EN

Operating Instructions

Cranial Perforator Handpiece

NOUVAG

REF 31637, V25/20

Intended use/Indication

In combination with an electrically operated motor system the Cranial Perforator with attached drill is intended to gently perform drilling in the skullcap (Cranium). As soon as the skull is pierced through the mechanical decoupling system in the perforator drill head takes care of a controlled termination of the drilling process, without injuring of the meningeal (dura mater). This is achieved by excentrically supported and coupled drill head parts. The inner, slightly standing out, drill head part coaxially coupled by a quantified pressure with the outer drill head part, disengages as soon as the skull is pierced and the drilling process is immediately stopped.

Contraindication/restrictions

Special interventions on the skull in which the use of motor-driven instruments represents too great a risk. Corresponding cases in the specialist literature must be taken into account.

Technical data

Cranial Perforator Handpiece, Ref. 1924nou	
Speed range:	80 – 1200 U/min.
Transmission ratio:	35 : 1
Max. torque at drill:	130 Ncm
Coupling motor side:	INTRA EN3964
Coupling drill side:	Hudson coupling
Weight:	330 g

Faults and causes of error

Faults	Cause	Solution
Motor runs but Perforator does not move	Instrument is not optimally connected to the motor	Press instrument firmly onto the motor until it engages
Drill does not rotate uniformly	Drill is not coupled properly	Insert drill properly into the Hudson coupling
Instrument is noisy	Poorly lubricated	Apply NouvaOil spray

Ambient conditions

	Transport and storage:	Operation:
Relative humidity:	10 % – 90 %	Max. 80 %
Temperature:	0°C – 60°C; (32°F – 140°F)	10°C – 30°C; (50°F – 86°F)
Atmospheric pressure:	700 hPa – 1060 hPa	800 hPa – 1060 hPa

NouvaCut perforation drill

Cranial-Perforator Handpiece

REF: 1924nou

Warranty coverage

Having purchased the Cranial Perforator entitles you to a 1-year guarantee. Returning the guarantee card for registration within 4 weeks of the date of purchase extends the guarantee for an additional 6 months.
Parts that are subject to wear are not covered by the guarantee. Improper use and repair, and non-adherence to our instructions voids your guarantee and releases us from any other claims.

Explanation of symbols

Important information	CE mark with Notified Body	Do not use when packaging is damaged
Warning	Specification of serial number	Do not reuse
Autoclave at 135°C	Specification of order number	Date of manufacturing
Can be thermally disinfected	Manufacturer	Expiry date

Service Centers

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

Disposal notice: *when disposing of the device, device parts and accessories, the stipulated statutory regulations must be followed.*

Safety instructions

Your safety, that of your team and, of course your patients' safety is our prime concern. It is therefore vital to observe the following instructions.

Fundamentals

- Improper use and repair of the Cranial Perforator 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 Cranial Perforator prior to autoclaving it. Autoclaving a Cranial Perforator soiled with blood or deposits can induce damage.
- Before use, initial operation and any application the user has to ensure that the Cranial Perforator and its accessories are in proper order. This means clean, sterile and functional.
- Use NouvaClean- and NouvaOil-spray to maintain the Cranial Perforator. Using other care products can result in malfunction and resultant loss of the guarantee.
- The Cranial Perforator may only be used by qualified staff and only for surgical procedures.
- Read the operating instructions carefully before using the Cranial Perforator. Read the preparation instructions carefully too.

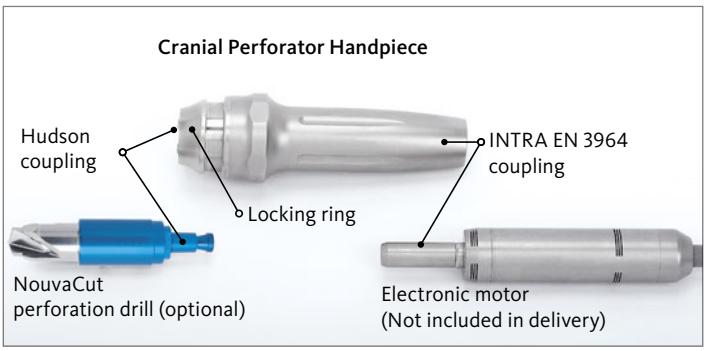
During use

- We do not deliver the instrument in a sterile state. The Cranial Perforator 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 clamping mechanism during operation.
- Do not use damaged or deformed drills. Otherwise malfunction or accidents can be the result.
- Ensure, that the shaft of the instrument to be used, is clean. A soiled shaft can result in poor centring or a lessening of capillary force.
- In order to use the Cranial Perforator safely, replace the Perforator drill with a new one.
- 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 with Hudson Coupling. Other couplings will not work.
- The Cranial Perforator 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 micro motor has to fully stop before you place the handpiece on the motor or use the drill.
- Do not run the Instrument without having inserted a drill.

