Instructions for Use
MatrixMIDFACE Plate and Screw System

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

DePuy Synthes
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Instructions for Use

MatrixMIDFACE Plate and Screw System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques MatrixMIDFACE (DSEM/CMF/0216/0113) and MatrixORBITAL (DSEM/CMF/0216/0114) carefully before use. Ensure that you are familiar with the appropriate surgical technique.

MatrixMIDFACE Plate and Screw System consist of Midface and Orbital Plates as well as Screws.

For specific surgical steps for MatrixMIDFACE Preformed Orbital Plates refer to the MatrixORBITAL surgical technique (DSEM/CMF/0216/0114).

Material(s)

Plates:	Material(s)	Standard(s)	
	TiCp	ASTM F 67	ISO 5832-2
Screws:	Ti-6Al-7Nb (TAN)	ASTM F 1295	ISO 5832-11

Intended use
MatrixMIDFACE Plate and Screw System is intended for use as trauma repair and reconstruction of the cranio-maxillofacial skeleton.

Indications
MatrixMIDFACE Plate and Screw System is indicated for use in trauma repair and reconstruction of the cranio-maxillofacial skeleton.

MatrixMIDFACE Orbital Plates are indicated for orbital fracture treatment.

MatrixMIDFACE Preformed Orbital Plates are indicated for use in:
- Orbital floor fractures
- Medial orbital wall fractures
- Combined orbital floor and medial wall fractures

Contraindications
No specific contraindications.

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and/or the Synthes "Important Information (SE_023827)" brochure as appropriate.
Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of internal fixation devices such as MatrixMIDFACE when used according to instructions for use and recommended technique are, stabilize bone segment and facilitate healing, restore anatomical relationship and function.

Performance Characteristics of the Device
Synthes has established the performance and safety of MatrixMIDFACE Plate and Screw System and that they represent state of the art medical devices for placement of an internal orthopedic fixation system into or onto all types of bones when used according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks

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 may 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, malunion, non-union or delayed union which may lead to breakage of the implant, reoperation.

Device-specific Adverse Events
Device-specific adverse events include but are not limited to:
- Malunion / non-union that may be associated with:
  - implant inappropriately dimensioned for the intended use
  - hole deformation due to plate bending
  - Construct failure due to inadequate strength design
  - Construct strength too weak for post-operative loading forces
  - Plate/mesh hole diameter too large or screw head too small
  - Wrong implant material/design
  - Misleading/incorrect label
  - Information provided to the end-user (i.e. IFU, TG, care guide) is insufficient, incorrect or imprecise
  - Insufficient screw holes left after plate has been cut
  - Reverse and repeated bending applied
- Adverse Tissue Reaction that may be associated with
  - Instruments debris/particle created during cutting
  - Instruments debris/particle created during implantation and/or removal
  - Incorrect label i.e. wrong data provided on the LMD i.e. wrong text, missing symbols, wrong expiry date
- Damage to vital organs / surrounding structures that may be associated with
  - Premature plate/mesh failure
  - Plate/mesh does not offer enough options for screw placement
  - Plate/mesh too thick for anatomical area
  - Fixation holes do not allow for appropriate fixation
  - insufficient mesh structure
  - Screw placement into nerve, tooth buds/roots and or any other critical structures
  - Screw core diameter is too small leading to screw breakage post-operatively
  - Screw deforms or breaks during insertion with generation of fragments that the surgeon is unaware of or unable to retrieve, potentially resulting in fragment migration
  - Screw recess strips due to blade cam-out
  - Burrs/sharp edges on edge of plate
  - Plate/mesh inadequately contoured resulting in inadequate reduction
  - Screw breaks during insertion and fragments are not retrieved
  - Screw breakage post-operatively
  - Blade cams-out of screw recess
  - Screw passes completely through plate
  - Generation of particle debris during surgical procedure
  - Screw strips bone post-operatively
  - Screw not safely retained resulting in loss of screw intra-operatively
  - Screw or plate migrates or deforms post-operatively
  - Plate hole does not hold screw head
  - Implant loses functionality post-operatively
  - Improper use of implant resulting in treatment failure
  - Wrong plate selection
  - Incorrect plate/screw position resulting in irreversible damage
  - Inappropriate use of screws or drill bits
  - Overheating of drill bit causing thermal necrosis of bone
- Injury to user that may be associated with:
  - Sharp edges caused during cutting of plates punctures surgical glove/hand
- Loosening that may be associated with:
  - Insufficient implant fixation
  - Screw breakage post-operatively
  - Inappropriate screw used
- Peripheral Nerve that may be associated with:
  - Screws inserted into nerve, tooth buds/roots and or any other critical structures
- Soft Tissue Damage that may be associated with:
  - Premature plate/mesh failure
  - Screw breakage post-operatively
  - Burrs/sharp edges on edge of plate
  - Implant loses its function post-operatively

– Systemic Infection that may be associated with:
  – Incomplete/incorrect processing leading to implantation of a non-sterile product
  – Sterile barrier compromised leading to implantation of a non-sterile product
  – Implantation of non-sterile product
  – Implantation of non-sterile unclean product due to incorrect label
  – Reuse of single use implant

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.

