OLYMPUS®

OPERATION MANUAL

INSTRUCTIONS

EVIS EXERA II

EVIS EXERA II DUODENOVIDEOSCOPE

OLYMPUS TJF TYPE **Q180V**

Refer to the endoscope's companion manual, the "OLYMPUS TJF TYPE Q180V REPROCESSING MANUAL", for reprocessing information.

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

CE 0197

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:


Refer to instructions.


Caution


Endoscope


TYPE BF applied part


Single use only

Lot number


Manufacturer

Authorized representative in the European Community

Serial number

Important Information — Please Read Before Use

Intended 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.

Do not use this instrument for any purpose other than its intended use. Select the endoscope to be used according to the objective of the intended procedure based on the full understanding of the endoscope's specifications and functionality as described in this instruction manual.

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 administrations 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 mode:

This is an observation mode using narrowband light.

Normal light observation mode (or WLI (White Light Imaging) observation mode):

This is an observation mode using standard white light illumination.

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 the “System chart” in the Appendix 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 2 (IEC 60601-1-2: 2001). However, when connected with an instrument that complies with the EMC standard for medical electrical equipment, edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.

Reprocessing before the first use/reprocessing and storage after use

This instrument was not cleaned, disinfected, or sterilized 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 inspect the items specified in this manual periodically. An endoscope with an observed irregularity should not be used, but should be inspected by following Section 5.1, “Troubleshooting guide” on page 64. 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.

Warnings and cautions

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

WARNING

- For more information on combining the endoscope with a particular electrosurgical generator, refer to “System chart” on page 73. Do not use an electrosurgical generator that does not comply with medical electrical equipment (EN 60601-1:2013). It could cause patient burns.
- After using this instrument, 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.
- Do not strike, hit, or drop the endoscope’s distal end, insertion tube, bending section, control section, universal cord, or endoscope connector. Also, do not bend, pull, or twist the endoscope’s distal end, insertion tube, bending section, control section, universal cord, or endoscope connector 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. 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.

WARNING

- 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. 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 while the 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.
- 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 (when using the image magnification function of the video system center).
- 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.
- When the endoscopic image does not appear on the monitor, the CCD may have been damaged. Turn the video system center OFF immediately. Continued power supply in such a case will cause the distal end to become hot and could cause operator and/or patient burns.
- 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.

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 not be visible.
- Do not coil the insertion tube or universal cord with a diameter of less than 12 cm. Equipment damage can result.
- Do not attempt to bend the endoscope's insertion section with excessive force. Otherwise, the insertion section may be damaged.

CAUTION

- Do not touch the electrical contacts inside the electrical connector. CCD damage may result.
- Do not apply shock to the distal end of the insertion section, particularly the objective lens surface at the distal end. Visual irregularities 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 leaks.
- Turn the video system center ON only when the videoscope cable is connected to both the video system center and the electrical connector on the endoscope. In particular, confirm that the video system center is OFF before connecting or disconnecting the videoscope cable from the electrical connector on the endoscope. Failure to do so can result in equipment damage, including destruction of the CCD.
- 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 leaks.
- 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 faulty contact can result.
- Electromagnetic interference may occur on this instrument 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 reorienting or relocating this instrument, or shielding the location.

- To check the electromagnetic interference from other equipment (any equipment other than this instrument or the components that constitute this system), the system should be observed to verify its normal operation in the configuration in which it will be used.

NOTE

This endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-180, CV-160.

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.

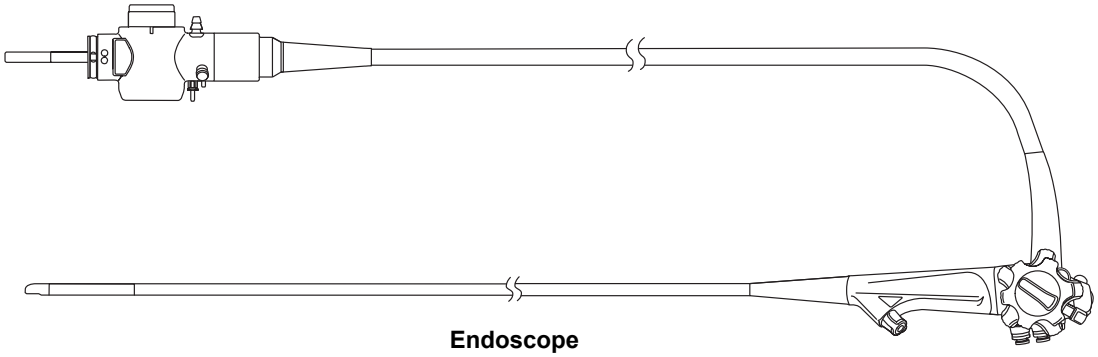
- Over-insufflating the lumen may cause patient pain, injury, bleeding, and/or perforation.
- Applying suction with the distal end in prolonged contact with the mucosal surface, with higher suction pressure than required, or with prolonged suction time may cause bleeding and/or lesions.
- The endoscope 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 the usefulness of doing so is determined to be greater than the risk that is posed to the patient.
- 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.
  - NBI has not been demonstrated to aid in differentiating or establishing the presence or absence of dysplasia or neoplastic changes within mucosa or mucosal lesions.

*1 Narrow Band Imaging. For more details, refer to the instruction manual for the video system center CV-180.

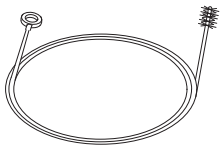
Chapter 1 Checking the Package Contents

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

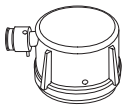
Before using this instrument for the first time, reprocess it according to the instructions described in the endoscope's companion "REPROCESSING MANUAL" with your endoscope model listed on the cover.



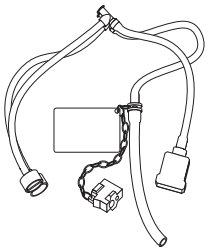
Endoscope



Channel cleaning brush (BW-20T)



Water-resistant cap (MH-553)

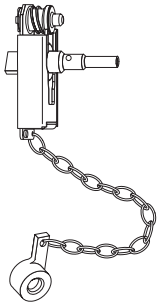


Injection tube (MH-946)

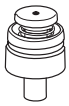
Channel-opening cleaning brush (MH-507)

Suction cleaning adapter (MH-856)

Mouthpiece (MB-142, 2 pcs)



Channel plug (MH-944)

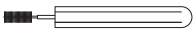


Suction valve (MH-443, 2 pcs)

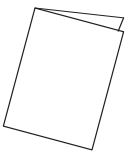
Air/water valve (MH-438, 2 pcs)

AW channel cleaning adapter (MH-948)

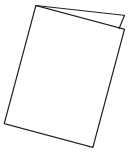
Biopsy valve (MB-358, 10 pcs)



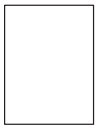
Single use soft brush (MAJ-1888, 5pcs)



