OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

Endoscope feature

Not equipped with the suction function

Accessories:

- Sterilization cap (MAJ-1538)
- Luer-Split (MAJ-2092)
- Single use combination cleaning brush (BW-411B)
- Forceps/irrigation plug (isolated type) (MAJ-891, sold separately)

MAJ-1538

BW-411B

MAJ-2092

MAJ-891

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

Contents

Chapter 1 General Policy

1.1 Instructions

- This manual contains the reprocessing 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 that cannot be solved occurs while reprocessing, contact Olympus.
- This manual is based on the requirement of ISO 17664: 2017.

Terms used in this manual

AER/EWD/WD:

AER is the abbreviation for Automated Endoscope Reprocessor, which is used for reprocessing the endoscopes and accessories. EWD is the abbreviation for Endoscope Washer-Disinfector, which is used for reprocessing the endoscopes and accessories. EWD refers to AER and AER is used in this manual. WD is the abbreviation for Washer-Disinfector, which is used for reprocessing the heat-stable endoscopes, accessories and medical instruments employing alkaline cleaning and thermal disinfection.

1.2 Importance of reprocessing

The medical literature reports incidents of cross-contamination resulting from improper reprocessing. 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 equipment
- Structure and handling of the endoscope and accessories
- Handling of pertinent chemicals

When selecting appropriate methods and conditions for reprocessing, 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 reprocessed endoscope and/or accessory may pose an infection control risk to the patients and/or operators who contact them.
- The endoscope reprocessor, video system center, light source, and/or front panels of equipment may cause an infection control risk. Perform proper cleaning and disinfection as described in their respective instruction manuals. A tap or basin that medical personnel come in contact with may cause an infection control risk as well. Perform proper replacement, cleaning, and disinfection.
- All disinfection methods (whether performed manually or by an AER/WD) and all sterilization methods (whether performed by ethylene oxide gas or steam) require thorough prior cleaning of the instruments being reprocessed. If the instruments are 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.
- The channel of the endoscope and all accessories used with the endoscope during the patient procedure must be reprocessed after each patient procedure, even if the channel or accessories were not used during the patient procedure. Insufficient reprocessing of these components may pose an infection control risk to patients and/or operators.
- Residual disinfectant solution may cause adverse reactions in patients. Therefore, rinse all external surfaces and the channel of the endoscope and accessories thoroughly with water to remove residual disinfectant solution after disinfection.
- 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, including the frequency of the above verification, as well as the instruction manual for the sterilization device.
- Establish an internal system of identifying contaminated versus reprocessed endoscopes and accessories to prevent both mix-ups and cross-contamination. Some national or professional guidelines recommend separating dirty (contaminated) area, clean area, and storage area. 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.

WARNING

- 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.

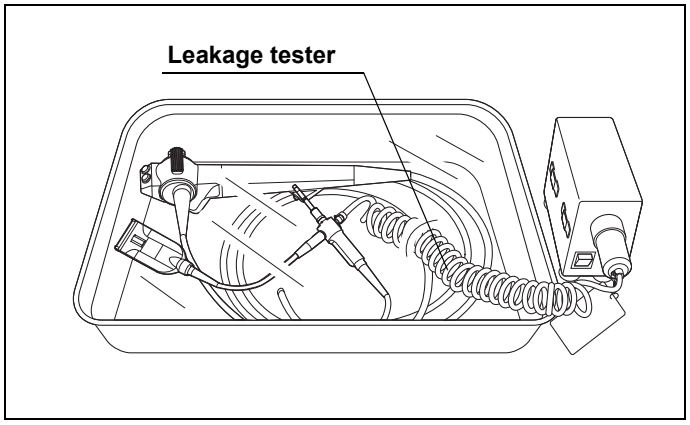


Figure 1.1

- Store alcohol in an airtight container. Alcohol stored in an open container may cause a fire hazard and may result in a loss of efficacy due to evaporation.
- The accessories listed on the front cover of this manual cannot be refurbished or repaired and are intended to be replaced once they show any signs of wear and tear. 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.
- The single use combination cleaning brush (BW-411B) 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 the endoscope and/or accessory damage.

WARNING

- Patient debris and used reprocessing chemicals pose infection control risks. To guard against contact with dangerous chemicals and potentially infectious material, wear appropriate personal protective equipment during reprocessing. 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 to minimize the risks from chemical vapors.
- Always remove contaminated personal protective equipment before leaving the reprocessing area to prevent contamination from spreading.
- Only Olympus-recommended or Olympus-endorsed 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 accessories and medical instruments.
- Only use the AER/WD that meets the requirements of the relevant parts of EN ISO 15883 series in the member states of the EU.
- Before using an AER/WD, confirm that it is capable of reprocessing the endoscope including the channel and accessories. Be sure to attach all required connectors/adaptors. Otherwise, insufficient reprocessing may pose an infection control risk. If you are uncertain as to the ability of your AER/WD to reprocess the endoscope including the channel and accessories, contact the manufacturer of the AER/WD for specific instructions and information on compatibility and required connectors/adaptors.
- 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 the repair facility for instructions regarding reprocessing.
- Prions, which are the pathogenic agents of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated by the reprocessing 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/vCJD, please follow the respective guidelines in your country.

WARNING

- 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 reprocessing methods not described in this reprocessing manual. If you choose 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.
- In case of performing any microbial test or other test using extraction fluid on the reprocessed endoscope, the reprocessing process has to be performed again according to the "REPROCESSING MANUAL" before patient procedure.

CAUTION

- Before immersing the endoscope in reprocessing fluids, confirm that the sterilization cap (MAJ-1538) is not attached to the endoscope. If the sterilization cap is attached, the reprocessing fluids will be able to penetrate the inside of the endoscope, and it can be damaged.
- When aerating or irrigating the endoscope channel, the air or water pressure must not exceed 0.3 MPa (3 kgf/cm^2, 43 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 solution and alcohol may damage electronic devices such as computers. Properly manage the quality and durability of the devices used in reprocessing rooms and the ventilation performance of the rooms.

1.5 Reprocessing before the first use

New endoscopes, repaired endoscopes, accessories, and the carrying case for endoscopes are not reprocessed 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 detergent solution.
- Do not reuse rinse water.
- Detergent and disinfectant solution is only effective when used according to the detergent and disinfectant manufacturer's instructions. Follow the manufacturer's instructions regarding activation (if required), concentration, temperature, contact time and use life required to successful cleaning and achieve disinfection.
- If the disinfectant solution is reused, check its efficacy by proper methods, such as using 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.
- Store the endoscope and accessories in a proper storage cabinet, following the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices.
- Improper storage practices, such as not thoroughly drying external and internal surfaces (lumens) prior to storage, will lead to an infection control risk.

Ch.1

1.7 Reprocessing before patient procedure

WARNING

- Improper storage practices, such as not thoroughly drying external and internal surfaces (lumens) 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, when the certain time passes after disinfecting/sterilizing, or in case the storage time recommended by the national authorities is exceeded.

