Intended use

The spinal milling cutters are applied in orthopaedics and traumatology, for example, with stenosis, degenerated vertebral discs or intervertebral disc hernias. With the rotary milling cutter intervertebral disks tissue, bony constrictions or functionally disturbing formations are scraped off.

Contraindications

Special procedures at the spine, in which the use of motorized cutters represent too great of a risk, particularly the treatment of the central nervous system in spinal surgery. Cases in the literature must be considered.

Technical data

<table>
<thead>
<tr>
<th>Picture</th>
<th>REF</th>
<th>Description</th>
<th>Head Ø</th>
<th>Working length</th>
<th>Working channel Ø</th>
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<td>3.7 mm</td>
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</tr>
</tbody>
</table>

| Technical data |

- Weight of handpiece: 100 g
- Maximum speed: 20,000 rpm
- Transmission: according to INTRA EU2964

Operation

• Only Nouvag rotational milling cutters, mentioned above (Accessories and spare parts), may be used.
• The rotational milling cutters must be replaced after 5 times of use (wear).
• Never remove the rotary milling cutters with the motor running.

Attaching the rotary milling cutters:

1. Inserting the milling cutters (A, B or C) into the support sleeves (D or E).
2. With open support sleeves (E) milling cutters are inserted from the front.
3. With support sleeves with distal protection (D), milling cutters are inserted from the rear.
4. Exception: Because of their large milling head the ball milling cutters (C) cannot be used with support sleeves with distal protection (D).
5. Introduce the milling cutter shaft into the open collet chuck of the handpiece as far as it goes and close the collet chuck by twisting the clamping sleeve of the handpiece (H).
6. The support sleeves (D or E) are attached to the handpiece (H) by screwing on the clamping nut (G).

Service centers

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

USA
Nouvag USA LLC • 60 Airport Parkway, Suite 701 • 78145 Haltom City • USA
Phone: (817) 892 9814 • Fax: (817) 897 9817 • Toll free (800) 673 7427
www.nouvagusa.com
If service, repair or spare parts are required, please contact your country’s dealer or representative.

Nouvag GmbH • Schulthässlestrasse 15 • D-78462 Konstanz • Germany
Phone: (07531) 1290-10 • Fax: (07531) 1290-12
info@nouvag.com • www.nouvag.com

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Nouvag AG • Gallenstrasse 31-33 • CH-9440 Grenchen
Phone: +41 (0)71 846 66 00 • Fax: +41 (0)71 846 31 36
info@nouvag.com • www.nouvag.com

Note accompanying documents

- Never carry out manipulations on the instrument, when the motor is still running, danger of injury!
- The handpiece may be operated with up to 20,000 rpm!
- Without the rotary milling cutter fixed the collet chuck must not be stored for extended periods in this position!
- Rotary milling cutters must only be used in the endoscope’s working channel to ensure adequate guidance and control of the cutting head!
- Cautions, risk of injury!
- The handpiece may be operated by qualified and trained personnel only!
- Improper use of the instrument, as well as non-observance of our instructions release us from all guarantees and any other claims!

Declaration of conformity

Autoclavable at 135°C
Suitable for thermal disinfection
Expiry date

Warning

- Never remove the rotary milling cutters with the motor running.
- The rotational milling cutters must be replaced after 5 times of use (wear).
- Never remove the rotary milling cutters with the motor running.

