Instructions for Use
MatrixNEURO™

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

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DePuy Synthes
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 (DSEM/CMF/0614/0016) carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Implant(s):	Material(s):	Standard(s):
Plates:	TiCp	ASTM F 76/DIN ISO 5832-2
Mesh:	TiCp	ASTM F 76/DIN ISO 5832-2
Selfdrilling Screws:	TAN	DIN ISO 5832-11
Selftapping Screws:	TAN	DIN ISO 5832-11
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 closure 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.

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.

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
Take care to protect soft tissue from trimmed edges.
Replace worn or damaged cutting instruments if the cutting function is not adequate.
Cut the implant immediately adjacent to the screw holes.
Avoid contouring of the implant in situ as that may lead to implant malposition.
Excessive and repetitive bending of the implant increases the risk of implant breakage.
When using plates, ensure countersink holes are facing upwards.
Predrill in dense bone when using 5 mm screws.
Use only a 1.1 mm drill bit for pre-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 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.
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.
– Consider an appropriate length of screw to avoid injury of underlying structure with too long screws or plate loosening and/or migration with too short screws.

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 with an appropriate number of screws 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
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.
The MatrixNEURO fixation system is not intended 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.

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

MRI Information

Torque, Displacement & Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 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 34 mm from the construct when scanned using the Gradient Echo (GE).Testing 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 10.7 °C (1.5 T) and 8.0 °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 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 container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information" (SE_023827).

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, 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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