EN

Instructions for use

Craniotome

NOUVAG

SYMBOLS

General warning sign	Observe instructions for use	Note	Use-by date
Manufacturer	Date of manufacture	Do not use if the package is damaged	Not for reuse
LOT Batch code	REF Catalog number	SN Serial number	EC REP Authorized representative in the European Community
Suitable for thermal disinfection	134°C Autoclave at 134°C	Separate collection required (WEEE)	CE 0197 European Conformity mark

INTENDED PURPOSE

MEDICAL INDICATIONS

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 by drilling at least three holes with the aid of a cranial perforator. The craniotome is used to execute the connecting milling lines between the three drill holes in order to lift off the cranium.

CONTRAINDICATIONS

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.

INTENDED USERS

Intended users are trained and qualified personnel, in professional settings (e.g. hospital, clinic).

TARGET POPULATION

The target population includes both minor and adult patients, depending on the medical indication.

AMBIENT CONDITIONS	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90%	max. 80%
Temperature	0–50 °C	10–30 °C
Atmospheric pressure	700–1'060 hPa	800–1'060 hPa

SAFETY INFORMATION

⚠ Improper use or repair of the device, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.

The use of third-party products is the responsibility of the operator. Functionality and patient safety cannot be guaranteed with third-party accessories.

Repairs may only be carried-out by authorized NOUVAG service technicians.

Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile and operational.

The use of the product other than that for which it was designed is not permitted. The responsibility is solely carried by the operator.

Manipulate the instrument only when the motor is at a standstill.

The device shall only be operated by qualified and trained personnel.

⚠ NOUVAG does not deliver the instrument in a sterile state. The craniotome requires cleaning, disinfecting and sterilising prior to first use and immediately after each use.

If you detect even only slightly abnormal conditions during operation, immediately stop using the product and contact your dealer.

Do not use bent, damaged or deformed burrs.

Ensure that the shaft of the instrument to be used is clean.

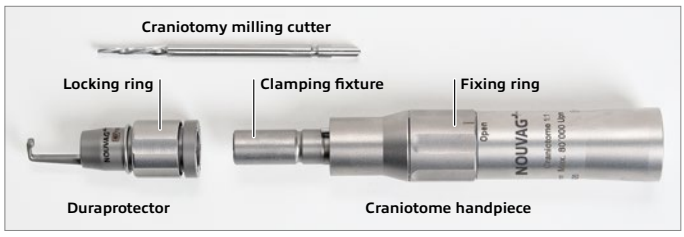
In order to use the craniotome safely, replace the burr with a new one after each surgery.

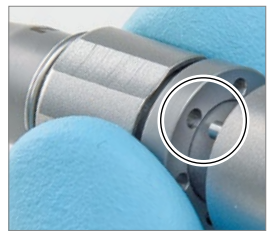
Before using on a patient, ensure that you run the product on a trial basis and pay particular attention to loosening, vibration, noises and temperature (production of heat).

Only use burrs which fit the craniotome. Unsuitable burrs can result in malfunction or accidents.

Do not run the craniotome without having inserted a burr.

OVERVIEW





When placing the duraprotector onto the craniotome handpiece, ensure that the two pins of the handpiece are aligned with the openings of the locking ring.

After inserting the burr and mounting the craniotome, the burr has a distance of approx. 3/10 mm to the duraprotector.

OPERATION

Open the locking ring of the duraprotector.

Lift the duraprotector off the craniotome's handpiece.

Open the fixing ring of the craniotome's handpiece.

Insert the cranial drill into the clamping fixture of the craniotome and stabilise how it fits by turning slightly.

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

Place the duraprotector back onto the handpiece of the craniotome and tighten the locking ring of the duraprotector.

REPROCESSING INSTRUCTIONS

⚠ In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for the re-use of the craniotome. The Robert-Koch-Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.

