EN

Operating instructions

ENT handpieces and accessories

NOUVAG

REF 19520EN, V10/18

Safety measures

- These operating instructions generally apply to the ENT handpieces and accessories.
- We deliver a non sterile Instrument. Clean, disinfect, and sterilize the Instrument and accessories before the first application and immediately after each use.
- Do not clean handpiece with compressed air.
- The handpiece may be applied with max. 50,000 rpm!
- Handpieces may only be connected to the electronic motor when it's at a standstill.
- Never operate the clamping mechanism during operation, or without a clamped tool or placeholder pin.
- Operation of instrument by qualified and trained personnel only!
- Improper use or repair, or failure to observe these instructions, relieve us from any obligation arising from warranty provisions or other claims.

Intended use and operation

The handpieces in conjunction with a drive system and corresponding rotating instruments serve for milling, grinding and drilling in the area of ENT surgery. Handpieces may only be operated by qualified and trained personnel. Improper operation can lead to malfunctions. The intended use is obvious to the trained user.

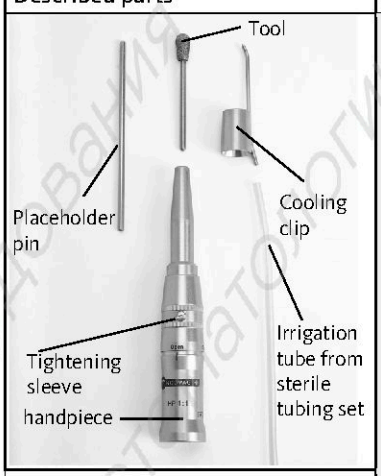
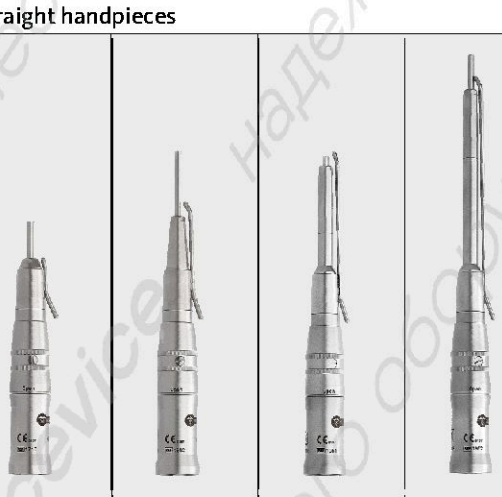
Contraindications/Limitations

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.

Symboles

CE 0197	Conform to EU standards	135°C	Autoclave with 135°C		Suitable for thermal disinfection		Date of expiry
	Warning		Manufacturer		Observe instructions for use		Note
REF	Order number	LOT	Lot number	SN	Serial number		Date of manufacturing

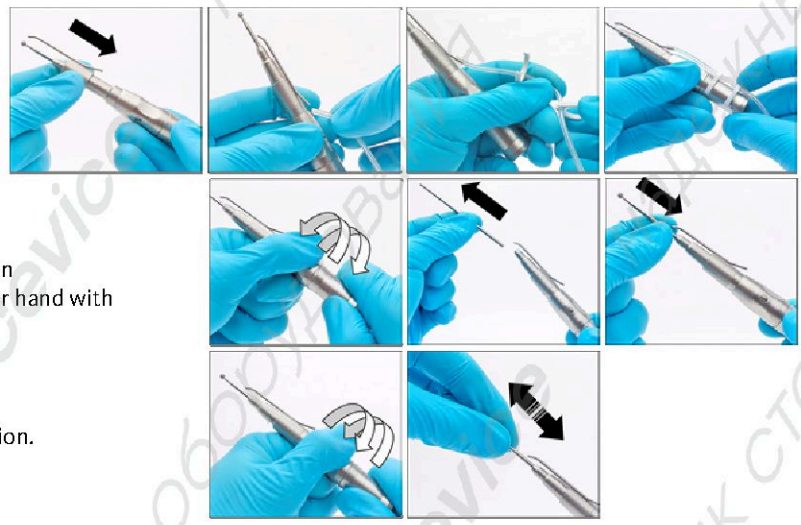
Technical data

Described parts	Straight handpieces				Angled handpieces		
							
REF (Order number)	1710	1950	1951	1952	1960	1961	1962
Transmission ratio	1:1	1:1	1:1	1:1	1:1	1:1	1:1
Coupling standard	ISO 3964	ISO 3964	ISO 3964	ISO 3964	ISO 3964	ISO 3964	ISO 3964
Shank-Ø (mm)	2,35	2,35	2,35	2,35	2,35	2,35	2,35
Max. speed (rpm)	50'000	50'000	50'000	50'000	50'000	50'000	50'000
Max. torque (Ncm)	6	6	6	6	6	6	6
Length of insertion part (mm)	0	21	44	75	21	44	75
Appropriate tool length (mm)	44	70	95	125	70	95	125
Weight including cooling clip (g)	80	85	85	90	113	113	119

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 tool:

