the Medical Devices and Human Tissue Advisory Committee (MDHTAC) in September 2023.
    - New condition to be applied to billing codes for surgical guides and biomodels to restrict the reimbursement for devices used in CMF surgery when implanting a device listed on the PL as well as limiting the quantity of billing codes payable per one clinical procedure to a maximum of 3 per episode of care.
    - Stakeholders (insurers) were also strongly encouraged to continue considering claims for reimbursement during the next few months to ensure all surgeries already scheduled for which devices have been manufactured for specific patients proceed as planned.
- Following questions and concerns raised by the hospital groups following advice at the Key Stakeholder meeting on 18 October 2023 and some sponsors, the PL Reform Taskforce released a further PHI Circular 67/23 clarifying the purpose and operation of the new condition.
- The PL reform taskforce continues to support stakeholders, specifically hospitals and sponsors, with the implementation of this condition.

Regards

s22
A/g Assistant Secretary, Prescribed List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders past and present.

I do not expect you to respond to my email outside your working hours. At the Department of Health and Aged Care we value and encourage flexible working. Feel free to read, act on or respond at a time that works for you.

From: s47F @Health.gov.au>
Sent: Monday, 23 October 2023 9:09 AM
To: s22 @Health.gov.au>
Cc: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; PLATONA, Adriana <Adriana.Platona@health.gov.au>
Subject: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi s22

I see there has been an additional PHI circular put out on Condition on billing codes for surgical guides and biomodels. Would you be able to send up a couple of dot points explaining this one? I've had a few people reach out to me wanting to discuss.

Thanks
s47F

s47F

Advisor
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
m: s47F
e: s47F @health.gov.au

From: s47E(d)
To: s47E(d)
Subject: FW: Waiver request - RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]
Date: Thursday, 26 October 2023 3:19:10 PM
Attachments: image001.png
image002.png
image003.png
image005.png

Hi team
For your visibility, the MO have approved a waiver for MS23-001597 as outlined below.
Thanks

s22
Departmental Liaison Officer
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
T: 02 6277 7220 | M: s22
E: s47E(d) @health.gov.au
Suite s22 | PO Box 6022
Parliament House, Canberra ACT 2600
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @health.gov.au>
Sent: Thursday, 26 October 2023 2:01 PM
To: s47F @Health.gov.au>; RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; s47E(d) @Health.gov.au>
Cc: PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Waiver request - RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]
Thanks

s22
Director, Prostheses Reform Policy Section
Prostheses List Reform Taskforce Branch | Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: s22
E: s22 @health.gov.au
Location: Sirius Building, s22
GPO Box 9848, Canberra ACT 2601, Australia
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2586 Indigenous signature block NEW (2)

From: s47F @Health.gov.au>
Sent: Thursday, 26 October 2023 2:01 PM
To: s22 @health.gov.au>; RINTOUL, Andrew

<Andrew.Rintoul@health.gov.au>; s47E(d) @Health.gov.au>
Cc: PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Waiver request - RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Thanks s22 – this is cleared.

s47F

From: s22 @health.gov.au>
Sent: Thursday, 26 October 2023 1:56 PM
To: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; s47F @Health.gov.au>; Minister Butler DLO s22 @Health.gov.au>
Cc: PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: Waiver request - RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

s47F

Additionally, can we please request a waiver so that we can get the Min Sub up and back asap please? PDMS number is MS23-001597.

Thanks

s22

Director, Prostheses Reform Policy Section

Prostheses List Reform Taskforce Branch | Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: s22
E: s22 @health.gov.au
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Please note: I do not work Fridays

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2586 Indigenous signature block NEW (2)

From: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>
Sent: Thursday, 26 October 2023 1:17 PM
To: s47F @Health.gov.au>
Cc: PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi s47F

We are putting together a Min Sub for the Minister on this and will get it to the office ASAP.

Kind regards

Andrew

Andrew Rintoul
A/g Assistant Secretary
Protheses List Reform Taskforce | Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: s22 | M: s22 E: andrew.rintoul@health.gov.au
Location: Sirius s22
PO Box 9848, Canberra ACT 2601, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s47F @Health.gov.au>
Sent: Thursday, 26 October 2023 11:23 AM
To: PLATONA, Adriana <Adriana.Platona@health.gov.au>
Cc: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; s22 @health.gov.au>
Subject: FW: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi Adriana,

We have concerns about the implementation timeframes on the changes for surgical guides and biomodels that were announced on 18 October, with further clarification issued on 20 October. There still appears to be a lack of clarity around the impact of the changes and how they will be implemented. We also understand that a number of surgeries will now be cancelled. To ensure a smooth implementation and minimal impact on patients, we ask that this change is delayed while further detail and clear communications about the change is worked through with hospitals.

