OLYMPUS

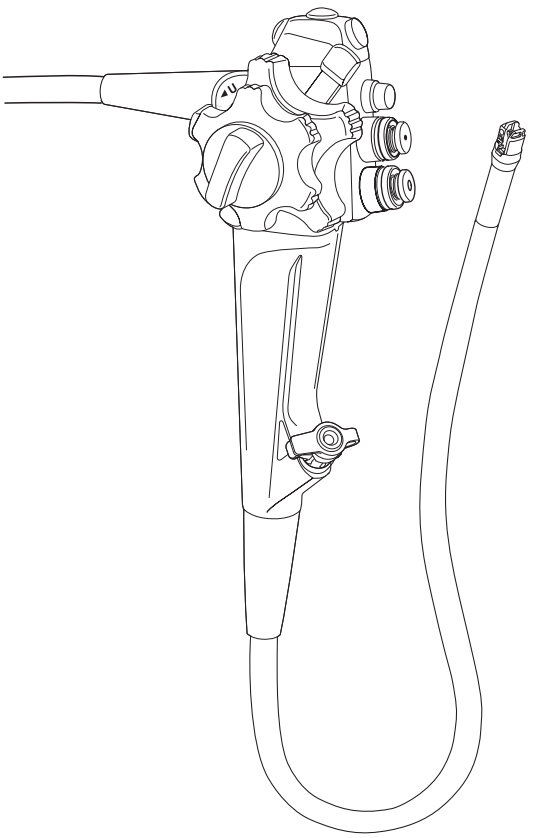
OPERATION MANUAL

INSTRUCTIONS

EVIS EXERA III

EVIS EXERA III DUODENOVIDEOSCOPE

OLYMPUS TJF-Q190V



Refer to the endoscope's companion manual, the "REPROCESSING MANUAL" with your endoscope model listed on the cover, for reprocessing information.

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Contents

Contents

Symbols

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

Symbol	Description	Symbol	Description
	Consult instructions for use.		Endoscope
	TYPE BF applied part		Single use only
LOT	Lot number		Manufacturer
	Date of Manufacture	EC REP	Authorized representative in the European Community
SN	Serial number	IPX7	Ingress protection rating is 7.
	Importer (into European European Union)		Keep away from sunlight
	Not Made with Natural Rubber Latex		Keep dry

For US Customers only

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

Important Information — Please Read Before Use

■ Intended use

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

■ Indications for use

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery within the duodenum.

■ Contraindications

None known.

■ Applicability of endoscopy and endoscopic treatment

If there are official standards on the applicability of endoscopy and endoscopic treatment that are defined by the hospital's administrators or other official institutions, such as academic societies on endoscopy, follow those standards. Before starting endoscopy and endoscopic treatment, thoroughly evaluate its properties, purposes, effects, and possible risks (their nature, extent, and probability). Perform endoscopy and endoscopic treatment only when its potential benefits are greater than its risks.

Fully explain to the patient the potential benefits and risks of the endoscopy and endoscopic treatment as well as any examination/treatment methods that can be performed in its place, and perform the endoscopy and endoscopic treatment only after obtaining the consent of the patient.

Even after starting the endoscopy and endoscopic treatment, continue to evaluate the potential benefits and risks, and immediately stop the endoscopy/treatment and take proper measures if the risks to the patient become greater than the potential benefits.

■ *Instruction manual*

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals for all equipment that will be used during the procedure and use the equipment as instructed.
Note that the complete instruction manual set for this endoscope consists of this manual and the "REPROCESSING MANUAL" with your endoscope model listed on the cover. It also accompanied the endoscope at shipment.

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, contact Olympus.

❍ Terms used in this manual

NBI (Narrow Band Imaging) observation:

This is optical-digital observation using narrowband light.

WLI (White Light Imaging) observation:

This is observation using white light.

Image sensor:

The image sensor is a device that converts light into electrical signals.

■ *User qualifications*

If there are official standards for user qualifications to perform endoscopy and endoscopic treatment that are defined by the hospital's medical administrators or other official institutions, such as academic societies on endoscopy, follow those standards. If there are no official qualification standards, the operator of this instrument must be a physician approved by the medical safety manager of the hospital or person in charge of the department (department of internal medicine, etc.).

The physician should be capable of safely performing the planned endoscopy and endoscopic treatment following guidelines set by the academic societies on endoscopy, etc., and considering the difficulty of endoscopy and endoscopic treatment. This manual does not explain or discuss endoscopic procedures.

■ *Instrument compatibility*

Refer to “Combination equipment” on page 111 to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014).
When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable.

■ *Reprocessing before the first use/reprocessing and storage after use*

This instrument was not reprocessed before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in the endoscope’s companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.
After using this instrument, reprocess and store it according to the instructions given in the endoscope’s companion “REPROCESSING MANUAL”. Improper and/or incomplete reprocessing or storage can pose an infection control risk, cause equipment damage, or reduce performance.

■ *Spare equipment*

Be sure to prepare another endoscope to avoid interruption of the examination due to equipment failure or malfunction.

■ *Maintenance management*

The probability of failure of the endoscope and ancillary equipment increases as the number of procedures performed and/or the total operating hours increase. In addition to the inspection before each procedure, the person in charge of medical equipment maintenance in each hospital should periodically inspect the items specified in this manual following applicable regulations, guidelines, etc. required of you. An endoscope with an observed irregularity should not be used, but should be inspected by following Section 5.2, “Troubleshooting guide”. If the irregularity is still observed after inspection, contact Olympus.

Maintenance of the forceps elevator has to be performed according to Chapter 6, “Inspection Schedule Related to Forceps Elevator” in the manual.

■ *Prohibition of improper repair and modification*

This instrument does not contain any user-serviceable parts. Do not disassemble, modify, or attempt to repair it; patient or operator injury and/or equipment damage may result.
Equipment that has been disassembled, repaired, altered, changed, or modified by persons other than Olympus' own authorized service personnel is excluded from Olympus' limited warranty and is not warranted by Olympus in any manner.

■ *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.

■ *Precautions*

Follow the warnings and cautions given below when handling this endoscope. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING

- Do not use this endoscope for any purpose other than its indications for use. Patient or operator injury and/or equipment damage may result.
- After using this endoscope, reprocess and store it according to the instructions given in the endoscope's companion "REPROCESSING MANUAL" with your endoscope model listed on the cover. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and/or infection.
- Before endoscopy, remove any metallic objects (watch, glasses, necklace, etc.) from the patient. Performing high-frequency cauterization treatment while the patient is wearing metallic objects may cause burns on the patient in areas around the metallic objects.

WARNING

- Do not strike, hit, or drop the distal end, insertion tube, bending section, control section, universal cord, or endoscope connector of the endoscope. Also, do not bend, pull, or twist the distal end, insertion tube, bending section, control section, universal cord, or endoscope connector of the endoscope with excessive force. The endoscope may be damaged and could cause patient injury, burns, bleeding, and/or perforations. It could also cause parts of the endoscope to fall off inside the patient.
- Never perform angulation control forcibly or abruptly. Never forcefully pull, twist, or rotate the angulated bending section. Patient injury, bleeding, and/or perforation may result due to unintended retroflexion of the bending section. It may also become impossible to straighten the bending section during an examination.
- Never insert or withdraw the endoscope's insertion section while the bending section is locked in position. Patient injury, bleeding, and/or perforation may result.
- Never operate the bending section, feed air or perform suction, insert or withdraw the endoscope's insertion section, or use EndoTherapy accessories without viewing the endoscopic image or while the endoscopic image is frozen. Patient injury, bleeding, and/or perforation may result.
- Never insert or withdraw the insertion section abruptly or with excessive force. Patient injury, bleeding, and/or perforation may result.
- If it is difficult to insert the endoscope, do not forcibly insert the endoscope; stop the endoscopy. Forcible insertion can result in patient injury, bleeding, and/or perforation.
- When using the electronic zoom function of the video system center, never insert or withdraw the endoscope's insertion section or use EndoTherapy accessories while the image is magnified. Patient injury, bleeding, and/or perforation can result.
- Do not touch the light guide on the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient burns can result.
- If the endoscopic image becomes dimmer during the procedure, it may indicate that blood or mucus is adhering to the light guide lens on the distal end of the endoscope. Immediately withdraw the endoscope from the patient, remove blood or mucus, and confirm that the light guide lens has no irregularities to use it again. If you continue to use the endoscope with its obstructed light guide lens, the temperature at the distal end of the endoscope may rise, which may cause patient injury or operator and/or patient burns.
- When the endoscopic image does not appear on the monitor, the image sensor may have been damaged. Turn the video system center OFF immediately. Continued power supply in such a case will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.

WARNING

- Do not rely on the NBI observation mode alone for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.
- During endoscopic treatment, keep the insertion section and the bending section as straight as possible. If there is a loop or a bend on the insertion section or the bending section, the operation cannot be performed as intended, and patient injury, bleeding, and/or perforation can result.
- Never use the endoscope unless the single use distal cover is properly attached to the distal end. If the single use distal cover is not attached properly, it may slip off or fall off the distal end during the examination. This could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. Also, continuing the examination with the single use distal cover off may cause patient injury by the uncovered distal end of the endoscope. In addition, if the single use distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.
- If the single use distal cover should fall off the distal end during the examination, the single use distal cover is seen partly on the endoscopic image. When the single use distal cover should fall off the distal end or seems to fall off, immediately stop the examination, and slowly withdraw the endoscope from the patient. Continuing the examination after the single use distal cover has fallen off may cause patient injury by the uncovered distal end of the endoscope and this could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. In addition, if the single use distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed. If a single use distal cover falls off inside the patient's body, stop using the endoscope immediately and retrieve the single use distal cover in an appropriate way.
- Take caution applying suction when the distal end is in contact with the mucosal surface. The suction can cause the distal end to aspirate the mucosal membrane. Moving or withdrawing the endoscope under this condition may cause patient injury and/or bleeding. This can be more common while degassing in the stomach, suctioning debris, and operating in a narrow lumen (e.g., esophagus, duodenum). To prevent patient injury and bleeding, make sure to:
  - Only apply suction when the endoscope is stationary.
  - After releasing the suction valve, check the endoscopic image to confirm that the mucosal membrane is not aspirated before moving the endoscope. Releasing the suction valve might not immediately release the mucosal membrane if it becomes aspirated.

WARNING

- Never use a single use distal cover with cracks or pinholes. Replace it with a new one. If a single use distal cover with cracks or pinholes is used, it could fall off during the examination and/or, it may cause thermal injury due to electric current leaks from cracks or pinholes when high-frequency cauterization treatment is performed. Also, using the single use distal cover with cracks may cause patient injury due to sharp edges.

CAUTION

- Do not pull the universal cord during an examination. The endoscope connector will be pulled out from the output socket of the light source and the endoscopic image will disappear.
- Do not coil the insertion tube or universal cord with a diameter of less than 12 cm. Equipment damage may result.
- Do not attempt to bend or twist the endoscope's insertion section with excessive force. The insertion section may be damaged.
- Do not apply shock to the distal end of the endoscope including the objective lens surface. An abnormal endoscopic image and/or water leakage may result.
- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leakage.
- Turn the video system center ON only when the endoscope connector is connected to the light source. In particular, confirm that the video system center is OFF before connecting or disconnecting the endoscope connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- The endoscope's remote switches cannot be removed from the control section. Pressing, pulling, or twisting them with excessive force can break the switches and/or cause water leakage.
- If remote switch 1 does not return to the OFF position after being pressed strongly from the side, gently pull the switch upwards to return it to the OFF position.
- Do not hit or bend the electrical contacts on the endoscope connector. The connection to the light source may be impaired and a faulty contact can result.
- If endoscope's suction is insufficient, select another suction system without using the endoscope and use it according to the directions given in its instruction manual. Otherwise, a proper endoscopic image may not appear on the monitor.

CAUTION

- This endoscope supports radio communication function (receive frequency: 13.56 MHz) that identifies endoscopes. Electromagnetic interference may occur on this endoscope near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment, such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as moving the RF communications equipment away, reorienting or relocating this endoscope, or shielding the location.

- Be sure that this endoscope is not used adjacent to or stacked with other equipment (other than the components of this endoscope or system) to avoid electromagnetic interference.

NOTE

This endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-190.

■ *Precautions for disappeared or frozen endoscopic image*

WARNING

- If the endoscopic image disappears unexpectedly or the frozen image cannot be restored during an examination, immediately stop using the endoscope and withdraw it from the patient as described in Section 5.3, “Withdrawal of the endoscope with an irregularity”. Inserting or withdrawing the endoscope, using EndoTherapy accessories, performing suction, feeding air, or performing angulation control under these conditions could result in patient injury, bleeding, and/or perforation.
- Follow the precautions given below. Otherwise, the endoscopic image may disappear unexpectedly or the frozen image may not be restored during the examination.
  - Connect the endoscope connector to the light source completely by pushing the endoscope connector until it clicks. Otherwise, a faulty contact can result.
  - Do not bend, hit, pull, or twist the insertion section, bending section, control section, universal cord, and endoscope connector. The endoscope may be damaged, and water leakage and/or breakage of internal parts like the cable can result.
  - Before connecting the endoscope connector to the light source, confirm that the endoscope connector, including the electrical contacts, is completely dry and clean. If the endoscope is used with the electrical contacts wet and/or dirty, the endoscope and light source may malfunction.
  - If air bubbles emerge from the endoscope continuously during the leakage test, do not use the endoscope. Water may enter the endoscope and cause a short circuit. This may result in image sensor damage.

CAUTION

- Turn the video system center ON only when the endoscope connector is connected to the light source. In particular, confirm that the video system center is OFF before connecting or disconnecting the endoscope connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- Do not hit or bend the electrical contacts on the endoscope connector. The connection to the light source may be impaired and a faulty contact can result.

■ *Examples of inappropriate handling*

Details on clinical endoscopic technique are the responsibility of trained specialists. Patient safety in endoscopic examinations and endoscopic treatment can be ensured through appropriate handling by the physician and the medical facility. Examples of inappropriate handling are described below.

WARNING

- Over-insufflating the lumen may cause patient pain, injury, bleeding, and/or perforation.
- Applying suction with the distal end of the endoscope in prolonged contact with the mucosal surface, with higher suction pressure than required, or with prolonged suction time may cause bleeding and/or lesions.
- The endoscope has not been designed for use in retroflexed observation in parts of the body other than the stomach. Performing retroflexed observation in a narrow lumen may make it impossible to straighten the angle of the bending section and/or withdraw the endoscope from the patient. Retroflexed observation in parts of the body other than the stomach should be performed only when its usefulness is determined to be greater than the risk that is posed to the patient. Also, do not operate the endoscope forcibly in retroflexed observation.
- Inserting, withdrawing, and using EndoTherapy accessories without a clear endoscopic image may cause patient injury, burns, bleeding, and/or perforation.
- Inserting or withdrawing the endoscope, feeding air, applying suction, or operating the bending section without a clear endoscopic image may cause patient injury, bleeding, and/or perforation.
- For reasons described below, do not rely on the NBI[*1] observation mode alone for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.
  - NBI has not been demonstrated to increase the yield or sensitivity of finding any specific mucosal lesion, including colonic polyps or Barrett’s esophagus.

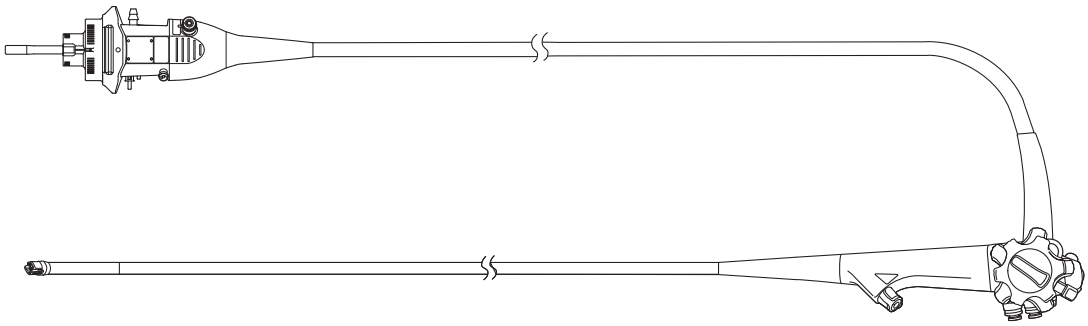
*1 Narrow Band Imaging. For more details, refer to the instruction manual for the video system center CV-190.

Chapter 1 Checking the Package Contents

1.1 Checking the package contents list

Match all items in the package with the components shown below. Inspect each item for damage. If the endoscope is damaged, a component is missing, or you have any questions, do not use the items; immediately contact Olympus.

❍ Endoscope



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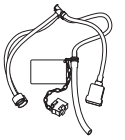
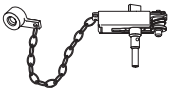
■ *Packaged items for the Americas, Europe, Australasia, Middle East, and Africa*

❍ Items

Single use combination cleaning brush (BW-412T, 3 pcs)



Injection tube (MH-946)



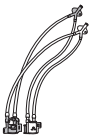
Channel plug (MH-944)

AW channel cleaning adapter (MH-948)

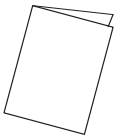
Suction cleaning adapter (MH-856)

ETO cap (MB-156)

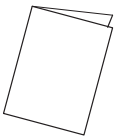
Mouthpiece (MA-392, 2 pcs)



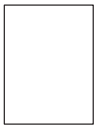
Distal-end flushing adapter (MAJ-2319)



Operation manual



Reprocessing manual



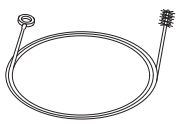
Instructions (warning for locking the guidewire)

NOTE

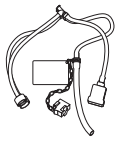
Single use distal cover (MAJ-2315) and single use biopsy valve (MAJ-1555) are sold separately.

■ *Packaged items for countries other than the Americas, Europe, Australasia, Middle East, and Africa*

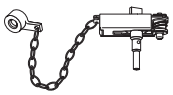
❍ Items



Channel cleaning brush (BW-20T)



Injection tube (MH-946)



Channel plug (MH-944)

Channel-opening cleaning brush (MH-507)

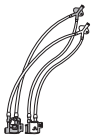
AW channel cleaning adapter (MH-948)

Suction cleaning adapter (MH-856)

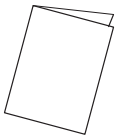
ETO cap (MB-156)

Biopsy valve (MB-358, 10 pcs)

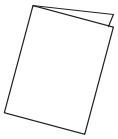
Mouthpiece (MA-392, 2 pcs)



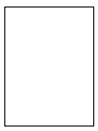
Distal-end flushing adapter (MAJ-2319)



Operation manual



Reprocessing manual



Instructions (warning for locking the guidewire)

NOTE

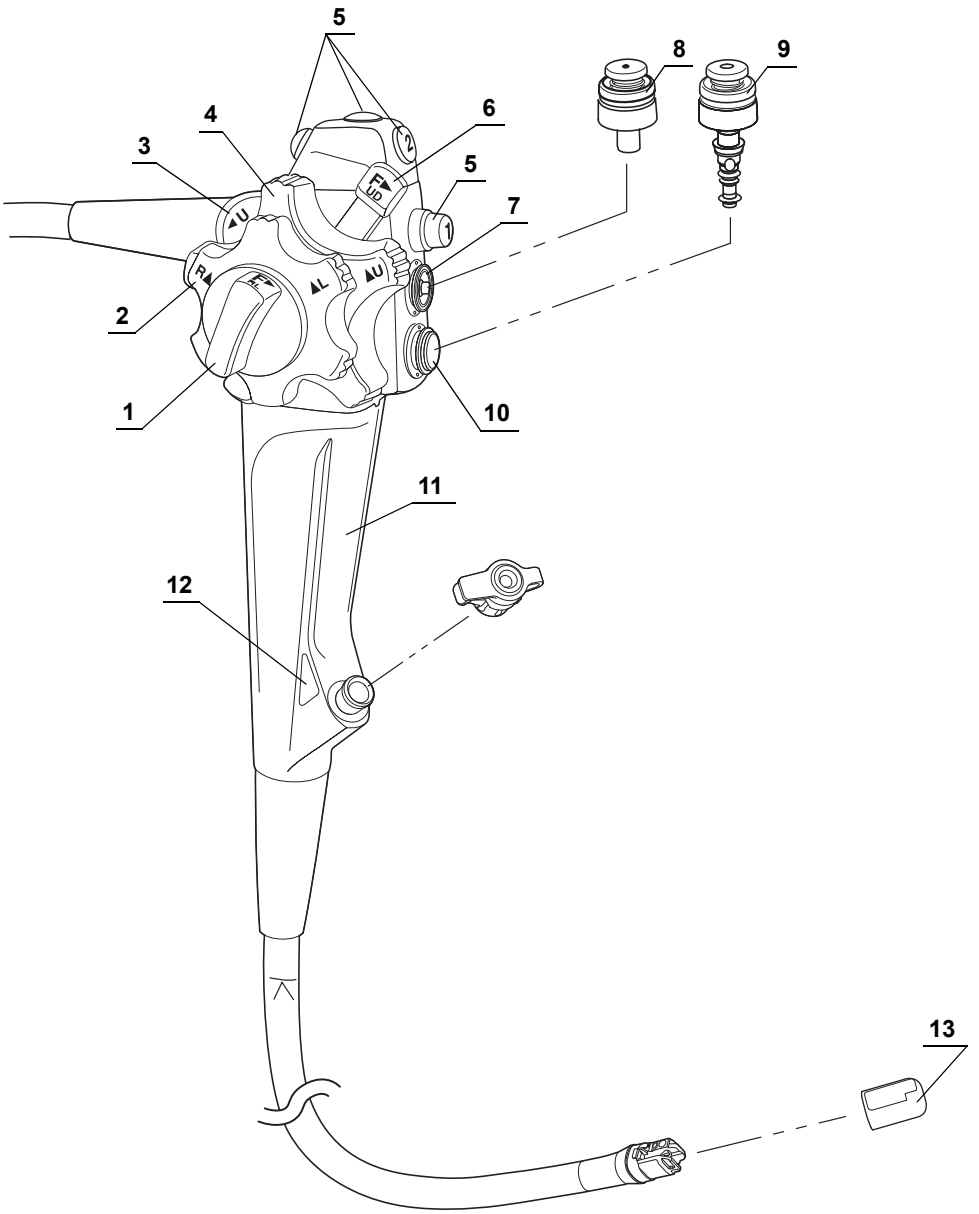
Single use distal cover (MAJ-2315) is sold separately.

Chapter 2 Instrument Nomenclature and Specifications

The instrument nomenclature, functions, and specifications are described in this chapter.

2.1 Nomenclature and functions

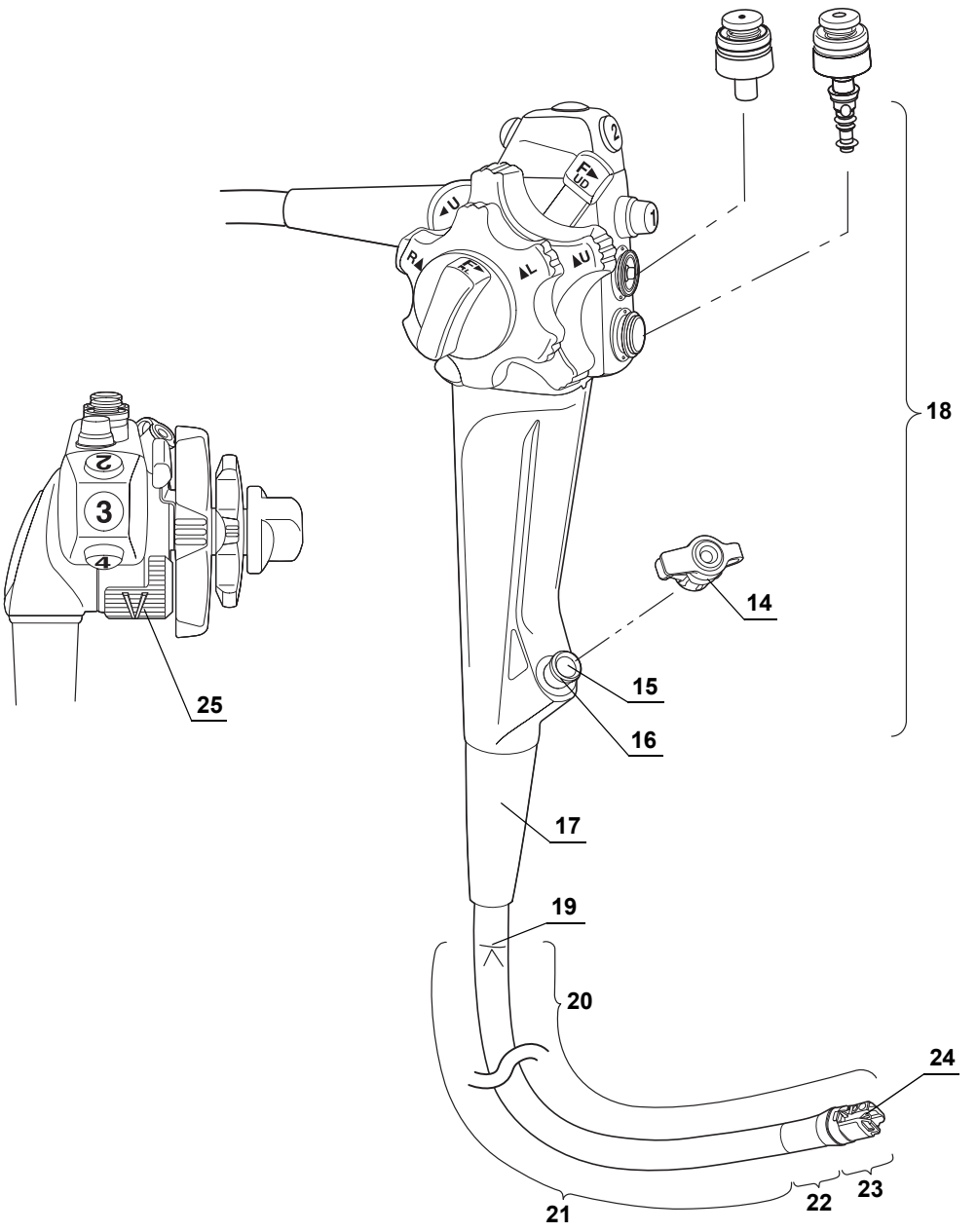
■ *Control section, insertion section*



No.	Nomenclature	Description
1	RIGHT/LEFT angulation lock	Turning this lock in the "F▶" direction frees angulation. Turning the lock in the opposite direction locks the bending section at the desired position.
2	RIGHT/LEFT angulation control knob	When this knob is turned in the "R▲" direction, the bending section moves RIGHT; when the knob is turned in the "▲L" direction, the bending section moves LEFT.
3	Elevator control lever	When this lever is moved in the "◀U" direction, the forceps elevator is raised. When the lever is moved in the opposite direction, the forceps elevator is lowered.
4	UP/DOWN angulation control knob	When this knob is turned in the "▲U" direction, the bending section moves UP; when the knob is turned in the "D▲" direction, the bending section moves DOWN.
5	Remote switches 1 to 4	The functions of remote switches 1 to 4 can be selected on the video system center. Refer to the instruction manual for the video system center when setting these functions.
6	UP/DOWN angulation lock	Moving this lock in the "F▶" direction frees angulation. Moving the lock in the opposite direction locks the bending section at the desired position.
7	Suction cylinder	Attach the suction valve to this cylinder.
8	Suction valve (MH-443)	This valve is depressed to activate suction. The valve is operated to remove any fluids, debris, flatus, or air from the patient.
9	Air/water valve (MH-438)	The hole in this valve is covered to insufflate air and the valve is depressed to feed water for lens washing. It also can be operated to feed air for removing any fluids or debris adhering to the objective lens.
10	Air/water cylinder	Attach the air/water valve to this cylinder.
11	Grip section	Grip here when using the endoscope.
12	Color code	This color code and numeral show the compatibility of EndoTherapy accessories. • Orange: TJF-Q190V The endoscope can be used with EndoTherapy accessories that have the same color code. For more information on combining the endoscope with particular EndoTherapy accessories, refer to "Combination equipment" on page 111 and the instruction manuals for the compatible accessories.
13	Single use distal cover (MAJ-2315)	Attach this single use distal cover to the distal end of the endoscope.

NOTE

Single use distal cover (MAJ-2315) is sold separately.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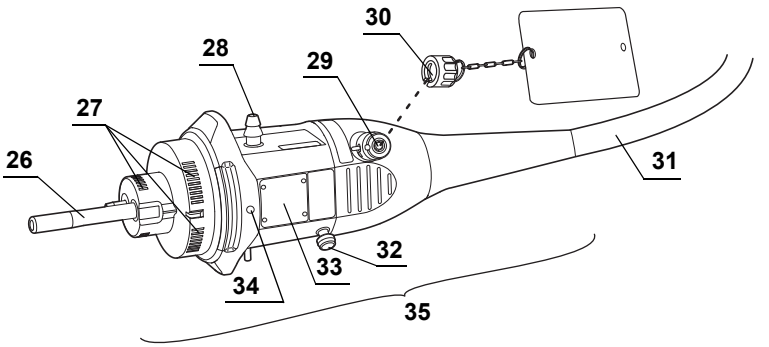
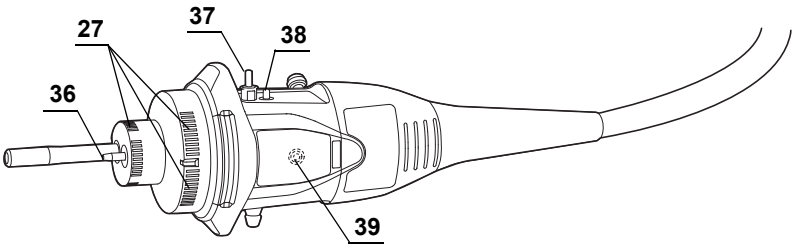
No.	Nomenclature	Description
14	Biopsy valve (MB-358) or single use biopsy valve (MAJ-1555)	This valve is attached to the instrument channel port, and the EndoTherapy accessory is inserted, or a syringe is attached.
15	Instrument channel inlet	An EndoTherapy accessory can be inserted into this port. The instrument channel inlet is connected to the instrument channel outlet on the distal end of the endoscope via the instrument channel. The instrument channel functions are as follows: • Channel for the insertion of EndoTherapy accessories • Suction channel • Fluid feed channel (from a syringe via the biopsy valve)
16	Instrument channel port	Attach the biopsy valve to this port.
17	Boot	Prevents the junction between the insertion tube and control section from bending.
18	Control section	Operates the bending section, feeds air and water, and performs suction.
19	Insertion section limit mark	This mark shows the maximum point to which the endoscope may be inserted into the patient's body.
20	Insertion section	This section is inserted into the patient body cavity.
21	Insertion tube	Connects the control section and bending section.
22	Bending section	This section moves the distal end of the endoscope when the UP/DOWN and/or RIGHT/LEFT angulation control knobs are operated.
23	Distal end	The objective lens and air/water nozzle are on this distal end of the endoscope.
24	Forceps elevator	The elevator moves EndoTherapy accessories when the elevator control lever is operated. In addition, the elevator is used to assist the locking function of the guidewire while inserting/withdrawing the wire-guided type EndoTherapy accessory.
25	Guidewire locking function mark	This mark shows that the endoscope uses the V system as guidewire locking mechanism.