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 tool.
3. Insert new tool or the placeholder pin.
4. Lock tightening sleeve by twisting in the opposite direction.
5. Check seating of the tool 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 procedure	1. 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! 2. The handpiece should always be treated with utmost care when being transported, cleaned, serviced, sterilised 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 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. Follow precisely the operating instructions of the devices and chemicals etc. used during preparation. 6. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection. 7. In case of excessive wear and damage due to use, the product life can be reached even before the maximum of 250 sterilization cycles. 8. Do not overload dishwashers. Avoid dead zones. Pay attention to secure storage in the machine. 9. Follow the applicable regulations in your country for reprocessing medical devices. 10. Only the cooling clip may be cleaned with ultrasound, the handpiece must never be subjected to ultrasonic cleaning! It would impair the functionality. 11. Nouvag AG recommends the use of a screen basket including a flush socket bar from 3mach (NOUVAG REF 51401), a re-usable container for comfortable preparation and storage (incl. transport) of products. The screen basket can be used to keep products safe both during the rinsing cycle and also during and after sterilisation until the products are used. The screen basket is suitable for use with sterilisation paper or a rigid sterilisation 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. The Robert-Koch 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.

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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 contaminating the environment.
Pre-cleaning before cleaning and disinfection	Remove drill, cooling tubes, tube clips and cooling clip. Wash down visible soiling with water. 1. Wipe visible impurities with a moist expandable cloth/tissue paper from the handpiece and accessories. 2. Brush the handpiece and accessories under running tap water using a soft brush (manufacturer Insituded GmbH, REF MED100.33). 3. Rinse the outer surface of the handpiece for 10 seconds with a water pistol (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, and possibly hard water with lime traces from the pre-cleaning cannot remain on the handpiece. 4. Rinse the cooling clip with a cleaning gun with jet nozzle attachment (manufacturer HEGA Medical, REF 4270) for at least 30 sec.
Cleaning	**Mechanical cleaning** 1. Place the handpiece after precleaning 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 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 (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. 2. Empty 3. Clean for 10 minutes at 55°C with a 0.5 % alkaline cleanser. Alternatively: at 40°C with 0.5 % enzymatic cleanser. 4. Empty 5. Neutralise for 3 min. with cold water and Neodisher®-Z from Mediclean; Dental. When using an enzymatic cleaner neutralisation is replaced by a 3 minute water rinse. 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 the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating to the Ao value (see DIN EN ISO 15883-1). We recommend an Ao value of 3,000 (5 minutes at 92°C) for the handpiece and accessories. Disinfection must be carried out with DI 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, take particular care with the 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 should be done 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. Dry the handpiece for at least 30 minutes.
Manual cleaning and disinfection	1. Immerse handpiece after pre-cleaning for 15 minutes in a bath with enzymatic cleaner (for example 2 % ID 215, Dürr Dental). Clean accessories such as e.g. the cooling clip for 15 minutes in an ultrasonic bath (1 % ID 215). Follow the instructions of the manufacturer of the detergent. 2. Perform a complete post-clean of the product, using a soft brush under running drinking water. Intensely rinse, if any, 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. **Warning** ⚠ Do not clean rotating instruments (handpiece) in an ultrasonic bath!
Manual disinfection	After cleaning, immerse the products for 5 minutes in a bath with a suitable disinfectant (for example 2 % ID 212, Dürr Dental). It must be ensured that all surfaces are completely wetted with the disinfectant. Follow the manufacturers 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 vertically, separated from the cooling clip, to make sure the outflow of water is favored. Dry products 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  REF 1958	Check for visual damage, corrosion, and wear. After the disinfection spray the handpiece with mounted spray adapter REF 1958 with NouClean spray thoroughly and briefly and 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. After attach 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 556-1/DIN EN ISO 17665-1) giving due consideration to the respective national requirements. **Minimum requirements:** 1. Pre-vacuum phases: 3 2. Sterilisation temperature: At least 132°C. 3. Holding time: At least 3 minutes (full cycle). 4. Drying time: At least 20 minutes (max. 30 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 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.
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. 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. Manual cleaning: Enzymatic cleanser ID 215, Dürr Dental 4. Manual disinfection: ID 212, Dürr Dental 5. Cleaning and disinfection unit: Miele G 7835 CD 6. Rack trolley: Miele E 450/1 7. Strainer basket/flush socket bar: 3mach (NOUVAG REF 51401) 8. Autoclave: Selectomat 666-HP (MMM) 9. Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH 10. Neutralizer: Neodisher®-Z Mediclean; Dental: Chemische Fabrik Dr. Weigert GmbH & Co. KG 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
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 NouClean spray.

Spareparts

REF	Description	Units
6024	Tubing set, sterile, 3 m, disposable	10
1703	Cooling clip for handpiece 1710	1
1956	Cooling clip for handpiece 1950 and 1960	1
1964	Cooling clip for handpiece 1951 and 1961	1
1966	Cooling clip for handpiece 1952 and 1962	1
20153	Placeholder pin, 45 mm for handpiece 1710	1
20562	Placeholder pin, 75 mm for 1950, 1951, 1960 and 1961	1
20588	Placeholder pin, 115 mm for 1952 and 1962	1
1881	Tube fixing clip for attaching to the handpiece (3 pc.)	1
1984	NouClean-Spray	1
1958	Spray adapter for Nou-Clean Spray	1

Service provider

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For service, maintenance, spare parts and general inquiries please contact your local dealer or representative.

Nouvag service providers worldwide: **www.nouvag.com**

Information on disposal

Disposal of device, components and accessories must strictly conform to local laws and regulations as set out by the relevant authorities.

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