NeuroLine
Reusable Cranial Perforator

English

Instructions for use

Product range

REF NLM-11/14-3.0
REF NLM-7/11-3.0
REF NLM-6/9-3.0

Important information, please read before use!

Failure to read and follow instructions for this device may result in serious patient injury or death.

Reusable product. The NLM perforators should be subjected to process CDS before / after surgical application.

Abbreviation

CDS	Process of Cleaning – Disinfection – Sterilization

Symbols

- Caution!
- Consult instructions for use!
- The product is not sterile
- CE 1011 Conformity with the requirements of Directive 93/42/EEC
- REF Catalogue number
- SN Serial number
- Manufacturer

Product information

Order code	NLM-11/14-3.0	NLM-7/11-3.0	NLM-6/9-3.0
Ø Inner [mm]	11	7	6
Ø Outer [mm]	14	11	9
Application	For use on skulls at least 3.0mm thick		

Delivery content

The articles NLM-x/y-3.0 NeuroLine reusable cranial perforators are individually wrapped and delivered in non-sterile condition, therefore they must be involved in the CDS procedure before use.
The Perforator holder dedicated to the perforator is delivered in a separate package.

Product packing

Perforator:

- External packing: paper box
- Internal packing: sponge
- Protective cap: protects the cutting edges of the perforator. The cap must be removed before use.
- Instructions for use (placed in the paper box)

Perforator holder:

- External packing: paper box
- Internal packing: PE bubble wrap

Information surfaces

- Outside of paper box, information is shown about the product and identifying data about the Manufacturer.
- Laser engraved inscriptions on the perforator:
  - Manufacturer's logo
  - Catalogue number
  - Serial number
- Instructions for use (this current document)

Structure of the perforators

Complete perforator	Components	Description
		1. Closing element
		2. Drive shaft
		3. Internal drill head
		4. External drill head

Intended user

The intended user of the device: Neurosurgeon.

Intended use

NeuroLine reusable perforators are designed to prepare hole(s) in skull bone. An integrated mechanism grants the automatic release and stop upon penetration of bone that is at least 3.0mm thick.

Disassembling the perforator

Be careful to prevent the cutting edges from injury. Use the protection cap.

Be careful that the components, especially cutting edges, are not damaged during assembly.

1. Turn the closing element (1.) in the direction of the OPEN arrow and remove it.

2. Remove the drive shaft (2.) from the outer drill head (4.)

3. Drop the inner drill (3.) from the outer drill head (4.). If necessary, push the inner drill head (3.) gently on the cutting edge side.

Process CDS (Cleaning – Disinfection – Sterilization)

1. Mechanical cleaning/disinfection (see below, section 1.)
2. Inspection and checks (see below, section 2.)
3. Packaging (see below, section 3.)
4. Sterilization (see below, section 4.)

1. Mechanical cleaning/disinfection

Cleaning should be accomplished as soon as possible.

The instrument must be completely disassembled to clean.

The washer-disinfector must comply with the standard requirements ISO 15883-2.

Phase	Step	Temp. [°C]	Time [min]	Water quality	Chemical
1.	Cleaning	80	30	Deionized water	Neodisher Septo Clean
2.	Neutralization	30	10	Deionized water	Neodisher Z
3.	Rinse	30	10	Deionized water	-
4.	Drying	40	10	-	-

2. Inspection and checks

- Allow the instrument to cool down to room temperature.
- After each complete cleaning, disinfecting and drying cycle, check that the instrument is dry, clean, operational, and free of damage (e.g. corroded, broken, cracked, worn, or fractured components).
- Dry the product if it is wet or damp.
- Repeat cleaning and disinfection of products that still show impurities or contamination.

3. Packaging

- Place the product on a suitable tray. Ensure that all cutting edges are protected.
  Application of the holder device NLM-S2-x/y is recommended during autoclaving.
  The risk of injury to the components placed in the holder is minimized. (see chapter Perforator holder device, NLM-S2-x/y)
- Pack trays appropriately for the intended sterilization process.
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

4. Sterilization

The instrument can only be sterilized in fully disassembled condition.
Validated sterilization process: steam sterilization using fractionated vacuum process.

	Mode	Sterilizing cycle		Drying cycle
1.	Pre-vacuum	121 °C	20 min	30 min

The autoclave must comply with the standard requirements EN 285 and must be validated according to EN ISO 17665.

When sterilizing several instruments at the same time in a steam sterilizer, ensure that the maximum lead capacity of the steam sterilizer specified by the manufacturer is not exceeded.

The manufacturer tested the product and verified that the product would withstand at least 40 sterilization cycles without any damage. In clinical practice, the life of the product depends on the intraoperative surgical usage and the reprocessing technology used by the hospital.

Validating other sterilization procedure is the user's responsibility.

The device is also suitable for autoclaving at 134 °C.

Perforator holder device, NLM-S2-x/y

Place perforator's components in the position indicated by the pictograms.

Product range of holder device:

NLM Perforator	NLM-11/14-3.0	NLM-7/11-3.0	NLM-6/9-3.0
Holder device	**NLM-S2-11/14**	**NLM-S2-7/11**	**NLM-S2-6/9**

Assembly of the perforator

Be careful to prevent the cutting edges from causing injury. Use the protection cap.

Check the components before assembling. Do not use the perforator if there is any obvious fault or damage.

All components must be assembled using only the same order coded parts. Drill heads between different model NeuroLine perforators are not interchangeable.