Operation manual



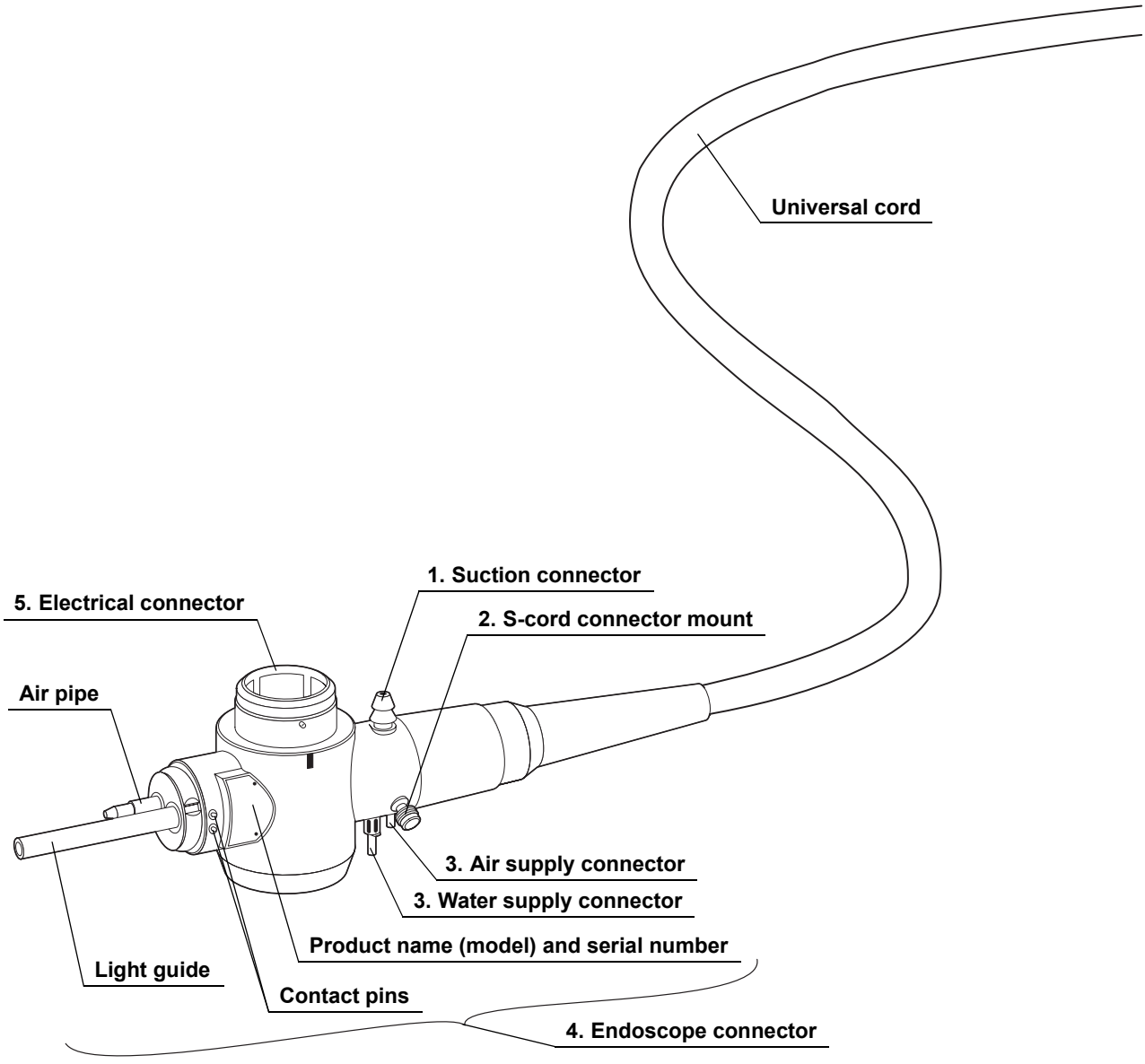
Reprocessing manual

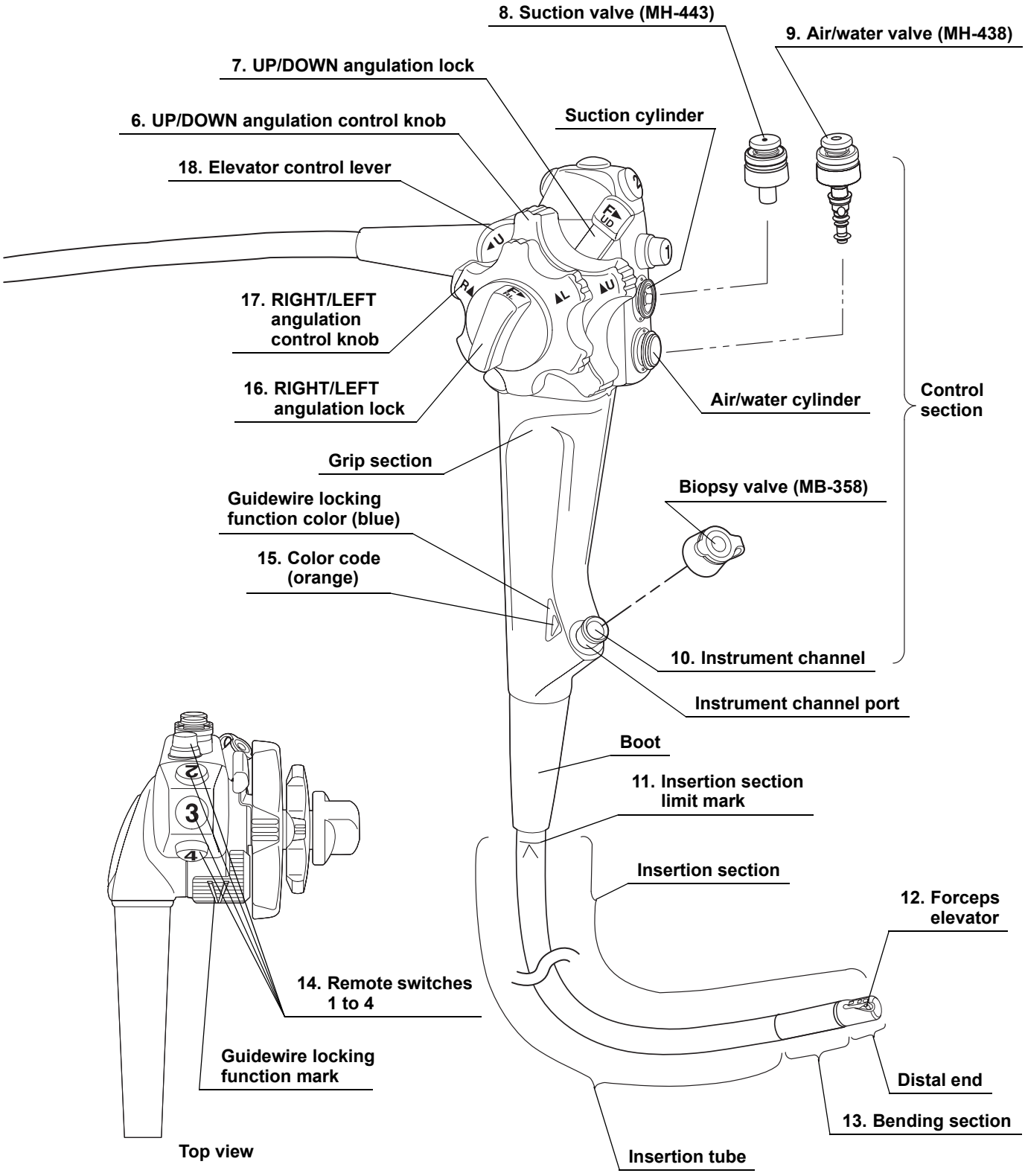


Instructions (caution for locking the guidewire)

Chapter 2 Instrument Nomenclature and Specifications

2.1 Nomenclature




8. Suction valve (MH-443)
9. Air/water valve (MH-438)
7. UP/DOWN angulation lock
6. UP/DOWN angulation control knob
Suction cylinder
18. Elevator control lever
17. RIGHT/LEFT angulation control knob
16. RIGHT/LEFT angulation lock
Air/water cylinder
Control section
Grip section
Biopsy valve (MB-358)
Guidewire locking function color (blue)
15. Color code (orange)
10. Instrument channel
Instrument channel port
Boot
11. Insertion section limit mark
Insertion section
12. Forceps elevator
14. Remote switches 1 to 4
Guidewire locking function mark
Distal end
13. Bending section
Insertion tube
Top view

2.2 Endoscope functions

1. **Suction connector**
   Connects the endoscope to the suction tube of the suction pump.
2. **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 unit ESG-100, it is not necessary to use the S-cord. Connect the fitting part of the chain for water-resistant cap to this mount, as required (refer to Section 2.4 on page 19).
3. **Water supply connector and air supply connector**
   Connects the endoscope to the water container via the water container tube to supply water to the distal end of the endoscope.
4. **Endoscope connector**
   Connects the endoscope to the output socket of the light source and transmits light from the light source to the endoscope.
5. **Electrical connector**
   Connects the endoscope to the video system center via the videoscope cable. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-180, CV-160. For more details, refer to the instruction manual for the CV-180, CV-160.
6. **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.
7. **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 any desired position.
8. **Suction valve (MH-443)**
   This valve is depressed to activate suction. The valve is used 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 used to feed air for removing any fluids or debris adhering to the objective lens.

10. **Instrument channel**

The instrument channel functions as:

- Channel for the insertion of EndoTherapy accessories
- Suction channel
- Fluid feed channel (from a syringe via the biopsy valve)

11. **Insertion section limit mark**

This mark shows the maximum point to which the endoscope may be inserted into the patient's body.

12. **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.

13. **Bending section**

This section moves the distal end of the endoscope when the UP/DOWN and RIGHT/LEFT angulation control knobs are operated.

14. **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.

15. **Color code (orange)**

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 the "System chart" in the Appendix and the instruction manuals for the compatible accessories.

16. **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 any desired position.

17. **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.

18. **Elevator control lever**

When this lever is moved in the "◀U" direction, the forceps elevator is raised. When the lever is turned in the opposite direction, the forceps elevator is lowered.

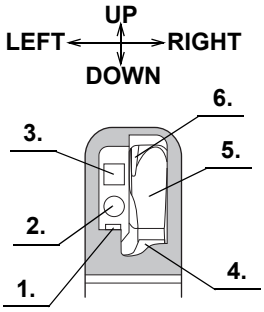
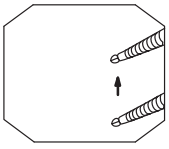
2.3 Specifications

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)

Specifications

❍ Endoscope functions

Model		TJF-Q180V
Optical system	**Field of view**	100°
	Direction of view	Backward side viewing 5°
	Depth of field	5 – 60 mm
Insertion section	**Distal end outer diameter**	ø 13.7 mm
	Distal end enlarged	1. Air/water nozzle 2. Objective lens 3. Light guide lens 4. Instrument channel outlet 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	10 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
Airflow rate		25 cm^3/s Note: Standard when CLV-180 (high air pressure) is used.
Bending section	**Angulation range**	UP 120°, DOWN 90°, RIGHT 110°, LEFT 90°

Total length		1550 mm
NBI observation mode[*1]		Available
Medical Devices Directive	CE 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a
EMC	**Applied standard:** **IEC 60601-1-2: 2001** **IEC 60601-1-2: 2007**	This instrument complies with the standards listed in the left column. CISPR 11 of emission: Group 1, Class B This instrument complies with the EMC standard for medical electrical equipment, edition 2 (IEC 60601-1-2: 2001) and edition 3 (IEC 60601-1-2: 2007). However, when connecting to an instrument that complies with the EMC standard for medical electrical equipment, edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.
Year of manufacture	**2001234** ↑	The last digit of the year of manufacture is the second digit of the serial number.
Degree of protection against electric shock		TYPE BF applied part

∗1 For more details, refer to the instruction manual for the CV-180.

2.4 Attaching the chain for water-resistant cap (MAJ-1119)

CAUTION

- Do not lift the endoscope by the chain for water-resistant cap. Doing so may result in the fitting part of the chain detaching from the S-cord connector mount, causing the endoscope to fall. This could cause operator or patient injury and/or equipment damage.
- Connect the fitting part only to the S-cord connector mount. Connecting the fitting part to the suction connector may impair the connection of the suction tube to the suction connector. It may also cause the suction tube to become disconnected from the endoscope and allow patient debris to spray.
- When attaching the water-resistant cap to the electrical connector, do not pinch the chain for water-resistant cap between the electrical connector of the endoscope and the water-resistant cap. Otherwise, equipment damage may result.
- The chain for water-resistant cap and the water-resistant cap itself cannot be ultrasonically cleaned; doing so could damage them. The water-resistant cap with the chain can only be ultrasonically cleaned if it is connected to an endoscope that is being cleaned in an endoscope reprocessor with an ultrasonic cleaning phase (such as OER, OER-A, OER-AW).
- The chain for water-resistant cap and the water-resistant cap itself cannot be ethylene oxide gas sterilized; doing so may damage them. If the water-resistant cap is connected to the endoscope by the chain, be sure to remove the chain and the water-resistant cap from the endoscope before ethylene oxide gas sterilization.
- The chain for water-resistant cap and the water-resistant cap itself cannot be steam sterilized (autoclaved); doing so can damage them severely.

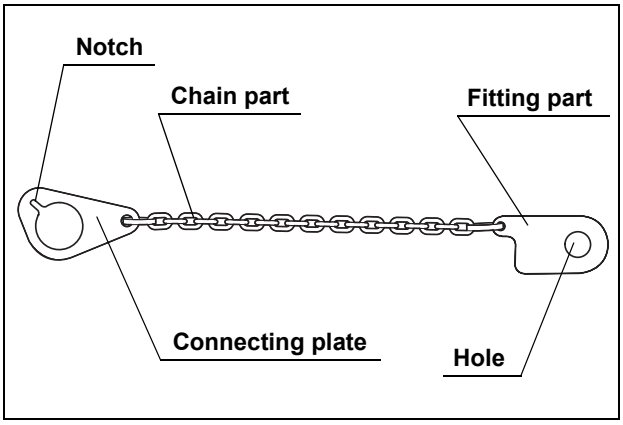


Figure 2.1

NOTE

To ensure that you do not forget to attach the water-resistant cap, it is recommended that you connect the chain for water-resistant cap to the endoscope's S-cord connector mount.

1. Confirm that the chain for water-resistant cap is free from cracks, flaws, wear, deformation, or other damages (see Figure 2.1).
2. Align the notch on the connecting plate with the pin on the venting connector of the water-resistant cap (MH-553, see Figure 2.2).
3. Place the connecting plate over the venting connector (see Figure 2.2).
4. Confirm that the connecting plate is securely attached to the foot of the venting connector and can be smoothly rotated (see Figure 2.2).

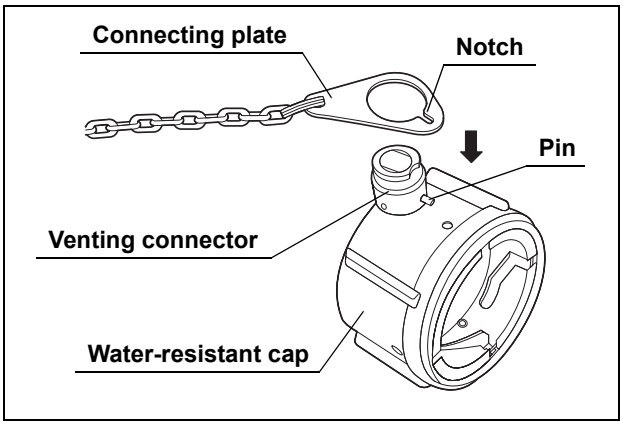


Figure 2.2

5. Place the hole on the fitting part over the endoscope's S-cord connector mount (see Figure 2.3).

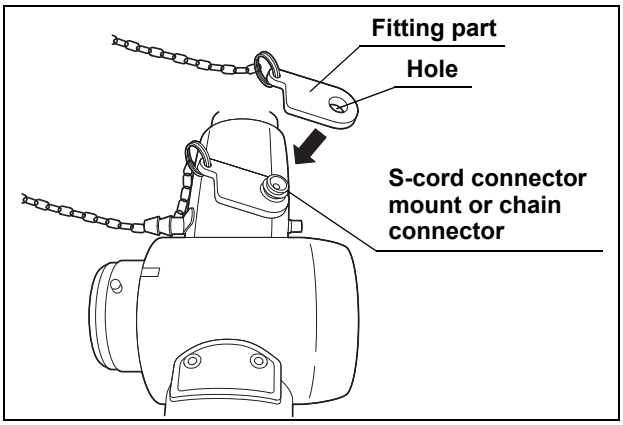


Figure 2.3

6. Confirm that the fitting part is securely attached to the foot of the S-cord connector mount and can be smoothly rotated.

NOTE

The instructions on the remaining pages of this manual are given under the assumption that the chain for water-resistant cap is detached from the endoscope.

