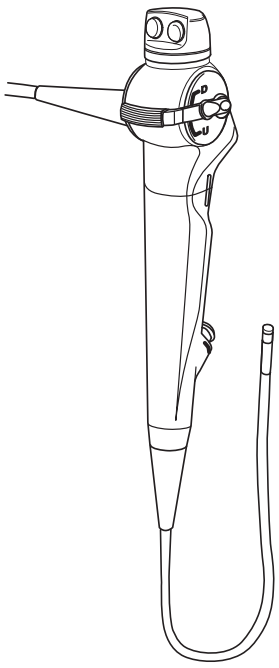
OLYMPUS

OPERATION MANUAL

INSTRUCTIONS

VISERA CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF TYPE V2



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

CE 0197

Contents

Contents

Symbols

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

Symbol	Description
	Refer to instructions.
	Endoscope
	TYPE BF applied part
	Caution
	Single use only
	Lot number
	Serial number
	Manufacturer
	Authorized representative in the European Community
	Translation
	Importer (into European Union)
	Date of Manufacture

Important Information — Please Read Before Use

■ Intended use

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

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 healthcare facilities administrations or other official institutions, such as academic societies on endoscopy, follow those standards. Before starting endoscopy and endoscopic treatment, thoroughly evaluate their properties, purposes, effects, and possible risks (their nature, extent and probability). Perform endoscopy and endoscopic treatment only when their potential benefits are greater than their 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 of 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, please contact Olympus.

❍ Terms used in this manual

NBI (Narrow Band Imaging) observation:

This is optical-digital observation using narrowband light.

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

This is observation using white light.

Image sensor:

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

■ *User qualifications*

If there are official standards for user qualifications to perform endoscopy and endoscopic treatment that are defined by the healthcare facilities 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 healthcare facility or person in charge of the department (department of urology, 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 “Combination equipment” on page 69 to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

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

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

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

■ *Spare equipment*

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

■ *Maintenance management*

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

■ *Prohibition of improper repair and modification*

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

■ *Signal words*

The following signal words are used throughout this manual:

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
NOTE	Indicates additional helpful information.

■ *Precautions*

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

WARNING

- Do not use this instrument for any purpose other than its indications for 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.
- After using this endoscope, reprocess and store it according to the instructions given in the endoscope's companion "REPROCESSING MANUAL" with your endoscope model listed on the cover. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and/or infection.
- Do not strike, hit, or drop the endoscope's distal end, insertion tube, bending section, control section, universal cord, video connector, or light guide connector. Also, do not bend, pull, or twist the endoscope's distal end, insertion tube, bending section, control section, universal cord, video connector, or light guide 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. When using an endoscope with the UP/DOWN angulation lock, never insert or withdraw the endoscope while the angulation lock is moved in the opposite direction of the "F▼" mark. Patient injury, bleeding, and/or perforation may result.
- Never operate the bending section, 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 use EndoTherapy accessories, insert or withdraw the insertion section, or perform angulation control while the image is frozen. 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.

WARNING

- Never insert or withdraw the insertion section abruptly or with excessive force. Patient injury, bleeding, and/or perforation may result.
- Do not touch the light guide on the light guide connector immediately after removing it from the light source because it is extremely hot. Operator or patient burns can result.
- Although the illumination light emitted from the endoscope's distal end is required for endoscopic observation, it may also cause alteration of living tissues such as protein denaturation of living tissue and perforation of the tissue by inappropriate using. Observe the following warnings for illumination.
  - Always set the minimum required brightness. The brightness of the image on a monitor may differ from the actual brightness at the distal end of the endoscope. Pay special attention to the brightness level setting of the light source, particularly when operating the electrical shutter function of a video system center. When both a light source and a video system center have the automatic brightness control function, use the function on the light source. This function can better maintain the illumination level. Refer to the instruction manual for the light source and the video system center for further details.
  - 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.
  - When the endoscope will not be used for a long period, be sure to turn OFF the light source or activate the light shield function (standby mode, etc.) so that the endoscope is not illuminated unnecessarily.
- Push the video connector into the video system center until it clicks, then confirm that the video connector is securely attached by pulling it gently. Improper connection will damage the image sensor. The damaged image sensor will display no image and make the distal end hot, which could cause operator and/or patient burns.
- Do not insert the video connector while the electrical contacts are wet and/or dirty. This may result in an electric shock, causing severe damage to the endoscope and compromising patient and/or operator safety.
- If the endoscopic image becomes dimmer during the procedure, it may indicate that blood or mucus is adhering to the light guide lens on the distal end of the endoscope. Carefully withdraw the endoscope from the patient and remove blood or mucus to restore optimum illumination and to ensure the safety of the examination. If you continue to use the endoscope with its obstructed light guide lens, the temperature at the distal end may rise and cause mucosal burns to the patient. It may also cause patient and/or operator injury.

WARNING

- When the endoscopic image does not appear on the monitor, the image sensor may have been damaged. Turn the video system center OFF immediately. Continued power supply in such a case will cause the distal end 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 and video cable during an examination. The light guide 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, universal cord, or video cable with a diameter of less than 10 cm. Equipment damage may result.
- Do not attempt to bend or twist the endoscope's insertion section with excessive force. The insertion section may be damaged.
- Do not apply shock to the distal end of the insertion section, particularly the objective lens surface at the distal end. Visual abnormalities may result.
- If the endoscope is dropped or the distal end of the endoscope receives a hard impact, the endoscope may be damaged even if no visible damage of the lens on the distal end can be found. In this case, stop using the endoscope, and contact Olympus.
- 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.
- Do not put or press the video connector and light guide connector on the insertion section when transporting or reprocessing. The insertion section may be damaged.
- Turn the video system center ON only when the video connector is connected to the video system center. In particular, confirm that the video system center is OFF before connecting or disconnecting the video connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- The endoscope's remote switches cannot be removed from the control section. Pressing, pulling, or twisting them with excessive force can break the switches and/or cause water leaks.
- Do not hit or bend the electrical contacts on the video connector. The connection to the video system center may be impaired and faulty contact can result.

CAUTION

- Do not pull the video cable during an examination. The endoscopic image may not be visible.
- Electromagnetic interference may occur on this endoscope near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment, such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this endoscope, or shielding the location.

- Be sure that this endoscope is not used adjacent to or stacked with other equipment (other than the components of this endoscope or system) to avoid electromagnetic interference.
- To check the electromagnetic interference from other equipment (any equipment other than this endoscope 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.
- When the endoscope gets strong static electricity, noise may be observed in the endoscopic image. This does not indicate a malfunction.

■ *Precaution for disappeared or frozen endoscopic image*

WARNING

- If the endoscopic image disappears unexpectedly or the frozen image cannot be restored during an examination, immediately stop using the endoscope and withdraw it from the patient as described in Section 5.3, “Withdrawal of the endoscope with an irregularity”. Continued use of the endoscope under this condition could result in patient injury, bleeding, and/or perforation.
- Follow the precautions given below. Otherwise, the endoscopic image may disappear unexpectedly or the frozen image may not be restored during the examination.
  - Connect the video connector to the video system center completely by pushing the video connector until it clicks. Otherwise, faulty contact can result.
  - Do not bend, hit, pull, or twist the insertion section, bending section, control section, universal cord, video cable, video connector, and light guide connector. The endoscope may be damaged, and water leaks and/or breakage of internal parts like the image sensor cable can result.
  - Make sure that the video connector and its electrical contacts are completely dry before connecting the video connector to the video system center. Wet contacts could cause the equipment to malfunction.
  - If air bubbles emerge from the endoscope continuously during the leakage test, do not use the endoscope. Water may enter the endoscope and cause a short circuit. This may result in image sensor damage.

CAUTION

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

■ *Examples of inappropriate handling*

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

- 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, 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 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.
  - NBI has not been demonstrated to aid in differentiating and establishing the presence or absence of dysplasia or neoplastic changes within mucosa or mucosal lesions.

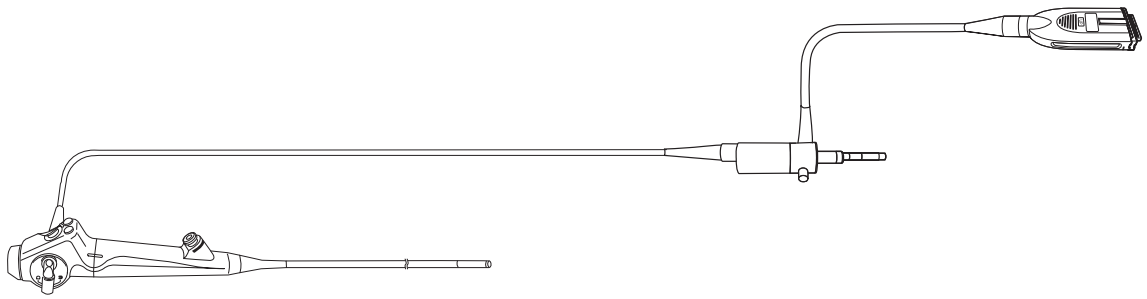
*1 Narrow Band Imaging. For more details, refer to the instruction manual for the video system center.

Chapter 1 Checking the Package Contents

1.1 Checking the package contents

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

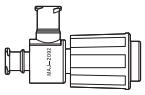
❍ Endoscope



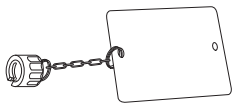
CYF-V2

❍ Packaged items

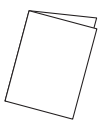
Single use combination cleaning brush (BW-411B)



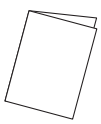
Luer-split (MAJ-2092)



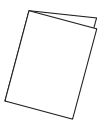
ETO cap (MB-156)



Instruction manual (luer-split)



