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.

Manuals are subject to change;
the most current version of each manual is always available online.
Printed on: Nov 05, 2021

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE 0123

© Synthes GmbH 2021. All rights reserved.
EUCMF09009 SE_530940 AD 06/2021

Low Profile Neuro

Devices in scope:

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

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

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 no 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.depuysynthes.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.

CE
0123

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