Chapter 3 Preparation and Inspection

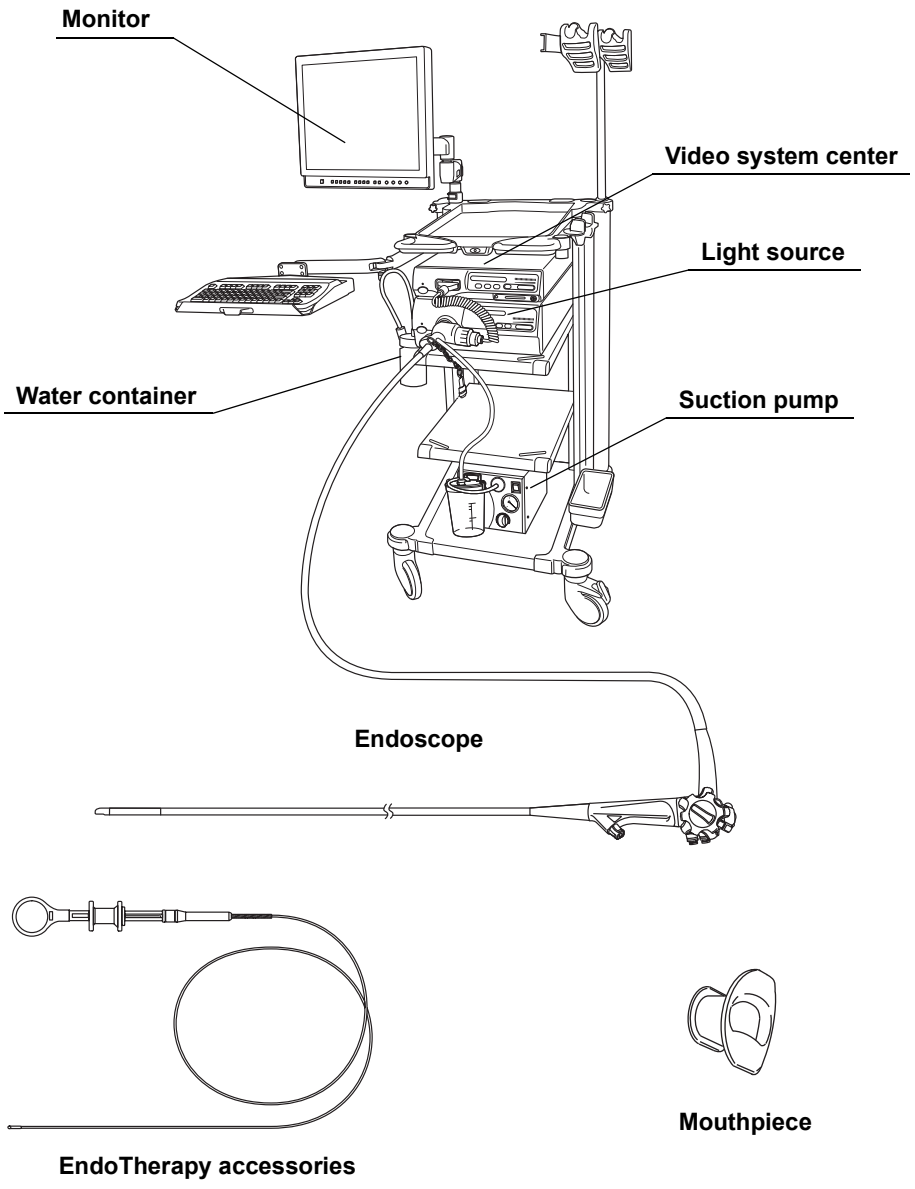
Before each case, prepare and inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as instructed in their respective instruction manuals. Should any irregularity be observed after inspection, follow the instructions as described in Chapter 5, “Troubleshooting”. If this instrument malfunctions, do not use it. Return it to Olympus for repair as described in Section 5.3, “Returning the endoscope for repair” on page 70.

WARNING

- Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.
- This instrument was not cleaned, disinfected, or sterilized before shipment. Before using this instrument 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.

3.1 Preparation of the equipment

Prepare the equipment shown in Figure 3.1 (for compatibility, refer to the “System chart” in the Appendix) and 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. Refer to the respective instruction manuals for each piece of equipment.



- **Lint-free cloths**
- **Personal protective equipment**

Figure 3.1

3.2 Inspection of the endoscope

Clean and disinfect or sterilize the endoscope as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover. Then remove the water-resistant cap from the endoscope connector.

Inspection of the endoscope

1. Inspect the control section and the endoscope connector for excessive scratching, deformation, loose parts, or other irregularities.
2. Inspect the boot and the insertion section near the boot for bends, twists, or other irregularities.
3. Inspect the external surface of the entire insertion section including the bending section and the distal end for dents, bulges, swelling, scratches, holes, sagging, transformation, bends, adhesion of foreign bodies, missing parts, protruding objects, or other irregularities.
4. Inspect the forceps elevator and the area which can be visually accessible in 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. If any foreign materials are observed, stop using the endoscope and take necessary measures according to Section 6.2, "Inspection before each patient procedure" on page 72.

WARNING

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

5. Holding the control section with one hand, carefully run your other hand back and forth over the entire length of the insertion section (see Figure 3.2). Confirm that no objects or metallic wire protrude from the insertion section. Also, confirm that the insertion tube is not abnormally rigid.

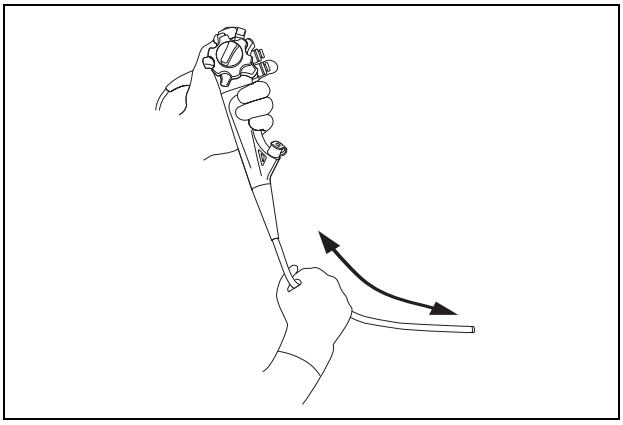


Figure 3.2

6. Using both hands, bend the insertion tube of the endoscope into a semicircle. Then, moving your hands as shown by the arrows in Figure 3.3, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable.

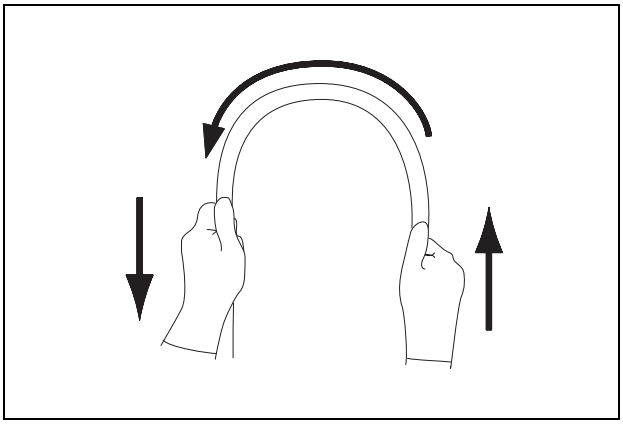


Figure 3.3

7. Gently hold the midpoint of the bending section and a point 20 cm from the distal end. Push and pull gently to confirm that the junction between the bending section and the insertion tube is not loose.
8. Inspect the objective lens and light guide lens at the distal end of the endoscope's insertion section for scratches, cracks, stains, or other irregularities.
9. Inspect the air/water nozzle at the distal end of the endoscope's insertion section for abnormal swelling, bulges, dents, or other irregularities.
10. Inspect the guidewire-locking groove of the forceps elevator for stains.

Inspection of the bending mechanisms

Perform the following inspections while the bending section is straight.

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 be abnormal. 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. Confirm that both the UP/DOWN and RIGHT/LEFT angulation locks move all the way in the "F▶" direction.
2. 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.
3. When the UP/DOWN and RIGHT/LEFT angulation control knobs are turned to their respective neutral positions as shown in Figure 3.4, confirm that the bending section returns smoothly to an approximately straight condition.

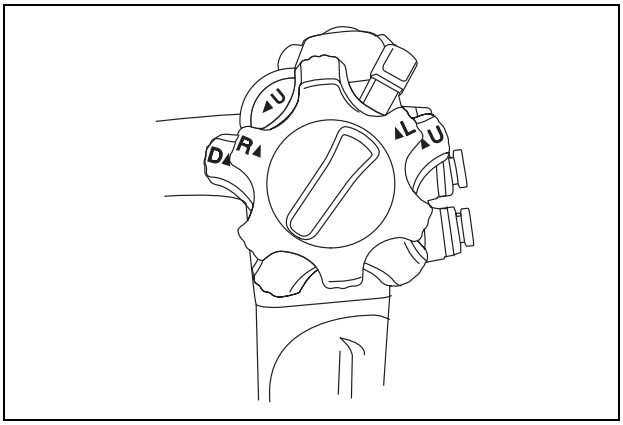


Figure 3.4

❍ 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. Then turn the UP/DOWN angulation control knob in the "▲U" or the "D▲" direction until it stops.
2. Confirm that the angle of the bending section is roughly stabilized when the UP/DOWN angulation control knob is released.
3. 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.

❍ 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. Then turn the RIGHT/LEFT angulation control knob in the "R▲" or the "▲L" direction until it stops.
2. Confirm that the angle of the bending section is roughly stabilized when the RIGHT/LEFT angulation control knob is released.
3. 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.

Inspection of the forceps elevator mechanism

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.

Perform the following inspections while the bending section is straight.

❍ Inspection for smooth operation

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

2. 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 operator feels heavy. Confirm that the lever can be operated smoothly and that the forceps elevator is raised smoothly. Also, confirm that the forceps elevator remains stationary when pushed from behind while holding the elevator control lever stationary (see Figure 3.5).
3. 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 (see Figure 3.5).

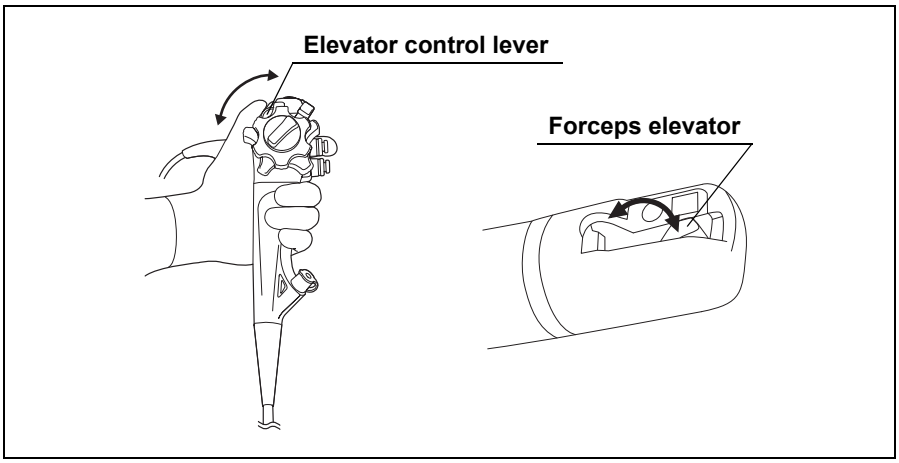


Figure 3.5

3.3 Preparation and inspection of accessories

Clean and disinfect or sterilize the air/water valve, suction valve, biopsy valve as described in the endoscope's companion "REPROCESSING MANUAL" with your endoscope model listed on the cover.

Inspection of the air/water and suction valves

WARNING

Confirm that the top hole of the air/water valve is not blocked (see Figure 3.6). If the hole is blocked, air is fed continuously and patient pain, bleeding, and/or perforation can result.

1. Confirm that the holes of the valves are not blocked (see Figure 3.6 and 3.7).
2. Confirm that the valves are not deformed or cracked (see Figure 3.6 and 3.7).

3. Check for excessive scratching or tears in the air/water valve's seals (see Figure 3.6).

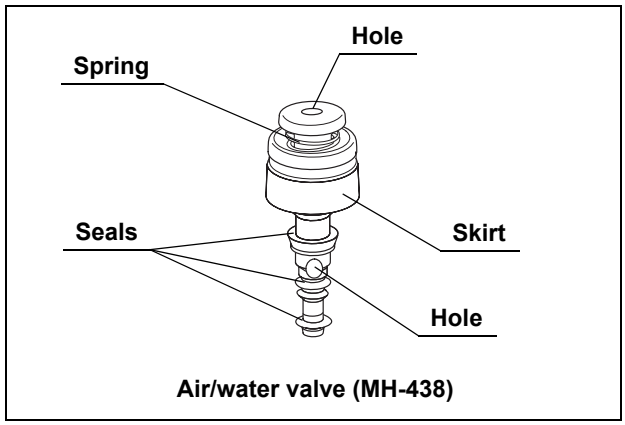


Figure 3.6

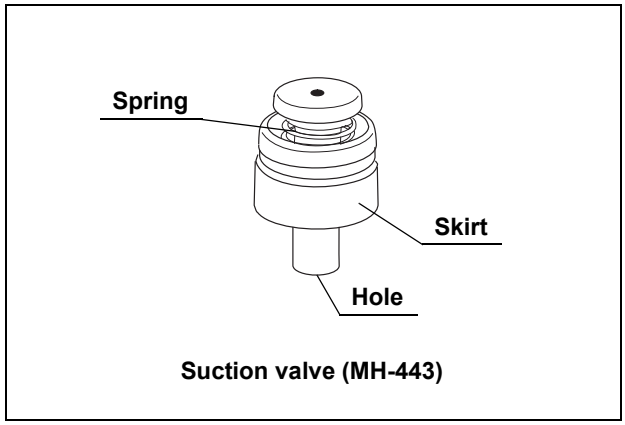


Figure 3.7

NOTE

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

Inspection of the biopsy valve

WARNING

The biopsy valve is a consumable that should be inspected as follows 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 (see Figure 3.8).

