EN

Instructions for use

Craniotome

NOUVAG

Art. No.: 31651, V35/22

Intended purpose

The Craniotome is used for opening the cranium. Using the so-called Duraprotector the clamped bone cutter can work on the cranium without damaging the underlying tissue. The Craniotome is used after the cranium has been prepared through at least 3 holes by means of a *cranial perforator*. This involves using the Craniotome to drill the connecting milling lines between the 3 drill holes in order to remove the cranium.

Contra indications/Restrictions

Relative or absolute contra indications may arise from the general medical diagnosis or in special cases where the patient risk is significantly higher with motor-driven systems. Corresponding cases in the technical literature must be considered.

Symbols

Observe notes	CE 0197 CE mark with notified body	Do not use if packaging is damaged	EC REP European authorized representative
Warnings	SN Serial number	Single use	Observe instructions for use
135°C Autoclave at least with 132°C	REF Order number	Date of manufacturing	Information on disposal
Suitable for thermal disinfection	Manufacturer	Use by date ...	

Technical data

Craniotome incl. Duraprotector medium, Art. No. 1926nou		
Electronic motor 21:	2099nou	2098nou
Speed range:	1000-50'000 U/min	1000-60'000 U/min.
Max allowed torque:	6Ncm	3 Ncm
Speed range:	1000- 50,000 rpm	1000 – 60,000 rpm.
Max. allowed torque:	6 Ncm	3 Ncm
Coupling:	in accordance with INTRA EN3964	
Weight:	130 g	

Faults and causes of error

Faults	Cause	Solution
Motor runs, but Craniotome does not move	Instrument is not optimally connected to the motor	Press the instrument firmly onto the motor until it engages
Drill does not rotate uniformly	Drill not clamped optimally	Tighten the fixing rings
Instrument is noisy	Poorly lubricated	Apply Lubrifluid spray

Ambient conditions

	Transport and Storage:	Operation:
Relative humidity:	Max. 90 %	Max. 80 %
Temperature:	0°C – 60°C	10°C – 30°C
Atmospheric pressure:	700 hPa – 1060 hPa	800 hPa – 1060 hPa

Post market surveillance

In the event of problems with the product or in the event of a serious incident, please immediately download, compile and send the following form: **https://nouvag.com/media/attachments/2022/05/19/for_8-308.pdf** as a PDF to this address: **complaint@nouvag.com**

Safety instructions

The following safety instructions shall be followed

Fundamentals

- Improper use and repair of the Craniotome and non-adherence to our instructions voids your guarantee and releases us from any other claims.
- The operator is responsible for use of any third-party products. Functionality and patient safety cannot be guaranteed with third-party accessories.
- Repairs may only be made by authorized Nouvag service technicians.
- Clean and lubricate the Craniotome prior to autoclaving it. Autoclaving a Craniotome soiled with blood or deposits can induce damage.
- Before use, initial operation and any application the user has to ensure that the Craniotome and its accessories are in proper order. This means clean, sterile and functional.
- Use Lubrifluid spray to maintain the Craniotome. Using other care products can result in malfunction and resultant loss of the guarantee.
- The Craniotome may only be used by qualified staff and only for surgical procedures.
- Read the operating instructions carefully before using the Craniotome. Read the preparation instructions carefully, too.

During use

- We do not deliver the instrument in a sterile state. The Craniotome requires cleaning, disinfecting and sterilizing prior to first use and immediately after each use.
- If you detect even only slightly abnormal conditions during operation, stop using the unit at once and contact your dealer.
- Never manipulate the sealing ring during operation.
- Do not use bent, damaged or deformed drills.
- Ensure that the shaft of the instrument to be used is clean. A soiled shaft can result in poor centring.
- In order to use the Craniotome safely, replace the drill with a new one after every operation.
- Before using on a patient, ensure that you run the product on a trial basis and pay particular attention to loosening, vibration, noises and temperature (production of heat).
- Only use drills which fit the Craniotome. Unsuitable drills can result in malfunction or accidents.
- The Craniotome may only be used by qualified staff and only for surgical procedures.
- Do not subject the product to strong vibration (in particular, by dropping it).
- The electronic motor has to fully stop before you place the handpiece on the motor or use the drill.
- Do not run the Craniotome without having inserted a drill.