■ *Endoscope connector*



Rear side



No.	Nomenclature	Description
26	Light guide	Connects the endoscope to the light source and transmits light to the distal end of the endoscope.
27	Electrical contacts	Connect the light source and the endoscope electrically.
28	Suction connector	Connects the endoscope to the suction tube of the suction pump.
29	Venting connector	Attach the ETO cap or leakage tester here.
30	ETO cap (MB-156)	The ETO cap must be attached prior to ethylene oxide gas sterilization and aeration. Also, it must be removed prior to immersion or clinical examination.
31	Universal cord	Connects the endoscope connector and the control section.
32	S-cord connector mount	Connects the endoscope with the Olympus electrosurgical unit via the S-cord. The S-cord conducts leakage current from the endoscope to the electrosurgical unit. To connect the S-cord, refer to the instruction manual for the electrosurgical unit. When the endoscope is used with the electrosurgical generator ESG-100 or ESG-400, it is not necessary to use the S-cord.
33	Product ID plate	UDI Indication, the product name (model), and serial number are marked here.
34	UP mark	When the endoscope connector is connected to the light source, the “O” mark faces upward.
35	Endoscope connector	Connects the endoscope to the light source to transmit light and to feed water to the distal end of the endoscope, and accessories and equipment are connected to this connector. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-190. For more details, refer to the instruction manual for the CV-190.
36	Air pipe	Connects the endoscope to the light source and transmits air to the distal end of the endoscope.
37	Water supply connector	Connects the endoscope to the water container via the water container tube to supply water to the distal end of the endoscope.
38	Air supply connector	Connects the endoscope to the water container via the water container tube to pressurize the water container.
39	Scope ID mark	The RFID (radio frequency identification) chip for the scope ID information is embedded here.

2.2 Specifications

■ Environment

Operating environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Standard storage environment (e.g. within the hospital)	**Ambient temperature**	5 – 40°C (41 – 104°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Transportation environment (conditions during transportation and short-term storage)	**Ambient temperature**	–47 to +70°C (–52.6 to +158°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)

■ Function list

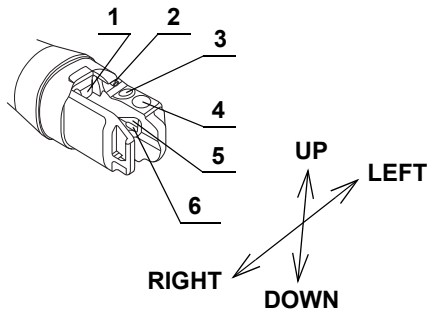
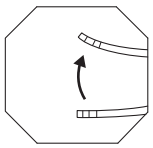
	Pre-freeze function[*1]	**Electronic zoom function**[*1]	**Electronic shutter function**[*1]	**Records of endoscope's information**[*1]	**NBI observation**[*1]	**High-frequency cauterization treatment**	**Endoscope position detecting function**
TJF-Q190V	–	○	○	○	○	○	○

○ **available** – **not available**

Table 2.1

*1 For more details, refer to the instruction manual for the CV-190.

■ *Specifications*

Model		TJF-Q190V
Optical system	**Field of view**	100°
	Direction of view	Backward side viewing 15°
	Depth of field	5 – 60 mm
Insertion section	**Distal end outer diameter with MAJ-2315**	ø 13.5 mm
	Distal end enlarged 1 Instrument channel outlet 2 Air/water nozzle 3 Objective lens 4 Light guide lens 5 Forceps elevator 6 Guidewire-locking groove	
	Insertion tube outer diameter	ø 11.3 mm
	Insertion section working length	1240 mm
Instrument channel	**Channel inner diameter**	ø 4.2 mm
	Minimum visible distance[*1]	10 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
Airflow rate[*2]		25 cm^3/s
Bending section	**Angulation range**	UP 120° DOWN 90° RIGHT 110° LEFT 90°
Total length		1560 mm

*1 Distance from the distal end of the endoscope.

*2 Standard when CLV-190 (high air pressure) is used.

EMC	**Applied standard**	IEC 60601-1-2: 2001 IEC 60601-1-2: 2007 IEC 60601-1-2: 2014 IEC 60601-2-18: 1996 IEC 60601-2-18: 2009 • This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014). When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable. • CISPR 11 of emission: Group 1, Class B
Degree of protection against electric shock		TYPE BF applied part
Ingress protection rating		IPX7
UDI Indication		 The UDI Indication is required by some countries' regulations regarding the identification of medical device also known as Unique Device Identification (UDI). The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix): - (01) 14-digit GS1 Global Trade Item Number; - (11) 6-digit date of manufacture; - (21) 7-digit serial number.

Chapter 3 Preparation and Inspection

The equipment prepared before using this endoscope and procedures for inspection of the endoscope and equipment are described in this chapter.

3.1 The workflow of preparation and inspection

The workflow of preparation and inspection is shown below.
Before each case, prepare and inspect this endoscope as instructed below. Inspect other equipment to be used with this endoscope as instructed in their respective instruction manuals. Should any irregularity be observed after inspection, follow the instructions as described in Chapter 5, “Troubleshooting”. If the endoscope malfunctions, do not use it. Return it to Olympus for repair as described in Section 5.4, “Returning the endoscope for repair”.

WARNING

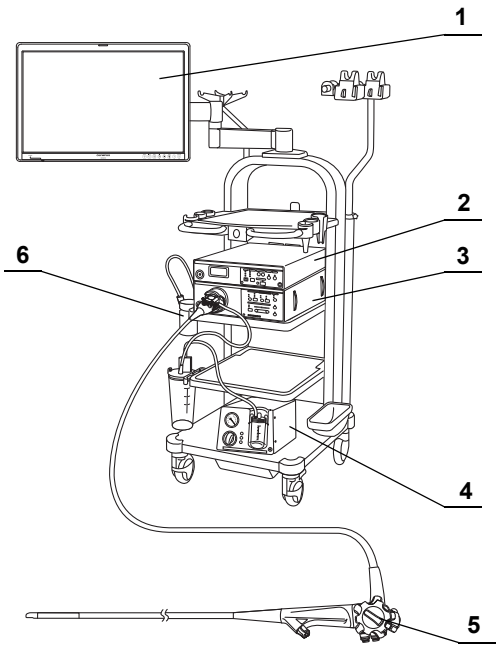
- Never use the endoscope on a patient if any irregularity is observed. The irregular endoscope may compromise patient or user safety and may result in more severe equipment damage. In addition, it may pose an infection control risk.
- This endoscope was not reprocessed before shipment. Before using this endoscope for the first time, reprocess it according to the instructions as described in the endoscope’s companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.

1. **Prepare the equipment to be used with the endoscope.**
→Section 3.2 on page 29
2. **Inspect the endoscope.**
→Section 3.3 on page 30
3. **Inspect the accessories.**
→Section 3.4 on page 39
4. **Attach the accessories to the endoscope.**
→Section 3.5 on page 43
5. **Inspect the ancillary equipment.**
→Section 3.6 on page 54
6. **Connect the ancillary equipment to the endoscope.**
→Section 3.7 on page 55
7. **Inspect the function of the ancillary equipment to be connected to the endoscope.**
→Section 3.8 on page 58

3.2 Preparation of the equipment

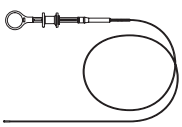
Prepare this endoscope, the accessories, equipment, and all personal protective equipment as shown in Figure 3.1. Prepare the equipment in “Combination equipment” on page 111 in accordance with the intended use.
Be sure to prepare another endoscope and EndoTherapy accessories (e.g. biopsy forceps, basket) to pick up a single use distal cover when it falls off inside the patient.
Also, refer to the respective instruction manuals for each piece of equipment before use.

❍ Endoscope system



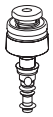
1 Monitor
2 Video system center
3 Light source
4 Suction pump
5 Endoscope*1
6 Water container

❍ Accessories and ancillary equipment

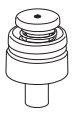


EndoTherapy accessories

Mouthpiece (MA-392*2)

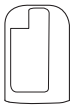


Air/water valve (MH-438*2)



Suction valve (MH-443*2)

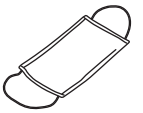
Biopsy valve (MB-358*2) or single use biopsy valve (MAJ-1555)



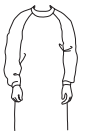
Single use distal cover (MAJ-2315)

❍ Personal protective equipment (e.g.)

Eyewear



Face mask



Moisture-resistant clothing

Chemical-resistant gloves

❍ Other

- **Lint-free cloths**
- **Sterile water**
- **Containers for sterile water**

Figure 3.1

*1 Prepare the endoscope that has been reprocessed as described in the “REPROCESSING MANUAL” with your endoscope model listed on the cover.

*2 Prepare the air/water valve, suction valve, mouthpiece, and biopsy valve that have been reprocessed as described in the “REPROCESSING MANUAL” with your endoscope model listed on the cover.

3.3 Inspection of the endoscope

Detach the ETO cap from the venting connector if it is attached.

■ Inspection of the endoscope

Inspect the endoscope for any irregularities following the instructions below.

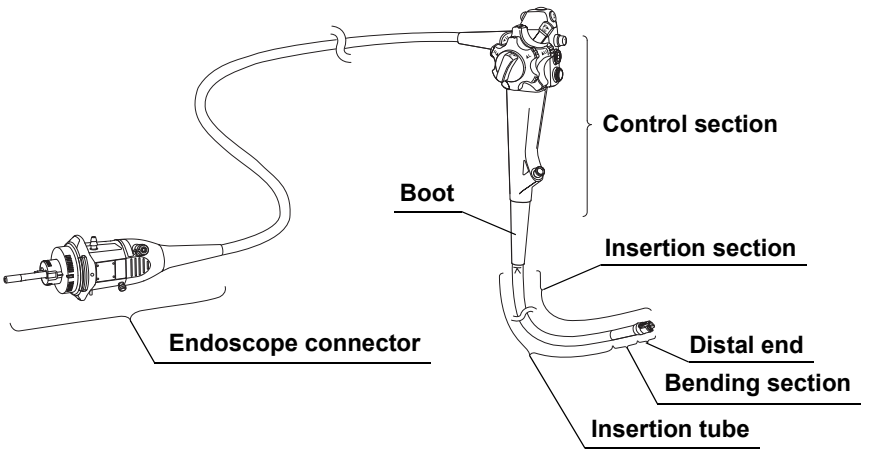


Figure 3.2

1 Inspect the endoscope connector for any irregularities such as excessive scratching, deformation, and loose parts.

2 Inspect the control section for any irregularities such as excessive scratching, deformation, and loose parts.

3 Inspect the boot and the insertion section near the boot for any irregularities such as bends, twists, tears, and cracks.

4 Inspect the external surface of the entire insertion section including the bending section and the distal end including the forceps elevator for any irregularities such as dents, bulges, swelling, scratches, peeling of coating, holes, sagging, transformation, bends, adhesion of foreign bodies, missing parts, and protruding objects.

5 Inspect the forceps elevator and the area around the forceps elevator for foreign materials such as debris and fluids, while moving the elevator control lever to raise and lower the forceps elevator. If any foreign materials are observed, stop using the endoscope and take necessary measures according to Section 6.2, “Inspection before each patient procedure”.

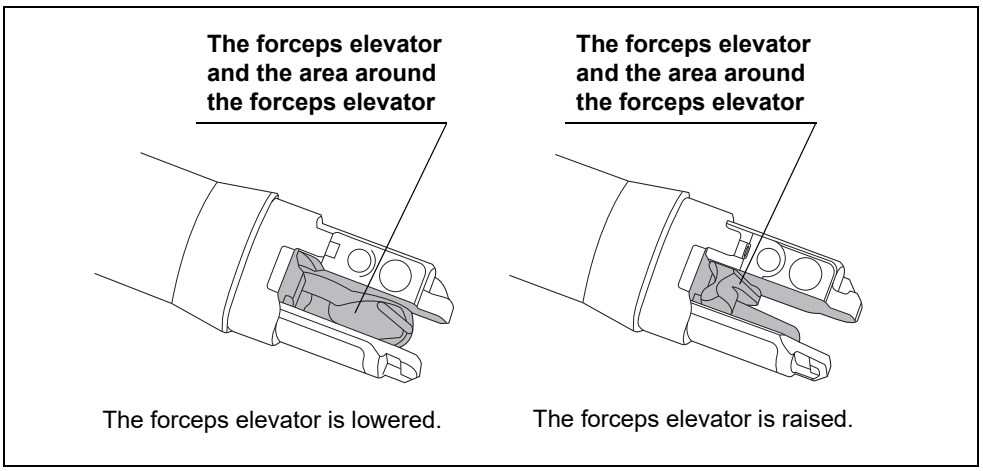


Figure 3.3

WARNING

Use of an endoscope with residual foreign materials for a patient procedure may pose an infection control risk.

6 Carefully run your one hand back and forth over the entire length of the insertion section in a stabilized condition, such as holding the control section with other hand or placing the control section on a hanger. Confirm that no objects or metallic wire protrude from the insertion section. Also, confirm that the insertion tube is not abnormally rigid.

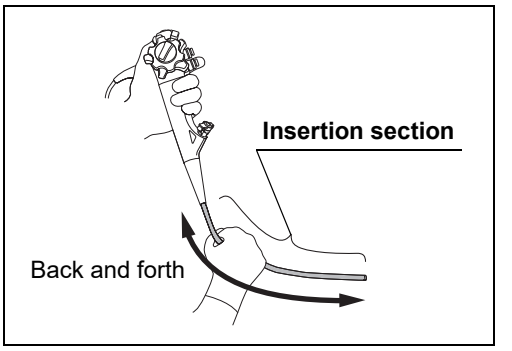


Figure 3.4

7 Using both hands, bend the insertion tube of the endoscope into a semicircle.
Then, moving your hands as shown by the arrows in Figure 3.4, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable.

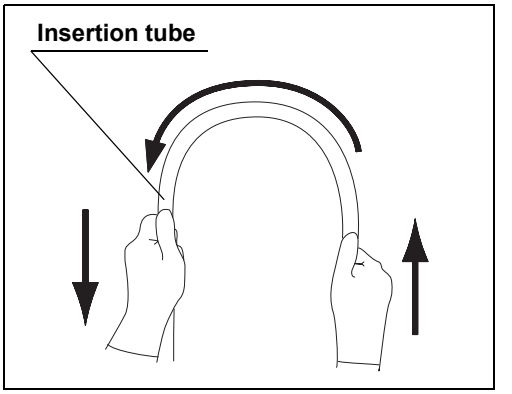


Figure 3.5

8 Gently hold the midpoint of the bending section and approximately 20 cm from the distal end of the endoscope.
Push and pull gently to confirm that the junction between the bending section and the insertion tube is not loose.

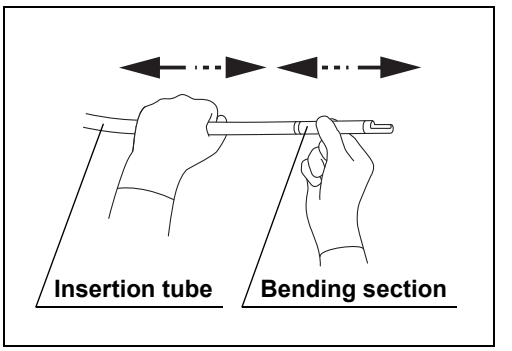


Figure 3.6

9 Inspect the entire distal end of the endoscope including the objective lens and light guide lens for any irregularities such as scratches, chips, cracks, stains, discoloration, deformation, and gaps around the lens.

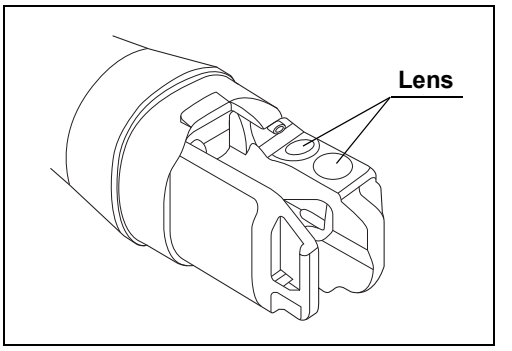


Figure 3.7

10 Inspect the air/water nozzle at the distal end of the endoscope for any irregularities such as abnormal swelling, bulges, and dents.

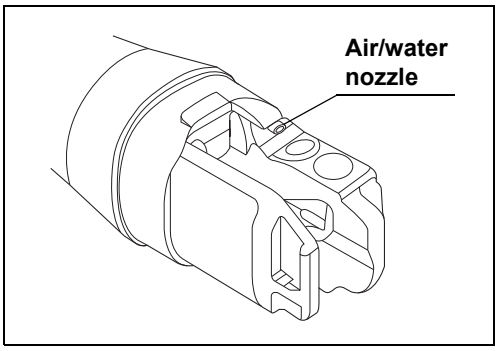


Figure 3.8

11 Inspect the guidewire-locking groove of the forceps elevator for stains.

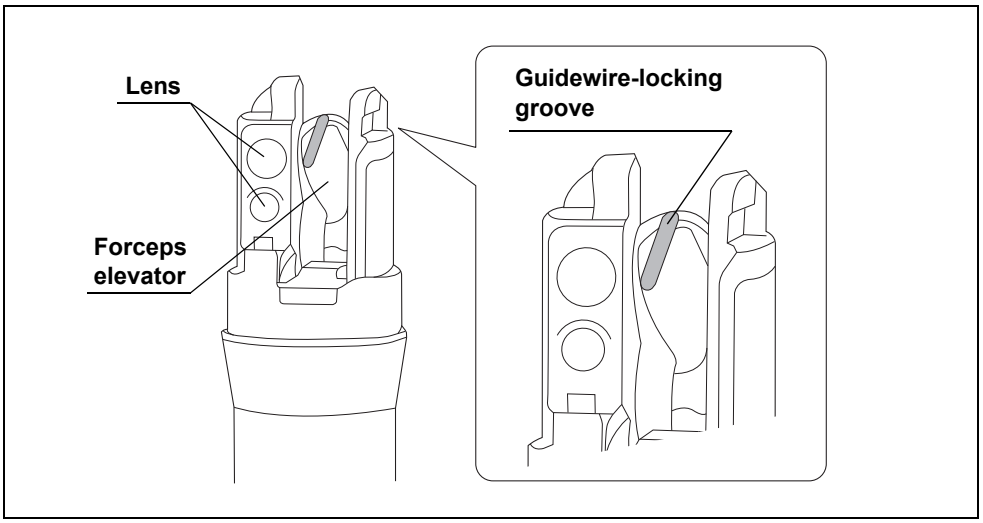


Figure 3.9

12 Inspect the adhesives attaching the bending section cover to the insertion section for any irregularities such as deterioration, pitting, cracking, and peeling.
Also, inspect the bending section cover for any irregularities such as bulges, swelling, scratches, and holes.

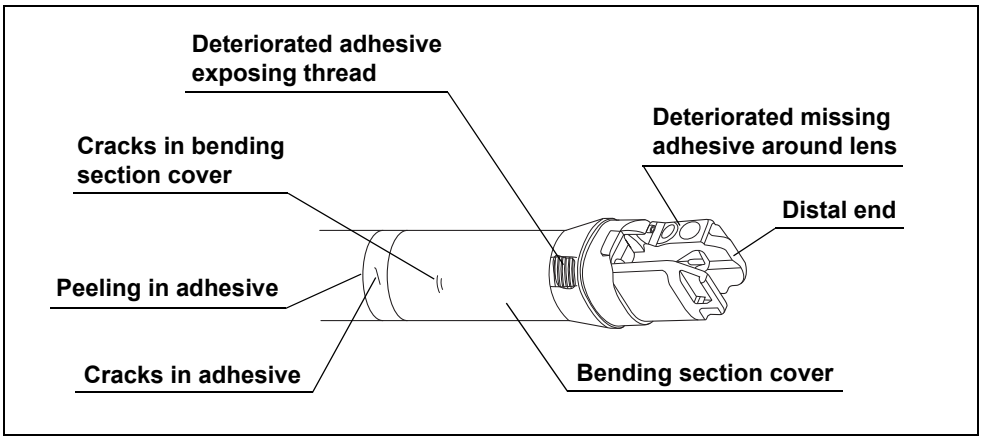


Figure 3.10

NOTE

The covering on both ends of the bending section is wound with thread. The adhesives cover them so that they are fixed. Therefore, the thread is exposed if the adhesives become chipped.

13 Wipe the light guide edges of the endoscope connector using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.

14 If foreign objects, such as detergent remnants, hard water residue, finger grease, dust, and lint may be on the electrical contacts on the endoscope connector (ex. wiping with lint-prone cloths, left unused for a long period of time), wipe the electrical contacts with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
Also, confirm that the electrical contacts are completely dry and clean.

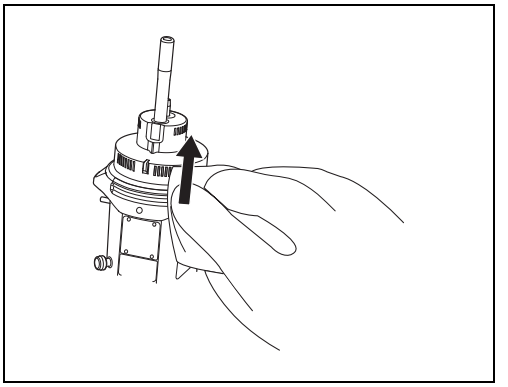


Figure 3.11

■ *Inspection of the bending mechanisms*

Perform the following inspection.

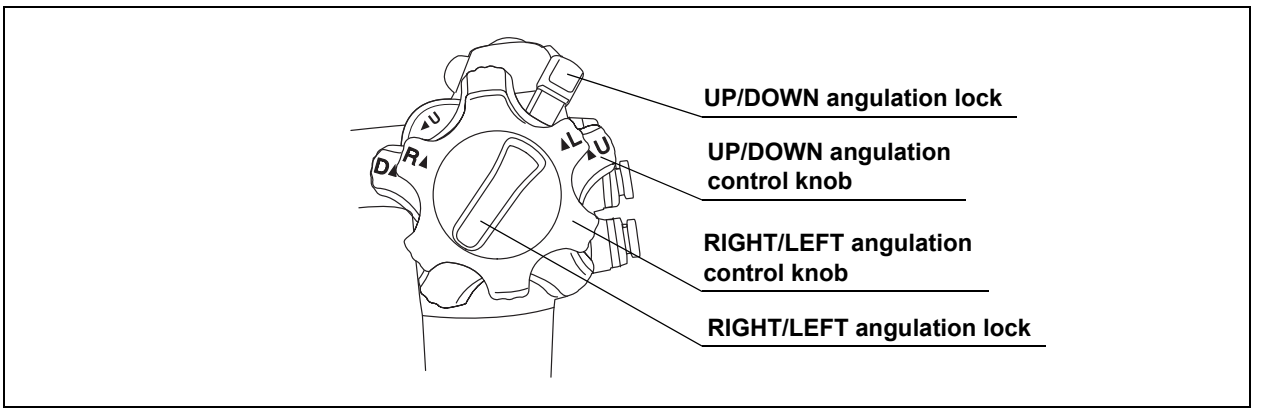


Figure 3.12

WARNING

If the movement of the UP/DOWN angulation lock, RIGHT/LEFT angulation lock, and the angulation control knobs is loose and/or not smooth, or the bending section does not angulate smoothly, the bending mechanism may have an irregularity. In this case, do not use the endoscope because it may be impossible to straighten the bending section during an examination.

Inspection for smooth operation

1 Turn the UP/DOWN and RIGHT/LEFT angulation control knobs to their respective neutral positions to straighten the bending section.

2 Move both the UP/DOWN and RIGHT/LEFT angulation locks all the way in the "F▶" direction to confirm that their respective locks are released.

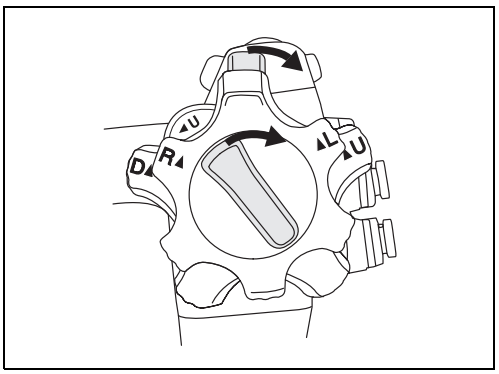


Figure 3.13

3 Turn the UP/DOWN and RIGHT/LEFT angulation control knobs slowly in each direction until they stop, and return them to their respective neutral positions. Confirm that the bending section angulates smoothly and correctly, that maximum angulation can be achieved, and that the bending section returns to its neutral position.

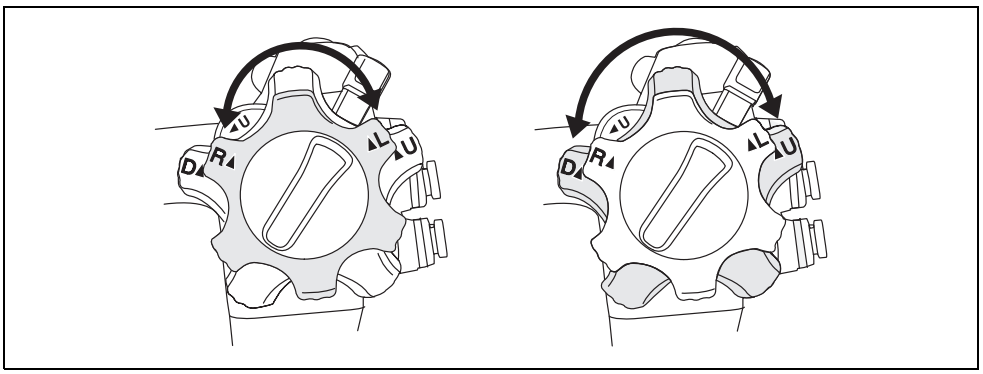


Figure 3.14

4 When the UP/DOWN and RIGHT/LEFT angulation control knobs are turned to their respective neutral positions, confirm that the bending section returns smoothly to an approximately straight position.

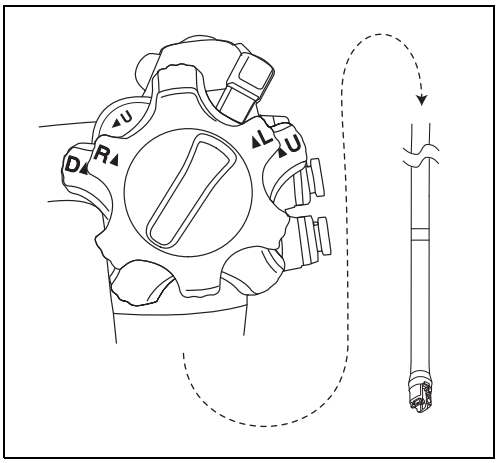


Figure 3.15

❍ Inspection of the UP/DOWN angulation mechanism

1 Move the UP/DOWN angulation lock all the way in the opposite direction of the “F▶” mark.

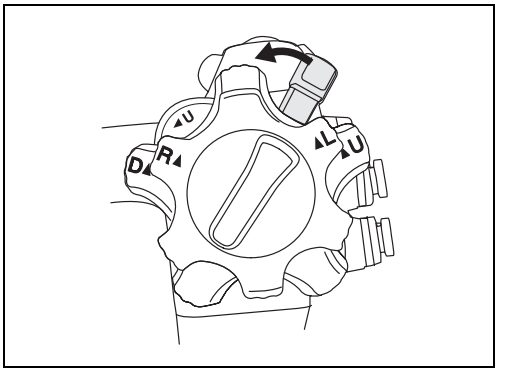


Figure 3.16

2 Turn the UP/DOWN angulation control knob in the “▲U” or the “D▲” direction until it stops.

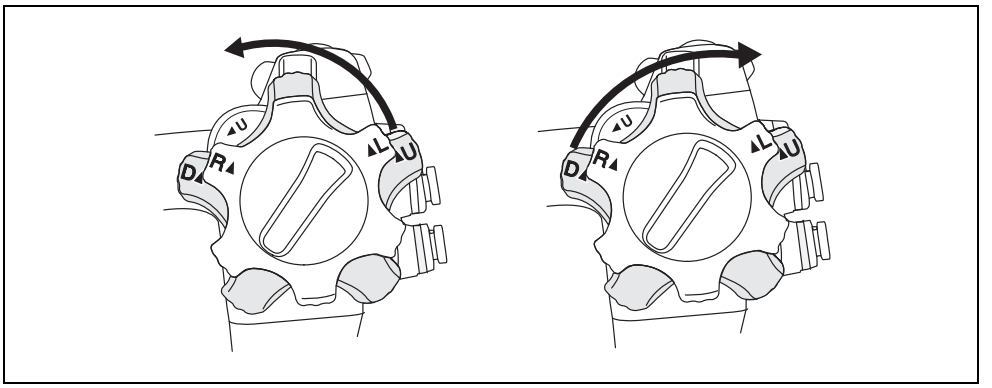


Figure 3.17

3 Confirm that the angle of the bending section is stabilized when the UP/DOWN angulation control knob is released.

4 Confirm that the bending section straightens out when the UP/DOWN angulation lock is moved all the way in the “F▶” direction and the UP/DOWN angulation control knob is released.

