

## SINGLE USE LIGATING DEVICE HX-400U-30



### 1 Symbols



Refer to instructions.



Single use only



Use by (expiration date)



Sterilized using ethylene oxide



Sterilization lot number



Lot number



Manufacturer



Authorized representative in the  
European Community



Keep away from sunlight



Importer  
(into European Union)



Do not resterilize



Keep dry



Not Made with Natural Rubber Latex



Do not use if package is damaged



Temperature limitation

*For US Customers only*

For a Symbols Glossary, visit us: <http://www.olympus-global.com/en/common/pdf/symbolsglossary.pdf>

### 2 Intended Use

This instrument has been designed to be used with an Olympus endoscope to deliver a nylon loop snare designed to prevent or control bleeding following polypectomy of pedunculated polyps. Do not use this instrument for any purpose other than its intended use.

### 3 Instruction Manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed. If you have any questions or comments about any information in this manual, please contact Olympus.

### 4 User Qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

### 5 Signal Words

#### **WARNING**

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

#### **CAUTION**

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

#### **NOTE**

Indicates additional helpful information.

### 6 Warnings, Cautions and Notes

Follow the warning, cautions and notes described below when handling this instrument. This information is supplemented by the warnings, cautions and notes described in each section.

### WARNING

- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the loop cannot be detached from the instrument or if any other unexpected circumstance takes place. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this manual.
- Use this instrument in an environment equipped to accommodate open surgery and have the hospitalization plan prepared in case any problem occurs that may not be resolved endoscopically.

### CAUTION

- Published literature has described the occurrence of shallow ulcers at the ligation site following procedures. Ligating of gastric lesions may require further medical treatment of the patient.
- In order to prevent the ligator loop from slipping off, care should be taken to ensure that there is adequate space remaining above the loop.
- According to the published literature, the most-frequent complication following polypectomy is bleeding. Risk is increased in patients who are on anti-coagulant or NSAID therapy.
- According to the published literature, patients who have had previous bowel surgery could be at risk of bowel obstruction when the loop becomes detached (up to 14 days after placement).

### NOTE

- According to the published literature, additional measures, such as clipping above the ligation site, may be required to hold the ligator in place.
- According to the published literature, the loop may be used on elevated lesions up to 40 mm in diameter.

## 7 Nomenclature and Functions

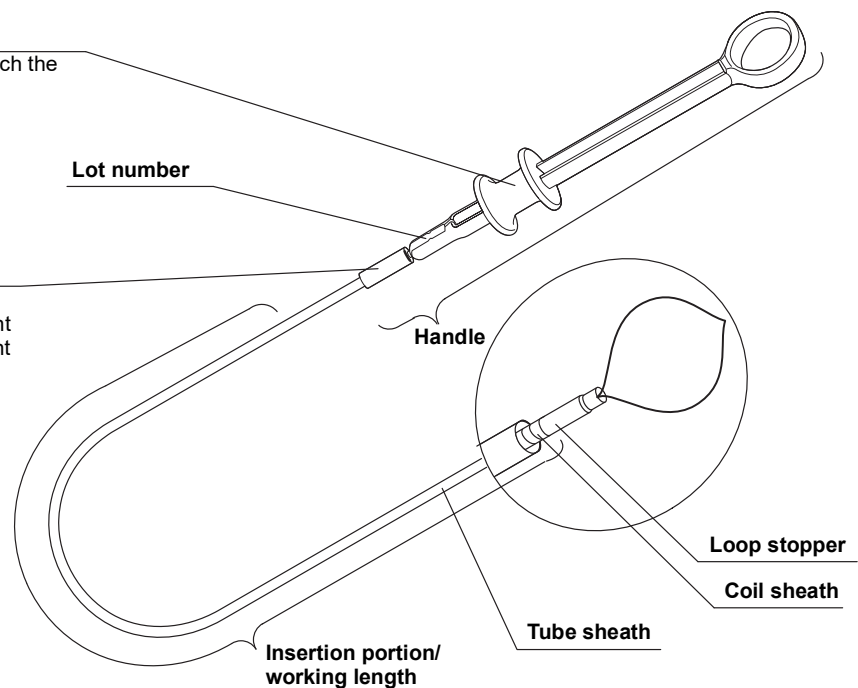
### Slider

To close the loop, pull the slider. To detach the loop, push the slider.

