Instructions for Use
MatrixMANDIBLE Plating System

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

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Jul 08, 2016

DePuy Synthes
COMPANIES OF Johnson&Johnson

CE
0123

 003210 SE_530312 AE 10/2015

Instructions for Use

MatrixMANDIBLE Plating System
Please read these instructions for use, the DePuy Synthes brochure "Important Information" and the corresponding surgical techniques MatrixMANDIBLE Plating System (DSEM/CMF/0814/0025) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The DePuy Synthes MatrixMANDIBLE Plating System consists of a variety of plates that come in multiple shapes and sizes to meet the anatomical needs of the patient. This system is designed for use with the DePuy Synthes MatrixMANDIBLE screws that come in multiple diameters and lengths to meet the anatomical needs of the patient.

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 1100)	DIN EN 573

Intended use
The DePuy Synthes MatrixMANDIBLE Plating System is intended for oral, maxillofacial surgery.
The DePuy Synthes MatrixMANDIBLE Reconstruction plates is intended for reconstructive surgery.
The DePuy Synthes MatrixMANDIBLE Subcondylar Plates are intended for the trauma of the mandible.

Indications
Mandible Trauma
Reconstructive surgery
Orthognathic surgery (surgical correction of dentofacial deformities)
Subcondylar Plates: Fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.

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:
- Loosening, bending, or breakage of the device
- 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

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.

Warnings
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 theuser's glove or skin.
Select the correct implant size, shape, and design.
Do not use 1.5 mm reconstruction plates for load-bearing procedure. Use only in primary and secondary mandibular reconstruction when a vacularized bone graft is used.
Do not use excessive force during screw insertion. Do not overtighten screws.

Precautions
- Check instruments for wear or damage before starting surgery.
- 2.0 mm diameter screws should only be used with a blue or gold plate if inserted into a bone graft, or if bone volume does not permit placement of a larger screw.
- Do not use screws shorter than 5 mm with 2.5 mm and 2.8 mm thick plates, as bone purchase might not be sufficient for stable fixation.
- Avoid reverse bends as it may weaken the plate and lead to premature implant failure.
- Avoid sharp bends. Sharp bends include a single out-of-plane bend of >30 degrees between two adjacent holes.
- Avoid deburring plates above surgical site.
- Do not use threaded drill guides as benders.
- Avoid placing the holes over the nerve or tooth root.
- If plate requires placement over the nerve root, drill monocorticle using the appropriate drill bit stop.
- 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.
- Minimize notching or scratching of the implant during contouring. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.
- Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation, or bone stripping.
- Stable fixation requires a minimum of 2–3 screws per segment.
- When using 2.5 mm and 2.8 mm reconstruction plates as a 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.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
- This description is not sufficient for immediate application of the instrument set. Instruction by a surgeon experienced in handling these products is highly recommended.

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 area to be fixated via standard surgical approach. For trauma, reduce the fracture as required.
2. Select and prepare (cut) implants
3. Select and form the bending template
4. Contour the plate
5. Position the plate over the fracture or osteotomy site
6. Drill the first hole
7. Measure screw length
8. Insert screw
9. Drill and place the remaining screws

Optional Technique for Bone Resection

10. Resect the mandible
11. Replace the implants
12. Apply bone graft
13. Verify intended fixation
14. Close incision

See the DePuy Synthes MatrixMANDIBLE Plating System 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

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com/ifu