Instructions for Use
MatrixNEURO™

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

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Instructions for Use

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques MatrixNEURO (036.000.608) carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material(s)

Material(s):	Standard(s):
Screws	
TAN	DIN ISO 5832-11
Plates	
TiCp	DIN ISO 5832-2
Instruments	
PPSU / SST	ISO 1183/DIN ISO 5832-1
SST (440A)	DIN ISO 5832-1
SST (1.4117)	DIN ISO 5832-1
SST	DIN ISO 5832-1

Intended Use
DePuy Synthes MatrixNEURO plate and screw system is intended for cranial closures and/or bone fixation.

Indications
Craniotomies, cranial trauma repair and reconstruction.

Contraindications
Use in areas with active or latent infection or insufficient quantity or quality of bone.

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

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 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
Cut the implant immediately adjacent to the screw holes.
Take care to protect soft tissue from trimmed edges.
Reconstruction mesh (gold) can only be cut with the cutter 03.503.605.
Replace worn or damaged cutting instruments if the cutting function is not adequate.
Excessive and repetitive bending of the implant increases the risk of implant breakage.
When using plates or reconstruction mesh (gold), ensure countersink holes are facing upwards
Do not exceed 1800 rpm while drilling.
Drill with the proper irrigation.
Use only a 1.1 mm drill bit for pre-drilling.
Fully engage the shaft perpendicular to the screw head.
Place the 1.5 mm self-drilling screw perpendicular to the bone at the appropriate plate hole.
Take care not to over tighten the screw.
In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy.
Synthes recommends at least three plates when repairing osteotomies. Additional fixation is recommended to ensure stability of large fractures and osteotomies.
When using mesh for larger defects, additional screws for fixation are recommended.
After implant placement is complete, irrigate and apply suction for removal of debris potentially generated during implantation.

Warnings
Not for use in patients who are not yet skeletally mature. Resorbable fixation products should be considered as an alternative.

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.

Magnetic Resonance environment
Torque & Displacement

Torque & Displacement according to ASTM F 2052-06e1 and ASTM F 2213-06
Non-clinical testing of MatrixNEURO implants in 1.5 T or 3.0 T environments did not reveal any relevant torque or displacement of the implants for a spatial magnetic field gradient of 9 T/m or less.

Radio Frequency (RF)- induced heating according to ASTM F 2182-09
In non-clinical testing, long MatrixNEURO implants (89 mm) produced a temperature rise of 6.7 °C (1.5 T) and 8.5 °C (3.0 T) at a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of MR scanning in 1.5 T and 3.0 T Philips Achieva MR scanners.
In non-clinical testing, MatrixNEURO implants with reduced length (31 mm) produced temperature rises of less than 2 °C at a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of MR scanning in 1.5 T and 3.0 T Philips Achieva MR scanners
From physical basics of RF interactions and long-term experience it can be assumed that in most cases a reduction of length and spatial extend results in a reduced temperature rise produced by MatrixNEURO implants.

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 a MR system with low field strengths 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 contain-

er. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Special operating instructions

1. Select Implant
   Select the appropriate implants.
   The MatrixNEURO Plate and Screw system contains a wide variety of plates, burr hole covers, mesh and screws.
2. Size implant (if required)
   The implants may be cut and sized to match the patient anatomy and the needs of the specific case.
3. Contour implant (if required)
   The implant can be further contoured to match patient anatomy.
   Avoid contouring of the implant in situ that may lead to implant malposition.
4. Position implant
   Position the implant on the desired location using the appropriate plate holder.
5. Pre-drill screw holes (optional)
   Synthes recommends predrilling in dense bone when using 5 mm screws.
6. Secure implant
   Screwdriver shafts are self retaining instruments.
   Use the appropriate number of screws to achieve the required stability.
   If the self-drilling screw does not retain good purchase, replace it with a 1.8 mm emergency screw of the same length.
   Replace worn or damaged screwdriver shafts if retention is not adequate.

Technique Tip

Before positioning the bone flap on the patient, it is advantageous to secure the implants to the bone flap first.

1. Secure the desired plates to bone flap.
2. Position the bone flap on the patient.
3. Secure the plates to the skull.

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://www.synthes.com/reprocessing

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