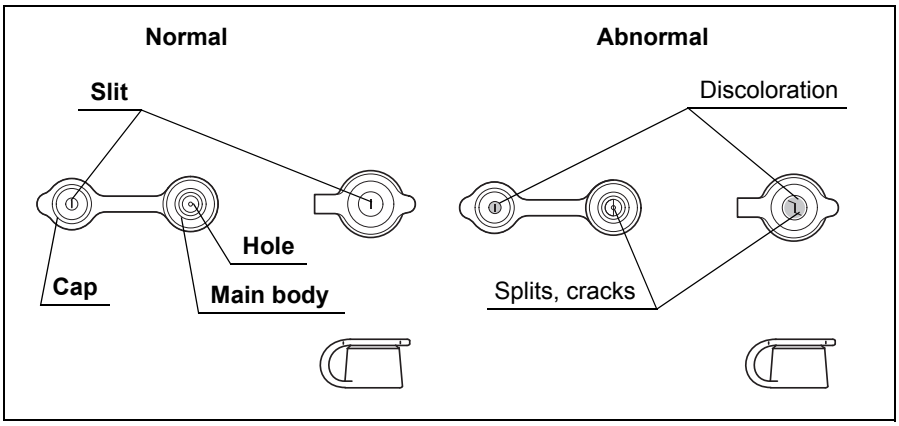


Figure 3.8

2. Attach the cap to the main body (see Figure 3.9).

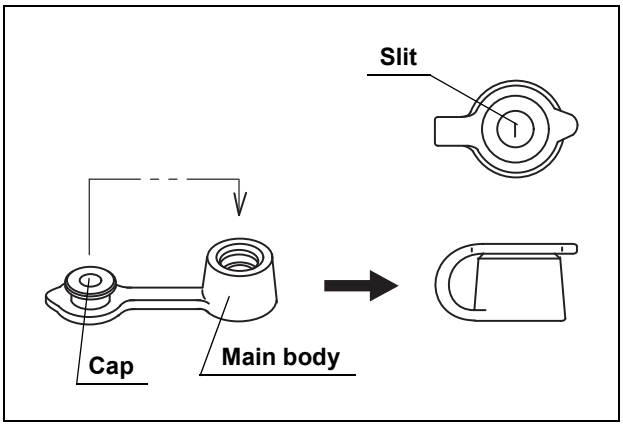


Figure 3.9

Inspection of the mouthpiece

CAUTION

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

NOTE

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 (see Figure 3.10).
2. Using your fingers, check all surfaces of the mouthpiece for scratches, cracks, or other irregularities (see Figure 3.10).

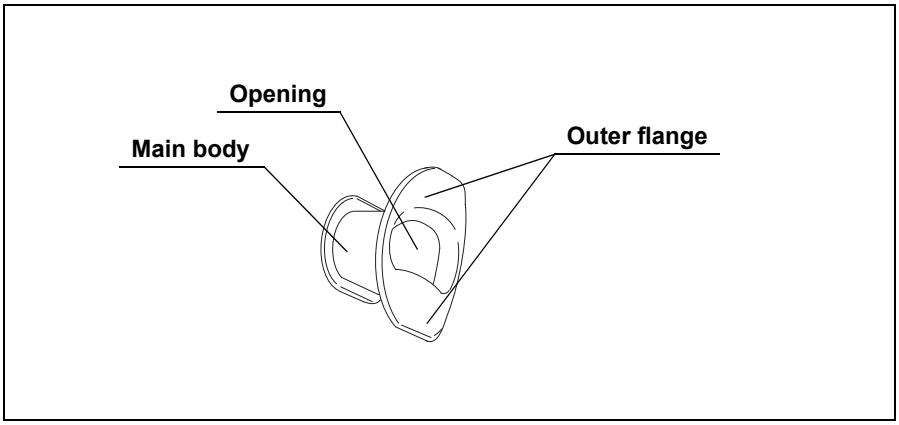


Figure 3.10

3.4 Attaching accessories to the endoscope

CAUTION

The air/water valve and the suction valve do not require lubrication. Lubricants can cause swelling of the valves' seals, which will impair valve function.

Attaching the suction valve

1. Align the two metal ridges on the underside of the suction valve with the two holes in the suction cylinder.
2. Attach the suction valve to the suction cylinder of the endoscope (see Figure 3.11 and 3.12). Confirm that the valve fits properly without any bulging of the skirt. Also, confirm that the valve cannot be rotated.

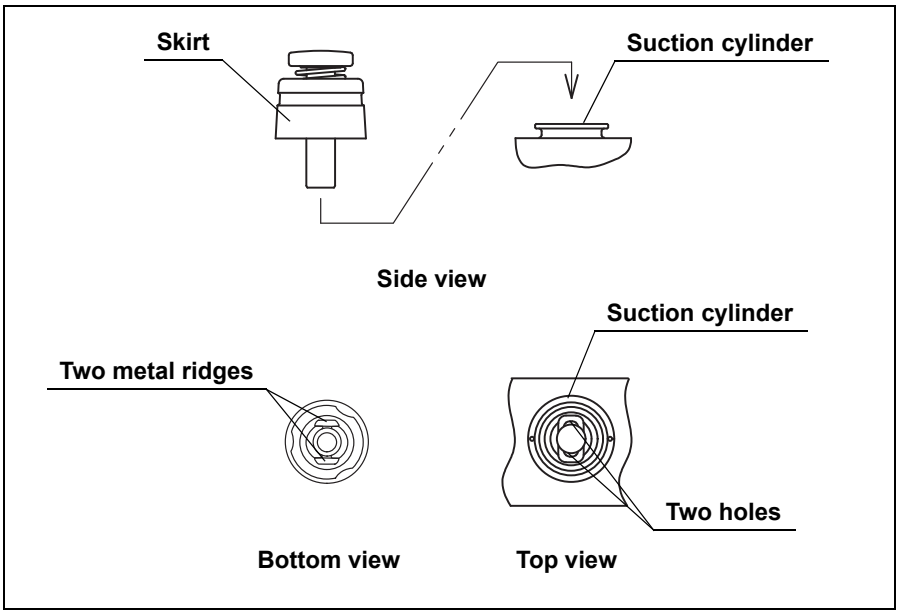


Figure 3.11

NOTE

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

Attaching the air/water valve

1. Attach the air/water valve to the air/water cylinder of the endoscope (see Figure 3.12).
2. Confirm that the valve fits properly without any bulging of the skirt.

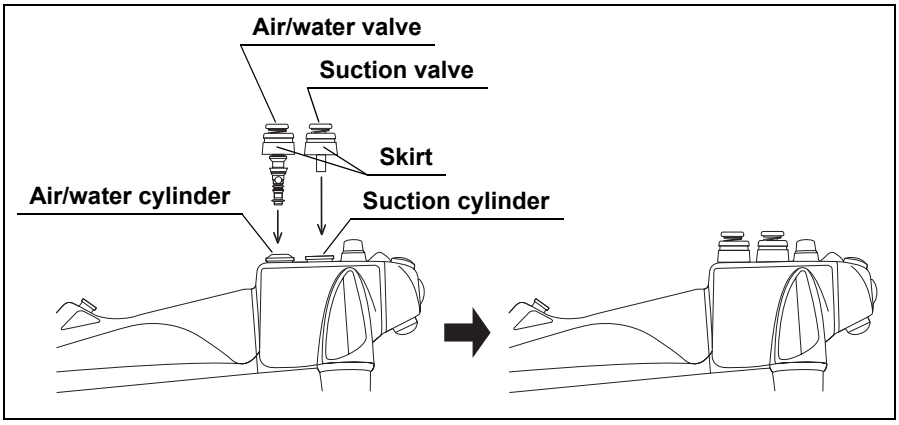


Figure 3.12

NOTE

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

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.

Attach the biopsy valve to the instrument channel port of the endoscope (see Figure 3.13). Confirm that the biopsy valve fits properly.

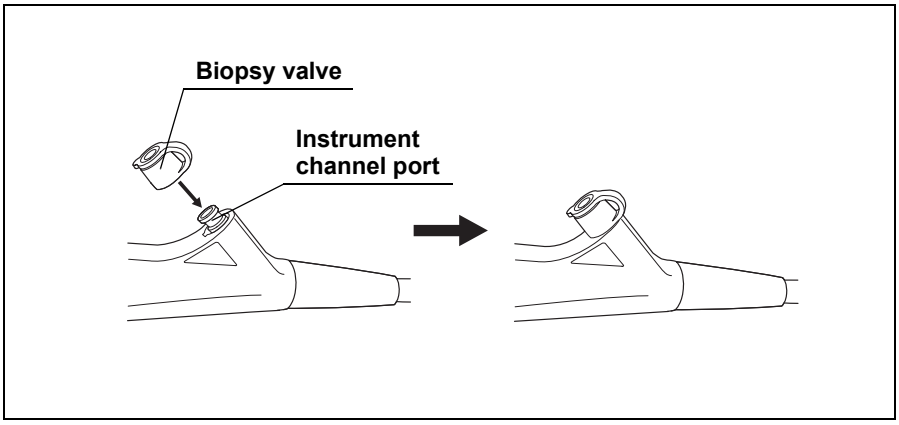


Figure 3.13

3.5 Inspection and connection of ancillary equipment

Inspection of ancillary equipment

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 connection adapter when detaching the connection adapter from the endoscope. Spilled water could splash on the equipment, and may cause equipment malfunction.

Prepare and inspect the light source, video system center, monitor, water container, suction pump, and EndoTherapy accessories as described in their respective instruction manuals.

NOTE

The NBI observation mode is available when the video system center CV-180 and the light source CLV-180 are used with the endoscope.

Connection of the endoscope and ancillary equipment

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.

1. If any ancillary equipment is ON, turn it OFF.
2. Insert the endoscope connector completely into the output socket of the light source.
3. 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 (see Figure 3.14 (1)).
4. Turn the water container's connection adapter 90° clockwise to align the air supply channel with the air supply connector on the endoscope connector (see Figure 3.14 (2)).
5. Push the water container's connection adapter again until it stops (see Figure 3.14 (3)).
6. Confirm that the water container's connection adapter fits properly and that it cannot be rotated (see Figure 3.14 (4)).

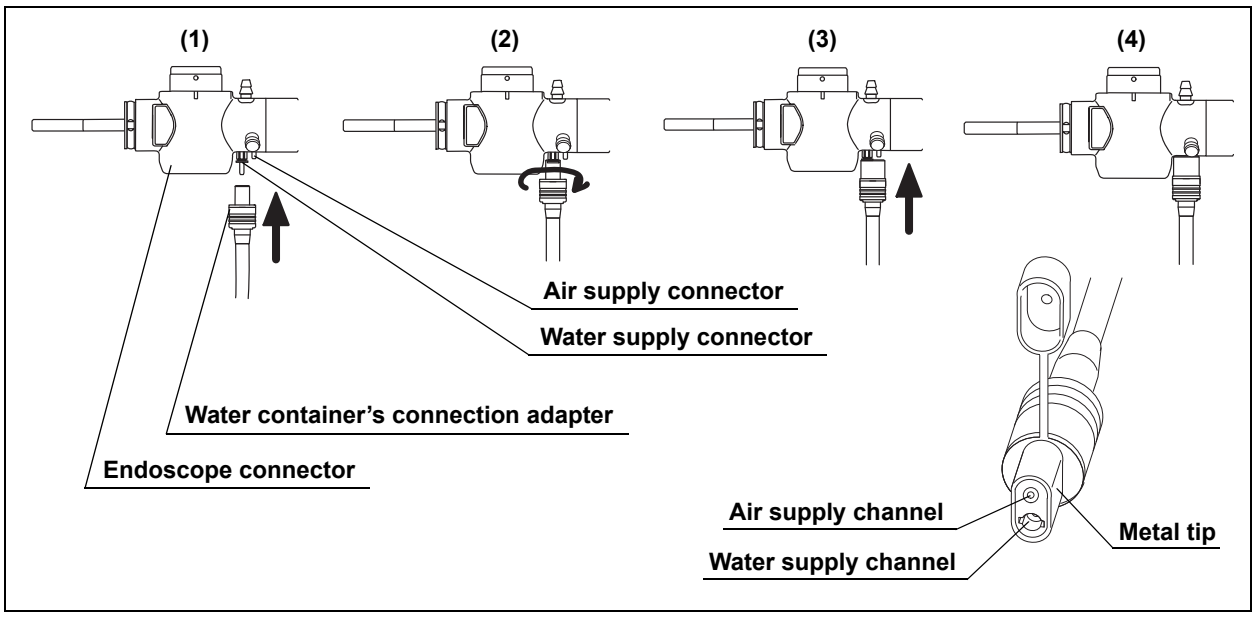


Figure 3.14

7. Align the mark on the videoscope cable EXERA, EXERA II, or 100 with mark 1 on the endoscope connector and push it in until it stops (see Figure 3.15).