Happy to discuss further.

s47F

From: s22 @Health.gov.au>
Sent: Tuesday, 24 October 2023 12:16 PM
To: s47F @Health.gov.au>
Cc: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22 @health.gov.au>
Subject: RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear s47F

Some background and detail about the new condition for surgical guides and biomodels that was announced on 18 October 2023 and effective 1 November 2023 for your information.

- The outcome of the post-listing review into surgical guides and biomodels was presented to the MDHTAC for consideration and advice at the September 2023 meeting. The key points considered were:
    - The post-listing review of surgical guides and biomodels was triggered by many concerns raised by stakeholders (including private health insurers, some sponsors and clinicians) regarding the questions about whether these devices meet the PL Part A criteria for listing.
    - The review report (that was undertaken by an external reviewer) concluded that surgical guides and biomodels have an established role in clinical practice predominantly in craniomaxillofacial (CMF) and oral surgery, and achieve comparable or improved outcomes by improving accuracy of implant placement, decreased operative and/or ischaemic time, reduced intraoperative fluoroscopy and reduced complication rates.
    - The review further advised that surgical guides and biomodels are considered

eligible for listing on PL Part A, but their eligibility depends on the clinical circumstances in which they are used.
    - The department undertook additional targeted consultation with some clinical societies after the review report was received – specifically in the orthopaedic and spinal categories.
    - Formulating conditions that could be imposed to restrict PL reimbursement for billing codes under certain clinical scenarios is difficult.
- The MDHTAC members discussed the findings of the review and the types of clinical categories that are relevant for reimbursement of these devices. The key points were:
    - The MDHTAC advice to the delegate was that for these devices that are already listed on the PL and used in CMF and oral surgery to remain on the PL. There was no evidence to support listing of these devices on the PL in any other category at this point
    - The listings for these devices needs to be restricted to reimbursement when the device is used for CMF procedures, the implants for which the surgical guides or biomodels listed under the billing code may be used for the purposes of PL reimbursement need to be specified
    - Additional conditions may also include capping the number of devices that may be claimed per procedure or the total amount of benefits payable.
    - Finally, for any other type of surgery (eg. Orthopaedic), sponsors will be required to apply for listing of the device in that specific category and provide the satisfactory data to demonstrate that the devices are both essential for implantation of an implantable device and lead to improved clinical outcomes.
    - If clinicians determine additional numbers of devices are required in a single procedure, the hospital and insurer are able to negotiate reimbursement for the additional devices.
- The PHI Circular 66/23 released on 18 October 2023 provided information about the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No.2) 2023 that will be effective 1 November 2023 and included:
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    - New condition to be applied to billing codes for surgical guides and biomodels to restrict the reimbursement for devices used in CMF surgery when implanting a device listed on the PL as well as limiting the quantity of billing codes payable per one clinical procedure to a maximum of 3 per episode of care.
    - Stakeholders (insurers) were also strongly encouraged to continue considering claims for reimbursement during the next few months to ensure all surgeries already scheduled for which devices have been manufactured for specific patients proceed as planned.
- Following questions and concerns raised by the hospital groups following advice at the Key Stakeholder meeting on 18 October 2023 and some sponsors, the PL Reform Taskforce released a further PHI Circular 67/23 clarifying the purpose and operation of the new condition.
- The PL reform taskforce continues to support stakeholders, specifically hospitals and sponsors, with the implementation of this condition.

Regards

s22

A/g Assistant Secretary, Prescribed List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
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Location: Sirius Building s22
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Cc: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; PLATONA, Adriana <Adriana.Platona@health.gov.au>
Subject: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

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Thanks

s47F

Advisor
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
m: s47F
e: s47F @health.gov.au

Australian Government

Department of Health and Aged Care

Ministerial Submission – Standard
MS23-001597
Version (1)
Date sent to MO: 27 October 2023

To: **Minister Butler**
Subject: **Outcome of the Post-Listing Review into Surgical Guides and Biomodels**

Critical date: 31 October 2023 – before the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) commence on 1 November 2023.

Recommendation/s:

1. That you indicate your preferred approach to the implementation of the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No.2) (the 'proposed 1 November 2023 Rules'). The following three options have been discussed with your office:

   Option 1: Continue to implement the recommendations of the Medical Devices and Human Tissue Advisory Committee (contained in the proposed 1 November 2023 Rules).

   Option 2: Delay implementation to 1 February 2024 ~~(or a date of your choosing - please indicate date)~~

   Option 3: Do not implement the recommendations of the MDHTAC. As this will be queried by stakeholders, it would be helpful for communications that you document your reasons.

