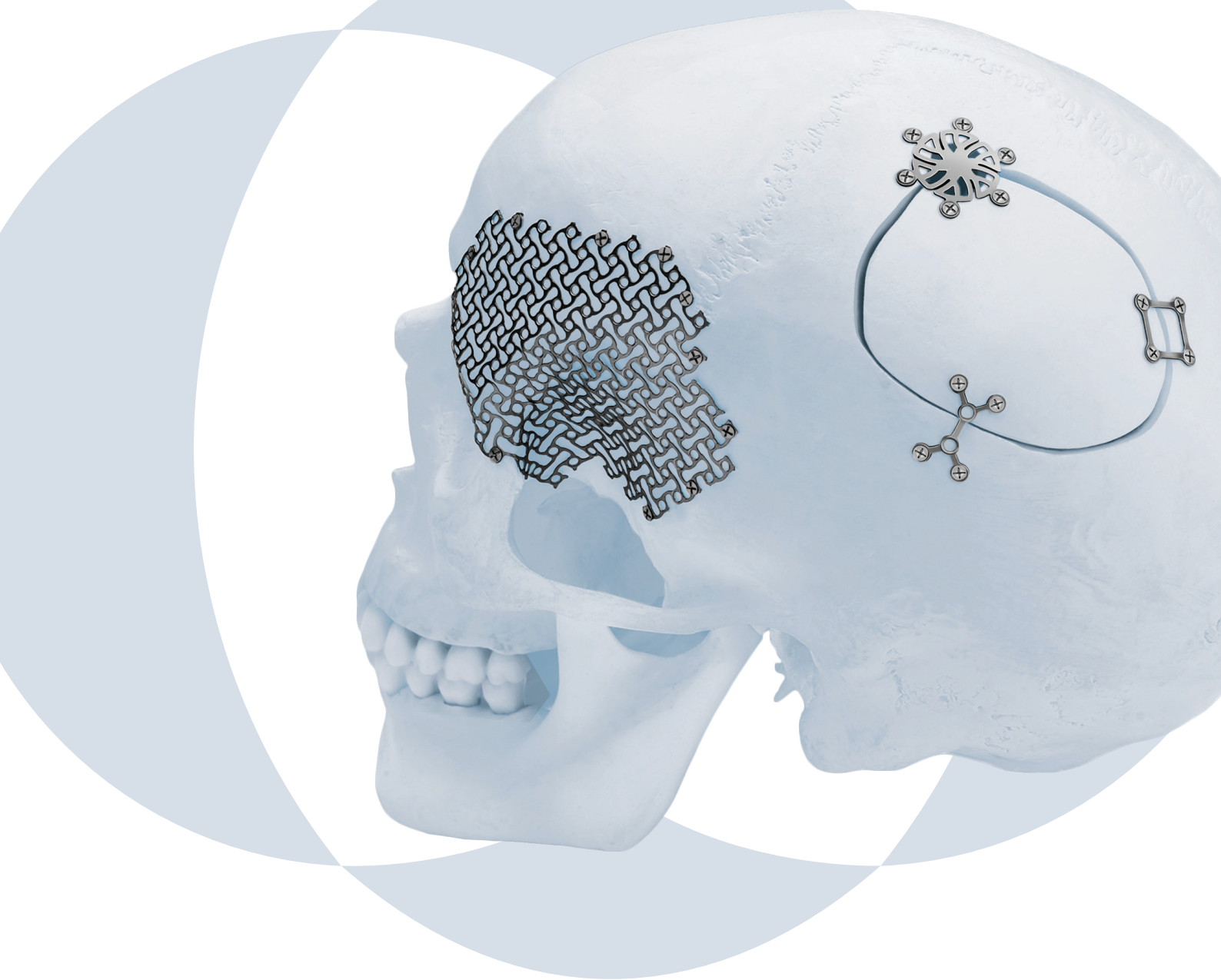


LOW PROFILE NEURO



This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

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 Image intensifier control

Warning

This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

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>

LOW PROFILE NEURO PLATING SYSTEM

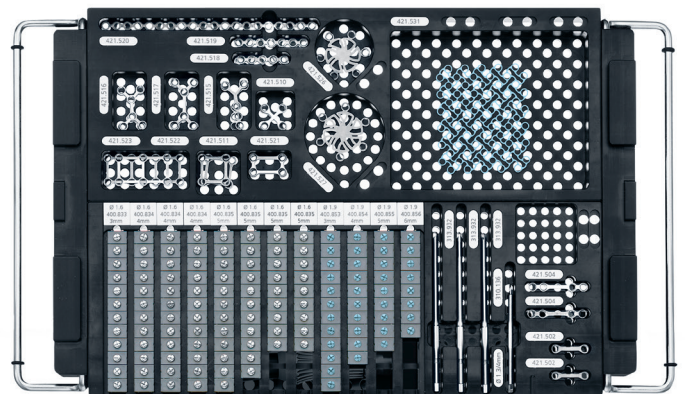
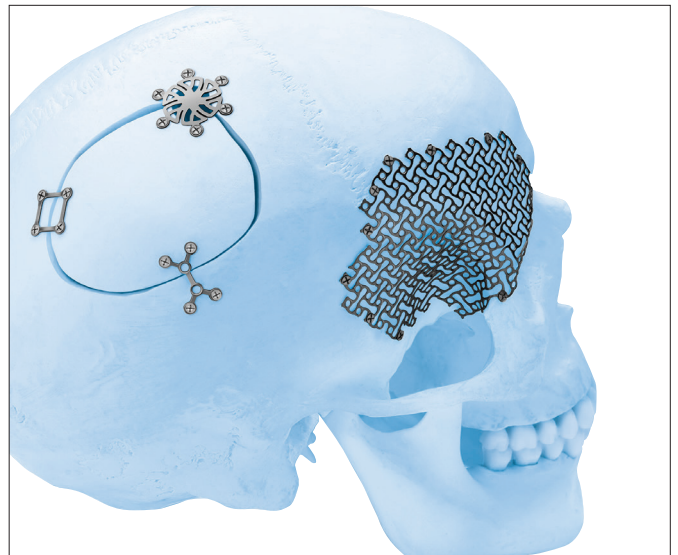
Introduction

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 precise reduction, stable fixation, preservation of blood supply, and early mobilization. Plate and screw osteosynthesis has been established and clinically recognized for some time.

The Low Profile Neuro Plating System is a cranial closure system that features low plate/screw profile, wide variety of implants, and modular storage options.

Features

- Low plate-and-screw profile of 0.60 mm for decreased palpability†
- Self-drilling,* self-retaining screws, with modified cruciform recess, facilitate replacement of bone flap†
- Wide variety of low-profile plates to repair the most common types of bony cranial defects and fractures
- Modular storage options to meet specific surgeon needs



* Self-tapping screws are also available.

† Mechanical test data on file at DePuy Synthes. Mechanical test results are not necessarily indicative of clinical performance.

Low-profile plates

