Genesee
BIOMEDICAL, INC.
Design beyond standard

INSTRUCTIONS FOR USE

SUTURE ORGANIZER
Model SR-SOP

DESCRIPTION

The Genesee BioMedical, Inc. Suture Organizer is designed with tightly coiled stainless-steel springs which provide an array of slits used to receive, hold, organize, and release retaining sutures during surgical procedures, enabling the surgeon to retract tissue from the surgical field. It is designed to attach and be used in conjunction with Genesee BioMedical's surgical retractors. The Suture Organizer's intended use includes coronary artery bypass graft and heart valve surgical procedures.

INSTRUCTION FOR USE

Attach the SR-SOP to the retractor arm (Figure 2): the two small pins on the base of the Suture Organizer are inserted into the holes in the arm and prevent rotation. Firmly tighten the mounting screw into the threaded hole in the retractor arm with a hexagonal wrench.

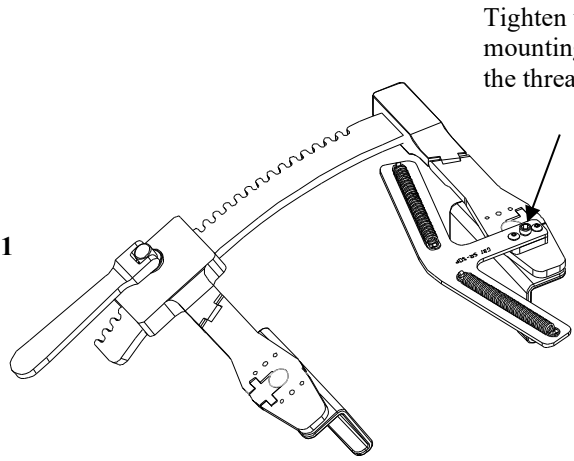


Figure 1

CLEANING AND STERILIZING

Use the operating room's routine procedures for cleaning surgical instruments. 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 1 minute. Use a soft-bristle brush (for example, a nylon toothbrush) to clean the device thoroughly.
2	Soaking	Room Temperature	Submerge the suture organizer 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 suture organizer 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 suture organizer with running water for 1 minute.
5	Dry	N/A	Dry with a clean, lint-free wipe.
6	Inspection	N/A	Visually inspect the suture organizer for any remaining contaminants or moisture. If any contaminants, repeat the process.

The instrument must be sterilized before each use. Use the hospital's standard procedure for sterilizing surgical instruments. The instrument is corrosion resistant stainless steel and may be steam autoclaved.

GBI recommends the following validated pre-vacuum steam sterilization method:

Table 2: Steam Sterilization Parameters

Instrument	Autoclave Cycle	Autoclave Temperature	Autoclave Duration	Drying time
Suture Organizer	Wrapped instrument	132°C	4 min	20 min
	Wrapped instrument	135°C	3 min	16 min

Limited Warranty

Genesee BioMedical's Suture Organizer, hereinafter referred to as "Product" is 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.

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