

Multi-Band Ligator Instructions for Use

Doc. No. : CE/TD-MBL-22-01

Ver.: A.02

Date of Release: 2022.08.15

【WARNING】

1. Please read the instructions for use before use. Use strictly according to the specifications in the instructions for use.
2. This product is single-use and valid for 2 years.
3. Do not use after the expiration date. The production date and expiration date can be found on the product packaging.
4. Before use, carefully check that the packaging is intact. Do not use if the primary packaging is damaged.
5. This device is designed for single use only. Attempting to reprocess or reuse may lead to device failure and/or disease transmission.
6. This device must not be used for other purposes beyond the intended use.
7. Before use, carefully inspect this device, paying particular attention to any twists, bends, or damage. Do not use if any anomalies that may affect use are found.
8. Only medical personnel with expertise in endoscopic therapy and who have received training should use this device.
9. Any serious incident related to this product should be reported to the competent authorities of the EU member state where the manufacturer, user and/or patient are located.

【PRODUCT NAME】

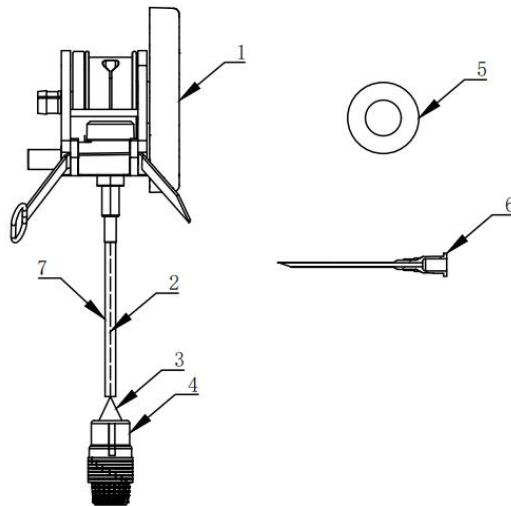
Multi-Band Ligator

【INTENDED USE】

This product is used with endoscope for vascular ligation of esophageal varicose veins or for ligation of internal hemorrhoids.

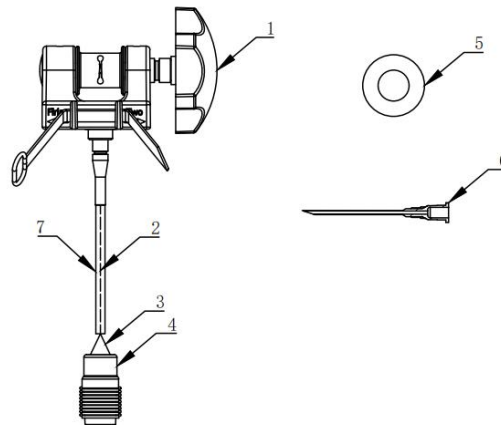
【PRODUCT COMPONENTS】

The Multi-Band Ligator (hereinafter referred to as the ligator) consists of the Control Handle, Release cord, Trigger cord, Barrel, Loop, and Irrigation adapter. The specifications and models of this equipment are determined by the number of Loops, components, the material of the Release cord and the presence of alertss on the Handle. The components are shown in Figures 1-4, while the specifications and models of this equipment are shown in Table 1. This product is single-use and valid for 2 years.



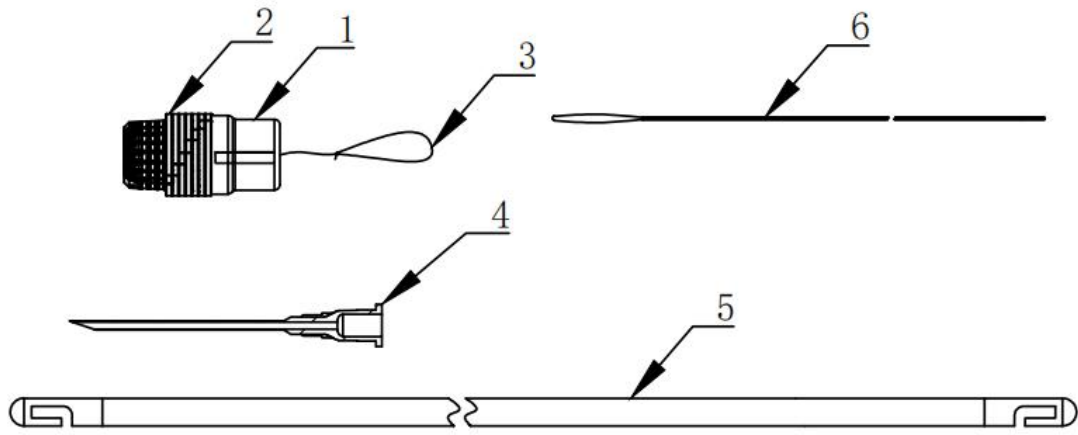
1. Control Handle 2. Release cord 3. Trigger cord 4. Barrel 5. Loop 6. Irrigation adapter 7. Loading catheter

Figure 1 Basic Structural Components Diagram (Type AP, BP)



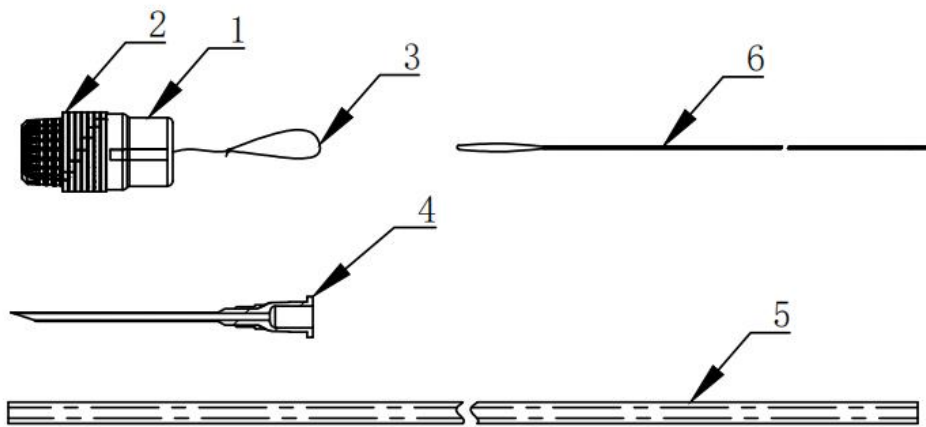
1. Control Handle 2. Release cord 3. Trigger cord 4. Barrel 5. Loop 6. Irrigation adapter 7. Loading catheter

Figure 2 Basic Structural Components Diagram (Type A, B)



1.Barrel 2.Loop 3.Trigger cord 4.Irrigation adapter 5.Loading catheter 6.Release cord

Figure 3 Multi-Band Ligator (model AM and model APM) Structural Components Diagram



1.Barrel 2.Loop 3.Trigger cord 4.Irrigation adapter 5.Loading catheter 6.Release cord

Figure 4 Multi-Band Ligator (model BM and model BPM) Structural Components Diagram

【SPECIFICATIONS AND MODELS】

Table 1 Specifications and models of Multi-Band Ligators

Material of the Release cord		Number of Loops	alerts	Component parts
Polyethylene(PE)	Stainless steel			
BL18-4A	BL18-4B	4	No	Control Handle, Loading catheter, Release cord, Trigger cord, Barrel, Loop, Irrigation adapter
BL18-5A	BL18-5B	5	No	
BL18-6A	BL18-6B	6	No	
BL18-7A	BL18-7B	7	No	
BL18-8A	BL18-8B	8	No	
BL18-9A	BL18-9B	9	No	
BL18-4AP	BL18-4BP	4	Yes	
BL18-5AP	BL18-5BP	5	Yes	
BL18-6AP	BL18-6BP	6	Yes	
BL18-7AP	BL18-7BP	7	Yes	

BL18-8AP	BL18-8BP	8	Yes	
BL18-4AM	BL18-4BM	4	No	Loading catheter, Release cord, Trigger cord, Barrel, Loop, Irrigation adapter
BL18-5AM	BL18-5BM	5	No	
BL18-6AM	BL18-6BM	6	No	
BL18-7AM	BL18-7BM	7	No	
BL18-8AM	BL18-8BM	8	No	
BL18-9AM	BL18-9BM	9	No	
BL18-4APM	BL18-4BPM	4	Yes	
BL18-5APM	BL18-5BPM	5	Yes	
BL18-6APM	BL18-6BPM	6	Yes	
BL18-7APM	BL18-7BPM	7	Yes	
BL18-8APM	BL18-8BPM	8	Yes	

【NAMING RULES】

BL 18- □ □ □ □

(1) (2) (3) (4) (5) (6)

(1) Product name code

(2) Product design serial number code

(3) Number of Loops code

(4) Release cord material code (A for polyethylene (PE); B for stainless steel)

(5) Sound alerts code (blank for no sound alerts function; P for sound alerts function)

(6) Product component code (blank for components including Control Handle; M for components without Control Handle)

For example, the BL18-7A model means the Multi-Band Ligator (Sound alert type) consists of a Control Handle, a Loading catheter, a Release cord made of polyethylene, a Trigger cord, a Barrel, 7 Loops and an Irrigation adapter.

