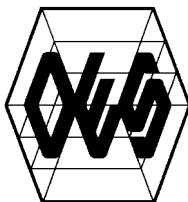


OLYMPUS[®]

INSTRUCTIONS



OLYMPUS ENDOSCOPY SYSTEM

OES BRONCHOFIBERSCOPE

OLYMPUS BF TYPE P30
OLYMPUS BF TYPE 1T30

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

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Symbols

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



Refer to instructions.



Do not reuse.



Lot number



Endoscope



Type BF applied part

Important Information — Please Read Before Use

Intended use

These instruments have been designed to be used with an Olympus light source, documentation equipment, video monitor, endo-therapy accessories and other ancillary equipment for endoscopy and endoscopic surgery and treatment within the airways and tracheobronchial tree.

Do not use the instruments for any purpose other than their intended uses.

Instruction manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the equipment as instructed.

Keep this and all related instruction manuals in a safe, accessible location.

If you have any questions or comments about any information in this manual, please contact Olympus.

User qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

Instrument compatibility

Refer to the "System chart" in the Appendix to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury and/or equipment damage.

Reprocessing and storage

This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, "Cleaning, Disinfection and Sterilization Procedures".

After using this instrument, reprocess and store it according to the instructions given in Chapters 5 through 9. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

Repair and modification

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

Some problems that appear to be malfunctions may be correctable by referring to Chapter 10, "Troubleshooting". If the problem cannot be resolved using the information in Chapter 10, contact Olympus.

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

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

WARNING

- Never use electrosurgical accessories because the distal end of this instrument is not insulated. Using electrosurgical accessories may result in operator and/or patient injury.
- Never perform angulation control, suction control or insert or withdraw the endoscope's insertion tube without viewing the endoscopic image. Patient injury can result.
- Do not touch the light guide of the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient injury can result.

CAUTION

- Do not pull on the universal cord. The endoscope connector will be pulled out from the output socket of the light source and the endoscopic image will not be visible.
- Do not coil the insertion tube or universal cord into a diameter of less than 12 cm. Equipment damage can result.
- Do not apply shock to the distal end of the insertion tube, particularly the objective lens surface at the distal end. Visual abnormalities may result.
- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leaks.

NOTE

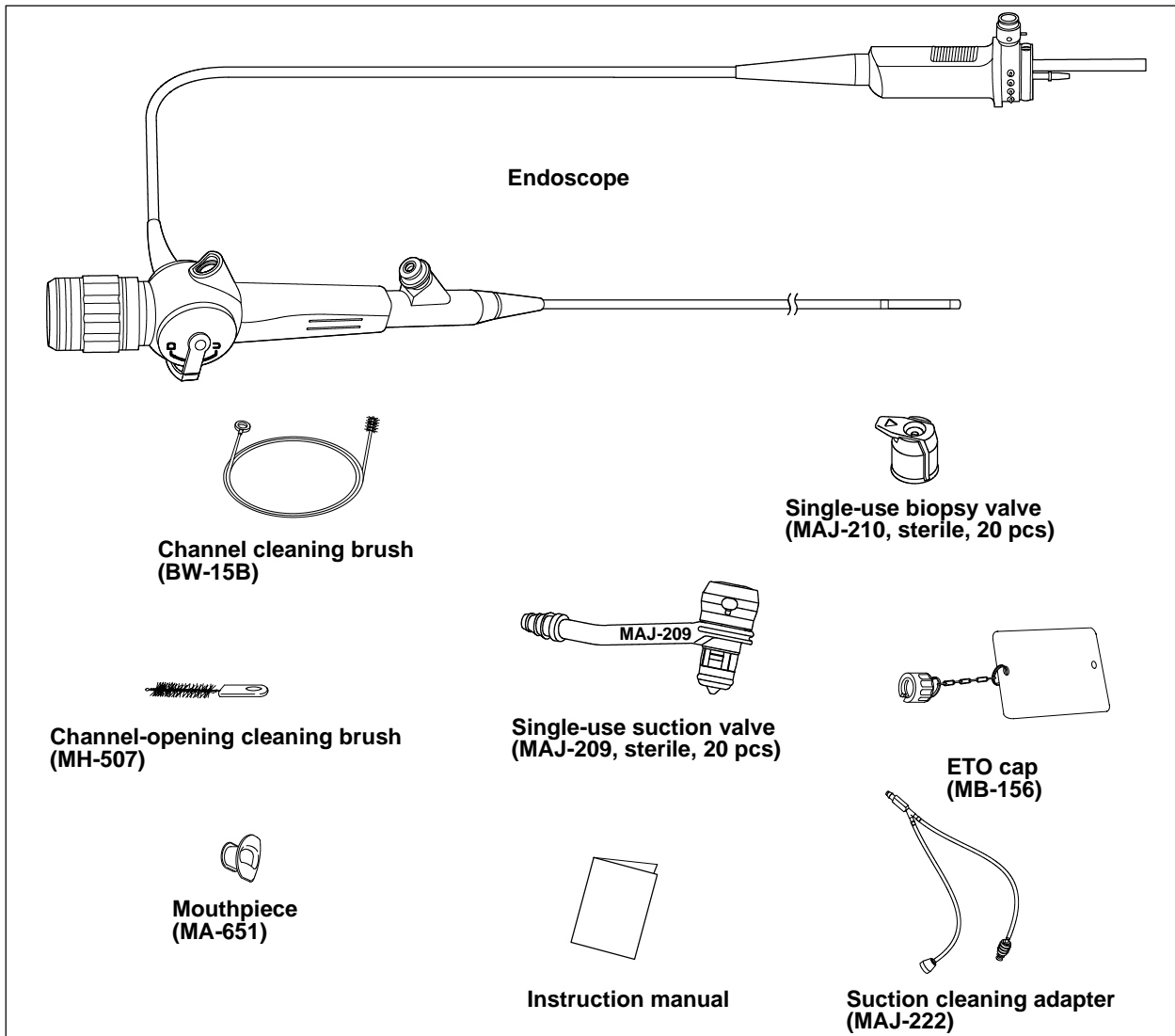
It is highly desirable that a backup endoscope be available to continue clinical procedures in case of a malfunction.

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 given below.

- Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and infection.
- Applying prolonged suction with the distal end in contact with the mucosal surface may cause bleeding or suction lesions.
- Inserting and using endo-therapy accessories without a clear endoscopic image may cause patient injury.
- Patient injury may be caused by:
 - inserting or withdrawing the endoscope or applying suction without a clear endoscopic image
 - forcefully pulling, twisting or rotating the angulated bending section

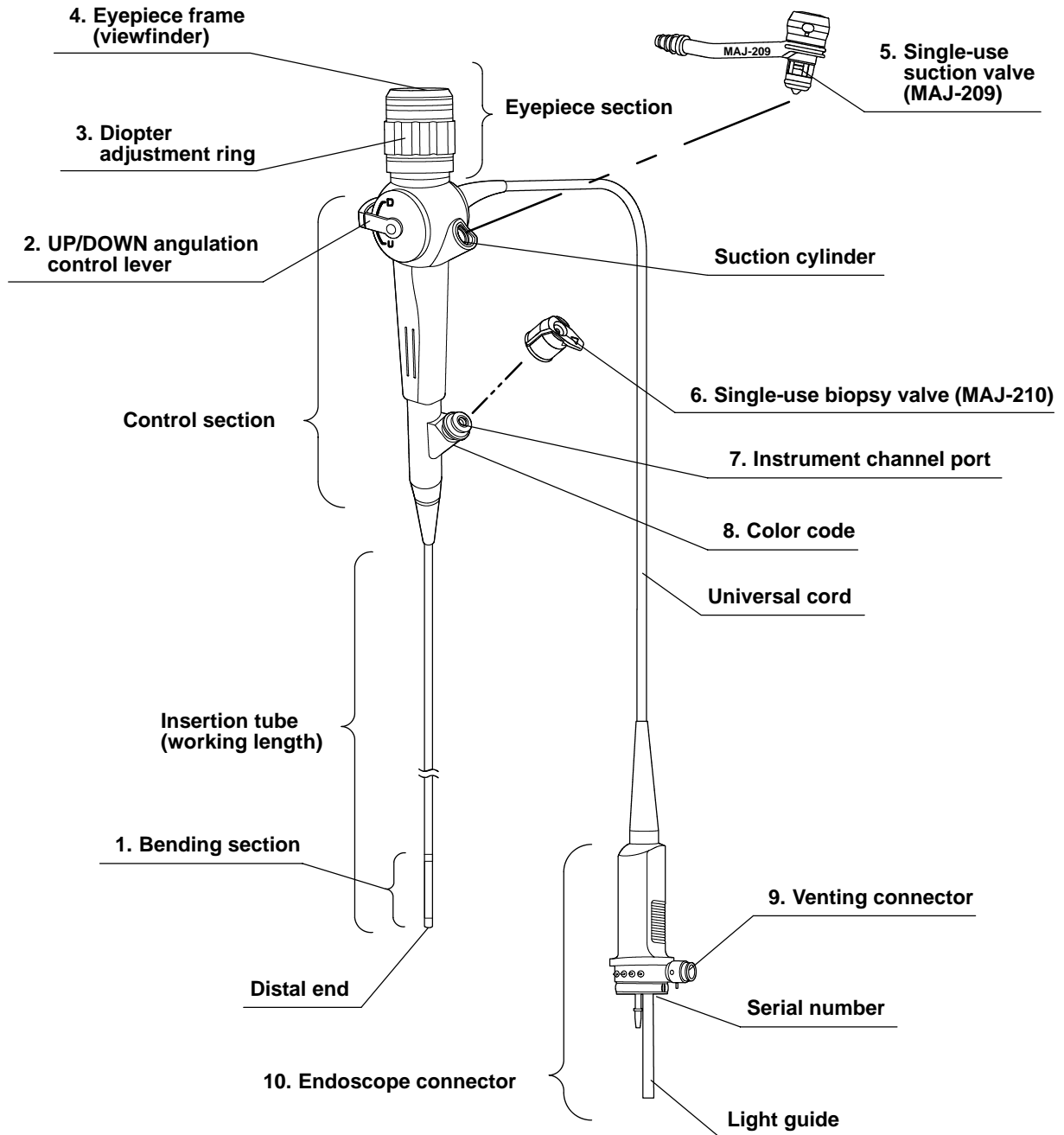
Chapter 1 Checking the Package Contents

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the instrument; immediately contact Olympus. This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, "Cleaning, Disinfection and Sterilization Procedures".



Chapter 2 Instrument Nomenclature and Specifications

2.1 Nomenclature



2.2 Endoscope functions

1. Bending section

The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.

2. UP/DOWN angulation control lever

When the lever is moved in the “U” direction, the bending section moves UP; when the lever is moved in the “D” direction, the bending section moves DOWN.

3. Diopter adjustment ring

The diopter adjustment ring adjusts the focus of the eyepiece.

4. Eyepiece frame (viewfinder)

The viewfinder contains an index mark indicating the UP direction of the bending section.

5. Single-use suction valve (MAJ-209)

The suction valve is depressed to activate suction. The valve is also used to remove any fluid and/or debris adhering to the objective lens.

WARNING

The suction valve is provided in a sterile condition. Do not open the package until ready to use.

6. Single-use biopsy valve (MAJ-210)

Accessories may be inserted through the slit in this valve. A syringe may also be inserted, for the injection of fluids.

WARNING

The biopsy valve is provided in a sterile condition. Do not open the package until ready to use.

7. Instrument channel port

The instrument channel port functions as:

- channel for the insertion of endo-therapy accessories
- suction channel
- fluid feed channel (from a syringe via the biopsy valve)

8. Color code

The color code is used to quickly determine the compatibility of endo-therapy accessories. The endoscope can be used with endo-therapy accessories that have the same color code.

- Blue: BF-P30
- Green: BF-1T30

9. Venting connector

The venting connector accepts either the ETO cap or the leakage tester's connector cap.

10. Endoscope connector

The endoscope connector connects the endoscope to the output socket of the light source and transmits light from the light source to the endoscope.

