

### INSTRUCTIONS



### EVIS EXERA II DUODENOVideoscope OLYMPUS TJF TYPE Q180V

#### Accessories:

- Water resistant cap (MH-553)
- Biopsy valve (MB-358)
- Air/water valve (MH-438)
- Suction cleaning adapter (MH-856)
- Channel cleaning brush (BW-20T)
- Single use channel cleaning brush (BW-201T)
- AW channel cleaning adapter (MH-948)
- Chain for water-resistant cap (MAJ-1119)
- Suction valve (MH-443)
- Mouthpiece (MB-142)
- Channel plug (MH-944)
- Injection tube (MH-946)
- Single use channel-opening cleaning brush (MAJ-1339)
- Single use combination cleaning brush (BW-412T)



MH-553



MAJ-1119



MB-358



MH-443



MH-438



MB-142



MH-856



MH-944



BW-20T  
BW-201T



MH-946



MAJ-1339



MH-948



BW-412T

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

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



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# **Chapter 1 General Policy**

## **1.1 Instructions**

- This manual contains the cleaning, disinfection, and sterilization methods recommended by Olympus for the endoscopes and accessories listed on the front cover.
- This instruction manual contains essential information on reprocessing endoscopes and accessories safely and effectively.
- Before reprocessing, thoroughly review this manual and the manuals of the reprocessing equipment and chemicals that will be used for reprocessing. Reprocess all the devices as instructed.
- Note that the complete instruction manual set for the endoscope and accessories consists of this manual and the "OPERATION MANUAL" with your endoscope model listed on the cover. Both manuals accompanied the endoscope at shipment.
- Keep this manual and all related manuals in a safe and accessible location (e.g., in the reprocessing area).
- If you have any questions or comments about any information in this manual, or if a problem occurs while reprocessing that cannot be solved, contact Olympus.

## 1.2 Importance of cleaning, disinfection, and sterilization

The medical literature reports incidents of cross-contamination resulting from improper cleaning, disinfection, or sterilization. It is strongly recommended that all individuals engaged in reprocessing closely observe all instructions given in this manual and the manuals of all ancillary equipment, and have a thorough understanding of the following items:

- Professional health and safety policies of your hospital
- Instruction manuals for the endoscope, accessories, and all the other reprocessing equipments
- Structure and handling of endoscope and accessories
- Handling of pertinent chemicals

When selecting appropriate methods and conditions for cleaning and disinfection and sterilization, follow the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices, in addition to the instructions given in this manual.

## 1.3 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.

## 1.4 Precautions

### **WARNING**

- An insufficiently cleaned, disinfected, or sterilized endoscope and/or accessories may pose an infection control risk to the patients and/or operators who contact them.
- All disinfection methods (whether performed manually or by an automated endoscope reprocessor), and all sterilization methods (whether performed by ethylene oxide gas or steam) require thorough prior cleaning of the instrument being reprocessed. If the equipment is not adequately cleaned prior to disinfection/sterilization, these processes will be ineffective. Immediately after each patient procedure and before disinfection/sterilization, thoroughly clean the endoscope and the accessories used with the endoscope.
- All channels of the endoscope, including the instrument channel and all accessories used with the endoscope during the patient procedure, such as all valves, must be cleaned and high-level disinfected or sterilized after each patient procedure, even if the channels or accessories were not used during the patient procedure. Insufficient cleaning and disinfection or sterilization of these components may pose an infection control risk to patients and/or operators.
- Disinfectant solutions are hazardous. After disinfection, rinse all external surfaces and channels of the endoscope and accessories thoroughly with water to remove residual disinfectant solution.
- The results of sterilization depend on various factors. These factors include how the equipment was packaged, and the placing and loading of the package in the sterilization device. Verify the sterilization process using biological and/or chemical indicators. Follow the guidelines for sterilization issued by national authorities, professional organizations and infection control professionals, as well as the instruction manual for the sterilization device.

**WARNING**

- Establish an internal system of identifying contaminated versus reprocessed endoscopes and accessories to prevent both mix-ups and cross-contamination. Touching a reprocessed endoscope and/or accessories with contaminated gloves or placing them on a contaminated hanger or surface, including letting them touch the floor, will recontaminate them.
- Prior to each patient procedure, confirm that the endoscope and accessories have been properly reprocessed and stored. If there are any doubts or questions, reprocess them again before the patient procedure, following the instructions given in this manual.
- Perform a leakage test on the endoscope after each precleaning procedure. Do not use the endoscope if a leak is detected. Use of an endoscope with a leak may cause a sudden loss of the endoscopic image, damage to the bending mechanism, or other malfunctions. Use of a leaking endoscope may also pose an infection control risk.

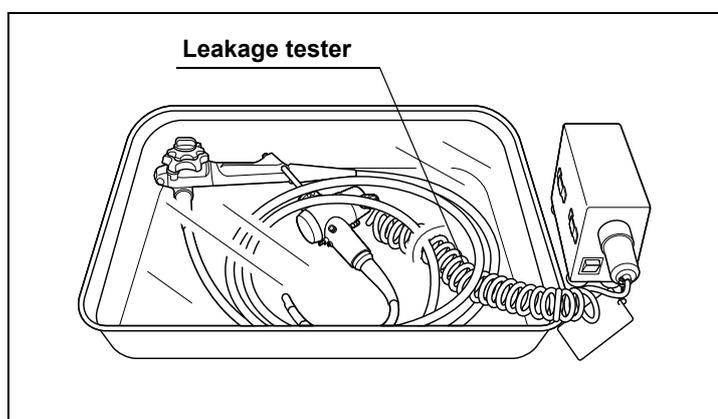


Figure 1.1

- Store alcohol in an air tight container. Alcohol stored in an open container may cause a fire hazard and may result in a loss of efficacy due to evaporation.

**WARNING**

- Do not use the AW channel cleaning adapter (MH-948) for patient procedures. It will cause continuous insufflation and could result in patient injury.

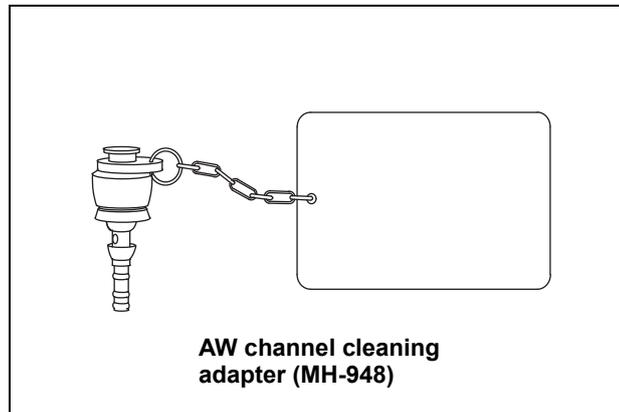


Figure 1.2

- The accessories listed on the front cover of this manual are consumables, meaning that these accessories cannot be refurbished or repaired and are intended to be replaced once they show any signs of wear. Should any irregularity be observed, use a replacement accessory instead. Using defective accessories may cause equipment malfunction, reduce the efficacy of reprocessing, present a risk to patients and/or operators, or damage the endoscope and/or accessories.
- Single-use brushes, such as the single use channel cleaning brush (BW-201T), the single use combination cleaning brush (BW-412T), and the single use channel-opening cleaning brush (MAJ-1339), are designed for cleaning only one endoscope and its related accessories. Dispose of the single-use brush immediately after use. Using a single-use brush to clean multiple endoscopes and/or accessories may reduce its cleaning efficacy and may damage the brush leading to brush breakage or endoscope and/or accessory damage.

**WARNING**

- Patient debris and reprocessing chemicals are hazardous. To guard against contact with dangerous chemicals and potentially infectious material, wear appropriate personal protective equipment during cleaning, disinfection, and sterilization. Such protective equipment should include appropriate eyewear, face mask, cap, moisture-resistant clothing, shoe covers, and chemical-resistant gloves that fit properly and are long enough to prevent skin exposure.
- The reprocessing room must be adequately ventilated. Adequate ventilation protects against the buildup of toxic chemical fumes.
- Always remove contaminated personal protective equipment before leaving the reprocessing area to prevent contamination from spreading.
- Only Olympus-recommended or Olympus-endorsed automated endoscope reprocessors (AERs) have been validated by Olympus. When using an AER that is not recommended by Olympus, the manufacturer of the AER is responsible for validating compatibility of the AER with each Olympus endoscope and accessory.
- Before using an AER, confirm that it is capable of reprocessing the endoscope including all channels and accessories. Be sure to attach all required connectors. Otherwise, insufficient reprocessing may pose an infection control risk. If you are uncertain as to the ability of your AER to reprocess the endoscope including all channels and accessories, contact the manufacturer of the AER for specific instructions and information on compatibility and required connectors.
- Instructions provided in this manual are not valid for Olympus devices repaired by a non-Olympus facility. The Olympus recommended reprocessing procedures have not been validated for reprocessing devices repaired by a non-Olympus facility. In the event that your device has been repaired by a non-Olympus facility, please contact that repair facility for instructions regarding reprocessing.

**WARNING**

- Prions, which are the pathogenic agent of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated by the cleaning, disinfection, and sterilization methods stated in this instruction manual. When using the endoscope and accessories on patients with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use them for such patients only, or immediately dispose of them after use in an appropriate manner to prevent the usage of exposed devices on other patients. For methods to handle CJD, please follow the respective guidelines in your country.
- The endoscope and accessories may be damaged by published methods for destroying or inactivating prions. For information on the durability of Olympus equipment against a particular reprocessing method, please contact Olympus. In general, Olympus cannot guarantee the effectiveness, safety, and durability of cleaning, disinfection, or sterilization methods not described in this reprocessing manual. If you chose to use a reprocessing method not recommended in this manual, the local institution and/or physicians must assume responsibility for its safety and efficacy. Make sure to carefully inspect each piece of endoscopic equipment for irregularities (damage) prior to each patient procedure. Do not use the equipment if any irregularity is found.
- Good quality control practices typically require appropriate documentation. Items such as: local SOPs (standard operating procedures), confirmation of operator training, routine testing of the disinfectant's MEC (minimal effective concentration), confirmation of the disinfectant's use-life, etc., should be documented as performed.

**CAUTION**

- When reprocessing the endoscope, confirm that the water resistant cap (MH-553) is securely attached to the electrical connector before immersing the endoscope in reprocessing fluids. If the water resistant cap is not securely attached, the reprocessing fluids could enter the endoscope and damage the endoscope.

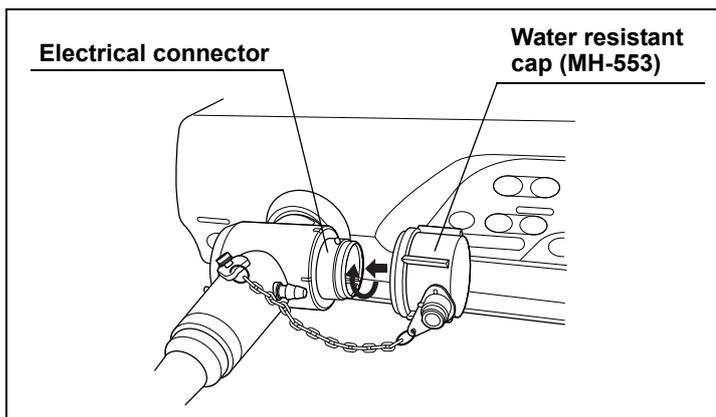


Figure 1.3

- When aerating or irrigating the endoscope channels, the air or water pressure must not exceed 0.5 MPa (5 kgf/cm<sup>2</sup>, 71 psig). Higher pressures may cause damage to the endoscope.
- Store spare accessories in their original packaging to prevent damage.
- To prevent damage, do not apply excessive force to the endoscope and accessories during reprocessing.
- Vapors from disinfectant solutions and alcohol may damage electronic devices such as computers.

## 1.5 *Reprocessing before the first use*

New endoscopes, repaired endoscopes, accessories, and the carrying case for endoscopes are not cleaned, disinfected, or sterilized prior to shipping from Olympus, regardless of whether those instruments are for new purchase, demo or loaner purposes. Reprocess all such endoscopes and accessories received from Olympus according to the instructions given in this manual before storage and before using them in a patient procedure.

## 1.6 Reprocessing and storage after use

### **WARNING**

- Do not reuse rinse water.
- High-level disinfectant solutions are only effective when used according to the disinfectant manufacturer's instructions. Follow the manufacturer's instructions regarding activation (if required), concentration, temperature, contact time and use life required to achieve high-level disinfection.
- If the disinfectant solution is reused, check its efficacy with a test strip according to the disinfectant manufacturer's recommendations prior to use.
- Do not reuse alcohol.
- Alcohol is not a sterilant or high-level disinfectant.
- To maintain sterility of equipment following sterilization, use sterile packaging and wraps according to national guidelines.

## 1.7 Reprocessing before patient procedure

### **WARNING**

- Improper storage practices, such as not thoroughly drying external and internal surfaces (lumens) including the forceps elevator recess prior to storage, will lead to an infection control risk.
- Improper handling, such as touching a reprocessed endoscope and/or accessories with contaminated gloves, placing a reprocessed device on a contaminated hanger or surface, allowing devices to touch the floor, etc., will recontaminate the device.

### **NOTE**

Some national or professional guidelines recommend reprocessing endoscopes prior to their first use of the day.

Confirm that the endoscope and accessories have undergone proper reprocessing following their last use and that they have been stored properly. Check the storage period of reprocessed endoscopes, and check for surface contamination (e.g., dust). Check the sterilization expiration date(s) of all items so marked and for tears or breaches in sterile packaging. If there are any doubts or questions concerning whether a device is contaminated, reprocess it again following the instructions given in this manual.

## **Chapter 2 Function and Inspection of the Accessories for Reprocessing**

Certain accessories are required for reprocessing the endoscope. This chapter describes the function of these accessories. It also describes how to inspect these accessories before using them to reprocess the endoscope.

### **2.1 Water resistant cap (MH-553)**

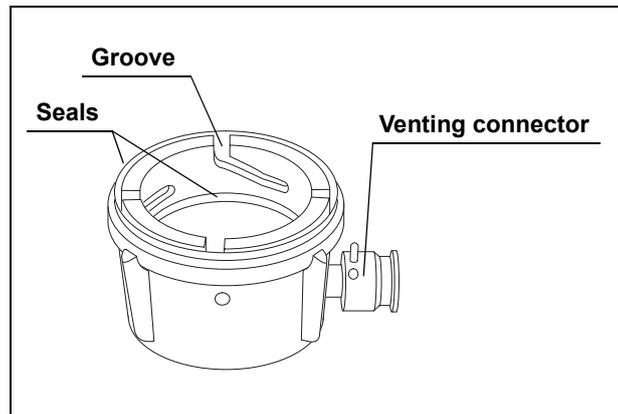


Figure 2.1

## ○ Function

The water resistant cap is attached to the electrical connector on the endoscope to protect the connector and the endoscope from water penetration during reprocessing. During leakage testing, the leakage tester (MB-155) is attached to the venting connector of the water resistant cap.

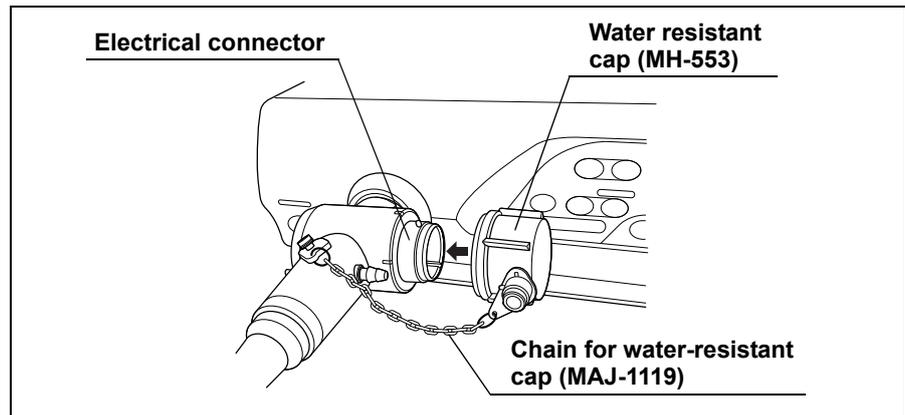


Figure 2.2

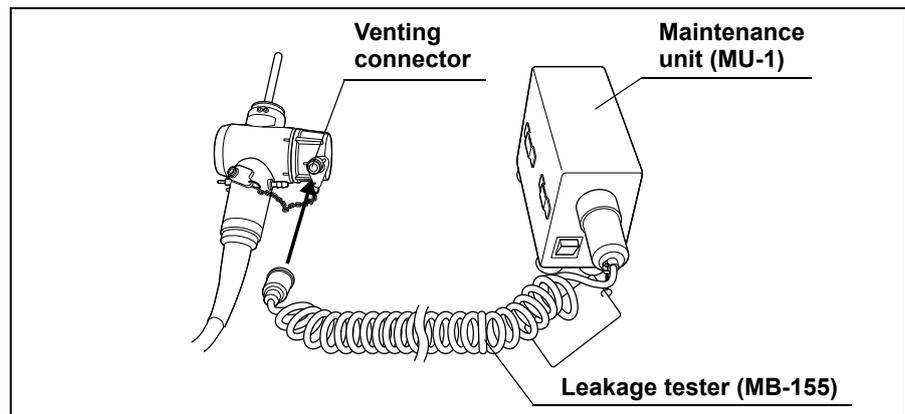


Figure 2.3

The water resistant cap must be attached to the electrical connector of the endoscope whenever the endoscope is immersed in reprocessing fluids. It is detached from the connector whenever the endoscope is used for patient procedures, being sterilized by ethylene oxide gas, or stored in an endoscope storage cabinet.

### **CAUTION**

Always use a dry water resistant cap. Any water remaining inside the cap may cause damage to the endoscope.

**NOTE**

Use the chain for water-resistant cap (MAJ-1119) to connect the water resistant cap to the endoscope. The water resistant cap can remain connected to the endoscope by the chain at all times (including during patient procedures, reprocessing, and storage of the endoscope).

**○ Inspection**

1. Confirm that the inside of the cap is dry and free from debris. Wipe with a dry, lint-free cloth if the inside of the cap is wet or if debris is detected.
2. Confirm that the seals inside the cap are free from scratches, cuts, and debris.
3. Check to ensure that the venting connector on the cap is not loose.

## **2.2 Channel plug (MH-944)**

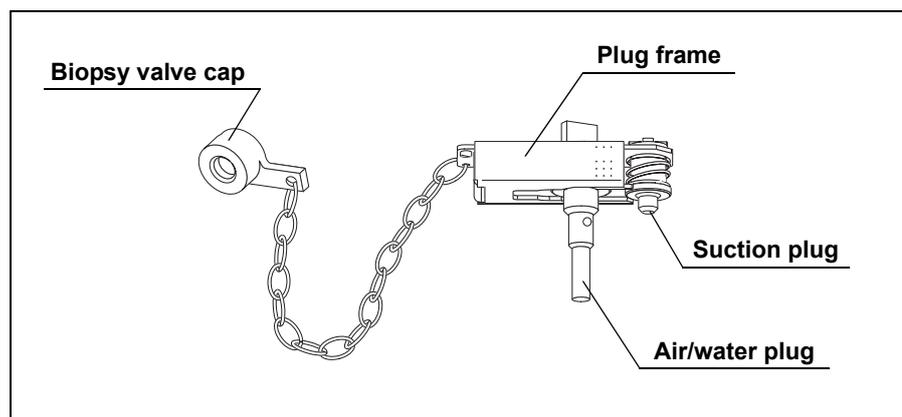


Figure 2.4

## ○ Function

The channel plug is used to plug the openings of the instrument channel port and the suction and air/water cylinders of the endoscope whenever the injection tube (MH-946) is used to flush the suction and air/water channels of the endoscope with reprocessing fluids.

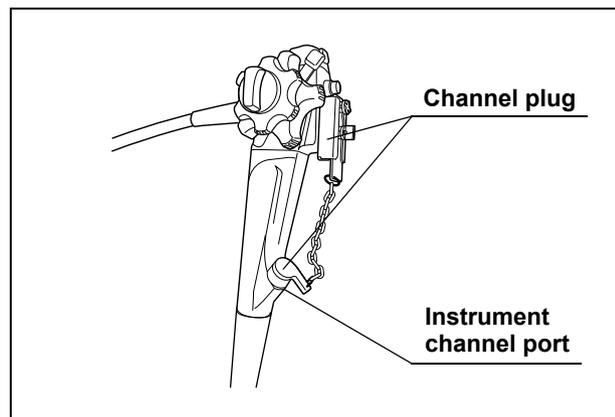


Figure 2.5

### NOTE

When attached to the endoscope, the channel plug is designed to allow a small amount of fluid to exit from the openings of the endoscope. This enables reprocessing fluids to contact the endoscope openings.

## ○ Inspection

Confirm that the suction plug, air/water plug, and the biopsy valve cap of the channel plug are free from cracks, scratches, and debris.

### NOTE

The channel plug does not need to be cleaned, disinfected, or sterilized prior to its first use.

## 2.3 Injection tube (MH-946)

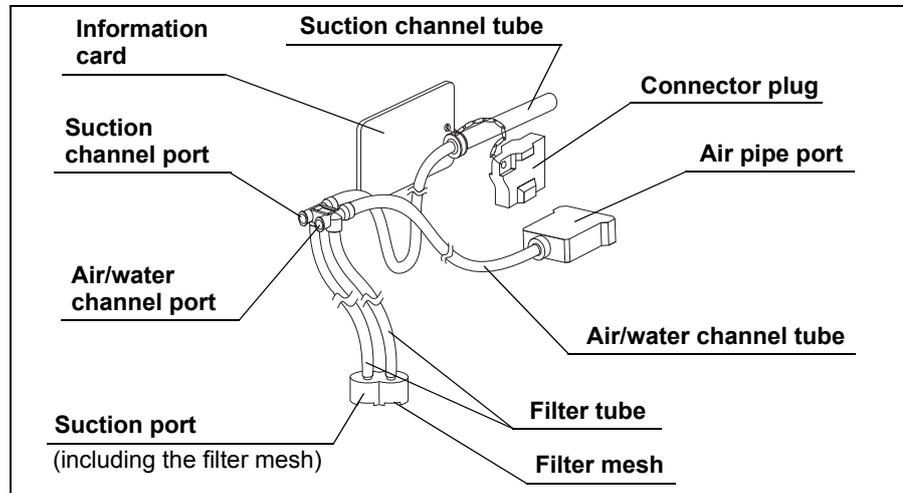


Figure 2.6

### ○ Function

The injection tube is used to inject reprocessing fluids into the instrument channel, suction channel, and air/water channels of the endoscope. It is also used to flush air through these channels to expel fluids.

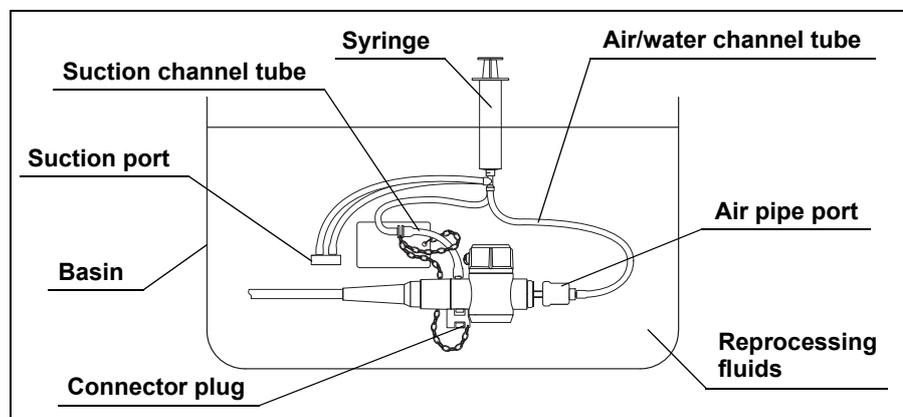


Figure 2.7

### ○ Inspection

1. Confirm that all components of the injection tube are free from cracks, scratches, flaws, and debris (see Figure 2.6).
2. Confirm that the filter mesh is in the suction port of the injection tube.

3. Attach a clean 30 ml syringe to the suction channel port of the injection tube. With the suction port of the injection tube immersed in the water referred to in Section 3.2, withdraw the syringe plunger and confirm that the water is drawn into the syringe. Depress the plunger and confirm that the water is emitted from the suction channel tube of the injection tube. Confirm that the water is not emitted from the suction port when removing the suction port from the water.

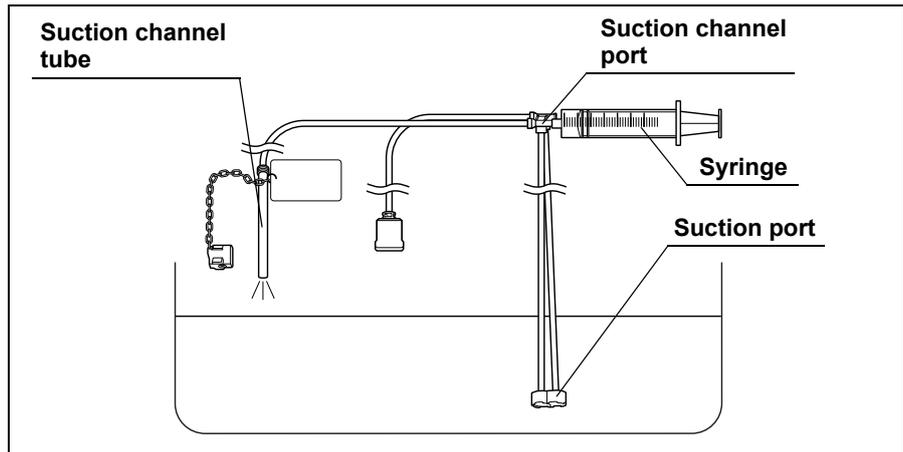


Figure 2.8

4. Move the syringe to the air/water channel port of the injection tube. With the suction port of the injection tube immersed in the water, withdraw the syringe plunger and confirm that the water is drawn into the syringe. Depress the plunger and confirm that the water is emitted from the air pipe port of the injection tube. Confirm that the water is not emitted from the suction port when removing the suction port from the water.

