Intended use and operation

The shaver handpiece is generally used in ENT surgery, for example in the area of the paranasal sinuses, the nasopharynx, the larynx or the anterior skull base. Shaver knives scrape off bone or cartilage fragments and soft tissues that are removed from the treatment site by the suction tube on the handpiece. The shaver handpiece is thus equipped for the intended use with a Shaver knife, which is then driven by a suitable motor. The shaver handpiece may only be operated by qualified and trained personnel.

Contraindication

Asymptomatic diseases with significant comorbidities (heart and lung disease, relevant bleeding disorders, diabetes or asthma). Corresponding cases in the specialist literature must be considered.

Technical data

**Shaver Handpiece, ENT: REF 2092**

- **Speed range in oscillation mode:** 300 – 5000 rpm
- **Oscillation frequency:** 0.3 – 3 Cycles/sec
- **Speed range in continuous mode:** 300 – 6000 rpm
- **Transmission ratio:** 4 : 1
- **Max. torque at the Shaver Blade:** 10 Ncm
- **Coupling motor side:** INTRA EN3964
- **Weight of straight/angled Handpiece:** 110 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 – 60°C</td>
</tr>
<tr>
<td>Atmospheric pressure:</td>
<td>700 – 1060 hPa</td>
</tr>
<tr>
<td></td>
<td>10 – 30°C</td>
</tr>
<tr>
<td></td>
<td>800 – 1060 hPa</td>
</tr>
</tbody>
</table>

Warranty coverage

Having purchased the Shaver Handpiece 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 month. 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
- Indication of serial number
- CE symbol with notified body
- Warning
- Indication of order number
- Autoclavable at 135°C
- Manufacturer
- Suitable for thermal disinfection

Safety measurements

- Improper use or repair of the device and failure to observe these instructions relieve us 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 performed by authorized NOUVAG service technicians.
- Clean and service the Shaver Handpiece before autoclaving. The autoclaving of a Shaver Handpiece with blood stains or other residues may cause failure and damage.
- Never operate the clamping mechanism of the Shaver Handpiece while the system is running. It could result in instrument damage.

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.

Use NouClean-spray for maintenance and care of the motor and the Shaver Handpiece. Using other care products can result in malfunction and/or cause the warranty to be revoked.

The Shaver Handpiece may only be used by qualified personnel and may only be applied for surgical interventions.

Clean and service the Shaver Handpiece before autoclaving. The autoclaving of a Shaver Handpiece with blood stains or other residues may cause failure and damage.

The instruments are not sterile on delivery. All sterilizable parts must be sterilized before use (refer to the reprocessing instructions).

Operation

Retract the clamping sleeve and insert the Shaver Blade into the Shaver Handpiece.

Turn Shaver Blade into the needed position and release the clamping sleeve. Check seating.

Attach the tube set's end at the cooling system of the Shaver Blade.

Attach suction tube with a handpiece clip (REF 1881) to the Shaver Handpiece.

Graft suction tube to the Shaver Handpiece suction nozzle.
Reprocessing instructions

Limitation on repeated preparation Frequent repeated preparation only has a minor impact on the Shaver Handpiece. The end of the product’s life is normally determined by wear and damage through use. The instrument was designed for 250 sterilization cycles.

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. Detach the Shaver Handpiece from the electronic motor.
2. Detach the Shaver Blade from the Shaver Handpiece and dispose of it properly.
3. Check the Shaver 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 Shaver 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 95°C to facilitate thermal disinfection.
4. When you remove the Shaver 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 Shaver Handpiece and brush away.
2. Use a brush to apply cleaning agent to all surfaces and gaps.
3. Rinse the Shaver Handpiece thoroughly under running water.

Manual disinfection Place the Shaver Handpiece into a RKI*-tested disinfectant for manual disinfection. (Action time according to the disinfectant manufacturer’s specifications).

Drying If a drying programme is not provided by the washer-disinfector, the Shaver 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 adapter into the Shaver Handpieces coupling flange as far as it will go.
3. Apply a short, approximately 3-seconds burst of NouClean-Spray and wipe off excess liquid with a moistened cloth.

Packaging Individually: Pack Shaver Handpiece in individual packaging for sterile items. The bag must be large enough to ensure that the seal is not under tension.

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 Shaver 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 sterilized Shaver Handpiece is not used immediately following sterilization, the packaging needs to be marked with the sterilization date. It is advisable to add a sterile 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.

Spare parts and accessories

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
<th>Quantity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>14991</td>
<td>O-Ring seal for the coupling module of Shaver Handpiece</td>
<td>1</td>
</tr>
<tr>
<td>6024</td>
<td>Single-use tube set, 3 m, sterile</td>
<td>10</td>
</tr>
<tr>
<td>1881</td>
<td>Clip-Set large, for tube set attachment at Handpieces</td>
<td>3</td>
</tr>
<tr>
<td>1873</td>
<td>Clip-Set small, for tube set attachment at motor cable</td>
<td>10</td>
</tr>
<tr>
<td>1984</td>
<td>NouClean maintenance and care spray, 500 ml (hazardous material, only single dispatch)</td>
<td>1</td>
</tr>
<tr>
<td>1958</td>
<td>Spray nozzle for NouClean-Spray; for the maintenance and care of Shaver Handpiece</td>
<td>1</td>
</tr>
</tbody>
</table>

Complete selection of 4 different kinds of Shaver Blades available with diameters of 2.5–5.5 mm in 4 different angles, as concave or convex models.

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.

For global Nouvag service centers refer to: www.nouvag.com