

MatrixNEURO. The next generation cranial plating system.

Surgical Technique



This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.

 **DePuy Synthes**
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

CODMAN NEURO

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Image intensifier control

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.

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

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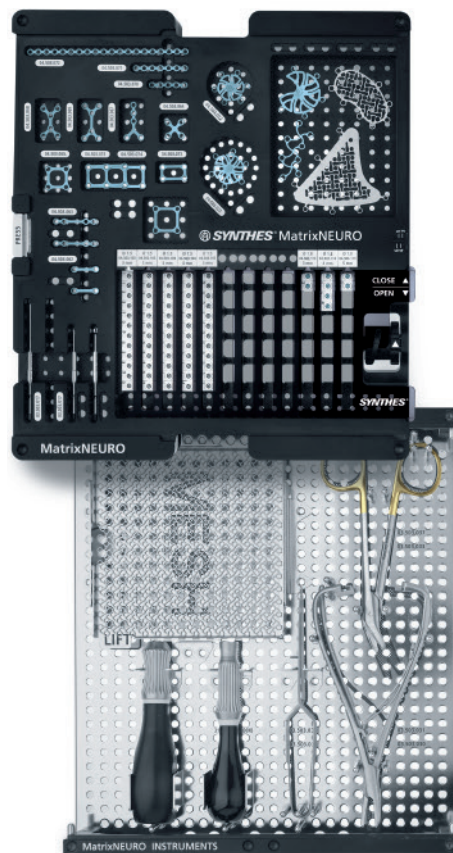
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Introduction

The aim of surgical fracture treatment is to reconstruct the bony anatomy and restore its function. According to the AO, internal fixation is distinguished by anatomical reduction, stable fixation, preservation of blood supply, and early, active mobilization. Plate and screw osteosynthesis has been established and clinically recognized for some time.

Keeping the AO philosophy at its core, Matrix is the new plating platform for internal fixation of the cranio-maxillo-facial skeleton—addressing neuro, craniofacial, mandibular, and orthognathic surgery. Matrix is a simple yet comprehensive system that offers flexibility and ease of use.

- All screws work with all plates within each Matrix system
- One blade for all screws within each Matrix system
- Reduced plate/screw profile, where applicable
- Self-retaining screws/blades that minimize cam-out
- Standardized instrumentation
- Color-coding by strength for easy identification
- Rounded edges on plates for less irritation to soft tissue, where applicable
- Reduced inventory for hospitals without compromising clinical solutions



MatrixNEURO Cranial Plating System

- Self-drilling screws for fast closure of bone flaps and rapid fixation of cranial fractures
- Wide variety of screws, plates and mesh allows the surgeon to select the most appropriate implants based upon patient needs

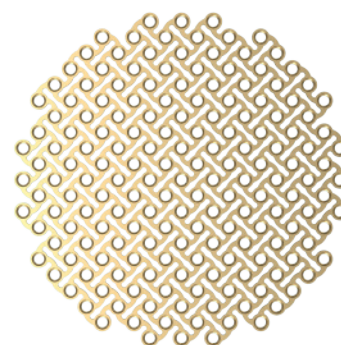
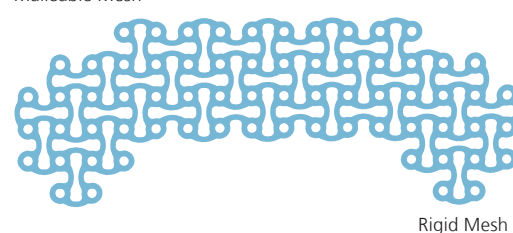
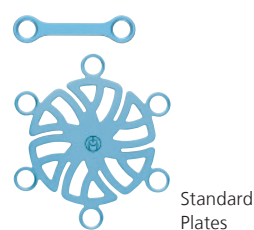