Operation manual



Reprocessing manual

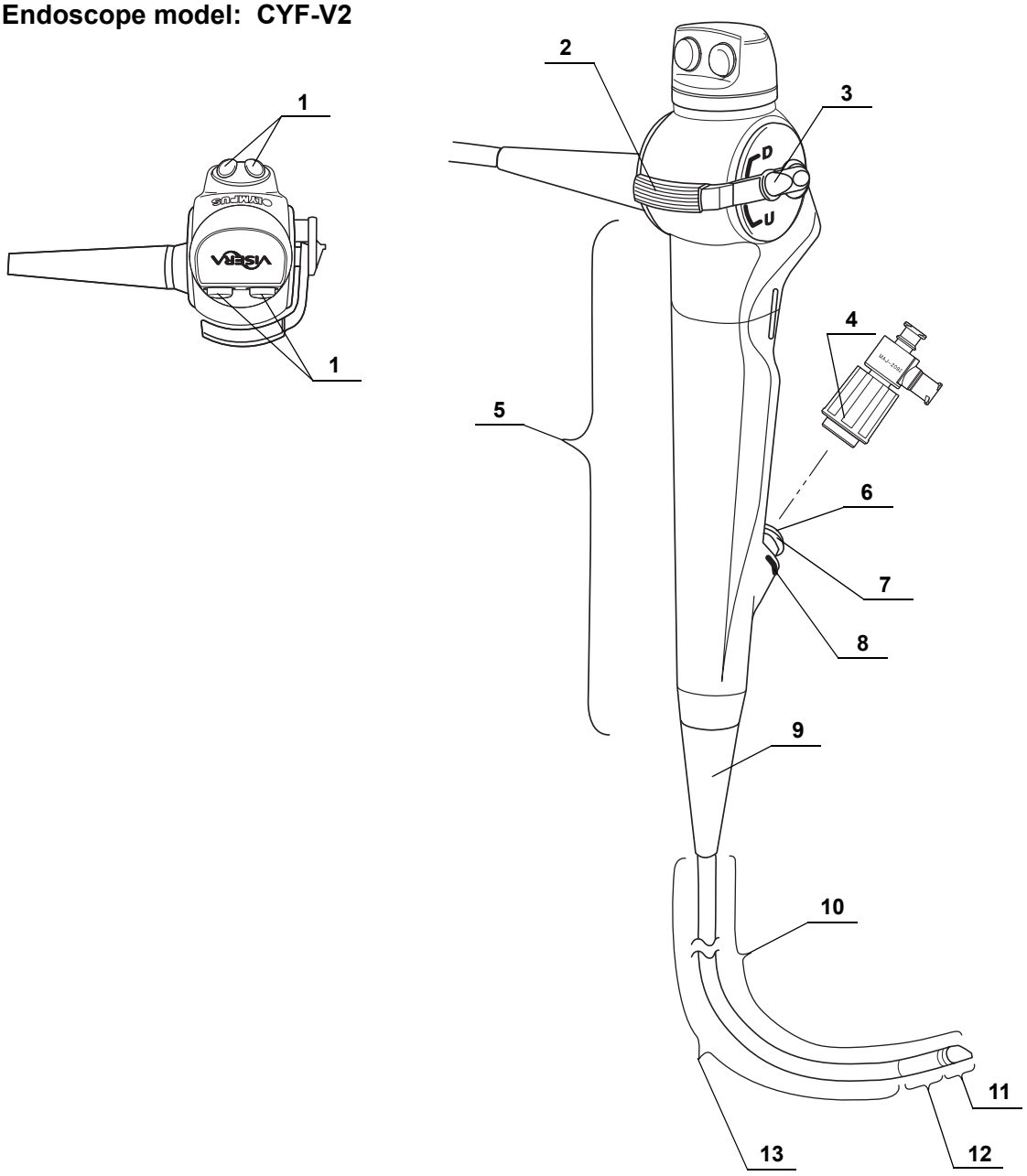
Chapter 2 Instrument Nomenclature and Specifications

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

2.1 Nomenclature and functions

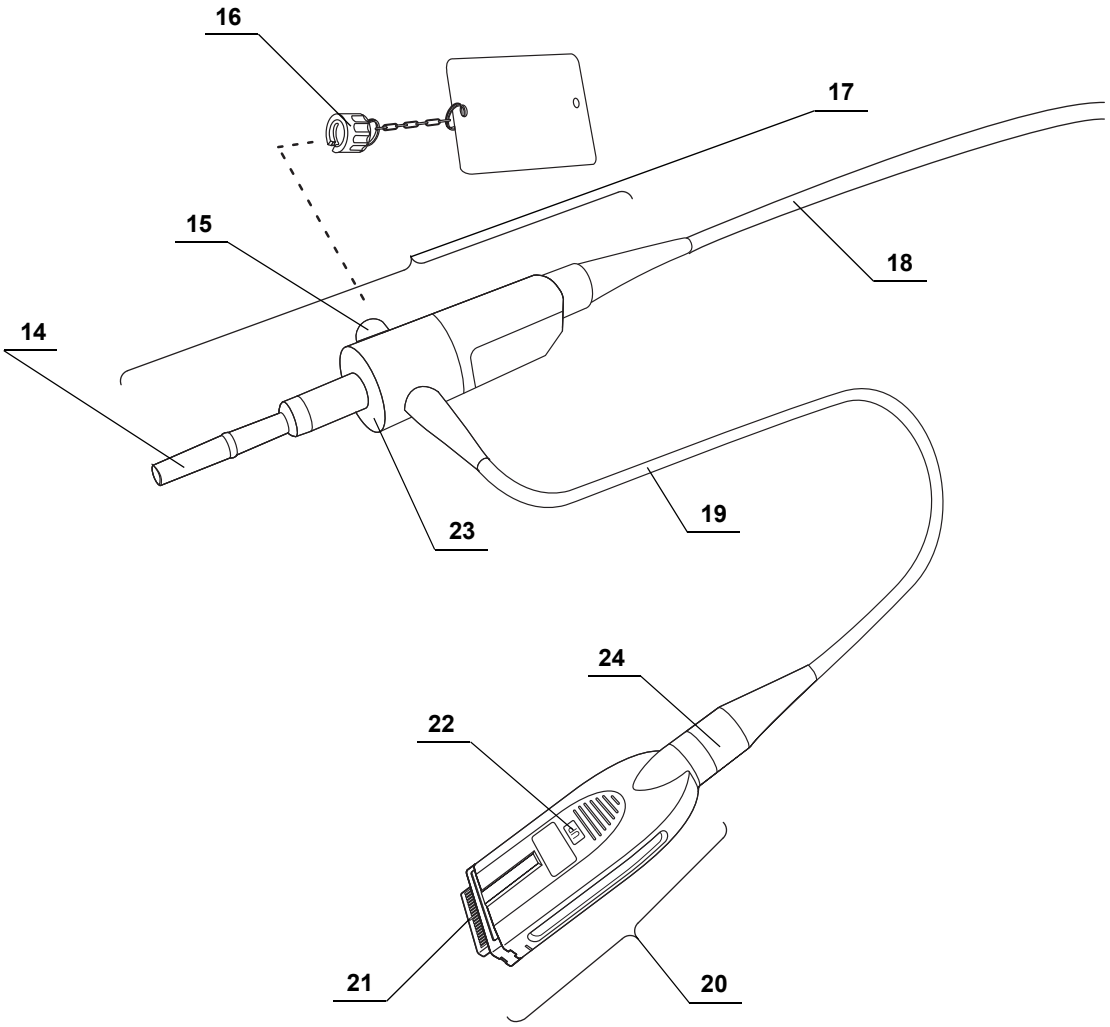
■ *Control section, insertion section*

Endoscope model: CYF-V2



No.	Nomenclature	Description	Endoscope model
1	Remote switches 1 to 4	The functions of the 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.	
2	UP/DOWN angulation control lever	When this lever is turned in the “U” direction, the bending section moves UP; when the lever is turned in the “D” direction, the bending section moves DOWN.	
3	UP/DOWN angulation lock	Moving this lever in the “F▼” direction frees angulation. Moving the lever in the opposite direction locks the bending section at any desired position.	
4	Luer-split (MAJ-2092)	Accessories are inserted through the forceps port of the luer-split. Fluid can be fed through the irrigation port.	
5	Control section	Operates the endoscope, such as controlling angulation.	
6	Instrument channel	An EndoTherapy accessory can be inserted to this channel. The instrument channel is connected to the distal end of the endoscope. The instrument channel functions are: • Channel for the insertion of EndoTherapy accessories • Fluid feed channel	
7	Instrument channel port	Attach the luer-split to this port.	
8	Color code	The color code is used to quickly determine the compatibility of EndoTherapy accessories. 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 “■ Compatible EndoTherapy accessories” on page 72 and the instruction manuals for the compatible accessories. • Blue: CYF-V2	
9	Boot	Avoids the junction between the insertion tube and control section from bending.	
10	Insertion section	This section is inserted into the patient body cavity.	
11	Distal end	The objective lens and light guide lens are on this distal end.	
12	Bending section	The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.	
13	Insertion tube	Connects the control section and bending section.	

■ *Light guide connector, video connector*



No.	Nomenclature	Description
14	Light guide	Connects the endoscope to the light source and transmits light to the distal end of the endoscope.
15	Venting connector	Attach the sterilization cap or leakage tester here.
16	ETO cap (MB-156)	The ETO cap equalizes the outer and inner pressure of the endoscope. The cap must be attached prior to gas sterilization (ethylene oxide gas, STERRAD® etc.) and aeration and removed prior to immersion or clinical examination. The cap must also be attached when the endoscope is transported outside the healthcare facility (shipment, return for repairs, etc.).
17	Light guide connector	The light guide connector connects the endoscope to the output socket of the light source and transmits light from the light source to the distal end of the endoscope.
18	Universal cord	Connects the light guide connector and the control section.
19	Video cable	Connects the light guide connector and the video connector.
20	Video connector	The video connector connects the endoscope to the video connector socket of the video system center so that the endoscopic image becomes visible. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center. For more details, refer to the instruction manual for the video system center.
21	Electrical contacts	Connects the video system center and the endoscope electrically.
22	UP mark	When the video connector is connected to the video system center, this mark is facing upward.
23	Serial number	The serial number is marked here.
24	Product ID plate	The UDI indication, product name (model) and NTSC/PAL label are marked here.

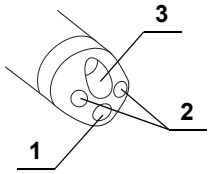
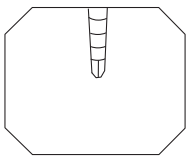
2.2 Specifications

■ Environment

Operating environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Standard storage environment (e.g. within the healthcare facility)	**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 function

Model		CYF-V2
Optical system	**Field of view**	120°
	Direction of view	0° (Forward viewing)
	Depth of field	3 – 50 mm
Insertion section	**Distal end outer diameter**	ø 4.8 mm (Bullet shape)
	Distal end enlarged 1 Objective lens 2 Light guide lens 3 Instrument channel outlet	
	Insertion tube outer diameter	ø 5.4 mm (16.2 Fr)
	Insertion section working length	380 mm
Instrument channel	**Channel inner diameter**	ø 2.2 mm (6.6 Fr)
	Minimum visible distance[*1]	2 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
Bending section	**Angulation range**	UP 210° DOWN 120°
Total length		660 mm
NBI observation mode[*2]		Available
High-frequency treatment		Compatible
Laser treatment		Not compatible

*1 Distance from the distal end of the endoscope.

*2 For more details, refer to the instruction manual for the video system center.

Common specifications

Medical Devices Directive		CE 0197 This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a
RoHS Directive		CE This device complies with the requirements of Directive 2011/65/EU and (EU) 2015/863 concerning electrical and electronic equipment.
EMC	**Applied standard**	IEC 60601-1-2: 2014 IEC 60601-2-18: 1996 IEC 60601-2-18: 2009 • This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014). When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable. • CISPR 11 of emission: Group 1, Class B
Degree of protection against electric shock		TYPE BF applied part
UDI Indication		 The UDI Indication is required by some countries' regulations regarding the identification of medical device also known as Unique Device Identification (UDI). The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix): • (01) 14-digit GS1 Global Trade Item Number; • (11) 6-digit date of manufacture; • (21) 7-digit serial number.

