
Instructions for Use

MatrixNEURO

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

04.503.081	MatrixNEURO Mesh Plate, 38 x 45 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium	04.503.123	MatrixNEURO Mesh Plate, crescent-shaped, small, thickness 0.6 mm, contourable, extra rigid, Pure Titanium
04.503.081S	MatrixNEURO Mesh Plate, 38 x 45 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium, sterile	04.503.123S	MatrixNEURO Mesh Plate, crescent-shaped, small, thickness 0.6 mm, contourable, extra rigid, Pure Titanium, sterile
04.503.082	MatrixNEURO Mesh Plate, 38 x 45 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium	04.503.124	MatrixNEURO Mesh Plate, crescent-shaped, large, thickness 0.6 mm, contourable, extra rigid, Pure Titanium
04.503.082S	MatrixNEURO Mesh Plate, 38 x 45 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium, sterile	04.503.124S	MatrixNEURO Mesh Plate, crescent-shaped, large, thickness 0.6 mm, contourable, extra rigid, Pure Titanium, sterile
04.503.083	MatrixNEURO Mesh Plate, 100 x 100 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium	04.503.125	MatrixNEURO Mesh Plate, circular, Ø 30 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium
04.503.083S	MatrixNEURO Mesh Plate, 100 x 100 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium, sterile	04.503.125S	MatrixNEURO Mesh Plate, circular, Ø 30 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium, sterile
04.503.084	MatrixNEURO Mesh Plate, 100 x 100 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium	04.503.126	MatrixNEURO Mesh Plate, circular, Ø 70 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium
04.503.084S	MatrixNEURO Mesh Plate, 100 x 100 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium, sterile	04.503.126S	MatrixNEURO Mesh Plate, circular, Ø 70 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium, sterile
04.503.085	MatrixNEURO Mesh Plate, 200 x 200 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium	04.503.127	MatrixNEURO Mesh Plate, circular, Ø 100 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium
04.503.085S	MatrixNEURO Mesh Plate, 200 x 200 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium, sterile	04.503.127S	MatrixNEURO Mesh Plate, circular, Ø 100 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium, sterile
04.503.086	MatrixNEURO Mesh Plate, crescent-shaped, small, thickness 0.4 mm, contourable, malleable, Pure Titanium	04.503.145	MatrixNEURO Mesh Plate, 100x100 mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium
04.503.086S	MatrixNEURO Mesh Plate, crescent-shaped, small, thickness 0.4 mm, contourable, malleable, Pure Titanium, sterile	04.503.146	MatrixNEURO Mesh Plate, 150x150 mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium
04.503.087	MatrixNEURO Mesh Plate, crescent-shaped, large, thickness 0.4 mm, contourable, malleable, Pure Titanium	04.503.147	MatrixNEURO Mesh Plate, 200x200mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium
04.503.087S	MatrixNEURO Mesh Plate, crescent-shaped, large, thickness 0.4 mm, contourable, malleable, Pure Titanium, sterile	04.503.149	MatrixNEURO Mesh Plate, diameter 70mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium
04.503.088	MatrixNEURO Mesh Plate, crescent-shaped, small, thickness 0.4 mm, contourable, rigid, Pure Titanium	04.503.150	MatrixNEURO Mesh Plate, diameter 100mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium
04.503.088S	MatrixNEURO Mesh Plate, crescent-shaped, small, thickness 0.4 mm, contourable, rigid, Pure Titanium, sterile	04.503.145S	MatrixNEURO Mesh Plate, 100x100 mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium, sterile
04.503.089	MatrixNEURO Mesh Plate, crescent-shaped, large, thickness 0.4 mm, contourable, rigid, Pure Titanium	04.503.146S	MatrixNEURO Mesh Plate, 150x150 mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium, sterile
04.503.089S	MatrixNEURO Mesh Plate, crescent-shaped, large, thickness 0.4 mm, contourable, rigid, Pure Titanium, sterile	04.503.147S	MatrixNEURO Mesh Plate, 200x200mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium, sterile
04.503.090	MatrixNEURO Mesh Plate, circular, Ø 30 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium	04.503.149S	MatrixNEURO Mesh Plate, diameter 70mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium, sterile
04.503.090S	MatrixNEURO Mesh Plate, circular, Ø 30 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium, sterile	04.503.150S	MatrixNEURO Mesh Plate, diameter 100mm, thickness 0.6 mm, contourable, reconstruction, Pure Titanium, sterile
04.503.091	MatrixNEURO Mesh Plate, circular, Ø 70 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium	Screws	
