OLYMPUS®

INSTRUCTIONS

OLYMPUS
EndoTherapy

Rotatable Clip Fixing Device
HX-110LR HX-110QR HX-110UR

Clip
HX-610-090 HX-610-135

Long Clip
HX-610-090L

Short Clip
HX-610-090S HX-610-135S

Colored Short Clip
HX-610-090SC

AUTOCLAVABLE

CE 0197

Contents

Symbols

The meaning(s) of the symbol(s) shown on the package, the back cover of this instruction manual and/or this instrument are as follows:

Refer to instructions.

Single use only

Use by (expiration date)

Sterilized using irradiation

Sterilization lot number

Lot number

Manufacturer

Authorised representative in the European Community

Important Information – Please Read Before Use

Intended Use

This instrument has been designed to be used with an Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of

(1) endoscopic marking,

(2) hemostasis for

  (a) mucosal/sub-mucosal defects < 3 cm,

  (b) bleeding ulcers,

  (c) arteries < 2 mm,

  (d) polyps < 1.5 cm in diameter,

  (e) diverticula in the colon,

(3) as a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

Do not use this instrument for any purpose other than its intended uses.

NOTE

Due to the range of procedures, the indications for use of this instrument should be evaluated by the physician, taking into account factors such as the anatomical site, histology, lesion type and the patient's condition. In addition, the cautions and notes contained in "Warnings, Cautions and Notes" on page 5 should be thoroughly reviewed before starting the procedure.

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.
Keep this and all related instruction manuals in a safe, accessible location.
If you have any questions or comments about any information in this manual, please contact Olympus.

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.

Instrument Compatibility

Refer to the tables in Section 2.2, “Specifications” to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury or equipment damage.

Reprocessing and Storage

This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 5, “Reprocessing”.

After using this instrument, reprocess and store it according to the instructions given in Chapter 5, “Reprocessing” and Chapter 6, “Storage”. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

Clips are shipped in a sterile condition. Store them following the instructions given in Chapter 6, “Storage”. Improper storage can present an infection control risk, cause equipment damage or reduce performance.

All clips are single-use, disposable items that are not to be reprocessed after use. Do not reuse or attempt to sterilize them after use.

Repair and Modification

This instrument and clip do not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair them; patient or user injury and/or equipment damage can result.

Signal Words

The following signal words are used throughout this manual:

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.

Warnings, Cautions and Notes

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

WARNING

- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or if any other unexpected circumstance takes place. In this case, refer to Chapter 4, “Emergency Treatment”.

- It might be impossible to stop bleeding depending on the hemorrhage situation because the clip performance for hemostasis is limited. Prepare more than one hemostatic device and select appropriate hemostatic device or use it together to respond to different hemorrhage situations appropriately. Choose a surgical hemostasis if necessary.
- Re-bleeding may occur on the clipping site, depending on the local condition. Check the patient for any re-bleeding after the operation as appropriate.

CAUTION

- Do not use this instrument when hemostasis cannot be verified visually within the endoscopic field of view after application.
- Do not perform MRI procedures on patients who have clips placed within their gastrointestinal tracts. This could be harmful to the patient.

NOTE

- Limited studies indicate that lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with a forward-viewing endoscope.
- Limited studies indicate that the treatment of esophageal varices may require clipping in combination with a sclerosing agent.
- Limited studies indicate that clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.

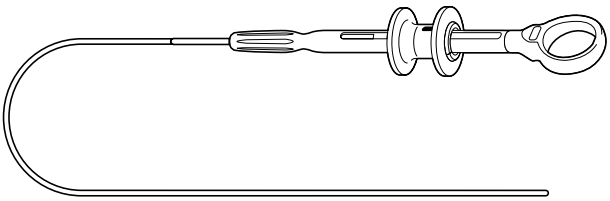
- Limited studies have shown that the number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type and patient condition and history. A sufficient quantity of clips should be prepared in consideration of all of these factors prior to the procedure.
- Limited studies indicate that the hemostasis clips remain in place for an average of 9.4 days; re-bleeding may occur if the clips detach within 24 hours.
- Limited studies indicate that the use of clips in the presence of bacterial contamination may potentiate or prolong infection.

Chapter 1 Checking the Package Contents

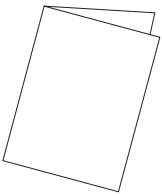
1.1 Checking the Package Contents

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument or clip is damaged, a component is missing or you have any questions, do not use the instrument or clip; immediately contact Olympus.
This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in Chapter 5, “Reprocessing”.

❍ Rotatable Clip Fixing Device

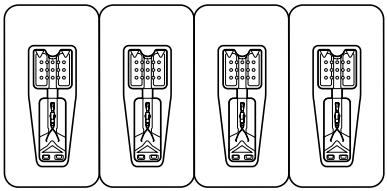


Rotatable clip fixing device (Reusable)

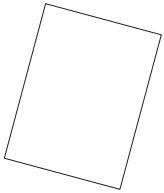


Instruction manual

❍ Clip (HX-610-090 or HX-610-135)



Clip (Sterile, single use only, 40 pieces)



Access information sheet

❍ Long Clip (HX-610-090L)

Long clip (Sterile, single use only, 40 pieces)
Access information sheet

❍ Short Clip (HX-610-090S or HX-610-135S)

Short clip (Sterile, single use only, 40 pieces)
Access information sheet

❍ Colored Short Clip (HX-610-090SC)