Accessories and spare parts

Duraprotectors

Large, Art. No. 1927

Medium, Art. No. 1923

Children, Art. No. 1925

Craniotomy milling cutter

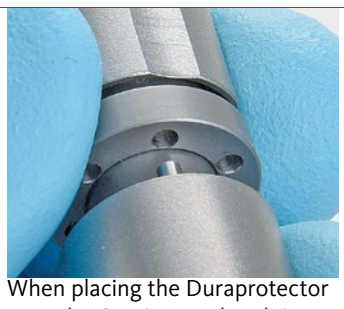
Craniotomy milling cutter, twisted, Pediatrics, REF: HSS.CS.016

Craniotomy milling cutter, twisted, medium, REF: HSS.CM.016

Craniotomy milling cutter, twisted, large, REF: HSS.CL.016

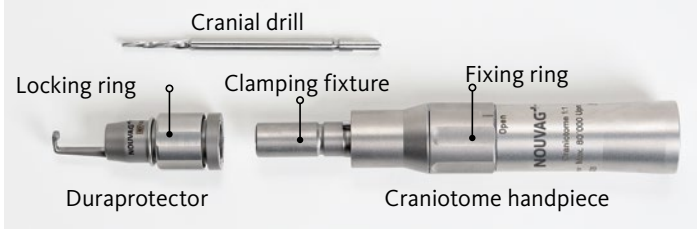
Craniotomy milling cutter, routed, medium, REF: HSR.CM.017

Overview



When placing the Duraprotector onto the Craniotome handpiece, ensure that the handpiece's two cams engage in the openings.

After inserting the drill and assembling the Craniotome, the drill has a clearance of about 3/10 mm from the protector.



Manufacturer and Service points

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For global Nouvag servicepoints see: **www.nouvag.com**

Please contact your country's dealer or representative if you require service, repair and spare parts.

Information on disposal:
When disposing of the device, device parts and accessories, the stipulated statutory regulations must be followed.

Fixing the cranial cutter

Open the Duraprotector's locking ring.

Lift the Duraprotector off the Craniotome's handpiece.

Open the Craniotome handpiece's fixing ring.

Insert the cranial drill into the Craniotome's clamping fixture and stabilise how it fits by turning slightly.

Close the Craniotome handpiece's fixing ring. The drill now resists being pulled out.

Place the Duraprotector back onto the Craniotome handpiece and tighten the Duraprotector's locking ring.

