

PATIENT SPECIFIC PLATE FOR MANDIBLE

Customized to fit the patient anatomy

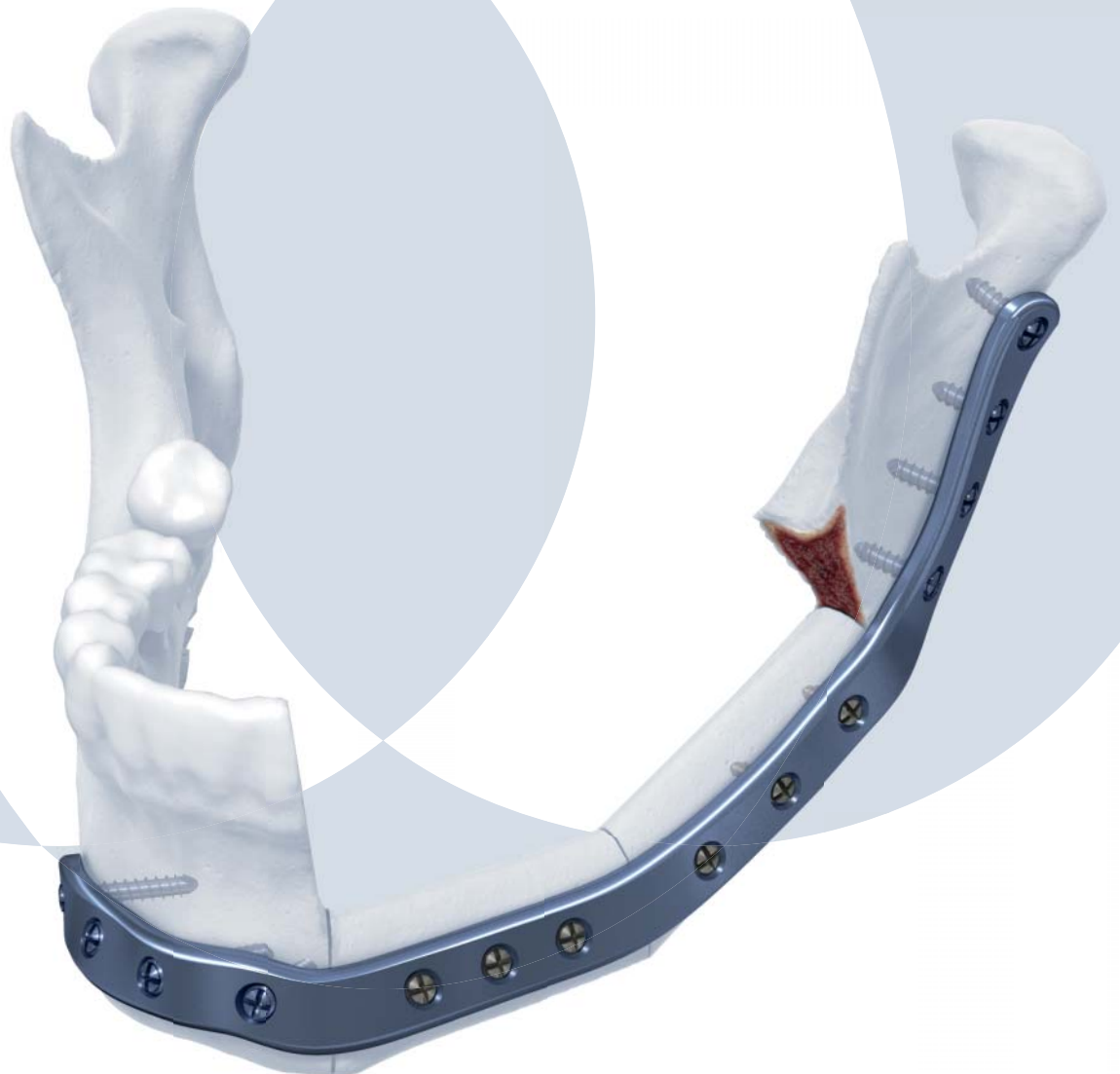


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PATIENT SPECIFIC PLATE FOR MANDIBLE