The BL18-7BPM model(Sound alert type) indicates that the product consists of a Loading catheter, a Release cord made of stainless steel, a Trigger cord, a Barrel, 7 Loops, and an Irrigation adapter.

Note: See the label on primary package for the specifications and model of this product.

【PRODUCT PERFORMANCE】

1. The Control Handle of the Multi-Band Ligator should rotate smoothly, and while rotating the Handle clockwise, it should not rotate in the counterclockwise direction.
2. When using the Multi-Band Ligator, the Loop should be able to be smoothly discharged from the Barrel.
3. For Multi-Band Ligator Sound alert type, a “click” sound should be audible when the Handle is rotated clockwise.
4. The Barrel should be able to withstand a negative pressure of ≥ 0.5 kPa without leakage, rupture, or deformation.

【INDICATIONS】

- 1.For vascular ligation of esophageal varicesveins.
- 2.For hemorrhoids with prolapse and bleeding symptoms, including internal hemorrhoids of grades I, II, III, and the internal portion of mixed hemorrhoids.

【CONTRAINDICATIONS】

- 1.For patients with epiglottic or esophageal strictures, obstructions, distortions, deformities, and

esophageal diverticula; Patients with esophageal fistula, esophageal ring, or esophageal web.

2.For patients with undiagnosed or uncorrected bleeding disorders and coagulation dysfunction.

3.For patients with unstable circulatory conditions.

4.For patients with confirmed suspected esophageal perforation; and those who are not suitable for endoscopic treatment.

5.For patients with rubber material allergies and other contraindications for gastrointestinal endoscopy.

6.Contraindications for hemorrhoid ligation include (but are not limited to): coagulation disorders, anal stenosis, and active inflammation at the rectal end.

【POTENTIAL COMPLICATIONS】

1.May lead to discomfort or pain behind the sternum, difficulties with swallowing, laryngeal and esophageal abrasions, tears, bleeding, or perforation.

2.May lead to erosion, ulcers, stricture, or obstruction at the ligation site, fever, allergic reactions, or hypotension.

3.May lead to respiratory aspiration, respiratory failure or cessation; arrhythmias or cardiac arrest.

4.Complications associated with endoscopic procedures may include (but are not limited to): perforation and bleeding.

5.Complications associated with the use of sedatives may include (but are not limited to): drug allergies, hypotension, arrhythmias or cardiac arrest, respiratory depression or cessation.

6.Complications from hemorrhoid ligation treatment may include (but are not limited to): bleeding, fever, infection, nausea, urinary retention, and the formation of strictures and obstructions.

7.Using a hemorrhoid ligator below the dentate line may cause severe pain.

【CLINICAL BENEFITS】

The procedure is less invasive, shorter, less costly and quicker to recover after surgery, which can effectively improve the treatment effect and reduce the recurrence rate.

【TARGET POPULATION】

1.Patients with varicose veins.

2.Patients with hemorrhoids.

3.Patients suitable for endoscopic surgery.

【INTENDED USERS】

Only medical personnel who have received training should use this device.

【PRECAUTIONS】

1. Please refer to the package label to determine the minimum endoscope diameter required for using this instrument.
2. When used for ligating small varicose veins, the ligation may be ineffective.
3. The esophageal ligator is not suitable for ligating varicose veins below the gastroesophageal junction.
4. Pushing the endoscope along a previously placed Loop may displace the Loop.
5. It is recommended to perform a routine endoscopic examination before instrument installation to confirm the diagnostic conclusion for treating esophageal varices veins.
6. The integrity of the working channel is crucial, as grooves or other obstructions in the working channel can potentially catch the Release cord, making the release of the Loop difficult.
7. Using a properly functioning endoscope is essential for the successful performance of multi-Band ligation procedures.

【PREOPERATIVE PREPARATION AND EXAMINATION】

1. Our company produces two models of Multi-Band Ligator; Please refer to the following two different assembly methods.
2. Each model can be equipped with either Stainless steel cord or PE cord according to customer requirements.
3. Inspect the appearance of the Handle. It features two control rotation positions. The one-way position allows the Handle to rotate only forward (Figure 1). The Two-way position allows the Handle to rotate in both directions (Figure 2).

【PRODUCT ASSEMBLING - GENERAL TYPE Handle】

Stainless steel cord-Type B, BM

1. Set the Handle's single and dual rotation control knobs. Before introducing the endoscope, ensure the Handle is in the two-way position.
2. Pass the Loading catheter and Stainless steel cord through the biopsy channel of the endoscope, and confirm that the Loading catheter extends beyond the end of the endoscope. Withdraw and discard the Loading catheter from the end of endoscope, revealing the wire loop of Stainless steel cord (Figure 3).
3. Slowly insert the Handle connector into the biopsy channel of the endoscope, ensuring that the Handle connector fits snugly with the biopsy channel port and secure it to the endoscope using a

Band.

Note:

(1)Olympus – Leave the rubber cap on the biopsy channel, pull up the plug on the cap, and then insert the Loading catheter and Handle connector (Figure 4a).

(2)Pentax – Remove the rubber cap from the biopsy channel, allowing the Loading catheter and Handle connector to pass through it. Insert the rubber cap along with the Handle as a single unit onto the biopsy channel's luer locking taper (Figure 4b).

(3)Fujinon – Insert the Loading catheter and Handle connector through the attached rubber cap into the endoscope's biopsy channel (Figure 4c).

4. Attach the Trigger cord to the wire Loop of Stainless steel cord and tighten it (Figure 5).

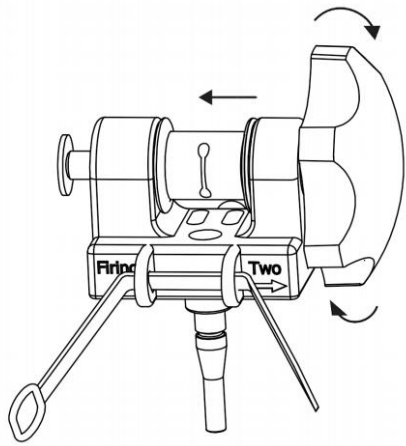
5. Attach the Barrel to the end of the endoscope channel, ensuring it is as close as possible to ensure a secure connection (Figure 6).

6. Set the rotation control position to the two-way position, turn the Handle clockwise to wind the Stainless steel cord onto the Handle shaft, and stop turning when you feel resistance. Then, set the rotation control position to the one-way position(Figure 7 and Figure 8).

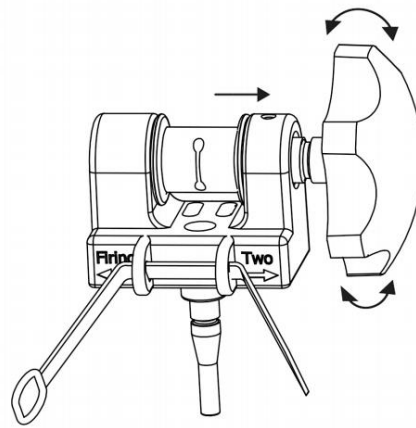
7. Lubricate the exterior of the endoscope and Barrel.

Note: Do not apply lubricant inside the Barrel.

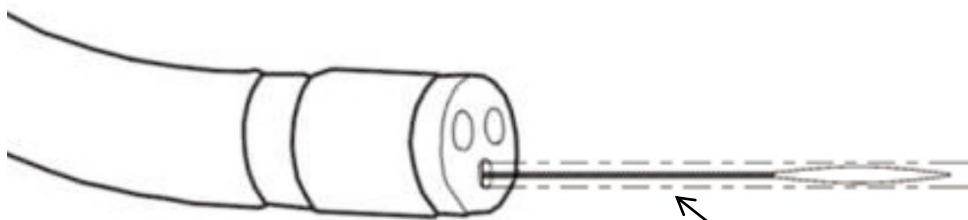
Note: Do not use alcohol on the instrument.