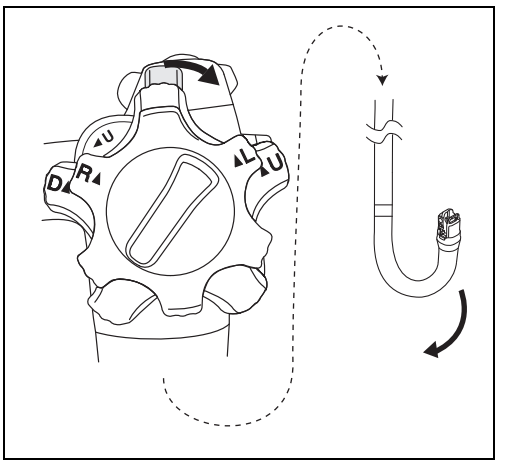


Figure 3.18

Inspection of the RIGHT/LEFT angulation mechanism

1 Turn the RIGHT/LEFT angulation lock all the way in the opposite direction of the “F▶” mark.

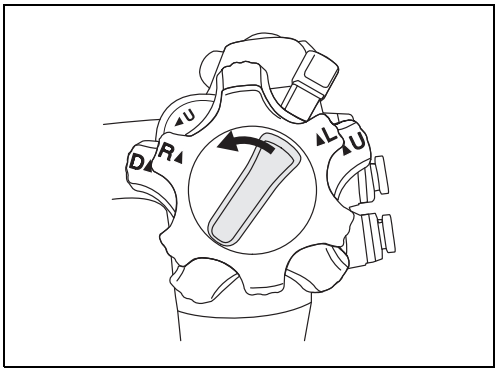


Figure 3.19

2 Then turn the RIGHT/LEFT angulation control knob in the “R▲” or the “▲L” direction until it stops.

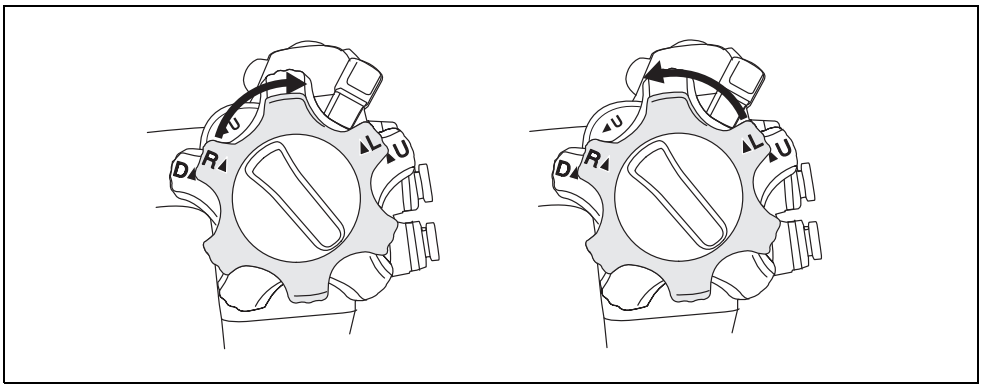


Figure 3.20

3 Confirm that the angle of the bending section is stabilized when the RIGHT/LEFT angulation control knob is released.

4 Confirm that the bending section straightens out when the RIGHT/LEFT angulation lock is turned in the “F▶” direction and the RIGHT/LEFT angulation control knob is released.

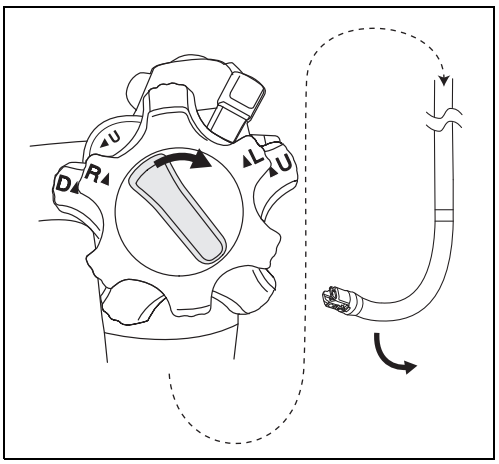


Figure 3.21

■ *Inspection of the forceps elevator mechanism*

Perform the following inspections while the bending section is straight.

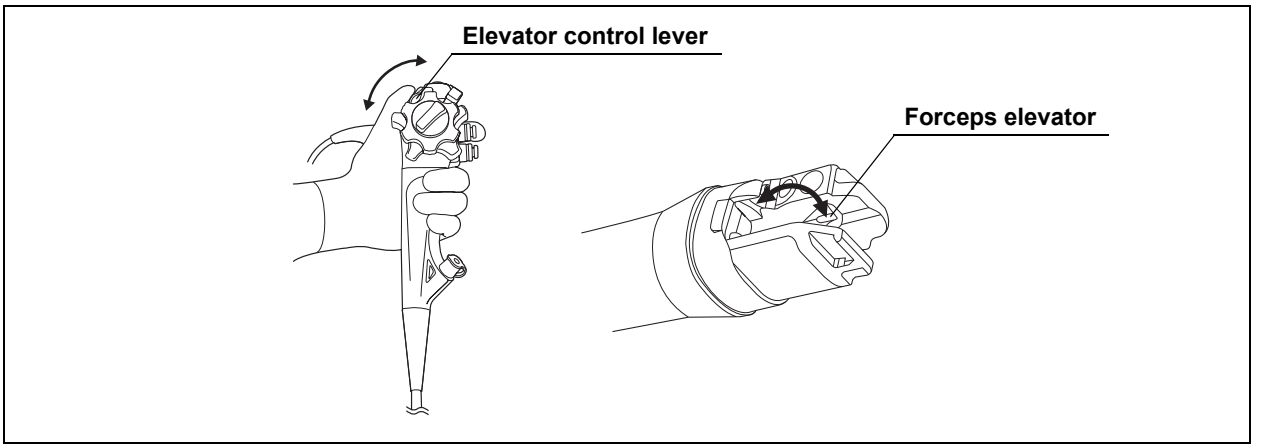


Figure 3.22

NOTE

In rare cases, the elevator control lever can move further in the "◀U" direction after the forceps elevator is completely raised for more effective locking of the guidewire. In this case, more resistance may be encountered when operating the elevator control lever. This does not indicate a malfunction.

1 Straighten the bending section.

2 Move the elevator control lever slowly all the way in the opposite direction of the "◀U" direction.

3 While observing the forceps elevator at the distal end of the insertion section, slowly move the elevator control lever in the "◀U" direction until the elevator control lever stops. Confirm that the lever can be operated smoothly and that the forceps elevator is raised smoothly.

4 Confirm that the forceps elevator remains stationary when pushed from behind while holding the elevator control lever stationary. (See Figure 3.22)

5 Move the elevator control lever slowly all the way in the opposite direction of the "◀U" direction. Confirm that the lever can be operated smoothly and that the forceps elevator lowers smoothly.

3.4 Inspection of accessories

■ Inspection of the air/water and suction valves

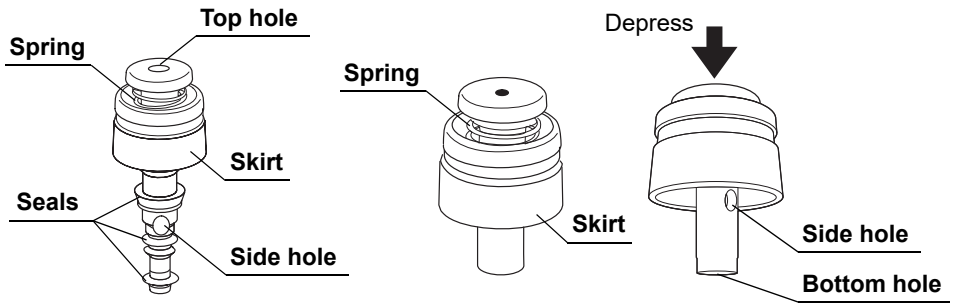


Figure 3.23

WARNING

Confirm that the top hole of the air/water valve is not blocked. If the hole is blocked, air is fed continuously and patient pain, bleeding, and/or perforation can result.

NOTE

The air/water and suction valves degrade as they are used. If the inspection of the air/water or suction valve reveals any irregularity, use new valves.

1. Confirm that the top hole of the air/water valve is not blocked.
2. With the valve tops depressed, confirm that the side holes of the valves are not blocked.
3. Confirm that the valves are not deformed or cracked.
4. Check for excessive scratching or tears in the air/water valve's seals.

■ *Inspection of the biopsy valve (MB-358)*

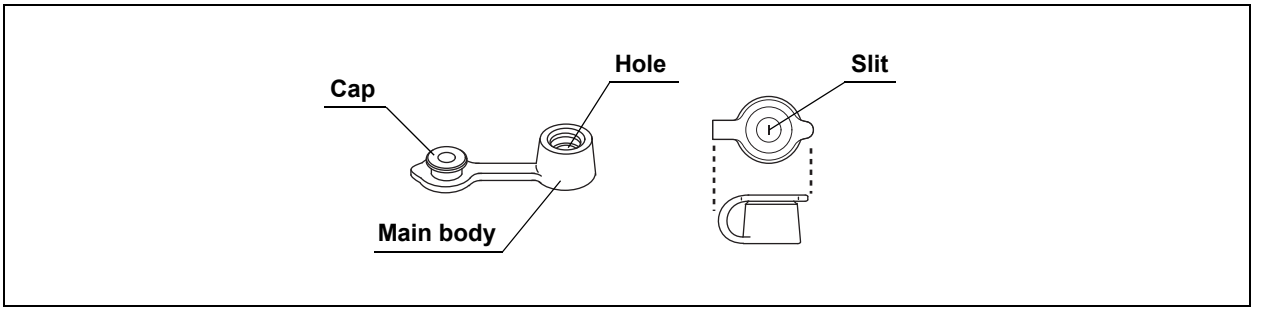


Figure 3.24

WARNING

The biopsy valve should be inspected as described below before each use. Replace it with a new one if any irregularity is observed during the inspection. An irregular, abnormal, or damaged valve can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection control risk.

1 Confirm that the slit and hole on the biopsy valve have no splits, cracks, deformations, discoloration, or other damage.

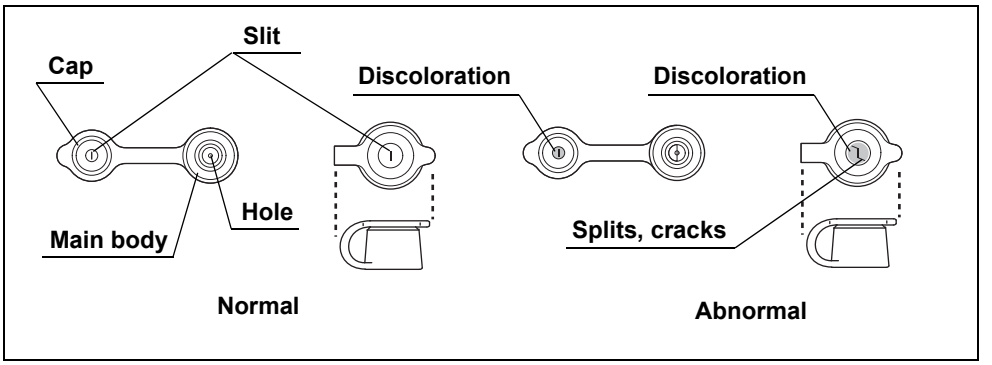


Figure 3.25

2 Attach the cap to the main body.

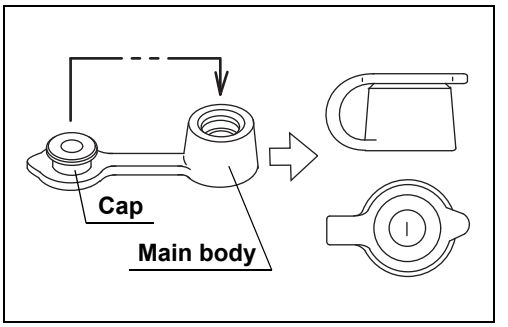


Figure 3.26

■ *Inspection of the single use biopsy valve (MAJ-1555)*

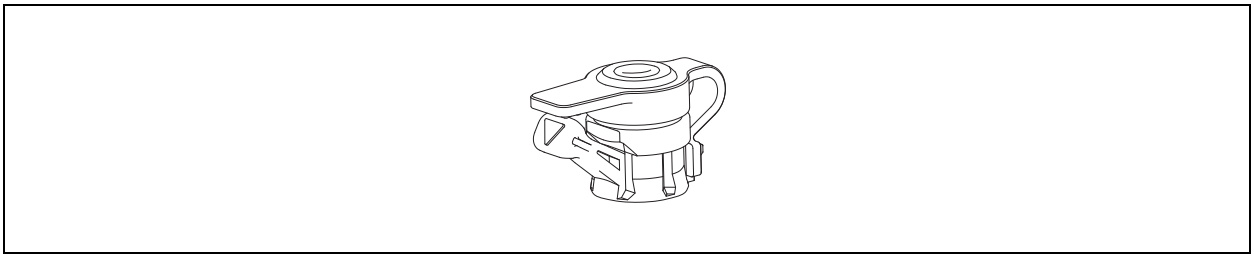


Figure 3.27

Inspect the single use biopsy valve as described in the single use biopsy valve's instruction manual.

■ *Inspection of the mouthpiece (MA-392)*

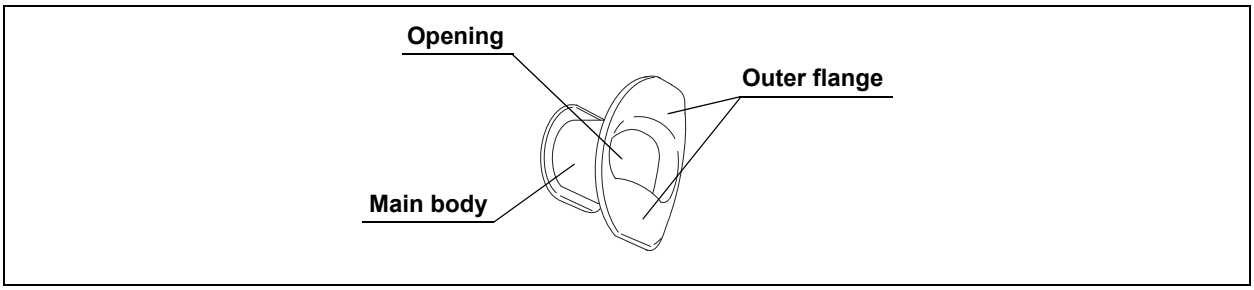


Figure 3.28

WARNING

Do not use a mouthpiece that is damaged, deformed, or reveals other irregularities, which may cause patient injury and/or equipment damage.

NOTE

- The mouthpiece MB-142 with the small opening is not compatible with TJF-Q190V. Do not use the mouthpiece MB-142 to prevent the damage of the endoscope's insertion section.
- Placing the mouthpiece in the patient's mouth before the procedure prevents the patient from biting and/or damaging the endoscope's insertion section.

1 Confirm that the mouthpiece is free from cracks, deformations, or discoloration.

2 Using your fingers, check all surfaces of the mouthpiece for scratches, cracks, or other irregularities.

■ *Inspection of the single use distal cover (MAJ-2315)*

WARNING

- Do not use a single use distal cover after the expiration date displayed on the sterile package. Using the single use distal cover after the expiration date may pose an infection control risk.
- Should any irregularity be observed when inspecting the single use distal cover, do not use it. A single use distal cover with irregularity could not serve the endoscope properly and/or could fall off during the examination. Using the endoscope without the single use distal cover could cause patient injury and this could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. In addition, if the single use distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.
- Only the single use distal cover (MAJ-2315) can be used with the TJF-Q190V model. If used in combination with a wrong single use distal cover, it may fall off the distal end of the endoscope during the examination. Continuing the examination after the single use distal cover has fallen off may cause patient injury by the uncovered distal end of the endoscope and this could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. In addition, if the single use distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.

Inspect the single use distal cover as described in the single use distal cover's instruction manual.

3.5 Attaching accessories to the endoscope

■ Attaching the suction valve

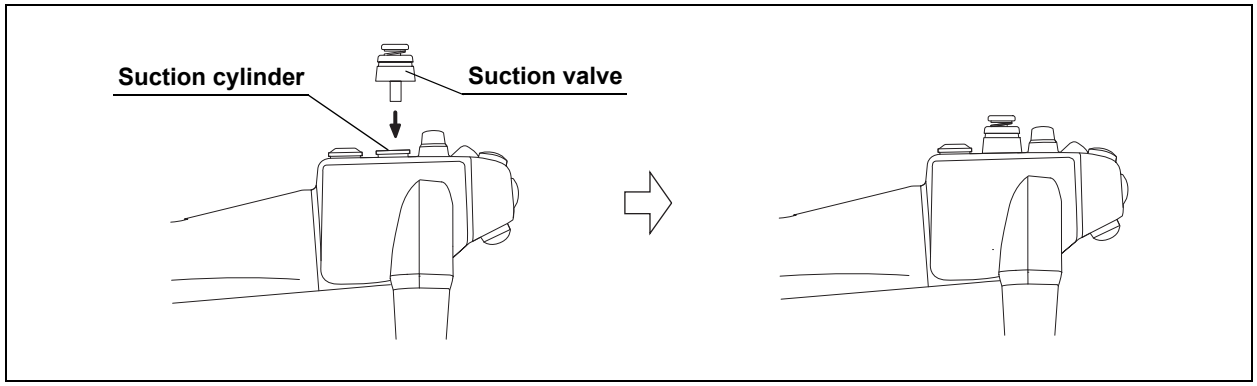


Figure 3.29

CAUTION

The suction valve does not require lubrication. Lubricants can cause swelling of the valve's seals, and the valve function may be impaired.

NOTE

The suction valve will make a whistling noise when it is dry; this does not indicate a malfunction.

1 Align the two metal ridges on the underside of the suction valve with the two holes in the suction cylinder.

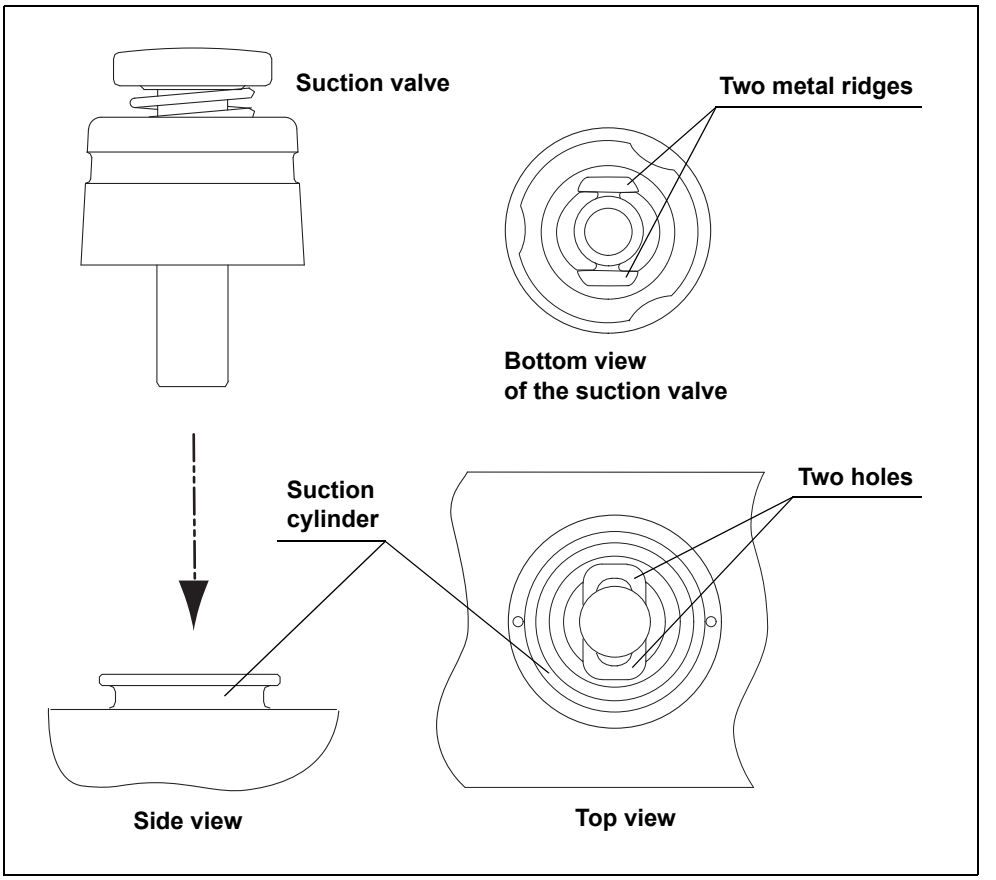


Figure 3.30

2 Attach the suction valve to the suction cylinder of the endoscope. (See Figure 3.29 and 3.30)

3 Confirm that the valve fits properly without any bulging of the skirt.

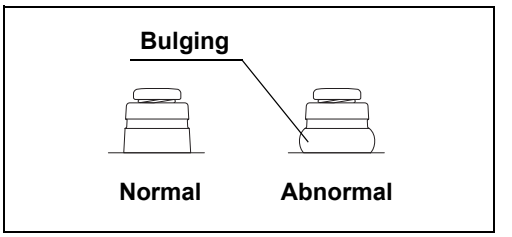


Figure 3.31

4 Confirm that the valve cannot be rotated.

■ *Attaching the air/water valve*

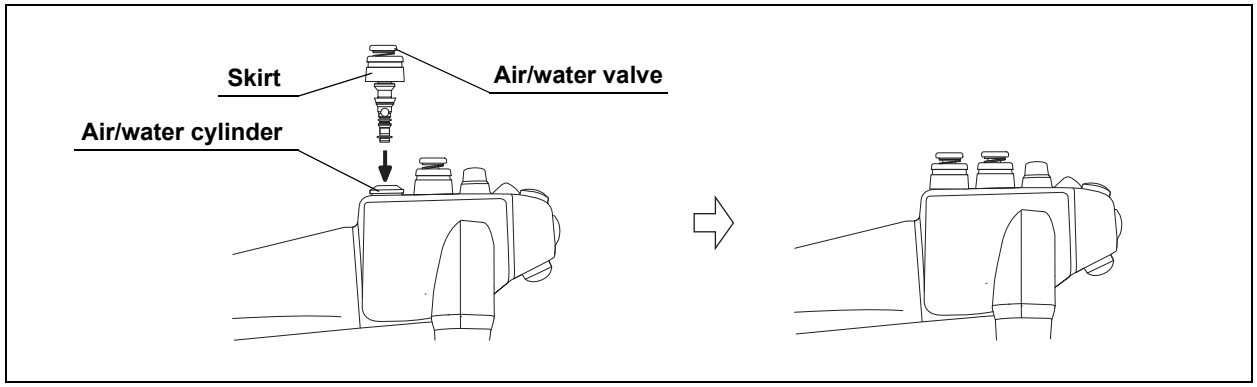


Figure 3.32

CAUTION

The air/water valve does not require lubrication. Lubricants can cause swelling of the valve's seals, and the valve function may be impaired.

NOTE

The air/water valve may stick at first, but it should operate smoothly after it is depressed a few times.

1 Attach the air/water valve to the air/water cylinder of the endoscope.

2 Confirm that the valve fits properly without any bulging of the skirt.

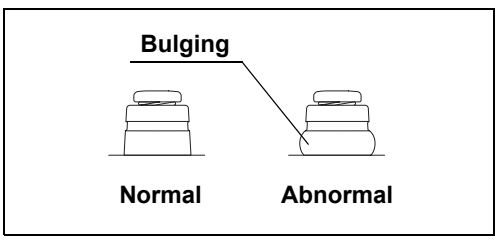


Figure 3.33

■ *Attaching the biopsy valve*

WARNING

If a biopsy valve is not properly connected to the instrument channel port, it can reduce the efficacy of the endoscope's suction system, and leak or spray patient debris, posing an infection control risk.

NOTE

If the slit seems to be closed, carefully insert an EndoTherapy accessory (such as a biopsy forceps) through the slit to reopen it.

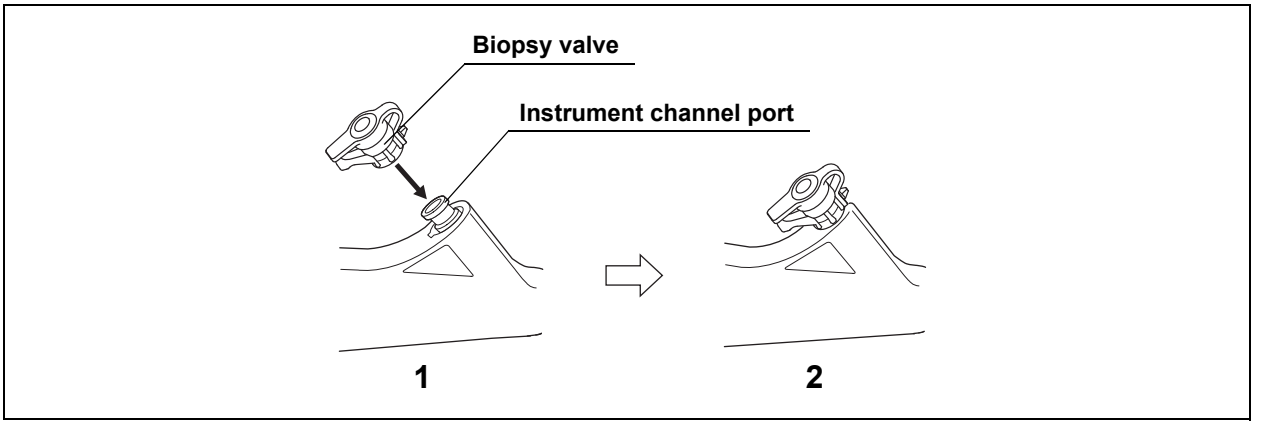


Figure 3.34

1 Attach the biopsy valve to the instrument channel port of the endoscope.

2 Confirm that the biopsy valve fits properly.

■ *Attaching the single use distal cover*

WARNING

- Never use the endoscope unless the single use distal cover is properly attached to the distal end. If the single use distal cover is not attached properly, it may slip off or fall off the distal end during the examination. This could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. Also, continuing the examination with the single use distal cover off may cause patient injury by the uncovered distal end of the endoscope. In addition, if the single use distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.
- When the endoscope is repeatedly inserted into the body cavity, always confirm that the single use distal cover is attached properly before insertion. If the single use distal cover is not attached properly, it may slip off or fall off the distal end during the examination. This could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. Also, continuing the examination with the single use distal cover off may cause patient injury by the uncovered distal end of the endoscope. In addition, if the single use distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.
- Never use a single use distal cover with cracks or pinholes. Replace it with a new one. If a single use distal cover with cracks or pinholes is used, it could fall off during the examination and/or, it may cause thermal injury due to electric current leaks from cracks or pinholes when high-frequency cauterization treatment is performed. Also, using the single use distal cover with cracks may cause patient injury due to sharp edges.

CAUTION

Do not apply anti-fogging products, olive oil, or products containing petroleum-based substances (e.g., Vaseline®) to the single use distal cover or the endoscope. These products may cause cracks in the single use distal cover. If a single use distal cover with cracks is used, it may cause patient injury such as:

- Thermal injury from electric current leaks when performing high-frequency cauterization treatment.
- Damage or cuts to the mucosal membrane from sharp edges due to the cracks on the single use distal cover.

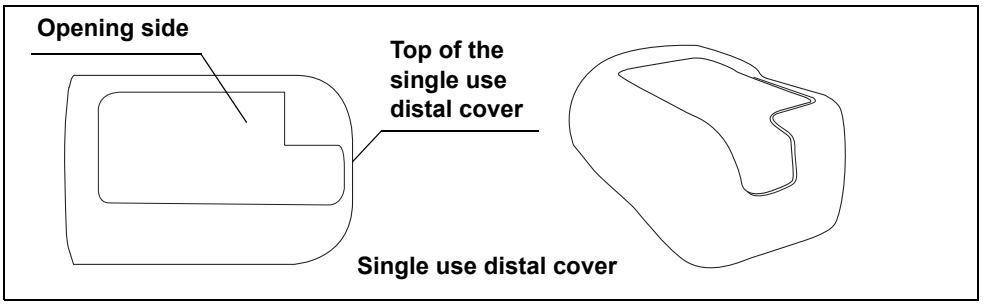


Figure 3.35

1 Confirm that the instrument channel outlet of the distal end is opened.

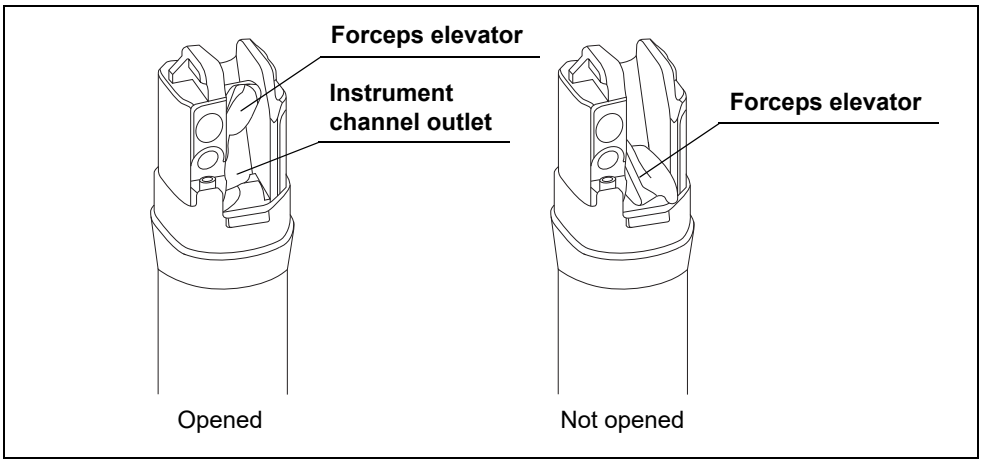


Figure 3.36

2 If the instrument channel outlet is not opened, move the elevator control lever in the opposite direction of the "◀U" direction until the forceps elevator stops to make the instrument channel outlet opened.

