

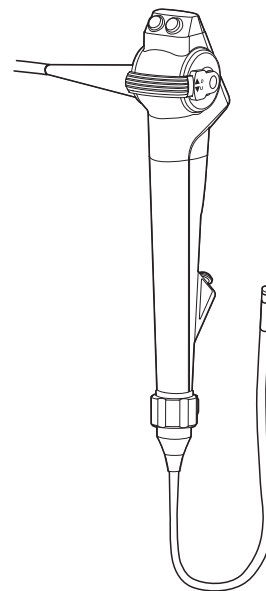
INSTRUCTIONS

EVIS EXERA III

EVIS EXERA III BRONCHOVIDEOSCOPE

OLYMPUS BF-XP190
OLYMPUS BF-P190
OLYMPUS BF-Q190
OLYMPUS BF-H190
OLYMPUS BF-1TH190

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

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

CE 0197

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









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| 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.
	Caution
	Endoscope
	TYPE BF applied part
	Single use only
	Lot number
	Use by (expiration date)
	Sterilization lot number
	Sterilized using irradiation
	Manufacturer
	Authorized representative in the European Community
	Serial number
IPX7	Ingress protection rating is 7.

For US Customers only

For a Symbols Glossary, visit us:

<http://www.olympus-global.com/en/common/pdf/symbolsglossary.pdf>

Important Information — Please Read Before Use

■ *Intended use*

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

This instrument is indicated for use within the airways and tracheobronchial tree.

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

Select the endoscope to be used according to the objective of the intended procedure based on the full understanding of the endoscope's specifications and functionality as described in this instruction manual.

■ *Applicability of endoscopy and endoscopic treatment*

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

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

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

■ **Instruction manual**

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals 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, 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 hospital's medical administrators or other official institutions, such as academic societies on endoscopy, follow those standards. If there are no official qualification standards, the operator of this instrument must be a physician approved by the medical safety manager of the hospital or person in charge of the department (department of internal medicine, etc.).

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

■ ***Instrument compatibility***

Refer to “Combination equipment” on page 83 to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

This instrument complies with the EMC standard for medical electrical equipment, edition 2 (IEC 60601-1-2: 2001) and edition 3 (IEC 60601-1-2: 2007). However, when connected with an instrument that complies with the EMC standard for medical electrical equipment, edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.

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

This instrument was not reprocessed before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in the endoscope’s companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.

After using this instrument, reprocess and store it according to the instructions given in the endoscope’s companion reprocessing manual. Improper and/or incomplete reprocessing or storage can pose an infection control risk, cause equipment damage, or reduce performance.

■ ***Spare equipment***

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

■ ***Maintenance management***

The probability of failure of the endoscope and ancillary equipment increases as the number of procedures performed and/or the total operating hours increase. In addition to the inspection before each procedure, the person in charge of medical equipment maintenance in each hospital should 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.

■ **Warnings and cautions**

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

- After using this endoscope, reprocess and store it according to the instructions given in the endoscope's companion "REPROCESSING MANUAL" with your endoscope model listed on the cover. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and/or infection.
- Before endoscopy, remove any metallic objects (watch, glasses, necklace, etc.) from the patient. Performing high-frequency cauterization treatment while the patient is wearing metallic objects may cause burns on the patient in areas around the metallic objects.
- Do not strike, hit, or drop the endoscope's distal end, insertion tube, bending section, control section, universal cord, or endoscope connector. Also, do not bend, pull, or twist the endoscope's distal end, insertion tube, bending section, control section, universal cord, or endoscope connector with excessive force. The endoscope may be damaged and could cause patient injury, burns, bleeding, and/or perforations. It could also cause parts of the endoscope to fall off inside the patient.
- Never perform angulation control forcibly or abruptly. Never forcefully pull, twist, or rotate the angulated bending section. Patient injury, bleeding, and/or perforation may result. It may also become impossible to straighten the bending section during an examination.
- Never insert or withdraw the endoscope's insertion section while the bending section is locked in position. Patient injury, bleeding, and/or perforation may result.
- Never operate the bending section, perform suction, insert or withdraw the endoscope's insertion section, rotate the insertion section, or use EndoTherapy accessories while no endoscopic image is observed or the endoscopic image is frozen. Patient injury, bleeding, and/or perforation may result.
- Never insert, withdraw, or rotate the endoscope's insertion section with excessive force or while an optimum field of view cannot be obtained. Patient injury, bleeding, and/or perforation may result. If it is difficult to insert the endoscope, do not forcibly insert the endoscope; stop the endoscopy. Forcible insertion can result in patient injury, bleeding, and/or perforation.
- Never insert or withdraw the insertion section abruptly or with excessive force. Patient injury, bleeding, and/or perforation may result.

WARNING

- Do not touch the light guide on the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient burns can result.
- 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 through improper usage. 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 attention to the brightness level setting of the light source, particularly when operating the electrical shutter function of a video system center. When using a light source and video system center that are compatible with the light source's automatic brightness control function, make sure to use the automatic brightness control function. 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.
- Do not connect the endoscope connector while the electrical contacts are wet and/or dirty, which 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 or that the light guide lens has been discolored. Immediately withdraw the endoscope from the patient, remove blood or mucus, and confirm that the light guide lens has no irregularities to use it again. If you continue to use the endoscope with its obstructed or discolored light guide lens, the temperature at the distal end may rise, which may cause patient injury or operator and/or patient burns.

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.
- When performing transnasal insertion with the endoscope, follow the warnings below.
 - The shape and size of the nasal cavity and its suitability for transnasal insertion may vary from patient to patient. No endoscope, including this one, can always be inserted transnasally into all patients. Before proceeding, always be sure to confirm that transnasal insertion is possible with the patient by considering both the size of the patient's nasal cavity as well as the size of the endoscope's insertion section. Patient injury can result or the endoscope could become lodged and difficult to withdraw.
 - Transnasal insertion is accompanied by the risk of inflammation of the nasal cavity. If this happens, the nasal passage will be constricted, making it more difficult to withdraw the endoscope. In this case, do not use force to withdraw the endoscope because patient injury, bleeding, and/or perforation may result.
 - Transnasal insertion is accompanied by the risk of bleeding in the nasal cavity. Be sure to be prepared to deal with any bleeding. When withdrawing the endoscope, observe the inside of the nasal cavity to ensure that there is no bleeding. Even when the endoscope has been withdrawn without bleeding, do not allow the patient to blow his or her nose strongly because this could cause it to start bleeding.
 - Before transnasal insertion, apply the appropriate pretreatment and lubrication to the patient to enlarge the nasal cavity. Otherwise, patient injury can result or the endoscope could become lodged and difficult to withdraw. When applying a pretreatment agent through a tube, insert the tube into the same path as the path planned for the endoscope's insertion. Otherwise, the treatment will have no effect. The effects of the pretreatment agent and lubricant will decrease the longer the procedure lasts. Apply the pretreatment agent or lubricant as required during the procedure – for example, when withdrawal seems to be difficult.
 - Transnasal insertion of the endoscope should be performed carefully. If resistance to insertion is felt, or the patient reports pain, stop the insertion immediately. Patient injury can result or the endoscope could become lodged and difficult to withdraw.

WARNING

- If it becomes impossible to withdraw the transnasally inserted endoscope, pull its distal end out of the mouth, cut the flexible tube using wire cutters, and after ensuring that the cut section will not injure the body cavity or nasal cavity of the patient, withdraw the endoscope carefully. Therefore, always prepare wire cutters in advance.
- When using the electronic zoom function of the video system center, never insert or withdraw the endoscope's insertion section or use EndoTherapy accessories while the image is electronically zoomed. Patient injury, bleeding, and/or perforation can result.
- The bending section will only bend to the UP or DOWN direction. To insert or withdraw, operate the endoscope by considering the direction in which the bending section is angulated. Never apply excessive force to the RIGHT or LEFT direction when inserting or withdrawing the endoscope. Patient injury, bleeding, and/or perforation can result.

CAUTION

- Do not pull the universal cord during an examination. The endoscope connector will be pulled out from the output socket of the light source and the endoscopic image will disappear.
- Do not coil the insertion tube or universal cord with a diameter of less than 12 cm. Equipment damage may result.
- Do not attempt to bend or twist the endoscope's insertion section with excessive force. The insertion section may be damaged.
- Do not apply shock to the distal end of the insertion section, in particular 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 leakage.
- Do not put or press the endoscope connector on the insertion section when transporting or reprocessing. The insertion section may be damaged.

CAUTION

- Turn the video system center ON only when the endoscope connector is connected to the light source. In particular, confirm that the video system center is OFF before connecting or disconnecting the endoscope connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- The endoscope's remote switches cannot be removed from the control section. Pressing, pulling, or twisting them with excessive force can break the switches and/or cause water leakage.
- Do not hit or bend the electrical contacts on the endoscope connector. The connection to the light source may be impaired and a faulty contact can result.
- 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.



- When using an endotracheal tube with the endoscope, select the tube that gives a sufficient gap between the insertion section of the endoscope and itself. A narrow gap may make it difficult for a patient to breathe and/or damage the endoscope.
- Before inserting the endoscope with an endotracheal tube into the patient, confirm that the insertion section of the endoscope can be inserted into the endotracheal tube smoothly by running it back and forth over the entire length of the insertion section and that the tube does not damage the endoscope. Any protrusions may damage the bending section cover or strip the external surface of the insertion section. When using lubrication, make above confirmation before applying lubrication.
- 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 CV-190.
- When the endoscope gets strong static electricity, noise may be observed in the endoscopic image. This does not indicate a malfunction.

■ **Warnings and cautions: 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 warnings given below. Otherwise, the endoscopic image may disappear unexpectedly or the frozen image may not be restored during the examination.
 - Connect the endoscope connector to the light source completely by pushing the endoscope connector until it clicks. Otherwise, a faulty contact can result.
 - Do not bend, hit, pull, or twist the insertion section, bending section, control section, universal cord, and endoscope connector. The endoscope may be damaged, and water leakage and/or breakage of internal parts like the image sensor cable can result.
 - Before connecting the endoscope connector to the light source, confirm that the endoscope connector, including the electrical contacts, is completely dry and clean. If the endoscope is used with the electrical contacts wet and/or dirty, the endoscope and light source may malfunction.
 - If air bubbles emerge from the endoscope continuously during the leakage test, do not use the endoscope. Water may enter the endoscope and cause a short circuit. This may result in image sensor damage.
 - When inserting the endoscope through the mouth, place the mouthpiece (MA-651) in the patient’s mouth as necessary before inserting the endoscope to prevent the patient from accidentally biting the insertion section. Biting the insertion section may result in a break in the cable or malfunction of the light guide.

■ **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.

- Applying suction with the distal end in contact with the mucosal surface, with higher suction pressure than required or with prolonged suction time may cause bleeding and/or lesions.
- The endoscope has not been designed for use in retroflexed observation. Performing retroflexed observation in a narrow lumen may make it impossible to straighten the angle of the bending section and/or withdraw the endoscope from the patient. In case the patient moves due to coughing and other reasons while the endoscope is angulated in the narrow lumen, the bending section of the endoscope may be pushed into the lumen and be retroflexed. Pretreatment to control patient's coughing reflex and other possible unexpected moves is the responsibility of trained specialists. Retroflexed observation should be performed only when the usefulness of doing so is determined to be greater than the risk that is posed to the patient.
- Inserting, withdrawing, and using EndoTherapy accessories without a clear endoscopic image may cause patient injury, burns, bleeding, and/or perforation.
- Inserting or withdrawing the endoscope, rotating the insertion section, applying suction, or operating the bending section without a clear endoscopic image may cause patient injury, bleeding, and/or perforation.
- For reasons described below, do not rely on the NBI^{*1} observation mode alone for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.
 - NBI has not been demonstrated to increase the yield or sensitivity of finding any specific mucosal lesion.
 - 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 CV-190.

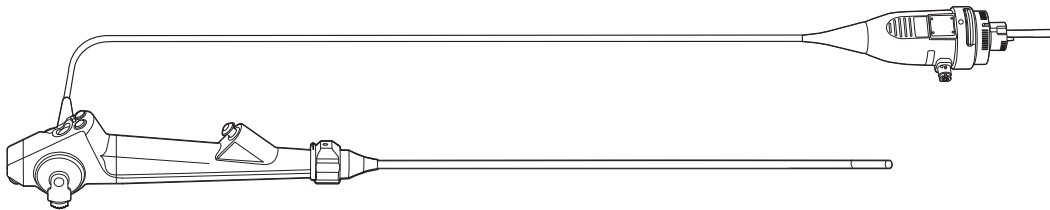
Chapter 1 Checking the Package Contents

1.1 Checking the package contents

Ch.1

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.

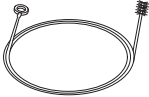





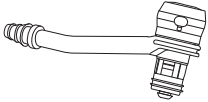
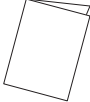
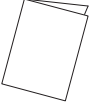
○ Endoscope



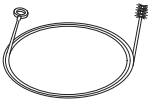

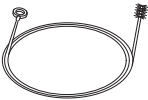





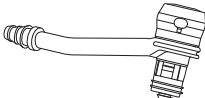
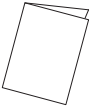
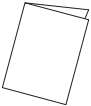
BF-XP190, BF-P190, BF-Q190, BF-H190, BF-1TH190

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

Ch.1

○ Accessories		
 <p>BF-XP190</p>		
Single use single-ended cleaning brush (BW-400B, 3 pcs)	Single use combination cleaning brush (BW-411B, 3 pcs)	Mouthpiece (MA-651, 2 pcs)
		
Sterilization cap (MAJ-1538)	Suction cleaning adapter (MAJ-222)	Single use biopsy valve (MAJ-210, 20 pcs (1 box))
		
Single use suction valve (MAJ-209, 20 pcs (1 box))	Operation manual	Reprocessing manual

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

○ Accessories		
BF-XP190	BF-XP190	Except BF-XP190
		
Single use single-ended cleaning brush (BW-400B, 3 pcs)	Suction connector cleaning brush (BW-15SH)	Channel cleaning brush (BW-15B)
		
Channel-opening cleaning brush (MH-507)	Mouthpiece (MA-651, 2 pcs)	Sterilization cap (MAJ-1538)
		
Suction cleaning adapter (MAJ-222)	Biopsy valve (MD-495, 10 pcs (1 set))	Suction valve (MAJ-207, 10 pcs (1 set))
		
