

GEM Microvascular Anastomotic COUPLER Device and System

Instructions	
Point of use:	Rinse all instruments with water after use.
Preparation for cleaning:	<ol style="list-style-type: none"> 1. Using a neutral (pH 7-10) detergent, wash each tool clean of all blood and debris after every use. Scrub each tool with a soft brush. Pay particular attention to areas where debris can accumulate. CAUTION: Use of a cleaner with a pH greater than 10 will remove the anodized layer of the Anastomotic Instrument and the Sterilization Tray. 2. Avoid use of any harsh material that can scratch or mar the surface of the instruments 3. Rinse the instruments thoroughly with running water. Apply a fine jet stream through the hole in the Anastomotic Instrument knob end and press the release button while rinsing to ensure that all surfaces of the instrument are cleaned.
Cleaning: Automated	Using an automated washing machine, clean at a temperature of 45° – 55° C, with a neutral (pH 7-10) cleaning solution for at least 10 minutes.
Cleaning: Manual	Place the instruments in an ultrasonic cleaner utilizing a neutral (pH 7-10) cleaning solution and clean ultrasonically for 15 minutes. Rinse the Anastomotic Instrument thoroughly again, applying a fine jet stream of water through the hole in the Anastomotic Instrument knob end.
Disinfection:	(Optional) Using an automated washing machine, thermally disinfect the Instrument at a temperature of 90° - 95° C, for a minimum of 5 minutes.

Drying:	Following cleaning by either manual or automated cleaning methods ensure instruments are fully dry. Do not exceed 100° C for 30 minutes.
Maintenance, Inspection and Testing:	<ul style="list-style-type: none"> • Ensure that all visible debris is removed to assure the continued quality of the instruments. • Lubricate the cleaned Anastomotic Instrument (including knob) with a water-soluble lubricant prior to sterilization. Failure to clean and lubricate the Anastomotic Instrument as directed may result in instrument failure.
Packaging:	Package the instruments using the appropriate method for the sterilization cycle chosen.
Sterilization:	<p>GRAVITY AUTOCLAVES Temperature Recommended Exposure Time (not Total Cycle Time) 250°F (121°C) 15 minutes (wrapped or nonwrapped) 270°F (132°C) 3 minutes (nonwrapped) 10 minutes (wrapped)</p> <p>PREVAC AUTOCLAVES Temperature Recommended Exposure Time (not Total Cycle Time) 270°F -273°F 3-5 minutes (nonwrapped) (132°C - 134°C) 4-5 minutes (wrapped)</p> <p>NOTE: It is recommended that each institution establish the efficacy of its sterilization procedure.</p>
Storage:	Recommended storage at controlled room temperature 20-25°C (68-77°F).

SERVICE: For Customer or Technical service, contact:

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