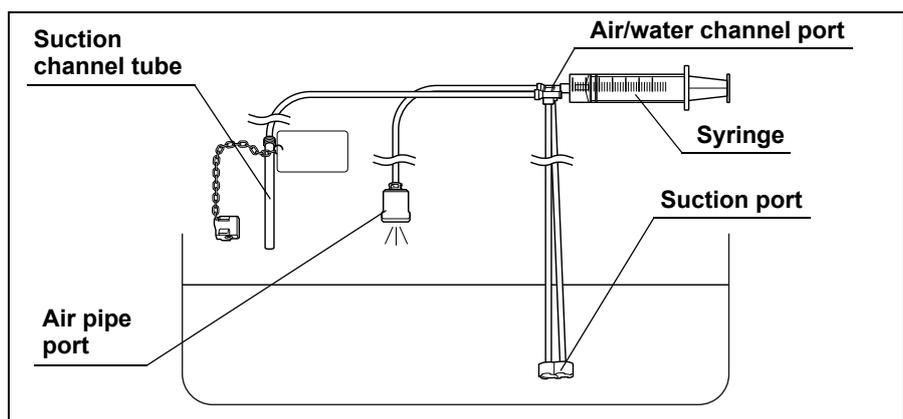


Figure 2.9

**NOTE**

The injection tube does not need to be cleaned, disinfected, or sterilized prior to its first use.

## 2.4 Channel cleaning brush (BW-20T)

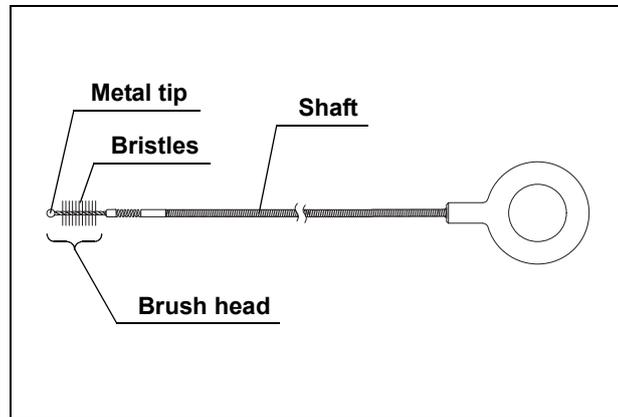


Figure 2.10

### ○ Function

The channel cleaning brush is used to brush the inside of the instrument channel and suction channel of the endoscope, and the interior and openings of the suction valve (MH-443), the air/water valve (MH-438) and the biopsy valve (MB-358).

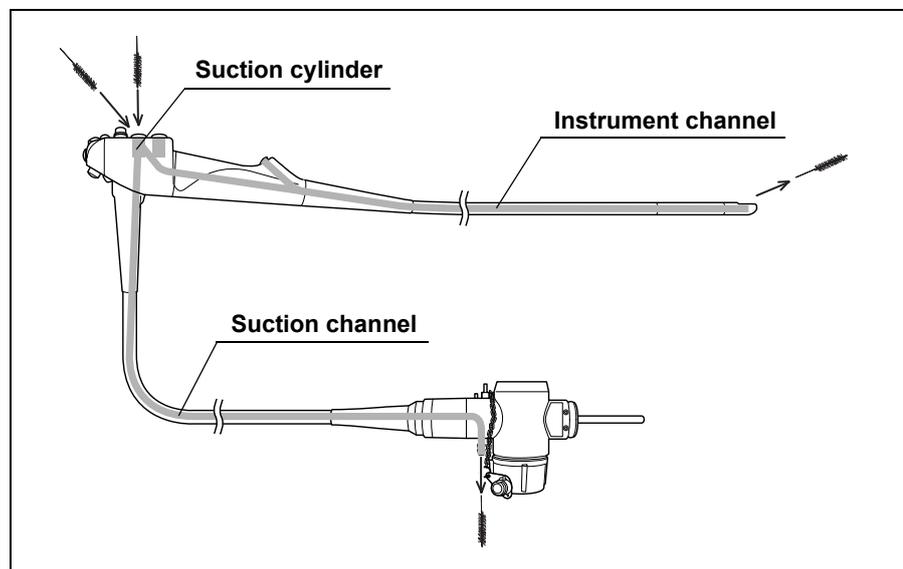


Figure 2.11

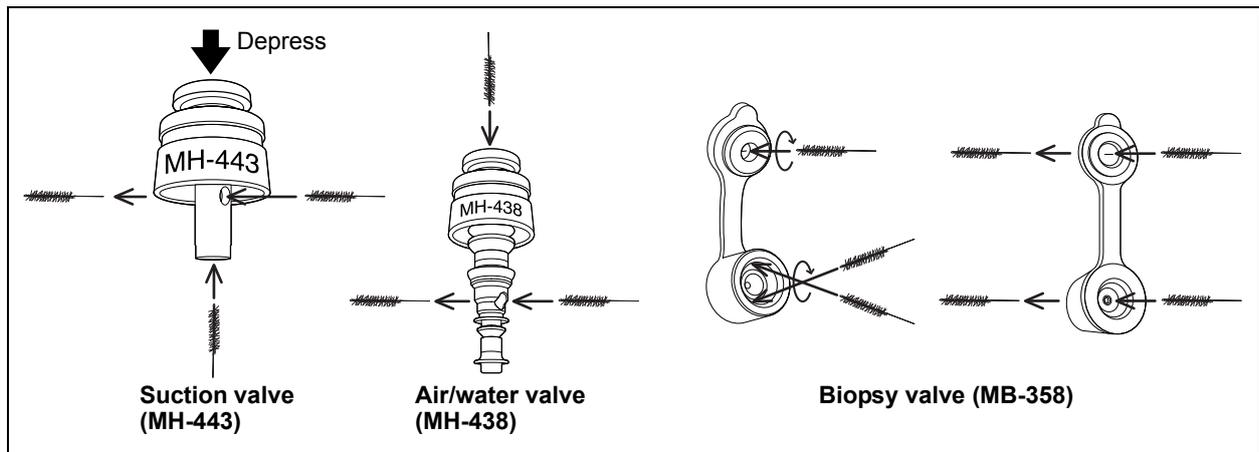


Figure 2.12

### ○ Inspection

1. Confirm that the brush head and the metal tip of the distal end are securely attached. Check the brush head for loose or missing bristles.
2. Check the bristles for damage. If the bristles are crushed, gently straighten them with your gloved fingertips.
3. Check for bends, scratches, and other damage to the shaft.
4. Visually check for debris on the shaft and/or the bristles of the brush head. If there is debris on the brush, immerse the brush in the water referred to in Section 3.2 and clean the brush until no debris is observed on the brush.

#### NOTE

The channel cleaning brush does not need to be cleaned, disinfected, or sterilized prior to its first use.

## 2.5 Suction cleaning adapter (MH-856)

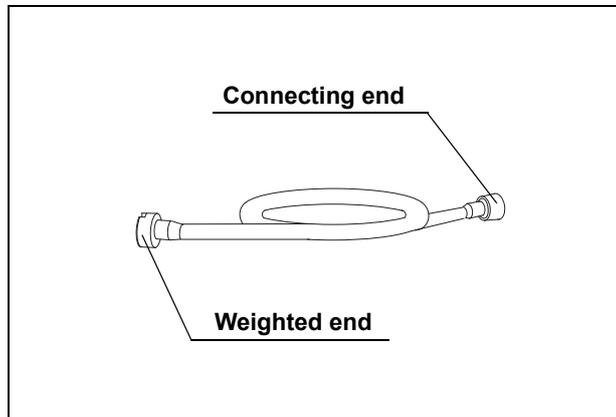


Figure 2.13

### ○ Function

The suction cleaning adapter is used to aspirate reprocessing fluids through the instrument channel port of the endoscope.

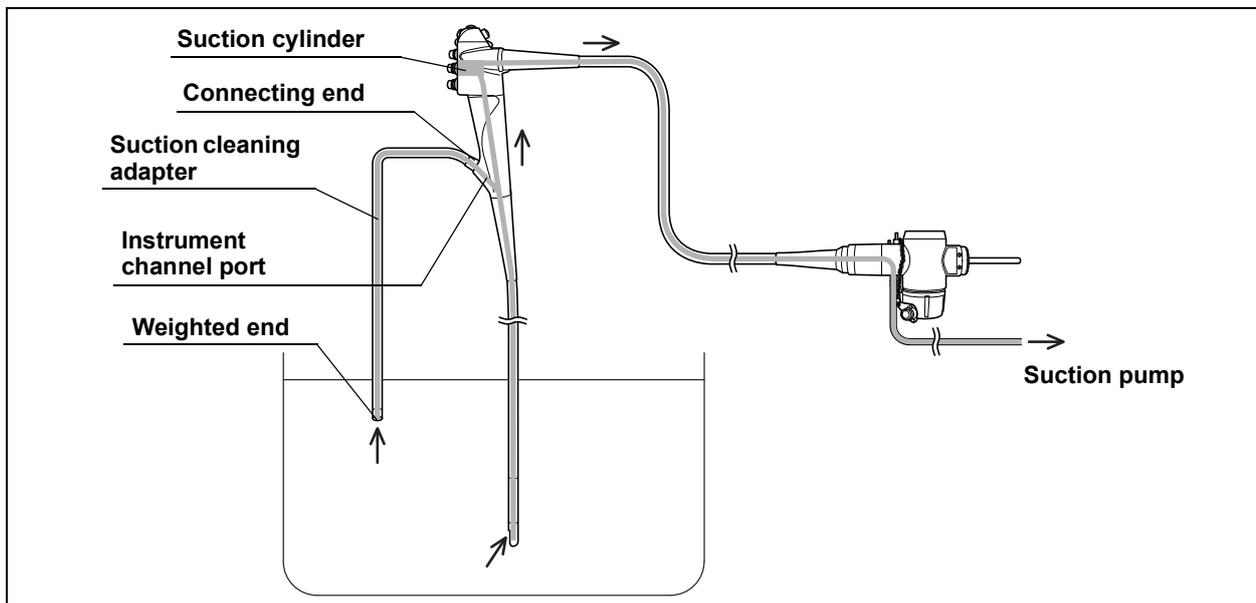


Figure 2.14

### ○ Inspection

Check for debris, cracks, scratches, and other damage.

#### NOTE

The suction cleaning adapter does not need to be cleaned, disinfected, or sterilized prior to its first use.

## 2.6 AW channel cleaning adapter (MH-948)

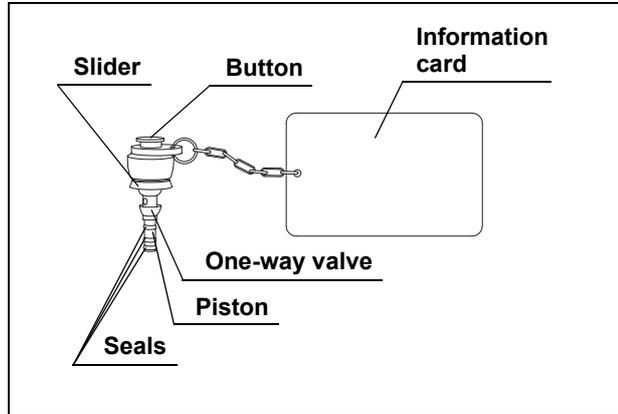


Figure 2.15

### ○ Function

During precleaning of the endoscope, the AW channel cleaning adapter is attached to the air/water cylinder of the endoscope. When the button of the adapter is depressed, the water in the water container is fed through the air/water nozzle of the endoscope to clean the nozzle and air/water channels of the endoscope. Air is continuously fed through these channels when the button is not depressed.

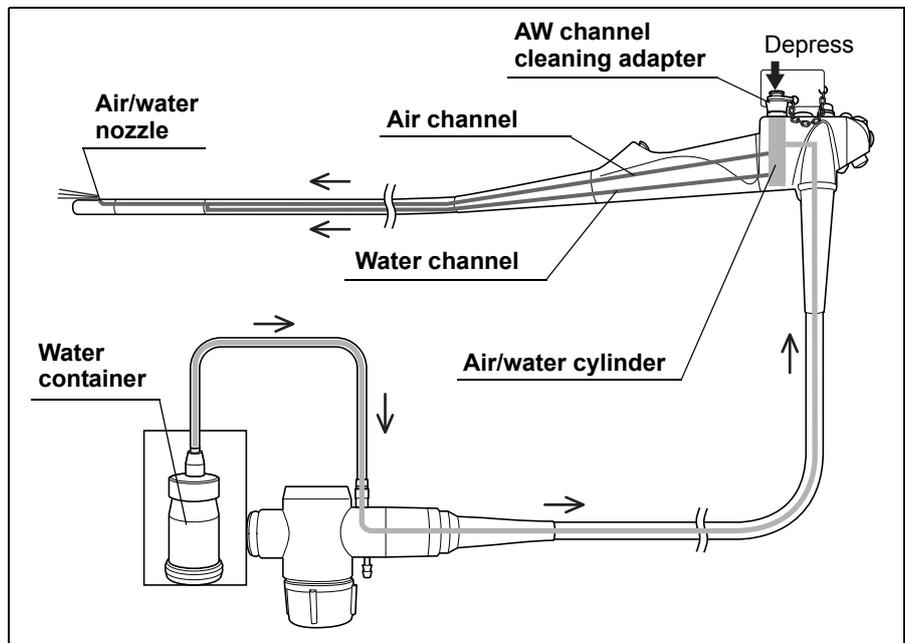


Figure 2.16

### ○ Inspection

Check for debris, cracks, scratches, and other damage.

**NOTE**

The AW channel cleaning adapter does not need to be cleaned, disinfected, or sterilized prior to its first use.

## 2.7 Single use channel cleaning brush (BW-201T)

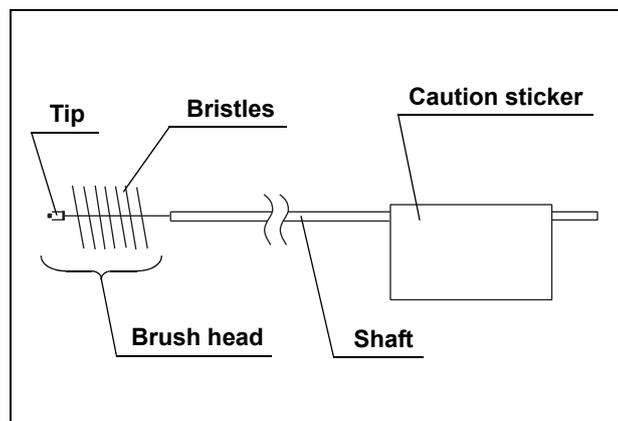


Figure 2.17

### ○ Function

The single use channel cleaning brush is used to brush the inside of the instrument channel and suction channel of the endoscope and the interior and/or openings of the suction valve (MH-443), the air/water valve (MH-438), and the biopsy valve (MB-358).

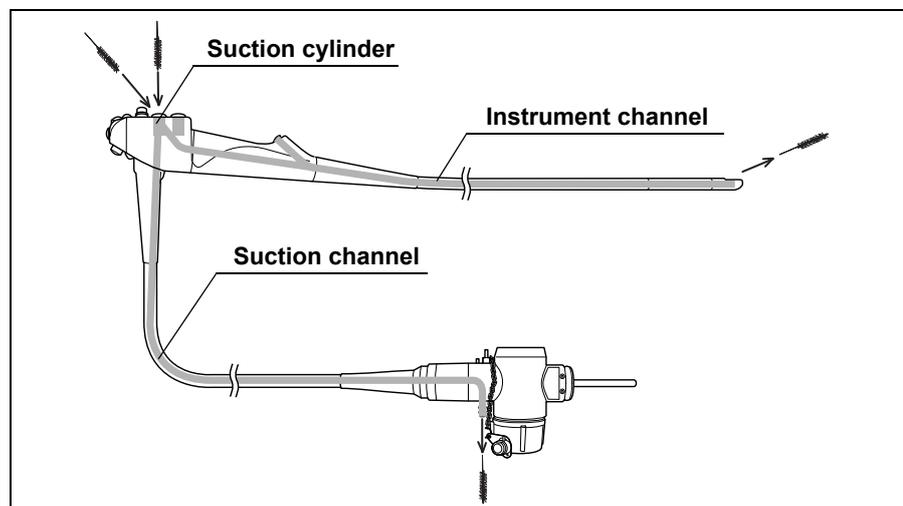


Figure 2.18

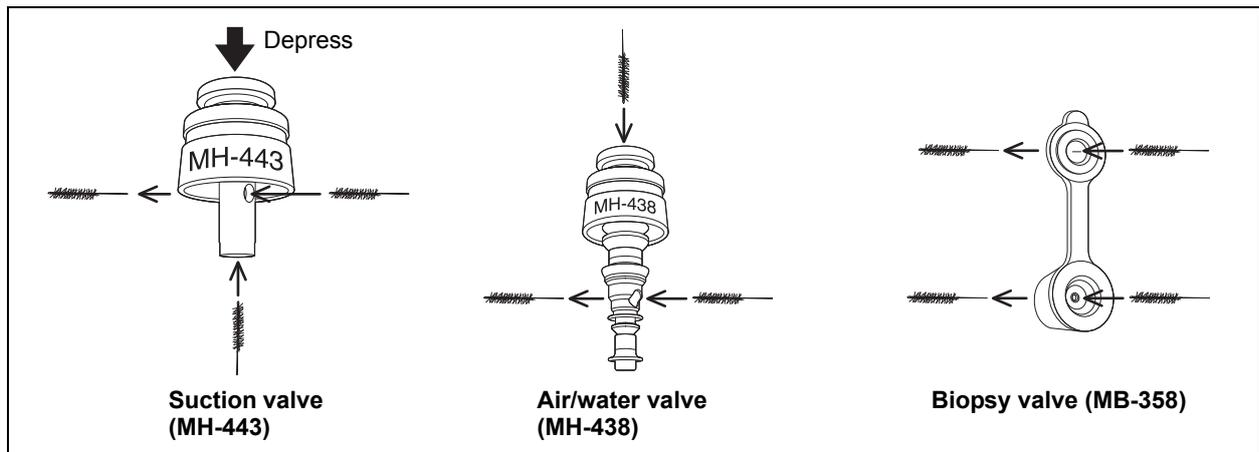


Figure 2.19

### ○ Inspection

1. Remove the brush from its packaging just prior to use.
2. Confirm that the tip and brush head at the distal end are securely attached. Check the brush head for loose or missing bristles.
3. Check the bristles for any damage. If the bristles are crushed, gently straighten them with your fingertips.
4. Check for bends, scratches, and other damage to the shaft.

#### NOTE

The single use channel cleaning brush does not need to be cleaned, disinfected, or sterilized prior to use.

## 2.8 Single use combination cleaning brush (BW-412T)

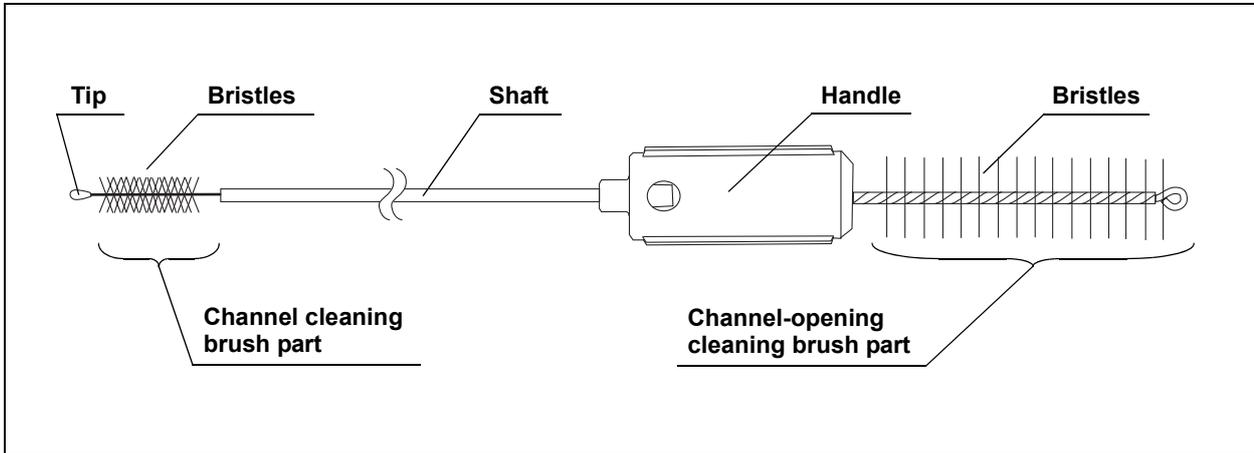


Figure 2.20

### ○ Function

The channel cleaning brush part of the single use combination cleaning brush is used to brush the inside of the instrument channel and suction channel of the endoscope, and the interior and/or openings of the suction valve (MH-443), the air/water valve (MH-438), and the biopsy valve (MB-358). The channel-opening cleaning brush part of the single use combination cleaning brush is used to brush the suction cylinder and the channel instrument port of the endoscope.

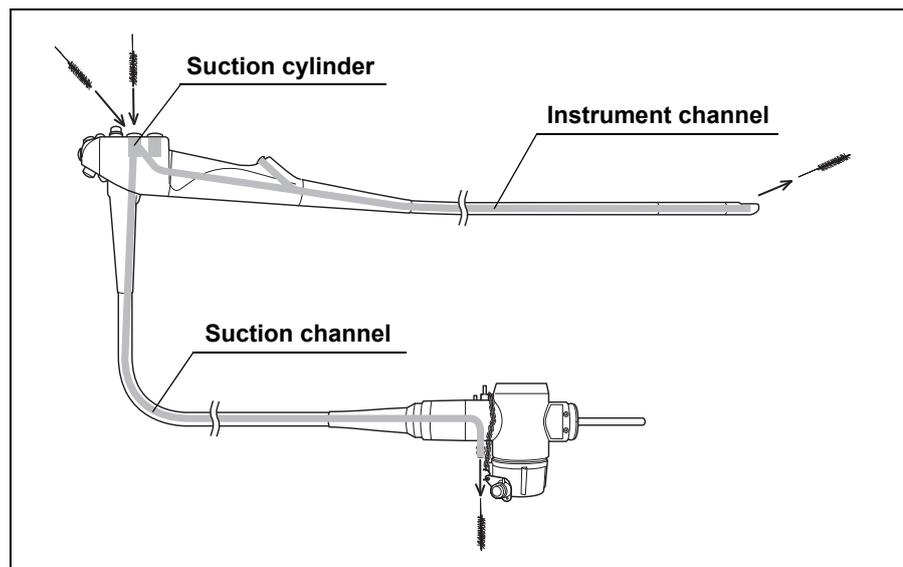


Figure 2.21

## 2.9 Single use channel-opening cleaning brush (MAJ-1339)

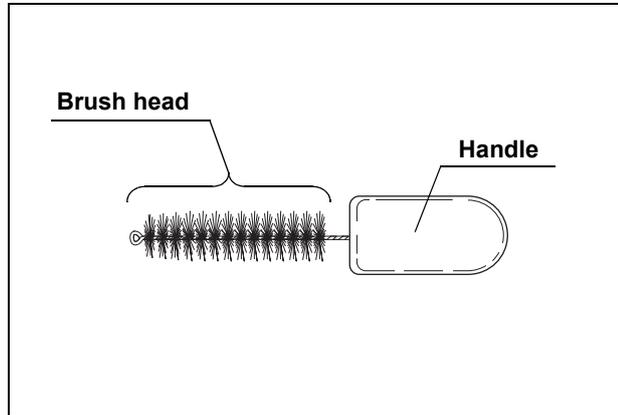


Figure 2.22

### ○ Function

The single use channel-opening cleaning brush is used to brush the suction cylinder, the instrument channel port, the distal end, the forceps elevator, and the forceps elevator recess.

