EN

Instructions for use

Cranial Perforator Handpiece

NOUVAG+

SYMBOLS

General warning sign	Observe instructions for use	Autoclavable at 134 °C	Suitable for thermal disinfection
Manufacturer	Date of manufacture	Batch code	Authorized representative in the European Community
Catalog number	Serial number	0197 European Conformity mark	

INTENDED PURPOSE

The Cranial Perforator handpiece utilizes an electrically operated motor system to delicately bore holes in the skull (cranium). Once the cranium is penetrated, a mechanical decoupling system in the drill head ensures a controlled cessation of the drilling process, preventing damage to the meninges (dura mater). This is accomplished through eccentrically mounted drill head parts connected by a clutch. The inner part of the drill head, slightly protruding and engaged by fixed pressure, rotates coaxially with the outer, sleeve-shaped part until disengagement of the coupling occurs upon penetration of the skull, halting further rotation.

CONTRA INDICATIONS

Special operations on the cranium in which the use of motorised instruments poses too great a risk. Corresponding cases in the specialist literature must be taken into consideration.

INTENDED USERS

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

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

POSSIBLE COMBINATIONS

REF	CONTROL UNIT	INTENDED USE
3390	HighSurg 30	Neurosurgery

SAFETY INFORMATION

⚠ The Cranial Perforator handpiece is supplied by us non-sterile. The Cranial Perforator handpiece must be cleaned, disinfected and sterilised before first use and immediately after each use!

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

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

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.

Before using the Cranial Perforator handpiece on the patient, it is essential to test run it and pay very careful attention to loosening, vibration, noise and temperature (heat development).

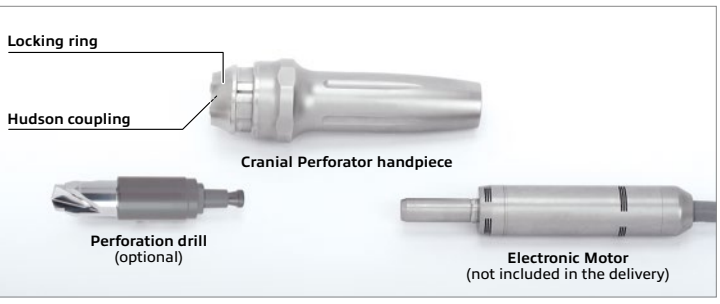
Only use drills with Hudson coupling that match the Cranial Perforator handpiece. Drills with other couplings will not work.

The Cranial Perforator handpiece should only be operated by qualified and trained personnel.

Do not clean the Cranial Perforator handpiece with compressed air!

The Cranial Perforator handpiece may be operated up to a maximum of 80’000 rpm.

OVERVIEW

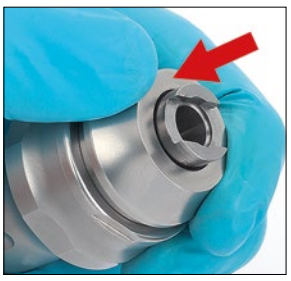


Hudson coupling on the cranial perforator handpiece.

Counterpart of the coupling on the shaft of the perforation drill.

USE

INSERTING THE PERFORATION DRILL



Open the locking ring by pulling back with your thumb and forefinger.

Insert the perforation drill with the locking ring open.

Ensure coupling by gently turning the drill head.

Release the locking ring and check the seating of the perforation drill.

Insert the electronic motor at the rear part of the Cranial Perforator handpiece and firmly press onto the handpiece coupling until it snaps into place. Check seating.

REPROCESSING INSTRUCTIONS

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

⚠ Never clean the Cranial Perforator handpiece in an ultrasonic bath! This will impair the functionality of the Cranial Perforator handpiece.

Reprocessing restrictions	Frequent reprocessing has little effect on the Cranial Perforator 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 Cranial Perforator handpiece 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 Cranial Perforator handpiece enables correct sterilisation! **2.** The Cranial Perforator handpiece should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. **3.** We recommend using mildly alkaline and enzymatic cleaners with a low silicate content to minimize staining (silicatization) on the Cranial Perforator handpiece. **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.** Operating instructions for the equipment and chemicals etc. used during reprocessing must be strictly followed. **6.** Dosage of chemicals, exposure times and temperatures for cleaning and disinfection must be strictly adhered to. **7.** The end of product life may be reached before the 250 sterilization cycles in case of excessive wear and damage from use. **8.** Do not overload the washer. Avoid rinsing blind spots. Ensure secure storage in the machine. **9.** Observe the regulations valid in your country for the reprocessing of medical devices. **10.** NOUVAG recommends using a screen basket with a rinsing bar from 3mach (NOUVAG REF 51401), which is a reusable container for convenient preparation, storage (including transport), and safekeeping of the products. The screen basket can be used for safe storage of the products during the rinsing process as well as during and after sterilization until the products are used. The screen basket is suitable for use with sterilization paper or a rigid sterilization container. It does not have a barrier effect on its own to protect 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 them 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 and dispose of the peforation drill. Detach the electronic motor and send it for reprocessing. Wash off visible soiling with water.** **1.** Wipe the Cranial Perforator handpiece with a damp disposable cloth/paper towel, removing all visible dirt. **2.** Brush the Cranial Perforator handpiece under running tap water using a soft brush (e.g. Insitumend GmbH, REF MED100.33). **3.** Rinse the outer surface of the Cranial Perforator handpiece for 10 seconds with a water pressure gun at a pressure of at least 2.0 bar (e.g. HEGA Medical, REF 6010 or REF 7060). Running 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 Cranial Perforator handpiece.