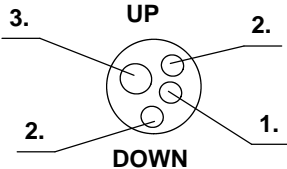
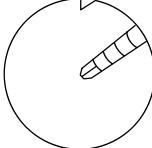
2.3 Specifications

Operating environment

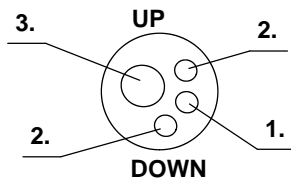
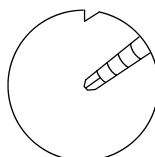
Operating environment	Ambient temperature	10 - 40°C (50 - 104°F)
	Relative humidity	30 - 85%
	Air pressure	700 - 1060 hPa (0.7 - 1.1 kgf/cm ²) (10.2 - 15.4 psia)

Specifications

○ BF-P30

Optical system	Field of view	120°
	Direction of view	Forward viewing
	Depth of field	3 - 50 mm
Insertion tube	Distal end outer diameter	ø 4.9 mm
	Distal end enlarged	1. Objective lens 2. Light guide lens 3. Instrument channel outlet
		
	Insertion tube outer diameter	ø 5.0 mm
	Working length	550 mm
Instrument channel	Channel inner diameter	ø 2.2 mm
	Minimum visible distance	5 mm from the distal end
	Direction from which endo-therapy accessories enter and exit the endoscopic image	
Bending section	Angulation range	UP 180°, DOWN 130°
	Total length	840 mm

○ BF-1T30

Optical system	Field of view	120°
	Direction of view	Forward viewing
	Depth of field	3 - 50 mm
Insertion tube	Distal end outer diameter	ø 5.9 mm
Insertion tube	Distal end enlarged	1. Objective lens 2. Light guide lens 3. Instrument channel outlet
		
Insertion tube	Insertion tube outer diameter	ø 6.0 mm
	Working length	550 mm
Instrument channel	Channel inner diameter	ø 2.8 mm
	Minimum visible distance	5 mm from the distal end
	Direction from which endo-therapy accessories enter and exit the endoscopic image	
Bending section	Angulation range	UP 180°, DOWN 130°
Total length		840 mm
Year of manufacture	1112345	↑ The year of manufacture is the second digit of the serial number.
Degree of protection against electric shock		TYPE BF applied part

Chapter 3 Preparation and Inspection

WARNING

- Before each case, prepare and inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as instructed in their respective instruction manuals. Should the slightest irregularity be suspected, do not use this instrument and see Chapter 10, “Troubleshooting”. If the irregularity is still suspected after consulting Chapter 10, contact Olympus. Damage or irregularity may compromise patient or user safety and may result in more severe equipment damage.
- This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, “Cleaning, Disinfection and Sterilization Procedures”.

3.1 Preparation of the equipment

Prepare the equipment shown in Figure 3.1 (for compatibility, see the “System chart” in the Appendix) and personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves, before each use. Refer to the respective instruction manuals for each piece of equipment.

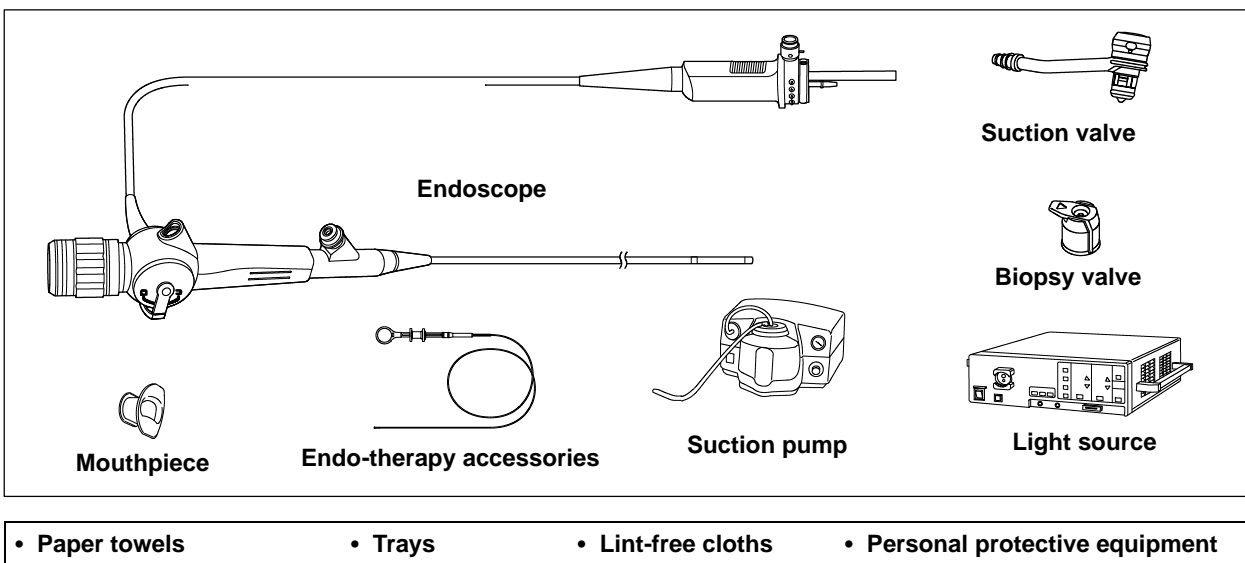


Figure 3.1

3.2 Preparation and inspection of the endoscope

Clean and disinfect or sterilize the endoscope as described in Chapters 5 through 8 of this manual.

Inspection of the endoscope

1. Inspect the control section and the endoscope connector for excessive scratching.
2. Inspect the boot and the insertion tube near the boot for bends, twists or other irregularities.
3. Inspect the surface of the insertion tube for dents, bulges, swelling or other irregularities.
4. Carefully run your fingertips over the entire length of the insertion tube. Inspect for any protruding objects or other irregularities (see Figure 3.2).

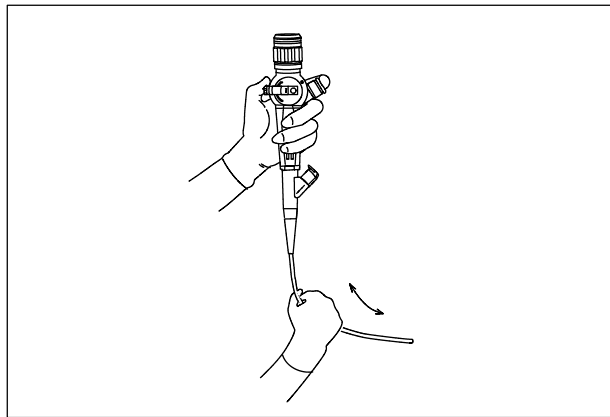


Figure 3.2

5. Inspect the covering of the bending section for sagging, swelling, cuts, holes or other irregularities.
6. Gently hold the midpoint of the bending section and a point 20 cm from the distal end. Push and pull gently to confirm that there is no play.
7. Inspect the objective lens at the distal end of the endoscope's insertion tube for cracks, scratches, deformations or other irregularities.
8. Confirm that the diopter adjustment ring turns smoothly and that the eyepiece section is attached securely to the control section. Inspect the eyepiece for cracks, scratches, deformations or other irregularities.

CAUTION

When cleaning or wiping the eyepiece lens surface, do not use abrasive cleansers because they may scratch the lens surface.

Inspection of the bending mechanism

Perform the following inspections while the bending section is straight.

1. Turn the UP/DOWN angulation control lever slowly in each direction until it stops. Confirm that the bending section angulates smoothly and correctly and that maximum angulation can be achieved.
2. Turn the UP/DOWN angulation control lever slowly to its neutral position. Confirm that the bending section returns smoothly to an approximately straight condition.

3.3 Preparation and inspection of accessories

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

WARNING

- This suction valve is disposable. Do not attempt to reuse or resterilize it.
- This suction valve is provided in a sterile condition. Do not open the package until ready to use.

NOTE

This suction valve is designed for use with BF-30, 40, 200, 240 and 160 series endoscopes.

Inspect the single-use suction valve for damage (see Figure 3.3).

1. Confirm that the valve is not deformed or cracked.
2. Confirm that the button can be pushed without excessive resistance.

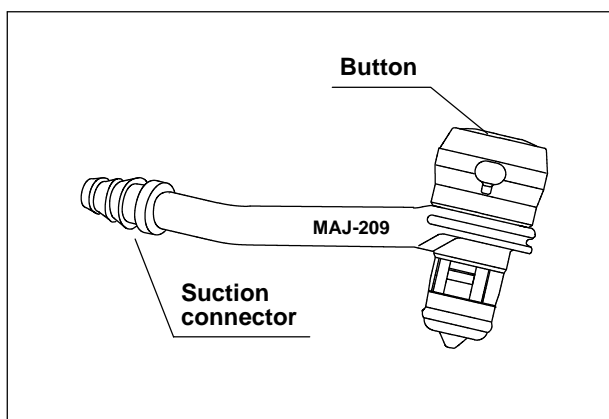


Figure 3.3

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

WARNING

This biopsy valve is disposable. Do not attempt to reuse or resterilize it.

CAUTION

This valve is provided in a sterile condition. Do not open the package until ready to use.

NOTE

This biopsy valve is designed for use with BF-30, 40, 200, 240 and 160 series endoscopes.

Confirm that the biopsy valve (see Figure 3.4) is free from cracks, tears or deformation.

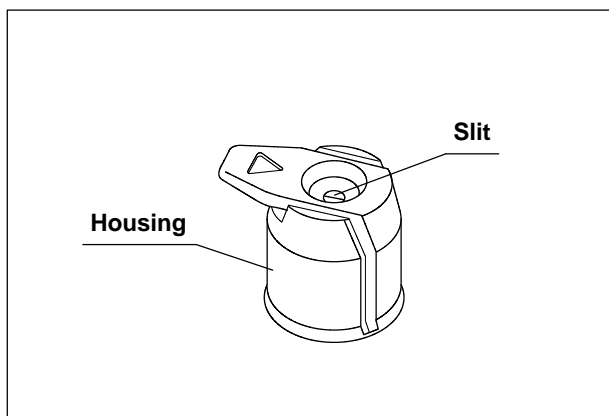


Figure 3.4

3.4 Attaching accessories to the endoscope

Attaching the suction valve

1. Insert the suction valve into the suction cylinder, then align the arm of the main body with the white mark on the endoscope (see Figure 3.5).
2. Press the top of the suction valve down with your finger until the valve clicks into position. Confirm that the suction valve is secure and operates smoothly.

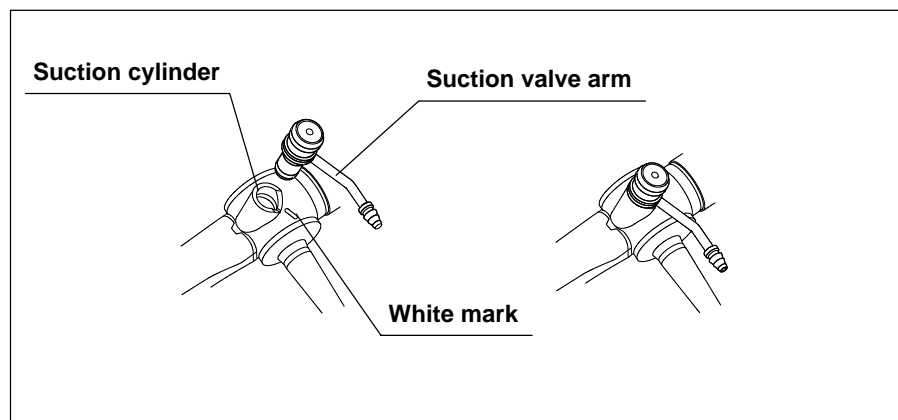


Figure 3.5

NOTE

Sometimes the suction valve will click before it is fully seated in the suction cylinder. Press the suction valve down firmly to ensure that it is fully seated in the suction cylinder.

Attaching the biopsy valve

Attach the biopsy valve to the instrument channel port of the endoscope (see Figure 3.6). Confirm that the biopsy valve fits properly.

NOTE

At lower temperatures, the biopsy valve may become stiff and difficult to attach. In this case, press it down more firmly to attach it.

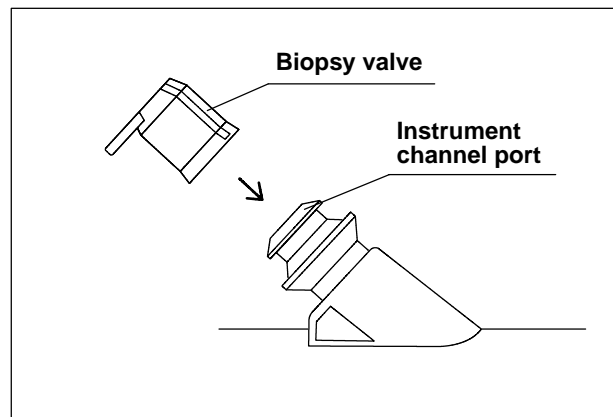


Figure 3.6

3.5 Preparation, inspection and connection of ancillary equipment

Preparation and inspection of ancillary equipment

Prepare and inspect the light source, suction pump and endo-therapy accessories as described in their respective instruction manuals.

Connection of the endoscope and ancillary equipment

1. Insert the endoscope connector completely into the output socket of the light source.
2. Connect the suction tube from the suction pump to the suction connector on the suction valve.