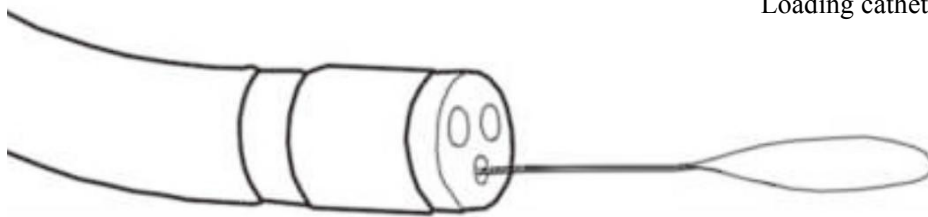
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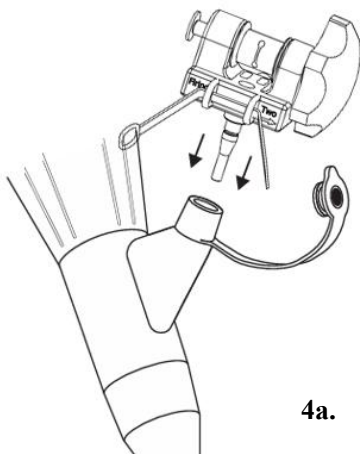
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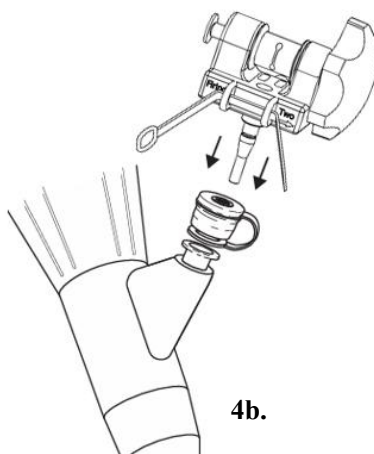
Loading catheter



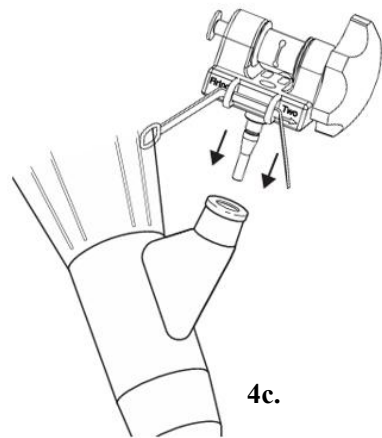
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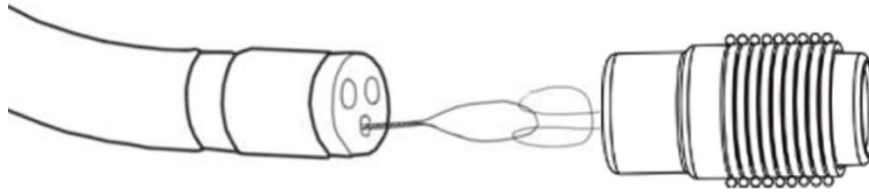
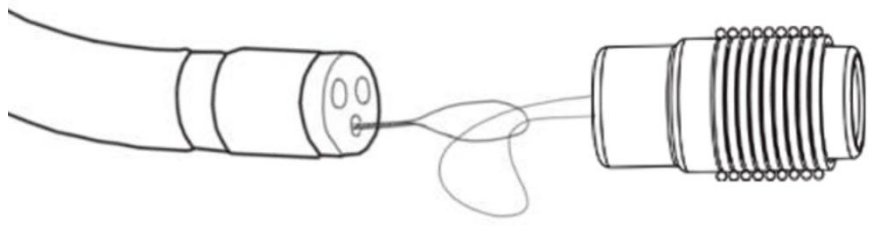
4a.



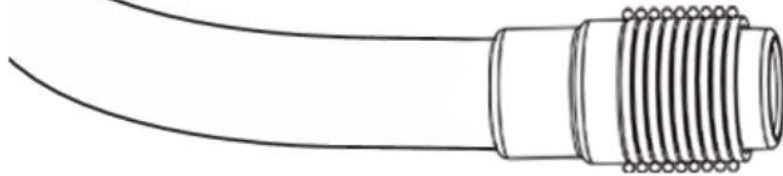
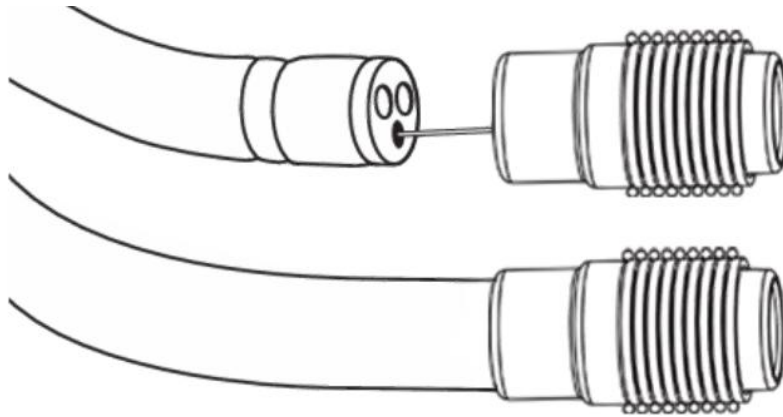
4b.



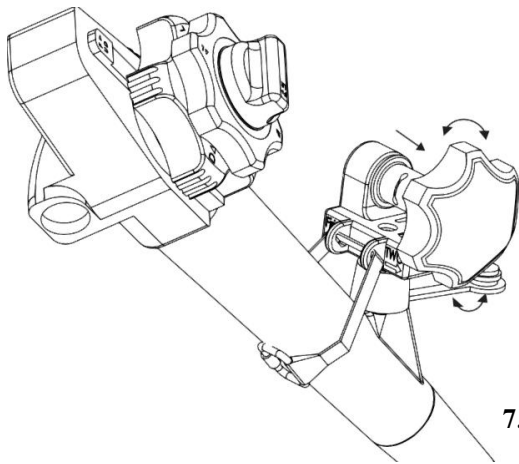
4c.



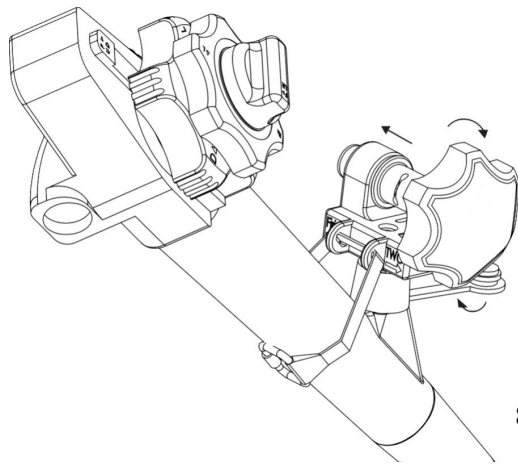
5.



6.



7.



8.

PE cord-Type A, AM

1. Set the Handle's single and dual rotation control knobs. Before introducing the endoscope, ensure the Handle is in the two-way position.
2. Slowly insert the Handle connector into the biopsy channel of the endoscope, ensuring that the Handle connector fits snugly with the biopsy channel port and secure it to the endoscope using a Band.

Note:

(1)Olympus – Leave the rubber cap on the biopsy channel, pull up the plug on the cap, and then insert the Loading catheter and Handle connector (Figure 9a).

(2)Pentax – Remove the rubber cap from the biopsy channel, allowing the Loading catheter and Handle connector to pass through it. Insert the rubber cap along with the Handle as a single unit onto the biopsy channel's luer locking taper (Figure 9b).

(3)Fujinon – Insert the Loading catheter and Handle connector through the attached rubber cap into the endoscope's biopsy channel (Figure 9c).

3. Insert one end of the Loading catheter into the white sealing gasket of the Multi-Band Ligator, advancing it in small increments until the other end of the Loading catheter extends from the endoscope channel (Figure 10).

4. Attach the Loading catheter through one end of the endoscope channel to the wire Loop of PE cord of the Multi-Band Ligator (Figure 11).

5. Pull the Loading catheter at the end of the endoscope until the wire Loop of PE cord is exposed, and then clip the wire Loop of PE cord onto the Handle shaft of the Multi-Band Ligator. Withdraw and discard the Loading catheter from the endoscope Handle channel entrance (Figure 12 and Figure 13).