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 graft¹
- Temporary bridging until delayed secondary reconstruction
- Secondary mandibular reconstruction
- Comminuted mandibular fractures
- Fractures of edentulous and/or atrophic mandibles
- Unstable mandibular fractures

Caution: Surgical implants must never be reused. An explanted metal implants must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

MR Information

The Patient Specific Plate for Mandible has not been evaluated for safety and compatibility in the MR environment. The Synthes Patient Specific Plate for Mandible has not been tested for heating or migration in the MR environment.

*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.



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

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.
- 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.
- 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.

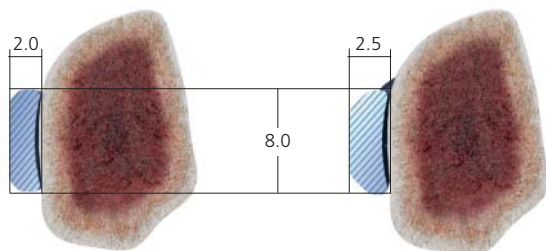
**Manufactured by Materialise and distributed by DePuy Synthes.

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:



Fibula reconstruction

Scapula reconstruction



Define screw hole pattern to

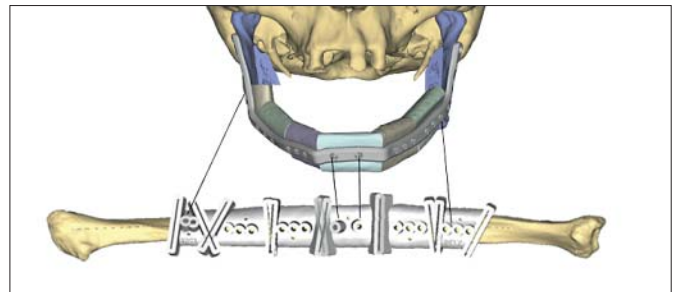
- Accommodate the planned osteotomy or resection site
- Avoid patient anatomy, for example tooth roots and nerves
- Avoid existing or future implants, such as plates, screws, or dental implants
- Minimum hole spacing of 5.5 mm, allowing for closer screw placement than any other MatrixMANDIBLE Plate

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.DePuySynthes.com

CASE PREPARATION

Use the Request for Service (RFS) Form to communicate the design specifications for the Patient Specific Plate for Mandible.



**Request for Service—
Patient Specific Plate for Mandible**



DePuySynthes
CMF

Surgeon name _____ Hospital name/Account number _____

Phone number _____ E-mail address _____

Secondary contact information (name, e-mail address, phone number) _____

Sales Consultant name _____

Shipping Information Consultant Home UPS Hold Station Storage or Office

Ship to Account, attn: _____

Other: (address, city, state, zip) _____

Patient number/name _____ Date of planned surgery _____

To initiate your request for a Patient Specific Plate for Mandible, the following information must be completed.
Note: The Patient Specific Plate for Mandible is designed for use with MatrixMANDIBLE™ screws.

Graft Type (Select one)

Fibula free flap Scapula free flap

Number of predicted segments _____ Other grafts _____

Iliac crest graft No graft planned

Graft/Free Flap

CT data: Patient specific Generic TBD

Side used for reconstruction: Left Right TBD

Surgical Plan

The recipient vessels will connect to: Left neck Right neck TBD/Not applicable

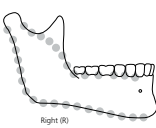
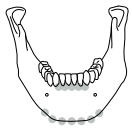
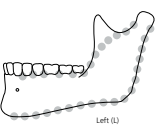
Neck dissection: Open Limited TBD/Not applicable


The predicted resecting tissue is: Malignant Benign TBD/Not applicable

Notes

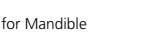
Predicted Resection and Reconstruction (Mandible Reconstruction)

Mark approximate location of osteotomies with (can be modified during the planning session)