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 expiration date marked on all items and check for tears or breaches in the 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 Sterilization cap (MAJ-1538)

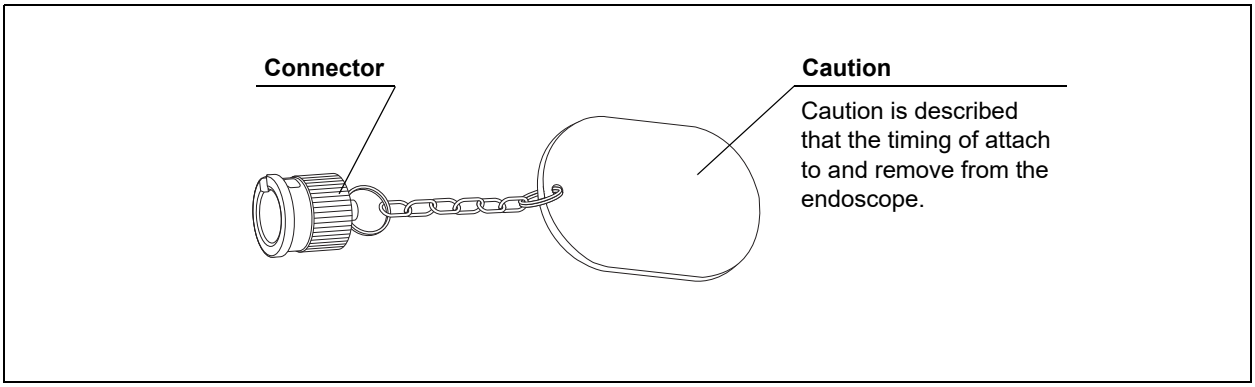


Figure 2.1

CAUTION

Improper attaching/removing of the sterilization cap may cause a damage to the endoscope.

Function

- When performing gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma), the sterilization cap must be attached to the venting connector on the light guide connector.
- When performing cleaning and disinfection including ETD, the sterilization cap must be removed from the venting connector on the endoscope connector.

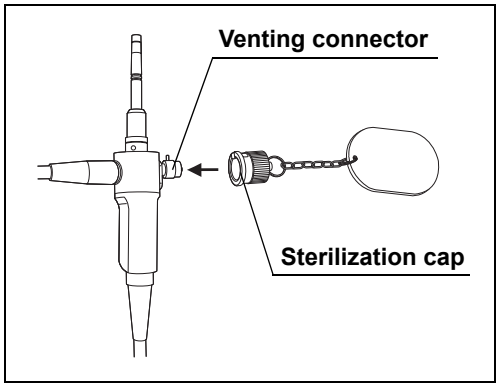


Figure 2.2

Inspection

Confirm that the sterilization cap is free from scratches, flaws, and debris.

2.2 Single use combination cleaning brush (BW-411B)

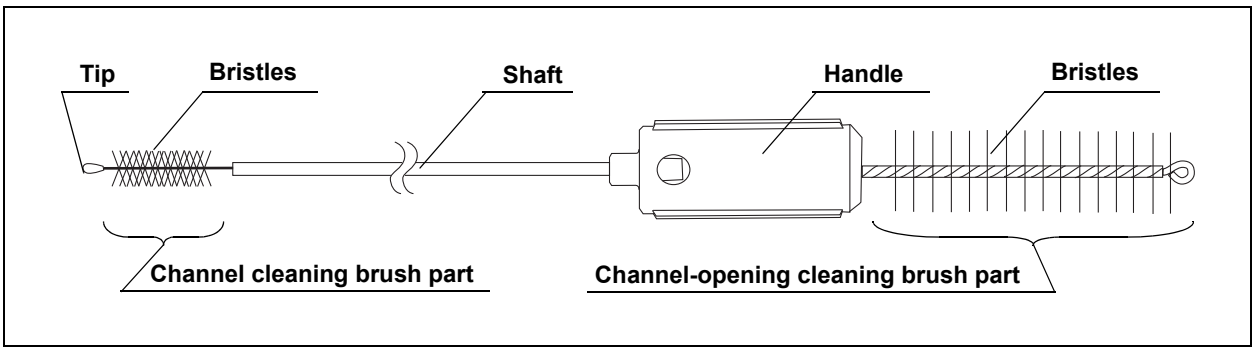


Figure 2.3

❍ Function

The channel cleaning brush part of the single use combination cleaning brush is used to brush the instrument channel of the endoscope.

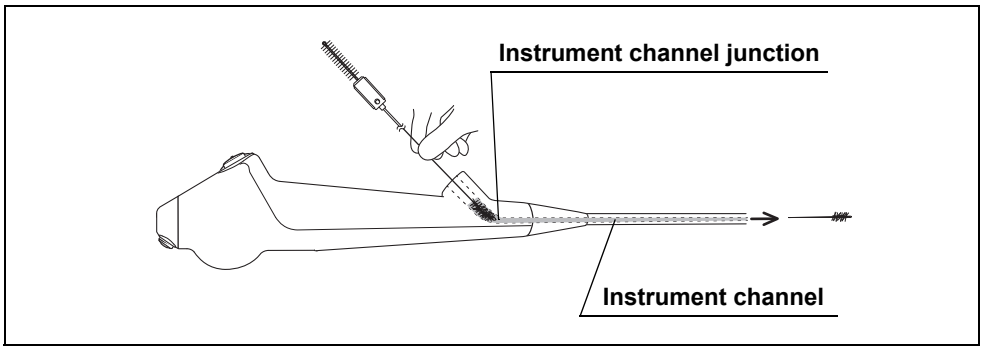


Figure 2.4

The channel-opening cleaning brush part of the single use combination cleaning brush is used to brush the instrument channel port of the endoscope.

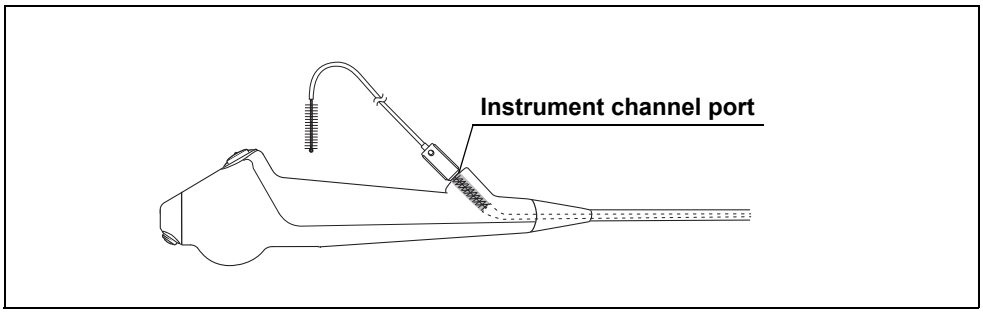


Figure 2.5

❍ Inspection

CAUTION

Do not reprocess the single use channel cleaning brush prior to use. The brush may be damaged.