Symbol

Goods are not sterile
Pieces per PU
Reprocessing instructions

General procedure
1. Every handpiece, including support sleeves and milling cutters, must be thoroughly cleaned, disinfected and sterilised before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected handpiece permits proper sterilisation.
2. The handpiece, including support sleeves and milling cutters, must always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored.
3. We recommend the use of mild alkaline and enzymatic cleaners with at least a low content of silicate as possible in order to avoid staining (silingating) the handpiece, support sleeves and milling cutter.
4. Only commercial grade DGHM/VHM-listed agents may be used for cleaning and disinfection. See these agent manufacturers’ directions and operating instructions for the method of use, action time and suitability of disinfection and cleaning substances.
5. Follow precisely the operating instructions of the devices and chemicals etc. used during preparation.
6. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection.
7. Due to excessive wear and damage through use the end of the product service life may be reached already before the 5/50 sterilisation cycles.
8. Do not overload dishwashers. Avoid dead zones. Pay attention to secure storage in the machine.
9. Follow the applicable regulations in your country for reproccessing medical devices.
10. The handpiece, including support sleeve and milling cutter must never be subjected to ultrasonic cleaning! This will impair the functionality.
11. Nouvac AG recommends using a screen basket with a flush socket bar (NOUVAG REF 51401), a re-usable container for comfortable automated cleaning/disinfection (incl. transport) of products. The screen basket can be used to keep products safe both during the rinsing cycle and also during and after sterilisation until the products are used. The screen basket is suitable for use with sterilisation paper or a rigid sterilisation container. It has no barrier effect itself in order to maintain sterility.

Preliminaries
After surgery immediately remove blood, secretion, tissue and bone residue with a disposable cloth/paper towel, do not allow to dry! Dried residues cause corrosion.

Cleaning and disinfection, pre-cleaning
1. Remove milling cutter and support sleeve. Wash down visible soiling with water.
2. Wipe visible impurities with a moist expladable cloth/tissue paper from the handpiece.
3. Clean the handpiece with a soft brush (Manufacturer Insitumed GmbH, REF MED100.33) under running tap water.
4. Rim the outer surface of the handpiece and the milling cutter for 10 seconds with a water pistol (at a pressure of at least 2 bar, manu- facturer HEGA Medical, REF LCR 3060). Rinse the inner and outer surfaces of the support sleeves for 10 seconds with the water-lot. Clean the handpiece thoroughly and finally, since the last step is always a machine cleaning done with disinfectant, and possibly hard wa- ter with lime traces from the pre-cleaning cannot remain on the handpiece.

Cleaning
Mechanical cleaning
Place the handpiece in the extractor basket after pre-cleaning. Place the milling cutters and support sleeves in a fine meshbasket and close it.

2. Mechanical cleaning is only successful if the pre-cleaning described above is followed.
3. Cleaning is done using the Vario TD 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 handpiece for visible contamination in grooves and gaps. Repeat the cleaning if necessary.

Disinfection
Mechanical disinfection
The cleaning/disinfection unit has a thermal disinfection programme which follows the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating to the Ao value (see DIN EN ISO 15883). We recommend an Ao value of 100 for the handpiece, including support sleeves and milling cutter. Disinfection must be carried out with DI water.

Drying
Mechanical drying
Dry the handpiece, support sleeve and milling cutter using the cleaning/disinfection unit’s (CDU) drying cycle. If required, manual drying can also be achieved by using a lint-free cloth. When drying manually, take particular care with the grooves and gaps of the handpiece.

Every CDU must provide a corresponding drying procedure through the manufacturer’s specifications for the method of use, action time and suitability of disinfection and cleaning substances.

Sterilisation
Sterilisation of the handpiece including support sleeve and milling cutter is performed with a fractionated pre-vacuum steam sterilisation technique (in accordance with DIN EN 1306-6/DIN EN ISO 17665-2) giving due consideration to the respective national requirements.

Minimum requirements:
1. Pre-vacuum phases: 5
2. Sterilisation temperature: At least 132°C.
3. Hold time: At least 5 minutes, full cycle.
4. Drying time: At least 20 minutes (max. 25 minutes).

When sterilising several products during one sterilisation cycle, do not exceed the maximum steriliser load. (see manufacturer’s details).

A drying cycle must be added in the case of autoclaves without a post-vacuum function. After sterilisation the perfect sterilisation result needs the following corresponding indications. According to the Robert Koch Institute preparation end with the documented release for use or dwell times.

Storage
Storing the sterile packaging
The sterilised product must be stored away from dust, humidity and contaminations.

Handling the sterile packaging
Before taking out the product, check that the sterilisation cycle is intact. When taking out the product, follow the respective aseptic procedures.

Note
There is no experience available from conducting other sterilisation procedures such as plasma sterilisation, low temperature sterilisation procedure, etc. Users bear full responsibility if they use a procedure which differs from the validated sterilisation procedure described!