**Request for Service—
Patient Specific Plate for Mandible**



DePuySynthes
CMF

Kit Configurations (check box for desired kit)

Description	Part number	Graft harvest guide	Planned outcome model mandible	Mandible cutting guide
Mandible Recon	<input type="checkbox"/> SD900.001	●	●	●
	<input type="checkbox"/> SD900.051	●		●
Basic Mandible Recon	<input type="checkbox"/> SD900.003	●	●	
Patient Specific Guide with planning	<input type="checkbox"/> SD900.111	□		□
Planning Session only	<input type="checkbox"/> SD900.090			

Select cutting guide style: Through slot Along cutting guide wall TBD

For slotted cutting guide position slots on: Anterior fibula surface Lateral fibula surface

DePuy Synthes Patient Specific Plate for Mandible may be designed to meet the individual needs of the patient and surgeon. See the Patient Specific Plate for Mandible brochure for complete details on plate design options which will be discussed during the planning session.

Plate Thickness: (see note 1) 2.0 mm thick 2.5 mm thick

Plate Configuration: (see note 2)

Standard Configuration desired: Yes No (see note 3) If no describe requested configuration desired _____

Plate Length: Angle, Left Angle, Right Double Angle Straight (does not involve either angle)

Important:

- The DePuy Synthes Patient Specific Plate for Mandible will be supplied with the understanding that the surgeon will make the sole determination as to the use and application of the plate.
- Some clinical situations may require extending the resection beyond the planned osteotomies; consider this when defining the number of screws and the position of the screws next to the planned osteotomy in the native bone.

Notes:

- The 2.0 mm thick plate can be used for reconstruction with vascularized and non-vascularized bone graft. Patient Specific Plate fatigue testing data shows increased life of both 2.0 mm and 2.5 mm profiles in comparison with MatrixMANDIBLE 2.5 mm thick plates. Bench test results may not necessarily be indicative of clinical performance. Test data on file at DePuy Synthes.
- Standard plate configuration
 - Minimum distance between two adjacent holes: 8 mm
 - Minimum number of screw holes: 4 per native bone and 2 per graft segment
 - No collision among screws as long as threaded drill guides are used (or cutting guides with built in drill guides where applicable)
 - Will be aligned with the inferior and posterior border of the mandible and graft segments
- Stable fixation requires a minimum of 2–3 screws per segment. When using the 2.0 mm or 2.5 mm plate as a bridging device with 2.4 mm or 2.9 mm screws, allow for 4 screws per segment. If limited bone length or poor quality bone exists, a minimum of three 2.9 mm locking screws may be used.

To submit CT scan data and Request for Service (RFS) use one of the following ways:

Preferred Method: Upload completed RFS and CT scan to ProPlan CMF Connect or ProPlan CMF Online*

Alternative Method: Mail via overnight delivery to: Materialise, Attn: CMF Team, 44650 Helm CT, Plymouth, MI, 48170

Be sure to include:


- Completed RFS Form
- CT scan data archived onto a CD or disk, labeled with physician name, scanner type, CT technologist name and phone number

To submit data electronically: Upload completed RFS and CT scan data to ProPlan CMF Connect or ProPlan CMF Online.* Additional patient data (ie photos, cephalometric data, and prior CT scans) may be uploaded concurrently with the RFS and CT scan data.

For access to ProPlan CMF Connect go to www.synthesccs.com and follow the instructions in the Online Request section.

*ProPlan CMF Online is for sales consultant use only.

Some devices in this document may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please consult your Sales Consultant for items approved for sale in Canada.




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CMF

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PLATE DESIGN

The DePuy Synthes Patient Specific Plate for Mandible is designed to meet the needs of the patient and the surgeon. The plate may be designed based on the planned anatomical outcome, completed in an online planning session with a Materialise clinical engineer using PROPLAN CMF planning services.

The plate is designed for use with DePuy Synthes MatrixMANDIBLE Screws.

Select screw size

Determine the appropriate screw size to be used in the case. MatrixMANDIBLE Screws of 2.4 mm or 2.9 mm diameter are recommended.