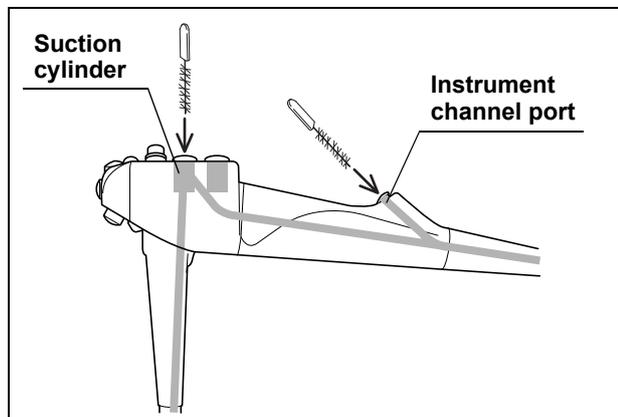


Figure 2.23

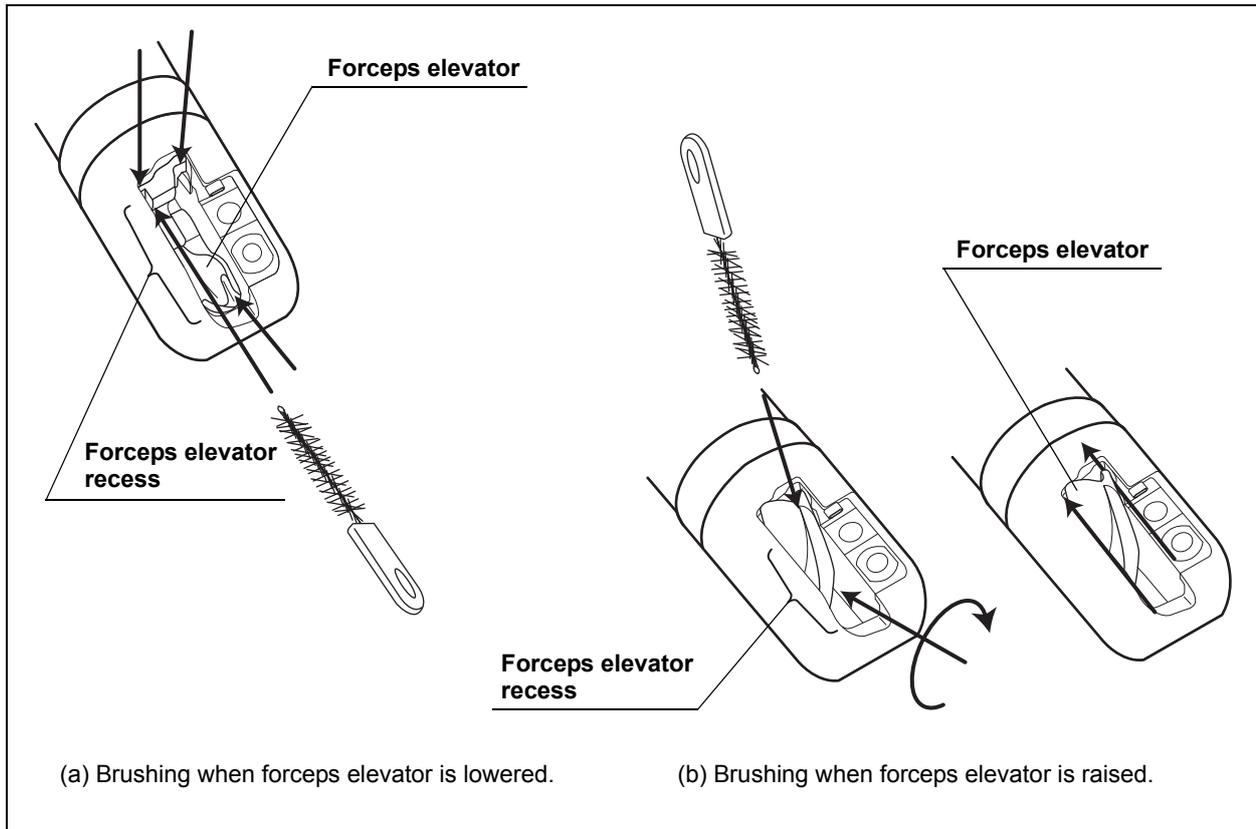


Figure 2.24

### ○ Inspection

1. Remove the brush from its packaging just prior to use.
2. Check the brush head for loose or missing bristles.
3. Check the bristles for any damage. If the bristles are crushed, gently straighten them with your fingertips.
4. Check for bends, scratches, and other damage to the shaft.

#### NOTE

The single use channel-opening cleaning brush does not need to be cleaned, disinfected, or sterilized prior to use.

## **2.10 Chain for water-resistant cap (MAJ-1119)**

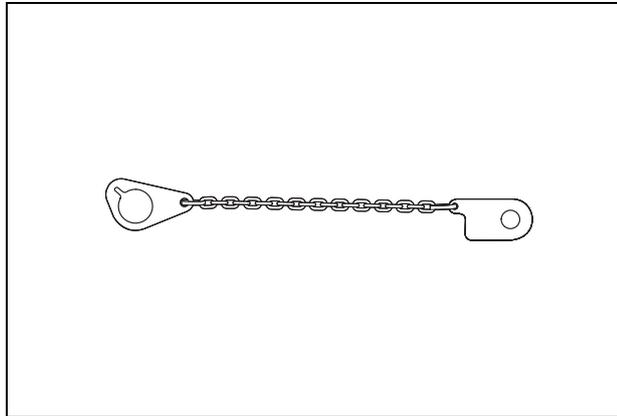


Figure 2.25

### **○ Function**

The chain for water-resistant cap is used to keep the water resistant cap (MH-553) with the endoscope at all times.

### **○ Inspection**

It is not necessary to inspect the chain before reprocessing.

# **Chapter 3 Compatible Reprocessing Methods and Chemical Agents**

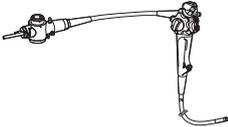
## **3.1 Compatibility summary**

The endoscope and accessories are compatible with several methods of reprocessing. However, not all reprocessing methods are compatible with all endoscopes and all accessories. Reprocessing with incompatible methods can cause equipment damage even if the number of reprocessing cycles is small. For appropriate reprocessing methods, refer to Table 3.1.

Follow the policies at your local institution when choosing which methods listed in Table 3.1 to employ.

### **CAUTION**

- Methods listed as “compatible” in Table 3.1 are compatible for routine use only when used according to manufacturer’s instructions. Repeated use and reprocessing of endoscopes and accessories leads to gradual wear and tear. But reprocessing methods that employ higher temperatures and more caustic/corrosive materials may lead to faster deterioration. In general, sterilization processes are harsher on equipment than disinfection processes. Before each patient procedure, inspect the endoscope and accessories for damage, according to the instructions described in this manual and its companion “OPERATION MANUAL”.
- Instructions provided in this manual regarding material compatibility are not valid for Olympus devices repaired by a non-Olympus facility. Olympus repairs devices to manufacturer’s specifications using original equipment manufacturer’s (OEM) materials. The use of non-OEM materials to repair an Olympus device may affect the material compatibility of the device with certain reprocessing chemicals or methods. In the event that your device has been repaired by a non-Olympus facility, please contact that repair facility for instructions regarding material compatibility.

										For sterilization	Steam sterilization (autoclaving)									
										For disinfection	Ethylene oxide gas sterilization (gas mixture 20% ethylene oxide gas/80% CO <sub>2</sub> , for countries other than the USA)									
											Ethylene oxide gas sterilization (100% ethylene oxide gas)									
										For alcohol flush	ACECIDE disinfectant solution* <sup>3</sup>									
											2 – 3.5% glutaraldehyde									
For cleaning	70% ethyl or 70% isopropyl alcohol																			
	Detergent solution																			
											Ultrasonic cleaning									
Endoscope										*1	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Water resistant cap (MH-553)										*2	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Chain for water-resistant cap (MAJ-1119)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Channel cleaning brush (BW-20T)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Air/water valve (MH-438)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Suction valve (MH-443)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Biopsy valve (MB-358)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Channel plug (MH-944)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Injection tube (MH-946)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
AW channel cleaning adapter (MH-948)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Suction cleaning adapter (MH-856)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible
Mouthpiece (MB-142)											Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible	Compatible

 compatible       not compatible

Table 3.1

- \*1 The endoscope is only compatible with ultrasonic cleaning as performed in an Olympus-recommended endoscope reprocessor such as OER-AW, OER-Pro (OER-AW and OER-Pro are not available in some areas). When using an AER that is recommended by Olympus other than listed above, please contact Olympus.
- \*2 The water resistant caps (MH-553) and the chain for water-resistant cap (MAJ-1119) can only be ultrasonically cleaned if attached to an endoscope that is being cleaned in an automated endoscope reprocessor with an ultrasonic cleaning phase.
- \*3 ACECIDE are not available in some areas.

**NOTE**

Accessories that are marked by the words “AUTOCLAVE” or “AUTOCLAVABLE”, or with green markings (such as a green component or label) are compatible with steam sterilization (autoclaving).

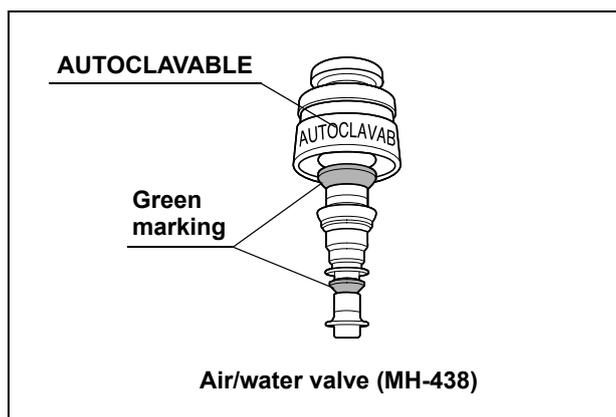


Figure 3.1

## 3.2 Water (for reprocessing)

Water is used for leakage testing and manual cleaning of the endoscope and accessories. For these purposes, use either fresh, potable tap water or water that has been processed (e.g., filtered, deionized or purified) to improve its chemical and/or microbiological quality. Consult with your hospital's infection control committee.

When rinsing the endoscope and accessories following high-level disinfection, use the water referred to in Section 3.5.

### **3.3 Detergent solution**

**WARNING**

- Excessive foaming prevents detergent from properly contacting the surfaces and channel walls of the endoscope and accessories, and may impair effective cleaning.
- Do not reuse detergent solutions.

Use a medical-grade, low-foaming, neutral pH detergent. Follow the instructions provided by the detergent manufacturer regarding concentration, temperature, contact time, and expiration date. Contact Olympus for the names of specific brands of detergent solution that have been tested for compatibility with endoscopes and accessories.

### **3.4 Disinfectant solution**

Use a high-level disinfectant cleared by your national regulatory agency for use in reprocessing flexible endoscopes. Follow the disinfectant manufacturer's instructions regarding activation (if required), concentration, temperature, contact time, and expiration date.

For further information regarding the compatibility of glutaraldehyde-based or non glutaraldehyde-based disinfectant solutions, contact Olympus.

### **3.5 Rinse water**

Use sterile water for rinsing the endoscope and accessories following high-level disinfection.

If sterile water is not available, use either fresh, potable tap water or water that has been processed (e.g., filtered, deionized or purified) to improve its chemical and/or microbiological quality, and flush the endoscope and accessories with the alcohol referred to in Section 3.6 after rinsing. Consult with your hospital's infection control committee regarding local policies on water quality.

### **3.6 Alcohol**

Use medical-grade 70% ethyl or 70% isopropyl alcohol.

## 3.7 Ethylene oxide gas sterilization

The endoscope and accessories listed as compatible with ethylene oxide gas sterilization in Table 3.1 can be sterilized by ethylene oxide gas and aerated within the parameters given in Tables 3.2 and 3.3. When performing ethylene oxide gas sterilization, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

### CAUTION

Exceeding the recommended parameters may cause equipment damage (see Tables 3.2 and 3.3).

#### ○ Parameters for 100% ethylene oxide gas sterilization cycles

Process phase	Parameter	Value
Sterilization	Temperature	55°C (130°F)
	Vacuum (Absolute pressure)	0.05 – 0.07 MPa (7.25 – 10.15 psia)
	Relative humidity	50 – 80%
	Ethylene oxide gas concentration	0.735 – 0.740 mg/cm <sup>3</sup> (735 – 740 mg/L)
	Exposure time	60 minutes
Aeration	Minimum aeration parameters	12 hours in an aeration chamber at 50 – 57°C (122 – 135°F) or 7 days at room temperature

Table 3.2

#### ○ Parameters for 20% ethylene oxide gas/80% CO<sub>2</sub> gas sterilization cycles, for countries other than the USA

Process phase	Parameter	Value
Sterilization	Temperature	57°C (135°F)
	Relative pressure	0.1 – 0.17 MPa
	Relative humidity	55%
	Ethylene oxide gas concentration	0.6 – 0.7 mg/cm <sup>3</sup> (600 – 700 mg/L)
	Exposure time	105 minutes
Aeration	Minimum aeration parameters	12 hours in an aeration chamber at 50 – 57°C (122 – 135°F) or 7 days at room temperature

Table 3.3

## 3.8 Steam sterilization (autoclaving)

The accessories listed as compatible with steam sterilization in Table 3.1 can be sterilized by steam within the parameters given in Table 3.4. When steam sterilizing, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

### CAUTION

- Do not steam sterilize the endoscope. Steam sterilization will cause severe damage.
- Exceeding the recommended parameters may damage the accessories (see Table 3.4).

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

Table 3.4



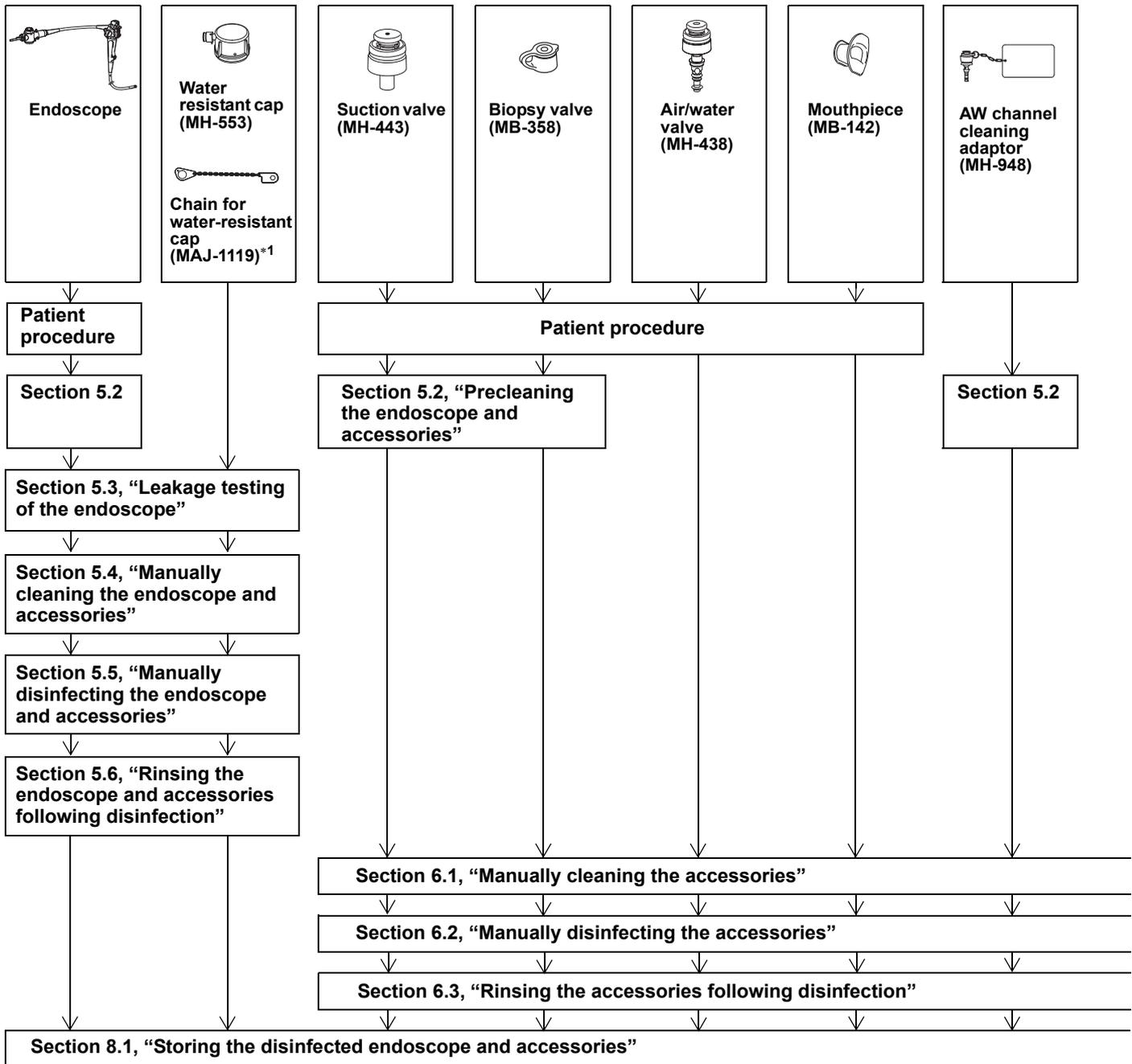
# **Chapter 4    *Reprocessing Work Flow for the Endoscope and Accessories***

This chapter describes the work flow for reprocessing the endoscope and accessories.

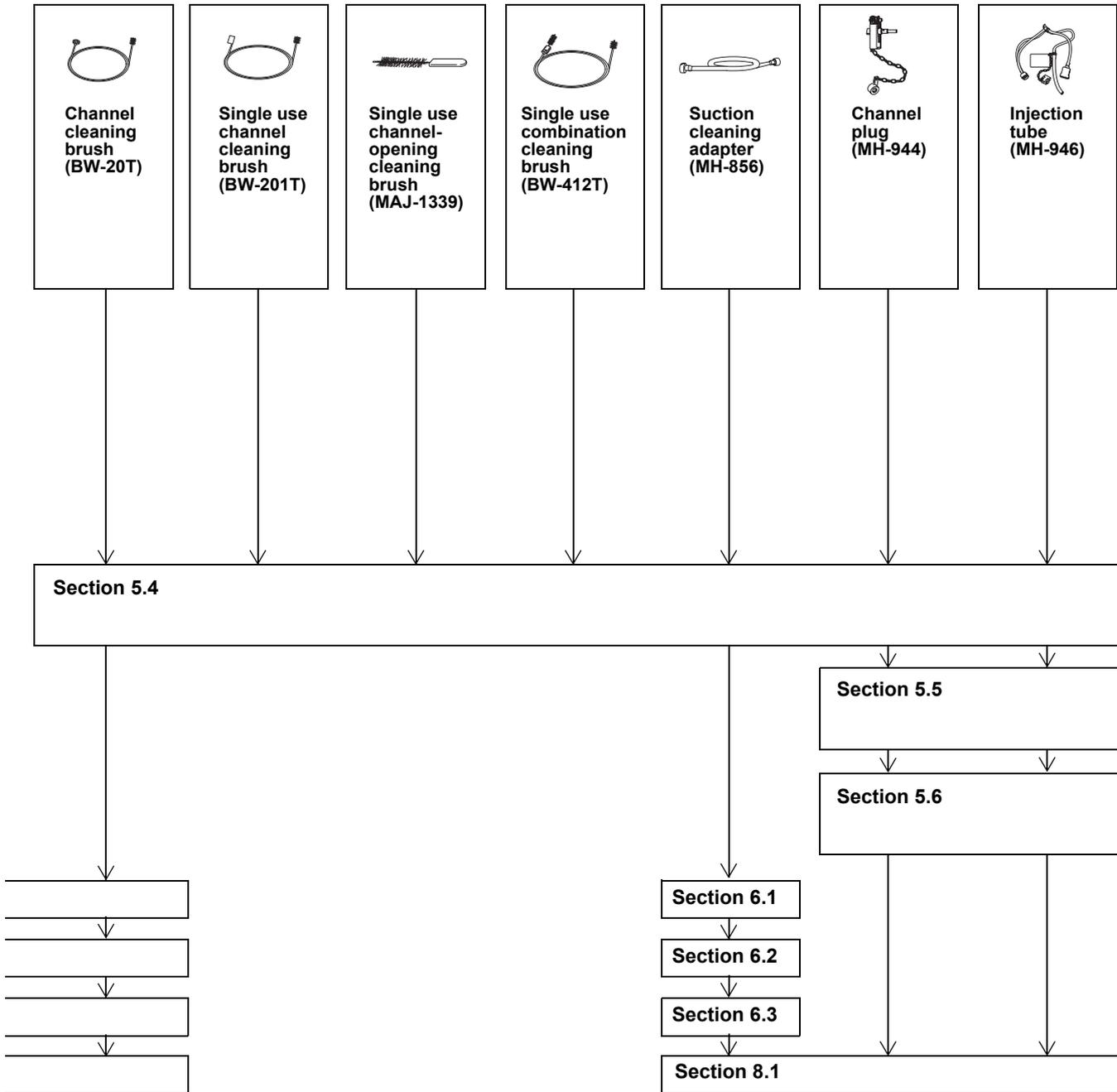
**WARNING**

Deviation from the recommended work flow may pose an infection control risk.

## 4.1 Work flow for manually cleaning and disinfecting the endoscope and accessories

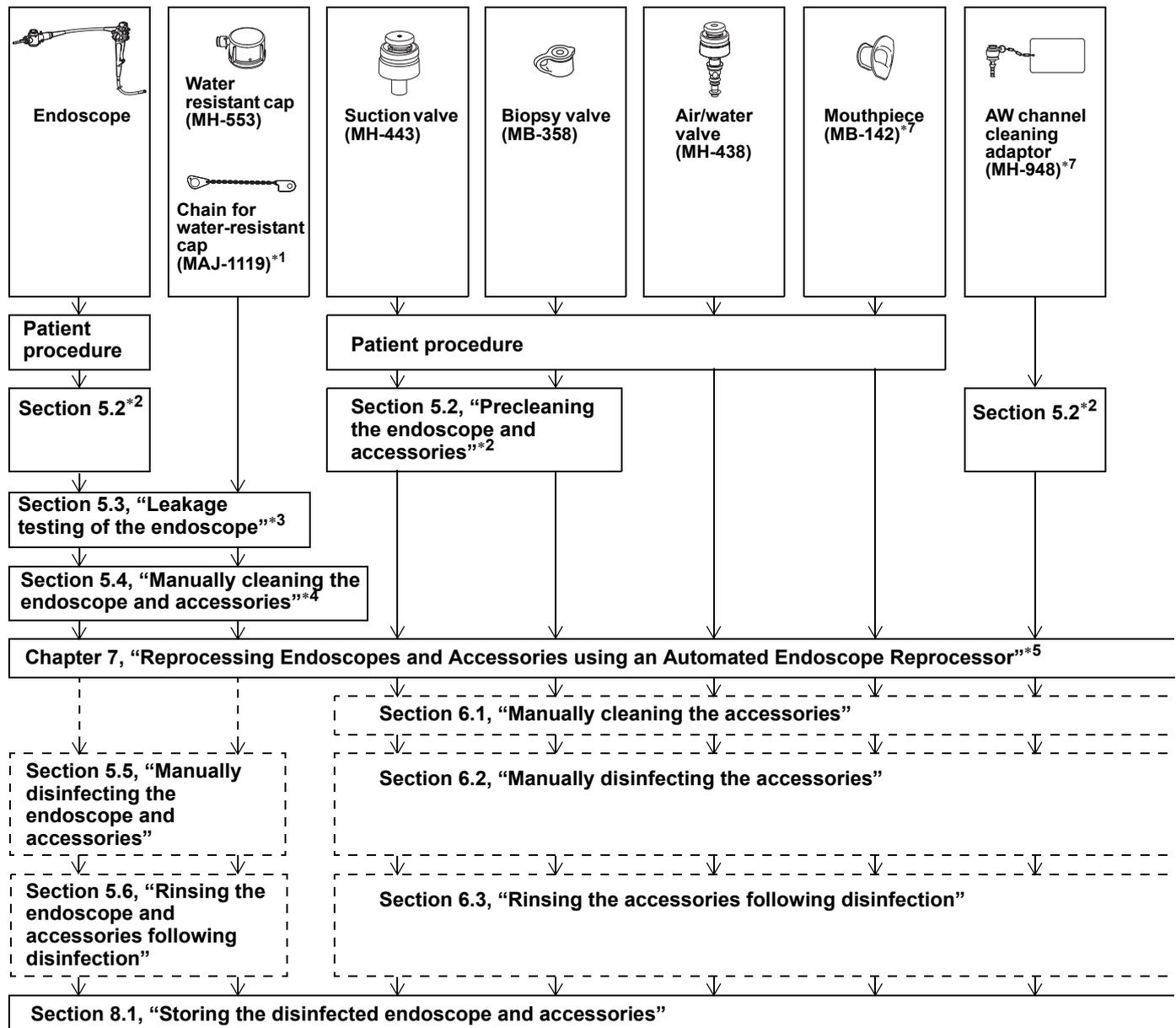


\*1 The water resistant cap (MH-553) should remain connected to the endoscope at all times using the chain for water-resistant cap (MAJ-1119).



## 4.2 Work flow for cleaning and disinfecting the endoscope and accessories using an AER

Some endoscopes can be cleaned and disinfected with an AER while others can not. Endoscopes which can be cleaned and disinfected vary, depending upon which model AER is used. Check the AER's instruction manual to confirm which endoscopes can be cleaned and disinfected in the AER.



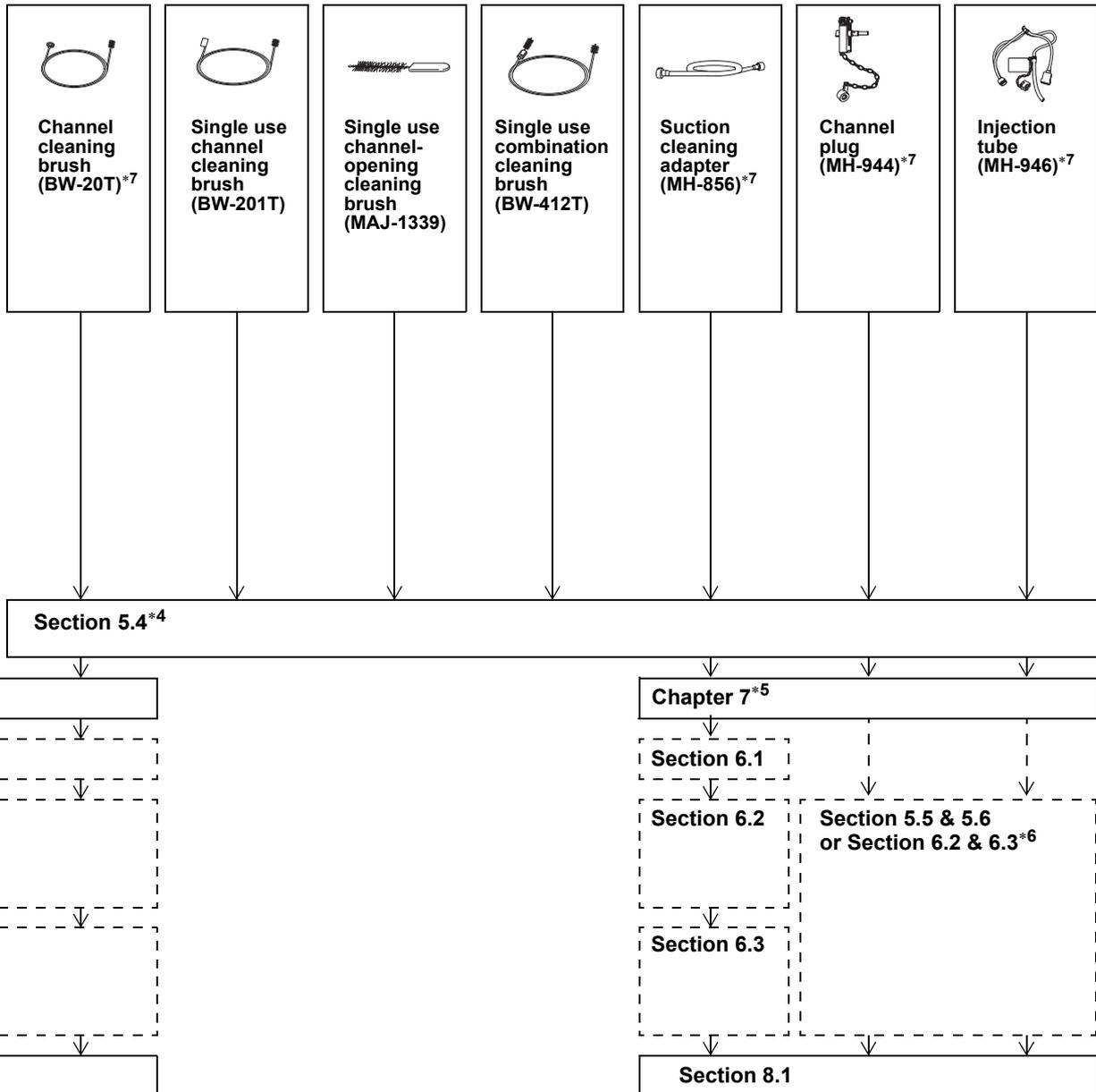
\*1 The water resistant cap (MH-553) should remain connected to the endoscope at all times using the chain for water-resistant cap (MAJ-1119).