Plate/screw profile

- Ultra Low Profile Plates (green):
Plate thickness = 0.3 mm, Plate/Screw profile = 0.4 mm
- Standard Plates (blue):
Plate thickness = 0.4 mm, Plate/Screw profile = 0.5 mm
- Malleable (silver) and Rigid (blue) Mesh:
Mesh thickness = 0.4 mm, Plate/Mesh profile = 0.5 mm
- Extra Rigid Mesh (pink):
Mesh thickness = 0.6 mm, Plate/Mesh profile = 0.9 mm
- Reconstruction Mesh (gold):
Mesh thickness = 0.6 mm, Plate/Mesh profile = 0.6 mm

MatrixNEURO Self-drilling Screws

- Thread design for rapid screw starting and low insertion torque*
- Available in 3 lengths: 3 mm, 4 mm and 5 mm

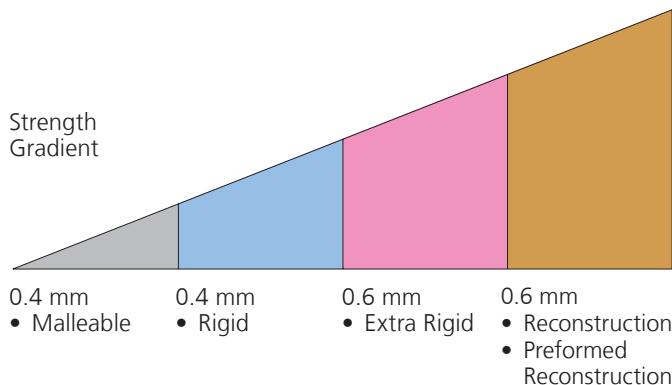


MatrixNEURO Plates

- Full selection of titanium plates and burr hole covers

MatrixNEURO Contourable Meshes

- Available in a variety of shapes and sizes
- Color-coded based on strength characteristic:
Silver (0.4 mm thick, malleable)
Blue (0.4 mm thick, rigid)
Pink (0.6 mm thick, extra rigid)
Gold (0.6 mm thick, reconstruction)

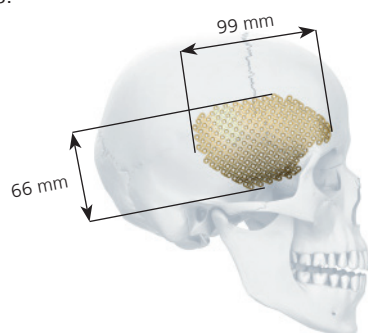


* Mechanical test data on file at DePuy Synthes (report nr 0000083130).

MatrixNEURO Preformed (Temporal, Frontal, FTP, Universal) Mesh Plates

Temporal

The Temporal implant is designed for reconstructions of Temporal defects. The reconstruction can be combined with standard bone flap fixation following Temporal-Parietal procedures.

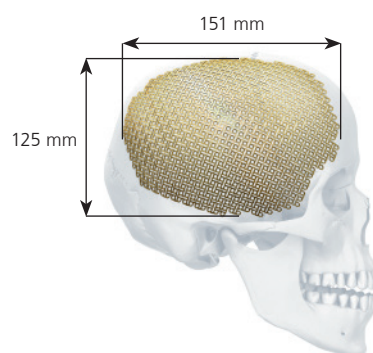


04.503.151S	MatrixNEURO Preformed Temporal Mesh Plate, left, 99 × 66 mm, thickness 0.6 mm, contourable, for Reconstruction, Pure Titanium, sterile
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04.503.152S	MatrixNEURO Preformed Temporal Mesh Plate, right, 99 × 66 mm, thickness 0.6 mm, contourable, for Reconstruction, Pure Titanium, sterile
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FTP

The FTP implant is designed for reconstruction of large defects in the Fronto-Temporo-Parietal region.

