

Low Profile Neuro

Surgical Technique



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

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The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

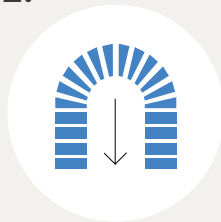
AO Principles^{1,2}

1.



Fracture reduction and fixation to restore anatomical relationships.

2.



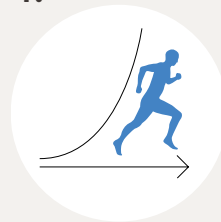
Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.



Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

¹ Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.

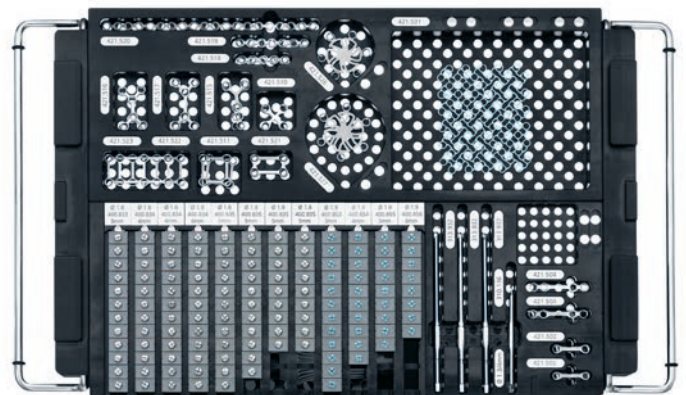
² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

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.

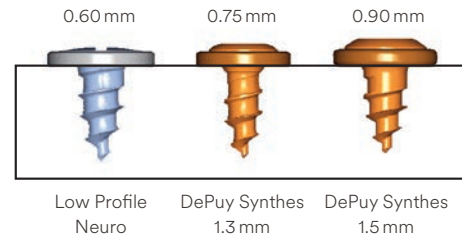
The Low Profile Neuro Plating System features low plate/screw profile, variety of implants, and modular storage options.



Low-profile plates

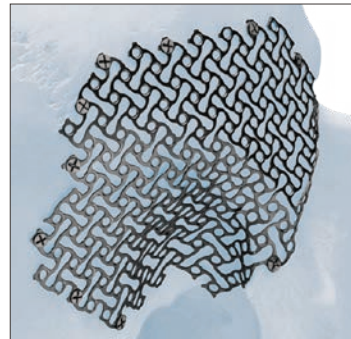
- Low Profile Plate thickness, 0.5 mm
- Variety of plate sizes to meet specific patient and surgeon needs
- Made from Commercially pure Titanium

Plate/screw profiles of various systems



Low-profile mesh

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



Self-drilling screws

- Screws are self-drilling*
- Made from titanium alloy (Ti-6Al-7Nb)
- Available in 3 mm–6 mm lengths
- Screws are color coded: Self-drilling screws are silver, emergency screws are blue