Operation manual	Reprocessing manual	

Ch.1

| 1.1 Checking the package contents

Ch.1



Chapter 2 Instrument Nomenclature and Specifications

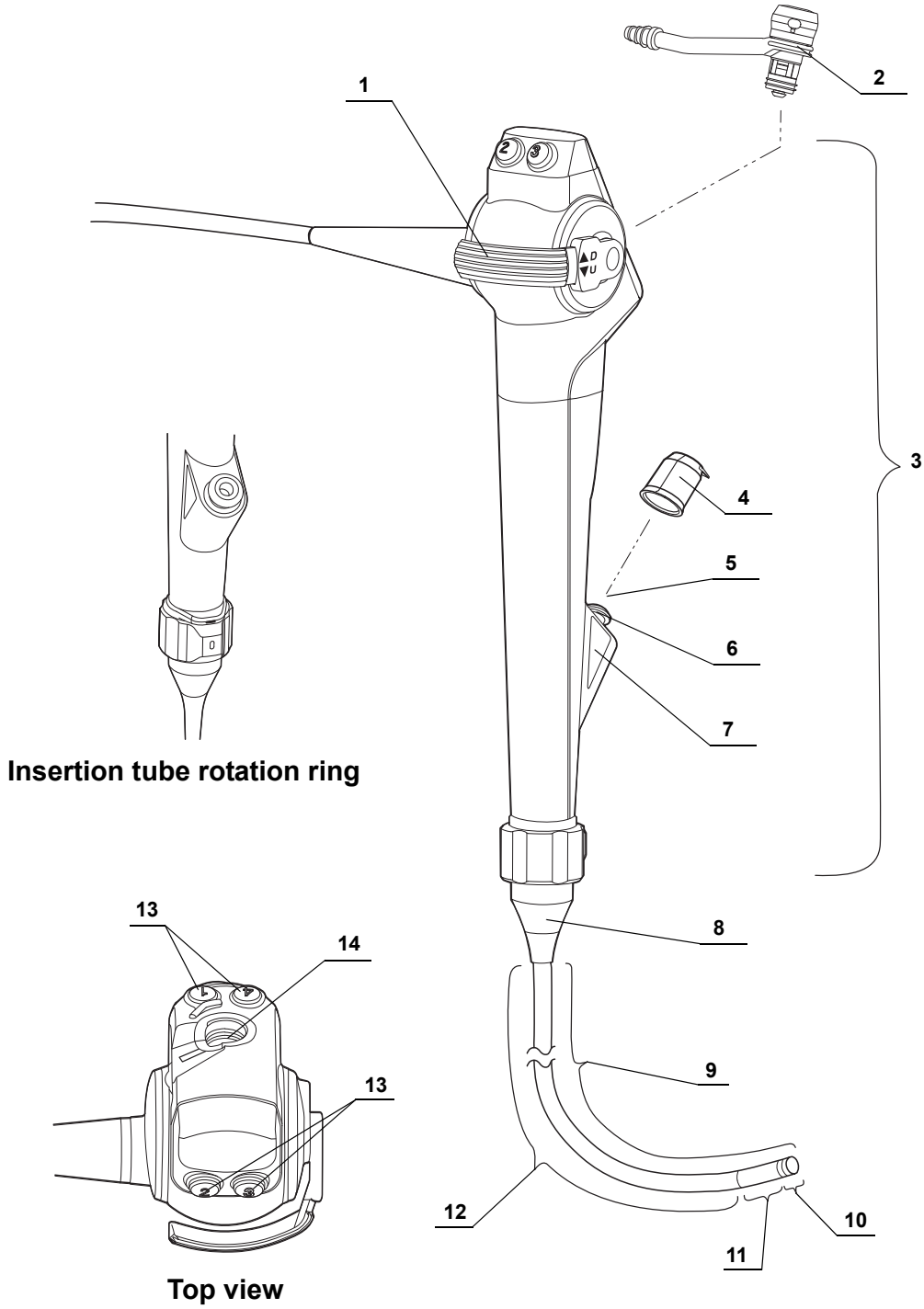
The instrument nomenclature, functions, and specifications are described in this chapter.

2.1 Nomenclature and functions

Ch.2

Control section, insertion section

Ch.2

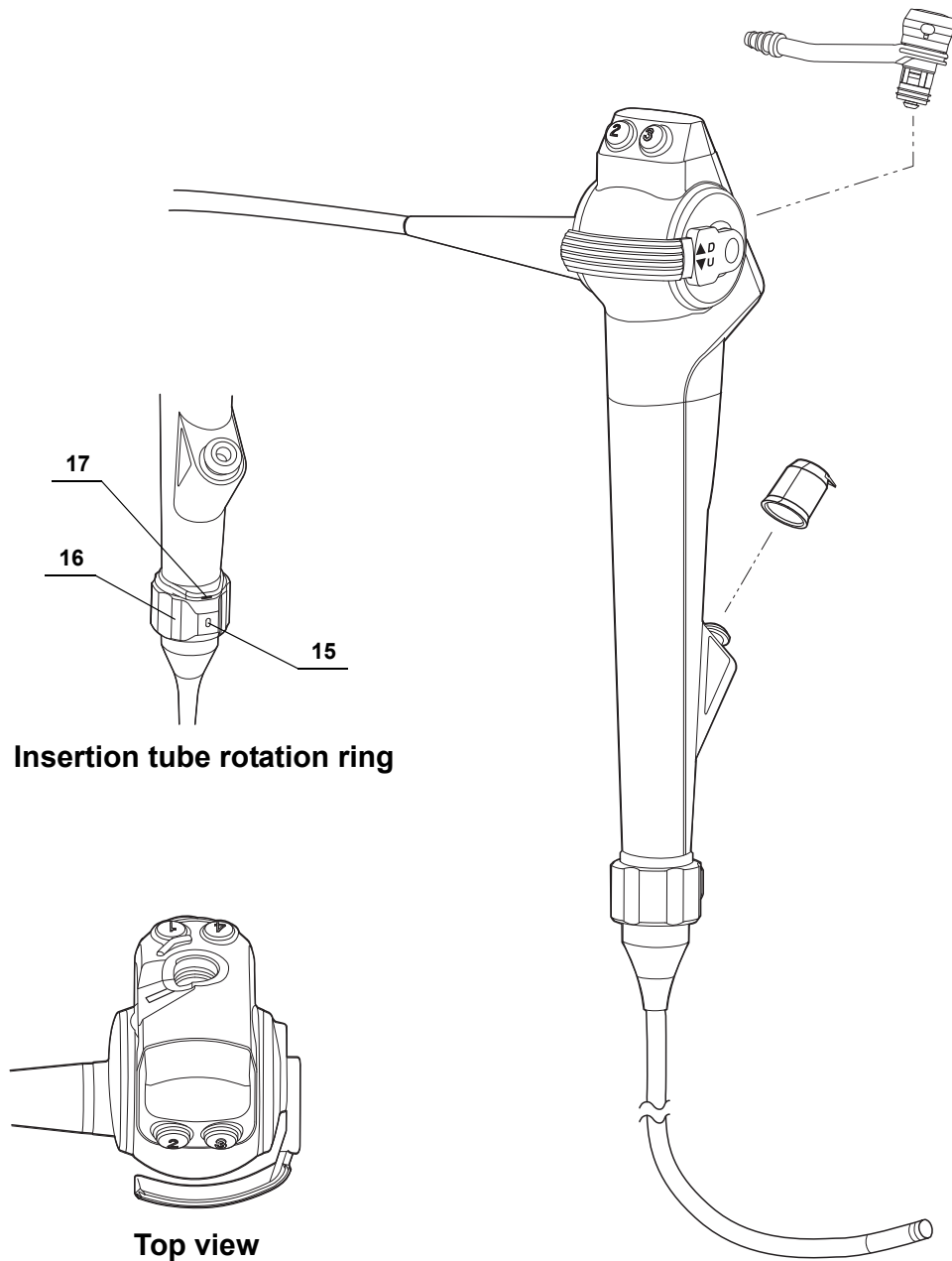


No.	Nomenclature	Description
1	UP/DOWN angulation control lever	When this lever is operated in the "U" direction, the bending section moves UP; when the lever is operated in the "D" direction, the bending section moves DOWN.
2	Single use suction valve (MAJ-209) or suction valve (MAJ-207*1)	The suction valve is depressed to activate suction. The valve is also used to remove any fluid or debris adhering to the objective lens.
3	Control section	Operates the endoscope, such as controlling angulation.
4	Single use biopsy valve (MAJ-210) or biopsy valve (MD-495*1)	This valve is attached to the instrument channel port, and an EndoTherapy accessory can be inserted or a syringe can be attached.
5	Instrument channel inlet	An EndoTherapy accessory can be inserted into this port. The instrument channel inlet is connected to the instrument channel outlet on the distal end via the instrument channel. The instrument channel functions are as follows: <ul style="list-style-type: none"> • Channel for the insertion of EndoTherapy accessories • Suction channel • Fluid feed channel (from a syringe via the biopsy valve)
6	Instrument channel port	Attach the biopsy valve to this port.
7	Color code	This color code and numeral show the compatibility of EndoTherapy accessories. <ul style="list-style-type: none"> • Blue: BF-Q190, BF-H190, BF-P190 • Yellow: BF-1TH190 • White: BF-XP190 The endoscope can be used with EndoTherapy accessories that have the same color code. For more information on combining the endoscope with particular EndoTherapy accessories, refer to "Combination equipment" on page 83 and the instruction manuals for the compatible accessories.
8	Boot	Protects the junction between the insertion tube and control section from bending.
9	Insertion section	This section is inserted into the patient body cavity. It can be rotated to the left and right at angles up to 120° respectively on the control section by rotating the insertion tube rotation ring.
10	Distal end	The objective lens and light guide lens are on this distal end.
11	Bending section	The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.
12	Insertion tube	Connects the control section and bending section.
13	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.
14	Suction cylinder	Attach the suction valve to this cylinder.

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

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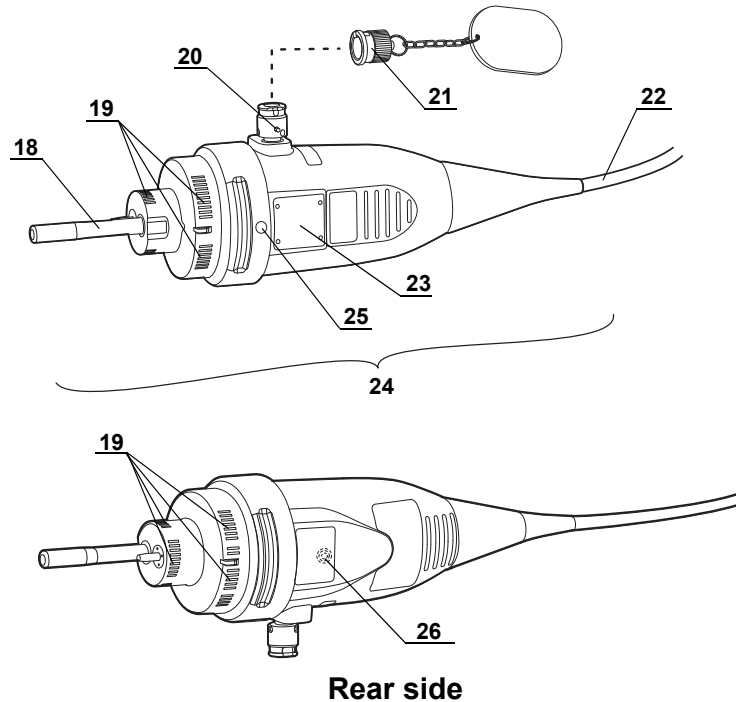


Insertion tube rotation ring

Top view

No.	Nomenclature	Description
15	UP indication	This indication shows the UP direction of the insertion tube. The direction of this indication is the same as the UP direction of the bending section. When returning the insertion tube to its neutral position, turn the insertion tube until the indication aligns with the “—” indication on the control section.
16	Insertion tube rotation ring	When the ring is turned in the right or left direction, the insertion tube turns in the same direction.
17	UP indication on the control section	This indication shows the neutral position of the insertion tube rotation ring when it is aligned with the UP indication of the insertion tube.

Endoscope connector



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No.	Nomenclature	Description
18	Light guide	Connects the endoscope to the light source and transmits light to the distal end of the endoscope.
19	Electrical contacts	Connect the light source and the endoscope electrically.
20	Venting connector	Attach the sterilization cap or leakage tester here.
21	Sterilization cap (MAJ-1538)	The sterilization 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 hospital (shipment, return for repairs, etc.).
22	Universal cord	Connects the endoscope connector and the control section.
23	Product (model) and serial number	The product name (model) and serial number are marked here.
24	Endoscope connector	Connects the endoscope to the light source to transmit light to the distal end of the endoscope and an accessory is connected to this connector. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-190. For more details, refer to the instruction manual for the CV-190.
25	UP mark	When the endoscope connector is connected to the light source, the "O" mark (UP mark) faces upward.
26	Scope ID mark	The RFID (radio frequency identification) chip for the endoscope identification information is embedded here.

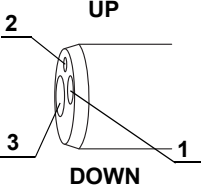
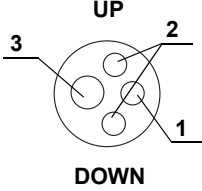
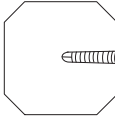
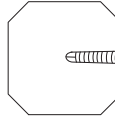
2.2 Specifications

■ Environment

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

Specifications

Model		BF-XP190	BF-P190
Optical system	Field of view	110°	110°
	Direction of view	0° (Forward viewing)	0° (Forward viewing)
	Depth of field	2 – 50 mm	2 – 50 mm
Insertion section	Distal end outer diameter	ø 3.1 mm (Tapered part of distal tip: ø 2.9 mm)	ø 4.2 mm
	Distal end enlarged 1 Objective lens 2 Light guide lens 3 Instrument channel outlet		
	Insertion tube outer diameter	ø 2.8 mm	ø 4.1 mm
	Insertion section working length	600 mm	600 mm
	Rotation range	Right: 120° Left: 120°	Right: 120° Left: 120°
	Instrument channel	Channel inner diameter	ø 1.2 mm
Minimum visible distance ^{*1}		1.5 mm	3 mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image			
Bending section	Angulation range	UP: 210° DOWN: 130°	UP: 210° DOWN: 130°
Total length		880 mm	880 mm
Pre-freeze function ^{*2}		Available	Available
Electronic zoom function ^{*2}		Not available	Not available
Electronic shutter function ^{*2}		Not available	Not available
Records of endoscope's information ^{*2}		Available	Available
NBI observation ^{*2}		Available	Available
High-frequency treatment		Not Compatible	Compatible
Laser treatment		Not Compatible	Not Compatible

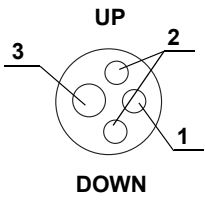
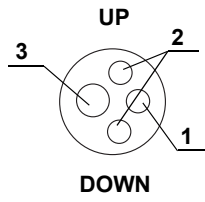
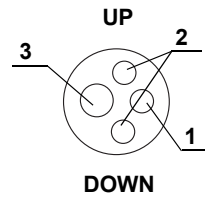
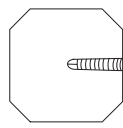
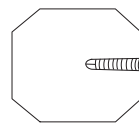
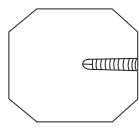
*1 Distance from the distal end of the endoscope.

