Australian Government

Department of Health

Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## Anatomics Pty Ltd

for approval to supply

## Anatomics Pty Ltd - Craniofacial fixation plate kit, non-biodegradable

| | |
|---|---|
| **ARTG Identifier** | 288564 |
| **ARTG Start date** | 4/05/2017 |
| **Product Category** | Medical Device Included Class IIb |
| **GMDN** | 46644 |
| **GMDN Term** | Craniofacial fixation plate kit, non-biodegradable |
| **Intended Purpose** | 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. |

| Manufacturer Details | Address | Certificate number(s) |
|---|---|---|
| Anatomics Pty Ltd | Suite 1/Ground Floor/23-27 Wellington Street<br>ST KILDA, VIC, 3182<br>Australia | DV-2017-MC-05953-1 |



### ARTG Standard Conditions

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

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.
- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.
- The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.
- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG.
- Where a medical device included in the Register contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the

medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

- A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

## Products Covered by This Entry

**1. Craniofacial fixation plate kit, non-biodegradable**

## Product Specific Conditions

No specific conditions have been recorded against this entry.

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

ARTG Identifier: 288564
ARTG Start Date: 4/05/2017

DePuy Synthes
CMF
COMPANIES OF Johnson & Johnson

# PATIENT SPECIFIC PLATE FOR MANDIBLE

Customized to fit the patient anatomy



## PRODUCT INFORMATION

TruMatch®
PERSONALIZED SOLUTIONS

# PATIENT SPECIFIC PLATE FOR MANDIBLE

## INTRODUCTION

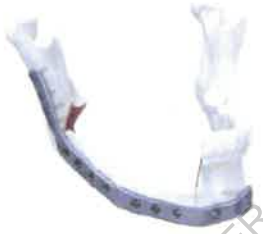
The design of the DePuy Synthes Patient Specific Plate for Mandible is customized to meet the individual needs of each patient and surgeon. By selecting plate design features, surgeons can customize the reconstruction plate to create a patient-specific solution. The Patient Specific Plate for Mandible is manufactured to the planned patient anatomy, eliminating the time needed for intraoperative adaption and eliminating induced mechanical stress from bending the plates in the OR.

## INDICATIONS

The DePuy Synthes Patient Specific Plate for Mandible is intended for use in oral and maxillofacial surgery, trauma, and reconstructive surgery.

**Specific Indications for Use:**

- Primary mandibular reconstruction with bone graft[1]
- Temporary bridging until delayed secondary reconstruction
- Secondary mandibular reconstruction
- Comminuted mandibular fractures
- Fractures of edentulous and/or atrophic mandibles
- Unstable mandibular fractures

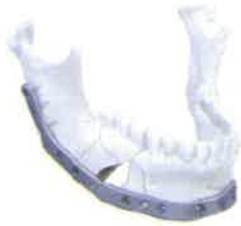


Primary mandibular reconstruction, used with vascularized or nonvascularized bone graft

Comminuted fractures

Temporary bridging until delayed secondary reconstruction*

Fractures of edentulous and/or atrophic mandibles



Unstable mandibular fractures

*Plate fracture is possible when any plate bears the entire functional load for extended periods. Therefore, the implantation of a bone graft immediately, or at a later date, is necessary to support the construct.

1. Prein J. Manual of Internal Fixation in the Cranio-Facial Skeleton. Berlin: Springer-Verlag 1998.

## TRUMATCH CMF SOLUTIONS

The Patient Specific Plate for Mandible, customized to meet the individual needs of each patient and surgeon, is part of a select group of products and services that comprise our Trumatch CMF Solutions portfolio. Trumatch CMF Solutions deliver advanced technology and procedural support for facial reconstruction, orthognathic surgery, distraction, and cranial reconstruction.

The customizable features of the Patient Specific Plate for Mandible and its compatibility with our surgical guides is an example of how our Trumatch personalized solutions seamlessly integrate virtual surgical planning, intraoperative tools, and patient specific devices to help you achieve goals of:

- **Accuracy** through visualization of anatomy and identification of surgical challenges within a 3D planning environment, intra-operative tools to accurately transfer the plan to the OR, and patient specific implants
- **Efficiency** through preoperative planning assisted by experienced clinical engineers to optimize preparation, surgical time, and the number of procedural steps
- **Patient Benefit** through seeking to achieve satisfying aesthetic results and minimize operative time



## FEATURES AND BENEFITS OF PATIENT SPECIFIC PLATE FOR MANDIBLE

| | |
|---|---|
| Customizable design features | • Screw hole positions and angulations can be defined individually to avoid screw interference with nerves, tooth roots, osteotomies, existing and future implants.<br>• Screw lengths can be predefined to ensure that screws do not interfere with one another. |
| Improved strength with lower profile* | • Both the 2.0 mm and 2.5 mm thick Patient Specific Platej for Mandible have improved fatigue life over the 2.5 mm MatrixMANDIBLE™ flat plates.<br>• 2.0 mm thick plates offer greater strength with lower profile as compared to 2.5 mm thick MatrixMANDIBLE flat plates.<br>• Patient Specific Plates for Mandible eliminate induced mechanical stress from bending plates in the OR. |
| Drill hole alignment optimized with PROPLAN CMF surgical guides** | When designed in conjunction with PROPLAN CMF planning services, the Patient Specific Plate for Mandible plate holes can be aligned to the drill holes in the surgical guides, for a seamless transfer of the plate to the reconstruction site. |

*Patient Specific Plate for Mandible fatigue testing data shows increased fatigue life of both 2.0 mm and 2.5 mm profiles in comparison with MatrixMANDIBLE 2.5 mm thick plates. Bench test result, may not necessarily be indicative of clinical performance. Test data on file at DePuy Synthes.

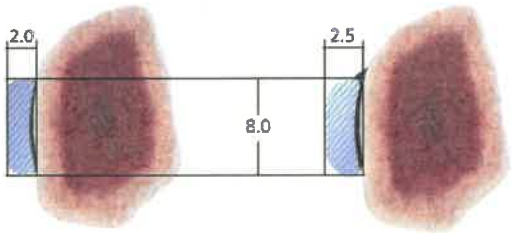
**Manufactured by Materialise and distributed by DePuy Synthes.

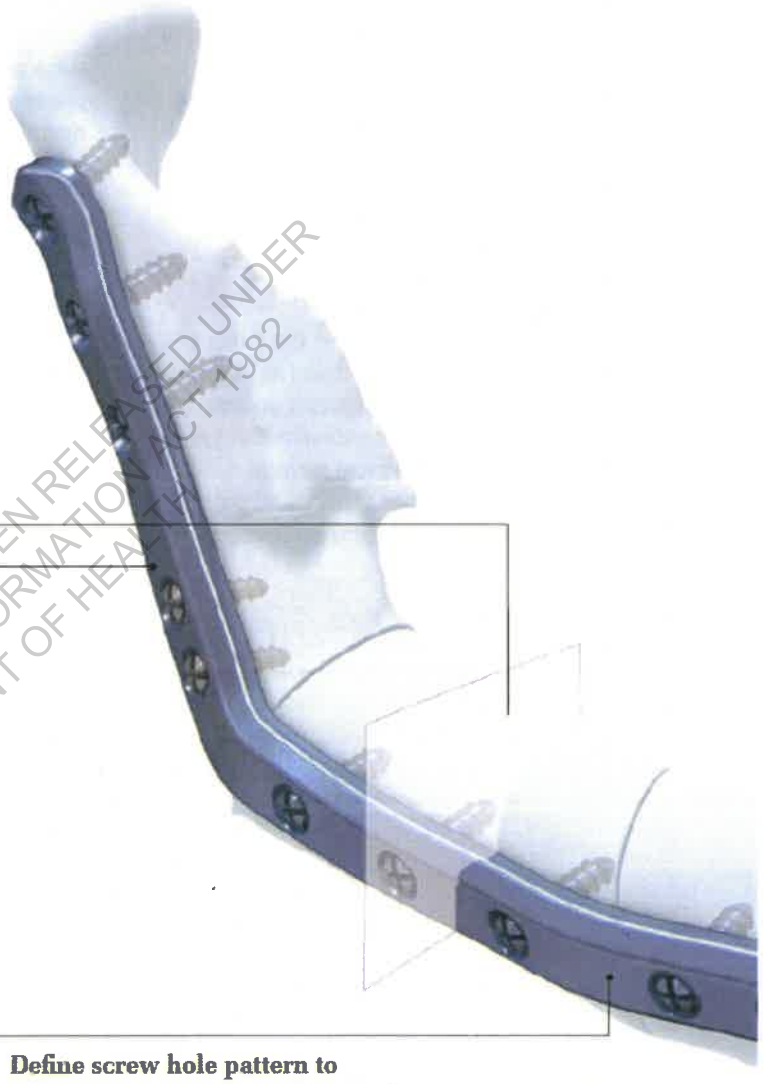
During the plate design process, surgeons will select the options for plate design, which may include the following:

### Choose plate profile

The Patient Specific Plate for Mandible is available in two plate profiles:

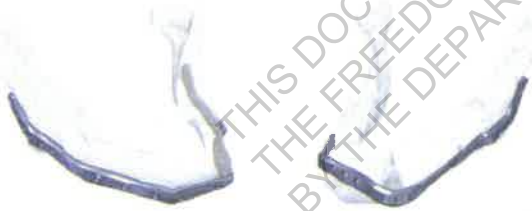
- 2.0 mm thick
- 2.5 mm thick



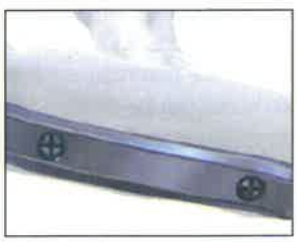
### Define plate trajectory

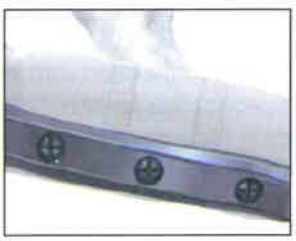
Plates are designed to meet the planned outcome anatomy, created in an online virtual surgical planning session. Plate design options may include—but are not limited to—the following:



Fibula reconstruction

Scapula reconstruction

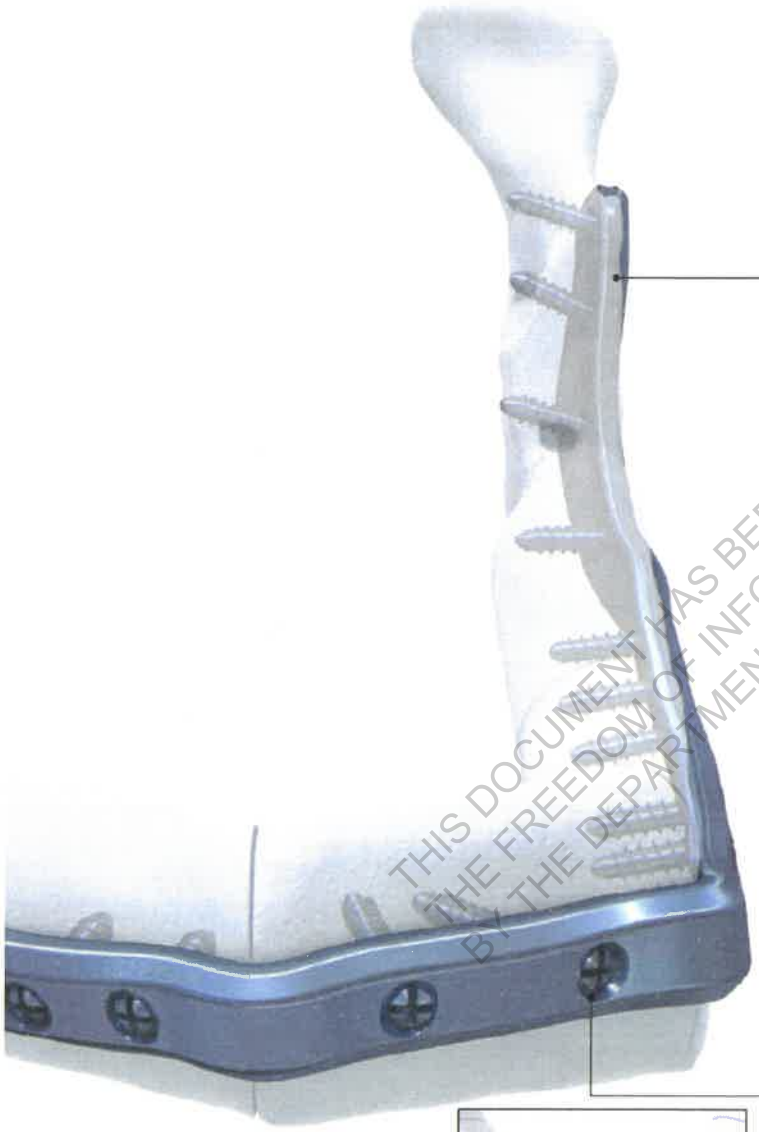




### Define screw hole pattern to

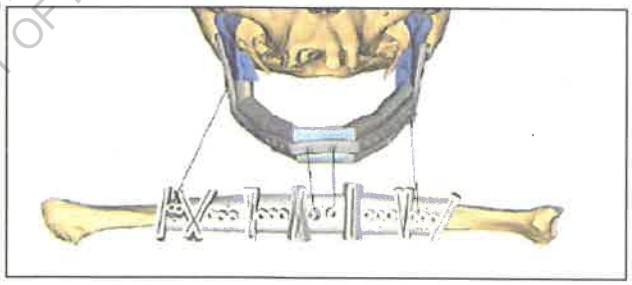
- Accommodate the planned osteotomy or resection site
- Avoid patient anatomy, for example tooth roots and nerves
- Avoid existing or future implants, such as plates, screws, or dental implants
- Minimum hole spacing of 5.5 mm, allowing for closer screw placement than any other MatrixMANDIBLE Plate

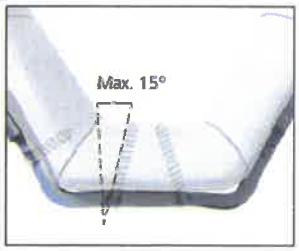
The Patient Specific Plate for Mandible is designed to be used with MatrixMANDIBLE Screws.



**PROPLAN CMF Surgical Guides***

- Surgical guides with built-in drill guides align the plate holes and position of the plate to match the virtual surgical plan






**Define screw hole angulation**

- Plate holes may be angulated to accommodate for surgical approach, or to avoid soft or hard tissues or implants.
- Plate holes may be designed perpendicular to the plate surface (default) or with an angulation of up to 15°, normal to the plate surface in any direction.

*Manufactured by Materialise and distributed by DePuy Synthes. For full description see PROPLAN CMF at www.DePuySynthescss.com

# WORKFLOW

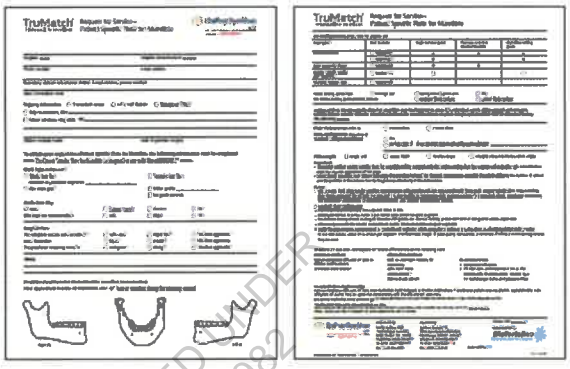
The workflow for the Patient Specific Plate for Mandible ensures that the surgeon is guided through a seamless interaction and development process. We work hand-in-hand with the surgeon and staff, Clinical Engineers and coordinators, from the time of the original request, through the plate design and to delivery of the final product.

