



XCALIBUR® HI-TORQUE AND HI SPEED HANDPIECE

Warnings / Precautions	<ul style="list-style-type: none"> • Disconnect the power before cleaning. • Do not fully immerse, or ultrasonically clean, this instrument • Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty. • Do not use organic solvents to clean the bur chuck. • 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, Visao™, and Xcalibur® Hi-Speed with angled cable. Use 3318510 for other handpieces.) 					
Limitations	After cleaning and sterilization, verify functionality prior to re-use.					
Instructions						
Point of Use	<p>This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.</p> <p>To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol</p>					
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.					
Preparation for decontamination			Remove the bur from the handpiece, otherwise disassembly is not required.			
Cleaning: Automated	<p>Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfectant manufacturers.</p> <p>Use alkaline or neutral pH detergent recommended by washer/disinfectant or detergent manufacturers.</p> <p>These products have been validated for effective cleaning using an automatic washer/disinfectant cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash & rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C.</p>					
Cleaning: Manual	<ul style="list-style-type: none"> • Do not immerse the handpiece • After surgery, clean the irrigation sleeves and bur guards with an enzymatic detergent solution. Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth. • A chuck brush cleaner (REF# 3112500) or an appropriately sized small (plastic bristle) bore brush may be inserted into the distal end of the XCALIBUR® handpiece, irrigation sleeves and bur guards to assist in removing fluids, tissue, or bone fragments, making sure to clean all passages. Use an enzymatic detergent solution to loosen and remove collected tissues from the unit. • Rinse out the distal end of the handpiece. Shake excess water from the handpiece. • Using distilled water, rinse saline from the irrigation nozzles. Drain the nozzle of all water. • Sterilize the handpiece, irrigation sleeves, and bur guards immediately after cleaning. 					
Disinfection	No particular requirements					
Packaging	No particular requirements					
Sterilization (Temperatures are minimum required, times are minimum required)	Cycle:	Gravity	Pre-vac	Pre-vac	Pre-vac (FR/WHO)	Pre-vac (UK)
	Temperature:	121°C	132°C	132°C	134°C	134°C
	Time:	40 min	4 min	9 min	18 min	3 min
	Drying:	8 min or until visibly dry				
STERRAD Sterilization: Compatible (Handpiece Only)						
100% EtO Sterilization Parameters:						
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.						
Maintenance, Inspection and Testing	<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>					
Storage	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.					
Additional Information	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 as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.