Cautions:

- For mandibular procedures the 2.0 mm diameter screws should only be used with the Patient Specific Plate for Mandible, if inserted into a bone graft, or, if bone volume does not permit the placement of a larger screw.
- In accordance with AO technique, it is important not to insert screws into infected bone.

Select plate length

The Patient Specific Plate for Mandible may be designed to be a minimum of 24.5 mm (four holes) or a maximum of 490 mm, to extend from condyle to condyle. The maximum length of the plate will be defined by the patient anatomy.

Warning: Correct selection of the implant is extremely important. The potential for success of fracture fixation is increased by the selection of the proper size, shape and design of the implant. Orient the plate so that the topside of the plate is facing out. If applicable, use the Patient Specific Plate for Mandible Case Report as a guideline to determine the appropriate screw size and type, locking or non-locking. It is recommended that screws of the same color as the selected plate are used.



SURGICAL TECHNIQUE

Required Set

01.503.150	MatrixMANDIBLE Implant and Instrument System
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Also Available

PROPLAN CMF Surgical Guides

388.72	Rod Cutter
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1

Expose and Reduce Mandible

Instruments

98.985	Bone Reduction Forceps, large
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398.986	Bone Reduction Forceps, small
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After completing the preoperative plan, expose and reduce the mandible segments as necessary.

2

Plate Adaptation

Caution: In order to achieve the planned outcome, the Patient Specific Plate for Mandible is NOT intended to be bent or contoured.

If the plate does not fit to the planned outcome patient anatomy, then plates from the MatrixMANDIBLE Plating System should be used.

To assist with the orientation of the plate, a Patient Specific Plate for Mandible is marked with 'R' indicating patient Right, or 'L' indicating patient Left.



3 Cut Plate (Optional)

Instruments

03.503.057	Short Cut Plate Cutter (deburring rasp only)
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388.72*	Rod Cutter (not shown)
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The Patient Specific Plate for Mandible is designed and manufactured to be the appropriate length per the patient anatomy.

However, if there is a change in the patient anatomy, or preoperative plan, the plate may be cut to the desired length.

The plate may be cut using the Rod Cutter. To avoid soft tissue damage, deburr the cut plate when appropriate using a manual deburring instrument. The deburring rasp of the Short Cut Plate Cutter may be used.

Notes The Short Cut Plate Cutter **MUST NOT** be used to cut the plate. Due to the lack of cutting features in the plate, damage to the instrument may result if used to cut the plate.

*Additionally available

STEPS FOR BONE RESECTION

4

Position the PROPLAN CMF Surgical Guides (Optional)

Instruments

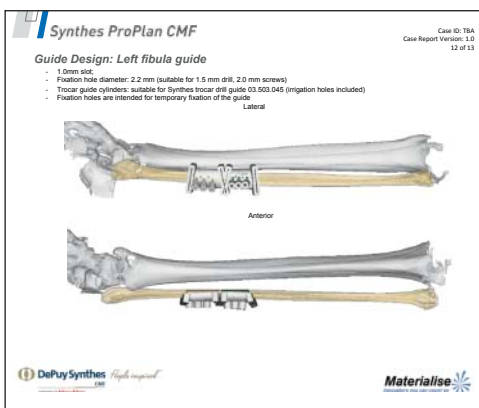
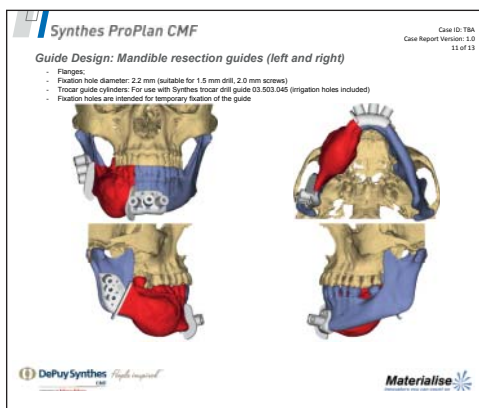
03.503.070	MatrixMANDIBLE/MatrixRIB Self-Retaining Screwdriver Blade, short
03.503.071	MatrixMANDIBLE/MatrixRIB Self-Retaining Screwdriver Blade, medium
03.503.072	MatrixMANDIBLE/MatrixRIB Self-Retaining Screwdriver Blade, long
311.004*	Fixed-Swivel Screwdriver Handle
311.007	Screwdriver Handle with hex coupling, large
311.023	Ratcheting Screwdriver Handle

Use the PROPLAN CMF Case Report to reference the proper positioning for the surgical guides at the resection and/or graft harvest sites.