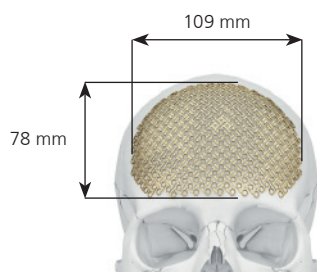


04.503.155S	MatrixNEURO Preformed FTP Mesh Plate, left, 151 × 125 mm, thickness 0.6 mm, contourable, for Reconstruction, Pure Titanium, sterile
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04.503.156S	MatrixNEURO Preformed FTP Mesh Plate, right, 151 × 125 mm, thickness 0.6 mm, contourable, for Reconstruction, Pure Titanium, sterile
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Frontal

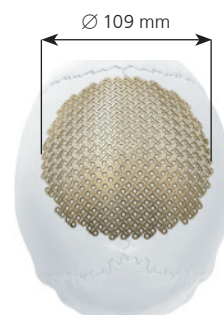
The Frontal implant is designed for reconstructions of the Frontal bone without involvement of the superior orbital rim.



04.503.157S	MatrixNEURO Preformed Frontal Mesh Plate, 109 × 78 mm, thickness 0.6 mm, contourable, for Reconstruction, Pure Titanium, sterile
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Universal

The Universal implant is a dome shaped, circular mesh which is best suited for defects of the Parietal and Occipital regions.



04.503.158S	MatrixNEURO Preformed Universal Mesh Plate, Ø 109 mm, thickness 0.6 mm, contourable, for Reconstruction, Pure Titanium, sterile
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Intended Use, Indications, Contraindications, General Adverse Events

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.

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 has to make the final decision on removal of the broken part based on associated risks 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.
-

Torque, Displacement and Image Artifacts according to ASTM F2213-06 (2011), ASTM F2052-15 and ASTM F2119-07

Non-clinical testing of a 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 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 a 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 an MRI 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.
-

1

Select Implant

Select the appropriate implants listed in the ordering information section on pages 12 and 13. For selection of Preformed Mesh Plate, refer to the descriptions on page 4. The MatrixNEURO Plate and Screw system contains a wide variety of plates, burr hole covers, mesh and screws.

2

Size implant (if required)

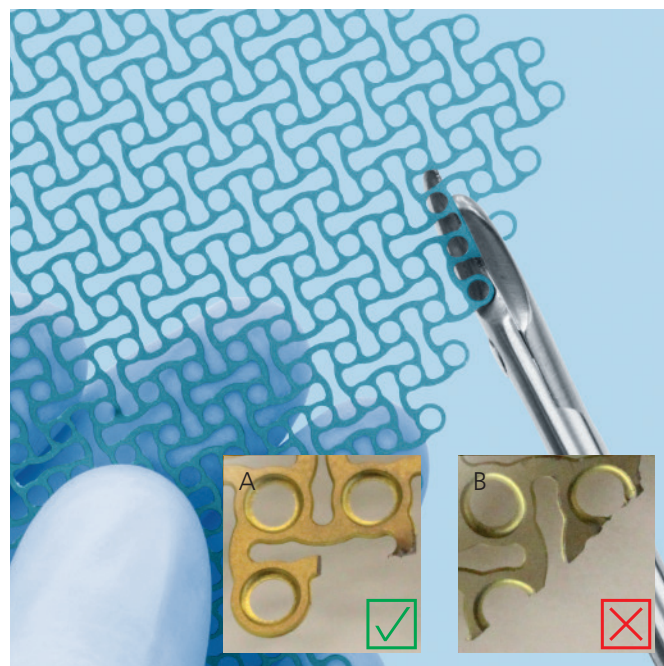
Instruments

03.503.033	Cutting Scissors for Mesh Plates, short
03.503.037	Cutting Scissors for Mesh Plates, long
03.503.605	MatrixNEURO Cutter for Reconstruction Mesh Plates

The implants may be cut and sized to match the patient anatomy and the needs of the specific case. Cut mesh around the screw holes as represented in Inset A. Do not cut through the screw holes (Inset B).

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.



