

TRUMATCH[®] Orthognathics

Surgical Technique

 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyshes.com/hcp/reprocessing-care-maintenance>

Table of Contents

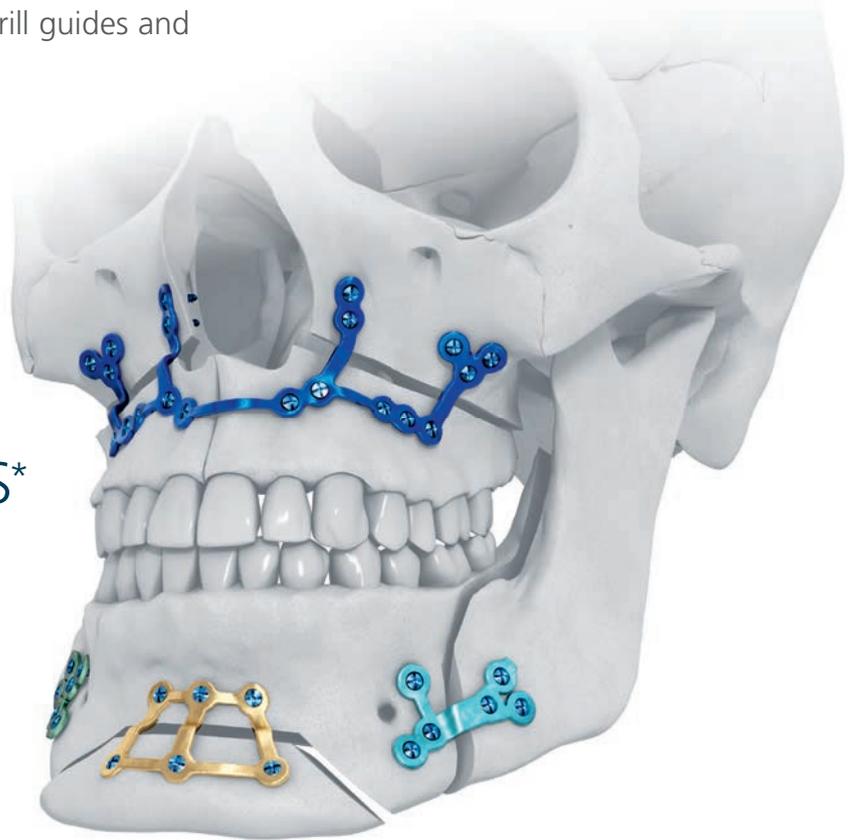
Introduction	TRUMATCH Orthognathics	2
	AO Principles	6
	Indications and Contraindications	7
	Introduction to the system	9

Surgical Technique	Maxillary / Le Fort I Plate Fixation	12
	Sagittal Split Fixation – BSSO Plates	19
	• Option 1: Splintless	20
	• Option 2: Splint control	29
	Genioplasty – Chin Plates	38

TRUMATCH® Orthognathics

TRUMATCH® Orthognathics is a guided system which helps address the challenge of vertical maxillary positioning in complex asymmetric cases. The combination of Titanium 3D-printed patient-specific osteotomy/drill guides and personalized plates supports:

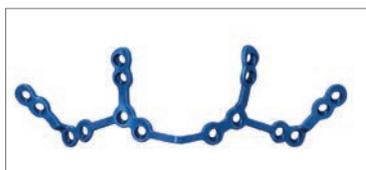
- the accurate transfer of the surgical plan to the operating room¹
- reducing the need for splints and plate bending¹
- avoiding vital anatomical structures and define best available bone volume for screw placement¹.



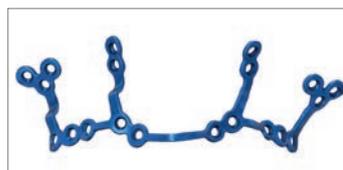
TI 3D-PRINTED PLATES*

Individually designed to meet the needs of each patient and surgeon.

Le fort I Plates



In line hole pattern
2+2 hole design



Mixed design and patterns



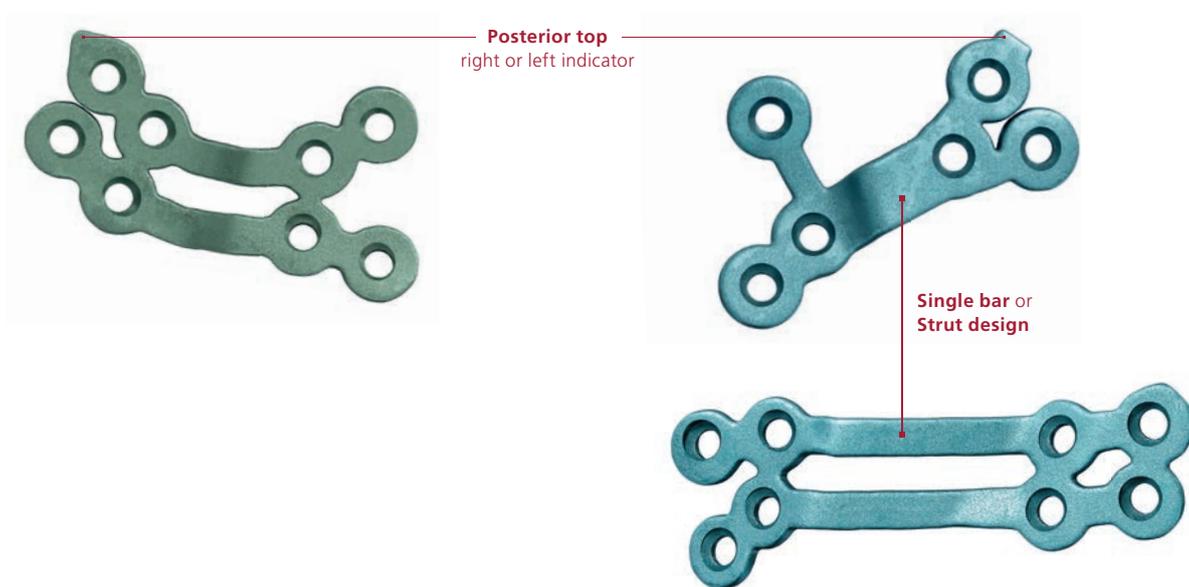
3+3 hole design
Clover leaf hole pattern

¹ Heufelder M., Wilde F., Pietzka S. Clinical accuracy of waferless maxillary positioning using customized surgical guides and patient specific osteosynthesis in bimaxillary orthognathic surgery. J. Cranio-Maxillo-Fac. Surg. 2017;45:1578. Results from case studies are not predictive of results in other cases. Results in other cases may vary.

* Manufactured by Materialise

- Intended to be used in combination with the Ti 3D printed guides
- Screw locations and vectors are based on surgical access, bone volume and the avoidance of anatomy (nerves, tooth roots)
- Color coded with matching guides to help improve communication in the OR
- Anatomic markers help enable correct placement of guide by indexing to bony anatomy
- LeFort I Plates: 0.8 to 1.5 mm thickness, compatible with MatrixORTHOGNATHIC™ Screws and MatrixMIDFACE™ Screws*
- BSSO Plates: 1.0 – 1.5 mm thickness, compatible with MatrixORTHOGNATHIC™ Screws*
- Genioplasty Plates: 0.8 – 1.5 mm thickness, compatible with MatrixORTHOGNATHIC™ Screws*

BSSO Plates



Genioplasty Plates



*For Information on the screws and drill bits, refer to the MatrixORTHOGNATHIC™ System and MatrixMIDFACE™ System labeling for applicable Indications, Contraindications, Warnings, and Precautions, and Instructions for Use.

TI 3D-PRINTED SURGICAL GUIDES*

Designed to assist with osteotomies and to accurately transfer the virtual surgical plan to the surgical site.

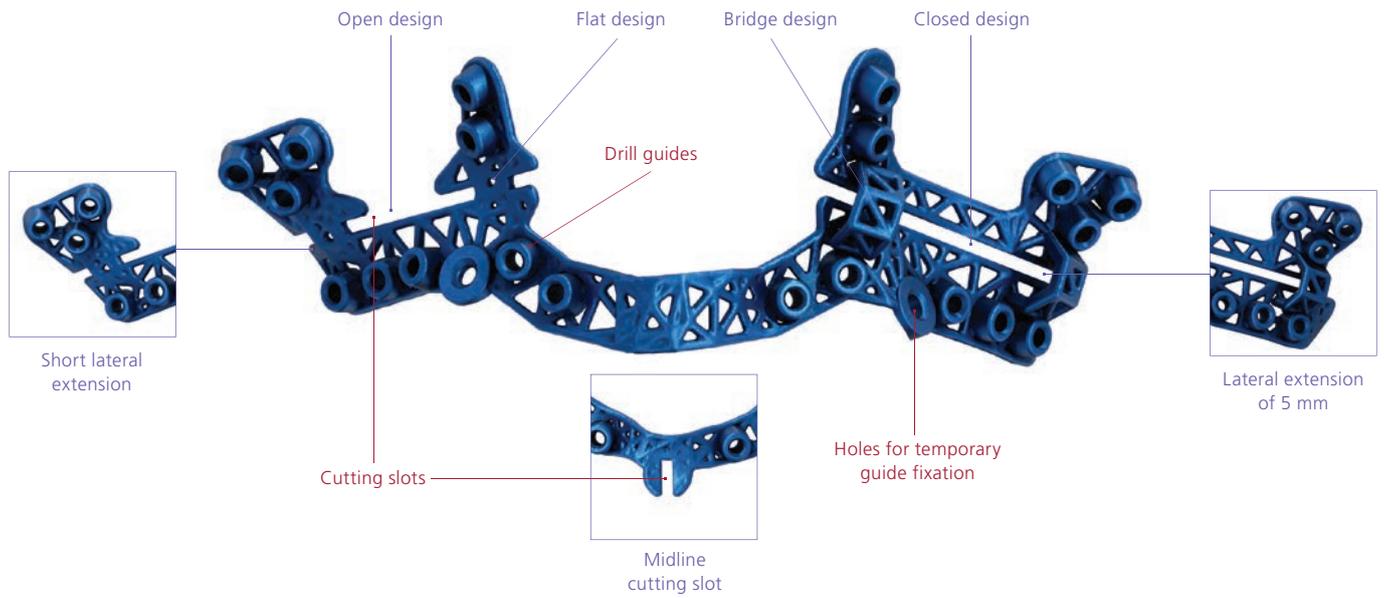
- Intended to be used in combination with the Ti 3D printed plates
- Design integrates the planned osteotomies, pilot hole locations and drilling vectors
 - Cutting slots to guide the osteotomies, designed based on surgeon's preference
 - Drilling locations and vectors defined based on surgical access, bone volume and the avoidance of anatomical obstacles (nerves, tooth roots)
- Temporary fixation holes
- Color coded to the matching plates
- Anatomical markers to facilitate correct guide placement
- Designed and validated for compatibility with MatrixORTHOGNATHIC™ and MatrixMIDFACE™ screws and drill bits**