Chapter 3 Preparation and Inspection

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

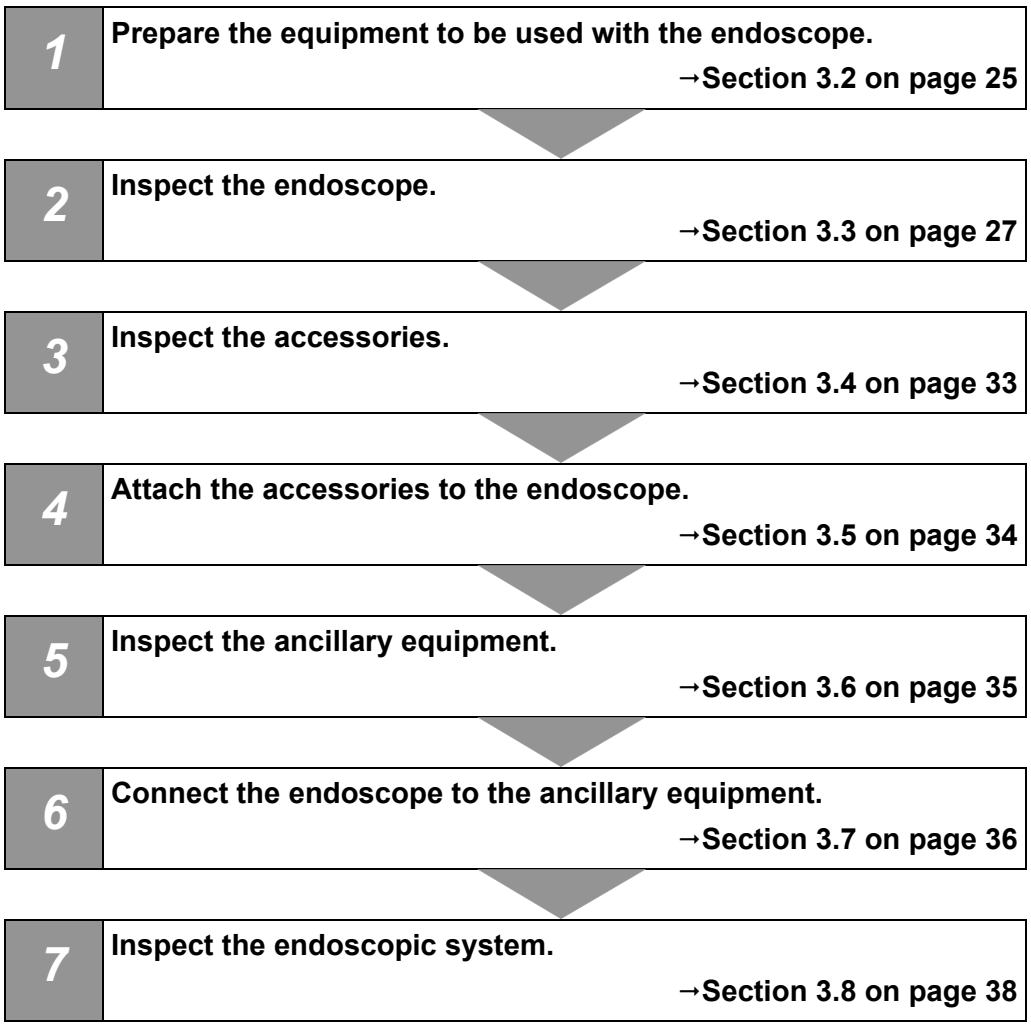
3.1 The workflow of preparation and inspection

The workflow of preparation and inspection is shown below.

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

WARNING

- Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.
- This endoscope was not reprocessed before shipment. Before using this endoscope for the first time, reprocess it according to the instructions as described in the endoscope’s companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.


1
Prepare the equipment to be used with the endoscope.
→Section 3.2 on page 25
2
Inspect the endoscope.
→Section 3.3 on page 27
3
Inspect the accessories.
→Section 3.4 on page 33
4
Attach the accessories to the endoscope.
→Section 3.5 on page 34
5
Inspect the ancillary equipment.
→Section 3.6 on page 35
6
Connect the endoscope to the ancillary equipment.
→Section 3.7 on page 36
7
Inspect the endoscopic system.
→Section 3.8 on page 38

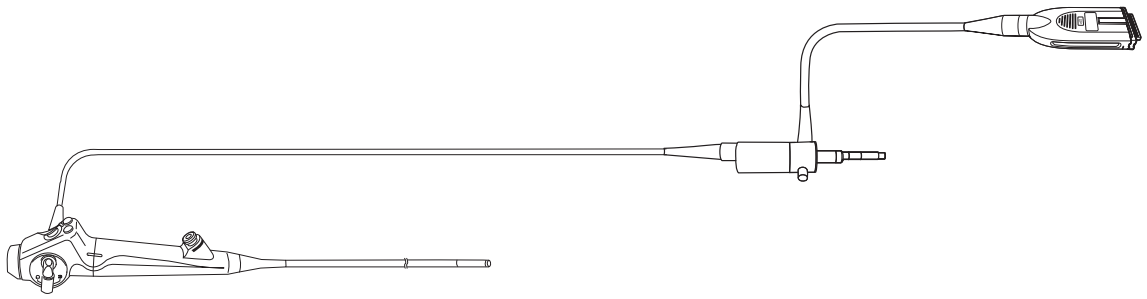
3.2 Preparation of the equipment

WARNING

- For cystoscopy procedures, prepare the endoscope and accessories that has been cleaned and then high-level disinfected or sterilized.
- For nephroscopy procedures, prepare the endoscope and accessories that has been cleaned and then sterilized.

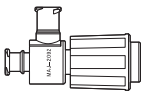
Prepare this endoscope, the accessories, equipment, and all personal protective equipment shown in Figure 3.1. Prepare the equipment in “Combination equipment” on page 69 in accordance with the intended use.
Also, refer to the respective instruction manuals for each piece of equipment before use.

❍ Endoscope



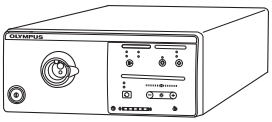
Endoscope*1

Accessories and ancillary equipment

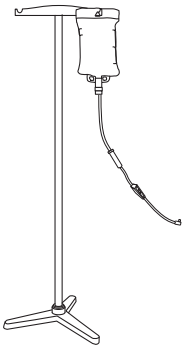


Luer-split (MAJ-2092)*2,*3 or Forceps/irrigation plug (isolated type) (MAJ-891)*2

Video system center



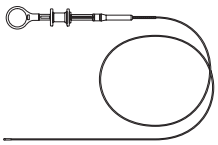
Light source



Irrigation system

Biopsy valve (MAJ-579, 10 pcs)

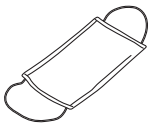
Monitor



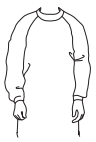
EndoTherapy accessories

Personal protective equipment (e.g.)

Eyewear



Face mask



Moisture-resistant clothing

Chemical-resistant gloves

Other

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

Figure 3.1

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

*2 Prepare the luer-split or the forceps/irrigation plug that is reprocessed as described in the respective instruction manuals.

*3 Prepare the sealing accessory as described in the instruction manual for the luer-split.

3.3 Inspection of the endoscope

CAUTION

Detach the ETO cap (MB-156) from the venting connector if it is attached, especially after gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma). Otherwise, the remote switches may not work normally due to a difference between internal and external pressures of the endoscope.

■ Inspection of the endoscope

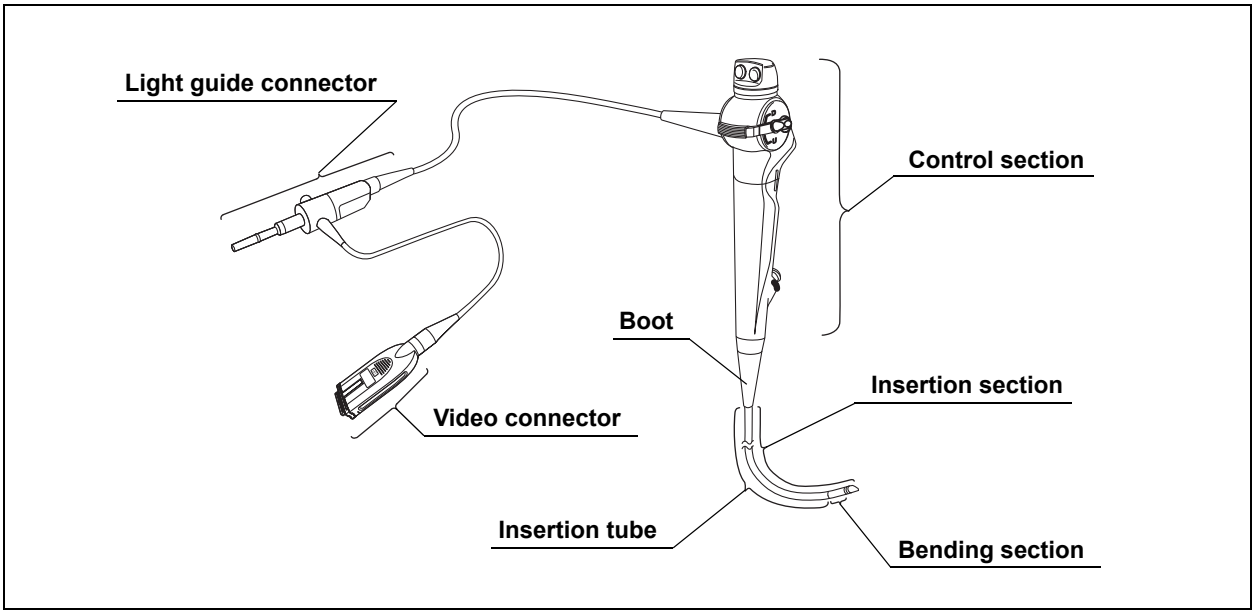


Figure 3.2

1. Inspect the control section, video connector, and light guide connector for excessive scratching, deformation, loose parts, or other irregularities.
2. Inspect the electrical contacts on the video connector for corrosion.
3. Inspect the boot and the insertion section near the boot for bends, twists, or other irregularities.
4. Inspect the external surface of the entire insertion section, including the bending section and the distal end for dents, bulges, swelling, scratches, peeling of coating, holes, sagging, transformation, bends, adhesion of foreign bodies, missing parts, protruding objects, or other irregularities.

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

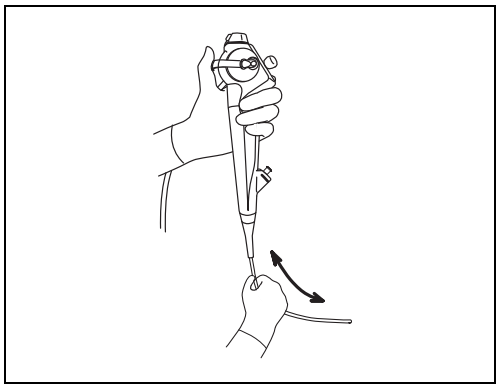


Figure 3.3

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 3.4, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable.

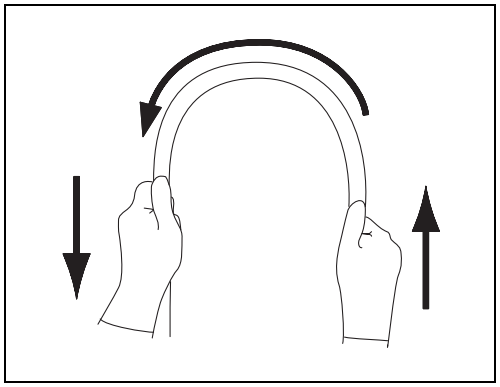


Figure 3.4

7 Gently hold the vicinity of the distal end and a point 10 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.

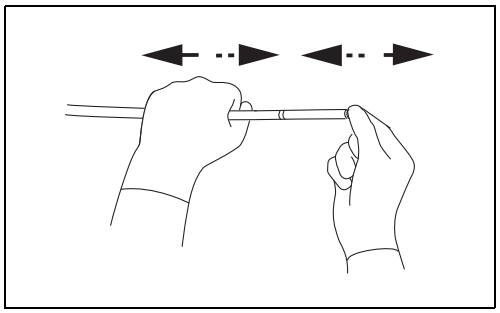


Figure 3.5

8 Inspect the lens at the distal end of the endoscope's insertion section for scratches, cracks, stains, gaps around the lens, or other irregularities. Also, inspect the entire distal end of the endoscope for chips or cracks.