- High strength and low profile, 0.5 mm thick†
- Variety of plates to meet specific patient and surgeon needs
- Made from Titanium

Low-profile mesh

- Available in a wide variety of shapes and sizes
- Rigid (0.6 mm thick, silver) and malleable (0.4 mm thick, blue) mesh
- Design allows screw placement through either side of mesh
- Available nonsterile or sterile-packed
- Made from Titanium

Self-drilling screws

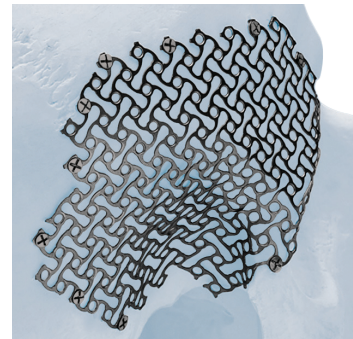
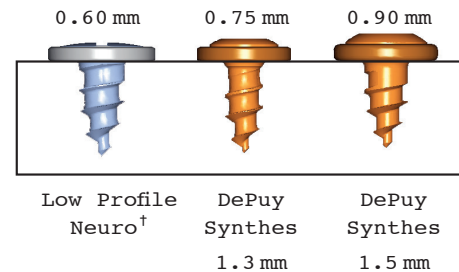
- Screws are self-drilling* for easy, one-step insertion
- Made from titanium alloy (Ti-6Al-7Nb)
- Modified cruciform recess provides:
 - High-torque capacity†
 - Optimal screw retention for quick and easy insertion of screws†
 - Low-profile rigid fixation†
- Available in 3 mm–6 mm lengths
- Screws are color coded: Self-drilling screws are silver, emergency screws are blue

Quick and easy handling

The screw clip simplifies the handling of screws, and allows the modules to be filled quickly:

- Snap in the clip, snap off the cover, and the module is filled with screws.
- Simply slide empty clips out of the opening.
- All clips are labelled with the respective screw length, all clips are colour coded.
- Unused screws can be re-sterilized in the clip
- Single-clip or four-clip packages are available

Plate / Screw Profiles of Various Systems

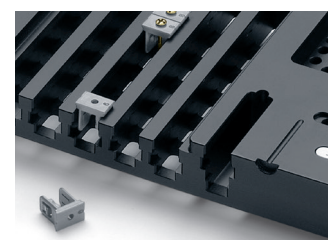


*Self-tapping screws (silver) are also available.

