

# Cleaning & Sterilization Instructions



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| <b>Isasan</b><br><b>Devices: Whitech Composite Burs</b> |   |
|---|---|
| <b>WARNINGS</b>   | <p><b>General</b></p> <ol style="list-style-type: none"> <li>1. Thoroughly dry the devices after all steps, if they will sit for more than 15 minutes prior to the next step.</li> <li>2. Follow all applicable solution or equipment manufacturer's instructions.</li> <li>3. All applicable solutions and equipment should meet national regulatory requirements.</li> <li>4. <b>These devices are NOT supplied sterile.</b><br/>Clean and sterilize prior to use, as follows.</li> </ol> |
| <b>Processing limitations</b>                           | None, other than wear, to be determined by the user   |
| <b>Initial treatment at the point of use</b>            | Reprocess the devices as soon as possible after use. Do not allow material to dry. Keep the devices immersed in solution from the time they are used until they are cleaned – use enzymatic cleaner, cleaning/disinfecting, cleaning, or water (in order of preference).  |
| <b>Preparation before cleaning</b>                      | Not applicable  |
| <b>Cleaning: Automated</b>                              | <ol style="list-style-type: none"> <li>1. Rinse the devices under cold, heavy running tap water.</li> <li>2. Ultrasonically clean the devices in enzymatic cleaner (Premier Brite Shield™ Enzymatic Static Soak and Ultrasonic Cleaner, or equivalent, dissolved in tap water) for at least five minutes. Avoid the devices in contact with each other during cleaning (do not pile).</li> <li>3. Rinse thoroughly with tap water.</li> </ol>   |
| <b>Cleaning: Manual</b>                                 | Not applicable  |
| <b>Disinfection</b>                                     | Not applicable  |
| <b>Drying</b>   | Dry by wiping with absorbent, disposable wipes, dry heat, or filtered, pressurized air.   |
| <b>Maintenance, Inspection and Testing</b>              | Visually examine the devices for contamination. Magnification is recommended. <b>Repeat the above steps for any devices that are still contaminated.</b>  |
| <b>Packaging</b>  | Sterilization pouch   |
| <b>Sterilization</b>                                    | Steam sterilize, pre-vacuum, average pressure of 30psi (207 kPa), minimum of 4 minutes, 132°C, and a minimum dry time of 22 minutes.  |
| <b>Storage</b>  | Store the devices in the sterilized wrap.   |
| <b>Additional Information</b>                           | None  |
| <b>Distributor Contact</b>                              | Isasan Srl – Via Bellini 17 – 22070 Rovello Porro (CO) – Italy – +39 (0)2 96754179  |

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use/reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

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