

Safety measures



- This operating instruction in general is valid for all ENT handpieces and its accessories
- We deliver these devices in non sterile condition. Clean, disinfect, and sterilize them before the first application and immediately after each use!
- Do not clean the handpieces with compressed air.
- The handpiece may be used at max. 80,000 rpm!
- Do not attach the handpieces while the motor is running!
- Never operate the clamping mechanism during operation or without a clamped instrument or placeholder pin.
- The devices may only be operated by qualified and trained personnel!
- Improper use or repair, or failure to observe these instructions, relieve us from any obligation arising from warranty provisions or other claims.

Intended purpose

The handpieces in conjunction with a control unit, electronic motor and a rotary instrument are used for milling, grinding and drilling for the following medical indication: **ENT surgery**

Handpieces may only be operated by qualified and trained personnel.

Contraindications / Limitations

Relative or absolute contraindications 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 systems. Relevant cases in the literature must be taken into consideration.

Symbole

	CE with notified body		Autoclave at 134°C		Suitable for thermal disinfection		European authorized representative
	Warning		Manufacturer		Observe instructions for use		Note
	Reference number		Lot number		Serial number		Date of manufacturing

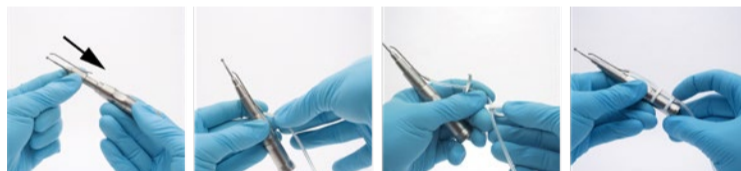
Technical Data

Described parts	Straight high speed Handpieces			Angled high speed Handpieces		
REF (Order number)	1903nou	1904nou	1905nou	1906nou	1907nou	1908nou
Transmission ratio	1:1					
Coupling standard	ISO 3964					
Shank Ø	2.35 mm Type 1, ISO 1797					
Max speed	80'000 rpm,					
Max. torque	3 Ncm					
Length of insertion part	8 mm	31 mm	62 mm	8 mm	31 mm	62 mm
Appropriate tool length	80 mm	95 mm	125 mm	70 mm	95 mm	125 mm
Weight including cooling clip	85 g	85 g	90 g	110 g	115 g	120 g

Operation

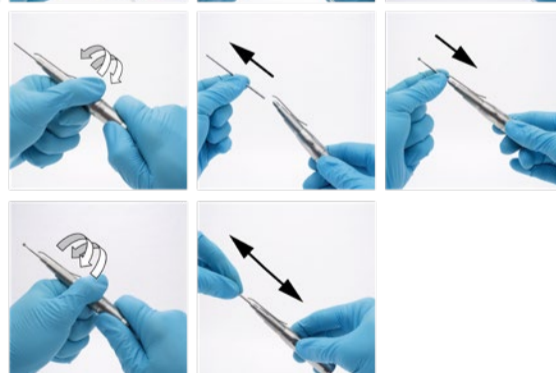
Assembly of the tubing set:

1. Attach the cooling clip to the handpiece.
2. Connect the irrigation tube with the cooling clip.
3. Attach tube fixing clip (REF 1881) to the irrigation tube and clamp it to the handpiece.







Inserting and exchanging the instrument:

1. Hold handpiece with one hand at the lower part and open the clamp by turning the tightening sleeve with the other hand with a countermotion until it clicks.
2. Extricate placeholder pin or previously used instrument.
3. Insert new instrument or the placeholder pin.
4. Lock tightening sleeve by twisting in the opposite direction.
5. Check seating of the instrument by gently pulling it.