†Mechanical test data on file at DePuy Synthes. Mechanical test results are not necessarily indicative of clinical performance.



Snap the screw clip into the module and snap off the cover



Push empty clips out of the opening

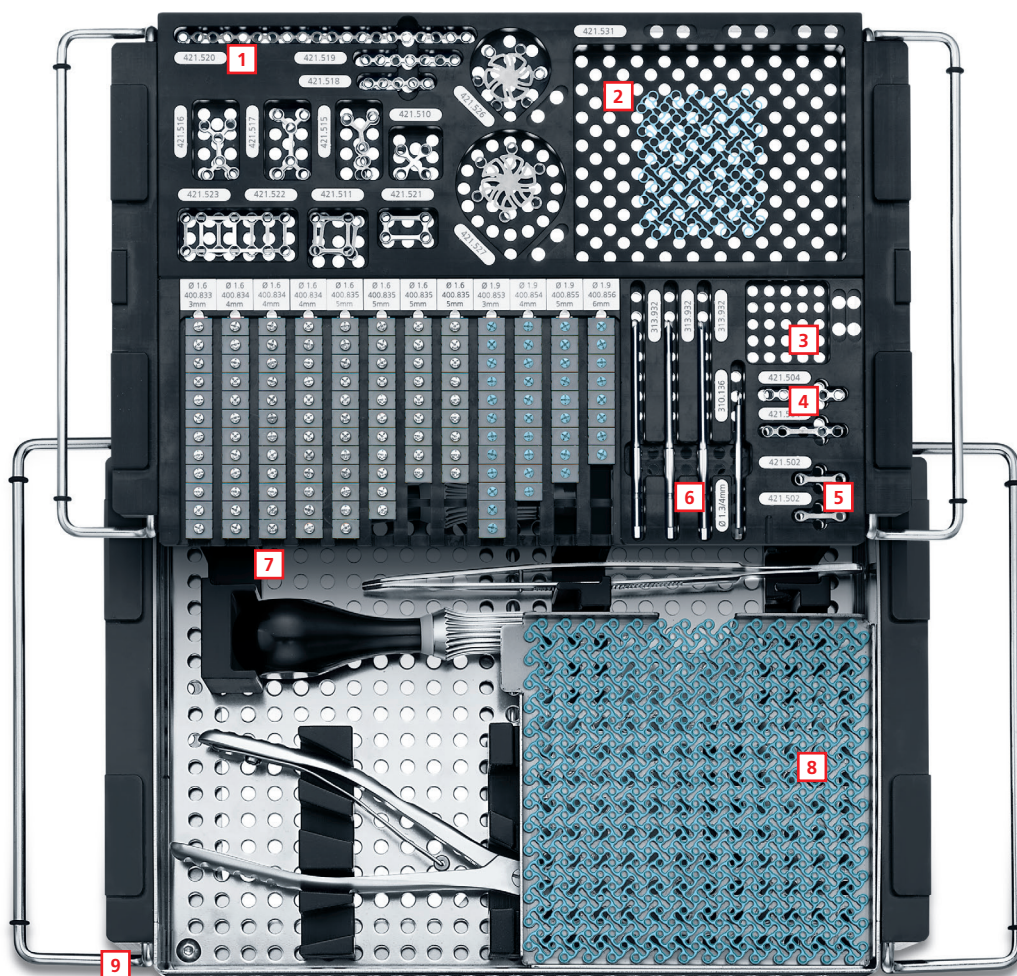
Standard module

Complete system for a broad spectrum of cranial indications. Different module sizes are obtainable as needed. The basic module (size 1/3) can be easily expanded to the standard module (size 2/3).

