



Instructions for use

 **Important information, please read this manual carefully before use and keep within reach of the users.**




 **Failure to read and follow instructions for this device and may result in serious patient injury. Improper use can lead to damage to the tissue, destruction of the instruments and/or system and injury to the operator, patient or other persons.**


 **Single use product!
It is intended for use on a single patient during a single procedure.**


Abbreviation


CDS Process of Cleaning – Disinfection – Sterilization


Symbols

-  Caution
-  Do not re-use
-  Consult instructions for use

 Sterilized using irradiation

 Do not resterilize

 Do not use if package is damaged

 Conforms to CE European Directive of Medical device directive 93/42/EEC

 Use-by date

 Temperature limit

 Humidity limitation

 Catalogue number

 Batch code

 Manufacturer

Product range

Craniotome Cutters:
NLC-xD, NLC-N-xD, NLC-Ae-xD, NLC-An-xD,
NLC-S-xD, NLC-Z-xD
NLC-xT, NLC-N-xT, NLC-Ae-xT, NLC-An-xT, NLC-S-xT, NLC-Z-xT
NLC-xS, NLC-N-xS, NLC-Ae-xS, NLC-An-xS, NLC-S-xS, NLC-Z-xS
NLC-xST, NLC-N-xST, NLC-Ae-xST, NLC-An-xST,
NLC-S-xST, NLC-Z-xST


Stainless steel Burrs:
NLB-X0xxX, NLB-N-X0xxX, NLB-Ae-X0xxX, NLB-An-X0xxX, NLB-S-X0xxX, NLB-Z-X0xxX


Carbide Burrs:
NLB-X1xxX, NLB-N-X1xxX, NLB-Ae-X1xxX, NLB-An-X1xxX, NLB-S-X1xxX, NLB-Z-X1xxX

Diamond Burrs:
NLB-X2xxX, NLB-N-X2xxX, NLB-Ae-X2xxX, NLB-An-X2xxX, NLB-S-X2xxX, NLB-Z-X2xxX

Delivery content

The NeuroLine disposable HS Tools are individually wrapped and delivered in sterile condition, ready for use.


 **Use only originally wrapped, sterile devices!**

 **The device must be considered non-sterile and therefore it is prohibited to use if**

- the Gamma indicator symbol on the sticker is not red or missing, or
- the expiry date has passed, or
- the foil pack is damaged or open.

Storage

Store the devices in a place without any extreme loads avoiding direct sunlight, high temperatures and humidity. Appropriate temperature 10 – 40°C, appropriate humidity 30 – 60 %.

 **NeuroLine disposable HS Tools are single use only, do not reuse or resterilize.**

Repeated use of disposable product carries a risk of infection and/or personal injury and/or damage to system.

Repeated application terminates the manufacturer's liability with immediate effect.

Intended use

NeuroLine disposable HS Tools are intended for use in neurosurgical bone surgery or cutting implant.

Intended user

The intended user of the devices: neurosurgeon.

Contraindication

The instruments are not suited for use in the CNS (brain and spinal cord).

Operating conditions

1. A suitable cutter or burr should be used with an appropriate attachment as specified in the catalogue for each product.
2. Ensure that the instruments are properly secured into the attachments.
3. Craniotome cutters are to be used with corresponding dura guard only.
4. Use the motor in a clockwise direction and/or "forward" mode.
5. Do not use the NeuroLine disposable HS Tools for work on metal (e.g. implants) and do not allow them to come in contact with metal during use as this might cause nicks in the blades. Use carbide device only to work on metals.

Safety recommendations

1. In order to avoid damages due to the incorrect assembly and/or operation use the device only in the ways specified herein.
2. Prior to device usage, check and ensure correct operational condition and physical appearance, do not use if damaged in any way otherwise risk of injury to the patient and operator may be the result.
3. Avoid excessive pressing force to prevent patient injury and/or damage of device. Excessive pressure may cause heat generation which could lead to thermal injury.
4. In order to prevent necrosis of bones and tissues, use an appropriate irrigation during use to cool the cutting surface.
5. Unintentional activation of the system while changing instruments can lead to injury and/or damage to the system, operator and/or patient.
6. The sharp cutting edge of an instrument could cause damage to surgical gloves, which can lead to injury, contamination and infection.
7. While NeuroLine disposable HS Tools is in use, ensure the device does not make contact with metals (e.g. implants). Use carbide device only to work on metals.
8. Ensure the appropriate use of personal protective equipment is used during operation (e.g. protective glasses).
9. Do not modify, reshape or repair the instruments under any circumstances.

10. For size 4 craniotome cutters (e.g. NLC-4T), the maximum usable speed is 30 000 RPM. This limit value is indicated on the product label. Do not exceed the speed limit, as this may cause patient injury and/or device malfunction.

Limited warranty

1. 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 optionally functioning for use on a single patient during a single procedure.
2. If this product fails to meet this warranty, the Manufacturer will, at its discretion, replace it or refund purchase price.

This 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, or
- the customer failure notification announced after the expiry date, or
- used any phase of process CDS, including gamma radiation, or
- the product is repeatedly used in different surgical procedure.

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, as well as the original manufacturer's packaging remains at disposal.

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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