Dependent upon customer

**1. Place Request**

Complete the Patient Specific Plate for Mandible Request for Service Form (RFS) to initiate your order. The RFS form can be obtained from:

- Your local Synthes Sales Consultant



4 business days

**2. Plate Design**

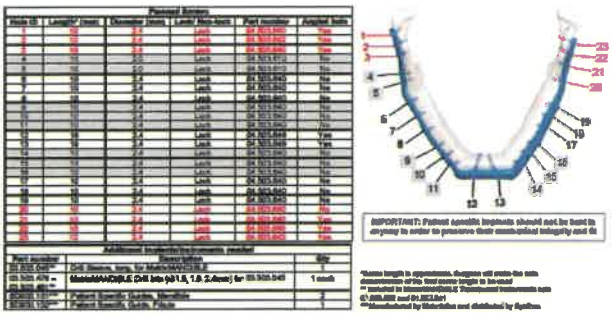
The Patient Specific Plate for Mandible is designed based on the information obtained from the RFS form or during the PROPLAN CMF planning session.

Some cases may require a Synthes Interactive Design Session hosted by a Synthes engineer, depending on the complexity of the case, or the type of products and services requested. During this session, the engineer will coordinate the details for the plate design with the surgeon.

Dependent upon customer feedback

**3. Approve Case Report**

Prior to manufacturing, the Patient Specific Plates for Mandible require surgeon's approval. This is done via surgeon review of a detailed Case Report which outlines the design of the plate in full color and from multiple views.



8 business days

**4. Manufacture and Shipment**

When the approvals are complete, the Patient Specific Plate for the Mandible will be manufactured and shipped per the instructions on the RFS form.

# ALSO AVAILABLE FROM DEPUY SYNTHES CMF

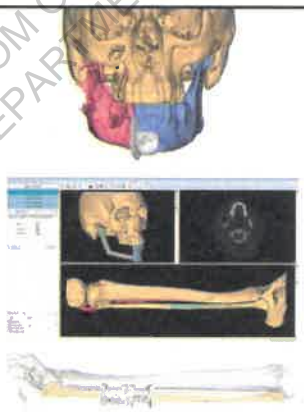
**Anatomic Models**
Anatomic bone models provide a tactile representation of the patient anatomy or plan for surgical outcome. Select from either acrylic or polyamide materials.

**Key Features & Benefits**
- Acrylic models can be highlighted to indicate tooth roots, nerves and other anatomy as specified
- Acrylic and poylamide models are steam sterilizable and can be used for demonstration in the OR.

**MatrixMANDIBLE™ Plating System**
The DePuy Synthes MatrixMANDIBLE Plating System is a product platform consisting of plates, screws and instrumentation trauma and reconstructive surgery.

**Key Features & Benefits**
- Comprehensive anatomic locking plate selection
- Flexibility in selecting the best screw and plate combination
- Reduced inventory for hospitals without compromising clinical solutions
- Simplified instrumentation compared to previous Synthes mandible sets
- Color-coding guides the user for correct implant and instrument selection

**PROPLAN CMF® Surgical Planning Services and Guides**
PROPLAN CMF is a computer-aided surgical planning service for preoperative case visualization, which includes patient specific products, such as surgical guides and anatomic models. Surgeons can work with Clinical Engineers to preoperatively plan cases such as orthognathic procedures, mandible and midface reconstruction, distraction procedures and cranial reconstruction, and transfer their surgical plan to the OR.



**Key Features & Benefits**
- Visualize patient anatomy and preoperative plan without making a single incision
- Make surgical decisions before going into the OR
- Allows for visualization of multiple surgical plans
- Improve OR efficiency

**Limited Warranty and Disclaimer: DePuy Synthes CMF products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.**

**WARNING: In the USA, this product has labeling limitations. See package insert for complete information.**

**CAUTION: Federal law restricts this device to sale by or on the order of a physician.**

Not all products are currently available in all markets.

DePuy Synthes CMF

A DIVISION OF Johnson & Johnson

People inspired

**Synthes CMF**
1302 Wrights Lane East
West Chester, PA 19380
Telephone: (610) 719-5000
To order: (800) 523-0322

www.depuysynthes.com

PROPLAN CMF products and services manufactured by

Materialise
innovators you can count on


J12248-A 1/14

stryker

Craniomaxillofacial

# Customized Mandible Reconstruction Plate



Patient Specific Design Powered by BluePrint Technology

# We're putting the control in your hands

Customized Mandible gives you the flexibility you've been looking for. Based on patient specific anatomical data (CT scan) and input from the surgeon, the Stryker Customized Mandible Recon Plate is designed to meet the individual needs of patients and surgeons. Patient specific solutions are created by selecting specific plate design features like profile height, length and run of the plate, number and position of screw holes as well as individual bar strengthening. These customized plates are manufactured to the planned patient outcome, eliminating the time needed for intraoperative adaptation.

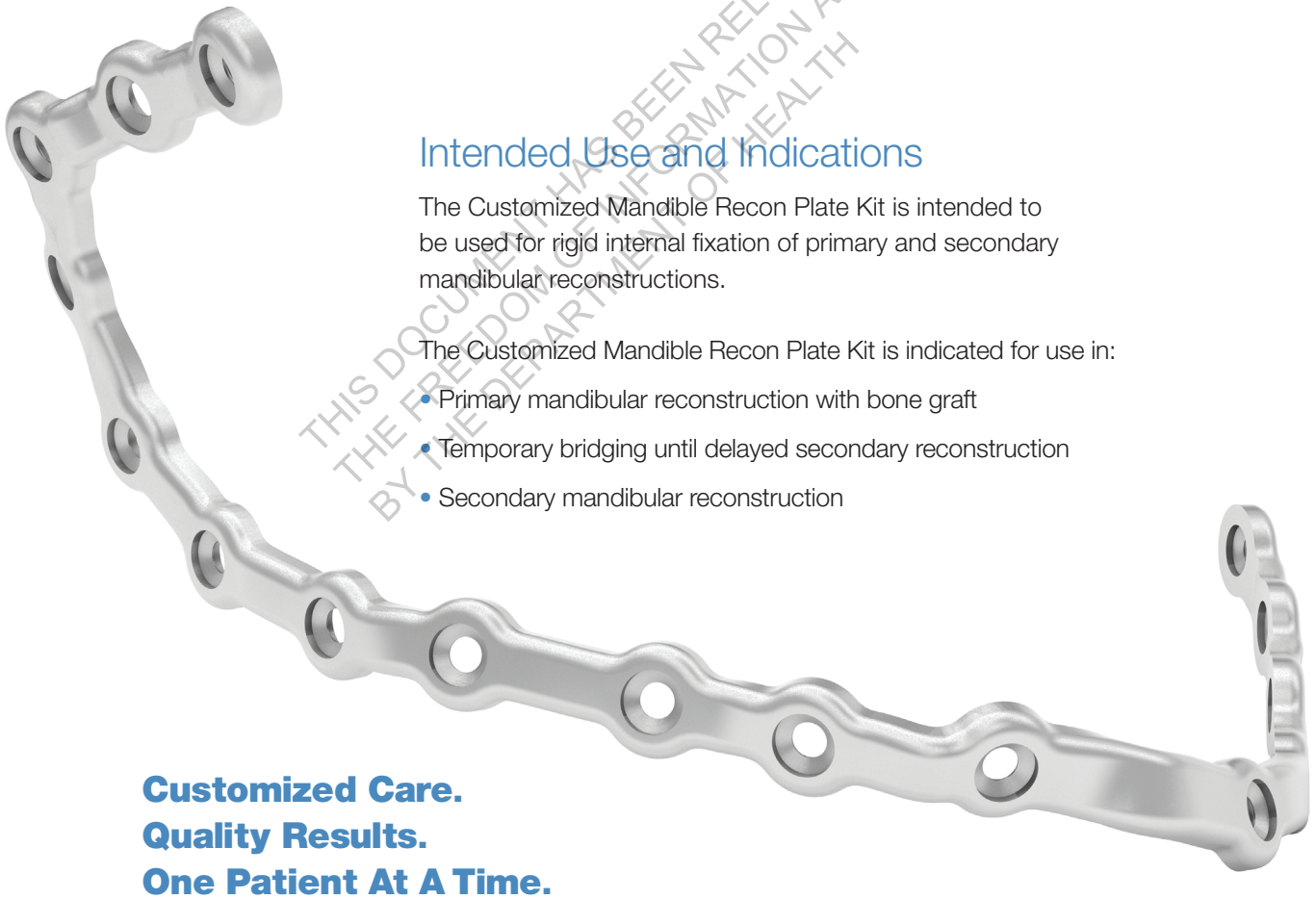


## Intended Use and Indications

The Customized Mandible Recon Plate Kit is intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions.

