EN

Operating instructions

4:1 Handpiece

NOUVAG

REF 31583 EN, V12/19

Safety measures

- The handpiece is delivered in non sterile condition. Clean, disinfect, and sterilize the handpiece before the first application and immediately after each use!
- Operate the handpiece with a maximum speed of 12 500 rpm.
- Attache the handpiece to the motor only when it's standing still.
- Perform manipulations on the instrument only when the motor is at a standstill.
- Any guarantees on our part or other claims against us become void in the case of inappropriate use of the handpiece or failure to comply with our instructions!
- Without a clamped burr, the handpiece should not be stored with the tensioning mechanism tightened. For storage of the handpiece use the placeholder pin, which is included in delivery.
- The instrument may only be used by competent and trained personnel.

Intended use / indication

The 4 : 1 Handpiece together with the appropriate instrument head is applied in Percutaneous Foot and Ankle Surgery especially for the treatment of Hallux Valgus and Hallux Rigidus. Therefor the handpiece with the according milling tool is applied for the removal of tissue mass and cartilages at the Metatarsophalangeal joint and the metatarsal while retaining these bones. In the dental field, the handpiece is used for drilling and grinding the zygomatic bone to insert zygomatic implants.

Contraindication / Limitations

a) An operation is not advisable In the case of arterial occlusive disease with indeterminate foot pulse because of lack of perfusion (Application: percutaneous foot surgery).
b) Severe Sinusitis, diseases of the maxillary sinuses and the jaw bone or zygomatic bone (Application: Dental field).
c) Poor physical health of patient.
d) Infectious Wounds - The hallux surgery may only be performed after treatment of the infection and the necrotized tissue.
e) Relative or absolute contraindications may result from the general medical findings or in special cases in which the patients risk for motor-driven tools is significantly increased. Cases described in the relevant literature must be taken in account.

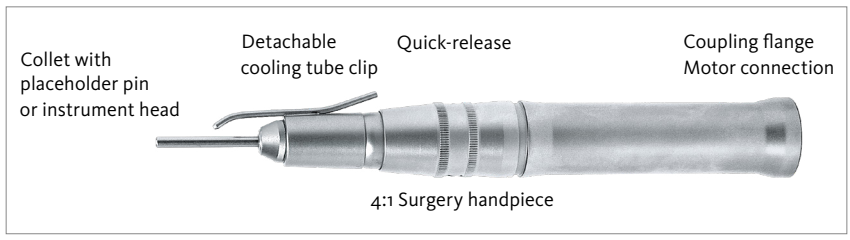
Symbols

LOT	LOT number	135°C	Autoclave at 135°C		Suitable for thermal disinfection		Date of manufacturing	REF	Order number
	Warning		Manufacturer	CE 0197	CE symbol with notified body	SN	Serial number		Observe instructions for use
	Important information		Do not reuse						

Technical data, 4 : 1 Handpiece

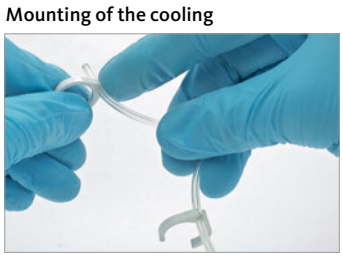
REF	1043nou
Transmission ratio	4 : 1
Maximum torque	20 Ncm
Max. Speed	12,500 rpm
Ø-Shaft	2.35 mm
Length of instruments	44 - 70 mm
Coupling	acc. to ISO 3964
Weight	110 g

Overview



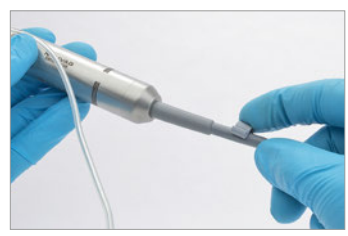
Operation

Mounting of the cooling


Attach clips to the tubing set

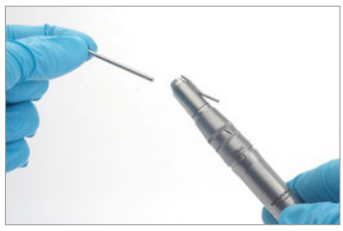

Connect the tubing set with the cooling tube and clamp the clips to the handpiece.


Connect the motor (optional) at the coupling flange.


Attach the cable clip to the motor cable and hook in the tube.

Clamping of a burr


Open the clamping mechanism.


Take out the placeholder pin ...


... and replace it with a fraise burr.


Close the collet and check for proper seating of the instrument head by slightly pulling it.

Possible combinations

4 : 1 Handpiece, REF 1043nou is exclusively used:

- In combination with the surgical motor systems HighSurg 11 OFA-Drill (REF 3363) and HighSurg 30 (REF 3360), which control the 4 : 1 Handpiece via the upstream electronic motor 21 and enable settings for speed and torque according to the tool used.
- In combination with the MD 30 implant motor system (REF 3330), which controls the handpiece via the upstream electronic motor 21 and enables settings for speed and torque according to the tools used.