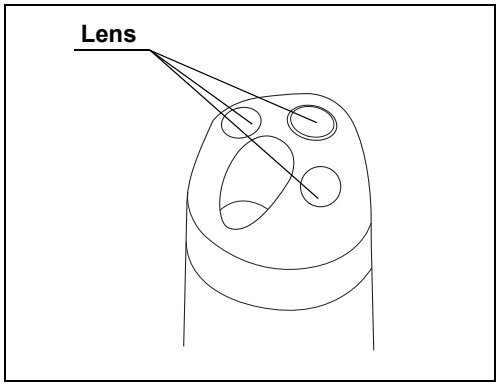


Figure 3.6

9 Inspect the adhesives attaching the bending section cover to the insertion section for deterioration, pitting or cracking.

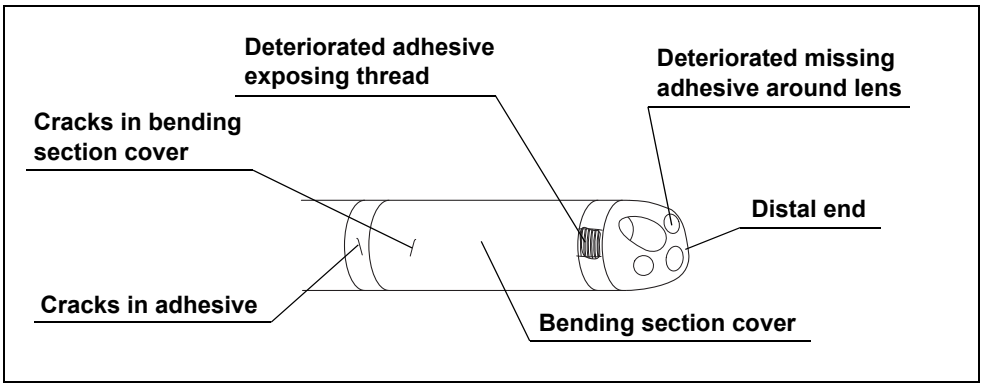


Figure 3.7

NOTE

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

■ *Inspection of the bending mechanism*

Perform the following inspections while the bending section is straight.

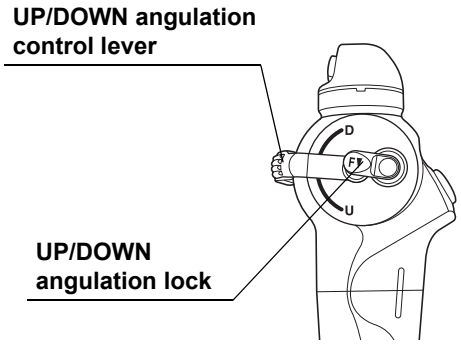


Figure 3.8

WARNING

- If the movement of the UP/DOWN angulation lock and the angulation control lever 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, and patient injury, bleeding, and/or perforation may result.
- Inspect the bending mechanism before the procedure. The bending section may bend in a different direction from the intended direction, and may cause patient injury, bleeding, and/or perforation.

Inspection for smooth operation

1 Straighten the bending section.

2 Confirm that the UP/DOWN angulation lock is placed in the free “F▼” position.

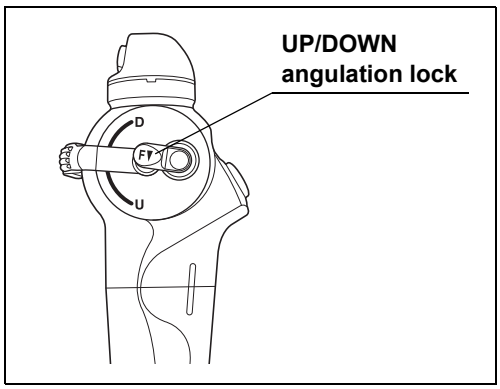


Figure 3.9

3 Operate the UP/DOWN angulation control lever slowly in each direction until it stops. Confirm that the bending section angulates smoothly and correctly, and that maximum angulation can be achieved.

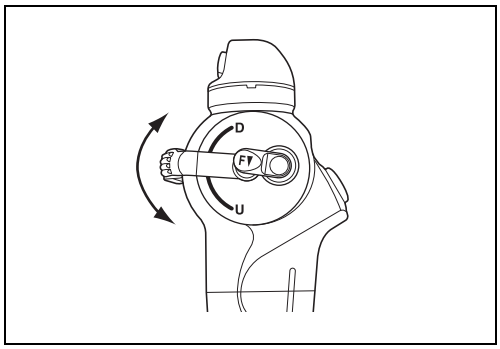


Figure 3.10

4 Operate the UP/DOWN angulation control lever slowly to its straight (neutral) position. Confirm that the bending section returns smoothly to an approximately straight position.

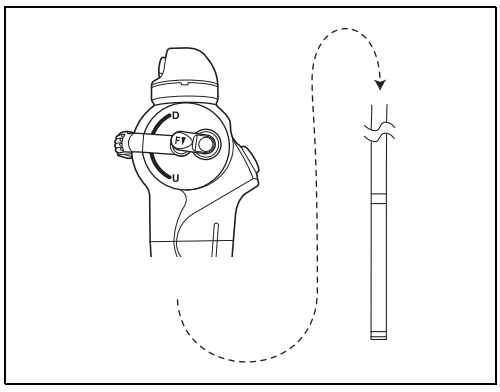


Figure 3.11

Inspection of the angulation mechanism

1 Move the UP/DOWN angulation lock in the opposite direction of the “F▼” mark into the locked position.

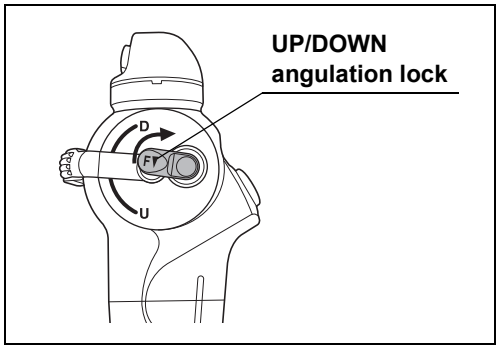


Figure 3.12

2 Move the UP/DOWN angulation control lever in the “U” or “D” direction until it stops.

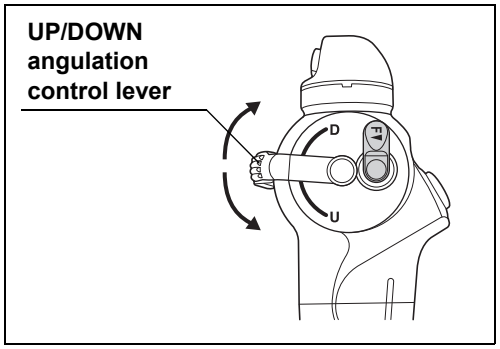


Figure 3.13

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

4 Confirm that the bending section returns to its straight (neutral) position when the UP/DOWN angulation lock is placed in the free position and the UP/DOWN angulation control lever is released.

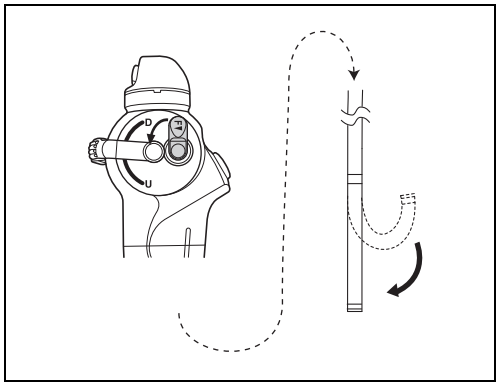


Figure 3.14

3.4 Inspection of accessories

■ Inspection of the luer-split (MAJ-2092)

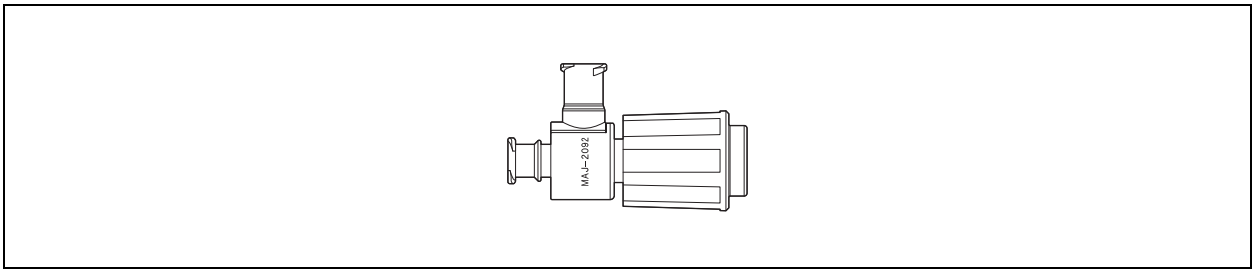


Figure 3.15

Inspect the luer-split as described in the instruction manual for the luer-split.

■ Inspection of the forceps/irrigation plug (MAJ-891)

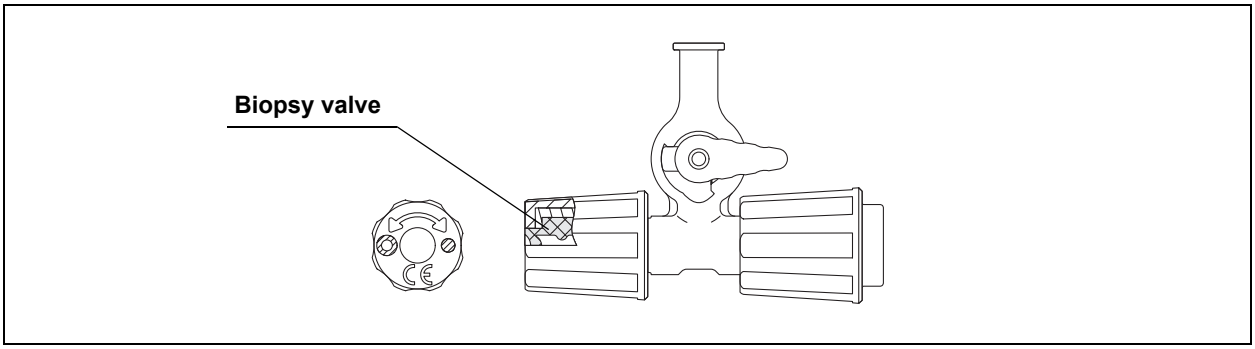


Figure 3.16

WARNING

- When performing high-frequency cauterization, use only forceps/irrigation plug (Isolated type). If forceps/irrigation plug (Non-isolated type) is used, operator injury can result.
- Do not use forceps/irrigation plug that is damaged, deformed or shows other irregularities. Doing so may reduce the efficacy of irrigation and may cause patient debris to leak or spray from the forceps/irrigation plug.