The Customized Mandible Recon Plate Kit is indicated for use in:

- Primary mandibular reconstruction with bone graft
- Temporary bridging until delayed secondary reconstruction
- Secondary mandibular reconstruction

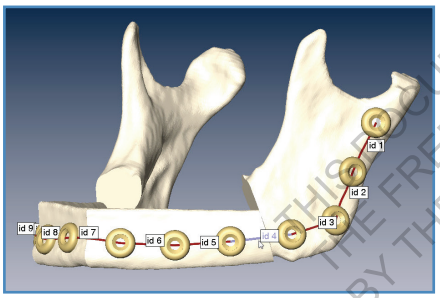


**Customized Care.**
**Quality Results.**
**One Patient At A Time.**

– Stryker CCI (CMF Customized Implants)


## Customized Mandible Workflow

Within the design session, the surgeon can interface with a design engineer using the proprietary BluePrint software to select specific plate design features such as profile height, length and 3D run of the plate to create patient specific solutions. Additionally, the designer can pass the control to the surgeon so that together they can define screw hole positions to avoid interference with nerves, tooth roots, osteotomies and existing or future implants.




Screw holes are placed along mandible

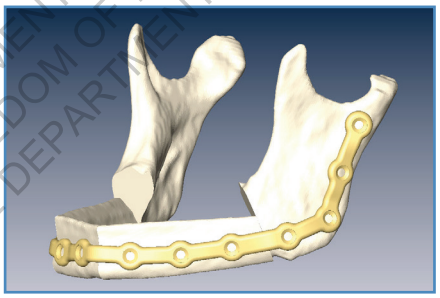


Plate is designed on screw hole placement

Upon approval, the plate design is virtually unfolded and milled out of titanium, eliminating the need for in-plane bends. The plate is then heat treated and contoured using specially designed instrumentation to ensure a precise fit and efficient transfer of the virtual plan to the operating room.

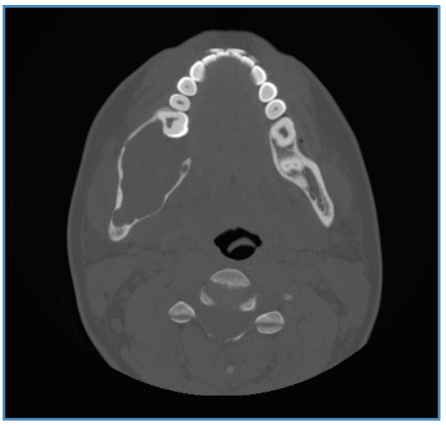


### Timeline

- Initiate case request and upload CT scan
- Online design session
- Design proposal delivered, reviewed and approved
- CAM and 2D milling
- Heat treatment and plate bending
- Anodizing and packing

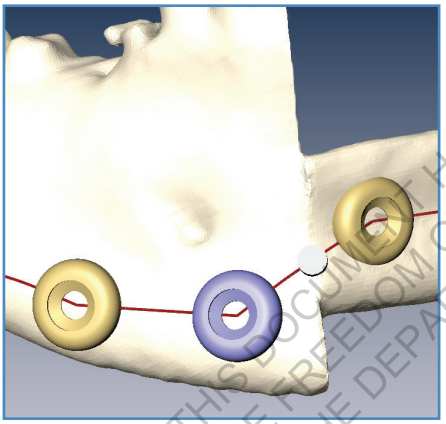
4 working days | 8 working days

# The value of true customization



## Patient Specific Design Derived From Patient CT Data

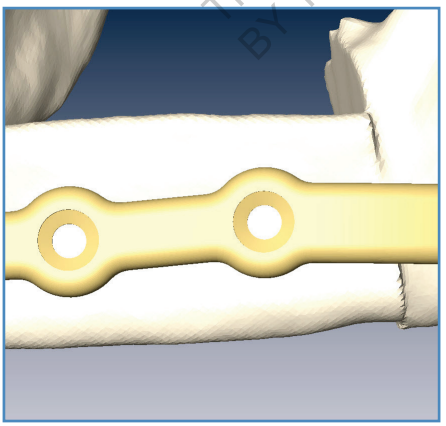
The Stryker CMF Customized Implant Team creates a virtual mandible reconstruction and an individual plate design with optional online participation of the surgeon. Plate design is based upon a CT scan of the patient.



## Customizable Design Features

Selecting specific plate design features like profile height, length and run of the plate allow for the creation of patient specific solutions.

Specific screw hole positions are defined individually to avoid screw interference with nerves, tooth roots, osteotomies and existing or future implants.

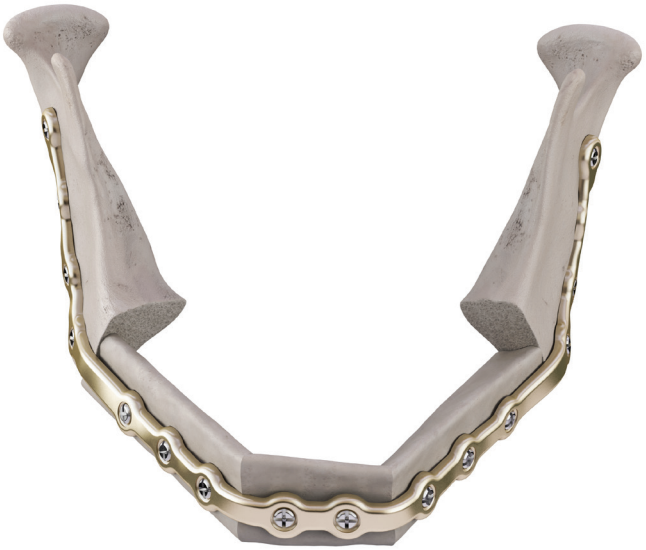


## Customized Strength Optimization

2.0mm and 2.8mm plate profile heights combined with increased individual bar widths may improve the fatigue strength by approximately 40% compared to standard Universal Mandible reconstruction plates.[1]

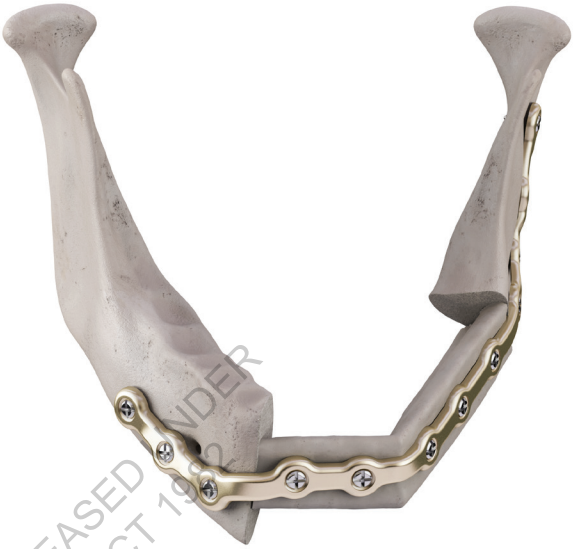
SMARTLock technology enables rigid plate-to-screw construct.

