
Instructions for Use

MatrixNEURO™

Not all products are currently available in all markets.

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



Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

Instructions for Use

Please read these instructions for use, the DePuy 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 67/DIN ISO 5832-2
Mesh:	TiCp	ASTM F 67/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 1.4112	ISO7153-1
	SST 1.4301	ISO7153-1
	SST 1.4021	ISO7153-1
	SST 1.4542	ASTM F 899/A 564

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 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.

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.
- Reconstruction Mesh (gold) and Preformed (Temporal, Frontal, Universal, FTP) Mesh Plates can only be cut with the MatrixNEURO Cutter for Reconstruction Mesh Plates ref.: 03.503.605.
- While handling the cut mesh, avoid the sharp edges.
- Avoid contouring of the implant in situ as that may lead to implant malposition.
- Bend the mesh in such a way that once affixed to the outer table, direct contact with the inner table and constituents of the central nervous system are avoided.
- Excessive and repetitive bending of the implant increases the risk of implant breakage.
- Reconstruction mesh (gold), and Preformed (Temporal, Frontal, Universal or FTP) Mesh Plates can only be bent with the MatrixNEURO Bender for Reconstruction Mesh ref.: 03.503.602.
- After implant placement is complete, discard any fragments or modified parts in an approved container.
- When using plates, Reconstruction Mesh (gold), or Preformed (Temporal, Frontal, Universal, FTP) Mesh 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.
- Screwdriver shafts are self-retaining instruments. Replace worn or damaged screwdriver shafts, if the retention is not adequate.
- 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 or mesh 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 overtighten 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.
- DePuy 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.
- For Preformed Mesh Plates ref.: 04.503.151S, 04.503.152S, 04.503.155S, 04.503.156S, 04.503.157S and 04.503.158S, screws placed into non-countersunk holes will lead to a higher profile compared to screws placed into countersunk holes.

Warnings

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.

If cerebral edema (brain swelling) is present, craniotomy closure could result in increased intracranial pressure leading to herniation syndromes and brain death. Therefore under these circumstances, do not proceed with a definitive craniotomy closure procedure to include either replacement of the cranial bone flap or placement of a cranial mesh implant.

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 (2011), ASTM F 2052-15 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 3.65 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 11.3 °C (1.5 T) and 8.5 °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 a MRI 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

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" (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.
4. Position implant
Position the implant on the desired location using the appropriate plate holder.
5. Pre-drill screw holes (optional)
6. Secure implant
Insert MatrixNEURO self-drilling Screws 1.5 mm to secure the implants.
If the self-drilling screw does not retain good purchase, replace it with a 1.8 mm emergency screw of the same length.

Note

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.depuyssynthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to: <http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance>



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