Lot number

### Tube joint (Yellow)

To retract or extend the loop into or out from the tube sheath, move the tube joint back and forth. The color of the tube joint indicates the minimum instrument channel diameter required for the endoscope to be compatible.



## 8 Specifications


### WARNING

- Use this instrument only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient or operator injury, malfunction and/or equipment damage may result.
- Do not use this instrument with an Olympus SIF endoscope. Depending on the endoscope's position inside the patient, the slider may be weighed down and the loop may not be able to detach from the instrument after ligation.
- Do not use this instrument with an endoscope equipped with a forceps elevator. When using the instrument with a two channel endoscope, never insert this instrument into the channel with a forceps elevator. Raising the forceps elevator may cause the slider to be weighed down and the loop may not be able to detach from the instrument after ligation.

### 8.1 Operating environment

Ambient temperature: 10 – 40°C (50 – 104°F), Relative humidity: 30 – 85%,  
Air pressure: 700 – 1060 hPa (0.7 – 1.1 kgf/cm<sup>2</sup>) (10.2 – 15.4 psia)

## 8.2 Compatible endoscopes

<b>Model</b>		<b>HX-400U-30</b>
<b>Working length (mm)</b>		2300
<b>Maximum insertion portion diameter (mm)</b>		ø 2.6
<b>Opening width (mm)</b>		30
<b>Compatible Olympus endoscopes</b> (All of these parameters should be met)	<b>Length and model</b>	Working length less than 1850 mm; GIF, OGF, CF, PCF, OSF
	<b>Channel inner diameter (mm) (color code)</b>	ø 2.8, ø 3.2 (Yellow), ø 3.7, ø 4.2, ø 6 (Orange)
	<b>Other</b>	Direction of view: 0° (Forward viewing type) only
<b>Medical Devices Directive</b>		This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a
		

## 9 Storage

### WARNING

Do not store the sterile package containing the instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised which could pose an infection control risk and/or cause tissue irritation.

Store the instrument in the sterile package at room temperature in a clean and dry environment. Do not store it in direct sunlight.

## 10 Preparation, Inspection and Operation

### WARNING

- When inspecting or using the instrument, always wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Otherwise, blood, mucus and other potentially infectious material from the patient could pose an infection control risk and/or cause skin-irritation.
- Do not use an instrument after the expiration date displayed on the sterile package. Doing so may pose an infection control risk or cause tissue irritation.
- Before use, prepare and inspect the instrument as instructed below. Should the slightest irregularity be suspected, do not use the instrument; use a spare instead. Damage or irregularity may compromise patient or user safety, pose an infection control risk, cause tissue irritation, punctures, hemorrhages or mucous membrane damage and may result in more severe equipment damage.
- Do not strike or crush the coil sheath during operation. Doing so can damage the distal end of the coil sheath, which could make it impossible to detach the loop after ligation. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this manual.

### CAUTION

- Do not coil the insertion portion with a diameter of less than 20 cm. This could damage the insertion portion.
- Never use excessive force to operate the instrument. This could damage the instrument.

### 10.1 Preparation

#### ○ Spare instrument

Always have a spare instrument available.

#### ○ Equipment to be used in an emergency

Always have the Olympus loop cutter (FS-5L/Q/U-1), pliers and/or wire cutters ready to cut the coil sheath, tube sheath and operation wire in case the loop cannot be detached from the instrument.

### 10.2 Inspection

Wear appropriate personal protective equipment in accordance with their respective instruction manuals. If an abnormality in the instrument is detected, use a spare instrument.

#### **Inspection of the sterile package**

### WARNING

Do not attempt to sterilize the instrument. This could pose an infection control risk, cause tissue irritation, equipment damage or malfunction.

Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised. Do not use the instrument.

## Appearance inspection

### WARNING

Do not use the instrument if its coil sheath is damaged. If a damaged instrument is used, it may not be possible to extend the hook after ligature, making it impossible to remove the loop.

1. Make sure that the distal end of the coil sheath has no deviations or crushed sections.
2. Gently run your fingertips over the entire length of the insertion portion to check for any folds, crushed areas, excessive bends, broken areas or other damages.

Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised.

### NOTE

The tube sheath is a delicate component. If you use a tube sheath that has a fold in it, there will be increased friction between the stopper and the tube sheath, making it difficult to extend the loop.