If required, prepare and inspect the camera, video monitor and video system according to their respective instruction manuals.

3.6 Inspection of the endoscopic system

Inspection of the endoscopic image

1. Turn ON the light source and inspect the endoscopic image as described in its instruction manual.
2. Adjust the brightness level as appropriate.
3. Turn the diopter adjustment ring until the fiber pattern is clear. Confirm that an object approximately 15 mm from the objective lens can be seen clearly.

NOTE

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

Inspection of the suction function

WARNING

Do not aspirate with a pressure of more than 670 hPa (0.68 kgf/cm², 9.7 psig). Using higher pressures may make it difficult to stop suction.

1. Immerse the distal end of the insertion tube in sterile water and depress the suction valve. Confirm that water is continuously aspirated into the suction bottle on the suction pump.
2. Release the suction valve. Confirm that suction stops and the valve returns to its original position.
3. Remove the distal end from the water. Depress the suction valve and aspirate air for a few seconds to remove water from the instrument channel.

Inspection of the instrument channel

CAUTION

Keep your eyes away from the distal end when inserting endo-therapy accessories. Extending the endo-therapy accessory from the distal end could cause eye injury.

1. Insert the endo-therapy accessory through the biopsy valve.
2. Confirm that the endo-therapy accessory extends smoothly from the distal end.

Inspection of the water feed

1. Insert a syringe filled with sterile water into the biopsy valve and depress the plunger.
2. Confirm that water is emitted from the distal end.

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 emitted from the endoscope's distal end.
- If fluid is not emitted from the endoscope's distal end, flush air through the channel.

Chapter 4 Operation

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

WARNING

- Anytime you suspect an abnormality in an endoscope function, stop the examination immediately and slowly remove the endoscope while viewing the endoscopic image. Using an endoscope that is not functioning properly may cause patient injury.
- If the endoscopic image should unexpectedly disappear, stop the examination immediately, without touching any of the UP/DOWN angulation control lever, slowly withdraw the endoscope from the patient. If an endo-therapy accessory is being used, withdraw it in the safest possible manner before withdrawing the endoscope.
- If the angulation control mechanism or any other part of the system is not functioning properly, stop the procedure immediately; do not operate the angulation control lever unless absolutely necessary. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it; leave it inside the patient and immediately contact Olympus. Forcibly withdrawing the endoscope may cause patient injury.
- Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During operation, wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.

4.1 Insertion

Holding and manipulating the endoscope

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. The right hand is free to manipulate the insertion tube (see Figure 4.1).

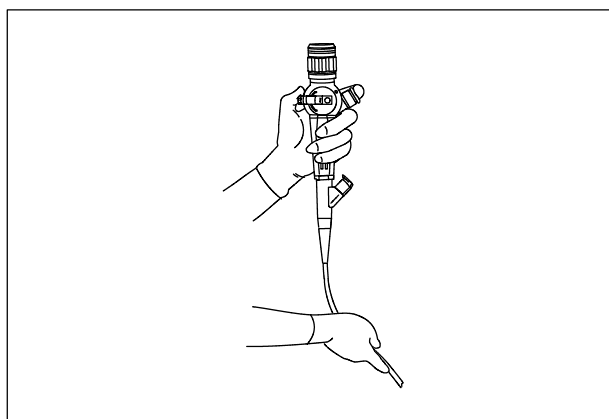


Figure 4.1

Insertion of the endoscope

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

CAUTION

- Do not apply olive oil or products containing petroleum-based lubricants (e.g. vaseline). These products may cause stretching and deterioration of the bending section's covering.
- To prevent the patient from accidentally biting the insertion tube during examination, it is strongly recommended that a mouthpiece be placed in the patient's mouth before inserting the endoscope.

2. Place the mouthpiece in the patient's mouth.
3. Always view the endoscopic image when passing the distal end of the endoscope from the mouth to the larynx.

CAUTION

Do not allow the insertion tube to be bent within a distance of 10 cm or less from the junction of the boot. Insertion tube damage can occur (see Figure 4.2).

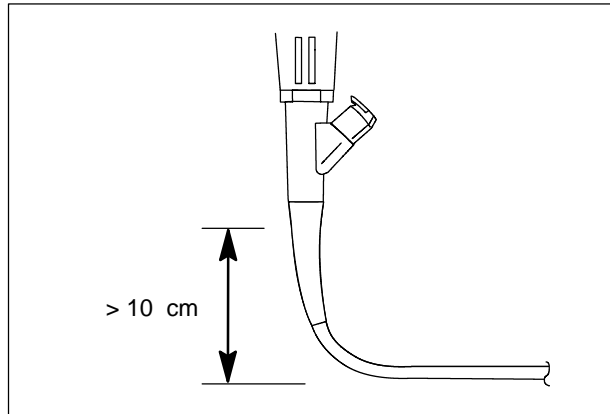


Figure 4.2

Angulation of the distal end

WARNING

If the angulation control mechanism or any other part of the system is not functioning properly, stop the procedure immediately; do not operate the angulation control lever unless absolutely necessary. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it; leave it inside the patient and immediately contact Olympus.

Operate the angulation control lever as necessary to guide the distal end for insertion and observation.

Feeding and aspirating fluids

○ Feeding fluids

Securely insert a syringe into the slit of the biopsy valve and press the plunger.

NOTE

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

○ Aspirating fluids

WARNING

Avoid aspirating solid matter or thick fluids, channel or valve clogging can occur. If the suction valve clogs and aspiration cannot be turned OFF, disconnect the suction tube from the suction valve. Stop the procedure and withdraw the endoscope from the patient while viewing the endoscopic image.

CAUTION

During the procedure, make sure that the suction bottle does not fill completely or overflow. Aspirating fluids into a full bottle can damage the suction pump.

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

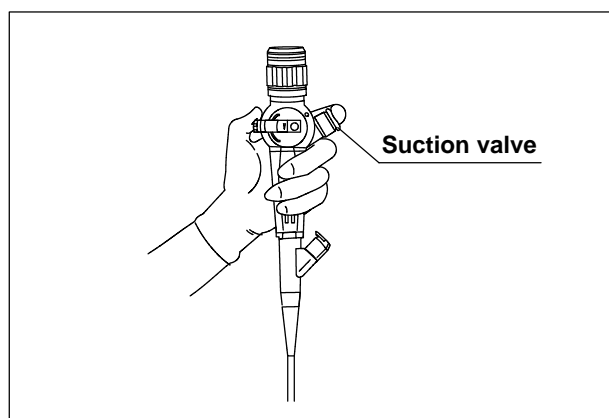


Figure 4.3

Observation of the endoscopic image

WARNING

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 use the minimum level of illumination, minimum time and suitable distance necessary for adequate viewing. Whenever possible, avoid close stationary viewing and do not leave the distal end of the endoscope close to mucous membrane for a long time.

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

Photography

Connect the camera to the endoscope's eyepiece, and take photographs as described in the camera's instruction manual.

Monitor observation

When observing the endoscopic image on the video monitor, refer to the instruction manuals of the light source and the OES video system.

Simultaneous observation by 2 people

By connecting the lecturescope to the endoscope's eyepiece a second observer can view the procedure.

4.2 Using endo-therapy accessories

For more information on combining the endoscope with particular endo-therapy accessories, refer to the “System chart” in the Appendix and the instruction manuals of the accessories.

WARNING

- Never use electrosurgical accessories because the distal end of this instrument is not insulated. Using electrosurgical accessories may result in operator and/or patient injury.
- If an endo-therapy accessory cannot be withdrawn from the endoscope, close the tip of the accessory or retract the tip of the accessory into its sheath and slowly withdraw the endoscope while observing the endoscopic image.
- 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.

Insertion of endo-therapy accessories into the endoscope

1. Refer to the “System chart” in the Appendix to determine instrument compatibility.
2. While holding the UP/DOWN angulation control lever stationary, slowly insert the endo-therapy accessory through the slit of the biopsy valve.

CAUTION

- If significant resistance is encountered and insertion is difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting endo-therapy accessories with excessive force may damage the endoscope and/or cause patient injury.
- Confirm that the tip of the endo-therapy accessory is closed or retracted into its sheath and slowly insert the endo-therapy accessory into the biopsy valve. Do not open the tip of the endo-therapy accessory or extend the tip of the endo-therapy accessory from its sheath while inserting the endo-therapy accessory into the instrument channel. The instrument channel and/or the endo-therapy accessory may become damaged.

- Hold the endo-therapy accessory close to the biopsy valve and insert it straight into the biopsy valve using slow, short strokes. Otherwise, the endo-therapy accessory could bend or break.
3. Hold the endo-therapy accessory approximately 4 cm from the biopsy valve and slowly advance it into the biopsy valve using slow, short strokes.

Operation of endo-therapy accessories

Operate the endo-therapy accessory according to the directions given in its instruction manual.

Withdrawal of endo-therapy accessories

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

WARNING

Do not withdraw the endo-therapy accessory if the tip is opened or extended from its sheath; patient injury and/or instrument damage may occur. If the endo-therapy accessory cannot be withdrawn from the endoscope, carefully withdraw both the endoscope and the endo-therapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

Laser cauterization

WARNING

- Do not perform laser cauterization while supplying oxygen. This may result in combustion during cauterization.
- To avoid patient injury 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 in the correct position in the endoscopic image.

CAUTION

- Before inserting or withdrawing the laser probe, move the UP/DOWN angulation control lever to its neutral position so that the bending section will be straight. If it is bent, there is a danger of damaging the instrument channel.

- Allow the tip of the laser probe to cool down before withdrawing 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.

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

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.
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

1. 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.
2. With the syringe attached, slowly withdraw the plunger to aspirate lavage fluid.

4.3 *Withdrawal of the endoscope*

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

4.4 Transportation of the endoscope

Transporting within the hospital

When carrying the endoscope by hand, hold the endoscope connector together with the control section in one hand and hold the distal end of the insertion tube securely, but gently without squeezing, in the other hand (see Figure 4.4).

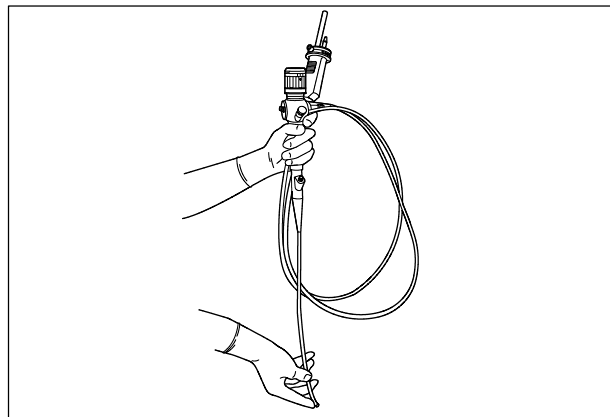


Figure 4.4

Transporting outside the hospital

Transport the endoscope in the carrying case.

CAUTION

- The carrying case cannot be cleaned or disinfected. Clean and disinfect or sterilize the endoscope before placing it in the carrying case. Disinfect or sterilize the endoscope again before use.
- Attach the ETO cap when transporting the endoscope, to avoid damage to the endoscope caused by changes in air pressure.

Chapter 5 *Reprocessing: General Policy*

5.1 *Instructions*

- Chapters 5, “Reprocessing: General Policy” through 8, “Cleaning and Disinfection Equipment” describe recommended procedures and equipment for cleaning and disinfecting or sterilizing this instrument.
- Thoroughly review the manuals of all equipment which will be used with this instrument and use the equipment as instructed.
- If you have any questions or comments about any reprocessing information in this manual, or if a problem that cannot be solved occurs while reprocessing, contact Olympus.
- The medical literature reports incidents of patient cross contamination resulting from improper cleaning, disinfection or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies.
- A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.
- All individuals responsible for reprocessing should thoroughly understand:
 - occupational health and safety regulations
 - all national and local hospital guidelines and policies
 - the instructions in this manual
 - the mechanical aspects of endoscopic equipment
 - pertinent germicide labeling

5.2 Precautions

WARNING

- Failure to properly clean and high-level disinfect or sterilize endoscopic equipment after each examination can compromise patient safety. To minimize the risk of transmitting diseases from one patient to another, after each examination the endoscope must undergo thorough manual cleaning followed by high-level disinfection or sterilization.
- If the endoscope is not cleaned meticulously, effective disinfection or sterilization may not be possible. Clean the endoscope and accessories thoroughly before disinfection or sterilization to remove microorganisms or organic material that could reduce the efficacy of disinfection or sterilization.
- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During cleaning and disinfection or sterilization, wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated personal protective equipment before leaving the reprocessing area.
- Thoroughly rinse off the disinfectant solution. Rinse the external surface of the endoscope, channels and cleaning equipment thoroughly with clean water to remove any disinfectant solution residue.
- The disinfection/sterilization room must be adequately ventilated. Adequate ventilation protects against the buildup of toxic chemical fumes.
- Store alcohol in an air-tight container. Alcohol stored in an open container is a fire hazard and will lose its efficacy due to evaporation.