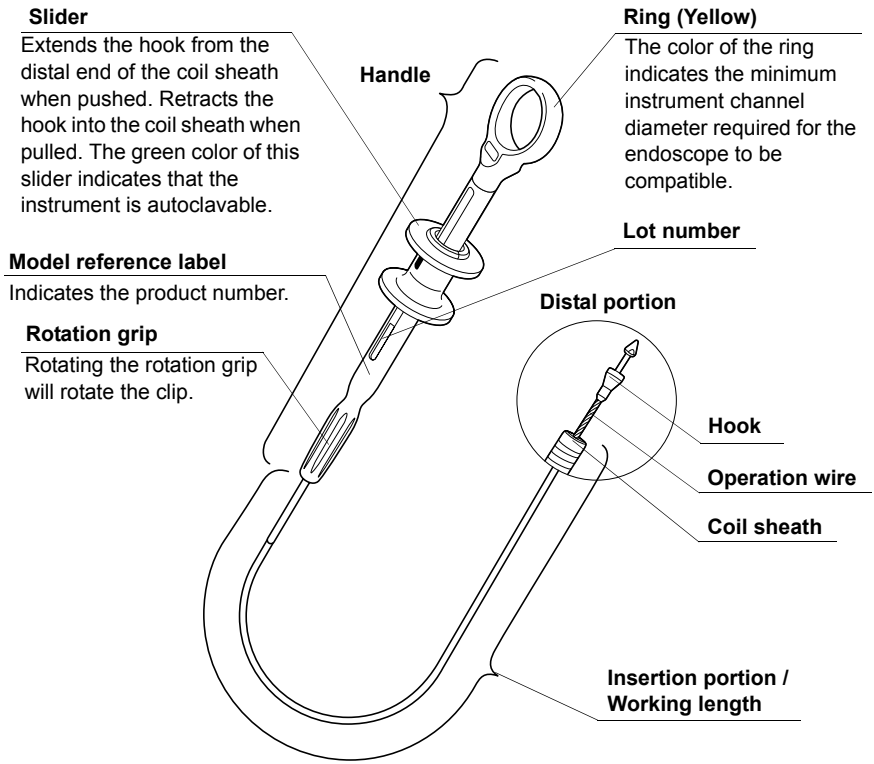
Colored short clip (Sterile, single use only, 24 pieces)
Access information sheet

Chapter 2 Instrument Nomenclature and Specifications

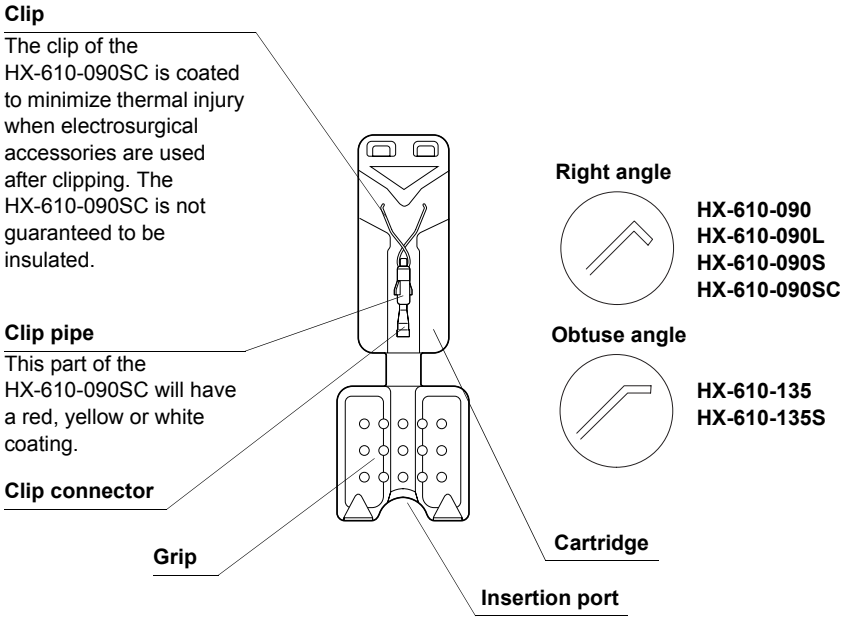
2.1 Nomenclature and Functions

This instrument must be used in combination with the clip.

❍ Rotatable Clip Fixing Device (Reusable)



❍ Clip (Single use only)



2.2 Specifications

The compatible Olympus endoscopes are listed in the tables on the following pages. New endoscopes released after the introduction of this instrument and clip may also be compatible for use in combination with this instrument and clip. For further details, contact Olympus.

WARNING

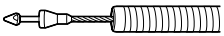
Use this instrument and clip only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient or operator injury, malfunction or equipment damage may result.

Operating Environment

Ambient Temperature	10 to 40°C (50 to 104°F)
Relative Humidity	30 to 85%
Air Pressure	700 to 1060 hPa (0.71 to 1.08 kgf/cm^2) (10.1 to 15.4 psia)

Specifications

Model		**HX-110LR**	**HX-110QR**
Shape of the distal end of the insertion portion			
Maximum insertion portion diameter (mm)		ø 2.75	
Working length (mm)		1650	1950
Compatible Olympus endoscopes (All of these parameters should be met.)	**Length and model**	Working length less than 1200 mm; EF, GIF, OGF, CF (Exclude I-, L-length), OSF	Working length less than 1500 mm; EF, GIF, OGF, CF (Exclude L-length), PCF (I-length only), OSF
	Channel inner diameter (mm) (Color code)	ø 2.8, ø 3.2 (Yellow); ø 3.7, ø 6 (Orange)	ø 2.8, ø 3.2 (Yellow); ø 3.7, ø 4.2, ø 6 (Orange)

Model		HX-110UR
Shape of the distal end of the insertion portion		
Maximum insertion portion diameter (mm)		ø 2.75
Working length (mm)		2300
Compatible Olympus endoscopes (All of these parameters should be met.)	**Length and model**	Working length less than 1850 mm; EF, GIF, OGF, CF, PCF, SIF (SIF-10 only)
	Channel inner diameter (mm) (Color code)	ø 2.8, ø 3.2 (Yellow); ø 3.7, ø 4.2, ø 6 (Orange)

Model	HX-610-090	HX-610-135
Shape of the clip		
Color of the packages	Yellow	Pink
Clip arm length	Standard	
General application	Hemostasis	

Model	HX-610-090L
Shape of the clip	
Color of the packages	Blue
Clip arm length	Long
General application	Hemostasis (for large tissue retention)

Model	HX-610-135S
Shape of the clip	
Color of the packages	Green
Clip arm length	Short
General application	Hemostasis (for smaller tissue retention)

Model	HX-610-090SC	HX-610-090S
Shape of the clip		
Color of the packages	Red White Yellow	White
Clip arm length	Short	
General application	Marking (for smaller tissue retention)	

Medical Device Directive CE 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a

Chapter 3 Preparation, Inspection and Operation

The clips were shipped in a sterile condition.

