Genesee
BIOMEDICAL, INC.
*Design beyond standard*

# INSTRUCTIONS FOR USE

# BMI 35 Sternal Valve Retractor with Atrial and Aortic Rakes

**Models: SRLP-1 and SRLP-AR**

**DESCRIPTION**

The GBI Large Patient Sternal Retractor is designed and intended for valve procedures and coronary artery bypass surgery for adult patients weighing 90 kg or more.

The retractor design features a curved rack and pivoting sternal blades to reduce the trauma caused by opening the chest. The device is opened and closed by the rotation of the cog handle. Hinges in the arms allow the curved rack to lie close to the patient's body during surgery. The blades are free to pivot 10° in either direction and will automatically align with the cut edges of the sternum to distribute pressure evenly over the length of the blades.

**Sternal Blades**

Two sets of sternal blades are supplied with each instrument.

Deep: 8.9 cm long, 3.8 cm deep
Extra Deep: 8.9 cm long, 5 cm deep

Each interchangeable blade has a small turret bearing and pin protruding from its upper face. The blades engage in slots in the arm and are retained in the arm by a simple latch mechanism. This feature allows the blade to be easily changed.

**Atrial and Aortic Retractor Attachments**

The atrial and aortic retractor mounting components are listed on the component list. The pillar clamp is easily attached to either arm of the sternal retractor in an upper or lower location. The mounting components allow the retractor rakes to be easily placed and adjusted to the desired position, angle, rotation, and reach. Exposure of the heart valves, or other heart tissue, may be obtained using one, two, or three of the rakes supplied. The ball clamps and pillar clamp firmly hold the atrial and aortic rakes, even after extended use.

**DIRECTIONS FOR USE**

Select the appropriate size of blades.

**To change or remove a sternal blade:**

a) Identify the small-hinged latch located in the outer edge of the arm.
b) Gently turn the blade so that it lies parallel to the central axis of the arm.
c) Open the latch by applying finger pressure from below (do not move it past the vertical position).
d) Slide the blade straight out.

**To insert a sternal blade:**

a) Lift latch to the vertical position by applying finger pressure from below (do not move it past the vertical position).

b) Hold the blade parallel to central axis of arm and slide the blade pin and bearing into the slot.

c) Close the latch and press firmly to lock.

The rack of the sternal retractor may be positioned at either end of the sternal incision; however, the lower position is typically best. Attach the pillar clamp to the retractor arm with the hole in the pillar clamp nearest the patient's midline. The two small pins on the base of the pillar clamp are inserted into the holes in the arm. Loosely screw the pillar screw into the threaded hole in the arm with a hexagonal wrench (note: Do not tighten the screw until the mounting bar is inserted). Insert the "H" mounting bar through the hole in the pillar clamp and slide about half the length of the mounting bar through the hole. Rotate the "H" bar around the pillar clamp to change the angle of the rake, which can be steep or shallow. Tighten the pillar clamp screw using a hexagonal wrench.

Using a hexagonal wrench, fully loosen the clamp screw of a ball clamp. Slide the ball clamp onto the "H" mounting bar using the lower hole in the ball clamp (note: For curved rakes, the lower hole in the ball clamp is identified by a polished finish). Slide the stem of a rake through the upper hole. Position the ball clamp and rake as desired and tighten the ball clamp screw. Repeat with other rakes as required.

To retract the atrium towards the patient's feet, place a ball clamp and a straight mounting bar on the lower end of the "H" mounting bar and tighten the ball clamp screw. Slide another ball clamp onto the end of the straight mounting bar and insert a small left rake. Position the rake and ball clamp and then tighten. Any of the rake blades and mounting bars may be adjusted during the procedure by partially loosening the ball clamp or pillar screw with a hexagonal wrench, adjusting the position of the component, and re-tightening the screw to hold the new position.

**DISASSEMBLY**

1) Remove the moving arm from the rack by rotating the cog handle until the moving arm is free to slide off.
2) Remove the sternal blades from the retractor.
3) Identify the small-hinged latch located in the outer edge of the arm adjacent to the blade bearing.
4) Gently turn the blade so that it aligns parallel to the central axis of arm.
5) Open the latch to the vertical position by applying finger pressure from below.
6) Slide the blade straight out. Note: Do not disassemble ball clamps or the pillar clamp as this will cause damage.