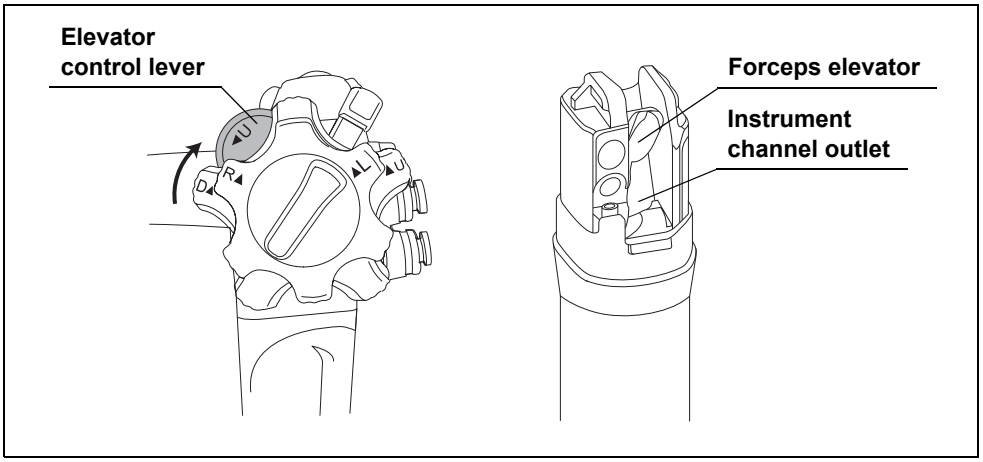


Figure 3.37

3 Gently hold the distal part of the bending section and the single use distal cover. Align the opening side of the single use distal cover with the lenses side of the distal end.

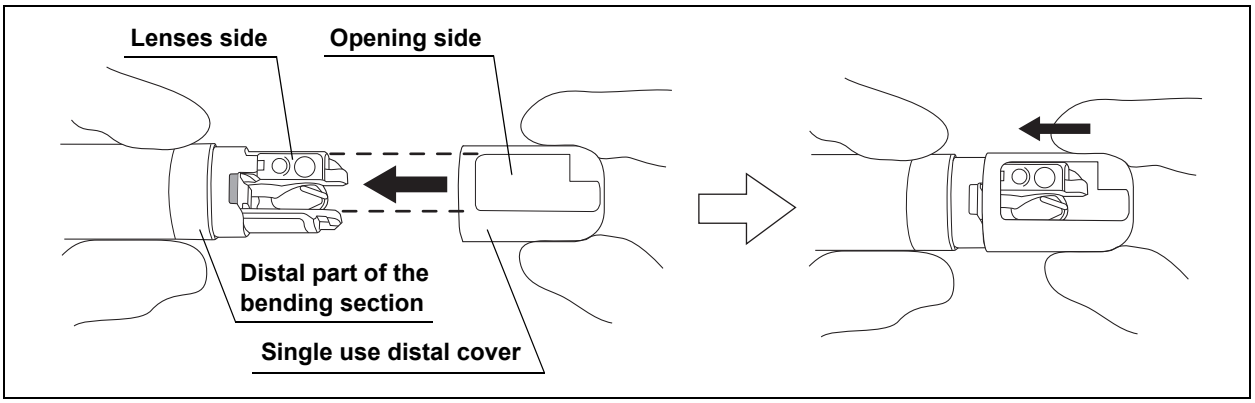


Figure 3.38

CAUTION

When attaching the single use distal cover, gently hold the bending section as close to the distal end as possible. Forcefully grasping other parts of the bending section can damage the mechanism of the bending section or deform its covering. It may also become impossible to straighten the bending section during an examination.

4 Put your finger onto the center on the top of the single use distal cover and push the top of the single use distal cover straight onto the distal end of the endoscope until the hook of the distal ring is completely visible within the opening of the single use distal cover.

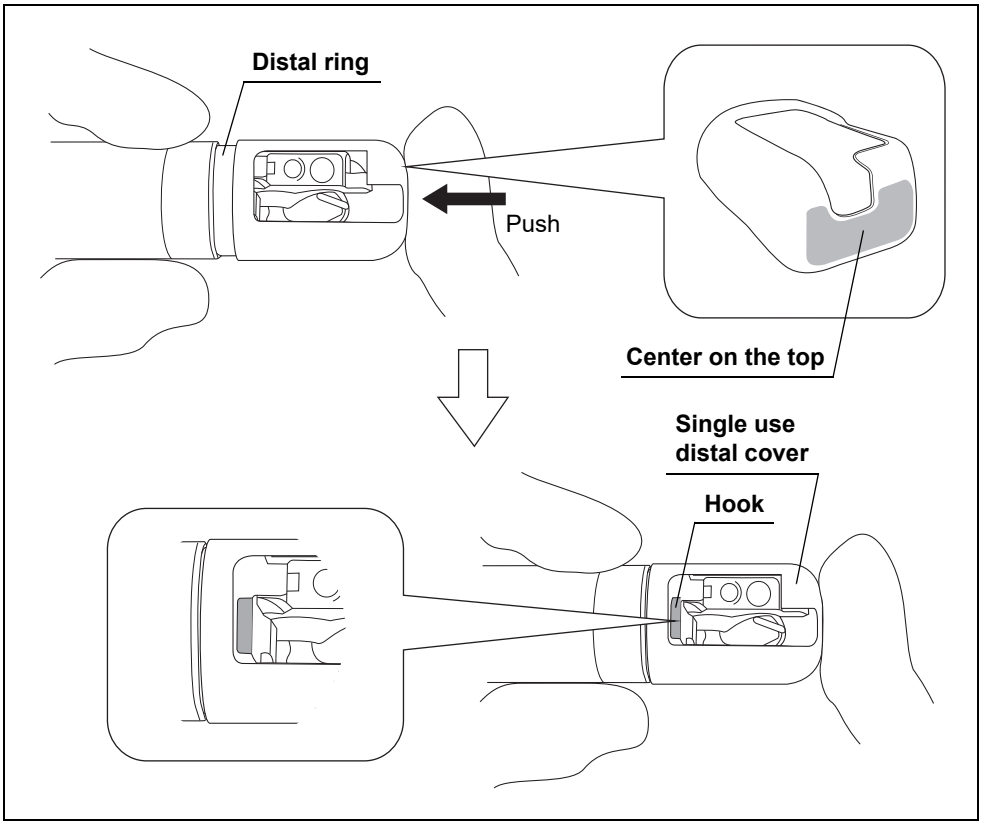


Figure 3.39

WARNING

Detach the single use distal cover from the distal end of the endoscope when the single use distal cover cannot be attached to the endoscope smoothly or any incorrect attaching procedure is noticed. With a new single use distal cover, repeat Step 1 through 4. If the single use distal cover is not attached properly, it may slip off or fall off the distal end during the examination. This could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. Also, continuing the examination with the single use distal cover off may cause patient injury by the uncovered distal end of the endoscope. In addition, if the single use distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed.

5 Hold the distal part of the bending section.
Pull the single use distal cover gently to confirm that the single use distal cover on the distal end of the endoscope does not slip and come off.

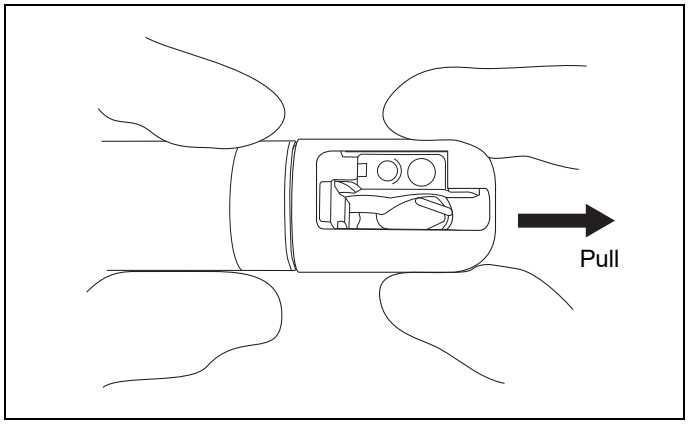


Figure 3.40

6 Twist the single use distal cover gently in both directions and confirm that the single use distal cover on the distal end of the endoscope does not slip and come off.

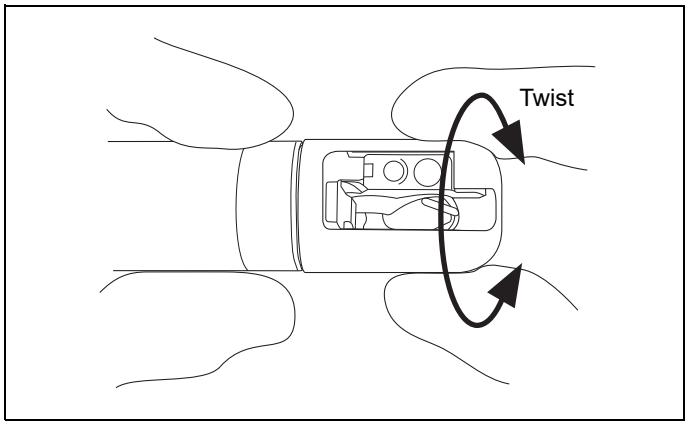


Figure 3.41

7 Confirm that the single use distal cover is free of cracks or deformation.

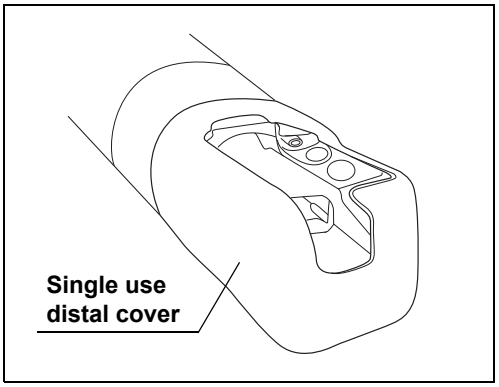


Figure 3.42

8 Confirm that there is no adhesion of foreign materials between the distal end of the endoscope and the single use distal cover.

NOTE

If finding irregularities on the single use distal cover or incorrect attaching the single use distal cover in the steps from 3 through 8, detach the single use distal cover from the distal end of the endoscope and replace it with a new one. Refer to "■ Detaching the single use distal cover" on page 52. With a new single use distal cover, repeat Step 1 through 8.

■ *Detaching the single use distal cover*

WARNING

- Do not reuse the single use distal cover. Reusing the single use distal cover could pose an infection risk. After use, dispose of it in an appropriate manner.
- When detaching the single use distal cover from the endoscope, hold the single use distal cover tightly. Otherwise, you may slip your finger and spray patient debris or fluids, and it may pose an infection control risk.

CAUTION

After the single use distal cover has been removed, ensure careful handling of the forceps elevator during cleaning, disinfection, sterilization, storage, and/or preparation of the endoscope. This helps to prevent any damage which could adversely affect the function of the forceps elevator.

1 Confirm that the instrument channel outlet of the distal end is opened.

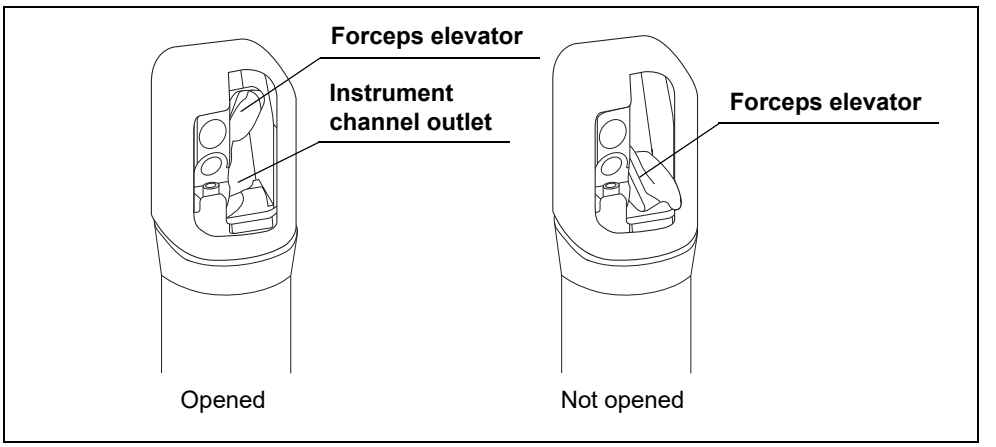


Figure 3.43

2 If the instrument channel outlet is not opened, move the elevator control lever in the opposite direction of the "◀U" direction until the forceps elevator stops to make the instrument channel outlet opened.

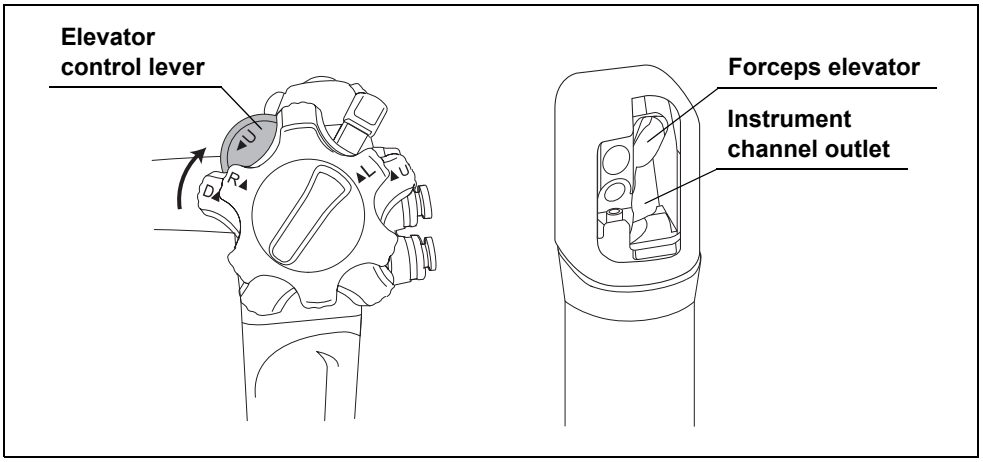


Figure 3.44

3 Gently hold the distal part of the bending section.

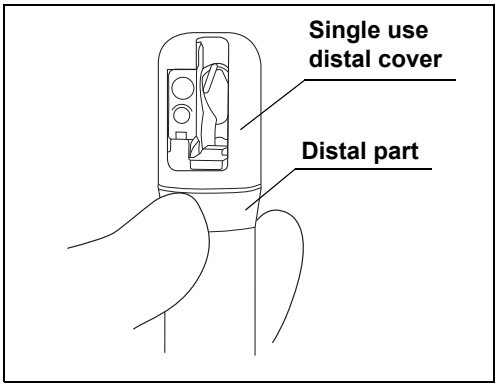


Figure 3.45

CAUTION

When detaching the distal cover, forcefully grasping other parts of the bending section can result in damage to the bending mechanism of the bending section or damage its covering.

4 While gently holding the distal part of the bending section, remove the single use distal cover, as follows:

a) Push back the top of the single use distal cover's gripper to begin removal.

b) Rotate the single use distal cover until its bottom is free from the distal ring's hook.

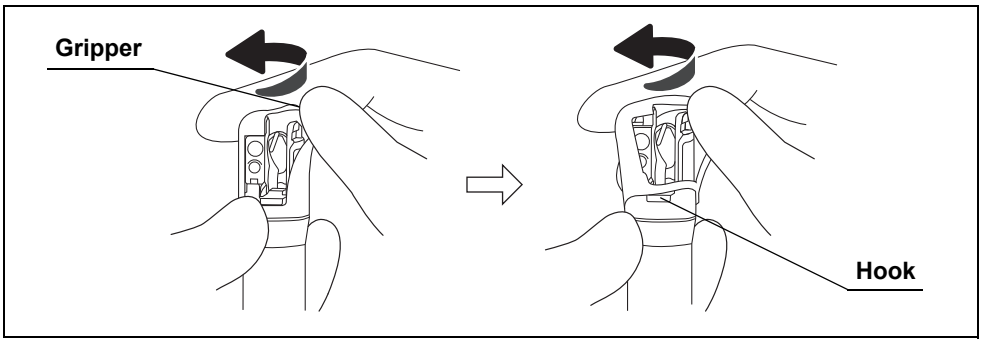


Figure 3.46

5 Dispose of the single use distal cover, as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.

3.6 Inspection of ancillary equipment

Inspect the following equipment as described in their respective instruction manuals.

- Light source
- Video system center
- Monitor
- Water container
- Suction pump
- EndoTherapy accessories

3.7 Connection of the endoscope and ancillary equipment

Connect the ancillary equipment to the endoscope as described below.

■ Connection to the light source

WARNING

If the endoscope connector and light source are not connected properly, the endoscopic image may flicker or may not be displayed. Continuous use of such an endoscope may cause patient injury, bleeding, and/or perforation.

CAUTION

Before connecting the endoscope connector to the light source, confirm that the endoscope connector, including the electrical contacts, is completely dry and foreign objects such as detergent remnants, hard water residue, finger grease, dust, and lint are not on the electrical contacts. If the endoscope is used with the electrical contacts wet and/or dirty, the endoscope and/or light source may malfunction.

1 If any ancillary equipment is ON, turn it OFF.

2 Hold the endoscope connector while the UP mark is facing upward.

3 Insert the endoscope connector completely into the output socket of the light source.

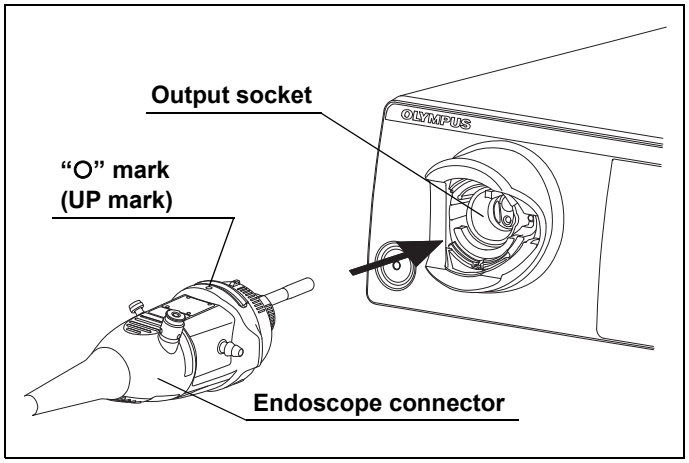


Figure 3.47

4 Push the connector until it clicks.

5 Confirm that the "○" mark (UP mark) on the endoscope connector is hidden by the light source.

■ *Connection of the water container*

CAUTION

- Attach the water container to the specified receptacle on the trolley (cart) or on the light source. If the water container is attached anywhere else, water may drip from the water container's water supply tube, and equipment malfunction can result.
- Take care not to spill water from the water container's metal tip when detaching the metal tip from the endoscope. Spilled water could splash on the ancillary equipment, which may cause equipment malfunction.

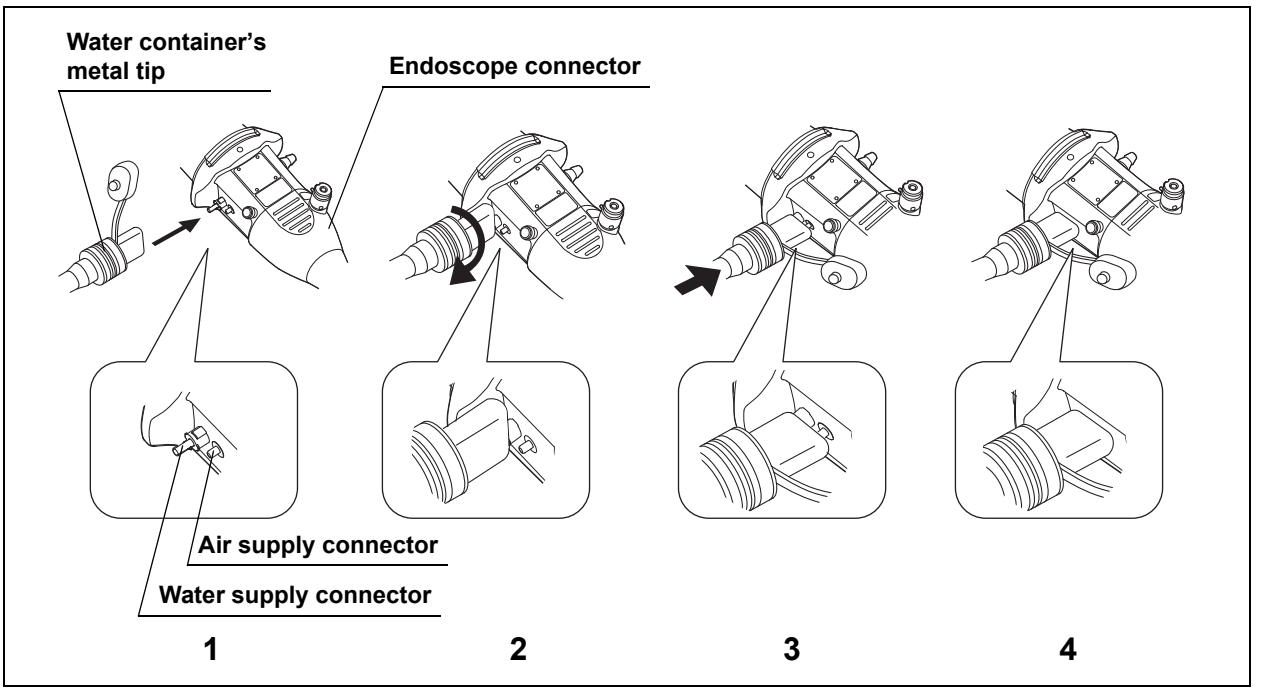


Figure 3.48

1 Place the water container's water supply channel onto the water supply connector on the endoscope connector at an angle of 90° and push it in until it stops.

2 Turn the water container's metal tip 90° clockwise to align the air supply channel with the air supply connector on the endoscope connector.

3 Push the water container's metal tip again until it stops.

4 Confirm that the water container's metal tip fits properly and that it cannot be rotated.

■ *Connection of the suction tube*

WARNING

Firmly connect the suction tube from the suction pump to the suction connector on the endoscope connector. If the suction tube is not attached properly, debris may drip from the tube and can pose an infection control risk, cause equipment damage, and/or reduce suction capability.

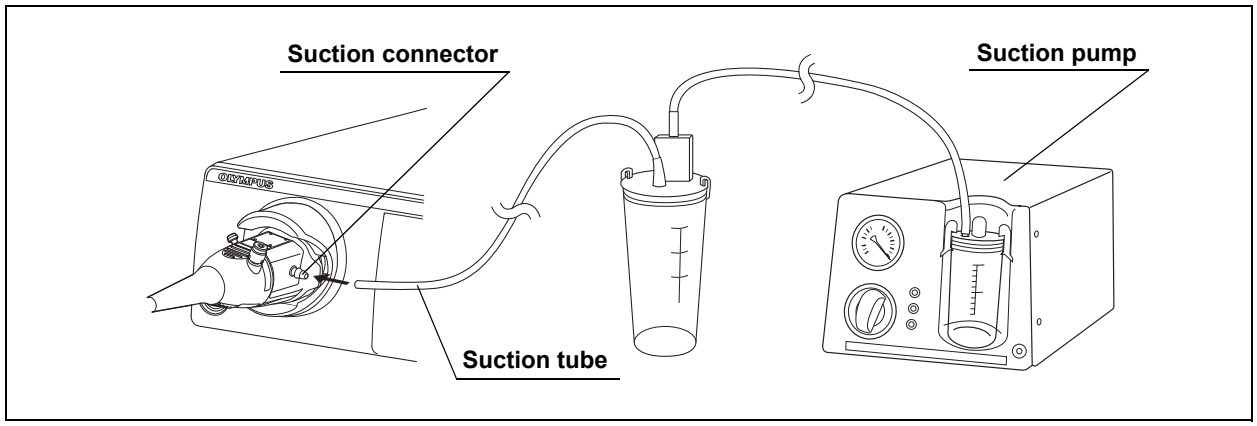
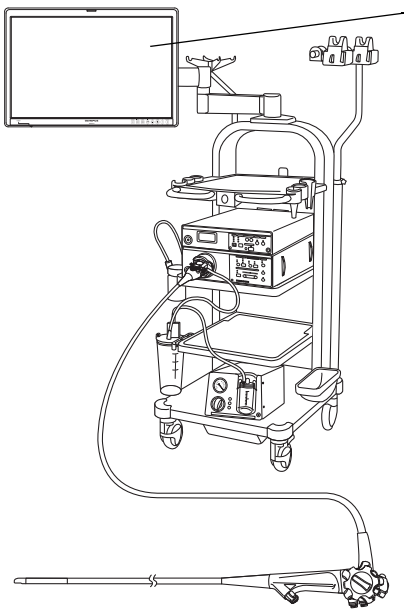


Figure 3.49

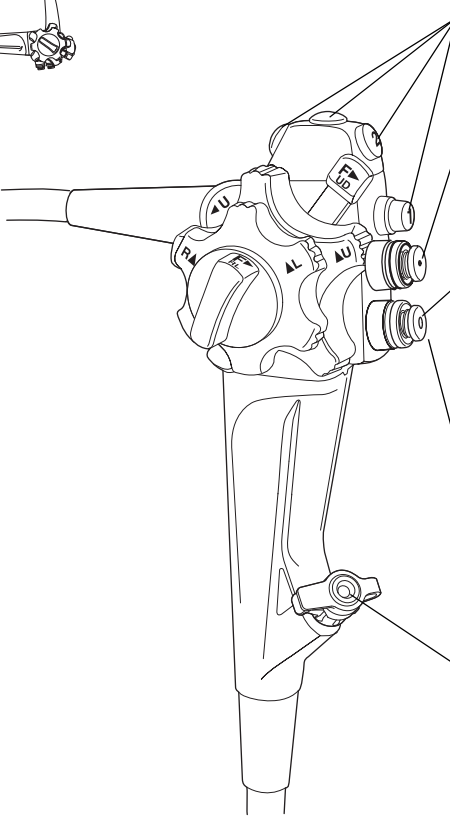
Connect the suction tube from the suction pump to the suction connector on the endoscope connector.

3.8 Inspection of the endoscopic system

■ Inspection summary



■ Inspection of the endoscopic image
→on page 59



■ Inspection of the remote switches
→on page 60

■ Inspection of the suction function
→on page 61

■ Inspection of the air-feeding function
→on page 63

■ Inspection of the objective lens cleaning function
→on page 64

■ Inspection of the instrument channel and forceps elevator
→on page 66

■ *Inspection of the endoscopic image*

Confirm that the WLI and NBI endoscopic images are normal.

WARNING

Do not stare directly into the distal end of the endoscope while the examination light is ON. Eye injury may result.

NOTE

If the object cannot be seen clearly, wipe the objective lens using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.

Turn the video system center, light source, and monitor ON and inspect the WLI and NBI endoscopic images as described in their respective instruction manuals.

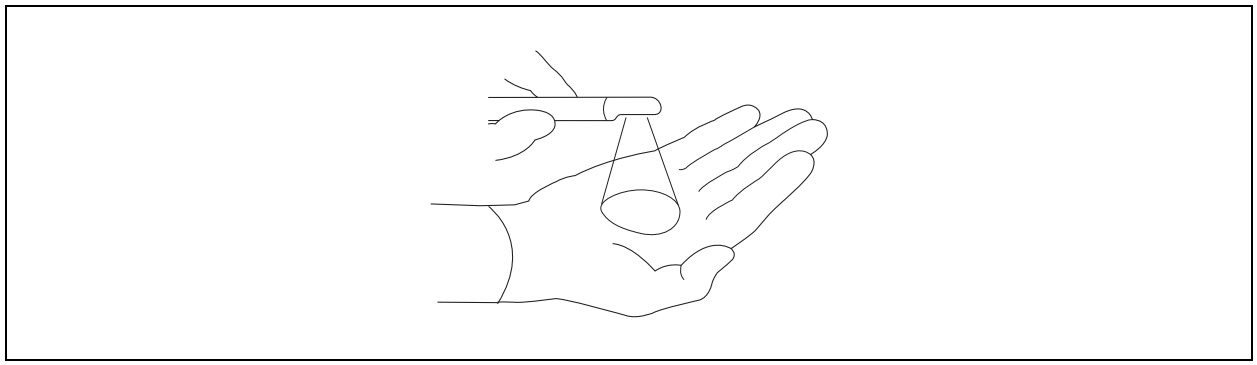


Figure 3.50

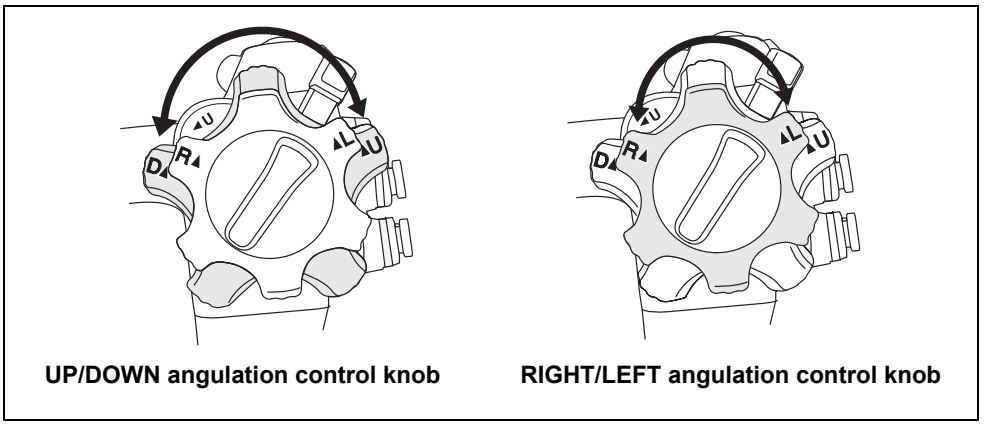
1 Turn the light source ON according to the directions given in its instruction manual.

