



Genesee

BIOMEDICAL, INC.

Design beyond standard

INSTRUCTIONS FOR USE



Family of Curved Sternal Valve Retractors With Atrial and Aortic Rakes

**Models: SRCL-1, SRCL-AR, CSR-1, CSR-AR,
PSRC-1, PSRC-AR, NSR-1, & NSR-AR**

DESCRIPTION

Genesee BioMedical Curved Sternal Retractors are designed and intended for adult, pediatric and congenital cardiac surgery. This device is available by prescription only.

Genesee BioMedical (GBI) provides these retractors in the following sizes:

Adult: suitable for adult patients weighing from 45 to 90 kg.

Child: suitable for young patients weighing from 15 to 45 kg.

Pediatric: suitable for pediatric patients weighing from 2 to 15 kg.

Neonate: suitable for pediatric patients weighing from 0.5 to 5 kg.

The unique 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, except for the neonate retractor which has one set of permanently attached blades.

Adult Blades

Adult: 8.9 cm long, 2.5 cm deep

Deep: 8.9 cm long, 3.8 cm deep

Child Blades

Large: 6.6 cm long, 1.9 cm deep

Small: 4.5 cm long, 1.5 cm deep

Pediatric Blades

Pediatric: 4.4 cm long, 1.3 cm deep

Newborn: 2.2 cm long, 1.0 cm deep

Neonate Blades

Neonate: 1.8 cm long, 0.9 cm deep

Each interchangeable blade has a small turret bearing and a pin protruding from its upper face. In the child, pediatric and adult models these engage in slots in the arm, and the blade is retained in the arm by a simple latch mechanism. This allows the blade to be easily changed. In the neonate retractor the turret bearings and sternal blades are retained in the arm with small screws that should not be removed. The screw threads are locked with a high temperature thread sealant.

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 (except neonate retractor):

- 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.
- 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. 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. Screw the pillar screw into the threaded hole in the arm with a hexagonal wrench. Do not tighten the screw. 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. 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

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

- b) Remove the Sternal Blades from the Retractor (adult, child or pediatric)
 - Identify the small hinged latch located in the outer edge of the arm adjacent to the blade bearing.
 - Gently turn the blade so that it aligns parallel to the central axis of arm.
 - Open the latch to the vertical position by applying finger pressure from below.
 - Slide the blade straight out. Note: Do not disassemble a ball clamp or pillar clamp as this will cause damage.

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.

- 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, latch mechanism, indent ball, rack and cog) must be lubricated regularly, preferably before each use with 3M "Blitz" M105 surgical instrument cleaner and lubricant or surgical instrument "milk".

STERILIZATION

The instrument and accessories must be sterilized before each use. Use the hospital standard procedure for sterilizing surgical instruments. The instruments are 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

**SRCL-1 & SRCL-AR Adult Retractor
Component Parts List**

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		Adult Curved Sternal Retractor	SRCL-1
	1	Adult Curved Sternal Rack with Fixed and Moving Arms	SR-CR
	2	Adult Standard Blade	SR-SBL
	2	Adult Deep Blade	SR-DBL
	1	Adult Retractor Cog Handle	SR-CH

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		Adult Curved Sternal Valve Retractor with Atrial and Aortic Rakes	SRCL-AR
	1	Adult Curved Sternal Rack with Fixed and Moving Arms	SR-CR
	2	Adult Standard Blade	SR-SBL
	2	Adult Deep Blade	SR-DBL
	1	Retractor Cog Handle	SR-CH
	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 Hexagonal 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

**CSR-1 & CSR-AR Child Retractor
Component Parts List**

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		Child Curved Sternal Retractor	CSR-1
	1	Child Curved Sternal Rack with Fixed and Moving Arms	CSR-CR
	2	Child Large Blade	CSR-CB
	2	Child Small Blade	CSR-SB
	1	Child Retractor Cog Handle	CSR-CH

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		Child Curved Sternal Valve Retractor with Atrial and Aortic Rakes	CSR-AR
	1	Child Curved Sternal Rack with Fixed and Moving Arms	CSR-CR
	2	Child Large Blade	CSR-CB
	2	Child Small Blade	CSR-SB
	1	Child Retractor Cog Handle	CSR-CH
	1	Pediatric Pillar Clamp	PAR-PC
	4	Pediatric Ball Clamp	PAR-BC
	2	Pediatric Mounting Bar	PAR-MB
	1	Pediatric "H" Mounting Rod	PAR-HR
	2	Small Hexagonal Wrench	SR-HW
	1	Long Left Atrial Rake	MIR-LAR
	1	Small Left Atrial Rake	MIR-SAR
	2	Medium Left Atrial Rake	MIR-MAR
	1	Large Right Atrial Rake	PAR-LRR
	1	Child Sterilization Tray	MIR-ST5

**PSRC-1 & PSRC-AR Pediatric Retractor
Component Parts List**

QUANTITY SUPPLIED	PRODUCT DESCRIPTION	PART CODE
1	Pediatric Curved Sternal Retractor	PSRC-1
1	Pediatric Sternal Rack with Fixed and Moving Arms	PSR-CR
2	Pediatric Sternal Blade	PSR-SB
2	Newborn Sternal Blade	PSR-NB
1	Pediatric Retractor Cog Handle	PSR-CH

QUANTITY SUPPLIED	PRODUCT DESCRIPTION	PART CODE
1	Pediatric Curved Sternal Valve Retractor with Atrial and Aortic Rakes	PSRC-AR
1	Pediatric Curved Sternal Rack with Fixed and Moving Arms	PSR-CR
2	Pediatric Sternal Blade	PSR-SB
2	Newborn Sternal Blade	PSR-NB
1	Pediatric Retractor Cog Handle	PSR-CH
1	Pediatric Pillar Clamp	PAR-PC
4	Pediatric Ball Clamp	PAR-BC
2	Pediatric Mounting Bar	PAR-MB
1	Pediatric "H" Mounting Rod	PAR-HR
2	Small Hexagonal Wrench	SR-HW
1	Small Left Atrial Rake	PAR-SLR
2	Medium Left Atrial Rake	PAR-MLR
2	Large Left Atrial Rake	PAR-LLR
1	Large Right Atrial Rake	PAR-LRR
1	Long Left Atrial Rake	PAR-LAR
1	Pediatric Sterilization Tray	PST-ST5

**NSR-1 & NSR-AR Neonate Retractor
Component Parts List**

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		Neonate Curved Sternal Retractor	NSR-1
	1	Pediatric Sternal Rack with Fixed and Moving Arms and attached Blades	NSR-CR
	1	Neonate Retractor Cog Handle	NSR-CH

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		Neonate Curved Sternal Valve Retractor with Atrial and Aortic Rakes	NSR-AR
	1	Neonate Curved Sternal Rack with Fixed and Moving Arms and Attached Blades	NSR-1
	1	Neonate Retractor Cog Handle	NSR-CH
	1	Neonate Pillar Clamp	NSR-PC
	3	Pediatric Ball Clamp	PAR-BC
	2	Neonate Mounting Bar	NAR-MB
	2	Small Hexagonal Wrench	SR-HW
	1	Small Atrial Rake	NAR-SR
	1	Medium Left Rake	NAR-MR
	1	Large Atrial Rake	NAR-LR
	1	Pediatric Sterilization Tray	PST-ST5

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

