

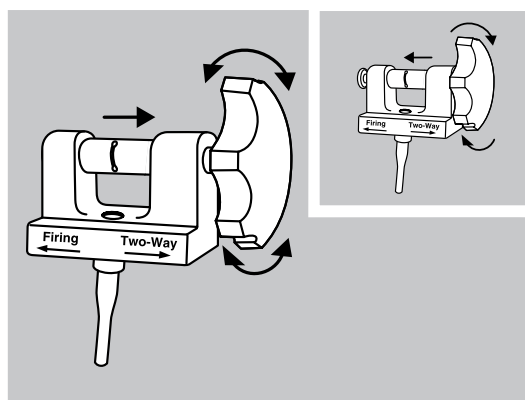
4,6,10 Shooter™

SAEED MULTI-BAND LIGATOR

Scope Compatibility

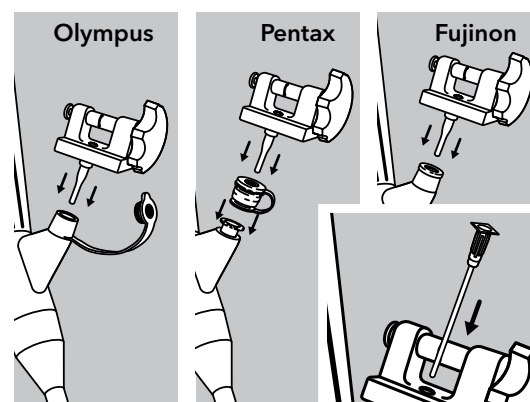
Order No.	Endoscope Outer Diameter
MBL-U-4	8.6 mm - 11.3 mm
MBL-U-6	
MBL-U-6-F	
MBL-U-10	
MBL-6-OV	9.5 mm - 11.5 mm
MBL-10	
MBL-4	9.5 mm - 13 mm
MBL-6	
MBL-4-XL	11 mm - 14 mm
MBL-6-XL	
MBL-6-XL-C	
MBL-6-XS	8.6 mm - 9.2 mm

System Prep 1



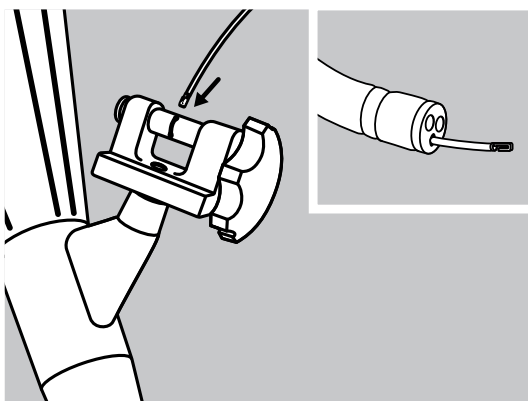
The firing position allows the handle to be rotated in the forward direction only. The **two-way position** allows the handle to rotate in both directions.

System Prep 2



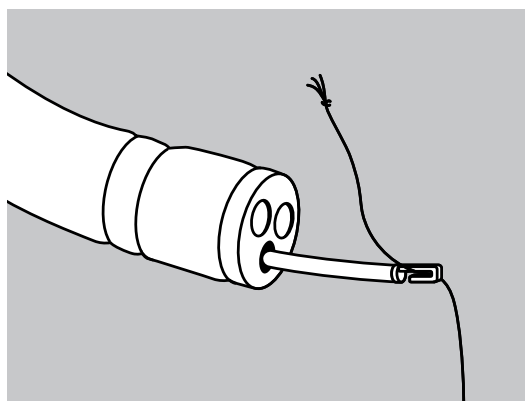
Insert the ligator handle into the endoscope accessory channel.
Note: The irrigation adapter may be used to puncture the white self-sealing valve prior to introducing the loading catheter.