Reprocessing instructions

Limitations	Frequent reprocessing has only little effect on the Craniotome. The end of the product life is usually determined by wear and tear and damage through use. The craniotome is designed for maximum 250 sterilization cycles.	
General handling	1. The instrument should always be treated with utmost care when being transported, cleaned, serviced, sterilized and stored. 2. We recommend the use of mild alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining the instrument. 3. Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See manufacturer's specifications for the method of use, actiontime and suitability of disinfection and cleaning substances. 4. Follow precisely the operating instructions of the devices and chemicals used during preparation. 5. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection. 6. Do not overload washer. Avoid blind spots while rinsing. Pay attention to secure storage in the machine. 7. Follow the regulations applicable in your country for reprocessing medical devices. 8. The instrument must not be cleaned in an ultrasonic bath. This leads to impairment of the functionality. 9. Nouvag AG recommends using a reusable fine-meshed strainer basket for preparation and storage (including transport) of small parts The fine-meshed strainer basket can be used for safe storage of the products both during the rinsing process, and during and after sterilization until the products are used. The strainer basket can be used for safe storage of the products, both during the rinsing process, and during and after sterilization until the products are used. The strainer basket is suitable for use with sterilization paper or a rigid sterilization container. On itself it has no barrier effect to protect sterility. 10. The instrument must not be cleaned in an ultrasonic bath. This leads to impairment of the functionality.	
Attention! ⚠	In relation to patients with Creutzfeldt Jakob disease or tis variant (vCJK) no responsibility can be assumed for re-use of the Craniotome. The Robert Koch institute recommends removing used products from circulation, in order to avoid infecting other patients, users and third parties.	
Point of use preparation	After surgery immediately remove blood, secretion, tissue and bone residue with a disposable cloth/paper towel, do not allow to dry! Dried residues cause corrosion.	
Storage and transport	Contaminated products must be stored and transported to the preparation site in a closed container to avoid damaging the products and the contamination of the environment.	
Pre-cleaning	Remove the Craniotomy Cutter from the instrument and dispose of it properly. Wash off visible dirt on the Craniotome with water. 1. Wipe the Craniotome with a disposable damp cloth / paper towel and remove all visible contamination. 2. Brush the instrument with a soft brush (e.g. Insitumed GmbH) under running tap water. 3. Flush the outside of the instrument for 10 seconds with a cleaning gun (with a minimum pressure of 2.0 bar, e.g. HEGA Medical) with local tap water. The final mechanical cleaning with demineralized water will eliminate any hard water traces. 4. Spray handpiece from the coupling side with Lubrifluid (REF 2128) until only clean liquid emerges. Wipe the handpiece clean with a paper towel.	
Cleaning	**Mechanical cleaning** 1. After pre-cleaning, small parts are placed in a fine-meshed sieve basket. 2. Mechanical cleaning is only successful after adhering to the pre-cleaning, described above! 3. Cleaning is carried out with the Vario-TD program in the cleaning and disinfection unit (CDU). For the cleaning the use of demineralized water (fully demineralized water) is recommended. 4. After completing the cleaning program (including thermal disinfection), check the small parts for visible dirt in grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario TD programme)** 1. Pre-clean for 4 minutes with cold water < 40°C. 2. Empty 3. Clean for 5 minutes at 55°C with 0.5 % alkaline or at 40°C with 0.5 % enzymatic cleaner. 4. Empty 5. Neutralise for 3 minutes with cold water < 40°C. 6. Empty 7. Inter-rinse for 2 minutes with cold water < 40°C. 8. Empty
Disinfection	**Mechanical Disinfection** The cleaning / disinfection device has a thermal disinfection program that follows the cleaning. Mechanical thermal disinfection must be carried out, taking into account the national requirements regarding the Ao value (see DIN EN ISO 15883-1). We recommend an Ao value of 3000 for the instrument and small parts. Disinfection must be carried out with demineralized water.	**Warning!** ⚠ When inadequately rinsed, or exposed to the disinfectant / detergent for too long, the instrument can corrode. Please see the corresponding detergent and disinfectant's instructions for use for dwell times.
Drying	**Mechanical drying** Drying of the instrument and small parts in the drying cycle of the cleaning / disinfection device (CDU). Each CDU has to provide a corresponding drying process on the part of the manufacturer (see ISO15883-1). Please note the relevant information and the instructions for use from the manufacturer of the CDU. Drying must take place for at least 30 minutes at 90°C.	**Manual drying** If necessary, manual drying can be achieved using a lint-free cloth. Pay particular attention to grooves and gaps. Set up the handpiece in an upright position without any attachments to allow water outflow. Let the instrument and small parts to dry for at least 30 Minutes.
Manual cleaning and disinfection	1. After cleaning, place the instrument and small parts for 15 minutes in an immersion bath with an enzymatic cleaner. The instructions of the cleaning agent manufacturer must be followed. 2. Perform a complete post-clean of the product under running drinking water, using a soft brush. Intensely rinse, if there is any cavities and lumen existing, with a water pressure gun (or similar) for at least 30 seconds. 3. To remove the detergent, rinse the product under running city water (drinking quality) for at least 30 seconds.	
Manual disinfection	After cleaning, immerse the product for 5 minutes in a bath with a suitable disinfectant. It must be ensured that all surfaces are completely wetted with the disinfectant. Follow the instructions for use of the disinfectant. After disinfection, thoroughly rinse all products with deionized water to remove the disinfectant (> 1 min.).	
Manual drying	Set up the handpiece in an upright position, separated from all attachments, to make sure the outflow of water is favored. Dry products with a lint-free paper towel. Then dry with suitable compressed air in accordance with the RKI recommendations. Pay particular attention to the drying of hard to reach areas.	
Inspection and care	Carry out a visual inspection for damage, corrosion and wear. Spray the handpiece for about 3 seconds from the coupling side with Lubrifluid (REF 2128). Wipe off excess oil with a paper towel.	
Sterilization	Sterilisation of the electronic motor is performed with a fractionated pre-vacuum steam sterilisation technique (DIN EN 13060/DIN EN 285) giving due consideration to the respective national requirements: **Minimum requirements:** 1. Pre-vacuum phases: 3 2. Sterilisation temperature: minimum 132°C – maximum 137°C. 3. Hold time: At least 5 minutes (full cycle). 4. Drying time: At least 10 minutes, maximum 25 minutes When sterilising several products during one sterilisation cycle, do not exceed the maximum steriliser load. (see manufacturer's details). A drying cycle must be added in the case of autoclaves without a post-vacuum function. After sterilisation the perfect sterilisation result needs to be checked using corresponding indications. According to the Robert-Koch Institute preparation ends with the documented release for use of the medical device. If the sterilised craniotome is not used, immediately after sterilisation, the material packaging must be labelled with the sterilisation date.	
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. During storage ensure that there is no direct exposure to sunlight. If the expiry date exceeded, the product must be reprocessed again.	**Handling the sterile packaging** Before taking out the product, check that the sterile packing is intact. When taking out the product, follow the respective aseptic procedures.
Information on validation of Reprocessing	The above preparation process has been verified by a validated procedure. The following Materials and machines were used: 1. Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH 2. Enzymatic cleaner: Neodisher®MediZym; Chemische Fabrik Dr. Weiger GmbH & Co.KG 3. Cleaning/disinfection unit: Miele G7836 CD 4. Rack trolley: Miele E429 5. Screen basket/rince strip: 3mach (Nouvag AG REF: 51401) 6. Autoclave: Selectomat 666-HP (MMM) 7. Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH Chemicals and machines other than those mentioned can also be used. In such case consult the manufacturers or suppliers to find out whether their products confer the same performance as the products that the procedure was validated with. If you should opt for a different procedure for reprocessing to the one given above, you are required to validate it.	
Note ☞	There is no experience available from conducting other sterilisation procedures such as plasma sterilisation, low temperature sterilisation procedure, etc. Users bear full responsibility if they use a procedure which differs from the validated sterilisation procedure described!	
Attention! ⚠	Please also comply with the applicable legislation in your country and the medical practice or hospital's hygiene rules. This especially applies to the varying requirements for an effective inactivation of prions.	