03.503.605 MatrixNEURO Cutter for Reconstruction Mesh Plates

3

Contour implant (if required)

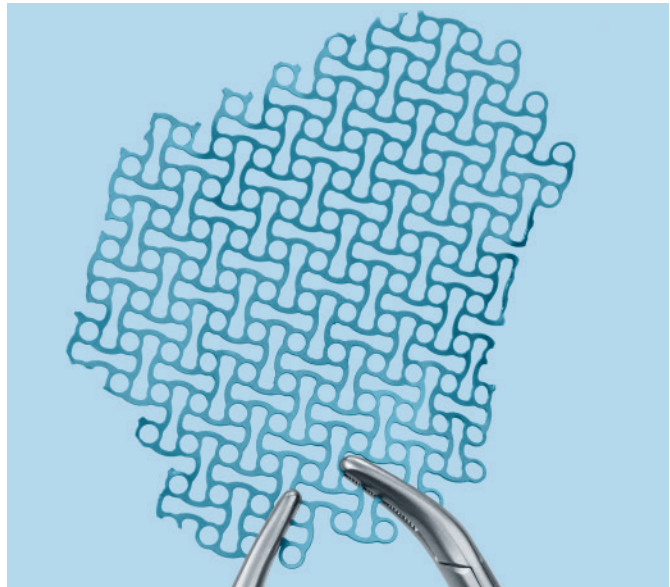
Instruments

03.503.030	Plate Bender, locking
03.503.031	Plate Bender, non-locking
03.503.602	MatrixNEURO Bender for Reconstruction Mesh Plates, bending diameter 70 mm

The implant can be further contoured to match patient anatomy.

Precautions:

- 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, FTP) Mesh Plates can only be bent with the MatrixNEURO Bender for Reconstruction Mesh Plates ref.: 03.503.602.
- After implant placement is complete, discard any fragments or modified parts in an approved container.



03.503.602 MatrixNEURO Bender for Reconstruction Mesh Plates

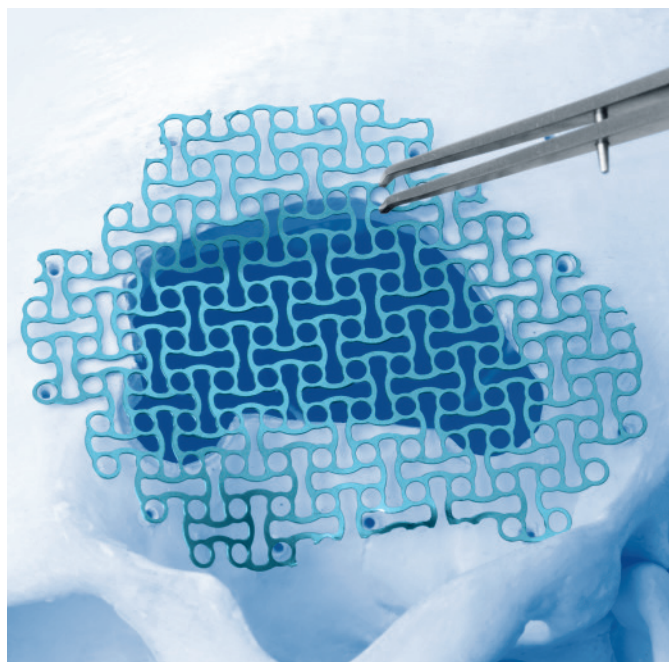
4

Position implant

Instruments

03.503.032	Plate Holder, short
03.503.034	Plate Holder, long

Position the implant on the desired location using the appropriate plate holder.



Precaution: When using plates, Reconstruction Mesh (gold), or Preformed (Temporal, Frontal, Universal, FTP) Mesh Plates ensure countersink holes are facing upwards.



5

Pre-drill screw holes (optional)

Instruments

03.503.244	Drill Bit Ø 1.1 mm with Stop, 4 mm, for J-Latch Coupling
03.503.264	Drill Bit Ø 1.1 mm with Stop, 4 mm, for Hex Coupling

Precautions:

- 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.

