Surgical Technique
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 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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## Surgical Technique

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Features and benefits

- **Preformed three-dimensional shape.** For minimal bending and cutting which reduces the amount of time needed to contour plate.
- **Contoured plate edges.** For easier plate insertion through skin incision and less interference between the plate and surrounding soft tissue.
- **Segmented design.** To customize plate size to address orbital topography and to maintain contoured plate borders with minimal sharp edges.
- **Rigid zone.** Restores the shape of the posterior orbital floor to help maintain the correct position of the globe.

Designed from CT-scan data, the three-dimensional implants closely approximate the topographical anatomy of the human orbital floor and medial wall to provide accurate reconstruction even after significant two-wall fractures.5,6

Intersection bars for minimal cutting and contoured plate borders

Medial wall

Rigid zone ensures consistent form in the posterior orbit

Orbital floor

Fixation arms

Screw hole pattern
S-shape to match the contour of the orbital floor

Intersection bars for minimal cutting and contoured plate borders

Lateral edge

Lateral edge

Lateral edge

Lateral edge
Orbital floor fractures are frequently associated with medial wall fractures. The complex geometry of the bony orbit makes anatomical reconstruction extremely challenging, particularly in two wall fractures and when the deep orbital cone is affected.

The orbital floor has an initial shallow convex section behind the rim, then inclines upward behind the globe, and inclines upward to meet the medial wall, creating a distinct bulge behind the globe. These convex curves of the medial wall and floor create a “postbulbar constriction” of the orbital cavity, which must be reconstructed when the orbit is rebuilt following fractures.² Treatment is directed at precise anatomical reconstruction of orbital shape and volume in order to restore the correct position of the eye.³,⁴

The MatrixMIDFACE Preformed Orbital Plates may be used for acute orbital fractures or in secondary reconstruction of enophthalmos and dystopia.
Intended Use
MatrixMIDFACE Preformed Orbital Plates are intended for use as trauma repair and reconstruction of the cranio-maxillofacial skeleton.

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

Contraindications
MatrixMIDFACE Preformed Orbital Plates are contraindicated for use in areas with active or latent infection or insufficient quantity or quality of bone.

Warnings:
- 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.

Precautions:
- 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 techniques (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.

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/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
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
Intended Use, Indications, Contraindications, Warnings, Precautions, General Adverse Events and MRI Information

- 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 not compatible with MRI
  - 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
MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 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 5.4 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.
Clinical Case*

Preoperative CT
25-year old male sustaining blunt trauma to left orbit. Ophthalmological exam unremarkable except for severe soft tissue swelling and bruising. CT demonstrated severe displacement of medial wall and floor, including the transition zone, putting the patient at risk for late enophthalmos and dystopia as well as strabismus.

Postoperative CT
Orbit approached through transconjunctival incision with lateral canthotomy. MatrixMIDFACE Preformed Orbital Plate, large, left placed without modification except slight bending and trimming of some of fixation holes. The implant was fixed to inferior orbital rim with two MatrixMIDFACE screws.

* Clinical Case and all images are courtesy of Dr. Bartlett, Children’s Hospital of Philadelphia, University of Pennsylvania, USA.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.
Implant placement according to the orbital landmarks
1. Orbital rim
2. Inferior orbital fissure
3. Posterior orbital ledge
4. Transition zone* between the orbital floor and medial wall
5. Optic canal
6. Lacrimal fossa

Preoperative planning**

* Transition zone is located at the infero-medial aspect of the orbital floor and refers to an inner buttress at the junction to the lower end of the medial orbital wall.
** Images courtesy of Prof. Dr. R. Schmelzeisen, Dr. Dr. M. C. Metzger, Department of Craniomaxillofacial Surgery, University of Freiburg, Germany.
Orbital Retractors

- Minimize orbital soft tissue prolapse
- Provide soft tissue protection
- Large and small retractor ends
- Right and left retractors
- Stainless steel, malleable

Graduation on both sides

Concave ends

Design follows orbital anatomy
Surgical Technique

1
Select implant

**Implants**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.503.801</td>
<td>Preformed Orbital Plate, small, left</td>
</tr>
<tr>
<td>04.503.802</td>
<td>Preformed Orbital Plate, large, left</td>
</tr>
<tr>
<td>04.503.811</td>
<td>Preformed Orbital Plate, small, right</td>
</tr>
<tr>
<td>04.503.812</td>
<td>Preformed Orbital Plate, large, right</td>
</tr>
</tbody>
</table>

Select the preformed orbital plate that best suits the patient’s orbital anatomy, the fracture type and extent, and which is based on the preoperative plan.

**Notes:**

- In three-wall fractures involving the lateral wall, an additional orbital implant must be used (e.g. Synthes orbital mesh plate).
- For the surgical technique for MatrixMIDFACE, refer to the surgical technique DSEM/CMF/0216/0113.
2

Size implant (if required)

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.503.033</td>
<td>Cutting Scissors for Mesh Plates, short</td>
</tr>
<tr>
<td>03.503.037</td>
<td>Cutting Scissors for Mesh Plates, long</td>
</tr>
</tbody>
</table>

Reduce the height of the medial wall and/or orbital floor length when not used for bridging the fracture. Always cut the implant along the cutting lines to ensure smooth edges, using scissors or mesh cutters.