\*2 Depending upon the model of the AER, you may be able to simplify the standard manual precleaning procedure. Refer to the instruction manual for the AER.

\*3 Check the instruction manual for your AER to determine how to leakage test the endoscope using the AER. When leakage testing an endoscope within an AER basin it may be difficult to fully angulate the bending section. Perform leakage testing in the AER and/or manually, depending upon the policy of your institution.

Some accessories can be cleaned and disinfected with an AER while others can not. Accessories which can be cleaned and disinfected vary, depending upon which model AER is used. Check the AER's instruction manual to confirm which accessories can be cleaned and disinfected in the AER.

Manually disinfect all endoscopes and accessories which cannot be reprocessed in the AER.

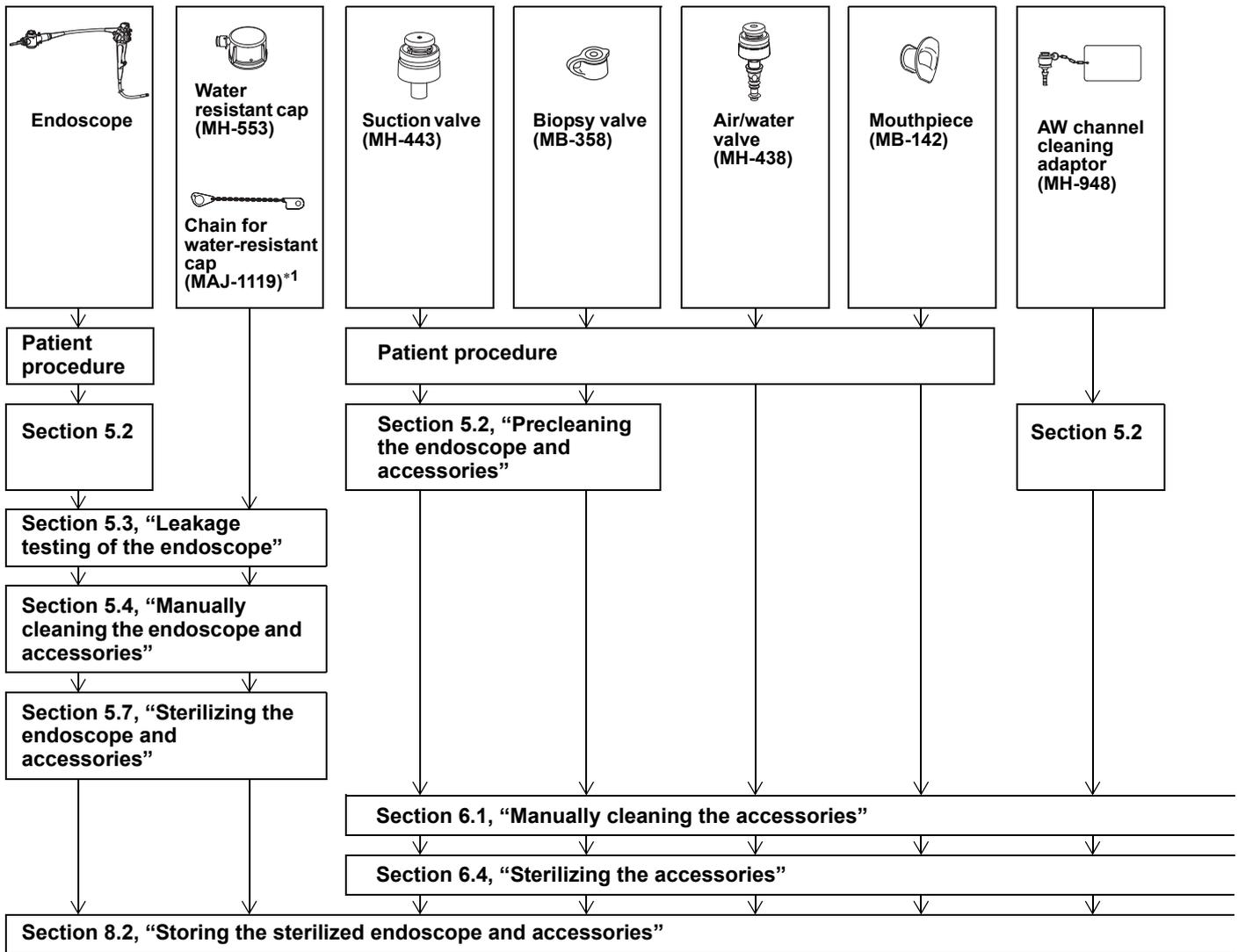


- \*4 Depending upon the model of the AER, you may be able to simplify the standard manual cleaning procedure. Refer to the instruction manual for the AER.
- \*5 If the endoscope and/or the accessories are compatible with the AER, clean and disinfect them in the AER, following the AER's instruction manual. If the endoscope and/or the accessories are not compatible with the AER, manually clean, disinfect and rinse them following the instructions of this manual, as shown in the dotted boxes.
- \*6 If the endoscope and the accessory(s) are not compatible with the AER, manually disinfect and rinse them, according to Sections 5.5 and 5.6. If the endoscope is compatible and the accessory(s) are not compatible, manually disinfect and rinse the accessory(s) according to Section 6.2 and 6.3.
- \*7 The accessory(s) are not compatible with the OER-Pro.

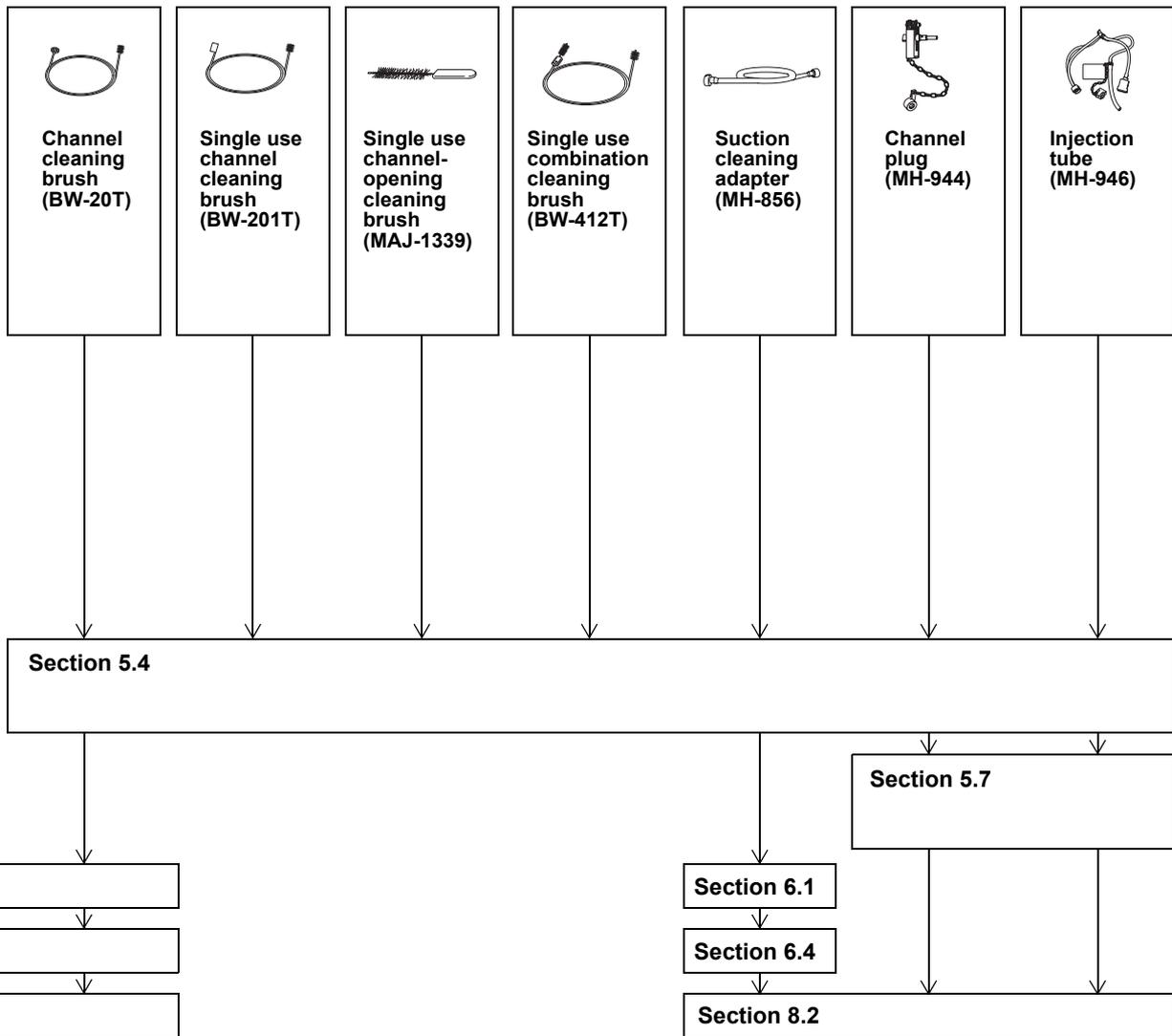
## 4.3 Work flow for manually cleaning and sterilizing the endoscope and accessories

**NOTE**

If required by the local policy of your institution, disinfect and rinse the endoscope and accessories manually, or clean and disinfect them with an AER between manual cleaning and sterilization.



\*1 The water resistant cap (MH-553) should remain connected to the endoscope at all times using the chain for water-resistant cap (MAJ-1119).



# Chapter 5 Reprocessing the Endoscope (and related reprocessing accessories)

Certain accessories are required to manually reprocess the endoscope. Some of these accessories are cleaned and disinfected along with the endoscope. The steps for reprocessing the endoscope and these accessories are explained in this chapter. Chapter 6, “Reprocessing the Accessories” describes the steps for reprocessing accessories which are not reprocessed together with the endoscope.

The reprocessing work flow of all accessories is outlined in Chapter 4, “Reprocessing Work Flow for the Endoscope and Accessories”.

**WARNING**

The TJF-Q180V endoscope has a forceps elevator. The surface and surrounding area of the forceps elevator, such as the groove, guidewire locking groove, and forceps elevator recess, have a complex shape. Reprocess these parts carefully following the procedure described in Chapter 5. Insufficient reprocessing may pose an infection control risk to patient and/or operators.

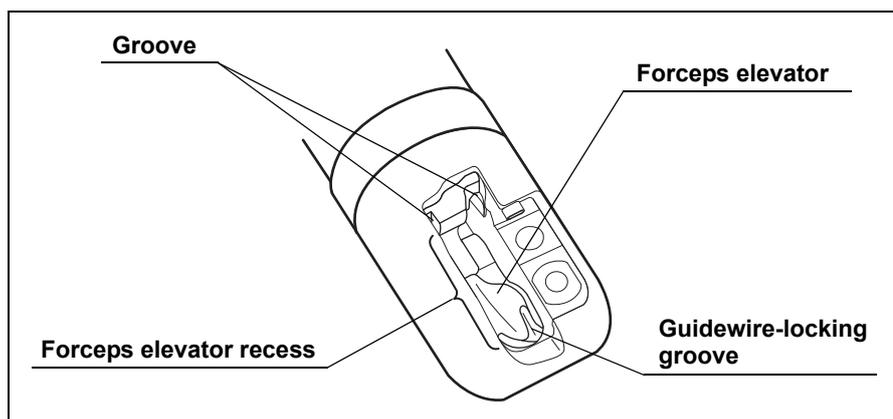


Figure 5.1

**NOTE**

The elevator wire channel of the TJF-Q180V is sealed. Therefore, the elevator wire channel does not need to be reprocessed.

**CAUTION**

- The insertion section of the endoscope is composed of the insertion tube, the bending section, and the distal end. The bending section is covered by a thin, easily damaged elastic covering. Do not allow reprocessing equipment to forcefully contact the bending section. Do not allow any sharp edges, such as the distal ends of EndoTherapy accessories (needles, forceps, snares, etc. used in the instrument channel of the endoscope) to contact the bending section. Such improper handling may damage the covering and cause the endoscope to leak.

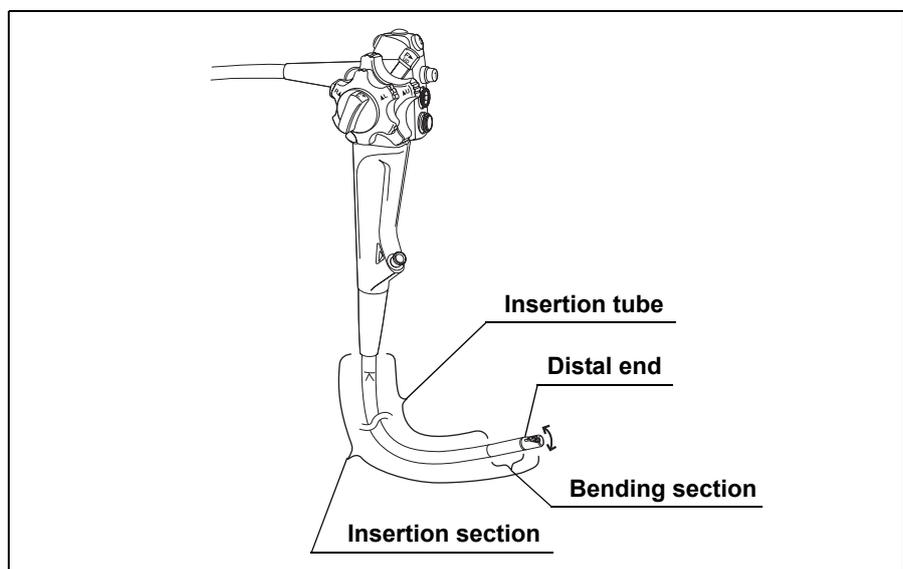


Figure 5.2

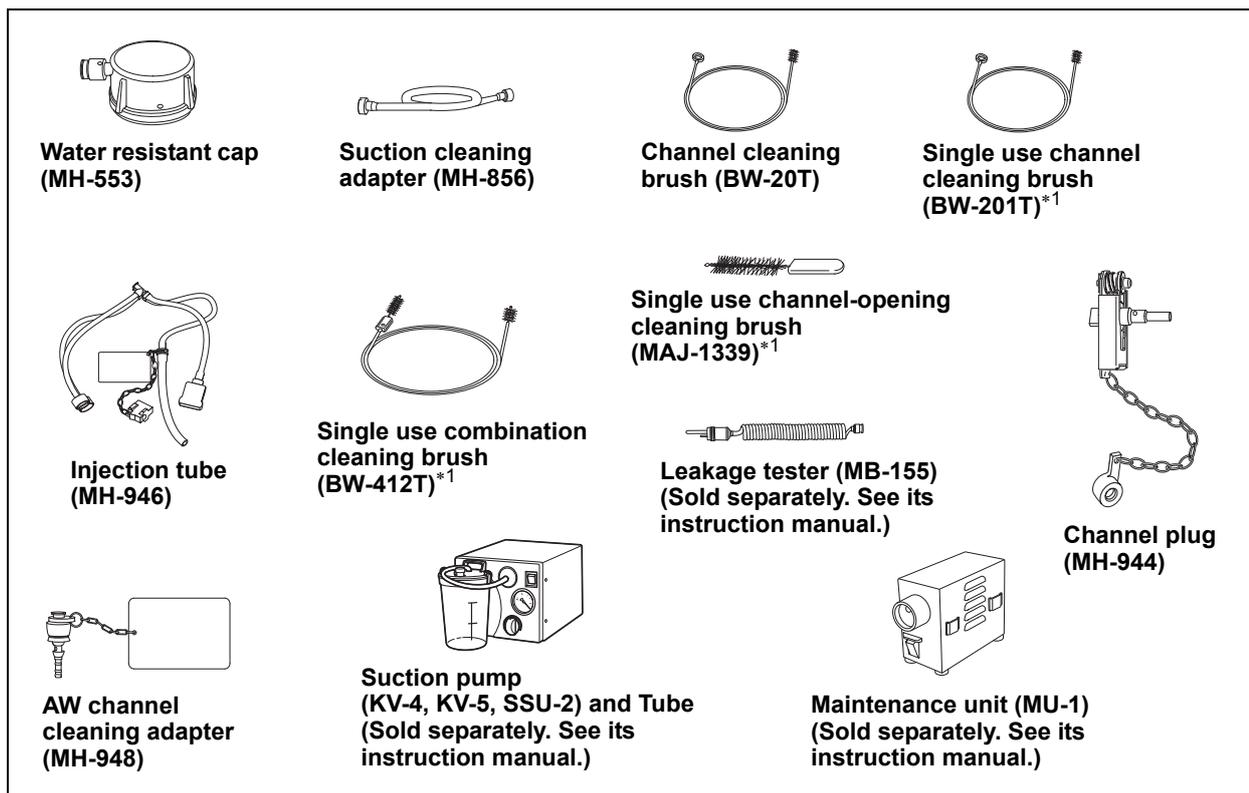
- Handle the insertion section carefully. Tightly gripping or sharply bending the insertion tube or the bending section can stretch or severely damage the insertion tube and/or the covering of the bending section.
- To prevent damage to the endoscope, do not immerse the endoscope with objects other than the equipment used for reprocessing the endoscope.
- To prevent damage, do not coil the insertion tube or the universal cord of the endoscope with a diameter less than 12 cm.

Use sterile equipment, such as sterile syringes and cloths, for all reprocessing steps occurring after immersion of the endoscope and accessories in disinfectant solution.

## 5.1 Preparing the equipment for reprocessing

### Equipment needed

Figure 5.3 shows the equipment necessary to perform the reprocessing steps described in this chapter.



- Personal protective equipment
- Detergent solution (See Section 3.3)
- Rinse water (See Section 3.5)
- Clean, soft brush(s)
- Sterile lint-free cloths\*2
- Sterile cotton swabs
- Sterile 30 ml (30 cc) syringe(s)
- Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Sterile, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Water for cleaning (See Section 3.2)
- Disinfectant solution (See Section 3.4)
- 70% ethyl or 70% isopropyl alcohol (See Section 3.6)
- Clean lint-free cloths\*2
- Clean sponge(s)
- Clean 30 ml (30 cc) syringe(s)
- Clean, 500 ml containers
- Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Sterile, small basins with tight-fitting lids (size: 25 (W) × 10 (H) × 25 (D) cm or more)

Figure 5.3

- \*1 These products may not be available in some areas.
- \*2 All cloths used in reprocessing are recommended to be lint-free. Lint or cloth fibers shed into reprocessing fluids may be injected into the endoscope channels. There is the potential for lint or cloth fibers to lodge in channels or become trapped in the air/water nozzle. If gauze is used to reprocess the endoscope, ensure that fibers do not get caught on or remain trapped by protruding components like the air/water nozzle.

## 5.2 *Precleaning the endoscope and accessories*

### **WARNING**

If the endoscope and accessories used in the patient procedure are not immediately cleaned after each patient procedure, residual organic debris will begin to dry and solidify, hindering effective removal and reprocessing efficacy. Preclean the endoscope and the accessories at the bedside in the patient procedure room immediately after each patient procedure.

### ***Equipment needed***

Prepare the following equipment.

 <b>Water resistant cap (MH-553)</b>	 <b>AW channel cleaning adapter (MH-948)</b>	 <b>Suction pump (KV-4, KV-5, SSU-2) and Tube (Sold separately. See its instruction manual.)</b>
<ul style="list-style-type: none"><li>• Water for cleaning (See Section 3.2)</li><li>• Clean lint-free cloths</li><li>• Clean 30 ml (30 cc) syringe(s)</li></ul>	<ul style="list-style-type: none"><li>• Detergent solution (See Section 3.3)</li><li>• Clean sponge(s)</li><li>• Clean, 500 ml containers</li></ul>	

## Preparation

Immediately following the patient procedure, with the endoscope still connected to the equipment used in the patient procedure (i.e., the light source, video system center, suction pump), perform the following precleaning steps at the patient bed side.

1. Turn the video system center and light source OFF.
2. Prepare a clean 500 ml container of the water referred to in Section 3.2.

## Wipe the insertion section

Dip a clean, lint-free cloth or sponge in the water and wipe the entire insertion section of the endoscope. Wipe from the boot at the control section toward the distal end.

## Aspirate water

**NOTE**

Monitor the suction bottle on the suction pump carefully to ensure that it does not overflow.

1. Turn the suction pump ON.
2. Close the cap on the biopsy valve.

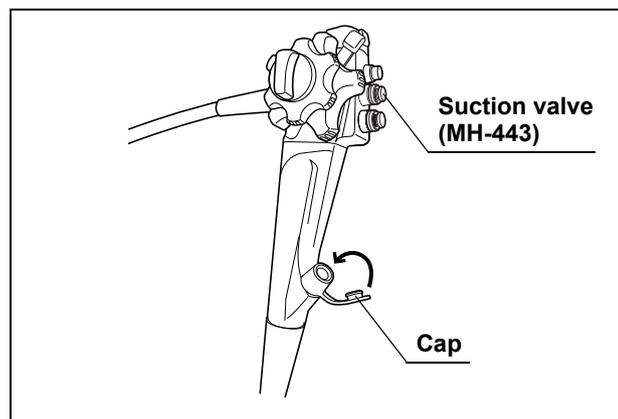


Figure 5.4

3. Immerse the distal end of the insertion section in the water. Depress the suction valve (MH-443) on the endoscope and aspirate the water through the endoscope for 30 seconds.
4. Remove the distal end from the water. Depress the suction valve and aspirate air for 10 seconds.

5. Turn the suction pump OFF.

### **Flush the air/water channel with water and air**

#### **CAUTION**

- To prevent clogging of the air/water nozzle of the endoscope, flush water into the air/water channel of the endoscope, using the AW channel cleaning adapter (MH-948) after each patient procedure.
- Do not apply lubricants to the AW channel cleaning adapter. Lubricants may cause malfunction of the AW channel cleaning adapter.

1. Turn the light source ON.
2. Switch "OFF" the airflow regulator on the light source.
3. Detach the air/water valve (MH-438) from the endoscope and place it in the detergent solution. Attach the AW channel cleaning adapter (MH-948) to the air/water cylinder of the endoscope.

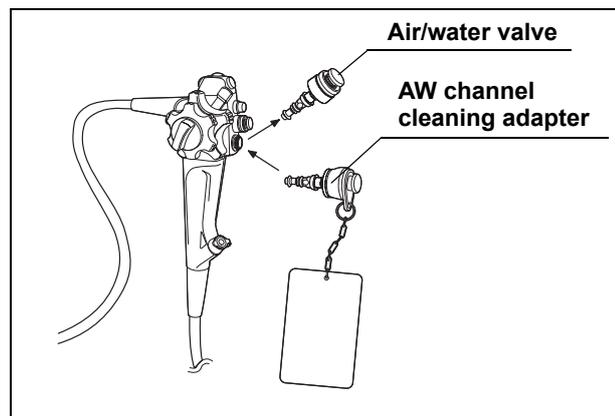


Figure 5.5

#### **NOTE**

- The air/water valve (MH-438) is to be reprocessed, according to Chapter 6, "Reprocessing the Accessories".
  - Water may drip from the air/water cylinder when the air/water valve is detached. The water dripping from the air/water cylinder is clean (i.e., sterile water in the water container). If water is dripping from the air/water cylinder, hold the control section higher than the water container.
4. Immerse the distal end of the insertion section in the water.
  5. Switch the airflow regulator on the light source to maximum output ("HIGH" or "3").

6. Depress the button of the AW channel cleaning adapter to flush the air/water channel with water from the water container for 30 seconds.
7. Release the button to flush air for 10 seconds.
8. Turn the light source OFF.

### ***Detach accessories from the endoscope***

1. Detach the videoscope cable (MAJ-1430, MAJ-843, or MH-976) from the electrical connector of the endoscope.
2. Detach the suction tube from the suction connector on the endoscope connector.
3. Detach the metal tip of the water container (MAJ-901 or MH-884) from the air/water supply connector on the endoscope connector. Put the metal tip of the water container tube into the receptacle on the lid of the water container, as described in the instruction manual for the water container.

### ***Attach the water resistant cap (MH-553)***

#### **CAUTION**

If the exterior surface of the electrical connector of the endoscope is scratched, the connection with the water resistant cap (MH-553) may no longer be waterproof and the cap's seal may be damaged. If the electrical connector is damaged, send the endoscope to Olympus for repair.

#### **NOTE**

The water resistant cap can be attached in two different positions. Attach the water resistant cap to the endoscope as shown in Figure 5.6 to allow the endoscope and cap to lay properly in the reprocessing basin.