1 Remove the brush from its packaging just prior to use.

2 Confirm that the channel cleaning brush part and tip at the distal end are securely attached.

3 Check the channel cleaning brush and channel-opening cleaning brush parts for loose or missing bristles.

4 Check the bristles of the channel cleaning brush and the channel-opening cleaning brush parts for any damage.

5 If the bristles are crushed, gently straighten them with your gloved fingertips.

6 Check for bends, scratches, and other damage to the shaft.

2.3 Single use channel-opening cleaning brush (MAJ-1339, sold separately)

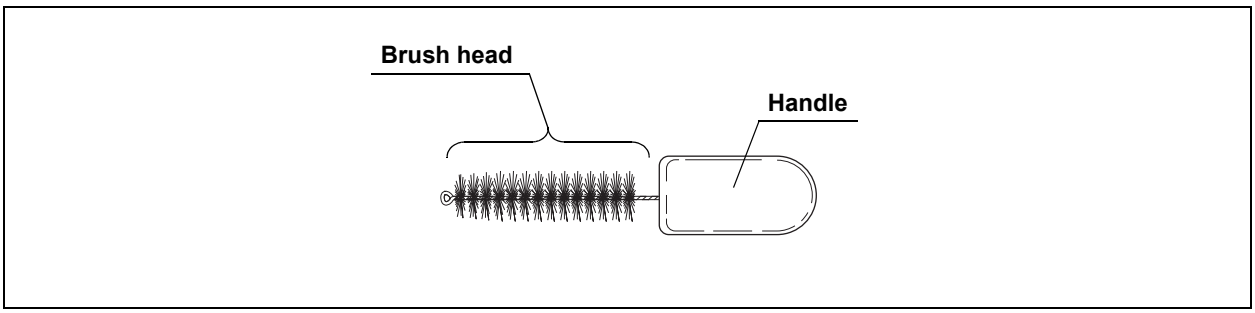


Figure 2.6

❍ Function

The single use channel-opening cleaning brush is used to brush the instrument channel port of the endoscope.

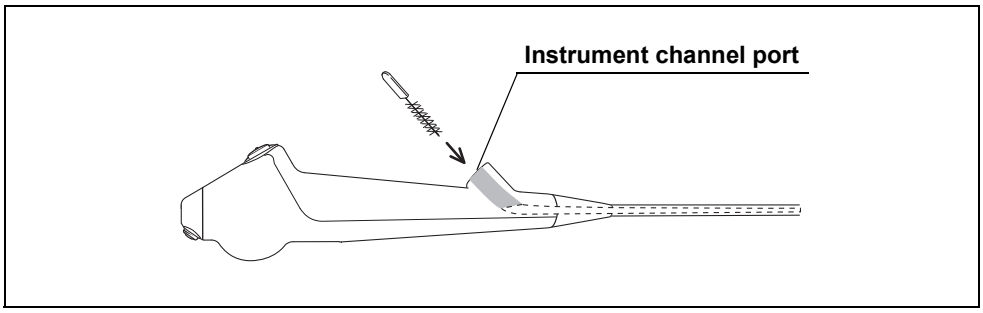


Figure 2.7

❍ 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 gloved fingertips.
4. Check for bends, scratches, and other damage to the shaft.

CAUTION

Do not reprocess the single use channel-opening cleaning brush prior to use. The brush may be damaged.

2.3 Single use channel-opening cleaning brush (MAJ-1339, sold separately)

Chapter 3 Compatible Reprocessing Methods

3.1 Compatibility summary

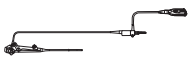
The endoscope and accessories are compatible with several methods of reprocessing. For information concerning the applicable reprocessing methods and parameters, refer to Section 3.2, “List of the compatible methods”. Additionally, some reprocessing methods may cause degradation of medical devices that shortens product life. For information concerning degradation of medical devices from reprocessing and its number of times, refer to Section 3.13, “Signs of degradation from reprocessing and its number of times”.
Follow the policies at your local institution when choosing which methods to employ.

CAUTION

- The 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. Furthermore, 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”.
- The instructions provided in this manual regarding compatible reprocessing methods 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 and reprocessing efficacy of the device with certain reprocessing chemicals or methods. In the event that your device has been repaired by a non-Olympus facility, contact the repair facility for instructions regarding compatible reprocessing methods.

3.2 List of the compatible methods

Reprocessing methods listed in Table 3.1 have been validated with this endoscope and accessories. For details on the chemicals and devices that can be used, refer to Section 3.4 and subsequent sections. About the compatible methods for the luer-split (MAJ-2092) and the forceps/irrigation plug (isolated type) (MAJ-891), refer to their instruction manuals, respectively.

			Endoscope 	Sterilization cap (MAJ-1538) 
Ultrasonic cleaning[*1]				
Manual cleaning	**Alkaline enzymatic detergent**			
	Neutral enzymatic detergent			
Manual disinfection	**Peracetic acid**			
	Glutaraldehyde			
Drying	**Alcohol**			
Automatic cleaning and disinfection	**AER**	**ETD Double (Peracetic acid)**		
		ETD 4 (Peracetic acid)		
		ETD 4 (Glutaraldehyde)		
		OER-AW[*2] **(Peracetic acid)**[*3]		
	WD (alkaline detergent, thermal disinfection)			

Sterilization	**Hydrogen perioxide *6**	**V-PRO® maX (Flexible cycle)**		
		STERRAD® NX® with ALLClear™ Technology (Advanced cycle)		***4*5**
		STERRAD® NX® (Advanced cycle)		***4*5**
		STERRAD® 100NX® with ALLClear™ Technology (Duo cycle)		***5**
		STERRAD® 100NX® (Duo cycle)		***5**
		STERRAD® 100S (Long cycle with booster)		***4*5**
		STERRAD® 100S (Long cycle)		
	Steam (autoclaving)			
	Ethylen oxide gas			
	Low Temperature steam and formaldehyde (LTSF)			

compatible **not compatible**

Table 3.1 List of compatible methods

*1 The endoscope is only compatible with ultrasonic cleaning as performed in an Olympus-recommended reprocessor, such as OER-AW. When using an AER/WD that is recommended by Olympus other than listed above, contact Olympus.

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

*3 ACECIDE disinfectant solution, which is peracetic acid, is exclusively for an Olympus-recommended endoscope reprocessor, such as OER-AW (ACECIDE may not be available in some areas).

*4 If sterilized alone, use appropriate packaging and sterilize under the appropriate parameters following the policies at your facility.

*5 This product can be used to sterilize the endospcope when combined with the endoscope which is compatible with the sterilization shown on the left.

*6 The cycles that are not listed in Table 3.1 can not be used for reprocessing.

3.3 Detergent solution for manual cleaning

WARNING

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

Use a neutral (20 – 45°C) or alnaline (20 – 40°C, <pH 10.8) low-foaming enzymatic detergent with no abrasion labeled for use with flexible endoscopes and accessories that has been approved by your national regulatory agency for use in reprocessing flexible endoscopes, accessories, and medical instruments. Follow the instructions provided by the detergent manufacturer regarding concentration, temperature,contact time, use life, expiration date, and rinsing unless otherwise specified by Olympus.The detergents shown in Table 3.2 were used for validation.

Trade name	Type	Manufacturer
neodisher® Mediclean forte	Alkaline enzymatic	Dr. Weigert
Endozime® AW	Neutral enzymatic	Ruhof

Table 3.2 Detergents used for validation

3.4 Disinfectant solution for manual disinfection

Use a peracetic acid or glutaraldehyde disinfectant with the properties shown in Table 3.3 that has been approved by your national regulatory agency for use in reprocessing flexible endoscopes, accessories, and medical instruments. If national or professional guidelines applicable to your institution define “high-level disinfection” and require the use of a high-level disinfectant for flexible endoscopes, accessories, and medical instruments, follow the requirement.