04.503.091S	MatrixNEURO Mesh Plate, circular, Ø 70 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium, sterile	04.503.103.01C	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 3 mm, Titanium Alloy (TAN), pack of 1 unit in Clip
04.503.092	MatrixNEURO Mesh Plate, circular, Ø 100 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium	04.503.103.01S	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 3 mm, Titanium Alloy (TAN), pack of 1 unit in Clip, sterile
04.503.092S	MatrixNEURO Mesh Plate, circular, Ø 100 mm, thickness 0.4 mm, contourable, malleable, Pure Titanium, sterile	04.503.103.04C	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 3 mm, Titanium Alloy (TAN), pack of 4 units in Clip
04.503.093	MatrixNEURO Mesh Plate, circular, Ø 30 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium	04.503.103.04S	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 3 mm, Titanium Alloy (TAN), pack of 4 units in Clip, sterile
04.503.093S	MatrixNEURO Mesh Plate, circular, Ø 30 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium, sterile	04.503.104.01C	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 4 mm, Titanium Alloy (TAN), pack of 1 unit in Clip
04.503.094	MatrixNEURO Mesh Plate, circular, Ø 70 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium	04.503.104.01S	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 4 mm, Titanium Alloy (TAN), pack of 1 unit in Clip, sterile
04.503.094S	MatrixNEURO Mesh Plate, circular, Ø 70 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium, sterile	04.503.104.04C	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 4 mm, Titanium Alloy (TAN), pack of 4 units in Clip
04.503.095	MatrixNEURO Mesh Plate, circular, Ø 100 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium	04.503.104.04S	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 4 mm, Titanium Alloy (TAN), pack of 4 units in Clip, sterile
04.503.095S	MatrixNEURO Mesh Plate, circular, Ø 100 mm, thickness 0.4 mm, contourable, rigid, Pure Titanium, sterile	04.503.105.01C	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 5 mm, Titanium Alloy (TAN), pack of 1 unit in Clip
04.503.096	MatrixNEURO Mastoid Plate, thickness 0.4 mm, small, Pure Titanium	04.503.105.01S	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 5 mm, Titanium Alloy (TAN), pack of 1 unit in Clip, sterile
04.503.096S	MatrixNEURO Mastoid Plate, thickness 0.4 mm, small, Pure Titanium, sterile	04.503.105.04C	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 5 mm, Titanium Alloy (TAN), pack of 4 units in Clip
04.503.097	MatrixNEURO Mastoid Plate, thickness 0.4 mm, medium, Pure Titanium	04.503.105.04S	MatrixNEURO Screw Ø 1.5 mm, self-drilling, length 5 mm, Titanium Alloy (TAN), pack of 4 units in Clip, sterile
04.503.097S	MatrixNEURO Mastoid Plate, thickness 0.4 mm, medium, Pure Titanium, sterile	04.503.113.01C	MatrixNEURO Emergency Screw Ø 1.8 mm, self-tapping, length 3 mm, Titanium Alloy (TAN), pack of 1 unit in Clip, sterile
04.503.098	MatrixNEURO Mastoid Plate, thickness 0.4 mm, large, Pure Titanium	04.503.113.01S	MatrixNEURO Emergency Screw Ø 1.8 mm, self-tapping, length 3 mm, Titanium Alloy (TAN), pack of 1 unit in Clip, sterile
04.503.098S	MatrixNEURO Mastoid Plate, thickness 0.4 mm, large, Pure Titanium, sterile	04.503.114.01C	MatrixNEURO Emergency Screw Ø 1.8 mm, self-tapping, length 4 mm, Titanium Alloy (TAN), pack of 1 unit in Clip
04.503.120	MatrixNEURO Mesh Plate, 38 x 45 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium	04.503.114.01S	MatrixNEURO Emergency Screw Ø 1.8 mm, self-tapping, length 4 mm, Titanium Alloy (TAN), pack of 1 unit in Clip, sterile
04.503.120S	MatrixNEURO Mesh Plate, 38 x 45 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium, sterile	04.503.115.01C	MatrixNEURO Emergency Screw Ø 1.8 mm, self-tapping, length 5 mm, Titanium Alloy (TAN), pack of 1 unit in Clip
04.503.121	MatrixNEURO Mesh Plate, 100 x 100 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium	04.503.115.01S	MatrixNEURO Emergency Screw Ø 1.8 mm, self-tapping, length 5 mm, Titanium Alloy (TAN), pack of 1 unit in Clip, sterile
04.503.121S	MatrixNEURO Mesh Plate, 100 x 100 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium, sterile	145.321S	MatrixNEURO Steril Kit, Standard 4 mm
04.503.122	MatrixNEURO Mesh Plate, 200 x 200 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium	145.324S	MatrixNEURO Steril Kit, Burr hole cover 17 mm
04.503.122S	MatrixNEURO Mesh Plate, 200 x 200 mm, thickness 0.6 mm, contourable, extra rigid, Pure Titanium, sterile	03.503.244	Drill Bit Ø 1.1 mm with Stop, length 44.5/4 mm, for J-Latch Coupling
		03.503.244S	Drill Bit Ø1.1 w/Stop L44.5/4 Sterile
		03.503.246	Drill Bit Ø 1.1 mm with Stop, length 44.5/6 mm, for J-Latch Coupling