2 Confirm that light is output from the endoscope's distal end.

3 Confirm that the WLI and NBI endoscopic images are free from noise, blur, fog, or other irregularities, observing the palm of your hand.

4 Confirm that the single use distal cover is not seen on the endoscopic image. If the single use distal cover is partly on the endoscopic image, it is not attached properly to the distal end. Detach the single use distal cover from the distal end and replace it with a new one in reference to "■ Detaching the single use distal cover" on page 52. Return to the beginning of "■ Attaching the single use distal cover" on page 47 and repeat the procedures from 1 to 8.

5 Turn the UP/DOWN and RIGHT/LEFT angulation control knobs slowly in each direction until they stop.



UP/DOWN angulation control knob **RIGHT/LEFT angulation control knob**

Figure 3.51

6 Confirm that the WLI and NBI endoscopic images do not momentarily disappear or display any other irregularities.

■ *Inspection of the remote switches*

WARNING

Check that all remote switches work normally even if they are not expected to be operated. Otherwise, the endoscopic image may freeze, or other irregularities may occur during examination and may cause patient injury, bleeding, and/or perforation.

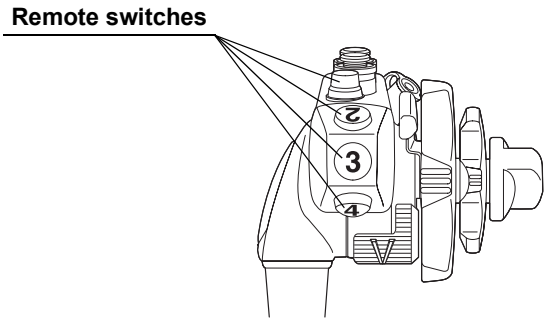


Figure 3.52

1 Press every remote switch.

2 Confirm that the assigned functions work normally.

■ *Inspection of the suction function*

WARNING

- If the suction valve does not operate smoothly, detach it and reattach it, or replace it with a new one. If the endoscope is used while the suction valve is not working properly, it may be impossible to stop suctioning, which could cause patient injury. If the reattached or replaced suction valve fails to operate smoothly, the endoscope may be malfunctioning; stop using it and contact Olympus.
- If the capped biopsy valve leaks, replace it with a new one. A leaking biopsy valve may spray patient debris or fluids, posing an infection control risk.

❍ Aligning the container with the endoscope

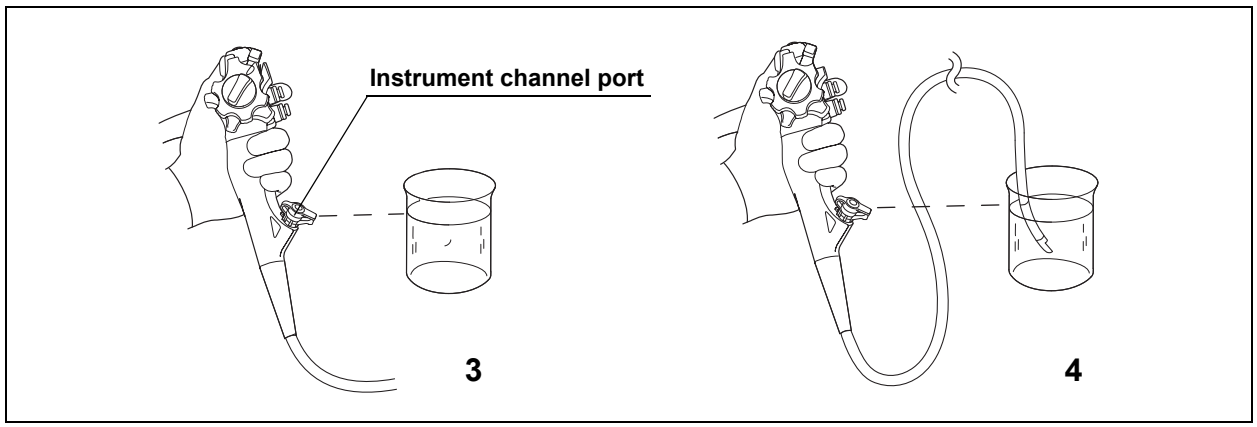


Figure 3.53

1 Turn the suction pump ON according to the directions given in its instruction manual.

2 Place the container of sterile water and the endoscope at the same height. For the inspection, adjust the suction pressure to the same level as it will be during the procedure.

3 Align the endoscope's instrument channel port with the same height as the water level in the water container.

4 Immerse the distal end of the endoscope in sterile water.

Inspection of the suction function

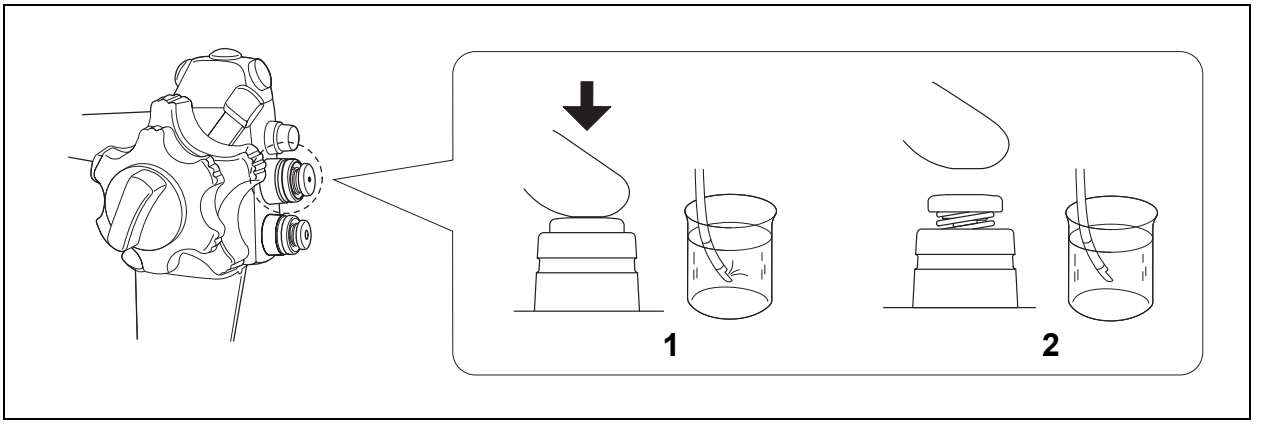


Figure 3.54

1 Depress the suction valve and confirm that water is continuously aspirated into the suction bottle of the suction pump.

2 Release the suction valve. Confirm that suction stops and that the valve returns smoothly to its original position.

3 Depress the suction valve and aspirate water for one second.

4 Release the suction valve for one second.

5 Repeat Step 3 and 4 several times and confirm that no water leaks from the biopsy valve.

6 Remove the distal end of the endoscope from the water. Depress the suction valve and aspirate air for a few seconds to remove any water from the instrument channel and suction channel.

■ *Inspection of the air-feeding function*

❍ Confirmation of emitting no air bubbles

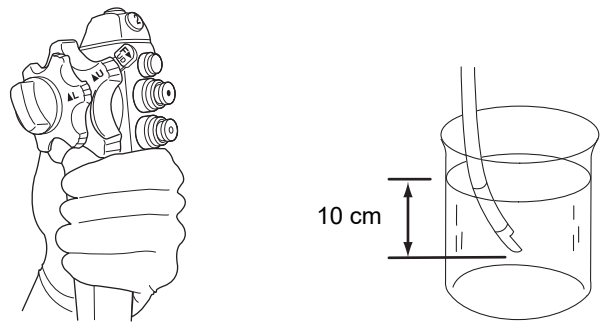


Figure 3.55

1 Set the airflow regulator on the light source to “High”, as described in the light source’s instruction manual.

2 Immerse the distal end of the endoscope in sterile water to a depth of approximately 10 cm.

3 Confirm that no air bubbles are emitted when the air/water valve is not operated.

WARNING

If a stream of air bubbles is emitted from the air/water nozzle even though the air/water valve is not being operated and the distal end of the endoscope is 10 cm or more below the surface of the sterile water, remove and reattach the air/water valve correctly, or replace it with a new one. If the endoscope is used while air is continuously fed, over-insufflation and patient injury may result.

NOTE

When the distal end of the endoscope is immersed less than 10 cm below the surface of the sterile water, a small amount of air bubbles may be emitted from the air/water nozzle even when the air/water valve is not operated. This does not indicate a malfunction.

❍ Confirmation of emitting air bubbles

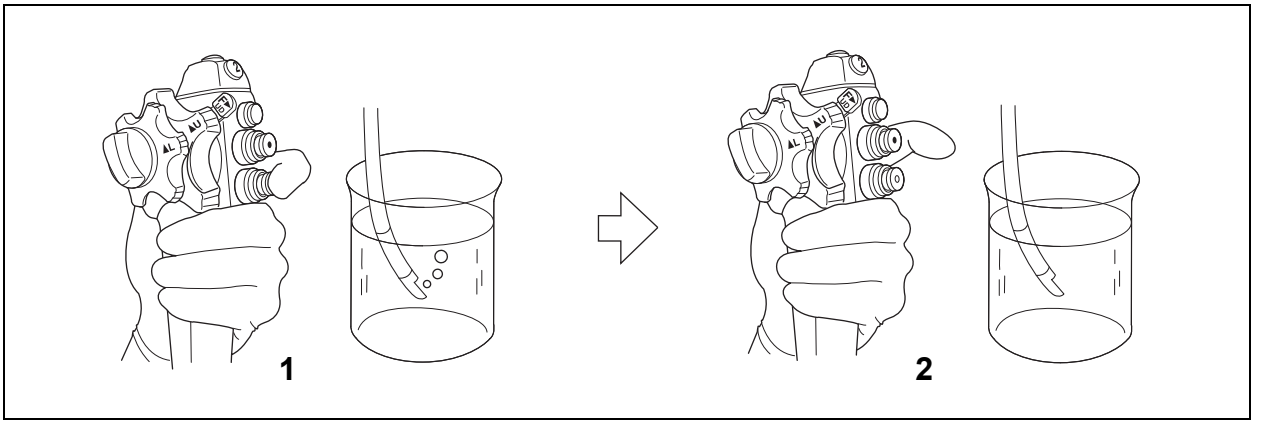


Figure 3.56

1 Cover the hole in the air/water valve with your finger and confirm that air bubbles are continuously emitted from the air/water nozzle.

2 Uncover the hole in the air/water valve and confirm that no air bubbles are emitted from the air/water nozzle.

■ *Inspection of the objective lens cleaning function*

WARNING

Nothing other than sterile water should be used for air/water feeding. No additives should be put into the sterile water. Non-sterile water may cause patient cross-contamination and/or infection.

NOTE

- When the air/water valve is depressed for the first time, it may take a few seconds before water is emitted.
- If the air/water valve returns to its original position slowly after water feeding, remove the air/water valve and moisten the seals with sterile water.
- During the inspection, place the distal end of the endoscope in a beaker or other container so that the floor does not get wet.

Inspection of the water feeding function

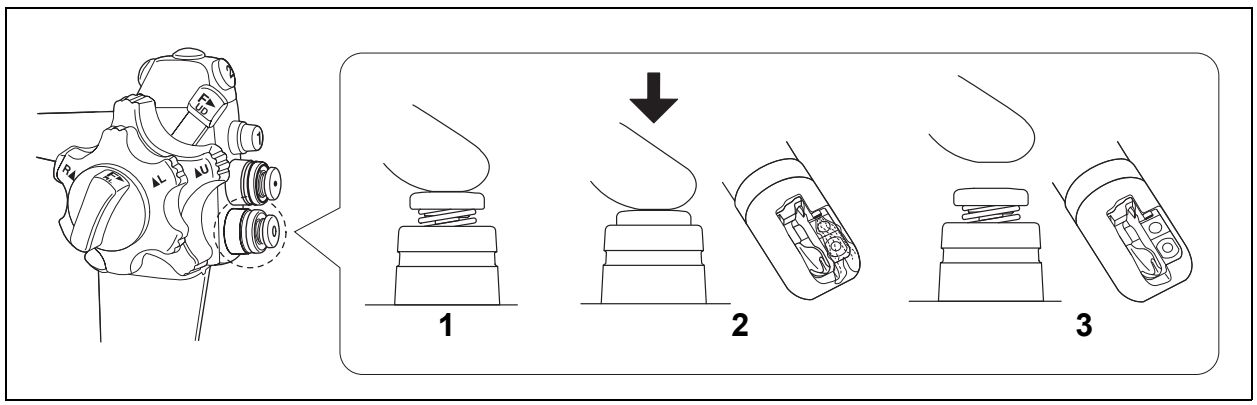


Figure 3.57

1 Keep the air/water valve's hole covered with your finger.

2 Depress the valve. Observe the endoscopic image and confirm that water flows on the entire objective lens.

3 Release the air/water valve. While observing the endoscopic image, confirm that the emission of water stops and that the valve returns smoothly to its original position.

Inspection of removing the remaining water from the objective lens

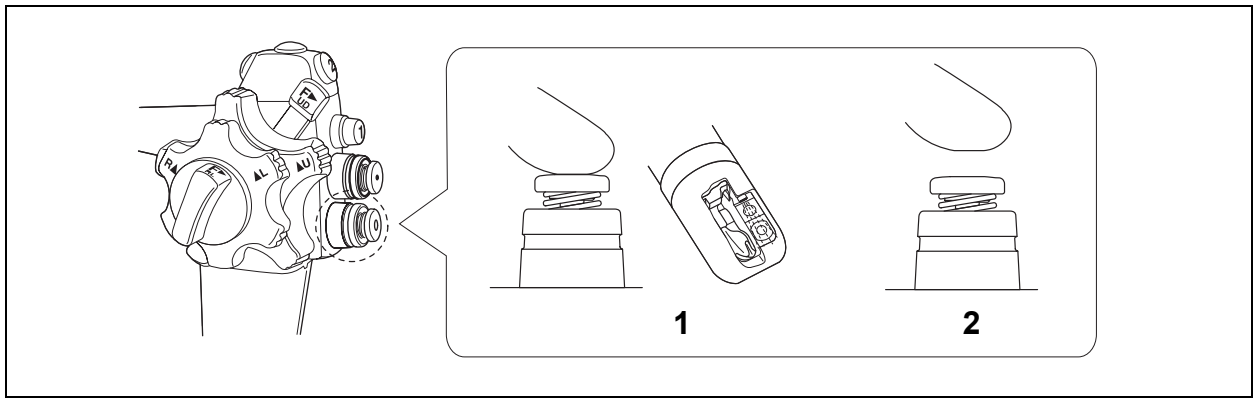


Figure 3.58

1 After checking the water feeding function and while observing the endoscopic image, feed air by covering the hole in the air/water valve with your finger. Confirm that the emitted air removes the remaining water from the objective lens and clears the endoscopic image.

2 Release the air/water valve.

■ *Inspection of the instrument channel and forceps elevator*

WARNING

- Keep your eyes away from the distal end of the endoscope when inserting EndoTherapy accessories. Extending the EndoTherapy accessory from the distal end of the endoscope could cause eye injury.
- Check the movement of the EndoTherapy accessory by operating the elevator control lever several times to raise the forceps elevator. Otherwise, the EndoTherapy accessory may move in unexpected directions, and patient injury, bleeding, and/or perforation may result.

1 Confirm that the instrument channel outlet of the distal end is opened.

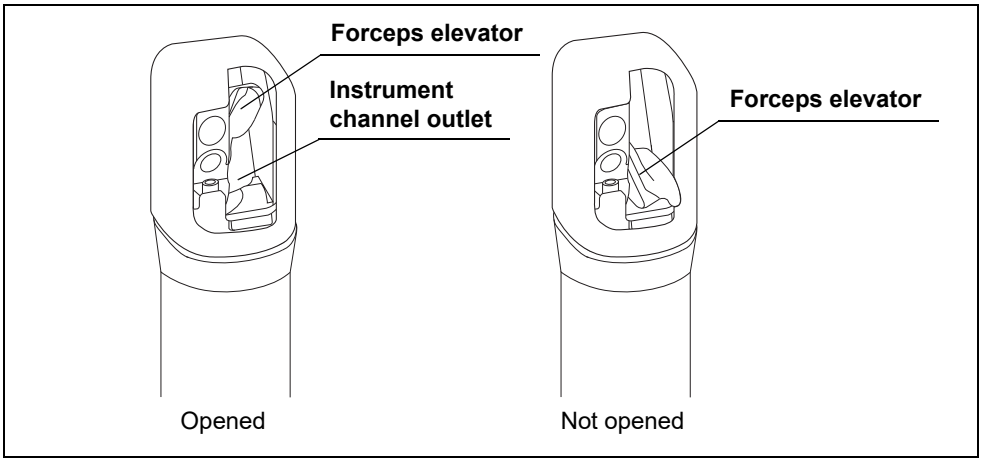


Figure 3.59

2 If the instrument channel outlet is not opened, move the elevator control lever in the opposite direction of the "◀U" direction until the forceps elevator stops to make the instrument channel outlet opened.

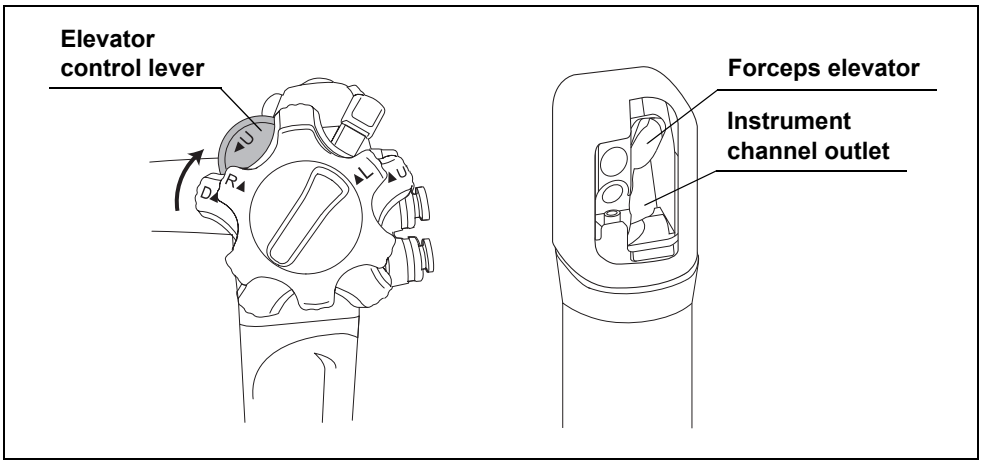


Figure 3.60

3 Insert the EndoTherapy accessory through the biopsy valve. Confirm that the EndoTherapy accessory extends smoothly from the distal end of the endoscope. Also, make sure that no foreign objects come out of the distal end of the endoscope.

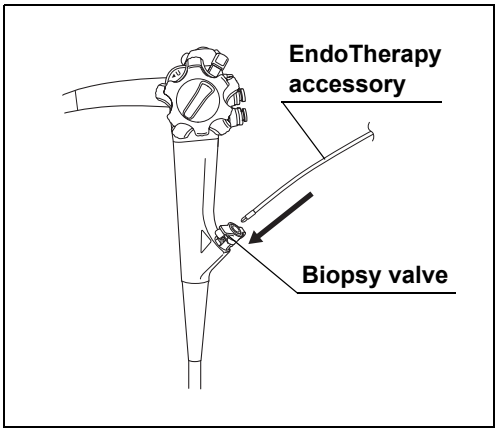


Figure 3.61

4 Extend the EndoTherapy accessory approximately 3 cm from the distal end.

5 Move the elevator control lever in the "◀U" direction.
With your eyes and on the monitor, confirm that the forceps elevator is raised smoothly.

6 With your eyes and on the monitor, check the movement of the EndoTherapy accessory by operating the elevator control lever several times to raise the forceps elevator.

7 Move the elevator control lever in the opposite direction of the "◀U" direction and confirm that the forceps elevator is lowered.

8 Confirm that the EndoTherapy accessory can be withdrawn smoothly from the biopsy valve.

Chapter 4 Operation

This manual does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this endoscope. Therefore, the operator of this endoscope must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.

4.1 Precautions

WARNING

- To guard against dangerous chemicals and potentially infectious materials during the procedure, wear personal protective equipment such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination. Continued illumination will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.
- Never insert or withdraw the endoscope under any of the following conditions. Patient injury, bleeding, and/or perforation can result.
  - While the EndoTherapy accessory extends from the distal end of the endoscope.
  - While the bending section is locked in position.
  - Insertion or withdrawal with excessive force.
  - While the image is electronically zoomed using the function of the video system center.
  - Insertion or withdrawal while the forceps elevator is raised.

WARNING

- If any of the following conditions occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in Section 5.3, “Withdrawal of the endoscope with an irregularity”. Continued use of the endoscope under these conditions could result in patient injury, bleeding, and/or perforation.
  - Should any irregularity be observed with the functionality of the endoscope.
  - If the endoscopic image on the monitor disappears or freezes unexpectedly.
  - If the angulation control knob is locked.
  - If the angulation control mechanism is not functioning properly.
  - If the electronic zoom function of the video system center malfunctions (when the function is used).
- If an abnormal endoscopic image appears or an abnormal function occurs but quickly corrects itself, the endoscope may have malfunctioned. In this case, stop using the endoscope because the irregularity can occur again and the endoscope may not return to its normal condition. Stop the examination immediately and slowly withdraw the endoscope while viewing the endoscopic image. Otherwise, patient injury, bleeding, and/or perforation can result.
- The endoscopic image may be distorted while switching between WLI observation mode and NBI observation mode. Therefore, do not perform any endoscopic operation or treatment while switching between WLI observation mode and NBI observation mode. Injury in the body cavity, bleeding, and/or perforation may result.
- If the single use distal cover should fall off the distal end during the examination, the single use distal cover is seen partly on the endoscopic image. When the single use distal cover should fall off the distal end or seems to fall off, immediately stop the examination, and slowly withdraw the endoscope from the patient. Continuing the examination after the single use distal cover has fallen off may cause patient injury by the uncovered distal end of the endoscope and this could result in thermal injury when the endoscope is used with high-frequency EndoTherapy accessories. In addition, if the single use distal cover falls off in the oral cavity, it may cause aspiration or respiratory distress if not promptly identified and removed. If a single use distal cover falls off inside the patient’s body, stop using the endoscope immediately and retrieve the single use distal cover in an appropriate way.
- Do not retrieve the stent through the instrument channel of the endoscope. A stent or piece(s) of a stent may stay in the instrument channel or the suction channel of the endoscope even after reprocessing. It may cause incomplete reprocessing, and pose an infection control risk, cause equipment damage, or reduce performance.

NOTE

- Set the brightness of the light source to the minimum level necessary to perform the procedure safely. If the endoscope is used for a prolonged period at or near maximum light intensity, vapor may be observed in the endoscopic image. This is caused by the evaporation of organic material (blood, moisture in stool, etc.) due to heat generated by the light guide near the light guide lens. If this vapor continues to interfere with the examination, remove the endoscope, wipe the distal end of the endoscope with lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol, reinsert the endoscope, and continue the examination.
- The color tone and brightness of the NBI observation mode are different from those of the WLI observation mode. Use the NBI observation mode only after fully understanding its features.

4.2 Insertion

■ Holding and manipulating the endoscope

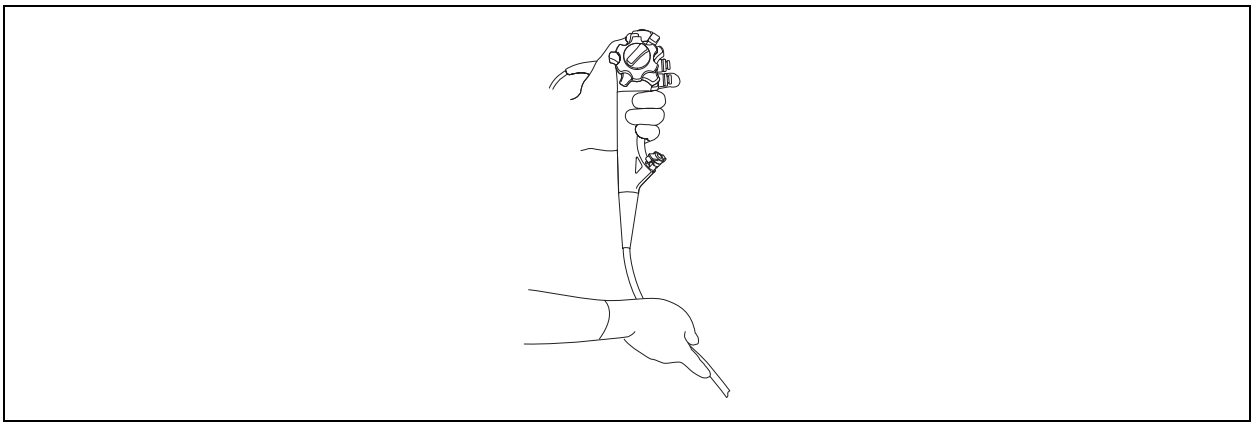


Figure 4.1

1 The control section of the endoscope is designed to be held in the left hand.

2 The air/water and suction valves can be operated using the left index finger or middle finger.

3 The UP/DOWN angulation control knob can be operated using the left thumb.

4 The right hand is free to manipulate the insertion section and the RIGHT/LEFT angulation control knob.

■ *Insertion of the endoscope*

WARNING

Keep the elevator control lever moved all the way in the opposite direction of the "◀U" direction while inserting or withdrawing the endoscope into or from the patient. If the elevator control lever is moved in the "◀U" direction until the operator feels resistance and the forceps elevator is raised while inserting or withdrawing the endoscope into or from the patient, this may cause patient injury.

CAUTION

- To prevent the patient from biting the insertion section during an examination, it is strongly recommended that a mouthpiece be placed in the patient's mouth before inserting the endoscope.
- When the patient has dental prostheses, remove them from the patient's mouth before placing a mouthpiece. The dental prostheses or mouthpiece may loosen during the examination.
- Confirm the patient's dental condition before using the mouthpiece. If any irregularity, such as teeth under treatment or lack of teeth is observed, the teeth may be broken.
- Do not apply anti-fogging products, olive oil, or products containing petroleum-based substances (e.g., Vaseline®) to the single use distal cover and the endoscope. These products may cause stretching and deterioration of the bending section's covering and cracks of the single use distal cover. If a single use distal cover with cracks is used, it may cause thermal injury due to electric current leaks when high-frequency cauterization treatment is performed.
- Do not allow the insertion section to be bent within a distance of 10 cm or less from the junction of the boot. Insertion section damage can occur.

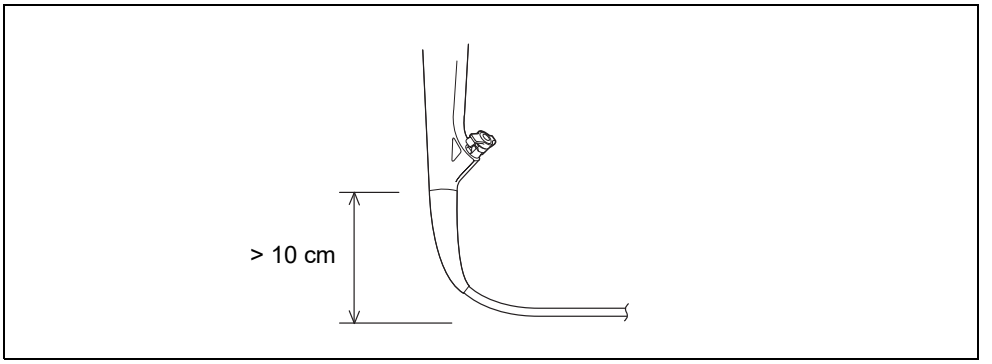


Figure 4.2

❍ Insertion of the endoscope

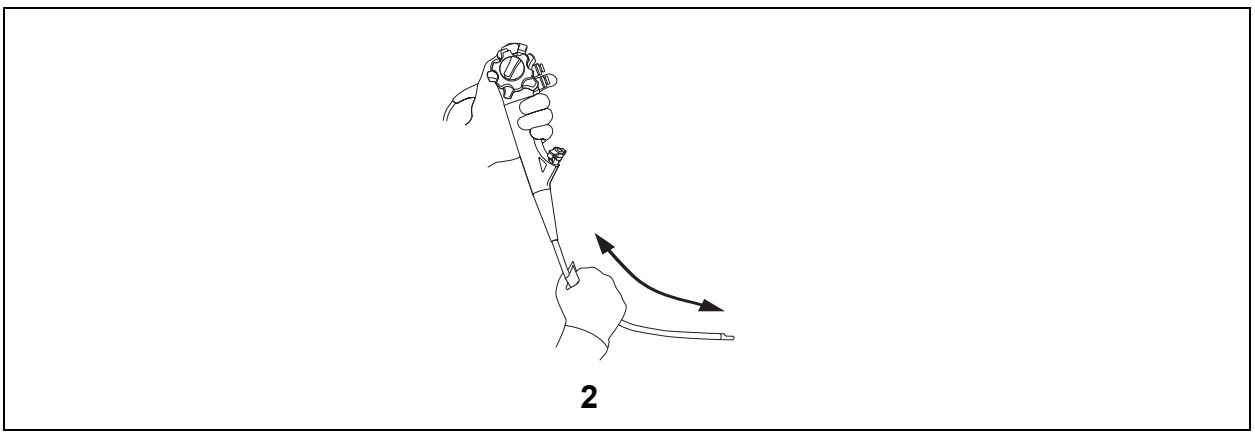


Figure 4.3

1. Move the elevator control lever in the opposite direction of the "◀U" direction until it stops.
2. If necessary, apply a medical-grade, water-soluble lubricant to the insertion section.
3. Place the mouthpiece between the patient's teeth or gums, with the outer flange on the outside of the patient's mouth.
4. Insert the distal end of the endoscope through the opening of the mouthpiece, then from the mouth to the pharynx while viewing the endoscopic image. Do not insert the insertion section into the mouth beyond the insertion section limit mark.