* Manufactured by Materialise

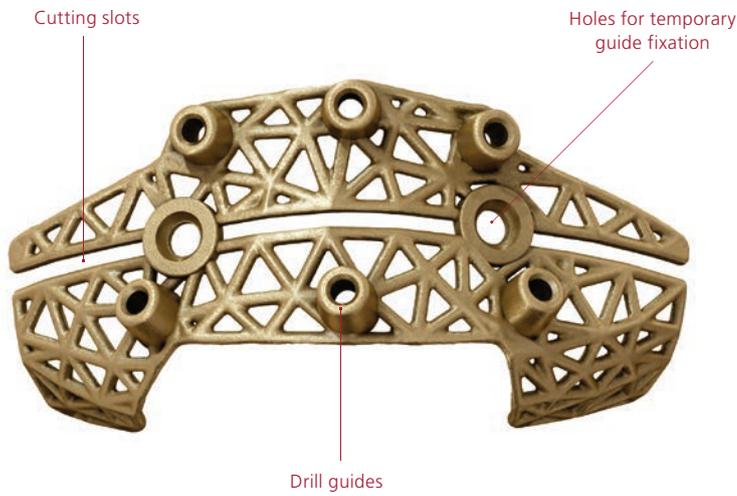
** Test data on file at DePuy Synthes. PSPO Validation Report #0000250338

Le Fort I guide

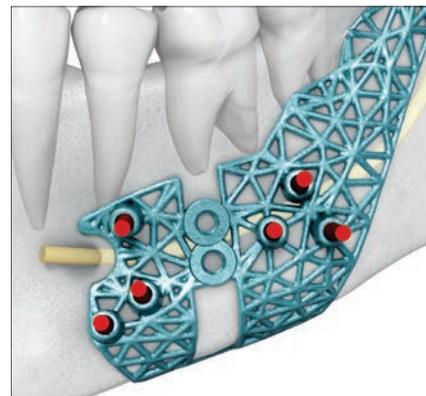
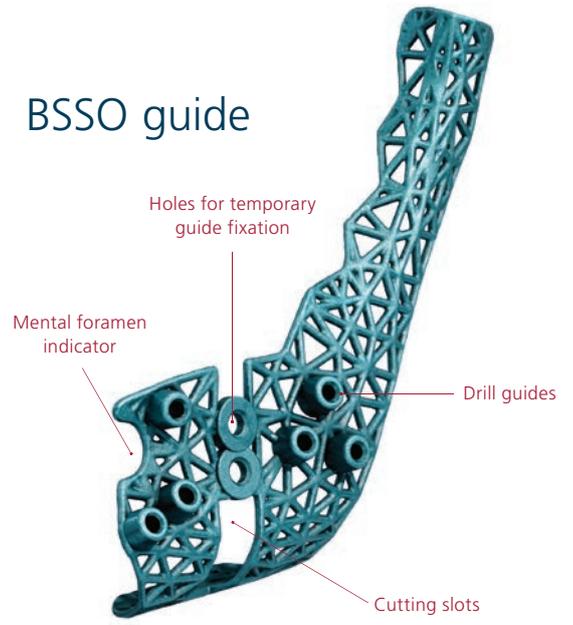


■ Features ■ Design Options

Genioplasty guide



BSSO guide



Screw vectors and position defined to avoid anatomical obstacles

AO Principles

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.^{1,2}

Anatomic reduction

Fracture reduction and fixation to restore anatomical relationships. The patient specific guides and plates offer the ability to address most simple and complex fixation needs.

Stable fixation

Stability by rigid fixation or splintage, as the personality of the fracture and the injury requires. The TRUMATCH Orthognathics system is optimized to achieve stable bone fixation.

Preservation of blood supply

Preservation of the blood supply to soft tissue and bone by gentle reduction techniques and careful handling.

Early, active mobilization

Early and safe mobilization of the part and patient. The TRUMATCH Orthognathics system, combined with AO technique, provides stable fixation enough to allow a functional aftercare.

¹ Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin Heidelberg New York: Springer. 1991.

² Rüedi TP, RE Buckley, CG Moran. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

Intended Use, Indications, Contraindications, Warnings/Precautions, General Adverse Events, Device Specific Adverse Events, MRI Information

Indications

The TRUMATCH CMF Titanium 3D Printed Guides and Plates consist of osteotomy and/or drilling patient specific guides and patient specific plate. TRUMATCH CMF Titanium 3D Printed plates are intended for bone repositioning surgical operations for different indications:

- Orthognathic surgery (Le Fort I osteotomy, bilateral sagittal split osteotomy, genioplasty, subapical osteotomy)
- Trauma reconstruction (secondary osteotomy and repositioning of the zygoma)
- Reconstruction surgery

Contraindications

- Smoking,
- Bad quality or insufficient bone tissue, or blood circulation issues,
- High sensitivity to Titanium materials,
- The presence of active or latent infections,
- Pregnancy.

The following conditions may be associated with an increased risk of failure:

- Doubt on the reliability of patient's anatomical scan, as the scan data may not guarantee that a patient's anatomy is accurately represented,
- Mental or neurological health troubles making the patient unable to accept or to follow postoperative precautions.

Warnings

- **The user should be aware of possible allergic reactions to materials used in the guides, plates or implants. The patient should be informed on this matter by the user.**
- **We do not recommend altering of the surgical guides or implants. Altering the size of plates, guides or implants may result in an inadequate fit to the patient's anatomy. It is the sole responsibility of the surgeon if the guide, plate or implant is altered in any way prior to, or during, surgery.**
- **Do not attempt to reuse or recondition the guides, plates and implants.**
- **TRUMATCH CMF Titanium 3D Printed Guides,**

Plates and Implants are to be used by a trained physician in the performance of surgery.

- **Be aware that these patient specific guides, plates and/or implants have been manufactured based of CT scans of the patient. If the patient's anatomy has changed significantly since the time of the CT scan, the guides, plates and implants should not be used.**
- **The guides, plates and/or implants should be properly cleaned before sterilization. Do not use if they are broken, cracked, or are visibly contaminated.**
- **The guides, plates and/or implants in this package are provided non-sterile. The guides, plates and/or implants in this package must be sterilized prior to use in surgery.**

Precautions

Pre-operative precautions:

- Do not apply excessive force on the guides, plates or implants, or place heavy objects on top.
- Perform a visual check of the guides, plates and/or implants in order to detect any sign of deterioration. Guides, plates and/or implants must not be in contact with objects that could affect the surface. In case of damage or defect, do not use the devices during surgery.
- Do not re-use after accidental dropping.

Intra-operative precautions:

- Do not apply force during screw placement as this could damage the plates and implants.

Post-operative precautions:

Warn the patient of the postoperative precautions to take to ensure an optimal treatment outcome:

- Treat quickly and effectively any infection even benign due to haematogenous risk of contamination.
- Be attentive to any sign of pain at the implantation site.
- Monitor the patient in accordance to the frequency and protocol defined by the surgeon.
- Avoid any stress of the plate/implant in order to avoid mechanical problems.

A decision to remove TRUMATCH CMF Titanium 3D Printed Plates or Implants must be determined by the surgeon. Do not re-use or replace guides, plates and/or implants in their initial packaging after they have been in contact with the patient.

Possible Adverse Effects

- Insufficient bone reconstruction, osteolysis, osteomyelitis, osteoporosis, inhibited revascularization or infection that may result in deformation or implant failure,
- Delayed or insufficient fracture healing that may cause implant failure,
- Pain, discomfort, abnormal sensation related to the implant,
- Sensitivity to material or allergic reaction to foreign body, infections.

Surgical technique may contribute to adverse effects independent from the guides, plates or implants.

The patient specific plates and implants are designed to fit the individual patient's anatomy. Consequently, if it is not possible to place and to maintain the plate and/or implant in the position defined during the pre-operative phase, the planning transfer cannot be guaranteed.

Magnetic Resonance Environment

- The patient must be informed that implants can affect the results of Computer Tomography or Magnetic Resonance Imaging (MRI) scans.
- The TRUMATCH CMF Titanium 3D Printed guides and plates have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefact in the MR environment. The safety in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Introduction to the System

TRUMATCH Orthognathics is a versatile system that can be used for Le Fort I, BSSO, genioplasty or any combination of them. The procedure can be performed fully with TRUMATCH Orthognathics, or in combination with standard MatrixORTHOGNATHIC, MatrixORTHOGNATHIC LOCK, MatrixMIDFACE or MatrixMANDIBLE (e.g. Le Fort I with patient specific plates and guides and BSSO with MatrixORTHOGNATHIC mandible plates). Some examples for the use of TRUMATCH Orthognathics are shown below.



Workflow overview

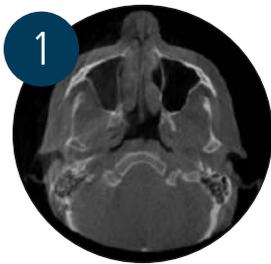
The workflow starts with the uploading of the CBCT/CT to the PROPLAN CMF Online platform. Scanning should be done using the recommendations from the TRUMATCH CMF Scan protocol available from DePuy Synthes. Depending on how the occlusion will be defined, digitally or traditionally, intraoral scans or scans of the dental casts (individual and in final occlusion) will also be uploaded on the same platform. Alternatively, dental casts can be mailed for scanning.



The image data sets are prepared (cleaned, segmented, merged), followed by a live interactive planning session with a Clinical Engineer. During this session the osteotomies are planned and executed under the instructions and the supervision of the surgeon. Detailed plate and guide design preferences as well as desired position are collected during this session.