Disinfectant	Peracetic acid	Glutaraldehyde
Percentage solution	2 W/V% solution (dissolving the powdery agent with water)	Undiluted solution (mixing undiluted solution with activator)
Disinfectant concentration	Peracetic acid approximately 1000 ppm	Glutaraldehyde approximately 2.4%
Operating temperature	Approximately 25°C	Approximately 25°C
Solution shelf life	Within 24 hours	Within 14 days

Table 3.3 Peracetic acid and Glutaraldehyde disinfectant with properties

Unless otherwise specified by Olympus, follow the disinfectant manufacturer’s instructions regarding activation (if required), concentration, temperature, contact time, use life, expiration date and rinsing. If the disinfectant manufacturer does not specify how many times the disinfectant should be rinsed, perform rinsing at least two times. The disinfectants shown in Table 3.4 were used for validation.

Trade name	Type	Manufacturer
Sekusept™ Aktiv	Peracetic acid	ECOLAB
Cidex® Activated Dialdehyde Solution	Glutaraldehyde	Advanced Sterilization Products

Table 3.4 Disinfectants used for validation

WARNING

- As per Advanced Sterilization Products® Safety Alert, dated January 3, 2005, entitled “Labeling Change to Cidex® OPA Solution Instructions for Use” – “In rare instances Cidex OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies. Therefore, ASP is contraindicating the use of Cidex OPA Solution for the reprocessing of any urological instruments to be used on patients with a history of bladder cancer.”.
- If the disinfectant solution is reused, check its efficacy by proper methods, such as using a test strip, according to the disinfectant manufacturer’s recommendations prior to use.
- The endoscope and accessories must be sterilized after using surgical operation. Refer to Section 3.12, “Steam sterilization (autoclaving)” and Section 3.11, “Hydrogen peroxide sterilization”.

3.5 Water

❍ General usage for the reprocessing

Use either fresh, potable 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.

3.6 Rinse water

CAUTION

Do not reuse rinse water.

■ Rinsing after disinfection

Olympus recommends using sterile water, fresh potable water or water that has been processed (e.g., filtered, deionized, or purified) to improve its chemical and/or microbiological quality. Some national or professional guideline recommend using sterile water for rinsing endoscopes, accessories, and medical instruments. Consult with your institution's infection control committee regarding local policies on water quality.

3.7 Alcohol

WARNING

- Do not reuse alcohol.
- Alcohol is not a sterilant or high-level disinfectant.

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

3.8 ETD (Endo Thermo Disinfectors)

- ETD series are intended to clean and disinfect endoscopes and their accessories.
- When cleaning and disinfecting the endoscope with ETD, use adapters, basket and configuration compatible with the endoscope model. Table 3.5 shows the accessories required when ETD is used.
- For details, refer to the instruction manual for ETD.

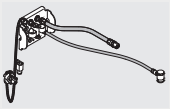
Model name	Accessories when ETD Double or ETD4 is used		
	Adapter 	**Basket** 	**Configuration** 
ETD Double	Olympus 1 (WD00120A)	(WD00117A)	Olympus 1-4
ETD4	3LUER (E0424464)	E603 (E0425553)	–

Table 3.5 Accessories required when ETD Double or ETD4 is used

- The detergents and disinfectants shown in Table 3.6 were used for validation.

Model name	Trade name	Type	Manufacture
ETD Double	EndoDet	Neutral	ECOLAB
	EndoDis	Peracetic Acid	ECOLAB
	EndoAct	Activator	ECOLAB
ETD4	Olympus Cleaner	Neutral enzymatic	ECOLAB
	Olympus Disinfectant	Glutaraldehyde	ECOLAB
	EndoDet	Neutral	ECOLAB
	EndoDet plus	Neutral enzymatic	ECOLAB
	EndoDis	Peracetic Acid	ECOLAB
	EndoAct	Activator	ECOLAB

Table 3.6

3.9 OER-AW(Olympus Endoscope Reprocessor)

- OER-AW is intended to clean and disinfect endoscopes and their accessories.
- OER-AW is not available in the member states of the EU.

NOTE

- When cleaning and disinfecting the endoscope in OER-AW, use connectors/retaining rack that are compatible with the endoscope model. The compatible connectors/retaining rack for the endoscope model should be listed in the “List of Compatible Endoscopes/Connecting Tubes” and the instruction manual for OER-AW or Table 3.7.

	Connectors		
	For air/water channel	**For instrument channel**	**For suction channel**
OER-AW*1	MAJ-1515*2		

Table 3.7

*1 These products are not available in the member states of the EU.

*2 The air/water channel, instrument channel, and suction channel can be reprocessed at the same time by connecting only the connecting tube (MAJ-1515) to the endoscope.

- When the endoscope is cleaned and disinfected simultaneously in combination with an endoscope of the same or another model using OER-AW, see the group number of the endoscopes shown in the “List of Compatible Endoscopes/Connecting Tubes” and the instruction manual for OER-AW to confirm the combination. The group number of the endoscope model should be listed in Table 3.8.

	OER-AW
CYF-VH, CYF-VHR	Group2*1

Table 3.8

*1 The group number is defined by the “List of Compatible Endoscopes/Connecting Tubes” and/or the instruction manual for OER-AW. Confirm endoscopes that can be combined referring to them before using OER-AW.

3.10 Washer-Disinfector

WARNING

- Use only a WD whose compatibility for cleaning medical instrument has been certified by the WD's manufacturers, and which meets ISO 15883-1, ISO 15883-2 requirement. Using an incompatible WD may pose an infection control risk and may considerably damage the medical instrument.
- Perform manual cleaning of the medical instrument as described in the instruction manual before loading them into a WD. If the medical instrument are not properly cleaned, subsequent reprocessing will be ineffective.

CAUTION

- For details on the operation of the WD, refer to the instruction manual of the WD.
- Do not use an undesignated detergent, neutralizer, or WD program. This could damage the medical instrument.
- Follow the instructions provided by the process chemical manufacturer regarding concentrations, temperature and exposure time of detergent and neutralizer.
- Regularly maintain the WD as recommended by its manufacturer.
- This endoscope cannot be loaded in the WD. For details, see Table 3.1.

Program

CAUTION

Make sure that the temperature of the water inflow into the cleaning units is sufficiently cold (e.g., ≤25°C) to avoid thermal coagulation of protein. Do not use programs starting with high temperatures.

The WD program should consist of the following stages:

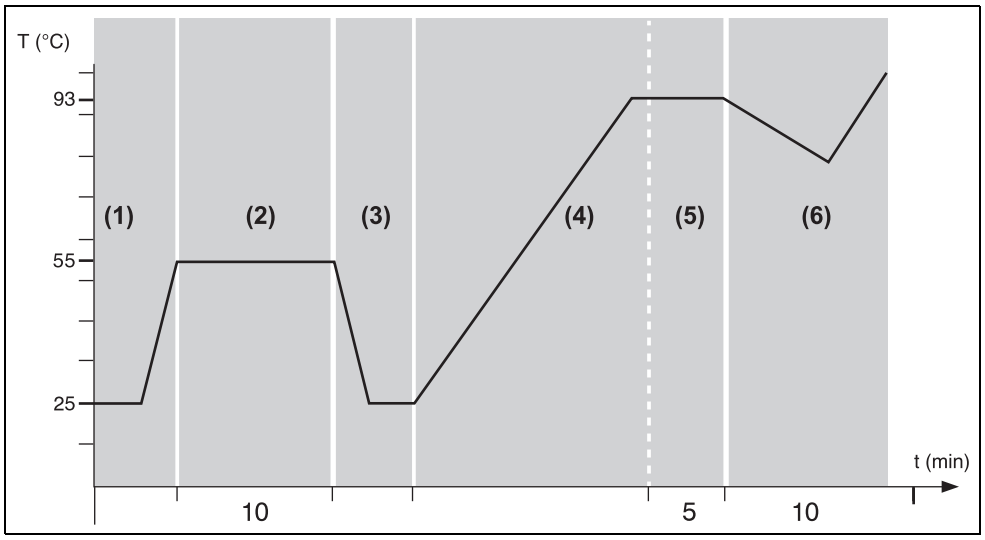


Figure 3.1

Step	Description
1	Pre-cleaning (≤25°C)
2	Cleaning (with detergent, 55°C, 10 min)
3	Rinsing (with or without neutralizer)
4	Heating (hot water)
5	Thermal disinfection which serves as the final rinsing (without detergent and neutralizer, 93°C, 5 min)
6	Drying (95°C, 10 min) (Setting values)