Reprocessing restrictions	Frequent reprocessing has only a limited impact on the handpiece. The end of the products service life is normally determined by wear and damage through use. The instrument is designed for 250 sterilization cycles.
General handling	**1.** The craniotome must be thoroughly cleaned, disinfected and sterilised before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected instrument permits proper sterilisation! **2.** The instrument must always be handled with the utmost care during transport, cleaning, care, sterilization and storage. **3.** We recommend the use of mild alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining (silicatising) the instruments. **4.** Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturers' specifications for the method of use, action time and suitability of disinfection and cleaning substances. **5.** Follow precisely the operating instructions of the devices and chemicals etcetera, used during preparation. **6.** Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection. **7.** Do not overload washer. Avoid rinsing blind spots. Pay attention to secure storage in the machine. **8.** Follow the applicable regulations in your country for reprocessing medical devices. **9.** The instrument must not be cleaned in an ultrasonic bath. This leads to impairment of the functionality. **10.** NOUVAG recommends using a screen basket with a rinse strip from 3mach (NOUVAG REF 51401), a re-usable container for comfortable preparation and storage (including transport) of products. The screen basket can be used to keep products safe both during the rinsing cycle and also during and after sterilisation until the products are used. The screen basket is suitable for use with sterilisation paper or a rigid sterilisation container. It has no barrier effect itself in order to maintain sterility.
Preparation at the point of use	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.
Safe-keeping 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.
Cleaning and disinfection, pre-cleaning	Remove the craniotomy milling cutter from the instrument and dispose of it properly. Wash off visible dirt on the craniotome with water. **1.** Wipe the handpiece and accessories with a damp disposable cloth/paper towel, removing any visible contamination. **2.** Brush the handpiece and accessories under running tap water using a soft brush (manufacturer for example Insitumed GmbH, REF MED100.33). **3.** Rinse the outer surface of the handpiece for 10 seconds with a water pistol (at a pressure of at least 2.0 bar; manufacturer e.g. HEGA Medical, REF 6010 or REF 7060). Local tap water is sufficient for this purpose, since the last step is always a machine cleaning with deionized water, so possibly hard water with lime traces from the pre-cleaning cannot remain on the handpiece. **4.** Rinse the handpiece with a cleaning gun with a jet nozzle attachment (manufacturer for example HEGA Medical, REF 4270) for at least 30 seconds.

