

s22

From: s47F @bupa.com.au>
Sent: Friday, 11 August 2023 8:51 AM
To: s47E(d)
Subject: Surgical guides and biomodels

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good Morning s22

Please find attached more billing of surgical guides and biomodels

X 17 guides

X 6 biomodels

PartName	PartId	ServiceCde	ServiceText	ServiceDate
MIG	1	PX00ZZ049	PROSTHETIC CODE	18/02/2023 12:00 A
MIG	2	PX00ZZ045	PROSTHETIC CODE	18/02/2023 12:00 A
MIG	3	PX00ZZ050	PROSTHETIC CODE	18/02/2023 12:00 A
MIG	4	PX00ZZ044	PROSTHETIC CODE	18/02/2023 12:00 A
MIG	5	PX00EO076	PROSTHETIC CODE	18/02/2023 12:00 A
MIG	6	PX00EO075	PROSTHETIC CODE	18/02/2023 12:00 A
MIG	7	PX00JJ038	PROSTHETIC CODE	18/02/2023 12:00 A
MIG	8	PX00MN234	PROSTHETIC CODE	18/02/2023 12:00 A
MIG	9	OT000041724	PROSTHETIC CODE	18/02/2023 12:00 A
<				
EO075	Aptus Screws Cortical Screws 1.5mm - 2.0mm Diameter	9	06.03 - Skeletal Reconstruction	06.03.1
EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	15	06.03 - Skeletal Reconstruction	06.03.1
JJ038	Ligacip* Multiple Clip Applier Metal/Plastic Applier Prelo	1	03.08 - Closure Devices	03.08.1
MN234	Surgicel Powder Absorbable Haemostatic Powder	1	03.05 - Haemostatic Devices	03.05.1
ZZ044	Orthotin Tmj Fossa Component Titanium Fossa	2	07.02 - Craniomaxillofacial	07.02.1
ZZ045	Orthotin Tmj Ramus Component Tin Coated Titanium	2	07.02 - Craniomaxillofacial	07.02.1
ZZ049	Lyka Smith Patient Specific Guides Patient Specific	17	07.02 - Craniomaxillofacial	07.02.1
ZZ050	Lyka-Smith Anatomical Biomodel Three-Dimensional	6	07.02 - Craniomaxillofacial	07.02.1
4587300	Expl TMJ usg tis flap, cart gft, allogft			

Kind Regards

s47F

s 47F

Claims Integrity, HealthCare Management
 Bupa, Level 16, 179 Turbot Street, Brisbane
 QLD, 4000.

P s47F

M s47F

E s47F

@bupa.com.au

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s22

From: s47F @bupa.com.au>
Sent: Friday, 11 August 2023 1:02 PM
To: s47E(d)
Subject: RE: Surgical guides and Biomodel Usage [SEC=OFFICIAL]

Hi s22

Yes correct, and in the other one 23, we are consistently being billed significant number of these prosthesis.

There are many many examples, I'm signing off for the weekend but can send more on Monday , I was also going to send through to s22 , or is she able to see this email folder as well?

Thanks for following up

s47F

From: s47E(d) @Health.gov.au>
Sent: Friday, 11 August 2023 12:59 PM
To: s47F @bupa.com.au>
Subject: RE: Surgical guides and Biomodel Usage [SEC=OFFICIAL]

Bupa is on a heightened alert - phishing remains a top threat. Check emails carefully, even if you know the sender. Consider the request, or how it makes you feel. Never enter passwords on unknown sites. Report emails of concern. **Pause. Reflect. Protect.**

Thanks s47F

Just a quick question. So that line with the 17 for ZZ049. What does the 17 relate to? Is that 17 guides on that claim? From that hospital? From a single patient?

Kind regards

s22

s22

Assistant Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
 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

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 [redacted] <[redacted]@bupa.com.au>
 Sent: Friday, 11 August 2023 8:39 AM
 To: s47E(d) [redacted] <[redacted]@Health.gov.au>
 Subject: Surgical guides and Biomodel Usage

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Good Morning s22 [redacted]

I am wanting to share some of the excessive billing of surgical guides and biomodels we are paying.

Please find attached billing of surgical guides and biomodels, snapshot of paid eclipse claim;

X 23 ZZ049 guides

X 12 ZZ045 biomodels

MIG (Miscellaneous Services)				
PartName	PartId	ServiceCde	ServiceText	ServiceDate
MIG	1	PX00ZZ049	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	2	PX00ZZ049	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	3	PX00ZZ045	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	4	PX00ZZ050	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	5	PX00ZZ050	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	6	PX00ZZ044	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	7	PX00EO091	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	8	PX00EO076	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	9	PX00EO075	PROSTHETIC CODE	17/02/2023 12:00 A

PartName	PartId	ServiceCde	ServiceText	ServiceDate
MIG	9	PX00EO075	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	10	PX00EO076	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	11	PX00JJ037	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	12	PX00MN234	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	13	OT000041724	PROSTHETIC CODE	17/02/2023 12:00 A
MIG	14	PX00EO091	PROSTHETIC CODE	23/02/2023 12:00 A
MIG	15	PX00EO076	PROSTHETIC CODE	23/02/2023 12:00 A
MIG	16	PX00ZZ058	PROSTHETIC CODE	23/02/2023 12:00 A
MIG	17	PX00ZZ058	PROSTHETIC CODE	23/02/2023 12:00 A

D04A	EO075	Aptus Screws Cortical Screws 1.5mm - 2.0mm Diameter	10	06.03 - Skeletal Reconstruction	06.03.04 - Scr
D04A	EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	10	06.03 - Skeletal Reconstruction	06.03.04 - Scr
D04A	EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	3	06.03 - Skeletal Reconstruction	06.03.04 - Scr
D04A	EO091	Aptus Speedtip C System Aptus Speedtip C Screws	4	06.03 - Skeletal Reconstruction	06.03.04 - Scr
D04A	JJ037	Ligacip* Multiple Clip Applier Metal/Plastic Applier	1	03.08 - Closure Devices	03.08.03 - Lig
D04A	MN234	Surgicel Powder Absorbable Haemostatic Powder	1	03.05 - Haemostatic Devices	03.05.02 - Pov
D04A	22044	Orthotin Tmj Fossa Component Titanium Fossa	2	07.02 - Craniomaxillofacial	07.02.05 - Mar
D04A	22045	Orthotin Tmj Ramus Component Tin Coated Titanium	2	07.02 - Craniomaxillofacial	07.02.05 - Mar
D04A	22049	Lyka Smith Patient Specific Guides Patient Specific	17	07.02 - Craniomaxillofacial	07.02.05 - Mar
D04A	22049	Lyka Smith Patient Specific Guides Patient Specific	6	07.02 - Craniomaxillofacial	07.02.05 - Mar
D04A	22050	Lyka-Smith Anatomical Biomodel Three-Dimensional	6	07.02 - Craniomaxillofacial	07.02.09 - An
D04A	22050	Lyka-Smith Anatomical Biomodel Three-Dimensional	6	07.02 - Craniomaxillofacial	07.02.09 - An
D04A	EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	4	06.03 - Skeletal Reconstruction	06.03.04 - Scr
D04A	EO091	Aptus Speedtip C System Aptus Speedtip C Screws	2	06.03 - Skeletal Reconstruction	06.03.04 - Scr
D04A	22058	Lyka Smith Jeil Leforte System Screws Self Tapping	5	07.01 - Craniomaxillofacial	07.01.06 - Scr
D04A	22058	Lyka Smith Jeil Leforte System Screws Self Tapping	1	07.01 - Craniomaxillofacial	07.01.06 - Scr
D04A	4587300	Expl TMJ usg tis flap, cart gft, allogft			
D04A	4587300	Expl TMJ usg tis flap, cart gft, allogft			
D04A	4572900	Osteotomy mandible with IF, bilateral			
D04A	4501804	Procure fat for graft via separate inc			
D04A	9251429	General anaesthesia, ASA 29			
D04A	4700000	Close rdctn disloc of TMJ			
D04A	9251599	Sedation, ASA 99			
D04A	5210200	R/O pin/screw/wire maxilla/mandible/zygo			
D04A	5209600	Ins pin or wire maxilla/mandible/zygoma			
D04A	9251420	General anaesthesia, ASA 20			
D04A	9555000	Allied health intervention, dietetics			

Kind Regards

s47F

s 47F

Claims Integrity, HealthCare Management
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[@bupa.com.au](mailto: @bupa.com.au)

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From: s47F @bupa.com.au>
Sent: Friday, 11 August 2023 8:52 AM
To: s47E(d)
Subject: Biomodels and guides

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good Morning s22

Please find more examples of billing for biomodels and guides;

X 9 guides

X 6 biomodels

Part Name	Part Id	ServiceCde	Service Text
MIG	1	PX00JJ037	LIGACLIP MULTIPLE CLIP APPLIER
MIG	2	PX00ZI924	OMNIMAX SCREWS
MIG	3	PX00ZZ044	ORTHOTIN TMJ FOSSA COMPONENT
MIG	4	PX00ZZ045	ORTHOTIN TMJ RAMUS COMPONENT
MIG	5	PX00ZZ049	LYKA SMITH PATIENT SPECIFIC GU
MIG	6	PX00ZZ050	LYKA-SMITH ANATOMICAL BIOMODEL
MIG	7	PX00ZZ058	LYKA SMITH JEIL LEFORTE SYSTEM

JJ037	Ligaclip* Multiple Clip Applier Metal/Plastic Applier Prelo	1	03.08 - Closure Devices	03.08.03 - Ligating D
ZI924	Omnimax Screws Imf Screws 2.0 Diameter, 7-11mm	4	07.01 - Craniomaxillofacial	07.01.06 - Screws
ZZ044	Orthotin Tmj Fossa Component Titanium Fossa Component With U	1	07.02 - Craniomaxillofacial	07.02.05 - Mandible,
ZZ045	Orthotin Tmj Ramus Component Tin Coated Titanium Mandibular	1	07.02 - Craniomaxillofacial	07.02.05 - Mandible,
ZZ049	Lyka Smith Patient Specific Guides Patient Specific Surgical	9	07.02 - Craniomaxillofacial	07.02.05 - Mandible,
ZZ050	Lyka-Smith Anatomical Biomodel Three-Dimensional Anatomical	6	07.02 - Craniomaxillofacial	07.02.09 - Anatomic
ZZ058	Lyka Smith Jeil Leforte System Screws Self Tapping And Self	13	07.01 - Craniomaxillofacial	07.01.06 - Screws

Kind Regards

s47F

s 47F

Claims Integrity, HealthCare Management
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From: s47F @healthpartners.com.au>
Sent: Monday, 7 August 2023 3:01 PM
To: s47E(d)
Subject: KT005 & KT004 - clarification for PHI billing
Attachments: Mapping document member s47F redacted.pdf; Hospital Claim member s47F 26th May 2023 redacted.pdf

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Good afternoon,

s 47G

s47F

Claims Manager & Clinical Advisor

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Mobile: s47F

s47F @healthpartners.com.au

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From: s47F @bupa.com.au>
Sent: Friday, 16 June 2023 11:21 AM
To: s47E(d)
Subject: Biomodels and guides

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22 and s22

Good morning, hope you are well,

I wanted to share with you the biomodel and guide usage I have seen recently for a couple of cases.

D04A	EO075	Aptus Screws Cortical Screws 1.5mm - 2.0mm Diameter	10	06.03 - Skeletal Reconstruction
D04A	EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	10	06.03 - Skeletal Reconstruction
D04A	EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	3	06.03 - Skeletal Reconstruction
D04A	EO091	Aptus Speedtip C System Aptus Speedtip C Screws	4	06.03 - Skeletal Reconstruction
D04A	JJ037	Ligacip* Multiple Clip Applier Metal/Plastic Applier Prelo	1	03.08 - Closure Devices
D04A	MN234	Surgicel Powder Absorbable Haemostatic Powder	1	03.05 - Haemostatic Devices
D04A	ZZ044	Orthotin Tmj Fossa Component Titanium Fossa	2	07.02 - Craniomaxillofacial
D04A	ZZ045	Orthotin Tmj Ramus Component Tin Coated Titanium	2	07.02 - Craniomaxillofacial
D04A	ZZ049	Lyka Smith Patient Specific Guides Patient Specific	17	07.02 - Craniomaxillofacial
D04A	ZZ049	Lyka Smith Patient Specific Guides Patient Specific	6	07.02 - Craniomaxillofacial
D04A	ZZ050	Lyka-Smith Anatomical Biomodel Three-Dimensional	6	07.02 - Craniomaxillofacial
D04A	ZZ050	Lyka-Smith Anatomical Biomodel Three-Dimensional	6	07.02 - Craniomaxillofacial
D04A	EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	4	06.03 - Skeletal Reconstruction
D04A	EO091	Aptus Speedtip C System Aptus Speedtip C Screws	2	06.03 - Skeletal Reconstruction
D04A	ZZ058	Lyka Smith Jeil Leforte System Screws Self Tapping And	5	07.01 - Craniomaxillofacial
D04A	ZZ058	Lyka Smith Jeil Leforte System Screws Self Tapping And	1	07.01 - Craniomaxillofacial
D04A	4587300	Expl TMJ usg tis flap, cart gft, allogft		
D04A	4587300	Expl TMJ usg tis flap, cart gft, allogft		
D04A	4572900	Osteotomy mandible with IF, bilateral		

And the second case

EO075	Aptus Screws Cortical Screws 1.5mm - 2.0mm Diameter	9	06.03 - Skeletal Reconstruction	06.03.04
EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	15	06.03 - Skeletal Reconstruction	06.03.04
JJ038	Ligacip* Multiple Clip Applier Metal/Plastic Applier Prelo	1	03.08 - Closure Devices	03.08.03
MN234	Surgicel Powder Absorbable Haemostatic Powder	1	03.05 - Haemostatic Devices	03.05.02
ZZ044	Orthotin Tmj Fossa Component Titanium Fossa	2	07.02 - Craniomaxillofacial	07.02.05
ZZ045	Orthotin Tmj Ramus Component Tin Coated Titanium	2	07.02 - Craniomaxillofacial	07.02.05
ZZ049	Lyka Smith Patient Specific Guides Patient Specific	17	07.02 - Craniomaxillofacial	07.02.05
ZZ050	Lyka-Smith Anatomical Biomodel Three-Dimensional	6	07.02 - Craniomaxillofacial	07.02.05
4587300	Expl TMJ usg tis flap, cart gft, allogft			
4587300	Expl TMJ usg tis flap, cart gft, allogft			
4501804	Procure fat for graft via separate inc			

Kind Regards

s47F

s 47F

Claims Integrity, HealthCare Management

Bupa, Level 16, 179 Turbot Street, Brisbane
QLD, 4000.

P s47F [REDACTED] M s47F [REDACTED]
E s47F [REDACTED] [@bupa.com.au](mailto:[REDACTED]@bupa.com.au)

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From: s 47F
Sent: Monday, 27 March 2023 3:30 PM
To: s47E(d)
Cc: s47F; s 47F
Subject: Prosthesis enquiry relation to supplier KLS Martin Prosthesis items KT004 and KT005

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good afternoon Prosthesis Compliance team,
 We have been billed for a prosthesis item KT005 UNIQOS Patient Specific surgical guides. On the prosthesis schedule, the ARTG code of 200232 is invalid on the ARTG search.
 Therefore, we believe that KT005 and KT004 that share the same ARTG code, should be removed from the prosthesis schedule in the absence of a valid ARTG code .
 Additional information is as follows;
 Date of service -09.12.2022
 MBS item- 52369.
 Can you please provide feedback on this issue.

Regards

s47F

s 47F

p| 1300 362 144 e| s 47F
 m| s47F a| s 47F

latrobehealth.com.au

Latrobe Health Services acknowledges the traditional owners of country, the Gunaikurnai nation, and recognises their continuing connection to land, waters and culture.
 We pay our respects to their Elders past, present and emerging.

s22

From: s22
Sent: Monday, 6 March 2023 2:03 PM
To: s22; s47E(d)
Cc: s22
Subject: FW: Orthopaedic Guides and biomodels [SEC=OFFICIAL]

FYI

From: s47F @bupa.com.au>
Sent: Monday, 6 March 2023 1:55 PM
To: s22 @health.gov.au>; s22 @health.gov.au>
Subject: Orthopaedic Guides and biomodels

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good Morning,

Hope you are both well,

We are starting to see a few orthopaedic cases coming through using guides and biomodels,

An example below of Corin Knee prosthesis with specific guides and biomodels.

Please let us know if you need more examples for hips, shoulder or spine.

CR286	Apex Knee, Tibial Base Plate - Cemented Tibial Baseplate, Ce	1	
CR296	Apex Ps Cemented Femoral Component The Femoral Component Of	1	
CR315	Apex Knee Retaining Bolt Tibial Insert, Retaining Bolt, Unco	1	
GO257	Apex Revision Knee Tibial Insert Apex Revision Knee Tibial I	1	
HK014	Palacos R+g Pro Or Palacos Mv+g Pro Single Mix Pmma With Gen	1	
MI317	Indermil Flexifuze Topical Tissue Adhesive With Applicator 0	1	
UI001	Osguide A Non-Sterile, Custom-Made Surgical Guide Manufactur	2	
UI002	Biomodel 3d Ct Based Patient Specific Biomodels Generated Fr	2	

Kind Regards

s47F

s47F

s 47F

Claims Integrity, HealthCare Management
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From: s 47F >
Sent: Thursday, 9 February 2023 7:50 AM
To: s47E(d)
Subject: TRIM: Lyka Smith Combined TMJ System - rebate code ZZ049

Categories: FOR APPROVAL

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good Morning, I am after some clarification on this Lyka Smith Prosthesis, rebate code ZZ049 and also ZZ050. This is increasingly being audited by health funds advising - Per the ARTG293845 and Prostheses Listing - ZZ049 and ZZ050 can only be claimed from the PHI where used as part of a "kit" for a TMJ procedure. ZZ049 and ZZ050 cannot be claimed when used in isolation or when used for a procedure other than a TMJ e.g. cannot be claimed for dental implants/ostectomies etc.

