EN

Instructions for use

Spine surgery contra-angle handpiece

REF 1910nou

NOUVAG+

SYMBOLS

General warning sign	Not sterile at delivery	Observe instructions for use	Note
Manufacturer	Date of manufacture	Autoclave at 134 °C	Suitable for thermal disinfection
LOT Batch code	REF Catalog number	SN Serial number	EC REP Authorized representative in the European Community
Pieces per packaging unit (PU)	Importer	CE 0197 CE symbol with notified body	

INTENDED PURPOSE

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.

CONTRA INDICATIONS

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. Relevant cases in the literature must be taken into consideration.

INTENDED USERS

Intended users are trained and qualified personnel, in professional settings (e.g. hospital, ambulatory).

AMBIENT CONDITIONS	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90%	max. 80%
Temperature	0 °C – 50 °C	10 °C – 30 °C
Atmospheric pressure	700 hPa – 1'060 hPa	800 hPa – 1'060 hPa

SAFETY INFORMATION

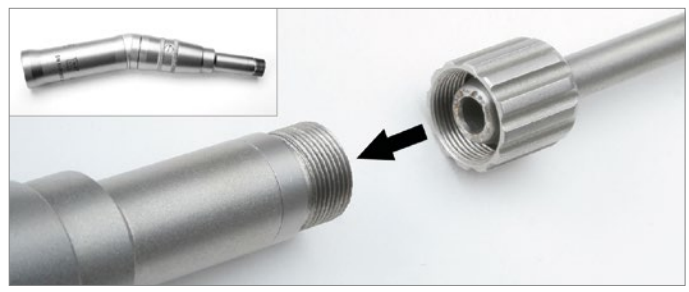
- The handpiece and accessories are supplied by us non-sterile. The handpiece and accessories must be cleaned, disinfected and sterilised before first use and immediately after each use!
- Prior to using the product, before startup, and before operation, the user must always ensure that the product and accessories are in good working order and are clean, sterile and operational.
- Improper use or repair of the product, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.
- The use of the product other than that for which it was designed is not permitted. The responsibility is solely carried by the operator.

- Manipulate the instrument only when the motor is at a standstill.
- Never operate the clamping mechanism during operation or without a clamped tool or spacer pin.
- The device shall only be operated by qualified and trained personnel.
- The handpiece may be operated up to a maximum of 20'000 rpm.
- Do not clean the handpiece with compressed air!
- For storage between uses, the spacer pin must be inserted into the handpiece.

OPERATION

INSERTING THE ROTARY BURRS

- Only rotary burrs from the NOUVAG range may be used.
- The rotary burrs must be replaced after five uses due to wear.
- When using the support sleeve with distal protection, bring it into the desired position before tightening the clamping nut.
- Tighten the clamping nut firmly! Check that the burr head does not rub against the distal guard!



Insert the burr shank into the open collet chuck of the angled handpiece as far as it will go and close the collet chuck by turning the clamping sleeve.
Screw the clamping nut onto the angled handpiece to fix the support sleeve in place.

INSERTION FROM THE FRONT

INSERTION FROM THE BACK

REPROCESSING INSTRUCTIONS

- In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for re-use of the handpiece. The Robert-Koch Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.
- Never clean the handpiece in an ultrasonic bath! This impairs the functionality of the handpiece.