Inspect the forceps/irrigation plug as described in the instruction manual for the forceps/irrigation plug.

3.5 Attaching accessories to the endoscope

■ Attaching the luer-split (MAJ-2092)

Attach the luer-split (MAJ-2092) to the instrument channel port according to the instructions given in the luer-split's instruction manual.

■ Attaching the sealing accessory

Attach the sealing accessory to the forceps port of the luer-split according to the instructions given in the instruction manual for the luer-split.

■ Attaching the forceps/irrigation plug (MAJ-891)

Attach the forceps/irrigation plug (isolated type) (MAJ-891) to the instrument channel port according to the instructions given in the forceps/irrigation plug's instruction manual.

3.6 Inspection of ancillary equipment

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

- Light source
- Video system center
- Monitor
- EndoTherapy accessories

2 Inspect the irrigation system to be used.

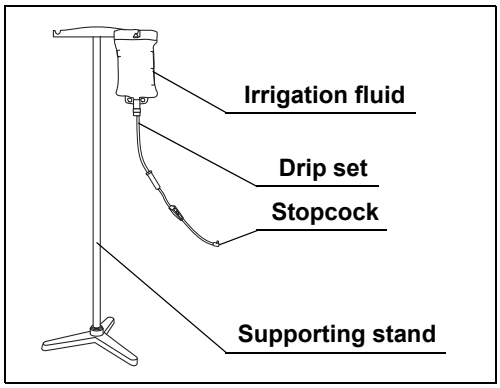


Figure 3.17

3.7 Connection of the endoscope and ancillary equipment

Connect the ancillary equipment to the endoscope as described below.

■ Connection to the light source and video system center

WARNING

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

CAUTION

Before connecting the video connector to the video system center, confirm that the electrical contacts are not wet. If the electrical contacts are wet, the endoscope and video system center may malfunction.

NOTE

Connect the endoscope's light guide connector to the light source, then connect the video connector to the video system center. This can prevent a twisting of the video cable, and the video connector can be connected smoothly.

1. If any ancillary equipment is ON, turn it OFF.
2. While holding the video connector with one hand, insert the light guide connector completely into the output socket of the light source.

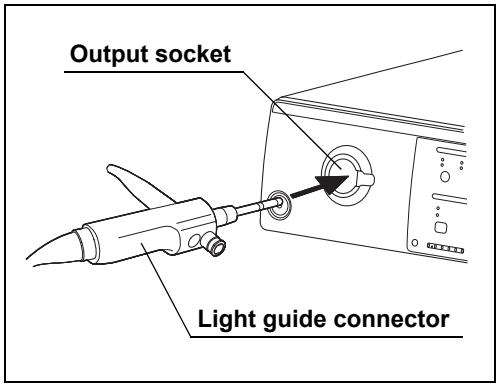


Figure 3.18

3. Make sure that the UP mark on the video connector is facing up. (See Figure 3.19)

4 Hold the video system center stationary with one hand. With the other hand, push the video connector into the video connector socket until it clicks.

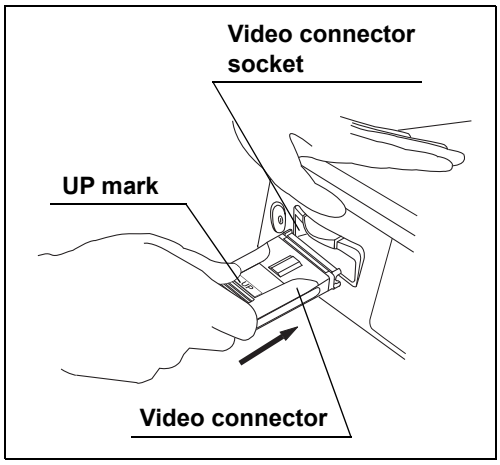


Figure 3.19

5 Confirm that the video connector is securely attached by pulling it gently.

■ *Connection of irrigation system*

Connect the irrigation tube from the irrigation system to the irrigation port on the luer-split or the forceps/irrigation plug.

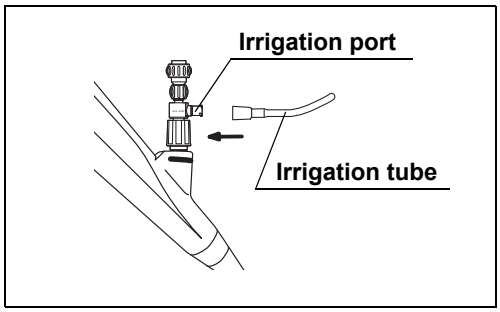
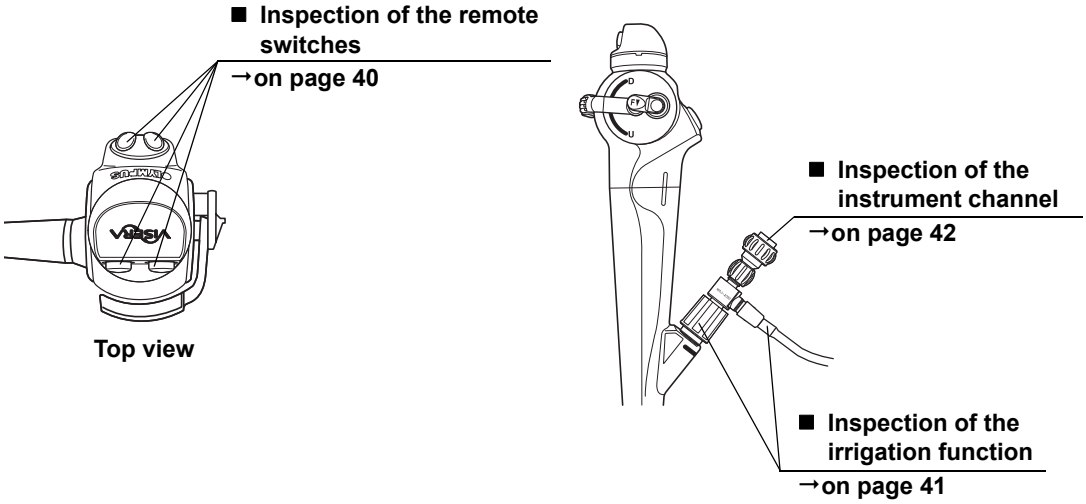


Figure 3.20

3.8 Inspection of the endoscopic system

■ Inspection summary



■ Inspection of the ancillary equipment

Turn ON the video system center, light source, and monitor. Inspect them as described in their respective instruction manuals.

■ *Inspection of the endoscopic image*

Confirm that the WLI and NBI endoscopic images are normal.

WARNING

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

1 Before inspection, wipe the objective lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.

2 Observe the palm of your hand in the WLI and NBI endoscopic images.

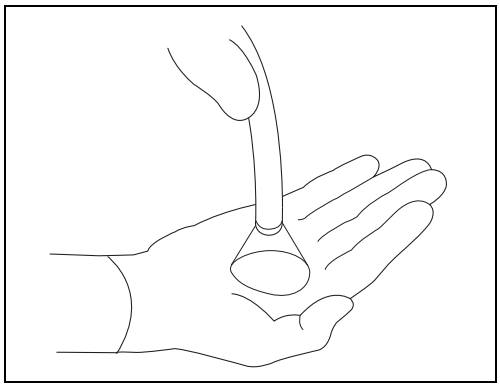


Figure 3.21

3 Confirm that light is output from the endoscope's distal end. (See Figure 3.21)

4 Adjust the brightness level as appropriate.

5 Confirm that the WLI and NBI endoscopic images are free from noise, blur, fog, or other irregularities.

6 Turn the UP/DOWN angulation control lever slowly in each direction until it stops.

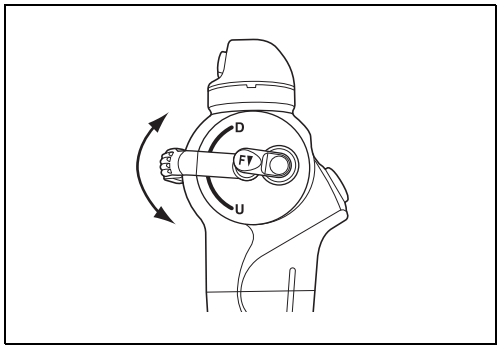


Figure 3.22

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

■ *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.

CAUTION

Detach the sterilization cap from the venting connector after gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma). Otherwise, the remote switches may not work normally due to a difference between internal and external pressures of the endoscope.

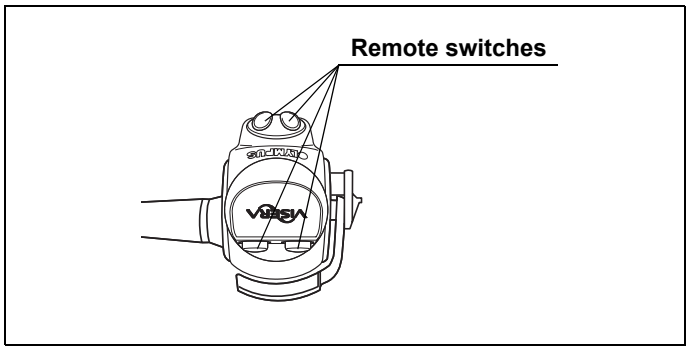


Figure 3.23

1 Depress every remote switch.

2 Confirm that the specified functions work normally.

■ *Inspection of the irrigation function*

1 Inject irrigation fluid through the irrigation tube.

2 Confirm that fluid is emitted from the instrument channel outlet at the distal end of the endoscope.

3 Confirm that no water leaks from the luer-split or the forceps/irrigation plug and irrigation tube.

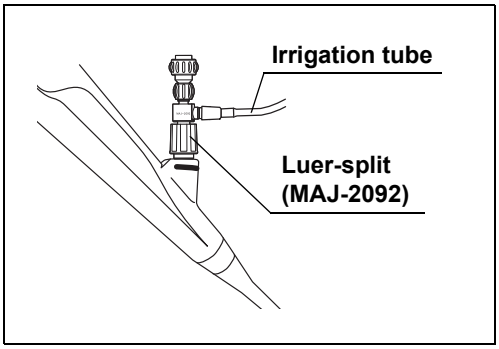


Figure 3.24

NOTE

The amount of irrigation fluid will be reduced when an EndoTherapy accessory is inserted in the instrument channel. Confirm the amount of irrigation fluid under these conditions in advance.

■ *Inspection of the instrument channel*

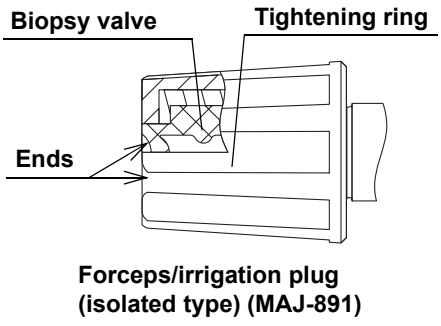
WARNING

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.

CAUTION

- Use EndoTherapy accessories with the same color code (ø 2.0 mm channel or less). The endoscope and/or the EndoTherapy accessory may be damaged.
- If significant resistance is encountered and insertion becomes very difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting EndoTherapy accessories with excessive force may damage the endoscope and/or the EndoTherapy accessories.
- Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath and slowly insert the EndoTherapy accessory into the forceps port of the forceps/irrigation plug. Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while inserting it into the channel. The endoscope and/or the EndoTherapy accessory may be damaged.
- Hold the EndoTherapy accessory close to the forceps port of the sealing accessory and insert it straight into the sealing accessory using slow, short strokes. The sheath of the EndoTherapy accessory could bend or break.

