Instructions for Use
Low Profile Neuro

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

DePuy Synthes
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Instructions for Use

Low Profile Neuro

400.833	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 3 mm
400.834	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 4 mm
400.835	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 5 mm
400.836	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 6 mm
400.843	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 3 mm
400.844	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 4 mm
400.845	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 5 mm
400.846	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 6 mm
400.853	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 3 mm
400.854	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 4 mm
400.855	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 5 mm
400.856	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 6 mm
421.500	Temporal Mesh Plate 1.6, contourable
421.501	Strut Plate 1.6, contourable
421.502	Cranial Plate 1.6, straight, 2 holes, 0.5 mm
421.504	Cranial Plate 1.6, straight, 4 holes, 0.5 mm
421.510	X-Plate 1.6, 4 holes, 0.5 mm
421.511	Frame Plate 1.6, square, 4 holes
421.512	Frame Plate 1.6, square, 4 holes
421.515	Y-Plate 1.6, 5 holes, 0.5 mm
421.516	Double Y-Plate 1.6, 6 holes, L 18 mm, 0.5 mm
421.517	Double Y-Plate 1.6, 6 holes, L 21 mm, 0.5 mm
421.518	Adaption Plate 1.6, 5 holes, 0.5 mm
421.519	Adaption Plate 1.6, 7 holes, 0.5 mm
421.520	Adaption Plate 1.6, 20 holes, 0.5 mm
421.521	Frame Plate 1.6, rectangular, 4 holes, 10x16 mm
421.522	Strut Plate 1.6, 2×3 holes
421.523	Strut Plate 1.6, 2×4 holes
421.525	Burr Hole Cover 1.6, 0.5 mm
421.526	Burr Hole Cover 1.6, 0.5 mm
421.527	Burr Hole Cover 1.6, 0.5 mm
421.528	Burr Hole Cover 1.6, 0.5 mm
421.531	Mesh Plate 1.6, 38×45 mm, 0.4 mm
421.532	Mesh Plate 1.6, 38×45 mm, 0.6 mm
421.533	Mesh Plate 1.6, 100×100 mm, 0.4 mm
421.534	Mesh Plate 1.6, 100×100 mm, 0.6 mm
421.535	Mesh Plate 1.6, 200×200 mm, 0.6 mm
421.536	Mesh Plate 1.6, crescent shaped, small, 0.4 mm
421.537	Mesh Plate 1.6, crescent shaped, large, 0.4 mm
421.538	Mesh Plate 1.6, crescent shaped, small, 0.6 mm
421.539	Mesh Plate 1.6, crescent shaped, large, 0.6 mm
421.540	Mesh Plate 1.6, ∅ 30 mm, 0.4 mm
421.541	Mesh Plate 1.6, ∅ 70 mm, 0.4 mm
421.542	Mesh Plate 1.6, ∅ 100 mm, 0.4 mm
421.543	Mesh Plate 1.6, ∅ 30 mm, 0.6 mm
421.544	Mesh Plate 1.6, ∅ 70 mm, 0.6 mm
421.545	Mesh Plate 1.6, ∅ 100 mm, 0.6 mm
421.546	Mastoid Plate 1.6, thickness 0.4 mm, large
421.547	Mastoid Plate 1.6, thickness 0.4 mm, medium
421.553	Burr Hole Cover 1.6, f/Shunt or Drainage
421.554	Burr Hole Cover 1.6, f/Shunt or Drainage
400.833.01C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-drill.
400.833.04C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-drill.
400.833.04S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 3 mm
400.833.05	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 3 mm
400.833S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 3 mm
400.834.01C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-drill.
400.834.04C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-drill.
400.834.04S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 4 mm
400.834.05	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 4 mm
400.834S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 4 mm
400.835.01C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-drill.
400.835.04C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-drill.
400.835.04S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 5 mm
400.835.05	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 5 mm
400.835S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 5 mm
400.836.01C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-drill.
400.836.04C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-drill.
400.836.04S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 6 mm
400.836.05	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 6 mm
400.836S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 6 mm
400.843.01C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-tapp.
400.843.05	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 3 mm
400.843S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 3 mm
400.844.01C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-tapp.
400.844.05	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 4 mm
400.844S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 4 mm