A detailed report of the case is sent later to the surgeon for final review and approval of the plates and guides. The case report, as well as 3D visualizations are also made available for detailed review in PROPLAN CMF Online, linked to the patient case.

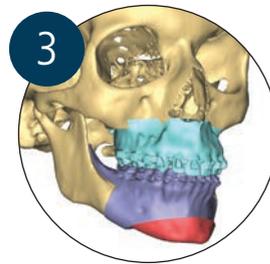
Only once the plates and guides designs are formally approved by the surgeons, the manufacturing commences, followed by their shipment directly to the hospital or via the local DePuy Synthes affiliate.



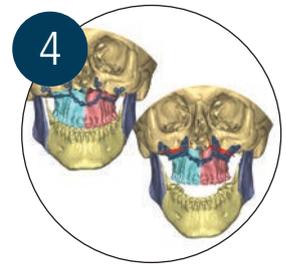
CT Scan patient/
Request for Service



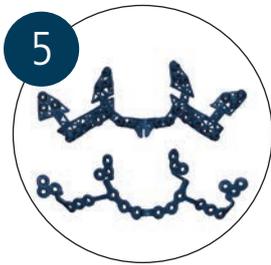
Interactive
virtual planning



Approve plan, plates and
guides preferences



Design plate
and guides



Approve plate
and guides



Manufacture



Deliver plate, guides, models, splints

The CT Scan

- The scan should be taken with the condyles fully seated in the glenoid fossa, the most retracted occlusal position (i.e. centric relation).
- An occlusal registration should be used at the time of scanning (e.g. wax bite).
- The TRUMATCH CMF Scan protocol should be used to ensure 3D images are according to the minimum requirements needed to accurately design the plates and guides

The planning session

During the planning session, the surgical approach is verified with the surgeon. Based on this response, the amount of dissection which is needed to place the guide and implant is assessed.

The planning session is key for communicating design instructions relative to the guides and plates.

When providing instructions for the plate and guide design, please consider:

- That a too anterior lateral cut could make the drilling and inserting of the screws in the anterior holes more difficult
- That a too posterior lateral cut could make the drilling of the posterior holes more difficult. The use of a 90-degree screwdriver or transbuccal set shall be considered in this situation.
- Including a mental foramen landmark in the BSSO guide can improve the accuracy of the anterior/posterior position of the guide
- Using the oblique line region to lock the BSSO guide in vertical position
- Registering the BSSO guide around the inferior border to improve the stability and unique fit of the guide
- The cutting tool you plan to use (e.g. saw blades, piezo tips, burs, etc.) which will allow for the tailoring of the width of the cutting slot in the guide.

The bone thickness, accessibility (surgical approach) and vital structures (inferior alveolar nerve and teeth roots) are also taken into consideration to determine the screw position and therefore the size of the implant.

Splint considerations

- An occlusal splint is not necessary for the positioning of the maxilla
- Depending on the confidence with the correct position of the condyles during the patient scanning and during the planning session, two options can be used for the BSSO technique:
 - Option 1 – Splintless
 - Option 2 – Splint control
- Option 1 is recommended for users who have developed a protocol that allows a high level of confidence relative to the correct position of the condyles in the virtual plan used to design the plates and guides
- Option 2 allows confirmation of accuracy in cases with maxillary impaction, segmental osteotomies, and/or cases where there is a lack of confidence relative to the correct position of the condyles in the virtual plan used to design the plates and guides.
- For segmental maxillary osteotomies, a final splint can be considered for increased stability. The splint can remain wired to the maxilla in addition to the maxillary plate during the BSSO procedure.
- Higher accuracy can be achieved if an intermediate splint is used to check for interference, in cases of posterior impaction and when used in combination with BSSO patient specific plates and guides

The case reports

The case report contains a detailed overview of the pre-op positions, surgical plan, cephalometric analyses, soft tissue movement, splint, guides and plate design. The report provides detailed information on osteotomies orientation, bone removal, bony interferences, movement values which are very useful for consultation prior and during the surgery. The report also provides the complete information on the planned screws for guides and plates fixation.

Important

- **Refer to the Case Report provided with the TRUMATCH CMF Titanium 3D Printed Guides, Plates and Implants to place the implant according to the pre-operative planning (type and size of screw to use).**
- **TRUMATCH CMF Titanium 3D Printed Guides, Plates and Implants must be placed respecting aseptic conditions.**
- **The device must be placed by the surgeon who has validated the planning and the design of the custom-made devices pre-operatively.**
- **For surgical approaches, please refer to the AO surgical reference (www.aosurgery.org)**

Maxillary / Le Fort I Plate Fixation

1

Place maxillary guide

Place the maxillary guide on the exposed maxilla
Guide will fit the bone without applying force.

Hold the guide in place.

Check all around and through the guide that no periosteum or other soft tissue is entrapped.

If the guide does not fit the bone, extend the dissection where remaining periosteal/muscular attachment may be interfering (often gingiva on the lower maxillary midline, masseter insertions laterally).



2

Attach maxillary guide

Instrument(s)

03.503.201/
202/203 Screwdriver Shafts MatrixMIDFACE,
self-holding, with Hexagonal Coupling,
lengths 52/76/96 mm

Drill the guide attachment holes. The attachment holes can be distinguished by their flat flange design.

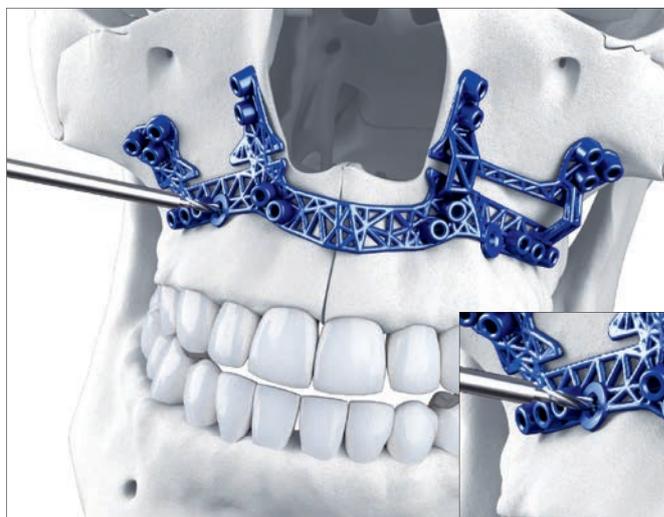
Insert the screws.

If more than 2 fixation holes were designed, insert medial screws first, then the lateral ones.

Check again all around and through the guide to ensure that no periosteum/soft tissue is entrapped.

Notes

- Use a 1.4mm drill bit with stop for 1.85mm screws
- Use a drill bit with the stop equivalent with the screw length (e.g. 6mm drill bit with stop for 5 and 6mm long screws)
- Use self-tapping screws



3 Predrill plate holes

Predrill all plate fixation holes. These holes will be used for the final implant positioning.

Keep the drill parallel to the drill cylinders following the designed and planned direction.

Notes

- No specific order is required, but drilling in sequence helps to ensure they were all pre-drilled
- Predrilling posteriorly on the buttresses first allows visualization of potential soft tissue interferences
- Use a 1.4mm drill bit with stop for 1.85mm screws
- To compensate for the height of the drilling cylinders, the drill bit length is obtained by adding 2mm to the screw length (e.g. 8mm drill bit with stop for 5 and 6mm long screws).

Precaution: Always irrigate during drilling to avoid thermal damage to the bone.



4 Mark/perform osteotomies

Consult the case report to visualize the cutting planes and their orientation.

Mark or perform partial cuts with the guide in place, then remove the guide.

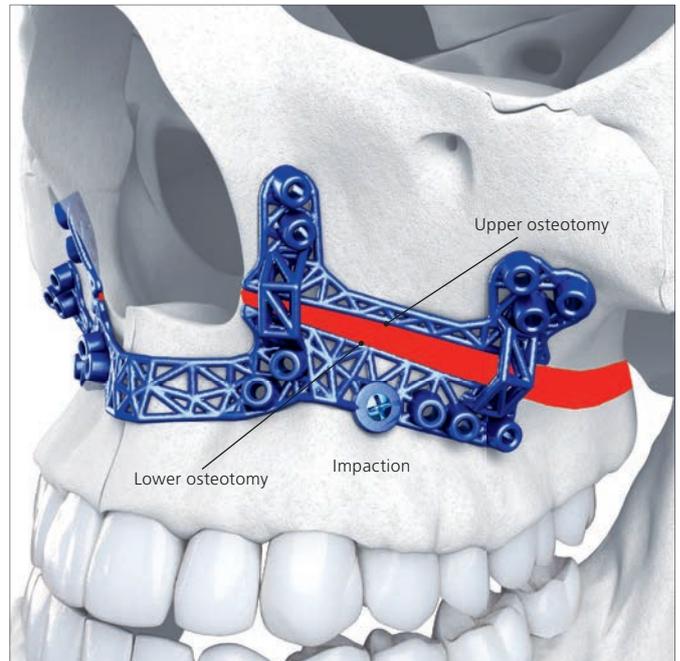
For maxillary segmentation, use the guide to mark the planned vertical osteotomy/ies.

For planned bone excision, ensure both the upper and lower (or left and right for vertical) osteotomies have been marked with the guide.

Ensure all osteotomies have been marked or cut along the entire length of the guide.

Remove the guide attachment screws.

Remove guide.

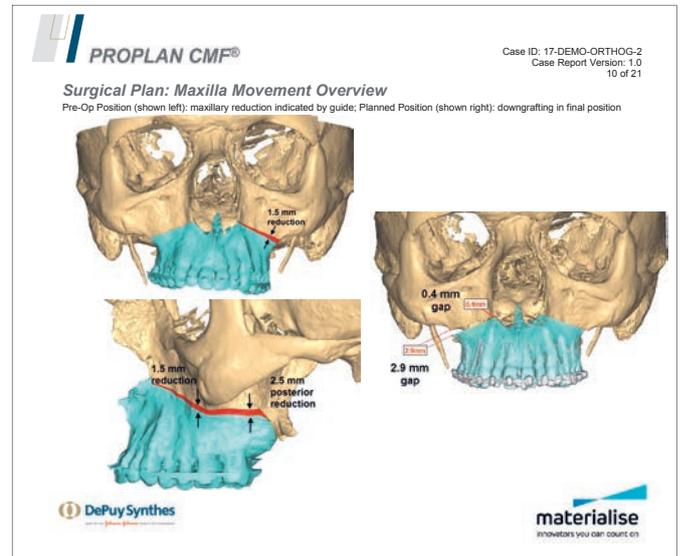


5 Complete osteotomies

Complete Le Fort I osteotomy and down fracture.