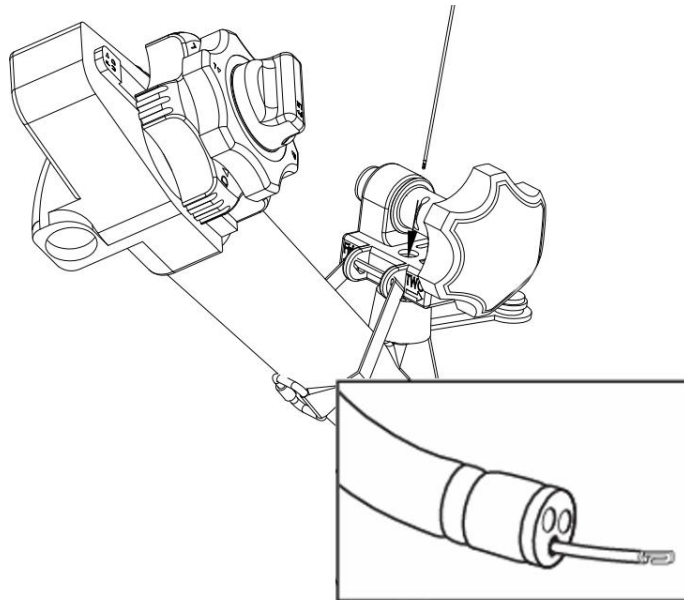
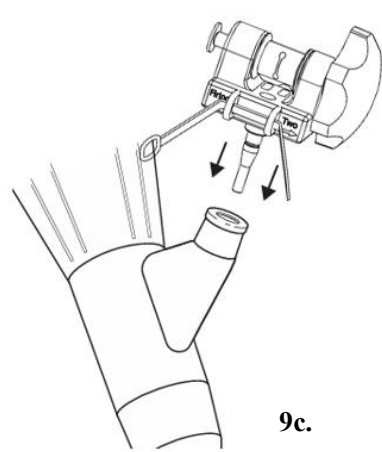
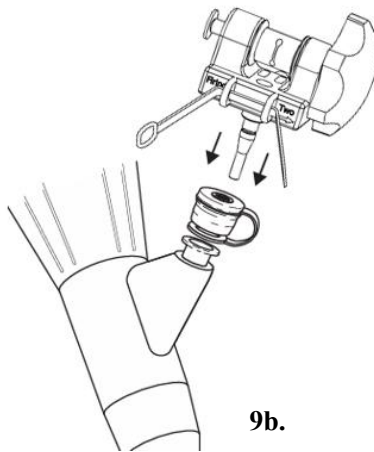
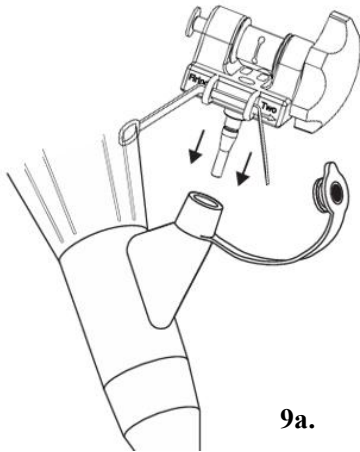
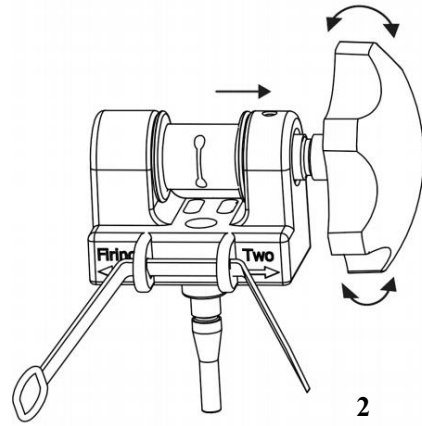
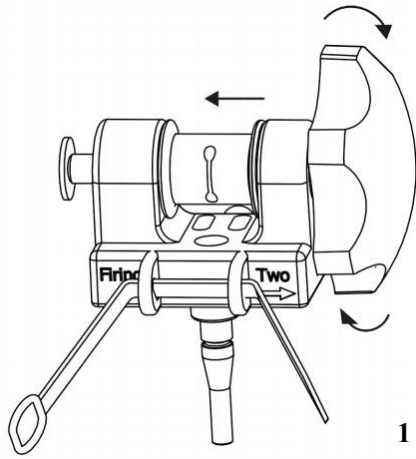
6. Attach the Barrel to the end of the endoscope channel, ensuring it is as close as possible to ensure a secure connection (Figure 14).

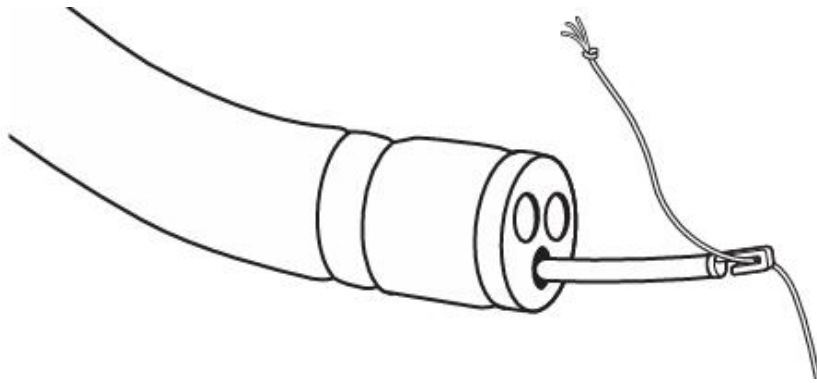
7. Set the rotation control position to the two-way position, turn the Handle clockwise to wind the Stainless steel cord onto the Handle shaft, and stop turning when you feel resistance. Then, set the rotation control position to the one-way position (Figure 15 and Figure 16).

8. Lubricate the exterior of the endoscope and Barrel.

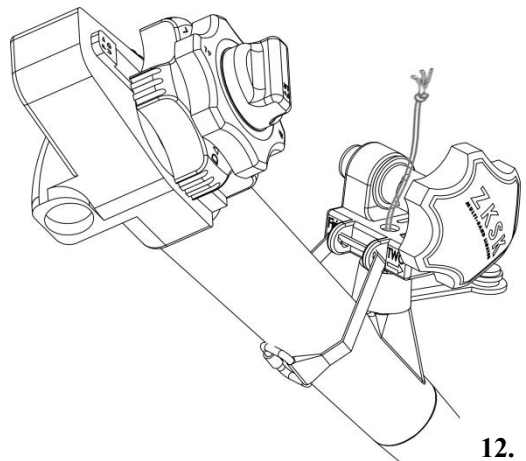
Note: Do not apply lubricant inside the Barrel.

Note: Do not use alcohol on the instrument.