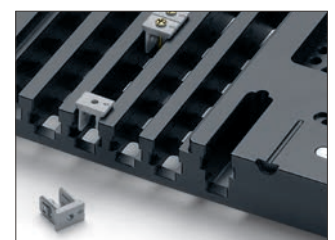


Screw clips

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



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



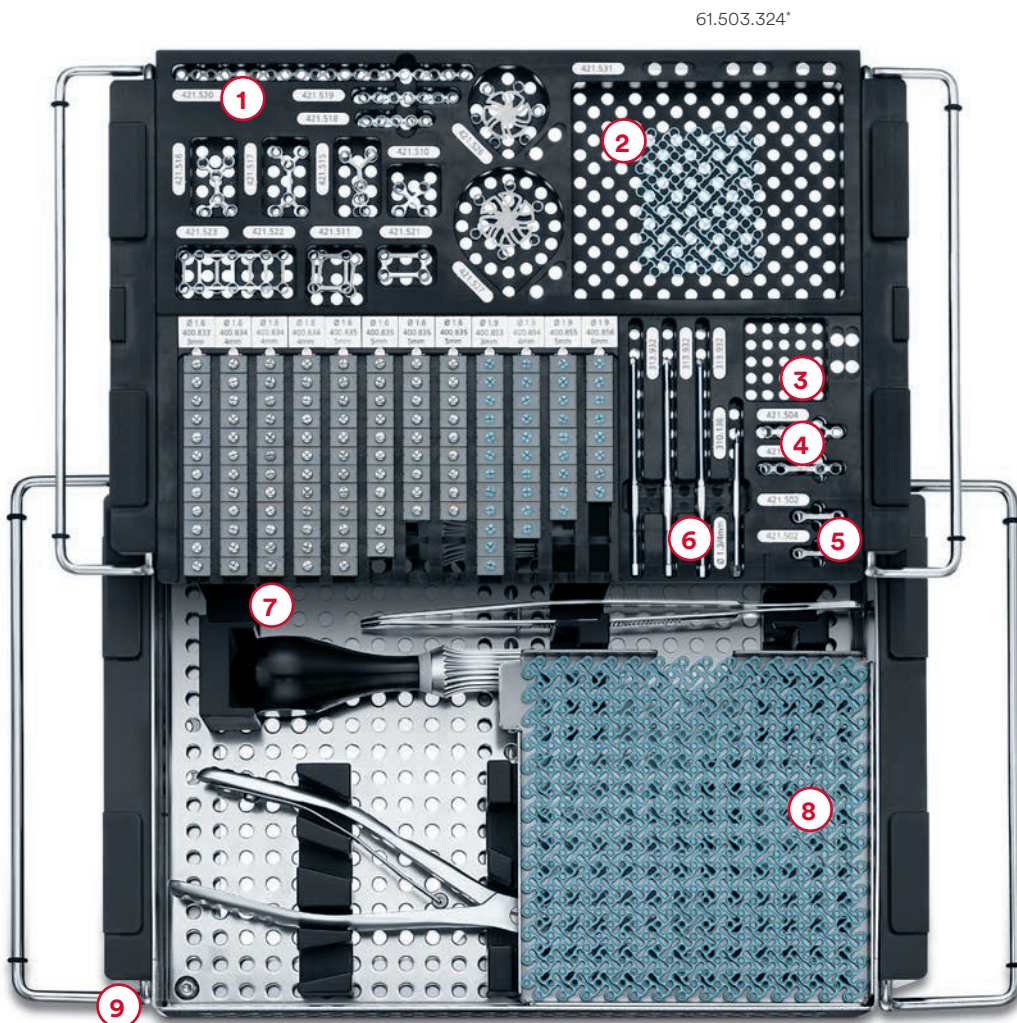
Push empty clips out of the opening

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

Standard module

Different module sizes are obtainable as needed.
The basic module (size 1/3) can be expanded to
the standard module (size 2/3).

1. Large plate selection
Large auxiliary bin
2. For mesh plates or optional plates
3. Small auxiliary bin
4. Label clips
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
8. Contourable mesh plates
9. Instrument carrier
Size for the standard module: The carrier and module
can be stacked on each other to save space



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

61.503.233*

Warnings

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

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks.

Instruction for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

MRI Information on Torque, Displacement, Image Artifacts and Radio Frequency (RF) – induced heating can be found in the corresponding System Instructions for Use.

Surgical Technique

1. Select implant

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

▲ Precaution:

When using plates, ensure countersink holes are facing upward.

2. Size implant (if required)

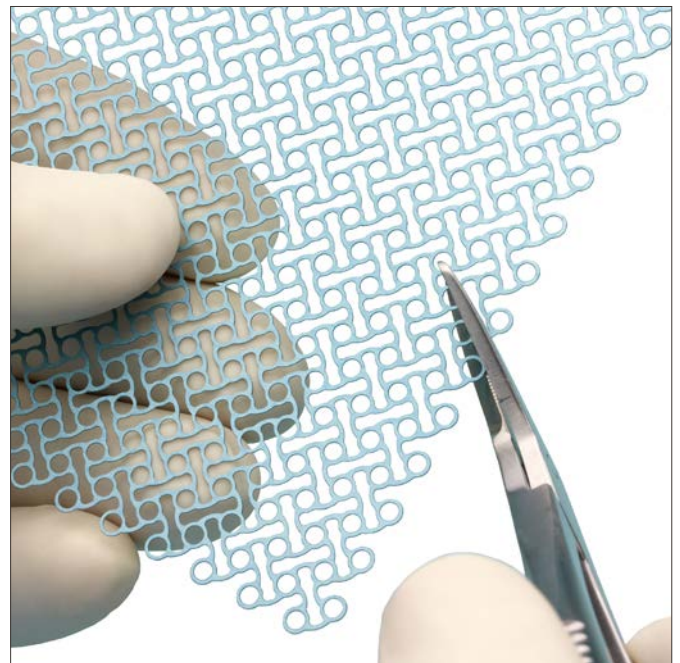
Instruments

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.
- While handling the cut mesh, avoid the sharp edges.