- 1 Large plate selection**
- 2 Large auxiliary bin**
For mesh plates or optional plates
- 3 Small auxiliary bin**
For additional plates
- 4 Label clips**
For individualized sets

- 5 Small straight plates**
For fixing a standard craniotomy
- 6 Space for various screwdriver shafts and drill bits**
- 7 Screw clips that snap into the rail**
Quick and easy filling of the module
- 8 Contourable mesh plates**
The special grid design prevents kinking even when cranial structures are irregular
- 9 Instrument carrier**
Size for the standard module: The carrier and module can be stacked on each other to save space

61.503.324*



* Tray only, contents not included with this article number.

61.503.233*

INTENDED USE, INDICATIONS, CONTRAINDICATIONS AND MRI INFORMATION

Intended Use

DePuy Synthes Low Profile Neuro 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.

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.**

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 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 5.4 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 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 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.

SURGICAL TECHNIQUE

1

Select Implant

Select the appropriate implants depending on use. The Low Profile Neuro Plating System contains a wide variety of plates, burr hole covers, mesh, and screws.

Precaution: When using plates, ensure countersink holes are facing upward.

2

Size implant (if required)

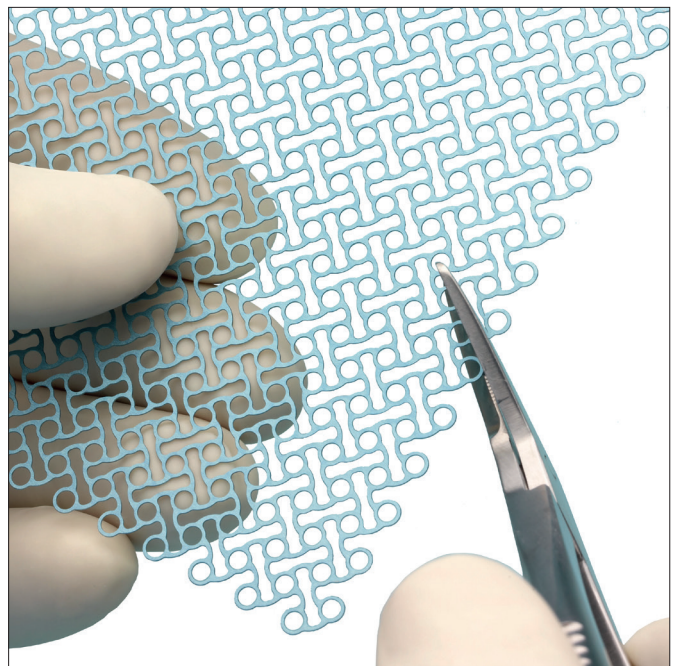
Instruments

391.952	Cutter for Strut Plates and Mesh Plates
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Implants may be cut and sized to match the patient anatomy.

Precautions:

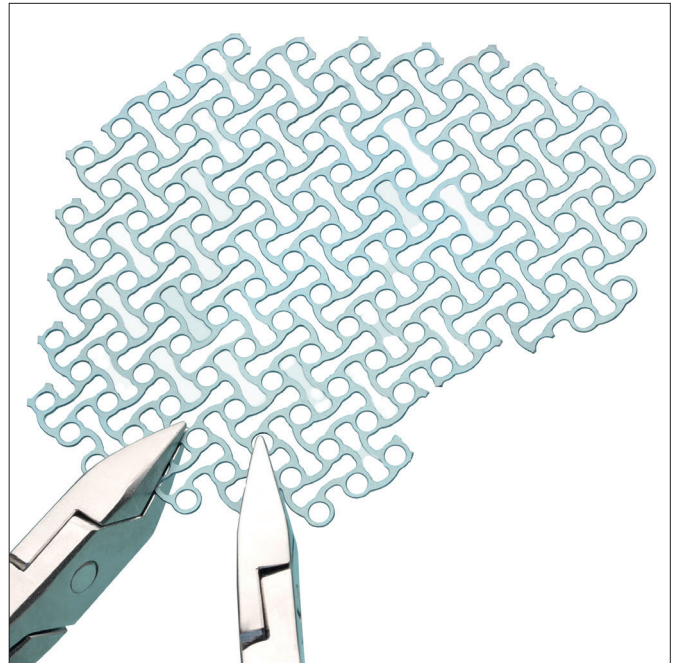
- Take care to protect soft tissue from trimmed edges.
- Replace worn or damaged cutting instruments if the cutting function is not adequate.
- Cut the implant immediately adjacent to the screw holes.



3 Contour implant (if required)

The implant can be contoured to match the patient's anatomy.