3. Confirm that there are no sharp protrusions, burrs or edges on the distal end of the insertion portion.
4. Make sure that there are no cracks on the handle.

## 10.3 Operation

### WARNING

- When using the instrument, always wear appropriate personal protective equipment. Otherwise, blood, mucus and other potentially infectious material from the patient could pose an infection control risk.
- Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view, do not use it. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not angulate the bending section of the endoscope abruptly while the distal end of the insertion portion is extended from the distal end of the endoscope. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Make sure that the tissue is sufficiently ligated if it is to be resected after the ligature. If not sufficiently ligated, it could cause patient injury, such as hemorrhages or mucous membrane damage during or after the operation.
- When the tissue is to be resected using an electrocautery snare after ligature, make sure that the electrocautery snare and loop are not in contact with each other before activating the output. If the output is activated when the electrocautery snare and loop are in contact as shown in Figure 1, the loop could be cut, resulting in patient injury, such as hemorrhages or mucous membrane damage. It may also fuse the loop and electrocautery snare together, preventing removal of the electrocautery snare.

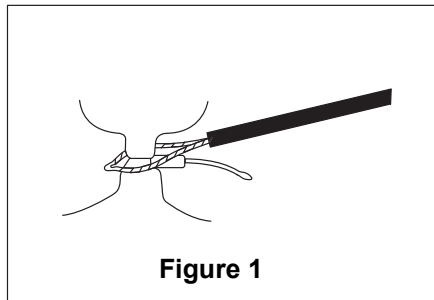


Figure 1

### CAUTION

When using the instrument with a two channel endoscope, never use electrocautery accessories at the same time. This could cause patient, operator or assistant injury, such as thermal injury.

## Inserting into the endoscope

### WARNING

- Do not insert the instrument into the endoscope if the loop is not completely retracted into the tube sheath. Otherwise, patient injury, such as punctures, hemorrhages or mucous membrane damage may result. It could also damage the endoscope and/or instrument.
- Do not advance or extend the instrument abruptly. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope and/or instrument.
- Do not force the instrument if resistance to insertion is encountered. Reduce the angulation of the endoscope until the instrument passes smoothly. Attempting to force the instrument could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It could also damage the endoscope and/or instrument.

## CAUTION

- When inserting the instrument into the endoscope, hold it close to the biopsy valve and keep it as straight as possible relative to the biopsy valve. Otherwise, the insertion portion could be damaged.
- Do not push the slider when inserting the instrument. The loop may come off the hook and get stuck inside the instrument channel of the endoscope.

1. Push the tube joint distally to retract the loop into the tube sheath.
2. Make sure the entire loop is retracted into the tube sheath.
3. Carefully insert the instrument into the biopsy valve.
4. Advance the instrument until the distal end of the insertion portion appears within the endoscopic field of view.

## Ligating tissue

### WARNING

- Do not force the distal end of the insertion portion against body cavity tissue. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not extend the loop abruptly from the distal end of the insertion portion. Also maintain a sufficient distance between the distal end of the insertion portion and the mucous membrane when extending the loop from the tube sheath. Otherwise, patient injury, such as punctures, hemorrhages or mucous membrane damage may result.
- Do not withdraw the instrument or change the angulation of the endoscope before the loop is detached from the instrument. Doing so may tear tissue inside the body cavity, resulting in patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not apply unnecessary force to the loop when ligating tissue during the procedure. Excessive force applied to the loop could cut the surrounding body cavity tissue, resulting in patient injury, such as hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not try to forcibly remove the loop if it becomes caught on the distal end of the coil sheath. Forcible removal of the loop could cause patient injury such as punctures, hemorrhages or mucous membrane damage.
- Do not pull the slider before surrounding the target tissue with the loop. Otherwise, the loop stopper would be dislodged.
- Do not extend the hook from the coil sheath abruptly. This could cause patient injury, such as punctures, hemorrhages, or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Do not hold the loop with the distal end of the tube sheath while the loop is surrounding the tissue (see Figure 2). Otherwise, when the tissue is ligated, the loop may be detached from the hook in the tube sheath and tangled with the hook. That may make the loop impossible to be removed. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this manual .