See the PROPLAN CMF Instructions For Use for Surgical Guides and the case report provided with the surgical guides for more information.

If surgical guides are designed to align to the Patient Specific Plate for Mandible plate holes, follow the steps for 'Drilling: Option 2 – Trocar Instrumentation,' to drill all of the holes that align with the plate holes.

Reference the section 'Select Screws' for additional information on screw placement



5

Resect Mandible

*Also available

6

Position plate

Instruments

398.66 Plate Holding Forceps with Ball*

Place plate over the fracture or resection site using the plate holding forceps with ball.

If PROPLAN CMF surgical guides were not selected during 'Case Preparation' select the appropriate screw diameter.



7

Select screw

Determine the appropriate screw size to be used in the case. MatrixMANDIBLE Screws of 2.4 mm or 2.9 mm are recommended.

Cautions:

- For mandibular procedures the 2.0 mm diameter screws should only be used with the Patient Specific Plate for Mandible, if inserted into a bone graft, or if bone volume does not permit the placement of a larger screw.
- Per AO technique, do not insert screws into infected bone.

Note: Stable fixation requires a minimum of 2–3 screws per segment. When using the 2.0 mm and 2.5 mm reconstruction plate as a bridging device with 2.4 mm or 2.9 mm locking screws, allow for four screws per segment. If limited bone length or poor bone quality exists, a minimum of three 2.9 mm locking screws should be used.



* Also available

8

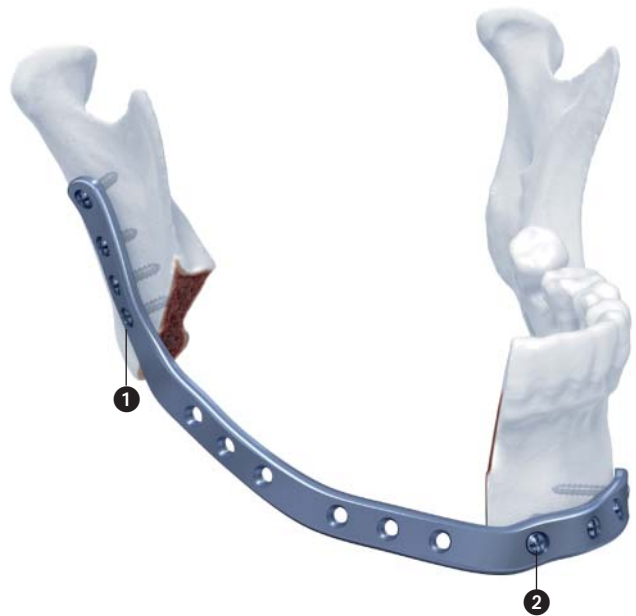
Drilling

Multiple drill guide options are available to meet surgeon preference including: the PROPLAN CMF Surgical Guides, short threaded drill guide, universal drill guide, or transbuccal instrumentation.

If surgical guides are used, the PROPLAN CMF Instructions for Use and PROPLAN CMF Case Report must be used as a reference for placement of the surgical guides.

For the techniques described below, regardless of the option chosen, drill the hole closest to the fracture or osteotomy site in the proximal (posterior) segment (1).

Then drill the hole closest to the fracture or osteotomy site in the distal (anterior) segment (2).