■ *Observation of the endoscopic image*

WARNING

Do not rely on the NBI observation mode alone for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.

Refer to the instruction manuals for the light source and video system center to adjust the brightness and image quality.

■ *Angulation of the distal end*

CAUTION

Avoid forcible or excessive angulation as this imposes stress on the wire controlling the bending section. This may cause stretching or tearing of the wire, which could impair the movement of the bending section.

NOTE

- When passing an EndoTherapy accessory through the instrument channel while the angulation is locked, the angle of the distal end of the endoscope may change. When it is necessary to keep the angulation stationary, hold the angulation control knobs in place with your hand.
- When operating the UP/DOWN or RIGHT/LEFT angulation lock, hold the angulation control knob stationary with your finger. If this is not done, the angulation will change.

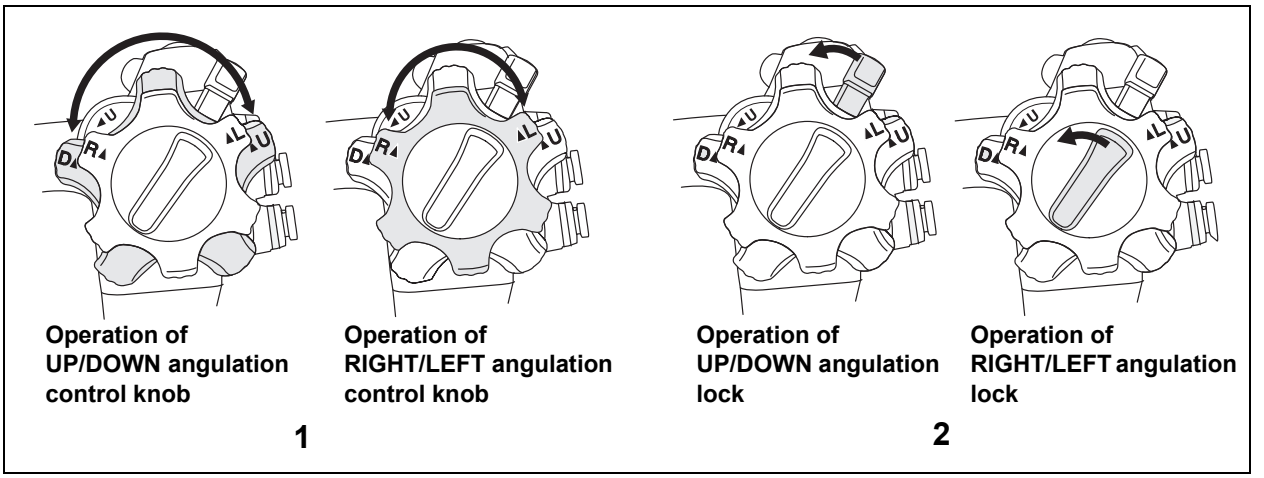


Figure 4.4

1 Operate the angulation control knobs as necessary to guide the distal end of the endoscope for insertion and observation.

2 The endoscope's angulation locks are used to hold the angulated distal end in position.

■ *Air/water feeding and suction*

❍ Air/water feeding

WARNING

Nothing other than sterile water should be used for air/water feeding. No additives should be put into the sterile water. Non-sterile water may cause patient cross-contamination and/or infection.

CAUTION

- If the sterile water level in the water container is too low, then air, not water, will be supplied. In this case, turn the airflow regulator on the light source OFF and add sterile water to the water container until it reaches the specified water level.
- If air/water feeding does not stop, turn the airflow regulator on the light source OFF and replace the air/water valve with a new one.
- Do not operate the air/water valve of the endoscope under the following conditions while the endoscope is inserted in the patient.
  - The airflow button “STBY” lamp of the light source is illuminated.
  - The water container is not connected to the endoscope connector.
  - The endoscope connector is not connected to the output socket of the light source.

  Operation of the air/water valve under such conditions may cause bodily fluids or debris from the patient to backflow from the distal end of the endoscope to the water container.

NOTE

If the endoscope is cold, condensation may form on the surface of the objective lens and the endoscopic image may appear cloudy. In this case, increase the temperature of the sterile water in the water container to 40 – 50°C (104 – 122°F) and then use the endoscope.

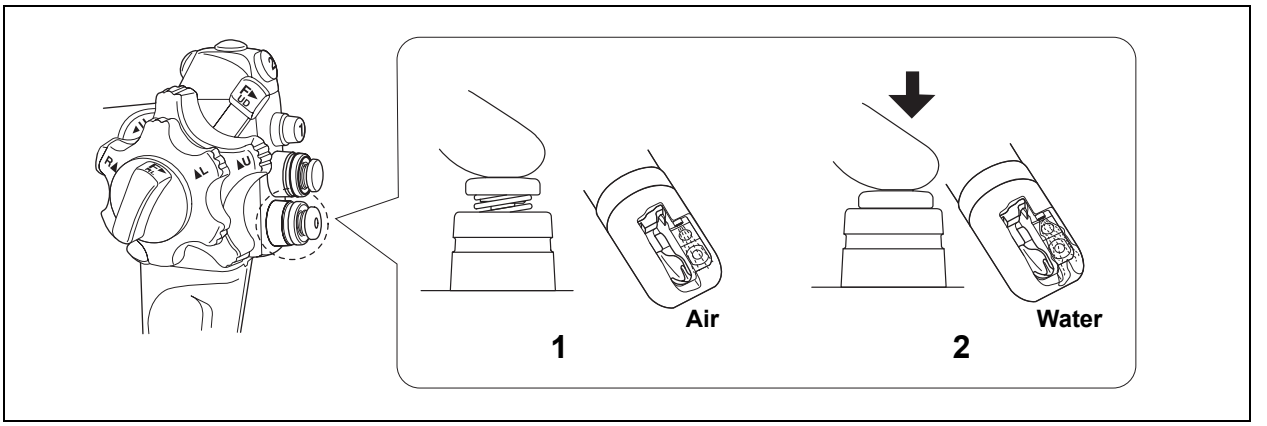


Figure 4.5

1 Cover the air/water valve's hole to feed air from the air/water nozzle at the distal end of the endoscope.

2 Depress the air/water valve to feed water onto the objective lens.

❍ Suction

WARNING

- When aspirating, maintain the suction pressure at the lowest level necessary to perform the procedure. Excessive suction pressure could cause aspiration of and/or injury to the mucous membrane. In addition, patient fluids could leak or spray from the biopsy valve, posing an infection control risk.
- When aspirating, attach the cap to the main body of the biopsy valve. An uncapped biopsy valve can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk.

CAUTION

- Avoid aspirating solid matter or thick fluids; instrument channel, suction channel, or suction valve clogging can occur. If the suction valve clogs and suction cannot be stopped, disconnect the suction tube from the suction connector on the endoscope connector. Turn the suction pump OFF, detach the suction valve, and remove solid matter or thick fluids.
- If the suction valve clogs and the suction cannot be used when solid matter, such as the clip or thick fluid, are aspirated, withdraw the endoscope and disconnect the suction tube from the suction connector on the endoscope connector. Attach a syringe containing sterile water to the suction connector. Straighten the insertion tube as much as possible and forcefully flush the connector with the water while the suction valve of the endoscope is slightly depressed. Repeat the flush until the thick fluid or solid matter is discharged from the distal end of the suction channel. After discharging, confirm that there is no irregularity in the suction function according to "■ Inspection of the suction function" on page 61, before using the endoscope again. If the thick fluid or solid matter cannot be discharged, stop using the suction function and contact Olympus.
- During the procedure, make sure that the suction bottle does not fill completely. Aspirating fluids into a full bottle may cause the suction pump to malfunction.

NOTE

Performing both air feeding and suction at the same time sometimes makes it easier to remove water droplets from the objective lens surface.

Depress the suction valve to aspirate excessive fluids or other debris obscuring the endoscopic image.

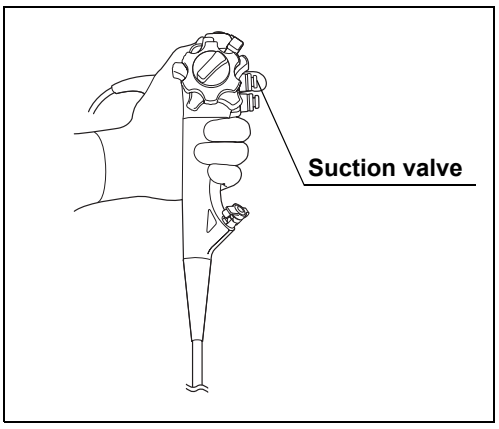


Figure 4.6

❍ Feeding liquid through the instrument channel

WARNING

- When using a syringe to inject liquid through the biopsy valve, insert the syringe straight into the biopsy valve. Otherwise, patient fluids and/or debris may leak or spray from the biopsy valve, and it may cause an infection control risk.
- When using a syringe to inject liquid through the biopsy valve, detach the valve's cap from the main body. Then insert the syringe into the valve. Otherwise, the biopsy valve could be damaged, and the syringe could be detached from the valve. Also, patient fluids and/or debris may leak or spray from the biopsy valve, and it may cause an infection control risk.
- When the biopsy valve is uncapped, place a piece of sterile gauze over it. Otherwise, patient fluids and/or debris may leak or spray from the biopsy valve, and it may cause an infection control risk.

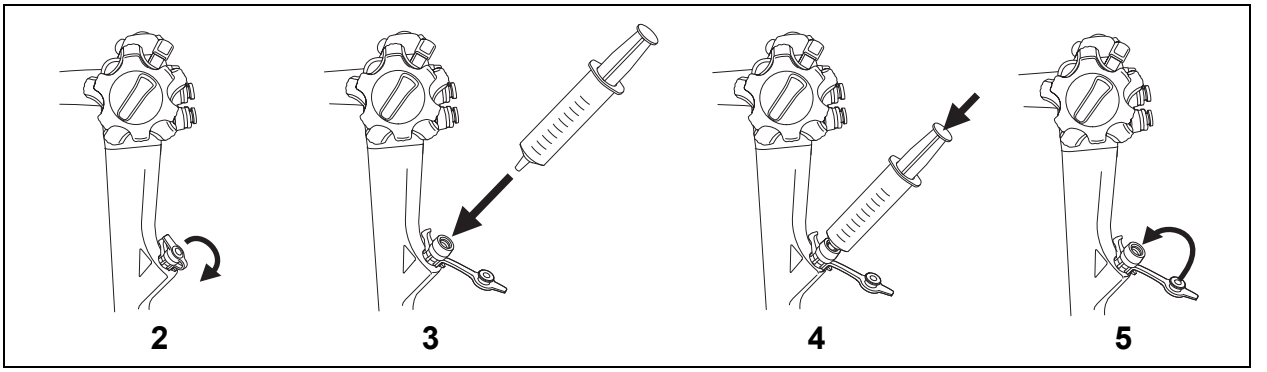


Figure 4.7

1 Fill a syringe with liquid to inject.

2 Detach the biopsy valve's cap from the main body.

3 Insert the syringe straight into the biopsy valve.

4 Depress the plunger to inject liquid.

5 Detach the syringe from the biopsy valve and attach the valve's cap to the main body.

4.3 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to “Combination equipment” on page 111 and the instruction manuals for the accessories. Also, refer to their respective instruction manuals for operating the accessories.

WARNING

- When using EndoTherapy accessories, keep the distance between the distal end of the endoscope and the mucous membrane greater than the endoscope’s minimum visible distance so that the EndoTherapy accessory remains visible in the endoscopic image. If the distal end of the endoscope is placed closer than its own minimum visible distance, the position of the accessory cannot be seen in the endoscopic image, which could cause serious patient injury and/or equipment damage. The minimum visible distance depends on the type of endoscope being used. Refer to Section 2.2, “Specifications”.
- When inserting or withdrawing an EndoTherapy accessory, confirm that its distal end is closed or completely retracted into the sheath. Slowly insert or withdraw the EndoTherapy accessory straight into or from the slit of the biopsy valve. Otherwise, the biopsy valve or instrument channel may be damaged and pieces of it could fall off. It may cause patient injury.
- If insertion or withdrawal of EndoTherapy accessories is difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and could cause some parts to fall off and/or cause patient injury.
- If the distal end of an EndoTherapy accessory is not visible in the endoscopic image, do not open the distal end or extend the needle of the EndoTherapy accessory. This could cause patient injury, bleeding, perforation, and/or equipment damage.
- Do not switch between WLI observation mode and NBI observation mode while using an EndoTherapy accessory. The endoscopic image may be distorted while switching between WLI observation mode and NBI observation mode. This could cause patient injury, bleeding, and/or perforation.
- When using EndoTherapy accessories, do not use the electronic zoom function of the video system center. It may not be possible to see the position of the accessory in the endoscopic image. This could cause patient injury, bleeding, and/or perforation.
- Do not insert EndoTherapy accessories without the forceps elevator being raised. If they are inserted without the forceps elevator being raised, the accessory cannot be observed in the endoscopic image and it may cause patient injury.

WARNING

- Check the movement of the EndoTherapy accessory by operating the elevator control lever several times to raise the forceps elevator. Otherwise, the EndoTherapy accessory may move in unexpected directions, and patient injury, bleeding, and/or perforation may result.
- Locate the cutting knife or the cutting wire as central as possible in the endoscopic image by adjusting the position of the distal end of endoscope, particularly while performing papillotomy. When the distal end of EndoTherapy accessory is positioned in the left or right side of the endoscopic image, and the elevator control lever is operated, the EndoTherapy accessory may move abruptly, resulting in patient injury, bleeding, and/or perforation.
- Operate the elevator control lever carefully. Otherwise, the EndoTherapy accessory may move in unexpected directions, and patient injury, bleeding, and/or perforation may result.

- While raising the forceps elevator, do not insert or withdraw the EndoTherapy accessory with excessive force, open or close the distal end of the EndoTherapy accessory, or extend the needle of the instrument. This could damage the instrument channel and/or the EndoTherapy accessory and could cause patient injury, bleeding, and/or perforation. If the EndoTherapy accessory cannot be inserted or withdrawn, the distal end of the EndoTherapy accessory cannot be opened or closed, or the needle of the instrument cannot be extended, move the elevator control lever in the opposite direction of the "◀U" direction to lower the forceps elevator.
- If the forceps elevator cannot be lowered while using an EndoTherapy accessory, stop the procedure immediately and contact Olympus without changing the position of the instrument.
- Do not inflate air or a nonflammable gas excessively into the patient. This could cause gas embolism.
- Do not use this endoscope for laser cauterization treatment. Patient injury or equipment damage may result.

CAUTION

- Select the EndoTherapy accessories compatible with the endoscope by referring to “Channel inner diameter” in “■ Specifications” on page 25.
- When using a biopsy forceps with a needle, confirm that the needle is not excessively bent. A bent needle could protrude from the closed cups of the biopsy forceps. Using biopsy forceps with a protruding needle could damage the instrument channel and/or cause patient injury.
- When using an injector, be sure not to extend or retract the needle from the catheter of the injector until the injector is extended from the distal end of the endoscope. The needle could damage the instrument channel if extended inside the channel, or if the injector is inserted or withdrawn while the needle is extended.

■ *Insertion of EndoTherapy accessories into the endoscope*

WARNING

- Do not insert EndoTherapy accessories forcibly or abruptly. The EndoTherapy accessory may extend from the distal end of the endoscope abruptly, which could cause patient injury, bleeding, and/or perforation.
- When the biopsy valve’s cap is detached from the main body, it is easier to insert an EndoTherapy accessory into the instrument channel port (see Figure 3.24). However, the open biopsy valve, after withdrawing an EndoTherapy accessory, can reduce the efficacy of the endoscope’s suction system and may leak or spray patient debris or fluids, posing an infection control risk. When not using an EndoTherapy accessory, attach the cap to the main body of the biopsy valve.
- When the biopsy valve’s cap is detached from the main body, it may cause patient debris or fluids to leak or spray from the endoscope, posing an infection control risk. When the biopsy valve’s cap has to be detached, place a piece of sterile gauze over it to prevent leakage.
- Do not let the EndoTherapy accessory hang down from the biopsy valve, which can create a space between the accessory and the valve’s slit or hole. This can damage the valve, which can reduce the efficacy of the endoscope’s suction system and may leak or spray patient debris or fluids, posing an infection control risk.
- When inserting an EndoTherapy accessory, hold it close to the biopsy valve and insert it slowly and straight into the biopsy valve. Otherwise, the EndoTherapy accessory and/or biopsy valve could be damaged. This can reduce the efficacy of the endoscope’s suction system and may leak or spray patient debris or fluids, posing an infection control risk.

CAUTION

Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while the accessory is in the instrument channel. The instrument channel and/or the EndoTherapy accessory may be damaged.

NOTE

When the tip of the EndoTherapy accessory extends approximately 1 cm from the distal end of the endoscope, the accessory will appear in the endoscopic image.

1 Select EndoTherapy accessories compatible with the endoscope from “Combination equipment” on page 111 and the accessories’ instruction manuals for operating instructions.

2 Raise the forceps elevator by moving the elevator control lever in the “◀U” direction until the operator feels resistance.

3 Hold the UP/DOWN and RIGHT/LEFT angulation control knobs stationary.

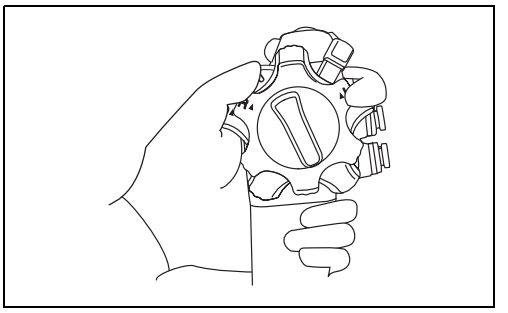


Figure 4.8

4 Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath.

5 Insert the EndoTherapy accessory slowly and straight into the slit of the biopsy valve.

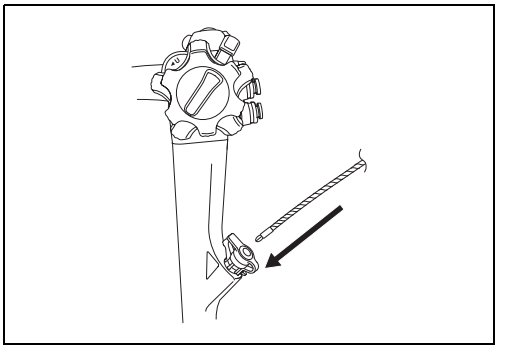


Figure 4.9

6 Hold the EndoTherapy accessory approximately 4 cm from the biopsy valve and advance it slowly and straight into the biopsy valve using short strokes while observing the endoscopic image. Confirm that the tip of the EndoTherapy accessory contacts the forceps elevator.

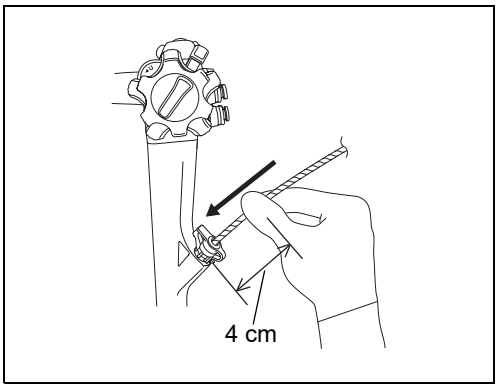


Figure 4.10

7 Move the elevator control lever in the opposite direction of the "◀U" direction to lower the forceps elevator.

8 Advance the EndoTherapy accessory slightly and move the elevator control lever in the "◀U" direction. Confirm that the accessory appears in the endoscopic image.

9 Manipulate the elevator control lever to adjust the height of the elevator.

■ *Operation of EndoTherapy accessories*

Operate the EndoTherapy accessory according to the directions given in its instruction manual.

■ *Withdrawal of EndoTherapy accessories*

WARNING

- Patient debris might spray when EndoTherapy accessories are withdrawn from the biopsy valve. To prevent this, hold a piece of gauze around the accessory and the biopsy valve during withdrawal.
- Do not withdraw the EndoTherapy accessory if the tip is open or extended from its sheath; patient injury, bleeding, perforation, and/or endoscope damage may occur.
- Withdraw the EndoTherapy accessory slowly and straight out of the biopsy valve. Otherwise, the valve's slit and/or hole could be damaged. This can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the EndoTherapy accessory and/or retract it into its sheath, then carefully withdraw both the endoscope and the EndoTherapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

1 Close the tip of the EndoTherapy accessory and/or retract it into its sheath.

2 While lowering the forceps elevator gradually, slowly withdraw the EndoTherapy accessory.

■ *Locking the guidewire*

The TJF-Q190V is designed to lock the guidewire in place during wire-guided type EndoTherapy accessory withdrawal or insertion, such as when a guidewire has been placed through a cannulation device into the biliary or pancreatic duct, and this device must be removed from the endoscope and exchanged for a different EndoTherapy accessory. When locking or replacing the guidewire, follow the warnings below.

WARNING

- Do not use a guidewire when its outer surface is damaged. This could allow leakage current to flow from the guidewire to the endoscope and/or the patient, and it could cause burns to the patient, operator, and/or assistant. Also, it could damage the endoscope, equipment, and/or EndoTherapy accessory.
- Manipulate the elevator control lever and the insertion section of the endoscope slowly while viewing the papilla when locking the guidewire at the distal end of the endoscope. Not viewing the endoscopic image carefully or locking the guidewire abruptly may result in patient injury, bleeding, and/or perforation.

WARNING

- Do not manipulate the elevator control lever and the insertion section abruptly while the guidewire is being locked. Patient pain, injury, bleeding, and/or perforation may result.
- Stop manipulation of the guidewire locking and restore the optimum field of view if the object is lost from the endoscopic image and/or the endoscopic image moves suddenly during the manipulation of the guidewire locking. Manipulation without the optimum field of view can cause patient pain, injury, bleeding, and/or perforation.
- If the patient reports pain while the guidewire is being locked at the distal end of the endoscope, stop locking the guidewire and ensure patient safety.
- Lock the guidewire at the distal end of the endoscope after making the insertion section of the endoscope as straight as possible. Confirm the insertion section with the X-ray image as required. If the guidewire is locked with the insertion section excessively bent, the distal end of the endoscope moves suddenly and patient pain, injury, bleeding, and/or perforation may result.
- Insert the guidewire into the biliary/pancreatic duct sufficiently when the guidewire is retained there. If the guidewire is not locked at the distal end of the endoscope with sufficient insertion, the guidewire can be withdrawn from the biliary/pancreatic duct. This may cause patient injury, bleeding, and/or perforation.
- Insert and withdraw a wire-guided type EndoTherapy accessory slowly and carefully when the guidewire is locked in the guidewire-locking groove at the distal end of the endoscope. If the EndoTherapy accessory is withdrawn or inserted along the guidewire with excessive force or rapidly while the guidewire is locked, or the guidewire is moved while it is locked at the distal end of the endoscope, the following may occur:
  - The guidewire comes off the guidewire-locking groove and cannot be locked at the distal end of the endoscope.
  - The guidewire penetrates deep inside the patient's body and patient injury, bleeding, and/or perforation can result.
  - The outer surface of the guidewire becomes damaged, ripped, or torn, and pieces of the outer surface might fall into the patient's body.
  - The outer surface of the guidewire is damaged, ripped, or torn, and leakage current can be discharged from damaged parts of the guidewire, which could cause burns to the patient, operator, and/or assistant, and damage the endoscope, equipment, and/or EndoTherapy accessory.
- Observe the endoscopic image and/or X-ray image to confirm that the guidewire is locked at the distal end of the endoscope when withdrawing or inserting a wire-guided type EndoTherapy accessory. Otherwise, patient injury, bleeding, and/or perforation can result.

WARNING

- Do not withdraw the endoscope if the guidewire is stuck in the guidewire-locking groove at the distal end. Doing so may result in patient injury, bleeding, and/or perforation. In this case, insert a wire-guided type EndoTherapy accessory over the guidewire from its proximal end while observing the endoscopic image to confirm that the guidewire does not penetrate patient tissue. When the EndoTherapy accessory passes through the groove, it removes the guidewire from the groove. If the guidewire is still stuck in the guidewire-locking groove, contact Olympus without changing the position of the instrument.
- The maximum angle of the forceps elevator is slightly increased compared to duodenoscopes without the assist function of the guidewire locking, due to the necessity to lock the guidewire at the distal end. Therefore, EndoTherapy accessories can be raised higher than with other duodenoscopes without the assist function of the guidewire locking. Closely observe the endoscopic image when using an EndoTherapy accessory with this endoscope, particularly while performing papillotomy. Do not manipulate the elevator control lever and/or EndoTherapy accessory without closely viewing the endoscopic image, as patient injury, bleeding, and/or perforation can result.
- The elevator control lever is more responsive than conventional duodenoscopes for more effective locking of the guidewire, requiring less movement to raise or lower the forceps elevator. Therefore, carefully observe the endoscopic image when using EndoTherapy accessories with this endoscope, particularly when performing papillotomy. Do not manipulate the elevator control lever and/or EndoTherapy accessory without carefully observing the endoscopic image, as patient injury, bleeding, and/or perforation may result.
- When the guidewire is placed into the biliary or pancreatic duct with papilla observed in the left or right side of the endoscopic image, the guidewire may move outside the view of the endoscopic image because the forceps elevator is raised extensively. In this case, do not operate the bending section. Also, do not insert or withdraw the insertion section forcibly or abruptly. Patient injury, bleeding, and/or perforation may result. If the guidewire moves outside the view of the endoscopic image, perform treatment carefully while observing the X-ray image, or lower the forceps elevator and locate the papilla as centrally as possible in the endoscopic image by adjusting the position of the distal end of endoscope, and then raise the forceps elevator again.

NOTE

- The assist function of the guidewire locking works most effectively with guidewires with a diameter of ø 0.64 mm (0.025 inch) or more.
- The assist function of the guidewire locking may not work effectively due to various shapes and sizes of the patient's duodenum, biliary duct, and pancreatic duct.
- The assist function of the guidewire locking may not work effectively under the following conditions:
  - When the papilla is observed on the upper right side of the endoscopic image.
  - If the elevator control lever is not held stationary.
  - If the proximal ends of the wire-guided type EndoTherapy accessory and the guidewire are not straight.
  - If the contrast media in the guidewire lumen of the EndoTherapy accessory is not washed with saline solution.
  - If the wire-guided type EndoTherapy accessory is kinked, deformed, or damaged.
  - If the combination of the guidewire and the wire-guided type EndoTherapy accessory is incorrect.
  - If the guidewire is not inserted sufficiently into the biliary/pancreatic duct.
  - If an attempt is made to lock more than one guidewire simultaneously.
  - If the position of the distal end of the endoscope and the papilla is not appropriate for the assist function of the guidewire locking. (See "NOTE" in "❍ Withdrawal of wire-guided type EndoTherapy accessories" on page 88).
- In rare cases, the elevator control lever can move further in the "◀U" direction after the forceps elevator is completely raised for more effective locking of the guidewire. In this case, more resistance may be encountered when operating the elevator control lever. This does not indicate a malfunction.
- When the assist function of the guidewire locking does not work effectively, using a guidewire with a length of less than 4.5 m may make it difficult to exchange the wire-guided type EndoTherapy accessories. Prepare the guidewire with a length of 4.5 m or more.
- Using a guidewire with a length of 4.5 m or more, wire-guided type EndoTherapy accessories can be exchanged without using the assist function of the guidewire locking.

Withdrawal of wire-guided type EndoTherapy accessories

1. Insert the guidewire into the proximal end of the wire-guided type EndoTherapy accessory and advance the guidewire until it reaches the desired position while observing the endoscopic and X-ray images.
2. When the forceps elevator is lowered, an operator and an assistant should work together to pull the end of the EndoTherapy accessory into the endoscope while observing the endoscopic and X-ray images.

3 When only the guidewire is extended from the endoscope's distal end, slowly move the elevator control lever in the "◀U" direction until the operator feels resistance (for center lock, see Figure 4.11).
Alternatively, when only the guidewire is extended from the endoscope's distal end, slowly move the elevator control lever in the "◀U" direction until the operator feels resistance with the papilla observed in the left side area of the endoscopic image shown in the Figure 4.12 (for side lock, see Figure 4.13).