Reprocessing restrictions	Frequent reprocessing has little impact on the handpiece, support sleeve and rotary burr.The end of the product's service life is normally determined by wear and damage caused by use. The handpiece and support sleeves are designed for a maximum of 250 sterilization cycles. The rotary burrs are designed for a maximum of 5 sterilisation cycles due to wear and tear s.
General handling	**1.** The handpiece, support sleeves, and rotary burrs must be thoroughly cleaned, disinfected, and sterilised before their first use (factory-new products) as well as immediately after each use. Only cleaned products can be properly sterilised! **2.** The handpiece, support sleeves, and rotary burrs must always be handled with the utmost care during transportation, cleaning, maintenance, sterilization, and storage. **3.** We recommend the use of mildly alkaline and enzymatic cleaners with as low a silicate content as possible to avoid staining (silicatization) on the handpiece and accessories. **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.** Operating instructions for the equipment and chemicals etc. used during reprocessing must be strictly followed. **6.** Dosage of chemicals, exposure times and exposure temperatures for cleaning and disinfection must be strictly followed. **7.** The end of the product service life may be reached before the maximum 250 sterilization cycles have been reached in the case of excessive wear and damage caused by use of the handpiece and the support sleeves, and after less than 5 sterilization cycles in the case of the rotary burrs. **8.** Do not overload the washer. Avoid rinsing blind spots. Ensure secure storage in the machine. **9.** Observe the regulations valid in your country for the reprocessing of medical devices. **10.** NOUVAG recommends the use of a screen basket or small parts, a reusable container for convenient preparation and storage (including transport) of the products. The screen basket can be used for safe storage of the products during the rinsing process as well as 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 does not have a barrier effect on its own to protect sterility.
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 support sleeve rotary and burr from the handpiece and wash off visible dirt with water. **2.** Brush the handpiece and accessories under running tap water using a soft brush (e.g. Insitumend GmbH, REF MED100.33). **3.** Rinse the outer surface of the handpiece and accessories for 10 seconds with a water pressure gun at a pressure of at least 2.0 bar (e.g. HEGA Medical, REF 6010 or REF 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 handpiece.

Cleaning	**Mechanical cleaning** **1.** After pre-cleaning, place the handpiece on a suitable attachment. Place the accessories (support sleeves, rotary burrs) 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 program (incl. thermal disinfection) check the handpiece and accessories for visible contamination in the grooves and gaps. Repeat cleaning 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 handpiece, support sleeve and rotary burr. Disinfection must be carried out with DI water.	**⚠ Warning** When not rinsed sufficiently or left in disinfectants or cleaning agents for too long, the handpiece and accessories may corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	**Mechanical drying** Drying of the handpiece, support sleeves and rotary burrs using the drying cycle of the cleaning/disinfection unit's (CDU) drying cycle. If required, manual drying can also be achieved by using a lint-free cloth. Pay particular attention to the grooves and spaces between the handpiece and accessories. Then spray the handpiece and accessories again with lubricant. 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.	**Manual drying** Set up the handpiece vertically so that water can run out more easily. Allow the handpiece and accessories to dry for at least 30 minutes. Then spray the handpiece and accessories again with lubricant.
Manual cleaning	**1.** After pre-cleaning, place the handpiece in an immersion bath with enzymatic cleaner for 15 minutes. Clean the accessories in an ultrasonic bath for 15 minutes. Follow the instructions of the cleaning agent manufacturer. **2.** Clean products completely with a soft brush under running drinking water. Rinse cavities and lumens, if any, intensively (>30 sec.) with a water pressure gun (or similar). **3.** To remove the cleaning agent, rinse products under running tap water (drinking quality) (>30 sec.).	**⚠ Warning** Do not clean the handpiece in an ultrasonic bath!
Manual disinfection	After cleaning, immerse the products in a bath of suitable disinfectant for 5 minutes. Make sure that all surfaces are covered with the disinfectant. Follow the instructions of the disinfectant manufacturer. After disinfection, rinse all products thoroughly with deionised water (>1 min.) to remove the disinfectant.	
Inspection and care	Carry out a visual inspection for damage, corrosion and wear. After cleaning and disinfecting, spray the handpiece with lubricant and wipe with a lint-free cloth moistened with DI water (see instructions on spray can).	
Sterilisation	The sterilization of the handpiece, support sleeves and rotary burrs is carried out with a fractionated pre-vacuum steam sterilisation process (in accordance with DIN EN 13060 / DIN EN 285) giving due consideration to the respective national requirements. **Minimum requirements:** **1.** Pre-vacuum phases: 3 **2.** Sterilisation temperature: minimum 132 °C – maximum 137 °C (within the sterile band) **3.** Holding time: At least 5 minutes (full cycle) **4.** Drying time: At least 10 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 vacuum function. After sterilisation an immaculate sterilisation 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. If the sterilised handpiece is not used immediately after sterilisation, it must be labelled with the sterilisation date on the packaging.	
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® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG **3.** Cleaning and disinfection unit: Miele G 7836 CD **4.** Rack trolley: Miele E429 **5.** Strainer basket/flush socket bar: 3mach (NOUVAG REF 51401) **6.** Autoclave: Selectomat 666-HP (MMM) **7.** 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.	

