EN

Operating instructions

Handpiece with tiltable spinal burr

NOUVAG

Ref. 31608, V13/16

Safety measures

- The instrument is not sterile on delivery! Prior first use and immediately after each application the handpiece and the rotary milling cutters must be cleaned, disinfected and sterilized!
- Don't clean instruments with compressed air!
- Let handpiece 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 6000 rpm!
- 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!
- 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!

Intended use

The spine milling cutters are applied in orthopedics 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. The spinal burr with its up to 35° tiltable instrument head is applied in hard to access areas.

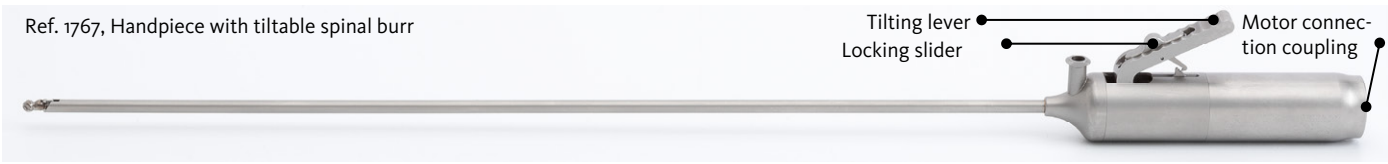
Contraindications

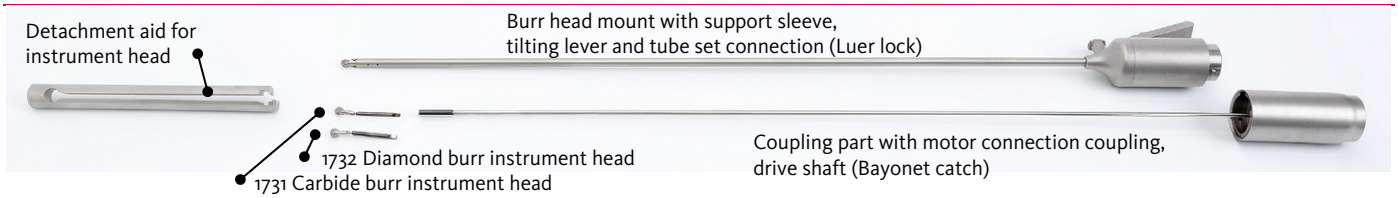
Special procedures at the spine, in which the use of motorized cutters represent too great of a risk, particularly the treatment of the central nervous system in spinal surgery. Cases in the literature must be considered.

Symbols

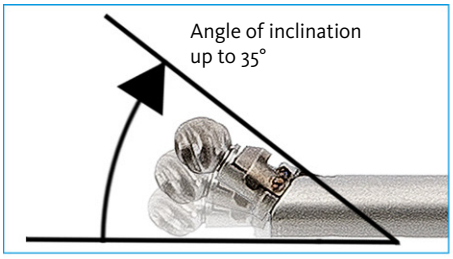
CE 0197	Declaration of conformity	135°C	Autoclavable at 135°C		Suitable for thermal disinfection		Expiry date
	Warning		Manufacturer		Note accompanying documents	SN	Serial number
REF	Order number	LOT	Lot number	NON STERILE	Goods are not sterile		Pieces per PU