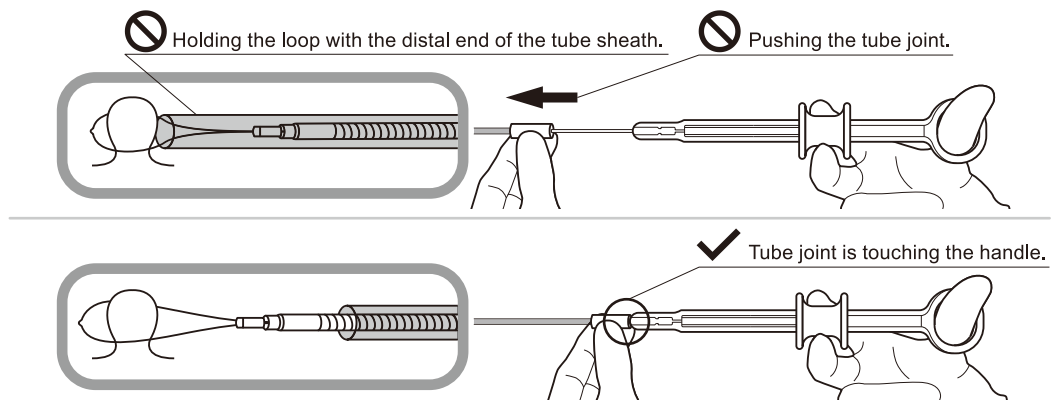
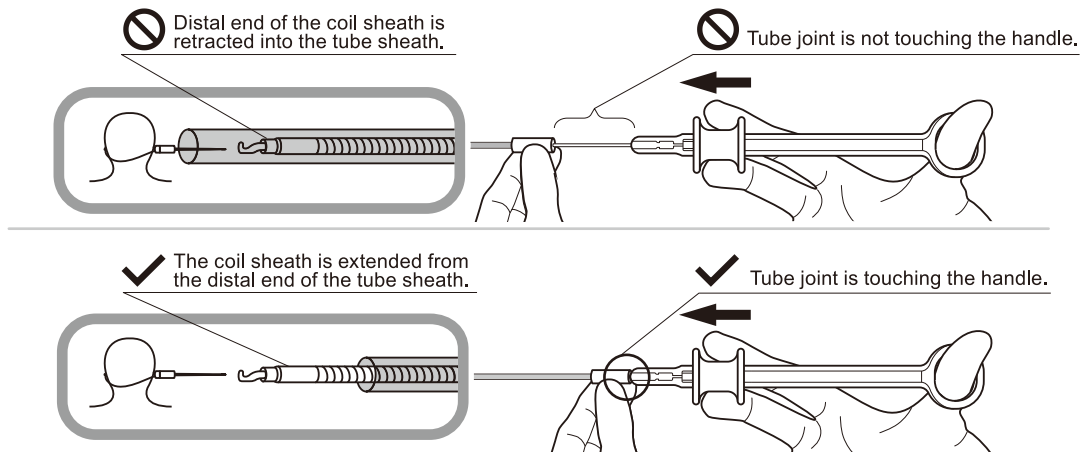


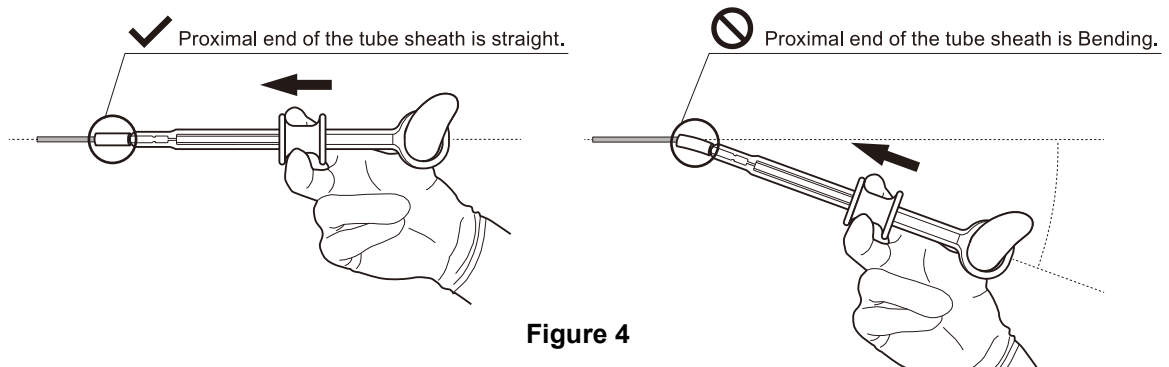
Figure 2

**WARNING**

- Do not remove the loop from the hook while the coil sheath is not extended from the tube sheath (see Figure 3). Otherwise, the loop may be tangled with the hook and become impossible to be removed. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this manual.

