Genesee
BIOMEDICAL, INC.
Design beyond standard

INSTRUCTIONS FOR USE



AVATR Thoracic and Sternal Retractor

Model: ATR-1 and ATR-AR

DESCRIPTION

This instrument is a multi-purpose retractor for general thoracic use and for Minimally Invasive Direct Coronary Artery Bypass surgery (MIDCAB). The retractor is especially useful for a left thoracotomy approach for redo CAB surgery and is useful for midline sternotomy in small adults (and mini-sternotomy exposure in average size adults) for valve and coronary artery surgery. This high-quality instrument is manufactured from corrosion resistant stainless steel in the USA to exacting standards.

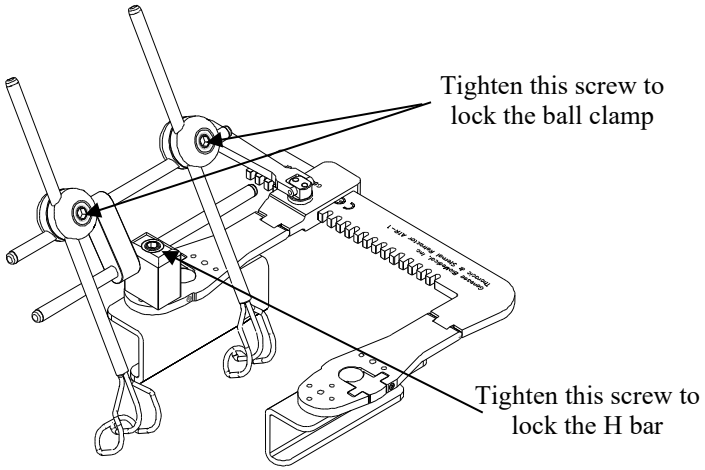
ACCESSORIES

Atrial and Aortic Rakes

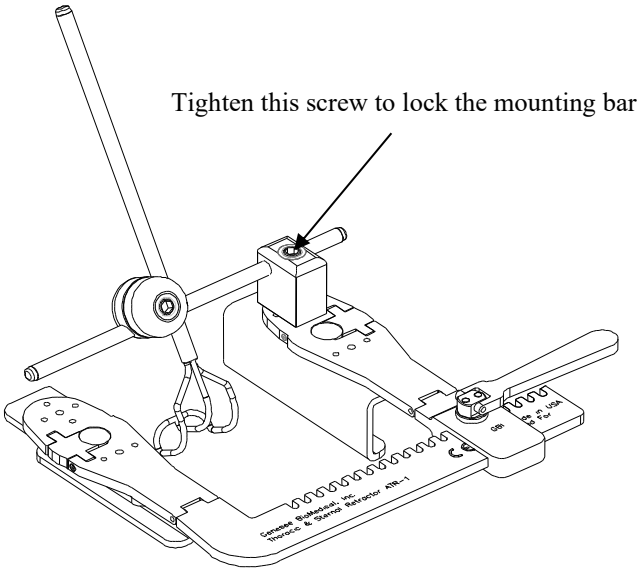
Atrial and Aortic retractors are available for valve surgery. The individual components are listed on the component list.

DIRECTIONS FOR USE

Two figures below show how to basically arrange the mechanism of the rake, mounting bar, pillar clamp, and ball clamp on the retractor.



Attach the pillar clamp onto one of the two arms of the retractor; the two small pins on the base of the pillar clamp go into the two small holes in an arm. Tighten the pillar clamp screw into the threaded hole in the block using a hexagonal wrench. Do not over tighten the screw. Insert approximately half the length of the "H" bar (or mounting bar) through the hole in the pillar clamp. Rotation of the "H" bar around the pillar clamp allows the angle of the retraction rake to vary from steep to shallow.



Using a hexagonal wrench fully loosen the clamp screw of the ball clamp. Slide the ball clamp onto the H-bar or 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. In valve surgery one, two or three valve retractor rakes may be required. Any of the rakes and mounting bars may be adjusted during the procedure by partially loosening the ball clamp or pillar screw, adjusting the position of the component and re-tightening the screw to hold the new position. Exposure of the aortic valve may be obtained using a single small or medium rake via a transverse or oblique aortic incision.

DISASSEMBLY

To disassemble the retractor, proceed as follows:

a) Remove the pillar block from the moving arm or fixed arm if necessary.
b) Remove the moving arm from the rack by rotating the cog handle clockwise until the moving arm is free to slide off.
c) Remove the cog from the moving arm.

Do not attempt to disassemble the ball clamps or pillar clamp, as they will be damaged.

CLEANING

Use the hospital's routine procedure 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 of the cog/handle assembly in the moving arm.
b) Slide the moving arm onto the rack, rotating the cog handle to engage the teeth on the rack.

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 any reusable accessories must be sterilized before each use. Place the instrument and all components into the sterilization tray and use the hospital's routine procedure for sterilizing surgical instruments. The retractor components are constructed of 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

AVATR Thoracic/Sternal Retractor
Component Parts List

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		**AVATR Thoracic/Sternal Retractor**	**ATR-1**
	1	AVATR Thoracic/Sternal Rack with Fixed and Moving Arms	ATR-1
	2	Standard Adult Blade	SR-SBL
	2	Deep Adult Blade	SR-DBL
	1	Cog/Handle Assembly- Medium	CH-M

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		**AVATR Thoracic/Sternal Retractor with Atrial and Aortic Rakes**	**ATR-AR**
	1	AVATR Thoracic/Sternal Rack with Fixed and Moving Arms	ATR-1
	2	Standard Adult Blade	SR-SBL
	2	Deep Adult Blade	SR-DBL
	1	Cog/Handle Assembly - Medium	CH-M
	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

AVATR Thoracic/Sternal Retractor
Additional Component Parts List (Purchased Separately)

PRODUCT DESCRIPTION	PART CODE
Extra Deep Adult Blade	SR-XDBL
Minimally Invasive Adult Standard Blade	MISBL
Minimally Invasive Adult 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.

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