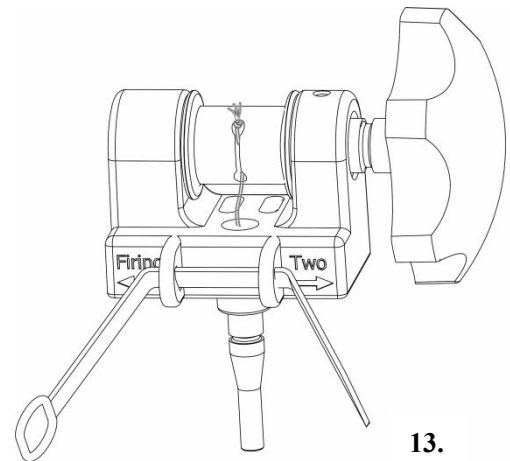




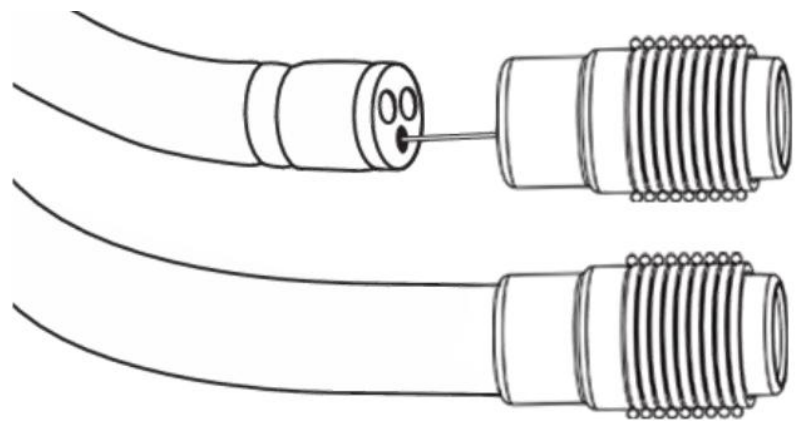
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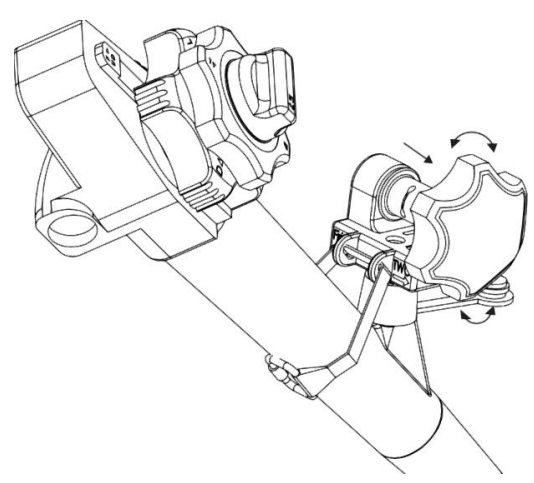
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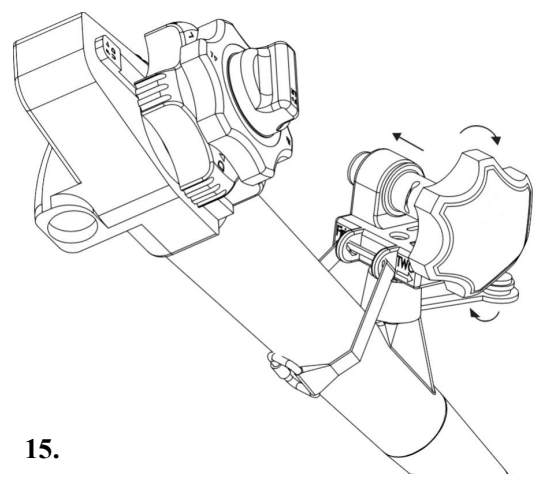
13.



14.



15.



16.

【PRODUCT ASSEMBLING - Handle Sound alert type】

Stainless steel cord-Type BP, BPM

1. Set the Handle's single and dual rotation control knobs. Before introducing the endoscope, ensure the Handle is in the two-way position.
2. Pass the Loading catheter and Stainless steel cord through the biopsy channel of the endoscope, and confirm that the Loading catheter extends beyond the end of the endoscope. Withdraw and discard the Loading catheter from the end of endoscope, revealing the wire Loop of Stainless steel cord (Figure 17).
3. Slowly insert the Handle connector into the biopsy channel of the endoscope, ensuring that the Handle connector fits snugly with the biopsy channel port and secure it to the endoscope using a Band.

Note:

- (1)Olympus – Leave the rubber cap on the biopsy channel, pull up the plug on the cap, and then insert the Loading catheter and Handle connector (Figure 18a).
 - (2)Pentax – Remove the rubber cap from the biopsy channel, allowing the Loading catheter and Handle connector to pass through it. Insert the rubber cap along with the Handle as a single unit onto the biopsy channel's luer locking taper (Figure 18b).
 - (3)Fujinon – Insert the Loading catheter and Handle connector through the attached rubber cap into the endoscope's biopsy channel (Figure 18c).
4. Attach the Trigger cord to the wire Loop of Stainless steel cord and tighten it (Figure 19).
 5. Attaching the Barrel to the end of the endoscope channel, ensuring it is as close as possible to ensure a secure connection (Figure 20).

Note: Align the black Band on the Barrel with the endoscope's channel (Figure 21).

Warning: If the black Band on the Barrel is not aligned with the endoscope channel, the Trigger cord may not deploy correctly, affecting the release of the Loop and limiting the field of view.

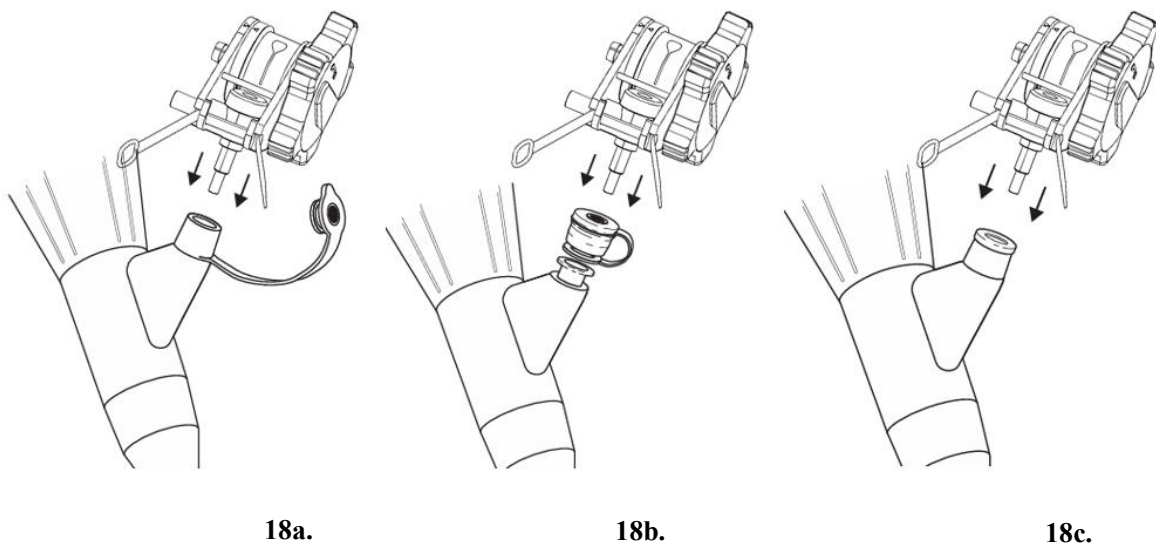
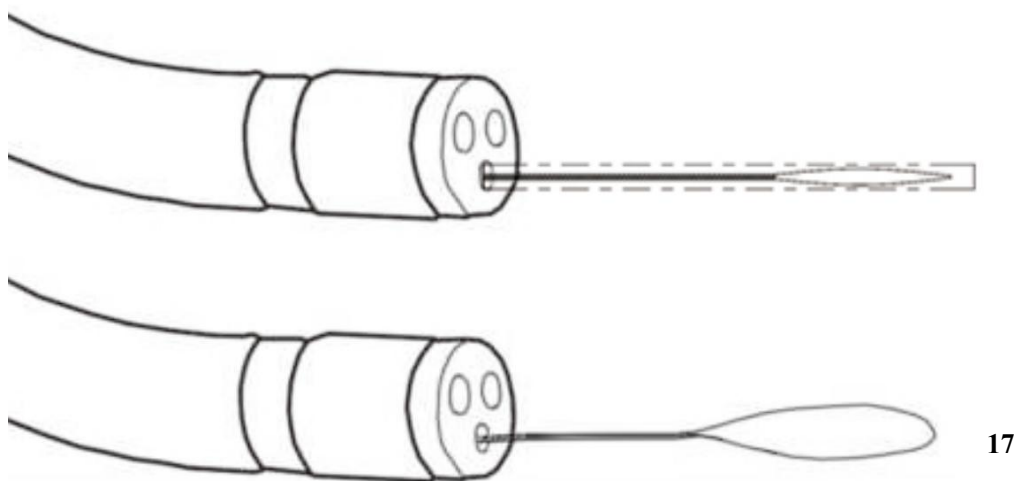
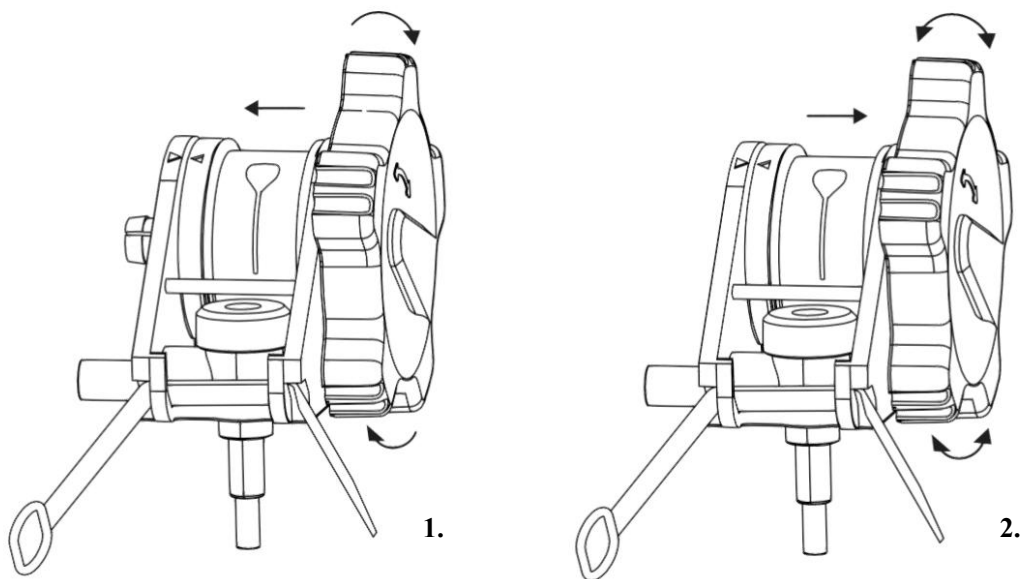
6. Set the rotation control position to the two-way position, turn the Handle clockwise to wind the Stainless steel cord onto the Handle shaft, and stop turning when you feel resistance. Then, set the rotation control position to the one-way position (Figure 22 and Figure 23).