CAUTION

- When aerating or irrigating the endoscope channels, the air or water pressure must not exceed 0.2 MPa (2 kgf/cm², 29 psig).
- Before immersing the endoscope in cleaning or disinfectant solution, confirm that the ETO cap is not attached to the endoscope connector.

Chapter 6 Compatible Reprocessing Methods and Chemical Agents

6.1 Compatibility summary

Olympus endoscopic equipment is compatible with several methods of reprocessing. Certain components and accessories, however, are not compatible with some methods, which can cause equipment damage. For appropriate reprocessing methods, refer to Table 6.1 below, the recommendations of your infection control committee and national and local hospital guidelines and policies.

	Steam sterilization (autoclaving)	ETO gas sterilization	2 - 3.2% glutaraldehyde	70% ethyl or isopropyl alcohol	Detergent solution	Ultrasonic cleaning
Endoscope						
ETO cap (MB-156)						
Channel cleaning brush (BW-15B)						
Channel-opening cleaning brush (MH-507)						
Mouthpiece (MA-651)						

 **Applicable**  **Not applicable**

Table 6.1

NOTE

Endo-therapy accessories which are marked by the words "AUTOCLAVE" or "AUTOCLAVABLE", or accessories with a green model reference label are compatible with autoclaving.

6.2 Detergent solution

Use a medical-grade, low-foaming, neutral pH detergent or enzymatic detergent and follow the manufacturer's dilution and temperature recommendations. Contact Olympus for the names of specific brands that have been tested for compatibility with the endoscope. Do not reuse detergent solutions.

WARNING

Excessive detergent foaming can prevent fluid from adequately contacting internal lumens (e.g. channels).

6.3 Disinfectant solution

In the U.S., agents used to achieve high-level disinfection are defined as liquid chemical germicides registered with the U.S. Food and Drug Administration as "sterilant/disinfectants" which are used according to the time, temperature and dilution recommended by the disinfectant manufacturer for achieving high-level disinfection. These conditions usually coincide with those recommended by the disinfectant manufacturer for 100% kill of mycobacterium tuberculosis.

In general, 2.0% - 3.2% glutaraldehyde solutions, when used according to the manufacturer's instructions for achieving high-level disinfection, are compatible with Olympus endoscopes. Contact Olympus for the names of specific brands that have been tested for compatibility with this endoscope.

If the disinfectant solution is reused, routinely check its efficacy with a test strip recommended by the manufacturer. Do not use solutions beyond their expiration date.

WARNING

Alcohol is not a sterilant or high-level disinfectant.

6.4 Rinsing water

Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, clean potable tap water or water which has been processed (e.g. filtered) to improve its microbiological quality may be used.

When non-sterile water is used after disinfection, wipe the endoscope and flush the channels with 70% ethyl or isopropyl alcohol, then air-dry all internal channels to inhibit the growth of residual bacteria. Do not reuse rinsing water.

6.5 ETO gas sterilization

This instrument and other accessories listed as compatible with ethylene oxide (ETO) gas sterilization in Table 6.1 can be sterilized by ETO gas and aerated within the parameters given in Table 6.2. When performing ETO gas sterilization, follow the hospital's protocol and the sterilization equipment manufacturer's instructions.

WARNING

- Before sterilization, the instrument must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
- Use biological indicators as recommended by your hospital's policy and follow the manufacturer's instructions, all national and local hospital guidelines and policies.
- All instruments must be properly aerated following ETO gas sterilization to remove toxic ethylene oxide residuals.
- Exceeding the recommended parameters may cause equipment damage.

CAUTION

- Attach the ETO cap to the endoscope connector before sterilizing. If the ETO cap is not attached to the endoscope during sterilization, the vacuum created within the sterilization chamber can rupture the covering of the bending section.
- Inspect the packages for openings, tears and other damage. If the packages are open or damaged, seal the components in a new package and sterilize again as described below.

ETO gas exposure parameters (gas mixture 12% ETO/88% CFC)

Process	Parameters	
ETO gas sterilization	Temperature	57°C (135°F)
	Pressure	0.1 - 0.17 MPa (1 - 1.7 kgf/cm ²) (16 - 24 psig)
	Humidity	55%
	Exposure time	1.75 hours
	ETO gas concentration	0.6 - 0.7 mg/cm ³ (600 - 700 mg/l)
Aeration	Minimum aeration parameters	12 hours in an aeration chamber at 50 - 57°C (122 - 135°F) or 7 days at room temperature

Table 6.2

6.6 Steam sterilization (autoclaving) of accessories

Steam sterilize (autoclave) within the parameters given in Table 6.3 below. When steam sterilizing, follow the hospital's protocol and the sterilization equipment manufacturer's instructions. Prior to steam sterilization (autoclaving) of accessories, meticulous manual cleaning followed by at least five minutes of ultrasonic cleaning at 38 - 47 kHz is required.

WARNING

- Use biological indicators as recommended by your hospital's policy and follow the manufacturer's instructions, all national and local hospital guidelines and policies.
- Exceeding the recommended parameters may cause equipment damage.

CAUTION

- Do not steam sterilize the endoscope. Steam sterilization (autoclaving) will severely damage the endoscope.
- Effective sterilization will not be possible if items are packed tightly together in the autoclave; always pack items loosely.
- Inspect each instrument package for openings, tears or other damage. If an instrument package is opened or damaged, seal the components in a new package and sterilize again.
- Allow the packages to dry within the autoclave, using the autoclave’s drying cycle (if available) or by opening the door of the autoclave and allowing the packages to air dry. Handling a wet package can compromise its sterility.

Process	Parameters	
Prevacuum	Temperature	132 - 134°C (270 - 274°F)
	Exposure time	5 minutes

Table 6.3 Steam sterilization (autoclaving) exposure parameters

Chapter 7 Cleaning, Disinfection and Sterilization Procedures

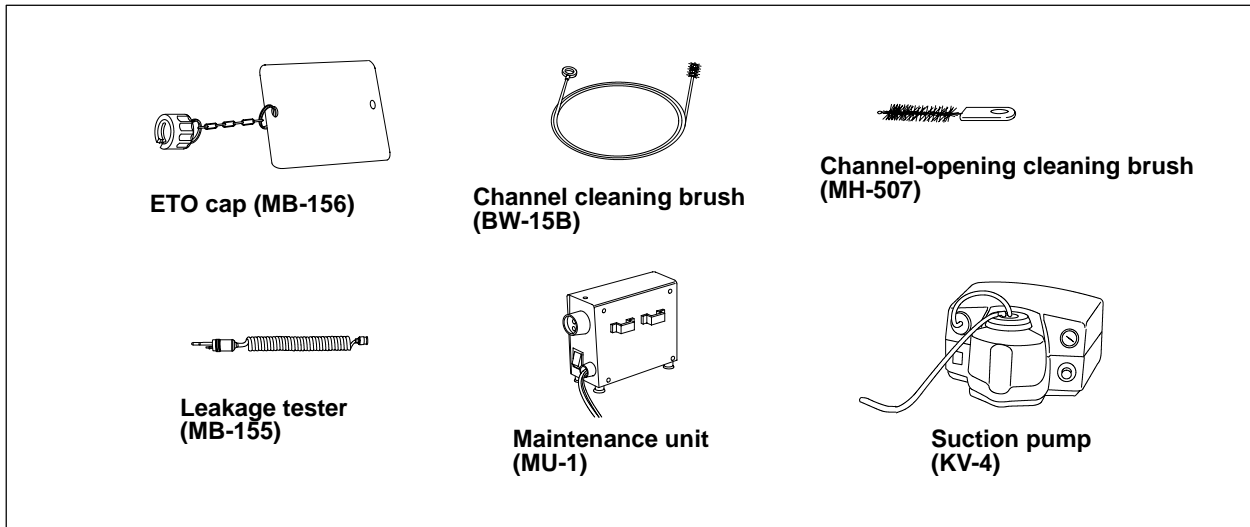
7.1 Required reprocessing equipment

Preparation of the equipment

Prior to cleaning, disinfection or sterilization, prepare the equipment shown in Figure 7.1.

CAUTION

- Use basins which are at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.
- For proper reprocessing results, do not coil the insertion tube or the universal cord with a diameter of less than 40 cm.
- Do not coil the endoscope's insertion tube or universal cord with a diameter of less than 12 cm. The endoscope can be damaged if coiled too tightly.



- | | | |
|---|---|---|
| <ul style="list-style-type: none"> • Detergent solution • Clean water • 70% ethyl or isopropyl alcohol • Disinfectant solution • Sterile water | <ul style="list-style-type: none"> • Large, non-metallic basins with tight fitting lids for detergent and disinfectant solution • Large basins for rinsing and leakage testing • 30 cm³ (30 ml) syringe • Soft brush • 500 cm³ (500 ml) containers | <ul style="list-style-type: none"> • Personal protective equipment • Clean, lint-free cloths • Sterile, lint-free cloths • Sterile cotton swabs • Small containers |
|---|---|---|

Figure 7.1

Reprocessing equipment parts and functions

For inspection of other equipment than that mentioned below, refer to the instruction manual for the equipment being used.

○ ETO cap (MB-156)

When performing ETO gas sterilization, the ETO cap must be attached to the venting connector on the endoscope connector (see Figure 7.2).

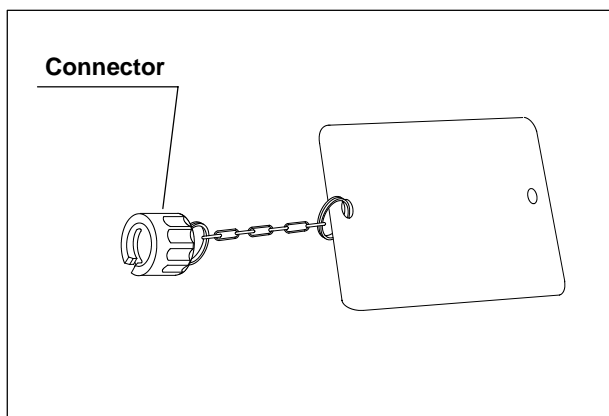


Figure 7.2

○ Suction cleaning adapter (MAJ-222)

The suction cleaning adapter is used to aspirate reprocessing fluids from the distal end of the endoscope through the instrument and suction channels (see Figure 7.3).

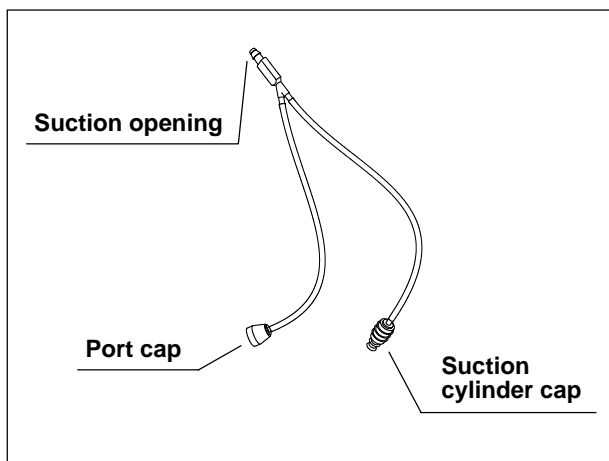


Figure 7.3

○ **Channel cleaning brush (BW-15B)**

The channel cleaning brush is used to brush the inside of the instrument and suction channels (see Figure 7.4).

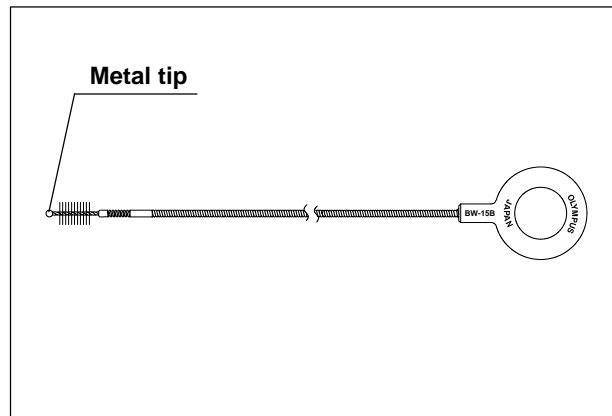


Figure 7.4

○ **Channel-opening cleaning brush (MH-507)**

The channel-opening cleaning brush is used to brush the suction valve housing, the suction cylinder and the instrument channel port (see Figure 7.5).