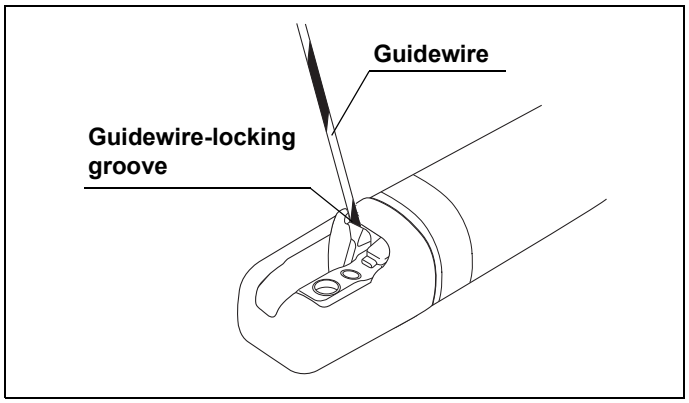


Figure 4.11

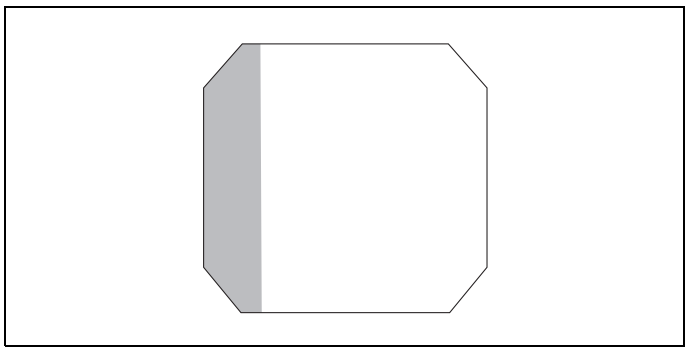


Figure 4.12

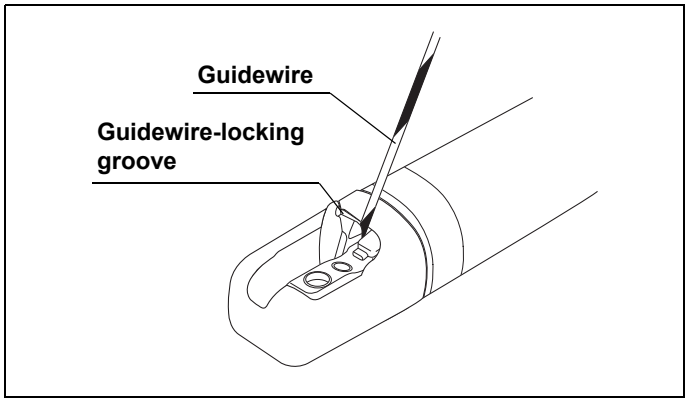


Figure 4.13

4 The guidewire is locked at the endoscope's distal end.

NOTE

- The stiff part of the guidewire is locked at the guidewire-locking groove more effectively.
- The assist function of the guidewire locking works more effectively when the papilla is observed on the left side of endoscopic image.

5 Withdraw the EndoTherapy accessory slowly while holding the elevator control lever stationary so that the elevator and guidewire do not move forward to the "◀U" direction. Observe the endoscopic and X-ray images while withdrawing the accessory.

NOTE

The guidewire may come off the guidewire-locking groove because the guidewire is bent due to the position of the distal end of the endoscope and the papilla, which may impair the assist function of the guidewire locking. In this case, change the position of the distal end.

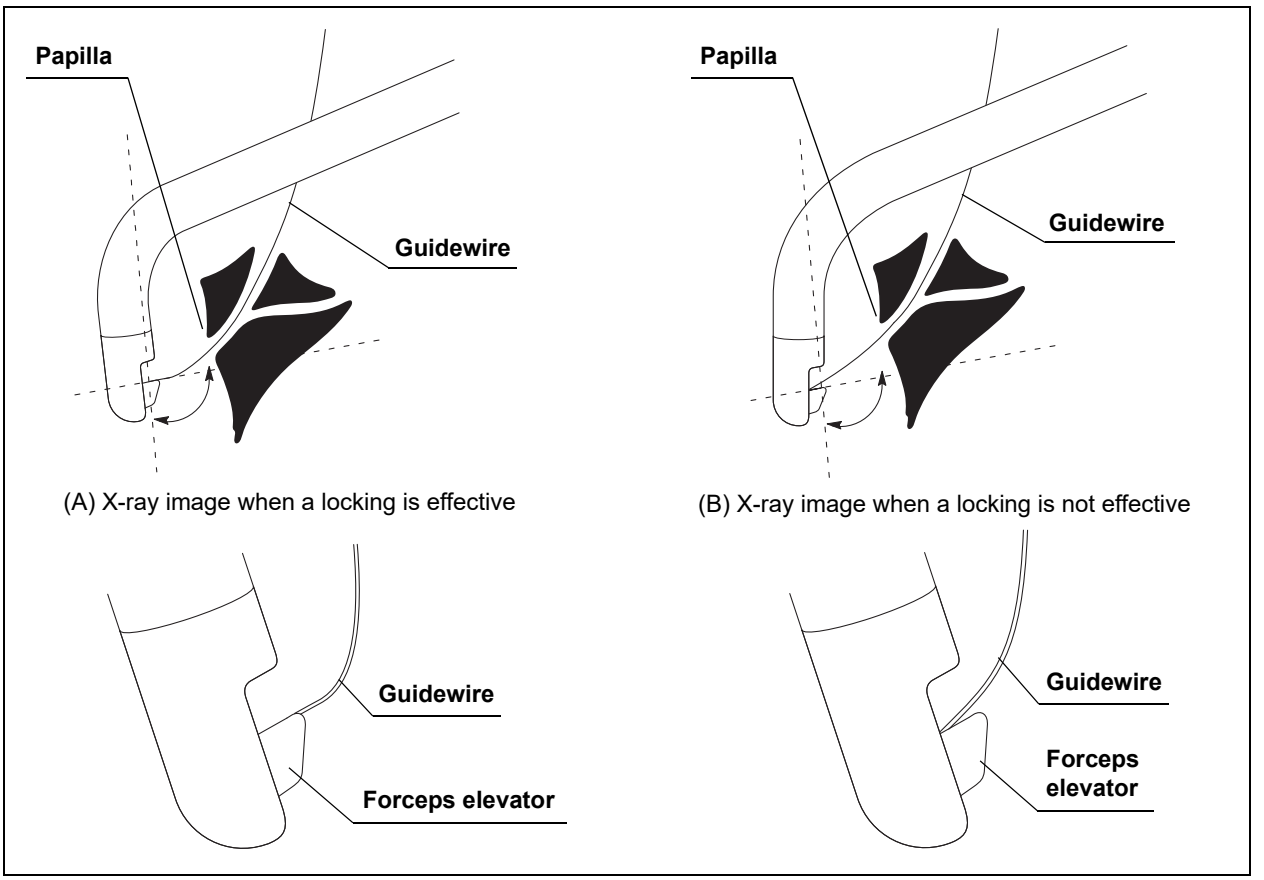


Figure 4.14

❍ Insertion of wire-guided type EndoTherapy accessories

1. When only the guidewire is extended from the endoscope's distal end, slowly move the elevator control lever in the "◀U" direction until the operator feels resistance with the papilla observed.
2. Hold the elevator control lever stationary so that the operator feels resistance in the "◀U" direction. Then insert a wire-guided type EndoTherapy accessory slowly from the proximal end of the guidewire while observing the endoscopic and X-ray images.
3. When the tip of the wire-guided type EndoTherapy accessory comes in contact with the forceps elevator, move the elevator control lever in the opposite direction of the "◀U" direction to lower the forceps elevator while observing the endoscopic image.
4. While observing endoscopic and X-ray images, an operator and an assistant should work together to insert the EndoTherapy accessory carefully without moving the guidewire from the desired position.

■ *Use of nonflammable gases*

If the intestines contain a flammable gas, replace it with air or a nonflammable gas such as CO_2 before performing high-frequency treatment.

WARNING

Performing treatment while the intestines are filled with a flammable gas could result in an explosion, a fire, and/or serious patient injury.

NOTE

Using CO_2 during endoscopic examinations may reduce post-examination pain.

When a nonflammable gas is used, the water container (MAJ-902), endoscopic CO_2 regulation unit (UCR), and either gas/water valve (MAJ-521, MAJ-2010) or air/water valve (MH-438) are used with the endoscope as described in their respective instruction manuals.

■ *High-frequency cauterization treatment*

If the intestines contain a flammable gas, replace it with air or a nonflammable gas such as CO_2 before performing high-frequency treatment.

WARNING

- Performing treatment while the intestines are filled with a flammable gas could result in an explosion, a fire, and/or serious patient injury. If the intestines contain a flammable gas, replace this gas with air or a nonflammable gas such as CO_2 before performing high-frequency treatment.
- Not all parts of the endoscope are electrically insulated. When applying high-frequency current, there is a danger of unintentional diathermy burns. Always wear electrically insulating, chemical-resistant gloves.
- Never emit high-frequency current before confirming that the distal end of the high-frequency EndoTherapy accessory is in the endoscope's field of view. Also, confirm that the electrode section and the mucous membrane in the vicinity of the target area are at an appropriate distance from the distal end of the endoscope. If the high-frequency current is emitted while the distal end of the EndoTherapy accessory is not visible or too close to the distal end of the endoscope, patient injury, bleeding, and/or perforation as well as equipment damage can result.
- To avoid patient injury, burns, bleeding, and/or perforation as well as damage to the endoscope, set the electrosurgical unit to the minimum necessary output level.

NOTE

- The application of high-frequency current may interfere with the endoscopic image. This does not indicate a malfunction.
- When the endoscope is used with the electrosurgical generator ESG-100 or ESG-400, it is not necessary to use the S-cord.

Prepare, inspect, and connect the electrosurgical unit and electrosurgical accessories as described in their respective instruction manuals.

4.4 Withdrawal of the endoscope

WARNING

- If blood and/or tissue is found on the insertion section surface (including the inside the single use distal cover) after withdrawing the endoscope, this could be a sign of patient injury. Carefully check the condition of the patient, and consider using an endoscope to observe the patient's upper digestive tract.
- Avoid patient fluids adhering to the withdrawn endoscope from coming in contact with the bed or floor. The patient fluids may pose an infection control risk to the patient and/or medical personnel.
- Take caution applying suction when the distal end is in contact with the mucosal surface. The suction can cause the distal end to aspirate the mucosal membrane. Moving or withdrawing the endoscope under this condition may cause patient injury and/or bleeding. This can be more common while degassing in the stomach, suctioning debris, and operating in a narrow lumen (e.g., esophagus, duodenum). To prevent patient injury and bleeding, make sure to:
  - Only apply suction when the endoscope is stationary.

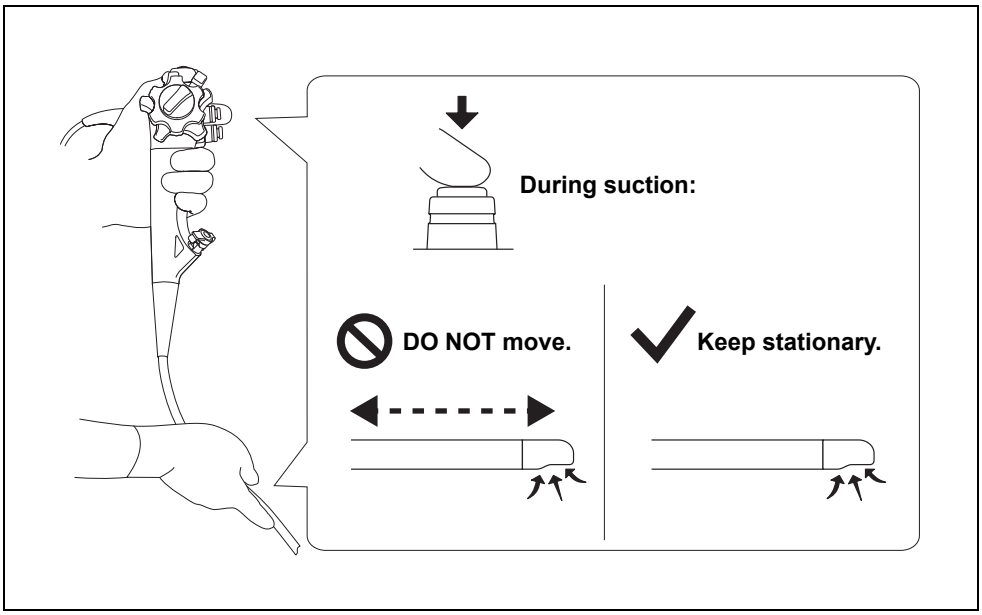


Figure 4.15

WARNING

– After releasing the suction valve, check the endoscopic image to confirm that the mucosal membrane is not aspirated before moving the endoscope. Releasing the suction valve might not immediately release the mucosal membrane if it becomes aspirated.

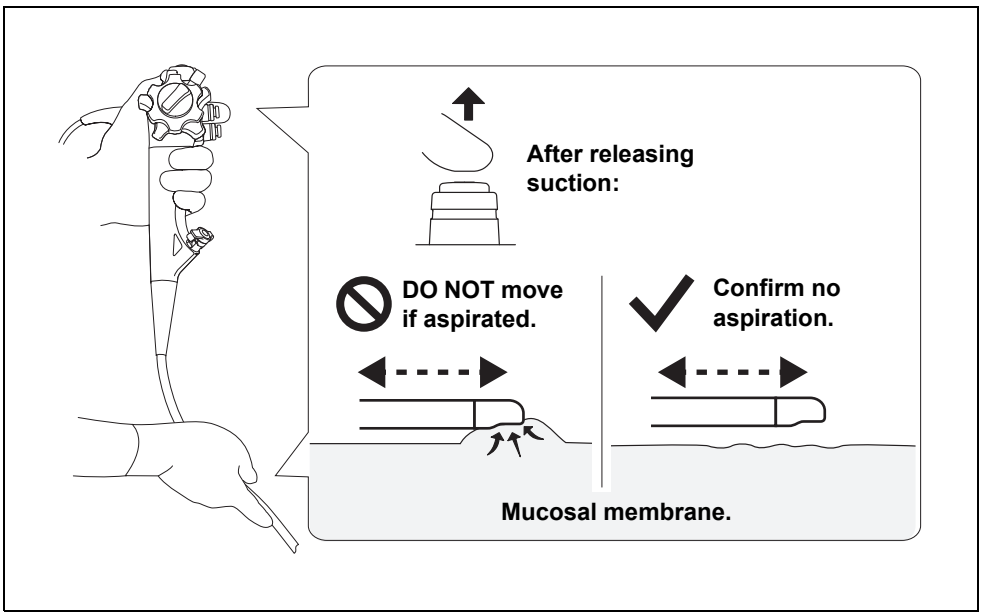


Figure 4.16

1 When using the electronic zoom function of the video system center, release the function.

2 Move the elevator control lever in the opposite direction of the "◀U" direction until it stops.

3 Aspirate accumulated air, blood, mucus, or other debris by depressing the suction valve.

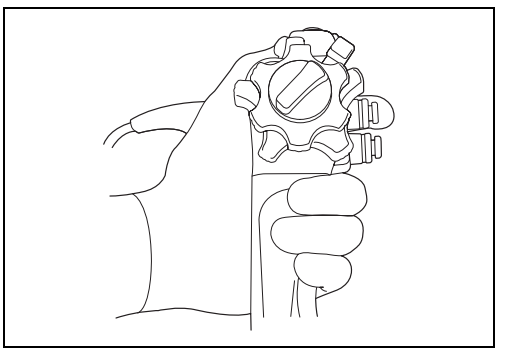


Figure 4.17

4 Turn the UP/DOWN and RIGHT/LEFT angulation locks to the "F▶" direction to release them.

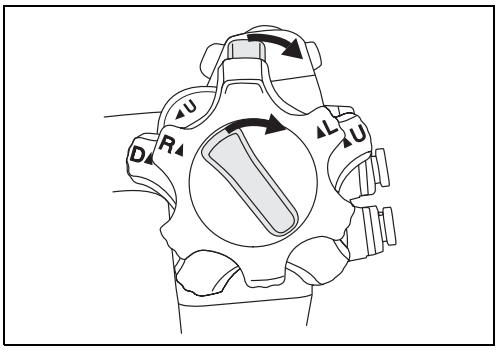


Figure 4.18

5 Carefully withdraw the endoscope while observing the endoscopic image. Remove the mouthpiece from the patient's mouth.

6 Reprocess the endoscope and accessories after the procedure as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.

4.5 Transportation of the endoscope

■ Transporting within the hospital

CAUTION

When carrying the endoscope, hold the endoscope connector securely. Holding only the universal cord or boot may damage the endoscope.

NOTE

Bringing the endoscope connector to the side of the angulation control knob makes it easier to hold the endoscope connector and control section in one hand. (See Figure 4.19)

When carrying the endoscope by hand, loop the universal cord, hold the endoscope connector with the control section in one hand, and hold the distal end of the insertion tube securely, but gently without squeezing, in the other hand.

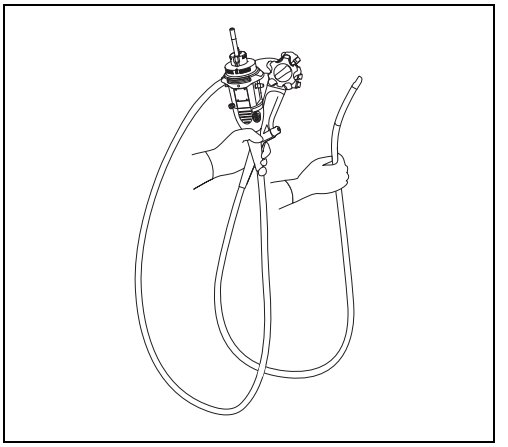


Figure 4.19

■ *Transporting outside the hospital*

WARNING

Always reprocess the endoscope after removing it from the carrying case. If the endoscope is not reprocessed, it could pose an infection control risk.

CAUTION

- Use a dedicated carrying case. Transporting the endoscope in another carrying case may cause equipment damage.
- The carrying case cannot be reprocessed. Reprocess the endoscope before placing it in the carrying case.
- Before putting the endoscope in the carrying case, make sure that the instrument channel outlet of the distal end is opened to move the elevator control lever in the "◀U" direction. Putting the endoscope in the carrying case while the forceps elevator is raised could damage the endoscope.

Transport the endoscope in the carrying case.

Chapter 5 Troubleshooting

The countermeasures against irregularities are described in this chapter.

5.1 Troubleshooting

If any irregularity is observed during the inspection described in Chapter 3, “Preparation and Inspection”, do not use the endoscope and solve the problem as described in Section 5.2, “Troubleshooting guide”.

If the problem still cannot be resolved, send the endoscope to Olympus for repair as described in Section 5.4, “Returning the endoscope for repair”.

Also, should any irregularity be observed while using the endoscope, stop using it immediately and withdraw the endoscope from the patient as described in Section 5.3, “Withdrawal of the endoscope with an irregularity”.

WARNING

- Never use the endoscope on a patient if any irregularity is observed. The irregular endoscope may compromise patient or user safety and may result in more severe equipment damage. In addition, it may pose an infection control risk.
- If any parts of the endoscope fall off inside the patient body due to equipment damage or failure, stop using the endoscope immediately and retrieve the parts in an appropriate way.

Olympus does not repair accessory parts. If an accessory part becomes damaged, contact Olympus to purchase a replacement.

5.2 Troubleshooting guide

The following table shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of accessories.

Troubles or failures due to other causes than those listed below should be serviced. As repair performed by persons who are not qualified by Olympus could cause patient or user injury and/or equipment damage, be sure to contact Olympus for repair following the instructions given in Section 5.4, “Returning the endoscope for repair”.

■ Angulation

Irregularity description	Possible cause	Solution
Resistance is encountered when rotating angulation control knob(s).	The angulation lock(s) are engaged.	Rotate angulation lock(s) in the “F▶” direction.

■ Air/water feeding

Irregularity description	Possible cause	Solution
No air feeding.	The air pump of the light source is not operating.	Press the “LOW”, “MED”, or “HIGH” button on the light source as described in the light source’s instruction manual.
	The air/water valve is damaged.	Replace it with a new one.
No water feeding.	The air pump of the light source is not operating.	Press the “LOW”, “MED”, or “HIGH” button on the light source as described in the light source’s instruction manual.
	There is no sterile water in the water container.	Add sterile water to fill the container to the specified water level.
	The air/water valve is damaged.	Replace it with a new one.
The air/water valve is sticky.	The air/water valve is dirty.	Remove the air/water valve. Reprocess the air/water valve and then attach it again.
	The air/water valve is damaged.	Replace it with a new one.
The air/water valve cannot be attached.	An incompatible air/water valve is used.	Use a compatible air/water valve.
	The air/water valve is damaged.	Replace it with a new one.
The air is continuously fed.	The air/water valve is damaged.	Turn the airflow regulator on the light source OFF and replace the valve with a new one.

Irregularity description	Possible cause	Solution
Water is continuously fed.	The air/water valve is damaged.	Turn the airflow regulator on the light source OFF and replace the valve with a new one.

■ *Suction*

Irregularity description	Possible cause	Solution
The suction function is absent or insufficient.	The biopsy valve is not attached properly.	Attach it correctly. Close the valve's cap.
	The biopsy valve is damaged.	Replace it with a new one.
	The suction pump is not set properly.	Adjust the suction pump's setting as described in its instruction manual.
	The suction valve is damaged.	Replace it with a new one.
The suction valve is sticky.	The suction valve is dirty.	Remove the suction valve. Reprocess the suction valve and attach it again.
	The suction valve is damaged.	Replace it with a new one.
The suction valve cannot be attached.	The suction valve is damaged.	Replace it with a new one.
	An incompatible suction valve is used.	Use a compatible suction valve.
Liquid leaks out of the biopsy valve.	The biopsy valve is damaged.	Replace it with a new one.
	The biopsy valve is not attached properly.	Attach it correctly. Close the valve's cap.
Suction cannot be stopped.	The suction valve is damaged.	Replace it with a new one.

■ *Image quality or brightness*

Irregularity description	Possible cause	Solution
The image is not displayed.	Not all equipment is ON.	Turn ON all equipment.
	The endoscope connector is not connected securely.	Insert the endoscope connector securely until it stops and clicks.
	Foreign objects such as detergent remnants, hard water residue, finger grease, dust, and lint are on the electrical contacts on the endoscope connector.	Wipe the electrical contacts on the endoscope connector using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol and completely dry them (refer to Section 3.3, “Inspection of the endoscope”). After drying them, connect the endoscope to the light source and confirm that a proper image is displayed when twisting the endoscope connector left and right.
The image is not clear.	The objective lens at the distal end of the endoscope is dirty.	Feed water to remove mucus, etc.
The image is excessively dark or bright.	The light guide lens at the distal end of the endoscope is dirty.	Wipe the light guide lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
	The glass at the endoscope connector end is dirty.	Wipe the glass with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
	The light source is not set properly.	Adjust the light source’s setting as described in its instruction manual.
The image is not proper.	An incompatible video system center is being used.	Use a compatible video system center.
	An incompatible light source is being used.	Use a compatible light source.
	Foreign objects such as detergent remnants, hard water residue, finger grease, dust, and lint are on the electrical contacts on the endoscope connector.	Wipe the electrical contacts on the endoscope connector using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol and completely dry them (refer to Section 3.3, “Inspection of the endoscope”). After drying them, connect the endoscope to the light source and confirm that a proper image is displayed when twisting the endoscope connector left and right.

■ *EndoTherapy accessories*

Irregularity description	Possible cause	Solution
The EndoTherapy accessory does not pass through the instrument channel smoothly.	An incompatible EndoTherapy accessory is being used.	Refer to “Combination equipment” on page 111 and select a compatible EndoTherapy accessory.
Guidewire cannot be locked.	Guidewire is not locked at its stiff part.	Lock the guidewire at its stiff part.
	Guidewire with a diameter less than ø 0.64 mm is used.	Select a guidewire with a diameter of ø 0.64 mm or more.
	Guidewire-locking groove is dirty.	Clean and disinfect or sterilize the guidewire-locking groove as described in the “REPROCESSING MANUAL” with your endoscope model listed on the cover.
	Contrast media is congealed in the guidewire lumen of the EndoTherapy accessory.	Clean the lumen of the EndoTherapy accessory and then insert/withdraw it.

■ *Single use distal cover*

Irregularity description	Possible cause	Solution
The single use distal cover cannot be attached.	An improper distal cover is used.	Use a proper single use distal cover (MAJ-2315).
	The forceps elevator is raised.	Lower the forceps elevator before attach the single use distal cover.

■ *Other*

Irregularity description	Possible cause	Solution
The remote switch does not work.	The wrong remote switch is operated.	Operate the correct remote switch.
	The remote switch function has been set incorrectly.	Set the remote switch function correctly as described in the video system center’s instruction manual.
The remote switch 1 does not return to the OFF position.	The remote switch 1 is pressed strongly from the side.	Pull it upwards gently.

5.3 Withdrawal of the endoscope with an irregularity

If an irregularity occurs while the endoscope is in use, take proper measures as described in either “■ Withdrawal when the WLI and NBI endoscopic images appear on the monitor” on page 105, “■ Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor” on page 106, or “■ Withdrawal when no endoscopic image appears on the monitor or a frozen image cannot be restored” on page 106.

After withdrawal, return the endoscope for repair as described in Section 5.4, “Returning the endoscope for repair”.

WARNING

If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation. If any irregularity with the endoscope is observed, contact Olympus.

■ *Withdrawal when the WLI and NBI endoscopic images appear on the monitor*

1 Turn all equipment OFF except the video system center, light source, monitor, and suction pump.

2 When the NBI endoscopic image is displayed, switch to the WLI endoscopic image by operating the video system center and light source.

3 When using the electronic zoom function of the video system center, release the function.

4 When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly while lowering the forceps elevator gradually.

5 Move the elevator control lever in the opposite direction of the "◀U" direction until it stops.

6 Aspirate accumulated air, blood, mucus, or other debris by depressing the suction valve.

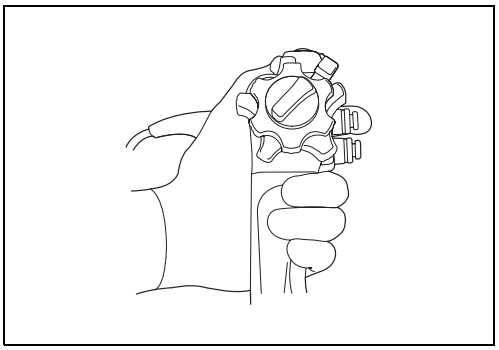


Figure 5.1

7 Turn the UP/DOWN and RIGHT/LEFT angulation locks in the "F▶" direction to release them.

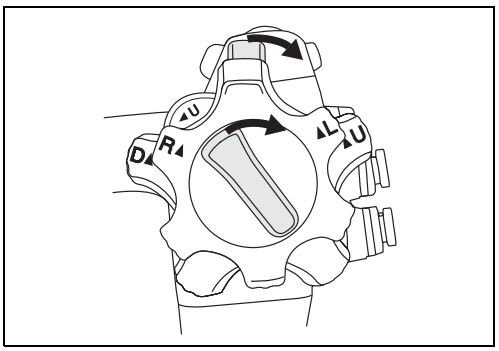


Figure 5.2

8 Carefully withdraw the endoscope while observing the endoscopic image. Remove the mouthpiece from the patient's mouth.

■ *Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor*

1. Turn all equipment OFF except the video system center, light source, monitor, and suction pump.
2. Operate the video system center and the light source to switch to the endoscopic image that is still displayed.
3. Follow the procedure given in "■ Withdrawal when the WLI and NBI endoscopic images appear on the monitor", beginning from Step 3 on page 105. Carefully withdraw the endoscope under the visible observation mode when the WLI endoscopic image is not displayed.

■ *Withdrawal when no endoscopic image appears on the monitor or a frozen image cannot be restored*

1. Turn all equipment OFF except the video system center, light source, monitor, and suction pump.
2. Turn the video system center and light source OFF and then ON again. If the WLI or NBI endoscopic image appears or the frozen image is restored, follow the procedure given in "■ Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor", beginning from Step 2 on page 106.
   If still no endoscopic image appears or the frozen image cannot be restored, perform the following steps.
3. Turn the video system center, light source, monitor, and suction pump OFF.
4. When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly while lowering the forceps elevator gradually.
5. Move the elevator control lever in the opposite direction of the "◀U" direction until it stops.

6 Turn the UP/DOWN and RIGHT/LEFT angulation locks in the "F▶" direction to release them.

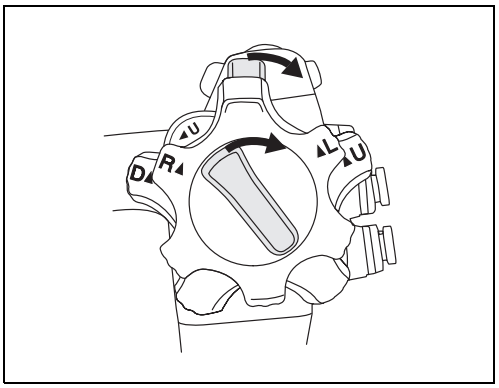


Figure 5.3

7 Turn the UP/DOWN and RIGHT/LEFT angulation control knobs to their respective neutral positions.

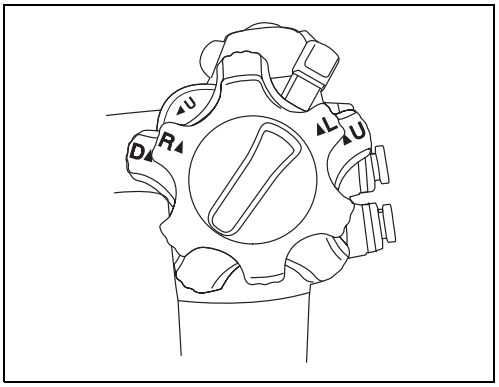


Figure 5.4

8 Release the angulation control knobs and carefully withdraw the endoscope. Remove the mouthpiece from the patient's mouth.

5.4 Returning the endoscope for repair

WARNING

Thoroughly reprocess the endoscope before returning it for repair. Improperly reprocessed equipment poses an infection control risk to each person who handles the endoscope within the hospital and at Olympus.

Before returning the endoscope for repair, contact Olympus. With the endoscope, include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem. Also, include a repair purchase order.
When returning the endoscope for repair, follow the instructions given in “■ Transporting outside the hospital” on page 97.

Chapter 6 Inspection Schedule Related to Forceps Elevator

6.1 Inspection after each patient procedure

1 Perform leakage testing of the endoscope according to the Section 5.4, “Leakage testing of the endoscope” in the “REPROCESSING MANUAL”. Confirm that there is no location around the forceps elevator from which a continuous series of air bubbles emerges during 30 seconds while immersing the endoscope in water, and moving the forceps elevator.

WARNING

The forceps elevator has to be moved during leakage testing. Otherwise, detecting leaks that occur only when the forceps elevator is raised or lowered may be impossible. Use of an endoscope with a leak may pose an infection control risk.