1 When using the forceps/irrigation plug (isolated type) (MAJ-891), turn the tightening ring so that the ends of the biopsy valve and tightening ring are aligned.



Forceps/irrigation plug (isolated type) (MAJ-891)

Figure 3.25

2 Straighten the insertion section of the endoscope.

3 Insert the EndoTherapy accessory straight into the forceps port of the sealing accessory while closing its distal end and retracting it into the sheath.

4 Confirm that the EndoTherapy accessory extends smoothly from the instrument channel outlet at the distal end of the endoscope. Also make sure that no foreign objects come out of the distal end.

5 Confirm that the EndoTherapy accessory is withdrawn smoothly from the biopsy valve.

Chapter 4 Operation

This manual does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this endoscope.

4.1 Precautions

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.
- Anytime you observe an irregularity in an endoscope function, stop the examination immediately and slowly remove the endoscope while viewing the endoscopic image if possible. Using an endoscope that is not functioning properly may cause patient injury.
- The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination. Continued illumination will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.
- Never insert or withdraw the endoscope under any of the following conditions. Patient injury, bleeding, and/or perforation can result.
  - While the EndoTherapy accessory extends from the distal end of the endoscope.
  - While the bending section is locked in position.
  - Insertion or withdrawal with excessive force.

WARNING

- If any of the following conditions occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in Section 5.3, “Withdrawal of the endoscope with an irregularity”.
  - If any irregularity is observed with the functionality of the endoscope.
  - If the endoscopic image on the monitor disappears or freezes unexpectedly.
  - If noise, blur or fog appear on the endoscopic image.
  - If the angulation control lever does not move.
  - If the angulation control mechanism is not functioning properly.

  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.
- The endoscopic image may be disturbed while switching between WLI observation mode and NBI observation mode. Therefore, do not perform any endoscopic operation or treatment while switching between WLI observation mode and NBI observation mode. Injury in the body cavity may result.
- When a part of the endoscopic image, normal colors, or a whole image is not displayed, the image sensor may be damaged. Using the damaged image sensor continuously for a long time makes the distal end of the endoscope extremely hot. Immediately turn OFF the video system center and light source. Otherwise, operator or patient burns may result.
- If the endoscopic image on the monitor should unexpectedly disappear or freeze during an examination and cannot be restored, turn the video system center OFF and then ON again. If the image still does not appear, stop the examination immediately, turn the video system center OFF, place the UP/DOWN angulation lock in the free “F▼” position, then, without touching the angulation control lever, slowly withdraw the endoscope from the patient.
- If the angulation control mechanism or any other part of the system is not functioning properly, stop the procedure immediately and place the UP/DOWN angulation lock in the free “F▼” position. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope are observed, contact Olympus.

WARNING

- 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 may be 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 performing high-frequency cauterization, do not get the external surface of the control section and its surroundings wet. Electric current may flow, and operator and patient injury can result.
- The endoscope must be always sterilized before using for percutaneous nephroscopic diagnosis.
- Adjust the white balance of the endoscope before the procedure to display the correct color on the monitor.
- Detach the ETO cap before the operation, as liquid may enter inside of the endoscope.

CAUTION

- Set the brightness of the light source to the minimum level necessary to perform the procedure safely.
- If the endoscope is dropped or the distal end of the endoscope receives hard impact, the endoscope may be damaged even if a crack or chip of the lens on the distal end can not be found. Stop using the endoscope and contact Olympus.
- The observation of X-ray image may interfere with the endoscopic image. This is normal and does not indicate a malfunction.

4.2 Insertion

■ Holding and manipulating the endoscope

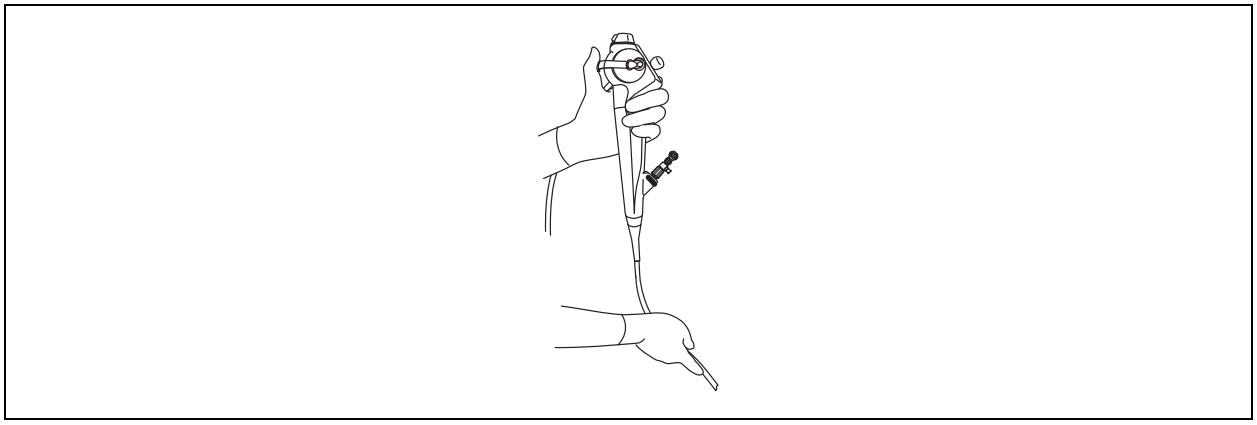


Figure 4.1

1. Hold the control section of the endoscope using your left hand.
2. Operate remote switches 1 and 4 using the left index finger.
3. Operate the UP/DOWN angulation control lever using the left thumb.
4. Maintain the insertion section using the right hand.

■ Irrigation

Feed the irrigation fluid through the irrigation tube.

NOTE

If it doesn't keep the view clear enough because of the amount of irrigation fluid while passing an EndoTherapy accessory through the channel, stop the examination. Then withdraw the EndoTherapy accessory and irrigation.

■ *Insertion of the endoscope*

CAUTION

- 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.

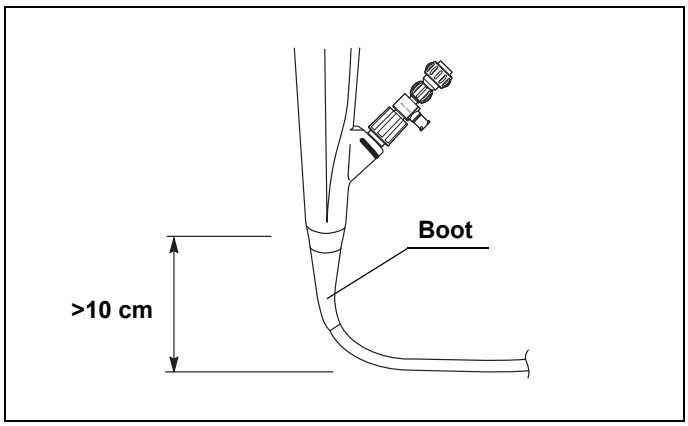


Figure 4.2

1 If necessary, apply a medical-grade, water-soluble lubricant to the insertion section.

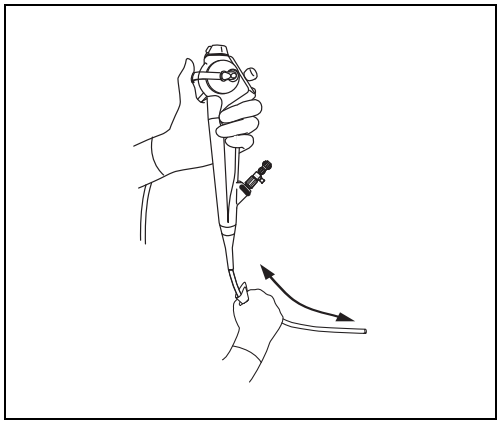


Figure 4.3

2 Insert the distal end of the endoscope into the body cavity while viewing the endoscopic image.

■ *Angulation of the distal end*

WARNING

- If the angulation control mechanism or any other part of the system is not functioning properly, stop the examination immediately and place the UP/DOWN angulation lock in the free "F▼" position. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope are observed, contact Olympus.
- Operate the UP/DOWN angulation control lever slowly while observing the endoscopic image. Otherwise, patient injury, bleeding, and/or perforation can result.

NOTE

- The endoscope's UP/DOWN angulation lock is used to hold the angulated distal end in position. When passing an EndoTherapy accessory through the channel while the angulation is locked, the angulation control lever should be held in place to help maintain the angle of the distal end. When it is necessary to keep the angulation stationary, hold the angulation control lever in place.
- When operating the UP/DOWN angulation lock, hold the UP/DOWN angulation control lever stationary with your fingers. The angulation will change.

Operate the UP/DOWN angulation control lever slowly to guide the distal end for insertion and observation.

■ *Observation of the endoscopic image*

WARNING

- Do not rely on the NBI observation mode alone for primary detection of lesions to make a decision regarding any potential diagnostic or therapeutic intervention.
- If the endoscopic image seems to be dark in the NBI observation mode, change to the normal observation mode. Otherwise, the examination might not be done properly.

NOTE

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.

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

4.3 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to the "■ Compatible EndoTherapy accessories" on page 72 and the instruction manuals for the accessories. Also, refer to their respective instruction manuals for operating the accessories.

WARNING

- When using EndoTherapy accessories, keep the distance between the distal end of the endoscope and the mucous membrane greater than the endoscope's minimum visible distance so that the EndoTherapy accessory remains visible in the endoscopic image. If the distal end of the endoscope is placed closer than its minimum visible distance, the position of the accessory cannot be seen in the endoscopic image. This could cause serious patient injury and/or equipment damage. The minimum visible distance depends on the type of endoscope being used. Refer to Section 2.2, "Specifications".
- When inserting or withdrawing an EndoTherapy accessory, confirm that its distal end is closed or completely retracted into the sheath. Insert or withdraw the EndoTherapy accessory slowly and straight into or from the forceps port of the sealing accessory. The sealing accessory 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 of the EndoTherapy accessory. This could cause patient injury, bleeding, perforation, and/or equipment damage.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the tip of the EndoTherapy accessory or retract the tip of the EndoTherapy accessory into its sheath. Then carefully withdraw both the endoscope and the EndoTherapy accessory together while observing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and/or cause patient injury.
- Do not use the channel cleaning brush for cytologic tissue sampling or other diagnostic or therapeutic purposes. Patient injury, cross-contamination, and/or equipment damage may occur.

CAUTION

Select the EndoTherapy accessories compatible with the endoscope by referring to "Channel inner diameter" in "■ Specifications" on page 21.

NOTE

When using EndoTherapy accessories, the image might become dark. In that case, adjust the brightness of the light source.

■ *Insertion of EndoTherapy accessories into the endoscope*

WARNING

Do not insert EndoTherapy accessories forcibly or abruptly. The EndoTherapy accessory may extend from the distal end of the endoscope abruptly, which could cause patient injury, bleeding, and/or perforation.