WARNING

- Do not use the clips after the expiration date displayed on the sterile package. Doing so may pose an infection control risk or cause tissue irritation.
- Before each case, prepare and inspect the instrument and clip as instructed below. Inspect other equipment to be used with the instrument and clip as instructed in their respective instruction manuals. Should the slightest irregularity be suspected, do not use the instrument or clip; contact Olympus.
  Damage or irregularity may compromise patient or user safety by, for example: posing an infection control risk, causing tissue irritation, perforation, bleeding or mucous membrane damage. It may also result in more severe equipment damage.
- The instrument was not sterilized before shipment. Before using the instrument for the first time, reprocess it according to the instructions in Chapter 5, “Reprocessing”.
  Do not use an instrument that has not been cleaned and sterilized. This poses an infection control risk or can cause tissue irritation.

- Before use, inspect several coil sheaths as instructed and make sure they are not crushed, bent or deformed. Do not use the clip fixing device if the coil sheath is damaged.
- Do not strike or crush the coil sheath during operation or reprocessing. Doing so can damage the distal end of the sheath, which could cause make it impossible to detach the clips after hemostasis. If a clip cannot be detached during use, follow the instructions given in Chapter 4, “Emergency Treatment”.
- Before use, confirm that the hook is not corroded, dented or discolored; do not use the instrument if any of these conditions are observed. A damaged hook may fall off the instrument’s distal end.
- Always monitor the endoscopic image during the procedure. Make sure that the instrument appears and operates normally. If the hook comes off of the distal end, retrieve it with a grasping forceps.

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 and clip. This could damage the instrument and/or clip.

3.1 Preparation

Equipment and Personal Protective Equipment

Prepare all equipment and personal protective equipment which will be used with the instrument and clip in accordance with their respective instruction manuals. Appropriate personal protective equipment may include: eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves.

Spare Instrument and Clips

Always have a spare instrument and clips available.

Reprocessing Equipment

Prepare the reprocessing equipment as described in Section 5.2, “Required Reprocessing Equipment” for immediate reprocessing after use.

Equipment to be Used in an Emergency

Always have pliers and/or wire cutters ready to cut the coil sheath, tube sheath and operation wire in case the clip cannot be detached from the instrument.

3.2 Inspection

Wear the personal protective equipment as specified in the table on page 50.

Before each case, always inspect the instrument and clip according to the following procedures.
If an abnormality in the instrument or clip is detected, use a spare instrument or clip, inspecting it thoroughly before use.

Inspection of the Sterile Package

WARNING

The clip is a single-use, disposable item. Do not use or attempt to sterilize it. Reusing the clip could pose an infection control risk, cause tissue irritation 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 or clip may have been compromised. Use a spare instead.

Appearance Inspection

If any of the following steps reveals irregularities, do not use the instrument or clip; use a spare instead.

WARNING

- Do not use the instrument if the distal end of the coil sheath is deformed. Using an instrument in this condition may result in the clip catching on the rim of the coil sheath after clipping and make it impossible to remove the clip from the coil sheath.
- Do not use the instrument if the coil sheath has any slips, the buckling and collapse. Using an instrument in this condition may become impossible to move through the endoscope channel.When you forcibly insert the instrument, it will protrude abruptly from the distal end of the endoscope. This could cause patient injury, such as perforation, bleeding or mucous membrane damage.

1. Confirm that the distal end of the coil sheath is perfectly round (not deformed or crushed), and that there are no sharp protrusions, burrs or edges when viewing the distal end of the coil sheath from the direction shown in Figure 3.1.

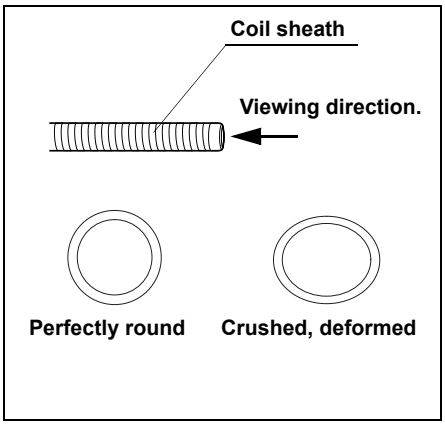


Figure 3.1

2. Gently run your fingertips over the entire length of the insertion portion to check for any slips, the bucking and collapse broken areas or other damage (see Figure 3.2, 3.3).

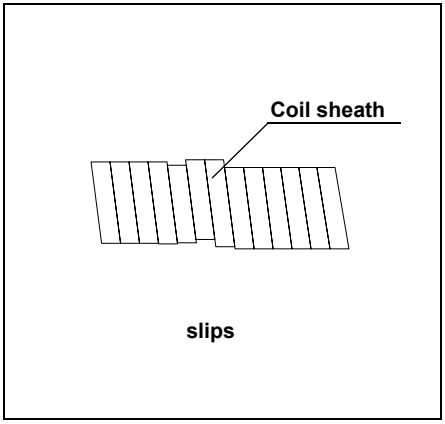


Figure 3.2

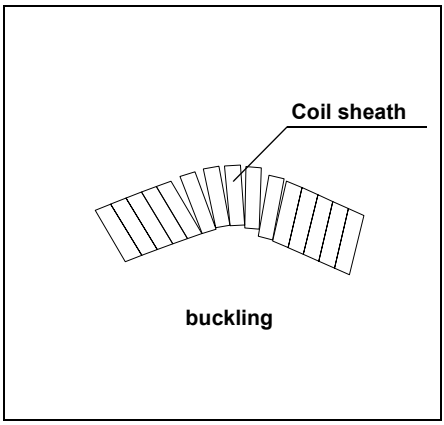


Figure 3.3

3. Move the slider back and forth. Confirm that the coil sheath is free from disconnection or looseness.
4. Push the slider to extend the hook from the distal end of the coil sheath. Confirm that the hook appears exactly as shown in the tables in Section 2.2, “Specifications” on page 11 and is not damaged.
5. Make sure that there are not cracks on the handle.

Inspection of Operation

If the instrument does not operate smoothly and as intended, do not use the instrument; use a spare instead.

1. Holding the instrument as shown in Figure 3.4, form a loop in the insertion portion approximately 20 cm in diameter.

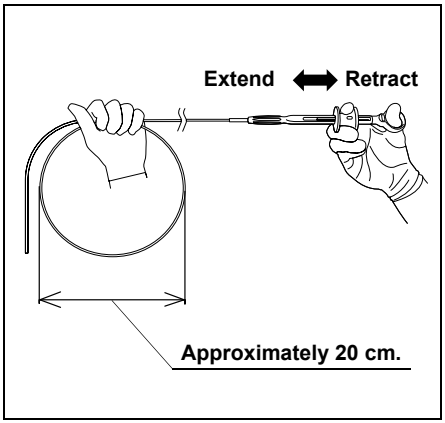


Figure 3.4

2. Operate the slider and confirm that the hook retracts into and extends from the coil sheath smoothly and as intended.

3.3 Operation

The operator of the instrument and clip 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. It only describes basic operation and precautions related to the operation of this instrument and clip.