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

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2.2 Specifications

Ch.2

Model		BF-Q190	BF-H190	BF-1TH190
Optical system	Field of view	120°	120°	120°
	Direction of view	0° (Forward viewing)	0° (Forward viewing)	0° (Forward viewing)
	Depth of field	3 – 100 mm	3 – 100 mm	3 – 100 mm
Insertion section	Distal end outer diameter	ø 4.8 mm	ø 5.5 mm	ø 6.2 mm
	Distal end enlarged 1 Objective lens 2 Light guide lens 3 Instrument channel outlet			
	Insertion tube outer diameter	ø 4.9 mm	ø 5.1 mm	ø 6.0 mm
	Insertion section working length	600 mm	600 mm	600 mm
	Rotation range	Right: 120° Left: 120°	Right: 120° Left: 120°	Right: 120° Left: 120°
	Instrument channel	Channel inner diameter	ø 2.0 mm	ø 2.0 mm
Minimum visible distance *1		3 mm	3 mm	3 mm
Direction from which EndoTherapy accessories enter and exit the endoscopic image				
Bending section	Angulation range	UP: 210° DOWN: 130°	UP: 210° DOWN: 130°	UP: 180° DOWN: 130°
Total length		880 mm	880 mm	880 mm
Pre-freeze function *2		Available	Available	Available
Electronic zoom function *2		Available	Available	Available
Electronic shutter function *2		Available	Available	Available
Records of endoscope's information *2		Available	Available	Available
NBI observation *2		Available	Available	Available
High-frequency treatment		Compatible	Compatible	Compatible
Laser treatment		Compatible	Compatible	Compatible

*1 Distance from the distal end of the endoscope.

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

Medical Devices Directive		 <p>This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a</p>
EMC	Applied standard	<p>IEC 60601-1-2: 2001 IEC 60601-1-2: 2007</p> <ul style="list-style-type: none"> • This instrument complies with the EMC standard for medical electrical equipment, edition 2 (IEC 60601-1-2: 2001) and edition 3 (IEC 60601-1-2: 2007). However, when connecting to an instrument that complies with the EMC standard for medical electrical equipment, edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1. • CISPR 11 of emission: Group 1, Class B
Year of manufacture		<p>The last digit of the year of manufacture is the second digit of the serial number. In this example, the year is 201<u>3</u>. Ex. 2<u>3</u>01234 (serial number)</p>
Degree of protection against electric shock		TYPE BF applied part
Ingress protection rating		IPX7

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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.

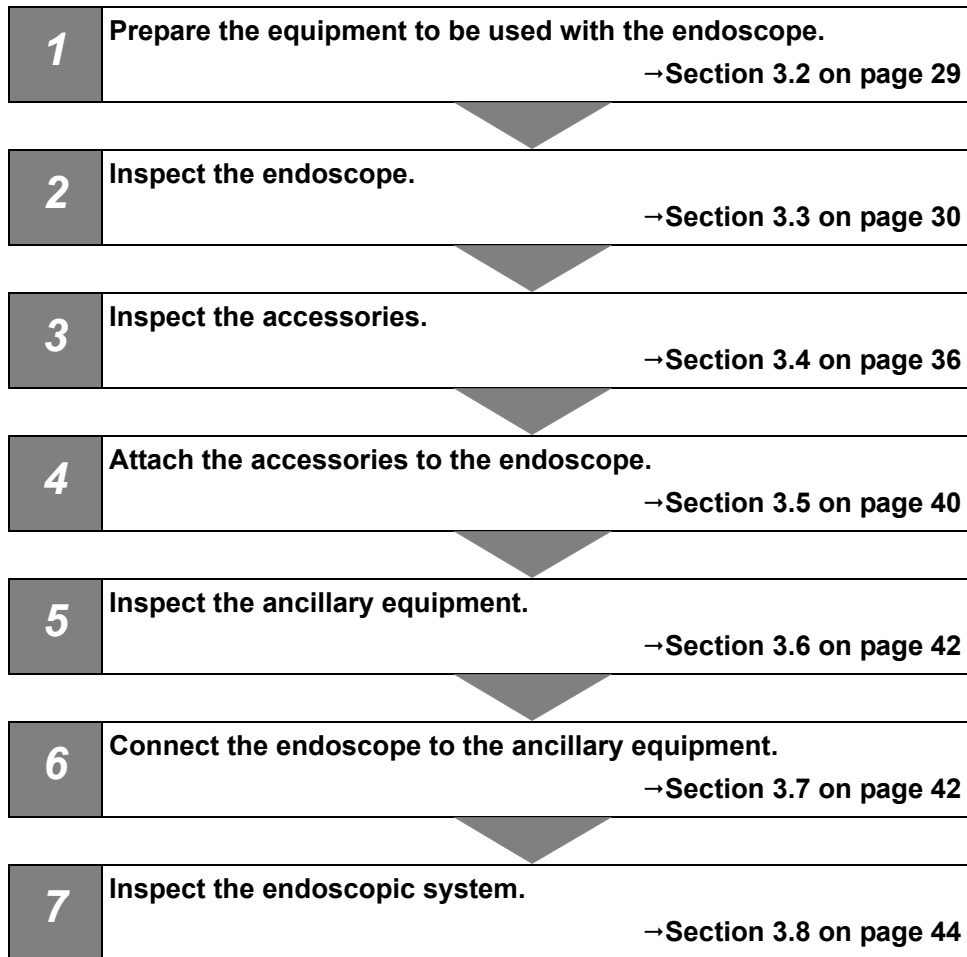
Before each case, prepare and inspect this endoscope as instructed below. Inspect other equipment to be used with this endoscope as instructed in their respective instruction manuals. Should any irregularity be observed after inspection, follow the instructions as described in Chapter 5, “Troubleshooting”.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

Ch.3**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.

3.1 The workflow of preparation and inspection

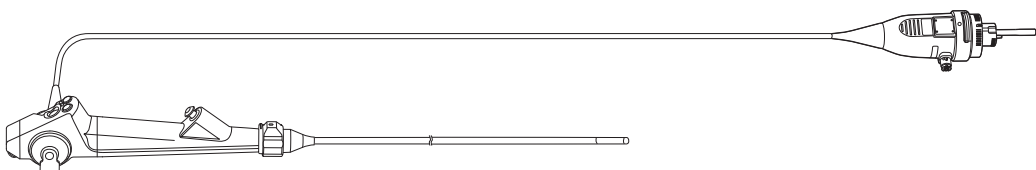
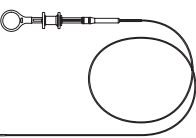
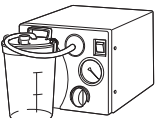

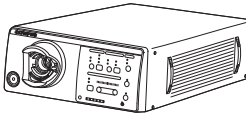
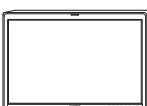
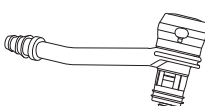






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3.2 Preparation of the equipment

Prepare this endoscope, the accessories, equipment, and all personal protective equipment as shown in Figure 3.1. Prepare the equipment in "Combination equipment" on page 83 in accordance with the intended use.

Also, refer to the respective instruction manuals for each piece of equipment before use.

<p>○ Endoscope</p>  <p style="text-align: center;">Endoscope*1</p>			
<p>○ Accessories and ancillary equipment</p>			
 <p>EndoTherapy accessories</p>	 <p>Suction pump</p>	 <p>Video system center</p>	 <p>Light source</p>
 <p>Monitor</p>	 <p>Suction valve (MAJ-207*2) or single use suction valve (MAJ-209)</p>	 <p>Biopsy valve (MD-495*2) or single use biopsy valve (MAJ-210)</p>	 <p>Mouthpiece (MA-651*2)</p>
<p>○ Personal protective equipment (e.g.)</p>			
 <p>Eyewear</p>	 <p>Face mask</p>	 <p>Moisture-resistant clothing</p>	 <p>Chemical-resistant gloves</p>

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○ Other	
<ul style="list-style-type: none">• Lint-free cloths• Containers for sterile water	<ul style="list-style-type: none">• 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 suction valve, mouthpiece, and biopsy valve that have been reprocessed as described in the “REPROCESSING MANUAL” with your endoscope model listed on the cover.

3.3 Inspection of the endoscope

Make sure that the UP indication on the insertion tube rotation ring is aligned with the UP indication on the control section.

CAUTION

Detach the sterilization cap (MAJ-1538) 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

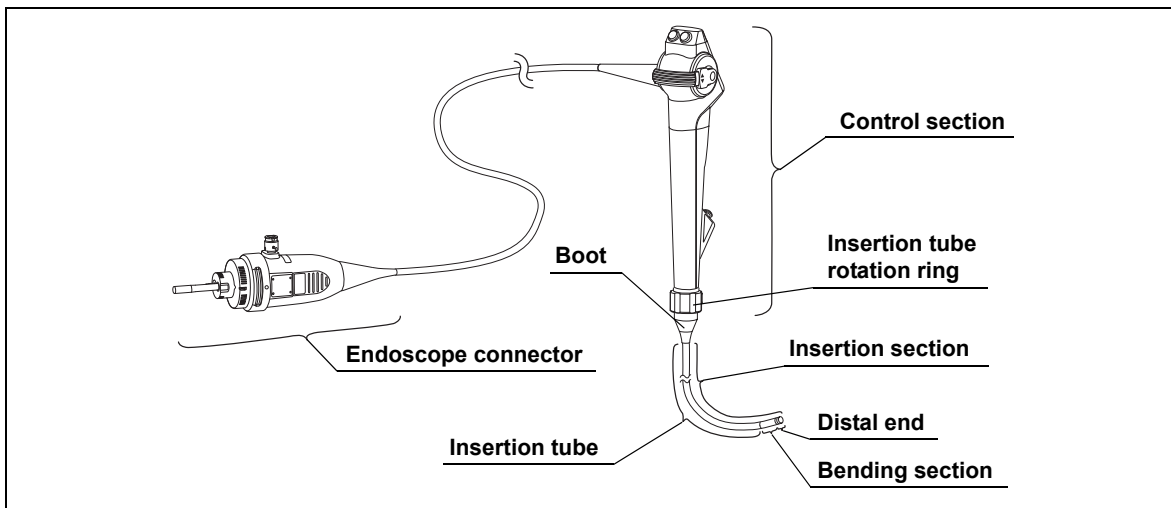


Figure 3.2

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

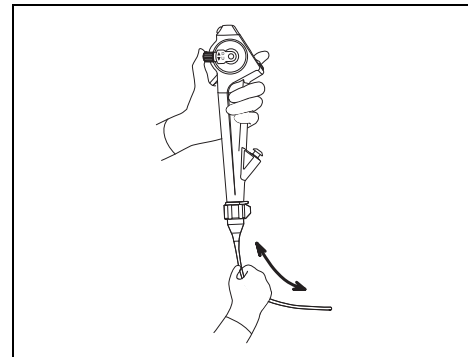


Figure 3.3

- 5** 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.

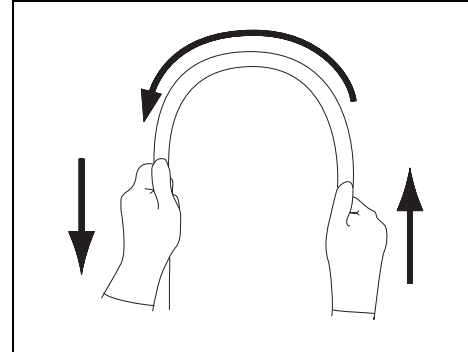


Figure 3.4

- 6** Gently hold the vicinity of the distal end and at the point 20 cm from the distal end. Push and pull gently to confirm that the junction between the bending section and the insertion tube is not loose.

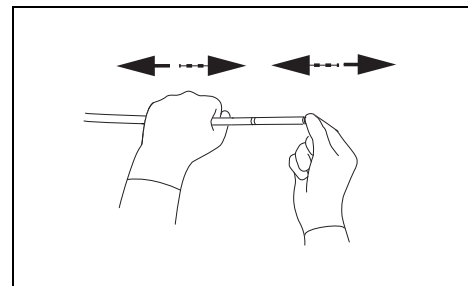


Figure 3.5

Ch.3

3.3 Inspection of the endoscope

- 7 Inspect the objective lens and light guide lens at the distal end of the endoscope's insertion section for scratches, cracks, stains, discoloration, deformation, gaps around the lens, or other irregularities. Also, inspect the entire distal end of the endoscope for chips or cracks.

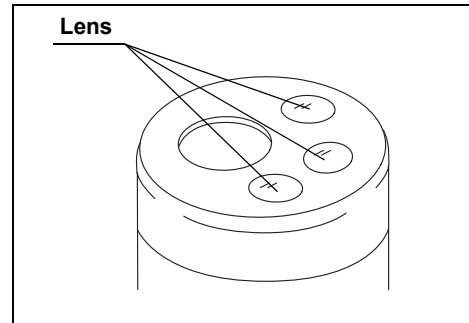


Figure 3.6

- 8 Inspect the adhesives attaching the bending section cover to the insertion section for deterioration, pitting or cracking. Also, inspect the bending section cover for bulges, swelling, scratches and holes.

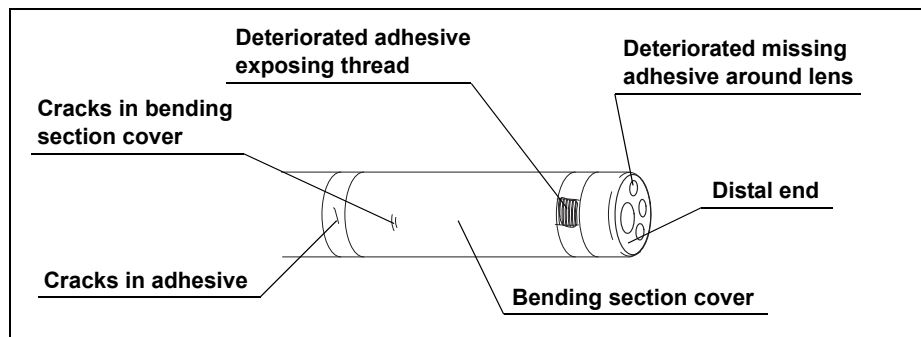


Figure 3.7

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.

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

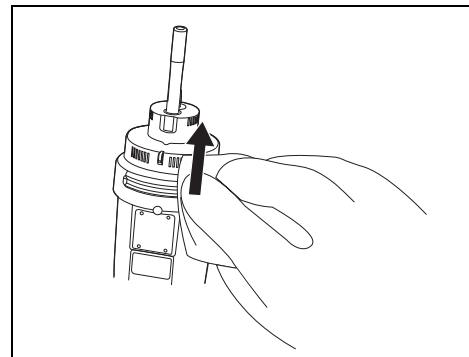


Figure 3.8

■ Inspection of the bending mechanism

Perform the following inspections while the bending section is straight.