As there is no 'specific condition' listed for these items and only a description for the intended purpose, can these prosthesis be used and payable when used for implants or another procedure and not TMJ? Do all prosthesis listed under ARTG listing 293845 need to be used at the same time to be able to claim any of these. I.e. Can ZZ049 + ZZ050 be used and claimed without using ZZ044, ZZ048, ZZ045, ZZ47, ZZ046?

Product Category	Sub Category	Product Group	Product Sub Group	Suffix	Billing Code
07 - Plastic and Reconstructive	07.02 - CRANIOMAXILLOFACIAL IMPLANTS	07.02.05 - Mandible, Maxilla and Temporomandibular Joint (TMJ)	07.02.05.02 - Fossa Replacement		ZZ044
07 - Plastic and Reconstructive	07.02 - CRANIOMAXILLOFACIAL IMPLANTS	07.02.05 - Mandible, Maxilla and Temporomandibular Joint (TMJ)	07.02.05.05 - Plate	Biomodelled	ZZ048
07 - Plastic and Reconstructive	07.02 - CRANIOMAXILLOFACIAL IMPLANTS	07.02.05 - Mandible, Maxilla and Temporomandibular Joint (TMJ)	07.02.05.05 - Plate		ZZ045
07 - Plastic and Reconstructive	07.02 - CRANIOMAXILLOFACIAL IMPLANTS	07.02.05 - Mandible, Maxilla and Temporomandibular Joint (TMJ)	07.02.05.07 - Surgical Guide	Biomodelled	ZZ047
07 - Plastic and Reconstructive	07.02 - CRANIOMAXILLOFACIAL IMPLANTS	07.02.05 - Mandible, Maxilla and Temporomandibular Joint (TMJ)	07.02.05.07 - Surgical Guide	Biomodelled	ZZ049
07 - Plastic and Reconstructive	07.02 - CRANIOMAXILLOFACIAL IMPLANTS	07.02.09 - Anatomical Biomodel			ZZ046
07 - Plastic and Reconstructive	07.02 - CRANIOMAXILLOFACIAL IMPLANTS	07.02.09 - Anatomical Biomodel			ZZ050

Regards

s47
F

s47F

Health Fund Contract Administrator



Little Company of Mary Health Care Ltd
Level 12 - 135 King Street, Sydney, NSW, 2000

P: s47F | M: s47F

E: s 47F

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From: s 47F
Sent: Thursday, 5 January 2023 1:50 PM
To: s47E(d)
Subject: Surgical guide ZZ049
Attachments: COMBINED TMJ _ ORTHOGNATHIC VSP REPORT - REVISION 1.1 (1).pdf

Categories: Added to tracker

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear PL compliance team

We've had a claim where the surgical guide, ZZ049 was claimed 11 times.

After reviewing the documents provided by the hospital (attached), we deemed 4 to be valid and 9 not valid to be claimed under ZZ049 as per our understanding below.

The following are valid to be claimed under ZZ049:

- 1 x Custom maxilla guide
- 1 x Fossa drilling guide
- 1 x Ramus drilling guide
- 1 x Ramus screw guide

The following however are not valid for claiming under ZZ049:

- 1 x Condyle – Not a surgical guide - it is a plastic model of the condyle to be excised.
- 1 x Condylectomy checker – Not a surgical guide – it is a plastic model to check the amount of condyle removed
- 1 x Trial fossa - Not a surgical guide - it is a trial implant
- 1 x Trial ramus - Not a surgical guide - it is a trial implant
- 1 x Test skull - Not a surgical guide - it is a plastic model of the orientation of the glenoid fossa to the excised ramus
- 1 x Intermediate splint is not a surgical guide and cannot be claimed under PL rebate code ZZ049
- 1 x Final splint is not a surgical guide and cannot be claimed under PL rebate code ZZ049.

The hospital has come back saying that PLAC has assessed these items and approved them on to be listed on the PL. I am not sure if this is the case though and am planning to ask them to provide information to support their understanding.

I would appreciate any advice you are able to offer.

Kind regards

s 47F

t: s47F . d: s47F

a: Level 5, Tower A, 260 Elizabeth Street, Sydney NSW 2000 (*Deliveries to Level 3*)

GPO Box 9812, Sydney NSW 2001

teachershealth.com.au



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BY THE DEPARTMENT OF HEALTH AND AGED CARE

VIRTUAL SURGICAL PLANNING CASE REPORT

Revision 1.1

Case Information

Patient Name:

s 47F

Lyka Smith Staff:

s 47F

Surgeon:

Contact:

Surgery Date:

11 JUNE 2022

Date of VSP Session:

10 FEBRUARY 2022

Hospital:

s 47F

Date Report was completed:

07 MAY 2022

Surgical Procedure

Bimaxillary Osteotomy + Right TMJR

- Le Fort I
- Sagittal Split Osteotomy

Parts Requested

- Orthognathic Splints
 - 1 x Intermediate Occlusion Splint – Material: MED610 (Plastic, Clear)
 - 1 x Final Occlusion Splint – Material: MED610 (Plastic, Clear)
- Patient-Specific Anatomical Biomodels
 - 1 x Initial Skull – Material: PA2200 (Plastic, White)
 - 1 x Initial Mandible – Material: PA2200 (Plastic, White)
 - 1 x Final Skull – Material: PA2200 (Plastic, White)
 - 1 x Final Mandible – Material: PA2200 (Plastic, White)
 - 1 x Fossa Skull – Material: PA2200 (Plastic, White)
 - 1 x Ramus Mandible – Material: PA2200 (Plastic, White)
- Custom Guides
 - 1 x Custom Maxilla Guide - Material: Ti64 (Grey, Metallic)
 - 1 x Condyle - Material: PA2200 (Plastic, White)
 - 1 x Condylectomy Checker – Material: PA2200 (Plastic, White)
 - 1 x Trial Fossa – Material: MED610 (Plastic, Clear)
 - 1 x Trial Ramus – Material: MED610 (Plastic, Clear)
 - 1 x Fossa Drilling Guide – Material: PA2200 (Plastic, White)
 - 1 x Ramus Drilling Guide – Material: PA2200 (Plastic, White)
 - 1 x Ramus Screw Guide – Material: PA2200 (Plastic, White)
 - 1 x Test Skull – Material: PA2200 (Plastic, White)
- Custom Implants
 - 2 x Custom Maxilla Plates – Material: Ti64 (Blue/Purple, Metallic)
 - 1 x Custom TMJ Ramus – Material: Ti64 (Gold, Metallic)
 - 1 x Custom TMJ Fossa + Bearing – Material: Ti64 (Gold, Metallic)/UHMWPE (White, Plastic)
- Lyka Smith Instrument Sets

Delivery details

- Parts to be delivered at least 1 business day prior to surgery date directly to hospital CSSD for sterilisation.

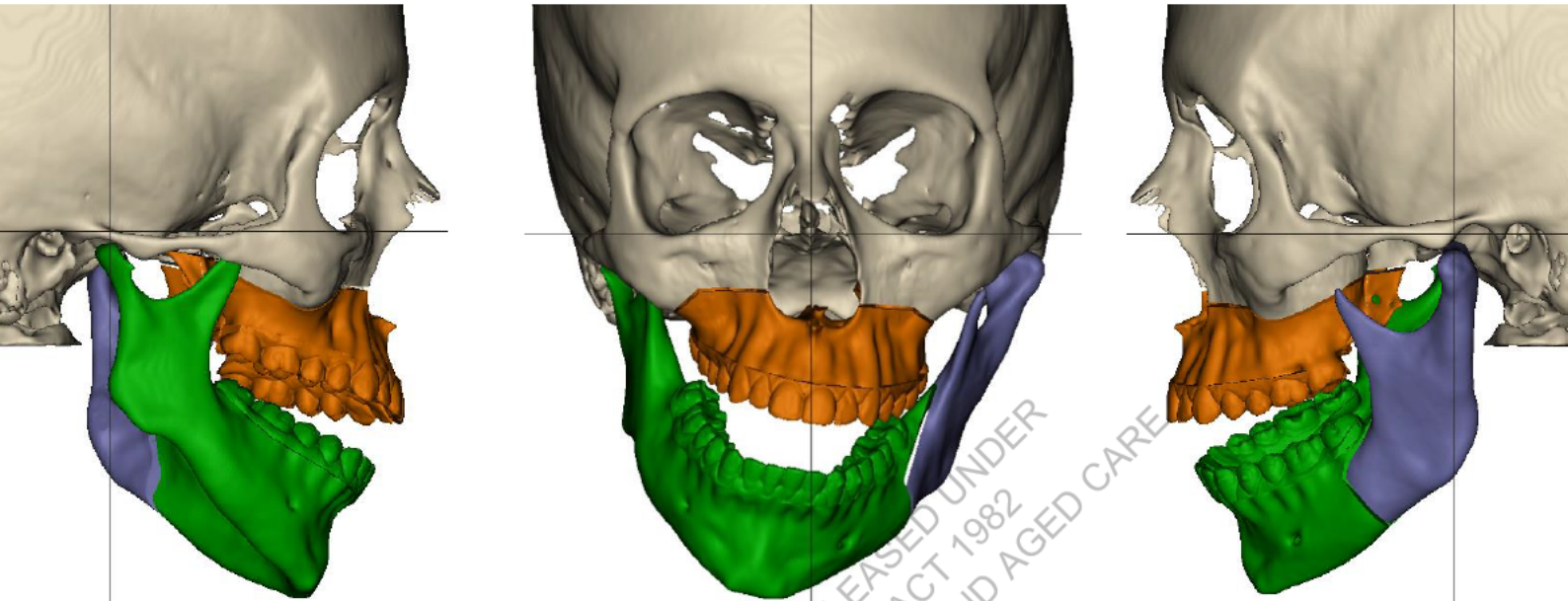
Design Report Authorisation

I hereby declare that the surgical planning and custom product conform to my specific requirements and are intended for the exclusive use of the patient mentioned above. I declare having the qualifications required by law to perform the planned intervention.

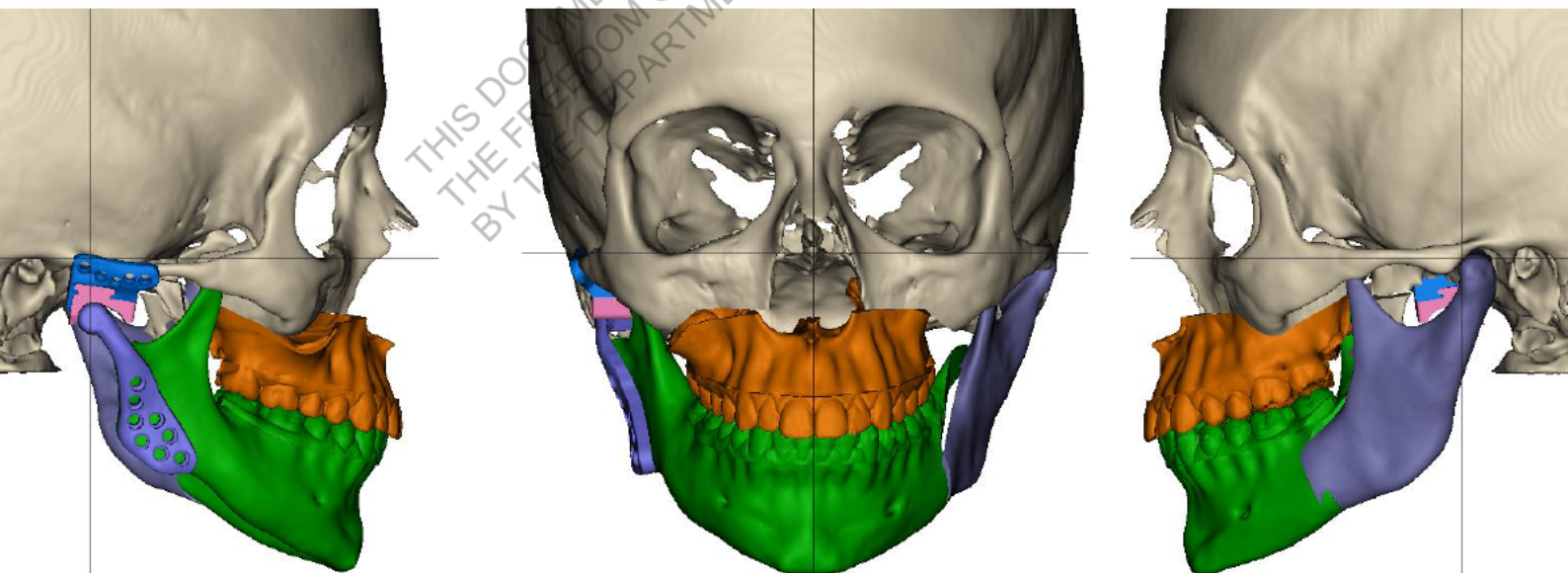
- Requesting Surgeon's Name: _____
- Requesting Surgeon's Signature: _____
- Date: _____