**Figure 3**

- With the proximal end of the tube sheath and handle kept straight against the biopsy valve of the endoscope, push the slider when detaching the loop (see Figure 4). Bending the proximal end of the tube sheath will increase frictional resistance, which may damage the handle when pushing the slider. In this case, refer to Section 12, "Emergency Treatment" and as shown "Equipment to be used in an emergency" on page 3 in this manual.

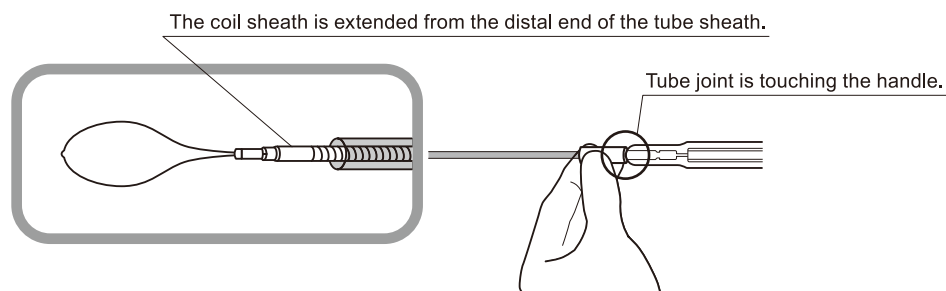
**Figure 4****CAUTION**

If the loop does not extend when the tube joint is pulled, straighten the angulated distal end of the endoscope until the loop can be extended smoothly. Otherwise, the endoscope and/or instrument may be damaged.

**NOTE**

Any unnecessary parts of the loop can be cut using the Olympus loop cutter (FS-5L/Q/U-1).

- To ligate the target tissue, angulate the endoscope and/or advance the instrument the required distance.
- Pull the tube joint until it touches the handle to extend the loop from the tube sheath (see Figure 5).

**Figure 5**

- Confirm the endoscopic field of view to see that the coil sheath is extended from the distal end of the tube sheath.

**NOTE**

When operating the tube joint, be careful not to move the slider.

4. Surround the tissue with the open loop.
5. Pull the slider to ligate the target tissue.
6. Push the slider until it stops to extend the hook from the coil sheath. Detach the loop from the hook.

### ***Withdrawing the instrument from the endoscope***

#### **WARNING**

Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucus and other patient debris and pose an infection control risk.

#### **CAUTION**

Do not withdraw the instrument from the endoscope if the coil sheath is not completely retracted into the tube sheath. This could damage the endoscope .

1. Pull the slider to retract the hook into the coil sheath and push the tube joint to retract the coil sheath into the tube sheath.
2. Withdraw the instrument from the endoscope.

## ***11 Disposal***

#### **WARNING**

- After use, dispose of the instrument in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.
- The instrument is a single-use, disposable item . Do not reuse or attempt to sterilize it. Reusing the instrument could pose an infection control risk, cause tissue irritation or malfunction.

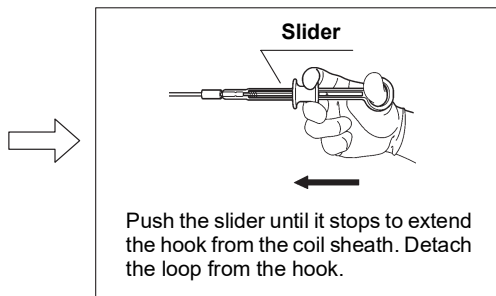
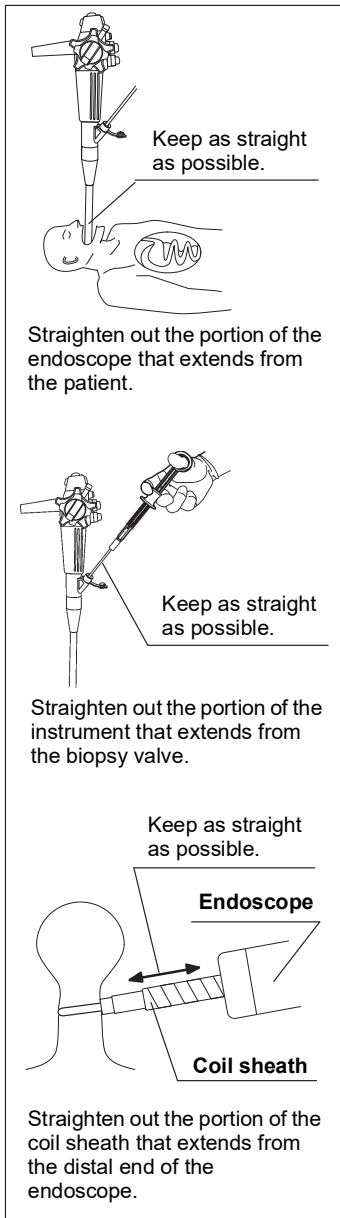
After using the instrument, dispose of it in an appropriate manner.