400.845.01C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-tapp.
400.845.05	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 5 mm
400.845S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 5 mm
400.846.01C	Cranial Screw PlusDrive™ ∅ 1.6 mm, self-tapp.
400.846.05	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 6 mm
400.846S	Cranial Screw PlusDrive™ ∅ 1.6 mm, L 6 mm
400.853.01C	Emergency Screw PlusDrive™ ∅ 1.9 mm, self-tapp.
400.853.05	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 3 mm
400.853S	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 3 mm
400.854.01C	Emergency Screw PlusDrive™ ∅ 1.9 mm, self-tapp.
400.854.05	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 4 mm
400.854S	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 4 mm
400.855.01C	Emergency Screw PlusDrive™ ∅ 1.9 mm, self-tapp.
400.855.05	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 5 mm
400.855S	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 5 mm
400.856.01C	Emergency Screw PlusDrive™ ∅ 1.9 mm, self-tapp.
400.856.05	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 6 mm
400.856S	Emergency Screw PlusDrive™ ∅ 1.9 mm, L 6 mm
421.500S	Temporal Mesh Plate 1.6, contourable
421.501S	Strut Plate 1.6, contourable
421.502S	Cranial Plate 1.6, straight, w/centre space
421.504S	Cranial Plate 1.6, straight, w/centre space
421.510S	X-Plate 1.6, 4 holes, 0.5 mm
421.511S	Frame Plate 1.6, square, 4 holes
421.512S	Frame Plate 1.6, square, 4 holes
421.515S	Y-Plate 1.6, 5 holes, 0.5 mm
421.516S	Double Y-Plate 1.6, 6 holes, L 18 mm, 0.5 mm
421.517S	Double Y-Plate 1.6, 6 holes, L 21 mm, 0.5 mm
421.518S	Adaption Plate 1.6, 5 holes, 0.5 mm
421.519S	Adaption Plate 1.6, 7 holes, 0.5 mm
421.520S	Adaption Plate 1.6, 20 holes, 0.5 mm
421.521S	Frame Plate 1.6, rectangular, 4 holes
421.522S	Strut Plate 1.6, 2×3 holes, 14×24 mm
421.523S	Strut Plate 1.6, 2×4 holes, 14×34 mm, 0.5 mm
421.525S	Burr Hole Cover 1.6, 0.5 mm
421.526S	Burr Hole Cover 1.6, 0.5 mm
421.527S	Burr Hole Cover 1.6, 0.5 mm
421.528S	Burr Hole Cover 1.6, 0.5 mm
421.531S	Mesh Plate 1.6, 38×45 mm, 0.4 mm
421.532S	Mesh Plate 1.6, 38×45 mm, 0.6 mm
421.533S	Mesh Plate 1.6, 100×100 mm, 0.4 mm
421.534S	Mesh Plate 1.6, 100×100 mm, 0.6 mm
421.535S	Mesh Plate 1.6, 200×200 mm, 0.6 mm
421.536S	Mesh Plate 1.6, crescent-shaped, small, 0.4 mm
421.537S	Mesh Plate 1.6, crescent-shaped, large, 0.4 mm
421.538S	Mesh Plate 1.6, crescent-shaped, small, 0.6 mm
421.539S	Mesh Plate 1.6, crescent-shaped, large, 0.6 mm
421.540S	Mesh Plate 1.6, ∅ 30 mm, 0.4 mm
421.541S	Mesh Plate 1.6, ∅ 70 mm, 0.4 mm
421.542S	Mesh Plate 1.6, ∅ 100 mm, 0.4 mm
421.543S	Mesh Plate 1.6, ∅ 30 mm, 0.6 mm
421.544S	Mesh Plate 1.6, ∅ 70 mm, 0.6 mm
421.545S	Mesh Plate 1.6, ∅ 100 mm, 0.6 mm
421.546S	Mastoid Plate 1.6, thickness 0.4 mm, large
421.547S	Mastoid Plate 1.6, thickness 0.4 mm, medium
421.553S	Burr Hole Cover 1.6, f/Shunt or Drainage
421.554S	Burr Hole Cover 1.6, f/Shunt or Drainage
310.136	Drill Bit ∅ 1.3 mm w/Stop, L 44.5/4 mm
310.137	Drill Bit ∅ 1.3 mm w/Stop, L 44.5/6 mm
310.138	Drill Bit ∅ 1.3 mm w/Stop, L 52/4 mm
310.139	Drill Bit ∅ 1.3 mm w/Stop, L 52/6 mm

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding brochure Low Profile Neuro (036.000.347) carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material(s)

Material(s):	Standard(s):
Implants:	
TiCP	ISO 5832-2
TiAlNb	ISO 5832-11
Instruments:	
Stainless Steel	ISO 7153-1

Intended use

Synthes Low Profile Neuro plate and screw system is intended for 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.

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
Precaution: Take care to protect soft tissue from trimmed edges.
Please replace worn or damaged cutting instruments if the cutting function is not adequate.
Do not exceed 1800rpm while drilling.
Please drill with the proper irrigation.
Be aware that most of the plates and meshes have a screw recess on one side only.

Warnings
The LPN fixation system is not intended for use in patients who are not yet skeletally mature. Resorbable fixation products should be considered as an alternative.

Magnetic Resonance environment
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
– Heating or migration of the device
– Artifacts on MR images

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 Low Profile Neuro 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 or 6 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

REF Reference Number

LOT Lot or batch number

Manufacturing date

Expiration date

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