Patient Anatomy

Pre-Operative Position

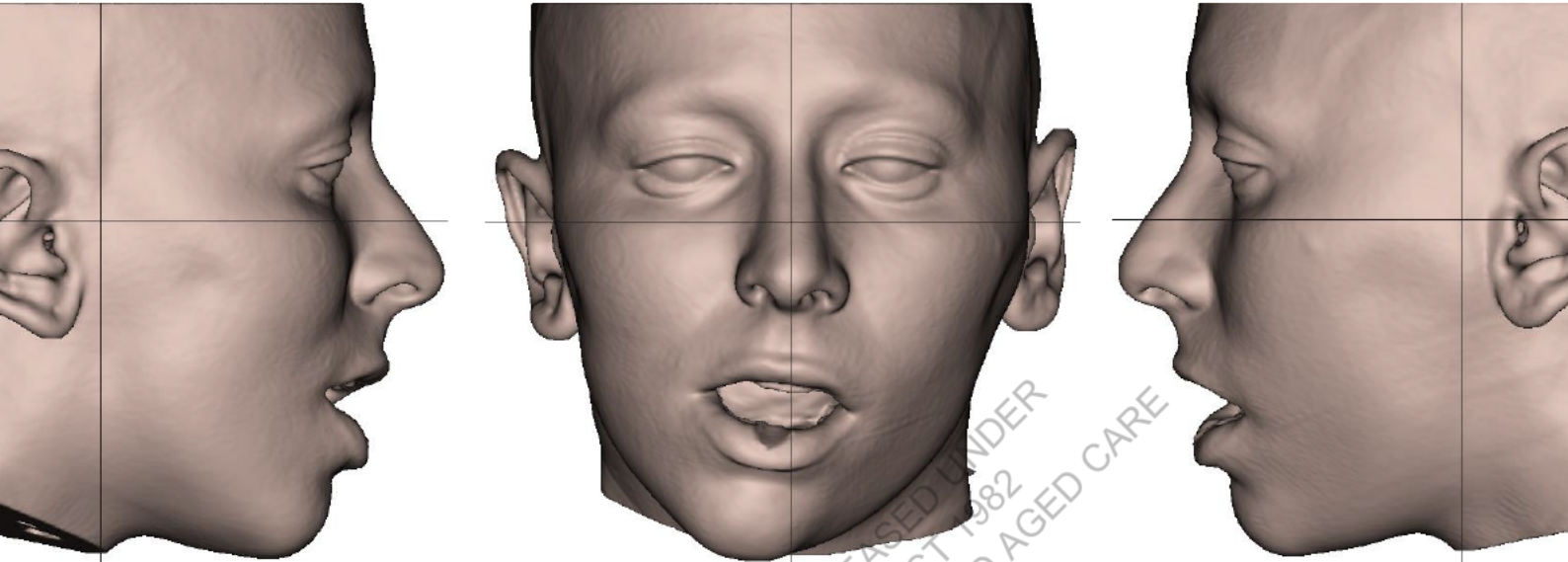


Planned Position

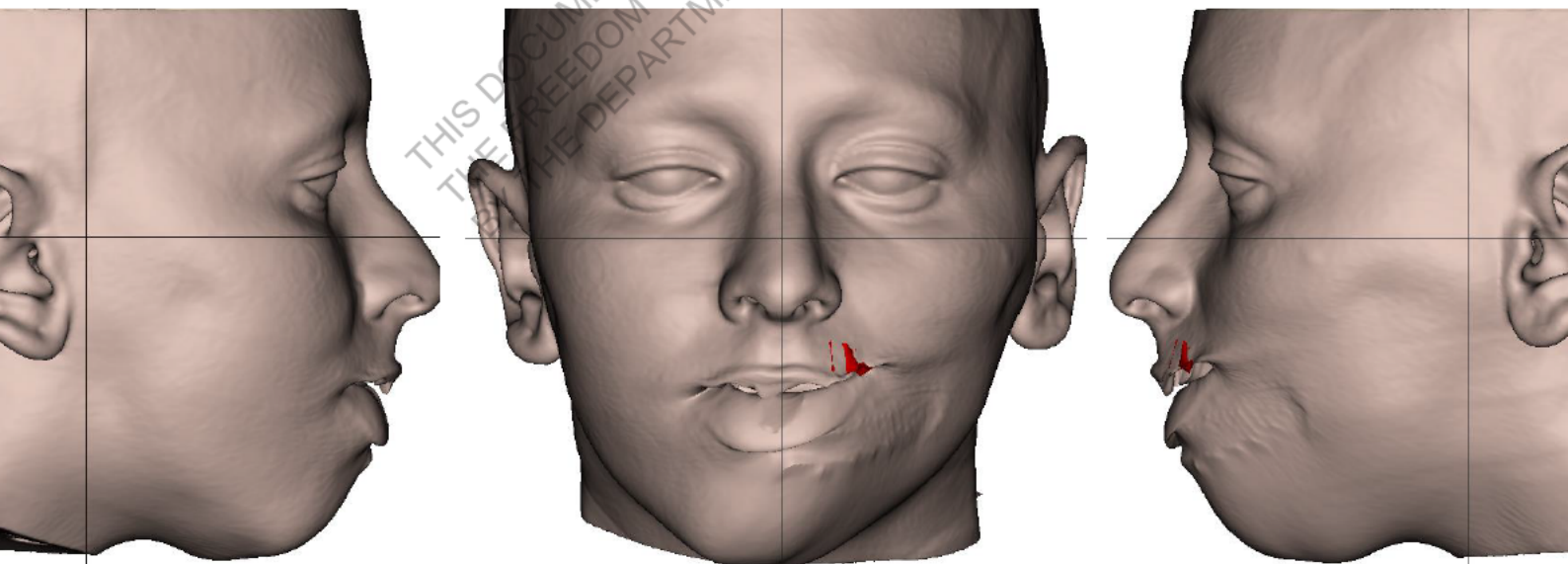


Soft Tissue Simulation

Pre-Operative Position

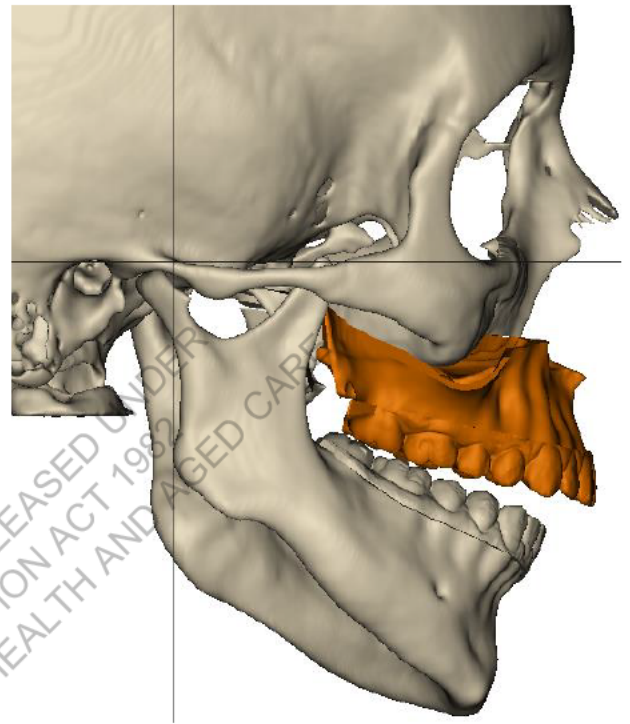
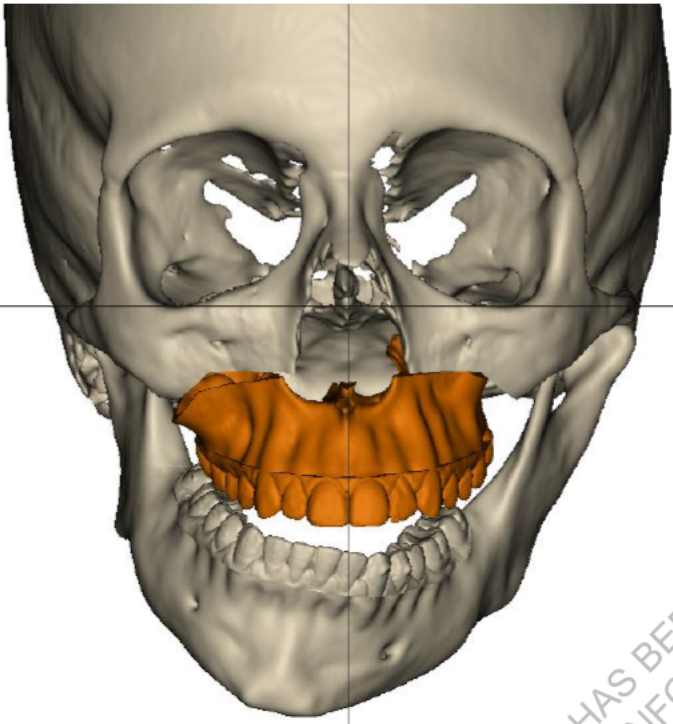


Planned Position



Movement Analysis: Intermediate Position

- **Le Fort I Osteotomy:**
 - Cant Correction
 - 5.0mm Forwards Advancement
 - 2.0mm Upwards Impaction

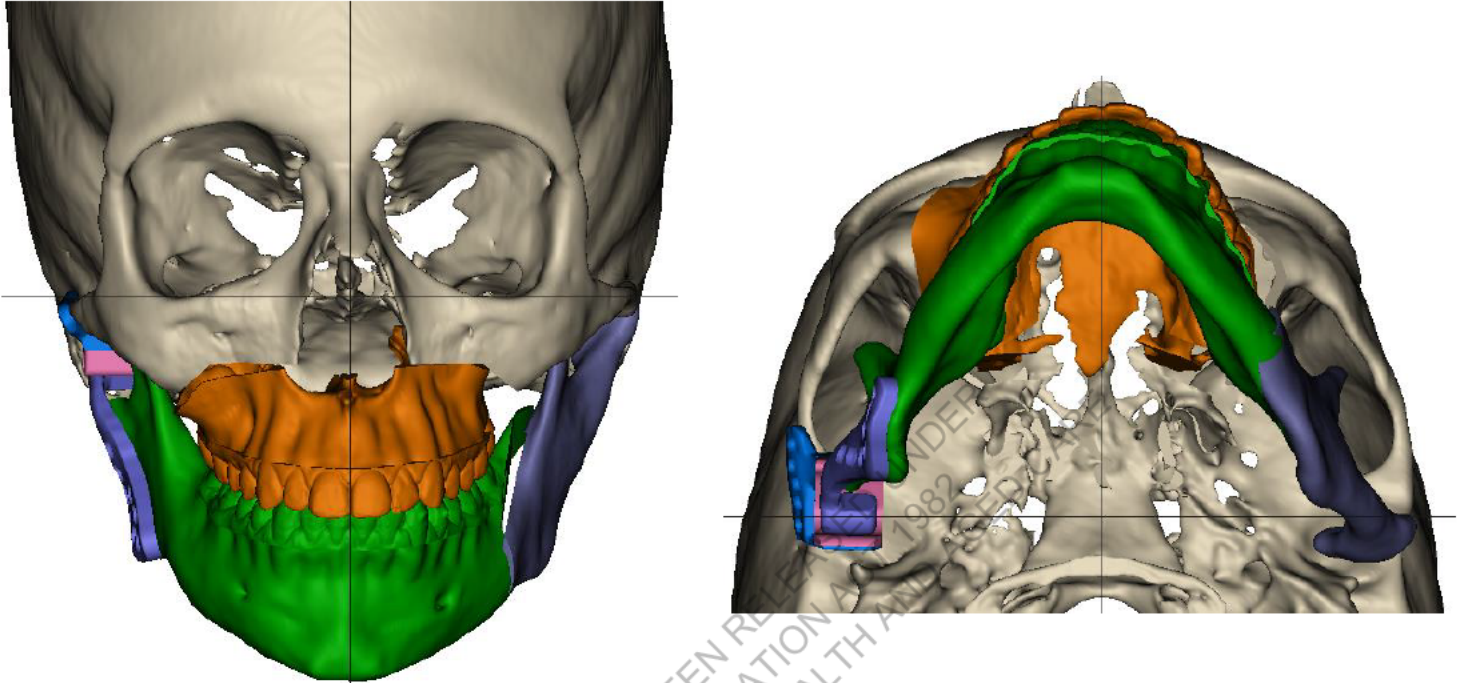


Maxillary Movement Analysis

Reference	Left/Right (mm)	Anterior/Posterior (mm)	Up/Down (mm)
Maxilla Incisal Midline	2.7 Left	5.0 Anterior	2.0 Up
Maxilla Canine R	2.4 Left	5.0 Anterior	1.0 Down
Maxilla Canine L	2.8 Left	5.0 Anterior	5.1 Up
Maxilla First Molar R	1.2 Left	5.0 Anterior	2.4 Down
Maxilla First Molar L	1.8 Left	5.0 Anterior	6.7 Up

Movement Analysis: Final Position

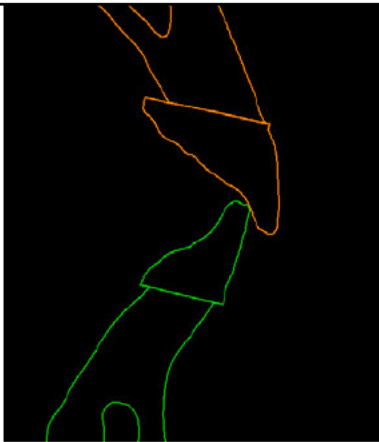

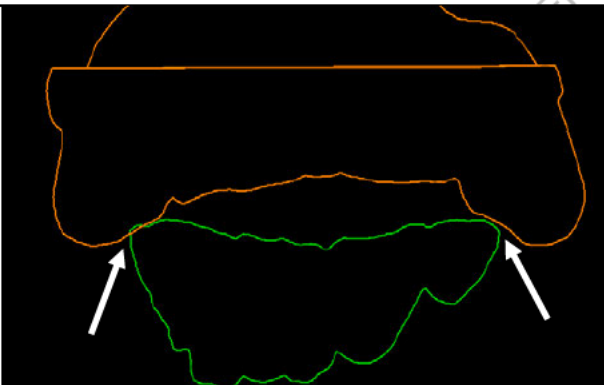
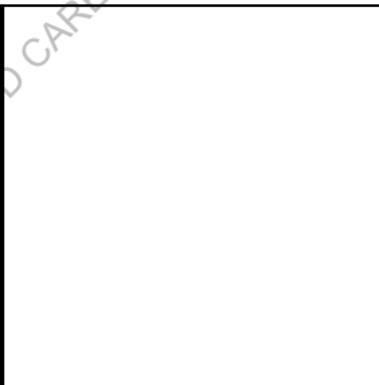
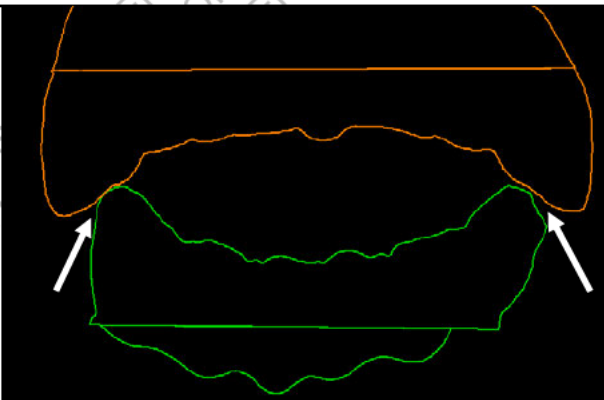

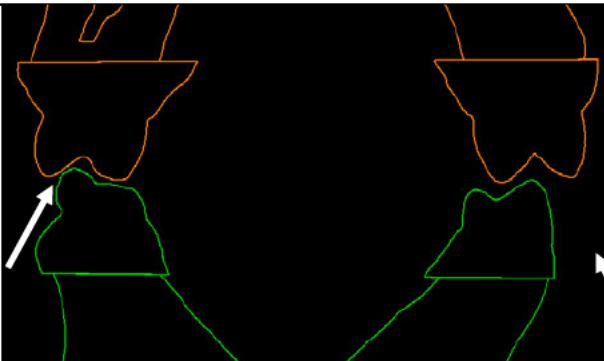

- **Sagittal Split Osteotomy:**
 - Mandible set to final occlusion as determined in planning session