03.503.246S	Drill Bit Ø1.1 w/Stop L44.5/6 Sterile
03.503.248	Drill Bit Ø 1.1 mm with Stop, length 44.5/8 mm, for J-Latch Coupling
03.503.248S	Drill Bit Ø1.1 w/Stop L44.5/8 Sterile
03.503.264	Drill Bit Ø 1.1 mm with Stop, length 52/4 mm, for Hexagonal Coupling
03.503.266	Drill Bit Ø 1.1 mm with Stop, length 52/6 mm, for Hexagonal Coupling
03.503.268	Drill Bit Ø 1.1 mm with Stop, length 52/8 mm, for Hexagonal Coupling

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
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

For cranial closures and/or bone fixation.

Indications

For use in the following 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.

Please replace worn or damaged cutting instruments if the cutting function is not adequate.

Take care to protect soft tissue from trimmed edges.

Excessive and repetitive bending of the implant increases the risk of implant breakage.

When using plates, ensure countersink holes are facing upwards

Do not exceed 1800 rpm while drilling.

Please drill with the proper irrigation.

Use only a 1.1mm 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.

DePuy Synthes recommends at least three plates when repairing osteotomies. Additional fixation is recommended to ensure stability of large fractures and osteotomies, or when using mesh.

After implant placement is complete, irrigate and apply suction for removal of debris potentially generated during implantation.

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.

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, the longest MatrixNEURO implant (9cm) 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 (3 cm) 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 container. 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. Cut the implant immediately adjacent to the screw holes.
3. Contour implant (if required)
The implant can be further contoured to match patient anatomy.

Notes

- Avoid contouring of the implant in situ that may lead to implant malposition.
 - Excessive and repetitive bending of the implant increases the risk of implant breakage.
4. Position implant
Position the implant on the desired location using the appropriate plate holder.
Please replace worn or damaged cutting instruments if the cutting function is not adequate.
 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.
Fully engage the shaft perpendicular to the screw head.
Please replace worn or damaged screwdriver shafts, if the retention is not adequate.
Place the 1.5 mm self-drilling screw perpendicular to the bone at the appropriate plate hole.
Take care not to overtighten the screw.
If the self-drilling screw does not retain good purchase, replace it with a 1.8 mm emergency screw of the same length.
Use the appropriate number of screws to achieve the required stability.

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.
Use the appropriate number of screws to achieve the required stability.

Troubleshooting

Please replace worn or damaged cutting instruments if the cutting function is not adequate.


Please replace worn or damaged screwdriver shafts, if the retention is not adequate.


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/reprocessing>


Additional device-specific information


 Reference Number

 Lot or batch number

 Manufacturing date

 Expiration date

 Notified body

 Caution, see instructions for use


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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
www.synthes.com