CAUTION

- When the bending section of the endoscope angulates significantly and insertion of an EndoTherapy accessory becomes very difficult, straighten the bending section as much as possible. Inserting the EndoTherapy accessory with excessive force may damage the instrument channel and/or the EndoTherapy accessory.
- Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath. Slowly insert the EndoTherapy accessory into the sealing accessory. Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while inserting the EndoTherapy accessory into the instrument channel. The instrument channel and/or the EndoTherapy accessory may be damaged.
- Hold the EndoTherapy accessory close to the forceps port of the sealing accessory and insert it straight into the forceps port of the sealing accessory using slow short strokes. Otherwise, the EndoTherapy accessory could bend or break.

1 Select EndoTherapy accessories compatible with the endoscope from the "■ Compatible EndoTherapy accessories" on page 72 and the accessories' instruction manuals for operating instructions.

2 Hold the UP/DOWN angulation control lever stationary so that the bending section is straight.

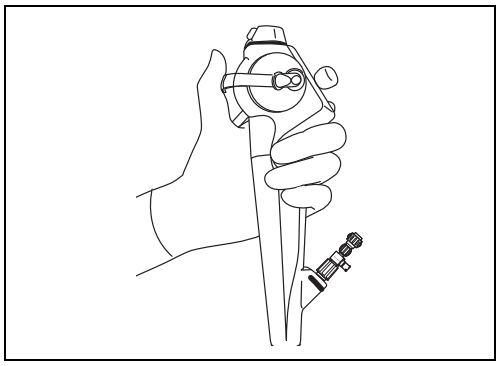


Figure 4.4

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

4 Insert the EndoTherapy accessory slowly and straight into the forceps port of sealing accessory.

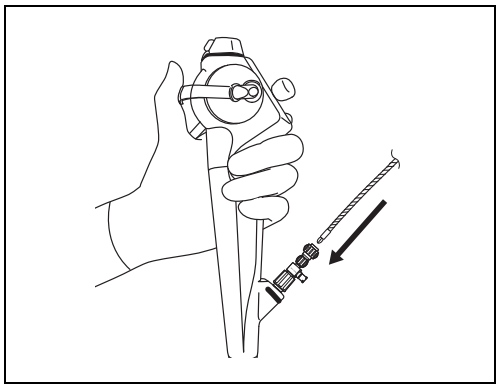


Figure 4.5

5 Hold the EndoTherapy accessory at a point approximately 4 cm from the sealing accessory and advance it slowly and straight into the sealing accessory using short strokes while observing the endoscopic image.

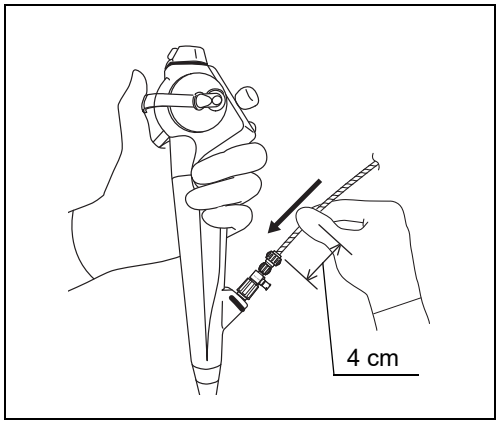


Figure 4.6

NOTE

When the tip of the EndoTherapy accessory extends approximately 2 mm from the distal end of the endoscope, the accessory will appear in the endoscopic image.

■ *Operation of EndoTherapy accessories*

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

■ *Withdrawal of EndoTherapy accessories*

WARNING

- Fluid might spray when the EndoTherapy accessories are withdrawn from the sealing accessory. To prevent this, hold a piece of gauze around the accessory and the sealing accessory during withdrawal.
- Do not withdraw the EndoTherapy accessory if the tip is open or extended from its sheath; patient injury and/or instrument damage may occur.
- Withdraw the EndoTherapy accessory slowly and straight out of the sealing accessory. Otherwise, the sealing accessory could be damaged. This may leak or spray fluid, posing an infection control risk.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the EndoTherapy accessory and/or retract it into its sheath. Then carefully withdraw both the endoscope and the EndoTherapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

Withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.

■ *High-frequency cauterization*

WARNING

- When performing high-frequency cauterization, use only an isolated-type of a luer-split or forceps/irrigation plug. If a non-isolated type is used, operator injury can result.
- Always confirm that the tissue is an appropriate distance away from the distal end of the endoscope. If high-frequency cauterization is performed when the distal end of the endoscope contacts the tissue, patient injury, burns, bleeding, perforation, and equipment damage may occur.
- Use non-electrolytic solution for irrigation. Once urine and/or blood is mixed into the solution, the non-electrolytic solution will be diluted, and electrosurgical faculty may be degraded. In this case, do not raise the power of the electrosurgical unit. Instead, replace the diluted solution with new solution. If the power setting is raised, patient injury can result.
- Do not perform high-frequency cauterization while supplying oxygen. This may result in combustion during cauterization.
- Always confirm that the electrode section of the electrosurgical accessory is at an appropriate distance from the distal end of the endoscope. Confirm that the entire green marking (in case of WLI observation mode) at the distal tip of the electrosurgical accessory can be observed on the endoscopic image. If the electrode is used when it is too close to the distal end of the endoscope, the endoscope and/or ancillary equipment may be damaged. Patient injury, burns, bleeding, perforation, and/or equipment damage may result.

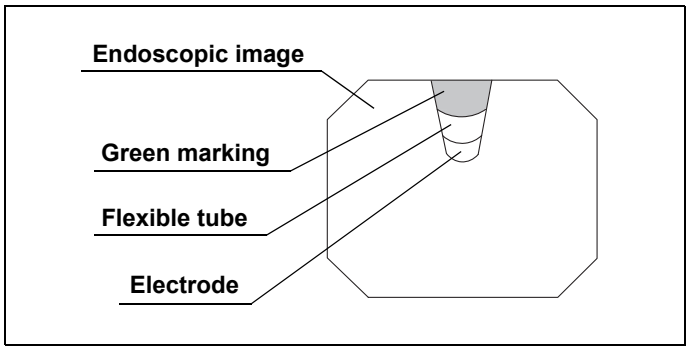


Figure 4.7

- Be sure to contact the electrode section of the EndoTherapy accessory with tissue when performing high-frequency cauterization treatment to prevent equipment damage and operator and/or patient burns.
- Improper connection between the patient plate and patient's skin surface may cause burns. For further details on the patient plate, refer to the patient plate's instruction manual.

WARNING

- Do not perform high-frequency cauterization without gloves. Operator injury can result.
- Before performing high-frequency cauterization, inspect the surface of the endoscope for any dents, bulges, or other irregularities. Otherwise, patient injury, burns, bleeding, perforation, and/or equipment damage may result.
- When performing high-frequency cauterization, do not use the electrosurgical unit's SPRAY coagulation mode. The endoscope may be damaged and it cause patient and/or operator burns.
- Set the electrosurgical unit to the minimum necessary output level. If the output level is too high, the endoscope's and/or accessory's insulation may be damaged and cause operator and/or patient burns.
- Prolonged excessive flow rates and/or irrigation fluid/gas pressures may result in excessive absorption into the vascular system (e.g., through an open vessel) or gas embolism.

NOTE

The application of high-frequency current may interfere with the endoscopic image. This does not indicate a malfunction.

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

4.4 Withdrawal of the endoscope

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 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 endoscope are observed, contact Olympus.
- Avoid patient fluids adhering to the withdrawn endoscope from coming in contact with the bed or floor. The patient fluids may pose an infection control risk to the patient and/or medical personnel.

1 Turn the UP/DOWN angulation lock to the free "F▼" position.

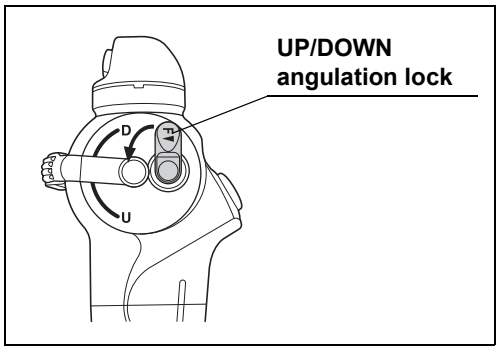


Figure 4.8

2 Carefully withdraw the endoscope while observing the endoscopic image.

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

4.5 Transportation of the endoscope

■ Transporting within the healthcare facility

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

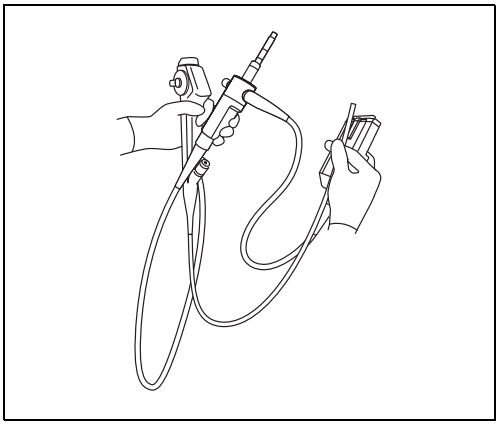


Figure 4.9

■ Transporting outside the healthcare facility

WARNING

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

CAUTION

- The carrying case cannot be reprocessed. Reprocess the endoscope before placing it in the carrying case.
- Attach the ETO cap (MB-156) when transporting the endoscope. Otherwise, the endoscope may be damaged by changes in air pressure.

Transport the endoscope in the carrying case.

Chapter 5 Troubleshooting

The countermeasures against troubles are described in this chapter.

5.1 Troubleshooting

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

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

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

WARNING

- Never use the endoscope on a patient if an irregularity is observed. Damage or an irregularity in the endoscope 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.

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

5.2 Troubleshooting guide

The following table shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of 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 5.4, “Returning the endoscope for repair”.

■ *Image quality or brightness*

Irregularity description	Possible cause	Solution
There is no video image.	Not all equipment is ON.	Turn ON all equipment.
	The video connector is not connected securely.	Insert the video connector with its UP mark facing upwards into the output socket of the video system center securely until it stops and clicks.
An image is not clear.	The objective lens is dirty.	Wipe the objective lens with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.
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.
	The light guide lens at the distal end of the endoscope is dirty.	Wipe the light guide lens with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.
	The glass at the light guide connector end is dirty.	Wipe the glass with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.

■ *Irrigation fluid feeding*

Irregularity description	Possible cause	Solution
No irrigation fluid feeding.	The instrument channel is obstructed.	Clean the channel with a channel cleaning brush as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.
	The forceps/irrigation plug is incorrectly assembled.	Reassemble it correctly as described in its instruction manual.
	The sealing accessory is worn out.	Replace it with a new one.
Irrigation fluid leaks.	The instrument channel is obstructed.	Clean the channel with a channel cleaning brush as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.
	The forceps/irrigation plug is incorrectly assembled.	Reassemble it correctly as described in its instruction manual.
	The sealing accessory is worn out.	Replace it with a new one.
	The ends of the biopsy valve and tightening ring are not aligned.	Turn the tightening ring so that the ends of the biopsy valve and tightening ring are aligned.

■ *Angulation*

Irregularity description	Possible cause	Solution
Resistance is encountered when rotating the UP/DOWN angulation control lever.	The UP/DOWN angulation lock is engaged.	Rotate the UP/DOWN angulation lock in the "F▼" direction.