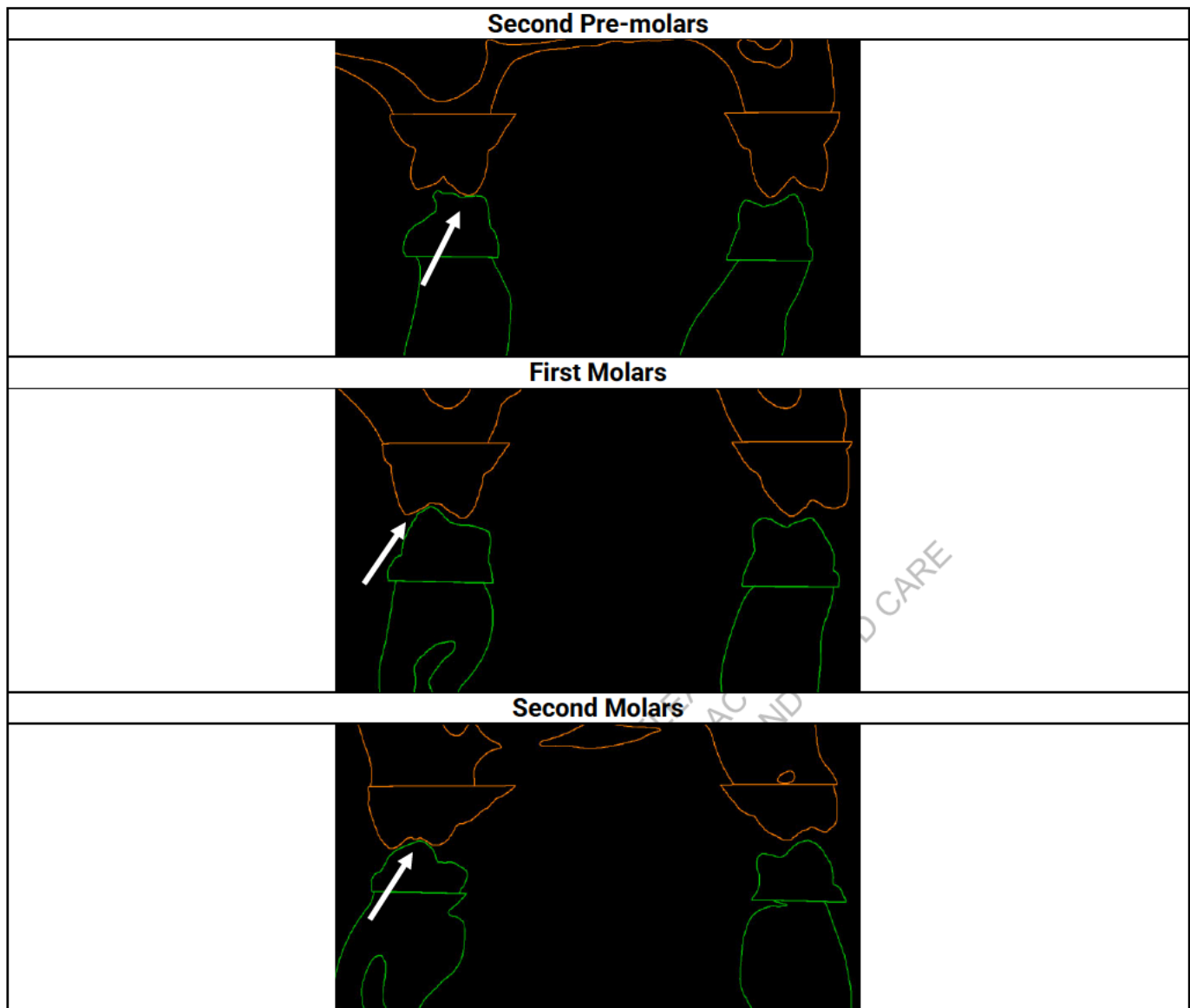


Mandibular Movement Analysis

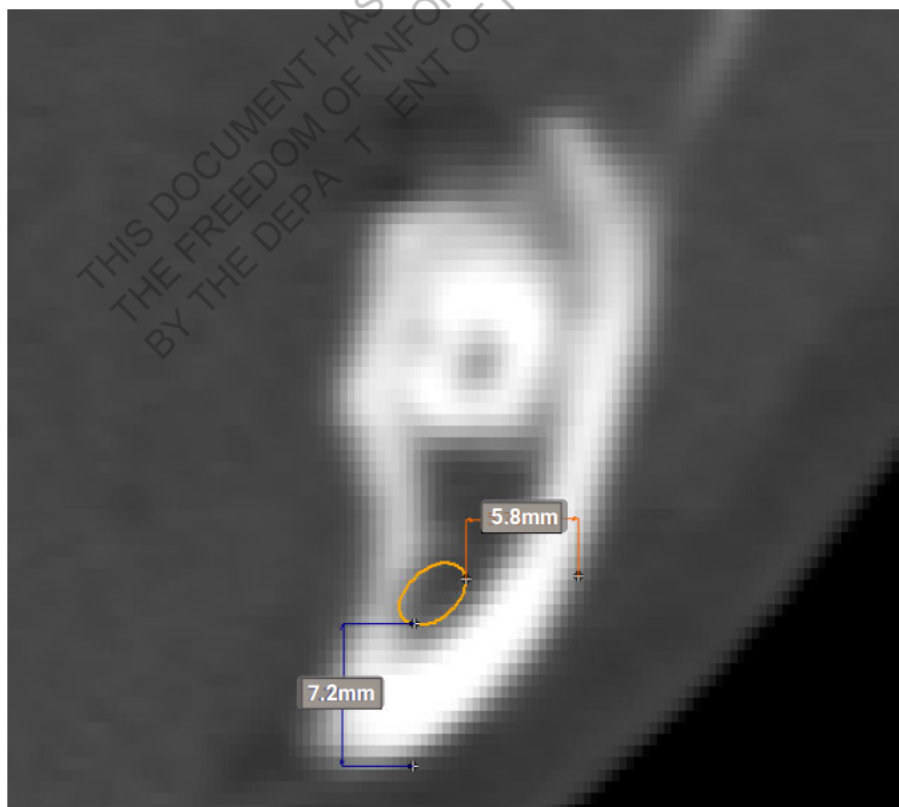
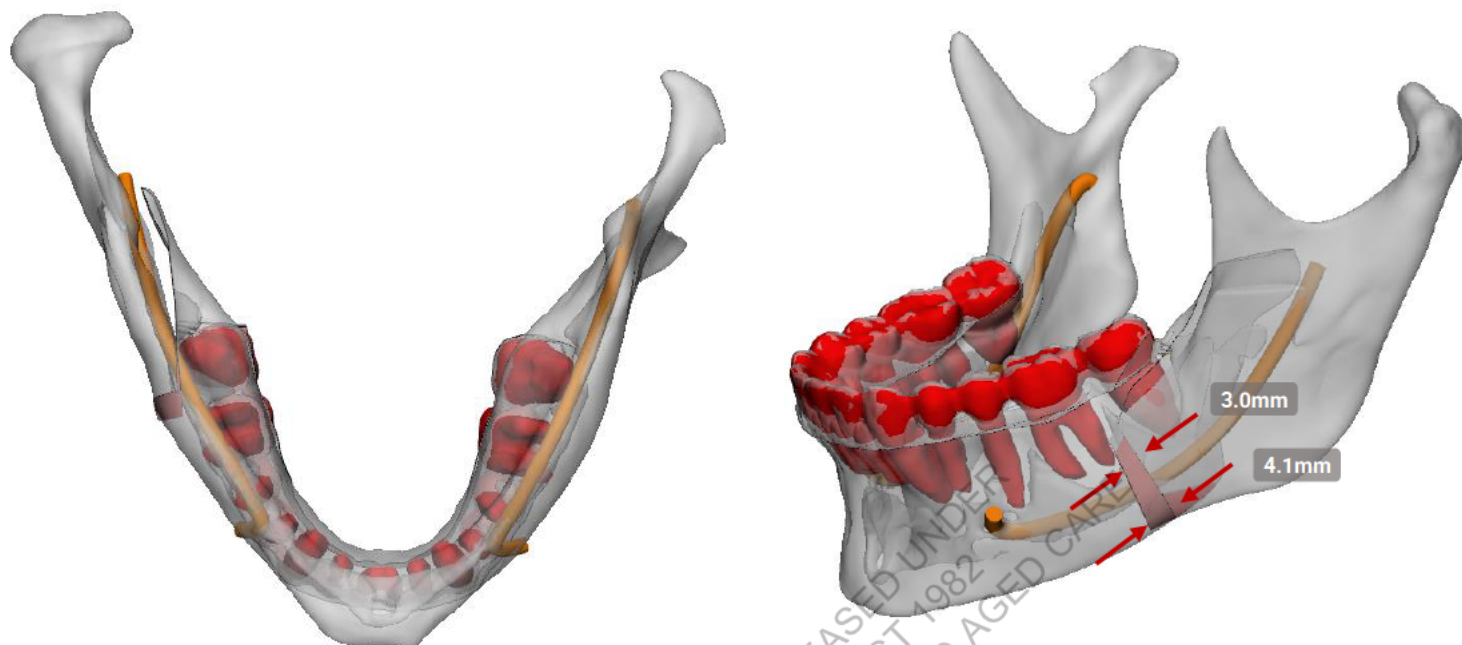
Reference	Left/Right (mm)	Anterior/Posterior (mm)	Up/Down (mm)
Mandible Incisal Midline	6.9 Left	9.0 Anterior	16.2 Up
Mandible Canine R	6.2 Left	8.4 Anterior	12.8 Up
Mandible Canine L	6.7 Left	8.8 Anterior	17.7 Up
Mandible First Molar R	4.9 Left	7.3 Anterior	7.4 Up
Mandible First Molar L	5.8 Left	8.0 Anterior	15.8 Up

Dental Contacts

Right		Left	
Central Incisors			
			
Lateral Incisors			
			
Canines			
			
First Pre-molars			
			

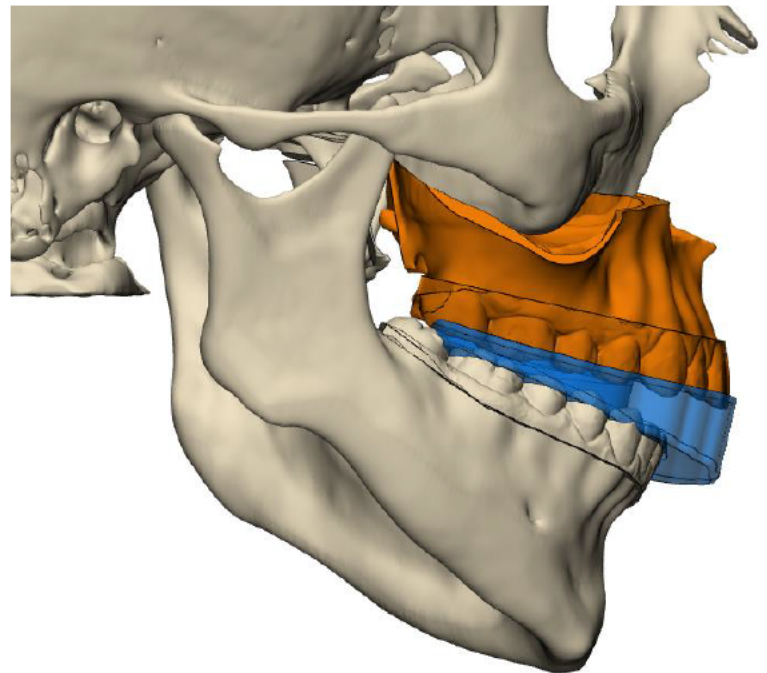
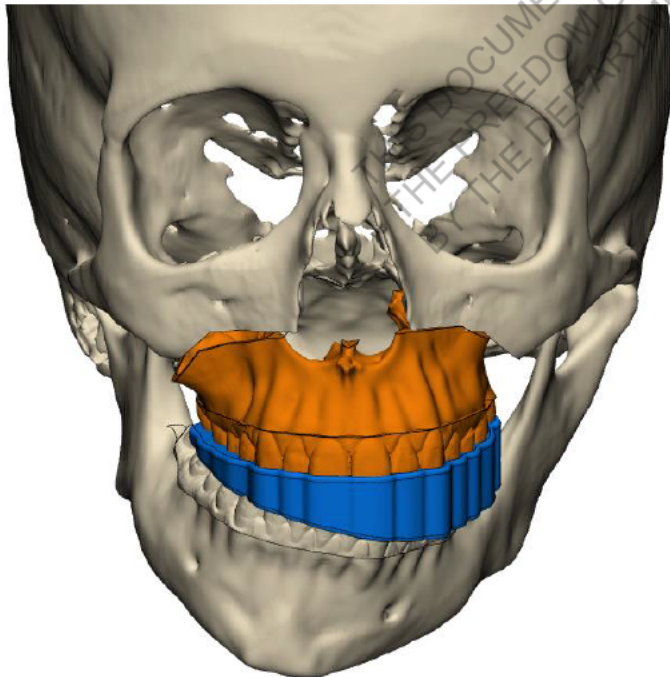
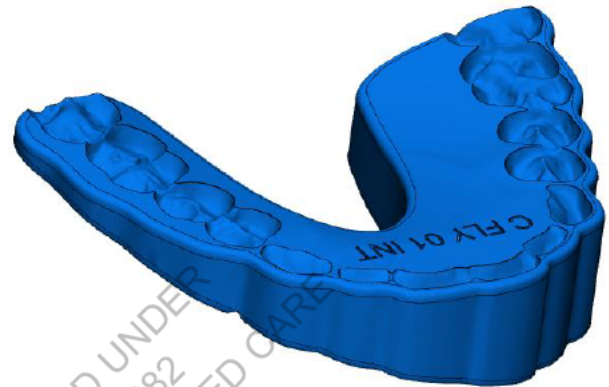


Sagittal Split Osteotomy Analysis



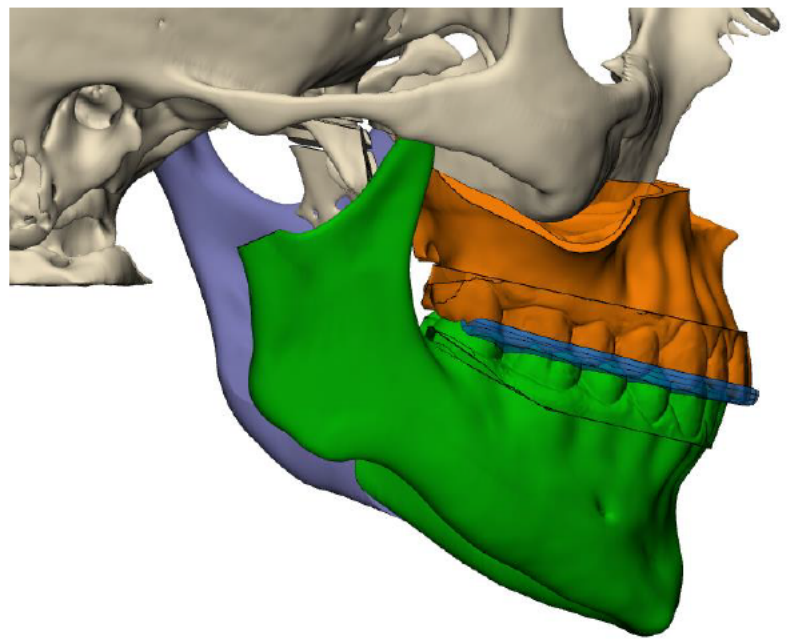
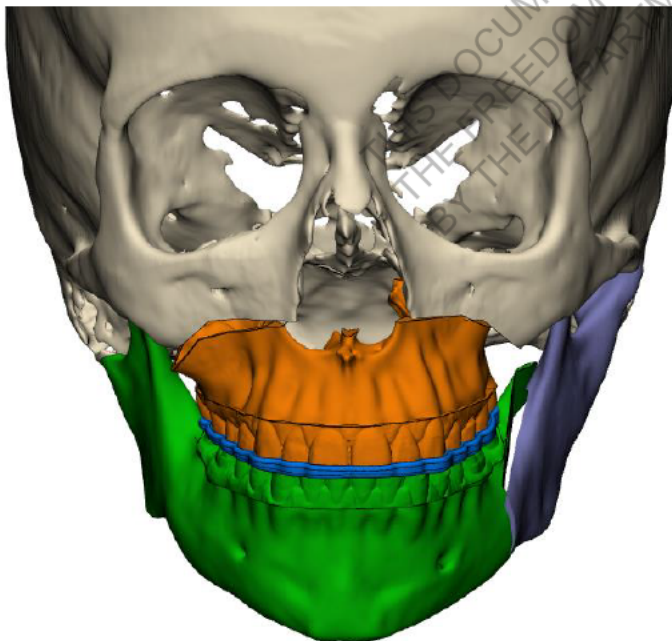
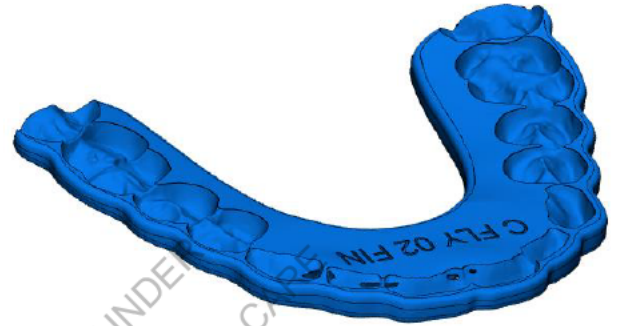
Intermediate Splint Design

Identifier s 47F



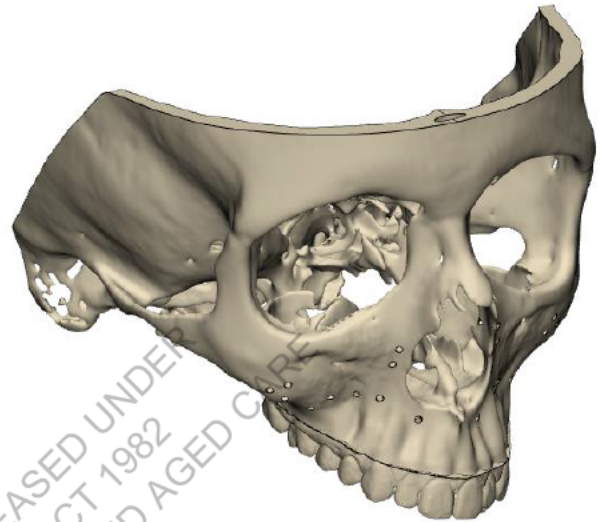
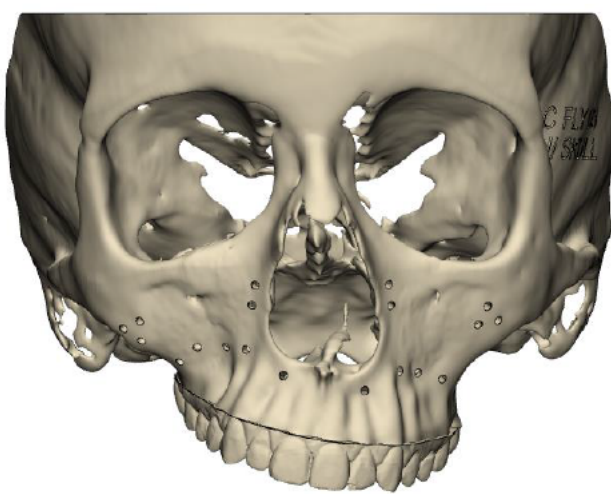
Final Splint Design

Identifier s 47F

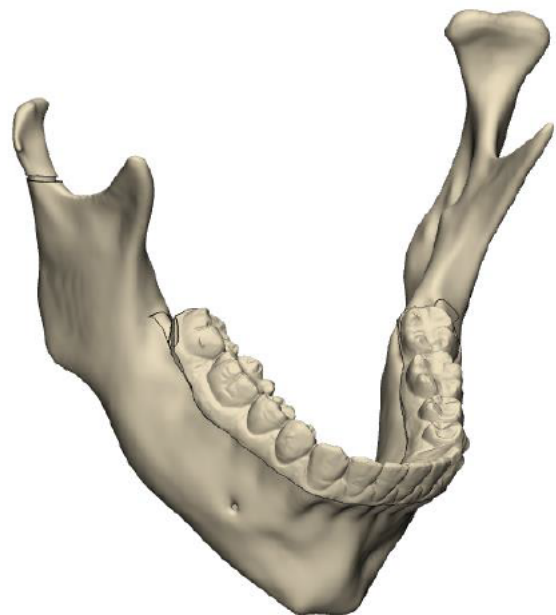
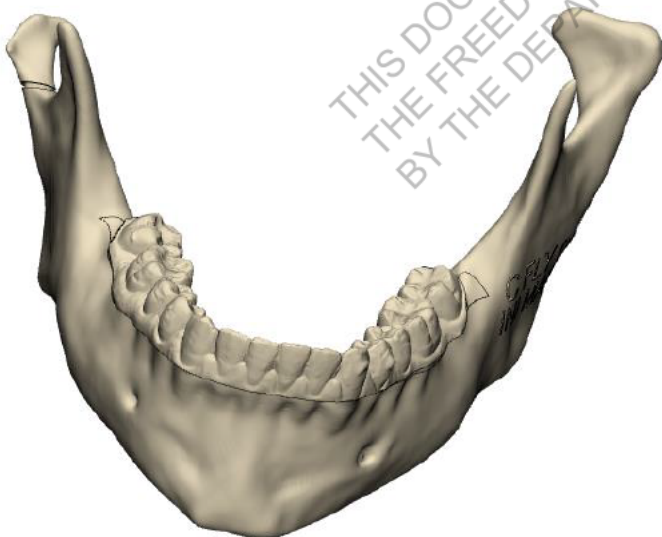