Wrong combination of products

Damage to the product and injury to the patient, user or third parties are possible.

- Only use the different products together if the purpose and the relevant technical data, such as working lengths, diameters, and so on match.
- Always follow the instructions for use of the products used in combination.

Accessories

Foot cutters for 4:1 handpiece	Head-Ø mm	No. of flutes	Head length mm	Tool length. mm	REF-number
	2.9	3	13.2	55	**2481**
	2.9	3	13.2	65	**2482**
	4.3	3	13.0	55	**2483**
	4.3	3	13.0	65	**2484**
	2.0	3	13.0	65	**2485**
	2.2	3	22.0	75	**2486**
	3.0	3	30.0	100	**2487**
	2.0	3	9.4	65	**2488**
	2.0	3	8.0	55	**2489**
	2.0	3	8.0	65	**2490**
	3.1	3	20.0	70	**2491**
	3.1	3	15.0	65	**2492**
	4.1	3	15.0	65	**2493**
	2.2	3	11.9	65	**2494**
	2.2	4	11.0	65	**2495**
	2.2	3	11.1	65	**2496**
	5.0	4	15.2	70	**2497**

Spare parts

REF	Description	Units
1958	Spray adapter for Nou-Clean Spray for the care of handpieces	1
1984	NouClean-Spray	1
1703	Cooling clip	1
1881	Clip set (white) for the tubing set attachment to the Handpiece	3
1873	Clip set (gray) for the tubing set attachment to the motor cable	10

Troubleshooting

Problem	Cause	Solution
Motor is running but cutter is not turning.	Handpiece is not correctly coupled.	Press handpiece firmly against the motor. Check for proper seating.
Cutter runs irregularely	Cutter is not clamped correctly	Adjust cutter correctly in the collet and lock it.

Ambient conditions

	Transport and storage:	Operation:
Relative humidity:	Max. 90 %	Max. 80 %
Temperature:	0 – 60°C	10 – 30°C
Atmospheric pressure:	700 – 1060 hPa	800 – 1060 hPa

Manufacturer and Service points

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The complete list of all Nouvag-authorized service points worldwide are to be found on our Website, under: **www.nouvag.com/en/service/service provider**

Disposal

When disposing of instruments, local legislations must be observed. Do not dispose of instruments with household waste. Observe the national regulations for the disposal of infectious waste.

Reprocessing instructions

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 instrument 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 instrument permits 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 instruments.
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 etcetera, used during preparation.
6. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection.
7. The end of the products service life is determined by wear and damage through use. For the handpiece it can be reached even before the 250 sterilization cycles, that they're designed for, due to wear and tear.
8. Do not overload washer. Avoid blind spots while rincing. 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 in an ultrasonic bath. The handpiece must never be subjected to ultrasonic cleaning! This will impair the functionality.
11. Nouvag AG recommends using a screen basket with a rinse strip from 3mach (NOUVAG REF 51401), a re-usable container for comfortable preparation and storage (including 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.

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

Remove cooling tube, clips for the cooling tube attachment and cooling clip from the micro saw handpiece.

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 Insitumed 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, so 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 a jet nozzle attachment (manufacturer HEGA Medical, REF 4270) for at least 30 seconds.

Cleaning

Mechanical cleaning

1. After pre-cleaning place the handpiece and its accessories 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 programme (inc. Thermal disinfection) check the handpiece and the cooling clip for visible contamination in grooves and gaps. Repeat the cleaning cycle, 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 Ao value (see DIN EN ISO 15883-1). We recommend an Ao value of 3,000 for the instrument. Disinfection must be carried out with DI water.

Warning ⚠

When inadequately rinsed or exposed to the disinfectant or detergent for too long, the instrument can corrode. 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 instrument. Then spray the instrument again with NouClean spray.
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 in an upright position without the cooling clip attached.
Dry the instrument for at least 30 minutes. Then spray it with NouClean spray. Afterwards reassemble the cooling clip back onto the instrument.

Manual cleaning and disinfection

1. Immerse the 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 % ID215). Follow the instructions of the manufacturer of the detergent.
2. Perform a complete post-clean of the product under running drinking water, using a soft brush. Intensely rinse, if there is any cavities and lumens existing, 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 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

1. First remove the cooling clip.
2. Perform a visual inspection for damage, corrosion and wear.
3. In the next step, spray the handpiece for cleaning and care. Nouvag AG recommends the use of NouClean spray. Place the spray attachment (REF 1958) on the spray can and spray the handpiece from the coupling side with NouClean spray for about 3 seconds until only clear liquid escapes from the saw handpiece.
4. Then wipe with a damp cloth (observe the instructions for use of the product).
5. After spraying the handpiece, re-install the cooling clip on 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 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. During storage, direct sunlight must 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.

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.