■ *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 "■ Compatible EndoTherapy accessories" on page 72 and select a compatible EndoTherapy accessory. Confirm that the color code on the EndoTherapy accessory matches that on the endoscope.
	The forceps/irrigation plug is incorrectly assembled.	Reassemble it correctly as described in its instruction manual.
	The bending section angulates sharply.	Straighten it as much as possible.
	The tightening ring on the forceps/irrigation plug is turned too tightly.	Turn the tightening ring so that the ends of the biopsy valve and tightening ring are aligned.

■ *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.

5.3 Withdrawal of the endoscope with an irregularity

If an irregularity occurs while the endoscope is in use, take proper measures as described in either "■ Withdrawal when the WLI and NBI endoscopic images appear on the monitor", "■ Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor", or "■ Withdrawal when all endoscopic images do not appear on the monitor or a frozen image cannot be restored" below. After withdrawal, return the endoscope for repair as described in Section 5.4, "Returning the endoscope for repair".

WARNING

If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope or EndoTherapy accessory 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 endoscope or EndoTherapy accessory 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, and monitor.

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.

5 Turn the UP/DOWN angulation lock to the free "F▼" position.

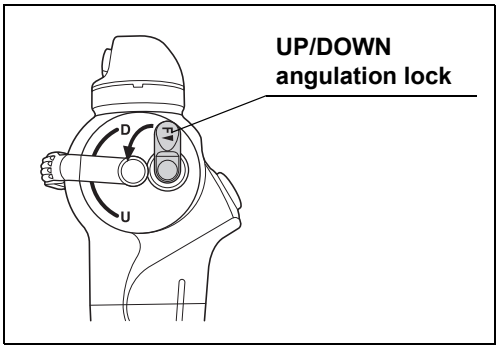


Figure 5.1

6 Carefully withdraw the endoscope while observing the endoscopic image.

■ *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, and monitor.

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 all endoscopic images do not appear on the monitor or a frozen image cannot be restored*

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

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 all endoscopic images still do not appear or the frozen image cannot be restored, perform the following steps.

3 Turn the video system center, light source, and monitor 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.

5 Turn the UP/DOWN angulation lock to the free "F▼" position.

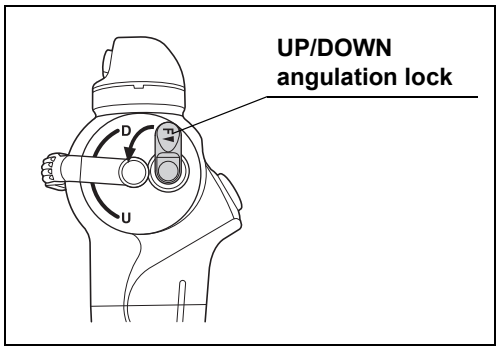


Figure 5.2

6 Turn the UP/DOWN angulation control lever to its neutral position and release the angulation control lever.

7 Withdraw the endoscope from the patient carefully.

5.4 Returning the endoscope for repair

WARNING

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

CAUTION

Olympus is not liable for any injury or damage that occurs as a result of repairs attempted by non-Olympus personnel.

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 healthcare facility” on page 59.

Appendix

The equipment compatible with this endoscope and the EMC information are described in this Appendix.

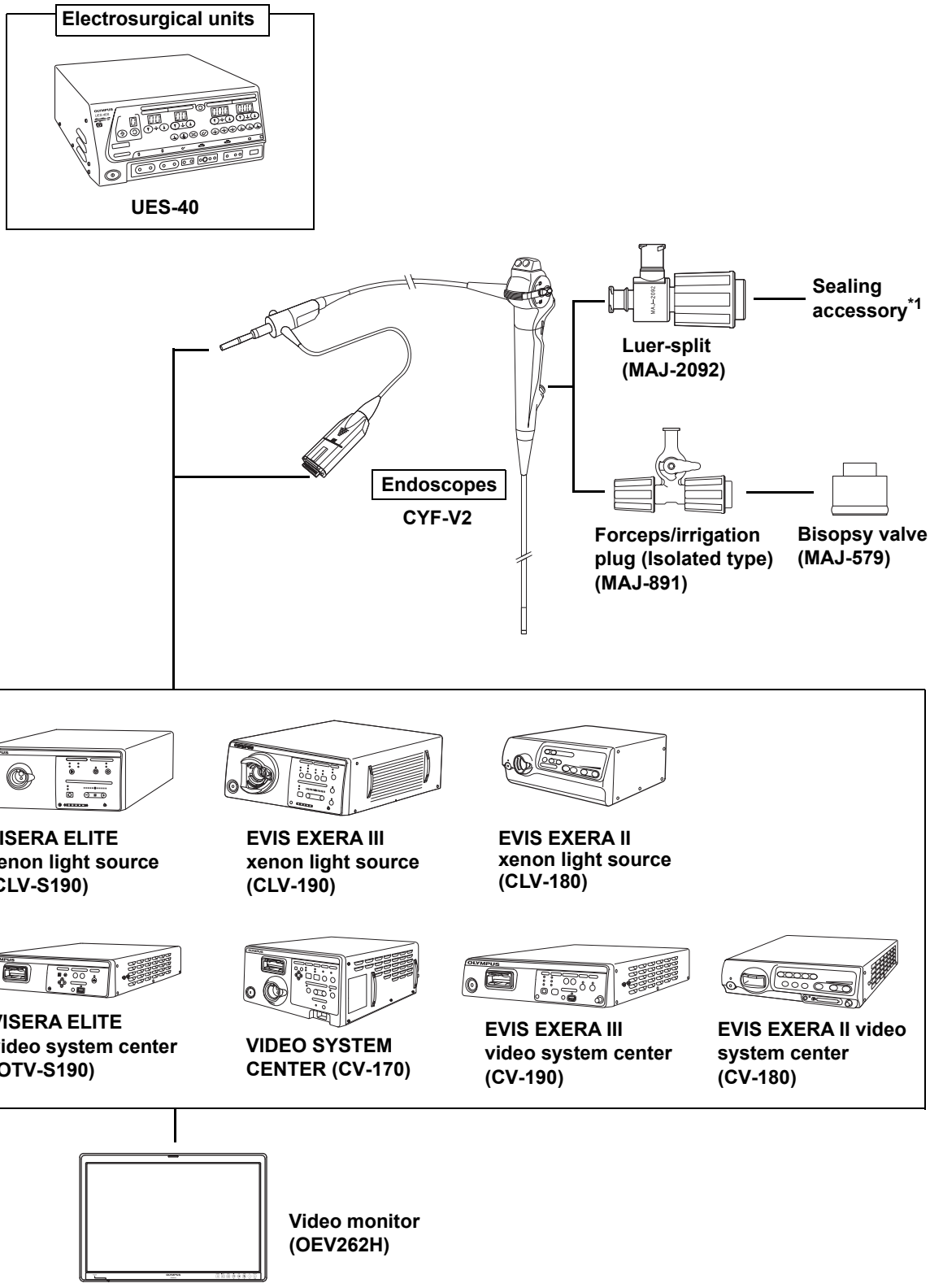
Combination equipment

■ System chart

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

WARNING

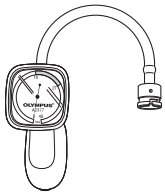
Be sure to use the equipment in one of the recommended combinations.
If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.



*1 Refer to the instruction manual for the MAJ-2092.

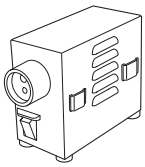
■ *Reprocessing equipment*

Single use combination cleaning brush (BW-411B)



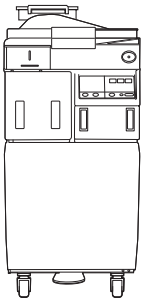
Leakage tester (WA23080A)

Leakage tester (MB-155)

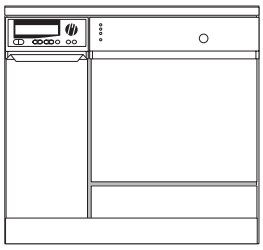


Maintenance unit (MU-1)

ETO cap (MB-156)



Endoscope reprocessor (OER-AW*1)



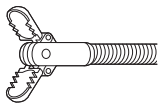
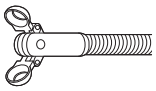
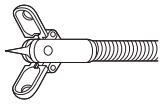
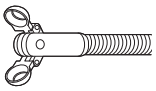
Washer-disinfector (ETD4, ETD double)

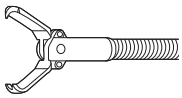
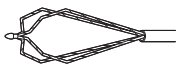
*1 OER-AW is not available in member states of the EU.

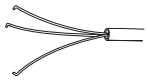
■ *Compatible EndoTherapy accessories*

❍ EndoTherapy accessories

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

	Biopsy forceps	Biopsy forceps (fenestrated)		Rotatable biopsy forceps (fenestrated)
	Alligator jaws type	Standard type	Standard type (with needle)	Standard type
Endoscope				
CYF-V2	FB-15C-1	FB-19SX-1 FB-21-SX-1	FB-34C-1	FB-19CR-1

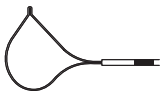
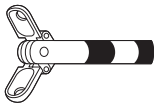
	Grasping forceps	Grasping forceps
	Sharp tooth type	Basket type
Endoscope		
CYF-V2	FG-38SX-1 FG-53SX-1	FG-24SX-1

	Disposable grasping forceps			
	Spiral basket type		Parallel basket type	Three nail type
Endoscope				
CYF-V2	FG-51D	FG-52D	FG-55D	FG-54D

App.

Electrosurgical accessories

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

	Electrosurgical snare	Coagulation electrode	Hot biopsy forceps
	Crescent type		
Endoscope			
CYF-V2	SD-7C-1 SD-18C-1	CD-6C-1	FD-7C-1

EMC information

Guidance and manufacturer's declaration — Electromagnetic emissions

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

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

Guidance and manufacturer's declaration — Electromagnetic immunity

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

Immunity test	IEC 60601-1-2 (2014) test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2, ±4, ±8, ±15 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 healthcare facility environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV for signal input/ output lines: ±2 kV	Same as left	Mains power quality should be that of a typical commercial or healthcare facility environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle/ 1 cycle	Same as left	Mains power quality should be that of a typical commercial or healthcare facility environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/ 30 cycle (60 Hz) Phase angle causing voltage dips: 0°		
	0% U_T (100% dip in U_T) for 250 cycle (50 Hz)/ 300 cycle (60 Hz)		
	U_T is the a.c. mains voltage prior to application of the test level.		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz, 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

Immunity test	IEC 60601-1-2 (2014) test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3V (150 kHz – 80 MHz)	Same as left	–
	6V (ISM band of 150 kHz – 80 MHz)	Same as left	
	ISM (industry, science, and medical care) band of 6.765 MHz – 6.795 MHz, 13.553 MHz – 13.567 MHz, 26.957 MHz – 27.283 MHz, and 40.66 MHz – 40.70 MHz between 0.15 MHz and 80 MHz		
Radiated RF IEC 61000-4-3	3V/m (80 MHz – 2.7 GHz)	Same as left	–
Proximity magnetic field from RF communication equipment IEC 61000-4-3	Refer to the table of the next page.	Same as left	

NOTE

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

NOTE

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

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

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

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

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

WARNING

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

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

Refer to the instruction manuals for each piece of equipment.

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Date of Issue 2022-02-14
RC7850 06

Printed in Japan 20220210 *0000