Remove all interferences.

Tip: Consult the case report to visualize the cutting planes, their orientation and regions with interferences.



6 Place and attach plate to the mobile segment

Instrument(s)

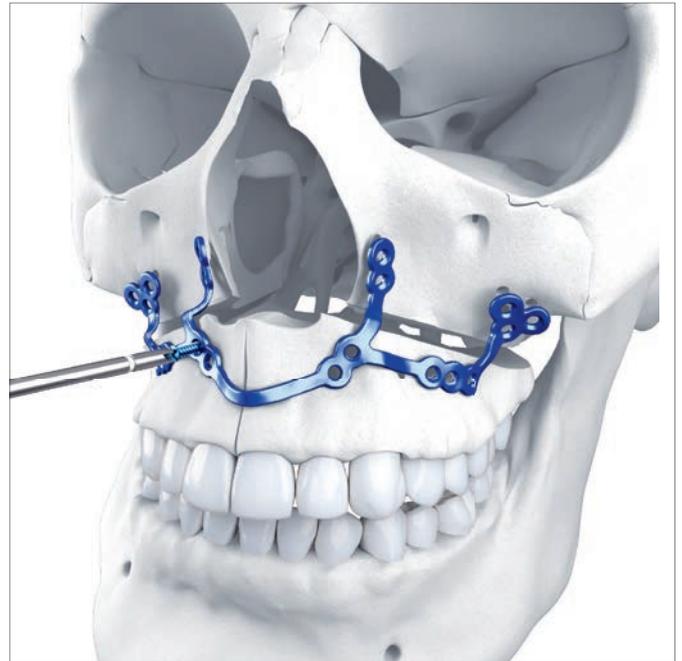
03.503.201/ 202/203	Screwdriver Shafts MatrixMIDFACE, self-holding, with Hexagonal Coupling, lengths 52/76/96 mm
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If an anatomic model was ordered, double check the implant against it to ensure the plates has not been deformed during the reprocessing.

Place plate on the mobile segment first, aligning the plate holes with the predrilled holes.

Fixate the implant on the mobile segment first
Insert all screws alternating sides, going from medial to most lateral.

Tip: In case of impaction, consider inserting only one screw closest to osteotomy in each of the four buttresses, then check the passive fit of the plate with the immobile segment to be certain the pre-drilled holes are in alignment with the plate holes. If they are not, then usually this indicates interference, and one may need to remove the plate from the mobile segment and address these.



7 Check for interferences

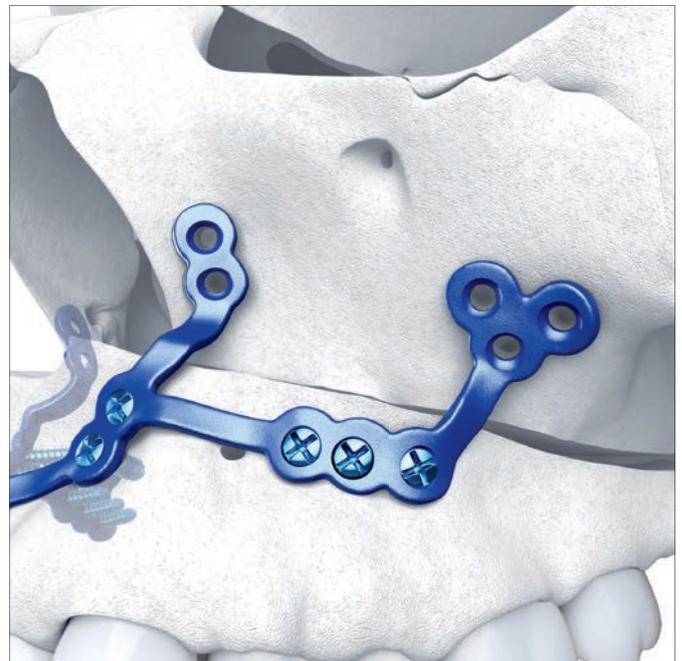
Position mobile segment and implant to the upper mid-face and hold the construct.

Plate shall fit on the bone in all regions and plate holes shall align with predrilled holes.

If this is not the case, check for potential bone interferences, usually in the posterior regions; consult the case report to help identifying these regions.

Do not force the plate for fitting, keep removing interfering bone until the plate fits.

Tip: If desired, an intermediate splint can be used to check for interferences in cases of posterior impaction when combined with BSSO patient specific implants. This splint does not need to be wired.



8 Attach plate to the upper midface

Instrument(s)

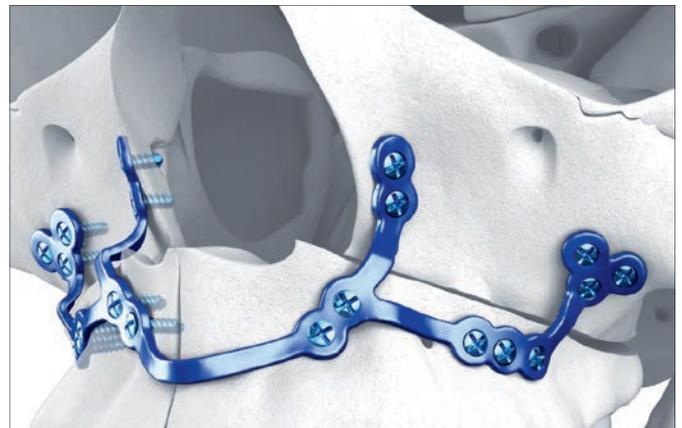
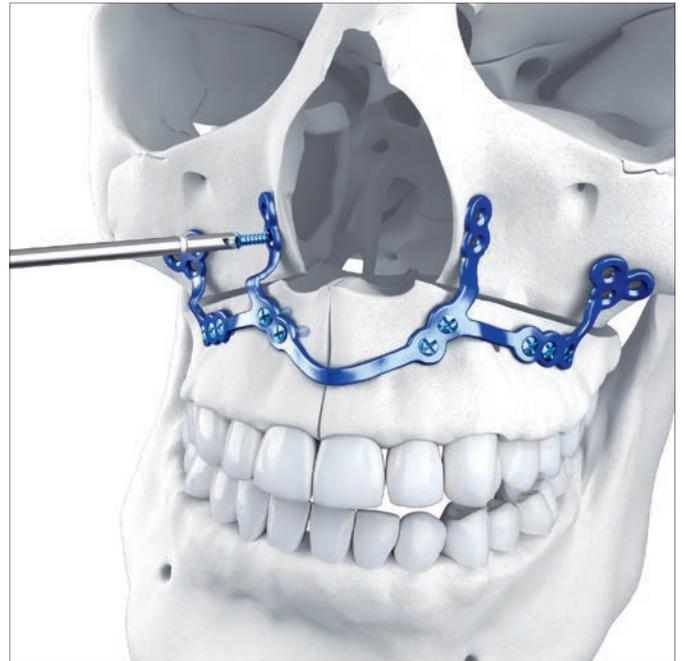
03.503.201/
202/203 Screwdriver Shafts MatrixMIDFACE,
self-holding, with Hexagonal Coupling,
lengths 52/76/96 mm

Fixate one screw in the predrilled holes of each of the 4 pillars, alternating sides.

Check if it's a passive fit and correctly positioned
Place remaining screws.

Precaution: Ensure from this point forward that retractors or bite-gags do not put pressure on the positioned maxilla to avoid implant deformation and displacement.

Tip: For segmental maxillary osteotomies, a final splint can remain wired to the maxilla in addition to the maxillary plate for increased stability of the maxillary segments. The splint is left in place during the BSSO procedure. If the BSSO will be performed using patient specific plates and guides, then follow the “splint control” technique described in the “BSSO” section of this guide.



Sagittal Split Fixation – BSSO Plates

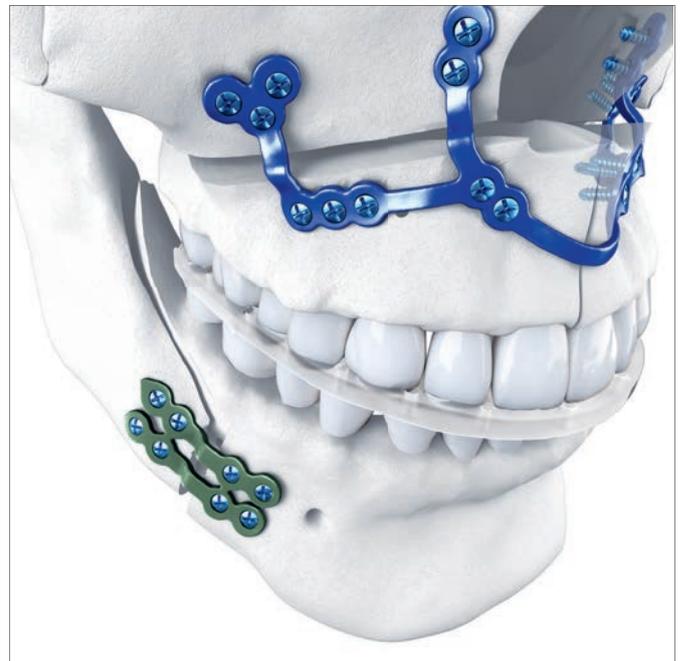
Introduction

Depending on the confidence with the correct position of the condyles during the patient scanning and during the planning session, two options can be used for the BSSO technique:

- Option 1 – Splintless
- Option 2 – Splint control

Important:

- **Option 1 is recommended for users who have developed a protocol that allows a high level of confidence relative to the correct position of the condyles in the virtual plan used to design the plates and guides**
- **Option 2 allows confirmation of accuracy in cases with maxillary impaction, segmental osteotomies, and/or cases where there is a lack of confidence relative to the correct position of the condyles in the virtual plan used to design the plates and guides.**



BSSO Option 1: Splintless



1 Attach guide

Instrument(s)

03.503.201/
202/203 Screwdriver Shafts MatrixMIDFACE,
self-holding, with Hexagonal Coupling,
lengths 52/76/96 mm

Place one mandible guide on the bone and ensure ideal fit. Only start the fixation when the guide contours on the mandible in the exact position outlined in the plan.