6

Secure implant

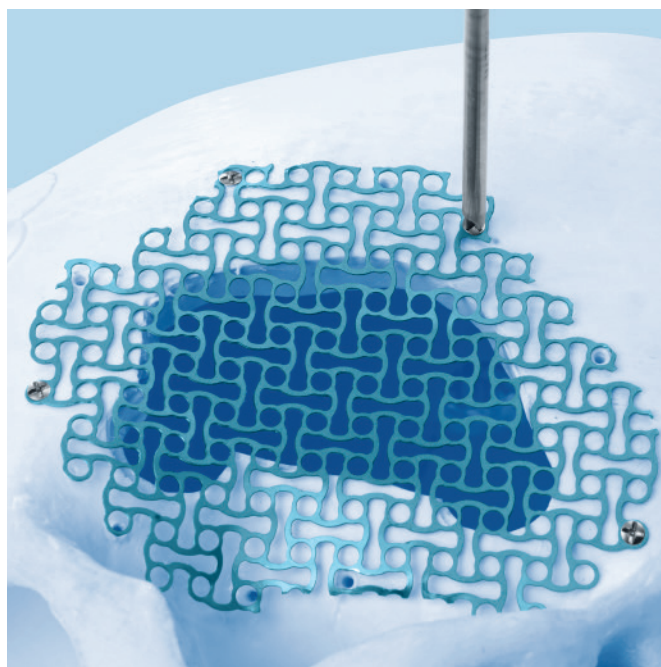
Instruments

311.005	Screwdriver handle, small
311.006	Screwdriver handle, medium
311.007	Screwdriver handle, large
03.503.016	Screwdriver shaft, short
03.503.017	Screwdriver shaft, medium

Insert MatrixNEURO self-drilling Screws Ø 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.

Precautions:

- 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.



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.



Ordering Information

Sets	
01.503.204	MatrixNEURO Basic Set
01.503.214	MatrixNEURO Standard Set
01.503.223	MatrixNEURO Basic Instrument Set
01.503.243	MatrixNEURO Standard Instrument Set incl. Insert for Mesh Plates
01.503.203	MatrixNEURO Set for use with sterile implants

Modules	
61.503.203	Module MatrixNEURO, 1/3, Basic, with Lid, without Contents
61.503.225	Module for Plates and Screws, for MatrixNEURO, size 1/2, with Lid
61.503.213	Instrument Tray, 1/3, Basic and
61.503.213.02	Labelling Clips for Instrument Tray MatrixNEURO, Standard
61.503.234	Instrument Tray for Low Profile Neuro and MatrixNEURO System, size 1/2, with Lid
61.503.230	Instrument Tray for MatrixNEURO Reconstruction Mesh Plates
61.503.200	Module for use with sterile implants, without Lid and
61.503.200.02	Labelling Clips for Module for use with sterile implants
61.503.208	Lid MatrixNEURO for No. 61.503.200
689.515	Vario Case, Framing, size 1/2, height 88 mm
689.537	Lid (Stainless Steel), size 1/2, for Vario Case

MatrixNEURO Screws, Titanium Alloy (TAN), self-drilling (silver)*	
04.503.103.01C	Screw Ø 1.5 mm, length 3 mm, pack of 1 unit in Clip
04.503.103.04C	Screw Ø 1.5 mm, length 3 mm, pack of 4 units in Clip
04.503.104.01C	Screw Ø 1.5 mm, length 4 mm, pack of 1 unit in Clip
04.503.104.04C	Screw Ø 1.5 mm, length 4 mm, pack of 4 units in Clip
04.503.105.01C	Screw Ø 1.5 mm, length 5 mm, pack of 1 unit in Clip
04.503.105.04C	Screw Ø 1.5 mm, length 5 mm, pack of 4 units in Clip