Table 3.9 WD program parameters

*1 Olympus tested the compatibility of medical instrument with the WD compatible with ISO 15883-1, 2. The drying temperature and the drying duration were 110°C and 20 minutes, respectively*2.

*2 This value may not be the actual temperature of the medical instrument being processed in the chamber, but it is a setting value for the WD. The drying temperature for which Olympus confirmed material compatibility is 110°C as the WD setting value. In the drying process, the temperature around the product can be affected by various factors (e.g., chamber size, loading amount, layout of instruments in the chamber).

NOTE

- ISO 15883-2 regulate that disinfection temperature give an A_0 of at least 600. Olympus recommends that WD provide an A_0 value of 3,000.
- Do not use a program that exceeds 55°C in the cleaning process and 93°C in the disinfection process.
- Do not use a program that exceeds 10 minutes in the disinfection process.
- Confirm that there are no sudden temperature fluctuations in the program you have selected.
- Olympus performed validation using a WD compliant with ISO 15883-1, 2 requirements.

❍ Detergent solution for WD

- Use a low-foaming, medical-grade, alkaline enzymatic detergent (20 – 55°C, <pH 10.8).
- Use a detergent whose compatibility for cleaning medical instrument is certified by the WD's manufacturer, and which are approved by a competent authority. Follow the instructions provided by the detergent manufacturer.
- The detergent shown in Table 3.10 was used for validation.

Trade name	Type	Manufacturer
neodisher® Mediclean forte	Alkaline enzymatic	Dr. Weigert

Table 3.10 Detergent used for validation

❍ Neutralizer

CAUTION

If rinsing with neutralizers after cleaning/disinfection is necessary, make sure to remove all traces of neutralizers by using the water as described in the instruction manuals for WD.

- Use neutralizers recommended in the instruction manuals for the WD and detergent.
- Follow the instructions provided by the neutralizer manufacturer regarding concentration, temperature, contact time and expiration date.

3.11 Hydrogen peroxide sterilization

WARNING

The endoscope and accessories must be sterilized after using surgical operation.

❍ STERRAD® 100S*/NX®/100NX®

WARNING

When sterilizing a flexible endoscope that has an instrument channel with the STERRAD® 100S Sterilization System, depending on the inner diameter/length of channel and the model of sterilizer, it is necessary to attach the booster (REF15400) that is provided by ASP (Advanced Sterilization Products) to the endoscope. Do not attach the booster to the distal end of the insertion section. For further details, refer to the ASP instruction manual or contact ASP directly.

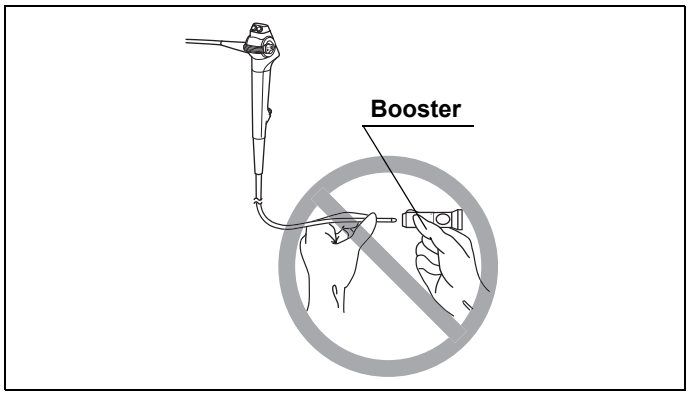


Figure 3.2

CAUTION

- When performing STERRAD® 100S/NX® (with/without ALL Clear Technology) /100NX® (with/without ALL Clear Technology) sterilization, the sterilization cap (MAJ-1538) must be attached to the venting connector in order to avoid rupture of the bending section.

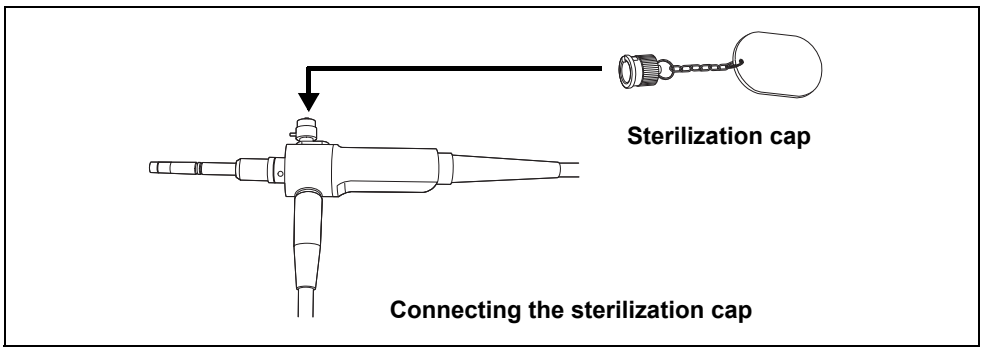


Figure 3.3

- Sterrad® may cause degradation. Please refer to Section 3.13 for details.
- Do not use cycles not listed Table 3.1. If used, severe damage may be caused or efficacy of sterilization may not be achieved.

NOTE

Use sterilization wraps and packaging compliant with ISO 11607-1: 2006+A1, ISO 11607-2: 2006+A1.

As for the sterilizer, contact ASP. Also, refer to the “STERRAD® 100S/NX® (with/without ALL Clear Technology) /100NX® (with/without ALL Clear Technology) instruction manual.

❍ V-PRO® maX

CAUTION

- When performing V-PRO® maX sterilization, the sterilization cap (MAJ-1538) must be attached to the venting connector in order to avoid rupture of the bending section. (See Figure 3.3)
- V-PRO® may cause degradation. Please refer to Section 3.13 for details.
- Do not use cycles not listed Table 3.1. If used, severe damage may be caused orefficacy of sterilization may not be achieved.

NOTE

Use sterilization wraps and packaging compliant with ISO 11607-1: 2006+A1,ISO 11607-2: 2006+A1.

As for the sterilizer, contact STERIS Corporation. Also, refer to the “V-PRO® maX” instruction manual.

3.12 Steam sterilization (autoclaving)

The medical instruments listed as compatible with steam sterilization in Table 3.1 can be sterilized by steam within the parameters given in Table 3.11. When steam sterilizing, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

Olympus recommends use of water and steam compliant with EN 285: 2015.