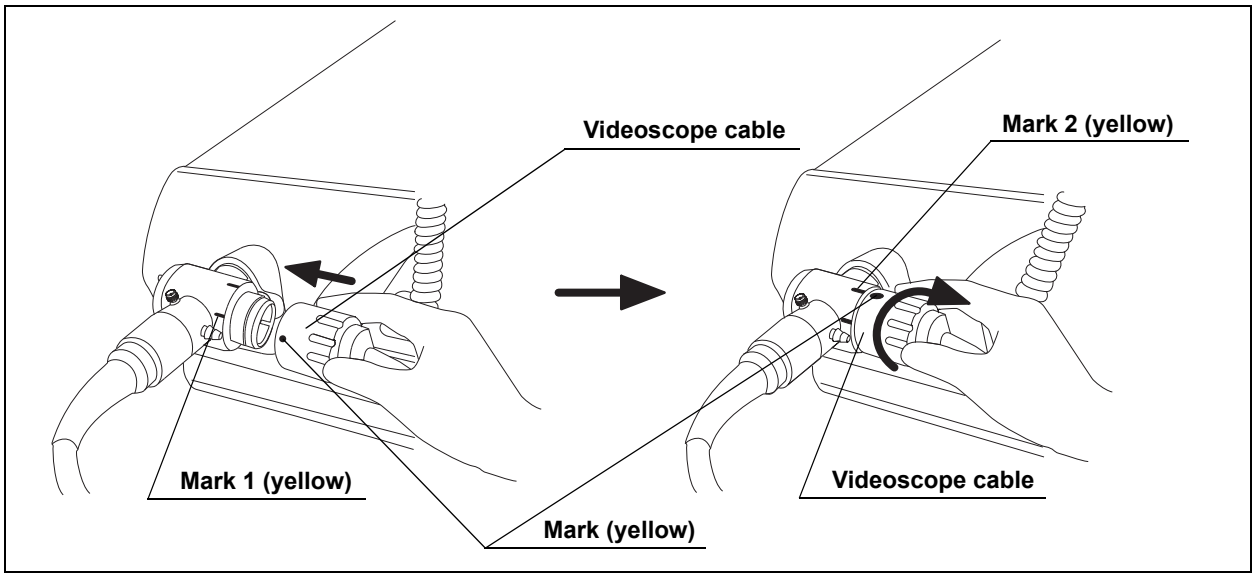


Figure 3.15

8. Turn the connector of the videoscope cable towards mark 2 until it stops (see Figure 3.15).

9. Confirm that the mark on the videoscope cable is aligned with mark 2 on the endoscope connector.

10. Connect the suction tube from the suction pump to the suction connector on the endoscope connector (see Figure 3.16).

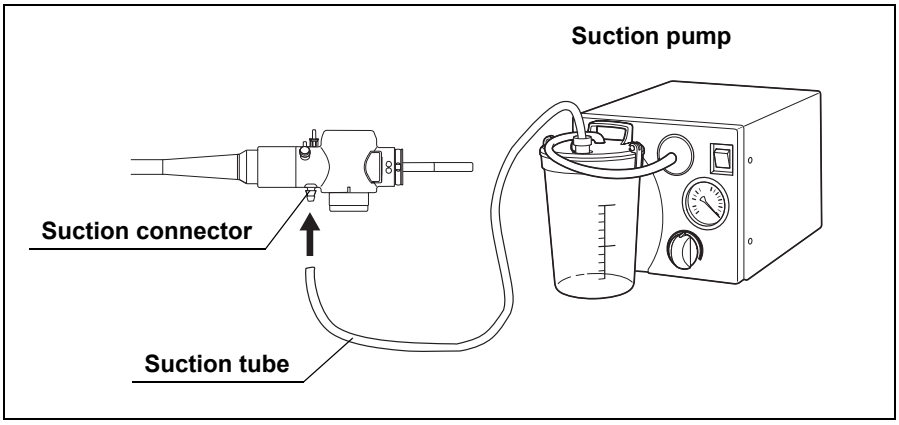


Figure 3.16

3.6 Inspection of the endoscopic system

Inspection of the endoscopic image

WARNING

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

1. Turn the video system center, light source, and monitor ON and inspect the WLI and NBI endoscopic image as described in their respective instruction manuals.
2. Confirm that light is outputting from the endoscope's distal end.
3. While observing the palm of your hand, confirm that the WLI and NBI endoscopic image is free from noise, blur, fog, or other irregularities.
4. Angulate the endoscope and confirm that the WLI and NBI endoscopic images do not momentarily disappear or display any other irregularities.

NOTE

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

Inspection of the remote switches

WARNING

All remote switches should be checked to work normally even if they are not expected to be used. The endoscopic image may freeze, or other irregularities may occur during examination and may cause patient injury, bleeding, and/or perforation.

Depress every remote switch and confirm that the specified functions work normally.

Inspection of the air-feeding function

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 insertion section in sterile water to a depth of 10 cm and confirm that no air bubbles are emitted when the air/water valve is not operated.
3. Cover the hole in the air/water valve with your finger and confirm that air bubbles are continuously emitted from the air/water nozzle.
4. Uncover the hole in the air/water valve and confirm that no air bubbles are emitted from the air/water nozzle.

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 insertion section is 10 cm or more below the surface of the sterile water, there may be an irregularity in the air-feeding function. If the endoscope is used while air is continuously fed, over-insufflation and patient injury may result. If air bubbles are emitted from the air/water nozzle, remove and reattach the air/water valve correctly, or replace it with a new one. If this fails to stop air bubbles from being emitted, do not use the endoscope because there may be a malfunction. Contact Olympus.

NOTE

When the distal end of the insertion section 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.

Inspection of the objective lens cleaning function

WARNING

Use sterile water only. Nonsterile 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.

1. Keep the air/water valve's hole covered with your finger and depress the valve. Observe the endoscopic image and confirm that water flows on the entire objective lens.
2. 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.
3. While observing the endoscopic image, feed air after feeding water 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.

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 biopsy valve leaks, replace it with a new one. A leaking 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.

1. 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.
2. Immerse the distal end of the insertion section in sterile water with the endoscope's instrument channel port at the same height as the water level in the water container. Press the suction valve and confirm that water is continuously aspirated into the suction bottle of the suction pump.
3. Release the suction valve. Confirm that suction stops and the valve returns to its original position.
4. Depress the suction valve and aspirate water for one second. Then, release the suction valve for one second. Repeat this several times and confirm that no water leaks from the biopsy valve.
5. 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 instrument channel and forceps elevator

WARNING

- Keep your eyes away from the distal end when inserting EndoTherapy accessories. Extending the EndoTherapy accessory from the distal end could cause an 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 unexpected directions, and patient injury, bleeding, and/or perforation may result.

1. Confirm that the forceps elevator is lowered, then insert the EndoTherapy accessory through the biopsy valve. Confirm that the EndoTherapy accessory extends smoothly from the distal end. Also, make sure that no foreign objects come out of the distal end.
2. Extend the EndoTherapy accessory approximately 3 cm from the distal end. Move the elevator control lever in the "◀U" direction and confirm that the forceps elevator is raised smoothly.
3. Check the movement of the EndoTherapy accessory by operating the elevator control lever several times to raise the forceps elevator.
4. Move the elevator control lever in the opposite direction of the "◀U" direction and confirm that the forceps elevator is lowered.
5. 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 instrument. Therefore, the operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.

WARNING

- To guard against dangerous chemicals and potentially infectious material 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.
- Turn the video system center ON to operate the light source's automatic brightness function. When the video system center is OFF, it cannot operate the light source's automatic brightness function, and the light intensity is set to the maximum level. In this case, the distal end of the endoscope can become hot and could cause operator and/or patient burns (when using the light source CLV-160, CLV-U40).

WARNING

- Never insert or withdraw the endoscope under any of the following conditions. Otherwise, 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 magnified (when using the image magnification function of video system center CV-180).
  - Insertion or withdrawal while the forceps elevator is raised.
- 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 5.2, “Withdrawal of the endoscope with an irregularity” on page 68.
  - 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 zoom malfunctions (when using the image magnification function of the video system center CV-180).

  Continued use of the endoscope under these conditions could result in patient injury, bleeding, and/or perforation.
- 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.

WARNING

- The endoscopic image may be disrupted while switching between WLI observation mode and NBI observation mode. Therefore, do not perform any endoscopic operation or treatment while switching between the WLI observation mode and NBI observation mode. Otherwise, injury in the body cavity may result.

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 with a lint-free cloth 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 is different from the WLI observation mode. Use the NBI observation mode only after fully understanding its features.

4.1 Insertion

Holding and manipulating the endoscope

The control section of the endoscope is designed to be held in the left hand. The air/water and suction valves can be operated using the left index finger. The UP/DOWN angulation control knob and the elevator control lever can be operated using the left thumb. The right hand is free to manipulate the insertion section and the RIGHT/LEFT angulation control knob (see Figure 4.1).

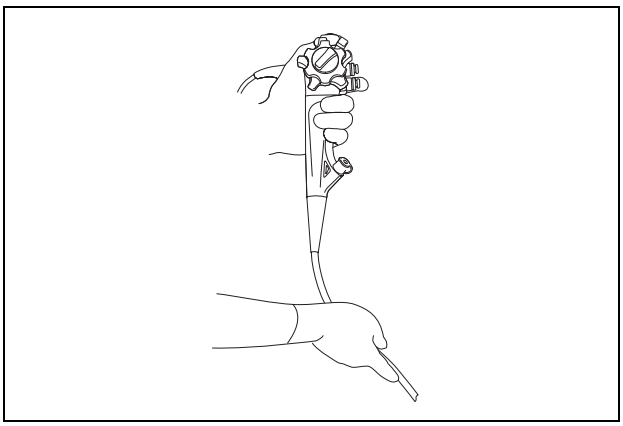


Figure 4.1

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 heavy 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.
- To prevent the patient from accidentally loosening a dental prosthesis, make sure that the patient removes it before the examination.

CAUTION

- To prevent the patient from breaking one or more teeth, make sure there are no missing teeth, or teeth that are not permanently capped, etc., before the examination.
- Do not apply olive oil or products containing petroleum-based lubricants (e.g., Vaseline®) to the endoscope. These products may cause stretching and deterioration of the bending section's covering.
- 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 (see Figure 4.2).

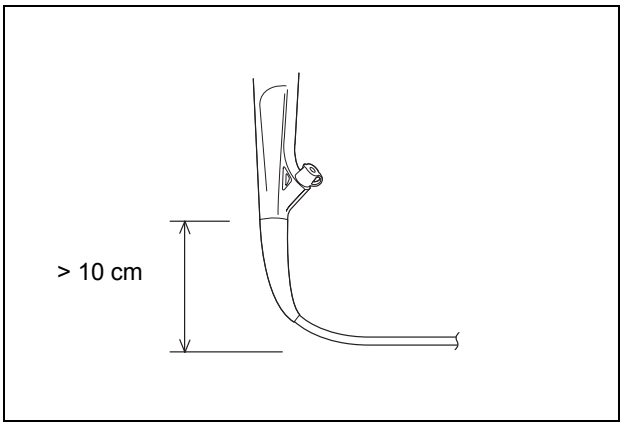


Figure 4.2

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.