MatrixNEURO Emergency scews, Titanium Alloy (TAN), self-tapping (blue)*	
04.503.113.01C	Emergency Screw Ø 1.8 mm, length 3 mm, pack of 1 unit in Clip
04.503.114.01C	Emergency Screw Ø 1.8 mm, length 4 mm, pack of 1 unit in Clip
04.503.115.01C	Emergency Screw Ø 1.8 mm, length 5 mm, pack of 1 unit in Clip

MatrixNEURO Sterile Kits	
145.321S	Standard, 4 mm (contains: 6 × ref. 04.503.104.01C + 3 × ref. 04.503.062)
145.324S	Burr Hole Cover, 17 mm (contains: 8 × ref. 04.503.104.01C + 2 × ref. 04.503.062 + 1 × 04.502.023)

MatrixNEURO Plates, thickness 0.4 mm, Pure Titanium*	
04.503.056	Strut Plate, contourable
04.503.057	Temporal Mesh Plate, contourable
04.503.061	Cranial Plate, straight, with centre space, 9 mm, 2 holes
04.503.062	Cranial Plate, straight, with centre space, 12 mm, 2 holes
04.503.063	Cranial Plate, straight, with centre space, 12 mm, 4 holes
04.503.064	X-Plate, 4 holes
04.503.065	Frame Plate, square, 4 holes, 14 × 14 mm
04.503.066	Frame Plate, square, 4 holes, 16 × 16 mm
04.503.067	Y-Plate, 5 holes
04.503.068	Double-Y-Plate, 6 holes, length 18 mm
04.503.069	Double-Y-Plate, 6 holes, length 21 mm
04.503.070	Adaption Plate, 5 holes
04.503.071	Adaption Plate, 7 holes
04.503.072	Adaption Plate, 20 holes
04.503.073	Frame Plate, rectangular, 4 holes, 10 × 16 mm
04.503.074	Strut Plate, 2 × 3 holes, 14 × 24 mm
04.503.075	Strut Plate, 2 × 4 holes, 14 × 34 mm

MatrixNEURO Ultra Low Profile Plates, thickness 0.3 mm, Pure Titanium*	
04.502.061	Cranial Plate, straight, with centre space 9 mm, 2 holes
04.502.062	Cranial Plate, straight, with centre space 12 mm, 2 holes
04.502.063	Cranial Plate, straight, with centre space 12 mm, 4 holes
04.502.064	X-Plate, 4 holes
04.502.065	Frame Plate, square, 4 holes, 14 × 14 mm
04.502.068	Double-Y-Plate, 6 holes, length 18 mm
04.502.073	Frame Plate, rectangular, 4 holes, 10 × 16 mm
04.502.074	Strut Plate, 2 × 3 holes, 14 × 24 mm

MatrixNEURO Burr Hole Covers, thickness 0.4 mm, Pure Titanium*	
04.503.021	Ø 12.0 mm
04.503.022	Ø 15.0 mm
04.503.023	Ø 17.0 mm
04.503.024	Ø 24.0 mm
04.503.026	Ø 12.0 mm, for Shunt or Drainage
04.503.027	Ø 15.0 mm, for Shunt or Drainage
04.503.028	Ø 17.0 mm, for Shunt or Drainage
04.503.029	Ø 24.0 mm, for Shunt or Drainage

MatrixNEURO Ultra Low Profile Burr Hole Covers, thickness 0.3 mm, Pure Titanium (green)*	
04.502.021	Ø 12.0 mm
04.502.022	Ø 15.0 mm
04.502.023	Ø 17.0 mm
04.502.024	Ø 24.0 mm
04.502.028	Ø 17.0 mm, for Shunt or Drainage