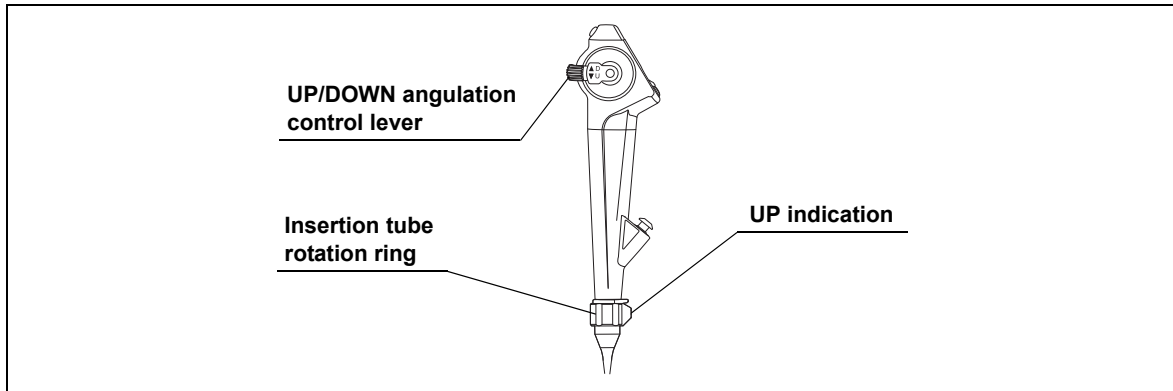


Figure 3.9

Ch.3

WARNING

- If the movement of the angulation control lever is loose and/or not smooth, or the bending section does not angulate smoothly, the bending mechanism may have an irregularity. In this case, do not use the endoscope because it may be impossible to straighten the bending section during an examination, and patient injury, bleeding, and/or perforation may result.
- When rotating the insertion section, the bending section bends to a different direction against the control section. Before operating the angulation control lever, make sure to check the position of the UP indication of the insertion tube rotation ring and endoscopic image. Otherwise, the bending section may bend to a different direction as intended and patient injury, bleeding, and/or perforation could result.

○ Inspection for smooth operation

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

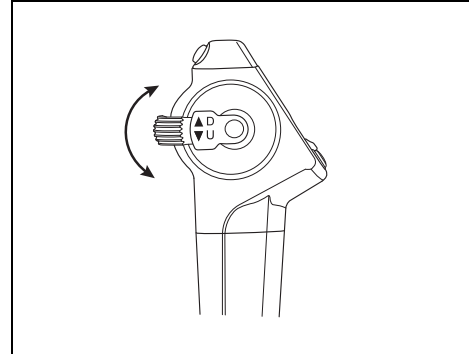


Figure 3.10

- 3 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.

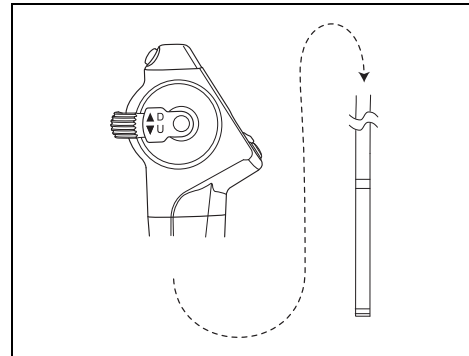


Figure 3.11

■ **Inspection of the insertion tube rotation mechanism**

WARNING

When rotating the insertion section, the bending section bends to a different direction against the control section. Before operating the angulation control lever, make sure to check the position of the UP indication of the insertion tube rotation ring. The bending section may bend to a different direction as intended and patient injury, bleeding, and/or perforation could result.

CAUTION

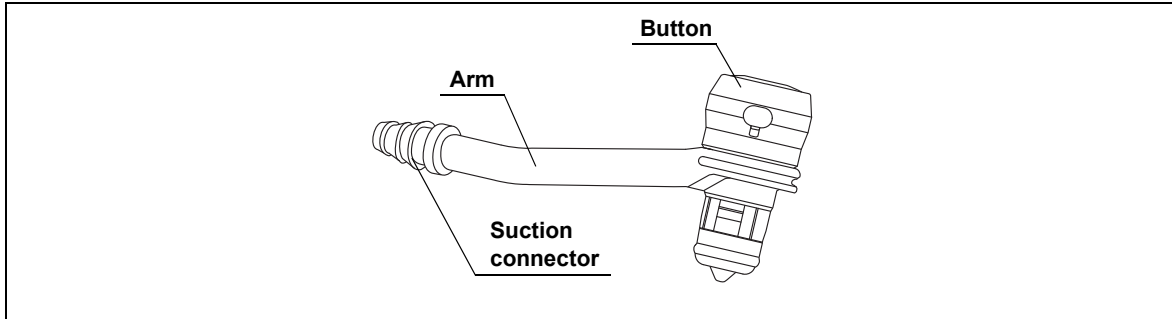
- Do not apply excessive force to the insertion tube rotation ring. The equipment may be damaged.
- Once the insertion tube and the insertion tube rotation ring hits against the stopper, do not apply excessive additional force. The insertion tube and the ring may be damaged.
- When rotating the insertion tube rotation ring, do not grip the bending section and/or the distal end of the endoscope with excessive force. The equipment may be damaged.
- When rotating the insertion tube rotation ring, do not apply excessive force holding the insertion section and/or the boot. The equipment may be damaged.

Ch.3

- 1** Straighten the insertion tube.
- 2** Turn the insertion tube rotation ring slowly in each direction until it stops. Confirm that the ring rotates in each direction smoothly and correctly.
- 3** Align the UP indication of the insertion tube rotation ring with the UP indication on the control section.

3.4 Inspection of accessories

■ Inspection of the suction valve (MAJ-207) or single use suction valve (MAJ-209)



Ch.3

Figure 3.12

WARNING

- Do not use the suction valve (MAJ-207) for more than six procedures.
- The single use suction valve (MAJ-209) is disposable. Do not attempt to reuse or resterilize it. The suction valve is provided in a sterile condition. Do not open the package until ready to use.

Inspect the suction valve (MAJ-207) or the single use suction valve (MAJ-209) as described in the suction valve's instruction manual.

■ Inspection of the biopsy valve (MD-495)

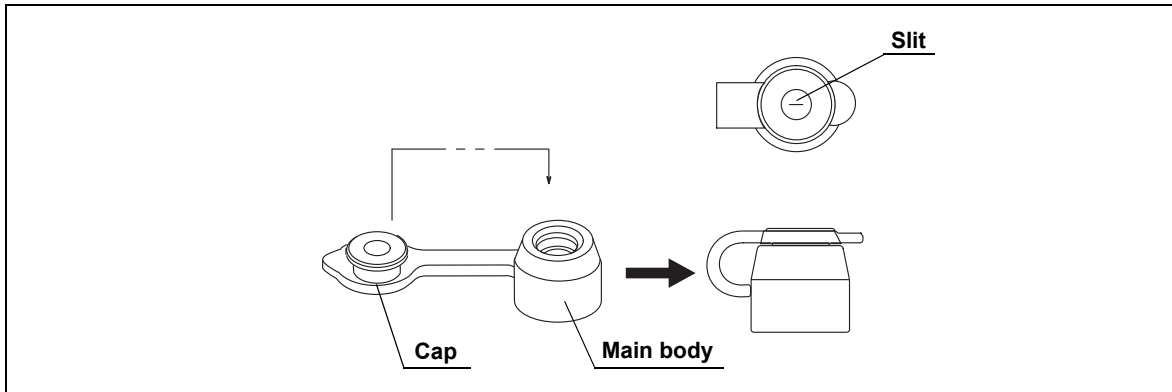


Figure 3.13

Ch.3

WARNING

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

Inspect the biopsy valve (MD-495) as described in the biopsy valve's instruction manual.

■ **Inspection of the single use biopsy valve (MAJ-210)**

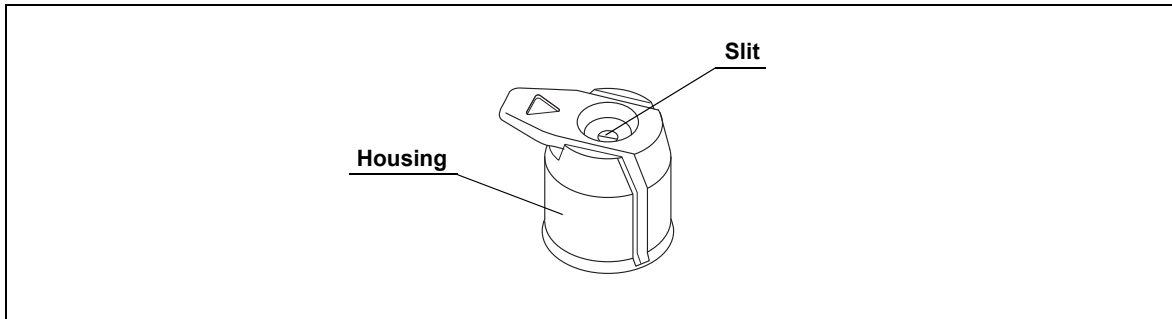


Figure 3.14

Ch.3

WARNING

- Do not use a single use biopsy valve after the expiration date displayed on the sterile package. Doing so may pose an infection control risk.
- Do not attempt to sterilize the single use biopsy valve. This could pose an infection control risk or cause equipment damage.

Inspect the single use biopsy valve (MAJ-210) as described in the single use biopsy valve's instruction manual.

■ Inspection of the mouthpiece (MA-651)

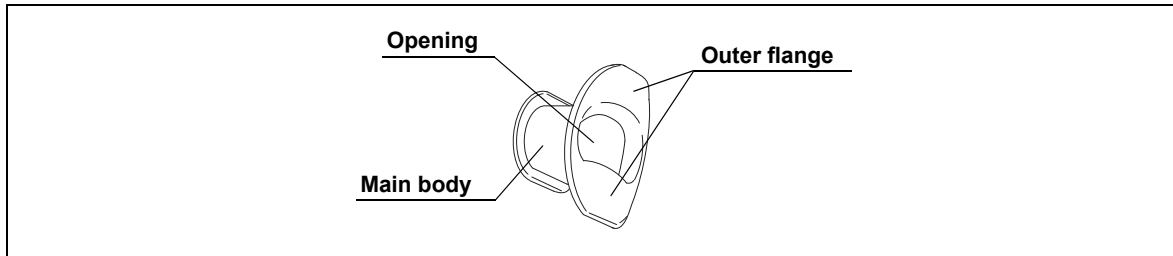


Figure 3.15

WARNING

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

Ch.3

NOTE

Placing the mouthpiece in the patient's mouth before the procedure prevents the patient from biting and/or damaging the endoscope's insertion section.

- 1** Confirm that the mouthpiece is free from cracks, deformation or discoloration.
- 2** Using your fingers, check all surfaces of the mouthpiece for scratches, cracks, or other irregularities.

3.5 Attaching accessories to the endoscope

■ Attaching the suction valve (MAJ-207) or the single use suction valve (MAJ-209)

WARNING

Firmly attach the suction valve to the suction cylinder. If the suction valve is attached to the endoscope improperly or a gap between the base of the suction valve and the top of the suction cylinder exists, the suction valve may detach from the endoscope and may cause patient debris to leak or spray from the gap.

Ch.3

CAUTION

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

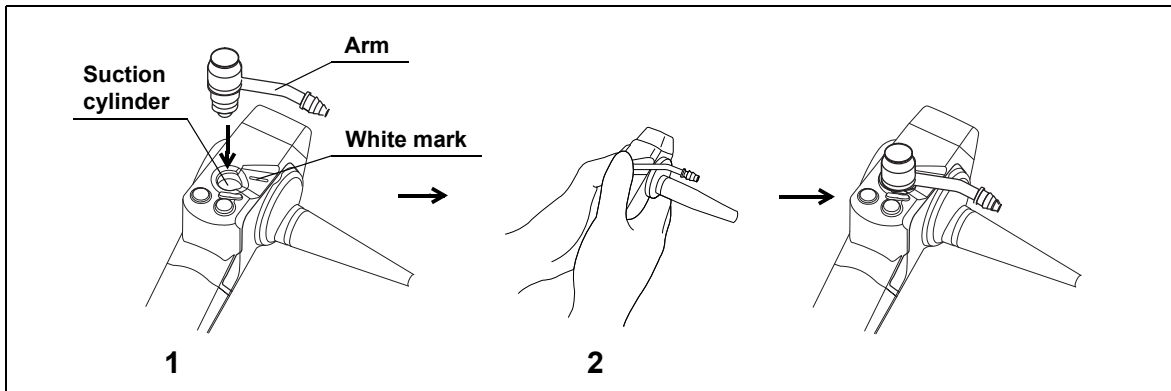


Figure 3.16

- 1 Place the suction valve into the suction cylinder, then align the arm of the main body with the white mark on the endoscope.
- 2 Press down on the suction valve's top surface with both thumbs until it "clicks" into place.

NOTE

Sometimes the suction valve will click before it is fully seated in the suction cylinder. Depress the suction valve into the suction cylinder until it fits completely to the suction cylinder without showing a gap.

- 3 Inspect and verify that the base of the valve is in contact with the suction cylinder properly. Improper attachment makes a gap between the base of the suction valve and the top of the suction cylinder.

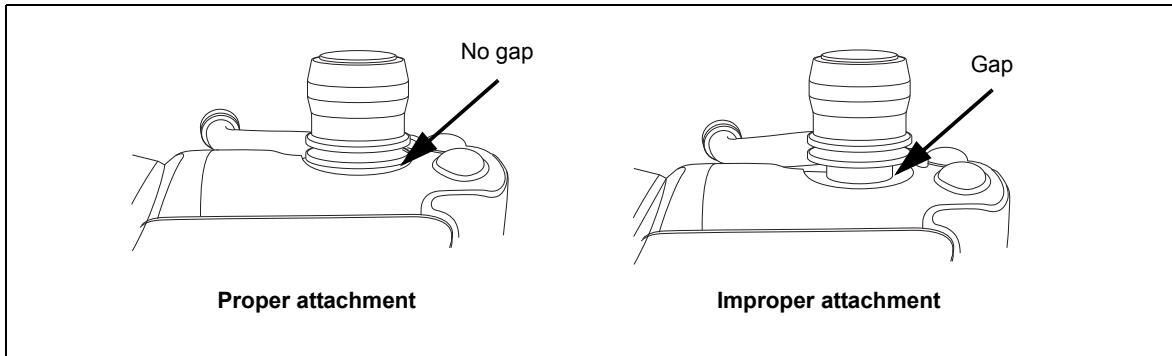


Figure 3.17

Ch.3

■ Attaching the biopsy valve (MD-495) or single use biopsy valve (MAJ-210)

WARNING

If a biopsy valve is not properly connected to the instrument channel port, it can reduce the efficacy of the endoscope's suction system and may cause patient debris to leak or spray from the endoscope.