Cleaning	**Mechanical cleaning** 1. Insert the craniotome into the washer. Craniotomy burrs are inserted into a fine-mesh screen basket after pre-cleaning 2. Mechanical cleaning is only successful if the pre-cleaning described above is adhered to! 3. Cleaning is done using the Vario TD program in the cleaning and disinfection unit (CDU). For the cleaning process it is advisable to use DI water (fully desalinated water). 4. After completing the cleaning program (incl. thermal disinfection), check the craniotome and accessories for visible contamination in the grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario TD program)** 1. Pre-clean with cold water for 4 minutes. 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 with cold water for 3 minutes. 6. Empty 7. Inter-rinse for 2 minutes with cold water. 8. Empty
Disinfection	**Mechanical disinfection** The cleaning/disinfection unit has a thermal disinfection program which follows after the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating to the A0 value (see DIN EN ISO 15883-1). We recommend an A0 value of 3000 for the instrument. Disinfection must be carried out with DI water.	⚠ **Warning** The craniotome may corrode if it is not rinsed sufficiently or if it remains in the disinfectant or cleaning agent for too long. For dwell times, please refer to the package insert of the respective cleaning and disinfecting agent.
Drying	**Mechanical drying** Dry the craniotome using the cleaning/disinfection unit's (CDU) drying cycle. If required, manual drying can also be achieved by using a lint-free cloth. When drying manually, take particular care with the grooves and gaps of the instrument. Then spray the instrument again with Lubrifluid. Every CDU must provide a corresponding drying procedure through the manufacturer (see ISO 15883-1). Please follow the corresponding CDU-manufacturer's directions and operating instructions.	**Manual drying** Set up the instruments vertically so that water can run out. Allow the instrument and small parts to dry for at least 30 minutes. Then spray the instrument with Lubrifluid. Then screw the duraprotector back over the clamping device.
Manual cleaning and disinfection	1. After pre-cleaning, place the craniotome and burr in an immersion bath with enzymatic cleaner for 15 minutes. Follow the instructions of the cleaning agent manufacturer. 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 lumens existing, with a water pressure gun (or similar) for at least 30 seconds. 3. To remove the detergent, rinse the products under running city water (drinking quality) for at least 30 seconds.	⚠ **Warning** Do not clean rotating instruments (handpiece) in the ultrasonic bath!
Manual disinfection	After cleaning, immerse the products 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 manufacturers instructions of the disinfectant. After disinfection thoroughly rinse all products with deionised water to remove the disinfectant (> 1 min.).	
Manual drying	Set up the craniotome vertically 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 recommendation. Pay particular attention to the drying of hard to reach areas.	
Inspection and care	1. First unscrew the duraprotector. 2. Perform a visual inspection for damage, corrosion and wear. 3. Spray the handpiece for cleaning and care. NOUVAG recommends the use of Lubrifluid. Attach the blue spray adapter to the spray can and spray the handpiece from the coupling side for about 3 seconds until only clear liquid flows out of the electronic motor. 4. Then wipe with a damp cloth (observe the instructions for use of the product). 5. After spraying the handpiece, screw the duraprotector back onto the handpiece.	
Sterilisation	Sterilisation of the handpiece is performed with a fractionated pre-vacuum steam sterilisation technique (in accordance with 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 (within the sterile band) 3. Holding time: At least 5 minutes (full cycle) 4. Drying time: At least 10 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 vacuum function. After sterilisation an immaculate sterilisation result must be detected by examining the appropriate 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, it must be labeled on the packaging with the sterilisation date.	
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. During storage, direct sunlight should be safely avoided. After the expiry date has passed, do not use the product any longer.	**Handling the sterile packaging** Before taking out the product, check the integrity of the sterile packaging. When taking out the product, follow the respective aseptic procedures.
Information for validating the preparation	The above reprocessing 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 & Co. KG 2. Enzymatic cleaner: Neodisher® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG 3. Cleaning and disinfection unit: Miele G 7836 CD 4. Rack trolley: Miele E429 5. Strainer basket/flush socket bar: 3mach (NOUVAG 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 a 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 correspondingly establish the suitability	

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!

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.

MALFUNCTIONS AND TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
Motor is running but craniotome is not moving	Instrument is not correctly coupled with motor	Press instrument firmly against the motor until it snaps into place. Check seat with counter-movement.
Burr does not rotate uniformly	Burr not clamped optimally	Screw the fixing rings on tight
Instrument is noisy	Poorly lubricated	Apply Lubrifluid spray

TECHNICAL DATA

CRANIOTOME INCL. DURAPROTECTOR, MEDIUM	1926nou
Weight	100 g
Torque max.	6 Ncm
Speed max.	60'000 rpm
Coupling to motor	ISO 3964

ACCESSORIES AND SPARE PARTS

CRANIOTOMY MILLING CUTTER

REF	DESCRIPTION
HSS.CL.016	twisted, large
HSS.CM.016	twisted, medium
HSS.CS.016	twisted, pediatric
HSR.CM.017	routed, medium

DURAPROTECTOR

REF	DESCRIPTION
1927nou	large
1923nou	medium
1925nou	pediatric

INFORMATION ON DISPOSAL

When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed.
When discarding the device components and accessories, please comply with the issued statutory regulations.

POST MARKET SURVEILLANCE

In the event of incidents related to the use of the medical device, please contact immediately the manufacturer by email complaint@nouvag.com or by phone.

To provide adequate information, please compile the incident questionnaire at the web address
Nouvag.com > Contact us > Incident questionnaire.

MANUFACTURER AND SERVICE POINTS

Switzerland
NOUVAG AG
St. Gallerstrasse 25
9403 Goldach

Phone +41 71 846 66 00
info@nouvag.com
www.nouvag.com

EC REP **Germany**
NOUVAG GmbH
Schulthaissstrasse 15
78462 Konstanz

Phone +49 7531 1290-0
info-de@nouvag.com
www.nouvag.com

CE 0197

A complete list of NOUVAG certified service points are found on the NOUVAG website: Nouvag.com > Service