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|  | <b>PI</b><br>Processing Instructions - EN | Document identifier<br><b>PI_ZP-EN_G</b> |                    |
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## 1 Important notes

### 1.1 General notes

These Processing Instructions apply to Dental polishers marketed by SUN Oberflächentechnik GmbH. Read these Processing Instructions completely. Keep these Processing Instructions for future reference. Failure to follow the Processing Instructions may result in injury or damage to the product.

These Processing Instructions are intended exclusively for properly trained professional staff. Properly trained professional staff are persons who are familiar with the hygiene requirements in dental practices.

These Processing Instructions contain specific instructions for the hygienic reprocessing of dental polishers in the professional field. For further details, follow the Instructions for Use for Dental polishers marketed by SUN Oberflächentechnik GmbH.

### 1.2 General safety instructions

Only use cleaned, disinfected and, if necessary, sterilized and dried dental polishers for treatment. It is essential to carry out the cleaning, disinfection and, if necessary, sterilization and drying steps before the first use.


Follow the recommendations of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute entitled "Infection prevention in dentistry – Hygiene requirements."


Ensure sufficient drying of all products after each cleaning, disinfection and sterilization cycle.

**CAUTION:** Do not store the products in a damp environment or together with damp objects. Moisture precipitation or residual moisture can present an increased risk of bacterial growth.

Make sure to use only properly validated processes for the specific equipment and product and to comply with the validated parameters in each processing cycle. The equipment used for reprocessing must be regularly maintained.

Make sure that the treatment you carry out with your equipment, the chemicals used, and your staff always achieves the desired results. In particular, make sure that the process you have chosen is effective if you have to deviate from our validated processes (e.g. because the equipment and chemicals described are not available). When selecting the chemicals to use, make sure that they are suitable for cleaning or disinfecting medical devices. Observe the manufacturer's dosage instructions and any instructions for safe handling of the chemicals.

Products labelled  on the packaging are single-use (disposable) products and must not be reused or reprocessed. Safe use cannot be guaranteed if these products are reused, as there is a risk of infection and the safety of the products cannot be guaranteed in this case.

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Products labelled ☒ for single use on the packaging must be processed once before first use.  
 Automated Cleaning and disinfection should be used preferential to manual Cleaning and disinfection.

### 1.3 Limit of reprocessing

Dental polishers may no longer be reprocessed and must be discarded one of the following applies:

- Breakouts are present on the polishing head
- Original geometry of the polishing head is no longer recognizable
- The polisher does not run concentrically (knocking sound)

## 2 Reprocessing

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| Preparation before cleaning          | Perform cleaning and disinfection immediately after use.<br>Equipment needed: <ul style="list-style-type: none"> <li>- Tap water</li> <li>- Nylon brush, if required<sup>1</sup></li> </ul> Procedure: <ul style="list-style-type: none"> <li>- Unmount the dental polisher from the handpiece before reprocessing.</li> <li>- Place the dental polishers in cold tap water for at least 5 minutes after use.</li> <li>- Gross contaminants may be removed with a nylon brush.</li> <li>- Rinse the dental polishers under running tap water.</li> </ul>   |
| Cleaning and disinfection, automated | Equipment needed: <ul style="list-style-type: none"> <li>- Washer-disinfector (WD according to EN ISO 15883)<sup>2</sup></li> <li>- Instrument stand<sup>3</sup> for WD</li> <li>- Detergent mildly alkaline pH &lt; 11<sup>4</sup></li> </ul> Procedure: <ul style="list-style-type: none"> <li>- Place instruments onto the instrument stand.</li> <li>- Place the filled instrument stand in the WD with the lid open so that the spray jets hit the instruments directly.</li> <li>- Add the detergent to the WD.</li> <li>- Select a suitable program in dependence on VARIO TD (Miele) Scheme <sup>5</sup> and start the cleaning and disinfection cycle.</li> <li>- Remove the instrument basket from the WD.</li> <li>- It must be ensured that the drying process integrated</li> </ul> |