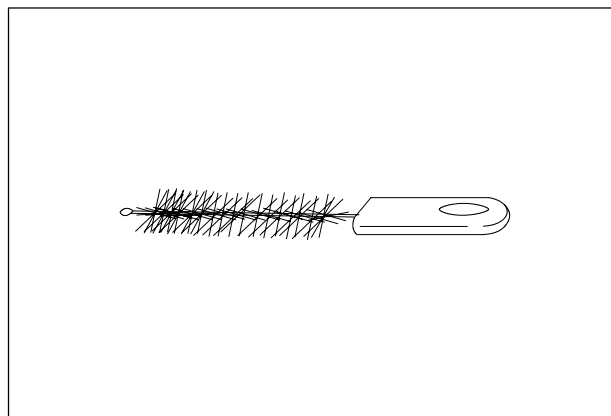


Figure 7.5

Inspection of the equipment

For inspection of other equipment than that mentioned below, refer to the instruction manual for the equipment being used.

CAUTION

The cleaning brushes are consumable items. Should the slightest irregularity be suspected, use a spare instead. Using a defective brush may cause equipment damage.

○ Inspection of the ETO cap

Check that the ETO cap is free from scratches, flaws and debris (see Figure 7.2).

○ Inspection of the suction cleaning adapter

Check for cracks, scratches, flaws, debris and other damage (see Figure 7.3).

○ Inspection of the channel cleaning brushes

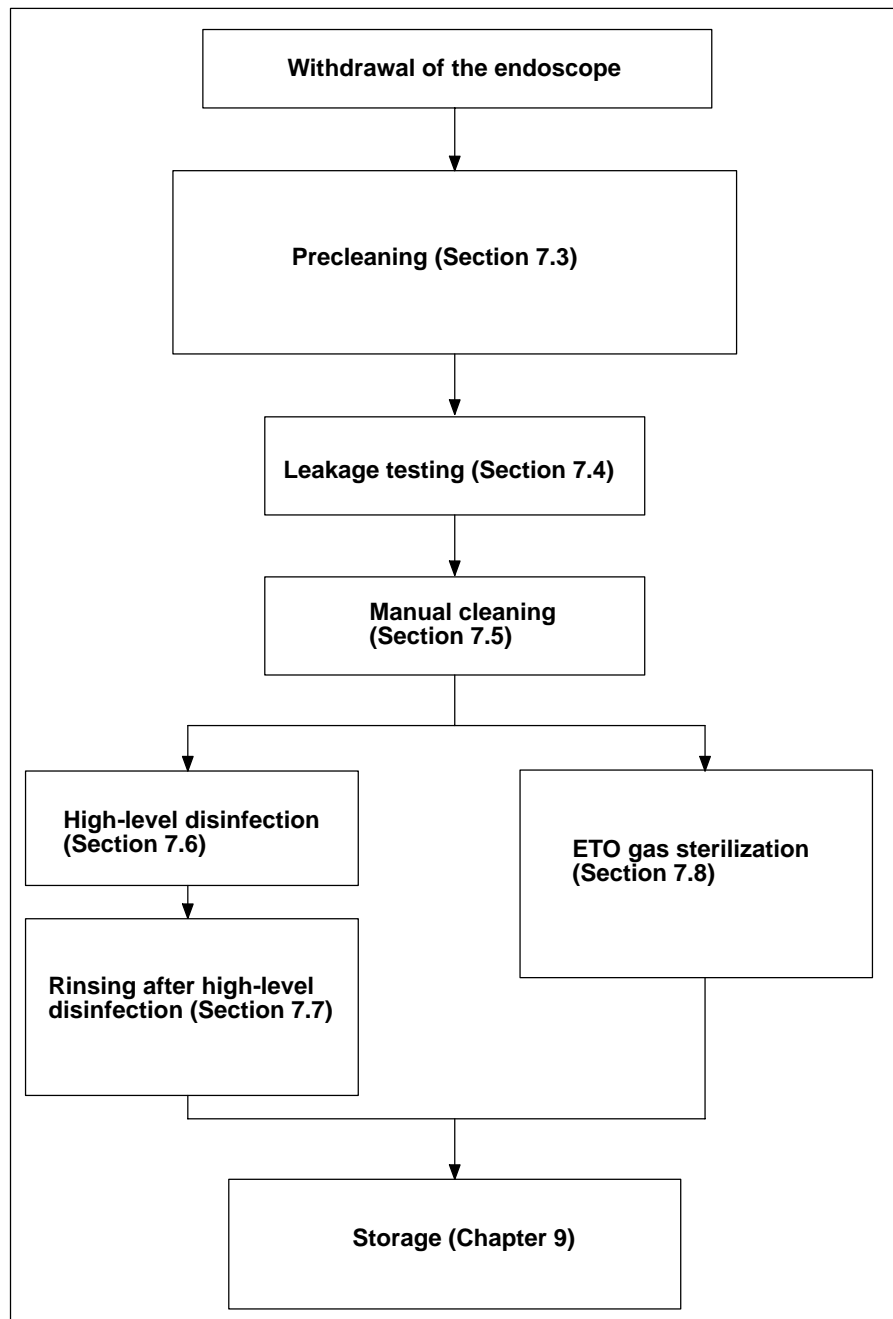
1. Confirm that the brush section and the metal tip at the distal end are securely in place. Check for loose or missing bristles (see Figure 7.4).
2. Check for bends, scratches and other damage to the shaft.
3. Check for debris on the shaft and/or in the bristles of the brush.

○ Inspection of the channel-opening cleaning brush

1. Check for loose or missing bristles (see Figure 7.5).
2. Check for debris on the shaft and/or in the bristles of the brush.

7.2 Cleaning, disinfection and sterilization procedures

Endoscope reprocessing summary chart



7.3 Precleaning

WARNING

If the endoscope is not immediately precleaned, residual organic debris will begin to solidify and it may be difficult to effectively reprocess the endoscope.

Preclean the endoscope at the bedside in the procedure room immediately after the procedure. The following steps are to be performed when the light source and suction pump are still connected to the endoscope.

Equipment needed

Prepare the following equipment:

- Personal protective equipment
- Clean, lint-free cloth
- 500 cm³ (500 ml) container
- Detergent solution

Wipe down the insertion tube

CAUTION

Handle the insertion tube carefully. Tightly gripping or sharply bending the insertion tube or bending section can stretch or severely damage the insertion tube and the covering of the bending section.

1. Prepare detergent solution in a 500 cm³ (500 ml) container.
2. Wipe the entire insertion tube with a clean, lint-free cloth soaked in detergent solution. Wipe from the boot at the control section toward the distal end.

Aspirate detergent solution

CAUTION

Monitor the suction bottle on the suction pump carefully to ensure that it does not overflow. Otherwise, suction pump damage could result.

1. Turn the suction pump ON.
2. Immerse the distal end of the insertion tube in detergent solution. Depress the suction valve and aspirate detergent solution into the instrument channel for 30 seconds (see Figure 7.6).
3. Remove the distal end of the insertion tube from the detergent solution. Depress the suction valve and aspirate air for 10 seconds.
4. Turn the suction pump OFF.

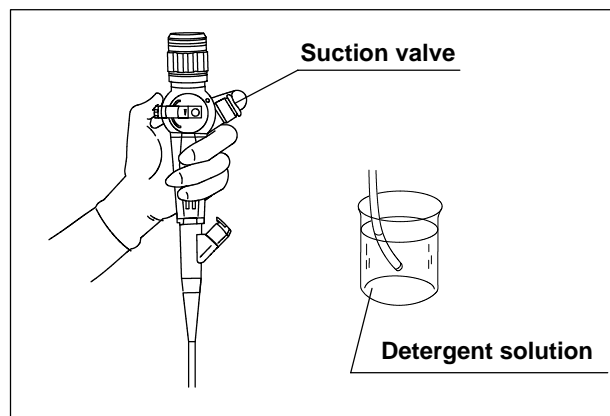


Figure 7.6

Disconnect the endoscope and removable parts

1. Disconnect the suction tube from the suction valve.
2. Remove the single-use suction valve (MAJ-209) from the endoscope as shown in Figure 7.7 below and discard it.

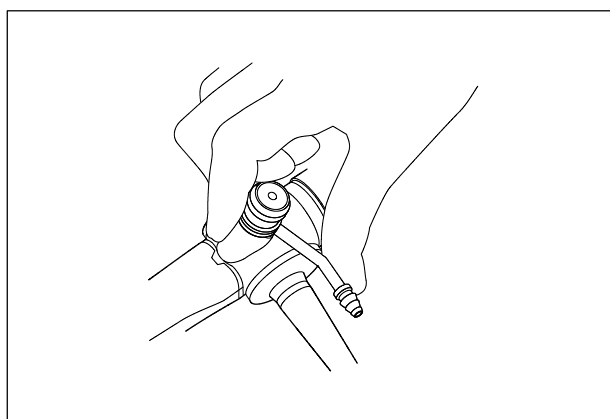


Figure 7.7

3. Remove the single-use biopsy valve (MAJ-210) as shown in Figure 7.8 below and discard it.

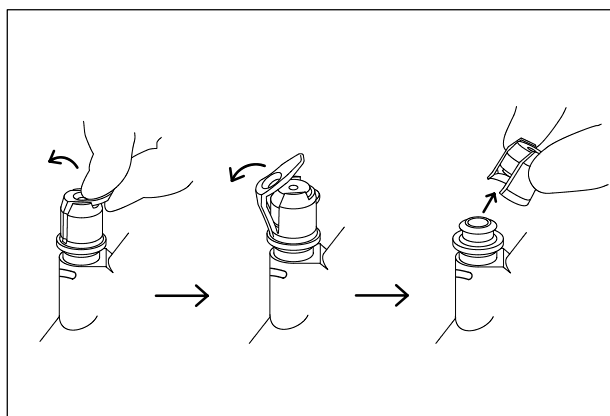


Figure 7.8

4. Disconnect the endoscope connector from the light source.

CAUTION

Do not touch the light guide of the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient injury may result.

5. Transport the endoscope and the container holding the other items to the reprocessing area.

7.4 **Leakage testing**

After precleaning, perform leakage testing on the endoscope to ensure that it is waterproof.

Equipment needed

Prepare the following equipment:

- Personal protective equipment
- Large basin
- Clean water
- Maintenance unit or light source (MU-1 or CLV-U40)
- Leakage tester (MB-155)

CAUTION

- Never connect or disconnect the leakage tester connector cap while immersed. Doing so could allow water to enter the endoscope and equipment damage can result.
- Rotate the leakage tester connector cap until it stops. If it is not fully and properly attached, the endoscope's interior will not be pressurized and accurate leakage testing will be impossible.
- During leakage testing, a continuous series of bubbles emerging from a location on the endoscope indicates a leak at that location. This means that water will be able to penetrate the inside of the endoscope. If you locate a leak, remove the endoscope from the water and contact Olympus.
- Always disconnect the leakage tester connector from the light source or maintenance unit before detaching the leakage tester's connector cap from the venting connector. Detaching the leakage tester's connector cap from the venting connector while the leakage tester is still connected to the light source will not allow the endoscope to depressurize properly. This may damage the endoscope.
- Always dry the leakage tester thoroughly. Any water remaining on the leakage tester may cause damage to the endoscope, maintenance unit or light source.

NOTE

When the leakage tester connector is in place, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

1. Fill a basin with clean water. Use a basin which is at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.

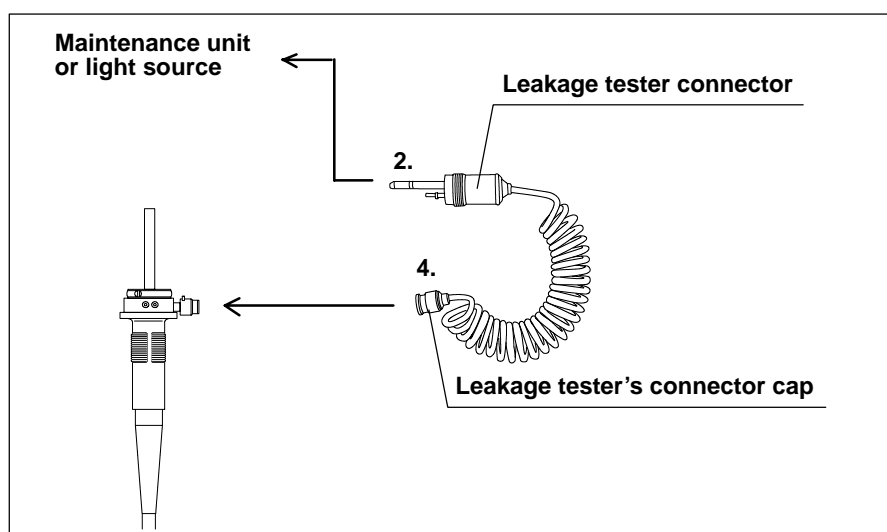


Figure 7.9

2. Insert the leakage tester connector into the output socket of the maintenance unit (MU-1) or the light source and turn the maintenance unit or the light source ON. Set the light source's airflow regulator switch to "HIGH" or "3" (see Figure 7.9).
3. Confirm that the leakage tester is emitting air by gently depressing the pin located inside the leakage tester's connector cap.
4. Attach the leakage tester's connector cap to the venting connector on the endoscope connector (see Figure 7.9).
5. With the leakage tester connected, immerse the endoscope in water and observe for approximately 30 seconds while angulating the bending section. Confirm that there is no location on the endoscope from which a continuous series of bubbles emerges.
6. Remove the endoscope from the basin with the leakage tester attached.
7. Turn the maintenance unit or the light source OFF.
8. Disconnect the leakage tester from the maintenance unit or the light source.