Check all around and through the guide to ensure adequate soft tissue stripping and that no periosteum/soft tissue is entrapped.

Drill at least 1 of the 2 guide attachment holes. The attachment holes can be distinguished by their flat flange design.

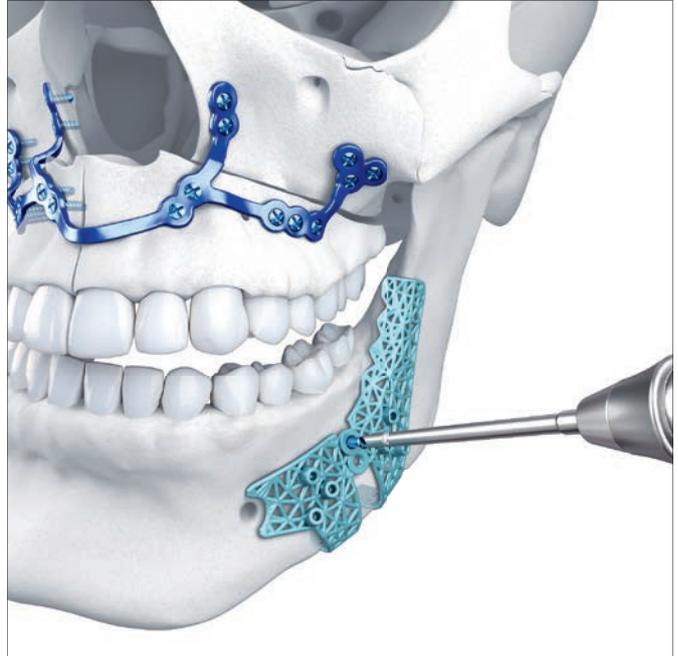
The second hole can provide better contact to the bone if deemed necessary but can also be used as a rescue hole in case guide needs repositioning.

Double check the acceptable fit of the guide all around and through the guide. Reposition the guide using the rescue-fixation hole if needed.

Attach guide with screw(s).

Notes:

- Use a 1.4mm drill bit with stop for 1.85mm screws
- Use a drill bit with the stop equivalent to the screw length (e.g. 6mm drill bit with stop for 5 and 6mm long screws)



2 Predrill posterior plate fixation holes

Predrill at least two posterior implant fixation holes.

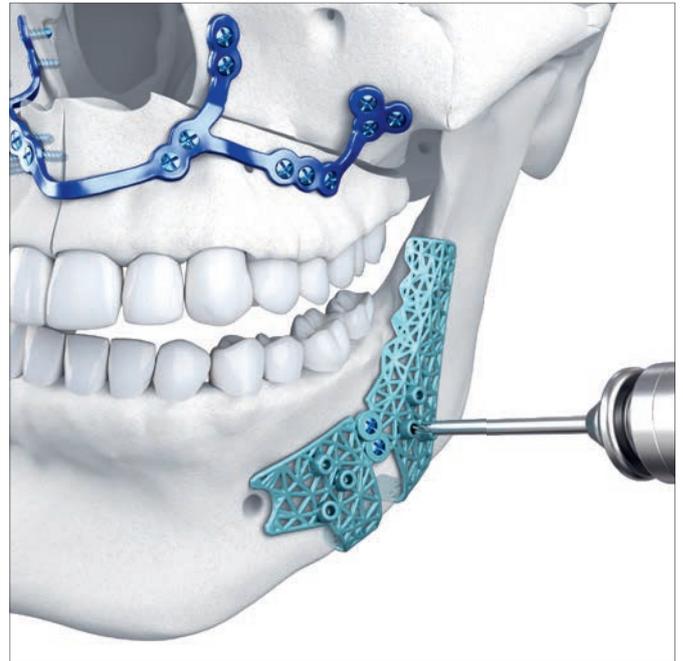
If an intraoral approach is used, predrill at least two of the posterior holes, whichever are the easiest to access intraorally.

The rest of the posterior holes can be drilled through the plate once it is fixated to the mandible, after performing the osteotomy, when it is more mobile and easier to access.

Notes

- Use a 1.4mm drill bit with stop for 1.85mm screws
- To compensate for the height of the drilling cylinders, the length of required stop is given by adding 2mm to the screw length (e.g. 8mm drill bit with stop for 5 and 6mm long screws)

Precaution: Always irrigate during drilling to avoid thermal damage to the bone



3 Predrill anterior plate fixation holes

Predrill at least two of the anterior plate fixation holes.

The rest of the anterior holes can be drilled through the plate once it is fixated to the mandible, after performing the osteotomy.

Notes

- Use a 1.4mm drill bit with stop for 1.85mm screws
- To compensate for the height of the drilling cylinders, the length of required stop is given by adding 2mm to the screw length (e.g. 8mm drill bit with stop for 5 and 6mm long screws)

Precaution: Always irrigate during drilling to avoid thermal damage to the bone



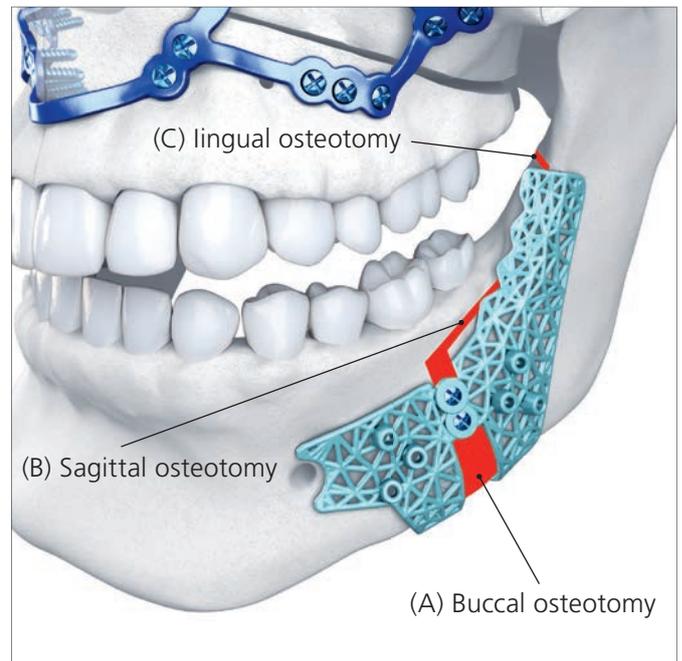
4 Mark/perform osteotomies

Mark the buccal osteotomies (A) with your method of choice (saw, bur, piezo, surgical marker).

The guide can be designed to **mark** the sagittal osteotomy (B) as well as the height of the lingual osteotomy (C).

Remove the guide attachment screws.

Remove the guide.



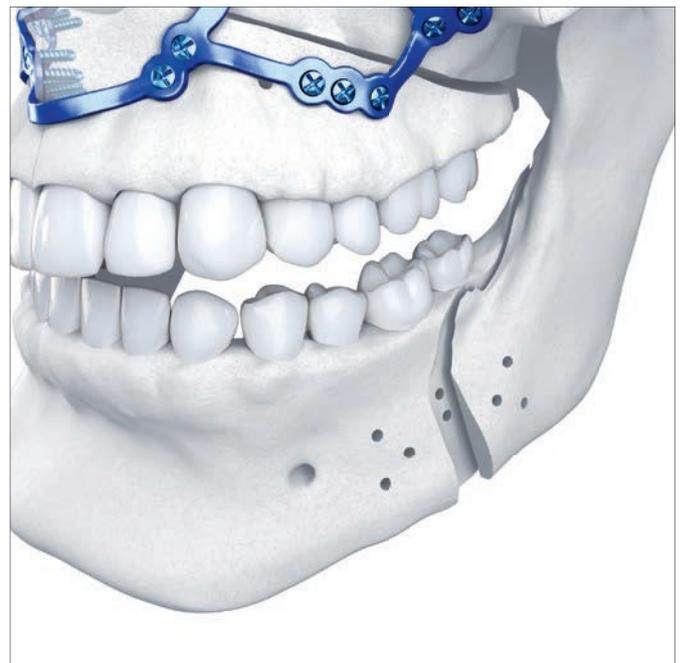
5 Complete osteotomies

Complete the sagittal split osteotomy using your preferred technique.

Fully mobilize the anterior mandible segment.

Tips

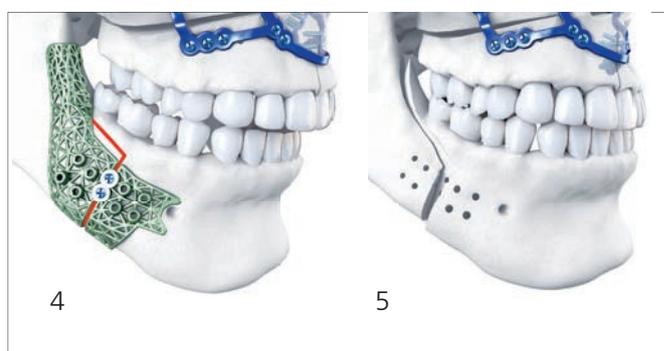
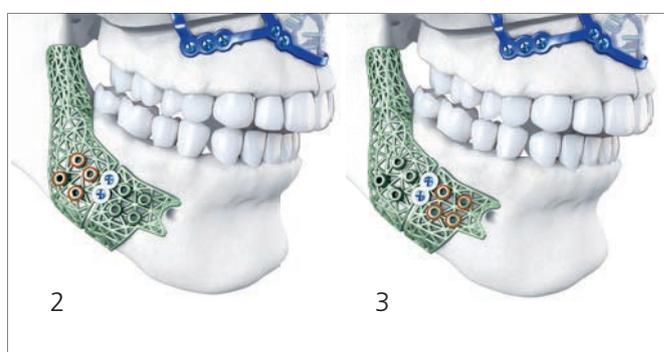
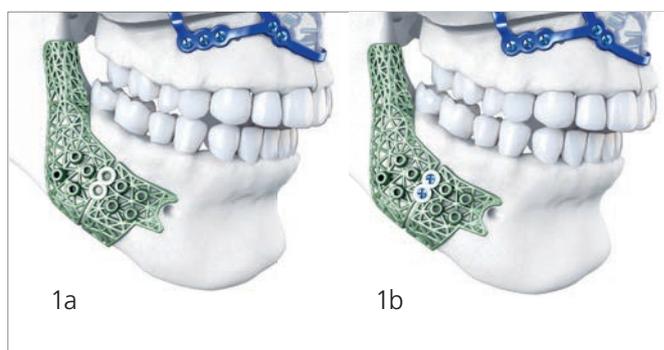
- **When clinical conditions allow, it is helpful to follow the sagittal osteotomy line of the plan as closely as possible. This will give a better prediction of the amount of bony interference to be removed.**
- **As in any osteotomy there may be slight variations during the execution that lead to additional points of interference that must be addressed.**
- **The virtual plan is helpful in showing where the interferences are more likely to occur.**