   1. **Option 1: Agreed / Not agreed / Please discuss**

   Option 2: Agreed / Not agreed / Please discuss

   Option 3: Agreed / Not agreed / Please discuss / Reasons:

2. **Note** the Department will contact all affected stakeholders with urgency (on or before 1 November) to inform them of your decision.

   2. **Note**

Signature .....

Date: 30 / 10 / 2023

Comments:

Contact Officer:	*Andrew Rintoul*	*A/g Assistant Secretary, Prostheses List Reform Taskforce*	Ph: s22 Mo
Clearance Officer:	*Penny Shakespeare*	*Deputy Secretary, Health Resourcing Group*	Ph: s22 Mo

Issues:

1. Surgical guides and biomodels are relatively new technology manufactured using 3D printing. Utilisation of and expenditure on these devices has been growing rapidly. Expenditure has increased from s47G in 2013-14, to $17,680,000 for 7488 items in 2020–21.

2. There have been disagreements among stakeholders about whether surgical guides and biomodels meet the Prescribed List (formerly known Prostheses List) (PL) criteria for listing, specifically whether these devices are explicitly designed and essential for insertion of an implantable device. Surgical guides and biomodels are listed on PL in Plastic and Reconstructive category in the subcategory for craniomaxillofacial (CMF) devices. There have been no new PL applications accepted for listing of any surgical guides or biomodels since around 2020.

3. Prior to 1 November 2023, there were no express conditions placed on any PL billing codes for surgical guides and biomodels, and hospitals could claim PL reimbursement for these devices for any procedures and for any number of devices, as soon as procedure is covered under a valid MBS item and is performed in a hospital for an insured person with appropriate cover. However it is known that insurers have been often rejecting or delaying PL claims for surgical guides and biomodels.

4. For these reasons, a post listing review was undertaken. This is the PL equivalent of a 'post market review' for medicines listed on the PBS, and the review was provided to the Medical Devices and Human Tissue Advisory Committee (MDHTAC) for consideration and recommendation, in a similar way as a medicines post-market review is provided to the Pharmaceutical Benefits Advisory Committee (PBAC) to consider and make recommendations to you.

5. Unlike the PBAC, you are not obliged by statute to follow the recommendations of the MDHTAC, and it is not a statutory body. However, it is an independent expert body, and if you choose not to follow its recommendations this will be queried by stakeholders and reasons for not implementing its recommendations will be sought.

6. The PL post listing review was conducted by an external consultant and commenced in June 2022. The review noted that surgical guides and biomodels are personalised devices used during the surgery (claimed together with an implant) but are also often used for planning and preparation prior to surgery or for manufacturing an implant (and claimed separately in additional to any implants). The review also noted that despite the surgical guides and biomodels being listed solely in the PL craniomaxillofacial subcategory, there is an increasing trend of claiming for these devices used with implants from different categories (e.g. for orthopaedic devices).

7. The post-listing review concluded that in order to meet the PL criteria for listing and remain listed, surgical guides and biomodels are required to be used for implanting/inserting an implantable device used in CMF procedures; that the procedures need to be complex; and the number of devices to be reimbursed per procedure needs to be set rather than unlimited.

8. It was agreed that representatives of the Medical Technology Association of Australia (MTAA), AusBiotech, Australian Private Hospitals Australia (APHA), Catholic Healthcare Australia (CHA), Day Hospitals Australia (DHA), Private Healthcare Australia (PHA), Members Health Fund Alliance (MHFA) would have an opportunity, on an in-confidence basis, to review and comment on the MDHTAC agenda papers prior to its meetings.

9. On 29 August 2023, the Department uploaded the MDHTAC papers (including updates on the post-listing reviews and reports) and advised the industry representatives.

10. The Department did not receive any feedback or concerns from any of the private hospital representatives about the review outcomes at this time.

11. On 7 September 2023, the MDHTAC considered the report of the surgical guides and biomodels post-listing review and recommended that:

    a. The surgical guides and biomodels that are already listed on the PL and used in CMF and oral surgery should remain on the PL. However, there was no evidence to support listing of these devices on the PL in any other category at this point.

    b. The listings for surgical guides and biomodels should be restricted to reimbursement when the device is used for CMF procedures, and the implants, for which the surgical guides or biomodels listed under the billing code may be used for the purposes of PL reimbursement, need to be specified.

    c. The number of devices that may be claimed per procedure or the total amount of benefits payable should be capped [limiting the claims to no more than 3-4 surgical guides or biomodels per procedure]. If there is a clinical need for additional devices in a single procedure, the hospital and insurer should negotiate reimbursement for the additional devices.

    d. For any other type of surgery (e.g. orthopaedic), sponsors should apply for listing of the device in that specific category and provide data to demonstrate that the device is necessary for implantation of an implantable device and lead to improved clinical outcomes.