WARNING

- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or if any other unexpected circumstances take place. In this case, refer to Chapter 4, “Emergency Treatment”.
- When using the instrument and clip, always wear appropriate personal protective equipment. Otherwise, blood, mucus and other potentially infectious material from the patient could pose an infection control risk. Appropriate personal protective equipment may include: 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.

- 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 perforation, bleeding or mucous membrane damage. It may also damage the endoscope, instrument and/or clip.
- 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 perforation, bleeding or mucous membrane damage.
- Do not force the distal end of the insertion portion against body cavity tissue. This could cause patient injury, such as perforation, bleeding or mucous membrane damage.
- When electrosurgical accessories are used after clipping, they could cause patient injury, such as thermal injury of body cavity tissue contacting the clip. Activate output only after checking the tissue around the clip.

CAUTION

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

Attaching the Clip

WARNING

- Do not use a clip that has not been properly attached. Otherwise, the clip may not operate correctly or it could be damaged.
- After attaching the clip, dispose of the cartridge properly. Otherwise, infection may result.

CAUTION

- After retracting the clip into the coil sheath, do not extend the clip out from the tube sheath until the clip is actually going to be used. If the clip is extended unnecessarily, it may be impossible to insert it into the endoscope.
- Do not disassemble a used cartridge and attempt to reuse the clip in it. Otherwise, the clip cannot be attached properly or may be damaged.

NOTE

To attach additional clips after the first one, detach the clip connector from the hook by following the instructions in “Detaching the Clip Connector” on page 38.

If the clip cannot be attached securely, do not use the clip and/or instrument; use a spare instead.

1. Open the package containing the cartridge.
2. Carefully pull the slider up to the ring (yellow).

3. Place the cartridge on the coil sheath (see Figure 3.5).

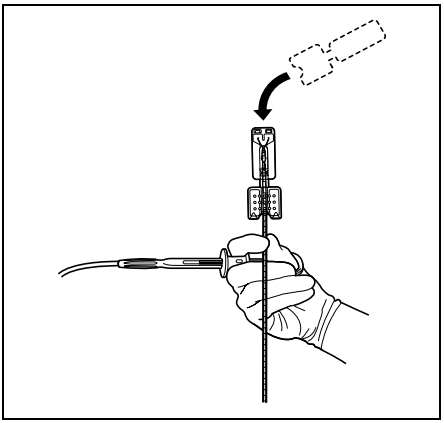


Figure 3.5

4. Hold the coil sheath in position by pinching the grip of the cartridge. At this time, confirm that the coil sheath can be suspended (see Figure 3.6).

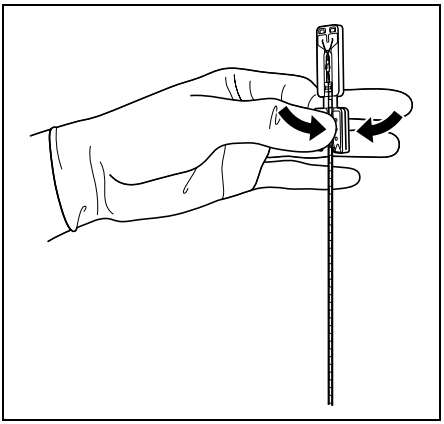


Figure 3.6

CAUTION

Keep pinching the grip of the cartridge until the clip has been attached completely. Otherwise, the positioning between the coil sheath and cartridge may be deviated and the clip may be unable to be mounted.

5. Push the slider forward (distally) until it clicks, then pull it toward you (proximally) until it stops (see Figure 3.7). The clip is now attached inside the coil sheath.

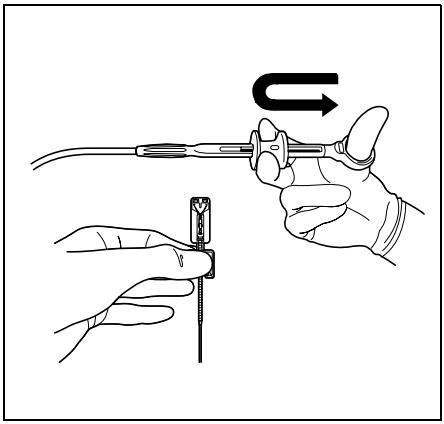


Figure 3.7

CAUTION

Do not push the slider too much forward. Otherwise, the clip may be damaged.

6. Confirm that the clip has been successfully removed from the cartridge and that it is not extending from the coil sheath.
7. After attaching the clip, dispose of the cartridge properly.

Insertion Into the Endoscope

WARNING

- 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 perforation, bleeding or mucous membrane damage. It may also damage the endoscope and/or instrument.
- Hold the slider still when inserting the instrument into the endoscope. Otherwise, the clip will open and may extend from the distal end of the endoscope abruptly. This could cause patient injury, such as perforation, bleeding or mucous membrane damage. It could also damage the endoscope, instrument and/or clip.
- Do not advance or extend the instrument abruptly. This could cause patient injury, such as perforation, bleeding or mucous membrane damage. It could also damage the endoscope, instrument and/or clip.
- When inserting the instrument into the endoscope, make sure that the clip is completely retracted into the coil sheath. Otherwise, patient injury, such as perforation, bleeding or mucous membrane damage may result. It could also damage the endoscope, instrument and/or clip.

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.
- Insert the instrument slowly. Abrupt insertion could damage the endoscope and/or instrument. If the insertion portion of the instrument is damaged, the rotation function will be impaired.
- As the distal end of the coil sheath is thicker than other parts, resistance may be felt when it passes through the section near the biopsy valve. In this case, do not advance it forcibly but gently advance it upright with respect to the biopsy valve. Otherwise, deformation of the coil sheath may result.

1. Confirm that the entire clip is retracted into the coil sheath.
2. Carefully insert the instrument into the biopsy valve (see Figure 3.8).

