EN

Operating instructions

Spine Surgery Contra-angle

NOUVAG

REF 31691 EN, V15/22

Safety measures

- The Spine Surgery Contra-angle, rotary spinal milling cutters and support sleeves are delivered in non sterile condition. Clean, disinfect and sterilize them before the first application and immediately after each use.
- Let the spine surgery Contra-angle only run with a clamped rotary milling cutter!
- 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 a spinal rotary milling cutter clamped in, the collet chuck of the spine surgery Contra-angle must not be stored in a tightened state for a longer period of time!
- Rotary milling cutters must only be used in the endoscope's working channel to ensure adequate guidance and control of the cutting head! Caution, risk of injury!
- Rotary milling cutters in conjunction with the handpiece may only be used by qualified and trained personnel.
- Improper use of the instrument and failure to follow our instructions will release us from any warranty and other claims!

Intended use/Indication

The rotary 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/Limitations

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.

Symboles

LOT	LOT number	134°C	Autoclave at 134°C		Suitable for thermal disinfection		Refer to instruction for use	REF	Order number
	Warning	NON STERILE	Not sterile at delivery	CE 0197	CE symbol with notified body		Pieces per packaging unit (**PU**)	SN	Serial number
	Important information		Manufacturer		Information on disposal	EC REP	Authorized European Representative		Date of manufacturing

Assortment

Illustration	REF	Description	Head-Ø	Support sleeve, inner -Ø	Working length	Support sleeve, outer-Ø	Parts/PU
	1918nou	Support sleeve without protector	–	3.2 mm	185 mm	4.0 mm	1
	1750nou	Spinal bur diamond, round	5.0 mm	–	225 mm	–	3
	1751nou	Spinal bur tungsten carbide, round	5.0 mm	–	225 mm	–	3
	1752nou	Carbide milling cutter, conical	5.0 mm	–	230 mm	–	3
	1753nou	Support sleeve without protector	–	3.0 mm	232 mm	3.5 mm	1
	1762nou	Spinal bur tungsten carbide round	3.0 mm	–	270 mm	–	3
	1763nou	Spinal bur, diamond round	3.0 mm	–	270 mm	–	3
	1764nou	Spinal bur, diamond round	3.7 mm	–	272 mm	–	3
	1765nou	Spinal bur tungsten carbide round	3.5 mm	–	270 mm	–	3
	1748nou	Support sleeve without protector	–	3.2 mm	232 mm	4.0 mm	1
	1749nou	Support sleeve with distal protector	–	3.2 mm	240 mm	4.0 mm	1
	1745nou	Spinal bur tungsten carbide round	3.0 mm	–	270 mm	–	3
	1746nou	Spinal bur diamond round	3.0 mm	–	270 mm	–	3
	1766nou	Spinal bur tungsten carbide round	3.5 mm	–	270 mm	–	3
	1747nou	Spinal bur diamond round	3.7 mm	–	272 mm	–	3
	1916nou	Support sleeve without protector	–	3.0 mm	316 mm	3.5 mm	1
	1755nou	Spinal bur tungsten carbide round	3.0 mm	–	354 mm	–	3
	1756nou	Diamond milling cutter round	3.0 mm	–	354 mm	–	3
	1759nou	Spinal bur tungsten carbide round	3.5 mm	–	354 mm	–	3
	1757nou	Spinal bur diamond round	3.7 mm	–	355 mm	–	3
	1914nou	Support sleeve without protector	–	3.2 mm	316 mm	4.0 mm	1
	1915nou	Support sleeve with distal protector	–	3.2 mm	323 mm	4.0 mm	1
	1737nou	Support sleeve with sloping protector	–	3.2 mm	325 mm	4.0 mm	1
	1911nou	Spinal bur tungsten carbide round	3.0 mm	–	354 mm	–	3
	1912nou	Spinal bur diamond round	3.0 mm	–	354 mm	–	3
	1738nou	Spinal bur tungsten carbide	3.5 mm	–	359 mm	–	3
	1913nou	Spinal bur diamond round	3.7 mm	–	355 mm	–	3
	1784nou	Spinal bur tungsten carbide round	4.0 mm	–	354 mm	–	3

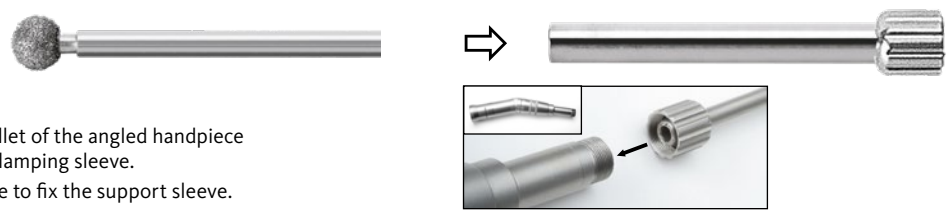
Operation

- Only the Nouvag rotary spinal milling cutters, listed above (Assortment), may be used.
- The rotary spinal milling cutters must be replaced after 5 times of use (wear).
- Never remove the rotary milling cutters while the motor is running.