## Primary Mandible Reconstruction (2.0mm)



**Full**

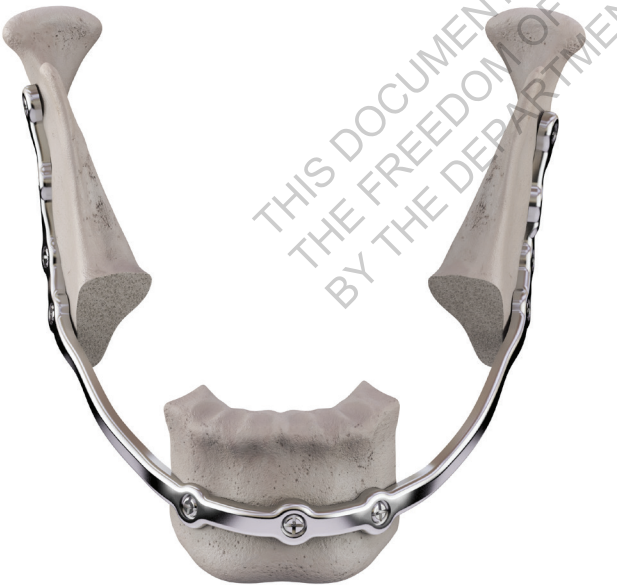
78-31020: CMRP, Full



**Hemi**

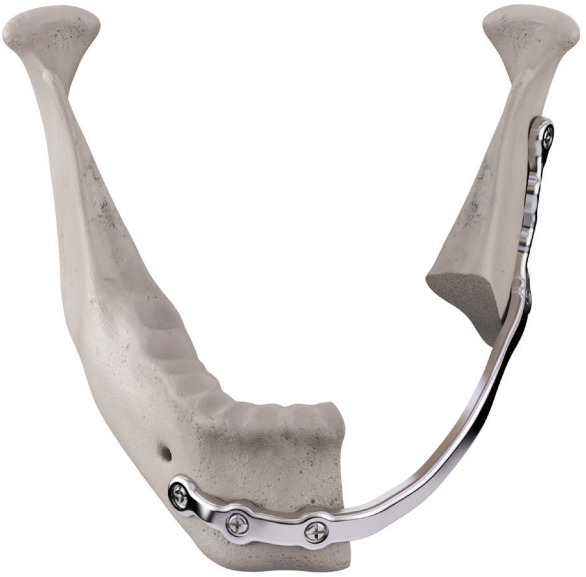
78-30020: CMRP, Hemi

## Secondary Mandible Reconstruction (2.8mm)



**Full**

78-31028: CMRP, Full



**Hemi**

78-30028: CMRP, Hemi

# Plate Design

## Choose Plate Profile

Customized Mandible Plates are available in two profiles:

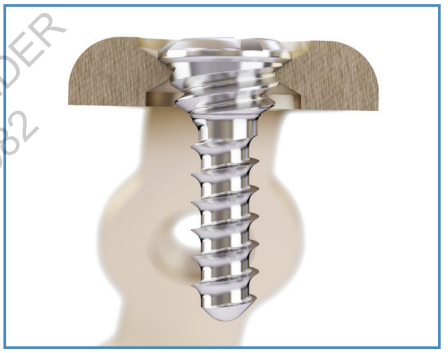
- 2.0mm thick
- 2.8mm thick

## Determine Screw Hole Location

- Planned osteotomy or resection site
- Patient anatomy, such as tooth roots and nerves
- Existing or future implants

## Define Individual Bar Width

- Bar width between two screw holes can be defined individually to ensure plate strengthening where desired



## SMARTLock Technology

- SMARTLock technology enables up to 10 degrees of angulation
- Stryker's proven technology has a long history of clinical effectiveness[2]

stryker®

**Reconstructive**

Hips

Knees

Trauma & Extremities

Foot & Ankle

Joint Preservation

Orthobiologics & Biosurgery

**MedSurg**

Power Tools & Surgical Accessories

Computer Assisted Surgery

Endoscopic Surgical Solutions

Integrated Communications

Beds, Stretchers & EMS

Reprocessing & Remanufacturing

**Neurotechnology & Spine**

Craniomaxillofacial

Interventional Spine

Neurosurgical, Spine & ENT

Neurovascular

Spinal Implants

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Fax: +61 2 9467 1010

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Auckland 1060 New Zealand
Ph: +64 9 573 1890
Fax: +64 9 573 1891

www.stryker.com

**References**

1. Dynamic Testing. Reports available at Stryker Leibinger GmbH & Co. KG

2. Evaluation of hardware-related complications in vascularized bone grafts with locking mandibular reconstruction plate fixation, Arch Otolaryngol Surg, 2007



Literature Number: 9410-400-420-SSP Rev. None
DDM/PS 1k 1/14


Printed in Australia

Australian Government

Department of Health

Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## Stryker Australia Pty Ltd

for approval to supply

## Stryker Australia Pty Ltd - Cranofacial fixation plate, non-biodegradable

| | |
|---|---|
| **ARTG Identifier** | 218563 |
| **ARTG Start date** | 14/12/2013 |
| **Product Category** | Medical Device Included Class IIb |
| **GMDN** | 46642 |
| **GMDN Term** | Cranofacial fixation plate, non-biodegradable |
| **Intended Purpose** | Intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions. |

| Manufacturer Details | Address | Certificate number(s) |
|---|---|---|
| Stryker Leibinger GmbH & Co KG | Botzinger Strasse 41<br>Freiburg, , 79111<br>Germany | DV-2010-MC-17559-3 |



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

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.,
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.,
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.,
- A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.,
- The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.,
- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG.,
- Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.,
- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III

medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

## Products Covered by This Entry

**1. Cranofacial fixation plate, non-biodegradable**

## 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: 218563
ARTG Start Date: 14/12/2013

Australian Government

Department of Health

Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## Stryker Australia Pty Ltd

for approval to supply

## Stryker Australia Pty Ltd - Cranofacial fixation plate, non-biodegradable

| | |
|---|---|
| **ARTG Identifier** | 218563 |
| **ARTG Start date** | 14/12/2013 |
| **Product Category** | Medical Device Included Class IIb |
| **GMDN** | 46642 |
| **GMDN Term** | Cranofacial fixation plate, non-biodegradable |
| **Intended Purpose** | Intended to be used for rigid internal fixation of primary and secondary mandibular reconstructions. |

| Manufacturer Details | Address | Certificate number(s) |
|---|---|---|
| Stryker Leibinger GmbH & Co KG | Botzinger Strasse 41<br>Freiburg, , 79111<br>Germany | DV-2010-MC-17559-3 |



### ARTG Standard Conditions

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

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.,
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.,
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.,
- A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.,
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- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG.,
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- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III

medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

## Products Covered by This Entry

**1. Cranofacial fixation plate, non-biodegradable**

## Product Specific Conditions

No specific conditions have been recorded against this entry.

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

ARTG Identifier: 218563
ARTG Start Date: 14/12/2013

Australian Government

Department of Health

Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## KLS Martin Australia Pty Ltd

for approval to supply

## KLS Martin Australia Pty Ltd Fixation device, Cranofacial fixation plate, non-biodegradable

| | |
|---|---|
| **ARTG Identifier** | 96619 |
| **ARTG Start date** | 27/08/2003 |
| **Product Category** | Medical Device Included Class IIb |
| **GMDN** | 46642 |
| **GMDN Term** | Cranofacial fixation plate, non-biodegradable |
| **Intended Purpose** | Non active implantable device |

| Manufacturer Details | Address | Certificate number(s) |
|---|---|---|
| Gebruder Martin GmbH & Co KG | KLS Martin Platz 1<br>, Tuttlingen, 78532<br>Germany | DV-2014-MC-12599-1 |



### ARTG Standard Conditions

The above Medical Device Included Class IIb 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. Cranofacial fixation plate, non-biodegradable**

### 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: 96619
ARTG Start Date: 27/08/2003

Australian Government

Department of Health
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## KLS Martin Australia Pty Ltd

for approval to supply

## KLS Martin Australia Pty Ltd Fixation device, Craniofacial bone screw, non-biodegradable

| | |
|---|---|
| **ARTG Identifier** | 96620 |
| **ARTG Start date** | 27/08/2003 |
| **Product Category** | Medical Device Included Class IIb |
| **GMDN** | 46638 |
| **GMDN Term** | Craniofacial bone screw, non-biodegradable |
| **Intended Purpose** | Non active implantable device |

| Manufacturer Details | Address | Certificate number(s) |
|---|---|---|
| Gebruder Martin GmbH & Co KG | KLS Martin Platz 1<br>, Tuttlingen, 78532<br>Germany | DV-2014-MC-12599-1 |



### ARTG Standard Conditions

The above Medical Device Included Class IIb 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. Craniofacial bone screw, non-biodegradable**

### 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: 96620
ARTG Start Date: 27/08/2003

# Anatomical Biomodels

## CT Based Patient Modelling

OMX SOLUTIONS
"Digital Innovation"