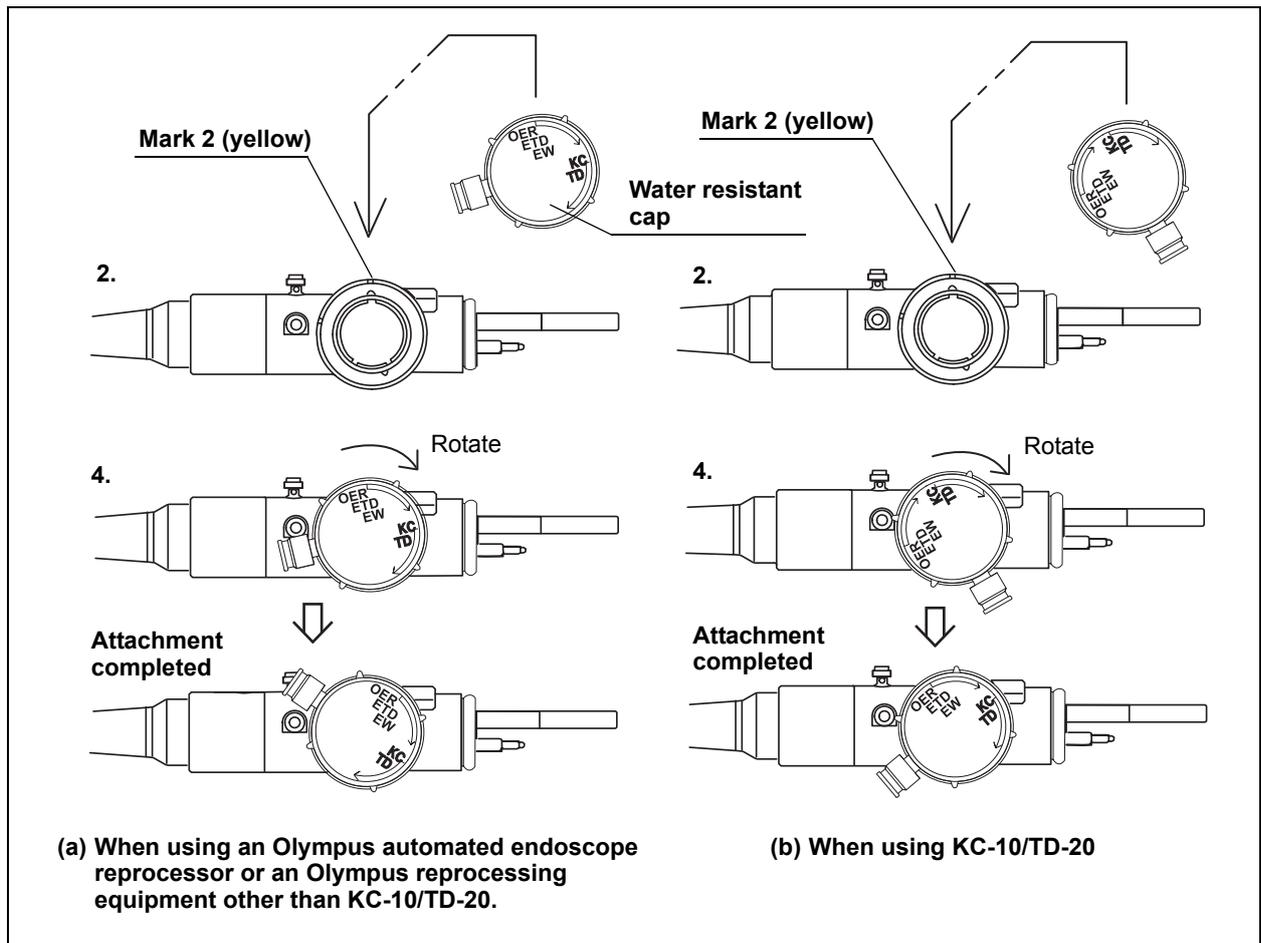


Figure 5.6

1. Confirm that the exterior surface of the electrical connector is free from scratches.
2. When using an Olympus automated endoscope reprocessor, or Olympus reprocessing equipment other than the KC-10/TD-20, align the OER/ETD/ EW characters or the EW characters on the water resistant cap with mark 2 on the electrical connector housing. When using the KC-10/TD-20, align the KC/TD characters on the cap with mark 2 on the housing.
3. Align the pins on the electrical connector with the grooves on the cap.

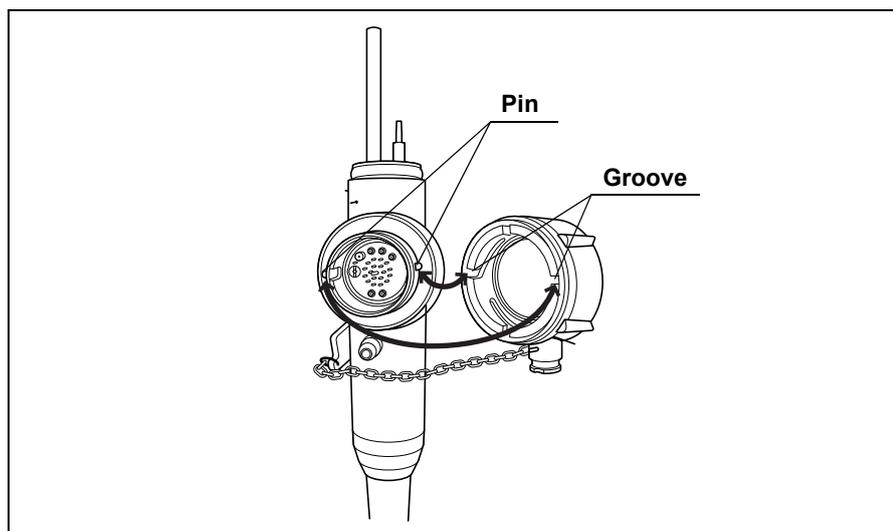


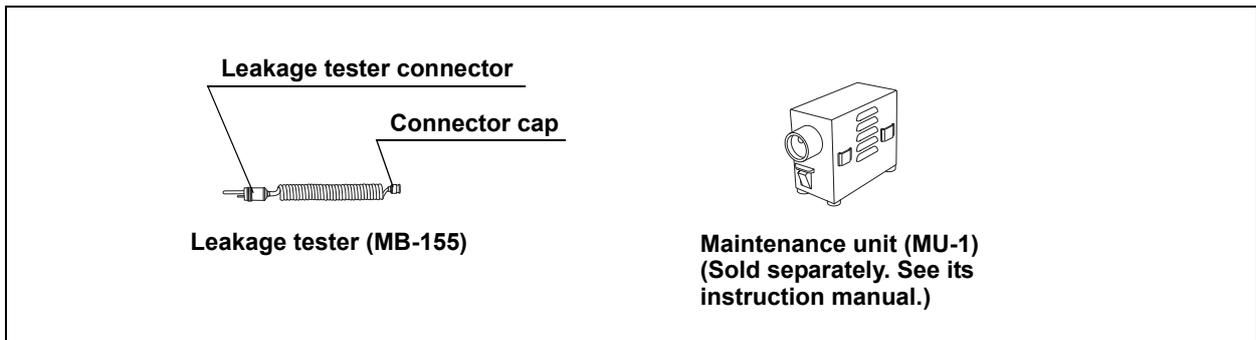
Figure 5.7

4. Attach the cap to the electrical connector by pushing in and rotating the cap clockwise until it stops (approximately 45 degrees).

## 5.3 Leakage testing of the endoscope

### Equipment needed

Prepare the following equipment.



- Water for cleaning (See Section 3.2)
- Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Detergent solution (See Section 3.3)

### Detach the endoscope from the light source

#### WARNING

Do not touch the light guide of the endoscope connector immediately after detaching it from the light source because it is extremely hot. Injury may result.

1. Detach the endoscope from the light source.
2. Transport the endoscope to the reprocessing area. Use a covered container if required by local policy.
3. Detach the AW channel cleaning adapter (MH-948), the suction valve (MH-443), and the biopsy valve (MB-358) from the endoscope and place them in the detergent solution.

#### NOTE

The AW channel cleaning adapter, the suction valve, and the biopsy valve are to be reprocessed according to Chapter 6, "Reprocessing the Accessories".

## **Perform the leakage test**

### **CAUTION**

- If you identify a leak during leakage testing, remove the endoscope from the water with both the water resistant cap (MH-553) and the leakage tester (MB-155) still attached. Contact Olympus regarding instructions for reprocessing a leaking endoscope in preparation for returning the endoscope to Olympus for repair.
- Do not attach/detach the water resistant cap or the leakage tester while immersed. Attaching/detaching under water could allow the water to enter the endoscope, resulting in endoscope damage.
- When attaching the connector cap of the leakage tester to the venting connector of the water resistant cap, make sure that both the connector cap and the venting connector are thoroughly dry. Water on the surface of either component may enter the endoscope and could cause endoscope damage.
- When attaching the connector cap of the leakage tester to the venting connector of the water resistant cap, push on and rotate the connector cap clockwise fully until it stops. If it is not fully and properly attached, the interior of the endoscope will not be properly pressurized and accurate leakage testing will be impossible.
- Detach the leakage tester from the maintenance unit (MU-1) or the light source before detaching the leakage tester from the water resistant cap. If the leakage tester is detached from the water resistant cap before detaching the leakage tester from the maintenance unit or the light source, the air pressure inside the endoscope will not vent properly. This may damage the endoscope.

1. Fill a clean, large basin with the water referred to in Section 3.2.
2. Attach the leakage tester connector of the leakage tester (MB-155) to the output socket of the maintenance unit (MU-1) or the light source. Turn the maintenance unit or the light source ON. Set the light source's airflow regulator switch to its maximum level.
3. Depress the pin located inside the connector cap of the leakage tester and listen to confirm that air is emitted from the connector cap.

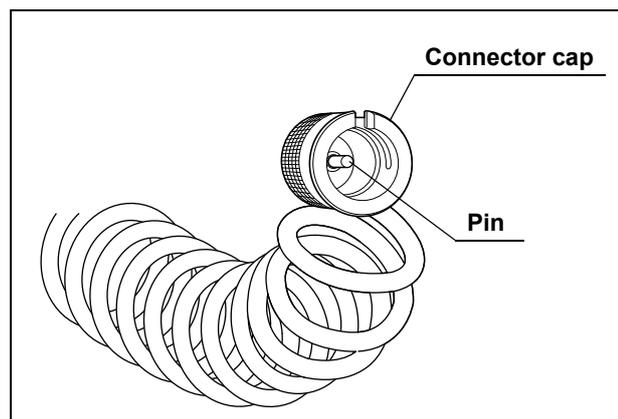


Figure 5.8

4. Confirm that both the connector cap of the leakage tester and the venting connector of the water resistant cap are dry. If not, dry with a clean, lint free cloth. Attach the connector cap to the venting connector by pushing on and rotating clockwise until it stops.
5. With the leakage tester attached, immerse the endoscope in the water and observe for approximately 30 seconds while deflecting the bending section of the endoscope by turning the endoscope's UP/DOWN and RIGHT/LEFT angulation control knobs, and while raising and lowering the forceps elevator by moving the endoscope's elevator control lever. Confirm that there is no location on the endoscope from which a continuous series of air bubbles emerge.

**NOTE**

- A continuous series of air bubbles emerging from any location on the endoscope indicates a leak at that location. If there is a leak in the instrument channel or suction channel of the endoscope, a continuous series of air bubbles will emerge from one or more channel openings (e.g., distal end, suction connector, suction cylinder, instrument channel port) on the submerged endoscope.

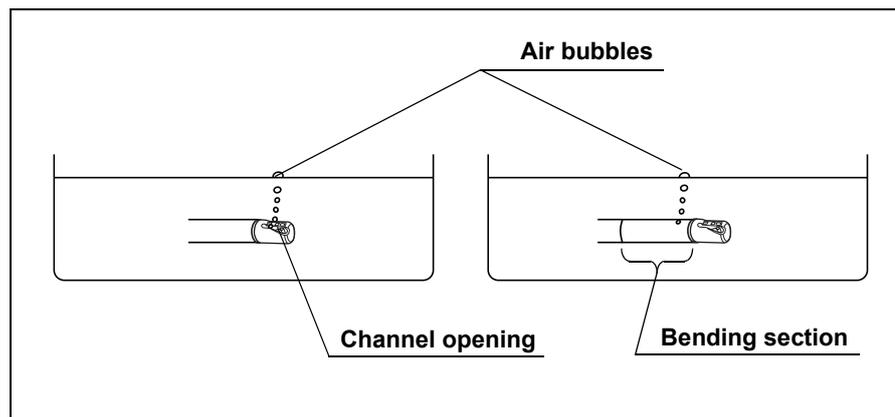


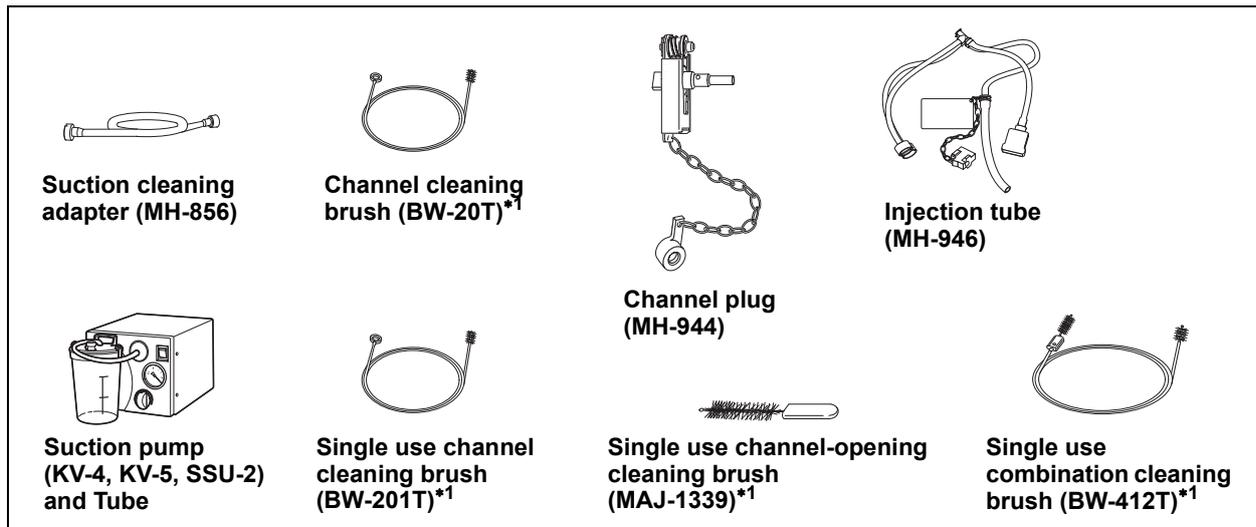
Figure 5.9

- During the leakage test, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.
6. Remove the endoscope from the water with the leakage tester still attached.
  7. Turn the maintenance unit or the light source OFF.
  8. Detach 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. Detach the leakage tester from the water resistant cap.
  10. Thoroughly dry the leakage tester using a clean, lint-free cloth.

## 5.4 Manually cleaning the endoscope and accessories

Prepare the following equipment.

### Equipment needed



- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Water for cleaning (See Section 3.2)</li> <li>• Clean, soft brush(s)</li> <li>• Clean sponge(s)</li> <li>• Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)</li> </ul> | <ul style="list-style-type: none"> <li>• Detergent solution (See Section 3.3)</li> <li>• Clean lint-free cloths</li> <li>• Clean 30 ml (30 cc) syringe(s)</li> </ul> |
|--|--|

\*1 Prepare either a single use combination cleaning brush (BW-412T) or a set of channel cleaning brush (BW-20T) and channel-opening cleaning brush (MH-507) or single use channel cleaning brush (BW-201T) and single use channel-opening cleaning brush (MAJ-1339).

## **Clean the external surface**

1. Fill a clean, large basin with the detergent solution at the concentration recommended by the detergent manufacturer.
2. Immerse the endoscope in the detergent solution.
3. Thoroughly brush or wipe all external surfaces of the endoscope, using a clean, lint-free cloth, brush or sponge. Pay particular attention to the air/water nozzle opening and the objective lens on the distal end of the insertion section, and ensure that all surfaces of the distal end are thoroughly cleaned.

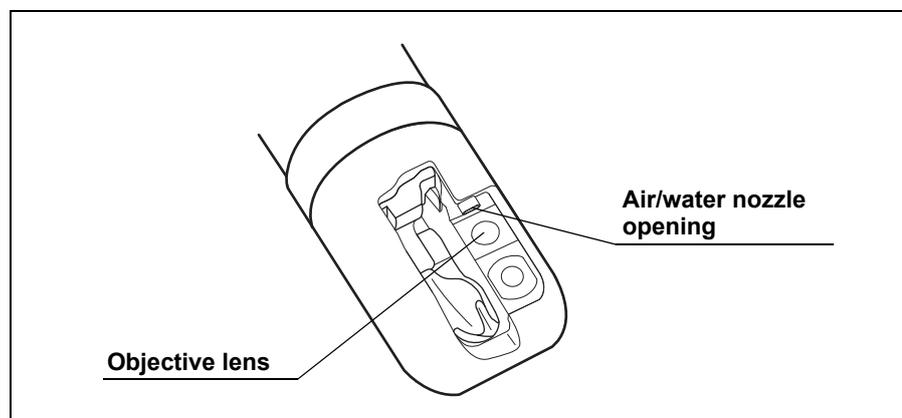


Figure 5.10

## **Brush the forceps elevator and the forceps elevator recess**

### **WARNING**

To avoid splashing the detergent solution when the brush is pulled out from the endoscope, keep the endoscope immersed in the detergent solution while brushing.

### **CAUTION**

When brushing the forceps elevator and the forceps elevator recess, gently use a single use channel-opening cleaning brush (MAJ-1339). Do not use a stiff brush or brush with excessive force even with the channel-opening cleaning brush. Using a stiff brush or brushing with excessive force may damage the distal end of the endoscope and cause the endoscope to leak.

1. Lower the forceps elevator by turning the elevator control lever in the opposite direction of the “◀U” direction until it stops. Perform the following brushing in the detergent solution.

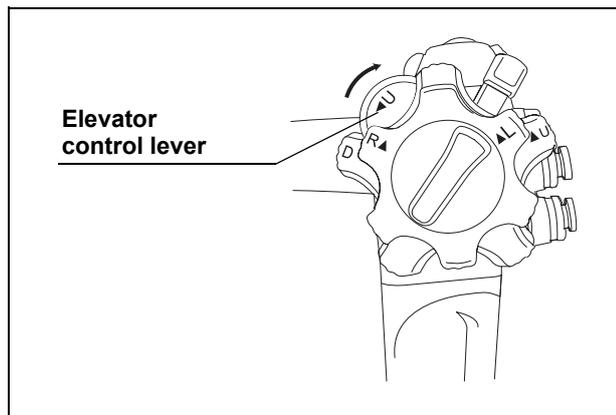


Figure 5.11

2. Straighten the bending section of the endoscope. Brush the forceps elevator including the guidewire-locking groove, two side grooves, and the forceps elevator recess with the single use channel-opening cleaning brush (MAJ-1339) as follows:
  - a) Insert the brush into the forceps elevator recess along the forceps elevator until the brush handle touches the distal end of the endoscope and pull the brush out of the forceps elevator recess;
  - b) Brush the guidewire-locking groove;
  - c) Brush the both grooves.

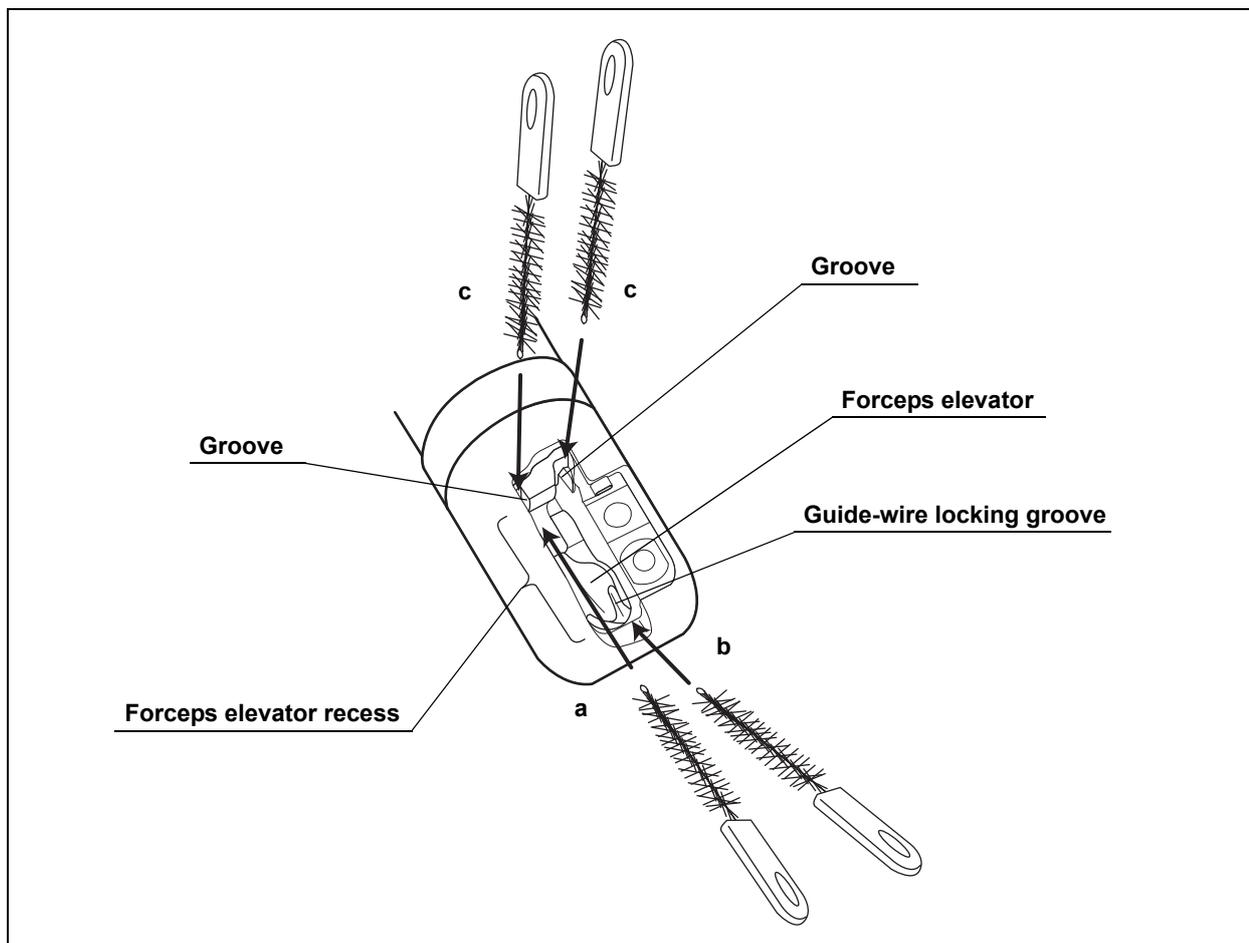


Figure 5.12

3. Raise the forceps elevator by turning the elevator control lever in the “◀U” direction until the operator feels heavy.

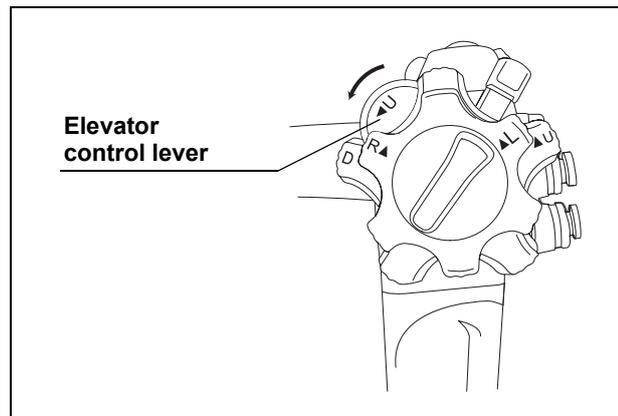


Figure 5.13

4. While holding the distal end, brush the forceps elevator and the forceps elevator recess with the single use channel-opening cleaning brush as follow:
  - a) Insert the brush into the forceps elevator recess along the back of the forceps elevator until the distal end of the brush touches the bottom of the forceps elevator recess;
  - b) Insert the brush into the forceps elevator recess and rotate the brush one full revolution;
  - c) Brush both sides of the forceps elevator.