6 Repeat on the other side

Repeat previous steps on the other side:

1. Attach guide
2. Predrill posterior plate fixation holes
3. Predrill anterior plate fixation holes
4. Mark/perform osteotomies
5. Complete osteotomies



7 Attach plates to posterior segments

Instrument(s)

03.503.201/
202/203 Screwdriver Shafts MatrixMIDFACE,
self-holding, with Hexagonal Coupling,
lengths 52/76/96 mm

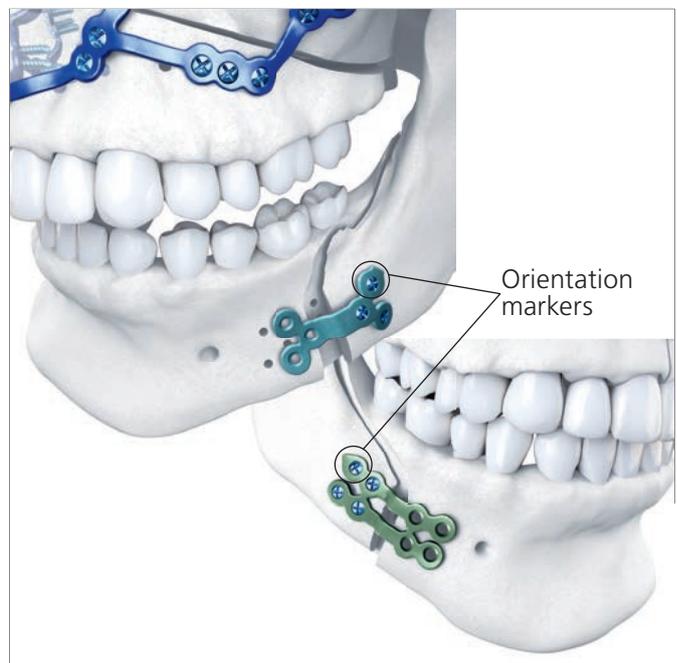
Place the plates on appropriate sides and fixate on the condylar segment only using the predrilled holes.

- Use the case report for a clear identification of the plate and its correct orientation; plates are color coded with their respective guides.
- The superior-posterior holes of each plate have a specific shape that helps identify its orientation.

Reestablish occlusion and check for appropriate alignment of the plate holes with the predrilled holes in the anterior segment. If not check and remove any interference.

Drill holes in the condylar segment that were not predrilled with the guide.

Insert all the screws in the condylar segment.



8 Attach plates to anterior segments

Starting with one side, place the condylar segment in the appropriate position.

The anterior holes of the plate should now line up with the previously drilled holes. If not, check for interferences.

Fixate the plate only using the predrilled holes.

Drill holes in the anterior segment that were not predrilled with the guide, following the planned drilling angulation and using the appropriate drill bit with stop.

Insert all the remaining screws in the anterior segment.



Repeat the process on the contralateral side.



9 Check final occlusion

Check for centric relation.

Malocclusion would require careful reevaluation of all steps to identify the problem.

Most often this is due to abnormal bony contact (i.e. interference) from an osteotomy that may be slightly different from that which was planned. This will require plate removal, identification of the points of interference (lingual, buccal or basal) and removal of any bone excess.

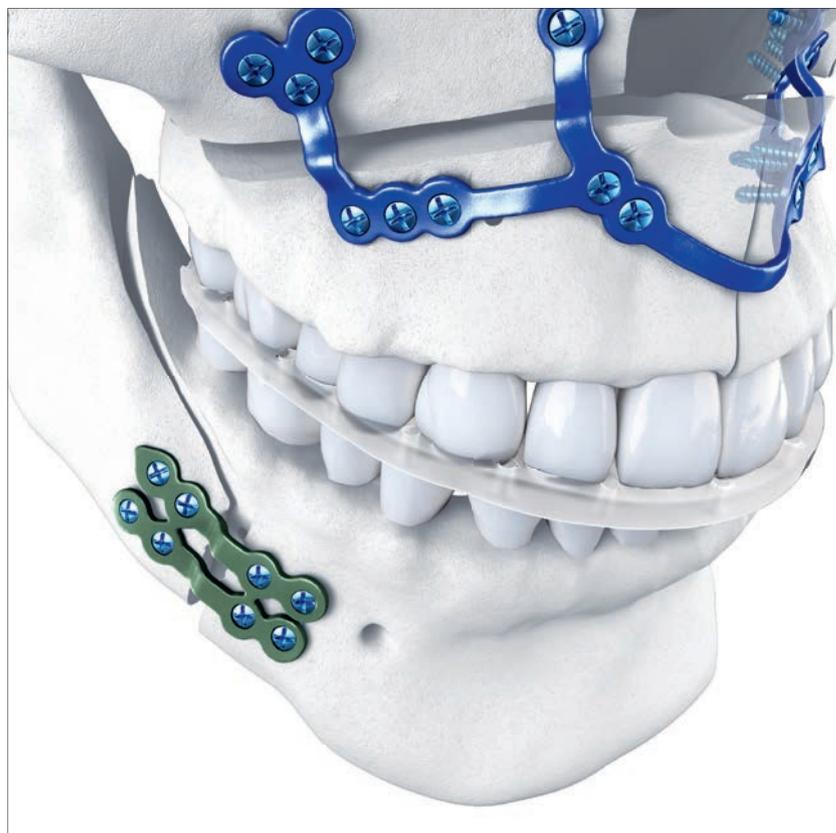
If the final occlusion is still not acceptable, place MMF, position the ramus as done conventionally and fixate condylar segment to the corpus by drilling new holes for the plate.

Inaccuracies in the maxilla due to bone interferences or large movements may also be the source for malocclusion, when combined with BSSO patient specific plates and guides. Solutions might include:

- Removal of the upper maxillary screws and placement of the patient in MMF followed by identification and removal of any remaining bony interferences in the maxilla, followed by reapplication of the plate
- Removal of the entire maxillary plate and placement of the patient in MMF followed by identification and removal of any remaining bony interferences in the maxilla, followed by reapplication of the plate.



BSSO Option 2: Splint Control



1 Attach guide

Instrument(s)

03.503.201/ 202/203 Screwdriver Shafts MatrixMIDFACE, self-holding, with Hexagonal Coupling, lengths 52/76/96 mm

Place one mandible guide on the bone and ensure ideal fit. Only start the fixation when the guide contours on the mandible in the exact position outlined in the plan.

Drill at least 1 of the 2 guide attachment holes. The attachment holes can be distinguished by their flat flange design.

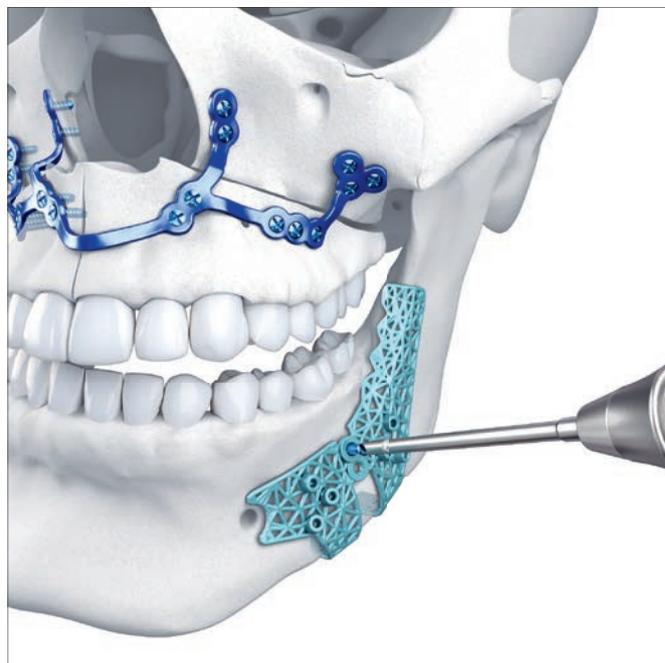
The second hole can provide better contact to the bone if deemed necessary but can also be used as a rescue hole in case the guide needs repositioning.

Double check the acceptable fit of the guide all around and through the guide. Reposition the guide using the rescue-fixation hole if needed.

Attach guide with screw(s).

Notes:

- Use a 1.4mm drill bit with stop for 1.85mm screws
- Use a drill bit with the stop equivalent to the screw length (e.g. 6mm drill bit with stop for 5 and 6mm long screws)



2 Predrill posterior plate fixation holes

Predrill at least two posterior implant fixation holes.

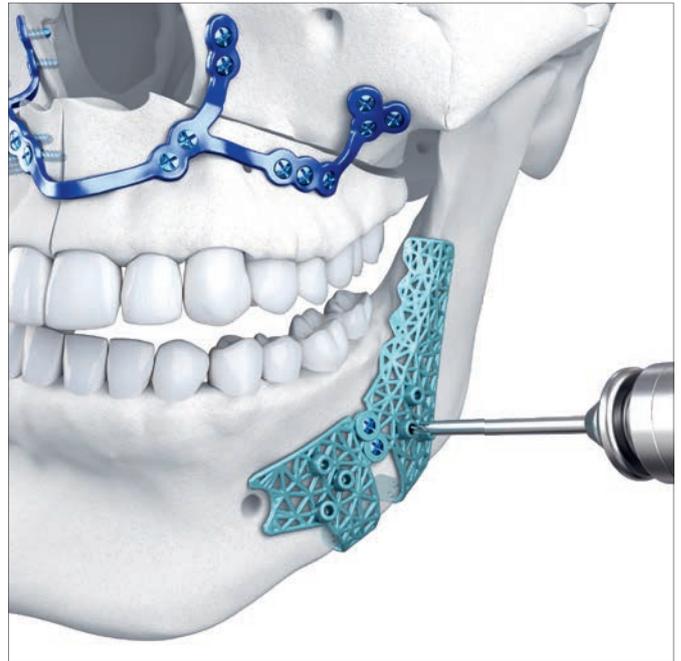
If an intraoral approach is used, predrill at least two of the posterior holes, either the ones closest to the lateral osteotomy, or the superior holes, depending on which are the easiest to access intraorally.