System Prep 3



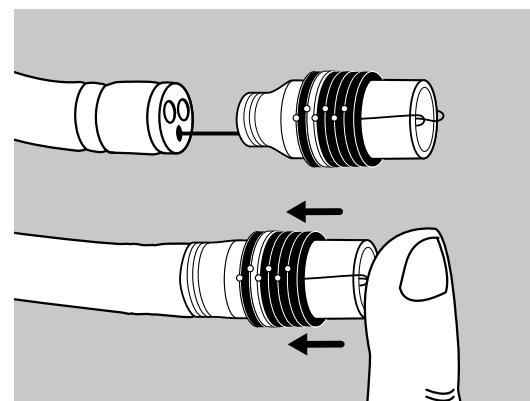
Introduce either end of the loading catheter through the white seal in the ligator handle and advance, in short increments, until it exits the tip of the endoscope.

System Prep 4



Attach the trigger cord, leaving approximately 2 cm of cord between the knot and the hook. Withdraw the loading catheter and trigger cord up through the endoscope and out through the ligator handle.

System Prep 5

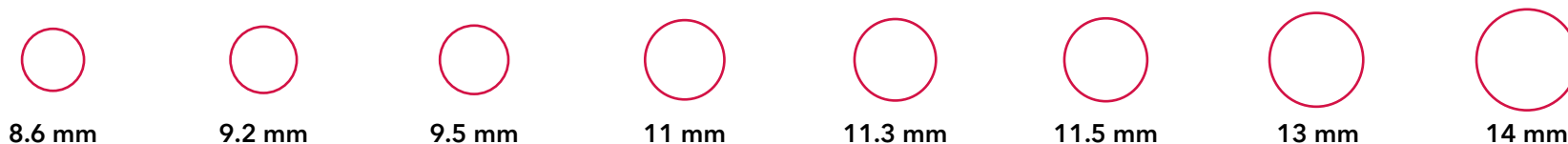


Secure friction fit adapter of the barrel to the tip of the endoscope, advance as far as possible.
Note: Failure to do so may result in barrel dislodgement. Avoid bands while pushing. When placing the barrel onto the distal end of the endoscope, ensure trigger cord does not become pinched between the barrel and endoscope.

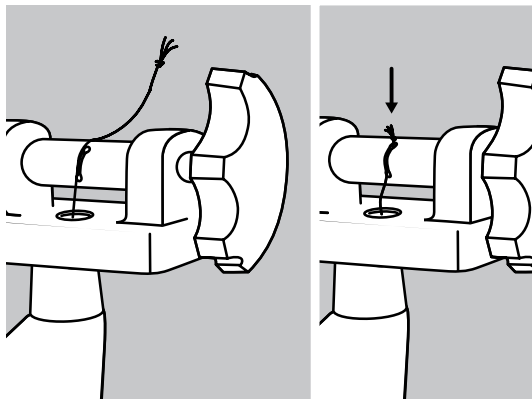
Scope Compatibility Scale

Use the scope compatibility table above and scale below to determine which 4,6,10 Shooter offering fits your scope.

Note: If your endoscope does not fit into one of the specific diameters below, do not use with the 4,6,10 Shooter.

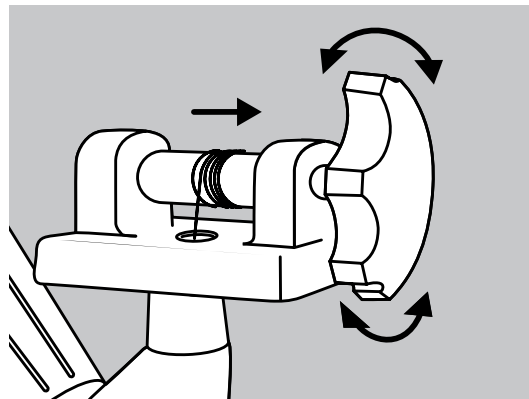


System Prep 6



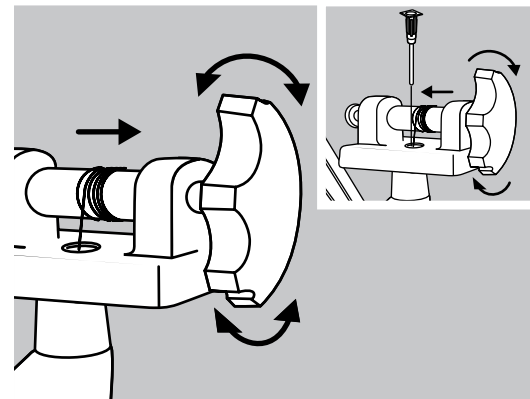
Place the trigger cord into the slot on the spool of the ligator handle and pull down until the knot is seated in the hole of the slot. The knot **must** be seated into the hole for the handle to function properly.

