LOW PROFILE NEURO

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
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

*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.

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
**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**
   - For mesh plates or optional plates

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

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

<table>
<thead>
<tr>
<th>Instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>391.952 Cutter for Strut Plates and Mesh Plates</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>347.981 Holding Forceps for Plates 1.0 to 2.4</td>
</tr>
</tbody>
</table>

Position the implant on the desired location using the appropriate plate holder.
Pre-drill screw holes (optional)

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>310.138</td>
<td>Drill Bit Ø 1.3 mm with Stop, length 52/4 mm, for Hexagonal Coupling</td>
</tr>
<tr>
<td>310.139</td>
<td>Drill Bit Ø 1.3 mm with Stop, length 52/6 mm, for Hexagonal Coupling</td>
</tr>
<tr>
<td>310.136</td>
<td>Drill Bit Ø 1.3 mm with Stop, length 44.5/4 mm, for J-Latch Coupling</td>
</tr>
<tr>
<td>310.137</td>
<td>Drill Bit Ø 1.3 mm with Stop, length 44.5/6 mm, for J-Latch Coupling</td>
</tr>
</tbody>
</table>

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.

Secure implant

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>313.931</td>
<td>Screwdriver Shaft PlusDrive 1.6, length 42 mm, for Hexagonal Coupling</td>
</tr>
<tr>
<td>313.932</td>
<td>Screwdriver Shaft PlusDrive 1.6, length 66 mm, for Hexagonal Coupling</td>
</tr>
<tr>
<td>311.005</td>
<td>Handle, small, with Hexagonal Coupling</td>
</tr>
<tr>
<td>311.006</td>
<td>Handle, medium, with Hexagonal Coupling</td>
</tr>
<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
</tr>
</tbody>
</table>

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.
## PRODUCT INFORMATION

<table>
<thead>
<tr>
<th>Length</th>
<th>Material</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mm</td>
<td>Titanium Alloy (TAN)</td>
<td>Blue</td>
</tr>
<tr>
<td>5 mm</td>
<td>Titanium Alloy (TAN)</td>
<td>Blue</td>
</tr>
<tr>
<td>4 mm</td>
<td>Titanium Alloy (TAN)</td>
<td>Blue</td>
</tr>
<tr>
<td>3 mm</td>
<td>Titanium Alloy (TAN)</td>
<td>Blue</td>
</tr>
</tbody>
</table>

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</tr>
<tr>
<td>4 mm</td>
<td>Titanium Alloy (TAN)</td>
<td>Silver</td>
</tr>
<tr>
<td>3 mm</td>
<td>Titanium Alloy (TAN)</td>
<td>Silver</td>
</tr>
</tbody>
</table>

## ORDERING INFORMATION

### Modules
- **Set 01.503.304**: Low Profile Neuro Basic Set
- **Set 01.503.314**: Low Profile Neuro Standard Set
- **Set 01.503.303**: Low Profile Neuro Set, for use with sterile implants
- **Set 01.503.213**: Low Profile Neuro Instrument Set, 1/3, standard
- **Set 01.503.233**: Low Profile Neuro Instrument Set, 2/3, incl. Insert for Mesh Plates

### Screws
- **040.833**: Cranial Screw PlusDrive Ø 1.6 mm, self-drilling, length 3 mm, Titanium Alloy (TAN), Silver
- **040.834**: Cranial Screw PlusDrive Ø 1.6 mm, self-drilling, length 4 mm, Titanium Alloy (TAN), Silver
- **040.835**: Cranial Screw PlusDrive Ø 1.6 mm, self-drilling, length 5 mm, Titanium Alloy (TAN), Silver
- **040.836**: Cranial Screw PlusDrive Ø 1.6 mm, self-drilling, length 6 mm, Titanium Alloy (TAN), Silver
- **040.843**: Cranial Screw PlusDrive Ø 1.6 mm, self-tapping, length 3 mm, Titanium Alloy (TAN), Silver
- **040.844**: Cranial Screw PlusDrive Ø 1.6 mm, self-tapping, length 4 mm, Titanium Alloy (TAN), Silver
- **040.845**: Cranial Screw PlusDrive Ø 1.6 mm, self-tapping, length 5 mm, Titanium Alloy (TAN), Silver
- **040.846**: Cranial Screw PlusDrive Ø 1.6 mm, self-tapping, length 6 mm, Titanium Alloy (TAN), Silver
- **040.853**: Emergency Screw PlusDrive Ø 1.9 mm, self-tapping, length 3 mm, Titanium Alloy (TAN), Blue
- **040.854**: Emergency Screw PlusDrive Ø 1.9 mm, self-tapping, length 4 mm, Titanium Alloy (TAN), Blue
- **040.855**: Emergency Screw PlusDrive Ø 1.9 mm, self-tapping, length 5 mm, Titanium Alloy (TAN), Blue
- **040.856**: Emergency Screw PlusDrive Ø 1.9 mm, self-tapping, length 6 mm, Titanium Alloy (TAN), Blue