MatrixNEURO Contourable Mesh, Pure Titanium*

04.503.081	38 × 45 mm, malleable
04.503.082	38 × 45 mm, rigid
04.503.083	100 × 100 mm, malleable
04.503.084	100 × 100 mm, rigid
04.503.085	200 × 200 mm, rigid
04.503.086	Crescent-shaped, small, malleable
04.503.087	Crescent-shaped, large, malleable
04.503.088	Crescent-shaped, small, rigid
04.503.089	Crescent-shaped, large, rigid
04.503.090	Circular, Ø 30 mm, malleable
04.503.091	Circular, Ø 70 mm, malleable
04.503.092	Circular, Ø 100 mm, malleable
04.503.093	Circular, Ø 30 mm, rigid
04.503.094	Circular, Ø 70 mm, rigid
04.503.095	Circular, Ø 100 mm, rigid
04.503.096	Mastoid Plate, small
04.503.097	Mastoid Plate, medium
04.503.098	Mastoid Plate, large
04.503.120	38 × 45 mm, thickness 0.6 mm, extra rigid
04.503.121	100 × 100 mm, thickness 0.6 mm, extra rigid
04.503.122	200 × 200 mm, thickness 0.6 mm, extra rigid
04.503.123	crescent-shaped, small, thickness 0.6 mm, extra rigid
04.503.124	crescent-shaped, large, thickness 0.6 mm, extra rigid
04.503.125	circular, Ø 30 mm, thickness 0.6 mm, extra rigid
04.503.126	circular, Ø 70 mm, thickness 0.6 mm, extra rigid
04.503.127	circular, Ø 100 mm, thickness 0.6 mm, extra rigid
04.503.145	100 × 100 mm, thickness 0.6 mm, contourable, reconstruction
04.503.146	150 × 150 mm, thickness 0.6 mm, contourable, reconstruction
04.503.147	200 × 200 mm, thickness 0.6 mm, contourable, reconstruction
04.503.149	Ø 70 mm, thickness 0.6 mm, contourable, reconstruction
04.503.150	Ø 100 mm, thickness 0.6 mm, contourable, reconstruction

MatrixNEURO Preformed Mesh Plate, thickness 0.6 mm, Pure Titanium, sterile, contourable, for Reconstruction

04.503.151S	Temporal Mesh Plate, left, 99 × 66 mm
04.503.152S	Temporal Mesh Plate, right, 99 × 66 mm
04.503.155S	FTP Mesh Plate, left, 151 × 125 mm
04.503.156S	FTP Mesh Plate, right, 151 × 125 mm
04.503.157S	Frontal Mesh Plate, 109 × 78 mm
04.503.158S	Universal Mesh Plate, Ø 109 mm

Instruments

03.503.016	Screwdriver Shaft 1.5, short, for Hex Coupling
03.503.017	Screwdriver Shaft 1.5, medium, for Hex Coupling
03.503.030	Plate Bender, locking
03.503.031	Plate Bender, non-locking
03.503.032	Plate Holder, short
03.503.034	Plate Holder, long
03.503.033	Cutting Scissors for Mesh Plates, short
03.503.037	Cutting Scissors for Mesh Plates, long
03.503.244	Drill Bit Ø 1.1 mm with Stop, 4 mm, for J-Latch Coupling
03.503.264	Drill Bit Ø 1.1 mm with Stop, 4 mm, for Hex Coupling
311.005	Screwdriver handle, small, with hex coupling
311.006	Screwdriver handle, medium, with hex coupling
311.007	Screwdriver handle, large, with hex coupling
03.503.602	MatrixNEURO Bender for Reconstruction Mesh Plates, bending diameter 70 mm
03.503.605	MatrixNEURO Cutter for Reconstruction Mesh Plates

* For sterile screws and plates add suffix "S" to article number. For label clips add suffix LC to article number.

Color of the meshes

Extra rigid = pink

Rigid = blue

Malleable = silver

Reconstruction = gold

Preformed Reconstruction = gold

Color of the plates

MatrixNEURO 0.4 mm = blue

MatrixNEURO Ultra Low Profile 0.3 mm = green

CODMAN NEURO



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