














SYMBOLS

-  General warning sign
-  Manufacturer
-  Batch code
-  Observe instructions for use
-  Date of manufacture
-  Catalog number
-  Note
-  Autoclave at 134°C
-  Serial number
-  Suitable for thermal disinfection
-  Separate collection required (WEEE)
-  Authorized representative in the European Community

 0197 European Conformity mark

INTENDED PURPOSE

MEDICAL INDICATIONS

OMS 5000 is used with a saw blade (instrument) to cut and remodel bones in the following medical indications:
// ENT surgery // Maxillofacial surgery // Plastic surgery // Neurosurgery // Hand surgery

CONTRA INDICATIONS

Contra indications are the those generally indicated for the specific medical indication, and those for active medical devices.

SIDE EFFECTS

Main side effect of surgical saws is osteonecrosis, caused by saw blade speed and vibration.

INTENDED USERS


Intended users are trained and qualified personnel, in professional settings (e.g. hospital, ambulatory).

TARGET POPULATION

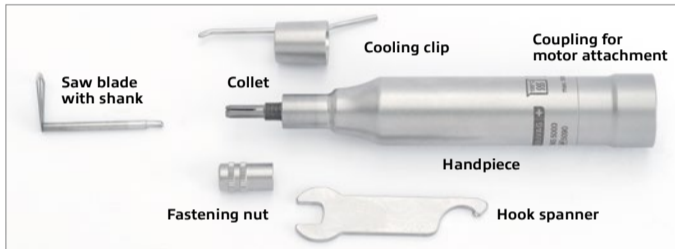
The target population includes both minor and adult patients, depending on the medical indication.

AMBIENT CONDITIONS	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90%	max. 80%
Temperature	0–60 °C	10–30 °C
Atmospheric pressure	700–1'060 hPa	800–1'060 hPa

SAFETY INFORMATION

-  Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile and operational.
- The use of the product other than that for which it was designed is not permitted. The responsibility is solely carried by the operator.
- The use of third-party products is the responsibility of the operator. Functionality and patient safety cannot be guaranteed with third-party accessories.
- Manipulate the instrument only when the motor is at a standstill.
- Improper use or repair of the device, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.
- Do not close the clamping mechanism without a saw or a pin inserted in the collet.
- The device shall only be operated by qualified and trained personnel

OVERVIEW

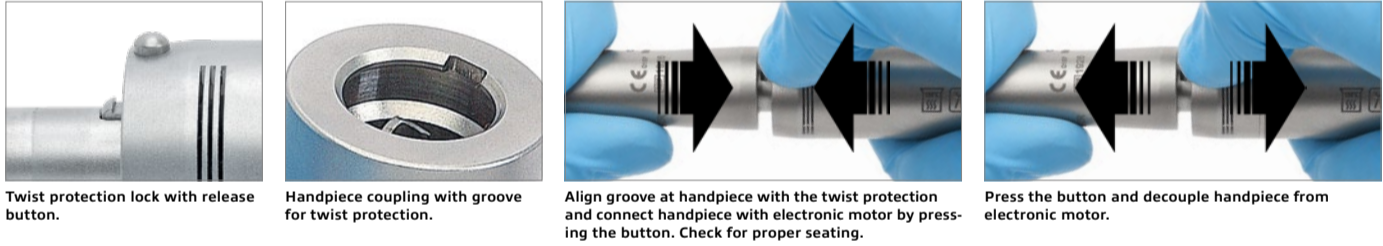


POSSIBLE COMBINATIONS

REF	CONTROL UNIT	INTENDED USE
3330	MD 30	Dental Implantology
3360	HighSurg 30	Plastic Surgery Spinal Surgery ENT Surgery Hand and foot surgery
3363	HighSurg 11 OFA-Drill	Foot surgery
3285	TCM 3000 BL	Dermabrasion and Reconstructive Surgery Rhinoplasty

OPERATION


COUPLING HANDPIECES WITH A GROOVE WITH THE ELECTRONIC MOTOR 21 WITH TWIST PROTECTION LOCK






DISASSEMBLY AND ASSEMBLY OF THE COMPONENTS TO REPLACE THE SAW BLADES AND TO FEED THE COMPONENTS INTO THE REPROCESSING





REPROCESSING INSTRUCTIONS

 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.

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	<ol style="list-style-type: none"> 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! The electronic motor 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 (silicatising) the instruments. 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. Follow precisely the operating instructions of the devices and chemicals etcetera, used during preparation. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection. The end of the products service life is determined by wear and damage through use. For the micro saw it can be reached even before the 250 sterilization cycles, that they're designed for, due to wear and tear. Do not overload washer. Avoid rinsing blind spots. Pay attention to secure storage in the machine. Follow the applicable regulations in your country for reprocessing medical devices. 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. NOUVAG 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.
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	<p>Remove saw blade, cooling tube, clips for the cooling tube attachment and cooling clip from the micro saw handpiece.</p> <ol style="list-style-type: none"> Wipe visible impurities with a moist expandable cloth/tissue paper from the micro saw and accessories. Brush the handpiece and accessories under running tap water using a soft brush (manufacturer for example Insitumed GmbH, REF MED100.33). 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 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. Rinse the cooling clip with a cleaning gun with a jet nozzle attachment (manufacturer for example HEGA Medical, REF 4270) for at least 30 seconds.

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 A0 value (see DIN EN ISO 15883-1). We recommend an A0 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 Lubrifluid. 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 Lubrifluid. 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. Clean accessories such as e.g. the cooling clip and the nut for 15 minutes in an ultrasonic bath. 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. 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	1. First unscrew the union nut and remove the cooling clip. 2. Perform a visual inspection for damage, corrosion and wear. 3. Spray the handpiece for cleaning and care. NOUVAG recommends the use of Lubrifluid. Attach the blue spray adapter to the spray can and spray the handpiece from the coupling side for about 3 seconds until only clear liquid flows out of the electronic motor. 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 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 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 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 micro-pencil saw 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 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 hook spanner.

TECHNICAL DATA

REF	5090nou
Weight	140 g
Torque max.	6 Ncm
Speed max.	15'000 rpm
Oscillation angle saw blade	25°
Transmission ratio	1 : 1
Coupling to motor	ISO 3964
Clamping depth saw blade shank	16 mm
Diameter saw blade shank	2,35 mm



ACCESSORIES AND SPARE PARTS


REF	DESCRIPTION	QUANTITY
1969	Hook spanner	1
2128	Lubricant spray LUBRIFLUID	1
5047	Cooling clip	1

INFORMATION ON DISPOSAL



When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed. When discarding the device components and accessories, please comply with the issued statutory regulations.

POST MARKET SURVEILLANCE

 In the event of incidents related to the use of the medical device, please contact immediately the manufacturer by email complaint@nouvag.com or by phone. To provide adequate information, please compile the incident questionnaire at the web address Nouvag.com > [Contact us](#) > [Incident questionnaire](#).

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