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

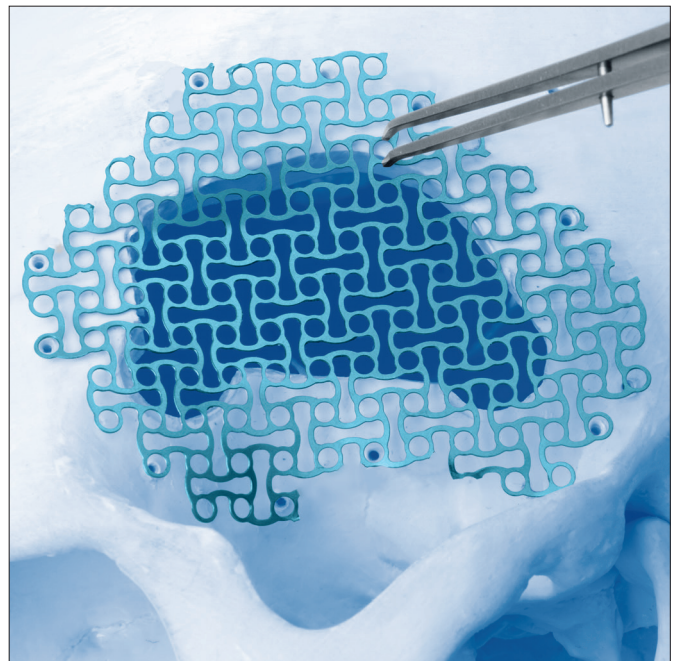


4 Position implant

Instruments

347.981	Holding Forceps for Plates 1.0 to 2.4
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Position the implant on the desired location using the appropriate plate holder.

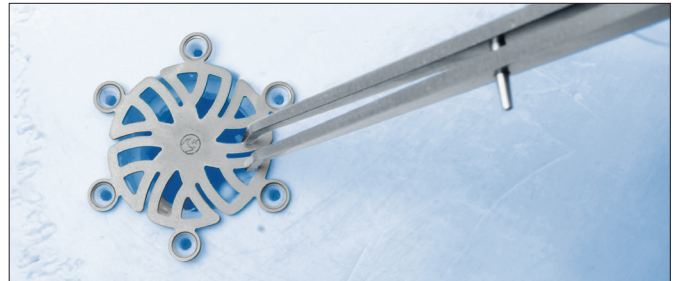


5

Pre-drill screw holes (optional)

Instruments

310.138	Drill Bit Ø 1.3 mm with Stop, length 52/4 mm, for Hexagonal Coupling
310.139	Drill Bit Ø 1.3 mm with Stop, length 52/6 mm, for Hexagonal Coupling
310.136	Drill Bit Ø 1.3 mm with Stop, length 44.5/4 mm, for J-Latch Coupling
310.137	Drill Bit Ø 1.3 mm with Stop, length 44.5/6 mm, for J-Latch Coupling



Precautions:

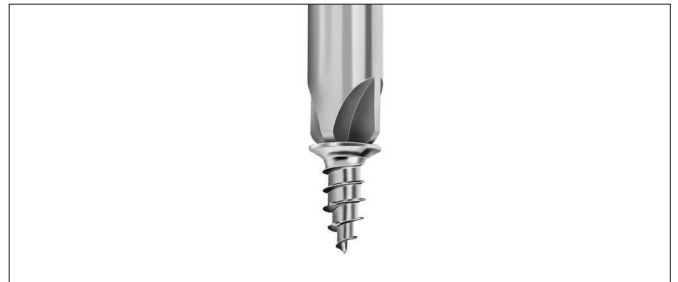
- DePuy Synthes recommends predrilling in dense bone when using 5 mm or 6 mm screws. Drill rate should never exceed 1,800 rpm. Higher rates can result in thermal necrosis of the bone, soft tissue burns, and an oversized hole to be drilled. The adverse effects of an oversized hole include reduced pullout force, increased ease of screws stripping in bone, and/or suboptimal fixation.
- Irrigate during drilling to avoid thermal damage to the bone.
- Handle devices with care and dispose worn bone cutting instruments in a sharps container.
- Use only a 1.3 mm drill bit for pre-drilling.