Cautions:

- **Drill rate should never exceed 1800 rpm. Higher rates can result in thermal necrosis of the bone, and an oversized hole to be drilled. The detriments of an oversized hole include reduced pullout force, increased ease of the screws stripping in bone, and/or suboptimal fixation.**
- **Always irrigate during drilling.**
- **Avoid placing plate holes, drilling pilot holes, or inserting screws over nerves and tooth roots.**

Option 1—Threaded drill guides, short

Instruments




03.503.043	MatrixMANDIBLE 1.5 mm Threaded Drill Guide, Short
03.503.044	MatrixMANDIBLE 1.8 mm Threaded Drill Guide, Short
03.503.046	MatrixMANDIBLE 2.4 mm Threaded Drill Guide, short
03.503.451	MatrixMANDIBLE 1.5 mm Drill Bit, J-latch, 90 mm, for 03.503.043
03.503.461	MatrixMANDIBLE 1.8 mm Drill Bit, J-latch, 90 mm, for 03.503.044
03.503.471	MatrixMANDIBLE 2.4 mm Drill Bit, J-latch, 90 mm, for 03.503.046

If wide exposure is used, select the appropriate diameter short threaded drill guide. Rotate the drill guide clockwise to engage the threads into the plate.

Notes:

- **Drill guides are color-coded to match the relevant screw size.**
- **A screw 2 mm longer may be chosen to ensure bicortical purchase.**
- **Drill bits with Quick Coupling attachment are also available.**

Drill size guide

Guide number	Screw diameter (mm)	Drill bit diameter (mm)	
03.503.043	2.0	1.5	
03.503.044	2.4	1.8	
n/a	2.7 (Emergency)	n/a	n/a
03.503.046	2.9	2.4	



Option 2 — Trocar Instrumentation

Instruments

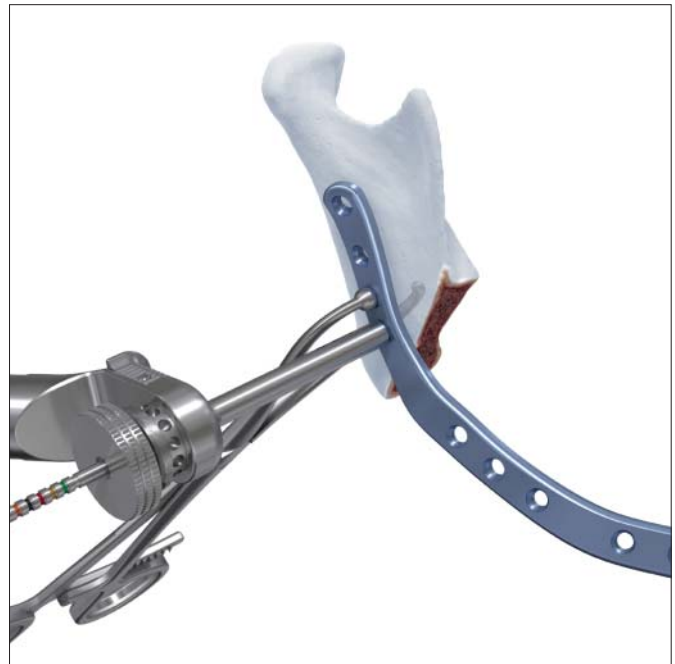
03.503.045	MatrixMANDIBLE Trocar Drill Guide, for 397.213
03.503.047	MatrixMANDIBLE Threaded Trocar Drill Guide, for 397.213
03.503.476	MatrixMANDIBLE 1.5 mm Calibrated Drill Bit, J-latch, for 3.503.045/03.503.047
03.503.477	MatrixMANDIBLE 1.8 mm Calibrated Drill Bit, J-latch, for 03.503.045/03.503.047
03.503.478	MatrixMANDIBLE 2.4 mm Calibrated Drill Bit, J-latch, for 03.503.045/03.503.047
397.211	Universal Trocar Handle
397.213	2.0 mm Cannula and Obturator

Optional instruments

397.232	Malleable C-Retractor
397.42	2.0 mm Cheek Retractor Blade
397.43	2.0 mm Cheek Retractor Ring

The cannula and obturator may be used with any mandibular approach.

