Genesee
BIOMEDICAL, INC.
Design beyond standard

INSTRUCTIONS FOR USE

ROBOTIC TOOL KIT

Left Suture Hook with Knurled Handle, Model RSH-L
Right Suture Hook with Knurled Handle, Model RSH-R
Closed Knot Pusher, Model RTK-RKP
Open Knot Pusher, Model RTK-KPO
Ball-tipped Suction Tube, Model RTK-BTS
Large Diameter Suction Tube, Model RTK-LDS
Robotic Ports and Obturators
Valve Sizer Set, Model RTK-VSS

UK CA CE

DESCRIPTION

The Genesee Robotic Tool Kit consists of surgical tools and instruments designed for use in robotic-assisted cardiac surgery. Key components include suture hooks, knot pushers, ports, suction tools, and accessories for cardiac procedures. Tools and components are available individually. All tools must be sterilized before each use.

The BALL-TIPPED SUCTION TOOL (Model: RTK-BTS) is designed for precise application of suction as needed in robotic-assisted surgical procedures.

The LARGE DIAMETER SUCTION TOOL (Model: RTK-LDS) is designed as a large bore sucker. The LARGE DIAMETER SUCTION TOOL can be used as a debris sucker in cardiac surgical exposures.

The SUTURE HOOKS are designed to facilitate suture handling and manipulation in robotic-assisted procedures. The robotic hooks are provided with a right-facing hook (Model: RSH-R) and a left-facing hook (Model: RSH-L).

The KNOT PUSHERS are designed to facilitate suture knot handling and manipulation in robotic-assisted procedures. Two knot pushers are available — one with an enclosed end (Model: RTK-RKP) and one with an open end (Model: RTK-KPO).

The ROBOTIC PORTS are stainless steel ports designed for minimal trauma access for valve repair and other cardiac procedures. The ROBOTIC PORTS include obturators for placement. PORTS are intended for use with robotic or transthoracic instruments.

The VALVE SIZER SET (Model: RTK-VSS) may be used for valve replacement during robotic-assisted or minimally invasive procedures. The sizers provide direct measurements for 25mm, 27mm, 29mm, 31mm, and 33mm diameter valves.

PACKAGING

The SUTURE HOOKS, KNOT PUSHERS, PORTS, SIZERS, and SUCTION TOOLS are provided NON-STERILE and must be cleaned and sterilized prior to initial use and each subsequent use. See Cleaning and Sterilization section.

STORAGE

Store in a room temperature dry place to protect the product and minimize contamination potential.

INDICATIONS

The SUTURE HOOKS, KNOT PUSHERS, PORTS, OBTURATORS, SIZERS, and SUCTION TOOLS are intended to aid in robotic-assisted cardiac surgery.

WARNINGS

Take care not to damage tissue during use.

PRECAUTIONS

Take care not to damage the SUTURE HOOKS, KNOT PUSHERS, PORTS, OBTURATORS, SIZERS, or SUCTION TOOLS during handling.

CLEANING AND STERILIZATION

Inspect each device before every use. The SUTURE HOOKS, KNOT PUSHERS, SUCTION TOOLS, PORTS, SIZERS, and OBTURATORS should not be used if there are visible signs of cracking, crazing, deformation or other damage that may affect function.

The SUTURE HOOKS, KNOT PUSHERS, PORTS, OBTURATORS, SIZERS, and SUCTION TOOLS are supplied NON-STERILE and must be cleaned thoroughly and sterilized prior to initial use and each subsequent use. Discard all packaging materials before cleaning and sterilizing.

It is recommended that the SUTURE HOOKS, KNOT PUSHERS, PORTS, OBTURATORS, SIZERS, and SUCTION TOOLS be reprocessed as soon as reasonably practical following use. The following manual cleaning and disinfection method is recommended by Genesee BioMedical, Inc. for the SUTURE HOOKS, KNOT PUSHERS, PORTS, OBTURATORS, SIZERS, and SUCTION TOOLS.

1. Rinse devices with a solution of warm tap water and a hospital approved surfactant for approximately two (2) minutes.
2. Scrub the devices with a soft-bristled cleaning brush to remove all grossly visible debris.
3. Place the devices in an ultrasonic bath containing enzymatic detergent prepared according to manufacturer's directions and ultrasonically clean for fifteen (15) minutes.
4. If necessary, scrub the accessories using a cleaning brush to remove any remaining visible debris.
5. Rinse devices with warm tap water for approximately two (2) minutes to remove detergent.
6. Dry and place the SUTURE HOOKS, KNOT PUSHERS, PORTS, OBTURATORS, SIZERS, and SUCTION TOOLS in the sterilization tray, close the lid and wrap for sterilization.

GBI recommends the following validated sterilization methods:

Sterilization Parameters

Sterilizer Type	Autoclave Cycle	Autoclave Temperature	Autoclave Duration	Drying Time
Gravity Displacement	Wrapped instrument	135°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

Increasing the recommended sterilization temperature or time may result in reduced device life cycles. Do not use aromatic solvent-based cleaners as disinfectant agents as these solvents may damage the components of the tool kit.

Ordering Information:

Model Number	Item
RSH-L	Knurled Handle Suture Hook, Left
RSH-R	Knurled Handle Suture Hook, Right
RTK-RKP	Closed Knot Pusher
RTK-KPO	Open Knot Pusher
RTK-BTS	Ball-tipped Suction Tube
RTK-LDS	Large Diameter Suction Tube
RPS-18110	Oval Thoracic Port with Obturator 18mm ID, 110mm Length
RPS-1890	Oval Thoracic Port with Obturator 18mm ID, 90mm Length
RPS-1870	Oval Thoracic Port with Obturator 18mm ID, 70mm Length
RPS-1850	Oval Thoracic Port with Obturator 18mm ID, 50mm Length
RP-18110	Oval Thoracic Port: 18mm ID, 110mm Length
RP-1890	Oval Thoracic Port: 18mm ID, 90mm Length
RP-1870	Oval Thoracic Port: 18mm ID, 70mm Length
RP-1850	Oval Thoracic Port: 18mm ID, 50mm Length
RPO-18110	Oval Obturator: 18mm ID, 110mm Length
RPO-1890	Oval Obturator: 18mm ID, 90mm Length
RPO-1870	Oval Obturator: 18mm ID, 70mm Length
RPO-1850	Oval Obturator: 18mm ID, 50mm Length
RTK-VSS	Valve Sizer Set (25mm, 27mm, 29mm, 31mm, 33mm)

Surgical Instrument Limited Warranty

Genesee BioMedical's 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.

Surgical Instrument 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

© 2022 Genesee BioMedical, Inc.

213162R08