Patient Specific Anatomical Biomodels

Initial Skull
Identifier s 47F

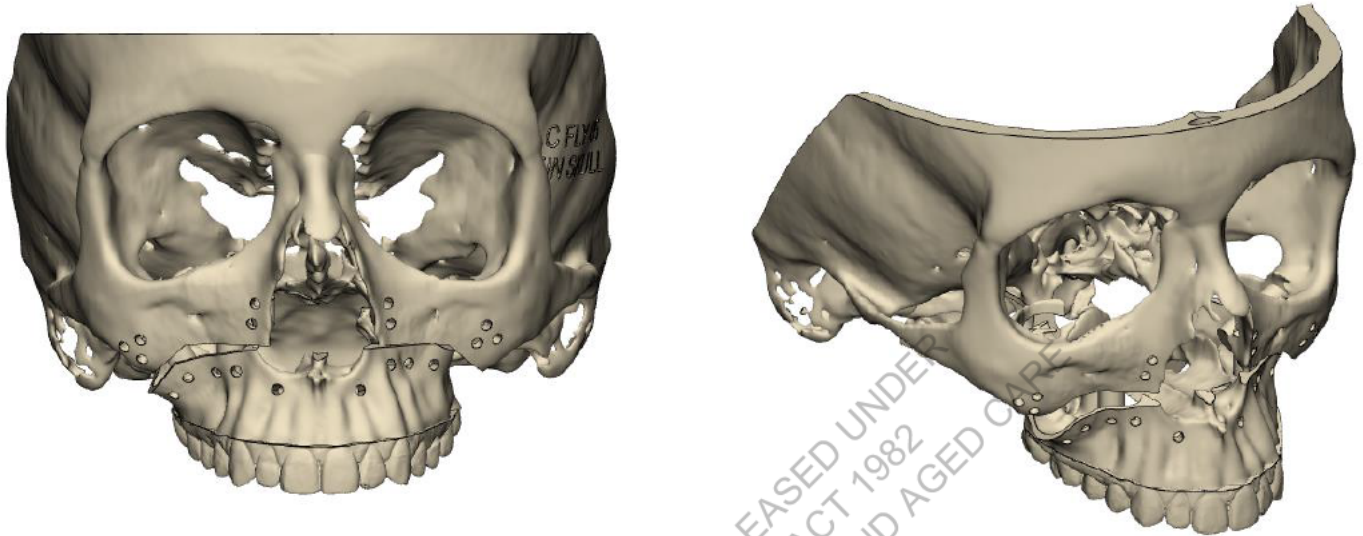


Initial Mandible
Identifier s 47F

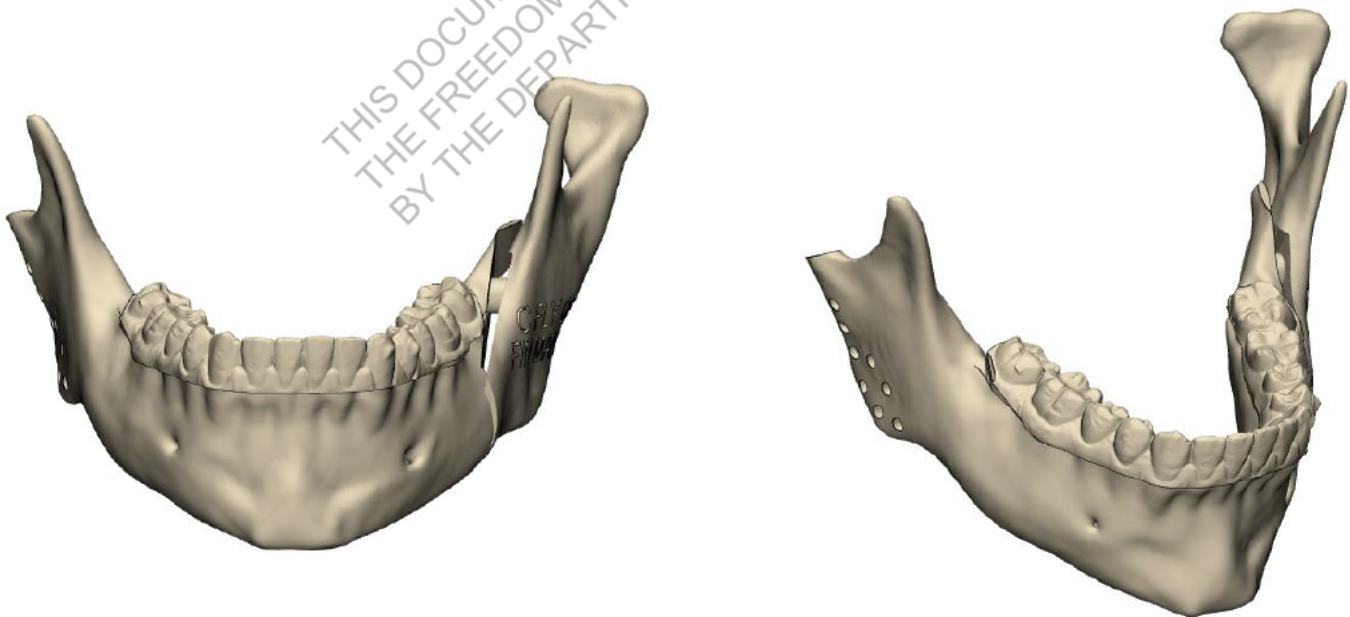


Patient Specific Anatomical Biomodels

Final Skull
Identifier s 47F



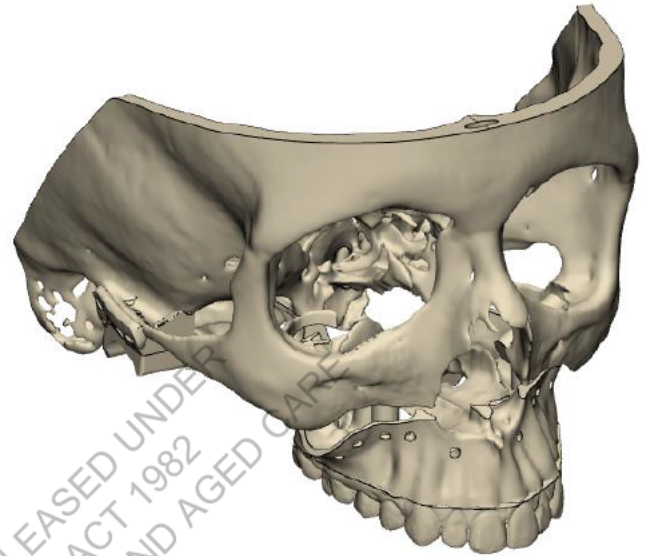
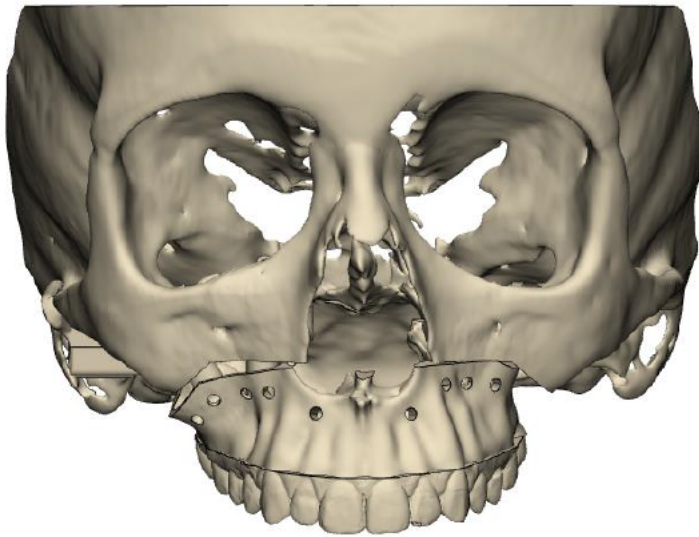
Final Mandible
Identifier s 47F



Patient Specific Anatomical Biomodels

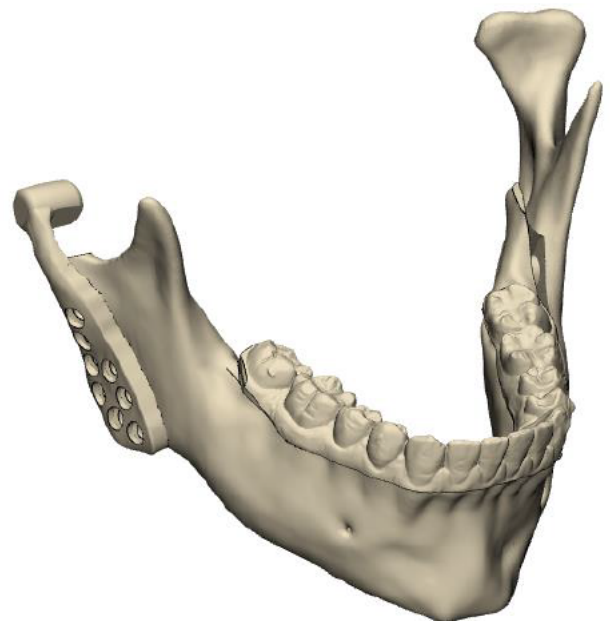
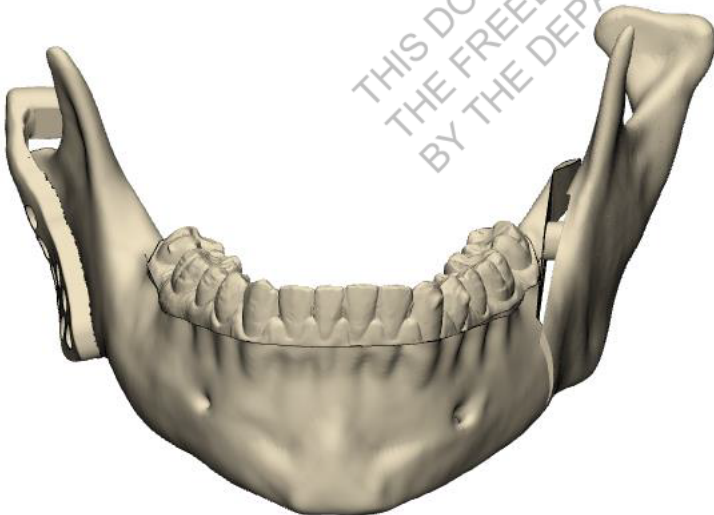
Fossa Skull

Identifier s 47F



Ramus Mandible

Identifier s 47F



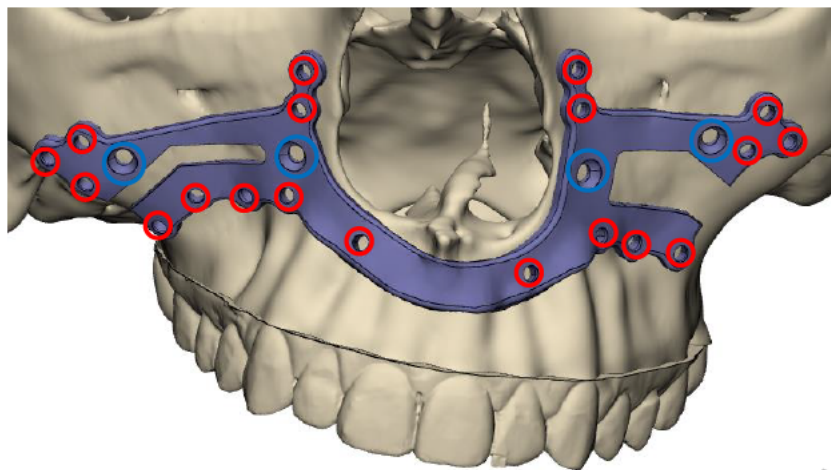
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Custom Plating System

Custom Maxilla Guide

Identifier

s 47F



Guide Fixation holes

- 4 x $\varnothing 2.0\text{mm}$ Screws

Pilot Hole Drilling Guides

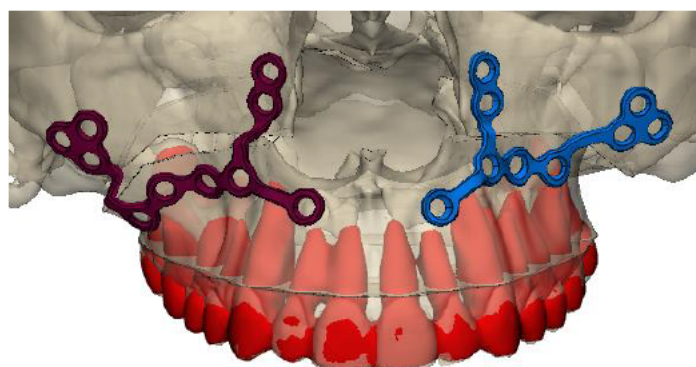
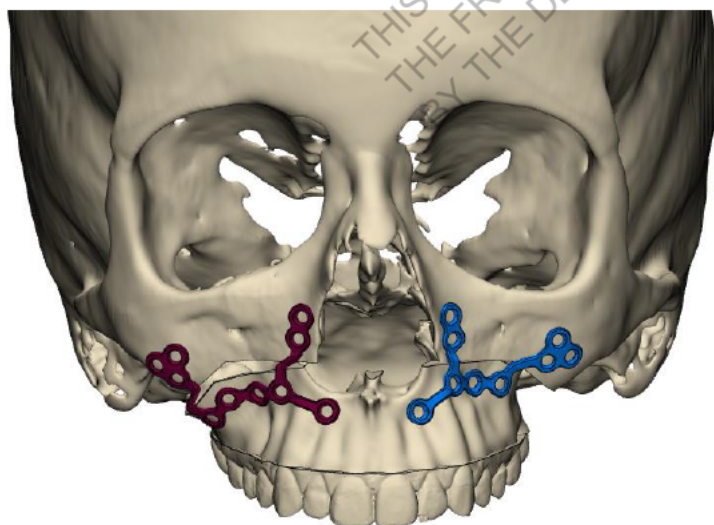
- 19 x $\varnothing 1.6\text{mm}$ Twist Drills

Custom Maxilla Plates

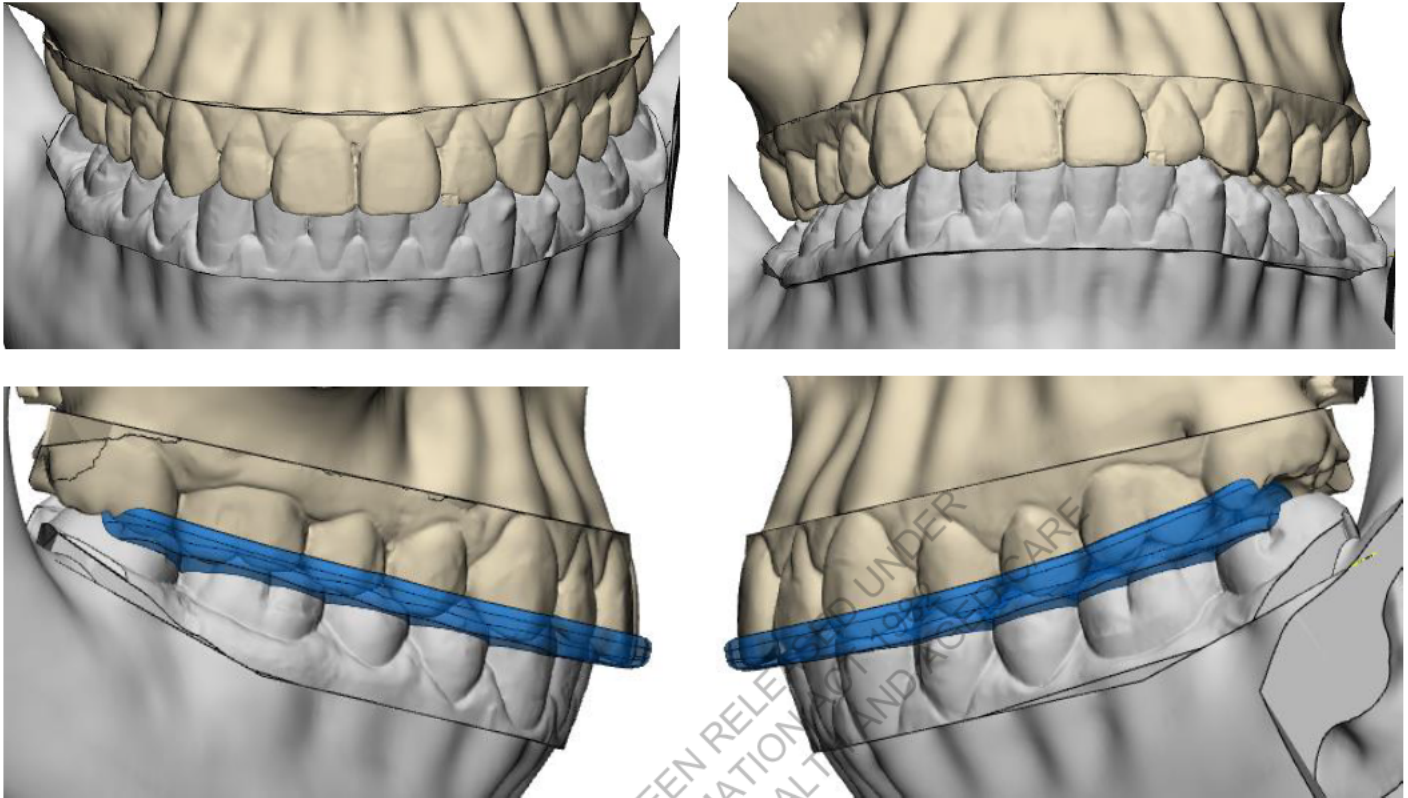
Identifier

s 47F

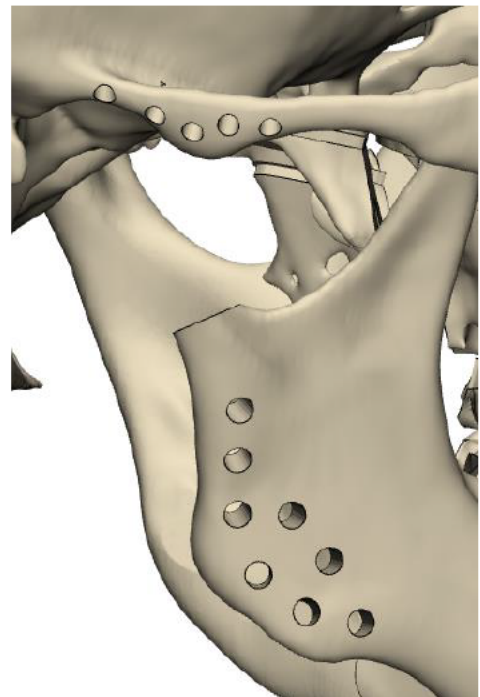
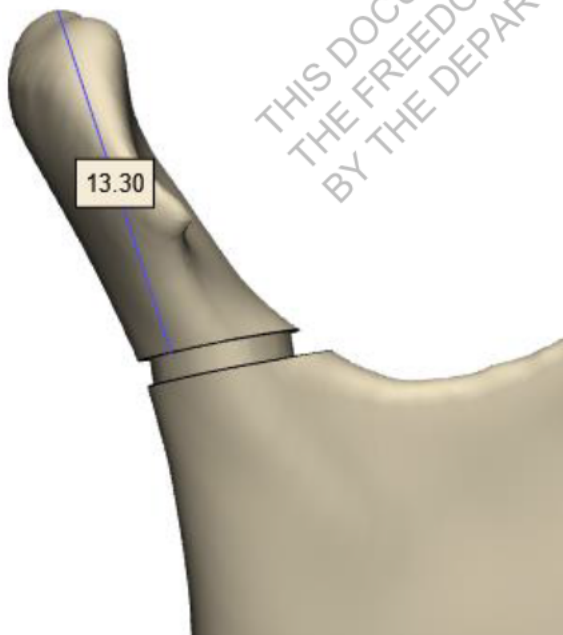
Plate Fixation: 19 x $\varnothing 2.0\text{mm}$ Screws