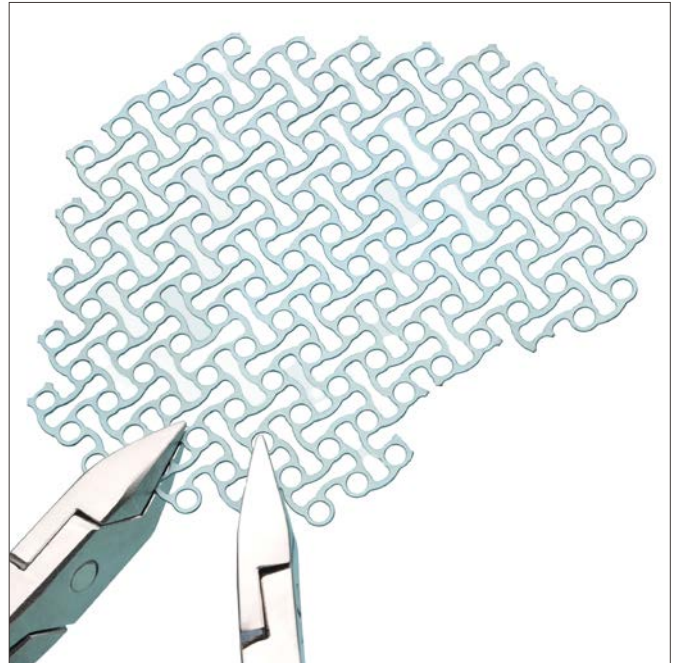


3. Contour implant (if required)

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

▲ Precautions:

- Excessive and repetitive bending of the implant increases the risk of implant breakage.
- 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.
- Avoid contouring of the implant in situ as that may lead to implant malposition.

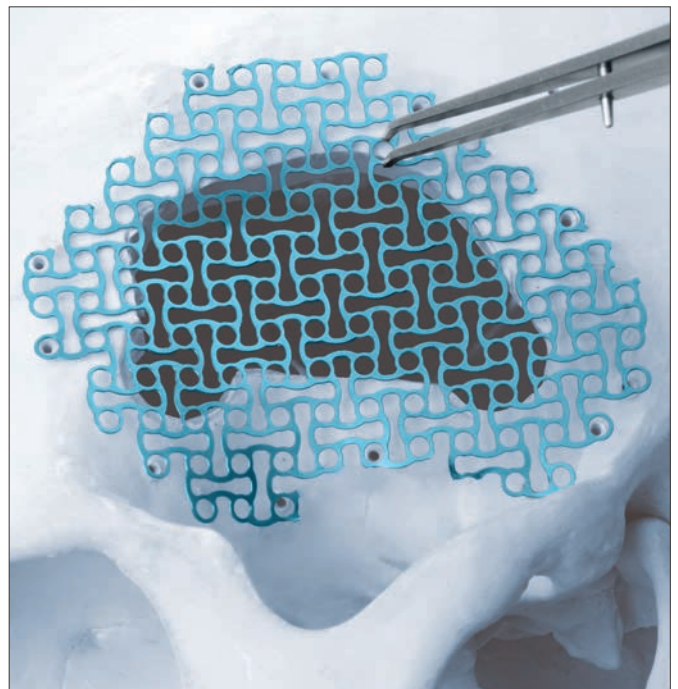


4. Position implant

Instruments

347.981 Holding Forceps for Plates 1.0 to 2.4

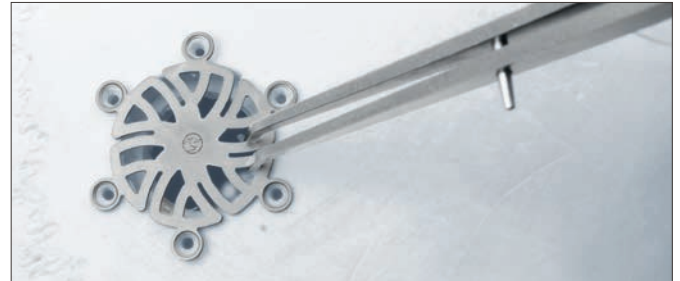
Position the implant on the desired location using the appropriate plate holder.