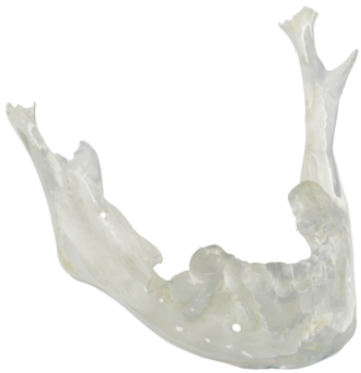


**Generated from the Patient's CT scan our anatomical biomodels enable surgeons the ability to see, touch and plan procedures with incredible accuracy.**

**OMX Solutions anatomical modelling is well suited for cases such as: distraction osteogenesis, orthognathics, skull base tumors, mandible and cranial reconstructions.**

## CT Based Patient Modelling

- made from bio-safe materials
- sterilised
- low cost
- extremely accurate, printed to sub millimetre accuracy



Available in Clear Resin and White Nylon

**All models are generated from CT scan files and are reliant on those scan parameters for accuracy. OMX Solutions provides specific CT Scan Protocols to enable the most accurate**



OMX SOLUTIONS Contact Us: 1300 336 026 enquiries@omx-solutions.com www.omx-solutions.com

# Instructions for Use Guides and Models

**This document contains general instructions for use for OMX Solutions Guides and Models. For case-specific instructions, refer to the Design Authorization Report.**

**DESCRIPTION**
OMX Solutions Guides and Models are custom-made devices designed to fit, or represent, the patient's anatomy. They are intended for improving and simplifying the performance of surgical interventions, the placement of implants or other patient specific implants.

**INDICATIONS FOR USE**
OMX Solutions Bio-Models are intended to be used as surgical tools to transfer a pre-operative plan to surgery. OMX Solutions Guides are intended to guide the marking of bone and/or guide surgical instruments in mandibular, maxillofacial and orthopedic surgical procedures.

OMX Solutions Guides and Models are intended for single use only.

**MATERIAL**
Nylon or Med610

**CONTRAINDICATIONS**
Do not use in the case of active infection of the surgical area where the surgery will be performed.

**WARNING**
- The user should be aware of possible allergic reactions to materials used in the guide or model. The patient should be informed on this matter by the user.
- These are patient-specific, single use, disposable guides or models.
- Do not attempt to reuse or recondition the guides or models.
- Do not alter the guides or models in any way.
- OMX Solutions guides are to be used by a trained physician in the performance of surgery.
- Be aware that these patient-specific guides and models have been manufactured based on CT/MRI scans of the patient. If the patient's anatomy has changed significantly since the time of the CT/MRI scan, the guides or models should not be used.
- The guides and models should be properly cleaned before sterilization. Do not use if the guides are broken, cracked, or are visibly contaminated or if the stainless steel tubes (if present) are not tightly secured;
- The guides and models in this package are provided non-sterile. The guides and models in this package must be sterilized prior to use.



**PRECAUTIONS**
- It is advised to use the guide or model within 6 months after performing the CT/MRI scans on which they are based. If the patient's anatomy has changed significantly since the time of the CT/MRI-scan, the guide or model should not be used, even if the time period of 6 months is not expired.
- Do not apply excessive force on the guides or place heavy objects on top.
- Markings on guides used for indicating anatomical references and case information must be legible. These include lines indicating anatomical directions, identifiers with case information such as implant size and the unique case identifier (see below). Notify your OMX Solutions representative if the markings are not legible or if the identifiers do not correspond to the intended patient or surgeon.

**PATIENT SPECIFIC GUIDE IDENTIFIERS**
A unique identifier is indicated on each guide and model. This alphanumeric code links the guide unambiguously to the patient case. The last two characters of the unique identifier are a part identifier that uniquely identifies the part within the patient case. A list of all unique identifiers is present in the case report shipped with each patient case.
Before using the guide, check the unique identifier for readability and confirm that it corresponds with the patient's identity.
If the guide contains an external tag with the unique identifier, this tag can be removed before coming in contact with the patient.

**POSSIBLE ADVERSE EFFECTS**

Infection following the surgical procedure. Introduction of foreign materials can result in an inflammatory response or allergic reaction.

**INSTRUCTIONS FOR USE**

- Fitting of the guide
  - The guide is designed to fit the patient anatomy. The supporting surface (bone, cartilage, teeth, soft tissue) should be completely freed to assure good fit of the guide.
    Take enough time to fit the guide on the patient. The case report shipped with every guide indicates the position of the guide relative to the surrounding anatomy. Try different positions and check whether or not the guide stays in place. Choose the most stable position, i.e., the position in which the least pressure must be exerted in order to keep the guide in place. Don't push the guide down too hard. Make sure critical anatomical structures are not damaged during fitting. OMX Solutions always offers the possibility to order anatomical models together with the guide. As such, fitting the guide can be tried on the anatomical models before surgery.
  - When a stable position for the guide is obtained, fixate the guide by means of fixation pins or screws (if present). Make sure fixation holes are correctly identified, and not mixed with holes for drilling (if present).
  - If it is not possible to place the guide on the patient in a unique and stable position, the guide does not guarantee an accurate transfer of the pre-operative planning.
    Even in a stable position it is possible that the guide doesn't make contact with the bone over its full length, since it isn't always possible to solve all of the undercuts. The undercuts depend on the shape of the patient's anatomy. During the design of the guide the amount of undercut is kept to a minimum in order to ensure a maximal contact between contact surface and guide.
  - Do not alter the guide before use. Small particles might come off, which could contaminate the operating region. In addition, altering the size of the guide may lead to its no longer fitting to the patient's anatomy. Therefore, it is the total responsibility of the user when altering the guide before surgery.

- During cutting and drilling
  - Make sure the guide maintains its position on the contact surface during cutting and/or drilling.
  - All necessary measures should be taken to avoid excessive heat generation during cutting and/or drilling. Please consult the procedures outlined by the manufacturer of the cutting and/or drilling equipment on this matter.
  - Do not try to use a sawing blade that is thicker than the indicated thickness of the cutting slot (if present).
  - Do not try to use a drill that is larger than the indicated diameter of the drill hole. The case report shipped together with the guide lists the drill diameters to be used.
  - Make sure the sawing blade follows the cutting surface or slot to obtain a correct osteotomy and to avoid cutting into the guide's cutting surface or slot.
  - Since the inner diameters of the drill holes are larger than the diameter of the drill (0.1 to 0.2 mm), try to drill along the centerline of the drill holes to obtain a correct hole and to avoid drilling into the inner wall of the drill hole.

**CLEANING AND STERILIZATION INSTRUCTIONS**

OMX Solutions Guides and Models are **NOT STERILE** and must be thoroughly cleaned and sterilized prior to use

- Cleaning

  Whenever possible, a washer/disinfector (according to ISO 15883) and ultrasonic cleaning equipment should be used to clean the guides and models. The detergents and/or enzymatic cleaner should be of neutral or near neutral pH (pH 7-9,5). The guides and models can be cleaned using manual cleaning and/or automated cleaning in a washer/disinfector with manual pre-cleaning and ultrasonic cleaning.

  Manual cleaning:

| Step | Cleaning instructions |
|---|---|
| 1 | Prepare a fresh, newly-made solution using warm de-ionized (DI) or purified water (PURW) and enzymatic cleaner or detergent. |
| 2 | Carefully wash the guide or model manually |
| 3 | Rinse the guide or model thoroughly with DI or PURW. |
| 3 | Dry the guide or model using a clean, soft, lint-free cloth or clean compressed air. |

  Manual pre-cleaning:

| Step | Minimum Duration | Cleaning instructions |
|---|---|---|
| 1 | 1 minute | Rinse the guide or model under running cold tap water. |
| 2 | 2 minutes | Manually clean the guide or model in a newly-made enzymatic cleaner or detergent solution. |
| 3 | 1 minute | Rinse the guide or model using cool to lukewarm running tap water. Use a syringe, pipette or water pistol to flush cylinders, slots, and other hard-to-reach areas. |
| 4 | 15 minutes | Clean the guide or model ultrasonically per manufacturer's recommended temperature (usually 32°-60°C) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners and medical equipment. |
| 5 | 2 minutes | Rinse the guide or model using DI or PURW. Use a syringe, pipette, or water pistol to flush cylinders, slots, and other hard-to-reach areas. |

  Automated cleaning in a washer/disinfector:

| Step | Minimum Duration | Cleaning instructions |
|---|---|---|
| Pre-wash | 2 minutes | Cold tap water |
| Wash | 10 minutes | Warm tap water (>40°C); use detergent |
| Neutralize | 2 minutes | Warm tap water with neutralizer, if necessary |
| Rinse | 2 minutes | Rinse with warm DI or PURW (>40°C) |
| Thermal disinfection | 7 minutes | At minimum 94°C |
| Dry | 40 minutes | At minimum 90°C |

  Before the cleaned products are packaged and sterilized, carefully examine them to see if they are clean and undamaged.

