The Micro Saw is delivered in non sterile condition. Clean, disinfect, and sterilize the Micro Saw before the first application and immediately after each use!

- Operate the Micro Saw with a maximum speed of 15,000 rpm.
- Attach the Micro Saw to the motor only when it is standing still.
- Never 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 surgery. This includes ENT surgery, maxillofacial surgery, plastic surgery, maxillofacial surgery 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 ankylosed teeth or to correct jaw deformities. 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 contraindications can arise from the general medical diagnosis, 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.

Technical data, Sagittal micro saw, MOS 5000

Overview
- Saw blade with shaft
- Calot drill (with chuck)
- Cooling clip
- Fastening nut
- Motor connection coupling
- Handpiece
- Wrench

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

- Remove or replace the saw blade
- Loosen or replace the saw blade
- Remove the cooling clip by twisting it back and forth.
- Remove the cooling clip from the saw handpiece.
- Fastening nut
- Saw blade clamping depth
- Saw blade thickness
- Transmission ratio
- Oscillation angle
- Maximum speed
- Weight

WARNING
- Do not reuse
- Do not not reuse

Symbols
- CE symbol with notified body
- SN
- RE number
- Order number
- Manufacturer
- Date of manufacturing

Saw blade
- Saw blade thickness
- Saw blade clamping depth

Twist protection lock
- Release button

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

Loosen fastening nut using the wrench.

Further open fastening nut with your fingers.

Remove or replace the saw blade.

Loosen cooling clip by twisting it back and forth.

Remove the cooling clip from the saw handpiece.

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 the use of the products used in combination.

Possibilities of combination

- In combination with the surgical motor systems HighSurg 11 (REF 255), HighSurg 11 OFA Drill (REF 255) and HighSurg 11 OFA-Drill (REF 255), which control the sawing handpiece via the upstream electronic motor 2 and enable setting for speed and torque according to the tools used.
- In combination with the surgical motor system TCM 5000 BL (REF 3490), which controls the sawing handpiece via the upstream electronic motor 2 and enables settings for speed and torque according to the tools used.
- In combination with the MD 30 implant motor system (REF 5050), which controls the sawing handpiece via the upstream electronic motor 2 and enables settings for speed and torque according to the tools used.

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
- The micro saw must be thoroughly cleaned, disinfected and sterilized before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected instrument permits proper sterilization!
- The instrument should always be treated with utmost care when being transported, cleaned, serviced, sterilized and stored.
- We recommend the use of mild alkaline and enzymatic cleaners with low a content of silicate as possible in order to avoid staining (alkaliing) the instruments.
- Sagsurgical® STH-VAH-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.
- Act accordingly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection.
- The end of the product service life is determined by wear and damage through use. The micro saw is designed for 250 sterilisation cycles.
- 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 functional parameters such as working length, diameters and so on.
- The saw blade must be thoroughly cleaned, disinfected and sterilized before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected instrument permits proper sterilization!

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 the use of the products used in combination.

Ambient conditions

Transport and storage: Operation:
- Relative humidity: Max. 90 %
- Max. 85 %
- Temperature: 0 – +60°C
- Atmospheric pressure: 700 – 1060 hPa

Attentive

In relation to patients with Creutzfeldt Jakob disease or its variant (vCJD) 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 I immediately remove blood, secretion, tissue and bone residue with a disposable cloth / paper towel, do not allow to dry! Dried residue causes corrosion.

Safekeeping 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, disinfection, post cleaning

- Remove saw blade, cooling tube, clips for the cooling tube attachment and cooling clip from the micro saw handpiece.
- 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 Instrument GmbH, REF ME/Demo 22)
- Rub the 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 F004 or F006). 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.
- Rub the 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 F004 or F006). 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.
- Rub the 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 F004 or F006). 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.
- Wash the cooling clip with a jet nozzle attachment (manufacturer 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.
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 dezertalised 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.
5. Repeat the cleaning cycle, if necessary.

Disinfection
Mechanical disinfection
The cleaning/disinfection unit has a thermal disinfection programme which follows after the cleaning. When performing mechanical disinfection thermal, give due consideration to the national requirements relating to the Au value (see DIN EN 15883-6). We recommend an Au value of 0.05 for the disinfection. Must be carried out with DI water.

Drying
Mechanical drying
Dry the micro saw using the cleaning/disinfection unit’s (CDU) drying cycle. If required, manually drying can be achieved by using a lint-free cloth. If manually drying, take particular care of the grooves and the grooves of the instrument. Then spray the instrument again with NouClean spray.
Each 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
1. Immers the micro saw handlespace after pre-cleaning for 5 minutes in a bath with enzymatic cleaner (for example 2 % ID 215, Dürr Dental). Clean accessories such as the cooling clip and the nut 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 under running drinking water, using a soft brush. Intensively rinse, if there are 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.
4. After disinfection throughly rinse all products with deionized water to remove the disinfectant (x = mm).

Manual drying and disinfection
1. After cleaning, immerse the products for 5 minutes in a bath with a suitable disinfectant (for example a 2 % ID 212, Dürr Dental). It must be ensured that all surfaces are completely wetted with the disinfectant. Follow the manufacturer’s instructions of the disinfectant.
2. After disinfection thoroughly rinse all products with deionized water to remove the disinfectant.

Information for validating the preparation
The above preparation process has been verified by a validated procedure. The following materials and machines were used:
- Pre-vacuum phase: 3
- Sterilisation temperature: At least 121°C
- Drying time: At least 20 minutes (max. 30 minutes).

Warning
Dry the micro saw handlespace. Do not dry in an ultra- sonic bath!

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 packag- ing to be intact. When taking out the product, follow the respective aseptic procedures.

Note
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
Mower is running but saw is not moving
Saw blade is not moving regularly
See blade is not correctly clamped
Press saw blade firmly against the motor until it stops. Check seat with countermovement.

Manufacturer and Service points
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Nouvag USA, LLC • 6201 Airport Freeway • Suite 200 Haltom City, Texas 76117 USA Toll free no. (800) 673 7427

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

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