The rest of the posterior holes can be drilled through the plate once it is fixated to the mandible, after performing the osteotomy, when it is more mobile and easier to access.

Notes

- Use a 1.4mm drill bit with stop for 1.85mm screws
- To compensate for the height of the drilling cylinders, the length of required stop is given by adding 2mm to the screw length (e.g. 8mm drill bit with stop for 5 and 6mm long screws).

Precaution: Always irrigate during drilling to avoid thermal damage to the bone



3 Mark anterior plate fixation holes

Only mark the anterior plate fixation holes either using a drill bit or a surgical marker.

Do not drill them completely.

This will allow maximum flexibility with final positioning (with aid of final splint).

Precaution: Always irrigate during drilling to avoid thermal damage to the bone



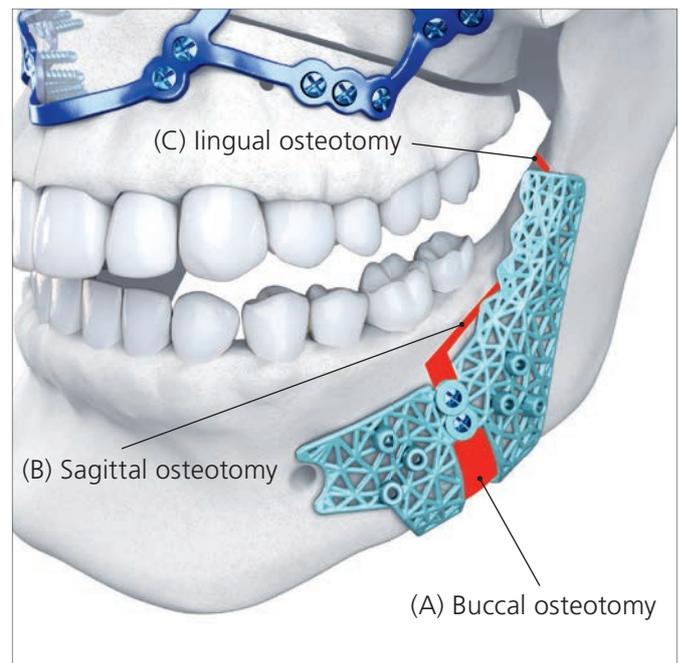
4 Mark/perform osteotomies

Mark the buccal osteotomies (A) with your method of choice (saw, bur, piezo, surgical marker).

The guide can be designed to mark the sagittal osteotomy (B) as well as the height of the lingual osteotomy (C).

Remove the guide attachment screws.

Remove the guide.



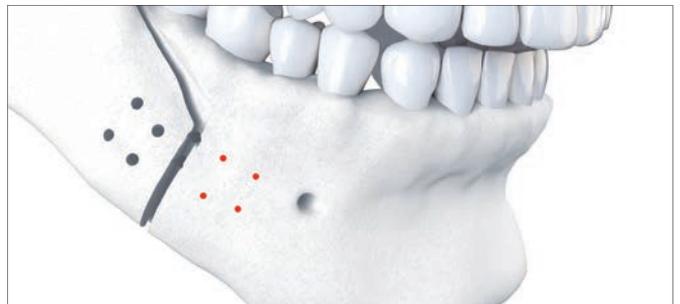
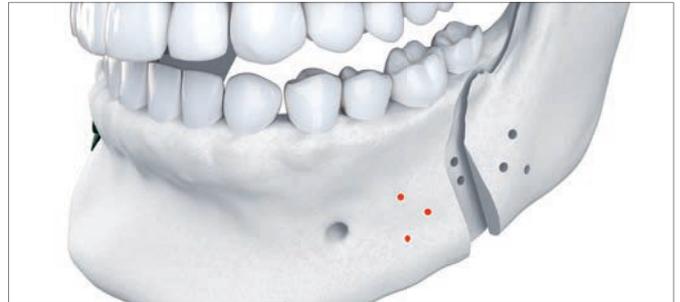
5 Complete osteotomies

Complete the sagittal split osteotomy using your preferred technique.

Fully mobilize the anterior mandible segment.

Tips

- When clinical conditions allow, it is helpful to follow the sagittal osteotomy line of the plan as closely as possible. This will give a better prediction of the amount of bony interference to be removed.
- As in any osteotomy there may be slight variations during the execution leading to additional points of interference that must be addressed.
- The virtual plan is helpful in showing where the interferences are more likely to occur.



PROPLAN CMF® Case ID: 17-DEMO-ORTHOG-2 Case Report Version: 1.0 11 of 21

Surgical Plan: Mandible Movement Overview

5.0 mm overlap, 4.3 mm overlap, 1.9 mm gap, 2.6 mm gap, 1.9 mm gap, 2.6 mm gap, 1.4 mm gap, 0.8 mm reduction

PROPLAN CMF® Case ID: 17-DEMO-ORTHOG-2 Case Report Version: 1.0 16 of 21

Guide Design: Titanium 3D printed Guide for Mandible

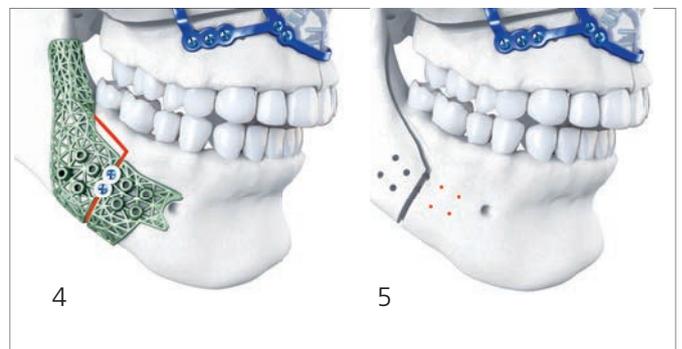
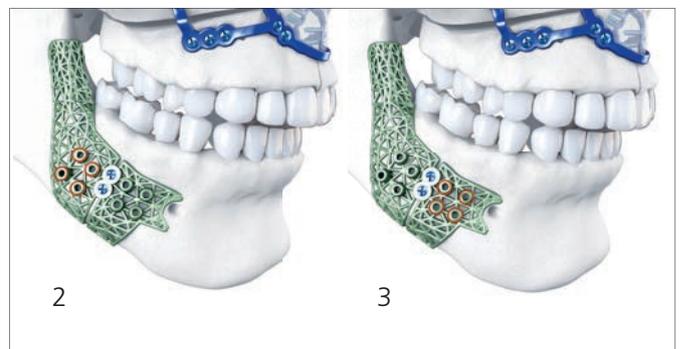
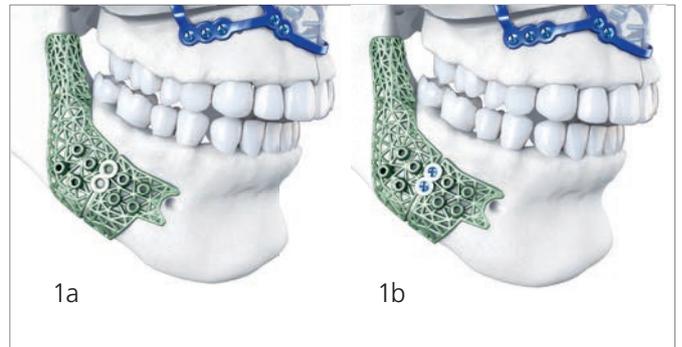
- Fixation hole (temporary fixation of guide): for use with MainORTHOGNATHIC Ø1.85 mm screws -> indicated in grey
- Pre-drill cylinders with angulation control: for use with 1.4/1.5 mm DePuy Synthes drill bits -> indicated in blue

DePuy Synthes **materialise** monitors you can count on

6 Repeat on the other side

Repeat previous steps on the other side:

1. Attach guide
2. Predrill posterior plate fixation holes
3. Mark anterior plate fixation holes
4. Mark/perform osteotomies
5. Complete osteotomies



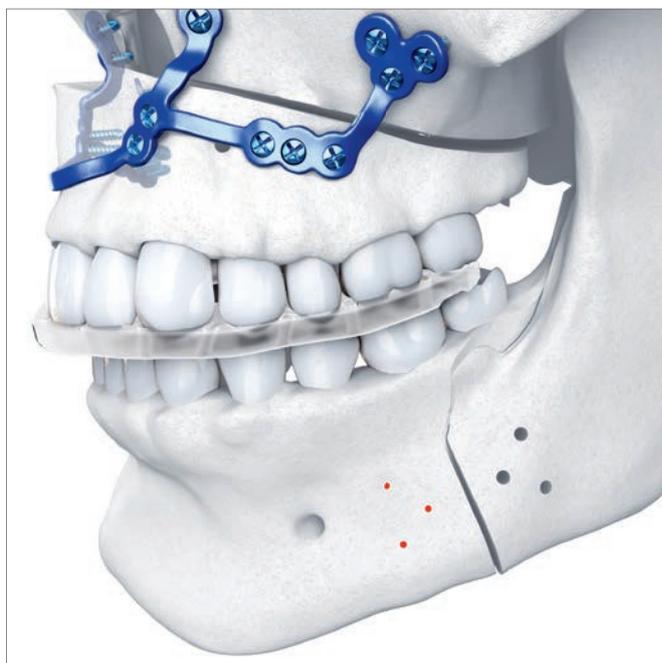
7

Place patient in MMF

Wire final occlusal splint to maxilla.

Bring mandible to fit the splint and wire the patient in MMF.

Passively bring the condylar segment and body segment into a proper anatomic relationship and remove any interferences points.



