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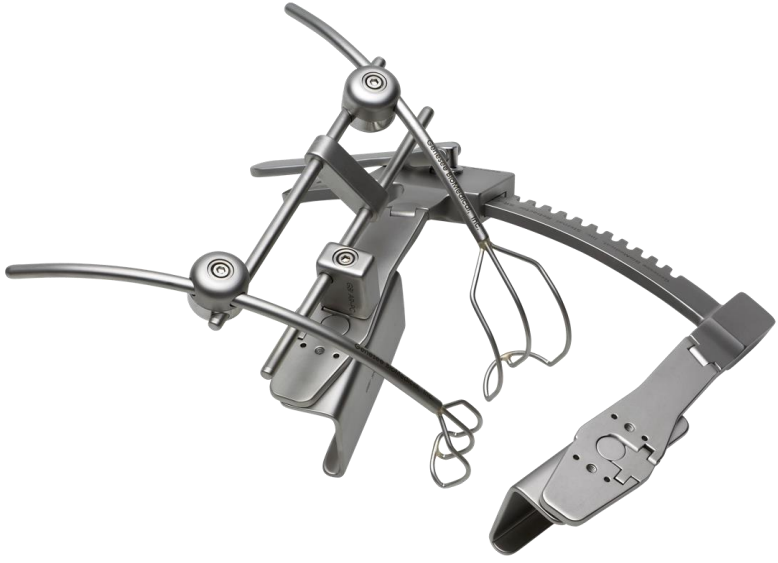
Design beyond standard

INSTRUCTIONS FOR USE



Adult Curved Sternal Retractor with Curved Atrial and Aortic Rakes

Model: SRCL-ARC

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DESCRIPTION

The adult sternal retractor is suitable for adult patients weighing 45kg to 90kg.

The retractors are intended for valve and cardiac surgery. The retractor may also be used for coronary artery bypass surgery.

The curved rack with pivoting sternal blades reduces the trauma caused by opening the chest. The retractor is opened and closed by rotating the cog handle. The 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 automatically align with the cut edges of the sternum to spread the pressure evenly over the length of the blades.

Sternal Blades

Two sets of sternal blades are supplied with each instrument.

Dimensions for Adult Sternal Blades

a) Standard: 89mm long, 25mm deep.
b) Deep: 89mm long, 38mm deep.

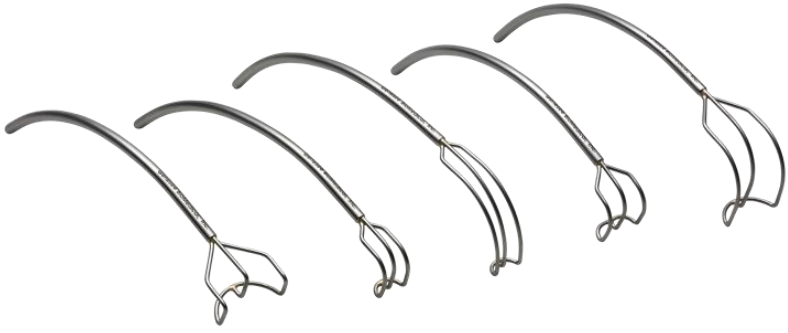
Each blade has a small turret bearing and a pin protruding from its upper face. These turrets engage in slots in the arm, and the blade is retained in the arm by a simple latch mechanism. This allows the blade to be easily changed. Take care not to lose removed parts.

DIRECTIONS FOR USE

Select the appropriate size of sternal retractor and sternal blades.
To change a sternal blade, first identify the small hinged latch located in the outer edge of the arm. Gently turn the blade so that it lies parallel to the central axis of the arm. Open the latch by applying finger pressure from below (do not move it past the vertical position). Slide the blade straight out. To insert the sternal blade, first lift latch to the vertical position. Hold the blade parallel to central axis of arm and slide the blade pin and bearing into the slot. Close the latch and press firmly to lock. The rack of the sternal retractor may be positioned at either end of the sternal incision. Usually the lower position is best.

ATRIAL AND AORTIC CURVED RAKES

The atrial and aortic curved rake mounting components are listed on the component list. The ball clamps firmly hold the atrial and aortic curved rakes throughout extended use. Ball clamps include upper and lower collets for attachment to the mounting bar or H bar. Proper orientation of the ball clamps is required for use of the curved rakes; the upper collet is used for the rakes and the lower collet is used for mounting bars or H bar. The upper section of the ball clamp is identified by the matte finished surface and the lower section is identified by the shiny polished surface. The pillar clamp is easily attached to either arm of the sternal retractor. (Curved Rakes are shown below.)



The mounting bar, H bar, pillar clamp and ball clamp mechanism allow the curved rakes to be placed and easily adjusted to the desired position, angle, rotation and reach. Exposure of the heart valves, or other cardiac tissue may be obtained using one, two or three of the rakes supplied (a transverse or oblique aortic incision for aortic valve exposure). The extra wide rake is intended mainly for tricuspid exposure.

DIRECTIONS FOR USE OF CURVED RAKES WITH ADULT RETRACTOR

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. Insert the "H" bar or mounting rod through the hole on the pillar clamp and slide about half the length of the “H” 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 by using the hexagonal wrench. Do not over-tighten the screw.

Using the hexagonal wrench or toggle, fully loosen the clamp screw of the ball clamp. To identify the upper and lower collets in the ball clamp, the upper surface of the clamp is finished with a matte surface the lower surface is finished with a polished shine. The ball clamps are available with toggle or wrench adjustment (shown below).

Note that the curved rakes can be used only in the upper collet of the 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 (shown below). 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" 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 then tighten. Any of the rakes 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

To disassemble the retractor, proceed as follows:

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

b) To remove the sternal blade, first 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.

c) Do not disassemble a ball clamp or pillar clamp as this will cause damage.

CLEANING

Use the operating room 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 the corroded or damaged 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) 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-ARC Adult Sternal Valve Retractor System with Curved Rakes
Component Parts List

QUANTITY SUPPLIED	PRODUCT DESCRIPTION	PART CODE
1	Adult Sternal Rack with Moving Arm	SR-CR
1	Adult Cog Handle	SR-CH
2	Adult Standard Retractor Blade	SR-SBL
2	Adult Deep Retractor Blade	SR-DBL
4	Adult Ball Clamp	AR-CC
1	Adult Pillar Clamp	AR-PC
1	Adult H-Bar	AR-HR
2	Adult Mounting Bar	AR-MB
2	Large Hex Wrench	AR-HW
1	Adult Curved Small Left Atrial Rake	AR-SLRC
2	Adult Curved Medium Left Atrial Rake	AR-MLRC
2	Adult Curved Large Left Atrial Rake	AR-LLRC
1	Adult Curved Long Left Atrial Rake	AR-LARC
1	Adult Curved Large Right Atrial Rake	AR-LRRC

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.

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