EN

Instructions for use

ENT Shaver Handpiece

NOUVAG+

SYMBOLS

General warning sign
Observe instructions for use
Note
Suitable for thermal disinfection
Manufacturer
Date of manufacture
Importer
Autoclavable at 134 °C
REF Catalog number
SN Serial number
LOT Batch code
EC REP Authorized representative in the European Community
Separate collection required (WEEE)
CE 0197 European Conformity mark

INTENDED PURPOSE

The shaver handpiece is generally used in ENT surgery, for example in the area of the paranasal sinuses, the nasopharynx, the larynx or the anterior skull base. Shaver knifes scrape off bone or cartilage fragments and soft tissues that are removed from the treatment site by the suction tube on the handpiece. The shaver handpiece is thus equipped for the intended use with a shaver knife, which is then driven by a suitable motor. The intended use is obvious to the trained user.

CONTRA INDICATIONS

Asymptomatic diseases with significant comorbidities (heart and lung disease, relevant bleeding disorders, diabetes or asthma). 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 devices. 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 is supplied by us non-sterile. The handpiece 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.

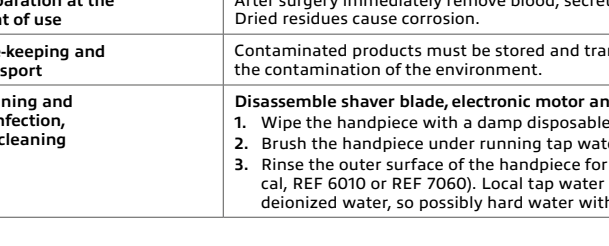
Manipulate the handpiece only when the motor is at a standstill.

The device shall only be operated by qualified and trained personnel.

Do not clean the handpiece with compressed air!

Only use NOUVAG shaver blades when working with the NOUVAG shaver handpiece.

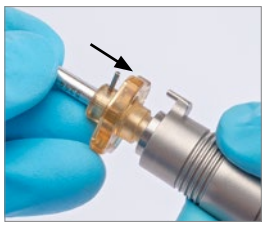
OVERVIEW



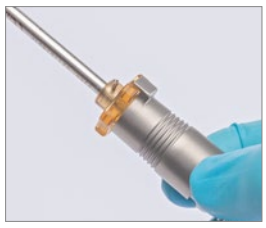
POSSIBLE COMBINATIONS

REF	CONTROL UNIT	INTENDED USE
3361	HighSurg 11	ENT Surgery
3365	HighSurg 30	ENT Surgery

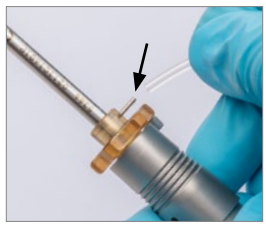
USE



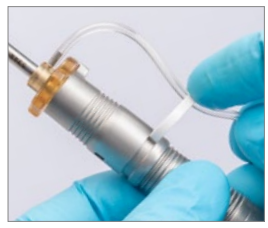
Retract the clamping sleeve and insert the shaver blade into the shaver handpiece.



Rotate shaver blade to the needed position and release the clamping sleeve. Check seating.



Attache the end of the tubing set to the cooling system of the shaver blade.



Attache suction tube with a handpiece clip (REF 1881) to the shaver handpiece.

Graft suction tube to the shaver handpiece suction nozzle.

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 only a limited impact on the handpiece. The end of the products service life is normally determined by wear and damage through use. The handpiece is designed for 250 sterilization cycles.
General handling	**1.** The handpiece 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 enables correct sterilisation! **2.** The handpiece should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. **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. **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 product life may be reached before the 250 sterilization cycles in case of excessive wear and damage from use. **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 with rinsing bar from 3mach (NOUVAG REF 51401), 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	**Disassemble shaver blade, electronic motor and suction tube from the handpiece. Wash off any visible soiling with water.** **1.** Wipe the handpiece with a damp disposable cloth / paper towel, removing all visible dirt. **2.** Brush the handpiece under running tap water using a soft brush (e.g. Insitumend GmbH, REF MED100.33). **3.** Rinse the outer surface of the handpiece 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 small parts (tube holder clips) 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 and accessories. Disinfection must be carried out with DI water.	⚠ **Warning** When inadequately rinsed or exposed to the disinfectant or detergent for too long, the handpiece and accessories can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	**Mechanical drying** Drying of the handpiece and accessories through the drying cycle of the cleaning/disinfection unit's (CDU). 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, separate from the cooling clip, 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). Check the cooling tubes for blockages and repeat the cleaning cycle if necessary. Then refit the cooling clip to the handpiece.	
Sterilisation	Sterilisation of the products is performed 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
Motor runs, but shaver blade does not move.	Shaver blade or shaver handpiece not optimally coupled.	Press the shaver handpiece firmly against the motor or shaver blade firmly against the shaver handpiece until it snaps into place. Check fit with counter movement.
Shaver blade does not run smoothly.	Shaver blade not optimally clamped.	Press the shaver blade firmly against the shaver handpiece until it snaps into place. Check seat with counter movement.
Handpiece is noisy.	Handpiece not lubricated or dirty.	Spray the handpiece with lubricant.

TECHNICAL DATA

ENT SHAVER HANDPIECE	REF 2092nou
Speed range in oscillation mode	300 – 5'000 rpm
Oscillation frequency	0.2 – 3.0 cycles/sec.
Speed range in continuous mode	300 – 6'000 rpm
Transmission ratio	4 : 1
Torque max. on shaver blade	12 Ncm
Coupling	ISO 3964
Weight	170 g

ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION	QTY.
1873	Clip set, for tubing set attachment to motor cable, PU 10 pcs.	1
1881	Clip-set, for tubing set attachment to handpiece, PU 3 pcs.	1
6024	Disposable tubing set, sterile, 3 m, PU 10 pcs.	1
14991	O-ring FPM Ø9.0×1.0 mm	1

INFORMATION ON DISPOSAL

When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed.
Used electrical and electronic equipment is hazardous waste and must not be disposed of with household waste.

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:
https://nouvag.com/en/service/complaint-form/

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