Saw blades and rasps for bone surgery

Safety measures

• The saw blades and rasps are delivered in non-sterile condition. Clean dis-
infect and sterilize them before the first application and immediately after each use.
• Use saw blades and rasps only in the designated, technically perfect and
maintained micro saw handpieces.
• Never manipulate saw blades or rasps with the motor running, risk of injury.
• Saw blades and rasps may be operated with up to 15,000 rpm.
• The saws must not be stored in tightened condition for an extended period of
  time without having a saw blade or a rasp clamped in the collet.
• The micro saw handpieces may only be used by expert and trained person-
  nel.
• Improper use of the saw blades and rasps, as well as failure to follow our
  instructions, release us from any warranty and other claims.
• Remove blunt and/or damaged saw blades and rasps, do not resharpen.

Intended use/Indication

The saw blades/rasps are applied in the field of Micro Surgery for cutting and rasping bone. The cross-section and the nature of the bone to be worked on determine
whether a micro saw handpiece is used or a larger saw handpiece would be better suited for it.

Contraindications/Limitations

Relative or absolute contra indications can arise from the general medical diagnose, or in special cases by a significantly increased risk to the patient through the use
of motor-driven systems. Relevant cases in the literature must be taken into consideration.

Symbols

LOT number
Autoclave at 135°C
Suitable for thermal
disinfection
Date of manufacturing
Order number
CE symbol with
 notified body
Serial number
Refer to
instruction for use
Not sterile
at delivery
Not sterile
at delivery
Pieces per packaging
unit (PU)

Assortment and operation

Saw blades for:
Micro Compass Saw, MSS 5000, REF 5040nou

Saw blade for:
Oscillating Micro Saw, OMS 5000, REF 5090nou

Saw blade for:
Micro Sagittal Saw, MOS 5000, REF 5110nou

Rasp for:
Micro Compass Saw, MSS 5000, REF 5040nou

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Micro Compass Saw, MSS 5000, REF 5040nou

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Loosen nut, using the
wrench.

Remove saw blade
and discard off.

Insert new blade
and tighten the nut.

Loosen nut, using the
wrench.

Remove saw blade
and discard off.

Insert new blade
and tighten the nut.

Loosen tightening
nut using the wrench.

Remove saw blade
and discard off.

Insert new blade
and tighten the nut.
Reprocessing instructions

1. The saw blades and rasps must be thoroughly cleaned, disinfected and sterilized before initial operation (products straight from the factory) and also immediately following each use. Only a clean and disinfected instrument permits proper use.

2. The saw blades and the rasps should always be treated with utmost care when being transported, cleaned, serviced, sterilized and stored.

3. Do not clean saw blades and rasps in ultrasonic baths. It would lead to the impairment of their functionality.

4. Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturers’ specifications for their use. The saw blades/rasps may only be cleaned and disinfected using the sterilization process and reprocessing method that is validated at your site.

5. Neutralise with cold water for 3 minutes.

6. Adhere strictly 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 saw blades and rasps it can be reached even before the 10 sterilization cycles, that they designed for.


9. Follow the applicable regulations in your country and the medical practice or hospital's hygiene rules. This especially applies to the disposal of infectious waste.

10. Don’t clean saw blades and rasps in ultrasonic baths. It would lead to the impairment of their functionality.

Disposal

In relation to patients with CreutzfeldtJakob disease or its variant (CJD) no responsibility can be assumed for re-use of the micro-saw.

The Robert-Koch Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.

General handling

- The saw blades and rasps must be thoroughly cleansed, disinfected and sterilized before initial operation (products straight from the factory) and also immediately following each use. Only a clean and disinfected instrument permits proper use.

- The saw blades and the rasps should always be treated with utmost care when being transported, cleaned, serviced, sterilized and stored.

- Do not clean saw blades and rasps in ultrasonic baths. It would lead to the impairment of their functionality.

- Noozing AG recommends using a screen basket for small parts, a re-usable container for comfortable storage and preparation (including transport parts).

- The 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 ef- fect in order to maintain sterility.

Preparation at the point of care

- After surgery immediately remove blood, secretion, tissue and bone residue with a disposable cloth/paper towel, do not allow to dry! Dried residues permit re-contamination.

Cleaning and disinfection, pre-cleaning

- Remove the saw blade/rasp from the saw handpiece and wash off visible dirt with water.

- Wipe visible impurities with a moist endurable cloth from/through paper from the saw blade/Rasp.

- Brush the saw blade/rasp/under running tap water using a soft brush (manufacturer Insitumed GmbH; REF MED100.33).

- Rinse for 10 seconds at a pressure of at least 2.0 bar; manufacturer for example: HEGA Medical, REF 6010 or 7060). Local tap water is suitable for this purpose, since the last step is always a machine cleaning with deionized water, so possibly hard water with lime traces from the pre-cleaning carried remain on the handpiece.

Cleaning

- Mechanical cleaning

  1. After pre-cleaning place the saw blade/rasp in the strainer basket for small parts.

  2. The mechanical cleaning is only successful if the pre-cleaning described above, is adhered to.

  3. Cleaning is done using the Vario-CDT 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 (incl. thermal disinfection) check the saw blade/rasp for visible contamination in grooves and gaps. Repeat the cleaning cycle if necessary.

Disinfection

- The cleaning/disinfection unit has a thermal disinfection programme which follows after the cleaning.

- When performing mechanical thermal disinfection, give due consid- eration to the national requirements relating to the A0 value (see DIN EN ISO 15883-1).

- We recommend an A0 value of 5.000 for the saw blade/rasps. Disinfection must be carried out with DI water.

- Automatic cleaning process (Vario-CDT programme)

  1. Pre-clean with cold water for a minutes.


  3. Rinse saw blade/rasp for 10 seconds with a water pistol (at a pressure of at least 2.0 bar; manufacturer for example HEGA Medical, REF 6010 or 7060). Local tap water is suitable for this purpose, since the last step is always a machine cleaning with deionized water, so possibly hard water with lime traces from the pre-cleaning carried remain on the handpiece.

Manufacturing and Service points

- Robert-Koch-Institute 
  • Toll free no. (800) 673 7427 – USA
  • Schulthaißstr. 15
  • St.Gallerstr. 23 – 25
  • www.nouvag.com

- Noozing AG 
  • St.Gallerstr. 23 – 25
  • CH-9403 Goldach
  • +41 (0)71 846 66 00

- Noozing GmbH 
  • St.Gallerstr. 23 – 25
  • CH-9403 Goldach
  • +41 (0)71 846 55 40

- Noozing AG GmbH 
  • Schulthaißstr. 15
  • D-68462 Konstanz
  • Tel. +49 (0)7531 1290-0
  • Cell +49 (0)7531 1290-12
  • info-de@nouvag.com

- Noozing USA, LLC 
  • 6201 Airport Freeway
  • Suite 200
  • Haltom City, Texas 76117 – USA
  • Phone 1-877-808-9174
  • Fax 1-877-808-9178

www.nouvagusa.com www.nouvag.com

Troubleshooting

- Noozing AG authorized service points worldwide are to be found on our Website, under: www.nouvag.com/en/service/service-providers

Disposal

- When disposing of instruments, local legislations must be observed. Do not dispose of instruments with household waste. Observe the national regulations for the disposal of infectious waste.