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

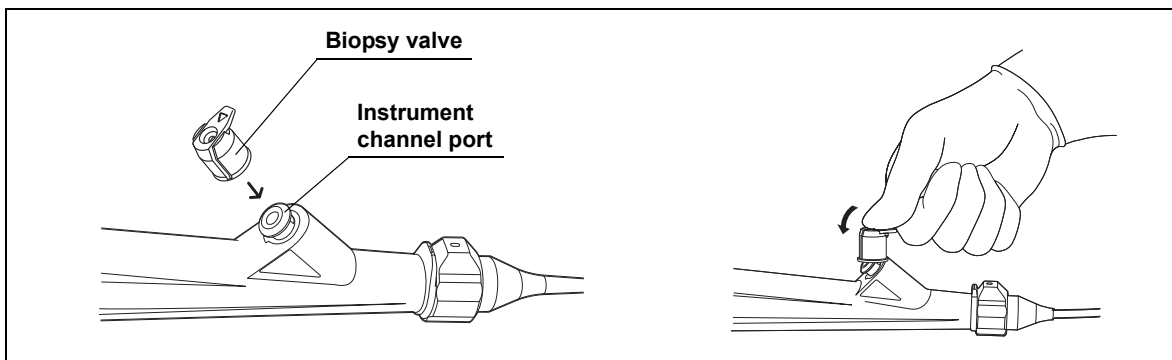


Figure 3.18

- 2 Confirm that the biopsy valve fits properly.

NOTE

At low temperature, the biopsy valve may become stiff and difficult to attach.

3.6 *Inspection of ancillary equipment*

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

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

Ch.3

3.7 *Connection of the endoscope and ancillary equipment*

Connect the ancillary equipment to the endoscope as described below.

■ *Connection to the light source*

WARNING

- If the endoscope connector and light source are not connected properly, the endoscopic image may flicker or may not be displayed. Continuous use of such an endoscope may cause patient injury, bleeding, and/or perforation.
- Firmly connect the suction tube from the suction pump to the suction connector on the suction valve. If the suction tube is not attached properly, debris may drip from the tube. The patient, operator and/or equipment could be contaminated and equipment malfunction can result.

CAUTION

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

- 1 If any ancillary equipment is ON, turn it OFF.
- 2 Hold the endoscope connector while the UP mark is facing upward.
- 3 Insert the endoscope connector completely into the output socket of the light source.

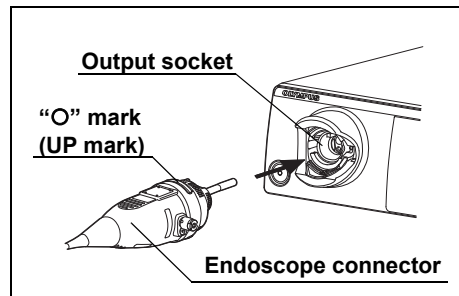


Figure 3.19

- 4 Push the connector until it clicks.
- 5 Confirm that the "O" mark (UP mark) on the endoscope connector is hidden by the light source.

Ch.3

■ Connection of the suction tube

WARNING

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

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

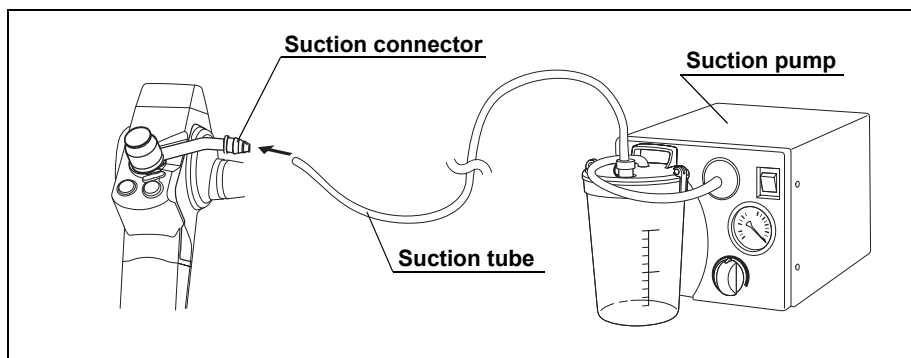
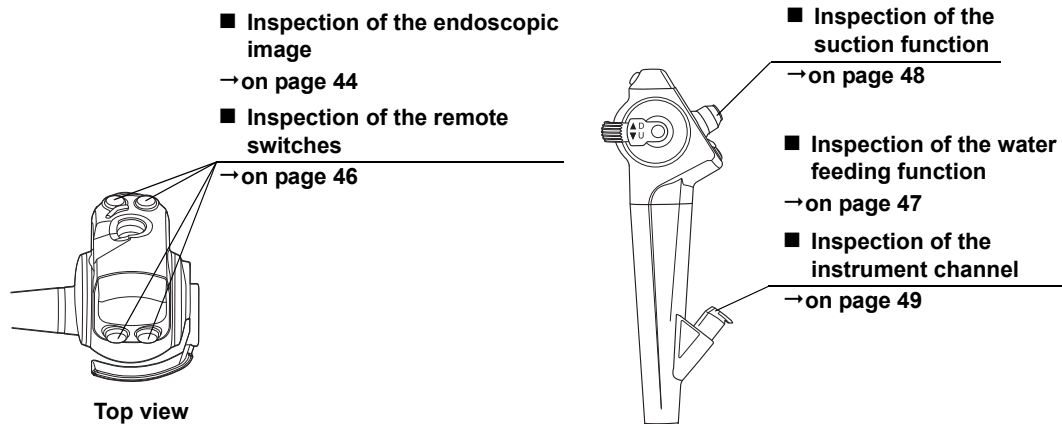


Figure 3.20

3.8 Inspection of the endoscopic system

■ Inspection summary

Ch.3



■ 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.

NOTE

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

- 1 Observe the palm of your hand using the WLI and NBI endoscopic images.

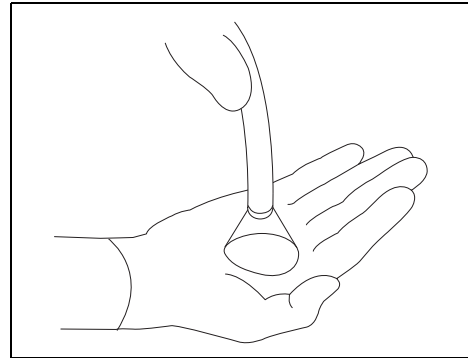


Figure 3.21

- 2 Confirm that light is output from the endoscope's distal end. (See Figure 3.21)
- 3 Adjust the brightness level as appropriate.
- 4 Confirm that the WLI and NBI endoscopic images are free from noise, blur, fog, or other irregularities.
- 5 Operate the UP/DOWN angulation control lever slowly in each direction until it stops.

Ch.3

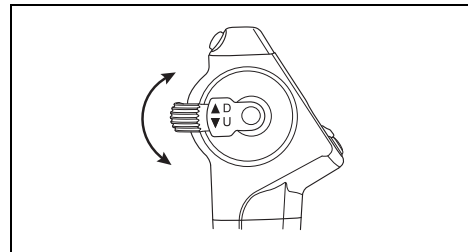


Figure 3.22

- 6 Turn the insertion tube rotation ring slowly in each direction until it stops.

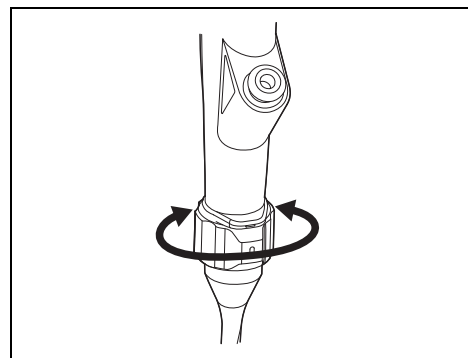


Figure 3.23

- 7 Confirm that the WLI and NBI endoscopic images do not momentarily disappear or display any other irregularities.
- 8 Align the UP indication of the insertion tube rotation ring with the UP indication on the control section.

■ **Inspection of the remote switches**

WARNING

Check that all remote switches work normally even if they are not expected to be used. Otherwise, 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.

Ch.3

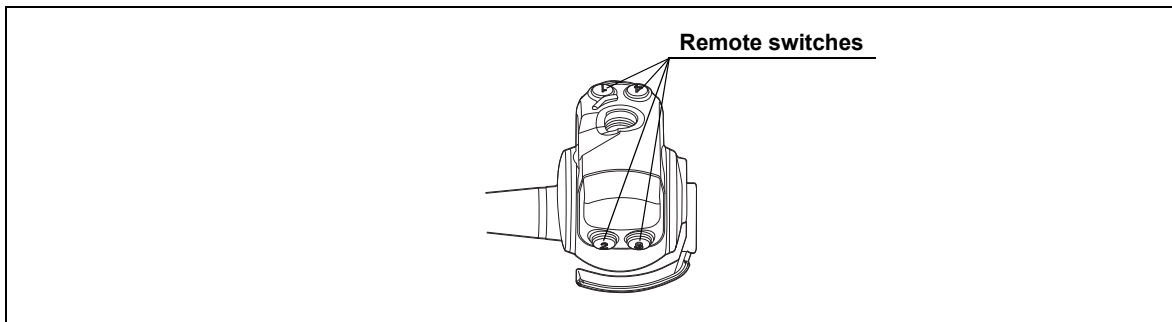


Figure 3.24

- 1** Depress every remote switch.
- 2** Confirm that the specified functions work normally.

■ **Inspection of the water feeding function**

- 1** Insert a syringe filled with sterile water into the biopsy valve.
- 2** Depress the plunger. Confirm that water is discharged from the distal end of the endoscope.

NOTE

- For proper operation, the syringe must be inserted fully and held perpendicular to the biopsy valve. Angled or incomplete insertion may result in fluid leakage from the biopsy valve.
- Do not depress the suction valve during water feeding. If the suction valve is depressed during water feeding, water will be aspirated into the suction tube instead of being discharged from the endoscope's distal end.
- If fluid is not discharged from the endoscope's distal end, flush air through the channel.

Ch.3

■ Inspection of the suction function

WARNING

- Set the aspiration pressure of the suction pump within the range of -34 kPa to 0 kPa. Excessive aspiration pressure may make it difficult to stop suction.
- If the suction valve does not operate smoothly, detach it and reattach it, or replace it with a new one. If the endoscope is used while the suction valve is not working properly, it may be impossible to stop suctioning, which could cause patient injury. If the reattached or replaced suction valve fails to operate smoothly, the endoscope may be malfunctioning; stop using it and contact Olympus.

Ch.3

- 1 Turn ON the suction pump.
- 2 Adjust the suction pressure within the range of -34 to 0 kPa.
- 3 Immerse the distal end of the insertion section in sterile water.

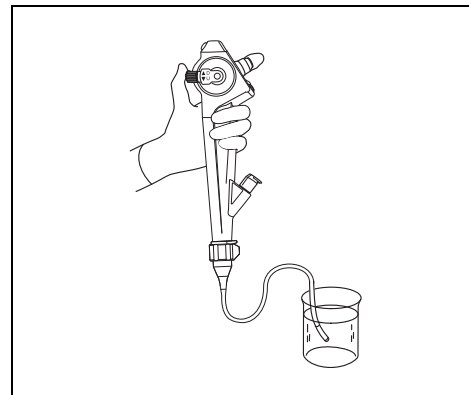


Figure 3.25

- 4 Depress the suction valve and confirm that water is continuously aspirated into the suction bottle on the suction pump.
- 5 Release the suction valve. Confirm that suction stops and that the suction valve returns smoothly to its original position.
- 6 Remove the distal end of the insertion section from the water. Depress the suction valve and aspirate air for a few seconds to remove water from the instrument channel and suction channel.

■ 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 eye injury.

CAUTION

- 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.

Ch.3

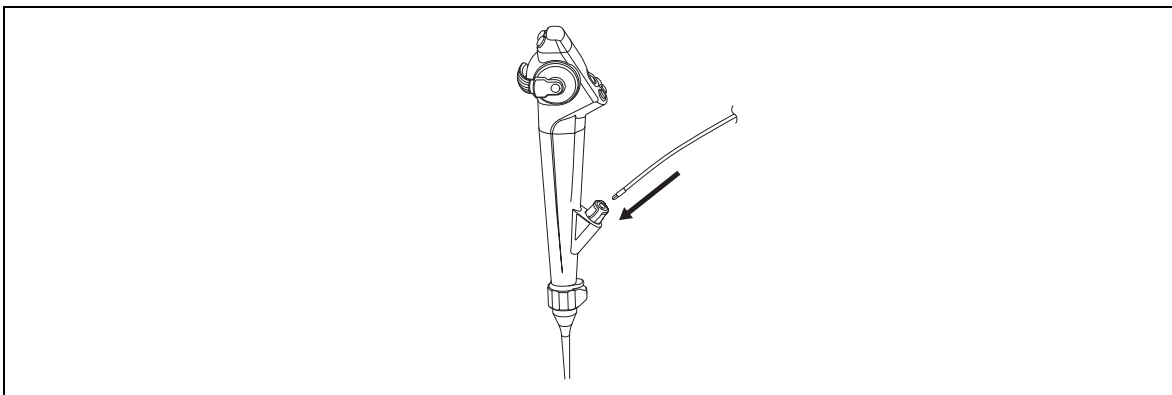


Figure 3.26

- 1 Straighten the insertion section of the endoscope.
- 2 Insert the EndoTherapy accessory straight through the biopsy valve while closing its distal end and retracting it into the sheath.
- 3 Confirm that the EndoTherapy accessory extends smoothly from the distal end of the endoscope. Also make sure that no foreign objects come out of the distal end.
- 4 Confirm that the EndoTherapy accessory can be withdrawn smoothly from the biopsy valve.

| 3.8 Inspection of the endoscopic system

Ch.3



Chapter 4 Operation

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

4.1 Warnings and cautions: operation

WARNING

- To guard against dangerous chemicals and potentially infectious materials during the procedure, wear personal protective equipment, such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination. Continued illumination will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.
- If significant resistance is felt during insertion, do not insert, withdraw or turn the insertion tube of the endoscope with excessive force. Patient injury, bleeding, and/or perforation may occur.
- 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.
- Transnasal insertion is accompanied by the risk of inflammation of the nasal cavity. If this happens, the nasal passage will be constricted, making it more difficult to withdraw the endoscope. In this case, do not use force to withdraw the endoscope because patient injury, bleeding, and/or perforation may result.

Ch.4

WARNING

- Transnasal insertion is accompanied by the risk of bleeding in the nasal cavity. Be sure to be prepared to deal with any bleeding. When withdrawing the endoscope, observe the inside of the nasal cavity to ensure that there is no bleeding. Even when the endoscope has been withdrawn without bleeding, do not allow the patient to blow his or her nose strongly because this could cause it to start bleeding.
- Before transnasal insertion, apply the appropriate pretreatment and lubrication to the patient to enlarge the nasal cavity. Otherwise, patient injury can result or the endoscope could become lodged and be difficult to withdraw. When applying a pretreatment agent through a tube, insert the tube into the same path as the path planned for the endoscope's insertion. Otherwise, the treatment will have no effect. The effects of the pretreatment agent and lubricant will decrease as the procedure lasts longer. Apply the pretreatment agent or lubricant as required during the procedure – for example, when withdrawal seems to be difficult.
- 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 the endoscopic image on the monitor appears blurry or foggy unexpectedly.
 - 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.
- 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.

WARNING

- When performing high-frequency cauterization, do not allow the external surface of the control section and its surroundings to become wet. Unintended leakage current may cause operator and/or patient injury.

NOTE

Set the brightness of the light source to the minimum level necessary to perform the procedure safely. If the endoscope is used for a prolonged period at or near maximum light intensity, vapor may be observed in the endoscopic image. This is caused by the evaporation of organic material (blood, etc.) due to heat generated by the light guide near the light guide lens. If this vapor continues to interfere with the examination, remove the endoscope, wipe the distal end with lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol, reinsert the endoscope and continue the examination.

