Genesee
BIOMEDICAL, INC.
Design beyond standard

HEART-CHILL® CARDIAC & PHRENIC INSULATOR

FOR THERMALLY INSULATING THE HEART AND PHRENIC NERVES

Storage and Handling Instructions

STORAGE

The insulators should be stored at room temperature, in a dry place, and out of direct sunlight.

DESCRIPTION

The cardiac and phrenic insulator forms an insulation barrier between the heart and the pericardial cavity. It aids myocardial preservation and minimizes potential injury of the phrenic nerves in cardiac surgery procedures involving the infusion of cold cardioplegia solution and/or the use of cardiac topical cooling by soft ice slush or cold saline.

The insulator is two layers, soft, closed-cell polyethylene foam which contains an internal stiffener of a malleable metal strip. This stiffener facilitates the positioning and stability of the insulator under the heart. The stiffener is easily bent so that the insulator conforms to the posterior shape of the pericardial cavity. The device is available in large, medium (regular) and small sizes.

INDICATIONS FOR USE

The cardiac insulator is indicated for use in patients undergoing cardiac surgery, in conjunction with the use of cold cardioplegia and/or topical cardiac cooling.

CONTRAINDICATIONS

In patients undergoing primary cardiac surgery there are no known contraindications for use. In patients undergoing reoperation, pericardial adhesions may be a contraindication for use.

DIRECTIONS FOR USE

The suggested method of use should be modified by the surgeon to suit individual technique and preference. Following commencement of cardiopulmonary bypass the heart will be immobilized by perfusion of cold cardioplegia solution. The internal stiffener of the insulator should be grasped in the surgeon's hands, and using the thumbs, the insulator should be bent in a concave curve (Fig. 1).

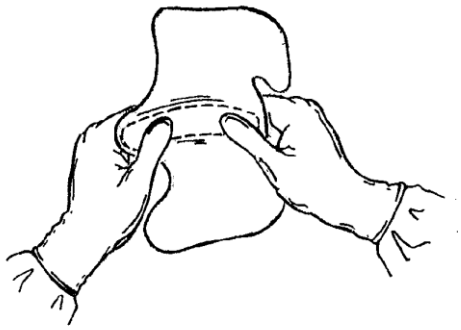


Figure 1

The larger side of the insulator should be folded over the central portion (Fig. 2), and the smaller side folded over the larger (Fig. 3).

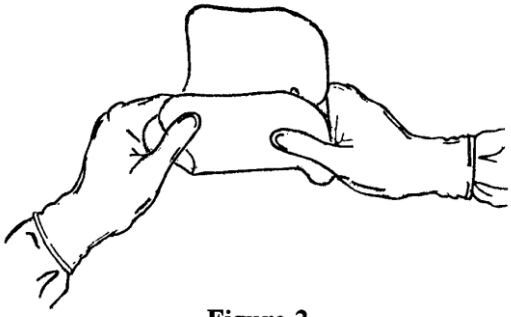


Figure 2

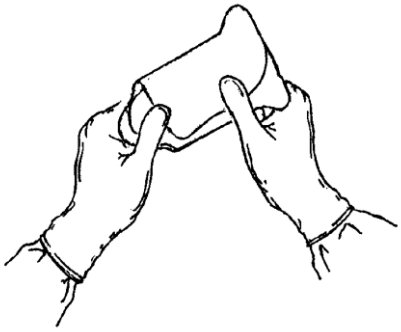


Figure 3

The folded insulator is held in the surgeon's right hand, while the surgeon's left hand is used to lift the apex of the heart. The folded insulator is then pushed gently under the heart. When part way into position, the sides are unfolded. A slight force

applied to the distal end of the stiffener will push the insulator into a final position under the heart. The stiffener should be bent so that the insulator conforms to the posterior pericardial cavity.

The insulator should be positioned so as to not interfere with the left pulmonary veins or venous return from the inferior vena cava. The central protrusion on the insulator should lie in the space between the left pulmonary vein and the inferior vena cava. Soft ice slush or cold saline may then be placed into the space between the heart and the insulator. Ice slush should not be placed between the insulator and the pericardial cavity. Frequent aspiration of melted ice from the space between the insulator and the pericardial cavity will help prevent chilling of the phrenic nerves. **Remove the insulator at the conclusion of cardiac surgery.**

PRECAUTIONS

This is a single patient use, disposable product. Do not attempt to clean, resterilize or reuse. Position so as not to interfere with venous return from the inferior vena cava or left pulmonary veins.

WARNINGS

Do not place ice slush between the insulator and pericardial cavity. Aspirate this space frequently. Take care to remove the entire insulator before closing the pericardium. Do not use if unit package has been tampered with or opened.

DISCLAIMER OF WARRANTY

ALTHOUGH THE GENESEE BIOMEDICAL HEART-CHILL® CARDIAC & PHERENIC INSULATORS, HEREINAFTER REFERRED TO AS "PRODUCT", HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, GENESEE BIOMEDICAL HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS HANDLED AND USED. GENESEE BIOMEDICAL, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. 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 PRESIDENT OF GENESEE BIOMEDICAL, HAS ANY AUTHORITY TO BIND GENESEE BIOMEDICAL TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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CAUTION

Federal law (USA) restricts this product to sale by or on the order of a physician.

PRODUCT CODE

Genesee BioMedical HEART-CHILL® Cardiac and Phrenic Insulator.

Size	Product Code
Large	CPI-L
Medium	CPI-M
Small	CPI-S

HOW SUPPLIED

The Genesee BioMedical HEART-CHILL® Cardiac & Phrenic Insulator is supplied sterile, (sterilized by gamma radiation) packaged singly, 10 per box.

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