- Sterilization

**Recommended sterilization specifications**

The guides can be sterilized once prior to use. The guides are intended for single use only and should only be used once. Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved.

Sterilize the guides or models using **pre-vacuum steam sterilization** before use.

During sterilization of single devices pouches may be used.

Only standard medical grade steam sterilization polyethylene or Tyvek pouches should be used. Ensure that the pouch is large enough to contain the devices without stressing the seals or tearing the pouch.

Use one of the following standard steam sterilization settings:

- Pre-vacuum Cycle UK, NL[1,2]: Minimum temperature: 134°C
  Minimum exposure time: 3 minutes'
  Minimum vacuum drying time: 30 minutes
- World Health Organization Pre-vacuum Cycle[2,3]:
  Minimum temperature: 134°C (273.2°F)
  Minimum exposure time: 18 minutes'
  Minimum vacuum drying time: 30 minutes

**CONTACT DETAILS**

For any questions or concerns, please contact your OMX Solutions representative and/or the OMX Solutions customer service.

In case you encounter any problem when using the guide, please bring this to OMX Solutions' attention (OMX Solutions Level 30, 35 Collins Street 3000 Melbourne, Victoria, Australia Tel: 1300 336 026 00).



1 Minimum validated steam sterilization time required to achieve a $10^{-6}$ sterility assurance level (SAL).
2 In the case local or national specifications for steam sterilization requirements are stricter or more conservative than those
3 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.

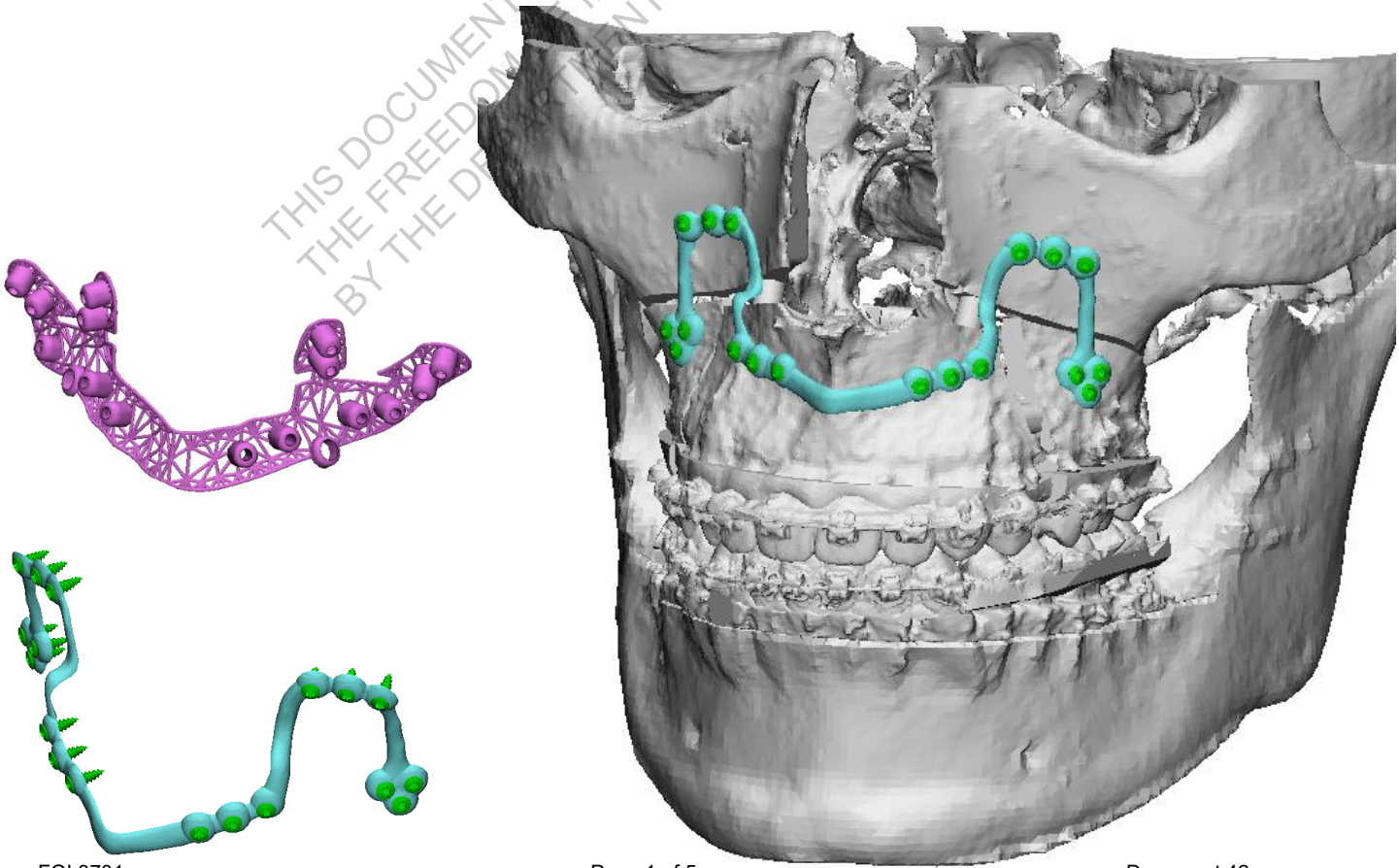
Lyka Smith
Health Services

# PATIENT SPECIFIC CUSTOM PLATES [PSCP]:

## Custom made plates for Orthognathic, Trauma and Reconstruction Applications

Patient Specific Custom Plating systems modelled directly from patient CT data facilitates enhanced surgical precision.





# PRODUCT OVERVIEW

## Introduction

Lyka Smith Patient Specific Custom Plates are designed with bespoke characteristics as required on a case by case dependency. Certain design features such as plate bounding coverage, screw placement and overall measurements can be adjusted to suit the individual patient's anatomy. Patient Specific Custom Plates reduce the intraoperative bending or plate alteration time required for standard plate configurations and enable a variety of benefits not possible with stock plate sizes.



# INTENDED USE AND INDICATIONS

## Intended Use

Lyka Smith Patient Specific Custom Plates are intended for oral maxillofacial and plastic reconstructive surgery.

## Indications:

- Orthognathic movements
- Trauma
- Reconstructive surgery

## Clinical applications may include:

- Maxillary osteotomy movements
- Comminuted fractures
- Fixation for harvested bone site placement
- Combined orthognathic movements
- Permanent or temporary bridging reconstruction

# FEATURES AND BENEFITS

### Modelled from patient CT Data

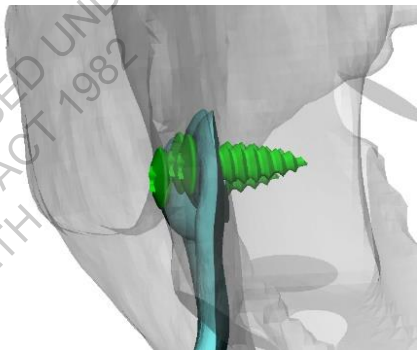
Patient Specific Custom Plates are manufactured to suit the individual patient anatomy.

Planning is conducted with the requesting clinician in a collaborative approach which takes into consideration medical and engineering principles.