9. Wait 30 seconds, or until the covering of the bending section contracts to its pre-expansion size. Disconnect the leakage tester's connector cap from the venting connector.
10. Thoroughly dry the leakage tester.

7.5 **Manual cleaning**

After completing the leakage test, perform manual cleaning according to the procedures described below.

Equipment needed

Prepare the following equipment:

- Personal protective equipment
- Soft brush
- Clean, lint-free cloth
- Large basins
- Detergent solution
- Suction pump
- 30 cm³ (30 ml) syringe
- Clean water
- Suction cleaning adapter (MAJ-222)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)

CAUTION

To prevent damage to the endoscope, never immerse it together with objects other than the reprocessing accessories.

Cleaning the external surface

1. Fill a basin with water and low foaming detergent solution at a temperature and concentration recommended by the detergent manufacturer. Use a basin which is at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.
2. Immerse the endoscope in the detergent solution.
3. With the endoscope immersed, use a soft brush or lint-free cloth to thoroughly brush or wipe all external surfaces of the endoscope.

Brushing the channels

WARNING

- To avoid splattering detergent solution when the channel cleaning brush is pulled out, keep the endoscope submerged.
- The channel cleaning brush is an item that is subject to wear. Repeated using may cause the brush head being bent or kinked, as a result the brush head may be come off. Confirm that the brush is free from any damages or other irregularities before each use. If the brush head comes off after brushing, immediately retrieve it and carefully check that it is not left inside the channel of the endoscope by passing a new cleaning brush or other endo-therapy accessories.

If the brush head is left in the channel, it can drop into the patient body during the procedure. Depending on the staying location, the missing part may not be recoverable by passing a new brush or other endo-therapy accessories. In this case, contact Olympus.

While the endoscope is submerged, brush the instrument/suction channels, suction cylinder and instrument channel port according to the following procedures (see Figure 7.10).

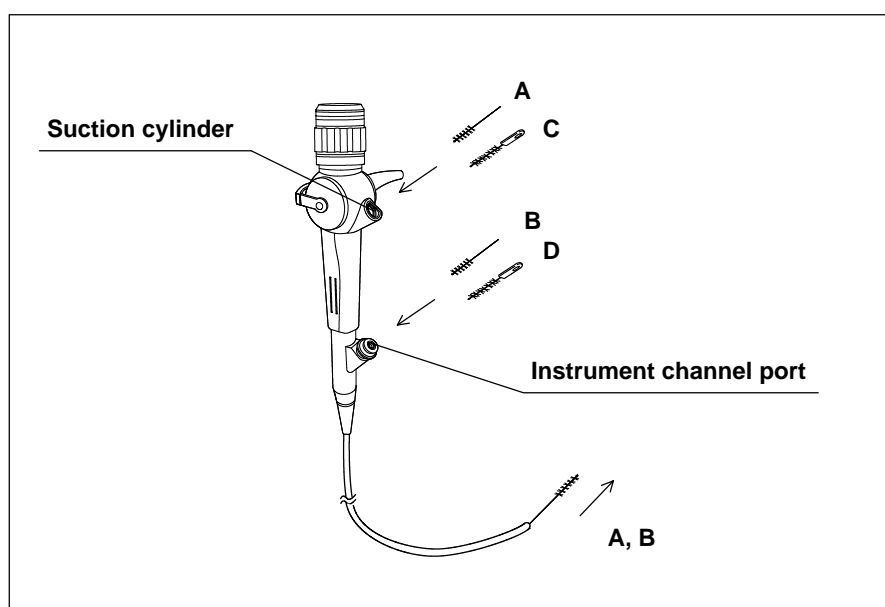


Figure 7.10

○ **Brushing the suction channel in the insertion tube (location A)**

1. Straighten the endoscope's bending section. Grip the channel cleaning brush at a point 3 cm from the bristles.
2. Insert the channel cleaning brush into the suction cylinder as illustrated by A in Figure 7.10. Using short strokes, feed the brush through the insertion tube until it emerges from the distal end of the endoscope.
3. Clean the bristles with your fingertips in the detergent solution. Carefully pull the brush out through the channel.
4. Clean the bristles in the detergent solution again.
5. Repeat until all debris is removed.

○ **Brushing the instrument channel (location B)**

1. Grip the channel cleaning brush at a point 3 cm from the bristles.
2. Insert the channel cleaning brush straight into the instrument channel port as illustrated by B in Figure 7.10. Using short strokes, feed the brush through the instrument channel until it emerges from the distal end of the endoscope.
3. Clean the bristles with your fingertips in the detergent solution. Carefully pull the brush out through the channel.
4. Clean the bristles in the detergent solution again.
5. Repeat until all debris is removed.

○ **Brushing the suction cylinder (location C)**

CAUTION

When inserting the channel-opening cleaning brush into the suction cylinder, do not forcibly insert the brush beyond the middle of the brush section. Otherwise, the brush may become stuck in the suction cylinder.

1. Insert the channel-opening cleaning brush into the suction cylinder as illustrated by C in Figure 7.10, until half of the brush section is inserted.
2. Turn the inserted brush once.
3. Pull the brush out and clean the bristles in the detergent solution.

4. Repeat until all debris is removed.

○ **Brushing the instrument channel port (location D)**

1. Insert the channel-opening cleaning brush (MH-507) into the instrument channel port as illustrated by D in Figure 7.10 until the brush handle touches the channel opening.
2. Turn the inserted brush once.
3. Pull the brush out and clean the bristles in the detergent solution.
4. Repeat until all debris is removed.
5. Reprocess the cleaning brushes as described in Section 7.9, "Cleaning, disinfection and sterilization procedures for reusable parts and reprocessing equipment".

Aspirating detergent solution into the instrument/suction channels

1. Attach the suction cleaning adapter's port cap to the instrument channel port. Attach the suction cylinder cap to the suction cylinder (see Figure 7.11).
2. Connect the suction tube from the suction pump to the suction opening of the suction cleaning adapter.
3. Turn the suction pump ON.
4. Immerse the endoscope's distal end in the detergent solution.
5. Aspirate the detergent solution for approximately 30 seconds.
6. Turn the suction pump OFF.
7. Disconnect the suction tube from the suction cleaning adapter.

Flushing detergent solution into the instrument/suction channels

1. Completely immerse the endoscope and suction cleaning adapter in the detergent solution.
2. Attach the 30 cm³ (30 ml) syringe to the suction opening.
3. Withdraw the plunger of the syringe to fill the instrument/suction channels and suction cleaning adapter with the detergent solution (see Figure 7.11).

4. With the endoscope and suction cleaning adapter completely immersed in the detergent solution, disconnect the suction cleaning adapter.

CAUTION

To prevent damage, do not pull the tubes of the suction cleaning adapter when disconnecting it from the endoscope. Always pull off the caps.

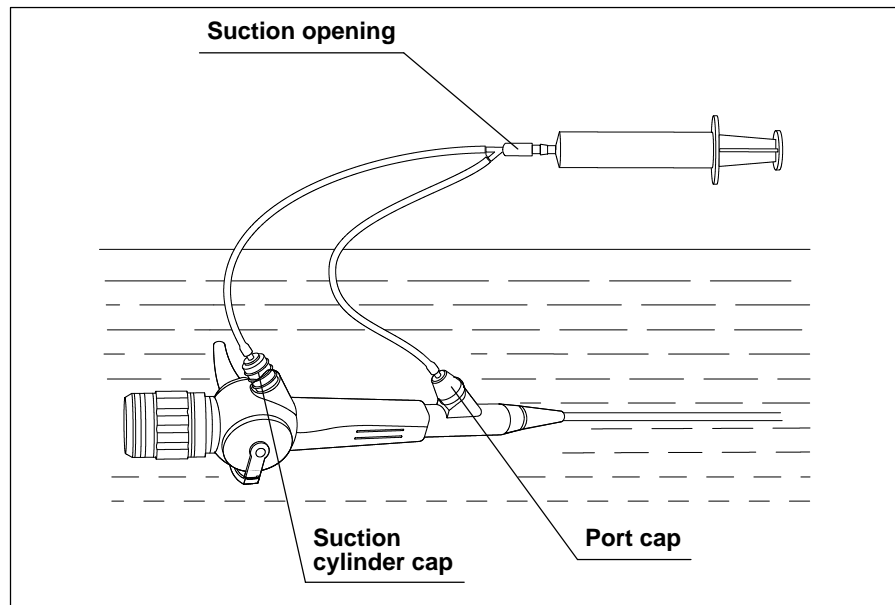


Figure 7.11

Soaking the endoscope and all equipment in detergent solution

1. Using a lint-free cloth, wipe off all debris from the endoscope's external surfaces while the endoscope is immersed in the detergent solution.
2. Cover the basin with a tight fitting lid to minimize the release of detergent vapors.
3. Soak the endoscope and all equipment for the amount of time and at the temperature recommended by the detergent manufacturer.

Removing and rinsing the endoscope and all equipment

1. Remove the endoscope and all equipment from the detergent solution and place them in clean water.
2. Gently agitate them to thoroughly rinse.

Removing detergent solution from the instrument/suction channels

1. Attach the suction cleaning adapter to the endoscope. Connect the suction tube from the suction pump to the suction opening on the suction cleaning adapter.
2. Turn the suction pump ON. Aspirate water for 30 seconds.
3. Remove the endoscope, together with the suction cleaning adapter, from the water. Aspirate air for 20 seconds.
4. Turn the suction pump OFF.
5. Disconnect the suction cleaning adapter from the endoscope.
6. Disconnect the suction tube from the suction cleaning adapter.

Dry external surfaces

1. Use a lint-free cloth to thoroughly wipe and dry the external surfaces of the endoscope and suction cleaning adapter.
2. Inspect the endoscope for residual debris. Should debris remain, repeat the procedures given in this section.

Presoak for excessive bleeding and/or delayed reprocessing

CAUTION

Follow the steps below only in case of excessive bleeding and/or delayed reprocessing; unnecessary presoaking should be avoided. Consecutive extended immersions may damage the endoscope.

Preclean and perform a leakage test on the endoscope as described in Section 7.3, "Precleaning" and Section 7.4, "Leakage testing".

1. Fill a basin with detergent solution at the temperature and concentration recommended by the detergent manufacturer. Use a basin which is at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.
2. Carefully coil the endoscope's insertion tube and universal cord, and completely immerse the endoscope in the detergent solution.

CAUTION

Do not coil the insertion tube or universal cord with a diameter of less than 12 cm. Equipment damage can result.

3. Connect the suction cleaning adapter to the endoscope. Completely immerse the endoscope in the detergent solution.
4. Attach the 30 cm³ (30 ml) syringe to the suction cleaning adapter. Withdraw the plunger of the syringe to fill the instrument/suction channels and suction cleaning adapter with the detergent solution (see Figure 7.11).
5. With the endoscope and suction cleaning adapter completely immersed in the detergent solution, disconnect the suction cleaning adapter.

CAUTION

To prevent damage, do not pull the tubes of the suction cleaning adapter when disconnecting it from the endoscope. Always pull off the caps.

6. Soak the endoscope for 1 hour at the temperature recommended by the detergent manufacturer.
7. Remove the endoscope from the detergent solution.
8. After soaking the endoscope, manually clean it following the procedures described in this section, then disinfect or sterilize the endoscope following the procedures described in Section 7.6, "High-level disinfection" or Section 7.8, "Sterilization".

7.6 High-level disinfection

After manual cleaning, disinfect the endoscope according to the procedures described below.

Equipment needed

Prepare the following equipment:

- Personal protective equipment
- Clean, lint-free cloths
- Large basin
- Disinfectant solution
- Suction cleaning adapter (MAJ-222)

WARNING

All disinfection steps should be performed with the endoscope and all equipment completely immersed. If the equipment is connected or disconnected while not immersed, disinfectant solution may not adequately contact all surfaces of the equipment. As a result, the effectiveness of disinfection may be reduced.

