PATIENT SPECIFIC PLATE FOR MANDIBLE

Customized to fit the patient anatomy
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

*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.

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, intraoperative 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.  
• 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 Plate(s) for Mandible have improved fatigue life over the 2.5 mm MatrixMANDIBLE™ flat plates.  
• 2.0 mm thick plates offer greater strength with lower profile as compared to 2.5 mm thick MatrixMANDIBLE flat plates.  
• 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:

- 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.
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.

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

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

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

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.

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.

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.
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 polyamide 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.