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BIOMEDICAL, INC.
Design beyond standard

INSTRUCTIONS FOR USE



MINIMAX
Minimally Invasive Thoracic Retractor
with Interchangeable Blades

Models: MMX-1, MMX-1R & MMX-1RS

DESCRIPTION

The MINIMAX Minimally Invasive Thoracic Retractor is a multi-purpose retractor for minimally invasive thoracic use and is applicable for TAVR and left thoracotomy approaches. Depending on the model, this retractor includes 3 or 6 interchangable pairs of blades in 3 different sizes.

This high quality instrument is manufactured from corrosion-resistant stainless steel (except for the anodized aluminum radiolucent blades available in models: MMX-1R and MMX-1RS) in the USA to exacting standards. The retractor rack is 124mm long and the arm is 79mm long. Standard blades are 25mm deep and 27mm wide. Deep blades are 40mm deep and 27mm wide. Wide deep blades are 40mm deep and 45mm wide. The retractor is shown with the 3 blade sizes in Figure 1.

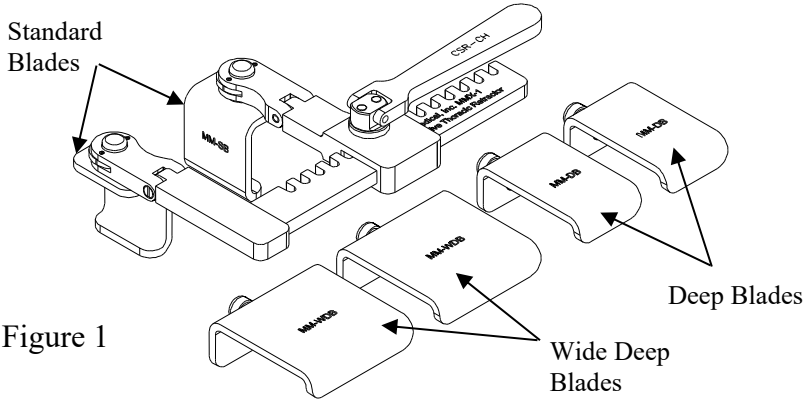


Figure 1

DISASSEMBLY

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

b) It is usually not necessary to disassemble the sternal blades from the arms of the retractor. To remove the sternal blade, press the circular latch and the blade will be released from the arm (Figure 2).

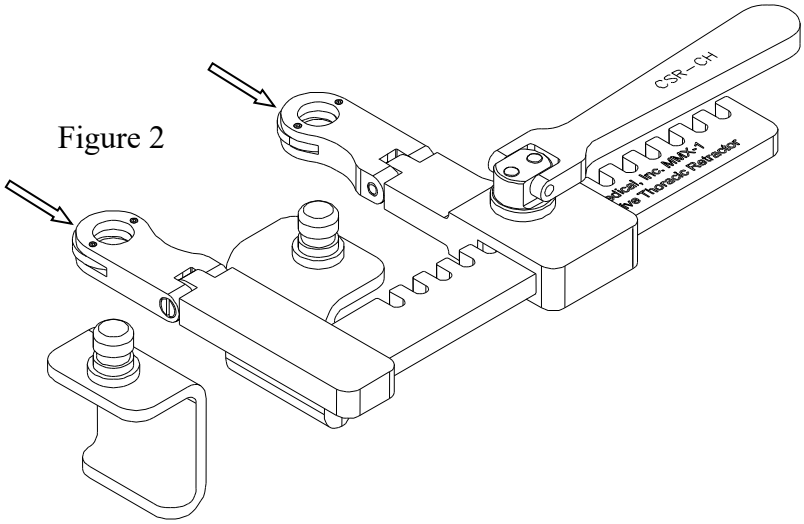


Figure 2

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 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:
- Align the turret on the top of the blade under the round slot in the arm.
- Place the blade under the arm so that the protruding turret enters the slot.
- Insert and snap into place.

LUBRICATION
The moving parts of the instrument 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 cleaned and 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 anodized aluminum (models MMX-1R and MMX-1RS) 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

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MMX-1, MMX-1R, and MMX-1RS
MiniMax Minimally Invasive Thoracic Retractor
Component Parts List

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		**Adult Minimally Invasive Thoracic Retractor with Standard-Steel Blades Includes:**	**MMX-1**
	1	Adult Sternal and Thoracic Rack with Fixed and Moving Arms	MMX-1
	1	Cog/Handle Assembly - Medium	CH-M
	2	Standard Stainless Steel Blade	MM-SB
	2	Deep Stainless Steel Blade	MM-DB
	2	Wide Deep Stainless Steel Blade	MM-WDB
	1	Sterilization Tray - Small	PST-STS

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		**Adult Minimally Invasive Thoracic Retractor with Radiolucent Blades Includes:**	**MMX-1R**
	1	Adult Sternal and Thoracic Rack with Fixed and Moving Arms	MMX-1
	1	Cog /Handle Assembly - Medium	CH-M
	2	Standard Radiolucent Blade	MM-SBR
	2	Deep Radiolucent Blade	MM-DBR
	2	Wide Deep Radiolucent Blade	MM-WDBR
	1	Sterilization Tray - Small	PST-STS

QUANTITY SUPPLIED		PRODUCT DESCRIPTION	PART CODE
1		**Adult Minimally Invasive Thoracic Retractor with Radiolucent and Standard Steel Blades Includes:**	**MMX-1RS**
	1	Adult Sternal and Thoracic Rack with Fixed and Moving Arms	MMX-1
	1	Cog/HandleAssembly - Medium	CH-M
	2	Standard Stainless Blade	MM-SB
	2	Deep Stainless Steel Blade	MM-DB
	2	Wide Deep Stainless Steel Blade	MM-WDB
	2	Standard Radiolucent Blade	MM-SBR
	2	Deep Radiolucent Blade	MM-DBR
	2	Wide Deep Radiolucent Blade	MM-WDBR
	1	Sterilization Tray - Small	PST-STS

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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

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