Genesee
BIOMEDICAL, INC.
Design beyond standard.

Instructions for Use

Intra-Art® Coronary Artery Probe

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DESCRIPTION

The Genesee Intra Art Coronary Artery Probe is a surgical instrument designed for use in cardiac surgery. The device is used to probe and size the coronary arteries during coronary artery bypass surgery. The probes must be sterilized before each use.

PACKAGING

The Coronary Artery Probes are provided NON-STERILE and must be cleaned and sterilized prior to initial use and each subsequent use. See Cleaning and Sterilization section.

STORAGE

Store in a room temperature dry place to protect the product and minimize contamination potential.

INDICATIONS

The Coronary Artery Probes are intended to probe coronary arteries during coronary artery surgery. The probes can be used in the following scenarios:

- To ensure that the anastomotic site is downstream from the area of coronary stenosis.

- To demonstrate that no area of stenosis occurs downstream of the anastomosis.
- To measure the diameter of the lumen of the artery should a coronary occluder be required to prevent bleeding.
- To dilate the vessel if required.

WARNINGS
Take care not to damage tissue during use.

PRECAUTIONS
Take care not to damage the Coronary Artery Probes during handling.

CLEANING AND STERILIZATION
Inspect each device before every use. The Coronary Artery Probes should not be used if there are visible signs of cracking, crazing, deformation, or other damage that may affect function.

The Coronary Artery Probes are supplied NON-STERILE and must be cleaned thoroughly and sterilized prior to initial use and each subsequent use. Discard all packaging materials before cleaning and sterilizing.

It is recommended that the Coronary Artery Probes be reprocessed as soon as reasonably practical following use. The following manual cleaning and disinfection method has been validated and is recommended by Genesee BioMedical, Inc. for the Coronary Artery Probes.

1. Rinse devices with a solution of warm tap water and a hospital approved surfactant for approximately two (2) minutes.

2. Scrub the devices with a soft-bristled cleaning brush to remove all grossly visible debris.

3. Place the devices in an ultrasonic bath containing enzymatic detergent prepared according to manufacturer's directions and ultrasonically clean for fifteen (15) minutes.

4. If necessary, scrub the accessories using a cleaning brush to remove any remaining visible debris.

5. Rinse devices with warm tap water for approximately two (2) minutes to remove detergent.

6. Dry and place the Coronary Artery Probes in the sterilization tray, close the lid and wrap for sterilization.

GBI recommends the following validated sterilization methods:

Sterilization Parameters

Sterilizer Type	Autoclave Cycle	Autoclave Temperature	Autoclave Duration	Drying Time
Gravity Displacement	Wrapped instrument	135°C	10 min	30 min
Pre-Vacuum	Wrapped instrument	132°C	4 min	20 min
Pre-Vacuum	Wrapped instrument	135°C	3 min	16 min

Increasing the recommended sterilization temperature or time may result in reduced device life cycles. Do not use aromatic solvent-based cleaners as disinfectant agents as these solvents may damage the components of the probe.

ORDERING INFORMATION:

140 MM Length

Model Number	Product Description
CPH-1.00	1.00 mm Coronary Artery Probe
CPH-1.25	1.25 mm Coronary Artery Probe
CPH-1.50	1.50 mm Coronary Artery Probe
CPH-1.75	1.75 mm Coronary Artery Probe
CPH-2.00	2.00 mm Coronary Artery Probe
CPH-2.25	2.25 mm Coronary Artery Probe
CPH-2.50	2.50 mm Coronary Artery Probe
CPH-2.75	2.75 mm Coronary Artery Probe
CPH-3.00	3.00 mm Coronary Artery Probe

191 MM Length

Model Number	Product Description
CPH-1.00L	1.00 mm Coronary Artery Probe
CPH-1.25L	1.25 mm Coronary Artery Probe
CPH-1.50L	1.50 mm Coronary Artery Probe
CPH-1.75L	1.75 mm Coronary Artery Probe
CPH-2.00L	2.00 mm Coronary Artery Probe
CPH-2.25L	2.25 mm Coronary Artery Probe
CPH-2.50L	2.50 mm Coronary Artery Probe
CPH-2.75L	2.75 mm Coronary Artery Probe
CPH-3.00L	3.00 mm Coronary Artery Probe

Surgical Instrument Limited Warranty

Genesee BioMedical's Surgical Instruments, hereinafter referred to as "Product" are subject to the following warranty: GENESEE BIOMEDICAL WARRANTS FOR A PERIOD OF ONE YEAR FROM THE DATE OF SHIPMENT THAT THE PRODUCT IS FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP UNDER NORMAL INTENDED USE AND SERVICE.

During the one year period, Genesee BioMedical will repair or replace, at Genesee BioMedical's sole option, any defective Product at no charge to purchaser provided that purchaser obtains a Return Goods Authorization from Genesee BioMedical and returns the product to Genesee BioMedical at Genesee BioMedical's expense.

Every claim under this warranty shall be deemed waived unless made in writing and received by Genesee BioMedical within thirty (30) days from the date the defect to which each claim relates is discovered or should have been discovered.

Surgical Instrument Limitation of Liability

GENESEE BIOMEDICAL MAKES NO OTHER REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, IN FACT OR IN LAW, INCLUDING WITHOUT LIMITATION, THE WARRANTY OF MERCHANTABILITY OR THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OTHER THAN THE LIMITED WARRANTY SET FORTH ABOVE. GENESEE BIOMEDICAL SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON, EXCEPT THE CHIEF EXECUTIVE OFFICER OR THE PRESIDENT OF GENESEE BIOMEDICAL, HAS ANY AUTHORITY TO BIND GENESEE BIOMEDICAL TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT OTHER THAN THE LIMITED WARRANTY SET FORTH ABOVE.

The exclusion and limitations set out above are not intended to, and should not be construed so as to

contravene mandatory provisions of applicable law. If any part or term of the Limitation of Liability is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Limitation of Liability shall not be affected, and all rights and obligations shall be construed and enforced as if this Limitation of Liability did not contain the particular part or term held to be invalid.

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