WARNING

- Use packages appropriate for steam sterilization. If packages are not appropriate for steam sterilization, the equipment may not be properly sterilized.
- The results of sterilization depend on various factors such as how the sterilized medical instrument are pacned and positioned, and the method of placing and loading it in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual for the sterilization device.
- Perform steam sterilization under the conditions described in this section. If steam sterilization is performed under conditions other than those described here, the intended sterilization effect may not be achieved.

CAUTION

- Do not steam sterilize the endoscope. Steam sterilization will cause severe damage.
- Do not exceed 137°C (279°F) during steam sterilization, nor an exposure time greater than 20 minutes. Otherwise, the medical instrument may be damaged.
- When performing steam sterilization, be sure to complete the drying process (accompanied with vacuum exhaust). Otherwise, sterilization will not be achieved.

Process phase	Parameter	Value	
Prevacuum steam sterilization cycle	**Setting temperature**	134°C (274°F)	134°C (274°F)
	Setting exposure time	3 minutes	18 minutes
Drying	**Setting drying time**	A minimum of 20 minutes	
	• If the sterilization pouch of accessory taken out of the sterilizer is wet, sterilization effect may not be maintained. Reconsider conditions such as drying time and sterilize again. • Drying time depends on various factors including kinds of sterilizer, type of sterilization pouch and volume of loading. Confirm the appropriate drying time beforehand.		

Table 3.11

NOTE

- Perform autoclaving with a prevacuum steam sterilization cycle compliant with ISO 17665-1: 2006 and EN 285: 2015.
- Use sterilization wraps and sterilization pouches compliant with ISO 11607-1: 2006+A1, ISO 11607-2: 2006+A1.

3.13 Signs of degradation from reprocessing and its number of times

When reprocessed devices with chemicals, AER and sterilizer as described above, you will eventually start to see signs of degradation. There are also limits to the number of times a given reprocessing method can be used on a particular device.

CAUTION

Improper reprocessing shown below may significantly reduce the life time of a medical device.

- Reprocessing without observing the instructions of the manufacturer
- Application of multiple sterilization methods
- Immersion in a chemical for an excessive amount of time

❍ Endoscope

- Reprocessing may cause the following degradations. If any of these signs of degradation happens, contact Olympus.
  - Cracked, peeled or discolored adhesives at either end of the bending section and at objective lens and light guide lens shown as Figure 3.4.
  - Abnormal bulges or swelling, scratches and holes in the bending section and cracks in the bending section cover
  - Wrinkling or peeling of the insertion tube
- Olympus has verified no degradation happens when the listed number of disinfection or sterilization cycle is performed. When this endoscope is disinfected or sterilized more than the following times, the degradation shown in Figure 3.4 may occur.If such degradations happens, maintenance is required. For more details, contact Olympus.

STERRAD® 100S/NX®/100NX®	100 times
V-PRO® maX	50 times

– Cracks, deterioration or peeling may occur in bending section shown as Figure 3.4, insertion section or universal cord.

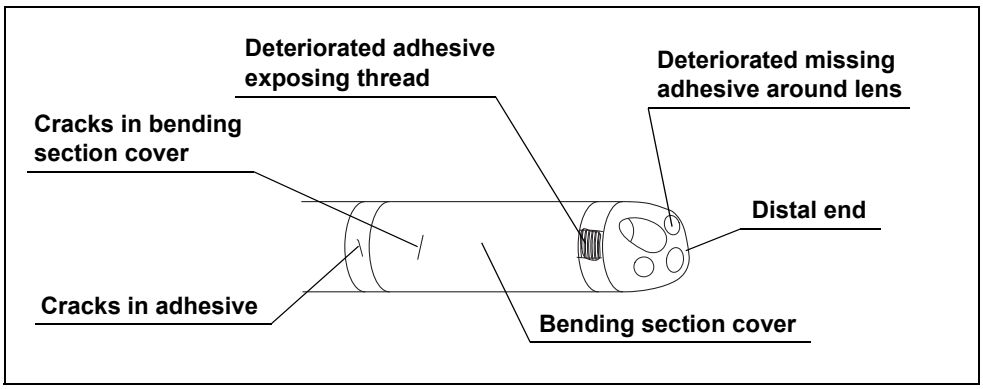


Figure 3.4

❍ Accessory (MAJ-1538)

When these accessories are reprocessed more than the following times (see Table 3.12), these accessories do not function due to degradations. Please discard and replace it with a new one.

Reprocessing method			Sterilization cap (MAJ-1538)
Manual cleaning	**Alkaline enzymatic detergent**		200 times
	Neutral enzymatic detergent		200 times
Manual disinfection	**Peracetic acid**		200 times
	Glutaraldehyde		200 times
Drying	**Alcohol**		Not compatible
Automatic cleaning and disinfection	**AER**	**ETD Double (Peracetic acid)**	200 times
		ETD4 (Peracetic acid)	Not compatible
		ETD4 (Glutaraldehyde)	Not compatible
		OER-AW*1 (Peracetic acid)	Not compatible
	WD (Alkaline detergent, thermal disinfection)		200 times
Sterilization	**Hydrogen perioxide**	**V-PRO® maX (Flexible cycle)**	100 times
		STERRAD® NX® with ALLClear™ Technology (Advanced cycle)	100 times
		STERRAD® NX® (Advanced cycle)	100 times
		STERRAD® 100NX® with ALLClear™ Technology (Duo cycle)	100 times
		STERRAD® 100NX® (Duo cycle)	100 times
		STERRAD® 100S (Long cycle with booster)	100 times
		STERRAD® 100S (Long cycle)	100 times
	Steam sterilization (autoclaving)		200 times
	Ethylen oxide gas		Not compatible
	Low Temperature steam and formaldehyde (LTSF)		Not compatible

Table 3.12

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

Chapter 4 Reprocessing Workflow for Endoscopes and Accessories

4.1 Summary of reprocessing workflow

This chapter describes the workflow for reprocessing the endoscope and accessories.

