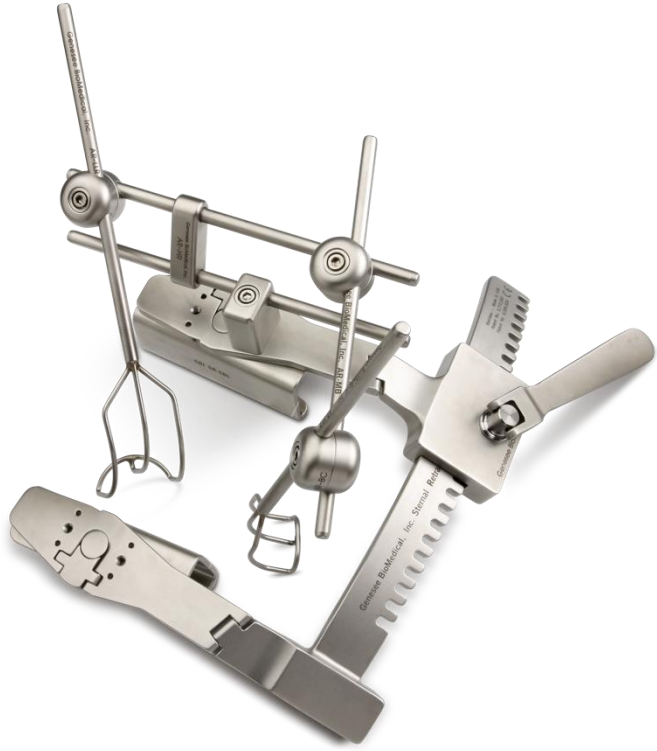
Genesee
BIOMEDICAL, INC.
Design beyond standard

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.
N**eonate:** 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, 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 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 Retractor with Curved Rack with Fixed and Moving Arms	SR-CR
	2	Standard Adult Blade	SR-SBL
	2	Deep Adult Blade	SR-DBL
	1	Cog/Handle Assembly - Large	CH-L

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

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

PRODUCT DESCRIPTION	PART CODE
Extra Deep Adult Blade	SR-XDBL
Minimally Invasive Standard Blade	MISBL
Minimally Invasive Deep Blade	MISDBL
Adult Toggle Ball Clamp ype	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 Atrial Rake (Long Handle)	AR-LARL

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 Sternal Blade	CSR-CB
	2	Standard Sternal Blade	CSR-SB
	1	Cog/Handle Assembly- Medium	CH-M
	1	Sterilization Tray - Large	MIR-STS

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 Sternal Blade	CSR-CB
	2	Standard Sternal Blade	CSR-SB
	1	Cog/Handle Assembly- Medium	CH-M
	1	Pediatric Pillar Clamp	PAR-PC
	4	Pediatric Ball Clamp	PAR-BC
	2	Mounting Bar	PAR-MB
	1	"H" Mounting Rod	PAR-HR
	2	Small Hex Wrench	SR-HW
	1	Long Atrial Rake	MIR-LAR
	1	Small Atrial Rake	MIR-SAR
	2	Medium Atrial Rake	MIR-MAR
	1	Pediatric Large Right Atrial Rake	PAR-LRR
	1	Sterilization Tray - Large	MIR-STS

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	Standard Blade	PSR-SB
	2	Newborn Blade	PSR-NB
	1	Cog/Handle Assembly - Small	CH-S
	1	Sterilization Tray - Small	PST-STS

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	Standard Blade	PSR-SB
	2	Newborn Blade	PSR-NB
	1	Cog/Handle Assembly - Small	CH-S
	1	Pediatric Pillar Clamp	PAR-PC
	4	Pediatric Ball Clamp	PAR-BC
	2	Mounting Bar	PAR-MB
	1	"H" Mounting Rod	PAR-HR
	2	Small HexWrench	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 Atrial Rake	PAR-LAR
	1	Sterilization Tray - Small	PST-STS

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

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		**Neonate Curved Sternal Retractor**	**NSR-1**
	1	Neonate Curved Sternal Rack with Fixed and Moving Arms and Attached Blades	NSR-1
	1	Cog/Handle Assembly– Extra Small	CH-XS
	1	Sterilization Tray - Small	PST-STS

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	Cog Handle – Extra Small	CH-XS
	1	Neonate Pillar Clamp	NSR-PC
	3	Pediatric Ball Clamp	PAR-BC
	2	Neonate Mounting Bar	NAR-MB
	2	Small HexWrench	SR-HW
	1	Small Neonate Rake	NAR-SR
	1	Medium Neonate Rake	NAR-MR
	1	Large Neonate Rake	NAR-LR
	1	Sterilization Tray - Small	PST-STS

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



© 2026 Genesee BioMedical, Inc. All rights reserved. 298046R18