Operating instructions

Craniotome

Product description
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 per-
favor. This involves using the Craniotome to drill the connecting milling lines between the 3 drill holes in order to remove the cranium.

Technical data, Craniotome
Craniotome incl. Duraprotector medium, Art. No. 1926

- Speed range: 1000 – 50,000 rpm.
- Max. allowed torque: 6 Ncm
- Coupling: in accordance with INTRA EN3964
- Weight: 130 g

Ambient conditions

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

Explanation of symbols

- CE mark with Notified Body
- Do not use if the packaging is damaged
- Warning
- Specification of serial number
- Do not reuse
- Autoclavable at 135°C
- Specification of order number
- Manufacturing date
- Can be thermally disinfected
- Manufacturer
- Use-by-date

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 instruc-
tions.

Fundamentals

Improper use and repair of the Craniotome and non-adher-
ence to our instructions voids your guarantee and releases
us from any other claims.

The operator is responsible for use of any third-party pro-
ducts. Functionality and patient safety cannot be guaranteed
with third-party accessories.

Reparis 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.

During use

We do not deliver the instrument in a sterile state. The Cra-
niotome 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 dea-
lor.

Never manipulate the sealing ring during operation.

Do not use bent, 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 ca-
pillary force.

In order to use the Craniotome safely, replace the drill with a
new one after every operation.

Accessories

- Duraprotector
  - Large, Art. No. 1927
  - Medium, Art. No. 1923
  - Children, Art. No. 1925

- Drill for Craniotome, medium, Art. No. 1789
- Drill for Craniotome, children, Art. No. 1788
- Drill for Craniotome, large, Art. No. 1790
Remove surface contaminants with a disposable cloth/paper towel. 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 Cranio-
tome in the bag with the paper side facing upwards at room temperature for at least one hour.

Place the Craniotome and Duraprotector into RKI*-tested disinfectant for manual disinfection. (Action time according to the disinfectant effect and potential detrimental consequences. 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.

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. 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.

Storage

Set: Sort Craniotomes onto trays intended for the purpose or place on all-purpose sterilization trays.

Inspection, assembly and maintenance

Performance a visual inspection for damage, corrosion and wear.

Drying

If a drying programme is not provided by the washer-disinfector, the Craniotome and the Duraprotector must be dried manually or in a drying cabinet.

Preparation instructions

Limitation on repeated preparation

Frequent repeated preparation only has a minor impact on the Craniotome. The end of the product’s service life is normally determined by wear and damage through use.

INSTRUCTIONS

At the site of use

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

Preparation for cleaning

1. Remove the Cranio-
tome from the micro-
tomotor.
2. Remove the Duraprotector from the Craniotome handpiece.
3. Remove the drill from the Cranio-
tome handpiece and dispose of it properly.
4. Check the Cranio-
tome handpiece and the Duraprotector 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 Cranio-
tome handpiece into the load carrier (channel rinsing has to be ensured).
2. Fit the Duraprotector into a fine-mesh basket and close the basket.
3. Set a cleaning cycle that offers sufficient cleaning and rinsing. Perform the last rinse with deionized water.
4. Perform a 20-minute rinse cycle at 97°C to facilitate thermal disinfection.
5. When you remove the Cranio-
tome and the Duraprotector, 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 Cranio-
tome and the Duraprotector and brush away.
2. Use a brush to apply cleaning agent to all surfaces and gaps.
3. Rinse the Cranio-
tome and the Duraprotector thoroughly under running water.

Manual disinfection

Place the Cranio-
tome and Duraprotector 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 Cranio-
tome and the Duraprotector must be dried manually or in a drying cabinet.

Inspection, assembly and maintenance

Perform a visual inspection for damage, corrosion and wear.

1. Screw the Duraprotector back onto the Craniotome handpiece.
2. Place the spray adapter (Art. No. 1958) on the NouClean spray.
3. Insert the cranial drill into the Craniotome’s coupling flange and press in as far as it will go.
4. Perform a short approx. 3-second burst of NouClean spray and wipe off excess liquid with a moistened cloth.

Packaging

Individually packed Craniotome in individual packaging for sterile items. The bag must be large enough to ensure that the seal is not under ten-
sion.

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 Cranio-
tome 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 sterilized Cranio-
tome 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.

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.

Service Centers

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

Preparation instructions