Planned Occlusal Position



Planned Condylectomy/ Screw Locations

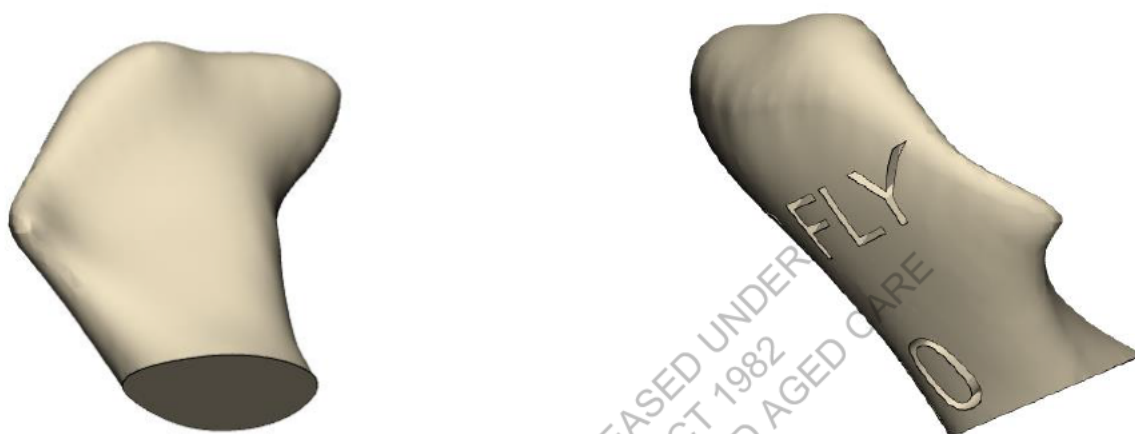


Custom Surgical Guides

1 x Osteotomised Condyle

Identifier: s 47F

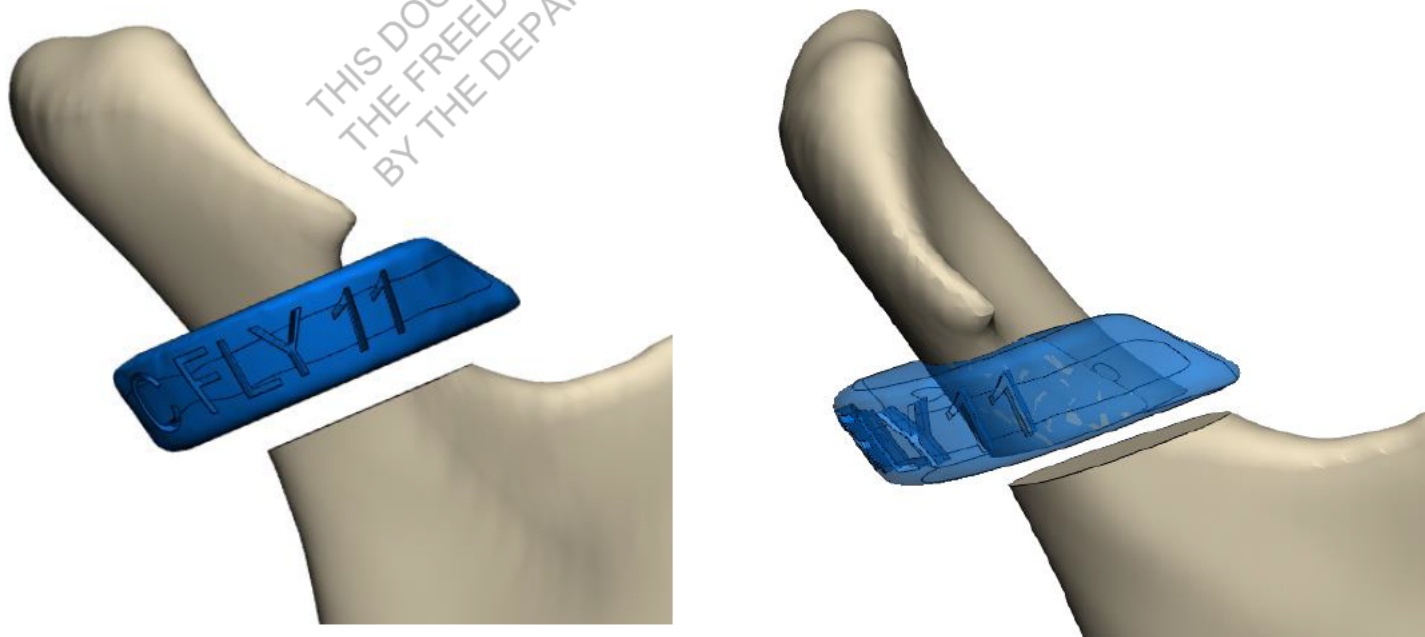
Intended Use: Used as a guide to ensure the right amount of the condyle head is resected to prevent interference when placing the prosthesis



1 x Condylectomy Checker

Identifier: s 47F

Intended Use: To ensure enough condyle has been removed from the mandible to safely clear the replacement fossa/bearing.

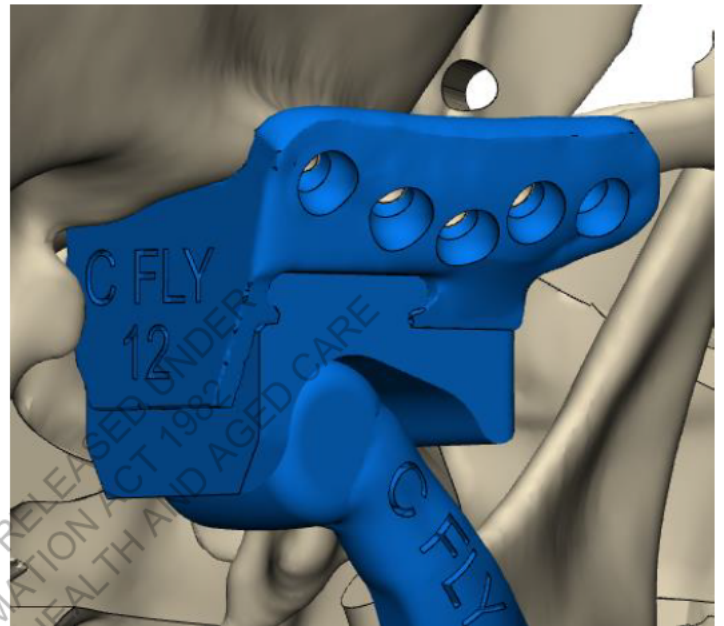
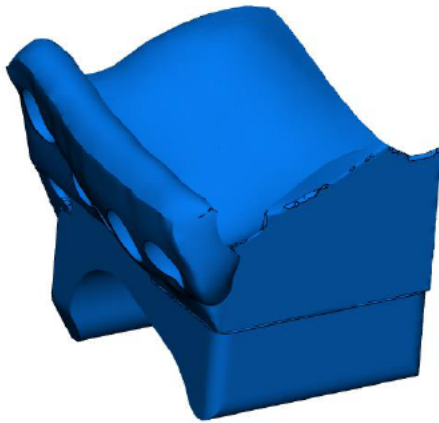


Custom Surgical Guides

1 X Trial Fossa

Identifier s 47F

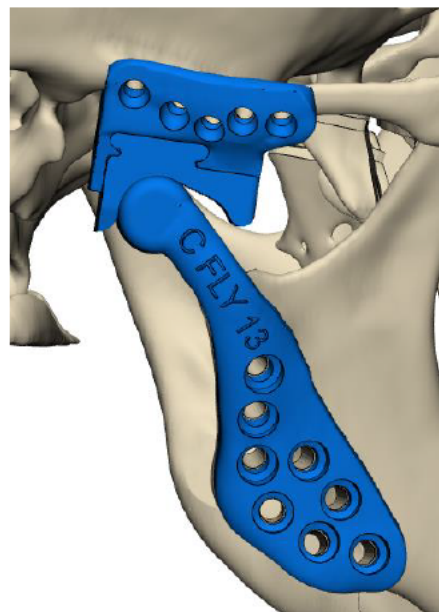
Intended Use: Guides to check that the fossa prosthesis will fit correctly over the zygomatic and temporal bone. These reduce the need to repeatedly handle the prosthesis – reducing risk of infection/mishandling of the joint.



1 x Trial Ramus

Identifier s 47F

Intended Use: Guides to check that the ramus prosthesis will fit correctly over the mandible and line up with the posterior border. These reduce the need to repeatedly handle the prosthesis – reducing the risk of infection/mishandling of the joint.

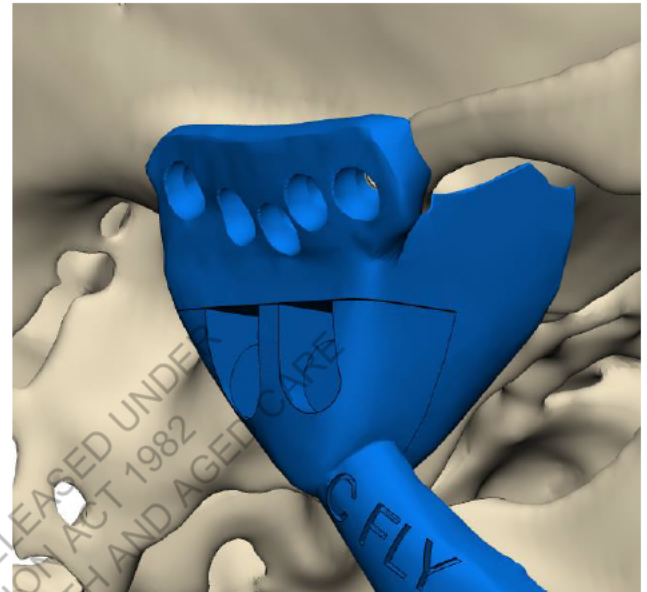
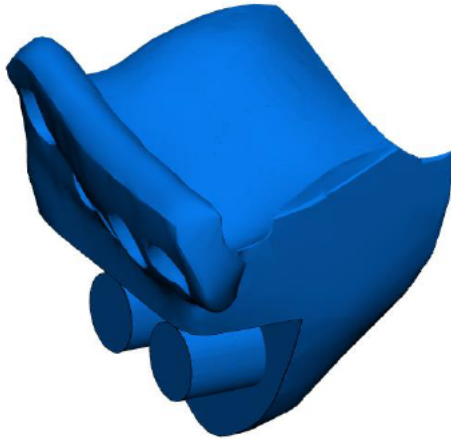


Custom Surgical Guides

1 x Fossa Drilling Guide

Identifier: s 47F

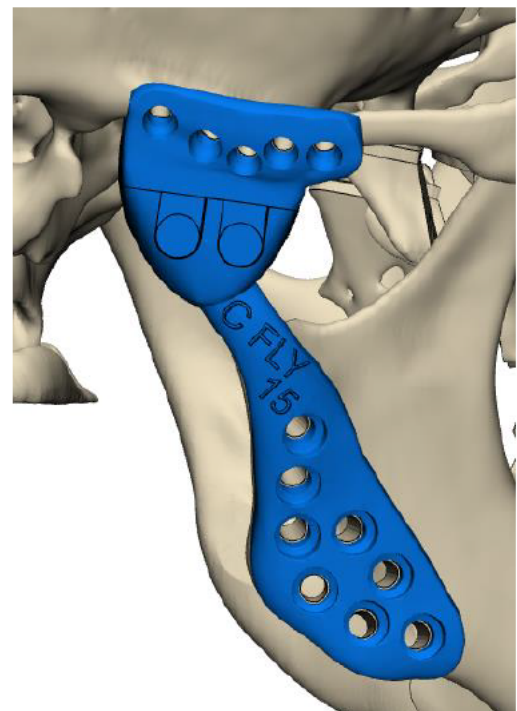
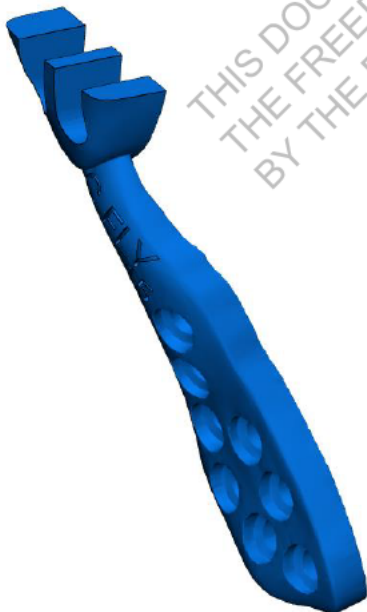
Intended Use: Interlocking guides to help positioning of drill locations with both the custom fossa and ramus component interlocked into final correct position.



1 x Ramus Drilling Guide

Identifier: s 47F

Intended Use: Interlocking guides to help positioning of drill locations with both the custom fossa and ramus component interlocked into final correct position.

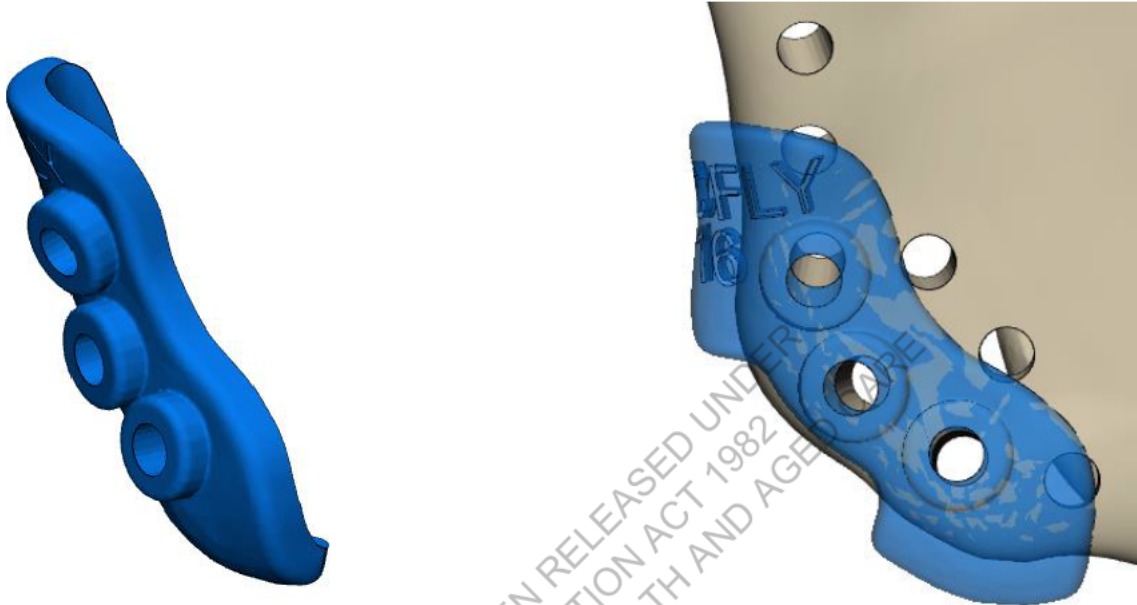


Custom Surgical Guides

1 x Ramus Screw Guide

Identifier s 47F

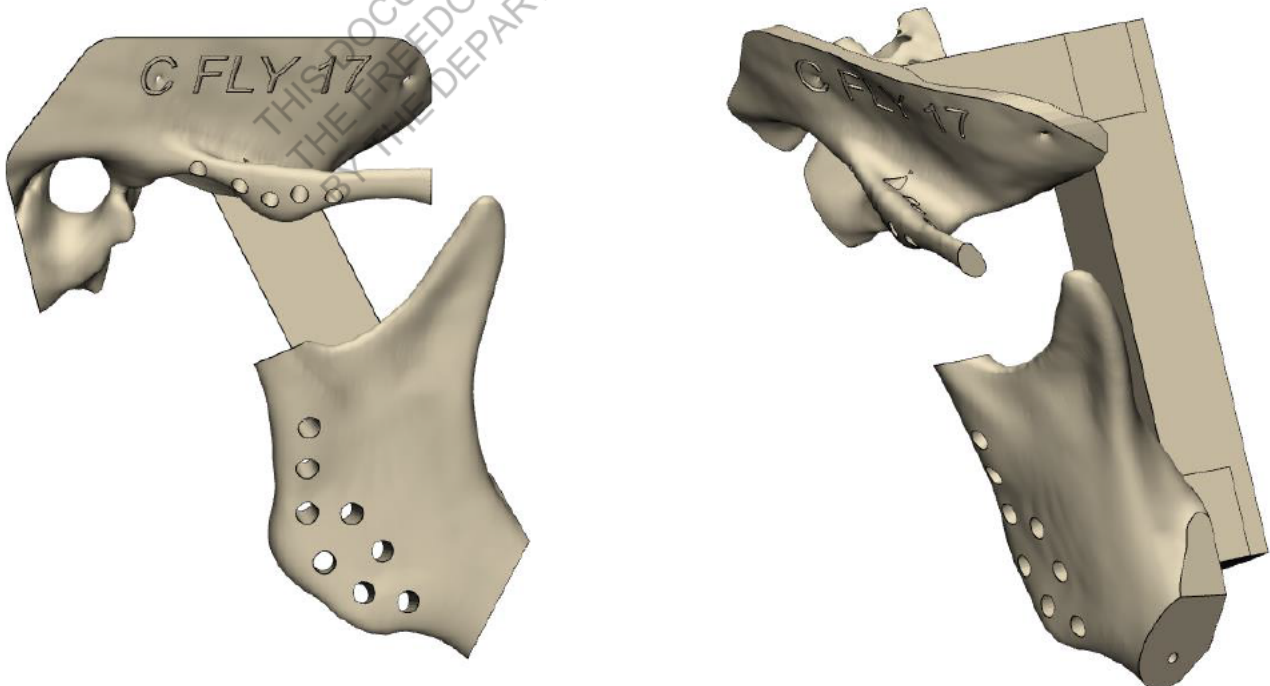
Intended Use: Guides the correct angulation of the lower screw holes of the ramus component to assist with accurate positioning of the prosthesis.