Ch.4

4.2 Insertion

■ Holding and manipulating the endoscope

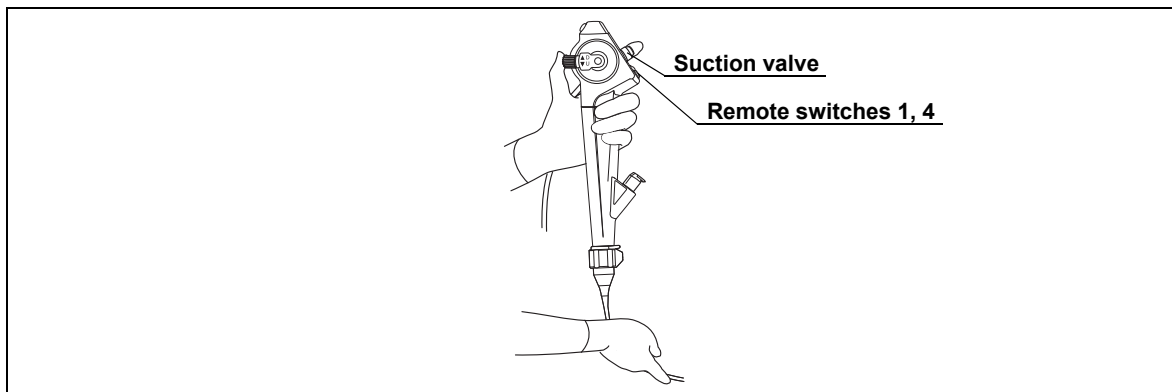


Figure 4.1

- 1** The control section of the endoscope is designed to be held in the left hand. The suction valve can be operated using the left index finger. The UP/DOWN angulation control lever can be operated using the left thumb.
- 2** Maintain the insertion section using the right hand.

■ **Insertion of the endoscope**

WARNING

- Make sure that the UP indication on the insertion tube rotation ring is aligned with the UP indication on the control section.
- The shape and size of the nasal cavity and its suitability for transnasal insertion may vary from patient to patient. No endoscope, including this one, can always be inserted transnasally into all patients. Before proceeding, always be sure to confirm that transnasal insertion is possible with the patient by considering both the size of the patient's nasal cavity as well as the size of the endoscope's insertion section. Otherwise, patient injury can result or the endoscope could become lodged and difficult to withdraw.
- Transnasal insertion of the endoscope should be performed carefully. If resistance to insertion is felt, or the patient reports pain, stop the insertion immediately. Otherwise, patient injury can result or the endoscope could become lodged and difficult to withdraw.

Ch.4

CAUTION

- When inserting the endoscope through the mouth, place the mouthpiece (MA-651) in the patient's mouth as necessary before inserting the endoscope to prevent the patient from accidentally biting the insertion section. Biting the insertion section may result in a break in the cable or malfunction of the light guide.
- When the patient has dental prostheses, remove them from the patient's mouth before placing a mouthpiece. Otherwise, the dental prostheses or mouthpiece may loosen during the examination.
- Confirm the patient's dental condition before using the mouthpiece. If any irregularity, such as teeth under treatment or lack of teeth is observed, the teeth may be broken.
- Do not apply 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.

CAUTION

- 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.

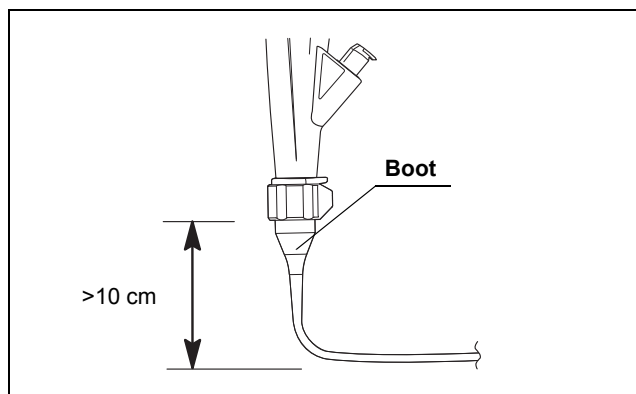


Figure 4.2

Ch.4

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

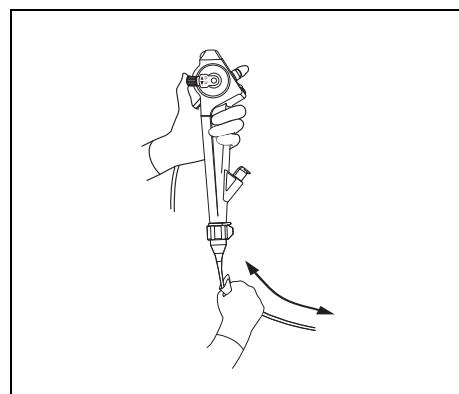


Figure 4.3

- 2** If necessary, insert the flexible endotracheal tube into the trachea to lead the endoscope smoothly.
- 3** Place the mouthpiece between the patient's teeth or gums, with the outer flange on the outside of the patient's mouth.
- 4** Insert the distal end of the endoscope through the opening of the mouthpiece, then from the mouth to the pharynx, while viewing the endoscopic image. When using an endotracheal tube, insert the endoscope into the endotracheal tube.

■ **Observation of the endoscopic image**

WARNING

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

NOTE

The color tone and brightness of the NBI observation mode is different from the WLI observation mode. Use the NBI observation only after fully understanding its features.

Ch.4

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

■ **Angulation of the distal end**

WARNING

- When rotating the insertion section, the bending section bends to a different direction against the control section. Before operating the angulation control lever, make sure to check the position of the projection of the insertion tube rotation ring. Otherwise, the bending section may bend to a different direction as intended and patient injury, bleeding, and/or perforation could result.
- Operate the UP/DOWN angulation control lever slowly while observing the endoscopic image. Otherwise, patient injury may result.

CAUTION

Avoid forcible or excessive angulation, as this imposes load on the wire controlling the bending section and may cause stretching or tearing of the wire and trouble in the action of the bending section.

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

■ **Operation of the insertion tube rotation**

WARNING

- When rotating the insertion section, the bending section bends to a different direction against the control section. Before operating the angulation control lever, make sure to check the position of the projection of the insertion tube rotation ring. Otherwise, the bending section may bend to a different direction as intended and patient injury, bleeding, and/or perforation could result.
- Do not turn the insertion tube rotation ring without viewing the endoscopic image. Patient injury, bleeding, and/or perforation may result.
- Do not turn the insertion tube rotation ring with excessive force while the UP/DOWN angulation control lever is locked. Patient injury, bleeding, and/or perforation may result.

CAUTION

- Do not apply excessive force to the insertion tube rotation ring. The equipment may be damaged.
- Once the insertion tube and the insertion tube rotation ring hits against the stopper, do not apply excessive additional force. The insertion tube and the ring may be damaged.
- When rotating the insertion tube rotation ring, do not grip the bending section and/or the distal end of the endoscope with excessive force. The equipment may be damaged.
- When rotating the insertion tube rotation ring, do not apply excessive force holding the insertion section and/or the boot. The equipment may be damaged.

Ch.4



Turn the insertion tube rotation ring as necessary to guide the endoscope for insertion and observation. Always check the UP indication of the insertion tube rotation ring that indicates the bending direction against the control section.

■ **Feeding fluids**

CAUTION

Do not depress the suction valve while feeding fluids. The fluids will be aspirated into the suction pump.

- 1** Securely insert a syringe into the slit of the biopsy valve.
- 2** Depress the plunger to feed fluids.

Ch.4



■ Suction

WARNING

- When aspirating, attach the biopsy valve to the instrument channel port. If the valve is not attached properly, it can reduce the efficacy of the endoscope's suction system and may cause patient debris to leak or spray. It can pose an infection control risk.
- For MD-495
When aspirating, attach the cap to the main body of the biopsy valve. An uncapped biopsy valve can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk.
- When aspirating, maintain the suction pressure at the lowest level necessary to perform the procedure. Excessive suction pressure could cause aspiration of and/or injury to the mucous membrane. In addition, patient fluids could leak or spray from the biopsy valve, posing an infection control risk.
- Avoid aspirating solid matter or thick fluids; channel or suction valve clogging can occur. If the suction valve clogs and suction cannot be stopped, disconnect the suction tube from the suction connector on the suction valve. Turn the suction pump OFF, detach the suction valve, and remove solid matter or thick fluids.

Ch.4

CAUTION

During the procedure, make sure that the suction bottle does not fill completely or overflow. Aspirating fluids into a full bottle may cause the suction pump to malfunction.

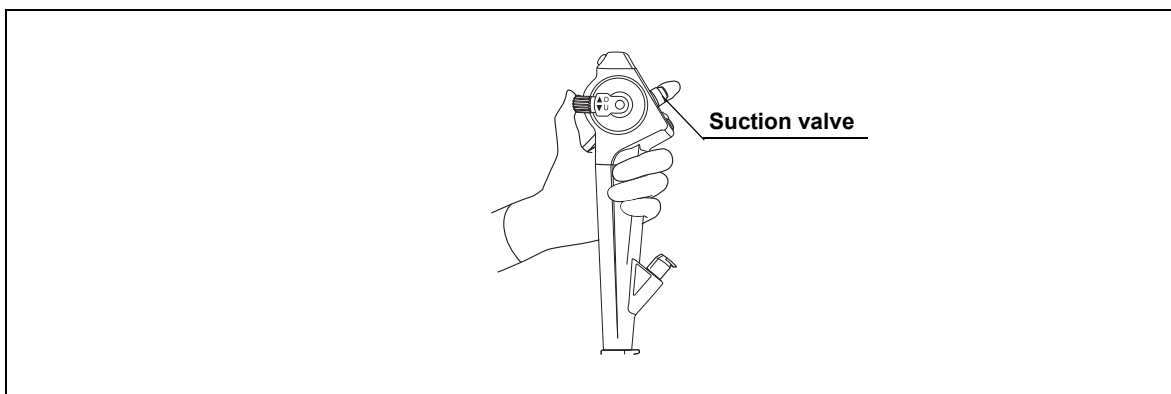


Figure 4.4

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

4.3 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to “■ Compatible EndoTherapy accessories” on page 86 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 slit of the biopsy valve. Otherwise, the biopsy valve or instrument channel may be damaged and pieces of it could fall off. It may cause patient injury.
- If insertion or withdrawal of EndoTherapy accessories is difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and could cause some parts to fall off and/or cause patient injury.
- If the distal end of an EndoTherapy accessory is not visible in the endoscopic image, do not open the distal end 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.
- Do not switch between WLI observation mode and NBI observation mode while using an EndoTherapy accessory. The endoscopic image may be disturbed while switching between WLI observation mode and NBI observation mode. This could cause patient injury, bleeding, and/or perforation.

Ch.4

CAUTION

- Select the EndoTherapy accessories compatible with the endoscope by referring to “Channel inner diameter” in “■ Specifications” on page 23.
- When using a biopsy forceps with a needle, confirm that the needle is not bent excessively. A bent needle could protrude from the closed cups of the biopsy forceps. Using such a biopsy forceps could damage the instrument channel and/or cause patient injury.
- When using an injector, be sure not to extend or retract the needle from the catheter of the injector until the injector is extended from the distal end of the endoscope. The needle could damage the instrument channel if extended inside the channel, or if the injector is inserted or withdrawn while the needle is extended.

NOTE

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

Ch.4

■ *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.
- For MD-495
When the biopsy valve's cap is detached from the main body, it is easier to insert an EndoTherapy accessory into the instrument channel port (see Figure 3.13). However, the open biopsy valve, after withdrawing an EndoTherapy accessory, can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk. When not using an EndoTherapy accessory, attach the cap to the main body of the biopsy valve.
- For MD-495
When the biopsy valve's cap is detached from the main body, it may cause patient debris or fluids to leak or spray from the endoscope, posing an infection control risk. When the biopsy valve's cap has to be detached, place a piece of sterile gauze over it to prevent leakage.
- Do not let the EndoTherapy accessory hang down from the biopsy valve, which can create a space between the accessory and the valve's slit or hole. This can damage the valve, which can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk.

WARNING

- When inserting an EndoTherapy accessory, hold it close to the biopsy valve and insert it slowly and straight into the biopsy valve. Otherwise, the EndoTherapy accessory and/or biopsy valve could be damaged. This can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk.

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.
- Hold the EndoTherapy accessory close to the slit of the biopsy valve and insert it straight into the slit using slow short strokes. Otherwise, the EndoTherapy accessory could bend or break.
- Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while the accessory is in the instrument channel. The instrument channel and/or the EndoTherapy accessory may become damaged.
- When the endoscope is bent at a sharp angle and the bending section and/or the insertion tube appear in the endoscopic image, be sure not to extend the EndoTherapy accessory from distal end of the endoscope. Equipment damage may result.

Ch.4

- 1** Select EndoTherapy accessories compatible with the endoscope from “Compatible EndoTherapy accessories” on page 86 and the accessories' instruction manuals for operating instructions.
- 2** Hold the UP/DOWN angulation control lever stationary.

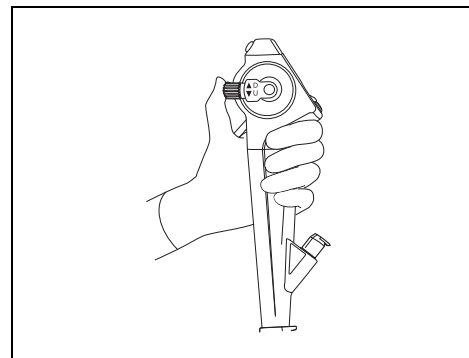


Figure 4.5

- 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 slit of the biopsy valve.

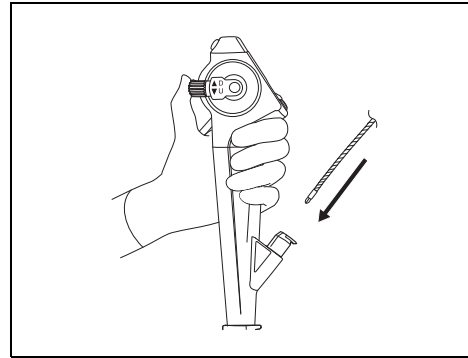


Figure 4.6

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

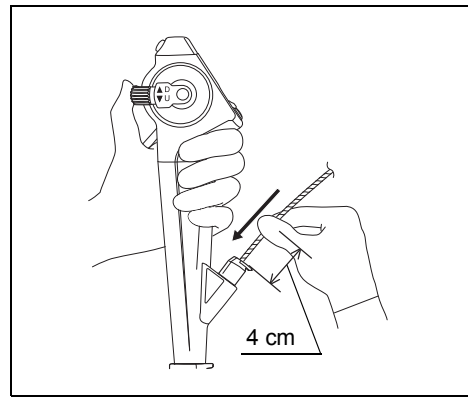


Figure 4.7

NOTE

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

Ch.4

■ **Operation of EndoTherapy accessories**

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

■ **Withdrawal of EndoTherapy accessories**

WARNING

- Do not withdraw the EndoTherapy accessory if the tip is open or extended from its sheath; patient injury, bleeding, perforation and/or endoscope damage may occur.
- Fluid might spray when the EndoTherapy accessories are withdrawn from the biopsy valve. To prevent this, hold a piece of gauze around the accessory and the slit of the biopsy valve during withdrawal.
- Withdraw the EndoTherapy accessory slowly and straight out of the biopsy valve. Otherwise, the biopsy valve could be damaged. This can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris, 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.

