

BIPOLAR ELECTROSURGICAL INSTRUMENTS

Warnings / Precautions	To prevent stains, use distilled or demineralized water, and use a neutral detergent, to reprocess these instruments					
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>Any tubing and / or other tip protectors used during shipping must be removed prior to cleaning and sterilization.</p> <p>Rinse instrument immediately after use in distilled or demineralized water</p>					
Containment and Transportation	It is recommended that instruments are reprocessed as soon as is practical following use.					
Preparation for decontamination	Fully disassemble modular designed instruments for effective cleaning. For instruments equipped with cleaning ports, inject cleaning solution through the instrument with an irrigation syringe.					
Cleaning: Automated (Do NOT use ultrasonic washer)	<p>Remove instruments and equipment from any sterilization trays before placing into washer baskets.</p> <p>Orient devices following recommendations of washer/disinfecter manufacturers.</p> <p>Use alkaline or neutral pH detergent recommended by washer/disinfecter or detergent manufacturers.</p> <p>These products have been validated for effective cleaning using an automatic washer/disinfecter 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	<p>Soak in lukewarm (less than 43°C), mild (pH 7.0 - 8.5), enzymatic detergent and deionized water for a minimum of 2 minutes, then clean ultrasonically in a lukewarm (less than 43°C), mild (pH 7.0 - 8.5), detergent and deionized water for at least 10 minutes. Rinse thoroughly with deionized water immediately and wipe dry.</p> <p>Examine instruments for any staining or deterioration; remove from use as appropriate.</p> <p>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.</p> <p>Following cleaning, lightly lubricate instruments with movable parts. Use a lubricant intended for sterilizable instruments such as a water-soluble instrument milk or a sterile Vaseline. Do not use silicone spray.</p>					
Disinfection	No particular requirements					
Packaging	No particular requirements					
Sterilization (Temperatures are minimum required, times are minimum required)	Cycle:	Gravity	Flash: Gravity	Pre-Vac	Pre-Vac (FR/WHO)	Pre-Vac (UK)
	Temperature:	121°C	132°C	132°C	134°C	134°C
	Time:	30 min	10 min	4 min	18 min	3 min
	Drying:	8 minutes, or until visibly dry				
	EtO: Not validated		STERRAD Sterilization: Not validated			
Maintenance, Inspection and Testing	Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired. After cleaning and sterilization, verify functionality prior to re-use.					
Storage	No particular requirements					
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 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.