After creating a stab incision, pass the cannula with obturator carefully through the soft tissue, then remove the obturator.

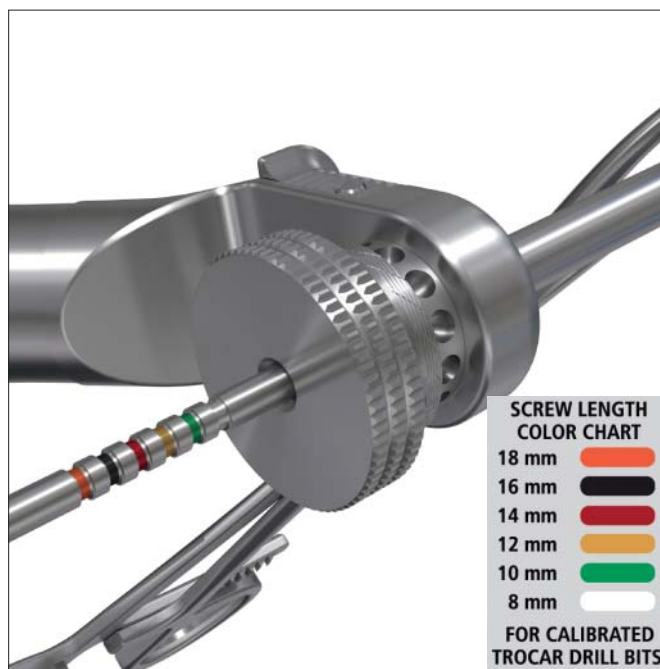


Pass the drill guide through the cannula and snap it in place. Position the tip of the cannula on the plate, at the hole intended for the screw. If the threaded drill guide is used, rotate the drill guide clockwise to engage the threads in the plate.

With the correct diameter calibrated drill bit, drill directly through the drill guide. The depth of drilling can be determined by observing where the colored rings on the drill match the fixed surface on the drill guide, and correlating these to the screw length chart in the transbuccal module.

Notes:

- **A screw 2 mm longer may be chosen to ensure full bicortical purchase.**
- **To achieve optimal angular stability with locking screws, the hole must be drilled coaxial with the plate hole, using a threaded drill guide. However, a certain amount of variation can be tolerated.**



Three different cheek retractor options are available for use with the cannula and obturator.

If longer trocar drill guides are required (alternative to Option 1) the MatrixMANDIBLE trocar drill guide and threaded trocar drill guide can be used with the drill bits from the transbuccal module.

Optional instruments

397.232	Malleable C-Retractor
397.42	2.0 mm Cheek Retractor Blade
397.43	2.0 mm Cheek Retractor Ring

Three different cheek retractor options are available for use with the cannula and obturator.

If longer trocar drill guides are required (alternative to Option 1) the MatrixMANDIBLE trocar drill guide and threaded trocar drill guide can be used with the drill bits from the transbuccal module.

Option 3—Universal drill guide Instruments

Optional instruments

03.503.451 MatrixMANDIBLE 1.5 mm Drill Bit, J-latch, 90 mm, for 03.503.043

03.503.461 MatrixMANDIBLE 1.8 mm Drill Bit, J-latch, 90 mm, for 03.503.044

03.503.471 MatrixMANDIBLE 2.4 mm Drill Bit, J-latch, 90 mm, for 03.503.046

323.204 2.0 mm/2.4 mm Universal Drill Guide

Note: This option should only be used if there is a change to the patient anatomy or surgical plan that requires a deviation from the angulation planned during the Case Preparation step.

The universal drill guide may be used when good visualization is available.

If using a locking screw, align the drill guide coaxial to the plate hole.

Note: Drill bits with mini quick coupling are also available.



