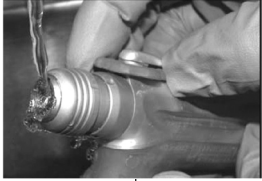


## MAGNUM®, STRAIGHTSHOT®, M4, SC1 HANDPIECES

<b>Warnings / Precautions</b>	<ul style="list-style-type: none"> <li>• Disconnect the power before cleaning.</li> <li>• Do not fully immerse, or ultrasonically clean, this instrument.</li> <li>• Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty.</li> <li>• Do not use any cleaning instruments in the cannulated shaft of the handpiece.</li> <li>• Do not use organic solvents to clean the bur chuck.</li> <li>• For drill handpiece cleaning, cover handpiece cable connector end with Handpiece Cable Cap, Small, catalog no. 3318510 or Handpiece Cable Cap, Large, catalog no. 3318515. (Note: Use 3318515 for Straightshot® M4/SC1, Visao®, and Xcalibur® Hi-Speed with angled cable. Use 3318510 for other handpieces.</li> <li>• After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning.</li> </ul>			
<b>Limitations</b>	After cleaning and sterilization, verify functionality prior to re-use.			
<b>Instructions</b>				
<b>Point of Use</b>	<ul style="list-style-type: none"> <li>• This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.</li> <li>• To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol.</li> </ul>			
<b>Containment and Transportation</b>	It is recommended that instruments are reprocessed as soon as is practical following use.			
<b>Preparation for decontamination</b>	Remove the bur from the handpiece, otherwise disassembly is not required.			
<b>Cleaning: Automated</b>	<p>Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers.</p> <p>Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers.</p> <p>These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash &amp; rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C.</p>			
<b>Cleaning: Manual</b>	<ul style="list-style-type: none"> <li>• Do not immerse the handpiece.</li> <li>• Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth.</li> <li>• Gently clean the handpiece with a moistened soft bristle brush or pipe cleaner, making sure to clean all passages. Use an enzymatic detergent solution to loosen and remove collected tissues from the unit.</li> <li>• Hold the handpiece with the front end pointed downward during rinsing.*</li> </ul> <div style="display: flex; align-items: flex-start;">  <div style="flex-grow: 1;"> <p><i>*Additional Cleaning Instructions for XPS® Straightshot® M4/SC1 Microdebrider:</i></p> <ul style="list-style-type: none"> <li>• During the normal cleaning cycle, run a gentle stream of warm water into the collet (front end), and into the lock lever of the Straightshot® M4/SC1 handpiece.</li> <li>• While warm water is running into the collet, rotate the mechanism for several revolutions (rotate the wheel); and while water is running into the lock lever, actuate the lock lever several times (locking and unlocking).</li> <li>• Shake excess water from the handpiece.</li> <li>• PRECAUTION: Ensure the use of a very gentle stream of warm clean water during this additional cleaning step.</li> </ul> </div> </div> <ul style="list-style-type: none"> <li>• Dry the handpiece and cable with a lint-free towel. Make sure to dry off the electrical connection on the cable ends.</li> <li>• Apply a small amount of silicone spray into the front-end collet and outside of the handpiece.</li> <li>• Sterilize the handpiece immediately after cleaning.</li> </ul>			
<b>Disinfection</b>	Do not cold soak in glutaraldehyde.			
<b>Packaging</b>	<p>A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals.</p> <p>In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.</p>			
<b>Sterilization</b> (Temperatures are minimum required, times are minimum required)	All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.			
	<b>Cycle:</b>	<b>Gravity</b>	<b>Pre-vac</b>	<b>Pre-vac (FR/WHO)</b>
	<b>Temperature:</b>	121°C	132°C	134°C
	<b>Time:</b>	40 min	4 min	18 min
	<b>Drying:</b>	8 minutes, or until visibly dry		
	<b>STERRAD Sterilization:</b> 100S Compatible			
	<b>100% EtO Sterilization Parameters:</b>			
	Temperature	54 - 55°C	Relative Humidity:	60 +/-5%
	Ethylene oxide concentration	600 +/- 25 mg/L	Gas exposure time (full-cycle):	120 minutes
	Aeration at: 48-52°C, 8 hr.			
<b>Maintenance, Inspection and Testing</b>	<p>Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired.</p> <p>After cleaning and sterilization, verify functionality prior to re-use.</p>			
<b>Storage</b>	It is extremely important that the handpiece be rapidly and completely vacuum dried before storage to prevent corrosion and residue deposits in the bearing and motor.			
<b>Additional Information</b>	Increase temperatures higher than those stated when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149° C (300° F). Heating above 149° C (300° F) may damage the handpiece and will void the warranty.			

Note: The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

Note: All validations performed per AAMI TIR12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.