Instructions for Use
MatrixWAVE MMF

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

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 SE_635014 AA 08/2015

Instructions for Use

MatrixWAVE MMF
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

The MatrixWAVE MMF System is a bone-borne maxillomandibular fixation system that consists of a wave shaped plate that is attached to the mandible and maxilla with self-drilling locking screws. The adaptable plate can be stretched in-plane to optimize screw hole location to avoid tooth roots. The plate is available in 2 heights to accommodate the use of rigid internal fixation and individual patient anatomy. The self-drilling locking screws sit proud to the plate for additional anchor points for optional bridle wires. The dental arches are brought into occlusion by wiring around the plate hooks and/or accessible screw heads.

Material(s)
Plates and screws: commercially pure titanium and titanium alloy (Ti-6Al-7Nb)
Wires, instruments: stainless steel

Intended use
The system is intended for temporary stabilization of mandibular and maxillary fractures and osteotomies to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (approximately 6-8 weeks). The system affords the ability to compress bone segments across a fracture. The system is not intended to be used as a tension band.

Indication
The MatrixWAVE MMF System is indicated for the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

Contraindications
The contraindications for the use of this device are the following:
– Unstable fractures that cannot be stabilized in occlusion using the system
– Patients in whom damage to un-erupted permanent teeth by screw insertion may be anticipated
– Patients for whom maxillomandibular fixation represents a higher than usual psychological or physical risk
– Patients who are unwilling or unable to adhere to restrictions in eating and mouth opening associated with maxillomandibular fixation
– Patients with poor bone density in whom failure of screw fixation may be anticipated

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

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.

For implants only:
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
Excessive or significant reverse bends may weaken the plate and lead to plate failure. Do not implant a plate that has been damaged by excessive bending.

Placing the device too deep into the vestibule may cause mucosal injury.

Avoid damaging the plate threads with the drill.

Drill rate should never exceed 1,800 rpm. Higher rates can result in thermal necrosis of the bone, soft tissue burns, and an oversized hole to be drilled. The disadvantages of an oversized hole include reduced pullout force, increased ease of the screws stripping in bone, and/or suboptimal fixation. Always irrigate during drilling. Avoid placing the drill hole over the nerve or tooth roots.

Irrigate and apply suction for removal of debris potentially generated during implantation or removal.

The plate can be stretched up to 10 mm from the neutral position between each screw hole. If the plate is stretched too aggressively it can lead to plate failure.
Do not adjust or bend the plate in the areas of the screw holes as doing so may deform the hole and prevent screw locking.

Take care not to injure the soft tissue when using the application instrument to adjust the plate. When adjusting the plate, take care not to compromise the screw purchase of the previously inserted screw.

The overall length of the plate may change during adjustment and require in-situ cutting. Hold the plate during in-situ cutting to avoid creating a loose fragment in the intraoral cavity. When cutting the plate in-situ take care to avoid harming the gingival. Ensure the cut surface of the plate is positioned so as to not irritate the soft tissue.

Use the application instrument to manipulate the plate. If cracks or damage to the plate are observed due to manipulation, the plate should be removed and replaced with a new plate.

MatrixWAVE MMF plates, screws and instruments are designed and validated for use together. The use of plates, screws or instruments from other manufacturers along with DePuy Synthes products can result in incalculable risks to health care providers and/or patients.

Take care not to damage the plate with the application instrument as this could lead to plate failure.

Take care not to injure the soft tissue when using the application instrument.

Excessive tightening of the screws will cause the plate to rotate. In the final phases of screw tightening, gently tighten each screw to reduce the risk of mechanical damage to the plate, screw, screwdriver, or the bone hole.

Excessively tightening wires may cause wire failure and over the anterior dentition lead to tooth movement/displacement over time.

Do not bend the hooks more than 45° in-plane and avoid excessive bending as it may cause the hooks to break. Do not bend hooks out of plane more than required to place the wire. Take care not to bend hooks in a manner that may irritate the soft tissue.

In the final phases of screw tightening, gently tighten each screw to reduce the risk of mechanical damage to the plate, screw, screwdriver, or the bone hole.
Do not squeeze screw heads with the application instrument as doing so may compromise screw purchase in the bone.

Warnings
Device-specific 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.

Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

Avoid tooth roots, nerves and the fracture site during screw insertion. Failure to comply may lead to damage of soft tissues/tooth roots.

MRI Information

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 MR 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

Please refer to the MatrixWAVE MMF System Surgical Technique Guide for detailed instructions for use.

– Select the plate with the correct plate height
– Fit the plate
– Insert first self-drilling locking screw
– Adjust the plate
– Insert remaining screws
– Apply wire
– Post-Application Adjustments

Reprocessing of the device

Detailed instructions for reprocessing implants, instruments and cases are described in the enclosed Important Information. Assembly and disassembly instructions of instruments “Dismantling multipart instruments” can be downloaded from:
http://www.synthes.com/sites/intl/MedicalCommunity/ReprocessingCareMaintenance/Pages/Reprocessing-Care-Maintenan.aspx

Interpretation of Symbols

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