Ch.4

■ High-frequency cauterization treatment

Endoscope model: all models except BF-XP190

WARNING

- Never use the high-frequency EndoTherapy accessories for the BF-XP190 because the distal end of the BF-XP190 is not insulated. Patient injury may 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.
- 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.

Ch.4

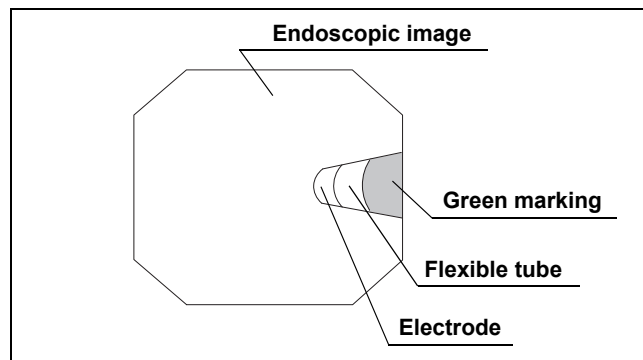


Figure 4.8

- Be sure to contact the electrode section of the high-frequency 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.
- Do not perform high-frequency cauterization without gloves. Operator injury can result.

WARNING

- 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 can 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.

NOTE

- Some Olympus endoscopes are equipped with a feedback circuit to lead leakage current from the endoscope to the electrosurgical unit. However, the BF-190 series endoscopes are not equipped with a feedback circuit, because leakage current from the electrosurgical accessory to the endoscope is minimal as the insertion tube is short. Therefore, the S-cord is unnecessary when using the BF-190 series endoscopes.
- The application of high-frequency current may interfere with the endoscopic image. This does not indicate a malfunction.

Ch.4

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

■ Argon plasma coagulation (APC)

Endoscope model: all models except BF-XP190

WARNING

- The argon gas itself is neither combustible nor a promoter of combustible substances, but the argon plasma is very hot and could ignite combustible substances. Flammable substances burn easily when argon is irradiated in the presence of combustible gas such as high-concentration or pure oxygen. Be sure to observe the following cautions.
 - Before and during APC, do not feed oxygen or other combustible gases and liquids into the tracheobronchial system.
 - If it is required to activate APC for a few seconds, change between APC and oxygen feeding.
 - Keep the distal end of the APC probe in the endoscopic image before and during activation. Never activate APC in a position you cannot observe.
- Do not perform APC without gloves. Operator injury can result.
- Always confirm that the tissue is an appropriate distance away from the distal end of the endoscope. If APC is performed with the distal end of the endoscope in contact with the tissue, patient injury may occur.
- Make sure that the distal end of the APC probe always lies more than 10 mm from the endoscope's distal end (see Figure 4.9). The protrusion by 10 mm or more can be identified when the first black ring on the APC probe's distal end is visible in the endoscopic image. Otherwise, the treated region cannot be irradiated correctly and the endoscope may be damaged. Using a damaged endoscope may cause patient injury.

Ch.4

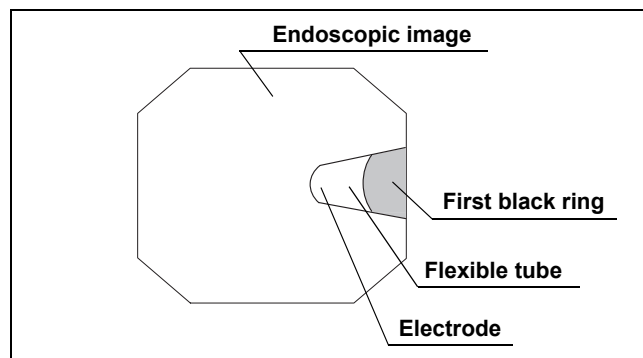


Figure 4.9

- Make sure that the patient plate is properly attached to patient's skin. Improper connection between the patient plate and patient's skin surface may cause burns. For further details on patient plates, refer to the patient plate's instruction manual.

4.3 Using EndoTherapy accessories

WARNING

- Do not bring the distal end of the APC probe close to a metal stent. The tissue around the metal stent may be burned.
- Set the APC 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 patient and/or operator burns.
- Before performing APC, inspect the surface of the endoscope for any dents, bulges or other irregularities. The endoscope may be damaged and cause patient and/or operator burns.

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

Ch.4

NOTE

- The outer surfaces of the BF-190 series endoscopes except the BF-XP190 are insulated. This allows APC to be performed.
- Some Olympus endoscopes are equipped with a feedback circuit to lead leakage current from the endoscope to the electrosurgical unit. However, the BF-190 series endoscopes are not equipped with a feedback circuit because leakage current from the electrosurgical accessory to the endoscope is minimal as the insertion tube is short. Therefore, the S-cord is unnecessary when using the BF-190 series endoscopes.

■ **Laser cauterization**

Endoscope model: all models except BF-P190 and BF-XP190

WARNING

- The BF-P190 and the BF-XP190 are incompatible with laser cauterization. Performing laser cauterization may cause patient injury and/or equipment damage.
- Do not perform laser cauterization while supplying oxygen. This may result in combustion during cauterization.
- To avoid patient injury, burns, bleeding, perforation and/or damage to the endoscope, never emit laser radiation before confirming that an appropriate distance between the target and the endoscope's distal end is maintained and the tip of the laser probe is surely in the correct position in the endoscopic image.
- Always wear protective eyewear when performing laser cauterization. Otherwise, operator injury may occur.

Ch.4

CAUTION

- Before inserting or withdrawing the laser probe, return the UP/DOWN angulation control lever to its neutral position so that the bending section will be straight. If it is bent, the instrument channel and/or the laser probe may be damaged.
- Allow the tip of the laser probe to cool down before pulling it from the channel. If the laser probe is withdrawn while hot, channel damage may occur.
- Do not use a damaged laser probe. A laser probe with a damaged sheath or distal end may cause patient injury and/or equipment damage.
- When using guide light of the laser unit, to avoid halation of the endoscopic image, set the guide light output of laser unit to the minimum necessary.

NOTE

The application of laser cauterization may change the color tone of the endoscopic image. This does not indicate a malfunction.

Prepare, inspect and connect the laser unit and laser probe as described in their instruction manuals.

■ **Ultrasonic observation**

Endoscope model: all models except BF-XP190

WARNING

- When withdrawing the ultrasonic probe with balloon sheath from the endoscope, make sure that the balloon is completely deflated. Withdrawing the probe while the balloon is inflated could result in patient injury and/or damage the ultrasonic probe.
- When using the ultrasonic probe with balloon sheath, always lubricate the balloon with a medical-grade, water-soluble lubricant before inserting the balloon sheath into the instrument channel. Otherwise, the balloon could rupture or come off. This could result in patient injury.

Prepare inspect and connect the ultrasonic observation unit and ultrasonic probe as described in their instruction manuals.

Ch.4

NOTE

The ultrasonic probe with balloon sheath can be used in combination with the BF-1TH190.

■ Bronchoalveolar lavage

○ Using the BAL (bronchoalveolar lavage) kit

- 1 Disconnect the suction tube from the suction valve. Connect the suction tube to the suction connector of a commercially available BAL kit. Connect the BAL kit's suction line to the suction connector of the suction valve.

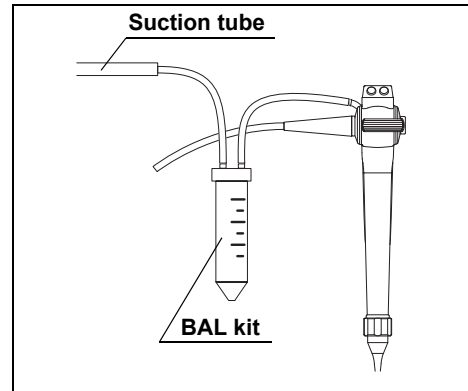


Figure 4.10

Ch.4

- 2 Securely insert a syringe filled with lavage fluid (e.g., saline) into the slit of the biopsy valve and press the plunger to feed lavage fluid.
- 3 Depress the suction valve to aspirate lavage fluid.

○ Using a syringe

CAUTION

Angled or incomplete insertion may result in leakage of solution from the valve.

- 1 Securely insert a syringe into the slit of the biopsy valve.
- 2 Press the plunger to feed lavage fluid.

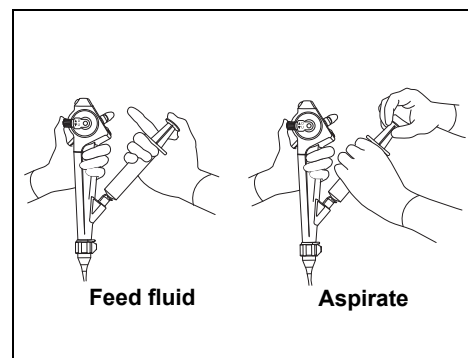


Figure 4.11

- 3 With the syringe attached, slowly withdraw the plunger to aspirate lavage fluid.

4.4 *Withdrawal of the endoscope*

WARNING

- If blood unexpectedly adheres to the surface of the insertion section of the withdrawn endoscope, carefully check the condition of the patient.
- If it becomes impossible to withdraw the transnasally inserted endoscope, pull its distal end out of the mouth, cut the flexible tube using wire cutters, and after ensuring that the cut section will not injure the body cavity or nasal cavity of the patient, withdraw the endoscope carefully. Therefore, always prepare wire cutters in advance.
- 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 irregularity with the endoscope is 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.

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- 1** When using the electronic zoom function of the video system center, release the function.
- 2** Aspirate blood, mucus, or other debris by depressing the suction valve.
- 3** Carefully withdraw the endoscope while observing the endoscopic image.
- 4** Remove the mouthpiece from the patient's mouth.
- 5** Reprocess the endoscope and accessories after the procedure as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.

4.5 Transportation of the endoscope

■ *Transporting within the hospital*

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

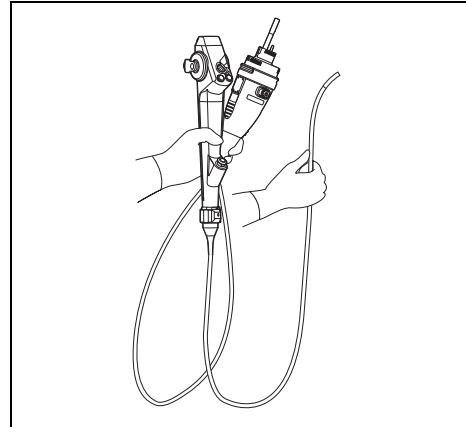


Figure 4.12

Ch.4

■ *Transporting outside the hospital*

WARNING

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

CAUTION

- Use a dedicated carrying case. Transporting the endoscope in another carrying case may cause equipment damage.
- The carrying case cannot be reprocessed. Reprocess the endoscope before placing it in the carrying case.
- Attach the sterilization cap (MAJ-1538) when transporting the endoscope. Otherwise, the endoscope may be damaged by changes in air pressure.

Transport the endoscope in the carrying case.

4.5 Transportation of the endoscope

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Chapter 5 Troubleshooting

The countermeasure 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.

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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
The image is not displayed.	Not all equipment is ON.	Turn ON all equipment.
	The endoscope connector is not connected securely.	Connect the endoscope connector securely until it stops and clicks.
	Foreign objects such as detergent remnants, hard water residue, finger grease, dust, and lint are on the electrical contacts on the endoscope connector.	Wipe the electrical contacts on the endoscope connector using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol and completely dry them as described in Section 3.3, "Inspection of the endoscope". After drying them, connect the endoscope to the light source and confirm that a proper image is displayed when twisting the endoscope connector left and right.
The image is not clear.	The objective lens at the distal end of the endoscope is dirty.	Wipe the objective lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
The image is excessively dark or bright.	The light guide lens at the distal end of the endoscope is dirty.	Wipe the light guide lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
	The glass at the endoscope connector end is dirty.	Wipe the glass with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
	The light source is not set properly.	Adjust the light source's setting as described in its instruction manual.

Irregularity description	Possible cause	Solution
The image is not proper.	An incompatible video system center is being used.	Use a compatible video system center.
	An incompatible light source is being used.	Use a compatible light source.
	Foreign objects such as detergent remnants, hard water residue, finger grease, dust, and lint are on the electrical contacts on the endoscope connector.	Wipe the electrical contacts on the endoscope connector using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol and completely dry them as described in Section 3.3, "Inspection of the endoscope". After drying them, connect the endoscope to the light source and confirm that a proper image is displayed when twisting the endoscope connector left and right.

■ Water feeding

Irregularity description	Possible cause	Solution
The fluid is leaking from the biopsy valve.	The biopsy valve is attached incorrectly.	Attach it correctly. Close the valve's cap (for MD-495).
	The syringe is not inserted securely.	Insert it securely.
The biopsy valve cannot be attached.	An incorrect biopsy valve is used.	Use a correct biopsy valve.
	The biopsy valve is damaged.	Replace it with a new one.

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■ Suction

Irregularity description	Possible cause	Solution
The suction function is absent or insufficient.	The biopsy valve is attached incorrectly.	Attach it correctly. Close the valve's cap (for MD-495).
	The biopsy valve is damaged.	Replace it with a new one.
	The suction pump is not set properly.	Adjust the suction pump's setting as described in its instruction manual.
	The suction valve is damaged.	Replace it with a new one.
The suction valve is sticking.	The suction valve is damaged.	Replace it with a new one.
The suction valve does not return to its original position.	The aspiration pressure is too high.	Lower the aspiration pressure.
The suction valve cannot be attached.	An incorrect suction valve is used.	Use a correct suction valve.
	The suction valve is damaged.	Replace it with a new one.

■ EndoTherapy accessories

Irregularity description	Possible cause	Solution
The EndoTherapy accessory does not pass through the instrument channel smoothly.	An incompatible EndoTherapy accessory is being used.	Refer to "■ System chart" on page 83 and select a compatible EndoTherapy accessory. Confirm that the color code on the EndoTherapy accessory matches that on the endoscope.
	The bending section angulates sharply.	Straighten it as much as possible.

■ Others

Irregularity description	Possible cause	Solution
The remote switch does not work.	The wrong remote switch is operated.	Operate the correct remote switch.
	The remote switch function has been set incorrectly.	Set the remote switch function correctly as described in the video system center's instruction manual.
	The remote switch is left depressed due to a difference between internal and external pressures of the endoscope that is made in the pressure reduction process of gas sterilization.	If the sterilization cap is attached to the venting connector, detach it. If not, attach the sterilization cap to the venting connector once and then detach it.

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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” on page 80 or “■ Withdrawal when no endoscopic image appears on the monitor or a frozen image cannot be restored” on page 80.