2 Clean the forceps elevator and elevator recess according to the instructions described in “Brush the forceps elevator recess” in Section 5.5, “Manually cleaning the endoscope and accessories” in the “REPROCESSING MANUAL”. Inspect whether there is debris on the forceps elevator, and in the forceps elevator recess according to the instructions described in “Brush the forceps elevator recess”. Repeat brushing and/or flushing the forceps elevator and the forceps elevator recess until no debris is observed upon inspection.

WARNING

Use of an endoscope from which debris was not sufficiently removed in the manual cleaning process may pose an infection control risk.

6.2 Inspection before each patient procedure

Inspect the forceps elevator and elevator recess while raising and lowering the forceps elevator to confirm that there is not any foreign materials, such as debris and fluids, but not limited to, according to the Step 5 of "■ Inspection of the endoscope" on page 30. If residual foreign materials such as debris and fluids are observed, do not use the endoscope, confirm if there is no deviation in cleaning and reprocessing procedure from the protocol given in the "REPROCESSING MANUAL", take corrective action(s) if necessary, and perform reprocessing again according to the "REPROCESSING MANUAL".

If residual foreign materials such as debris are still observed after the repeated reprocessing, do not use the endoscope, and send it to Olympus for repair.

WARNING

Use of an endoscope with residual foreign materials for a patient procedure may pose an infection control risk.

6.3 Periodic maintenance

Send the endoscope to Olympus for inspection of the forceps elevator by Olympus once a year or after every 100 times of reprocessing whichever comes first. Contact OLYMPUS for any questions regarding periodic maintenance.

Appendix

The equipment compatible with this endoscope, the labeling information for irrigation system, and the EMC information are described in this Appendix.

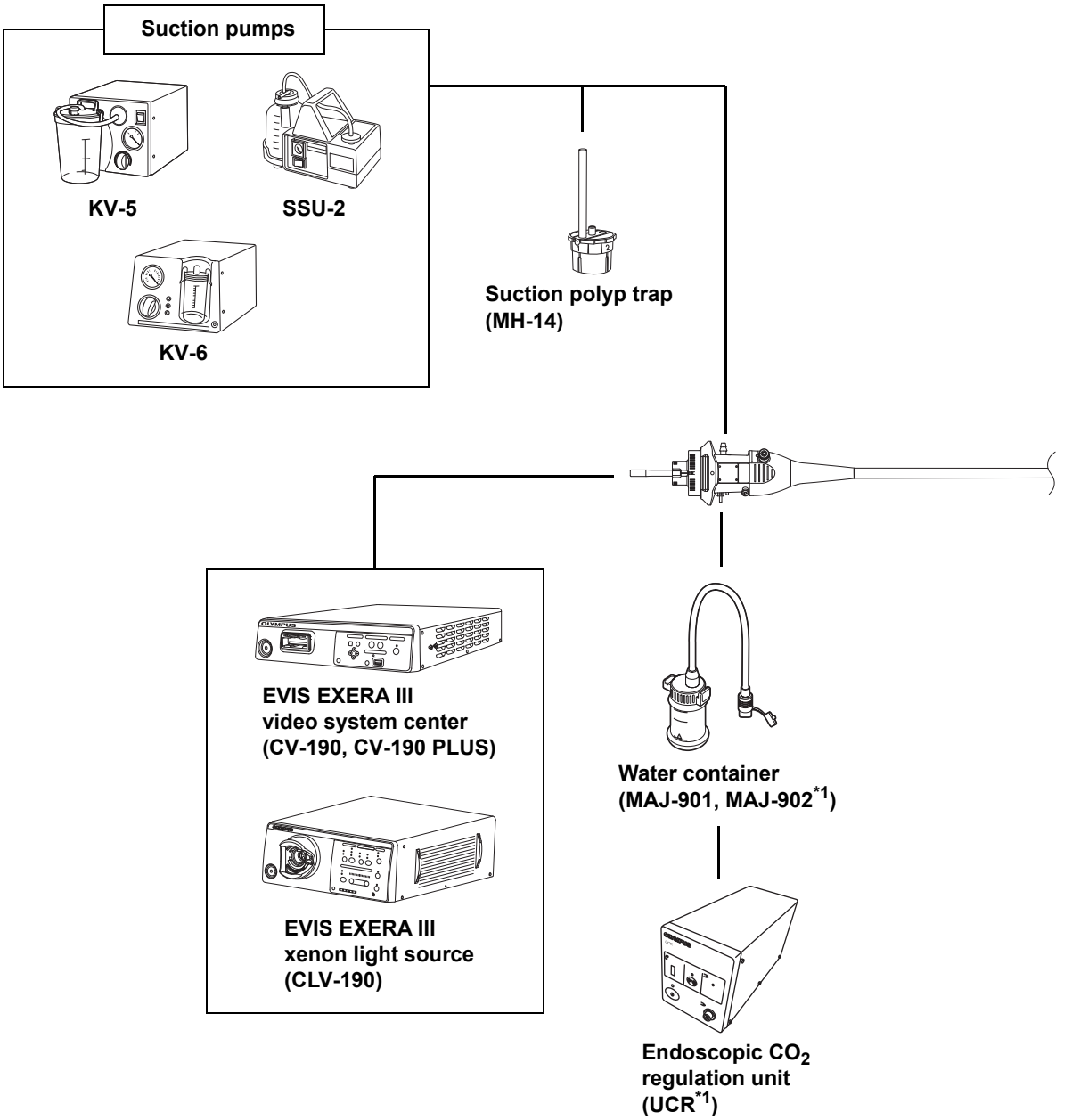
Combination equipment

■ System chart

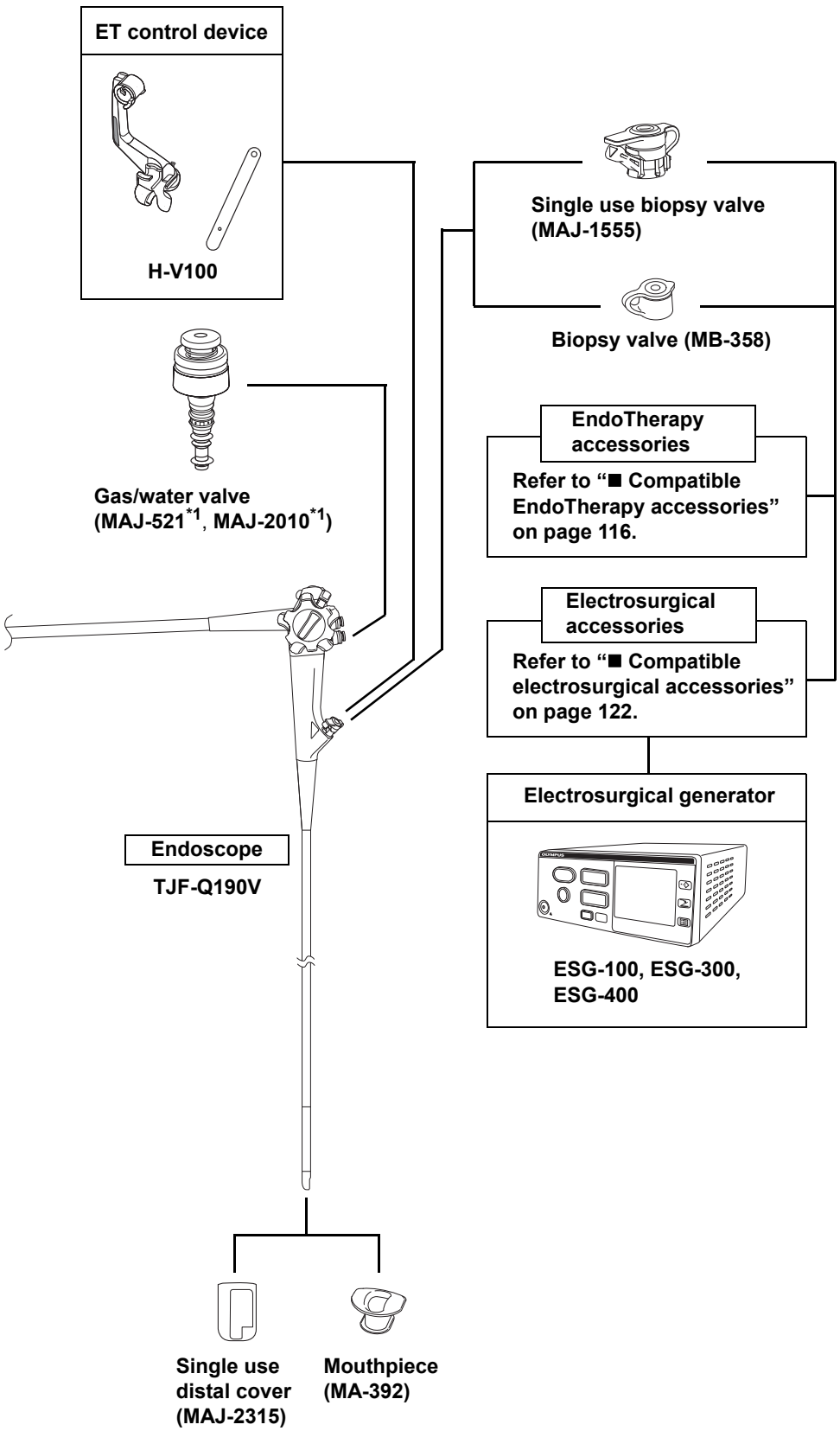
The recommended combinations of equipment and accessories that can be used with this endoscope are listed below. Some items may not be available in some areas. New products released after the introduction of the endoscopes may also be compatible for use in combination with the endoscopes. For further details, contact Olympus.

WARNING

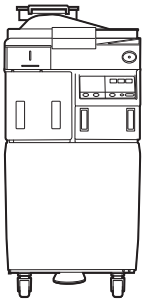
Be sure to use the equipment in one of the recommended combinations. If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.



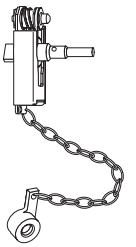
*1 Use a nonflammable gas.


ET control device
H-V100
Single use biopsy valve (MAJ-1555)
Biopsy valve (MB-358)
Gas/water valve (MAJ-521*1, MAJ-2010*1)
EndoTherapy accessories
Refer to "■ Compatible EndoTherapy accessories" on page 116.
Electrosurgical accessories
Refer to "■ Compatible electrosurgical accessories" on page 122.
Electrosurgical generator
ESG-100, ESG-300, ESG-400
Endoscope
TJF-Q190V
Single use distal cover (MAJ-2315)
Mouthpiece (MA-392)

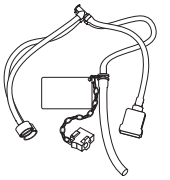
■ *Reprocessing equipment*



Endoscope reprocessor (OER-AW*1, OER-Pro*1)

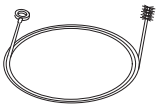


Channel plug (MH-944)



Injection tube (MH-946)

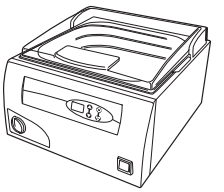
Suction cleaning adapter (MH-856)



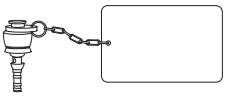
Channel cleaning brush (BW-20T)

Single use combination cleaning brush (BW-412T)

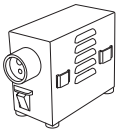
Channel-opening cleaning brush (MH-507)



Ultrasonic cleaner (ENDOSONIC)



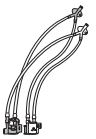
AW channel cleaning adapter (MH-948)



Maintenance unit (MU-1)

Leakage tester (MB-155)

ETO cap (MB-156)



Distal-end flushing adapter (MAJ-2319)

*1 These products may not be available in some areas.

■ *Compatible video system center*

Endoscope	Video system center				
	CV-140	CV-160	CV-180	CV-190	CV-190 PLUS
TJF-Q190V	–	–	–	○	○

○ compatible – not compatible

■ *Compatible light source*

Endoscope	Light source			
	CLV-U40	CLV-160	CLV-180	CLV-190
TJF-Q190V	–	–	–	○

○ compatible – not compatible

■ *Compatible accessories*

Endoscope	Mouthpiece			
	MAJ-1632	MB-142	MA-474	MA-392
TJF-Q190V	–	–	–	○

○ compatible – not compatible

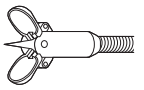
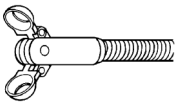
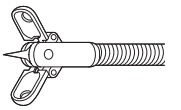
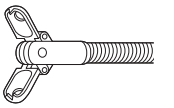
■ *Compatible distal cover*

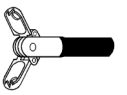
Endoscope	Distal cover		
	MAJ-311	MAJ-411	MAJ-2315
TJF-Q190V	–	–	○

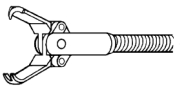
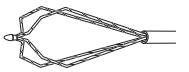
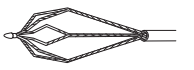
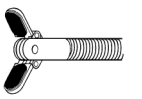
○ compatible – not compatible

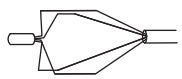
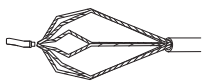
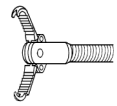
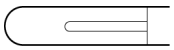
■ *Compatible EndoTherapy accessories*

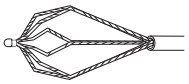
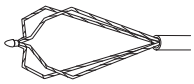
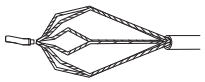
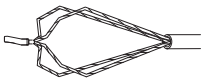
Note that some of the accessories may not be available in some areas.

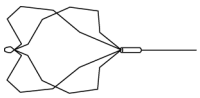
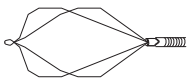
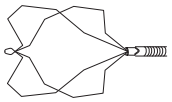
	Biopsy forceps	Biopsy forceps (fenestrated)		
	Standard type (with needle)	Standard type	Standard type (with needle)	Rat tooth type
Endoscope				
TJF-Q190V	FB-13U-1	FB-19N-1 FB-26N-1 FB-28R-1	FB-24Q-1 FB-50U-1	FB-37U-1

	Biopsy forceps (fenestrated)		Biopsy forceps with swing jaws (fenestrated)	Single use cytology brush
	Single side open type	Single side open with rat tooth type	Rat tooth	
Endoscope				
TJF-Q190V	FB-45Q-1	FB-46Q-1	FB-39Q-1 FB-40Q-1	BC-23Q BC-24Q BC-V600P-3010

	Grasping forceps			
	Rat tooth	Basket type	Flower basket type	Rubber tips (non-latex)
Endoscope				
TJF-Q190V	FG-8U-1 FG-9U-1 FG-14P-1	FG-16U-1 FG-18Q-1 FG-22Q-1 FG-23Q-1	FG-301Q	FG-20P-1

	Single use grasping forceps		Rotatable grasping forceps	Heat probe
	Basket type	Flower basket type	Rat tooth with alligator jaw type	
Endoscope				
TJF-Q190V	FG-402Q FG-403Q	FG-401Q	FG-44NR-1	CD-110U CD-120U

	Single use retrieval basket (rotatable)		Single use retrieval basket (wire-guided)	
	Flower basket type	Basket type	Flower basket type	Basket type
Endoscope				
TJF-Q190V	FG-V421PR	FG-V422PR	FG-V431P	FG-V432P

	Single use retrieval nitinol basket V	Single use mechanical lithotriptor		
		Slide type		Guidewire type
Endoscope				
TJF-Q190V	FG-V451P	BML-201Q BML-V232QR-30 BML-V237QR-30 BML-V242QR-30	BML-V232QR-26	BML-V437QR-30 BML-V442QR-30

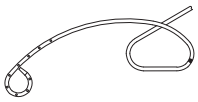
	Cannula			
	Standard type	**Slit type**	**Short taper type**	**Long taper type**
Endoscope				
TJF-Q190V	PR-104Q-1 PR-304Q	PR-126Q-1 PR-326Q	PR-109Q-1 PR-113Q-1 PR-309Q PR-313Q	PR-110Q-1 PR-310Q

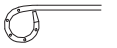
	Cannula	Single use cannula		
	Ball-tip type	**Standard type**	**Slit type**	**Taper type**
Endoscope				
TJF-Q190V	PR-24Q-1	PR-416Q PR-V216Q PR-V416Q	PR-427Q PR-V227Q PR-V427Q	PR-V434Q PR-V435Q

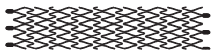
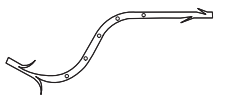
	Single use cannula			Single use bending cannula
	Short taper type	**Long taper type**	**Ball-tip type**	
Endoscope				
TJF-Q190V	PR-414Q PR-418Q PR-V214Q PR-V414Q PR-V418Q PR-V614M	PR-420Q PR-V220Q PR-V420Q	PR-23Q PR-V223Q	PR-233Q

	Spray catheter		Biliary drainage tube	
	Standard type (with nozzle)	Spray type (with nozzle)	7 Fr., 8.5 Fr., 10 Fr., 12 Fr.	
Endoscope				
TJF-Q190V	PW-1V-1	PW-5V-1 PW-6P-1	PBD-210	PBD-211

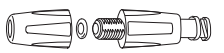
	Biliary drainage tube			
	10 Fr.	7 Fr., 8.5 Fr., 10 Fr.		
Endoscope				
TJF-Q190V	PBD-421 PBD-V621R	PBD-200 PBD-V600R	PBD-201 PBD-V601R	PBD-202 PBD-V602R

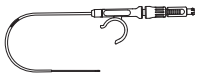
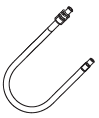
	Biliary drainage tube	Single use nasal biliary drainage tube (5 Fr., 6 Fr., 7 Fr.)		
	7 Fr.	α type	Reverse α type	Pigtail α type
Endoscope				
TJF-Q190V	PBD-203	PBD-V811W	PBD-V812W	PBD-V813W

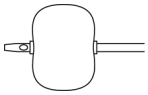
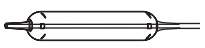
	Single use nasal biliary drainage tube (5 Fr., 6 Fr., 7 Fr.)		Single use biliary drainage stent V (7 Fr., 8.5 Fr., 10 Fr., 12 Fr.)	Single use biliary drainage stent V (7 Fr.)
	α short type	Pigtail type	Bend type	Pigtail type
Endoscope				
TJF-Q190V	PBD-V814W	PBD-V803W	PBD-1030 PBD-1031 PBD-1032 PBD-V630P PBD-V631P PBD-V632P	PBD-1033

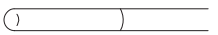
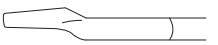
	X-suit NIR® biliary metallic stent	X-suit NIR® covered biliary metallic stent	Pancreatic stent	
			7 Fr.	7 Fr., 8.5 Fr., 10 Fr.
Endoscope				
TJF-Q190V	SME-200P	SME-210P	PBD-230	PBD-234

App.

	Single use stent insertion kit V			
	Female Luer lock of the conventional component insertion kit	Guide catheter of the conventional component insertion kit	Guide catheter of the one-action insertion kit	Pusher catheter of the one-action and conventional component insertion kits
Endoscope				
TJF-Q190V	MAJ-1417 MAJ-1418 MAJ-1419 MAJ-1420	MAJ-1417 MAJ-1418 MAJ-1419 MAJ-1420	MAJ-1421 MAJ-1422	MAJ-1416 MAJ-1417 MAJ-1418 MAJ-1419 MAJ-1420 MAJ-1421 MAJ-1422

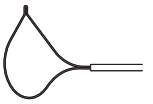
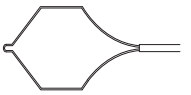
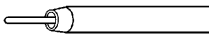
	Single use stent insertion kit V		Biliary drainage tube insertion kit	
	Insertion kit			
Endoscope				
TJF-Q190V	MAJ-1818	MAJ-1819 MAJ-1820 MAJ-1821	MAJ-255 MAJ-256 MAJ-508	MAJ-348 MAJ-509 MAJ-510 MAJ-511

	Balloon catheter	Single use biliary balloon dilator	Single use balloon dilator V (with Knife)	EZDilate wire guided balloon
Endoscope				
TJF-Q190V	B5-2Q B7-2Q B7-2LA B-V231P-A B-V231P-B B-V232P-A B-V232P-B B-V432P-A B-V432P-B B-V242Q-A B-V242Q-B B-V442Q-A B-V442Q-B B-V233P-A B-V233P-B B-V243Q-A B-V243Q-B B-V433P-A B-V433P-B B-V443Q-A B-V443Q-B	BD-210N	BD-VC431Q	BD-410X

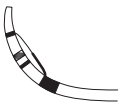
	Ultrasonic probe	
Endoscope		
TJF-Q190V	UM-2R UM-3R UM-S20-17S UM-S20-20R	UM-DG20-31R

■ *Compatible electrosurgical accessories*

Please note that some of the accessories may not be available in some areas.

	Electrosurgical snare		Precutting knife	Papillotomy knife
	Crescent type	Hexagonal type		Pull type with stabilizer
Endoscope				
TJF-Q190V	SD-7P-1	SD-8P-1	KD-10Q-1 KD-11Q-1	KD-16Q-1 KD-17Q-1 KD-18Q-1 KD-19Q-1 KD-20Q-1 KD-21Q-1 KD-22Q-1 KD-30Q-1

	Papillotomy knife	Papillotomy knife (Wire-guided)	Single use papillotomy knife (Wire-guided)	
	Push-pull type with stabilizer	Pull type	Pull type	Pull type (Clever Cut)
Endoscope				
TJF-Q190V	KD-27Q-1 KD-28Q-1	KD-6G10Q-1 KD-6G11Q-1 KD-6G12Q-1 KD-6G13Q-1	KD-201Q	KD-210Q

	Single use papillotomy knife (Wire-guided)	Triple lumen sphincterotome	Single use triple lumen sphincterotome	
	Pull type (Clever Cut)	Pull type	Pull type	Pull type (Clever Cut)
Endoscope				
TJF-Q190V	KD-211Q KD-V211M	KD-301Q	KD-401Q	KD-411Q KD-431Q KD-V411M KD-V431M

	Single use sphincterotome V	Single use preloaded sphincterotome V	
		Pull type (Pre-curved)	
Endoscope			
TJF-Q190V	KD-VC411Q KD-VC412Q KD-VC431Q KD-VC433Q	KD-V611M KD-V631M	KD-VC611Q KD-VC631Q

	Single use triple lumen needle knife		Single use guidewire	
Endoscope				
TJF-Q190V	KD-V441M	KD-V451M	G-240-2527S G-240-2545S G-240-3527S G-240-3545S G-260-2527S G-260-2545S G-260-3527S G-260-3545S	G-240-2527A G-240-2545A G-240-3527A G-240-3545A G-260-2527A G-260-2545A G-260-3527A G-260-3545A

Labeling information for irrigation system

The information on labeling recommended for guidance[*1] is listed below.

*1 Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation through Flexible Gastrointestinal Endoscopes Guidance for Industry and Food and Drug Administration Staff.

■ Backflow-prevention valve

The following list shows devices including the backflow-prevention valve.

- Air/water valve (MH-438)
- Gas/water valve (MAJ-521[*1], MAJ-2010[*1])
- AW channel cleaning adapter (MH-948)

*1 For more details, refer to the respective instruction manuals.

■ *Distal irrigation system and proximal irrigation system*

The following figure shows the areas of distal irrigation system and proximal irrigation system for each channel.

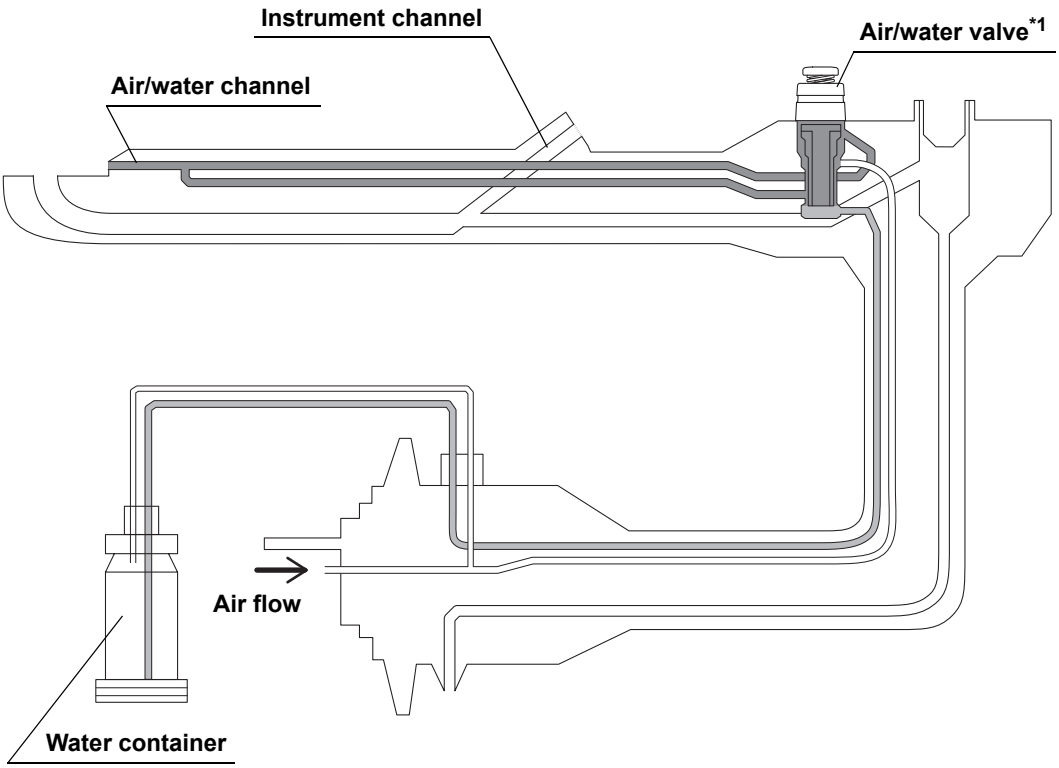
❍ Terms used in this section

Distal Irrigation System:

All components of the irrigation system between the patient and the backflow-prevention valve, including the backflow-prevention valve.

Proximal Irrigation System:

All components of the irrigation system between the water bottle and the backflow-prevention valve, excluding the backflow-prevention valve.



Distal irrigation system

Proximal irrigation system

*1 These accessories have a backflow preventive feature.

■ *Consumable device*

None.

■ *Reusable device*

The following lists show the devices included in reusable devices.

- Reusable
  - Endoscope
  - Air/water valve (MH-438)
  - Gas/water valve (MAJ-521*1, MAJ-2010*1)
- Reusable, after 24 hour multi-patient use
  - Water container (MAJ-901*1, MAJ-902*1)

*1 For more details, refer to the respective instruction manuals.

EMC information

Guidance and manufacturer's declaration — Electromagnetic emissions

This model is intended for use by medical personnel in healthcare facility environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC 61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	This instrument stabilizes its own radio variability and has no effect such as flicker in lighting apparatus.

Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended for use by medical personnel in helthcare facility environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.
This instrument can be used with the high-frequency electrosurgical equipment that designated by Olympus.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2, ±4, ±8, ±15 kV	Contact: ±2, ±4, ±6 kV Air: ±2, ±4, ±8 kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or helthcare facility environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV for signal input/ output lines: ±2 kV	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Same as left	Mains power quality should be that of a typical commercial or helthcare facility environment.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle/1 cycle	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	Same as left	Mains power quality should be that of a typical commercial or helthcare facility environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	–	40% U_T (60% dip in U_T) for 5 cycle		
	70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/ 30 cycle (60 Hz) Phase angle causing voltage dips: 0°	70% U_T (30% dip in U_T) for 25 cycle		
	0% U_T (100% dip in U_T) for 250 cycle (50 Hz)/ 300 cycle (60 Hz)	< 5% U_T (> 95% dip in U_T) for 5 seconds		
	U_T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz or 60 Hz)	3 A/m (50 Hz, 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3V (150 kHz – 80 MHz)	3V (V_1) (150 kHz – 80 MHz)	Same as left	Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ Where “P” is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and “d” is the recommended separation distance in meters [m].
	6V (ISM band of 150 kHz – 80 MHz)	–	Same as left	
	ISM (industry, science, and medical care) band of 6.765 MHz – 6.795 MHz, 13.553 MHz – 13.567 MHz, 26.957 MHz – 27.283 MHz, and 40.66 MHz – 40.70 MHz between 0.15 MHz and 80 MHz			
Radiated RF IEC 61000-4-3	3V/m (80 MHz – 2.7 GHz)	3V/m (E_1) (80 MHz – 2.5 GHz)	Same as left	Recommended separation distance $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz – 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz – 2.5 GHz Where “P” is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and “d” is the recommended separation distance in meters [m].
Proximity magnetic field from RF communication equipment IEC 61000-4-3	Refer to the table of the next page.	–	Same as left	

NOTE

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Electromagnetic interference may occur in the vicinity of high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:

NOTE

- Field strength from fixed RF transmitters as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)].

  a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this model is used exceeds the applicable RF compliance level above, this model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this model.

  b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Test frequency [MHz]	Band [MHz]	Modulation*1	Maximum power [W]	Immunity test level [V/m]
385	380 – 390	Pulse modulation*1 18 Hz	1.8	27
450	430 – 470	FM ±5 kHz deviation 1 kHz sine	2	28
710	704 – 787	Pulse modulation*1 217 Hz	0.2	9
745				
780				
810	800 – 960	Pulse modulation*1 18 Hz	2	28
870				
930				
1720	1700 – 1990	Pulse modulation*1 217 Hz	2	28
1845				
1970				
2450	2400 – 2570	Pulse modulation*1 217 Hz	2	28
5240	5100 – 5800	Pulse modulation*1 217 Hz	0.2	9
5500				
5785				

*1 The carrier shall be modulated using a 50% duty cycle square wave signal.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the video system center, including cables specified by Olympus. Otherwise, degradation of the performance of this equipment could result.

❍ Guidance and manufacturer's declaration — Cables used for EMC compliance testing

Refer to the instruction manuals for each piece of equipment.

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