6

Secure implant

Instruments

313.931	Screwdriver Shaft PlusDrive 1.6, length 42 mm, for Hexagonal Coupling
313.932	Screwdriver Shaft PlusDrive 1.6, length 66 mm, for Hexagonal Coupling
311.005	Handle, small, with Hexagonal Coupling
311.006	Handle, medium, with Hexagonal Coupling
311.007	Handle, large, with Hexagonal Coupling



To load the screw onto the blade, place the blade perpendicular to the screw in the module and fully insert the blade into the screw recess. The screw should be securely attached to the blade.

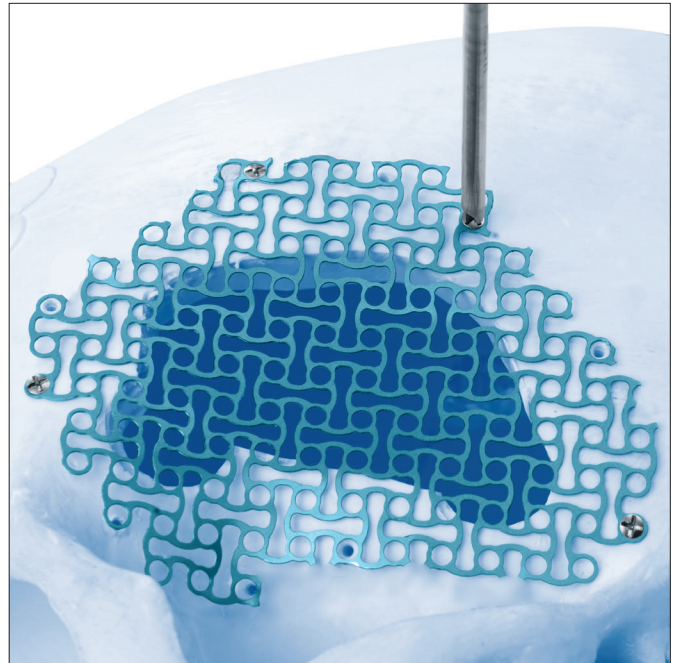
If the self-drilling or self-tapping screw (silver) does not retain good purchase, replace it with a 1.9 mm emergency screw (blue) of the same length.

Precautions:

- Fully engage the shaft perpendicular to the screw head.
- Place the 1.6 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. When using mesh for larger defects, additional screws for fixation are recommended.
- After implant placement is complete, discard any fragments or modified parts in an approved sharps container. Irrigate and apply suction for removal of debris potentially generated during implantation.

Note:

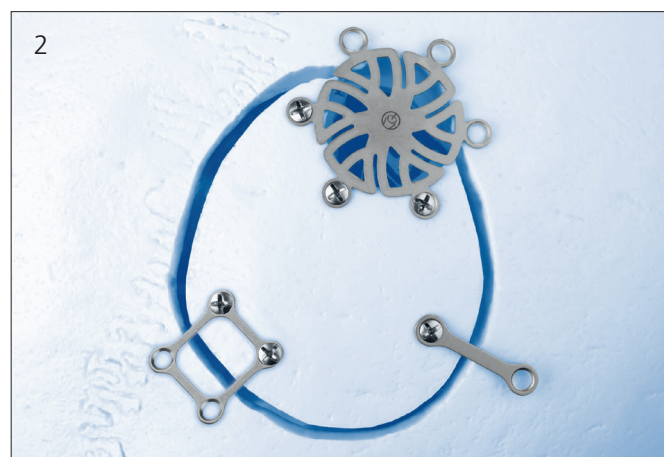
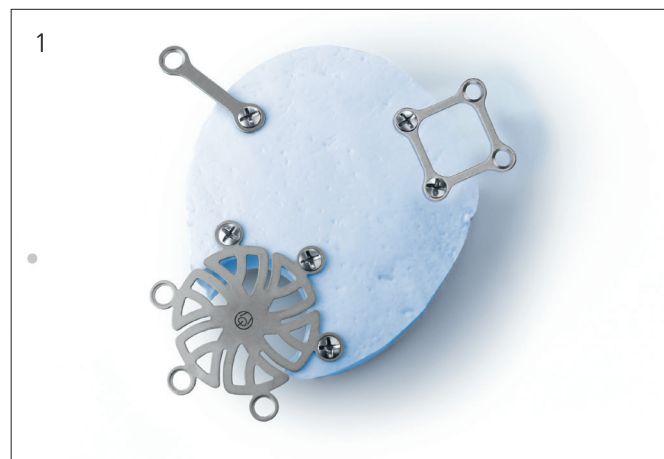
Screwdriver shafts are self-retaining instruments. Please replace worn or damaged screwdriver shafts, if the retention is not adequate.