Warnings and Precautions

Precautions
Precautions MatrixMIDFACE and MatrixORBITAL Surgical Techniques

– Confirm functionality of instruments and check for wear during reprocessing. Replace worn or damaged instruments prior to use.
– It is recommended to only use the instruments identified for use within the MatrixMIDFACE (DSEM/CMF/0216/0113) and MatrixORBITAL Surgical Technique Guide (DSEM/CMF/0216/0114) with the MatrixMIDFACE implants.
– Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.
– Always irrigate and apply suction for removal of debris potentially generated during implantation or removal.
– If contouring is necessary, the surgeon should avoid bending the device at a screw hole.
– Avoid sharp bends, repetitive and reverse bending as it increases the risk of implant breakage.
– In order to determine the appropriate amount of screws needed to achieve stable construct fixation, the surgeon should consider the fracture size and shape.
– Take care to protect soft tissue from trimmed plate edges.
– Confirm that drill bit length and diameter correspond to selected screw length prior to drilling.
– Always irrigate during drilling to avoid thermal damage to the bone and ensure drill bit is concentric to plate hole.
– 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.
– 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.
– Confirm screw length prior to implantation.
– Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation, or bone stripping. If bone becomes stripped, remove the screw from the bone and replace with an emergency screw.
– Confirm that plate positioning allows for adequate clearance of nerves and any other critical structures.
– The lateral anterior part of the MatrixMIDFACE Preformed Orbital plate is intentionally prebent higher than the Orbital rim anatomy to allow free plate movement during plate positioning. the lateral anterior part can be further contoured to match patient anatomy.
– Avoid contouring of the implant in situ that may lead to implant malposition and/or posterior cantilever effect.
– Predrilling not recommended for 3 mm self-drilling screws.
– Confirm that plate positioning allows for adequate clearance of nerves, tooth buds and/or tooth roots and any other critical structures.

Precautions MatrixMIDFACE Surgical Technique
– Bending templates are not intended to be implanted or used as a drill guide for surgical planning.

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.
– 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. Be aware that implants are not as strong as native bone. Implants subjected to substantial loads may fail.
– Instruments, screws and cut plates may have sharp edges or moving joints that may pinch or tear user's glove or skin.
– Take care to remove all fragments that are not fixated during the surgery.
– While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate post-operative management to avoid refracture.

MRI Information
Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-15 and ASTM F2119-07
Non-clinical testing of a 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 3.65 T/m. The largest image artifact extended approximately 20 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a Siemens Prisma 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal simulations of a worst case scenario lead to temperature rises of 9.3 °C (1.5 T) and 6 °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 nonclinical 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.

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

Implant Removal
The MatrixMIDFACE is for permanent implantation and not intended for removal once implanted. However, the treating surgeon may decide to remove the implant based on a risk-benefit evaluation in the following situations:
– Implant breakage, migration or other clinical failure
– Pain due to the implant Infection

Trouble Shooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Disposal
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.
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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".

Non-Sterile Device

Special Operating Instructions
Surgical steps are described in the MatrixMIDFACE and Matrix ORBITAL surgical techniques as follow:

MatrixMIDFACE

Trauma Repair and Reconstruction – Midface Plates
1. Expose and reduce fracture
2. Select and prepare the implant
3. Contour the plate
4. Position the plate
5. Drill the hole
6. Screw insertion

Orbital Plates
1. Select plate design
2. Adapt plate to the bone
3. Drill the hole
4. Fixate plate to the bone

MatrixORBITAL (Preformed Orbital Plates)

1. Select Implant
2. Size implant (if required)
3. Contour implant (if required)
4. Retract soft tissue
5. Insert Implant
6. Drill the hole (when using self-tapping screws)
7. Secure implant
8. Confirm plate placement

See the respective Surgical Technique of the DePuy Synthes MatrixMIDFACE and MatrixORBITAL for full instructions for use.

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.

Clinical Processing of the Device
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 Synthes reusable devices, instrument trays and cases, as well as processing of 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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