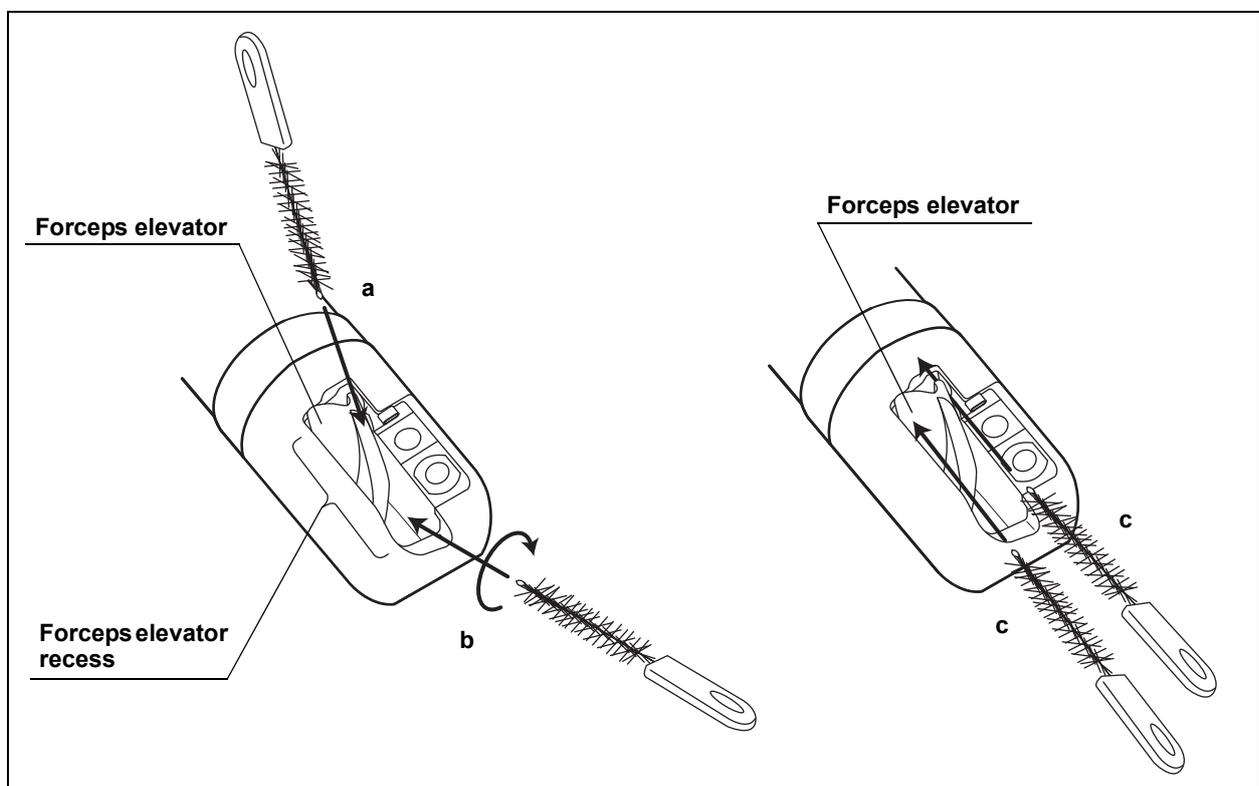


Figure 5.14

5. Operate the elevator control lever to raise and lower the forceps elevator in the detergent solution at least three times.
6. Inspect whether there is debris on the forceps elevator and in the forceps elevator recess.
7. Repeat Steps 1 through 6 until no debris is observed upon inspection of the forceps elevator and the forceps elevator recess.
8. Lower the forceps elevator by turning the elevator control lever in the opposite direction of the “◀U” direction until it stops.
9. Brush the distal end of the endoscope except the forceps elevator and the forceps elevator recess, using the single use channel-opening cleaning brush, until no debris is observed upon inspection of the brush.

## **Brush the channels**

### **WARNING**

- Be sure to thoroughly brush the inside of the instrument channel, the instrument channel port, the suction channel, and the suction cylinder of the endoscope. Insufficient brushing may pose an infection control risk.

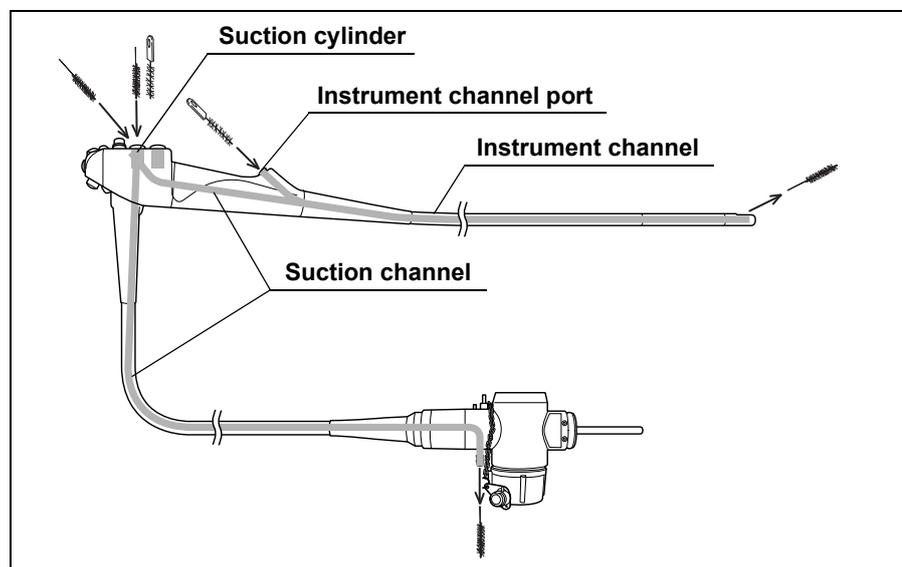


Figure 5.15

- To avoid splashing the detergent solution when the brush is pulled out from the endoscope, keep the endoscope immersed in the detergent solution while brushing.

**WARNING**

- The channel cleaning brush (BW-20T) is consumable. The single use channel cleaning brush (BW-201T) and the single use combination cleaning brush (BW-412T) are for single use. Repeated usage of these brushes may cause the brush head to become bent or kinked, which could cause it to come off during use. Confirm that the brush is free from any damage or other irregularities before and after use. If a piece of the brush comes off inside the endoscope channel, immediately retrieve it. Confirm that no parts remain inside either the instrument channel or the suction channel of the endoscope by carefully passing a new brush through both channels. Any part left in the channels can drop into the patient during a subsequent patient procedure. Depending on the location of the missing part, the part may not be retrievable by passing a new brush. In this case, contact Olympus.

**CAUTION**

- Do not attempt to pass the channel cleaning brush or the single use channel cleaning brush backwards – i.e., by inserting the brush directly into the open end of the instrument channel at the distal end of the endoscope's insertion section or directly into the suction connector on the endoscope connector. It may get caught, making retrieval impossible.

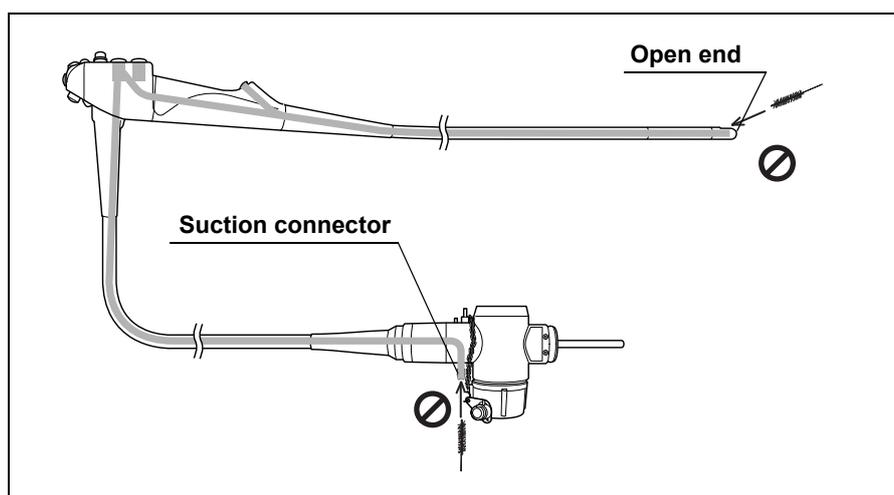


Figure 5.16

- Do not coil the insertion section or the universal cord of the endoscope with a diameter of less than 40 cm. If the diameter is less than 40 cm, it may be difficult to pass the brush completely through the channels.

- **Brush from the suction cylinder to the distal end of the insertion section** (This brushes the instrument channel in the insertion section and the suction channel in the control section.)

**CAUTION**

When withdrawing the channel cleaning brush (BW-20T) from the suction cylinder of the endoscope, make sure that the shaft of the brush does not rub against the cylinder opening. Excessive rubbing of the brush against the cylinder edge may damage the cylinder.

1. Straighten the bending section of the endoscope. Grip the channel cleaning brush (BW-20T), the channel cleaning brush part of the single use combination cleaning brush (BW-412T), or the single use channel cleaning brush (BW-201T) at a point 3 cm from the bristles.
2. Insert the brush at a 45° angle into the opening located in the side wall of the suction cylinder. Using short strokes, feed the brush through the instrument channel until it emerges from the distal end of the endoscope's insertion section.

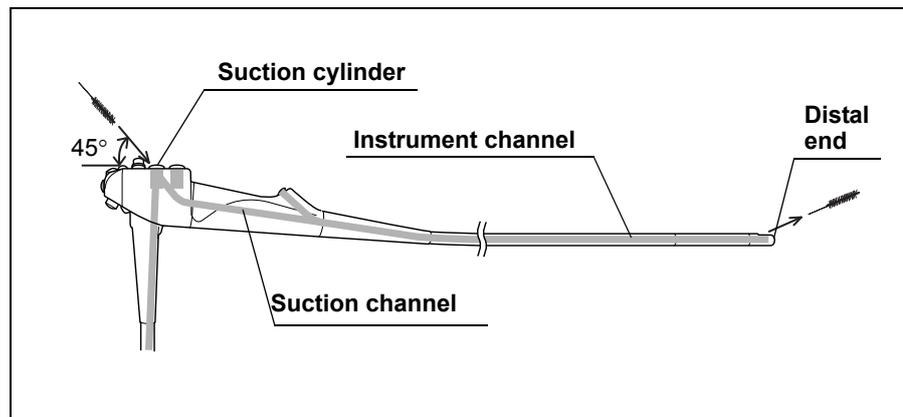


Figure 5.17

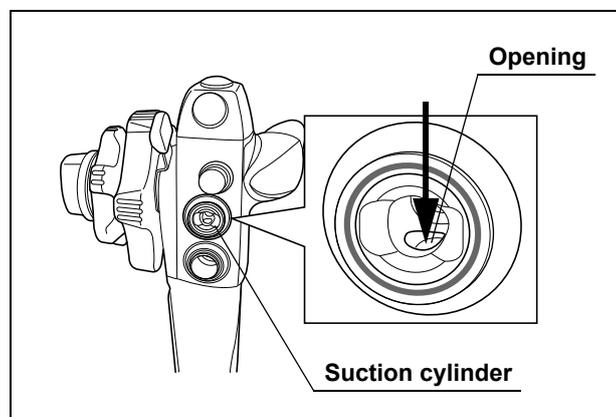


Figure 5.18

3. Inspect whether there is debris on the bristles when the brush emerges from the distal end. Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.
4. Carefully pull the brush back through the channel and out of the suction cylinder.
5. Inspect whether there is debris on the bristles when the brush emerges from the suction cylinder. Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.
6. Repeat Steps 2 through 5 until no debris is observed upon inspection of the brush.

○ **Brush from the suction cylinder to the endoscope connector** (This brushes the suction channel in the universal cord and the endoscope connector.)

1. Grip the channel cleaning brush (BW-20T), the channel cleaning brush part of the single use combination cleaning brush (BW-412T), or the single use channel cleaning brush (BW-201T) at a point 3 cm from the bristles.
2. Insert the brush straight into the suction cylinder. Using short strokes, feed the brush through the suction channel until it emerges from the suction connector on the endoscope connector.

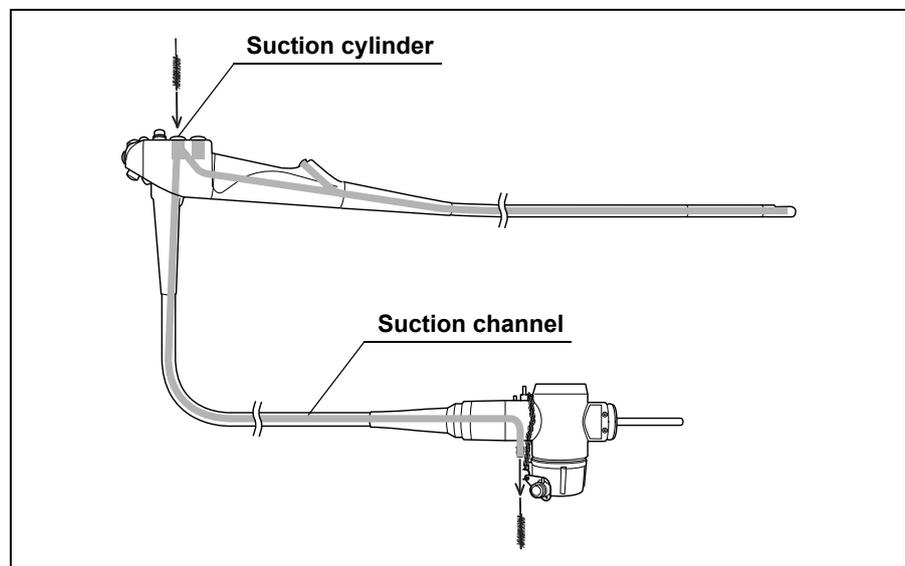


Figure 5.19

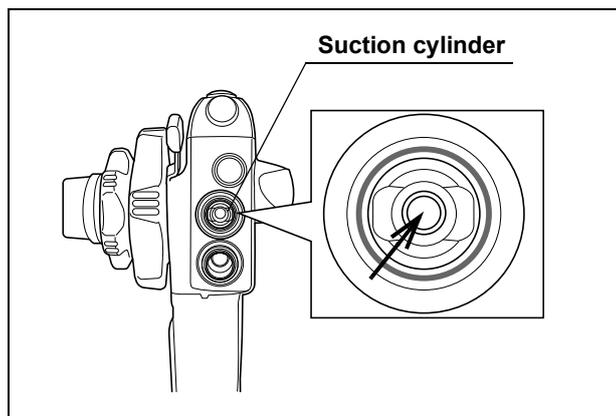


Figure 5.20

3. Inspect whether there is debris on the bristles when the brush emerges from the suction connector. Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.
4. Carefully pull the brush back through the channel and out of the suction cylinder.
5. Inspect whether there is debris on the bristles when the brush emerges from the suction cylinder. Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.
6. Repeat Steps 2 through 5 until no debris is observed upon inspection of the brush.

**NOTE**

The channel cleaning brush and the single use channel cleaning brush will be used later to brush the accessories described in Section 6.1.

## ○ Brush the suction cylinder

### **CAUTION**

When inserting the single use channel-opening cleaning brush (MAJ-1339), the channel-opening cleaning brush part of the single use combination cleaning brush (BW-412T), into the suction cylinder, do not forcibly insert the brush beyond the mid portion of the brush, to prevent the brush from getting stuck.

1. Insert the single use channel-opening cleaning brush into the suction cylinder, until half of the brush section is inserted.

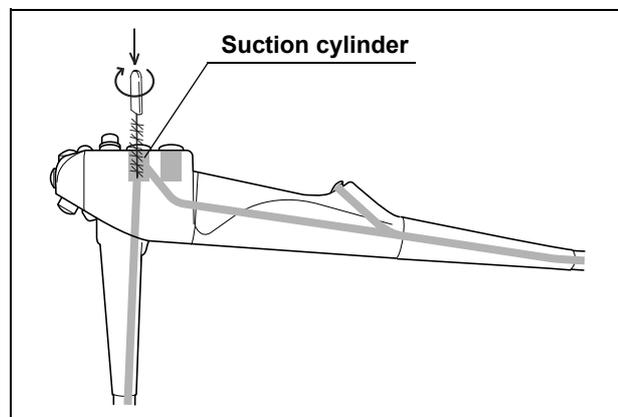


Figure 5.21

2. Rotate the inserted brush one full revolution.
3. Pull the brush out of the cylinder.
4. Inspect whether there is debris on the bristles. Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.
5. Repeat Steps 1 through 4 until no debris is observed upon inspection of the brush.

○ **Brush the instrument channel port**

1. Insert the single use channel-opening cleaning brush (MAJ-1339), the channel-opening cleaning brush part of the single use combination cleaning brush (BW-412T), into the instrument channel port, until the brush handle touches the channel opening.

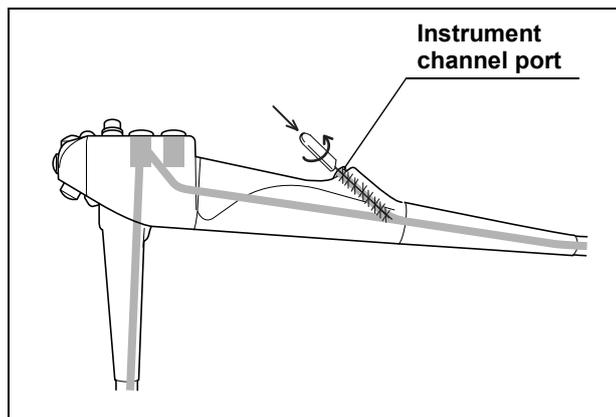


Figure 5.22

2. Rotate the inserted brush one full revolution.
3. Pull the brush out of the instrument channel port.
4. Inspect whether there is debris on the bristles. Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.
5. Repeat Steps 1 through 4 until no debris is observed upon inspection of the brush.
6. Dispose of the single use channel-opening cleaning brush, according to Section 8.3.
7. Remove the endoscope from the detergent solution.

## **Aspirate detergent solution through the instrument channel and the suction channel**

**NOTE**

Monitor the suction bottle on the suction pump carefully to ensure that it does not overflow.

1. Attach the suction cleaning adapter (MH-856) to the instrument channel port.
2. Attach the suction tube from the suction pump to the suction connector on the endoscope connector. Turn the suction pump ON.

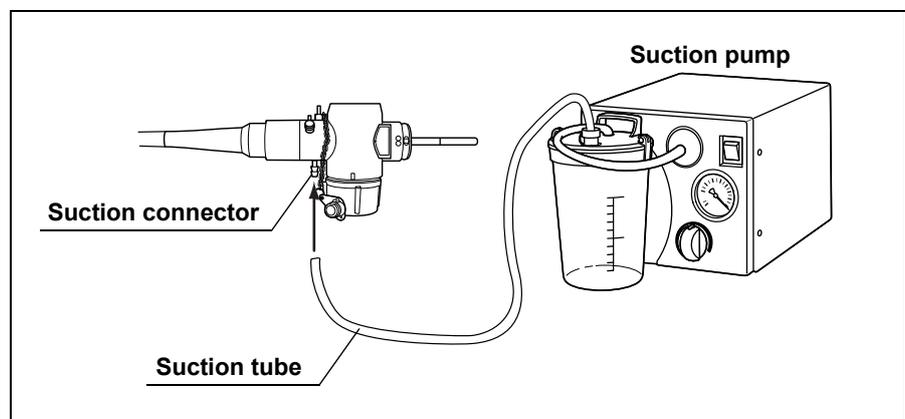


Figure 5.23

3. Immerse both the distal end of the insertion section and the weighted end of the suction cleaning adapter in the detergent solution.

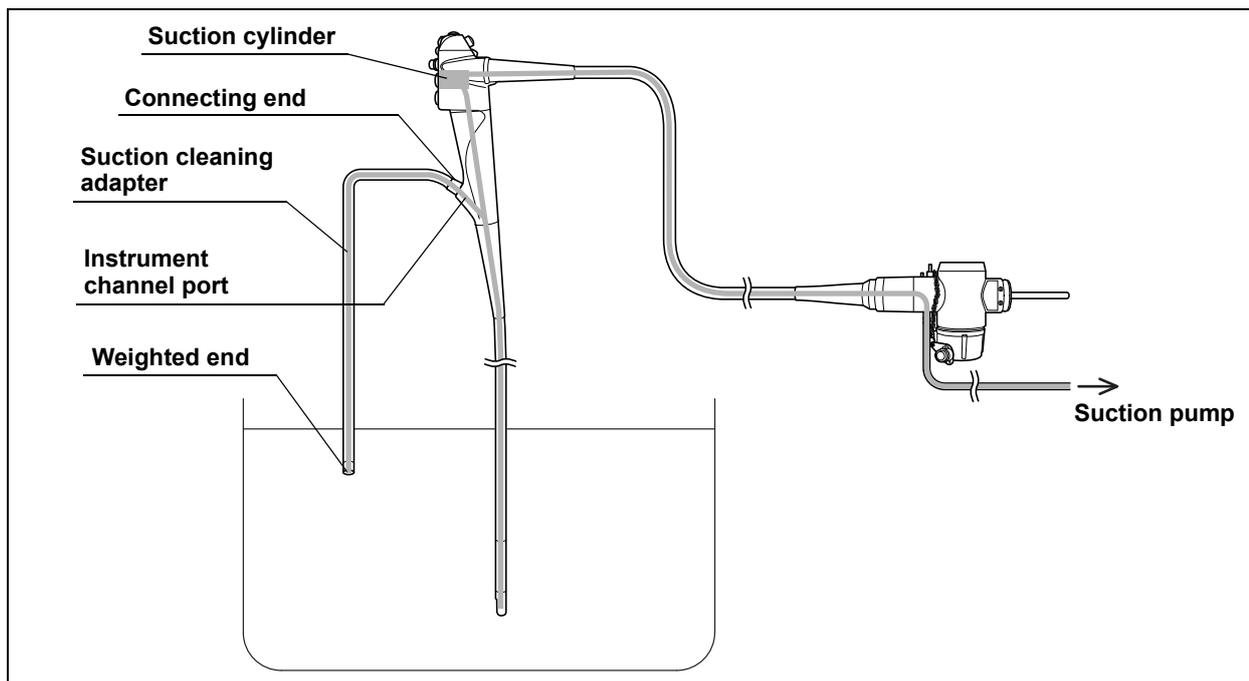


Figure 5.24

4. Cover the suction cylinder of the endoscope with your gloved finger and aspirate the detergent solution through the instrument channel and the suction channel of the endoscope for approximately 30 seconds.

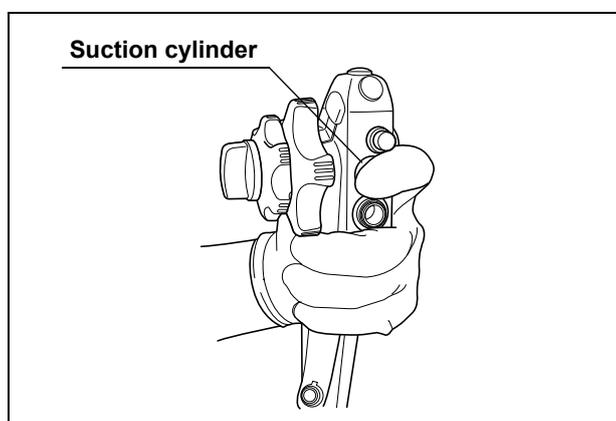


Figure 5.25

5. Turn the suction pump OFF.
6. Detach the suction tube and the suction cleaning adapter from the endoscope.

**NOTE**

The suction cleaning adapter is to be reprocessed according to Chapter 6, "Reprocessing the Accessories".

### **Flush the forceps elevator recess with detergent solution**

1. Immerse the distal end in detergent solution.
2. Operate the elevator control lever to raise and lower the forceps elevator at least three times.
3. Raise the forceps elevator by turning the elevator control lever in the “◀U” direction until the operator feels heavy.
4. Insert the distal end of a clean 30 ml syringe into the forceps elevator recess and flush the interior of the forceps elevator recess with 30 ml of the detergent solution by pumping the syringe.

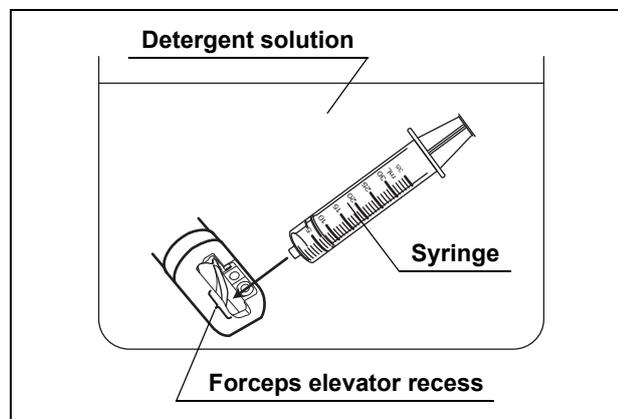


Figure 5.26

5. Lower the forceps elevator by turning the elevator control lever in the opposite direction of the “◀U” direction until it stops.

## Flush the air/water channel with detergent solution

1. Attach the biopsy valve cap of the channel plug (MH-944) to the instrument channel port of the endoscope.

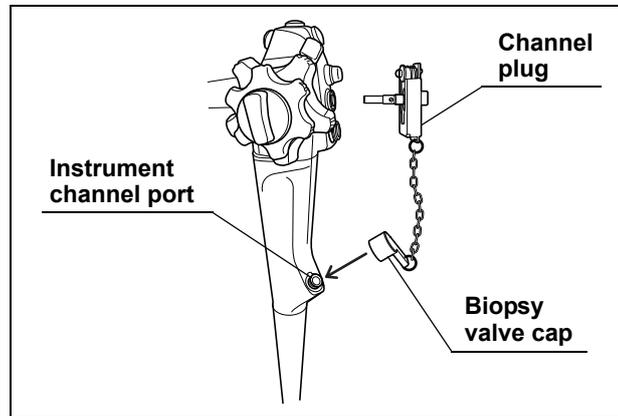


Figure 5.27

2. Attach the channel plug to the air/water and suction cylinders of the endoscope as follows:
  - a) Insert the air/water plug of the channel plug into the air/water cylinder;
  - b) Insert the suction plug of the channel plug into the suction cylinder;
  - c) Push the plug frame towards the control section of the endoscope, until the plug frame contacts the control section;
  - d) While pushing the plug frame towards the control section, slide the plug frame towards switch 1, until the plug frame stops. The channel plug should now be firmly locked in place.

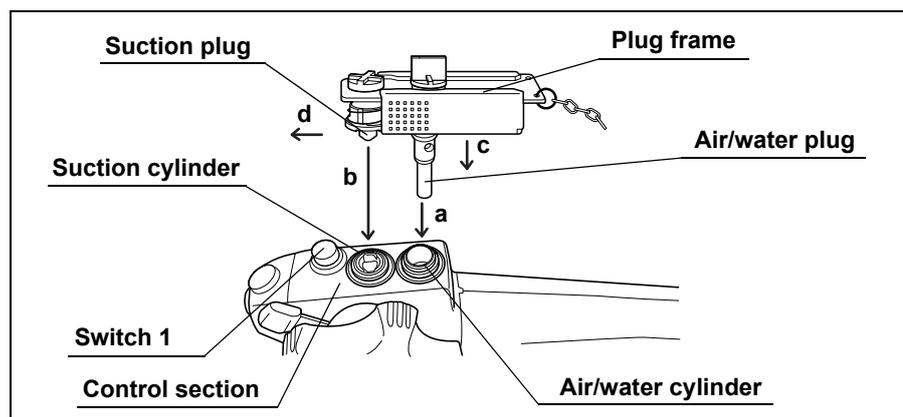


Figure 5.28

3. Attach the injection tube (MH-946) to the endoscope connector, as follows:
  - a) Attach the connector plug of the injection tube to the air and water supply connectors on the endoscope connector;
  - b) Attach the air pipe port of the injection tube to the air pipe on the endoscope connector;
  - c) Attach the suction channel tube of the injection tube to the suction connector on the endoscope connector.