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.

1. Operate the angulation control knobs as necessary to guide the distal end for insertion and observation.
2. The endoscope's angulation locks are used to hold the angulated distal end in position.

NOTE

- When passing an EndoTherapy accessory through the instrument channel while the angulation is locked, the angle of the distal end 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.

Air/water feeding and suction

WARNING

- 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.
- Before using a syringe to inject liquid through the biopsy valve, detach the valve's cap from the main body. Then insert the syringe straight into the valve and inject the liquid. If the cap is not detached and/or the syringe is not inserted straight, the biopsy valve could be damaged. This could reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection control risk.

WARNING

- If the biopsy valve is left uncapped during the procedure, debris or fluids could leak or spray from it, posing an infection control risk. When the valve is uncapped, place a piece of sterile gauze over it to prevent leakage.

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.

Air/water feeding

1. Cover the air/water valve's hole to feed air from the air/water nozzle at the distal end (see Figure 4.3).
2. Depress the air/water valve to feed water onto the objective lens (see Figure 4.3).

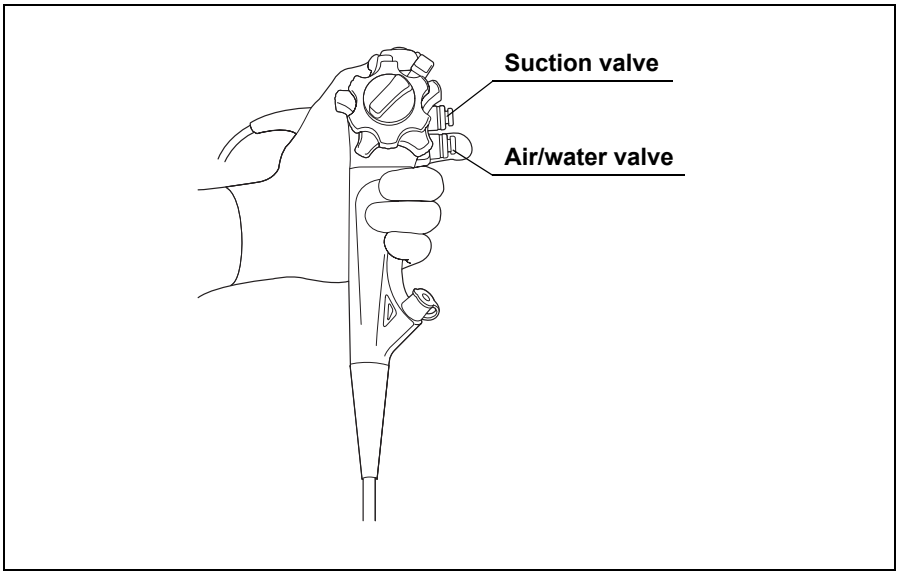


Figure 4.3

Suction

WARNING

- 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.
- 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

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.

Depress the suction valve to aspirate excess fluids or other debris obscuring the endoscopic image (see Figure 4.3).

NOTE

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

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 light source's instruction manual for instructions on how to adjust the brightness.

4.2 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to the “System chart” in the Appendix and the instruction manuals for 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 2.3, “Specifications” on page 16.
- 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 may be damaged and pieces of it could fall off.
- 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 instrument. 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 disturbed while switching between WLI observation mode and NBI observation mode. This could cause patient injury, bleeding, and/or perforation.

WARNING

- When using EndoTherapy accessories, always use the widest possible angle. When the image is magnified, 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 (when using the image magnification function of video system center CV-180).
- 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.
- 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 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 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.

WARNING

- Do not inflate air or a nonflammable gas excessively into the patient. This could cause gas embolism.

CAUTION

- 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. Otherwise, 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 3.9 on page 30). 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. Doing so 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.

WARNING

- 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.

1. Select EndoTherapy accessories compatible with the instrument from the "System chart" in the Appendix. Refer to the accessories' instruction manuals for operating instructions.
2. Raise the forceps elevator by turning the elevator control lever in the "◀U" direction until the operator feels heavy.
3. Hold the UP/DOWN and RIGHT/LEFT angulation knobs stationary.
4. Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath and insert the EndoTherapy accessory slowly and straight into the slit of the biopsy valve.

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 become damaged.

5. 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.
6. Move the elevator control lever in the opposite direction of the "◀U" direction to lower the forceps elevator. Advance the EndoTherapy accessory slightly and move the elevator control lever in the "◀U" direction. Confirm that the accessory appears in the endoscopic image.
7. 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 instrument 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, stop the procedure immediately and contact Olympus without changing the position of the instrument.

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-Q180V 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. Otherwise, patient injury, bleeding, and/or perforation may result.

WARNING

- Do not manipulate the elevator control lever and the insertion section abruptly while the guidewire is being locked. Otherwise, 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.

WARNING

- 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.
- 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.

WARNING

- 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 or 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:
  - 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 (refer to "NOTE" on page 60).

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.

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.

NOTE

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 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 heavy with the papilla observed in the gray-colored area of the endoscopic image shown in the Figure 4.4 (for center lock, see Figure 4.5). 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 heavy with the papilla observed in the left side area of the endoscopic image shown in the Figure 4.6 (for side lock, see Figure 4.7).

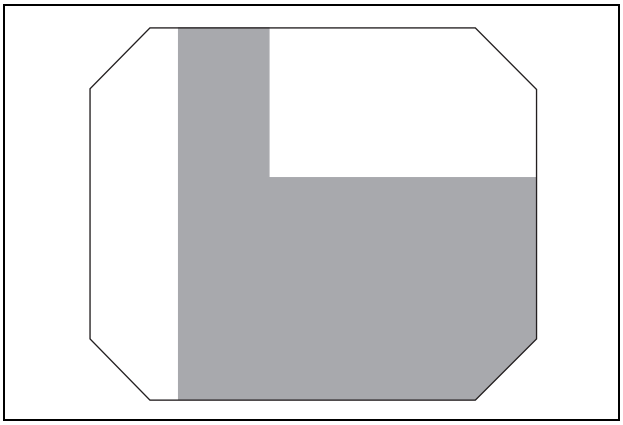


Figure 4.4

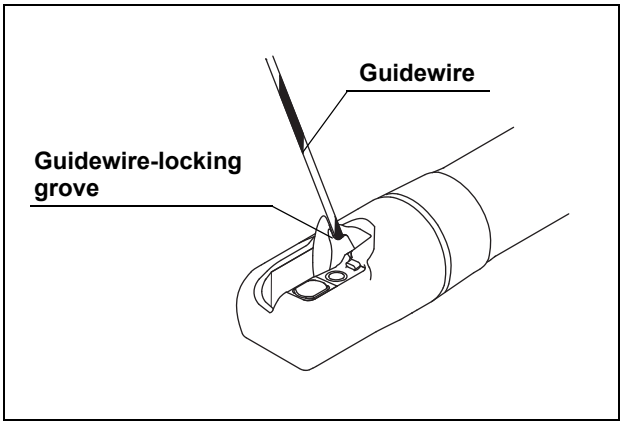


Figure 4.5

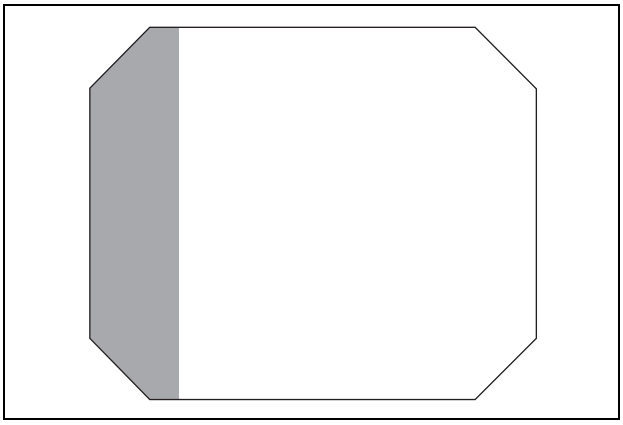


Figure 4.6

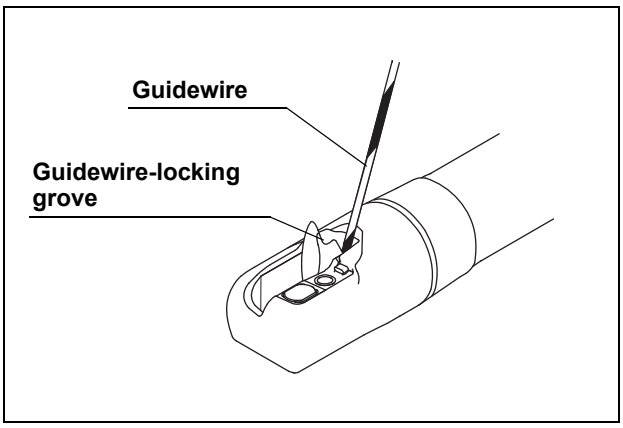


Figure 4.7

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 (see Figure 4.8).

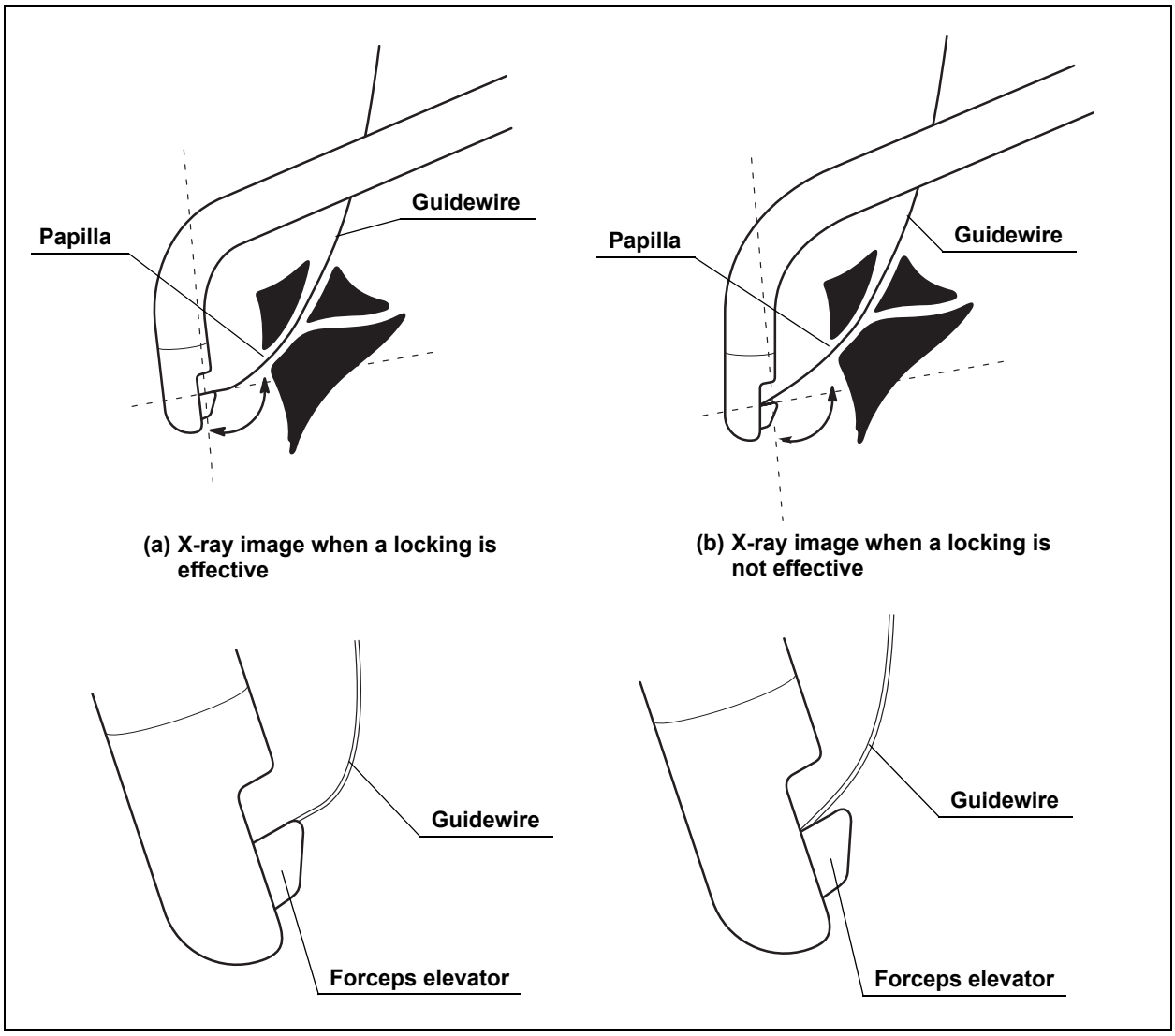


Figure 4.8

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 heavy with the papilla observed in the gray-colored area of the endoscopic image shown in the Figure 4.4 on page 58 (for center lock, see Figure 4.5 on page 58). 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 heavy with the papilla observed in the left side area of the endoscopic image shown in the Figure 4.6 on page 59 (for side lock, see Figure 4.7 on page 59).
2. Hold the elevator control lever stationary so that it can no longer move forward 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.