Inserting the rotary spinal milling cutter *(The illustrations of the instruments are shown in shortened form.)***:**

Milling cutter-Ø **>** Working channel-Ø

Front - loading



1. Insert the milling cutter shank into the open collet of the angled handpiece up to the stop. Close the collet by turning the clamping sleeve.
2. Screw the clamping nut to the angled handpiece to fix the support sleeve.

Milling cutter-Ø **<** Working channel-Ø

Rear - loading

If a support sleeve with distal protection is used, twist it to the required position, before you tighten the clamping nut.

Tighten the clamping nut sufficiently! Make sure the milling cutter's head is not touching the nozzle of the distal protection!

Possible combinations

The angled handpiece with mounted support sleeve and rotary spinal milling cutter is driven in conjunction with the electronic motor 21 and the matching controller, the High-Surg 30 (REF 3360), which allows for speed settings.

Wrong combination of products

Damage to the product and injury to the patient, user or third parties are possible.

- Only use the different products together if the purpose and the relevant technical data, such as working lengths, diameters, and so on match.
- Always follow the instructions for use of the products used in combination.

Reprocessing instructions

Restrictions	Reprocessing has only a limited impact on the handpiece, support sleeves and rotary spinal milling cutters. The end of the products service life is normally determined by wear and damage through use. The handpiece and the support sleeves are designed for max. 250 sterilization cycles, the milling cutters, due to excessive wear, for 5 sterilization cycles.	
General handling	1. Every handpiece, including support sleeves and rotary spinal milling cutters must be thoroughly cleaned, disinfected and sterilized before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected instrument permits proper sterilization! 2. The handpiece, including support sleeve and the milling cutter must always be treated with utmost care when being transported, cleaned, serviced, sterilized and stored. 3. We recommend the use of mild alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining (silicatising) the instruments. 4. Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturers' specifications 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 etcetera, used during preparation. 6. Adhere exactly 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 spinal milling cutters it can be reached even before the 5 sterilization cycles, that they're designed for. For handpiece and the support sleeves it can be reached before 250 sterilization cycles. 8. Do not overload washer. Avoid rinsing blind spots. Pay attention to secure storage in the machine. 9. Follow the applicable regulations in your country for reprocessing medical devices. 10. Don't clean the handpiece, support sleeves and the spinal milling cutters in an ultrasonic bath. It would lead to the impairment of their functionality. 11. Nouvag AG recommends using a screen basket for small parts, a re-usable container for comfortable preparation and storage (including transport) of products. The screen 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 effect itself in order to maintain sterility.	
Attention! ⚠	In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for re-use of the handpiece, milling cutters and support sleeves. The Robert-Koch Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.	
Preparation at the point of use	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.	
Safe-keeping and transport	Contaminated products must be stored and transported to the preparation site in a closed container to avoid damaging the products and the contamination of the environment.	
Cleaning and disinfection, pre-cleaning	1. Disassemble milling cutter and support sleeve from the handpiece and wash off visible dirt with water. 2. Wipe visible impurities with a moist expandable cloth/tissue paper from the handpiece, milling cutters/support sleeves. 3. Brush the handpiece, milling cutters and support sleeves under running tap water using a soft brush (manufacturer Insitumed GmbH, REF MED100.33). 4. Rinse handpiece, milling cutter and support sleeve for 10 seconds for example with a water pressure gun (at a pressure of at least 2.0 bar; manufacturer for example HEGA Medical, REF 6010 or 7060). Local tap water is sufficient 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 cannot remain on the parts. 5. Spray the handpiece from the coupling side with «Lubrifluid spray» (REF: 2128) until only pure liquid emerges.	
Cleaning	**Mechanical cleaning** 1. After pre-cleaning place the handpiece, milling cutters and support sleeves in the strainer basket. 2. Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! 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 (inc. Thermal disinfection) check the handpiece, milling cutters/support sleeves for visible contamination in grooves and gaps. Repeat the cleaning cycle, if necessary.	**Automatic cleaning process (Vario-TD programme)** 1. Pre-clean with cold water for 4 minutes. 2. Empty 3. Clean for 5 minutes at 55°C with 0.5 % alkaline or at 40°C with 0.5 % enzymatic cleaner. 4. Empty 5. Neutralise with cold water for 3 minutes. 6. Empty 7. Inter-rinse for 2 minutes with cold water. 8. Empty