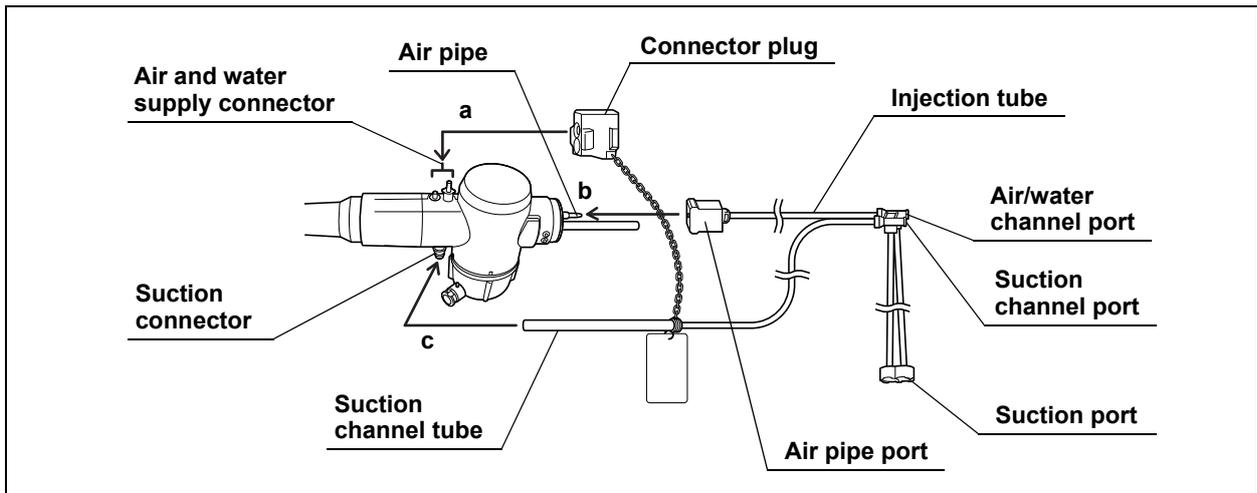


Figure 5.29

4. Immerse the suction port of the injection tube in the detergent solution.
5. Attach a clean 30 ml syringe to the air/water channel port of the injection tube.

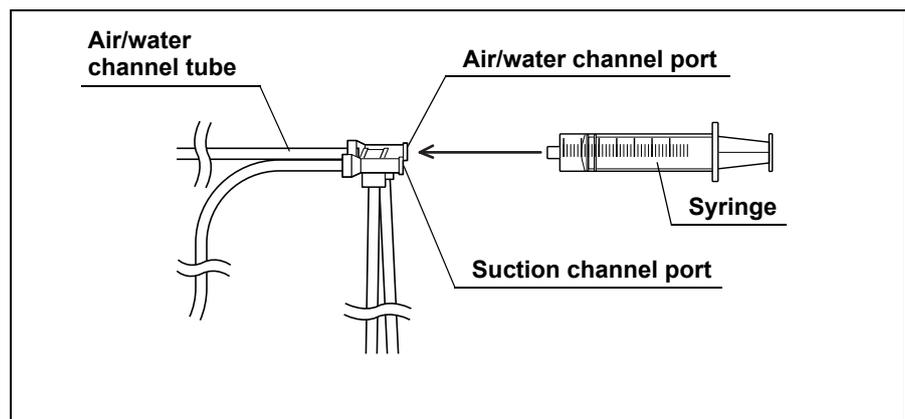


Figure 5.30

6. Flush the air/water channel with 90 ml of the detergent solution by pumping the syringe at least three times.

### **Immerse the endoscope and accessories in detergent solution**

1. Wipe all external surfaces of the endoscope, the channel plug (MH-944), and the injection tube (MH-946) to remove debris while they are immersed in the detergent solution, using a clean, lint-free cloth, brush or sponge.
2. Leave the endoscope with attached accessories immersed in the detergent solution, according to the instructions of the detergent manufacturer.
3. Remove the endoscope with attached accessories from the detergent solution.

### **Remove detergent solution from all channels**

1. Fill a clean large basin with the water referred to in Section 3.2.
2. Immerse the endoscope with attached accessories in the water and gently agitate them to thoroughly rinse.
3. Immerse the suction port of the injection tube (MH-946) in the water. (See Figure 5.29)
4. Attach a clean 30 ml syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of water (i.e., pump the syringe at least three times).

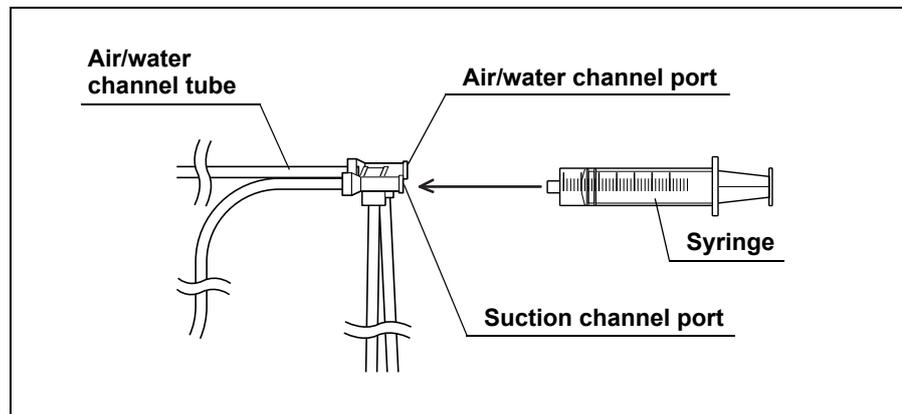


Figure 5.31

5. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of water (i.e., pump the syringe at least three times).
6. Remove the endoscope with attached accessories from the water.
7. Place them in a clean basin and cover the distal end and the control section of the endoscope with a clean, lint-free cloth(s) to prevent splashing from the channel openings.
8. Attach the syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of air. (See Figure 5.31).
9. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of air.
10. Remove the cloth(s) from the endoscope.
11. Detach the channel plug and the injection tube from the endoscope.

### ***Dry external surfaces***

1. Dry the external surfaces of the endoscope, the channel plug, and the injection tube by wiping with a clean, lint-free cloth(s).
2. Inspect all items for residual debris. Should any debris remain, repeat the entire cleaning procedure until all debris is removed.

## 5.5 Manually disinfecting the endoscope and accessories

### Equipment needed

Prepare the following equipment.

- |  |  |
|--|--|
| <ul style="list-style-type: none"><li>• Disinfectant solution (See Section 3.4)</li><li>• Sterile 30 ml (30 cc) syringe(s)</li></ul> | <ul style="list-style-type: none"><li>• Clean 30 ml (30 cc) syringe(s)</li><li>• Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)</li></ul> |
|--|--|

### Preparation

1. Fill a clean large basin with the disinfectant solution. Check the concentration of the disinfectant solution according to the manufacturer's instructions to verify that the concentration is above the recommended minimum.
2. Immerse the endoscope in the disinfectant solution.
3. Attach the channel plug (MH-944) and the injection tube (MH-946) to the endoscope and immerse in the disinfectant solution. (See Figures 5.27, 5.28, and 5.29)

### Flush all channels and around the forceps elevator with disinfectant solution

#### **WARNING**

Make sure that the disinfectant solution contacts all internal channel surfaces of the endoscope and accessories by completely removing all air bubbles from all channels. Air bubbles may inhibit disinfection of the channel's surfaces. When filling the channels with the disinfectant solution, flush until no more air bubbles are seen exiting the channel openings.

#### **NOTE**

Removal of air bubbles can be facilitated by forcefully flushing the disinfectant solution through the channels.

1. Confirm that the suction port of the injection tube (MH-946) is immersed in the disinfectant solution.
2. Attach a clean 30 ml syringe to the suction channel port of the injection tube and forcefully flush the suction channel with 90 ml of the disinfectant solution – i.e., by pumping the syringe at least three times. Confirm that no air bubbles exit the distal end of the endoscope's insertion section during the third flush.

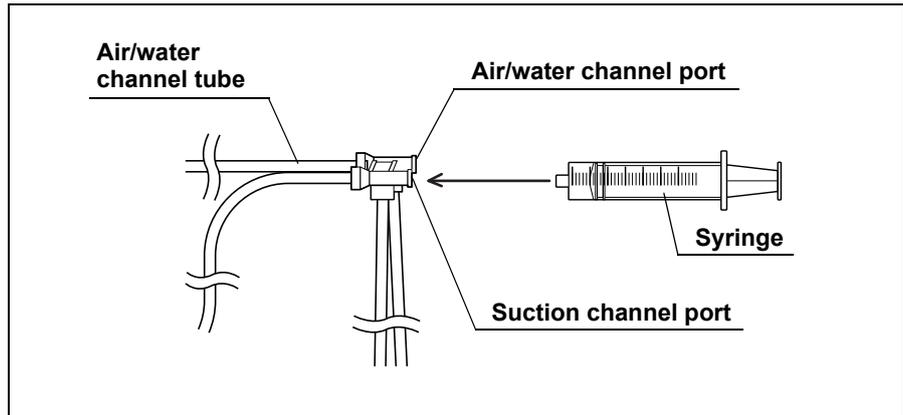


Figure 5.32

3. Move the syringe to the air/water channel port of the injection tube and forcefully flush the air/water channel with 90 ml of the disinfectant solution. Confirm that no air bubbles exit the distal end during the third flush.
4. Raise the forceps elevator by turning the elevator control lever in the “◀U” direction until the operator feels heavy.
5. Insert the distal end of a clean 30 ml syringe into the forceps elevator recess and flush the interior of the forceps elevator recess with 30 ml of the disinfectant solution by pumping the syringe.

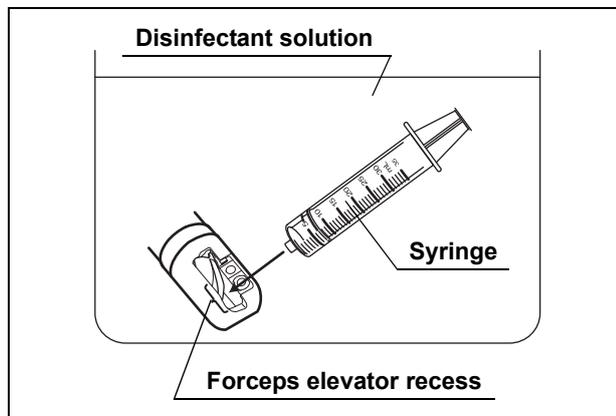


Figure 5.33

6. Lower the forceps elevator by turning the elevator control lever in the opposite direction of the “◀U” direction to put the forceps elevator in intermediate position of the range of movement.

### ***Immerse the endoscope and accessories in disinfectant solution***

#### **WARNING**

Make sure that the disinfectant solution contacts all external surfaces of the endoscope and accessories. If accessories, such as the injection tube, remain attached to the endoscope during disinfection, the disinfectant solution cannot adequately contact the mated surfaces between the endoscope and the accessory. Detach the channel plug and the injection tube from the endoscope while immersed. If the endoscope and accessories are not completely immersed, any protruding section(s) of the device(s) will not be adequately disinfected. Always check to confirm that the endoscope and accessories are completely below the surface of the disinfectant solution.

#### **CAUTION**

Do not immerse the endoscope and accessories in the disinfectant solution for a longer contact time, at a higher temperature, or at a greater concentration than recommended by the disinfectant manufacturer. Such immersion may cause damage to the endoscope and accessories.

1. Detach the syringe from the accessories. While immersed, detach the channel plug (MH-944) and the injection tube (MH-946) from the endoscope. Confirm that the endoscope and all accessories are completely submerged in the disinfectant solution.
2. Confirm that there are no air bubbles on the surfaces of the endoscope and accessories. If air bubbles adhere to the surfaces, wipe them away using your gloved finger or a clean, lint-free cloth.
3. Cover the basin of the disinfectant solution with a tight-fitting lid to minimize the diffusion of disinfectant vapors.
4. Leave the endoscope, the channel plug, and the injection tube immersed in the disinfectant solution according to the instructions of the disinfectant manufacturer. Confirm the recommended contact time, temperature, and concentration. Use a clock or timer to accurately measure the disinfection contact time.

## Remove the endoscope and accessories from disinfectant solution

1. Attach the channel plug (MH-944) and the injection tube (MH-946) to the endoscope. (See Figures 5.27 and 5.28)

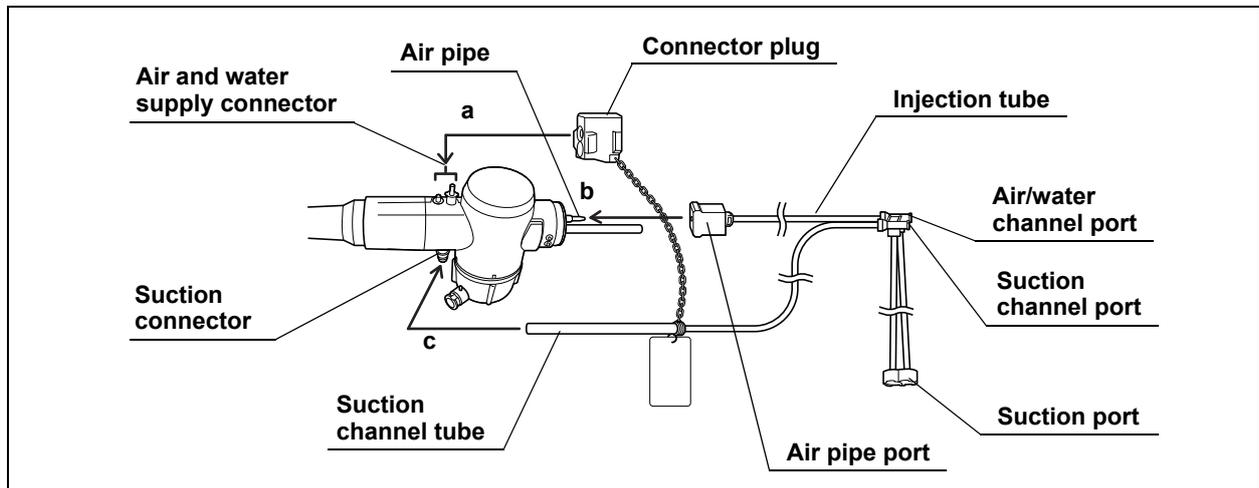


Figure 5.34

2. Remove the suction port of the injection tube from the disinfectant solution.
3. Attach a sterile 30 ml syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of air – i.e., pump the syringe at least three times. (See Figure 5.29 and 5.31)
4. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of air. (See Figure 5.30)
5. Remove the endoscope with attached accessories from the disinfectant solution.

## 5.6 Rinsing the endoscope and accessories following disinfection

### **WARNING**

After rinsing, thoroughly dry the channels of the endoscope and accessories. Otherwise, bacteria may proliferate in the channels and pose an infection control risk.

### **Equipment needed**

Prepare the following equipment.

- |  |  |
|--|--|
| • Rinse water (See Section 3.5)  | • Sterile lint-free cloths* <sup>1</sup>   |
| • Sterile cotton swabs* <sup>1</sup>   | • Sterile 30 ml (30 cc) syringe(s)* <sup>1</sup>   |
| • Sterile, large basins* <sup>1</sup><br>(size: 40 (W) × 40 (H) × 25 (D) cm or more) | • Sterile, small basins with tight-fitting lids* <sup>1</sup><br>(size: 25 (W) × 10 (H) × 25 (D) cm or more) |
| • 70% ethyl or 70% isopropyl alcohol (See Section 3.6)                               |  |

- \*<sup>1</sup> Following high-level disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories after high-level disinfection, the use of sterile equipment (e.g., basin, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital's infection control committee regarding local policies or requirements regarding reprocessing equipment.

## **Rinse the endoscope and accessories**

Use appropriate rinse water as instructed in Section 3.5. If nonsterile water is used for rinsing the endoscope and accessories, flush the endoscope and accessories with 70% ethyl or 70% isopropyl alcohol after rinsing, according to the procedures described below.

**NOTE**

- Some national or professional guidelines recommend flushing all channels of the endoscope with 70% ethyl or 70% isopropyl alcohol regardless of whether sterile or nonsterile water is used to rinse the endoscope. Check with your local infection control committee for advice.
- Flushing the interior and recessed parts of the endoscope and accessories with alcohol facilitates drying. Olympus recommends the use of alcohol.

1. Fill a sterile large basin with the rinse water referred to in Section 3.5.
2. Immerse the endoscope with attached accessories in the rinse water. Detach the channel plug (MH-944) and injection tube (MH-946) from the endoscope.
3. Wipe all external surfaces of the endoscope and accessories, using a sterile, lint-free cloth.
4. Attach the channel plug and the injection tube to the endoscope. Immerse the suction port of the injection tube in the rinse water. (See Figures 5.27, 5.28, and 5.34)
5. Attach a sterile 30 ml syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of the rinse water – i.e., pump the syringe at least three times. (See Figure 5.31)
6. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of the rinse water. (See Figure 5.30)
7. Raise the forceps elevator by turning the elevator control lever in the “◀U” direction until the operator feels heavy.
8. Insert the distal end of a clean 30 ml syringe into the forceps elevator recess and flush the interior of the forceps elevator recess with 30 ml of the rinse water by pumping the syringe.
9. Lower the forceps elevator by turning the elevator control lever in the opposite direction of the “◀U” direction to put the forceps elevator in intermediate position of the range of movement.

10. Remove the endoscope with attached accessories from the rinse water and place them in a sterile basin.
11. Cover the distal end and the control section of the endoscope with a sterile, lint-free cloth(s) to prevent splashing from the channel openings.
12. Attach the syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of air. (See Figure 5.31)
13. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of air. (See Figure 5.30)
14. Remove the cloth(s) from the endoscope.
15. Detach only the injection tube from the endoscope.
16. Attach a sterile suction tube from the suction pump to the suction connector on the endoscope connector. Turn the suction pump ON and aspirate air for at least 15 seconds. Air will flow through the instrument channel and the suction channel of the endoscope. Turn the suction pump OFF.

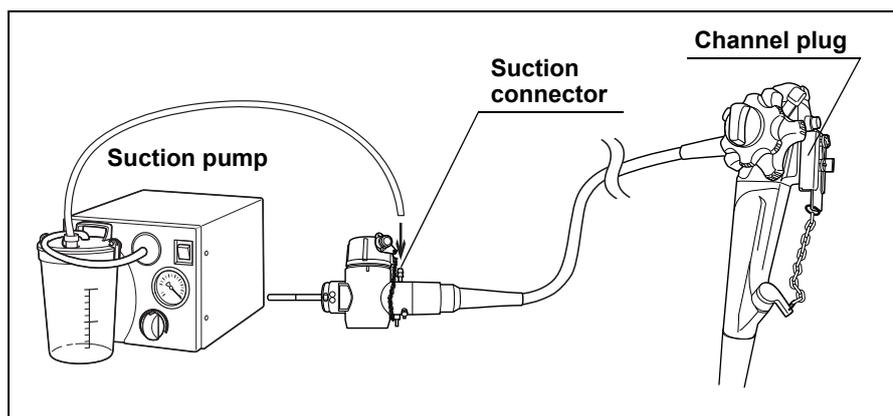


Figure 5.35

17. Detach the suction tube and the channel plug from the endoscope.
18. Thoroughly dry the external surfaces of the endoscope, the channel plug, and the injection tube, by wiping with a sterile, lint-free cloth(s).
19. Thoroughly dry the inside of the suction cylinder, the air/water cylinder, the instrument channel port of the endoscope, and forceps elevator recess, using a sterile cotton swab(s).

## **Alcohol flush**

1. Fill a sterile small basin with the alcohol referred to in Section 3.6.
2. Attach the channel plug (MH-944) and the injection tube (MH-946) to the endoscope. Immerse the suction port of the injection tube in the alcohol. (See Figures 5.27, 5.28 and 5.34)
3. Cover the distal end and the control section of the endoscope with a sterile, lint-free cloth(s) to prevent splashing alcohol from the channel openings.
4. Attach a sterile 30 ml syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of the alcohol – i.e., pump the syringe at least three times. (See Figure 5.31)
5. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 30 ml of the alcohol. (See Figure 5.30)
6. Raise the forceps elevator by turning the elevator control lever in the “◀U” direction until the operator feels heavy.
7. Insert the distal end of a clean 30 ml syringe into the forceps elevator recess and flush the interior of the forceps elevator recess with 30 ml of the alcohol by pumping the syringe.
8. Lower the forceps elevator by turning the elevator control lever in the opposite direction of the “◀U” direction to put the forceps elevator in intermediate position of the range of movement.
9. Remove the suction port of the injection tube from the alcohol.
10. Attach the syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of air. (See Figure 5.31)
11. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of air. (See Figure 5.30)
12. Remove the cloth(s) from the endoscope.
13. Detach the channel plug and the injection tube from the endoscope.
14. Thoroughly dry the external surfaces of the endoscope, the channel plug, and the injection tube, by wiping with a sterile, lint-free cloth(s).
15. Thoroughly dry the inside of the suction cylinder, the air/water cylinder, the instrument channel port of the endoscope, and the forceps elevator recess, using a sterile cotton swab(s).

## 5.7 Sterilizing the endoscope and accessories

### Ethylene oxide gas sterilization of the endoscope and accessories

#### WARNING

- Thoroughly dry the endoscope and accessories before sterilization.
- All instruments must be properly aerated following ethylene oxide gas sterilization in order to remove toxic ethylene oxide residuals.

#### CAUTION

- Exceeding the recommended sterilization parameters may cause damage to the endoscope and/or accessories.
- Detach the water resistant cap (MH-553) from the electrical connector on the endoscope connector prior to ethylene oxide gas sterilization. The detached water resistant cap may remain connected to the endoscope via the chain for water-resistant cap (MAJ-1119). If the water resistant cap (MH-553) is attached to the electrical connector during the ethylene oxide gas sterilization cycle, the air inside the endoscope will expand and rupture the covering of the bending section.

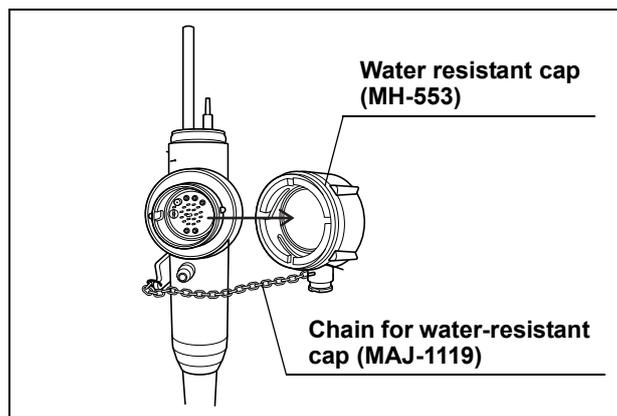


Figure 5.36

1. Flush and dry all channels of the endoscope, the channel plug (MH-944), and the injection tube (MH-946), according to the “Alcohol flush” instructions in Section 5.6.
2. Wipe and dry all external surfaces of the endoscope and accessories, using a sterile, lint-free cloth(s) moistened with alcohol.
3. Thoroughly dry the inside of the suction cylinder, the air/water cylinder and the instrument channel port of the endoscope, using a sterile cotton swab(s).
4. Detach the water resistant cap (MH-553) from the electrical connector.
5. Seal the endoscope and accessories in individual packaging appropriate for ethylene oxide gas sterilization, according to your institution’s protocol.
6. Sterilize and aerate the packaged endoscope and accessories, according to the parameters described in Section 3.7. In addition, always comply with the instructions of the sterilizer manufacturer.

### ***Steam sterilization (autoclaving) of the accessories***

**WARNING**

Allow the accessories in the sterile packaging to dry within the sterilization device, using the device’s prevacuum cycle. If any water remains in the packaging after the sterilization cycle, the cycle may have been ineffective. Remove the accessory from the packaging, thoroughly dry, seal in new sterile packaging, and sterilize again.

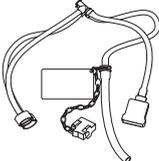
1. Seal the accessories in individual packaging appropriate for steam sterilization, according to your institution’s protocol.
2. Sterilize the packaged accessories, according to the parameters described in Section 3.8. In addition, always comply with the instructions of the sterilizer manufacturer.

## 5.8 Presoaking the endoscope

If there was excessive bleeding during the patient procedure or if precleaning could not be performed immediately after the patient procedure, presoaking the endoscope in detergent solution before manually cleaning the endoscope may be required to wet and loosen debris that has dried and hardened onto the endoscope's surfaces. Follow the procedure described below.

### Equipment needed

Prepare the following equipment.

 <p><b>Water resistant cap (MH-553)</b></p>	 <p><b>Channel plug (MH-944)</b></p>	 <p><b>Injection tube (MH-946)</b></p>
<ul style="list-style-type: none"><li>• Detergent solution (See Section 3.3)</li><li>• Clean 30 ml (30 cc) syringe(s)</li></ul>	<ul style="list-style-type: none"><li>• Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)</li></ul>	

### CAUTION

Presoak the endoscope only if the endoscope was used in a patient procedure with excessive bleeding or if reprocessing of the endoscope was delayed, allowing debris to dry. Unnecessary long-term immersions should be avoided. Consecutive reprocessing sessions using extended immersion may damage the endoscope.