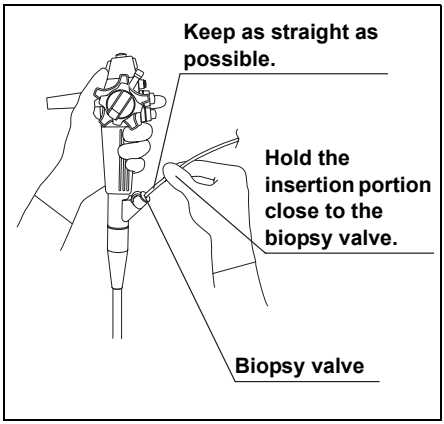


Figure 3.8

3. Advance the instrument until the distal end of the insertion portion appears within the endoscopic field of view.

Clipping Tissue

WARNING

- Do not extend the clip abruptly from the distal end of the coil sheath. Also, when pushing the clip out of the coil sheath, keep a sufficient distance between the distal end of the coil sheath and the mucous membrane. If the clip is extended without keeping this distance, the clip may hit against the tissue unintentionally, and perforation, hemorrhage or mucous membrane damage or dropping off of the clip, or break up of the clip may result.
- Do not force the clip against body cavity tissue. The clip may be deformed and does not close properly. This could result in reduced performance.
- Do not try to forcibly remove the clip if it becomes caught on the distal end of the coil sheath. Forcible removal of the clip could cause patient injury such as perforation, bleeding or mucous membrane damage.
- Do not withdraw the instrument if clipping is not completely finished (when the slider is not pulled out all the way in the proximal direction). Doing so may tear tissue inside the body cavity, resulting in patient injury, such as perforation, bleeding or mucous membrane damage.

- When clipping tissue, do not change the angulation of the endoscope before the clip is detached from the instrument. Doing so may result in patient injury, such as perforation, bleeding or mucous membrane damage.

CAUTION

- When aspirating body fluid via the endoscope, do not aspirate a clip or clip connector which has been dropped inside the body cavity, as this could disable the endoscope's suction function. If a clip or clip connector is accidentally aspirated into the endoscope, follow the procedure given in “Removal of an Aspirated Clip or Clip Connector” on page 39.
- If the clip does not extend when the slider is pushed, straighten the angulated distal end of the endoscope until the clip can be extended smoothly. Otherwise, the endoscope and/or instrument may be damaged.

NOTE

After the clip is deployed, do not move the slider in the distal direction prior to withdrawing the instrument from the patient. Doing so could extend the hook from the coil sheath, which could cause the clip connector to fall off into the patient.

1. Gently push the slider so that the clip projects from the coil sheath until the white part of the clip is visible. At this time, the clip should appear in the endoscopic image as shown in Figure 3.9(b).

NOTE

Once the clip of the rotatable clip fixing device is extended from the coil sheath, the clip cannot be accommodated in the coil sheath again. If it is required to discontinue clipping after extending the clip from the distal end of the sheath, either close the clip and withdraw the entire endoscope or let the clip inside the body and then collect the clip.

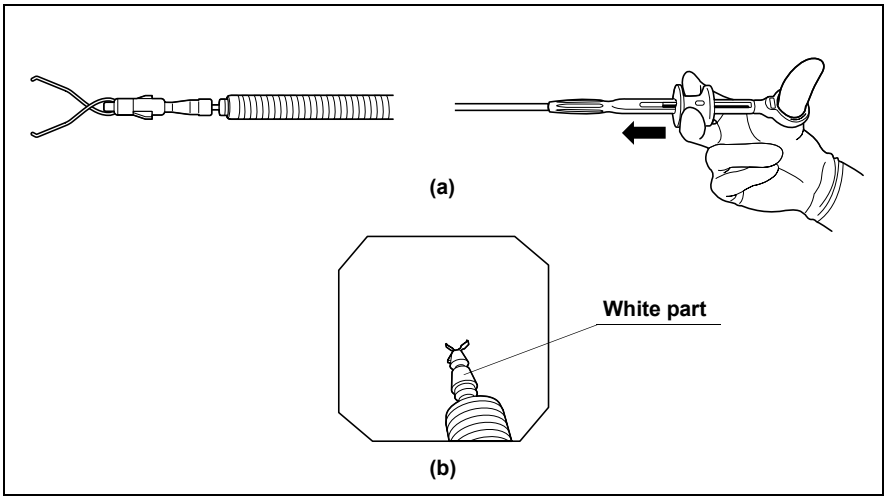


Figure 3.9

2. Pull the slider slowly towards you to open the clip (see Figure 3.10).

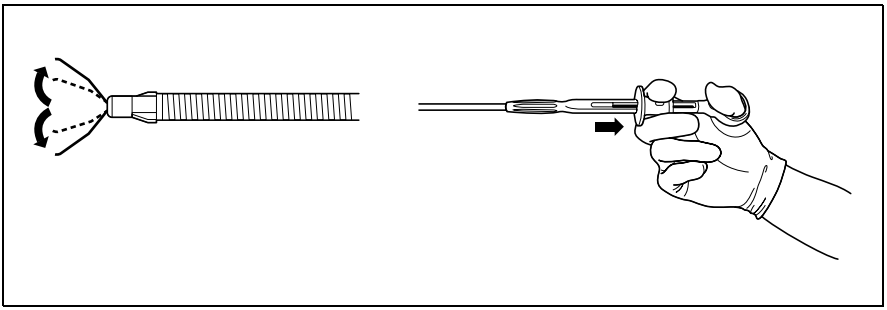


Figure 3.10

NOTE

Do not pull the slider quickly. This will open and close the clip.

3. Hold only the ring (yellow) and rotate the rotation grip to orient the clip so that it may be applied to the tissue (see Figure 3.11).

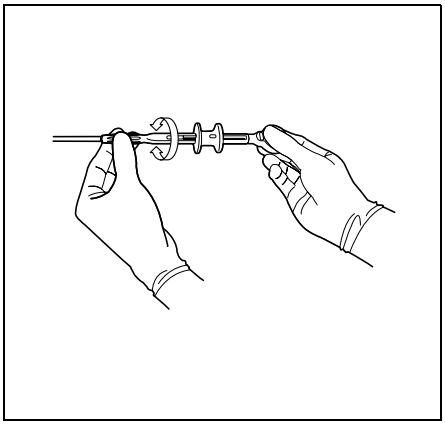


Figure 3.11

NOTE

- Rotating the rotation grip also causes the slider to rotate together. Therefore, be sure to remove your finger from the slider when rotating the rotation grip.
- Rotate the rotation grip slowly. If it is rotated quickly, the clip rotation may jump.
- If the endoscope is bent sharply, there may be a delay between the rotation of the rotation grip and that of the clip.
- If the clip will not rotate smoothly, straighten out the part of the insertion tube extending from the forceps port as straight as possible and rotate the rotation grip (see Figure 3.12).