Technique Tip

Secure the implants to the bone flap before positioning the bone flap on the patient.

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



ORDERING INFORMATION

Set		Plates*	
01.503.304	Low Profile Neuro Basic Set	421.501	Strut Plate 1.6, thickness 0.4 mm, contourable, Pure Titanium
01.503.314	Low Profile Neuro Standard Set	421.502	Cranial Plate 1.6, straight, with centre space, 2 holes, thickness 0.5 mm, Pure Titanium
01.503.303	Low Profile Neuro Set, for use with sterile implants	421.504	Cranial Plate 1.6, straight, with centre space, 4 holes, thickness 0.5 mm, Pure Titanium
01.503.213	Low Profile Neuro Instrument Set, 1/3, standard	421.510	X-Plate 1.6, 4 holes, thickness 0.5 mm, Pure Titanium
01.503.233	Low Profile Neuro Instrument Set, 2/3, incl. Insert for Mesh Plates	421.511	Frame Plate 1.6, square, 4 holes, 14 × 14 mm, thickness 0.5 mm, Pure Titanium
Modules		421.512	Frame Plate 1.6, square, 4 holes, 16 × 16 mm, thickness 0.5 mm, Pure Titanium
61.503.303	Module Low Profile Neuro 1/3, Basic, with Lid, without Contents	421.515	Y-Plate 1.6, 5 holes, thickness 0.5 mm, Pure Titanium
61.503.324	Module Low Profile Neuro, 2/3, standard, with Lid, without Contents	421.516	Double Y-Plate 1.6, 6 holes, length 18 mm, thickness 0.5 mm, Pure Titanium
61.503.200	Module Neuro, 1/3, without Lid, without Contents, for use with sterile implants	421.517	Double Y-Plate 1.6, 6 holes, length 21 mm, thickness 0.5 mm, Pure Titanium
61.503.308	Lid Low Profile Neuro for No. 61.503.200	421.518	Adaption Plate 1.6, 5 holes, thickness 0.5 mm, Pure Titanium
61.503.213	Instrument Tray Neuro, standard	421.519	Adaption Plate 1.6, 7 holes, thickness 0.5 mm, Pure Titanium
61.503.233	Instrument Tray Neuro, 2/3, incl. Insert for Mesh Plates	421.520	Adaption Plate 1.6, 20 holes, thickness 0.5 mm, Pure Titanium
61.503.234	Instrument Tray for Low Profile Neuro and MatrixNEURO System, size 1/2, with Lid	421.521	Frame Plate 1.6, rectangular, 4 holes, 10 × 16 mm, thickness 0.5 mm, Pure Titanium
Screws*		421.522	Strut Plate 1.6, 2 × 3 holes, 14 × 24 mm, thickness 0.5 mm, Pure Titanium
400.833	Cranial Screw PlusDrive Ø 1.6 mm, self-drilling, length 3 mm, Titanium Alloy (TAN), Silver	421.523	Strut Plate 1.6, 2 × 4 holes, 14 × 34 mm, thickness 0.5 mm, Pure Titanium
400.834	Cranial Screw PlusDrive Ø 1.6 mm, self-drilling, length 4 mm, Titanium Alloy (TAN), Silver	Contourable Mesh plates*	
400.835**	Cranial Screw PlusDrive Ø 1.6 mm, self-drilling, length 5 mm, Titanium Alloy (TAN), Silver	421.500	Temporal Mesh Plate 1.6, thickness 0.4 mm, malleable, Pure Titanium, Blue
400.836**	Cranial Screw PlusDrive Ø 1.6 mm, self-drilling, length 6 mm, Titanium Alloy (TAN), Silver	421.531	Mesh Plate 1.6, 38 × 45 mm, thickness 0.4 mm, malleable, Pure Titanium, Blue
400.843	Cranial Screw PlusDrive Ø 1.6 mm, self-tapping, length 3 mm, Titanium Alloy (TAN), Silver	421.532	Mesh Plate 1.6, 38 × 45 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver
400.844	Cranial Screw PlusDrive Ø 1.6 mm, self-tapping, length 4 mm, Titanium Alloy (TAN), Silver	421.533	Mesh Plate 1.6, 100 × 100 mm, thickness 0.4 mm, malleable, Pure Titanium, Blue
400.845	Cranial Screw PlusDrive Ø 1.6 mm, self-tapping, length 5 mm, Titanium Alloy (TAN), Silver	421.534	Mesh Plate 1.6, 100 × 100 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver
400.846	Cranial Screw PlusDrive Ø 1.6 mm, self-tapping, length 6 mm, Titanium Alloy (TAN), Silver	421.535	Mesh Plate 1.6, 200 × 200 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver
400.853	Emergency Screw PlusDrive Ø 1.9 mm, self-tapping, length 3 mm, Titanium Alloy (TAN), Blue	421.536	Mesh Plate 1.6, crescent-shaped, small, thickness 0.4 mm, malleable, Pure Titanium, Blue
400.854	Emergency Screw PlusDrive Ø 1.9 mm, self-tapping, length 4 mm, Titanium Alloy (TAN), Blue	421.537	Mesh Plate 1.6, crescent-shaped, large, thickness 0.4 mm, malleable, Pure Titanium, Blue
400.855	Emergency Screw PlusDrive Ø 1.9 mm, self-tapping, length 5 mm, Titanium Alloy (TAN), Blue	421.538	Mesh Plate 1.6, crescent-shaped, small, thickness 0.6 mm, rigid, Pure Titanium, Silver
400.856	Emergency Screw PlusDrive Ø 1.9 mm, self-tapping, length 6 mm, Titanium Alloy (TAN), Blue	421.539	Mesh Plate 1.6, crescent-shaped, large, thickness 0.6 mm, rigid, Pure Titanium, Silver
		421.540	Mesh Plate 1.6, Ø 30 mm, thickness 0.4 mm, malleable, Pure Titanium, Blue
		421.541	Mesh Plate 1.6, Ø 70 mm, thickness 0.4 mm, malleable, Pure Titanium, Blue
		421.542	Mesh Plate 1.6, Ø 100 mm, thickness 0.4 mm, malleable, Pure Titanium, Blue
		421.543	Mesh Plate 1.6, Ø 30 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver

* All plates and screws can also be obtained sterile by adding "S" after the article number, such as 421.502S (see flyer 036.000.349). Label clips can be ordered for all articles by adding "LC" after the article number such as 421.502LC.

** DePuy Synthes recommends pre-drilling in dense bone.

421.544	Mesh Plate 1.6, Ø 70 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver
421.545	Mesh Plate 1.6, Ø 100 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver
421.546	Mastoid Plate 1.6, thickness 0.4 mm, malleable, large, Blue
421.547	Mastoid Plate 1.6, thickness 0.4 mm, malleable, medium, Blue

Burr hole covers*

421.525	Burr Hole Cover 1.6, for burr holes up to Ø 12.0 mm, thickness 0.5 mm, Pure Titanium
421.526	Burr Hole Cover 1.6, for burr holes up to Ø 15.0 mm, thickness 0.5 mm, Pure Titanium
421.527	Burr Hole Cover 1.6, for burr holes up to Ø 17.0 mm, thickness 0.5 mm, Pure Titanium
421.528	Burr Hole Cover 1.6, for burr holes up to Ø 24.0 mm, thickness 0.5 mm, Pure Titanium
421.553	Burr Hole Cover 1.6 for Shunt or Drainage, for burr holes up to Ø 15.0 mm, thickness 0.5 mm, Pure Titanium
421.554	Burr Hole Cover 1.6 for Shunt or Drainage, for burr holes up to Ø 17.0 mm, thickness 0.5 mm, Pure Titanium

Instruments

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310.137	Drill Bit Ø 1.3 mm with Stop, length 44.5/6 mm, for J-Latch Coupling
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310.139	Drill Bit Ø 1.3 mm with Stop, length 52/6 mm, for Hexagonal Coupling
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347.981	Holding Forceps for Plates 1.0 to 2.4
391.952	Cutter for Strut Plates and Mesh Plates

Screw overview

	Tube bag		Screw clip		Screw clip – sterile	
	set of 1	set of 5	set of 1	set of 4	set of 1	set of 4
Self-drilling	xxx.xxx	xxx.xxx.05	xxx.xxx.01C	xxx.xxx.04C	xxx.xxxS	xxx.xxx.04S
Self-tapping	xxx.xxx	xxx.xxx.05	xxx.xxx.01C	–	xxx.xxxS	–
Emergency	xxx.xxx	xxx.xxx.05	xxx.xxx.01C	–	xxx.xxxS	–

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