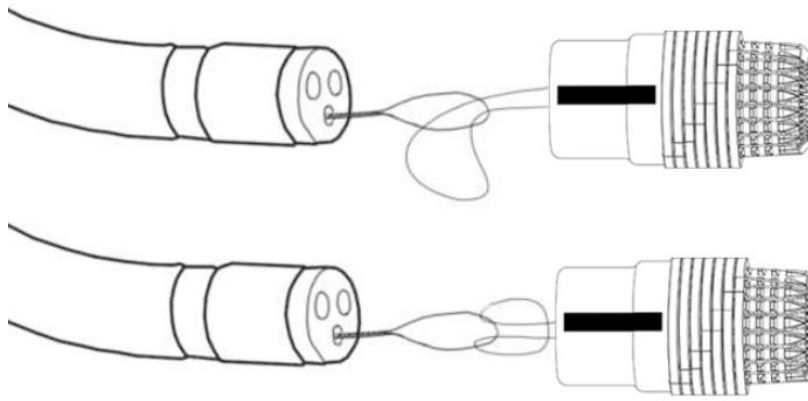
Note: Remove the heat shrink film from the Barrel.

7. Lubricate the exterior of the endoscope and Barrel.

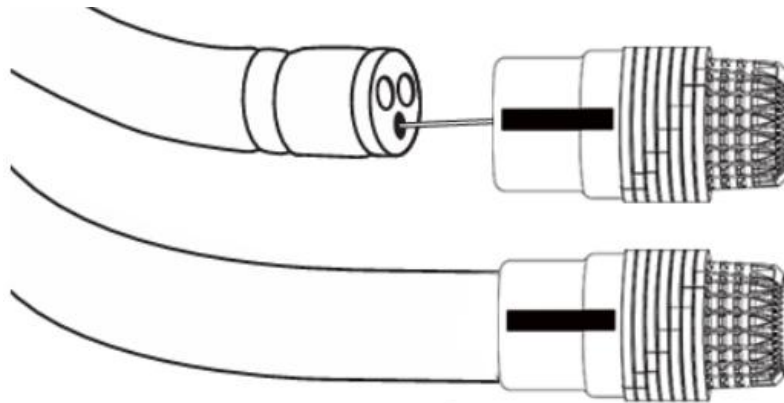
Note: Do not apply lubricant inside the Barrel.

Note: Do not use alcohol on the instrument.

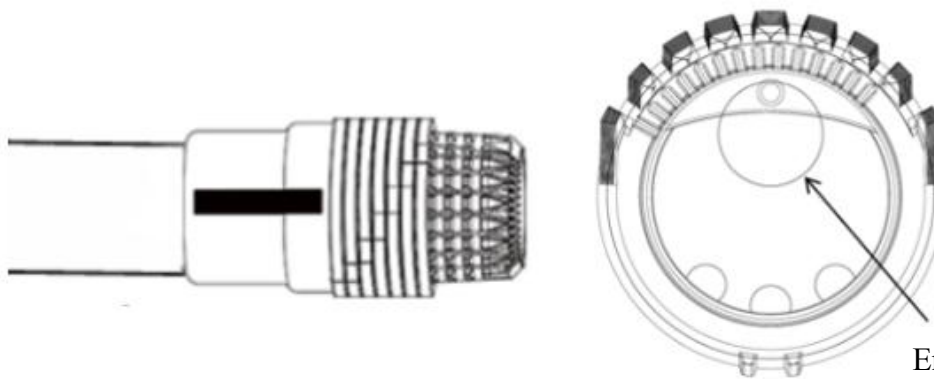




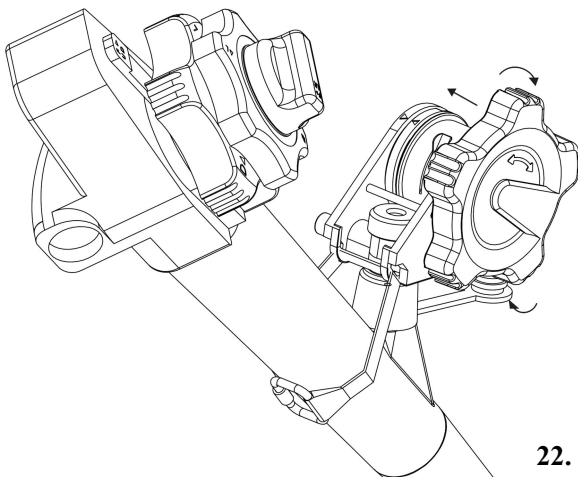
19.



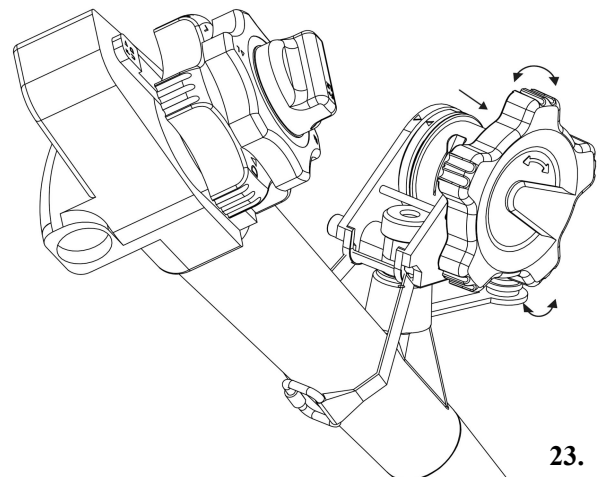
20.



Endoscope
channel 21.



22.



23.

PE cord-Type AP, APM

1. Set the Handle's single and dual rotation control knobs. Before introducing the endoscope, ensure the Handle is in the two-way position.
2. Slowly insert the Handle connector into the biopsy channel of the endoscope, ensuring that the Handle connector fits snugly with the biopsy channel port and secure it to the endoscope using a Band.

Note:

(1)Olympus – Leave the rubber cap on the biopsy channel, pull up the plug on the cap, and then insert the Loading catheter and Handle connector (Figure 24a).

(2)Pentax – Remove the rubber cap from the biopsy channel, allowing the Loading catheter and Handle connector to pass through it. Insert the rubber cap along with the Handle as a single unit onto the biopsy channel's luer locking taper (Figure 24b).

(3)Fujinon – Insert the Loading catheter and Handle connector through the attached rubber cap into the endoscope's biopsy channel (Figure 24c).

3. Insert one end of the Loading catheter into the white sealing gasket of the Multi-Band Ligator, advancing it in small increments until the other end of the Loading catheter extends from the endoscope channel (Figure 25).

4. Attach the Loading catheter through one end of the endoscope channel to the wire Loop of PE cord of the Multi-Band Ligator (Figure 26).

5. Pull the Loading catheter at the end of the endoscope until the wire Loop of PE cord is exposed, and then clip the wire Loop of PE cord onto the Handle shaft of the Multi-Band Ligator. Withdraw and discard the Loading catheter from the endoscope Handle channel entrance (Figure 27 and Figure 28).

6. Attach the Barrel to the end of the endoscope channel, ensuring it is as close as possible to ensure a secure connection (Figure 29).

Note: Align the black Band on the Barrel with the endoscope channel (Figure 30).

Warning: If the black Band on the Barrel is not aligned with the endoscope channel, the Trigger cord may not deploy correctly, affecting the release of the Loop and limiting the field of view.