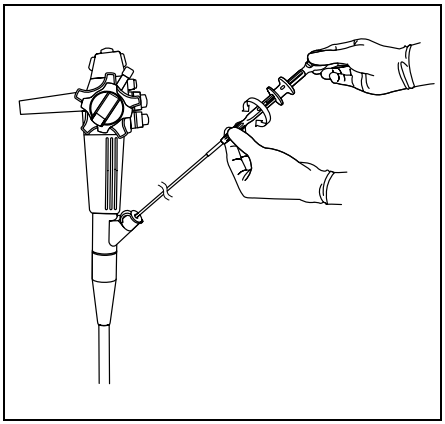


Figure 3.12

4. Press the clip against the targeted lesion.

5. Pull the slider firmly to close the clip on the target site (see Figure 3.13).

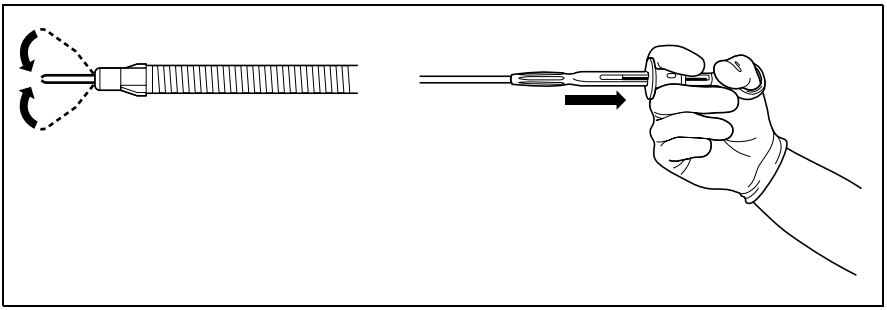


Figure 3.13

6. Gently pull the slider up to the thumb ring (yellow) gently to detach the closed clip from the coil sheath (see Figure 3.14).

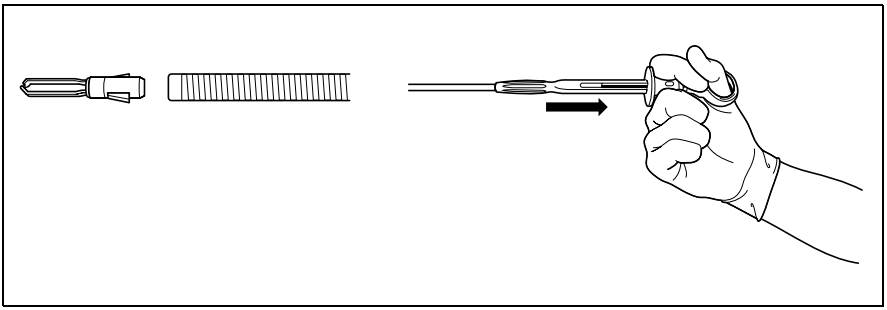


Figure 3.14

Withdrawing the Instrument From the Endoscope

WARNING

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

CAUTION

- Do not withdraw the instrument from the endoscope if the forceps elevator is up. This could damage the endoscope and/or instrument.
- Do not withdraw the instrument from the endoscope if the hook is not completely retracted into the coil sheath. This could damage the endoscope and/or instrument.
- Do not withdraw the instrument abruptly from the endoscope. Otherwise, damage to the endoscope or instrument may result.
- As the distal end of the coil sheath is thicker than other parts, resistance may be felt when it passes through the section near the biopsy valve. In this case, do not withdraw it forcibly but gently pull it upright with respect to the biopsy valve. Otherwise, deformation of the coil sheath may result.

1. Lower the forceps elevator when using an endoscope equipped with a forceps elevator.
2. Withdraw the instrument from the endoscope.

Detaching the Clip Connector

WARNING

After removing the clip connector, dispose of it properly. Otherwise, infection may result.

1. Push the slider so that the hook is extended from the coil sheath. Now bend the clip connector with respect to the hook and remove (see Figure 3.15).

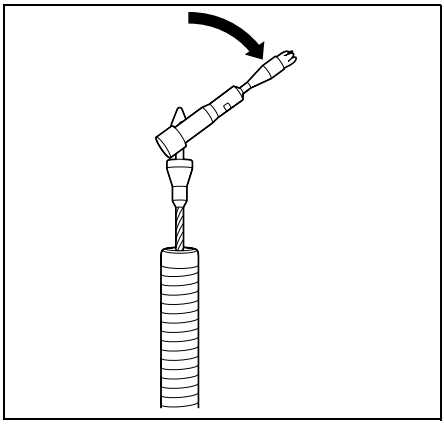


Figure 3.15

2. After removing the clip connector, dispose of it properly.

Removal of an Aspirated Clip or Clip Connector

If a clip or clip connector is accidentally aspirated into the endoscope, follow the procedure below to remove it.

1. Withdraw the endoscope from the body cavity, keeping the insertion portion and bending section straight. Leave the biopsy valve mounted on the endoscope.
2. Remove the suction tube and connect a syringe filled with tap water to the endoscope's suction connector (see Figure 3.16).

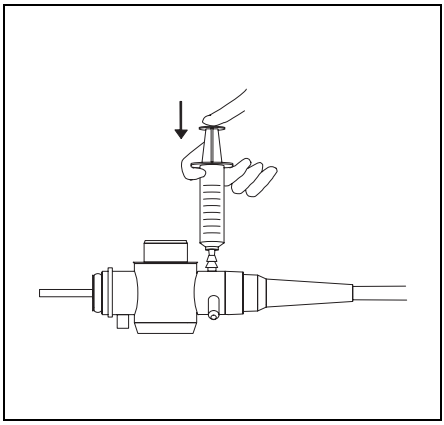


Figure 3.16

3. While gently pressing the suction valve, inject the tap water into the endoscope's suction connector (see Figure 3.17).