Preparation

1. Fill a basin with disinfectant solution at the temperature and concentration recommended by the disinfectant manufacturer. Use a basin which is at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.
2. Attach the suction cleaning adapter to the endoscope.
3. Attach the 30 cm³ (30 ml) syringe to the suction cleaning adapter.

Flushing disinfectant solution into the instrument/suction channels

1. Immerse the endoscope and all equipment in the disinfectant solution.
2. Pull the plunger of the syringe to fill the instrument/suction channels and suction cleaning adapter with the disinfectant solution.
3. With the endoscope and suction cleaning adapter completely immersed in the disinfectant solution, disconnect all equipment from the endoscope. Leave the endoscope and all equipment immersed in the disinfectant solution.

Soaking the endoscope and all equipment in disinfectant solution

1. If air bubbles adhere to the surfaces of the endoscope or suction cleaning adapter, remove them using a lint-free cloth.
2. Cover the basin with a tight fitting lid to minimize the release of disinfectant vapors.
3. Soak the endoscope and all equipment in disinfectant solution for the amount of time and at the temperature recommended by the disinfectant manufacturer.

Removing the endoscope and all equipment from disinfectant solution

1. Before removing the endoscope from the disinfectant solution, attach the suction cleaning adapter to the endoscope.
2. Attach the 30 cm³ (30 ml) syringe to the suction cleaning adapter and flush the channels with 90 cm³ (90 ml) of air.
3. Remove the endoscope and all equipment from the disinfectant solution.
4. Disconnect all equipment from the endoscope.

7.7 Rinsing after high-level disinfection

After high-level disinfection, rinse the endoscope according to the procedures described below.

Use water of appropriate microbiological quality. Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, fresh potable tap water or water which has been processed (e.g. filtered) to improve its microbiological quality may be used, followed by a 70% ethyl or isopropyl alcohol rinse (see "Non-sterile water rinse and alcohol flush" on page 59). Consult with your hospital's infection control committee.

Equipment needed

Prepare the following equipment:

- Small container
- Personal protective equipment
- Sterile, lint-free cloths
- Large basin
- Sterile water (for sterile water rinse)
- Clean water (non-sterile water)
- 70% ethyl or isopropyl alcohol
- Suction pump
- 30 cm³ (30 ml) syringe
- Sterile cotton swabs
- Suction cleaning adapter

(MAJ-222)

○ **Sterile water rinse**

1. Fill a basin with sterile water. Use a basin which is at least 40 cm by 40 cm (16" by 16") in size and deep enough to allow the endoscope to be completely immersed.
2. Immerse the endoscope and all equipment in the sterile water. Using a sterile, lint-free cloth, thoroughly rinse and wipe all external surfaces.
3. Connect the suction cleaning adapter and suction pump to the endoscope.
4. Turn the suction pump ON.
5. Aspirate the sterile water for 30 seconds.
6. Remove the endoscope from the water and aspirate air for 60 seconds.
7. Turn the suction pump OFF.
8. Hold the control section with the instrument channel port pointing down and disconnect the suction cleaning adapter from the endoscope (see Figure 7.12).
9. Use a sterile, lint-free cloth to thoroughly wipe and dry the external surfaces of the endoscope and all equipment.

NOTE

Flushing the channels with 70% ethyl or isopropyl alcohol after rinsing them with sterile water facilitates drying inside the channels.

10. Discard rinse water.

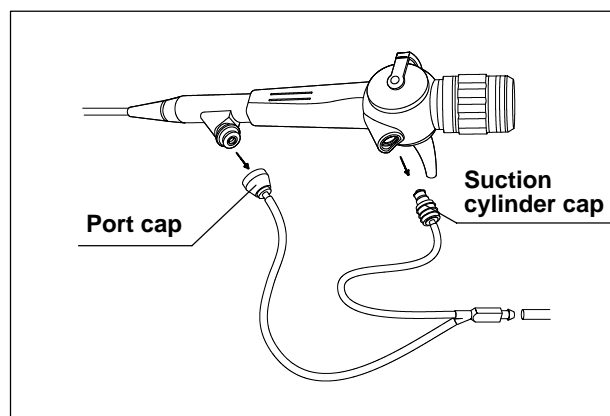


Figure 7.12

○ Non-sterile water rinse and alcohol flush

CAUTION

Alcohol is flammable. Handle with care.

1. Fill a small container with 70% ethyl or isopropyl alcohol.
2. Inject non-sterile water and air following the procedures given in “Sterile water rinse” on page 58.
3. Immerse the distal end of the endoscope in the alcohol. Aspirate alcohol for 5 seconds.
4. Remove the distal end of the endoscope from the alcohol and aspirate air for 20 seconds.
5. Turn the suction pump OFF.
6. Hold the control section with the instrument channel port pointing down and disconnect the suction cleaning adapter from the endoscope (see Figure 7.12).
7. Use a sterile, lint-free cloth to thoroughly wipe and dry the external surfaces of the endoscope and all equipment.
8. Use a sterile, lint-free cloth moistened with alcohol to thoroughly wipe the external surfaces of the endoscope and all equipment.
9. Use sterile cotton swabs to dry the inside of the suction cylinder and instrument channel port.
10. Discard rinse water.

7.8 Sterilization

ETO gas sterilization

As an alternative to high-level disinfection, the endoscope can be sterilized by ethylene oxide (ETO) gas. After performing manual cleaning and drying as described in Section 7.3, “Precleaning” and Section 7.5, “Manual cleaning”, follow the procedures given below.

WARNING

- Before sterilization, the instrument must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
- Exceeding the recommended parameters may cause equipment damage.

CAUTION

If ETO gas sterilization is performed while the ETO cap is not attached, the covering of the bending section can be damaged.

1. Attach the ETO cap to the venting connector before ETO gas sterilization.
2. Seal the instrument in a package appropriate for ETO gas sterilization according to your hospital’s protocol.
3. Sterilize the package according to the recommended ETO gas exposure parameters as described in Section 6.5, “ETO gas sterilization” and the sterilizer manufacturer’s instructions.
4. Aerate the components following the minimum aeration parameters specified in Section 6.5, “ETO gas sterilization”.
5. Store the components following the instructions given in Chapter 9, “Storage”.

7.9 **Cleaning, disinfection and sterilization procedures for reusable parts and reprocessing equipment**

This section includes the cleaning, disinfection and sterilization procedures for the reusable parts and reprocessing equipment listed below. For all other parts, refer to their respective instruction manuals. For compatible reprocessing methods, refer to Section 6.1, "Compatibility summary".

Equipment needed

Prepare the following equipment:

- Personal protective equipment
- Soft brush
- Large basin
- Detergent solution
- Clean water (non-sterile water)
- Sterile water (for sterile water rinse)
- Clean, lint-free cloths
- Disinfectant solution
- Sterile, lint-free cloths
- Small container
- 70% ethyl or isopropyl alcohol
- 30 cm³ (30 ml) syringe

○ Reusable parts which are normally reprocessed with the endoscope

- Suction cleaning adapter (MAJ-222)

○ Reusable parts which are normally reprocessed separately from the endoscope

- Mouthpiece (MA-651)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)

Manual cleaning

CAUTION

Make sure that the items immersed in detergent solution do not contact one another.

1. Fill a basin with clean water and low-foaming detergent solution at the temperature and concentration recommended by the detergent manufacturer. Use a basin which is deep enough to allow all equipment to be completely immersed.
2. Immerse all equipment in the detergent solution.
3. Using a clean, soft brush or lint-free cloth, meticulously clean all external surfaces in the detergent solution.
4. Clean the bristles of the cleaning brushes thoroughly while the brushes are immersed.
5. Soak all equipment for the amount of time and at the temperature recommended by the detergent manufacturer.
6. Remove all equipment from the detergent solution and place it in clean water.
7. Inspect all equipment. If debris remains, ultrasonically clean it at 38 - 47 kHz for 5 minutes.
8. Remove all equipment from the clean water.
9. Use a clean, lint-free cloth to thoroughly wipe and dry all external surfaces of all equipment.

High-level disinfection

1. Fill a basin with disinfectant solution at the temperature and concentration recommended by the disinfectant manufacturer. Use a basin which is deep enough to allow all equipment to be completely immersed.
2. Immerse all equipment in the disinfectant solution.
3. Using a lint-free cloth and/or 30 cm³ (30 ml) syringe, wipe and/or flush all surfaces with the disinfectant solution to remove all air bubbles.
4. Rub the bristles of the cleaning brushes to remove all air bubbles.
5. Soak all equipment for the amount of time and at the temperature recommended by the disinfectant manufacturer.

Rinsing after high-level disinfection

After high-level disinfection, rinse all equipment according to the procedures described below.

Use water of appropriate microbiological quality. Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, fresh potable tap water or water which has been processed (e.g. filtered) to improve its microbiological quality may be used, followed by a 70% ethyl or isopropyl alcohol rinse (see "Non-sterile water rinse and alcohol flush" on page 64). Consult with your hospital's infection control committee.

○ Sterile water rinse

1. Fill a basin with sterile water. Use a basin which is deep enough to allow all equipment to be completely immersed.
2. Remove all equipment from the disinfectant solution and immerse it in the sterile water.
3. Gently agitate all equipment to thoroughly rinse it.
4. Remove all equipment from the sterile water.
5. Use a sterile, lint-free cloth to thoroughly wipe and dry all external surfaces.
6. Discard rinse water.

○ **Non-sterile water rinse and alcohol flush**

CAUTION

Alcohol is flammable. Handle with care.

1. Fill a small container with 70% ethyl or isopropyl alcohol.
2. Rinse with non-sterile water following the procedures given in “Sterile water rinse” above.
3. Immerse all equipment in the alcohol and gently agitate it.
4. Remove all equipment from the alcohol.
5. Use a sterile, lint-free cloth to thoroughly wipe and dry all external surfaces.
6. Discard rinse water.

Sterilization

○ ETO gas sterilization

CAUTION

The cleaning brushes are not compatible with ETO gas sterilization.

After cleaning and drying as described in “Manual cleaning” on page 62, follow the procedures given below.

1. Seal the individual parts or equipment separately in packages appropriate for ETO gas sterilization according to your hospital's protocol.
2. Sterilize the packages according to the recommended ETO gas exposure parameters as described in Section 6.5, “ETO gas sterilization” and the sterilizer manufacturer's instructions.
3. Aerate the components following the minimum aeration parameters specified in Section 6.5, “ETO gas sterilization”.
4. Store the components following the instructions given in Chapter 9, “Storage”.

○ Steam sterilization (autoclaving)

After cleaning as described in “Manual cleaning” on page 62, steam sterilize (autoclave) according to the instructions given below.

1. Seal the individual parts or equipment separately in packages appropriate for steam sterilization (autoclaving) according to your hospital's protocol.
2. Steam sterilize the packages according to the recommended steam sterilization (autoclaving) exposure parameters as described in Section 6.6, “Steam sterilization (autoclaving) of accessories” and the sterilizer manufacturer's instructions.
3. Following steam sterilization (autoclaving), let all components gradually cool down to room temperature. Sudden changes in temperature may damage the instruments.

Chapter 8 Cleaning and Disinfection Equipment

The endoscope is compatible with some endoscope washers recommended by Olympus. Refer to the respective instructions manual for details on operation.

Chapter 9 Storage

CAUTION

- The storage cabinet must be clean, dry, well ventilated and maintained at ambient temperature. Storing the endoscope in direct sunlight, at high temperatures, in high humidity or exposed to X-rays and/or ultraviolet-rays may damage the endoscope or present an infection control risk.
 - Prior to storage, detach all removable parts from the endoscope. It will allow air to circulate through the internal lumens of the endoscope and will assist drying.
 - Do not store the endoscope in the carrying case. Use the carrying case only for shipping the endoscope. Routinely storing the endoscope in a humid, non-ventilated environment, such as the carrying case, may present an infection control risk.
1. Before storage of a high-level disinfected endoscope, thoroughly dry all parts of the endoscope (especially all internal lumens, the distal end and lenses) and all accessories.
 2. Use a cotton swab moistened with 70% ethyl or isopropyl alcohol to carefully wipe the objective, light guide and eyepiece lenses.
 3. Hang the endoscope in the storage cabinet with the distal end hanging freely. Make sure that the insertion tube hangs vertically and as straight as possible.

Chapter 10 Troubleshooting

If the endoscope is visibly damaged, does not function as expected or is found to have irregularities during the inspection described in Chapter 3, "Preparation and Inspection", do not use the endoscope. Contact Olympus.