Accessories

Ref.	Diameter inner/outer	Intended use	Adult	Pediatric	Color coating
1978E	6 mm/9 mm	for skull bone down to 1 mm		•	Yellow
1920E	6 mm/ 9 mm	for skull bone down to 3 mm	•		Yellow
1977E	7 mm/11 mm	for skull bone down to 1 mm		•	Red
1976E	7 mm/11 mm	for skull bone down to 3 mm	•		Red
1979	9 mm/13 mm	for skull bone down to 1 mm		•	Green
1921	9 mm/13 mm	for skull bone down to 3 mm	•		Green
1980E	11 mm/14 mm	for skull bone down to 1 mm		•	Blue
1922E	11 mm/14 mm	for skull bone down to 3 mm	•		Blue

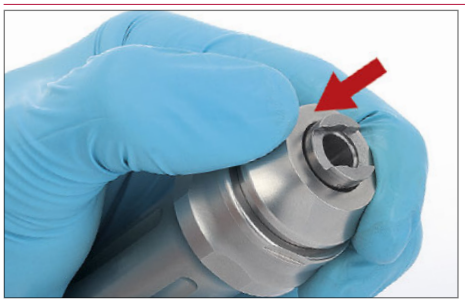
Operation



Hudson coupling at the Cranial Perforator Handpiece.

The counter part of the Hudson coupling at the perforator drill has to be inserted aligned with the notch of the other part.

Insertion of the NouvaCut-Perforation-Drill

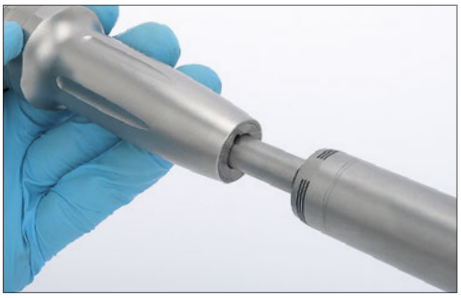


Open the locking ring, with both the pointing finger and the thumb, by pulling it backwards.

Insert the Cranial Perforator Drill with locking ring in open position.

Slightly turn the Perforator drill to fit into the notches of the Hudson coupling. (also check the previous pictures)

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



Insert electronic motor (optional) at the rear of the Cranial Perforator Handpiece (not included in delivery)

Press electronic motor firmly to the INTRA coupling until it engages.

Preparation instructions

Restrictions	Frequent reprocessing has only limited impact 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 instrument permits proper sterilization! 2. The instrument should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. 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 (silicatization) 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. The end of the products service life is determined by wear and damage through use. For the Cranial Perforator Handpiece it can be reached even before the 250 sterilization cycles, that they're designed for, due to wear and tear. 8. Do not overload washer. Avoid rinsing blind spots. Pay attention to secure storage in the machine. 9. Follow the applicable regulations in your country for reprocessing medical devices. 10. The Cranial Perforator Handpiece must never be subjected to ultrasonic cleaning! This will impair the functionality. 11. Nouvag AG 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 sterilization until the products are used. The screen basket is suitable for use with sterilization paper or a rigid sterilization container. It has no barrier effect itself in order to maintain sterility.
Attention! ⚠	In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for a re-use 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.
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.

Pre-cleaning for cleaning and disinfection

Remove the NouvaCut perforation drill and dispose of expertly. Detach the electronic motor and supply it to the reprocessing. Wash off visible dirt with water.

1. Wipe the perforator handpiece with a damp disposable cloth / paper towel and remove all visible contamination.
2. Brush the perforator handpiece with a soft brush (e.g. Insitumed GmbH) under running tap water.
3. Rinse the outside of the handpiece for 10 seconds with a cleaning gun (with a minimum pressure of 2.0 bar, manufacturer e.g. HEGA Medical). Local tap water is sufficient for this, as the last step is always mechanical cleaning with demineralized water and any hard water with traces of lime from the pre-cleaning process cannot remain on the handpiece.
4. Spray the perforator handpiece with NouvaClean spray (REF: 2127) into the motor coupling until only clear liquid emerges.

Cleaning

Mechanical cleaning

1. After pre-cleaning place the Perforator handpiece 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 programme (including thermal disinfection) check perforator handpiece for visible contamination in grooves and gaps. Repeat the cleaning cycle if necessary.