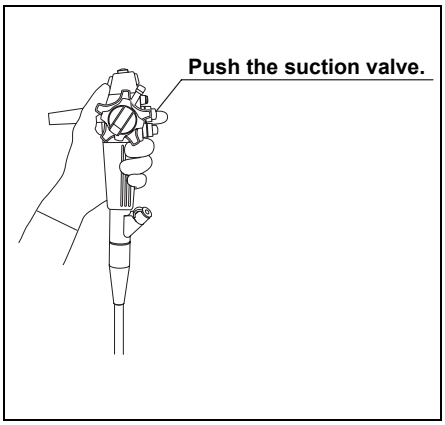


Figure 3.17

4. Irrigation should discharge the clip or clip connector from the endoscope. If one injection is not enough to discharge the clip or clip connector, repeat steps 2. and 3. until the clip or clip connector is discharged.

Chapter 4 Emergency Treatment

4.1 Emergency Treatment

WARNING

Do not try to forcibly withdraw the instrument from the endoscope if the clip cannot be detached from the instrument. Forcibly withdrawing the instrument could cause patient injury such as perforation, bleeding or mucous membrane damage.

If the clip cannot be detached from the instrument, follow the procedures described in this section.

If the distal end of the coil sheath or clip pipe is crushed or deformed, it may not be possible to detach the clip from the instrument.

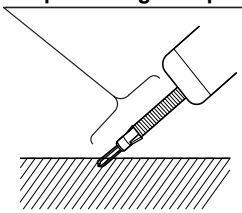
Keep as straight as possible.

Straighten out the portion of the endoscope that extends from the patient.

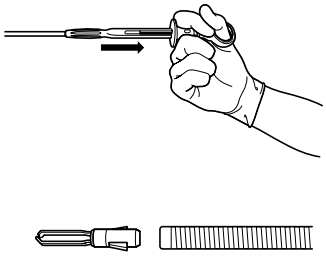
Keep as straight as possible.

Straighten out the portion of the instrument that extends from the biopsy valve.

Keep as straight as possible.

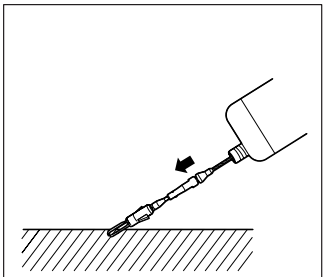


Straighten out the coil sheath that extends from the distal end of the endoscope.

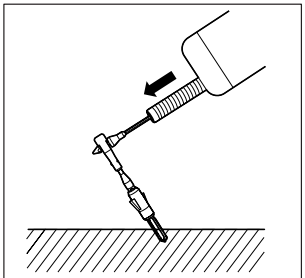


Confirm that the slider has been pulled out as far as possible.

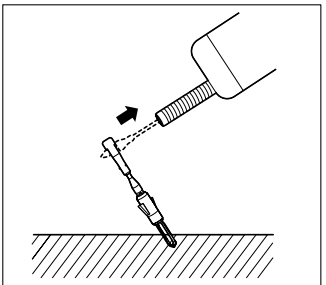
When the clip cannot be detached from the instrument.



1. Push the slider to extend the hook from coil sheath.

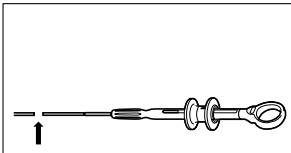


2. While adjusting the endoscope angle, push the coil sheath to bend the clip with respect to the hook.



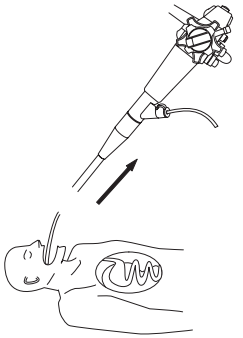
3. Pull the slider to withdraw the hook inside the coil sheath, and remove the clip from the rotatable clip fixing device.

When the clip cannot be detached from the instrument.

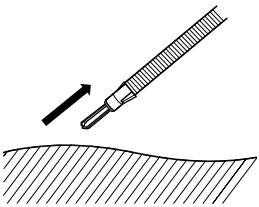


Cut the coil sheath and operation wire using pliers and/or wire cutters.

Withdraw the endoscope.



A certain amount of force is sometimes required to withdraw the endoscope.



Leave the clip in place until tissue necrosis occurs and the clip comes free. This may take some time.

Carry out open surgery or other possible treatment.

Chapter 5 Reprocessing

WARNING

This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in this Chapter. Do not use an instrument that has not been cleaned and sterilized. This poses an infection control risk or can cause tissue irritation.

5.1 General Policy

- The medical literature reports incidents of patient cross contamination resulting from improper cleaning or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies.
  A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.
- All individuals responsible for reprocessing should thoroughly understand:
  - your institution’s reprocessing procedures
  - occupational health and safety regulations
  - national and local hospital guidelines and policies

- the instructions in this manual
- the mechanical aspects of endoscopic equipment
- pertinent germicide labeling

Olympus endo-therapy accessories are compatible with 2.0% to 3.2% glutaraldehyde solution. However, routine biological monitoring is not feasible with glutaraldehyde and, therefore, it should not be used to sterilize reusable medical devices that are compatible with other methods of sterilization that can be biologically monitored, such as steam sterilization.

WARNING

- Failure to properly clean and sterilize the instrument after each examination can compromise patient safety. During use, the instrument normally comes in contact with intact mucous membranes. To minimize the risk of transmitting diseases from one patient to another, after each examination the instrument must undergo thorough cleaning followed by sterilization.
- If the instrument is not cleaned meticulously, effective sterilization cannot be obtained. Clean the instrument thoroughly before sterilization to remove microorganisms or organic material which can limit the effectiveness of the sterilization process.

- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and infectious material. During cleaning and sterilization, 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. Always remove contaminated protective clothing before leaving the reprocessing area.
- The reprocessing procedures described in this manual should be completed the same day the instrument has been used. If reprocessing is delayed, residual organic debris will solidify and it may be difficult to effectively reprocess the instrument.
- Reprocess the instrument immediately after use, first by immersing it in a neutral, low-foaming, medical-grade detergent solution, then following the remaining steps as instructed in this chapter. Failure to reprocess the instrument immediately after use, or using other than a medical-grade detergent may cause corrosion at the instrument's hook. This could cause the hook to break and/or come off inside the patient.