Some problems that appear to be malfunctions may be correctable by referring to Section 10.1, "Troubleshooting guide". If the problem cannot be resolved by the described remedial action, stop using the endoscope and send it to Olympus for repair.

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

WARNING

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

10.1 Troubleshooting guide

○ Image quality or brightness

Irregularity description	Possible cause	Solution
An image is not clear.	The objective lens is dirty.	Clean the objective lens with a cotton swab moistened with 70% ethyl or isopropyl alcohol.
	The eyepiece lens is dirty.	Clean the eyepiece lens with a cotton swab moistened with 70% ethyl or isopropyl alcohol.
	Optics is not adjusted to operator's eyesight.	Rotate the diopter adjustment ring until fiber pattern is clear.
An image is excessively dark or bright.	The light source is not set properly.	Set the light source as described in its instruction manual.

○ Water feeding

Irregularity description	Possible cause	Solution
Fluid is leaking from the biopsy valve.	The biopsy valve is not attached properly.	Attach it correctly as described in Section 3.4, page 17.
	The syringe is not inserted securely.	Insert it securely.
The biopsy valve cannot be attached.	The biopsy valve is damaged.	Replace it with a new biopsy valve.

○ Suction

Irregularity description	Possible cause	Solution
Suction is absent or insufficient.	The biopsy valve is not attached properly.	Attach it correctly as described in Section 3.4, page 17.
	The biopsy valve is damaged.	Replace it with a new one.
	The suction pump is not set properly.	Adjust the suction pump's setting as described in its instruction manual.
	The suction valve is damaged.	Replace it with a new one.
The suction valve is sticky.	The suction valve is 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.

○ Endo-therapy accessories

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

10.2 *Returning the endoscope for repair*

WARNING

Thoroughly clean and high-level disinfect or sterilize the endoscope before returning it for repair. Improperly reprocessed equipment presents an infection control risk to each person who handles the endoscope within the hospital or at Olympus.

CAUTION

Olympus is not liable for any injury or damage which 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 28.

Appendix

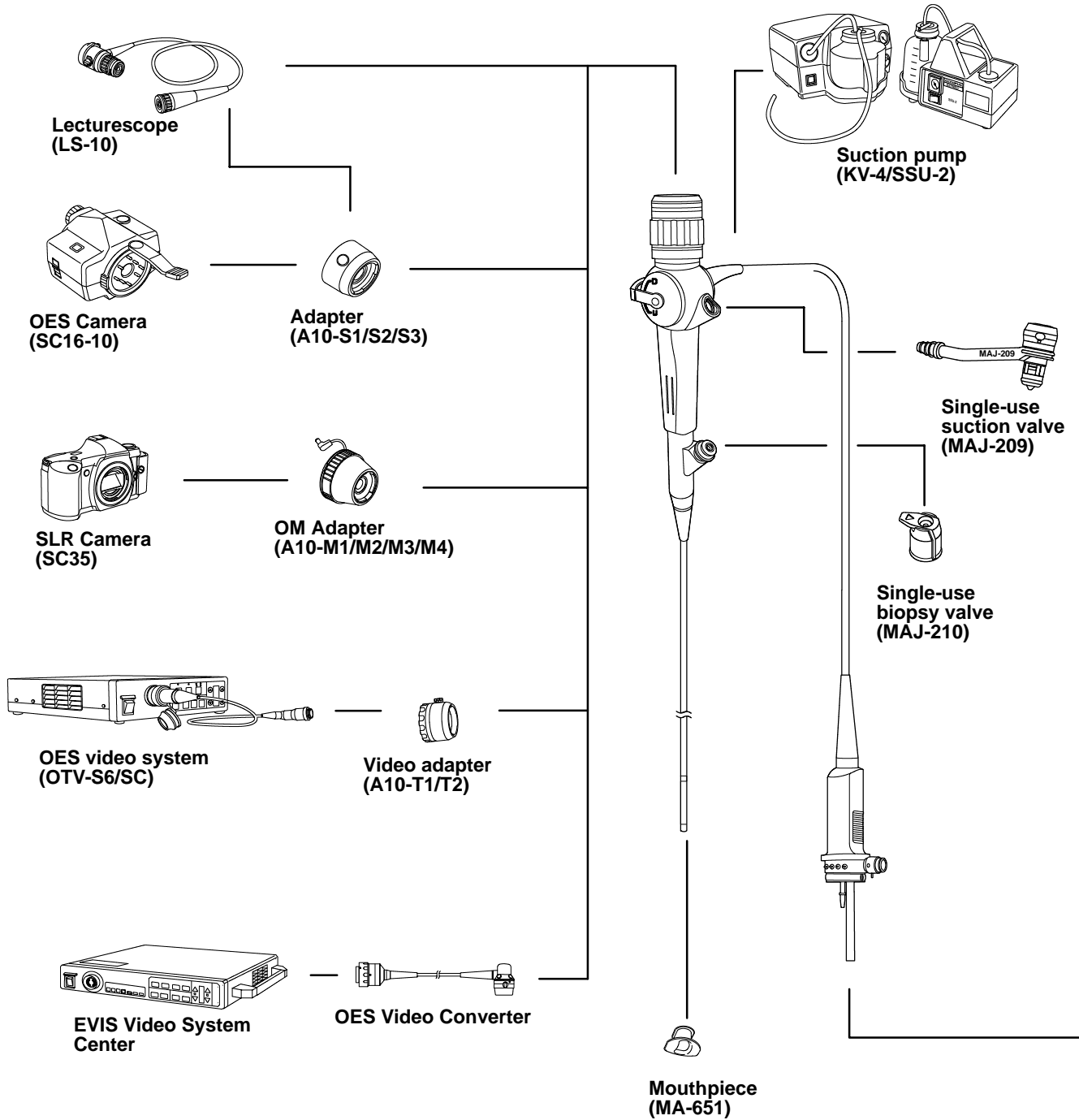
System chart

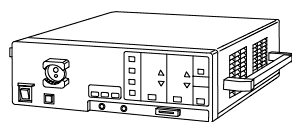
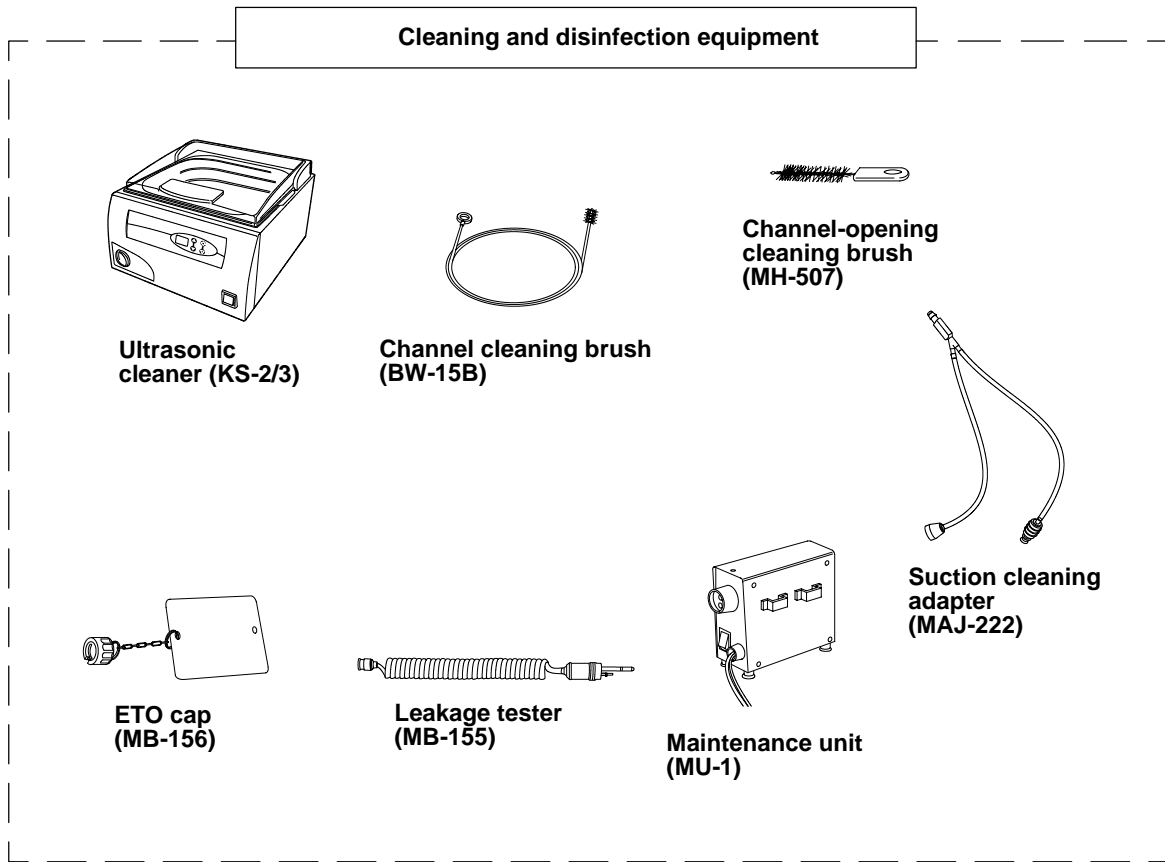
The recommended combinations of equipment and accessories that can be used with this instrument are listed below. Some items may not be available in some areas. New products released after the introduction of this instrument may also be compatible for use in combination with this instrument. For further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

WARNING

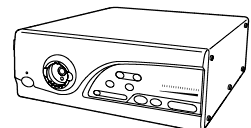
If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

Endoscopic equipment combinations



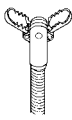
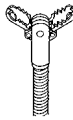
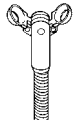
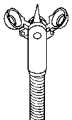


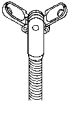
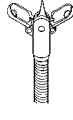
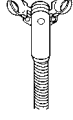
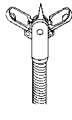
EVIS universal light source (CLV-U40)

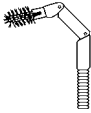







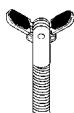

EVIS EXERA light source (CLV-160, CLE-145)

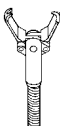


Endo-therapy accessories



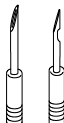

	BIOPSY FORCEPS			
	Alligator jaws	Swing type	Fenestrated	Fenestrated with needle
				
BF-1T30	FB-15C-1	FB-52C-1	FB-20C-1	FB-34C-1
BF-P30	FB-15C-1	FB-52C-1	FB-19C-1	FB-34C-1

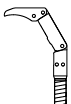
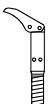

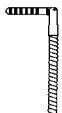
	BIOPSY FORCEPS		ROTATABLE BIOPSY FORCEPS	
	Ellipsoid	Ellipsoid with needle	Fenestrated	Ellipsoid with needle
				
BF-1T30	FB-21C-1	FB-22C-1	FB-19CR-1	FB-22CR-1
BF-P30	FB-21C-1	-	FB-19CR-1	-

	CYTOLOGY BRUSH			
	Double-joint	With sheath	Standard type	Disposable
				
BF-1T30	BC-8C☆	BC-9C☆	BC-10C☆	BC-202D-1210 to 5010
BF-P30	BC-8C☆	BC-5C☆	BC-10C☆	BC-202D-1210 to 5010


	GRASPING FORCEPS		GRASPING FORCEPS	
	Sperial basket type		Rubber tips (non-latex)	W-shape
				
BF-1T30	FG-51D	FG-52D	FG-20P-1	FG-25C-1
BF-P30	FG-51D	FG-52D	FG-20P-1	-

	GRASPING FORCEPS	MAGNETIC EXTRACTOR	CANNULA	WASHING PIPE
	Rat tooth		Standard type	Spray type
				
BF-1T30	FG-26C-1	IE-2P☆	PR-2B-1	PW-6P-1
BF-P30	-	IE-2P☆	PR-2B-1	PW-6P-1

	INJECTOR	DISPOSABLE INJECTOR	ASPIRATION NEEDLE	BALLOON CATHETER
				
BF-1T30	NM-3K/8L-1/9L-1☆	NM-21 to 25L	NA-1C/2C	B5-2C
BF-P30	NM-3K/8L-1/9L-1☆	NM-21 to 25L	NA-1C/2C	B5-2C

	MEASURING DEVICE		CYTOLOGY CURETTE	
	Standard	Bendable		
				
BF-1T30	M1-1C☆	M2-1C/2C☆	CC-4CR-1☆	CC-5CR-1☆
BF-P30	M1-1C☆	M2-1C/2C☆	CC-4CR-1☆	CC-5CR-1☆

Appendix

	YAG LASER PROBE
	
BF-1T30	CYL-E302/E303☆
BF-P30	CYL-E303☆

☆: These accessories may not be available in some areas.

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