



HELIX® BURS

Warnings / Precautions	Remove burs from the handpiece before cleaning and sterilizing. Before sterilization, carefully inspect the bur tips, bur flutes, under a microscope or magnifying glass for any irregularities or eccentricities. Discard any burs that show signs of damage or wear. Cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilization is not recommended as damage to the bur may occur.			
Limitations	Discard any burs that show signs of damage or wear.			
INSTRUCTIONS				
Point of Use	Remove burs from the handpiece before cleaning and sterilizing. Promptly and thoroughly rinse instruments with deionized water after each use.			
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.			
Preparation for decontamination	Promptly and thoroughly rinse instruments with deionized water after each use.			
Cleaning: Automated (Do NOT use ultrasonic washer)	Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfectant manufacturers. Use alkaline or neutral pH detergent recommended by washer/disinfectant or detergent manufacturers. 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.			
Cleaning: Manual	Soak in lukewarm*, mild* enzymatic detergent, and deionized water for a minimum of two minutes. Then clean ultrasonically in lukewarm* solution of mild* detergent and deionized water for at least 30 seconds. Rinse thoroughly with deionized water and wipe dry. *less than 43°C; pH 7.0 - 8.5 Note: When using an ultrasonic cleaner or a spray washing machine, follow the manufacturer's recommendations, particularly with regard to articulated instruments and positioning of instruments.			
Disinfection	Do not cold soak in glutaraldehyde.			
Packaging	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. In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.			
Sterilization (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.			
	Cycle:	Gravity:	Gravity:	Pre-vac:
	Temperature:	121°C	132°C	132°C
	Time:	30 min	10 min	4 min
	Drying: 8 minutes, or until visibly dry			
	100% EtO Not validated		STERRAD Sterilization Not validated	
Maintenance, Inspection and Testing	Discard any burs that show signs of damage or wear.			
Storage	Store in a clean, dry area.			
Additional Information	None			

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.