- With the cleaning and sterilization methods stated in this instruction manual, prions, which are considered to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated. When using this instrument on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this product for such patient only and/or immediately dispose of this product after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.
- This instrument is not durable, or does not have sufficient durability against the respective methods stated in the guidelines of each country for destroying or inactivating prions. For information on the durability against each method, please contact Olympus. If cleaning and sterilization methods not stated in this instruction manual are performed, Olympus cannot guarantee the effectiveness, safety and durability of this instrument. Make sure to confirm that there is no abnormality before use, and use under responsibility of a physician. Do not use if any abnormality is found.

5.2 Required Reprocessing Equipment

Wear the personal protective equipment as specified in the Table on page 50.

1. Prepare the following equipment. The required amount of detergent solution, lubricant and other equipment depends on the number of instruments to be reprocessed.
2. Fill an immersion basin with detergent solution and fill a second immersion basin with lubricant at the temperatures and concentrations recommended by the manufacturers. Also fill the ultrasonic cleaner with a detergent solution appropriate for ultrasonic cleaning.

Equipment Needed for Reprocessing

To perform proper reprocessing, the equipment in the following table is required. For details on preparation and directions for use of the following equipment, refer to the respective instruction manuals or contact the equipment manufacturer.

Contact Olympus for the names of specific brands of detergent solutions and lubricants.

Equipment Needed

Protective equipment	Appropriate personal protective equipment may include: Eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves.
Immersion basin for detergent solution	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the insertion portion is coiled with a diameter of not less than 20 cm.
Detergent solution for immersion	Use a neutral pH, low-foaming, medical grade detergent solution.
Ultrasonic cleaner	Use a medical grade ultrasonic cleaner with a frequency range of 38 to 47 kHz, and with a depth and a diameter large enough to allow complete immersion of the instrument when the insertion portion is coiled with a diameter of not less than 20 cm. Compatible ultrasonic cleaners include OLYMPUS ULTRASONIC CLEANER KS-2.
Detergent solution for ultrasonic cleaning	Use a neutral pH, low-foaming, medical grade detergent solution with no abrasive.
Lubricant	Use a medical grade water soluble or low-viscosity emulsion type lubricant.
Immersion basin for lubricant	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the insertion portion is coiled with a diameter of not less than 20 cm.
Lint-free cloths	
Packages for steam sterilization	Use packages compatible with steam sterilization (autoclaving). The packages should be large enough to accommodate the instrument when the insertion portion is coiled with a diameter of not less than 20 cm.

Sealing device for packages	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate sealing device according to the packages to be used.
Autoclave	Use an autoclave that will operate at the conditions specified in Section 5.5, “Sterilization”.

5.3 Cleaning

WARNING

When cleaning, avoid exposure to the reprocessing chemicals. It may pose an infection control risk or cause skin irritation.

CAUTION

- When reprocessing, 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.

Immersion

WARNING

Immerse the instrument in detergent solution immediately after use. If the instrument is not cleaned immediately, it may be difficult to effectively reprocess, and this could result in reduced performance.

1. Immerse the entire instrument in the detergent solution for the time specified in manufacturer's instructions. If no time is specified, immerse for between 5 minutes and 3 hours.
2. Remove the instrument from the detergent solution.

Ultrasonic Cleaning

1. Immerse the entire instrument in the ultrasonic cleaner containing detergent solution.
2. Clean ultrasonically for 30 minutes. For details on operation of the ultrasonic cleaner, refer to the instruction manual of the ultrasonic cleaner.
3. Remove the instrument from the detergent solution.

Rinsing

CAUTION

- After ultrasonic cleaning, rinse the instrument thoroughly to remove residual detergent. Residual detergent solution could cause tissue irritation in the next patient.
- Do not forcefully squeeze, wipe or scrub the instrument. This could cause damage to the instrument or result in reduced performance.

1. Rinse the instrument under clean running tap water.
2. Confirm that no debris is left on the surfaces of the instrument.
3. Wipe the exterior of the instrument with a clean, dry lint-free cloth.

5.4 Lubrication

WARNING

When lubricating, avoid exposure to the lubricant. It may pose an infection control risk or cause skin irritation.

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.

1. Immerse the insertion portion in the lubricant for 2 to 3 seconds.
2. Remove the instrument from the lubricant.
3. Move the slider back and forth two or three times to retract the hook into and extend it from coil sheath.
4. Wipe the exterior of the instrument with a clean, dry lint-free cloth and allow the instrument to air dry.

5.5 Sterilization

Sealing the Package

WARNING

Before placing the instrument in the package, always retract the hook into the coil sheath. Otherwise, they could tear the package during sterilization or storage and compromise its sterility, which could pose an infection control risk or cause tissue irritation.

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.

1. Before sterilization, the instrument must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
2. Coil the insertion portion and place the instrument in the package.
3. Seal the package. For details on sealing, refer to the instruction manual of the package and the sealing device.

Steam Sterilization (Autoclaving)

WARNING

- Use biological indicators as recommended by your hospital's policy and follow the manufacturer's instructions, all national and local hospital guidelines and policies.
- Always leave space between the packages in the autoclave. If the packages are placed too close together, effective sterilization will not be possible.
- Allow the packages to dry within the autoclave using the autoclave's drying cycle (if applicable) or by opening the door of the autoclave and allowing the packages to air dry. Handling a wet package can compromise its sterility.
- The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual of the sterilization device.

1. Place the sealed package containing the instrument in the autoclave and sterilize in accordance with the conditions listed below. For details on operation of the autoclave, refer to the instruction manual for the autoclave or other manufacturer instructions.

2. After steam sterilization, let the instrument gradually cool down to room temperature. Sudden changes in temperature may damage the instrument.

NOTE

Autoclavable products have a green reference label. Products that do not have green reference labels are not autoclavable.

	Temperature	Exposure Time
Prevacuum	132 to 134°C (270 to 274°F)	5 minutes

Table 5.1 Recommended steam sterilization (autoclaving) conditions

Chapter 6 Storage

WARNING

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

CAUTION

Do not coil the insertion portion with a diameter of less than 20 cm. This could damage the insertion portion.

6.1 Inspection Before Storage

Prior to storage, inspect the sterile package as follows:

Confirm that the sterile package containing the instrument is free from tears, inadequate sealing or water damage. If tears, inadequate sealing or water damage is detected, repackage and sterilize again as described in Section 5.5, “Sterilization”.

6.2 Storage

Store the instrument in the sterile package at room temperature in a clean and dry environment. Do not store it in direct sunlight. Ensure that the packaged instrument is not crushed by surrounding objects during storage. Follow any additional storage instructions provided by the manufacturer of the sterile package.

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