Instructions for Use
MatrixMANDIBLE Preformed Reconstruction Plates

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COMPANIES OF Johnson&Johnson

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Instructions for Use

MatrixMANDIBLE Preformed Reconstruction Plates
Please read these instructions for use, the DePuy Synthes brochure "Important Information" and the corresponding surgical techniques MatrixMANDIBLE Preformed Reconstruction Plates (DSEM/CMF/0915/0093) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The plates' shapes are anatomical approximations of mandible models obtained from CT scans.
The plates are:
– anatomically shaped
– right/left
– 3 sizes: small, medium and large
– 2/3 plate covering the vertical ramus and going up to the opposite mental foramen covering all main tumor resections
– Plate thickness 2.5mm
– Reduced number of undercuts due to reduced need for plate bending and higher fatigue strength
– MatrixMANDIBLE LOCK Screws.

Part(s):	**Material(s):**	**Standard(s):**
Plates	Titanium (TiCP)	ISO 5832-2
Screws	TAN (Ti-6Al-7Nb)	ISO 5832-11
Instruments	Stainless Steel	ISO 7153-1
Bending Templates	Aluminum Alloy (Al 1050A)	DIN EN 573

Intended use
The DePuy Synthes MatrixMANDIBLE Preformed Reconstruction Plates are specifically preformed plates intended for mandibular reconstruction with bone graft (vascularized or not), temporary bridging until secondary reconstruction, the treatment of the comminuted fractures of the mandible and the treatment of fractures in edentulous and atrophic mandibles, and unstable and/or infected mandibular fractures.

Indications
Madibular Reconstruction
– Primary mandibular reconstruction after resection (used with bone graft or vascularized bone graft)
– Temporary bridging after resection until secondary reconstruction
Mandibular Trauma
– Comminuted fractures of the mandible
– Fractures of edentulous and atrophic mandibles
– Unstable and/or infected mandibular fractures

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, neurological impairments, etc.), thrombosis, embolism, infection 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 hyperreactions, 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:
– Non-union, mal-union or delayed union which may lead to breakage of the implant
– Pain, discomfort or abnormal sensation due to the presence of the device
– Infection, nerve and/or tooth root damage and pain
– Soft tissue irritation, laceration or migration of the device through the skin
– Allergic reactions from material incompatibility
– Glove tear or user puncture
– Graft failure
– Restricted or impaired bone growth
– Possible transmission of bloodborne pathogens to the user
– Injury of patient
– Soft tissue thermal damage
– Bone necrosis
– Parasthesia
– Loss of tooth

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 DePuy 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.

Warning
These devices can break intraoperatively 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 the associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part be removed. Instruments, screws, and cut plates may have sharp edges or moving joints that may pinch or tear the user's glove or skin.

Precautions
Stable fixation requires a minimum of 3–4 screws in both proximal (posterior) and distal (anterior) segments, depending on indication.

When using the MatrixMANDIBLE Preformed Reconstruction Plates as a temporary bridging device with 2.4 or 2.9 mm locking screws, allow for four screws per segment. If limited bone length or poor bone quality exists, a minimum of three 2.9 mm locking screws should be used.

If the Condylar Head Add-On System will be used, the last three holes in the region of the ramus should not be bent or restricted.

For extensive bending, bending screws may be used. Extensive bending includes bends that exceed 20 degrees in torsion and "in-plane" bending, and 30 degrees for "out-of-plane" bending.

Avoid reverse bends, repetitive bends, and sharp bends (sharp bends include a single out-of-plane bend between two adjacent holes of >30°). Reverse, repetitive, or sharp bends may weaken the plate and lead to premature plate failure.

Do not use threaded drill guides as benders.

When bending out-of-plane in a single point (using the "LAST HOLE BEND" feature of the bending pliers with nose or the bending irons), bend in a controlled manner. Do the bend in small increments. Do not excessively bend outwards in a single point, or plate breakage may occur. Distribute sharp bending over several holes whenever possible.

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 damaging the plate threads with the drill.
Always Irrigate during drilling to avoid thermal damage to the bone.
Irrigate and apply suction for removal of debris potentially generated during implantation or removal.

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.

To achieve optimal angular stability with locking screws, the hole must be drilled coaxially with the plate hole, or at a right angle to the plate.

For maximum stability, locking screws are recommended. Use nonlocking screws if a bone fragment has to be repositioned by pulling it against the plate, or if a high screw angulation is needed.

2.0 mm diameter screws should only be used with the MatrixMANDIBLE Preformed Reconstruction Plates if inserted into a bone graft, or if bone volume does not permit the placement of a larger screw.

In accordance with AO technique, it is important not to insert screws into infected bone.

After implant placement is complete, discard any fragments or modified parts in an approved sharps container.

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

Magnetic Resonance environment
Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07
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 approximately 31 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 F2182-11a
Non-clinical electromagnetic and thermal simulations of worst case scenario lead to temperature rises of 13.7 °C (1.5 T) and 6.5 °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 thermo regulation 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
DePuy 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 DePuy Synthes brochure “Important Information”.

Special Operating Instructions
1. Expose the fracture or osteotomy site. For trauma, reduce the fragments anatomically.
2. Determine the size of the preformed plate using the provided sizers as per the Technique Guide.
3. Select, preform, and form the bending template inside the preformed plate.
4. Cut plate to desired length.
5. Contour the plate.
6. Position the plate over the planned resection or fracture zone.
7. Select screw size.
8. Drill the first hole.
9. Determine the screw length.
10. Insert screws.
11. Drill and place the remaining screws.

Optional Technique for Bone Resection
12. Resect the mandible.
13. Replace the implants.
14. Apply bone graft.
15. Closure.

See the DePuy Synthes MatrixMANDIBLE Preformed Reconstruction Plates Technique Guide for full instructions for use.

Troubleshooting
Bending inserts may remain in the plate if removal may induce any risks.

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the DePuy Synthes brochure “Important Information”. Assembly and disassembly instructions of instruments “Dismantling multipart instruments” can be downloaded from
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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