High-frequency cauterization treatment

WARNING

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

WARNING

- 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.

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

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 unit ESG-100, it is not necessary to use the S-cord.

4.3 Withdrawal of the endoscope

WARNING

If blood unexpectedly adheres to the surface of the insertion section of the withdrawn endoscope, carefully check the condition of the patient.

1. When using the image magnification function of the video system center CV-180, 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.
4. Turn the UP/DOWN and RIGHT/LEFT angulation locks to the "F▶" direction to release them.
5. Carefully withdraw the endoscope while observing the endoscopic image. Remove the mouthpiece from the patient's mouth.

4.4 Transportation of the endoscope

Transporting within the hospital

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 (see Figure 4.9).

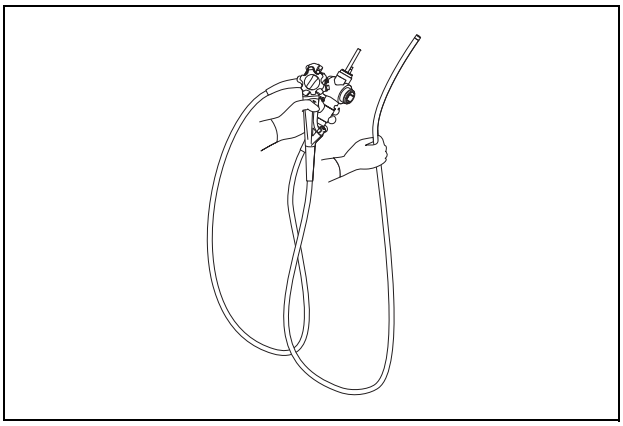


Figure 4.9

Transporting outside the hospital

Transport the endoscope in the carrying case.

WARNING

Always clean, disinfect, or sterilize the endoscope after removing it from the carrying case. If the endoscope is not cleaned, disinfected, or sterilized, it could pose an infection control risk.

CAUTION

- The carrying case cannot be cleaned, disinfected, or sterilized. Clean and disinfect or sterilize the endoscope before placing it in the carrying case.
- To avoid damage to the endoscope caused by changes in air pressure, do not attach the water-resistant cap when transporting the endoscope.
- Before putting the endoscope in the carrying case, always make sure that the forceps elevator is not raised. Putting the endoscope in the carrying case while the forceps elevator is raised could damage the endoscope.

Chapter 5 Troubleshooting

If the endoscope is visibly damaged, does not function as expected, or is found to have irregularities during the inspection described in Chapter 3, “Preparation and Inspection”, do not use the endoscope. Contact Olympus.
Some problems that appear to be malfunctions may be correctable by referring to Section 5.1, “Troubleshooting guide”. If the problem cannot be resolved by the described remedial action, stop using the endoscope and send it to Olympus for repair.
Olympus does not repair accessory parts. If an accessory part becomes damaged, contact Olympus to purchase a replacement.

WARNING

- Never use the endoscope on a patient if an irregularity is observed. Damage or an irregularity in the instrument may compromise patient or user safety and may result in more severe equipment damage.
- 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.

Should any irregularity in the function of the endoscope and/or endoscopic image be observed during use, stop the examination immediately and carefully withdraw the endoscope from the patient as described in Section 5.2, “Withdrawal of the endoscope with an irregularity” on page 68.

5.1 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 consumables.
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 5.3, “Returning the endoscope for repair” on page 70.

Endoscope functions

❍ Angulation

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

❍ Air/water feeding

Irregularity description	Possible cause	Solution
No air feeding.	The air pump is not operating.	Press the "LOW", "MED", "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 is not operating.	Press the "LOW", "MED", "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.

❍ Suction

Irregularity description	Possible cause	Solution
The suction is absent or insufficient.	The biopsy valve is not attached properly.	Attach it correctly.
	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.

❍ Image quality or brightness

Irregularity description	Possible cause	Solution
There is no video image.	Not all power switches are ON.	Turn all power switches ON.
An image is not clear.	The objective lens is dirty.	Feed water to remove mucus, etc.
An image is excessively dark or bright.	The light source is not set properly.	Adjust the light source's setting as described in its instruction manual.
An image is abnormal.	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.

EndoTherapy accessories

Irregularity description	Possible cause	Solution
EndoTherapy accessory does not pass through the instrument channel smoothly.	An incompatible EndoTherapy accessory is being used.	Refer to the “System chart” in the Appendix and select a compatible EndoTherapy accessory. Confirm that the color code on the EndoTherapy accessory matches that on the endoscope.
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.

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.

5.2 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”, “Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor”, or “Withdrawal when no endoscopic image appears on the monitor or a frozen image cannot be restored” below. After withdrawal, return the endoscope for repair as described in Section 5.3, “Returning the endoscope for repair” on page 70.

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 irregularities with the scope are 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 image magnification 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.
7. Turn the UP/DOWN and RIGHT/LEFT angulation locks in the “F▶” direction to release them.
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 of Step 3 above in “Withdrawal when the WLI and NBI endoscopic images appear on the monitor”. 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. If no endoscopic image still 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.
7. Turn the UP/DOWN and RIGHT/LEFT angulation control knobs to their respective neutral positions (see Figure 3.4 on page 26).
8. Release the angulation control knobs and carefully withdraw the endoscope. Remove the mouthpiece from the patient’s mouth.

5.3 Returning the endoscope for repair

WARNING

Thoroughly clean and high-level disinfect or sterilize 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 63.

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 5.3, “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 raising and lowering the forceps elevator.

WARNING

The forceps elevator has to be raised and lowered during leakage testing. Otherwise, detecting leaks which 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 and flush the forceps elevator recess” in Section 5.4, “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 Step 14 in “Brush and flush 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 4 of “Inspection of the endoscope” in Section 3.2, “Inspection of the endoscope” in the “OPERATION MANUAL”. 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 is 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 Annual inspection

Send the endoscope to Olympus for inspection of the forceps elevator by Olympus once a year.
Contact Olympus for any questions regarding annual inspection.

Appendix

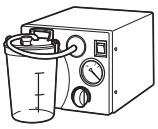
System chart

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 this instrument may also be compatible for use in combination with the endoscope. For further details, contact Olympus.

WARNING

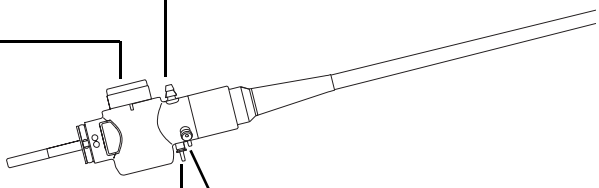
If combinations of equipment other than those shown below are used, full responsibility is assumed by the medical treatment facility.

Suction pumps



KV-4, KV-5

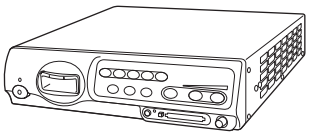
SSU-2



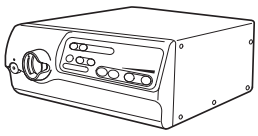
Endoscope

TJF-Q180V

Videoscope cable EXERA II (MAJ-1430)

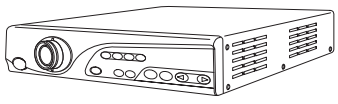


EVIS EXERA II video system center (CV-180)

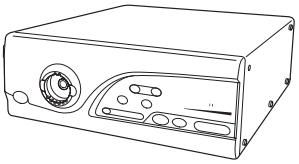


EVIS EXERA II light source (CLV-180)

Videoscope cable EXERA (MAJ-843)

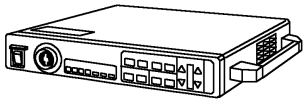


EVIS EXERA video system center (CV-160)

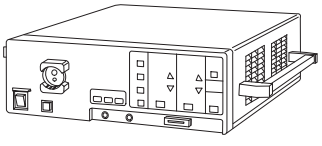


EVIS EXERA light source (CLV-160)

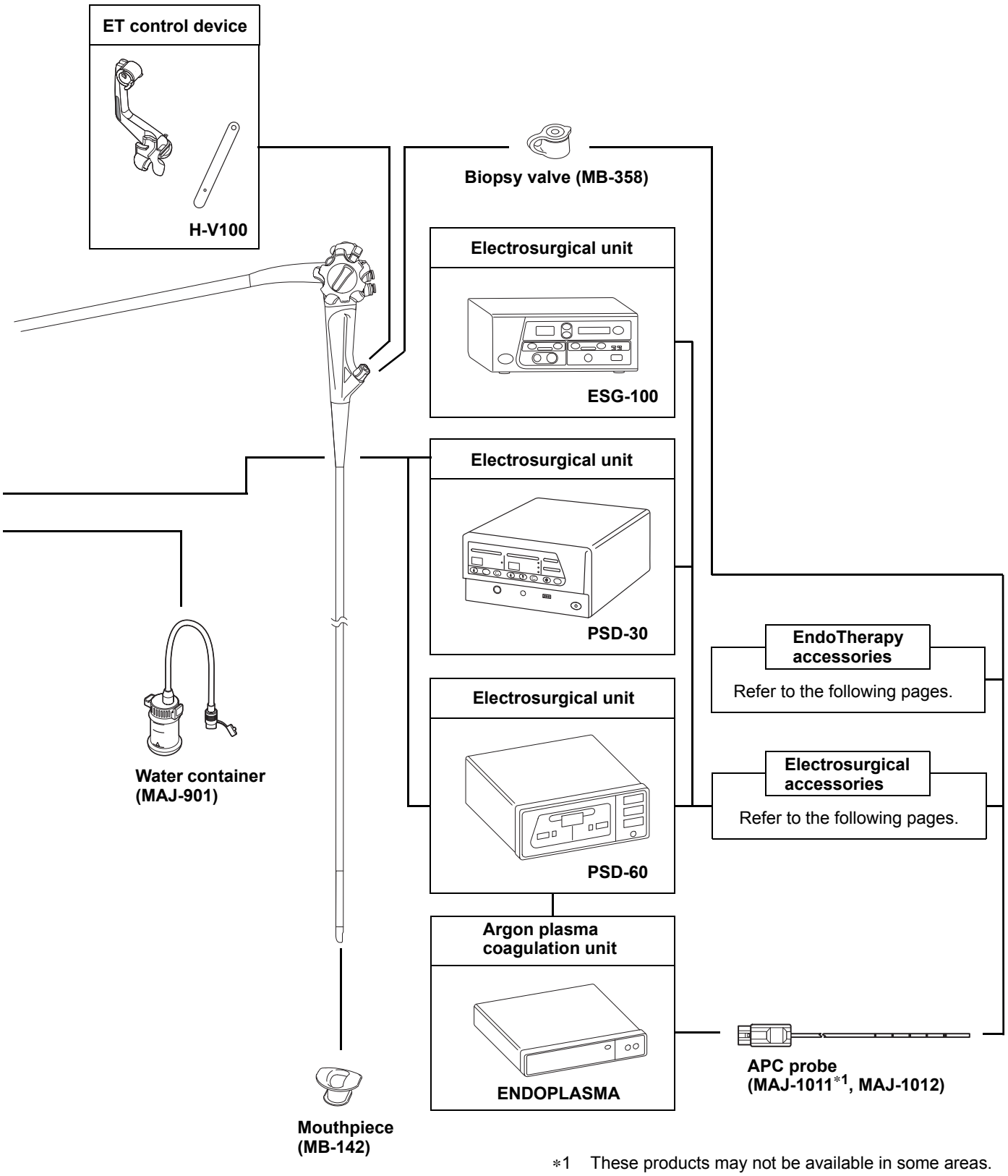
Videoscope cable 100 (MH-976*1, MD-148*1)



EVIS video system center (CV-140)

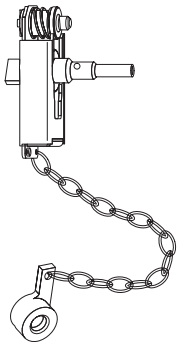


EVIS universal light source (CLV-U40)

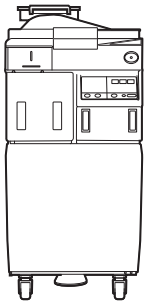


∗1 These products may not be available in some areas.

