stomdevice

EN Operating instructions

Micro Oscillating Saw OMS 5000, REF 5090nou

NOUVAG

REF 31695 EN, V47/18

Safety measures

- The Micro Saw is delivered in non sterile condition. Clean, disinfect, and sterilize the Micro Saw before the first application and immediately afte each use!
- Operate the Micro Saw with a maximum speed of 15 000 rpm.
- Attache the Micro Saw 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 electronic motor or failure to comply with our instructions!
- Without a saw blade clamped, the Micro Saw should not be stored with the tensioning mechanism tightened.
- The instrument may only be used by competent and trained personnel.

Intended use / indication

The saws are intended for bone-working surgery. This includes ENT surgery, maxillofacial surgery, plastic surgery, neurosurgery and hand surgery. With the bone saw and clamped saw blade (standalone medical device), a piece of bone is removed to correct misalignments. In dental facilities, this is used in jaw osteotomy to convert the jawbone. The saws may only be operated by expert and trained personnel. The intended use is obvious to the trained user.

Contraindication / Limitations

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 systems. Relevant cases in the literature must be taken into consideration.

Symbols

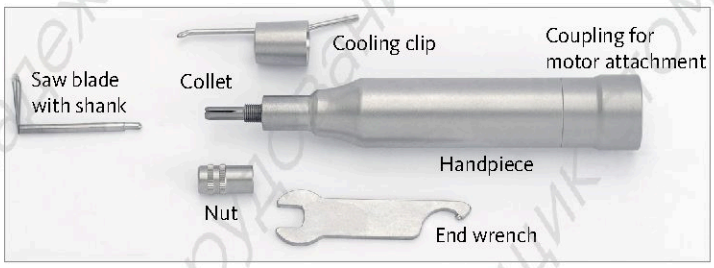
LOT	LOT number	135°C	Autoclave at 135°C		Suitable for thermal disinfection		Date of manufacturing	REF	Order number
	Warning		Manufacturer	CE 0197	CE symbol with notified body	SN	Serial number		Observe instructions for use
	Important information		Do not reuse						

Technical data, Electronic motor 21

REF	5090nou
Weight, without cable	142 g
Maximum torque	6 Ncm
Max. Speed	80 000 rpm
Oscillation angle saw blade	25°
Transmission ratio	1 : 1
Coupling	acc. to ISO 3964
Clamping depth, saw blade	16 mm
Ø saw blade shank	2.35 m

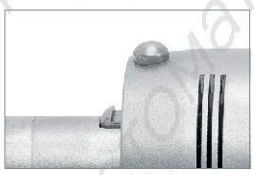


Overview



Operation

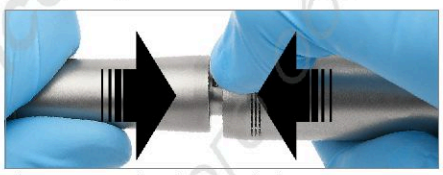
Coupling handpieces with a groove with the electronic motor with twist protection lock



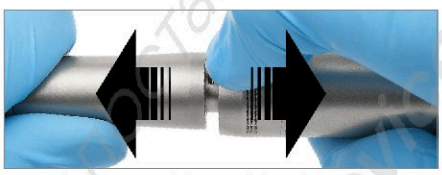
Twist protection lock with release button.



Handpiece coupling with groove for twist protection.



Align groove at handpiece with the twist protection and connect handpiece with electronic motor by pressing the button. Check for proper seating.



Press the button and decouple handpiece from electronic motor.

Disassembly and assembly of the components to replace the saw blades and to feed the components into the reprocessing



Loosen the nut with the wrench.



Continue the opening of the nut with your fingers.



Remove saw blade out of the collet and replace it if needed.



Loosen cooling clip by twisting it left and right.



Pull cooling clip off the sawing handpiece.

Possible combinations

Micro Oscillating Saw, OMS 5000, REF 5090nou

Is exclusively used:

- In combination with the surgical motor systems HighSurg 11 (REF 3361), HighSurg 11 OFA-Drill (REF 3363) and HighSurg 30 (REF 3360), which control the sawing handpiece via the upstream electronic motor 21 and enable settings for speed and torque according to the tools used.
- In combination with the surgical motor system TCM 3000 BL (REF 3285), which controls the sawing handpiece via the upstream electronic motor 21 and holds a program with a fixed speed for the micro saw.
- In combination with the MD 30 implant motor system (REF 3330), which controls the sawing 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.

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

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 micro saw 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 electronic motor 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 product service life is determined by wear and damage through use. The micro saw is designed for 250 sterilisation cycles. 8. Do not overload washer. Avoid rinsing blind spots. 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 micro saw 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 micro saw. 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 saw blade, 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 micro saw 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 micro saw 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.

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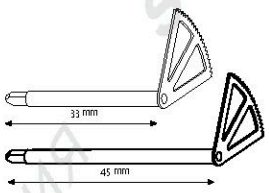
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Cleaning	**Mechanical cleaning** 1. After pre-cleaning place the micro saw and its accessories in the strainer basket. 2. Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! 3. Cleaning is done using the Vario 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 micro saw, the nut 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 micro saw 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 micro saw in an upright position without the nut and the cooling clip attached. Dry the instrument for at least 30 minutes. Then spray it with NouClean spray. Afterwards reassemble the nut and the cooling clip back onto the instrument.

Manual cleaning and disinfection	1. Immerse the micro saw 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 and the nut 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 micro saw (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 micro saw 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 unscrew the union nut and remove the cooling clip. 2. Perform a visual inspection for damage, corrosion and wear. 3. In the next step, spray the saw 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 saw 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 saw handpiece, re-install the cooling clip on the saw handpiece and screw the union nut onto the collet chuck.	
Sterilisation	Sterilisation of the micro saw 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. 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.	
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.	

Accessories and spare parts

	Description	Units
40347	End wrench	1
1958 REF	Spray adapter for Nou-Clean Spray for maintenance and care of handpieces	1
1984	NouClean-Spray	1
5047	Cooling clip	1



Saw blades	Cutting depth	Cutting width	Shank length	PU *	REF
6 mm	3.0 mm	6 mm	45 mm	1	5101nou
9 mm	6.3 mm	6 mm	33 mm	1	5100nou
	6.3 mm	6 mm	45 mm	1	5099nou
16 mm	13.3 mm	6 mm	33 mm	1	5093nou
	13.3 mm	6 mm	45 mm	1	5096nou
16 mm	13.3 mm	10 mm	33 mm	1	5094nou
	13.3 mm	10 mm	45 mm	1	5097nou
16 mm	13.3 mm	15 mm	45 mm	1	5098nou

** PU: Packaging units*

Troubleshooting

Problem	Cause	Solution
Motor is running but saw is not moving	Saw handpiece is not correctly coupled with motor	Press saw handpiece firmly against the motor until it snaps into place. Check seat with countermovement.
Saw blade is not moving regularly	Saw blade is not correctly clamped	Clamp saw blade correctly and tighten nut with the end wrench.

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.

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