Instructions for Use
MatrixORTHOGNATHIC

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

MatrixORTHOGNATHIC
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical technique DSEM/CMF/0716/0144 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

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.

Materials

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

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 as a stable internal bone fixation system 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 mandibular maxillary osteotomy 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 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.
- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. (90° Screwdriver – This corresponds to a maximum input speed of 3600 rpm [gear ratio of 2:1]). Higher drill speed rates can result in:
  - thermal necrosis of the bone
  - soft tissue burns
  - an oversized hole, which can lead to reduced pull-out 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.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.
- 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.
- 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, genioplasty, and vertical ramus osteotomy fixation.
- The ∅ 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.
- 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 orthognatic 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]

1 Schendel SA, Wolford LM, Epker BN. Surgical advancement of the mandible in growing children: Treatment results in twelve patients. J Oral Surg. 1976;45.
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.

Warnings
- Using an internal fixation system on patients with active or latent infection may cause potential risks which may include construct failure and deterioration of infection. It is at the physician's discretion to evaluate the patient's medical conditions and select a fixation device most appropriate for the individual patient. It is also at the physician's discretion to consider all other necessary treatment methods to effectively manage the infection.
- Confirm the quality of bone at the selected plate position. Using an internal fixation system on patients with insufficient quantity or quality of bone may cause potential risks which may include device loosening and construct failure. It is at the physician's discretion to evaluate the patient's medical conditions and select a fixation device most appropriate for the individual patient.
- 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.
- 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.
- Take care to remove all fragments that are not fixated during surgery.

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 F 2213-06, ASTM F 2052-06e1 and ASTM F 2119-07
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 F 2182-11a
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
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 diameter and length drill bit (see MatrixORTHOGNATHIC surgical technique DSEM/CMF/0716/0144) 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
1. 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.
2. Select and form bending template
   Select the appropriate length of bending template according to the plate selection and form it to the bone anatomy.
3. 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.
4. Primary plate fixation
   If pilot hole is desired, select the appropriate diameter and length drill bit (see DSEM/CMF/0716/0144) 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 in DSEM/CMF/0716/0144, specialized implants and instruments for orthognathic surgery. Screws should be placed monocortically.
5. 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.
6. Final plate fixation
   Using an appropriate diameter and length drill bit
   (see DSEM/CMF/0716/0144) to pre-drill, insert the remaining ∅ 1.85 mm Matrix screws of the appropriate length in holes 4 and 5
   (see DSEM/CMF/0716/0144).

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 (DSEM/CMF/1115/0098) with an appropriate diameter and length drill bit (see DSEM/CMF/0716/0144) to pre-drill and insert the ∅ 1.85 mm Matrix screws of the appropriate length in the specified sequence 1-2-3 (see DSEM/CMF/0716/0144). 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 DSEM/CMF/0716/0144) 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 (DSEM/CMF/1115/0098) 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 DSEM/CMF/0716/0144). 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.

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.depuysynthes.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.depuysynthes.com/hcp/reprocessing-care-maintenance

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