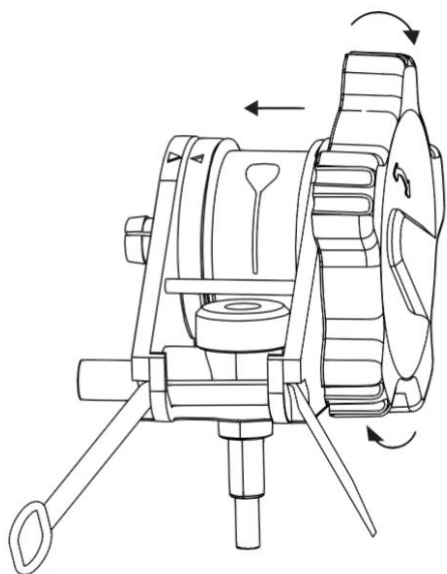
7. Set the rotation control position to the two-way position, turn the Handle clockwise to wind the Stainless steel cord onto the Handle shaft, and stop turning when you feel resistance. Then, set the rotation control position to the one-way position (Figure 31 and Figure 32).

Note: Remove the heat shrink film from the Barrel.

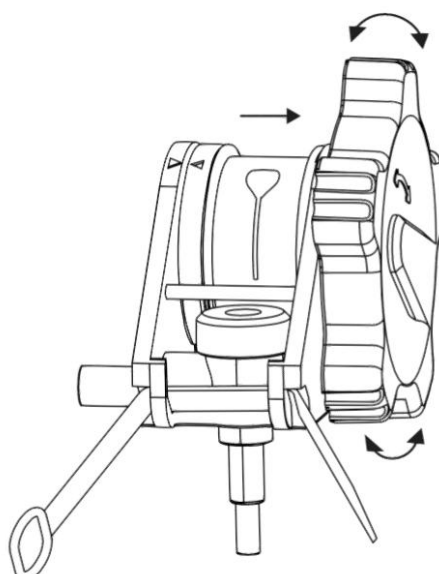
8. Lubricate the exterior of the endoscope and Barrel.

Note: Do not apply lubricant inside the Barrel.

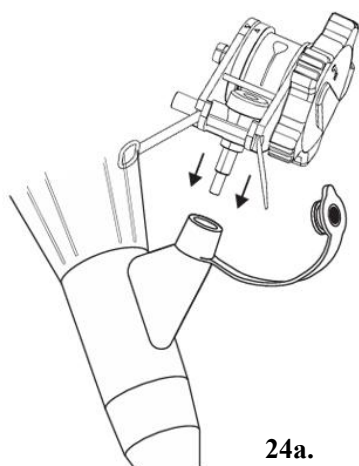
Note: Do not use alcohol on the instrument.



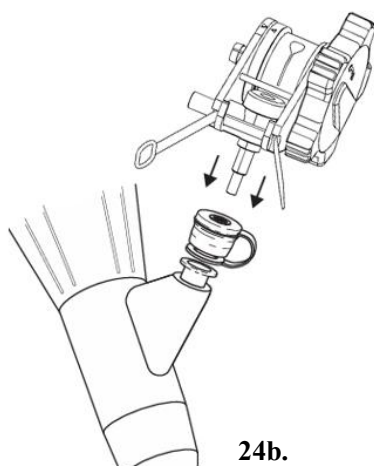
1.



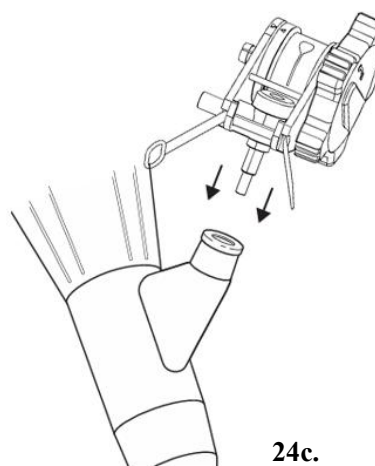
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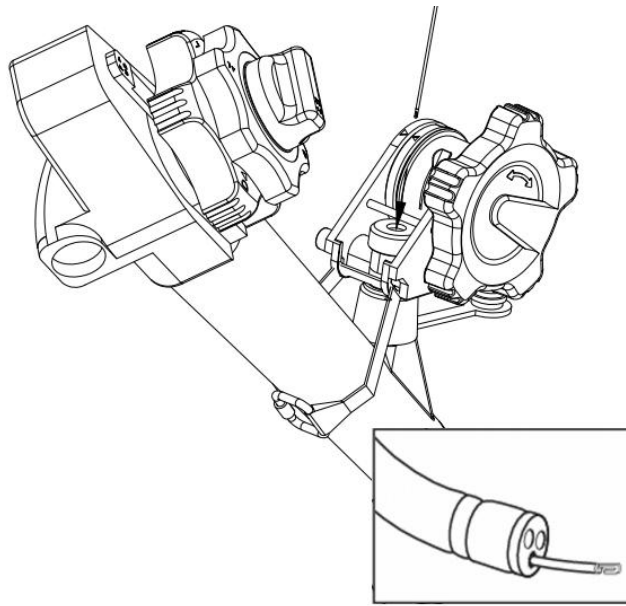
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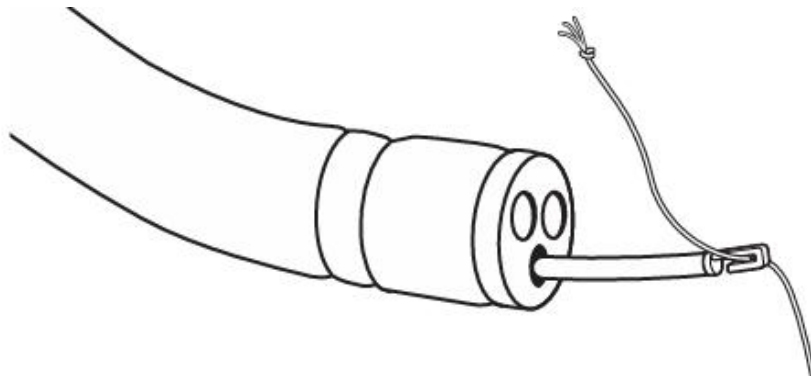
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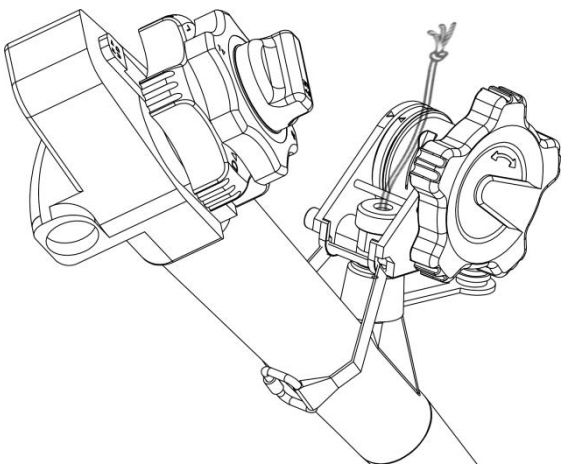
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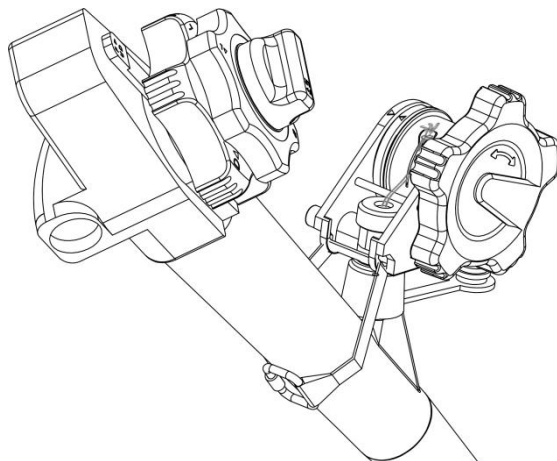
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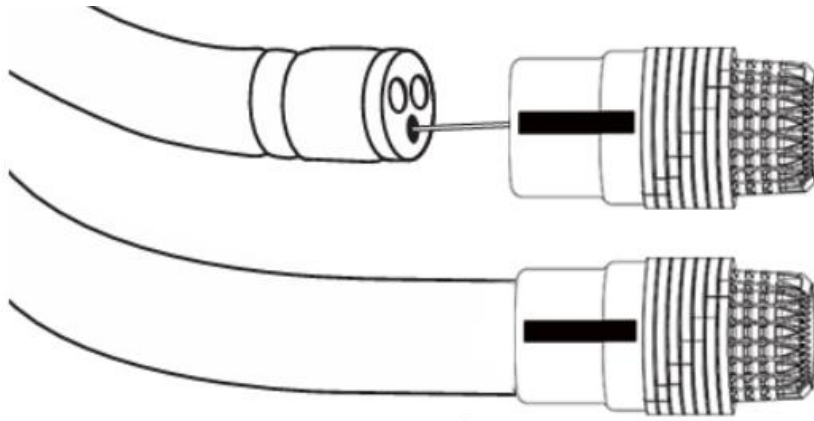
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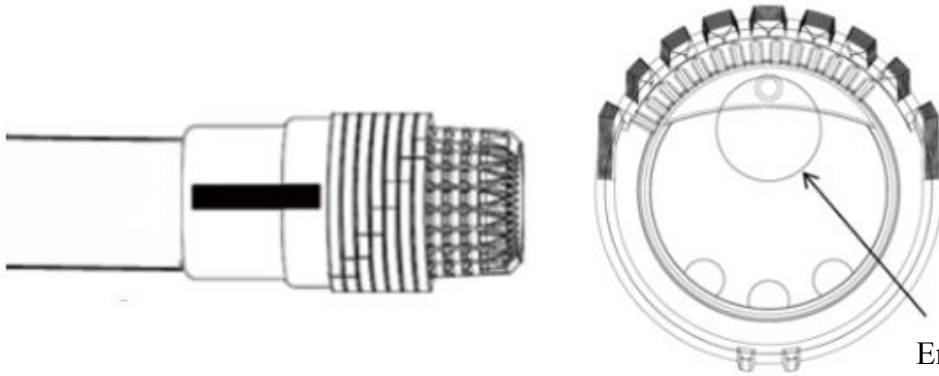
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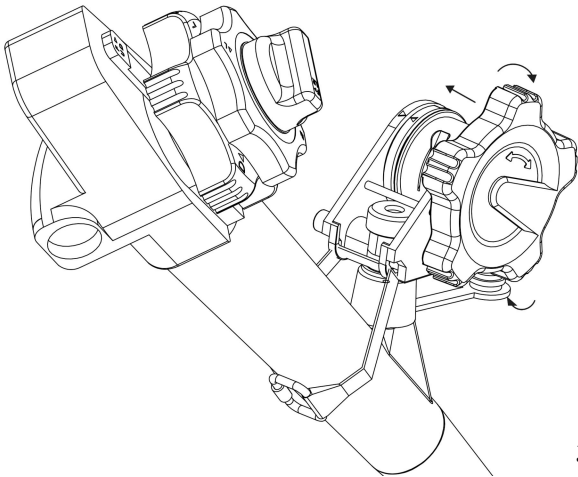
28.



