Operating Instructions

Cranial Perforator

Product description

In combination with an electrically operated motorsystem the Cranial Perforator with attached drill is intended to gently perform drillings 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.

Technical data

<table>
<thead>
<tr>
<th>Cranial Perforator, Ref. 1924</th>
<th>Faults and causes of error</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Speed range:</strong> 80 – 1200 U/min.</td>
<td><strong>Faults</strong></td>
</tr>
<tr>
<td><strong>Transmission ratio:</strong> 35 : 1</td>
<td><strong>Cause</strong></td>
</tr>
<tr>
<td><strong>Max. torque at drill:</strong> 130 Ncm</td>
<td><strong>Solution</strong></td>
</tr>
<tr>
<td><strong>Coupling motor side:</strong> INTRA EN3964</td>
<td><strong>Motor runs but Perforator does not move</strong></td>
</tr>
<tr>
<td><strong>Coupling drill side:</strong> Hudson coupling</td>
<td><strong>Instrument is not optimally connected to the motor</strong></td>
</tr>
<tr>
<td><strong>Weight:</strong> 330 g</td>
<td><strong>Press instrument firmly onto the motor until it engages</strong></td>
</tr>
</tbody>
</table>

Faults and causes of error

<table>
<thead>
<tr>
<th>Faults</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motor runs but Perforator does not move</td>
<td>Instrument is not optimally connected to the motor</td>
<td>Press instrument firmly onto the motor until it engages</td>
</tr>
<tr>
<td>Drill does not rotate uniformly</td>
<td>Drill is not coupled properly</td>
<td>Insert drill properly into the Hudson coupling</td>
</tr>
<tr>
<td>Instrument is noisy</td>
<td>Poorly lubricated</td>
<td>Apply NouClean</td>
</tr>
</tbody>
</table>

Ambient conditions

<table>
<thead>
<tr>
<th>Transport and storage:</th>
<th>Operation:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relative humidity:</strong></td>
<td>Max. 90 %</td>
</tr>
<tr>
<td><strong>Temperature:</strong></td>
<td>0°C – 60°C</td>
</tr>
<tr>
<td><strong>Atmospheric pressure:</strong></td>
<td>700 hPa – 1060 hPa</td>
</tr>
</tbody>
</table>

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
- Specification of order number
- Date of manufacturing
- Can be thermally disinfected
- Manufacturer
- Expiry date

Service Centers

Switzerland
Nouvag AG • St.Gallerstr. 23–25 • CH-9403 Goldach
Phone +41 (0)71 846 66 00
info@nouvag.com • www.nouvag.com

Germany
Nouvag GmbH • Schulthaißstrasse 15 • D-78462 Konstanz
Phone +49 (0)7531 1290–0 • Fax +49 (0)7531 1290–12
info-de@nouvag.com • www.nouvag.com

USA
Nouvag USA LLC • 6201 Airport Freeway • Suite 200
Haltom City, TX 76117 • USA
Phone +1 (817) 887 9814 • Fax +1 (817) 887 9817 • Toll free (800) 673 7427
carrie@nouvagusa.com • www.nouvagusa.com

For global Nouvag services centres see: www.nouvag.com

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 NouClean 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.
- The micromotor has to fully stop before you place the handpiece on the motor or use the drill.
- In order to use the Cranial Perforator safely, replace the Perforator drill with a new one.
- Do not run the Instrument without having inserted a drill.

- 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).

Accessories

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Diameter inner/outer</th>
<th>Intended use</th>
<th>Adult</th>
<th>Pediatric</th>
<th>Color coating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1978</td>
<td>6 mm/9 mm</td>
<td>for skull bone down to 1 mm</td>
<td>•</td>
<td></td>
<td>Yellow</td>
</tr>
<tr>
<td>1920</td>
<td>6 mm/ 9 mm</td>
<td>for skull bone down to 3 mm</td>
<td>•</td>
<td></td>
<td>Yellow</td>
</tr>
<tr>
<td>1977</td>
<td>7 mm/11 mm</td>
<td>for skull bone down to 1 mm</td>
<td>•</td>
<td></td>
<td>Red</td>
</tr>
<tr>
<td>1976</td>
<td>7 mm/11 mm</td>
<td>for skull bone down to 3 mm</td>
<td>•</td>
<td></td>
<td>Red</td>
</tr>
<tr>
<td>1979</td>
<td>9 mm/13 mm</td>
<td>for skull bone down to 1 mm</td>
<td>•</td>
<td></td>
<td>Green</td>
</tr>
<tr>
<td>1921</td>
<td>9 mm/13 mm</td>
<td>for skull bone down to 3 mm</td>
<td>•</td>
<td></td>
<td>Green</td>
</tr>
<tr>
<td>1980</td>
<td>11 mm/14 mm</td>
<td>for skull bone down to 1 mm</td>
<td>•</td>
<td></td>
<td>Blue</td>
</tr>
<tr>
<td>1922</td>
<td>11 mm/14 mm</td>
<td>for skull bone down to 3 mm</td>
<td>•</td>
<td></td>
<td>Blue</td>
</tr>
</tbody>
</table>
Operation

