Genesee
BIOMEDICAL, INC.
Design beyond standard

INSTRUCTIONS FOR USE



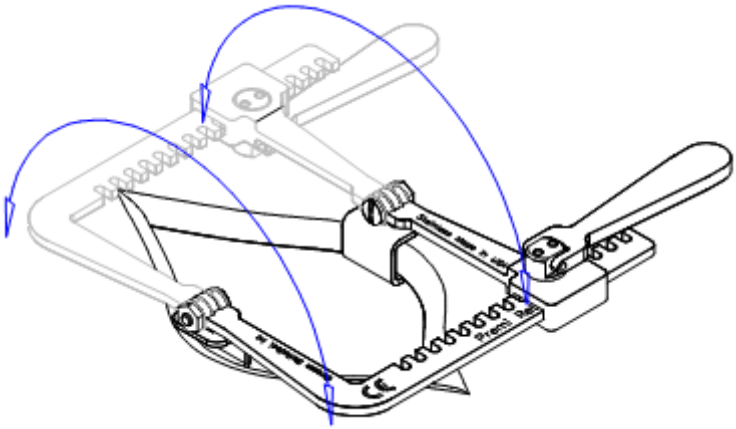
Premature Hinged Sternal Retractor

Model: PHR-1

DESCRIPTION

The Genesee BioMedical, Inc. Premature Hinged Sternal Retractors are designed and intended for exposing the heart via a mid-line sternotomy for cardiac exposure. They are suitable for patients weighing from 0.5 to 2 kg.

The instrument design features two sternal blades, one connected by a hinge to the fixed arm and the other connected by a hinge to the moving arm of the retractor. Rotation of the cog handle clockwise separates the sternal blades. Following the opening of the sternal cavity, the retractor may be flipped over (as shown in the figure below) to provide improved access to the apex of the heart and the positioning of heart-lung machine and other lines.



DIRECTIONS FOR USE

Bring the sternal blades together by rotating the cog handle fully counterclockwise. Following the skin incision and the mid-line sternotomy, the retractor blades are inserted between the medial sternal edges. Depending upon the surgeon's preference the rack may be placed close to the patient's abdomen or near the patient's neck. The sternum may then be opened a controlled amount by rotating the cog handle clockwise until the desired exposure is obtained. The rack may then be flipped over, if desired, to improve exposure.

DISASSEMBLY

Remove the moving arm from the rack by rotating the cog handle clockwise until the moving arm is free to slide off the rack.

If the rack and cog/handle are removed, take care not to lose the parts. Place any loose parts in the sterilization tray during cleaning. **Do not** attempt to disassemble the hinged retraction blades (the screws have a thread-locking compound to prevent loosening and inappropriate disassembly).

CLEANING
Use the operating room's routine procedures for cleaning surgical instruments. The retractor may be partially disassembled before cleaning. Table 1 provides instructions for a validated manual cleaning procedure.

Table 1: Manual Cleaning Instructions

Step	Process	Temperature	Cleaning Instructions
1	Rinsing	Room Temperature	Remove contaminants using running water for at least 3 minutes. Use a soft-bristle brush (for example, a nylon toothbrush) to clean the device thoroughly.
2	Soaking	Room Temperature	Submerge the retractor parts completely for a minimum of 5 minutes with enzymatic detergent and water, mixed according to manufacturer's directions. Remove visible contaminants with a soft-bristled brush.
3	Ultrasonic Clean	Room Temperature	Submerge the retractor parts completely in an ultrasonic cleaner with enzymatic detergent and water, mixing according to manufacturer's directions. Sonicate for 10 minutes.
4	Rinsing	Warm	Rinse the retractor parts with running water for 2 minutes.
5	Dry	N/A	Dry with a clean, lint-free wipe.
6	Inspection	N/A	Visually inspect each retractor part for any remaining contaminants or moisture. If any contaminants, repeat the process.

REASSEMBLY
Inspect all parts after **each and every use** for any corrosion or suspected damage. If corrosion or damage is identified, **do not** use any corroded or damaged parts. Contact Genesee BioMedical, Inc. for repair or replacement. Do not use parts from any other manufacturer. Use of parts from any other manufacturer may cause damage to the retractor. The use of parts from other manufacturers will void the warranty.

Replace the Cog/Handle Assembly on the moving arm.

- Insert cog into the holes in the moving arm (from the top side, arm marking showing as in the figure above).
- Slide the moving arm partially onto the rack.
- Engage the cog in the teeth in the rack and rotate the handle counterclockwise to bring the two retraction blades together.

LUBRICATION
The moving parts of the instrument must be lubricated before each use with either 3M "Blitz" M105 surgical instrument cleaner and lubricant or surgical instrument "milk".

STERILIZATION

The instrument must be sterilized before each use. Use the hospital's standard procedure for sterilizing surgical instruments. The instrument is corrosion-resistant stainless steel and may be steam autoclaved in the sterilization tray supplied with the instrument.

GBI recommends the following validated sterilization methods:

Sterilizer Type	Autoclave Cycle	Autoclave Temperature	Autoclave Duration	Drying Time
Gravity Displacement	Wrapped instrument	132°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

PHR-1 Premature Hinged Retractor
Component Parts List

QUANTITY SUPPLIED	PRODUCT DESCRIPTION	PART CODE
1	**Premature Hinged Sternal and Thoracic Retractor** Includes Straight Rack, Fixed Arm, Moving Arm with Attached Blades and Cog Handle	**PHR-1**

Instrument and Retractor Limited Warranty

Genesee BioMedical's Retractors and 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 the 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.

Instrument and Retractor 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.

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