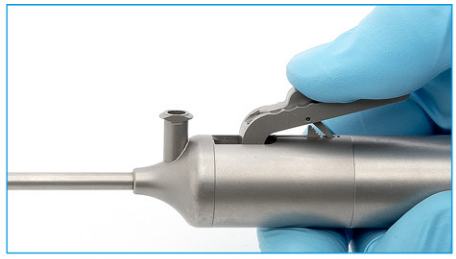
Device overview





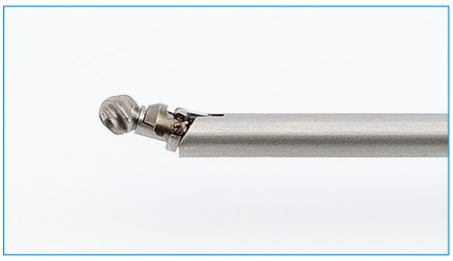
Operation

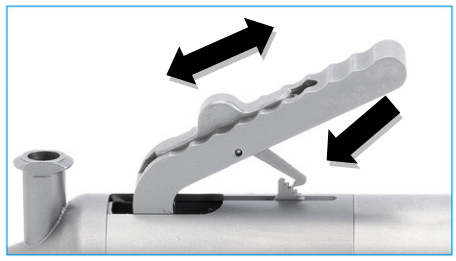




Changing angle of inclination

By pressing the tilting lever the angle of inclination at the instrument head is changed. The inclination angle can be up to 35°.

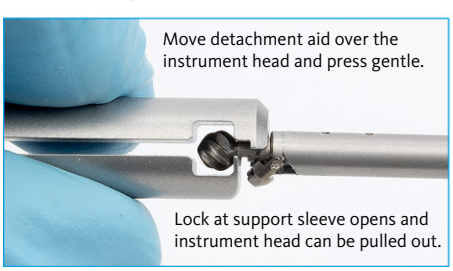


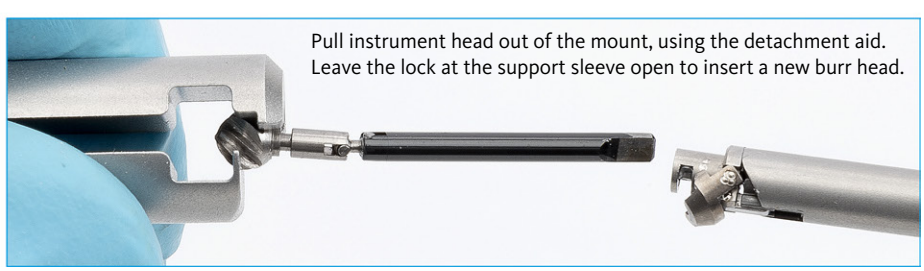


Locking slider

By pulling the locking slider with your thumb backwards, the locking mechanism is activated. By pressing the tilting lever, the locking mechanism can be adjusted to the desired angle.

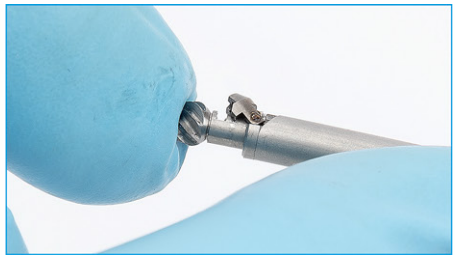
Disconnecting the instrument head



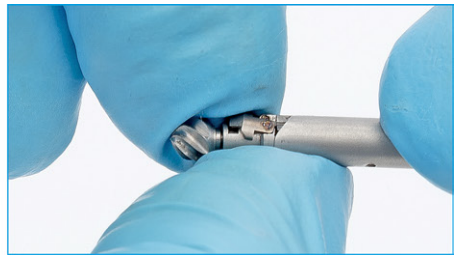


Installing the instrument head (burr)

Slide instrument head with the dark shaft ahead into the burr head mount.



Click burr head with slight pressure into place.



Fix burr head in place by closing the lock with your finger. Check seating with a slight countermovement.

Tube set connection

Attach the Luer Lock connector of the tube set to the connector on the handpiece. Clamp tube set with a clip to the motor cable if needed.

Technical data

Weight of handpiece	205 g
Maximum speed	6000 rpm
Maximum torque	2 Ncm
Transmission	1 : 1
Useful working length	310 mm
Total length	410 mm
Instrument head Ø (burr)	3.7 mm
Tilting angle of instrument head	0 – 35°
Coupling	after INTRA EN23964

Reprocessing instructions

Reprocessing restrictions	Frequent but careful reprocessing will have little effect on the life span of the handpiece and rotary milling cutters. The end of the products' service life will normally be determined by wear and damage while being used.