WARNING

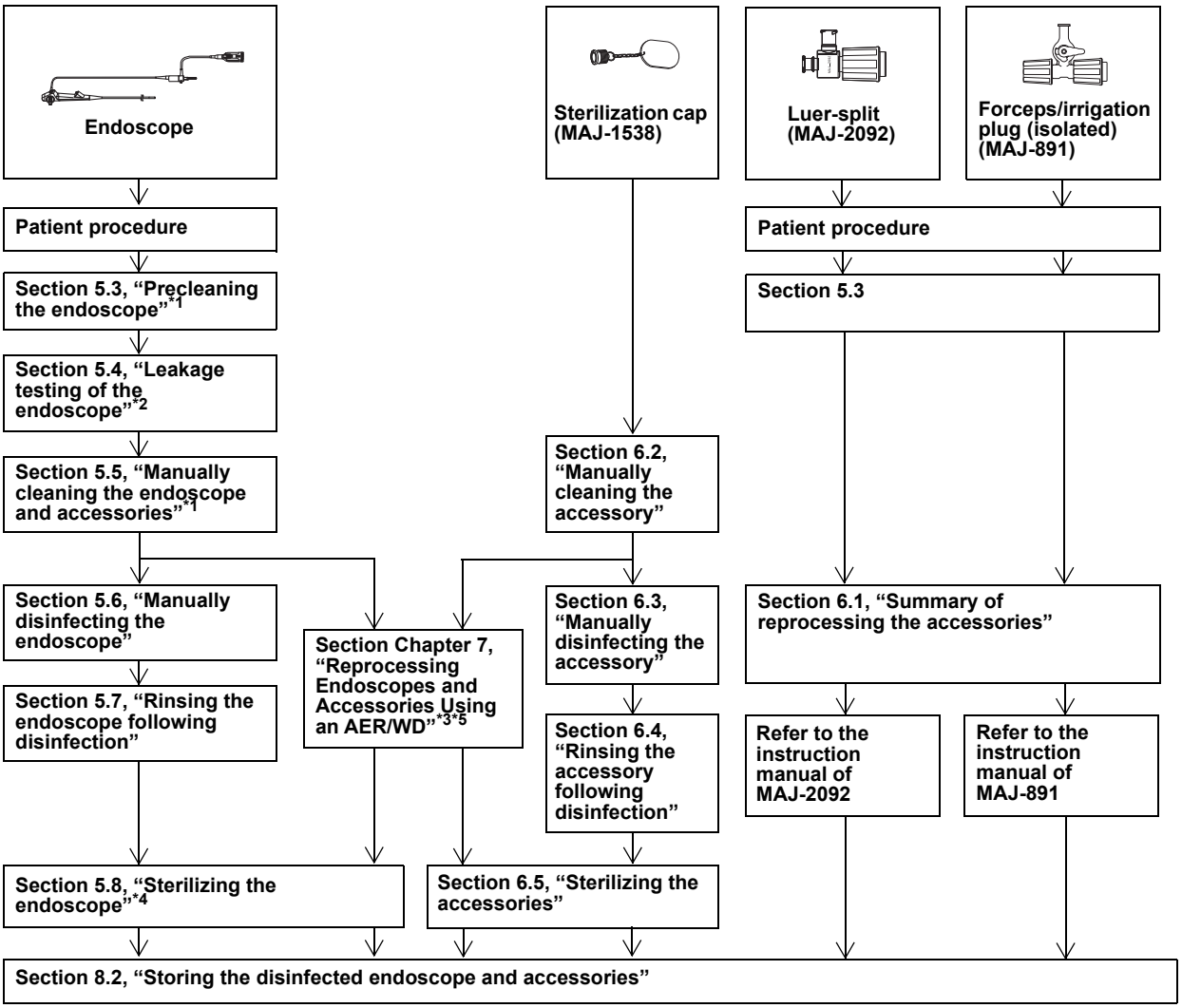
Deviation from the recommended workflow may pose an infection control risk.

4.2 Workflow for reprocessing endoscopes and accessories

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

WARNING

Conduct all steps of precleaning and manual cleaning as instructed in this manual even when you use an AER/WD that has instructions that would allow you to skip some steps in precleaning and manual cleaning of endoscopes.



*1 Depending upon the model of the OER series, you may be able to simplify Section 5.3, “Precleaning the endoscope” and Section 5.5, “Manually cleaning the endoscope and accessories”. Refer to the instruction manual for the OER you have.

*2 Check the instruction manual for the OER to determine how to test the endoscope for leakages using the AER/WD. When leakage testing an endoscope within an AER/WD basin, it may be difficult to fully angulate the bending section.

*3 If required by the local policy of your institution, manual disinfection can be performed instead of reprocessing the endoscope and accessories using AER/WD or reprocessing the endoscope and accessories using AER/WD can be skipped.

*4 When the endoscope is disinfected, sterilization of the endoscope is not required.

*5 When the accessories are disinfected using AER, sterilization of the accessories is not required. However, when the accessories are disinfected using WD, sterilization of the accessories are required.

Chapter 5 Reprocessing the Endoscope (and related reprocessing accessories)

5.1 Summary of reprocessing the endoscope

Certain accessories are required to manually reprocess the endoscope. The steps for reprocessing the endoscope 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 workflow of all accessories is outlined in Chapter 4, “Reprocessing Workflow for Endoscopes and Accessories”.

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.

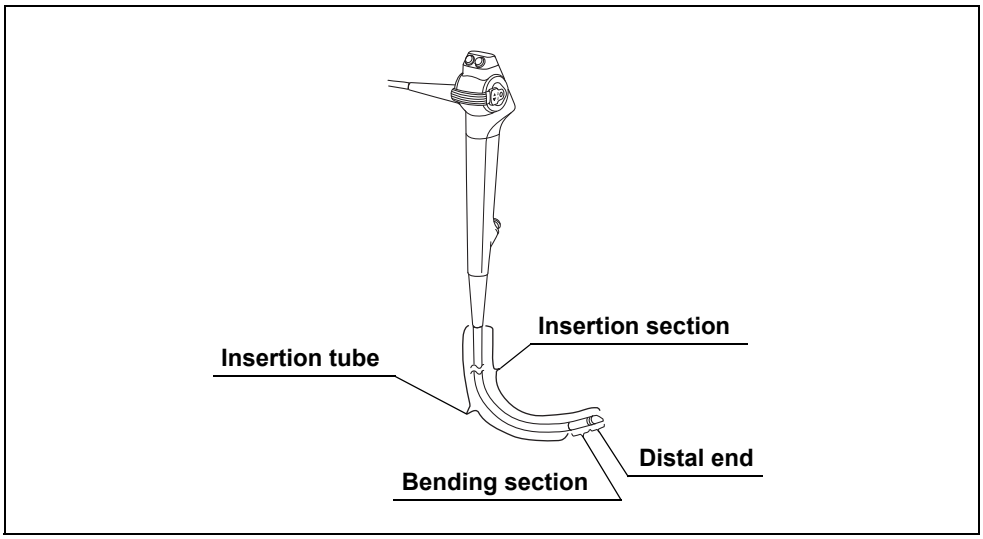


Figure 5.1

CAUTION

- 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 10 cm.

5.2 Preparing the equipment for reprocessing

■ Equipment needed

The following equipment is prepared to perform the reprocessing steps described in this chapter.

❍ Accessories for reprocessing

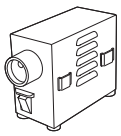
Single use combination cleaning brush (BW-411B)

Sterilization cap (MAJ-1538)

❍ Accessories and equipment for leakage test

Leakage tester (MB-155) (Sold separately. Refer to its instruction manual.)

+



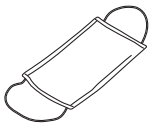
Maintenance unit (MU-1) (Sold separately. Refer to its instruction manual.)

or

Leakage tester (WA23080A) (Sold separately. Refer to its instruction manual.)

❍ Personal protective equipment (e.g.)

Eyewear



Face mask

Moisture-resistant clothing

Chemical-resistant gloves[*1]

❍ Other

- **Clean lint-free cloths[*2]**
- **Clean sponges**
- **Clean 30 ml (30 cc) syringes**
- **Clean 500 ml containers**
- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Sterile, large basins[*3] (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Sterilization wraps**
- **Water (Refer to Section 3.5, "Water")**
- **Disnfectant solution (Refer to Section 3.4, "Disinfectant solution for manual disinfection")**
- **70% ethyl or 70% isopropyl alcohol (Refer to Section 3.7, "Alcohol")**
- **Sterile lint-free cloths[*2, *3]**
- **Sterile cotton swabs[*3]**
- **Sterile 30 ml (30 cc) syringes[*3]**
- **Small basins**
- **Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Sterilization pouches**
- **Instrument tray**
- **Detergent solution (Refer to Section 3.3, "Detergent solution for manual cleaning")**
- **Rinse water (Refer to Section 3.6, "Rinse water")**

*1 Gloves are recommended to be long enough so that your skin is not exposed.

