Instructions for Use
MatrixORTHOGNATHIC LOCK

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

CE
0123

 EUCMF07018 SE_531341 AB 08/2014

Instructions for Use

MatrixORTHOGNATHIC LOCK
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques 036.001.388 carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The MatrixORTHOGNATHIC LOCK SYSTEM is made up different implant and instrument families:
SCREWS:
- MatrixMIDFACE Screw ∅ 1.5 mm, self-tapping, in clip, 4–18 mm long
- MatrixMIDFACE Screw ∅ 1.5 mm, self-drilling, in clip, 4–8 mm long
- Matrix LOCK Screw ∅ 1.5 mm, self-tapping in clip, 4–18 mm long
- Matrix LOCK Screw ∅ 1.5 mm, self-drilling, in clip, 4–8 mm long
- Matrix Screw ∅ 1.85 mm, self-tapping, in clip, 4–18 mm long
- Matrix Screw ∅ 1.85 mm, self-drilling, in clip, 4–8 mm long
- MatrixMIDFACE Emergency Screw ∅ 1.8 mm, self-tapping, in clip, 4–18 mm long
- Matrix Screw ∅ 1.85 mm, self-tapping, in clip, 4–28 mm long
- Matrix Screw ∅ 1.85 mm, self-drilling, in clip, 4–8 mm long
- Matrix LOCK Screw ∅ 1.85 mm, self-tapping, in clip, 4–18 mm long
- Matrix LOCK Screw ∅ 1.85 mm, self-drilling, in clip, 4–8 mm
- Matrix Screw ∅ 2.1 mm, self-tapping, in clip, 4–18 mm long

PLATES:
- Matrix LOCK L-Plate with Positioning Hole, 3+2 holes, left or right, short/medium/large/extra large, thickness 0.8 mm
- Matrix LOCK Anatomic L-Plate with Positioning Hole, 3+2 holes, left or right, short/medium/large/extra large, thickness 0.8 mm
- Matrix LOCK Maxillary Plate with Positioning Hole, left or right, prebent, lengthening 0, 3, 5, 7, 15, 20 mm, thickness 0.8 mm
- Matrix LOCK Chin Plate, single curved, max 5, 7, 9, 11, 13, 15, 17, 19 mm Offset, 5+4+4 holes, thickness 0.8 mm
- Matrix LOCK SplitFix Plate with/without slider, straight or curved, 6 holes, length 28/33/40 mm, width 7/9 mm, thickness 0.8 mm
- Matrix LOCK Sagittal Split Plate, curved, 6 holes, intersection bar 5/7/9/11/13/15/17/19 mm, 6 holes, thickness 1.0 mm
- Matrix LOCK Sagittal Split Plate with Positioning Holes, straight, intersection bar 5/7/9/11/13/15/17 mm, 6 holes, thickness 1.0 mm
- Matrix LOCK T-Plate, holes 11/6+3/5+4, thickness 1.0 mm
- Matrix LOCK Strut Plate, holes 4/6/8, thickness 1.0 mm

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)
Material(s): Standard(s):
Implants:
Plates: Commercially Pure Titanium (ISO 5832-2 Gr 4A)

Screws: Titanium Aluminum Niobium Alloy (ISO 5832-11)

Instruments:
Drill bits: Stainless steel (ISO7153-1)
Drill sleeve: Stainless steel (ISO7153-1, DIN EN 10088-1-3)
Bending templates: Aluminum (ASTM B209M)

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

Indications
The Synthes 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.

Side effects
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.
Transient and in rare cases permanent sensation disruption due to 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 of the e.g. TMJ may occur due to inappropriate placement/selection of the implants.

Sterile device

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 resterilization) 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.
Drilling speed should never exceed 1800 RPM. Higher rates can result in thermal generated necrosis of the bone and an increased hole diameter. The detriments of an oversized hole include reduced pullout force, increased ease of screws stripping in bone, and/or suboptimal fixation. Always irrigate during drilling.
Use the appropriate amount of screws to achieve stable fixation. Stable fixation requires a minimum of two screws per segment.
The 1.5 mm MatrixMIDFACE screw is not recommended for sagittal split fixation or genioplasty fixation.

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.

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.

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
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
– Heating or migration of the device
– Artifacts on MR images

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 1.4 mm drill bit length 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 ∅ 1.4 drill bit length 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 ∅ 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 ∅ 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 ∅ 1.4 mm drill bit length 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 ∅ 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 a ∅ 1.4 mm drill bit to pre-drill, insert the remaining ∅ 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 ∅ 1.4 mm drill bit length to allow for the adequate clearance of nerves, tooth buds and/or tooth roots.
   Insert the appropriate length ∅ 1.85 mm Matrix screws to fixate the plate to the underlying bone.

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from http://www.synthes.com/reprocessing

Additional device-specific information

Reference Number

Lot or batch number


Manufacturing date


Expiration date

Notified body


Caution, see instructions for use

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
www.synthes.com