## ***12 Emergency Treatment***

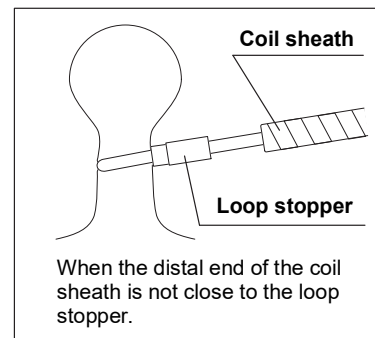
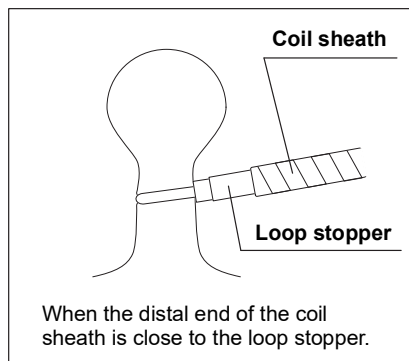
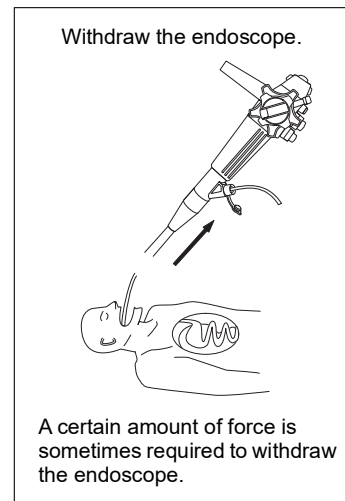
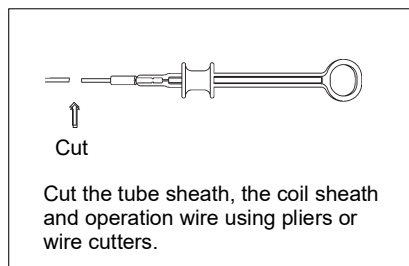
#### **WARNING**

Do not try to forcibly withdraw the instrument from the endoscope when the loop cannot be detached from the instrument. Forcibly withdrawing the instrument could cause patient injury such as punctures, hemorrhages or mucous membrane damage.

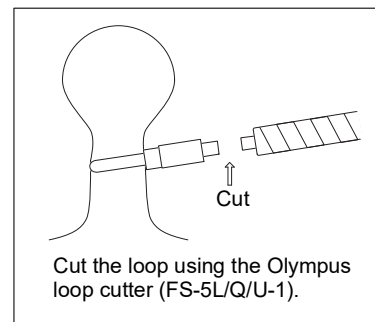
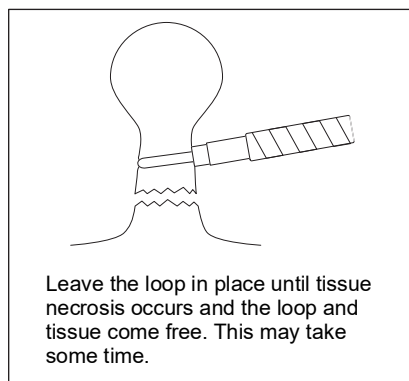
If the loop cannot be detached from the instrument, follow the procedures described in this section. If there are any deviations or crushed sections on the distal end of the coil sheath, it may not be possible to detach the loop from the instrument.



When the loop cannot be detached from the instrument.



Insert the endoscope again along the tube sheath.



Withdraw the tube sheath, coil sheath and operating wire together.

Perform open surgery or other possible treatment.

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