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!

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.

MALFUNCTIONS AND TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
Support sleeve/rotary burr vibrates during use.	Support sleeve/rotary burr is not clamped correctly.	Insert the rotary burr into the collet chuck as far as it will go. Tighten the support sleeve lock.
Milling result is unsatisfactory.	The rotary burr is worn.	Replace the rotary burr.

ACCESSORIES AND SPARE PARTS

				SUPPORT SLEEVE			BURR		
REF	DESCRIPTION			LENGTH	INNER Ø	OUTER Ø	LENGTH	HEAD Ø	QUANTITY
1918nou	**Support Sleeve, without protector, ø4.0×185mm**			**185**	**3.2**	**4.0**			1
1750nou	Diamond burr, round, ø5.0×225mm						225	5.0	3
1751nou	Carbide burr, round, ø5.0×225mm						225	5.0	3
1752nou	Carbide burr, conical, ø5.0×228mm						230	5.0	3
1753nou	**Support Sleeve, without protector, ø3.5×232mm**			**232**	**3.0**	**3.5**			1
1762nou	Carbide burr, round, ø3.0×270mm						270	3.0	3
1763nou	Diamond burr, round, ø3.0×270mm						270	3.0	3
1765nou	Carbide burr, round, ø3.5×270mm						270	3.5	3
1764nou	Diamond burr, round, ø3.7×272mm						272	3.7	3
1748nou	**Support Sleeve, without protector, ø4.0×232mm**		▼	**232**	**3.2**	**4.0**			1
1749nou	**Support Sleeve, with distal protector, ø4.0×240mm**	▼		**240**	**3.2**	**4.0**			1
1745nou	Carbide burr, round, ø3.0×270mm	•	•				270	3.0	3
1746nou	Diamond burr, round, ø3.0×270mm	•	•				270	3.0	3
1766nou	Carbide burr, round, ø3.5×270mm		•				270	3.5	3
1747nou	Diamond burr, round, ø3.7×272mm		•				272	3.7	3
1916nou	**Support Sleeve, without protector, ø3.5×316mm**			**316**	**3.0**	**3.5**		–	1
1755nou	Carbide burr, round, ø3.0×354mm						354	3.0	3
1756nou	Diamond burr, round, ø3.0×354mm						354	3.0	3
1759nou	Carbide burr, round, ø3.5×354mm						354	3.5	3
1757nou	Diamond burr, round, ø3.7×355mm						355	3.7	3
1914nou	**Support Sleeve, without protector, ø4.0×316mm**		▼	**316**	**3.2**	**4.0**			1
1915nou	**Support Sleeve, with distal protector, ø4.0×323mm**	▼		**323**	**3.2**	**4.0**			1
1737nou	**Support Sleeve, with chamfered protector, ø4.0×325mm**	▼		**325**	**3.2**	**4.0**			1
1911nou	Carbide burr, round, ø3.0×354mm	•	•				354	3.0	3
1912nou	Diamond burr, round, ø3.0×354mm	•	•				354	3.0	3
1738nou	Carbide burr, round, ø3.5×354mm		•				354	3.5	3
1913nou	Diamond burr, round, ø3.7×355mm		•				355	3.7	3
1784nou	Carbide burr, round, ø4.0×354mm		•				354	4.0	3

POST MARKET SURVEILLANCE

If you have any complaints in relation to the use of the medical device, please contact the manufacturer immediately by e-mail complaint@nouvag.com or by phone.

In order to provide adequate information, please complete the complaint form:
Nouvag.com > Contact > Complaint Form.

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