### Customizable design features

Screw hole positions and angulations defined individually to avoid screw interference with nerves, tooth roots, osteotomies, existing or future implants.

Screw length prediction and pre-visualization of screw trajectories to ensure a collision free construct.





### Plate Thickness and Screw Profile Options

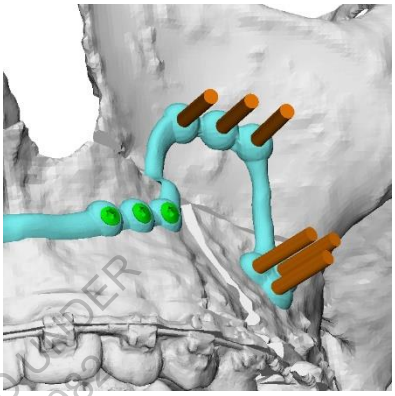
Variations to plate thickness and screw profile options can be made throughout the design phase, enabling for complex contouring to achieve a minimal profile height and maintain maximum structural strength.

1.0 mm to 1.5 mm plate thicknesses for improved rigidity with lower profiles can accommodate a variety of screw profile options from embedded countersunk to a raised mating screw hole well.

### Fixation Positioning and Placement

Lyka Smith Patient Specific Custom Plates allow for individualized fixation planning which can be adjusted to suit:

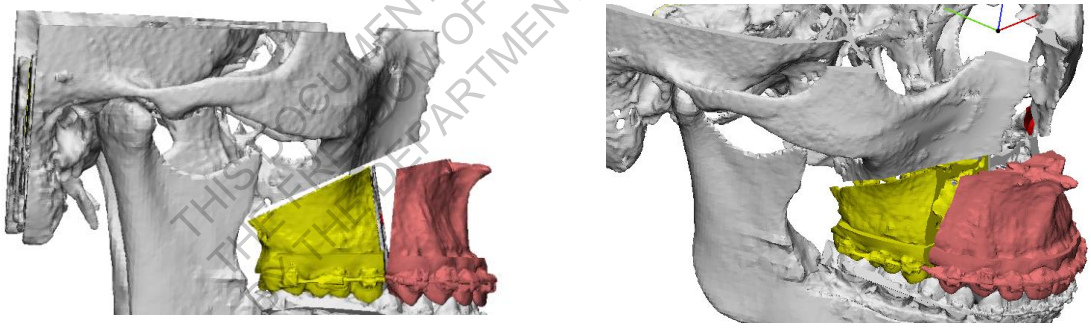
- Patient anatomy, optimal bone density and tooth root avoidance
- Planned osteotomy positions or bone removal segments
- Existing dental implants or combined plating systems
- Soft tissue margins and surgical points of access





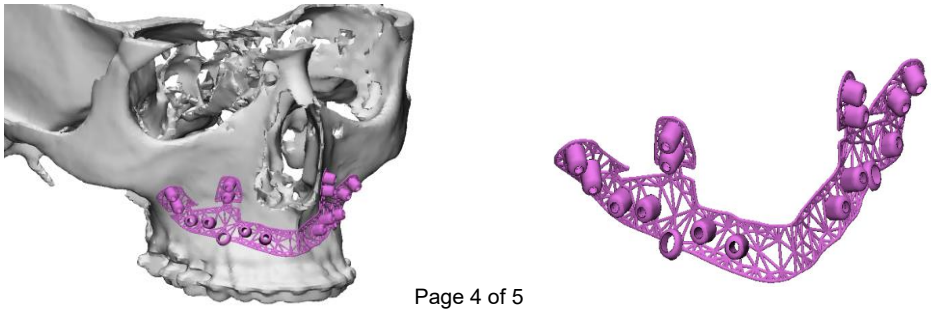
## DESIGN PROCESS

**Step 1 -** Surgeon/Clinician will plan points of resection, planned movements and or bone removal site.

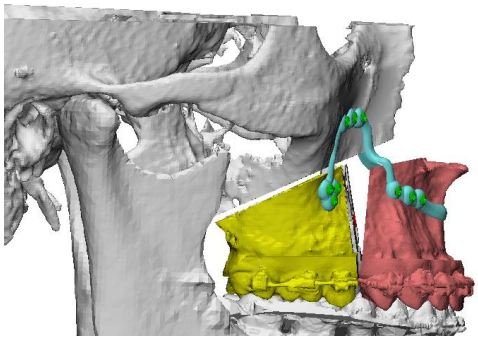


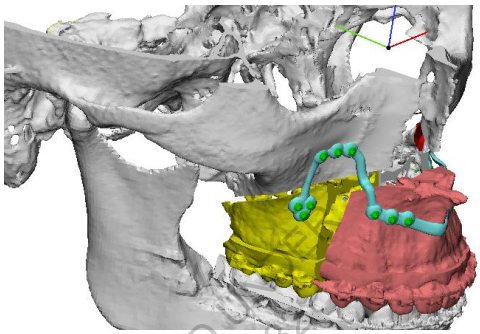
The example above shows movements for a 3x part segmental maxillary osteotomy and advancement.

**Step 2 –** Lyka Smith design team in conjunction with the surgeon plan the Patient Specific Guide [PSG] design and features to achieve planned movements, fixation points and osteotomies



**Step 3 –** Patient Specific Custom Plate design, profile and fixation points are planned. Surgeons/Clinicians can select from many pre-set fields and bounding conditions or design from the ground up bespoke requirements as needed.





**Step 4 –** Final design verification and surgeon approval. A final design report will be issued to the surgeon for approval. Once Step 4 has been completed Lyka Smith will begin production on the Patient Specific Custom Plate, usual lead time is between 15 and 20 business days.

Once produced the Patient Specific Custom Plates will be delivered to the hospital or medical centre prior to the case.

For more information contact your local Lyka Smith Health Service representative or custom service at:



**Phone:** +61 2 8896 6032

**Email:** admin@lykasmith.com

**Website:** www.lykasmith.com

**Address:** Level 15, Deloitte Building, 60 Station Street East, Parramatta, NSW, 2150, Australia

Lyka Smith
Health Services

# Patient Specific Anatomical Models [PSAM]

*"because every case presents new challenges"* Lyka Smith

Generated from the Patient's CT scan anatomical biomodels enable surgeons the ability to see, touch and plan procedures with incredible accuracy. Lyka Smith Patient Specific Anatomical Models (PSAM)s are produced via digital manufacturing methods which enable extremely high levels of model accuracy.

Patient specific anatomical models are well suited for cases such as:

- Distraction osteogenesis
- Custom TMJ Reconstruction Planning
- Combined Orthognathics or single jaw surgery
- Skull base tumors, mandible and cranial reconstructions.

Models are available in Clear Resin and White Nylon

Made from medically tested materials, patient specific anatomical models can be sterilized, are low cost and extremely accurate, printed to sub millimeter accuracy.



To order PSAM for your next case speak to your appointed representative or case manager. For new enquiries simply log onto the www.lykasmith.com website to learn more.

All models are generated from CT scan files and are reliant on those scan parameters for accuracy. Lyka Smith provides specific CT Scan Protocols to enable the most accurate CT Based Patient Modelling.

Lyka Smith
Health Services

Australian Government

Department of Health
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## AA-Med Pty Ltd

for approval to supply

## AA-Med Pty Ltd - Lyka Smith Combined TMJ System - Prosthesis, internal, joint, temporomandibular, total

| | |
|---|---|
| **ARTG Identifier** | 293845 |
| **ARTG Start date** | 14/09/2017 |
| **Product Category** | Medical Device Included Class IIb |
| **GMDN** | 36042 |
| **GMDN Term** | Prosthesis, internal, joint, temporomandibular, total |
| **Intended Purpose** | 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. |

| Manufacturer Details | Address | Certificate number(s) |
|---|---|---|
| Lyka Smith Pty Ltd | Level 15 / 60 Station Street East<br>Parramatta, NSW, 2150<br>Australia | DV-2017-MC-14458-1 |



### ARTG Standard Conditions

The above Medical Device Included Class IIb 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. Lyka Smith Combined TMJ System - Prosthesis, internal, joint, temporomandibular, total**

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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ARTG Start Date: 14/09/2017