Preparation Instructions

Restrictions	Frequent reprocessing hardly affects the Instrument. The products life end usually is determined by damage, wear and tear caused by usage. The handpiece is designed for 250 sterilization cycles.
General handling	<ul style="list-style-type: none"> • Every handpiece and accessories must be cleaned, disinfected and sterilised according to the instructions before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected handpiece permits a proper sterilisation! • The handpiece should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. • We recommend the use of mild alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining (silicating) the handpiece. • Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturer's specifications for the method of use, action time and suitability of disinfection and cleaning substances. • Follow precisely the operating instructions of the devices and chemicals used during preparation. • Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection. • In case of excessive wear and damage due to use, the product life can be reached before 250 sterilization cycles. • Do not overload the washer. Avoid blind spots while rinsing. Pay attention to secure storage in the machine. • Follow the applicable regulations in your country for reprocessing medical devices. • Nouvag AG recommends using a reusable fine-meshed strainer basket for small parts, for preparation and storage (including transport) of the products.
Attention	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- och Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.
Preliminaries 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 contamination of the environment.	
Pre-cleaning	Remove drill, cooling tubes, tube clips and cooling clip. Wash down visible soiling with water. 1. Wipe visible impurities with an expandable moist cloth/tissue paper from the handpiece and accessories. 2. Brush the handpiece and accessories under running tap water using a soft brush (e.g. Insitumed GmbH, REF MED100.33). 3. Rinse the outer surface of the handpiece for 10 seconds with a cleaning gun (at a pressure of at least 2.0 bar; e.g. HEGA Medical, REF 6010 or 7060) and local tap water. Machine cleaning with deionized water will remove all hard water traces. 4. Rinse the cooling clip with a cleaning gun with jet nozzle attachment (e.g. HEGA Medical, REF 4270) for at least 30 sec.	
Cleaning	Mechanical cleaning 1. After pre-cleaning place the handpiece on a suitable attachment. Place the small parts (drill, tube clip, and cooling clip) in a strainer basket and close it. 2. Mechanical cleaning is only successful if the pre-cleaning described above is adhered to! 3. Cleaning is carried out 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 (and its accessories) for visible contamination in grooves and gaps. Repeat the cleaning if necessary.	Automatic cleaning process (Vario TD programme) 1. Pre-clean for 4 minutes with cold water < 40°C. 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 for 3 minutes with cold water < 40°C. 6. Empty 7. Inter-rinse for 2 minutes with cold water < 40°C. 8. Empty
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 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 demineralized water.	 Warning The handpiece can corrode when inadequately rinsed or by lengthy exposure to the disinfectant or detergent. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	Mechanical drying Dry the handpiece 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, pay particular attention to grooves and gaps of the handpiece. 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. Drying must be carried out at 90°C for at least 30 minutes.	Manual drying if necessary Set the handpiece up in an upright position with the cooling clip separately, in order to abet the outflow of water. Let the handpiece and small parts dry for at least 30 minutes.
Manual cleaning and disinfection	1. Immerse handpiece for 15 minutes in a bath with enzymatic cleaner. The instructions of the cleaning agent must be followed. Clean accessories such as the cooling clip for 15 minutes in an ultrasonic bath with enzymatic cleaner. Follow the instructions of the detergent. 2. Perform a complete post-clean of the product, using a soft brush under running drinking water. Intensely rinse, cavities and lumens with a water pressure gun (or similar) for at least 30 seconds. 3. To remove the detergent, rinse the products under running city water (drinking quality) for at least 30 seconds.	
Manual disinfection	After cleaning, immerse the products for 5 minutes in a bath with a suitable disinfectant. It must be ensured that all surfaces are completely wetted with the disinfectant. Follow the manufacturer's instructions of the disinfectant. After disinfection thoroughly rinse all products with deionised water to remove the disinfectant (> 1 min.)	
Manual drying	Set up the handpiece in an upright position, separated from the cooling clip, to assure the outflow of water. Dry products with a lintfree 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	After disinfection, check for visual damage, corrosion, and wear. Then spray the handpiece thoroughly with Lubrifiuid and the blue adapter, for about 3 seconds, and briefly wipe with a DI water moistened cloth (see instructions on the spray can). Check the cooling clip for blockage. If necessary repeat the cleaning cycle. Then, attach the cooling clip back onto the handpiece.	
Sterilisation	Sterilisation of the handpiece is performed with a fractionated pre-vacuum steam sterilisation technique (in accordance with DIN EN 13060 or DIN EN 285) giving due consideration to the respective national requirements. Minimum requirements: 1. Pre-vacuum phases: 3 2. Sterilisation temperature: Min. 134°C, Max. 137°C (inside the sterility range). 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 post-vacuum function. After sterilisation, 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 sterilized Handpiece is not used immediately after sterilization, the packaging must be labelled with the sterilization date.	
Storage	Storing the sterile packaging The sterilised product must be stored away from dust, humidity and contamination. During storage, direct sunlight must be safely avoided. After the expiry date has passed, the entire reprocessing procedure must be repeated.	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 reprocessing process described above was verified in a validated procedure. Following materials and machines were used: 1. Alkaline cleaner: Neodisher® Mediclean forte; Chemische Fabrik Dr. Weigert GmbH & Co. KG 2. Enzymatic cleaner: Neodisher® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG 3. Washer-disinfector: Miele G 7835 CD 4. Insert trolley: Miele E429 5. Sieve basket/spill tray: 3mach (Nouvag AG REF:51401) 6. Steam steriliser: Selectomat 666-HP (MMM) 7. Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH Chemicals and machines other than those mentioned can also be used. If you decide to use a reprocessing method other than the one described above, you must validate it.	
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.	

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/media/attachments/2022/05/19/for_8-308.pdf as a PDF to this address: complaint@nouvag.com



Attention
Ultrasonic cleaning is not suitable for handpieces
Never clean handpieces in an ultrasonic bath.
This will impair the functionality of the handpieces.

Troubleshooting

Problem	Cause	Solution
Motor is running but tool does not move.	Handpiece is not properly attached to the motor.	Press handpiece firmly to the motor until it engages. Check fitting.
Tool functions irregularly	Tool is not properly clamped	Open the chuck, fix tool properly and close chuck.
Handpiece is loud	Ball bearings are not lubricated or are soiled	Spray handpiece interior with Lubrifiuid spray.

Spare parts / Accessories

REF	Description	Units
6024	Tubing set, sterile, 3 m, disposal	10
1956	Cooling clip for handpiece 1903 and 1906	1
1964	Cooling clip for handpiece 1904 and 1907	1
1966	Cooling clip for handpiece 1905 and 1908	1
20562	Placeholder pin, 75 mm for 1903 and 1906	1
20588	Placeholder pin, 115 mm for 1904, 1905, 1907 and 1908	1
1881	Tube fixing clip for attaching to the handpiece (3pc.)	1
1969	Wrench for handpiece	1
1940	Cleaning wire for cooling clip	1
2128	Lubrifiuid	1

Manufacturer and service centers

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A complete list of Nouvag certified service centers are found on the Nouvag website at: <https://nouvag.com/service>

Disposal



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