Insertion of the Perforator drill

1. Hudson coupling at the Cranial Perforator Handpiece.

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

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

4. Insert Elektronikmotor (optional) at the back of the Cranial Perforator Handpiece.

5. Press Elektronikmotor firmly on the INTRA coupling until it engages.


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

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

9. Slightly turn the Perforator drill to fit into the notches of the Hudson coupling. (view page top for details)

10. Release locking ring and check fitting of the Perforator Drill.

11. Insert Elektronikmotor (optional) at the back of the Cranial Perforator Handpiece.
**Preparation instructions**

**Limitation on repeated preparation**  
Frequent repeated preparation only has a minor impact on the Cranial Perforator. The end of the product's service life is normally determined by wear and damage through use.

**INSTRUCTIONS**

**At the site of use**  
Remove surface contaminants with a disposable cloth/paper towel.

**Storage and transport**  
No special requirements. Avoid long waiting periods until preparation due to risk of drying and corrosion.

**Preparation for cleaning**
1. Remove the Cranial Perforator from the micromotor.
2. Remove the drill from the Cranial Perforator Handpiece and dispose of it properly.
3. Check the Cranial Perforator Handpiece for external changes, damage and wear.

**Automatic cleaning and disinfection**  
Equipment: cleaning/disinfection device with a special load carrier which facilitates the connection of handpieces to the cleaning/disinfection device and the rinsing of channels. Use neutral or alkaline cleaning agents at the recommended concentration.
1. Fit the Cranial Perforator Handpiece into the load carrier (channel rinsing has to be ensured).
2. Set a cleaning cycle that offers sufficient cleaning and rinsing. Perform the last rinse with deionized water.
3. Perform a 10-minute rinse cycle at 93°C to facilitate thermal disinfection.
4. When you remove the Cranial Perforator Handpiece, check for any dirt in gaps and grooves that is still visible. Repeat the cleaning cycle or clean manually as required.

**Manual cleaning**  
Equipment: neutral or alkaline cleaning agent, soft brush, running water:
1. Rinse surface contaminants from the Cranial Perforator Handpiece and brush away.
2. Use a brush to apply cleaning agent to all surfaces and gaps.
3. Rinse the Cranial Perforator Handpiece thoroughly under running water.

**Manual disinfection**  
Place the Cranial Perforator Handpiece into RKI*-tested disinfectant for manual disinfection. (Action time according to the disinfectant manufacturer's specifications).
* RKI disinfectant list (Robert Koch Institute)

**Drying**  
If a drying programme is not provided by the washer-disinfector, the Cranial Perforator Handpiece must be dried manually or in a drying cabinet.

**Inspection, assembly and maintenance**  
Perform a visual inspection for damage, corrosion and wear.
1. Place the spray adapter (Ref. 1958) on the NouClean spray.
2. Insert the spray adaptor into the Cranial Perforator Handpiece INTRA EN3964 coupling flange and press in as far as it will go.
3. Apply a short, approx. 3-second burst of NouClean spray and wipe off excess liquid with a moistened cloth.
   - If a sufficient lubricant delivery is not possible because of back pressure, pull the spray adapter out, hold the moistened cloth around the instrument and the adapter and spray into the couplings opening. Clean spilling with the cloth.

**Packaging**  
Individually: Pack Cranial Perforator Handpiece in individual packaging for sterile items. The bag must be large enough to ensure that the seal is not under tension.
Sets: Sort Cranial Perforator Handpieces onto trays intended for the purpose or place on all-purpose sterilization trays.

**Sterilization**  
Autoclave in the vacuum autoclave at 135°C for at least 5 minutes. When sterilizing several instruments in one sterilization cycle, do not exceed the sterilizer's maximum load. A drying cycle must be added in the case of autoclaves without a post-vacuum function.
Dry the Cranial Perforator Handpiece in the bag with the paper side facing upwards at room temperature for at least one hour.
* The temperature hold times are based on the country-specific guidelines and standards.

**Storage**  
No special requirements. If a sterilised Cranial Perforator Handpiece is not used immediately following sterilization, the packaging needs to be marked with the sterilization date. It is advisable to add a sterilization indicator.

The above-indicated instructions were validated by NOUVAG AG as being suitable for preparing a medical device to be reused. The preparer is responsible for ensuring that the actually performed preparation involving the equipment, materials and personnel used in the preparation facility achieves the desired results. This normally requires validation and routine monitoring of the procedure. Likewise, each deviation from the provided instructions should be carefully analyzed for its effect and potential detrimental consequences.