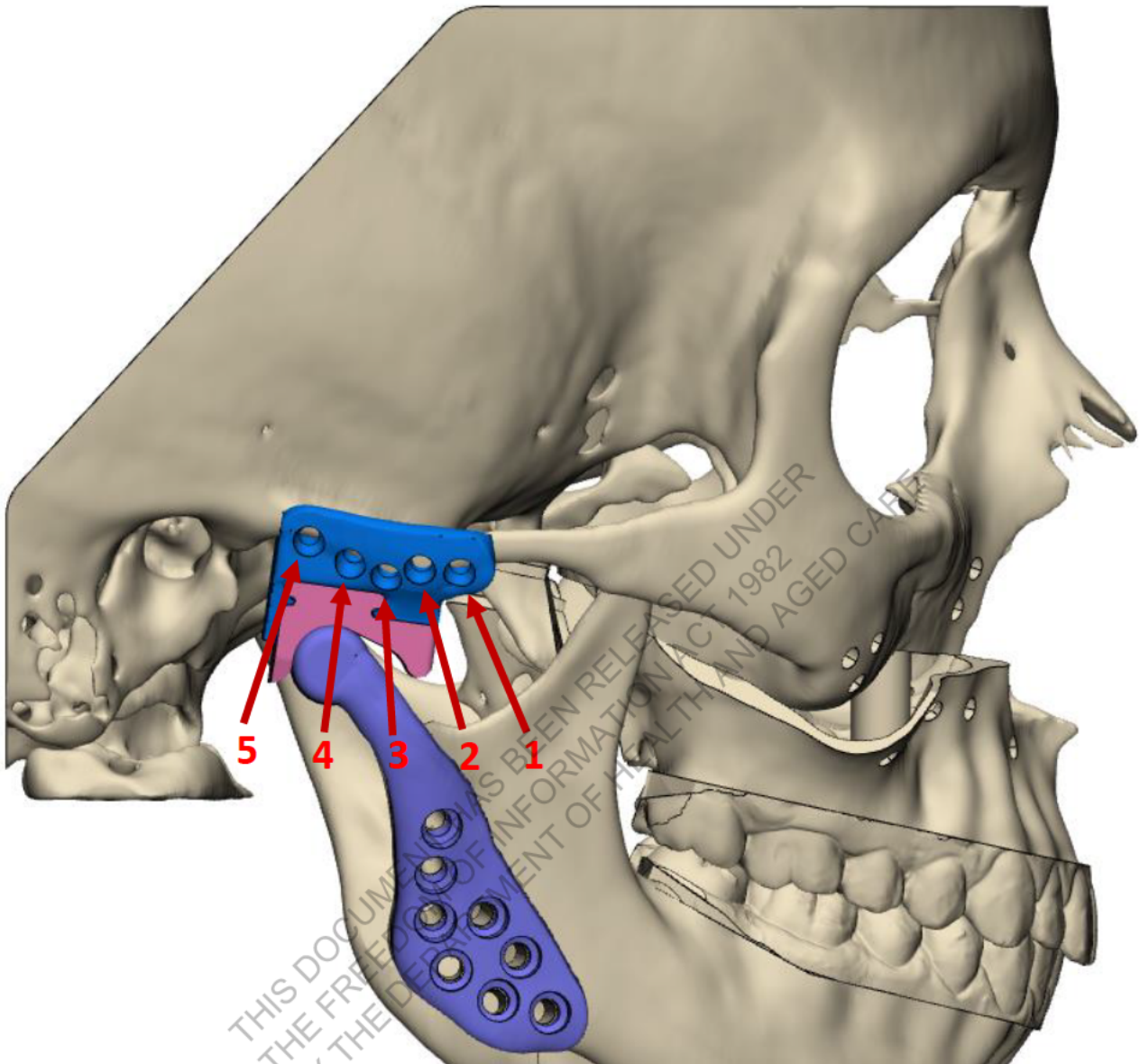
1 x Test S

Identifier s 47F

Intended Use: Model which shows the correct orientation between the glenoid fossa and the ramus in its final habitual position, can be used to test fit the prostheses to examine the fossa/ramus relationship



Right Fossa Placement/Screw Length Plan



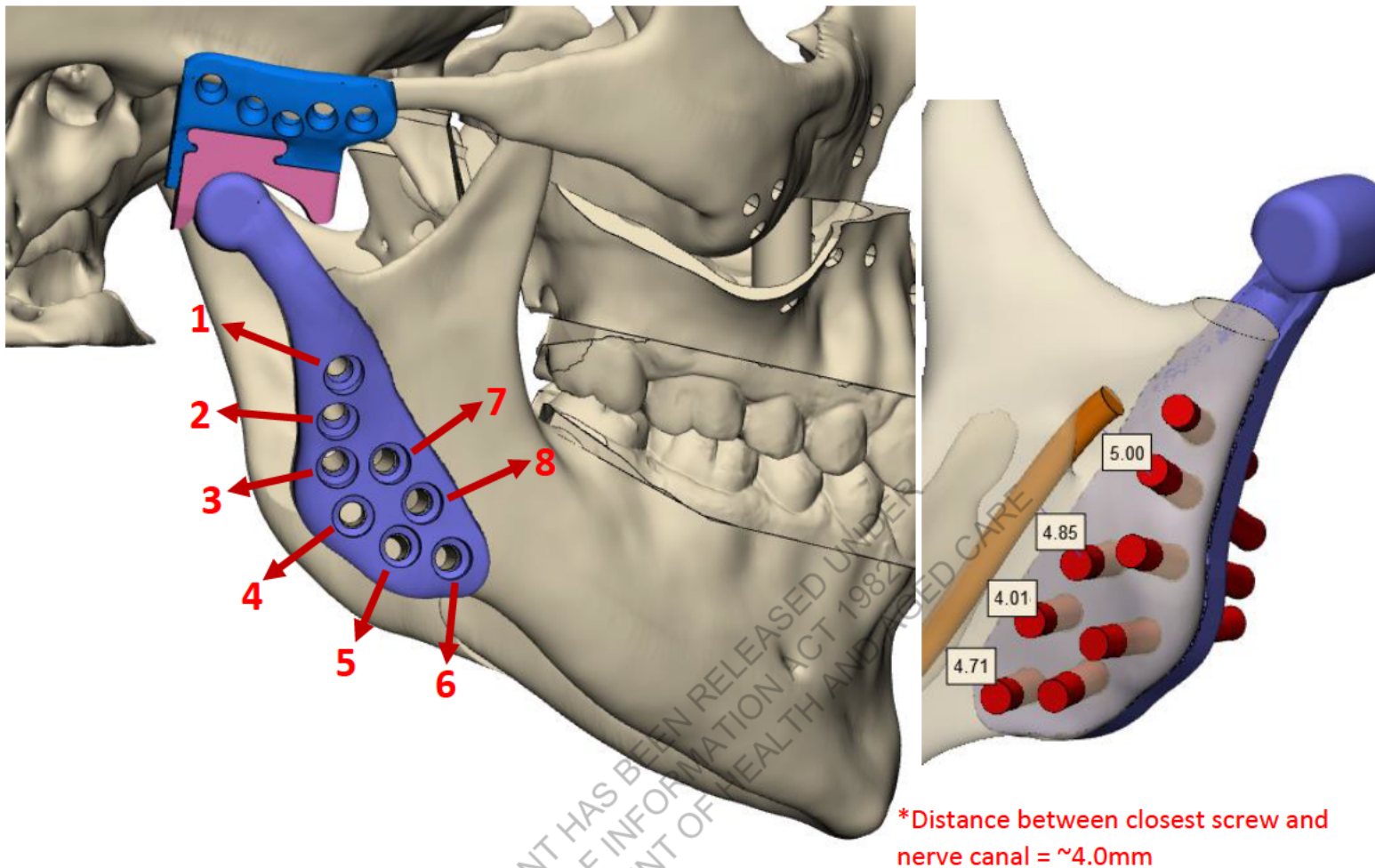
Fossa Ø2.0mm Screw Length Plan:

1	6mm	2	7mm	3	7mm
4	6mm	5	8mm		

Drilling Guide

- All holes concentric. Use Ø1.50mm (blue banded) drill bit for drilling pilot holes
- Use Ø2.0mm Cortical Screws

Right Ramus Placement/Screw Length Plan



Ramus Ø2.50mm Screw Length Plan:

1	9mm	2	9mm	3	9mm	4	9mm
5	8mm	6	9mm	7	9mm	8	9mm

Drilling Guide:

- All holes concentric. Use **Ø2.0mm** (purple banded) drill bit for drilling pilot holes
- Use **Ø2.50mm** Cortical Screws

END REPORT

Statement of Residual Risks

As the manufacturer of the custom-made devices and with consideration to its specific requirements, we have evaluated the risks associated with the use of this product and have reduced those risks as far as possible. We would however like to draw your attention on the following residual risks and points which should be taken in consideration prior to proceeding with the use of this product:

- Lyka Smith cannot control the mechanical forces experienced during installation/use of the custom devices. It is the responsibility of the healthcare practitioner not to damage the device or injure the patient during use.
- The custom medical devices to be provided are manufactured from biocompatible materials: MED610, PA2200, Ti64. We cannot guarantee patient biological response to a foreign body or allergic reaction.
- Custom implants are intended to be used to bridge osteotomy gaps/ fractures and facilitate functional forces during bone healing. Implants are subject to fatigue under excessive forces & cyclic loading. Lyka Smith cannot control improper or excessive activities by the patient.
- There are inherent dimensional variations that may be present when converting patient data into CAD software and manufacturing of the devices.
- Custom devices are provided non-sterile. We cannot guarantee the sterility of the device at time of use, this responsibility falls on the hospital. Instructions for use and material safety data sheet are sent with each device to assist proper handling & cleaning/sterilisation.
- Lyka Smith attempts to control the device shipments as far as possible but cannot guarantee the state of the products in transport and storage.
- We do not supply an operative technique for using these custom devices: it is understood that due to your experience with this type of surgery no further information is required for the safe use of these devices.
- Because of the individuality of each custom device, no clinical evaluation has been performed.

Please note this is not a definitive list of all possible risks associated with the use of this device; further risks may exist which have not been identified as part of design and development. If, upon reflection, you believe that the attached surgical plans offer the best method of treatment, please sign the accompanying prescription.

Authorisation for Production and Release

By signing below, you confirm that:

By signing off on the above details, you are agreeing that the information supplied is correct and accurate. You have determined that Custom-Made Medical Devices will be necessary to provide the most effective treatment of this patient's condition.

I declare that I have the qualifications required by law to perform the planned intervention.

I acknowledge that this design will be specifically manufactured to the specifications provided by myself to meet specific surgical intended use and therefore understand that such device will not be subject to Regulatory approvals.

I have read and understood the risks of using this device as specified in the accompanying "statement of residual risks" and acknowledge the risk/benefit ratio associated with use of the device by end-user and/or patient.

I also acknowledge that the use of the above listed devices is only allowed to be used by and for the patient/physician stated in this document. Without written permission, the device(s) is/are not allowed to be supplied.

I approve herewith the custom-made device(s) as per the list above for the mentioned patient and authorise Lyka Smith to manufacture and supply the device.

Name:

Signed:

Date:

If digital authorisation supplied via email/test; insert time/date here and attach any written evidence.

s22

From: s47F @bupa.com.au>
Sent: Monday, 28 November 2022 9:55 AM
To: s47E(d)
Subject: Anomalous billing of Lyka-Smith biomodels and guides

Categories: Added to tracker, 3 INVESTIGATION

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good Morning s22

I wanted to share with you the anomalous billing of Lyka-Smith biomodels and guides paid by Bupa for three separate claims on the same day from various private hospitals in different states, perhaps something we could discuss at the meeting today an example of something that a condition could possibly be added to the PL to discourage this or perhaps another solution. Is there any chance the CAG from this group could have this shared with them please.

On the first claim

9 surgical guides were billed and **6 biomodels totalling \$29,073.00**

On the second claim

7 surgical guides were used and **2 biomodels total of \$17,735.00**

On the third claim

9 surgical guides were billed and **6 biomodels total of \$29,073.00**

Use of guides and biomodels Lyka-Smith- 3 separate claims billed on the same day

Claim DRG	Item Number	Item Desc	Services	Cat	Sub	Fee Charged
D04A	EO091	Aptus Speedtip C System Aptus Speedtip C Screws 2.0mm Diameter	6 06.03 - Skeletal Reconstruction	06.03.04 - Screws		\$1,254.00
D04A	ZZ044	Orthotin Tmj Fossa Component Titanium Fossa Component With U	1 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$4,891.00
D04A	ZZ045	Orthotin Tmj Ramus Component Tin Coated Titanium Mandibular	1 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$5,700.00
D04A	ZZ049	Lyka Smith Patient Specific Guides Patient Specific Surgical	9 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$18,099.00
D04A	ZZ050	Lyka-Smith Anatomical Biomodel Three-Dimensional Anatomical	6 07.02 - Craniomaxillofacial	07.02.09 - Anatomical Biomodel		\$10,974.00
D04A	ZZ058	Lyka Smith Jell Leforte System Screws Self Tapping And Self	5 07.01 - Craniomaxillofacial	07.01.06 - Screws		\$210.00
D04A	ZZ059	Lyka Smith Jell Le Fort Locking Screws Titanium Locking Scre	5 07.01 - Craniomaxillofacial	07.01.06 - Screws		\$440.00
D04A	ZZ059	Lyka Smith Jell Le Fort Locking Screws Titanium Locking Scre	2 07.01 - Craniomaxillofacial	07.01.06 - Screws		\$176.00

Claim DRG	Item Number	Item Desc	Services	Cat	Sub	Fee Charged
D12B	EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	14 06.03 - Skeletal Reconstruction	06.03.04 - Screws		\$966.00
D12B	EO091	Aptus Speedtip C System Aptus Speedtip C Screws 2.0mm Diameter	4 06.03 - Skeletal Reconstruction	06.03.04 - Screws		\$836.00
D12B	MN234	Surgical Powder Absorbable Haemostatic Powder 3.0grams	1 03.05 - Haemostatic Devices	03.05.02 - Powder		\$134.00
D12B	ZZ044	Orthotin Tmj Fossa Component Titanium Fossa Component With U	2 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$9,782.00
D12B	ZZ045	Orthotin Tmj Ramus Component Tin Coated Titanium Mandibular	2 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$11,400.00
D12B	ZZ049	Lyka Smith Patient Specific Guides Patient Specific Surgical	7 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$14,077.00
D12B	ZZ050	Lyka-Smith Anatomical Biomodel Three-Dimensional Anatomical	2 07.02 - Craniomaxillofacial	07.02.09 - Anatomical Biomodel		\$3,058.00

Item Number	Item Desc	Services	Cat	Sub	Fee Charged
EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	5 06.03 - Skeletal Reconstruction	06.03.04 - Screws		\$345.00
EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	3 06.03 - Skeletal Reconstruction	06.03.04 - Screws		\$207.00
EO076	Aptus Screws Cortical Screws 2.3mm - 2.5mm Diameter	1 06.03 - Skeletal Reconstruction	06.03.04 - Screws		\$69.00
EO091	Aptus Speedtip C System Aptus Speedtip C Screws 2.0mm Diameter	1 06.03 - Skeletal Reconstruction	06.03.04 - Screws		\$209.00
MN234	Surgical Powder Absorbable Haemostatic Powder 3.0grams	1 03.05 - Haemostatic Devices	03.05.02 - Powder		\$134.00
ZZ044	Orthotin Tmj Fossa Component Titanium Fossa Component With U	1 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$4,891.00
ZZ045	Orthotin Tmj Ramus Component Tin Coated Titanium Mandibular	1 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$5,700.00
ZZ049	Lyka Smith Patient Specific Guides Patient Specific Surgical	9 07.02 - Craniomaxillofacial	07.02.05 - Mandible, Maxilla And		\$18,099.00
ZZ050	Lyka-Smith Anatomical Biomodel Three-Dimensional Anatomical	6 07.02 - Craniomaxillofacial	07.02.09 - Anatomical Biomodel		\$10,974.00

Kind Regards

s47F

s47F

Claims Integrity, HealthCare Management
Bupa, Level 16, 179 Turbot Street, Brisbane
QLD, 4000.