System Prep 7



With the handle in the **two-way position**, slowly rotate the handle clockwise to wind the trigger cord onto the handle spool. **Note:** Care must be exercised to avoid deploying a band while winding the trigger cord.

Instructions for Ligation



With handle in the **two-way position**, introduce the endoscope. **After intubation** place the handle in the **firing position**. Visualize the selected varix or hemorrhoid and aspirate into the Opti-Vu barrel. Maintain suction, deploy the band by rotating the ligator handle clockwise until band release is **felt**. If irrigation is necessary, insert irrigation adapter into the white seal of the handle.

Ligation of internal hemorrhoids

Step 1



With the Multi-Band Ligator handle in the **two-way position**, introduce the endoscope into the rectum. Retroflex the endoscope to visualize the selected internal hemorrhoid. **After** retroflexion, place the handle in the firing position. Aspirate the internal hemorrhoid into the Opti-Vu barrel. **Caution:** Ligation should only be performed on internal hemorrhoids located above the dentate line. Maintain suction on the internal hemorrhoid and deploy the band by rotating the ligator handle clockwise until band release is **felt**, indicating deployment.

Step 2



Release the suction button of the endoscope, insufflate air, then advance the endoscope slightly to release the ligated hemorrhoid. Repeat the ligation process as needed.

Refer to current instructions for use for detailed information.

Scope Compatibility Scale

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Note: If your endoscope does not fit into one of the specific diameters below, do not use with the 4,6,10 Shooter.



14 mm



13 mm



11.5 mm



11.3 mm



11 mm



9.5 mm



9.2 mm



8.6 mm

Certificate of Approval

This is to certify that the Management System of:

Wilson-Cook Medical, Inc.

4900 Bethania Station Road, Winston-Salem, NC, 27105, United States

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00016927

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design and Manufacturing of Reusable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and Surgery.



Cliff Muckleroy

Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited



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Certificate Schedule

Location	Activities
4900 Bethania Station Road, Winston-Salem, NC, 27105, United States	ISO 13485:2016 Design and Manufacturing of Reusable and Disposable Diagnostic and Therapeutic Devices used in the Fields of Gastrointestinal Endoscopy, Bronchoscopy and Surgery.
5951 Grassy Creek Road, Winston-Salem, NC, 27105, United States	ISO 13485:2016 Manufacturing, Quality Control, Packaging, Labeling, and Finished Goods Shipping.
5941 Grassy Creek Road, Winston-Salem, NC, 27105, United States	ISO 13485:2016 Manufacturing, Purchasing, Receiving, Incoming Quality Control, and Raw material Storage.





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Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 045999 0034 Rev. 00

Manufacturer:

Wilson-Cook Medical, Inc.

4900 Bethania Station Road
Winston-Salem NC 27105
USA

Product Category(ies): Class IIa Products

Disposable (Cold) Biopsy Forceps, Active Cords, Injection
Needles, Aspiration Needles, Gastrostomy Adaptors, Nasal
Jejunal Feeding Tubes, Ligation Devices, Hemostasis Devices

Class IIb Products

Hot Biopsy Forceps, Biliary Stents, Sphincterotomes,
Papillotomes, Endoscopic Ultra Fiducial Needles, Polypectomy
Devices, Gastrostomy Devices, Gastrostomy Replacement
Devices, Gastro Jejunal Feeding Tubes, (Endoscopic Clipping
Devices).

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72157229

Valid from: 2020-06-30

Valid until: 2024-05-26

Date, 2020-06-30

Christoph Dicks
Head of Certification/Notified Body