Cleaning	**Mechanical cleaning** **1.** After pre-cleaning, place the Cranial Perforator handpiece on a suitable attachment. Place the small parts in the strainer basket. **2.** Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! **3.** Cleaning is done using the Vario TD programme 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 Cranial Perforator handpiece for visible contamination in the grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario TD programme)** **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 programme 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 3.000 for the handpiece. Disinfection must be carried out with DI water.	⚠ **Warning** When inadequately rinsed or exposed to the disinfectant or detergent for too long, the Cranial Perforator handpiece can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	**Mechanical drying** Drying of the Cranial Perforator handpiece through the drying cycle of the cleaning/disinfection unit's (CDU). If required, manual drying can also be achieved by using a lint-free cloth. Pay particular attention to the grooves and spaces between the Cranial Perforator handpiece. Then spray the Cranial Perforator handpiece again with lubricant. 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 Cranial Perforator handpiece vertically so that water can run out more easily. Allow the Cranial Perforator handpiece to dry for at least 30 minutes. Then spray the Cranial Perforator handpiece again with lubricant.
Manual cleaning	**1.** After pre-cleaning, place the Cranial Perforator handpiece in an immersion bath with enzymatic cleaner for 15 minutes. Follow the instructions of the cleaning agent manufacturer. **2.** Clean products completely with a soft brush under running drinking water. Rinse cavities and lumens, if any, intensively (>30 sec.) with a water pressure gun (or similar). **3.** To remove the cleaning agent, rinse products under running tap water (drinking quality) (>30 sec.).	⚠ **Warning** Do not clean the Cranial Perforator handpiece in an ultrasonic bath!
Manual disinfection	After cleaning, immerse the products in a bath of suitable disinfectant for 5 minutes. Make sure that all surfaces are covered with the disinfectant. Follow the instructions of the disinfectant manufacturer. After disinfection, rinse all products thoroughly with deionised water (>1 min.) to remove the disinfectant.	
Inspection and care	Carry out a visual inspection for damage, corrosion and wear. After cleaning and disinfecting, spray the Cranial Perforator handpiece with lubricant and wipe with a lint-free cloth moistened with DI water (see instructions on spray can).	
Sterilisation	Sterilisation of the products is performed with a fractionated pre-vacuum steam sterilisation process (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 Cranial Perforator handpiece is not used immediately after sterilisation, it must be labelled with the sterilisation date on the packaging.	
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 for the packaging to be intact. When taking out the product, follow the respective aseptic procedures.
Information for validating the preparation	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 & 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 runs, but perforation drill does not move.	Cranial Perforator handpiece is not optimally coupled to motor.	Press the Cranial Perforator handpiece onto the motor until it snaps into place. Check fit with a counter movement.
Perforation drill does not run smoothly.	Perforation drill is not optimally clamped.	Turn the perforation drill slightly when clamping.
Cranial Perforator handpiece is loud.	Cranial Perforator handpiece is poorly lubricated or dirty.	Spray the Cranial Perforator handpiece with lubricant spray.

ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION	ADULT	PEDIATRIC
1978E	Perforation drill Ø 9/6 mm, disposable, sterile		■
1920E	Perforation drill Ø 9/6 mm, disposable, sterile	■	
1977E	Perforation drill Ø 11/7 mm, disposable, sterile		■
1976E	Perforation drill Ø 11/7 mm, disposable, sterile	■	
1979	Perforation drill Ø 13/9 mm, disposable, sterile		■
1921	Perforation drill Ø 13/9 mm, disposable, sterile	■	
1980E	Perforation drill Ø 14/11 mm, disposable, sterile		■
1922E	Perforation drill Ø 14/11 mm, disposable, sterile	■	

TECHNICAL DATA

REF | CRANIAL PERFORATOR HANDPIECE	1924nou	1924nou
REF | ELECTRONIC MOTOR 21	2098nou	2099nou
Speed range	80 – 1'200 rpm	80 – 900 rpm
Permissible maximum torque	90 Ncm	150 Ncm
Reduction ratio	53 : 1	53 : 1
Coupling motor	ISO 3964	ISO 3964
Coupling drill	Hudson	Hudson
Weight	415 g	415 g

POST MARKET SURVEILLANCE

If you have any complaints in relation to the use of the medical device, please contact the manufacturer immediately by e-mail complaint@nouvag.com or by phone.

In order to provide adequate information, please complete the complaint form: https://nouvag.com/en/service/complaint-form/

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