1. Insert the internal drill head (3.) into the external drill head (4.)

2. Insert the drive shaft (2.) into the outer drill head (4.)

3. Pull the closing element (1.) to the protruding part of the drive shaft, then rotate it in the direction of the CLOSE arrow on the outer drill head (4.) until the thread allows, then gently pull it.

Functional test

Check the perforator's operability before each surgical application!

The perforator's cutting edges are very sharp, therefore protect your fingers with a piece of multilayer gauze while performing the tests.

1. Hold the perforator as shown in the figure and while grabbing the drive shaft, rotate the drill parts (internal and external drill heads).

Expectation: unobstructed rotation.

2. Hold the perforator as shown in the figure and press the drill-bit.

Expectation: smooth, firm springing effect.

If any of the checking steps do not result in the indicated test output, stop using the perforator, perform a CDS procedure and return it to the Manufacturer.

Operating conditions

1. Pairing with universal Hudson fitting. Make sure that the perforator shaft is completely and safety implanted into the drive.
2. Use the drive in a clockwise direction and "forward" mode.
3. The recommended speed of use is 800-1000rpm (up to 1300rpm). Use a drive only of the above speed range.

Application

NeuroLine reusable perforators are designed to prepare hole(s) in skull bone, so that the perforator passes through a specific thickness of bone layer and – thanks to a built-in safety mechanism – automatically release as well as immediately stopping the drilling process.

NLM-x/y-3.0 models are recommended for such patients, where the skull thickness is at least 3.0mm.

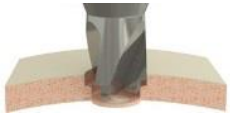
Careful selection of an appropriate type of perforator for the particular patient, and/or different areas and/or condition of the skull.

Prudent and careful use is essential at any type of application.

Instruments made of stainless steel must not be placed in physiological salin solution as prolonged contact leads to corrosion.

Surgical application

1. To start perforation, place the non-skid tip of the perforator on the surface of the skull, hold perpendicular and press firmly onto the bone, then drill with the appropriate speed.
2. If the compressive force is terminated and/or the perforator is not driven during the drilling period, then the drill stops. If necessary, the drilling can be restarted at any time. If you notice any abnormality, do not continue to use the perforator.
3. When the perforator reaches the inner surface of the skull, loss of pressure occurs at the perforator drill head, then the perforator safety mechanism is activated and the drill is stopped: the hole is completed.
4. NeuroLine perforators form a bone plate at the bottom of the hole, which protects the dura from the cutting edges and shifts the dura from the bone.

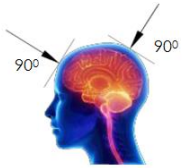


The bone plate can be removed simply by using a forceps or an elevator.

If you suspect that the dura adheres to the bone (e.g. according to the cranial suture or in case of older patients), be especially careful to avoid damage of the dura.

Warnings

1. The surgeon should always be aware that it may happen that the perforator's safety mechanism does not release. Avoid excessive pressing force to prevent patient injury, the damage of the dura and penetration into the brain.
2. Reduce the pressing force and proceed with caution when the perforator is approaching the inner surface of the skull, dura or brain injury may occur.
3. Hold the driver unit and the perforator perpendicular (90°) to the skull. The perforator is optimized for stable directional drilling angle of 90° degrees.



The perforator's design is optimized for stable directional drilling angle of 90° degrees, do not rock or tilt it in order to speed up the drilling process. Failure to observe this instruction could cause product malfunction, patient injury or dural laceration.

4. Extreme caution must be taken when perforating in areas of the skull that have 1mm or greater variations in bone thickness. Drill may nick or cut dura or brain (similar effect as not being 90 degrees).
5. A condition such as the dura adheres, or high intracranial pressure or any other underlying disorders exist at the area of penetration, the perforator may nick or cut the dura or the brain.
6. Take special care NOT to exceed the speed of 1300rpm. This may result in damage of patient's dura or brain.
7. NeuroLine perforators are designed to release safely and reliably, if the skull thickness is at least 3.0mm. Caution must be observed at all times, in particular at the areas of thin-boned, for example the area of the temporal bone, or for elderly or patients with sick/damaged bone. Drilling should be proceeded with extreme caution, because bone consistencies, strength and thickness may be different in these cases, and may result in injury to the patient: damage of the dura or the brain may occur.
8. Not recommended for use the perforator in a previously drilled burr hole or near to such areas, because the risk of injury is significantly higher: damage of the dura or the brain may occur.
9. The device must be used with a medical highspeed motordrill trepan adapter/speed reducer which is equipped with Hudson-connection/fitting.
10. Manufacturer recommends to Customer to return the device for annual inspection and function test.

Warranty

The Manufacturer's warranty of the NLM perforators is limited to 40 surgical application or one year, whichever condition is first met.

The Manufacturer is the only authorized party to service the device. Performance of any repairs or modifications of the equipment by unauthorised persons shall relive the manufacturer of any liability for its performance. Any actions such repair or modification performed during the warranty period shall void all warranty.

The Manufacturer grants that this product is free from defects regarding materials and workmanship, and - if the conditions and circumstances described in this guide are fulfilled -, safely and optimally functioning during surgical procedures.

If this product fails to meet this warranty, the Manufacturer will, at its discretion, replace it or refund purchase price.

The warranty is void, if

- the product is not used in accordance with its intended purpose and/or as described in this instruction guide, or
- damage occurred to the product.

Customer complaint by the manufacturer is to be investigated only if none of the factors causing the loss of validity of the warranty factor exists.

Any other expressed or presumptive warranties are hereby disclaimed.

Disposal of product

After use, the institutional and/or in accordance with national legislation and standards for the treatment of infected devices taking into account the waste treated.

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