8 Attach plates to posterior segments

Instrument(s)

03.503.201/ 202/203 Screwdriver Shafts MatrixMIDFACE, self-holding, with Hexagonal Coupling, lengths 52/76/96 mm

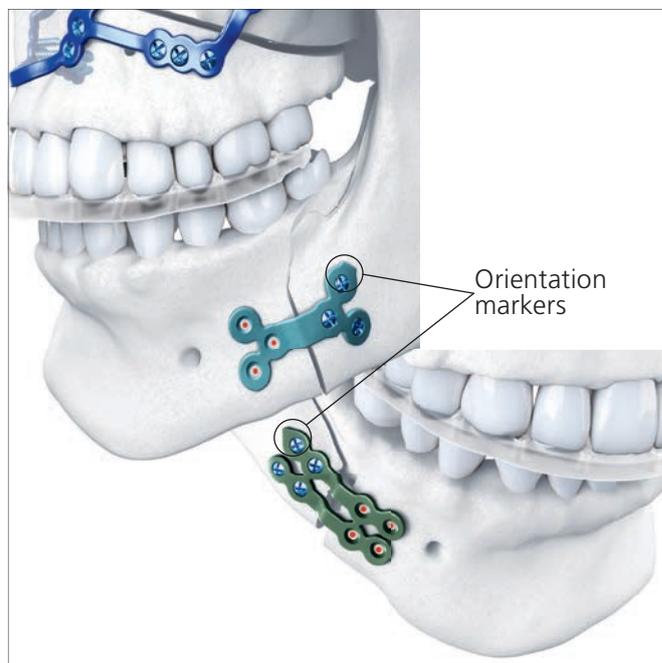
Choose the predesigned plate for the appropriate side and fixate it to the condylar segment only, using the pre-drilled holes.

- Use the case report for a clear identification of the plate and its correct orientation; plates are color coded with their respective guides.
- The superior-posterior holes of each plate have a specific shape that helps identify its orientation.

Again, with the condylar segment in the fossa, check for and remove any interferences.

Drill the remaining holes in the condylar segment.

Insert all the screws in the condylar segment.



9 Attach plates to anterior segments

Instrument(s)

03.503.201/
202/203 Screwdriver Shafts MatrixMIDFACE,
self-holding, with Hexagonal Coupling,
lengths 52/76/96 mm

Starting with one side, place the condylar segment in the appropriate position.

The anterior holes of the plate should now line up with the previously made markings.

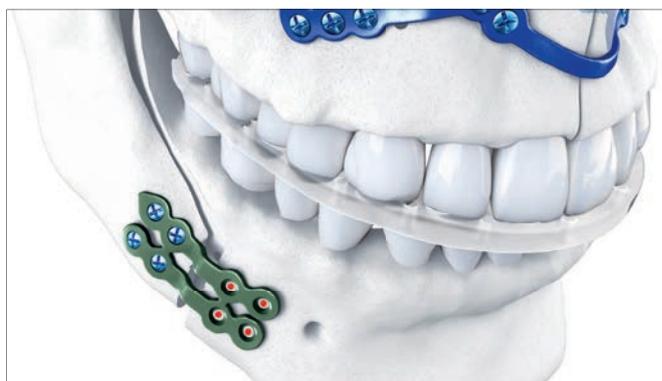
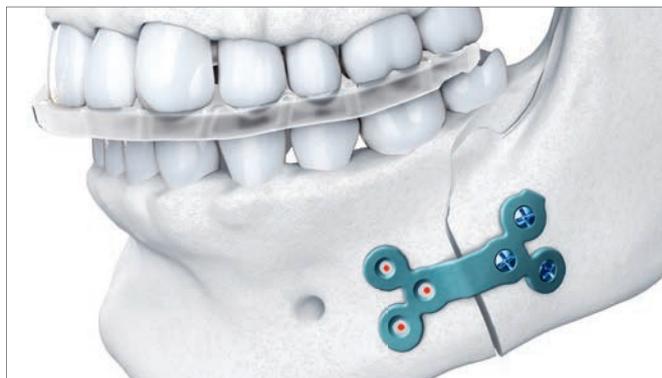
Drill (or fully drill) the holes next to the osteotomy line using the plate holes as guidance.

The anterior segment can now be fixated with the screws next to the osteotomy line.

Drill (or fully drill) the remaining anterior holes using the plate holes as guidance.

Insert all the remaining screws in the anterior segment.

Repeat the process on the contralateral side.



Genioplasty – Chin Plates

Introduction

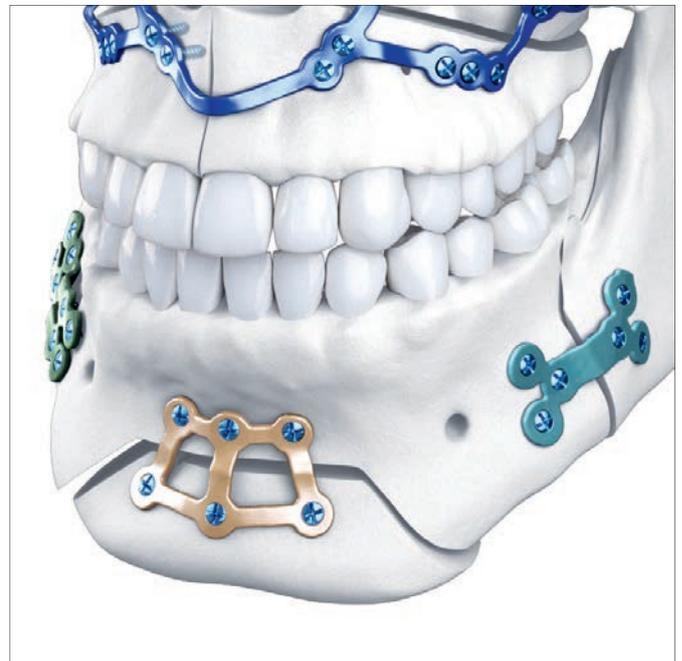
During the planning session, consider the amount of dissection required to place the implant.

Consider the size of the implant and the desired shape to achieve a best fit with minimal size, but without compromising the best fit.

The clinical engineer can identify the recommended area of the mandible for optimal guide fit.

Consider the orientation of the osteotomies according to the desired mobilization of the chin segment to avoid interferences. The case report helps with their visualization.

Discuss during the planning session the options for your cutting technique. Guide will be customized for your preferences (e.g. slot width).



1 Place guide

Take chin guide and place on dissected chin.

Guide shall fit the bone without applying force.

If not, check all around and through the guide to ensure that no periosteum/soft tissue is entrapped and extend dissection if needed.

Hold the guide in place.



2 Attach guide

Instrument(s)

03.503.201/
202/203 Screwdriver Shafts MatrixMIDFACE,
self-holding, with Hexagonal Coupling,
lengths 52/76/96 mm

Predrill the two guide attachment holes. The attachment holes can be distinguished by their flat flange design.

Double check the optimal fit of the guide all around and through the guide after fixation.

Use self-tapping screws.

Insert screws in the drilled guide attachment holes.

Notes

- Use a 1.4mm drill bit with stop for 1.85mm screws
- Use a drill bit with the stop equivalent to the screw length (e.g. 6mm drill bit with stop for 5 and 6mm
- long screws)



3 Pre-drill plate fixation holes

Pre-drill all the plate fixation holes in sequence to ensure that they are all pre-drilled. Keep the drill parallel to the drill cylinders following the designed and planned direction.

These holes will be used for the final implant positioning.

Notes:

- Use a 1.4mm drill bit with stop for 1.85mm screws
- To compensate for the height of the drilling cylinders, the drill bit length is obtained by adding 2mm to the screw length (e.g. 8mm drill bit with stop for 5 and 6mm long screws)

Precaution: Always irrigate during drilling to avoid thermal damage to the bone



4 Mark/Perform osteotomies

Mark (or cut) the buccal osteotomies with your method of choice (saw, bur, piezo, surgical marker).

Remove attachment screws.

Remove the guide.

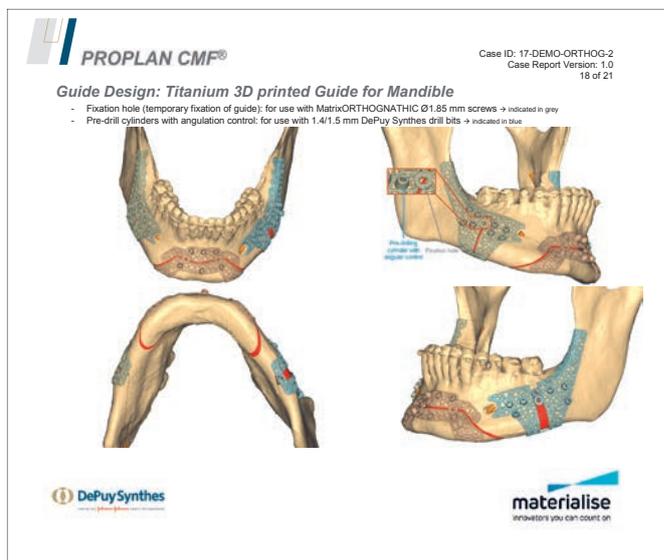


5 Complete osteotomies

Complete the osteotomy. Fully mobilize the segment, checking for interferences.

Consult the case report to visualize the cutting planes, their orientation and regions with interferences.

Remove all interferences.



6 Place and attach plate (mobile segment)

Instrument(s)

03.503.201/ 202/203	Screwdriver Shafts MatrixMIDFACE, self-holding, with Hexagonal Coupling, lengths 52/76/96 mm
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Fixate the implant on the mobile segment.

Consult the case report to visualize the appropriate screw length for each hole.

Insert all screws.



7 Place and attach plate (mandible)

Instrument(s)

03.503.201/ 202/203	Screwdriver Shafts MatrixMIDFACE, self-holding, with Hexagonal Coupling, lengths 52/76/96 mm
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Position mobile segment and implant to the mandible and hold the construct.

Plate shall be flush on the bone in all regions.
If this is not the case, check for potential bone interferences; consult the case report to help identifying these regions.

Do not force the plate for fitting, keep removing interfering bone until the plate fits.

Insert all screws in previously drilled implant fixation holes.





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