9

Measure screw length (Optional)

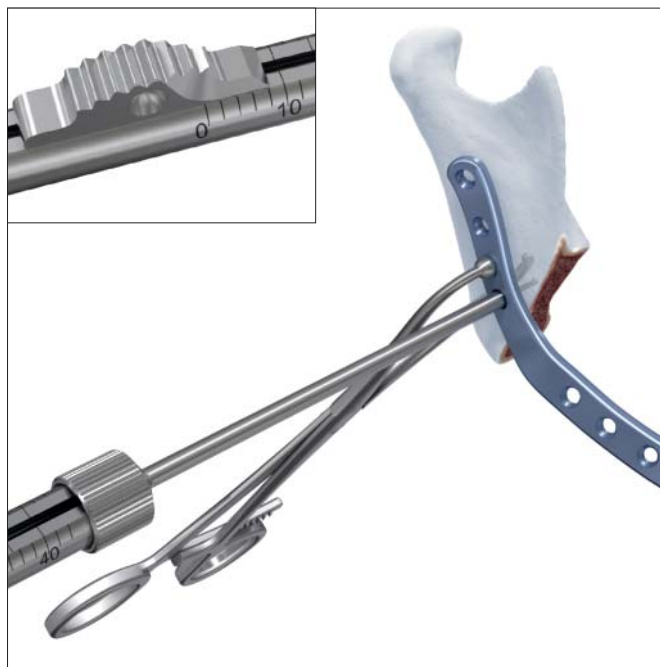
Instrument

03.503.036 MatrixMANDIBLE Depth Gauge

The PROPLAN CMF Case Report may include suggested screw length. Screw length provided is approximate.

Surgeons will make the determination of the final screw length to be used in the procedure.

If required, determine the appropriate screw length using the depth gauge.



10

Apply bone graft¹

A vascularized or non-vascularized bone graft may be applied for a primary reconstruction. The Patient Specific Plate for Mandible may bridge continuity defects without bone graft temporarily, prior to a secondary reconstruction.*

If PROPLAN CMF Surgical Guides are used, the PROPLAN CMF Instructions for Use and PROPLAN CMF Case Report must be used as a reference for placement of the surgical guides at the graft harvest site.



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

*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.

11

Insert screws

Instruments

03.503.070	MatrixMANDIBLE/ MatrixRIB Self-Retaining Screwdriver Blade, short
03.503.071	MatrixMANDIBLE/ MatrixRIB Self-Retaining Screwdriver Blade, medium
03.503.072	MatrixMANDIBLE/ MatrixRIB Self-Retaining Screwdriver Blade, long
311.004*	Fixed-Swivel Screwdriver Handle
311.007	Screwdriver Handle with hex coupling, large
311.023	Ratcheting Screwdriver Handle

Insert the proper length locking or nonlocking screw through the plate and into the hole closest to the fracture or planned osteotomy site in the proximal segment. Tighten the screw until secured.

Note: For maximum stability, locking screws are recommended. Use nonlocking screws if a bone fragment must be repositioned by pulling it against the plate, or if 10-15° of screw angulation is needed.

If using the 2.0 mm cannula, remove the drill guide, then insert the self-retaining screwdriver with the screw engaged on the blade.

Technique tip: To engage the screw on the blade, align the blade over the cruciform recess and slowly rotate it counterclockwise until the blade drops into the recess. Firmly press the blade to fully seat it into the screw. Gently rocking the engaged screwdriver facilitates the removal of the screwdriver blade.



12

Drill and place remaining screws

Insert the second screw on the opposite side of the planned resection or fracture, following the previously described procedure.

Insert all remaining screws, alternating to each side of the resection or fracture. Securely tighten all screws unless resection is to follow. Apply additional fixation as desired.



Alternate Technique

1. Expose and reduce the mandible
2. Position the plate
3. Select screws
4. Drill screw holes
5. Insert screws
6. Once the plate is in place, remove the plate and screws, taking note of each screw's placement.
 - The screw caddy provided in the instrument tray can be used for this purpose.
7. Resect the mandible
8. Apply the bone graft to the plate
9. Replace the implants
 - Place the plate back onto the mandible in its original position.
 - Reinsert each predetermined screw. Check all screws to ensure a secure fit in the plate.

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.



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