### Plates
- **421.501**: Strut Plate 1.6, thickness 0.4 mm, contourable, Pure Titanium
- **421.502**: Cranial Plate 1.6, straight, with centre space, 2 holes, thickness 0.5 mm, Pure Titanium
- **421.504**: Cranial Plate 1.6, straight, with centre space, 4 holes, thickness 0.5 mm, Pure Titanium
- **421.510**: X-Plate 1.6, 4 holes, thickness 0.5 mm, Pure Titanium
- **421.511**: Frame Plate 1.6, square, 4 holes, 14 x 14 mm, thickness 0.5 mm, Pure Titanium
- **421.512**: Frame Plate 1.6, square, 4 holes, 16 x 16 mm, thickness 0.5 mm, Pure Titanium
- **421.515**: Y-Plate 1.6, 5 holes, thickness 0.5 mm, Pure Titanium
- **421.516**: Double Y-Plate 1.6, 6 holes, length 18 mm, thickness 0.5 mm, Pure Titanium
- **421.517**: Double Y-Plate 1.6, 6 holes, length 21 mm, thickness 0.5 mm, Pure Titanium
- **421.518**: Adaption Plate 1.6, 5 holes, thickness 0.5 mm, Pure Titanium
- **421.519**: Adaption Plate 1.6, 7 holes, thickness 0.5 mm, Pure Titanium
- **421.520**: Adaption Plate 1.6, 20 holes, thickness 0.5 mm, Pure Titanium
- **421.521**: Frame Plate 1.6, rectangular, 4 holes, 10 x 16 mm, thickness 0.5 mm, Pure Titanium
- **421.522**: Strut Plate 1.6, 2 x 3 holes, 14 x 24 mm, thickness 0.5 mm, Pure Titanium
- **421.523**: Strut Plate 1.6, 2 x 4 holes, 14 x 34 mm, thickness 0.5 mm, Pure Titanium

### Contourable Mesh Plates
- **421.500**: Temporal Mesh Plate 1.6, thickness 0.4 mm, malleable, Pure Titanium, Blue
- **421.531**: Mesh Plate 1.6, 38 x 45 mm, thickness 0.4 mm, malleable, Pure Titanium, Blue
- **421.532**: Mesh Plate 1.6, 38 x 45 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver
- **421.533**: Mesh Plate 1.6, 100 x 100 mm, thickness 0.4 mm, malleable, Pure Titanium, Blue
- **421.534**: Mesh Plate 1.6, 100 x 100 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver
- **421.535**: Mesh Plate 1.6, 200 x 200 mm, thickness 0.6 mm, rigid, Pure Titanium, Silver
- **421.536**: Mesh Plate 1.6, crescent-shaped, small, thickness 0.4 mm, malleable, Pure Titanium, Blue
- **421.537**: Mesh Plate 1.6, crescent-shaped, large, thickness 0.4 mm, malleable, Pure Titanium, Blue
- **421.538**: Mesh Plate 1.6, crescent-shaped, small, thickness 0.6 mm, rigid, Pure Titanium, Silver
- **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

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* 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.
### Burr hole covers

<table>
<thead>
<tr>
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<th>Description</th>
<th>Dimensions</th>
<th>Material</th>
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<tbody>
<tr>
<td>421.525</td>
<td>Burr Hole Cover 1.6, for burr holes up to 12.0 mm</td>
<td>12.0 mm</td>
<td>Pure Titanium</td>
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<tr>
<td>421.526</td>
<td>Burr Hole Cover 1.6, for burr holes up to 15.0 mm</td>
<td>15.0 mm</td>
<td>Pure Titanium</td>
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<tr>
<td>421.527</td>
<td>Burr Hole Cover 1.6, for burr holes up to 17.0 mm</td>
<td>17.0 mm</td>
<td>Pure Titanium</td>
</tr>
<tr>
<td>421.528</td>
<td>Burr Hole Cover 1.6, for burr holes up to 24.0 mm</td>
<td>24.0 mm</td>
<td>Pure Titanium</td>
</tr>
</tbody>
</table>

### Instruments

<table>
<thead>
<tr>
<th>Article Number</th>
<th>Description</th>
<th>Dimensions</th>
<th>Coupling Type</th>
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<tbody>
<tr>
<td>310.136</td>
<td>Drill Bit Ø 1.3 mm with Stop, length 44.5/4 mm</td>
<td>1.3 mm</td>
<td>J-Latch Coupling</td>
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<td>347.981</td>
<td>Holding Forceps for Plates 1.0 to 2.4</td>
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<tr>
<td>391.952</td>
<td>Cutter for Strut Plates and Mesh Plates</td>
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</table>

### Screw overview

<table>
<thead>
<tr>
<th>Screw Type</th>
<th>Tube bag set of 1</th>
<th>Tube bag set of 5</th>
<th>Screw clip set of 1</th>
<th>Screw clip set of 4</th>
<th>Screw clip – sterile set of 1</th>
<th>Screw clip – sterile set of 4</th>
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<tbody>
<tr>
<td>Self-drilling</td>
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<td>Self-tapping</td>
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<td>–</td>
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