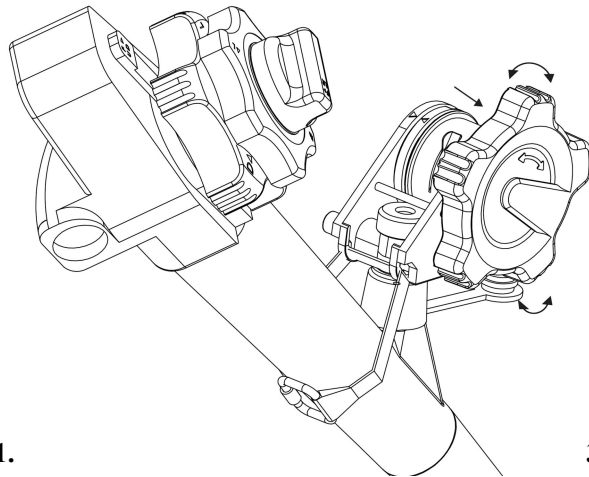
29.



Endoscope
channel 30.



31.



32.

【INSTRUCTIONS FOR USE】

Instructions for use of esophageal varices veins ligation

1. Insert the endoscope into the esophagus. After insertion, set the Handle to the firing position.

2. Observe the selected varicose veins and suction it into the Barrel.

Note: Before releasing the Loop, the endoscopist's hand must be on the Handle of the instrument, not on the endoscope controls.

3. While maintaining suction, release the Loop—rotate the Handle clockwise until you feel the Loop has been released, this indicates that the Loop has been released (models Sound alert type).

Note: If the Loop does not release, set the Handle to the two-way position and slightly loosen the cord. Then, set the Handle back to the firing position and continue.

4. Release the endoscope suction button, inflate air, and slightly withdraw the endoscope to release the ligated varicose veins.

Note: Each instrument includes an Irrigation adapter. If you need to flush the biopsy channel to clean the view, connect the Irrigation adapter to a syringe filled with sterile water and insert it into the white sealing gasket on the Handle. Flush when necessary.

Note: Biopsy channel flushing can also be performed using the irrigation device attached to the side Irrigation adapter of the Handle to maintain a clear view.

5. Repeat the ligation as needed.

Note: To control acute bleeding, multiple Loops may be required for each varicose vein.

6. If more ligation is needed, remove the endoscope and install a new device.

Instructions for use of internal hemorrhoid ligation

Note: Prior to assembling and using the device, a flexible sigmoidoscopy must be performed on the hemorrhoid site.

1. Insert the endoscope into the rectum.

2. Examine the internal hemorrhoids with the endoscope, first selecting the largest one. Set the Handle to the firing position and then suction the internal hemorrhoid into the Barrel. Before releasing the Loop, ensure the endoscopist's hand is on the instrument Handle, not on the endoscope controller (Figure 33).

3. Maintain suction on the internal hemorrhoid while releasing the Loop—rotate the Handle clockwise until you feel the Loop has been released, this indicates that the Loop has been released

(models Sound alert type).

Note: If the Loop does not release, set the Handle to the two-way position and slightly loosen the cord. Then set the Handle back to the firing position and continue.

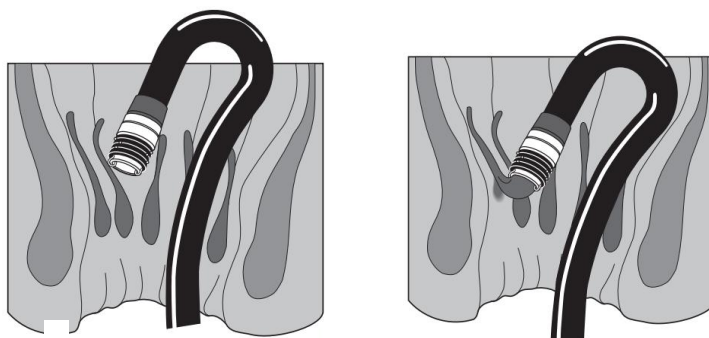
4. Release the endoscope suction button, inflate air, and slightly withdraw the endoscope to release the ligated internal hemorrhoid.

Note: Each instrument includes an Irrigation adapter. If you need to flush the biopsy channel to clean the view, connect the Irrigation adapter to a syringe filled with sterile water and insert it into the white sealing gasket on the Handle. Flush as necessary.

Note: Biopsy channel flushing can also be performed using the irrigation device attached to the side Irrigation adapter of the Handle to maintain a clear view.

5. Repeat the ligation process as needed.

6. If more ligation is needed, remove the endoscope and install a new device.



33.

Steps for Disassembling the Multi-Band Ligator

1. After completing the ligation, remove the endoscope from the patient.

2. Disassemble the instrument as follows:

If all Loops have been fired:

- Remove the Handle and associated cord from the biopsy channel.
- Remove the Barrel from the endoscope's head.

If there are un-fired Loops left on the Barrel:

- Set the Handle to the two-way position.
- Remove the Barrel from the endoscope's head, cut the Trigger cord, and then pull the associated cord through the channel to remove it from the endoscope's head.

【WASTE DISPOSAL】

After use, dispose of the product and packaging in accordance with institutional rules and

policies/relevant regulations, otherwise it may cause environmental pollution or human hazards.

【DATE OF MANUFACTURE】

See the label on product external package.




















【EXPIRATION DATE】

Valid for 2 years from date of manufacture.

【STORAGE AND TRANSPORTATION CONDITIONS】

The product should be protected from heavy pressure, direct sunlight, and rain during transportation. It should be stored indoors, avoiding direct sunlight, in a clean, well-ventilated environment free from corrosive gases.

【SYMBOLS DESCRIPTION】

	Manufacturer		Authorized representative in the European Community
	Date of manufacture		Expiration date
	Lot number		Catalogue number
	Do not use if primary package is damaged		Do not re-use
	Consult instructions for use		Medical device
	Unique device identifier		CE marking
	Keep away from sunlight		Keep away from rain
	Caution		Stacking layers Limit
	Endoscopic channel diameter		Contains natural rubber
	Non-sterile		

【CONTACT INFORMATION】



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