INSTRUCTIONS

At location of use	Remove surface soiling with a cloth or paper towel.
Storage and transport	No particular requirements. Due to the risk of drying and corrosion, reprocessing must be performed without undue delay; the period of time between use and reprocessing should not exceed 8 hours.
Cleaning preparations	Unscrew support sleeve and unclamp milling cutters. Remove any surface soiling on the handpiece, support sleeve and milling cutters with a disposable/paper towel. Further dismantling of the handpiece is not necessary. Place all parts for max. 15 min. into a certified disinfectant e.g. 3% Korsolex® extra. Do not put parts in ultrasonic bath. * Refer to RKI disinfectant list (Robert Koch Institute).
Automatic cleaning and disinfection	Equipment: Cleaning/disinfection equipment with a special load carrier, which allows the connection of handpieces for irrigation of channels. Start rinsing the handpiece from the rear side. Use an RKI*-certified, neutral or alkaline cleaning agent in the recommended concentration. 1. Load handpiece, support sleeves and milling cutters in the load carrier (irrigation of channels must be ensured). 2. Start the reprocess in a laboratory disinfector with pre-rinsing (twice), cleaning at 55°C using e.g. neodisher Mediclean, rinsing with deionized water 3. Carry out a 10-minute rinse cycle (disinfection) at 93°C with drying at 50°C. 4. When taking the pieces out, check to see whether there is still any dirt in the grooves and interstices. If necessary, repeat the cycle or clean manually.
Manual cleaning	Equipment: RKI*-certified neutral cleaning agent, soft brush, flowing demineralized water (max. 20°C). *Procedure:* 1. Rinse the handpiece, support sleeves and milling cutters with deionized water. 2. Lay the handpiece, support sleeves and milling cutters into neutral cleaning detergent. Clean with lint-free tissue and suitable brushes to reach all lumen. 3. Rinse the handpiece, support sleeve and milling cutters with deionized water.
Drying	If there is no drying programme available in the cleaning/disinfecting device, the handpiece, the support sleeves and the milling cutters must be dried manually or in a hot-air cabinet at 60°C for a minimum of 2 hours.
Inspection and maintenance Ref. 1958	Carry out a visual inspection for damage, corrosion and wear. After cleaning and disinfecting the handpiece spray it thoroughly with Nou-Clean Spray and wipe it with a damp cloth (see instructions on spray can). Then reclamp the milling cutter and attach the support sleeve. Check rotating members on good mobility. 
Packaging	Individually: pack the handpiece in individual packaging for sterile items. The package must be large enough to ensure that the seal is not subject to strain. Nouvag AG recommends to add a sterility indicator. Sets: Sort the handpieces into suitable trays or pack them in soft packaging.
Sterilization	Carry out a steam sterilization at 135°C for at least 5 minutes ** with a 3 pre-vacuum step procedure followed by a drying step for 10 minutes. For autoclaves without a post-vacuum process, a drying phase must be carried out. If a sterilization packaging (paper/film) is used, it must dry at room temperature with the paper side up for at least 1 hour. **The temperature hold time must comply with the local guidelines and standards.
Storage	No particular requirements. If the sterilized handpiece is not used immediately after sterilization, the material packaging must be labeled with the sterilization date. Including a sterility indicator is recommended.

The instructions given above have been deemed suitable for the preparation of a medical product for its re-use. It is the responsibility of the person carrying out the preparation that the preparation actually carried out with the equipment, materials and personnel in the preparation installation achieves the desired results. This normally requires validation and routine monitoring of the procedures. In the same way, if there is any deviation from the instructions provided then the person responsible for the preparation must carefully assess its effectiveness and any possible detrimental consequences.

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Please contact your country's dealer or representative if you require service, repair and spare parts.

Notice on disposal:
When disposing of the device, device parts and accessories, the stipulated statutory regulations must be followed.