Automatic cleaning process (Vario TD programme)

1. Pre-clean for 4 minutes with cold water.
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 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 Perforator handpiece. Disinfection must be carried out with DI water.

Warning ⚠

When inadequately rinsed or exposed to the disinfectant or detergent for too long, the instrument can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.

Drying

Mechanical drying

Dry the Perforator handpiece 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 Perforator handpiece again with NouvaOil spray for 3 seconds (see chapter „Inspection and care") .
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 perforator-handpiece in an upright position. Let Instrument dry for at least 30 seconds.

Manual cleaning and disinfection

1. Place the Perforator handpiece after pre-cleaning into an immersion bath with the appropriate enzymatic cleaner in a concentration and duration recommended by the cleaning agent manufacturer.
2. Clean the Perforator handpiece completely with a soft brush under running drinking water. Thoroughly Flush (> 30 sec.) cavities and lumens, if present with a water pressure Gun (or equivalent).
3. Flush the Instrument under running City water (drinking quality) to remove the detergent (> 30 sec.).

Warning ⚠

Do Not clean rotary instruments (handpiece) in an ultrasonic bath.

Manual disinfection

After cleaning, place the Perforator handpiece for 5 minutes in an Immersion bath with a suitable disinfectant and clean in the concentration and duration recommended by detergent manufacturer. Place the instrument after cleaning for 5 minutes in a immersion bath with the suitable disinfection agent. Make sure that all the surfaces are wetted with the disinfection agent. Follow the instructions of the disinfection manufacturer. After disinfection rinse the instrument thoroughly with desalinated water (> 1 minute).

Manual drying

Set up the Perforator Instrument in an upright position to favor the draining of water. Dry the Instrument with a lint free paper cloth. Finally dry the Perforator handpiece with suitable compressed air, according to the recommendation of the RKI. Pay particular attention to the drying of areas that are difficult to access.

Inspection and care

1. Carry out a visual inspection for damage, corrosion and wear.
2. Spray perforator handpiece from the coupling side for approximately 3 seconds for cleaning and care with NouvaOil spray (REF: 2128).
3. Then wipe with a damp cloth (follow the instructions of use of the product).

Sterilization

The perforator handpiece is sterilized using a fractional pre-vacuum steam sterilization process (in accordance with DIN EN 556-1 / DIN EN ISO 17665-1), taking into account the respective national requirements.

Minimum requirements:

1. Pre-vacuum phases: 3
2. Sterilization temperature: At least 132°C.
3. Holding time: at least 4 minutes (full cycle).
4. Drying time: at least 10 minutes (maximum 25 minutes).

When sterilizing several products in one sterilization cycle, the maximum load of the sterilizer must not be exceeded (see information from the manufacturer). A drying phase must be carried out for autoclaves without post-vacuum. After sterilization, the perfect sterilization result must be checked with the help of appropriate indications. According to the Robert Koch Institute, processing ends with the documented release of the medical device for use. If the sterilized instrument is not used immediately after sterilization, it must be labeled on the packaging with the sterilization date.

Storage

Storage of the sterile packaging

The sterilized product is stored protected against dust, moisture and contamination. Avoid direct sunlight during storage. The product may no longer be used after the expiry date.

Handling of the sterile packaging

Before the product is removed, the integrity of the sterile packaging must be checked. The corresponding aseptic regulations must be observed when removing.

Information for the validation of the preparation

The effectiveness of the reprocessing mentioned above has been proven by a validated procedure. The following materials and machines were used:

1. Alkaline cleaner: Neodisher® Mediclean forte; 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 7835 CD
4. Rack trolley: Miele E450/1
5. Strainer basket/Rinsing bar: 3mach (NOUVAG REF 51401)
6. Autoclave: Tuttnauer EHS, 3870
7. Sterile packaging: Steriking foil

Chemicals and machines other than those mentioned can also be used. In this case, it must be agreed with the manufacturers or suppliers whether their products perform the same as the products with which the method was validated. If you decide to use a reprocessing other than the one mentioned above, it is your duty to demonstrate suitability accordingly.

Note

There are no empirical values regarding the implementation of other sterilization processes, e.g. Plasma sterilization, low temperature sterilization procedures etc. The user bears full responsibility when using a procedure other than the validated sterilization procedure described!

Attention! ⚠

Please also observe the legal regulations applicable in your country as well as the hygiene regulations of the doctor's office or the hospital. This applies in particular to the different requirements for an effective prion inactivation.