
Instructions for Use

MatrixORTHOGNATHIC LOCK

This instruction for use is not intended for distribution in the USA.

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Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques DSEM/CMF/0716/0145 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Positioning hole:

The majority of plates include positioning holes. They allow minor intra-operative corrections of the occlusion and bone segments and help positioning of the condylar heads. Matrix LOCK Straight and Anatomic L-Plates, Maxillary Plates, Straight Sagittal Split Plates and SplitFix Plates include positioning holes for precise adjustment and positioning of intraoperative bone segments, to achieve correct occlusion.

Material(s)

Implants(s):	Material(s):	Standard(s):
Plates	Commercially Pure Titanium Gr 2 & Gr 4A	ISO 5832-2
Screws	Titanium Aluminum Niobium Alloy	ISO 5832-11

Intended use

The MatrixORTHOGNATHIC LOCK system is intended for use as a stable internal bone fixation system in orthognathic surgery (surgical correction of dentofacial deformities).

Indications

The MatrixORTHOGNATHIC LOCK system is indicated for use in oral, craniofacial and maxillofacial surgery such as: trauma, reconstruction, orthognathic surgery (surgical correction of dentofacial deformities) of the craniofacial skeleton, mandible and chin, and surgical treatment of obstructive sleep apnea.

Contraindications

No specific contraindications.

General Adverse Events

As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:

Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hypersensitivity reactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.

Device Specific Adverse Events

Transient and in rare cases permanent sensation disruption (e.g. nerve traction) may occur when large maxillary/mandibular advancements are performed.

Skeletal relapse leading to malocclusion may occur when large maxillary/mandibular advancements are performed.

Permanent pain and/or discomfort may occur due to inappropriate placement/selection of the implants.


Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Single-use device

 Do not re-use

Products intended for single-use must not be re-used.

Re-use or reprocessing (e.g. cleaning and reesterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions

- Confirm that plate positioning, drill bit and screw length allow for adequate clearance of nerves, tooth buds and/or tooth roots, and the edge of the bone.
- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone.
- Higher drill speed rates can result in:
 - thermal necrosis of the bone
 - soft tissue burns
 - an oversized hole, which can lead to reduced pullout force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.
- Always irrigate during drilling to avoid thermal damage to the bone.
- After implant placement is complete, irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- Avoid damaging the plate threads with the drill.
- Avoid drilling over nerve or tooth roots.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures.
- Be sure to keep drill clear of loose surgical materials.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.
- Use the appropriate amount of screws to achieve stable fixation for fractures. Stable fixation requires a minimum of two screws per bone segment for osteotomies.
- The 1.5 mm MatrixMIDFACE screw is not recommended for sagittal split fixation and genioplasty fixation.
- The \varnothing 2.1 mm Self-tapping screw is not recommended for slider fixation.
- Cut the implant adjacent to the screw holes.
- Take care to protect soft tissue from trimmed edges.
- Ensure that the desired condylar position has been achieved.
- Bending templates should not be used as an implant or drill guide for surgical planning.
- Predrilling is recommended in dense bone.
- Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation, or bone stripping.
- Confirm the quality of bone at the selected plate position.
- Physicians should inform their patients about the implant's load restrictions and develop a plan for postoperative behavior and increasing physical loads.
- Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.
- Check instruments periodically for wear or damage.
- Replace worn or damaged instruments prior to use.
- Important considerations in achieving quality outcomes for orthognathic surgery in growing patients include accurate diagnosis, proper treatment planning, and appropriate age sequencing of procedures.¹
- Damage to developing tooth roots may result in dento-oseous ankylosis and localized dentoalveolar growth impairment.²

Warnings

- Do not alter the bend of the prebent plates by more than 1 mm in either direction.
- Do not excessively bend the plates as it may produce internal stresses which may become the focal point for eventual breakage of the implant.
- Take care to remove all fragments that are not fixed during surgery.

Mandible/Sagittal Split/SplitFix Plate Fixation:

- The slider is used strictly for intraoperative use only; do not leave it in situ.
- Previous changes in the temporomandibular joint may affect surgical outcome.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.
- Steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

Combination of medical devices

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Drill bits are combined with other electrically-powered systems.

Magnetic Resonance Environment

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 5.4 T/m. The largest image artifact extended no more than 56 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF)-induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal simulations of worst case scenario lead to temperature rises of 3.16°C (1.5 T) and 2.53°C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

Precautions:

The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Treatment before device is used

Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Special operating instructions

1. Select plate design
After the osteotomy has been performed and the new position of the maxilla has been established, select the appropriate plate shape and thickness that best suits the bony anatomy, treatment objective and the quantity and quality of bone.
Plate recommendations:
 - For medial and lateral buttress fixation: L-Plates with positioning hole
 - For medial buttress fixation: Prebent Maxillary Plates with positioning hole
 - For lateral buttress fixation: Anatomic L-Plates with positioning hole
2. Select and form bending template
Select the appropriate shape and length of bending template according to the plate selection and form it to the bony anatomy.
3. Adapt plate to the bone
Cut and contour the plate according to the bending template and bony anatomy using the plate cutter and the bending pliers, respectively. Bend the plate between the holes as necessary. Ensure that the plate is adapted to the bony anatomy.
When using locking screws, an exact match is not required. With locked screws, plate stability does not depend on the plate-to-bone contact.
Optional: Confirm plate position on the bone using the positioning hole.
4. Fixate plate to the bone
If pilot hole is desired, select the appropriate diameter and length drill bit (see MatrixORTHOGNATHIC LOCK surgical technique DSEM/CMF/0716/0145) to allow for the adequate clearance of nerves, tooth buds and/or tooth roots. Insert the remaining Matrix screws of appropriate length to fixate the plate to the underlying bone.