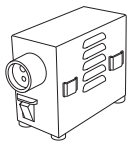
Cleaning and disinfection equipment



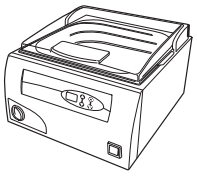
Channel plug (MH-944)



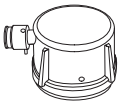
Endoscope washer (EW-30*1)
Endoscope reprocessor (OER*1, OER-A*1, OER-AW*1)
Endo thermo disinfector (ETD system*1)



Maintenance unit (MU-1)



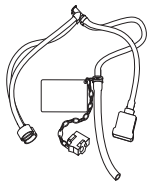
Ultrasonic cleaner (KS-2, ENDOSONIC)



Water-resistant cap (MH-553)

Channel cleaning brush (BW-20T)

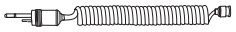
Single use combination cleaning brush (BW-412T*1)



Injection tube (MH-946)

AW channel cleaning adapter (MH-948)

Suction cleaning adapter (MH-856)



Leakage tester (MB-155)

Single use channel cleaning brush (BW-201T*1)

Channel-opening cleaning brush (MH-507)

Single use channel-opening cleaning brush (MAJ-1339*1)

Single use soft brush (MAJ-1888)

Chain for water-resistant cap (MAJ-1119)

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

❍ Video system center

Endoscope	CV-140	CV-160	CV-180
TJF-Q180V	○	○	○

○ compatible – not compatible

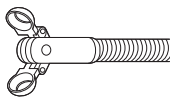
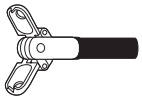
❍ Light source

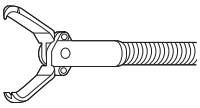
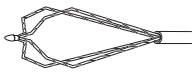
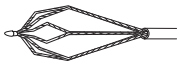
Endoscope	CLV-U40	CLV-160	CLV-180
TJF-Q180V	○	○	○

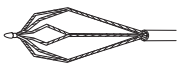
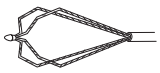
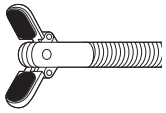
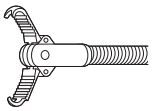
○ compatible – not compatible

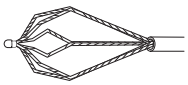
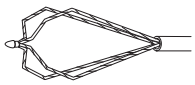
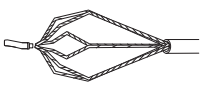
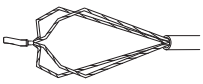
❍ EndoTherapy accessories

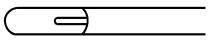
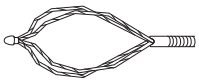
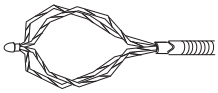
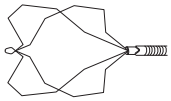
Note that some of these accessories may not be available in some areas.

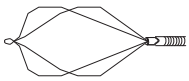
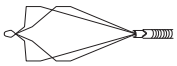
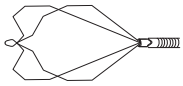
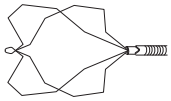
	Biopsy forceps			
	Standard type	**Rat tooth**	**Alligator type**	**Alligator type with rat tooth**
Endoscope				
TJF-Q180V	**FB-19N-1, FB-26N-1**	**FB-39Q-1, FB-40Q-1**	**FB-45Q-1**	**FB-46Q-1**

	Disposable cytology brush	Grasping forceps		
		Rat tooth	**Basket type**	**Flower basket type**
Endoscope				
TJF-Q180V	**BC-23Q, BC-24Q**	**FG-14P-1**	**FG-18Q-1, FG-22Q-1, FG-23Q-1**	**FG-301Q**

	Disposable grasping forceps		Grasping forceps	Rotatable grasping forceps
	Flower basket type	**Basket type**	**Rubber tips (Non-latex)**	**Rat tooth with alligator jaws**
Endoscope				
TJF-Q180V	**FG-401Q**	**FG-402Q, FG-403Q**	**FG-20P-1**	**FG-44NR-1**

	Disposable rotatable grasping forceps		Disposable grasping forceps (Wire-guided type)	
	Flower basket type	**Basket type**	**Flower basket type**	**Basket type**
Endoscope				
TJF-Q180V	**FG-V401QR, FG-V421PR**	**FG-V402QR, FG-V422PR**	**FG-V411Q, FG-V431P**	**FG-V412Q, FG-V432P**

Endoscope	Heat probe	Mechanical lithotriptor		Disposable mechanical lithotriptor
		Basket type	Slide type	Slide type
				
TJF-Q180V	CD-11Z, CD-21Z, CD-110U, CD-120U	BML-1Q-1, BML-2Q-1	BML-3Q-1, BML-4Q-1	BML-201Q, BML-V232QR-30, BML-V237QR-30, BML-V242QR-30

Endoscope	Disposable mechanical lithotriptor			
	Slide type	Slide type	Slide type	Guidewire type
				
TJF-Q180V	BML-202Q, BML-V232QR-26	BML-203Q	BML-204Q	BML-V437QR-30, BML-V442QR-30

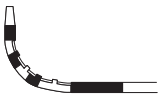
Endoscope	Cannula			
	Standard type	Metal-tip type	Hard type	Slit type
				
TJF-Q180V	PR-104Q-1, PR-304Q	PR-128Q-1	PR-108Q-1	PR-126Q-1, PR-326Q

Endoscope	Cannula			
	Short taper type	Long taper type	Ball-tip type	Side-hole type
				
TJF-Q180V	PR-109Q-1*1, PR-113Q-1, PR-309Q, PR-313Q	PR-110Q-1*1, PR-112Q-1, PR-310Q	PR-24Q-1	PR-130Q

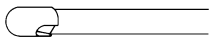
*1 These accessories are not compatible with guidewires with a diameter of ø 0.64 mm (0.025 inch) or more.

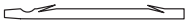
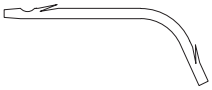
Endoscope	Cannula	Disposable cannula		
	Metal-tip type	Standard type	Metal-tip type	Hard type
				
TJF-Q180V	PR-131Q*1	PR-216Q, PR-416Q, PR-V216Q, PR-V416Q	PR-229Q	PR-217Q

Endoscope	Disposable cannula			
	Slit type	Taper type	Short taper type	Long taper type
				
TJF-Q180V	PR-227Q, PR-427Q, PR-V227Q, PR-V427Q	PR-V234Q, PR-V235Q, PR-V434Q, PR-V435Q	PR-214Q, PR-218Q, PR-225Q, PR-414Q, PR-418Q, PR-V214Q, PR-V218Q, PR-V414Q, PR-V418Q, PR-V614M	PR-220Q, PR-420Q, PR-V220Q, PR-V420Q

Endoscope	Disposable cannula		Disposable bending cannula	Washing pipe
	Ball-tip type	Metal-tip type		Spray type
				
TJF-Q180V	PR-23Q, PR-V223Q	PR-231Q*1, PR-232Q*1	PR-233Q	PW-5V-1, PW-6P-1

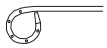
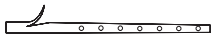
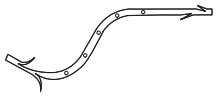
*1 These accessories are not compatible with guidewires with a diameter of ø 0.64 mm (0.025 inch) or more.

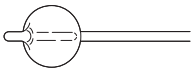
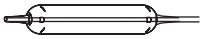
	Washing pipe	Biliary drainage tube		
	Retro jet	7 Fr., 8.5 Fr., 10 Fr., 12 Fr.	7 Fr., 8.5 Fr., 10 Fr.	10 Fr.
Endoscope				
TJF-Q180V	PW-8Q-1	PBD-210	PBD-211	PBD-421, PBD-V621R

	Biliary drainage tube			
	10 Fr.	7 Fr., 8.5 Fr., 10 Fr.		
Endoscope				
TJF-Q180V	PBD-422, PBD-V622R	PBD-200, PBD-V600R	PBD-201, PBD-V601R	PBD-202, PBD-V602R

	Biliary drainage tube	Nasal biliary drainage tube (7 Fr., 5 Fr.)		
	7 Fr.	α Short type	Pigtail type	α type
Endoscope				
TJF-Q180V	PBD-203	PBD-20Z, PBD-24Z	PBD-21Z, PBD-25Z	PBD-22Z, PBD-26Z

	Nasal biliary drainage tube (7 Fr., 5 Fr.)	Single use nasal biliary drainage tube (5 Fr., 6 Fr., 7 Fr.)		
	Reverse α type	α type	Reverse α type	Pigtail α type
Endoscope				
TJF-Q180V	PBD-23Z, PBD-27Z	PBD-V811W	PBD-V812W	PBD-V813W

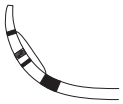
	Single use nasal biliary drainage tube (5 Fr., 6 Fr., 7 Fr.)		Pancreatic stent	
	α short type	Pigtail type	7Fr.	7Fr., 8.5Fr., 10Fr.
Endoscope				
TJF-Q180V	PBD-V814W	PBD-V803W	PBD-230	PBD-234

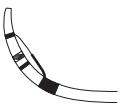
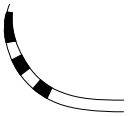
	Balloon catheter	Biliary balloon dilator	Guide catheter
Endoscope			
TJF-Q180V	B7-2LA, B5-2LA, B-230Q-A, B-230Q-B, B-V231P-A, B-V231P-B	B-400N	MD-984

❍ Electrosurgical accessories

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

	Papillotomy knife	Papillotomy knife (Wire-guided type)	Disposable papillotomy knife (Wire-guided type)	
	Push-pull type	Pull type	Pull type	Pull type
Endoscope				
TJF-Q180V	KD-29Q-1	KD-6G10Q-1 to KD-6G18Q-1	KD-200Q	KD-201Q

	Disposable papillotomy knife (Wire-guided type)		Triple lumen sphincterotome	Disposable triple lumen sphincterotome
	Pull type (Clever Cut)	Pull type (Clever Cut)	Pull type	Pull type
Endoscope				
TJF-Q180V	KD-210Q	KD-211Q, KD-V211M	KD-301Q, KD-321Q	KD-401Q, KD-421Q

	Disposable triple lumen sphincterotome	Single use triple lumen needle knife		
	Pull type (Clever Cut)			
Endoscope				
TJF-Q180V	KD-411Q, KD-431Q, KD-V411M, KD-V431M	KD-441Q	KD-V441M	KD-V451M

Endoscope	Disposable guidewire			
TJF-Q180V	**G-V210-3545S, G-V210-3527S**	**G-V210-3545A, G-V210-3527A**	**G-240-2527S, G-240-2545S, G-240-3527S, G-240-3545S**	**G-240-2527A, G-240-2545A, G-240-3527A, G-240-3545A**

EMC information

Guidance and manufacturer's declaration — Electromagnetic emissions

This model is intended 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 in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	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	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5	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 hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 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 hospital 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		
	< 5% U_T (> 95% dip in U_T) for 5 seconds		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.
Definition:	U_T is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended 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.

Portable and mobile RF communications equipment should be used no closer to any part of this model, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz – 80 MHz)	3 V (V_1)	Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m (80 MHz – 2.5 GHz)	3 V/m (E_1)	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
Definition:	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).		

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.

❍ Recommended separation distances between portable and mobile RF communications equipment and this model

This model is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this model can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this model as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter P (W)	**Separation distance according to frequency of transmitter (m) (calculated as V_1=3 and E_1=3)**		
	150 kHz – 80 MHz	**80 MHz – 800 MHz**	**800 MHz – 2.5 GHz**
	$d = 1{,}2\sqrt{P}$	$d = 1{,}2\sqrt{P}$	$d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
Others:	For transmitters rated at a maximum output power not listed above, the recommended separation distance ‘d’ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ‘p’ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.		

NOTE

- At 80 MHz and 800 MHz, the separation distance for 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.

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