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 speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. Higher drill speed rate 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 and/or the need for emergency screws.
- Always 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

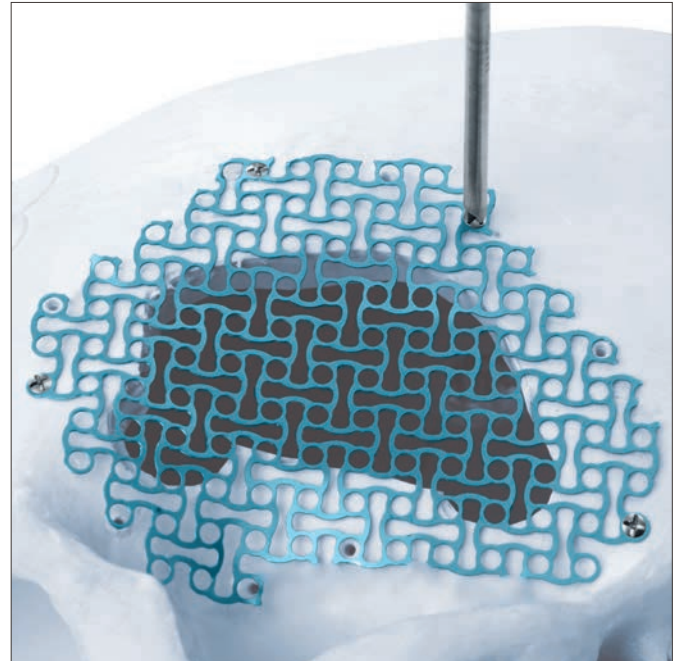


To load the screw onto the blade, place the blade perpendicular to the screw in the module and fully insert the blade into the screw recess. The screw should be securely attached to the blade.

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 or mesh 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 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, discard any fragments or modified parts in an approved sharps container. Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- 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.
- 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, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially pure Titanium
Modules		421.512	Frame Plate 1.6, square, 4 holes, 16 × 16 mm, thickness 0.5 mm, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially pure Titanium
61.503.213	Instrument Tray Neuro, standard	421.519	Adaption Plate 1.6, 7 holes, thickness 0.5 mm, Commercially 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, Commercially 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, Commercially pure Titanium
Screws*		421.522	Strut Plate 1.6, 2 × 3 holes, 14 × 24 mm, thickness 0.5 mm, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially 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, Commercially pure Titanium, Silver
		421.540	Mesh Plate 1.6, Ø 30 mm, thickness 0.4 mm, malleable, Commercially pure Titanium, Blue
		421.541	Mesh Plate 1.6, Ø 70 mm, thickness 0.4 mm, malleable, Commercially pure Titanium, Blue

* All plates and screws can also be obtained sterile by adding "S" after the article number, such as 421.502S..

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.

421.542	Mesh Plate 1.6, Ø 100 mm, thickness 0.4 mm, malleable, Commercially pure Titanium, Blue
421.543	Mesh Plate 1.6, Ø 30 mm, thickness 0.6 mm, rigid, Commercially pure Titanium, Silver
421.544	Mesh Plate 1.6, Ø 70 mm, thickness 0.6 mm, rigid, Commercially pure Titanium, Silver
421.545	Mesh Plate 1.6, Ø 100 mm, thickness 0.6 mm, rigid, Commercially 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, Commercially pure Titanium
421.526	Burr Hole Cover 1.6, for burr holes up to Ø 15.0 mm, thickness 0.5 mm, Commercially pure Titanium
421.527	Burr Hole Cover 1.6, for burr holes up to Ø 17.0 mm, thickness 0.5 mm, Commercially pure Titanium
421.528	Burr Hole Cover 1.6, for burr holes up to Ø 24.0 mm, thickness 0.5 mm, Commercially 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, Commercially 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, Commercially pure Titanium

Instruments

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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	–

* All plates and screws can also be obtained sterile by adding "S" after the article number, such as 421.502S.

Label clips can be ordered for all articles by adding "LC" after the article number such as 421.502LC.

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Not all products are currently available in all markets.
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