Instructions for Use
MatrixORTHOGNATHIC

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

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Instructions for Use

MatrixORTHOGNATHIC
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques 036.000.413 carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The MatrixORTHOGNATHIC SYSTEM is made up different implant and instrument families:
SCREWS:
– Matrix Screw ∅ 1.5 mm, self-tapping, in clip, 4–18 mm long
– Matrix Screw ∅ 1.5 mm, self-drilling, in clip, 4–8 mm long
– MatrixMIDFACE Emergency Screw ∅ 1.8 mm, self-tapping, in clip, 3–18 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 Screw ∅ 2.1 mm, self-tapping, in clip, 4–18 mm long
– PLATES:
– Matrix 90° L-Plates, 2+2 holes, reversible, 0.5/0.7/0.8 mm thickness, short, medium or long
– Matrix L-plates, 3+3 holes, reversible, thickness 0.5/0.7/0.8 mm, short, medium, long
– Matrix Anatomic L-plates, 3+3 holes, reversible, thickness 0.5/0.7/0.8 mm, short, medium, long
– Matrix L-plates, 4+3 holes, reversible, thickness 0.5/0.7/0.8 mm, short, medium, long
– Maxillary plates, prebent, thickness 0.8 mm, left or right, offset 2–10 mm
– MatrixMIDFACE Adoption plates, 20 holes, thickness 0.5/0.7/0.8 mm
– Matrix Sagittal Split plates, thickness 1.0 mm, curved or straight, bar length 6–12 mm
– Matrix SplitFix plates, 4 holes, thickness 0.7 mm, 33 or 40 mm length
– Slider for Matrix SplitFix plate
– Matrix Chin Plates, double curved 5 holes, thickness 0.7 mm, 4–10 mm offset
– Matrix Vertical Ramus Osteotomy Plates, thickness 0.7 mm, left or right, 0–6 mm offset
– Matrix I-Plates, with centre space 7 mm, 2+2 Holes, thickness 0.5/0.7 mm
MODULE:
68.511.001 – Module for MatrixORTHOGNATHIC Plate,
Screw and Instrument Set, 3/3, with Lid, without contents.

All non-sterile plates are packed separately in a pouch.
Single non-sterile screws are inserted in a clip and one clip is packed per pouch.
Multiple non-sterile screws are inserted in a clip and 4 clips are packed per pouch.

All sterile plates are packed separately in a blister.
Single sterile screws are inserted in a clip and one clip is packed per blister.
Multiple sterile screws are inserted in clip and 4 clips are packed per blister.

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

Indications
The MatrixORTHOGNATHIC 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

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 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.
Ensure that the desired condylar positioning has been achieved.
Drilling speed should never exceed 1800 RPM. Higher rates can result in thermal generated necrosis of the bone and 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.

Warnings
Previous changes in the temporomandibular joint may affect surgical outcome.
Do not excessively bend the plates as it may produce internal stresses which may become the focal point for eventual breakage of the implant.
Do not alter the bend of the prebent plates by more than 1 mm in either direction.
The slider is used strictly for intraoperative use only; do not leave it in situ.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
Drill bits is (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
General Fixation:
1. Select plate design
   After the osteotomy has been performed and the new position/advancement of the maxilla (LeFort I), the genioglossus segment (Genioplasty) or the occlusion and the joint-bearing segment (BSSO) have been established, select the appropriate plate shape and thickness that best suits the bone anatomy, treatment objective and the quantity and quality of bone.
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 (L-plates only) 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.
4. Fixate plate to the bone
   If a pilot hole is desired, select the appropriate ∅ 1.4 mm diameter 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.
   Sagittal Split Fixation – SplitFix Plate
5. Select plate design
   After sagittal split osteotomy, adjust the occlusion and the joint-bearing segment, and stabilize by intermaxillary fixation. Select the appropriate SplitFix plate that best suits the bone anatomy, treatment objective and the quantity and quality of bone.

1. Select and form bending template
   Select the appropriate length of bending template according to the plate selection and form it to the bone anatomy.
2. Adapt plate to the bone
   Contour the plate according to the bending template and bone anatomy using the bending pliers. Bend the plate between the holes as necessary. Ensure that the plate is adapted to the bone anatomy.
3. Primary plate fixation
   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 SplitFix plate to the bone by drilling and inserting the proper length ∅ 1.85 mm Matrix screws in the specified sequence as shown on the in Technique Guide MatrixORTHOGNATHIC, specialized implants and instruments for orthognathic surgery" (016.000.413) on page 19 Fig. 2 (1,2, 3). Screws should be placed monocortically.
4. Intraoperative correction of occlusion
   Release the intermaxillary fixation and inspect the occlusion. If the occlusion needs to be adjusted, loosen the screw 3 in the slider plate. The distal bone segment can now be shifted horizontally and vertically until the occlusion has been corrected. Retighten the screw 3 in the slider. The process can be repeated if necessary.
5. 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 in holes 4 and 5 (see Technique Guide page 21).

Remove the screw 3 and slider plate component. Repeat this step on contralateral side. Ensure fixation of the mandible is adequate to withstand the sagittal forces.

Vertical Ramus Osteotomy Fixation:
1. Select plate design
   After the vertical ramus osteotomy has been performed, position the distal segment with the teeth wired into intermaxillary fixation on a pre-planned surgical splint. Select the appropriate plate design that best suits the bony step created from the overlap of the bony segments, and the quantity and quality of bone.
2. Adapt plate to the bone
   Contour the selected plate to the bone using the bending pliers. Bend the plate between the holes as necessary.
   In reducing the acute bend of the plate, the bony edge of the proximal segment can be trimmed down to enable easier adaptation of the plate to the bone. Ensure that the plate is adapted to the bone anatomy.
3. Primary plate fixation
   To fixate the Matrix Vertical Ramus Osteotomy plate to the bone, use a 90° screwdriver with a ∅ 1.4 mm drill bit to pre-drill and insert the ∅ 1.85 mm Matrix screws of the appropriate length in the specified sequence 1-2-3 (see Technique Guide page 27). The two screws on the proximal segment are fixed first. Place the third screw at the sliding slot by using Subcondylar ramus fixation set.
   The screws placed on the proximal bone segment can be fixed bi-cortically whereas the screws placed on the distal segment are recommended to be fixed mono-cortically in the region where the path of inferior alveolar nerve may be damaged.
4. Repeat steps for bilateral procedure
   Repeat steps 1–3 on the contralateral side.
5. Intraoperative correction of occlusion
   Release the intermaxillary fixation and inspect the occlusion. If the occlusion needs to be adjusted, loosen the screw (3) (see Technique Guide page 28) in the plate slot.
   The distal bone segment can now be shifted in the saggital plane until the occlusion is corrected.
   Retighten the screw (3) in the plate slot. The process can be repeated if necessary.
6. Final plate fixation
   Use a 90° screwdriver with a ∅ 1.4 mm drill bit, insert the remaining ∅ 1.85 mm Matrix screws of the appropriate length in holes (4) and (5) (see Technique Guide page 29). Alternatively, the screws may be inserted transorally with a standard screwdriver shaft.

Optional: Remove the screw (3) from the plate slot.
Repeat this step for the contra-lateral side.
Tighten all screws to ensure fixation of the mandible is adequate to withstand the sagittal forces.

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


Do not use when packaging is damaged

Notified body


Caution, see instructions for use

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