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

WARNING

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

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

- 1** Turn all equipment OFF except the video system center, light source, monitor, and suction pump.
- 2** When the NBI endoscopic image is displayed, switch to the WLI endoscopic image by operating the video system center and light source.
- 3** When using the electronic zoom function of the video system center, release the function.
- 4** When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly.
- 5** Aspirate accumulated air, blood, mucus, or other debris by depressing the suction valve.
- 6** Carefully withdraw the endoscope while observing the endoscopic image.
- 7** Remove the mouthpiece from the patient’s mouth.

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

- 1** Turn all equipment OFF except the video system center, light source, 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 given in “■ Withdrawal when the WLI and NBI endoscopic images appear on the monitor”, beginning from Step 3. Carefully withdraw the endoscope under the visible observation mode when the WLI endoscopic image is not displayed.
- 4** Remove the mouthpiece from the patient’s mouth.

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

Ch.5

- 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** Operate the UP/DOWN angulation control lever to its neutral position and release the angulation control lever.
- 6** Withdraw the endoscope from the patient carefully.
- 7** Remove the mouthpiece from the patient’s mouth.

5.4 *Returning the endoscope for repair*

WARNING

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

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 hospital” on page 73.

Ch.5

5.4 Returning the endoscope for repair

Ch.5



Appendix

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

Combination equipment

■ System chart

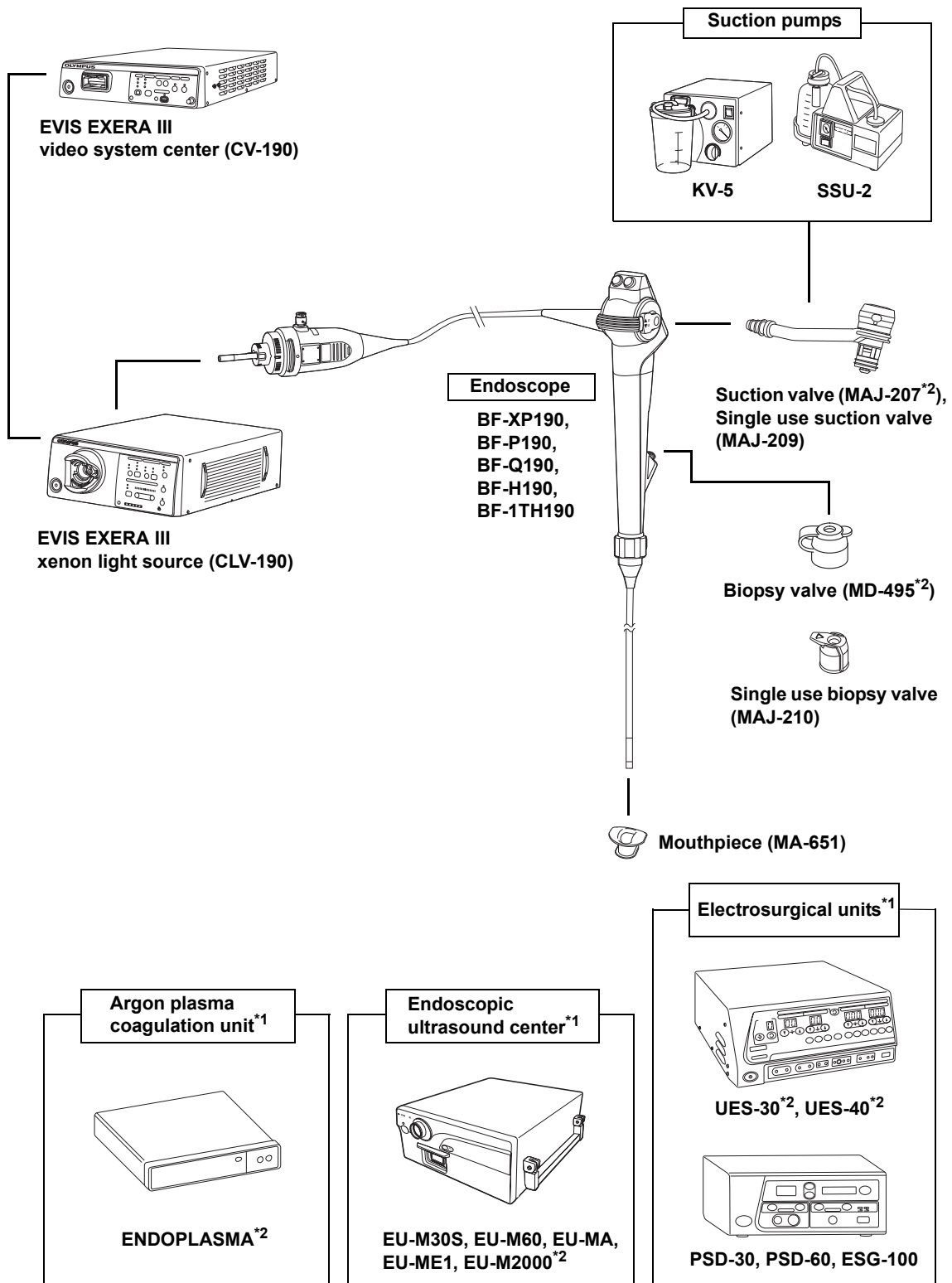
The recommended combinations of equipment and accessories that can be used with this endoscope are listed below. Some items may not be available in some areas. New products released after the introduction of the endoscope may also be compatible for use in combination with the endoscope. For further details,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

App.









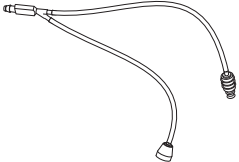
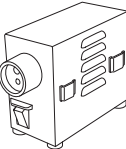

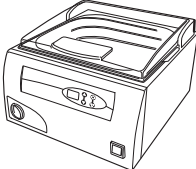
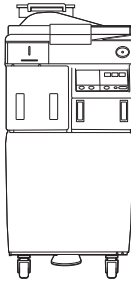
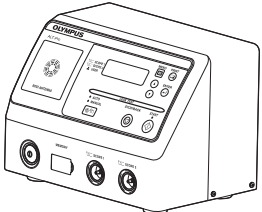


App.

*1 Except BF-XP190

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

Reprocessing equipment

BF-XP190	BF-XP190	Except BF-XP190
		
<p>Single use single-ended cleaning brush (BW-400B)</p>	<p>Suction connector cleaning brush (BW-15SH)</p>	<p>Channel cleaning brush (BW-15B*1)</p>
		
<p>Channel-opening cleaning brush (MH-507*1)</p>	<p>Single use combination cleaning brush (BW-411B*1)</p>	<p>Leakage tester (MB-155)</p>
		
<p>Suction cleaning adapter (MAJ-222)</p>	<p>Maintenance unit (MU-1)</p>	<p>Sterilization cap (MAJ-1538)</p>
		
<p>Ultrasonic cleaner (ENDOSONIC)</p>	<p>Endoscope washer (EW-30*2) Endoscope reprocessor (OER*2, OER-A*2, OER-AW*2, OER-Pro*2)</p>	<p>Automated endoscope leak tester (ALT-Pro*2)</p>

App.

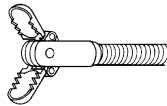
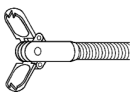
*1 Prepare either a single use combination cleaning brush (BW-411B) or a set of channel cleaning brush (BW-15B) and channel-opening cleaning brush (MH-507).

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

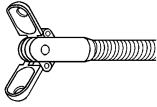
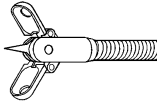
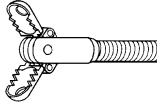
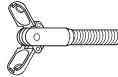
Compatible EndoTherapy accessories

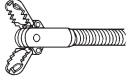
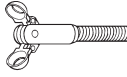
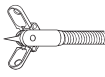
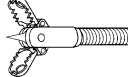
Note that some of the accessories may not be available in some areas.

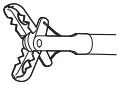
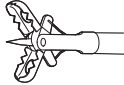
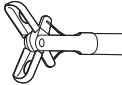
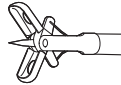
EndoTherapy accessories

	Biopsy forceps	
	Alligator jaws type	Rat tooth type
Endoscope		
BF-XP190	–	FB-56D-1
BF-P190 BF-Q190 BF-H190	FB-15C-1	FB-56D-1
BF-1TH190	FB-15C-1	–

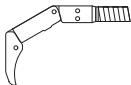
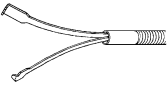
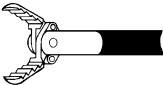
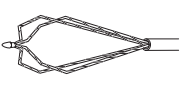
App.

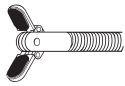
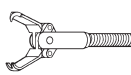
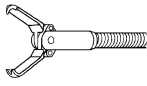

	Biopsy forceps (fenestrated)			
	Standard type	Standard type (with needle)	Alligator jaws type	Rat tooth type
Endoscope				
BF-XP190	–	–	–	–
BF-P190 BF-Q190 BF-H190	FB-19C-1 FB-21C-1	FB-34C-1	–	–
BF-1TH190	FB-20C-1 FB-35C-1	FB-24C-1 FB-34C-1	FB-36C-1	FB-37K-1





	Biopsy forceps with swing jaws (fenestrated)	Rotatable biopsy forceps (fenestrated)		Rotatable biopsy forceps with swing jaws (fenestrated)
	Rat tooth with alligator jaws type	Standard type	Standard type (with needle)	Rat tooth with alligator jaws type (with needle)
Endoscope				
BF-XP190	–	–	–	–
BF-P190 BF-Q190 BF-H190	FB-52C-1	FB-19CR-1	–	–
BF-1TH190	FB-52C-1	FB-19CR-1	FB-22CR-1	FB-55CR-1

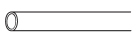



	Single use biopsy forceps with swing jaws (fenestrated)			
	Alligator jaws type	Alligator jaws type (with needle)	Standard type	Standard type (with needle)
Endoscope				
BF-XP190	–	–	–	–
BF-P190 BF-Q190 BF-H190	FB-211D	FB-221D	FB-231D	FB-241D
BF-1TH190	FB-211D	FB-221D	FB-231D	FB-241D

App.




	Curette	Grasping forceps		
	Double joint type	W Shape type	Alligator jaws type	Basket type
Endoscope				
BF-XP190	–	–	–	–
BF-P190 BF-Q190 BF-H190	CC-4CR-1	–	–	FG-17K-1
BF-1TH190	CC-4CR-1	FG-4L-1	FG-6L-1	FG-16L-1




	Grasping forceps			Single use grasping forceps
	Rubber tips (non-latex)	Rat tooth type	Sharp tooth type	Loop type
Endoscope				
BF-XP190	–	–	–	FG-36D
BF-P190 BF-Q190 BF-H190	FG-20P-1	–	–	FG-36D
BF-1TH190	FG-20P-1	FG-26C-1	FG-32C-1	FG-36D

	Single use grasping forceps			
	Spiral basket type	Spiral basket type	Three nail type	Parallel basket type
Endoscope				
BF-XP190	FG-51D	FG-52D	FG-54D	FG-55D
BF-P190 BF-Q190 BF-H190	FG-51D	FG-52D	FG-54D	FG-55D
BF-1TH190	FG-51D	FG-52D	FG-54D	FG-55D

	Cannula	Single use balloon catheter	Spray catheter	Injector
	Standard type		Spray type (with nozzle)	
Endoscope				
BF-XP190	–	–	–	–
BF-P190 BF-Q190 BF-H190	PR-2B-1	B5-2C	PW-6C-1	NM-8L-1 NM-9L-1
BF-1TH190	PR-2B-1	B7-2C	PW-6C-1	NM-4L-1 NM-5L-1 NM-6L-1 NM-7L-1




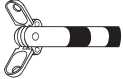
App.


	Single use cytology brush	Aspiration needle	
		No side hole type	Side hole type
Endoscope			
BF-XP190	BC-201C-1006 BC-203D-2006	-	-
BF-P190 BF-Q190 BF-H190	BC-202D-1210 BC-202D-2010 BC-202D-3010 BC-202D-5010	NA-1C-1	NA-2C-1
BF-1TH190	BC-202D-1210 BC-202D-2010 BC-202D-3010 BC-202D-5010	NA-1C-1	NA-2C-1

	Single use aspiration needle		Single use aspiration needle
	No side hole type	Side hole type	
Endoscope			
BF-XP190	-	-	-
BF-P190 BF-Q190 BF-H190	NA-401D-1321 NA-401D-1521	NA-411D-1321 NA-411D-1521	NA-601D-1519
BF-1TH190	NA-401D-1321 NA-401D-1521	NA-411D-1321 NA-411D-1521	NA-601D-1519

App.

○ Electrosurgical accessories

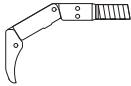
	Electrosurgical snare	Coagulation electrode	Electrosurgical knife	Hot biopsy forceps
	Crescent		Flat type	
Endoscope				
BF-XP190	–	–	–	–
BF-P190 BF-Q190 BF-H190	SD-7C-1 SD-18C-1	CD-6C-1	KD-31C-1	FD-7C-1
BF-1TH190	SD-7C-1 SD-18C-1	CD-6C-1	KD-31C-1	FD-6C-1

	APC probe
Endoscope	
BF-XP190	–
BF-P190 BF-Q190 BF-H190	–
BF-1TH190	MAJ-1011/1012 REF20132-178: APC probe 1000A OD 2.3 mm/6.9 Fr, L 1 m/3.3 ft

App.

○ Guide sheath kit

Endoscope	Single use guide sheath kit
BF-XP190	—
BF-P190 BF-Q190 BF-H190	K-201 K-202
BF-1TH190	K-203 K-204

	Guiding device
Endoscope	
BF-XP190	—
BF-P190 BF-Q190 BF-H190	CC-6DR-1
BF-1TH190	CC-6DR-1

App.

EMC information

○ Guidance and manufacturer's declaration — Electromagnetic emissions

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

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

App.

○ Guidance and manufacturer's declaration — Electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: $\pm 2, \pm 4, \pm 6$ kV Air: $\pm 2, \pm 4, \pm 8$ kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5	Differential mode: $\pm 0.5, \pm 1$ kV Common mode: $\pm 0.5, \pm 1, \pm 2$ kV	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	$40\% U_T$ (60% dip in U_T) for 5 cycle		
	$70\% U_T$ (30% dip in U_T) for 25 cycle		
	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 seconds		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.
Definition	U_T is the a.c. mains voltage prior to application of the test level.		

App.

○ Guidance and manufacturer's declaration — Electromagnetic immunity

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

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz – 80 MHz)	3 V (V ₁)	Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m (80 MHz – 2.5 GHz)	3 V/m (E ₁)	Recommended separation distance $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz – 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz – 2.5 GHz
Definition	Where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m).		

App.

NOTE

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



NOTE

- Field strength from fixed RF transmitters as determined by an electromagnetic site survey^{a)} should be less than the compliance level in each frequency range^{b)}.
 - a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this model is used exceeds the applicable RF compliance level above, this model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this model.
 - b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

App.


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

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

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

App.

NOTE

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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