**Precaution:** Take care to protect soft tissue from trimmed plate edges.
Contour implant (if required)

**Instrument**

03.503.038  Bending Pliers for MatrixMIDFACE Plates (two bending pliers required)

The implant can be further contoured to match patient anatomy.

**Precautions:**
- Avoid contouring of the implant in situ that may lead to implant malposition and/or posterior cantilever effect.
- The lateral anterior part of the plate (circled right) 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.
- 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.
4

Retract soft tissue

Instruments

<table>
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<tr>
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<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.503.801</td>
<td>Orbital Retractor, left</td>
</tr>
<tr>
<td>03.503.802</td>
<td>Orbital Retractor, right</td>
</tr>
</tbody>
</table>

The malleable orbital retractors can be used to retract the soft tissue as well as size the defect.

The spoon shaped shield of the malleable retractors is bent perpendicular to the handle.

Fat prolapsing beside the retractor shield can be retracted by the additional insertion of a flexible foil.

Note: Make an angled bend (red line) to allow the hand position to rest conveniently and away from the surgical view on the patient’s forehead. Twisting of the bent end can further improve or facilitate the handling.
5

Insert implant

Position the lateral edge of the plate along the inferior orbital fissure. Since the implant is anatomic and preformed, it should be positioned in the same location for every patient. The orientation of the implant does not need to change based on the anatomy of the fracture. Place the plate on the stable bony contour.

Note: Confirm appropriate dissection. Insert the medial wall section of the plate first (1). While inserting the rest of the plate, turn the plate (2) until the implant is in the correct anatomical position (3). (Refer to page 8 for orbital landmarks.)
6

Drill the hole (when using self-tapping screws)

Drill the hole with the appropriate diameter and length drill bit.

Notes:
— Screws are available in self-drilling (silver), self-tapping (bronze), and emergency (blue) designs.
— If a pilot hole is desired, use the appropriate 1.1 mm diameter MatrixMIDFACE drill bit for drilling up to 8 mm length and the 1.25 mm diameter MatrixMIDFACE drill bit for screw lengths of 10 mm or more.

Precautions:
— Confirm that plate positioning allows for adequate clearance of nerves and any other critical structures.
— Confirm that drill bit length and diameter correspond to selected screw length prior to drilling.
— 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 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 and ensure drill bit is concentric to plate hole.
— 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.
Secure Implant

Stabilize the implant with the appropriate number of MatrixMIDFACE screws inserted through selected screw holes in the plate.

Fixation arms should be removed when not used for fixation.

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**Note: Test for impingement**

A forced duction test must be completed to ensure unrestricted lateral and medial movement of the globe.

**Precautions:**

- 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 it with an emergency screw.
- In order to determine the appropriate amount of screws needed to achieve stable construct fixation, the surgeon should consider the fracture size and shape.
Confirm plate placement*

Sagittal view of the correct plate placement is demonstrated in the image. Placement on the posterior ledge should be confirmed intraoperatively.

* Image courtesy of Prof. Dr. M. Rasse, Department of Craniomaxillofacial Surgery, University of Innsbruck, Austria.
MatrixMIDFACE Preformed Orbital Plates, 0.4 mm thickness, malleable, pure titanium

<table>
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<tr>
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<tr>
<td>04.503.802</td>
<td>large</td>
<td>left</td>
</tr>
<tr>
<td>04.503.811</td>
<td>small</td>
<td>right</td>
</tr>
<tr>
<td>04.503.812</td>
<td>large</td>
<td>right</td>
</tr>
</tbody>
</table>
## MatrixMIDFACE Screws, Titanium Alloy (TAN)

### Self-tapping screws Ø 1.5 mm
- 04.503.204 length 4 mm
- 04.503.205 length 5 mm
- 04.503.206 length 6 mm
- 04.503.208 length 8 mm

### Self-drilling screws Ø 1.5 mm
- 04.503.224 length 4 mm
- 04.503.225 length 5 mm
- 04.503.226 length 6 mm
- 04.503.228 length 8 mm

### Emergency screws Ø 1.8 mm, self-tapping
- 04.503.234 length 4 mm
- 04.503.235 length 5 mm
- 04.503.236 length 6 mm
- 04.503.238 length 8 mm

---

### Screw/plate overview

<table>
<thead>
<tr>
<th></th>
<th>Pack of 1 unit</th>
<th>Pack of 4 units</th>
<th>Pack of 1 unit, sterile</th>
<th>Pack of 4 units, sterile</th>
<th>Labelling clips</th>
</tr>
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<tbody>
<tr>
<td>Self-tapping screws</td>
<td>04.503.xxx.01C</td>
<td>04.503.xxx.04C</td>
<td>04.503.xxx.01S</td>
<td>04.503.xxx.04S</td>
<td>04.503.xxxLC</td>
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<td>(in clips)</td>
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<tr>
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<td>04.503.xxx.04C</td>
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1 Labeling clips for self-drilling screws are marked with "SD".
## Instruments

### Orbital Retractors

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### Modules

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<tr>
<td>61.503.603</td>
<td>MatrixMIDFACE Instrument Tray</td>
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Bibliography


