**Intended use / Indication**

Sawzis 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 point of use.

**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 number (if applicable)**
- **SN (if applicable)**
- **REF (if applicable)**
- **Order number (if applicable)**
- **Autoclave at 15°C**
- **Date of manufacturing (if applicable)**
- **Manufacturer CE symbol with notified body**
- **Suitable for thermal disinfection**
- **Safety measures**
- **Relative or absolute contra indications**
- **Disassembly and assembly of the components**
- **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**

- 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 sawblade via the upstram electronic motor 21 and enable settings for speed and torque according to the tools used.
- In combination with the surgical motor system TCM 9000 BL (REF 398), which controls the sawblade via the upstram 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 5530), which controls the sawblade via the upstram electronic motor 21 and enables settings for speed and torque according to the tools used.

**Reprocessing instructions**

**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 deionized water, so possibly hard water with lime traces from the pre-cleaning cannot remain on the handpiece.**

**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.**

**Attention**

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 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**

- Remove saw blade, cooling tube, clips for the cooling tube attachment and cooling clip from the micro saw handpiece.
- The saw blade is delivered safety locked in the screw. Unlock the screw with the wrench.
- 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.

**Technical data, electronic motor 21**

<table>
<thead>
<tr>
<th>REF</th>
<th>Weight, without cable</th>
<th>Transmission ratio</th>
<th>Clamping depth, saw blade</th>
<th>Nut</th>
<th>Max. Speed</th>
<th>Coupling acc. to ISO 9346</th>
<th>Temperature</th>
<th>Max. torque</th>
<th>Weight, without cable</th>
</tr>
</thead>
<tbody>
<tr>
<td>5090nou</td>
<td>142 g</td>
<td>2:1</td>
<td>16 mm</td>
<td>M6</td>
<td>8000 - 10600 rpm</td>
<td>M10</td>
<td>0 – 60°C</td>
<td>6 Ncm</td>
<td>142 g</td>
</tr>
</tbody>
</table>

**Ambient conditions**

- **Relative humidity:** Max. 90 %
- **Max. 80 %**
- **Temperature:** 0 – 60°C
- **10 – 36°C**
- **Atmospheric pressure:** 700 – 1060 hPa
- **800 – 1060 hPa**
- **Max. Speed:** 80 000 rpm
- **Max. torque:** 6 Ncm
- **Weight, without cable:** 142 g

**Operation**

- **Press the button and decouple handpiece from electronic motor.**
- **Cooling clip**
- **Coupling for motor attachment**
- **Coolant**
- **Handpiece**
- **Collet**
- **Nut**
- **End wrench**

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

- **Loosen the nut with the wrench. Standstill!**
- **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.**

**General handling**

1. The instrument must be thoroughly cleaned, disinfected and thoroughly sterilized before initial operation (products right from the factory) and also immediately following each use. Only a cleaned and disinfected instrument permit's proper sterilisation!
2. The electronic motor should always be treated with utmost care when being transported, cleaned, serviced, sterilized and stored.
3. Always use the system with the anti microbial and lytic cleaners with as a least a content of silicate as possible in order to avoid staining (calcic- ing) the instruments.
4. All components which do not require further deconamination (DCM- /VAH-/V47/18-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. Products cannot be service life is determined by wear and damage through usage. The instrument is designed for 250 sterilization 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 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.

**Safety measures**

- **Always follow the instructions for use of the products used in combination.**
- **Without a saw blade clamped, the Micro Saw should not be stored with the tensioning mechanism tightened.**
- **The instrument may only be operated by competent and trained personnel.**
- **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!**
- **Do not handle saw blade, clamp the Micro Saw should not be stored with the tensioning mechanism tightened.**
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 2.5 for the instrument. Disinfection must be carried out with DI water.

Manual cleaning and disinfection

1. Immerse the micro saw handpiece after pre-cleaning for 5 minutes in a bath with enzymatic cleaner (for example: 2 % ID 212, Dürr Dental). Clean accessories such as the cooling clip and the nut for 5 minutes in an ultrasonic bath (5 % Detergent). 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 thoroughly rinse all products with deionised water to remove the disinfectant (× 3 ×).

Disinfection of the micro saw handpiece is performed with a fractionated pre-vacuum steam sterilisation technique (in accordance with DIN EN ISO 15883-1). Please follow the corresponding CDU-manufacturer’s directions and operating instructions.

Drying

Mechanical drying

Dry the micro saw using the cleaning/disinfection unit (CDU) drying cycle. If required, manual drying can 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 with NouClean spray. Every CDU must be connected to the 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 handpiece vertically, separated from the cooling clip, to make sure the outflow of water is favored. Dry products with a lint free paper towel (86-666 with AMAG). Make sure there is no air trapped inside the tubing. 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.

Sterilisation

Sterilisation of the micro saw handpiece is performed with a fractionated pre-vacuum steam sterilisation technique (in accordance with DIN EN ISO 15883-1). Steam sterilisation is not recommended. There is no experience available from conducting other sterilisation procedures such as plasma sterilisation, low temperature sterilisation processes or superheated steam sterilisation techniques. Note

4. If you should opt for a different procedure for reprocessing to the one given above, you are required to correspondingly establish the suitability.

Storage

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 package to be intact. When taking out the product, follow the respective aseptic procedures.

Information for validation of products

The above preparation process has been verified by a validated procedure. The following materials and machines were used:
1. Enzymatic cleaner: Neodisher® Medizyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG
2. Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG
3. Rack trolley: Miele E429
4. Strainer basket/flush socket bar: 3Mach (NOUVAG REF 51401)
5. Sterilisation temperature: At least 132°C
6. Drying time: At least 20 minutes (max. 30 minutes).
7. Minimum requirements: Pre-vacuum phases: 3
8. Holding time: At least 5 minutes (Full cycle).
9. Sterilisation temperature: At least 157°C
10. Drying time: At least 20 minutes (max. 30 minutes).
11. 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 package to be intact. When taking out the product, follow the respective aseptic procedures.

Attention!

Also please 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

<table>
<thead>
<tr>
<th>Article</th>
<th>Description</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>40497</td>
<td>End wrench</td>
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Automatic cleaning process (Vario TD programme)

1. Pre-clean with cold water for 4 minutes.
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).
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.

Cleaning

Mechanical cleaning

1. After cleaning, remove 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).
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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 2.5 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 (CDU) drying cycle. If required, manual drying can 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 with NouClean spray. Every CDU must be connected to the corresponding drying procedure through the manufacturer (see ISO 15883-1). Please follow the corresponding CDU-manufacturer’s directions and operating instructions.

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Troubleshooting

Motor is running but saw is not moving

Saw blade is not moving regularly

Saw blade is not correctly clamped

Saw blade is correctly clamped

Product is not correctly mounted

Packing unit (CDU)

Press saw handpiece firmly against the motor until it snaps into place. Check seat and mounting of the coupling.

Clamp saw blade correctly and tighten nut with the end wrench.

Automatic cleaning process (Vario TD programme)

1. Empty with cold water for 4 minutes.
2. Empty with clean for 5 minutes at 55 °C with 0.5 % alkaline or at 90°C with 0.5 % enzymatic cleaner.
3. Empty
4. Neutralise with cold water for 5 minutes.
5. Empty
6. Inter rinse for 2 minutes with cold water.
7. Empty

Warnings

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.

Disposal

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