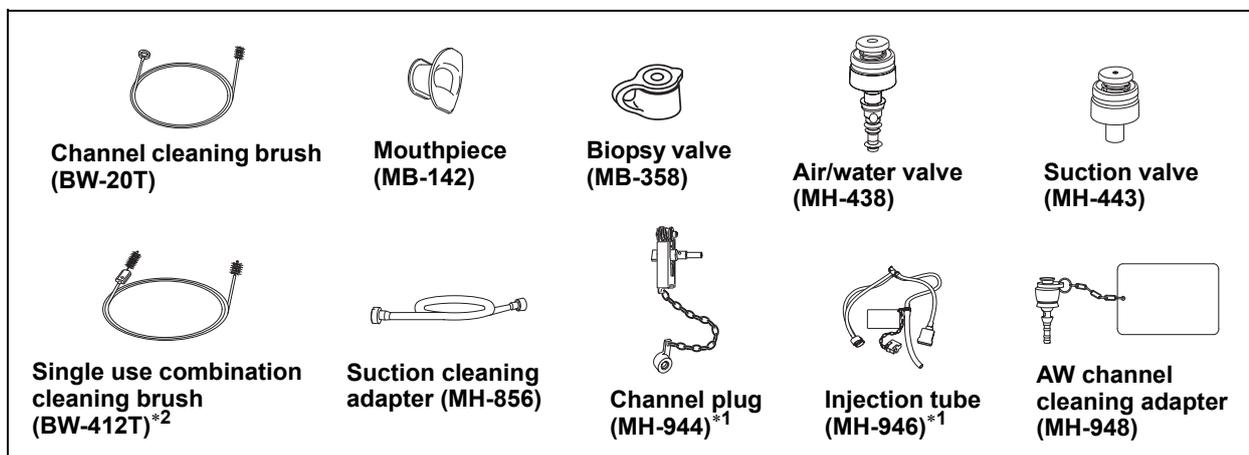
1. Fill a clean large basin with the detergent solution at the concentration recommended by the detergent manufacturer.
2. Attach the water resistant cap (MH-553) to the electrical connector. Completely immerse the endoscope in the detergent solution.
3. Flush all channels of the endoscope with the detergent solution, using the channel plug (MH-944) and the injection tube (MH-946).
4. Detach the channel plug and the injection tube from the endoscope and remove these accessories from the detergent solution.
5. Allow the endoscope to soak in the detergent solution until the debris is loosened. Do not immerse the endoscope for more than 10 hours.
6. Remove the endoscope from the detergent solution.
7. Manually clean the endoscope, according to the procedures described earlier in this Chapter 5.

# Chapter 6 Reprocessing the Accessories

**WARNING**

All accessories (except single-use accessories) must be cleaned and high-level disinfected or sterilized after each use, to prevent an infection control risk.

The following accessories are not cleaned or disinfected with the endoscope during manual cleaning and disinfection of the endoscope. These accessories must be reprocessed separately, as described in this Chapter.



- \*1 The channel plug (MH-944) and the injection tube (MH-946) are manually cleaned and disinfected with the endoscope during manual cleaning and disinfection of the endoscope, as described in Chapter 5, "Reprocessing the Endoscope (and related reprocessing accessories)". However, in case the endoscope is compatible with an automated endoscope reprocessor (AER) and these accessories are not compatible with the AER, these accessories must be cleaned and disinfected manually apart from the endoscope. This chapter also describes how to reprocess these accessories separate from the endoscope.
- \*2 It is needed when the single use combination cleaning brush (BW-412T) has been used to reprocess the endoscope.

Use sterile equipment, such as sterile syringes and cloths, for all reprocessing steps occurring after immersion of the accessories in the disinfectant solution.

### ***Equipment needed***

Prepare the following equipment.

- |  |   |
|--|---|
| • <b>Personal protective equipment</b>                 | • <b>Water for cleaning (See Section 3.2)</b>                 |
| • <b>Detergent solution (See Section 3.3)</b>          | • <b>Disinfectant solution (See Section 3.4)</b>              |
| • <b>Rinse water (See Section 3.5)</b>                 | • <b>70% ethyl or 70% isopropyl alcohol (See Section 3.6)</b> |
| • <b>Clean lint-free cloths</b>                        | • <b>Clean sponge</b>   |
| • <b>Sterile lint-free cloths*<sup>1</sup></b>         | • <b>Clean 30 ml (30 cc) syringe(s)</b>                       |
| • <b>Sterile 30 ml (30 cc) syringe(s)*<sup>1</sup></b> | • <b>Sterile, small basin or container*<sup>1</sup></b>       |
| • <b>Clean basin or container</b>                      | • <b>Clean basin or container with tight-fitting lids</b>     |
| • <b>Sterile basin or container*<sup>1</sup></b>       |   |

\*1 Following high-level disinfection, it is very important not to recontaminate the accessories with potentially infectious microorganisms. When rinsing and drying the accessories after high-level disinfection, the use of sterile equipment (e.g., basin, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the accessories with potentially infectious microorganisms. Consult with your hospital's infection control committee regarding local policies or requirements regarding reprocessing equipment.

## 6.1 Manually cleaning the accessories

### CAUTION

Make sure that you do not scratch the seals on the air/water valve (MH-438), the AW channel cleaning adapter (MH-948), and the biopsy valve (MB-358) with the brushes.

1. Fill a clean basin with the detergent solution at the concentration recommended by the detergent manufacturer.
2. Detach the cap of the biopsy valve (MB-358) from the main body of the valve, and immerse the valve in the detergent solution.

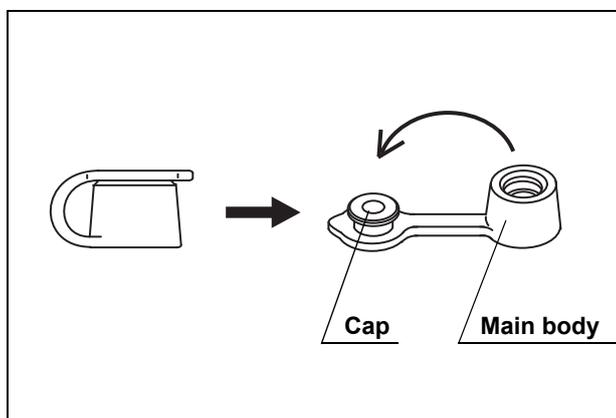


Figure 6.1

3. Immerse all other accessories in the detergent solution.
4. Wipe and clean the external surfaces of all accessories in the detergent solution, using a clean, lint-free cloth or sponge.
5. With the channel cleaning brush (BW-20T), the channel cleaning brush part of the single use combination cleaning brush (BW-412T), or the single use channel cleaning brush (BW-201T), brush the interior and openings of the suction valve (MH-443), the air/water valve (MH-438), and the biopsy valve (MB-358), until debris can no longer be seen.

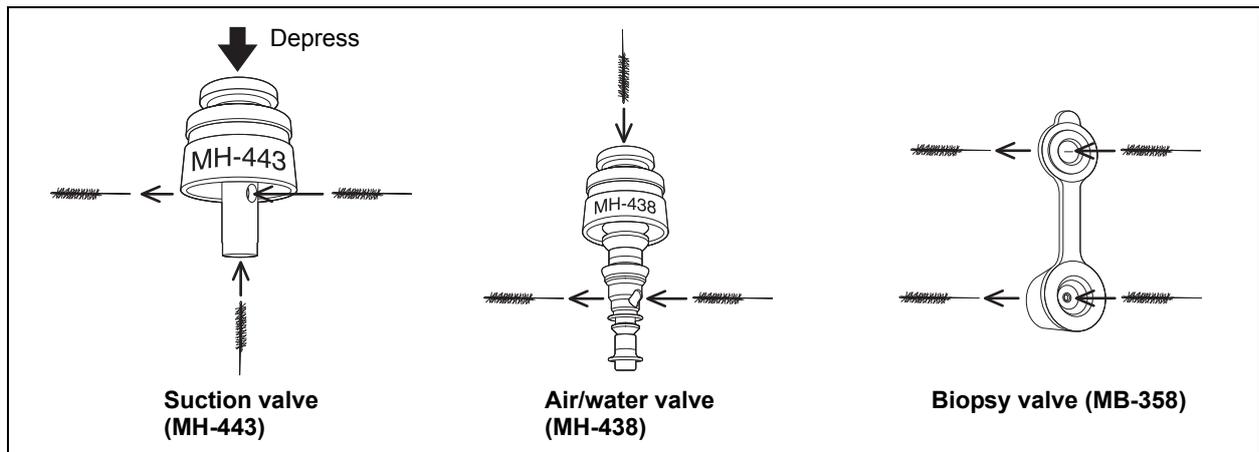


Figure 6.2

6. Dispose of the single use channel cleaning brush (BW-201T) and the single use combination cleaning brush (BW-412T), according to Section 8.3.
7. Fill and attach the syringe to the connecting end of the suction cleaning adapter (MH-856) and flush the adapter with the detergent solution. Ensure that all air bubbles are expelled.
8. Depress and release the pistons of the suction valve (MH-443), the air/water valve (MH-438), and the AW channel cleaning adapter (MH-948) several times while these items are submerged in the detergent solution. Make sure that all trapped air bubbles are expelled.
9. Using the syringe, flush the interiors, the openings, the springs, the backs of the skirts, and the holes of all accessories with the detergent solution until no air bubbles can be seen.
10. Clean the bristles of the channel cleaning brush (BW-20T) in the detergent solution, using your gloved fingertips to remove any debris.
11. Attach the syringe to the suction channel port of the injection tube (MH-946) and flush the filter tube and the suction channel tube of the injection tube with the detergent solution until all air bubbles are expelled.
12. Move the syringe to the air/water channel port of the injection tube and flush the filter tube and the air/water channel tube of the injection tube with the detergent solution until all air bubbles are expelled.
13. Leave all accessories immersed in the detergent solution, according to the instructions of the detergent manufacturer.
14. Remove all accessories from the detergent solution and inspect them. If debris remains on any accessory, ultrasonically clean it at 33 – 48 kHz for 5 minutes.

15. Fill a clean basin with the water referred to in Section 3.2 and immerse all accessories in the water.
16. Gently agitate the accessories in the water.
17. While immersed, depress and release the piston of the suction valve, the air/water valve, and the AW channel cleaning adapter several times. Ensure that all air bubbles are expelled.
18. Rub the bristles of the channel cleaning brush with your gloved fingertips under water to expel all trapped air bubbles.
19. Fill and attach the syringe to the connecting end of the suction cleaning adapter and flush the adapter with water.
20. Attach the syringe to the suction channel port of the injection tube and flush the filter tube and the suction channel tube with water.
21. Move the syringe to the air/water channel port of the injection tube and flush the filter tube and the air/water channel tube with water.
22. Remove the suction cleaning adapter from the water. Hold the adapter and tilt it to expel the water remaining in the adapter.
23. Remove the injection tube from the water. Attach the syringe to the suction channel port of the injection tube and flush the filter tube and the suction channel tube with air to expel all water.
24. Move the syringe to the air/water channel port of the injection tube and flush the filter tube and the air/water channel tube with air to expel all water.
25. Remove all other accessories from the water.
26. Wipe and dry the external surfaces of all accessories, using a clean, lint-free cloth(s).
27. Inspect all accessories for residual debris. If debris is found on any accessory, repeat the cleaning procedure until all debris is removed.

## **6.2 Manually disinfecting the accessories**

### **WARNING**

Make sure that the disinfectant solution contacts all external surfaces of the accessories. If a syringe remains attached to an accessory during disinfection, the disinfectant solution cannot adequately contact the mated surfaces between the accessory and the syringe. Detach the syringe from the accessories while immersed. If the accessories are not completely immersed, any protruding section(s) of the device(s) will not be adequately disinfected. Always check to confirm that the accessories are completely below the surface of the disinfectant solution.

1. Fill a basin with the disinfectant solution at the concentration recommended by the disinfectant manufacturer.
2. Immerse all accessories in the disinfectant solution.
3. Wipe the external surfaces of all accessories while submerged in the disinfectant solution, using your gloved fingers or a clean, lint-free cloth to dispel any attached air bubbles.
4. Depress and release the pistons of the suction valve (MH-443), the air/water valve (MH-438), and the AW channel cleaning adapter (MH-948) several times while submerged in the disinfectant solution to release any trapped air bubbles.
5. Using a clean 30 ml syringe, flush the interiors, the openings, the springs, the backs of the skirts, and the holes of all accessories with the disinfectant solution to release any trapped air bubbles.
6. Fill and attach the syringe to the connecting end of the suction cleaning adapter (MH-856) and flush the adapter with the disinfectant solution until all air bubbles are expelled.
7. Rub the bristles of the channel cleaning brush (BW-20T) with your gloved fingertips while submerged in the disinfectant solution until all air bubbles are released.
8. Attach the syringe to the suction channel port of the injection tube and flush the filter tube and the suction channel tube with the disinfectant solution until all air bubbles are expelled.
9. Move the syringe to the air/water channel port of the injection tube (MH-946) and flush the filter tube and the air/water channel tube with the disinfectant solution until all air bubbles are expelled.

10. Detach the syringe. Confirm that all accessories are completely submerged and free from air bubbles.
11. Cover the basin of the disinfectant solution with a tight-fitting lid to minimize the diffusion of disinfectant vapors.
12. Leave all accessories immersed in the disinfectant solution. Comply with the instructions of the disinfectant manufacturer regarding contact time and concentration.
13. Remove the suction cleaning adapter from the disinfectant solution. Hold the adapter and tilt it to expel the disinfectant solution remaining in the adapter.
14. Remove the injection tube from the disinfectant solution. Attach the syringe to the suction channel port of the injection tube and flush the filter tube and the suction channel tube with air to expel the disinfectant solution.
15. Move the syringe to the air/water channel port of the injection tube and flush the filter tube and the air/water channel tube with air to expel the disinfectant solution.
16. Remove all other accessories from the disinfectant solution.

### **6.3 Rinsing the accessories following disinfection**

#### **WARNING**

After rinsing, thoroughly dry the accessories. Otherwise, bacteria may proliferate and pose an infection control risk.

#### **Rinse the accessories**

Use appropriate rinse water as instructed in Section 3.5. If nonsterile water is used for rinsing the accessories, flush the accessories with 70% ethyl or 70% isopropyl alcohol after rinsing, according to the procedures described below.

#### **NOTE**

- Some national or professional guidelines recommend flushing endoscopic equipment with 70% ethyl or 70% isopropyl alcohol regardless of whether sterile or nonsterile water is used for rinsing.
- Flushing the interior and recessed parts of the accessories with 70% ethyl or 70% isopropyl alcohol facilitates drying. Olympus recommends the use of alcohol.

1. Fill a sterile basin with the rinse water referred to in Section 3.5.
2. Immerse all accessories in the rinse water.
3. Gently agitate the accessories while submerged.
4. Wipe the external surfaces of all accessories in the water, using a sterile, lint-free cloth(s).
5. Depress and release the pistons of the suction valve (MH-443), the air/water valve (MH-438), and the AW channel cleaning adapter (MH-948) several times while submerged in the water.
6. Flush the interiors, the openings, the springs, the backs of the skirts, and the holes of all accessories with the water, using a sterile 30 ml syringe.
7. Fill and attach the syringe to the suction cleaning adapter (MH-856) and flush the adapter with the rinse water until all air bubbles are expelled.
8. Rub the bristles of the channel cleaning brush (BW-20T) with your gloved fingertips while the brushes are submerged, until all air bubbles are removed.
9. Attach the syringe to the suction channel port of the injection tube (MH-946) and flush the filter tube and the suction channel tube with the rinse water until all air bubbles are expelled.
10. Move the syringe to the air/water channel port of the injection tube and flush the filter tube and the air/water channel tube with the rinse water until all air bubbles are expelled.
11. Remove the suction cleaning adapter from the water. Hold the adapter and tilt it to expel the rinse water remaining in the adapter.
12. Remove the injection tube from the rinse water. Attach the syringe to the suction channel port of the injection tube and flush the filter tube and the suction channel tube with air to expel the rinse water.
13. Move the syringe to the air/water channel port of the injection tube and flush the filter tube and the air/water channel tube with air to expel the rinse water.
14. Remove all other accessories from the rinse water. Place all accessories in a sterile basin.
15. Wipe and thoroughly dry the external surfaces of all accessories, using sterile, lint-free cloths.

## **Alcohol flush**

1. Fill a sterile, small container with the alcohol referred to in Section 3.6.
2. Immerse the suction valve (MH-443), the air/water valve (MH-438), the biopsy valve (MB-358), the AW channel cleaning adapter (MH-948), and the mouthpiece in the alcohol.
3. Depress and release the pistons of the suction valve, the air/water valve, and the AW channel cleaning adapter several times while they are submerged in the alcohol.
4. Remove the suction valve, the air/water valve, the biopsy valve, the AW channel cleaning adapter, and the mouthpiece from the alcohol.
5. Fill and attach the syringe to the connecting end of the suction cleaning adapter (MH-856) and flush the adapter with the alcohol until all air bubbles are expelled.
6. Attach the syringe to the suction channel port of the injection tube (MH-946) and flush the filter tube and the suction channel tube with the alcohol until all air bubbles are expelled.
7. Move the syringe to the air/water channel port of the injection tube and flush the filter tube and the air/water channel tube with the alcohol until all air bubbles are expelled.
8. Hold the suction cleaning adapter and tilt it to expel all alcohol remaining in the adapter.
9. Attach the syringe to the suction channel port of the injection tube and flush the filter tube and the suction channel tube with air to expel all alcohol.
10. Move the syringe to the air/water channel port of the injection tube and flush the filter tube and the air/water channel tube with air to expel all alcohol.
11. Wipe and thoroughly dry the external surfaces of all accessories, using a sterile, lint-free cloth(s).

## 6.4 Sterilizing the accessories

This section describes the methods for sterilizing those accessories which are listed in Table 3.1 as being compatible with ethylene oxide gas sterilization or steam sterilization (autoclaving).

### ***Ethylene oxide gas sterilization***

#### **WARNING**

- All accessories must be clean and thoroughly dry before ethylene oxide gas sterilization.
  - All accessories must be properly aerated to remove toxic ethylene oxide residuals following ethylene oxide gas sterilization.
1. Thoroughly dry all accessories, according to the “Alcohol flush” instructions in Section 6.3.
  2. Seal the accessories in individual packaging appropriate for ethylene oxide gas sterilization, according to your institution’s protocol.
  3. Sterilize and aerate the packaged accessories, according to the parameters described in Section 3.7. In addition, always comply with the instructions of the sterilizer manufacturer.

### ***Steam sterilization (autoclaving)***

#### **WARNING**

- Before taking the accessories out of the autoclave, let them cool down to room temperature. Otherwise, they may cause burns.
  - Allow the accessories in the sterile packaging to dry within the sterilization device, using the device’s prevacuum cycle. If any water remains in the packaging after the sterilization cycle, the cycle may have been ineffective. Remove the accessory from the packaging, thoroughly dry, seal in new sterile packaging, and sterilize again.
1. Seal the accessories in individual packaging appropriate for steam sterilization, according to your institution’s protocol.
  2. Sterilize the packaged accessories, according to the parameters described in Section 3.8. In addition, always comply with the instructions of the sterilizer manufacturer.

# Chapter 7 Reprocessing Endoscopes and Accessories using an Automated Endoscope Reprocessor

## **WARNING**

- Thoroughly dry the forceps elevator recess after cleaning and disinfection by your AER. Insufficiently drying may cause the bacterial proliferation and pose an infection control risk.
- When cleaning and disinfecting the endoscope in the OER-AW or the OER-Pro, use connectors that are compatible with the endoscope model. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope. The applicable connectors for the endoscope model should be listed in the instruction manual for the OER-AW, OER-Pro or Table 7.1.

	For air/water Channel	For instrument channel, suction channel
OER-AW* <sup>1</sup>		MAJ-1500* <sup>2</sup>
OER-Pro* <sup>1</sup>		MAJ-1500* <sup>2</sup>

Table 7.1

- \*1 OER-AW and OER-Pro is not available in some areas.
- \*2 The air/water channel, instrument channel, and suction channel can be reprocessed at the same time by connecting only the connecting tube (MAJ-1500) to the endoscope.

**CAUTION**

Put the forceps elevator in intermediate position of the range of movement by moving the elevator control lever and set it in your AER so that the forceps elevator recess can be sufficiently cleaned and disinfected.

Follow the work flow described in Section 4.2 when reprocessing endoscopes and accessories with an automated endoscope reprocessor (AER).

Be sure to attach all required connectors to the endoscope and accessories. For details concerning appropriate connectors, refer to the instructions of the AER manufacturer.

Manually clean and disinfect or sterilize any endoscopes and accessories which are not compatible with the AER.

## **Chapter 8 Storage and Disposal**

### **WARNING**

- After reprocessing, maintain appropriate transportation and storage procedures to keep reprocessed endoscopes and accessories away from contaminated equipment. If the reprocessed endoscope or accessories become contaminated before subsequent patient procedures, they could pose an infection control risk to patients and/or operators who touch them.
- Establish a local policy regarding the method and frequency of cleaning and disinfecting the endoscope storage cabinet, which staff members can access the cabinet, which items can be stored in the cabinet, etc.

### **CAUTION**

- Store the endoscope and accessories in an endoscope storage cabinet which also protects the equipment from physical damage.
- To prevent damage, do not store the endoscope and/or accessories in direct sunlight, at high temperatures, in high humidity, or exposed to X-rays or ultraviolet-rays.
- Do not coil the endoscope's insertion tube or universal cord with a diameter of less than 20 cm. Such improper storage may damage the endoscope.

## 8.1 Storing the disinfected endoscope and accessories

### WARNING

- Proper storage procedures are as important as proper reprocessing procedures in maintaining good infection control practices. Be sure that the endoscope storage cabinet is properly maintained, clean, dry, and well ventilated. All equipment must be thoroughly dried prior to storage. Microorganisms proliferate in wet/moist environments. Keep the cabinet doors closed to protect the equipment from environmental contaminants and accidental contact. Limit access to stored equipment by unauthorized personnel.
- Store only adequately reprocessed endoscopes and accessories in the endoscope storage cabinet.
- Do not store the endoscope and/or accessories in the endoscope's carrying case. The carrying case does not provide a proper storage environment for patient-ready endoscopes. Storing patient-ready endoscopes in the carrying case may pose an infection control risk. Use the carrying case only for shipping the endoscope and/or accessories. Any endoscope or accessory removed from a carrying case must be reprocessed prior to patient use or storage in an endoscope storage cabinet.
- Never put a dirty endoscope into the carrying case, as it will contaminate the carrying case. It is not possible to adequately decontaminate a contaminated carrying case for further use as a shipping case.

### CAUTION

To prevent damage the forceps elevator, make sure that the forceps elevator is not raised or that it does not strike any objects.

### NOTE

Some professional guidelines recommend storing endoscopes in an endoscope storage cabinet with the insertion tube and the universal cord hanging vertically.

1. Detach all accessories, including the air/water valve (MH-438), the suction valve (MH-443), and the biopsy valve (MB-358) from the endoscope. Detach the water resistant cap (MH-553) from the electrical connector on the endoscope connector. The water resistant cap should remain connected to the endoscope via the chain for water-resistant cap (MAJ-1119).

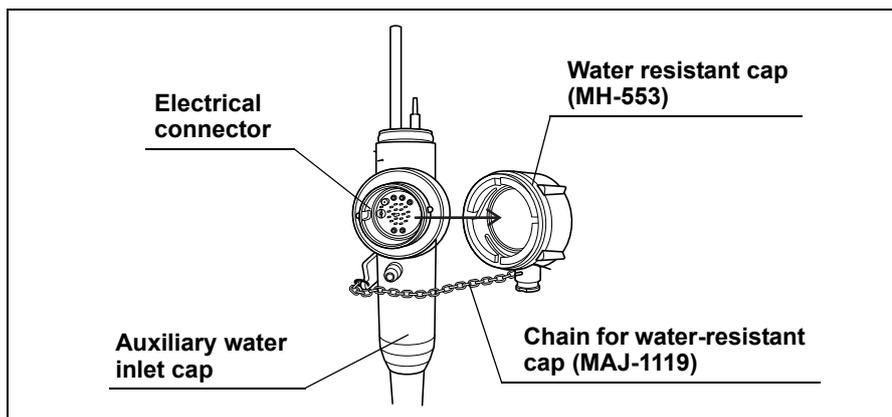


Figure 8.1

2. Confirm that all surfaces of the endoscope and accessories are dry.
3. Place the endoscope's angulation locks in the "F ▶" position.

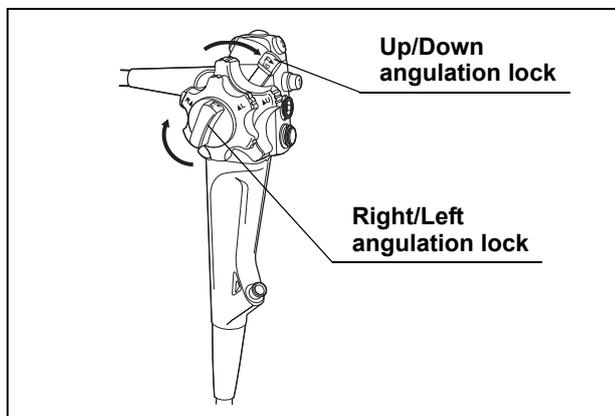


Figure 8.2

4. Store the disinfected endoscope and accessories properly. Olympus recommends storing endoscopes in the endoscope storage cabinet with the insertion tube and the universal cord hanging vertically.

## **8.2 Storing the sterilized endoscope and accessories**

1. Record the sterile expiration date on the sterile packaging. Do not damage the packaging.
2. Store the sterilized endoscope and accessories in a proper storage cabinet, following your institutional guidelines.

**NOTE**

Sterile endoscopes may be stored flat in their sterile packaging.

## **8.3 Disposal**

When disposing of the endoscope, accessories, packaging, and reprocessing supplies (such as gloves, cloths, and the liquids used for reprocessing), handle these items in a manner which will prevent the spread of contamination from the reprocessing area, and follow all applicable national and local laws regarding disposal.





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