12. MDHTAC recommended as an immediate measure that the billing codes for surgical guides and biomodels need to be specifically restricted for CMF use only to control the usage and related benefits. Accordingly, it recommended placing a new condition on all existing billing codes and any new billing codes.

13. The PL benefits for surgical guides and biomodels were set when 3D printing technology was new and expensive. The benefits have been significantly reduced under the PL reforms, but are still higher than expected. The review was planned in two stages - (1) eligibility and (2) benefits - and the second part has not yet commenced.

14. Sponsors of surgical guides and biomodels were advised about the proposed condition on 11 October 2023. All stakeholders were notified via PHI Circular 66/23 on 18 October 2023 of the outcomes of consideration of the review and about the 1 November 2023 Rules to implement the review outcomes. The PHI Circular included information on:

    a. A range of changes to be applied to the PL based on the outcomes of applications and considerations by the MDHTAC.

    b. The new condition on billing codes for surgical guides and biomodels restricting PL reimbursement for use of the device in CMF surgery when implanting a device listed on the PL and limiting the quantity of billing codes payable per single clinical procedure to a maximum of 3.

    c. Insurers were strongly encouraged to continue considering claims for reimbursement during a transitional period to ensure all surgeries already scheduled for which devices have been manufactured for specific patients proceed as planned.

15. Following questions and concerns raised by the private hospital groups following advice at a stakeholder meeting on 18 October 2023 and some sponsors, the PL Reform Taskforce released a further PHI Circular 67/23 on 20 October 2023 clarifying the intent and operation of the new condition.

16. Hospitals are concerned about the costs of devices that fall outside the restrictions which may result in private health insurers rejecting some claims for surgical guides and biomodels. Hospitals advised that they will be cancelling already scheduled surgeries after 1 November due to concerns that patients' claims will not be paid by private health insurers. This could include surgeries not within the existing PL listing criteria.

17. The Department has not been provided with any data about the projected number of scheduled surgeries, the type of surgeries and/or the period for these surgeries. The Department does not have any way of verifying the validity of these claims.

18. The 1 November 2023 Rules will come into effect shortly, and accordingly the new condition for the surgical guides and biomodels will commence, unless the MDHTP Rules are amended or you decide that they should not be made.

19. Given the stakeholders' concerns, this ministerial submission seeks your preferred approach to the implementation of the outcomes of the post-listing review into surgical guides and biomodels based on the three options below.

Option	Description	Further information (inc. risks and benefits)
Option 1: Continue with the implementation as per the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023.	The condition will take effect on 1 November 2023 as previously advised. The Department may further clarify the intent and operation of the condition in PHI Circular.	The issues concerning listing of surgical guides and biomodels on the PL are well-known and have been raised by stakeholders for some time. Affected stakeholders have been consulted through the post-listing review and have been aware of expected changes. Private hospitals representatives (as well as other industry representatives) had opportunity to raise their concerns with the Department since August 2023, but did not do so. PHA, on behalf of insurers, raised concerns in August about slow progress of the review and disappointment about recommendation to leave billing codes for surgical guides and biomodels on the PL. Continuing with the condition would implement the recommendations of the independent expert MDHTAC, after its consideration of the review.
Option 2: Delay implementation to 1 February 2024 (or a date of your choosing).	The condition will not apply immediately after the Amendment Rules are made but will commence on 1 February 2024 (or a date of the Minister's choosing). The sector would be informed urgently via a PHI circular.	This will require making an Amendment Rules as soon as practicable. The Department will need to prepare a new compilation, consult with legal drafters and register the Amendment Rules on the Federal Register of Legislation. This could address concerns about the threatened cancellation of surgical procedures that have been scheduled. It will delay resolution of a long-standing issue with the incorrect PL claims for surgical guides and biomodels.

Option 3: Do not implement.	The condition will be reverted to existing PL wording.	The billing codes for surgical guides and biomodels will continue to be listed unrestricted and claimed in circumstances when these devices do not meet the PL listing criteria. This will not implement the recommendations made by the MDHTAC in regard to surgical guides and biomodels, after its consideration of the review.

20. The Department will contact all affected stakeholders with urgency to communicate your decision.

Background:

The PL Reforms were announced as part of the 2021-22 Federal Budget Measure: *Modernising and Improving the Private Health Insurance Prostheses* List.

The main objective of these reforms is to improve the value and affordability of private health insurance for consumers, by more closely aligning benefits for medical devices used in the private health sector with those applicable in the public sector.

In May 2022, as part of the PL Reforms, post-listing reviews were identified to maintain the integrity of the PL:

a. Surgical guides and biomodels
b. Metal-backed patellae
c. Spinal cord stimulators
d. Urogynaecological mesh devices (mid-urethral slings).