
Instructions for Use Low Profile Neuro™

Not all products are currently available in all markets.

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



Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

Low Profile Neuro

Devices in scope:

Implants	421.515
400.833	421.515S
400.833.01C	421.516
400.833.04C	421.516S
400.833.04S	421.517
400.833S	421.517S
400.834	421.518
400.834.01C	421.518S
400.834.04C	421.519
400.834.04S	421.519S
400.834.05	421.520
400.834S	421.520S
400.835	421.521
400.835.01C	421.521S
400.835.04C	421.522
400.835.04S	421.522S
400.835S	421.523
400.836	421.523S
400.836.01C	421.525
400.836.04C	421.525S
400.836.04S	421.526
400.836S	421.526S
400.843	421.527
400.843.01C	421.527S
400.843.05	421.528
400.843S	421.528S
400.844	421.531
400.844.01C	421.531S
400.844.05	421.532
400.844S	421.532S
400.845	421.533
400.845.01C	421.533S
400.845.05	421.534
400.845S	421.534S
400.846	421.535
400.846.01C	421.535S
400.846.05	421.536
400.846S	421.536S
400.853	421.537
400.853.01C	421.537S
400.853S	421.538
400.854	421.538S
400.854.01C	421.539
400.854.05	421.539S
400.854S	421.540
400.855	421.540S
400.855.01C	421.541
400.855S	421.541S
400.856	421.542
400.856.01C	421.542S
400.856S	421.543
421.500	421.543S
421.500S	421.544
421.501	421.544S
421.501S	421.545
421.502	421.545S
421.502S	421.546
421.504	421.546S
421.504S	421.547
421.510	421.547S
421.510S	421.553
421.511	421.553S
421.511S	421.554
421.512	421.554S
421.512S	

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

Instructions for Use

Introduction

Associated device systems with these instructions for use are:
Low Profile Neuro

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.

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
Screws	TAN	ISO 5832-11

Instruments	Material(s):	Standard(s):
	Stainless steel	ISO 7153-1

This system does not include any devices with restricted substances.

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.

Patient Target Group

The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Not for use in patients who are not yet skeletally mature.

Intended User

This IFU alone does not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and /or the Synthes "Important Information" brochure (SE_023827) as appropriate.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits

Expected clinical benefits of internal fixation devices such as Low Profile Neuro when used according to instructions for use and recommended technique are:

- Stabilize bone segment and facilitate healing
- Restore anatomical relationship and function

Performance Characteristics of the Device

DePuy Synthes has established the performance and safety of Low Profile Neuro System and that they represent state of the art medical devices for cranial closure and/or bone fixation when used according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks

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:

- Adverse tissue reaction, allergy/hypersensitivity reaction
- Bone damage including intra-and post-operative bone fracture, osteolysis, or bone necrosis
- Damage to vital organs or surrounding structures
- Dural tear/inflammation or spinal fluid leak
- Infection
- Injury to user
- Pain or discomfort
- Soft tissue damage
- Symptoms resulting from implant migration, loosening, bending, or breakage

Sterile device


STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

 Do not use if package is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Single-use device

 Do not re-use

Products intended for single-use must not be re-used.

Re-use or clinical 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 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.

Warnings and Precautions

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.

Precautions

- When using plates, ensure countersink holes are facing upward.
- Take care to protect soft tissue from trimmed edges.
- Replace worn or damaged cutting instrument 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.
- 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.
- DePuy Synthes recommends pre-drilling 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 rates can result in:
 - thermal necrosis of the bone
 - soft tissue burns
 - an oversized hole, which can lead to reduced pullout force, increased ease of the screw stripping in bone, suboptimal fixation, and/or 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.
- Consider an appropriate length of screw to avoid injury of underlying structures with too long screws or plate loosening and/or migration with too short screws.
- 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 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 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 appropriate sharps container. Irrigate and apply suction for removal of debris potentially generated during implantation or removal.
- Screwdriver shafts are self-retaining instruments. Please replace worn or damaged screwdriver shafts, if the retention is not adequate.

Magnetic Resonance environment Torque, Displacement and Image Artifacts according to ASTM F2213, ASTM F2052 and ASTM F2119

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

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

Combination of Medical Devices

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Treatment before device is used

Non-Sterile Device

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".

Implant Removal

The Low Profile Neuro Plating System is for permanent implantation and not intended for removal once implanted. However, the treating surgeon may decide to remove the implant based on a risk-benefit evaluation in the following situations:

- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

Troubleshooting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 the bone flap.
2. Position the bone flap on the patient.
3. Secure the plates to the skull.

Clinical Processing 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.depuyssynthes.com/hcp/reprocessing-care-maintenance>

Disposal

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.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.



Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedicaldevices.com