<sup>1</sup> Nylon brush (e.g., Gebr. Brasseler REF 98740000, [www.kometdental.de](http://www.kometdental.de))

<sup>2</sup> Washer-disinfector (WD) (e.g., Miele 7836 with slide-in trolley)

<sup>3</sup> Instrument stand for WD (e.g., Gebr. Brasseler REF 9933L3000, [www.kometdental.de](http://www.kometdental.de))


<sup>4</sup> Detergent (e.g., neodisher MediClean by Chemische Fabrik Dr. Weigert)

<sup>5</sup> Program VARIO TD (Miele), e.g., 2 minutes of pre-cleaning with cold water, draining, 5 minutes of cleaning with tap water and 0.5% neodisher MediClean, draining, 3 minutes of neutralization with demineralized water, 2 minutes of rinsing with demineralized water, draining



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|                                   | in the WD is sufficient.   |
| Cleaning and disinfection, manual | <p>As an alternative to automated cleaning and disinfection, manual cleaning and disinfection can be used.</p> <p>Equipment needed:</p> <ul style="list-style-type: none"> <li>- Cleaning and disinfecting agent (e.g., Comet DC1 2.0%) Manufacturer's information regarding material compatibility need to be considered.</li> <li>- Ultrasonic bath</li> <li>- Tap water</li> </ul> <p>Procedure:</p> <ul style="list-style-type: none"> <li>- Place the instruments in the cleaning solution or tap water in an ultrasonic bath at 40°C / 5 min.</li> <li>- Rinse the instruments thoroughly with tap water for at least 30 seconds.</li> </ul> |
| Drying                            | <p>Equipment needed:</p> <ul style="list-style-type: none"> <li>- Compressed air if required and available</li> <li>- Dry and clean absorbent surface</li> </ul> <p>Procedure:</p> <ul style="list-style-type: none"> <li>- Allow the instruments to dry completely on a dry and clean absorbent surface.</li> <li>- Drying can be accelerated with compressed air. Watch out for hard-to-reach areas.</li> </ul>  |
| Control and testing               | <p>Check the instruments for cleanliness and integrity. Remember the limits of reprocessing.</p> <p>If any soil is still visible, the cleaning and disinfection cycle must be repeated.</p>  |
| Packaging                         | <p>Steam sterilization can be performed with or without wrapping the instruments.</p> <p>Equipment needed:</p> <ul style="list-style-type: none"> <li>- Transparent sterilization bags pursuant to EN 868-5<sup>6</sup></li> </ul> <p>Implementation</p> <ul style="list-style-type: none"> <li>- Double-wrap the instruments in transparent sterilization bags.</li> </ul>  |
| Sterilization                     | <p>If disinfection in the WD has been demonstrably successful, sterilization can be dispensed with.</p> <p>Equipment needed:</p> <ul style="list-style-type: none"> <li>- Steam sterilizer according to European standard for small steam sterilizers (EN 13060)</li> </ul> <p>Procedure:</p> <ul style="list-style-type: none"> <li>- Place wrapped instruments in suitable trays or stands.</li> <li>- Select a suitable program (e.g., 3 pre-vacuum phases,</li> </ul>  |

<sup>6</sup> Transparent sterilization bags (e.g., by Wipak Walsrode GmbH & Co. KG)

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|                        | sterilization temperature 134°C, 3 minutes of holding time (full cycle), 1 minute of drying time).<br>- Remove the instrument tray from the steam sterilizer.  |
| Storage                | Store the reprocessed products in a dry and dust-free place, protected from contamination. The use of sterile wrapping is recommended.   |
| Additional information | The above procedures have been validated by SUN Oberflächentechnik GmbH as suitable for the reprocessing of reusable dental polishers. The reprocessor is responsible for ensuring that the actual process carried out with the equipment, materials and personnel used at the treatment facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Country-specific requirements for re-validation must be observed. |

### 3 Contact

For product information of any kind, in case of problems or errors or for any questions regarding handling, please contact us:

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