P s47F

M s47F

E s47F

[@bupa.com.au](mailto:s47F@bupa.com.au)

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s22

From: s22
Sent: Friday, 30 September 2022 11:35 AM
To: Prostheses/Health
Cc: s22, s47E(d)
Subject: RE: Clarification_ZZ049 [SEC=OFFICIAL]

Thank you for forwarding on, s22 – yes, I'll take care of queries.
 FYI: I've set up a PL Compliance inbox s47E(d) @health.gov.au
 So feel free to use and share details with similar enquiries.

...and I hope you're enjoying the a/g Director duties.

All the best

s22

s22

Director, Prostheses Compliance and Assurance

T: s22

Prostheses List Reform Taskforce

From: s22 @health.gov.au> **On Behalf Of** Prostheses/Health
Sent: Friday, 30 September 2022 11:31 AM
To: s22 @health.gov.au>
Subject: FW: Clarification_ZZ049 [SEC=OFFICIAL]

Hi s22

Are you taking care of these queries?

Regards

s22

s22

Assistant Director – Prostheses Application Administration Section
Prostheses List Task Force

Technology Assessment and Access Division | Health Resourcing Group

Australian Government Department of Health and Aged Care

T: s22 | E: s22 @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: s 47F
Sent: Friday, 30 September 2022 9:16 AM

To: Prostheses/Health s47E(d) [@health.gov.au](mailto:s47E(d)@health.gov.au)>
Subject: Clarification_ZZ049

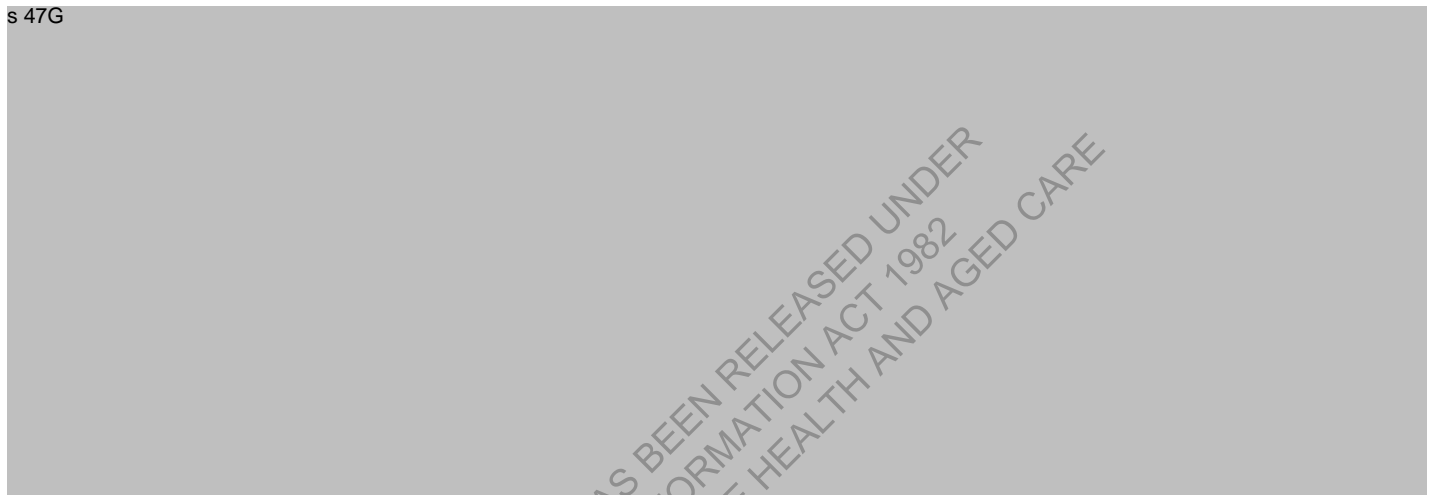
REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi,

We are increasingly faced with Health Funds denying custom made prostheses claims based on either the category of PL they are listed in, or "Intended Purpose" listed in ARTG. Despite repeated reminders that unless there is a conditional listing for the Prostheses, these should be paid if deemed appropriate to use by the specialist performing the surgery and if billed as per the Prostheses List.

We have recently received the following rejection/recovery note from one of the smaller health funds,

s 47G



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Cabrini and the specialist have followed the manufacturer's advice. These have been made, used and billed with the manufacturer's instructions. I have attached the prostheses used in this episode of patient care for your consideration.

We believe that the prostheses have been used as per the ARTG approval for these custom-made devices as there is no restriction placed on their use. It is not limited to the highlighted comment above. As per the ARTG Public Summary there are no "Specific Conditions" listed. The Prostheses List doesn't have any conditions listed and the description "Patient specific surgical guide" under the category, "Plastic & Reconstructive".

We will appreciate your advice and clarification on the matter.

Kind Regards

s 47F



Cabrini Health

Level 2, 141 Camberwell Road

T: s47F | M: s47F

Hawthorn East VIC 3123

Email: s 47F



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s22

From: s22
Sent: Thursday, 8 September 2022 10:44 AM
To: s47E(d)
Subject: FW: PHA supplementary PHI Prostheses charts and tables - (APRA June 2022 update)
Attachments: PHI Chart - Growth in Hospital Admissions versus Medical Devices Utilisation by Category - YE June 2017 to YE June 2022.pdf; PHI Chart - Prostheses benefits as a share of total hospital benefits paid - YE Jun 2019 to YE Jun 2022.pdf; PHI Chart - Prostheses benefits growth versus other PHI component benefits growth over 3 years to June 2022.pdf; PHI Chart - Prostheses benefits growth versus other PHI hospital component benefits growth - Jan2019 to June2022.pdf; PHI Table - Listed Prostheses benefits paid by Prostheses Categories in the Year to June 2022.pdf; PHI Table - Listed Prostheses Items utilisation by Prostheses Categories in the Year to June 2022.pdf

Categories: TO FILE

TO FILE

s22

Director, Prostheses Compliance and Assurance

T: s22

Prostheses List Reform Taskforce

From: s 47F
Sent: Tuesday, 30 August 2022 12:13 PM
To: FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Cc: PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22
 @health.gov.au>; s22 @health.gov.au>; s 47F
Subject: FW: PHA supplementary PHI Prostheses charts and tables - (APRA June 2022 update)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Elizabeth,

Please find attached the latest set of charts that s47F has done on Prostheses List movements to June 2022.

Over the last three years, with surgery rates flat or declined, the plastics category (surgical guides and biomodels) has seen increased expenditure of 66%. In contrast, rebates for cardiac, where there are a range of new products, only increased by 4.4% over the three years. (The overall average is 4.2% increase over the three years.)

The abuse of the surgical guides and biomodels is costing consumers dearly – a 13% increase in rebates in a year where surgery rates were lower. Again, I urge haste on your review. Every week of delay is costing consumers \$0.5 million.

We will do a bit more work to see what is contributing to the “other” category, which increased by 33% over the last three years.

Thanks

s47
F

s 47F



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Medical devices utilisation by Categories in the Year to June 2022

Prostheses Categories	Year Ending June 2022 Prostheses Items	Percentage Growth Rate over the last year	Percentage Growth Rate over the last 3 years	Utilisation increase over the last 3 years of:	Percentage Contribution to the increase in total prostheses utilisation over the last 3 years
Other	335,594	5.34%	21.4%	59,046	50.65%
Plastic and Reconstructive	113,557	5.78%	20.5%	19,326	16.58%
Ophthalmic	377,652	-0.81%	4.9%	17,676	15.16%
General Miscellaneous	1,065,767	-2.44%	1.6%	17,212	14.76%
Cardiac	96,614	-1.31%	14.8%	12,470	10.70%
Knee	140,692	-9.80%	2.9%	4,008	3.44%
Hip	123,663	-5.79%	2.1%	2,589	2.22%
Cardiothoracic	7,504	11.35%	15.7%	1,021	0.88%
Urogenital	39,214	-0.86%	-0.4%	-141	-0.12%
Vascular	84,229	-3.98%	-0.2%	-171	-0.15%
Specialist Orthopaedic	568,287	-7.23%	0.0%	-191	-0.16%
Spinal	210,420	-7.98%	-1.2%	-2,584	-2.22%
Neurosurgical	30,594	-13.69%	-11.8%	-4,081	-3.50%
Ear, Nose & Throat	27,048	18.35%	-26.2%	-9,600	-8.23%
TOTAL	3,220,835	-2.9%	3.8%	116,580	

Source: APRA

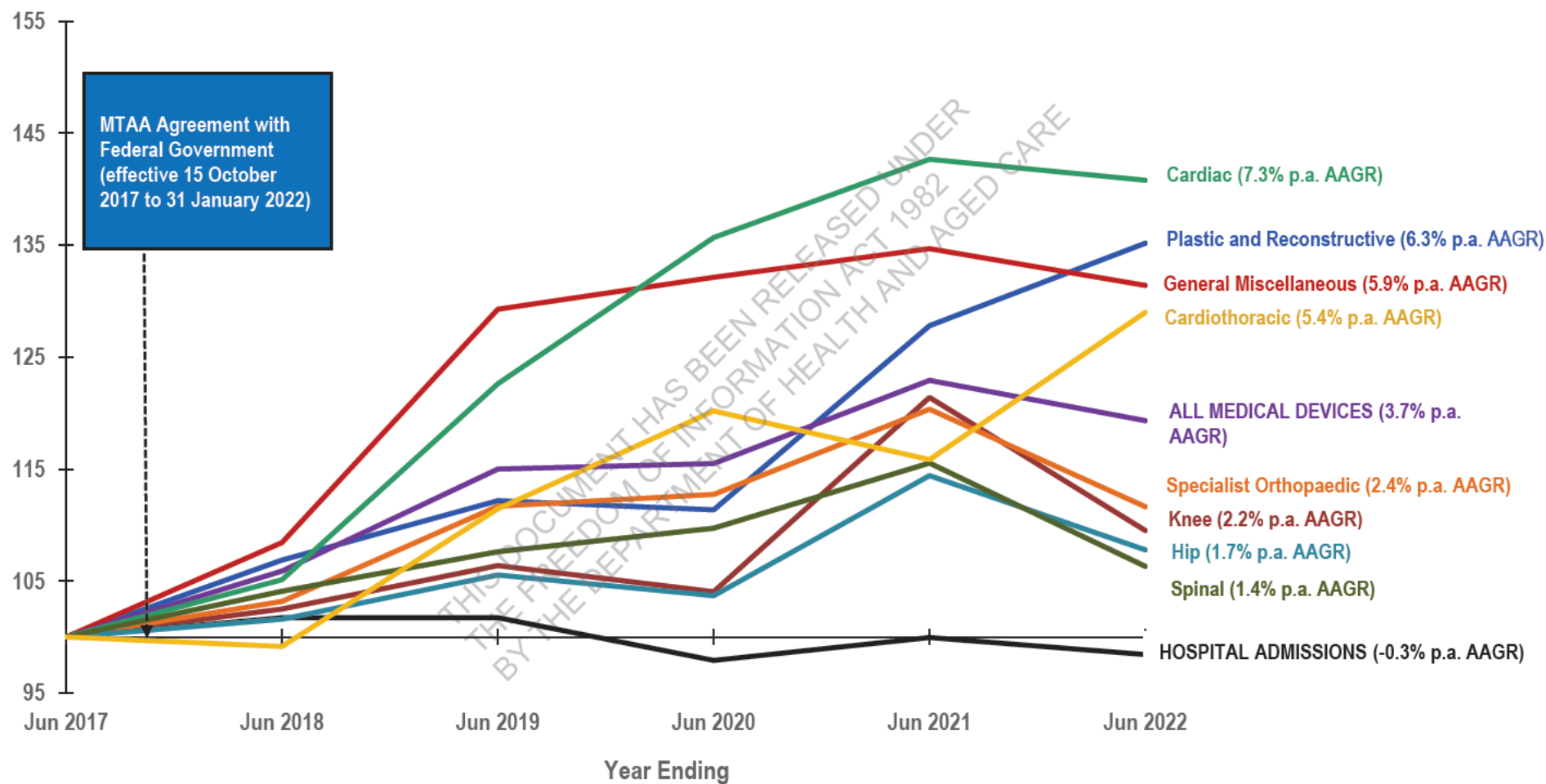
Medical devices benefits paid by Categories in the Year to June 2022

Prostheses Categories	Year Ending June 2022 Prostheses Benefits Paid (\$)	Percentage Growth Rate over the last year	Percentage Growth Rate over the last 3 years	Benefits increase over the last 3 years of:	Percentage Contribution to the increase in total prostheses benefits paid over the last 3 years
Other	\$324,693,717	5.99%	33.4%	\$81,250,477	91.9%
Plastic and Reconstructive	\$45,854,961	13.09%	66.2%	\$18,257,414	20.7%
Cardiac	\$362,100,646	-1.90%	4.4%	\$15,221,824	17.2%
General Miscellaneous	\$288,155,725	0.60%	3.2%	\$8,871,132	10.0%
Ophthalmic	\$108,065,869	2.38%	3.1%	\$3,270,065	3.7%
Specialist Orthopaedic	\$236,795,686	-7.22%	0.3%	\$672,947	0.8%
Hip	\$211,067,170	-4.32%	-0.1%	-\$149,681	-0.2%
Urogenital	\$30,513,224	1.14%	-0.9%	-\$287,614	-0.3%
Vascular	\$58,839,116	0.30%	-2.3%	-\$1,360,432	-1.5%
Cardiothoracic	\$19,267,813	-3.27%	-11.6%	-\$2,518,623	-2.8%
Knee	\$243,944,390	-10.05%	-2.3%	-\$5,740,134	-6.5%
Ear, Nose & Throat	\$26,244,148	-12.11%	-19.8%	-\$6,494,971	-7.3%
Spinal	\$146,991,800	-10.33%	-5.2%	-\$8,127,748	-9.2%
Neurosurgical	\$67,341,412	-12.22%	-17.7%	-\$14,474,109	-16.4%
TOTAL	\$2,169,875,677	-2.9%	4.2%	\$88,390,545	

Source: APRA

Growth in Hospital Admissions versus Medical Devices Utilisation by Category

Funded by Private Health Insurance



5 Year Movement: increase in percent, base year, Financial Year 2017 = 100

Source: APRA

s22

From: s 47F
Sent: Wednesday, 20 July 2022 12:37 PM
To: FLYNN, Elizabeth
Cc: s22; s22; s 47F
Subject: FW: UI001 and UI002 - possible false and misleading statement
Attachments: RE: 353528:Pre CASE:02061814

Follow Up Flag: Follow up
Flag Status: Flagged

Elizabeth,

Please find attached an email from Newclip, who claim to be the distributor of Specifica surgical guides.

In this email, they state, "I can confirm that the rebate codes UI001 and UI002 have been approved for use within Orthopaedic procedures"

This statement may breach the *Australian Competition Law*, as it may be deemed false and misleading.

Prior to considering a referral to the Australian Competition and Consumer Commission, I would welcome any advice from the department as to the accuracy of this statement, and any discussions with Specifica and Newclip as to how they are characterising decisions of the Prostheses List Advisory Committee.

Further, I would welcome advice on how Newclip, an orthopaedics company, can be the distributor of a device approved for TMJ procedures. PHA argues that a surgical guide or biomodel expressly manufactured for a different purpose is actually a different device, and I ask why Newclip should not be asked to apply for an orthopaedic surgical guide and biomodel rather than appropriate the listing of another company for a different device.

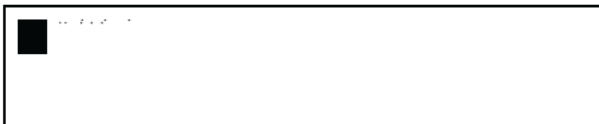
Thanks

s47
F

s47F

DIRECTOR OF POLICY AND RESEARCH

M: s47F | E: s 47F
www.privatehealthcareaustralia.org.au



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Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Specifica Pty Ltd

for approval to supply

Specifica Pty Ltd - Training model, anatomical, <specify>

ARTG Identifier 292561
ARTG Start Date 8/08/2017
Product Category Medical Device Included Class 1
GMDN 15811
GMDN Term Training model, anatomical, <specify>
Intended Purpose Improve and simplify the performance of surgical interventions by acting as an aid or reference to elaborate a pre-operative surgical plan, to transfer the plan to surgery and to determine the correct sizing of the fixture(s) eventually required as part of the surgical procedure.

Manufacturer Details	Address	Certificate number(s)
Specifica Pty Ltd	3/83 Connells Point Rd South Hurstville , NSW , 22 21 Australia	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Training model, anatomical, <specify>

Product Specific Conditions

- No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 292561
ARTG Start Date: 8/08/2017



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Specifica Pty Ltd

for approval to supply

Specifica Pty Ltd - Custom-made orthopaedic surgical guide, non-sterile

ARTG Identifier	292759
ARTG Start date	14/08/2017
Product Category	Medical Device Included Class 1
GMDN	60826
GMDN Term	Custom-made orthopaedic surgical guide, non-sterile
Intended Purpose	A non-sterile, custom-made surgical instrument intended to be used in an orthopaedic and/or craniomaxillofacial 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 3-D 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 sterilized prior to use.

Manufacturer Details	Address	Certificate number(s)
Specifica Pty Ltd	3/83 Connells Point Rd South Hurstville, NSW, 2221 Australia	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Custom-made orthopaedic surgical guide, non-sterile

Product Specific Conditions

No specific conditions have been recorded against this entry.