Operating instructions

Saw blades for Osteotomy

Safety measures

- The saw blades will not be delivered in sterile condition! The saw blades have to be cleaned, disinfected and sterilized before first time of use and after each use immediately!
- Use handpieces that are in perfect condition only. Fit saw blades only in handpieces provided for that purpose.
- Never manipulate Instrument with running motor to prevent risk of injuries!
- The saw blades can be used up to max. 15,000 rpm!
- Without a clamped saw blade the Saw with its clamping mechanism may not be stored for a longer period of time.
- The saw blades may only be operated by trained and experienced personnel!
- Improper use and repair of the saw blades as well as not complying with the instructions relieve us from any obligations regarding guarantee or other claims.

Intended use

The saw blades are applied in the fields of Micro Surgery for cutting bones. The cross section of a bone and the nature of the bone is crucial for the decision whether a Micro Saw can be used or if a bigger saw has to be applied.

Contraindications

Procedures, in which the use of motorized saws represent too great of a risk. Cases in the literature must be considered.

Symbols

<table>
<thead>
<tr>
<th>Declaration of conformity</th>
<th>Autoclavable at 135°C</th>
<th>Suitable for thermal disinfection</th>
<th>Expiry date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning</td>
<td>Manufacturer</td>
<td>Note accompanying documents</td>
<td>Serial number</td>
</tr>
<tr>
<td>REF</td>
<td>Order number</td>
<td></td>
<td>Lot number</td>
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<td></td>
<td>Lot number</td>
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<td>Goods are not sterile</td>
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Assortment

Saw blades for the Osseoscalpel Sagittal MOS 5000:

Saw blades with the thickness of 0,4 mm, are available in PUs of 6 pieces.

Saw blades for the Micro Oscillating Saw OMS 5000:

Saw blades with the thickness of 0,4 mm, are available in PUs of 1 piece.

Saw blades for the Micro Compass Saw MMS 5000:

Saw blades with the thickness of 0,4 mm, are available in PUs of 6 pieces.

Operation

- Clamp saw blades as deeply as possible in the holder; protruding instruments produce high centrifugal forces and vibrate.
  → Increased risk of accident and poorly results!
- Saw blades are exclusive for sawing bones! Contact with the template, guiding device or other metallic objects has to be avoid.
  → Otherwise damage of the sawblade!
- Saw blades must be set in motion before coming into contact with the bone!
  → Otherwise poorly results!
- Avoid a reduction in speed due to high working pressure!
  → Danger of thermal Necrosis!
- Do not tilt or lever; saw blades can bend or, in an extreme case, break!
  → Increased risk of accident!
- Reject bent saw blades immediately! Eliminate twisted saws immediately!
- Use sufficient cooling to remove the bone chippings from the operating field!
  → Saw blades can become clogged with chippings. Risk of thermal necrosis!
Reprocessing instructions

Restrictions of treatment
Frequent reprocessing hardly affects the saw blades. The end of the product lifetime is usually determined by damages and wear and tear caused by usage.

INSTRUCTIONS

At location of use
Remove surface contamination with a disposable cloth/paper towel.

Storage and transport
No special requirements. Avoid long wait times until preparation due to risk of drying and corrosion.

Cleaning preparations
Clean contaminants with water. Do not put the saw blades into ultrasonic bath.

Automatic cleaning and disinfection
Equipment: For cleaning use neutral or alkaline cleaning agents at the recommended concentration.
1. Place saw blades in fine-meshed basket.
2. Start program. Perform the final rinse with fully deionized water.
3. Perform a 10-minute rinse run (disinfection) at 93°C to facilitate thermal disinfection.
4. When removing the saw blades, check whether visible contamination still remains in the gaps and the grooves. If necessary, repeat the cycle or clean manually.

Manual cleaning
Equipment: Neutral or alkaline cleaning agent, soft brush, running water
Procedure:
1. Rinse and brush away the surface contamination on the saw blades.
2. Apply cleaning agent with brush to all surfaces and gaps.
3. Thoroughly rinse the saw blades under running water.

Manual disinfection
For manual disinfection, place the saw blades in a RKI*-tested disinfectant (insertion time according to disinfectant instructions). * Consider the list of disinfectants of RKI (Robert Koch Institute).

Drying
If there is no drying program provided at the Cleaning and Disinfection Device, dry the saw blades manually or in the drying chamber.

Inspection and maintenance
Check for visual damage, corrosion and wear.

Packaging
Single: Pack the saw blades in an individual sterile supply package. The bag must be large enough so that the seal is not under tension.

Sterilization
Autoclave in vacuum autoclaves at 135°C for at least 5 minutes**. Do not exceed the maximum load of the sterilizer, if several saw blades are sterilized during one sterilization cycle. Observe a drying phase for autoclaves without post-vacuum. Allow the saw blades to dry in the bag with the paper side upwards.
** The temperature hold times must comply with the local guidelines and standards.

Storage
No special requirements. If sterilized saw blades are not used immediately after sterilization, the packaging must be marked with the date of sterilization. Nouvag AG recommends to include a sterility indicator in the packaging.

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.

Troubleshooting

<table>
<thead>
<tr>
<th>Malfunction</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saw blade vibrates at use</td>
<td>Saw blade not correctly clamped</td>
<td>Fix blade properly and tighten nut well</td>
</tr>
<tr>
<td>Poor sawing result</td>
<td>Blade is not sharp anymore</td>
<td>Replace sawing blade</td>
</tr>
</tbody>
</table>

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If service is required, repairs or replacement parts, please contact the dealer or representative of your country.

Disposal:
When disposing of the devices, parts and accessories, the enacted requirements specified in legislation must be followed.