**CLEANING**

Use routine operating room 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 the corroded part. 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.

a) Replace the Cog/Handle Assembly on the Moving Arm. Insert the cog handle into the moving arm. Slide the moving arm partially onto the rack. Rotate the cog handle to engage the teeth on the rack.

b) Replace the Sternal Blades. Open the latch to the vertical position by applying finger pressure from below. Hold the blade parallel to central axis of arm and slide the blade pin and bearing into the slot. Close the latch and press it firmly to lock.

**LUBRICATION**

The moving parts of the instrument (clamp screws, pivot joints, and latch mechanism, including the indent ball in the arm, rack, and cog) are to be lubricated regularly, preferably before each sterilization using surgical instrument "milk" or equivalent surgical lubricant.

**STERILIZATION**

The instrument and accessories must be sterilized before each use. Use the hospital standard procedure for sterilizing surgical instruments. The instrument is corrosion-resistant stainless steel and may be steam autoclaved.

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 |

## SRLP-1 & SRLP-AR Adult Retractor
## Component Parts List

| QUANTITY SUPPLIED | | PRODUCT DESCRIPTION | PART CODE |
|---|---|---|---|
| **1** | | **BMI 35 Curved Sternal Retractor** | **SRLP-1** |
| | 1 | Large Curved Sternal Rack with Fixed and Moving Arms | SR-CRL |
| | 2 | Deep Adult Blade | SR-DBL |
| | 2 | Extra Deep Adult Blade | SR-XDBL |
| | 1 | Cog/Handle Assembly - Large | CH-L |

| QUANTITY SUPPLIED | | PRODUCT DESCRIPTION | PART CODE |
|---|---|---|---|
| **1** | | **BMI 35 Curved Sternal Valve Retractor with Atrial and Aortic Rakes** | **SRLP-AR** |
| | 1 | Large Curved Sternal Rack with Fixed and Moving Arms | SR-CRL |
| | 2 | Deep Adult Blade | SR-DBL |
| | 2 | Extra Deep Adult Blade | SR-XDBL |
| | 1 | Cog/Handle Assembly - Large | CH-L |
| | 1 | Adult Pillar Clamp | AR-PC |
| | 4 | Adult Ball Clamp | AR-BC |
| | 2 | Mounting Bars | AR-MB |
| | 1 | "H" Mounting Rod | AR-HR |
| | 2 | Large Hex Wrench | AR-HW |
| | 1 | Long Left Atrial Rake | AR-LAR |
| | 1 | Small Left Atrial Rake | AR-SLR |
| | 2 | Medium Left Atrial Rake | AR-MLR |
| | 2 | Large Left Atrial Rake | AR-LLR |
| | 1 | Large Right Atrial Rake | AR-LRR |

## SLRP-1 & SLRP-AR Adult Retractor
## Additional Component Parts List (Purchased Separately)

| PRODUCT DESCRIPTION | PART CODE |
|---|---|
| Minimally Invasive Standard Blade | MISBL |
| Minimally Invasive Deep Blade | MISDBL |
| Adult Toggle Ball Clamp | AR-BCT |
| Adult Toggle Pillar Clamp | AR-PCT |
| Small Left Atrial Rake (Long Handle) | AR-SLRL |
| Medium Left Atrial Rake (Long Handle) | AR-MLRL |
| Large Left Atrial Rake Long Handle (Long Handle) | AR-LLRL |
| Large Right Atrial Rake (Long Handle) | AR-LRRL |
| Long Left Atrial Rake (Long Handle) | AR-LARL |

**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 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.

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.

Manufacturing Facility:
**Genesee BioMedical, Inc.**
700 W Mississippi Ave Unit D5
Denver, CO 80223-4509, USA
Toll-Free: (800) 786-4890
Phone: (303) 777-3000
Fax: (303) 777-8866
www.geneseebiomedical.com

EU Authorised Representative:
**Quality First International OÜ**
Laki 30
12915 Tallinn
Estonia

UK Responsible Person:
**Quality First International**
1 Cook's Road
Stratford
London
E15 2PW



US Patent 5,772,583
US Patent 6,206,828
© 2026 Genesee BioMedical, Inc. 214132R05