
Instructions for Use Low Profile Neuro™

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

Instructions for Use

Low Profile Neuro

Please read these instructions for use, the DePuy Synthes brochure "Important Information" and the corresponding Surgical technique Low Profile Neuro (DSEM/CMF/0914/0034) carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material(s)

Implant(s):	Material(s):	Standard(s):
Plates, Meshes	TiCP	ISO 5832-2-1999
Screws	TAN	ISO 5832-11-1994

Instruments	Material(s):	Standard(s):
	Stainless steel	ISO 7153-1:1991+A1-1999

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.

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.

Device Specific Adverse Events

Device specific adverse events include but are not limited to: Screw Loosening/pull out, Plate breakage, Explantation, Pain, Seroma, Hematoma.

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 reesterilization) 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 DePuy 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

Cut the implant immediately adjacent to the screw holes.

Take care to protect soft tissue from trimmed edges.

Replace worn or damaged cutting instruments if the cutting function is not adequate.

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

When using plates, ensure countersink holes are facing upwards.

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.

Handle devices with care and dispose worn bone cutting instruments in a sharps container.

Irrigate during drilling to avoid thermal damage to the bone.

Use only a 1.3 mm drill bit for pre-drilling.

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 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 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.

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.

Magnetic Resonance environment

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07

Non-clinical testing of 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 conducted on a 3 T MRI system.

Radio Frequency (RF) – induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal simulations of 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 MR 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

Treatment before device is used

DePuy 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 DePuy 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.
3. Contour implant (if required)
The implant can be further contoured to match patient anatomy.
4. Position implant
Position the implant on the desired location using the appropriate plate holder.
5. Pre-drill screw holes (optional)
6. Secure implant
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.

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.

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://emea.depuySynthes.com/hcp/reprocessing-care-maintenance>

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