Disinfection	**Mechanical disinfection** The cleaning/disinfection unit has a thermal disinfection programme which follows after the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating to the A0 value (see DIN EN ISO 15883-1). We recommend an A0 value of 3.000 for the saw blades/rasps. Disinfection must be carried out with DI water.	**Warning** ⚠ When inadequately rinsed or exposed to the disinfectant or detergent for too long, the handpiece, milling cutters/support sleeves can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	**Mechanical drying** Dry the handpiece, milling cutters/support sleeves 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 parts. Every CDU must provide a corresponding drying procedure through the manufacturer (see ISO 15883-1). Please follow the corresponding CDU-manufacturer's directions and operating instructions.	**Secagem manual** Dry the handpiece, milling cutters and support sleeves for at least 30 minutes.
Manual cleaning and disinfection	1. After pre-cleaning, place handpiece, milling cutters and support sleeves for 15 minutes in a dipping bath with enzymatic cleaner. Follow the instructions of the detergent manufacturer. 2. Completely clean handpiece, milling cutters and support sleeves with a soft brush under running drinking water. Thoroughly flush (> 30 sec.) cavities and lumens, if present, with a water pressure gun (or equivalent). 3. Flush the products under running city water (drinking quality) to remove the detergent (> 30 sec.).	
Manual Disinfection	After cleaning, place the handpiece, milling cutters and support sleeves for 5 minutes in an immersion bath with a suitable disinfectant. It must be ensured that all surfaces are wetted with the disinfectant. It is to follow the instructions of the disinfectant manufacturer. After disinfection thoroughly rinse all products with deionized water to remove the disinfectant (> 1 min.)	
Manual Drying	Dry handpiece, milling cutters and support sleeves with a lint-free paper towel. Then dry with suitable compressed air in accordance with the RKI recommendation. Pay particular attention to the drying of hard to reach areas.	
Inspection and care	Perform a visual inspection for damage, corrosion and wear. To lubricate the handpiece, spray the handpiece from the coupling side with «Lubrifluid» spray (REF 2128) for approx. 3 seconds. Wipe off any escaping liquid with a disposable cloth.	
Sterilization	The sterilization of the handpiece, milling cutters and support sleeves is carried out with a fractionated pre-vacuum steam sterilization process (according to DIN EN 13060 bzw. DIN EN 285) taking into account the respective national requirements. **Minimum requirements:** 1. Pre-vacuum phases: 3 2. Sterilization temperature: At least 132°C – max. 137°C. 3. Holding time: At least 5 minutes (full cycle). 4. Drying time: At least 10 minutes When sterilizing several products during one sterilization cycle, do not exceed the maximum sterilizer load. (See manufacturer's details). A drying cycle must be added in the case of autoclaves without a post-vacuum function. After sterilization an immaculate sterilization result must be detected by examining the appropriate indications. According to the Robert-Koch Institute preparation ends with the documented release for use of the medical device.	
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. During storage, direct sunlight should be safely avoided. After the expiry date has passed, do not use the product any longer.	**Handling the sterile packaging** Before taking out the product, check for the packaging to be intact. When taking out the product, follow the respective aseptic procedures.
Information for validating the preparation	The above preparation process has been verified by a validated procedure. The following materials and machines were used: 1. Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG 2. Enzymatic cleaner: Neodisher® MediZym; Chemische Fabrik Dr. Weigert GmbH & Co. KG 3. Cleaning and disinfection unit: Miele G 7836 CD 4. Rack trolley: Miele E429 5. Autoclave: Selectomat 666-HP (MMM) 6. Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH Chemicals and machines other than those mentioned can also be used. In such a case consult the manufacturers or suppliers to find out whether their products confer the same performance as the products that the procedure was validated with. If you should opt for a different procedure for reprocessing to the one given above, you are required to correspondingly establish the suitability.	
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!	
Attention! ⚠	Please also comply with the applicable legislation in your country and the medical practice or hospital's hygiene rules. This especially applies to the varying requirements for an effective inactivation of prions.	

Troubleshooting

Problem	Cause	Solution
Support sleeve/milling cutter is vibrating during use.	Support sleeve/milling cutter is not properly clamped	Insert milling cutter up to the stop into the collet. Tighten support sleeve nut.
Milling result is unsatisfactory.	The milling cutter is worn.	Replace the milling cutter.

Ambient conditions

	Transport and storage:	Operation:
Relative humidity:	Max. 90 %	Max. 80 %
Temperature:	0 – 60°C	10 – 30°C
Atmospheric pressure:	700 – 1060 hPa	800 – 1060 hPa

Manufacturer and Service points

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The complete list of all Nouvag-authorized service points worldwide are to be found on our Website, under:
www.nouvag.com/en/service/service-provider

Post market surveillance

☞ In the event of problems with the product or in the event of a serious incident, please immediately download, compile and send the following form (**https://nouvag.com/en/contact-us/incident-questionnaire**) as a PDF to this address: **complaint@nouvag.com**

Disposal

When disposing of the device, device components and accessories, the regulations of the legislator must be followed.