Sagittal Split Fixation – SplitFix Plate

1. Select plate design
Perform the sagittal split osteotomy and establish the position of the distal mandibular segment. Select the appropriate plate shape and thickness that best suits bony anatomy, treatment objective and the quantity and quality of bone.
2. Select and form bending template
3. Adapt plate to the bone
Contour the plate according to the bending template and bony anatomy using the plate cutter and the bending pliers, respectively. Bend or cut the plate between the holes as necessary. Ensure that the plate is adapted to the bony anatomy.
When using locking screws, an exact match is not required. With locked screws, plate stability does not depend on the plate-to-bone contact.

- 4.A Fixate plate to the bone
Curved Sagittal Split plate
If pilot hole is desired, select the appropriate diameter and length drill bit (see DSEM/CMF/0716/0145) to allow for the adequate clearance of nerves, tooth buds and/or tooth roots.
Fixate the curved Sagittal Split plate to the underlying bone by drilling and inserting the proper length \varnothing 1.85 mm Matrix locking or non-locking screws.
- 4.B Fixate plate to the bone
Sagittal Split plate with positioning holes
Insert the appropriate length \varnothing 1.85 Matrix screw (non-locking) in the positioning hole in the proximal segment (containing the condyle). Place the plate in the desired position. Insert the screw until seated. Do not fully tighten.
Repeat the procedure for the positioning hole in the distal segment.
Check and position the condyle by adjusting the position of the proximal segment. Tighten the screws once desired position is obtained.
Insert the remaining screws of the appropriate length by alternating between the osteotomy sites, starting from the side with positioning hole in the proximal segment.

Mandible/Sagittal Split/SplitFix Plate Fixation

1. Select plate design
The SplitFix plates (straight and curved) with self-holding slider are available for cases in which intra-operative occlusal adjustments are necessary. Perform the sagittal split osteotomy, adjust the occlusion and the proximal segment, and stabilize by intermaxillary fixation. Select the appropriate SplitFix plate that best suits the bony anatomy, treatment objective and the quantity and quality of bone.
2. Select and form the bending templates
3. Adapt plate to the bone
Contour the plate according to the bending template and bony anatomy using the bending pliers. Bend the plate between the holes as necessary. Ensure that the plate is adapted to the bony anatomy.
When using locking screws, an exact match is not required. With locked screws, plate stability does not depend on the plate-to-bone contact.
4. Primary plate fixation
If pilot hole is desired, select the appropriate diameter and length drill bit (see DSEM/CMF/0716/0145) to allow for the adequate clearance of nerves, tooth buds and/or tooth roots.
Fixate the SplitFix plate to the bone by drilling and inserting the proper length \varnothing 1.85 mm Matrix screws in the specified sequence. Screws should be placed mono-cortically.
5. Intraoperative correction of occlusion
Release the intermaxillary fixation and inspect the occlusion.
If the occlusion needs to be adjusted, loosen screw in the slider plate.
The distal bone segment can now be shifted horizontally and vertically until the occlusion has been corrected.
Retighten screw in the slider. The process can be repeated as many times as necessary.
6. Final plate fixation
Using an appropriate diameter and length drill bit (see DSEM/CMF/0716/0145) to pre-drill, insert the remaining \varnothing 1.85 mm Matrix screws of the appropriate length.
Remove the slider plate component including the screw. Repeat this step on contralateral side. Ensure fixation of the mandible is adequate to withstand the sagittal forces.

Mandible/Genioplasty Plate Fixation

1. Select plate design
After the osteotomy has been performed and the position/ advancement of the genioglossus segment has been established, select the plate size that best suits the bony anatomy, treatment objective and the quantity and quality of bone. The Matrix LOCK Single Curved Chin Plates are available in 5 mm to 19 mm advancements.
2. Select and form the bending templates
3. Adapt plate to the bone
Cut and contour the plate according to the bending template and bony anatomy using the plate cutter and the bending pliers, respectively. Bend the plate between the holes as necessary. Ensure that the plate is adapted to the bony anatomy.
When using locking screws an exact match is not required. With locked screws plate stability does not depend on plate-to-bone contact.
The four median holes can be used either to fix a bone graft or to better stabilize the genioglossus segment.
4. Fixate plate to the bone
If pilot hole is desired, select the appropriate diameter and length drill bit (see DSEM/CMF/0716/0145) to allow for the adequate clearance of nerves, tooth buds and/or tooth roots.
Insert the appropriate length \varnothing 1.85 mm Matrix screws to fixate the plate to the underlying bone.

Device intended to be used by a trained physician

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.depuyssynthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

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



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2. Woford LM, Karras SC, Mehra P. Considerations for orthognathic surgery during growth, part 2: maxillary deformities. Am J Orthod dentofacial Orthop. 2001; 119: 102–105.