*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 channel. There is the potential for lint or cloth fibers to lodge in channel. If gauze is used to reprocess the endoscope, ensure that fibers do not get caught on or remain trapped by protruding components.

*3 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (basins, 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.

5.3 Precleaning the endoscope

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 immediately after each patient procedure.

NOTE

If necessary, a detergent solution can be used instead of Water. Please refer to Section 3.3, “Detergent solution for manual cleaning” to determine which type of detergents can be utilized.

■ Equipment needed

Prepare the following equipment.

• **Clean lint-free cloths**	• **Clean sponges**
• **Clean 30 ml (30 cc) syringes**	• **Water (See Section 3.5, “Water”)**
• **Clean 500 ml containers**	• **Small basins**

■ *Preparation*

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

1 Turn the video system center and the light source OFF.

2 Prepare a clean 500 ml container of the water as described in Section 3.5, “Water”.

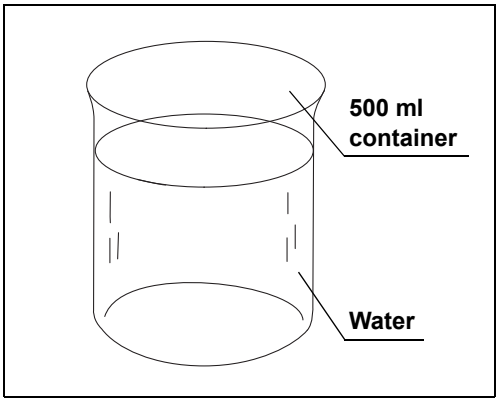


Figure 5.2

■ *Wipe the insertion section*

CAUTION

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

NOTE

If it is difficult to clean the endoscope while connecting it to the equipment, such as the light source and video system center, disconnect the endoscope from the equipment after wiping the external surface of the insertion section. For disconnecting the endoscope, refer to "■ Detach the endoscope from the video system center" and "■ Detach the endoscope from the light source" on page 44.

1 Dip clean lint-free cloths or sponges in the water.

2 With the lint-free cloths or sponges, wipe the entire insertion section of the endoscope from the boot at the control section toward the distal end.

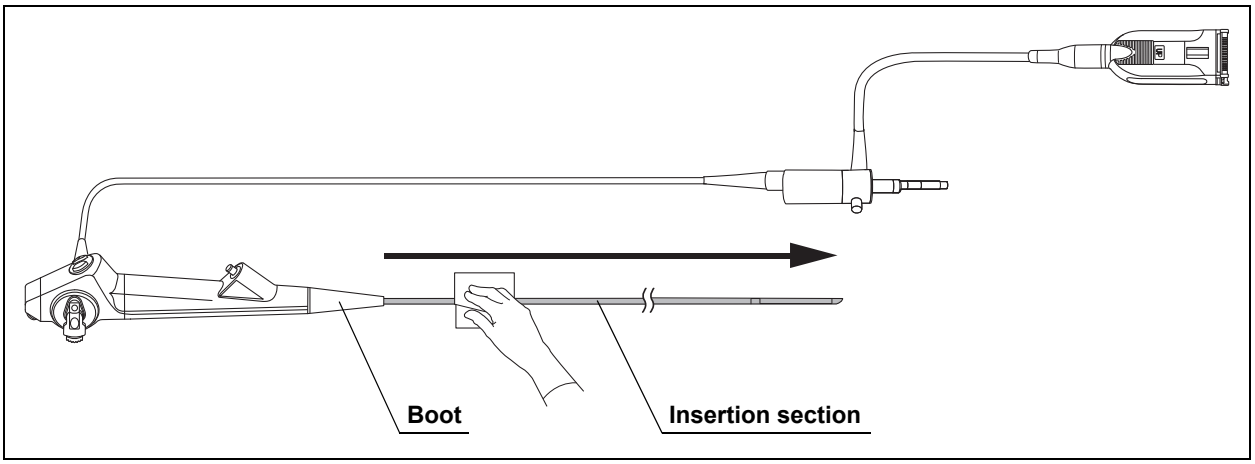


Figure 5.3

■ *Flush the instrument channel with water*

1 Loosen the locking ring, detach the luer-split (MAJ-2092) or the forceps/irrigation plug (isolated type) (MAJ-891) from the endoscope.

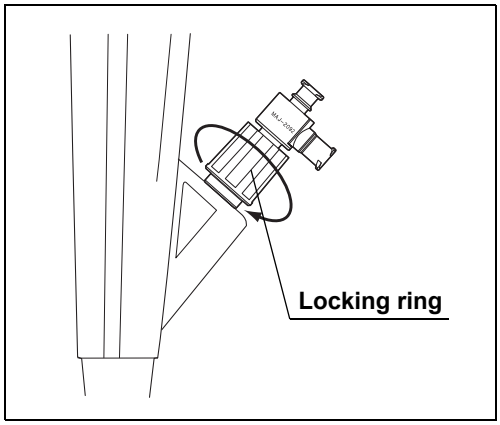


Figure 5.4

2 Fill a clean 30 ml syringe with the water.

3 Attach the syringe to the instrument channel port.

4 Flush the channel with 30mL of the water into the small basin.

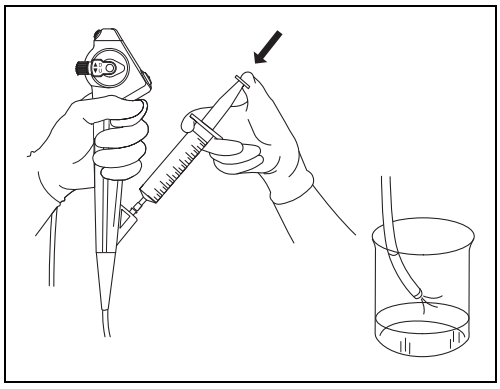


Figure 5.5

5 Detach the syringe from the endoscope.

6 Repeat Step 2 through 5 two additional times.

7 Fill a clean 30 ml syringe with air.

8 Attach the syringe to the instrument channel port.

9 Flush the channel with 30 ml of air.

10 Detach the syringe from the endoscope.

■ *Detach the endoscope from the video system center*

Detach the video connector from the video system center while holding the video system center with a hand so that it does not move and pushing the locking lever down.

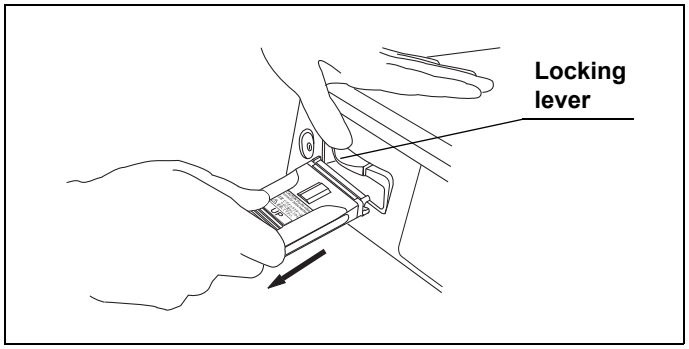


Figure 5.6

■ *Detach the endoscope from the light source*

WARNING

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

1. Detach the light guide connector of the endoscope from the light source while holding the video connector.
2. Transport the endoscope to the reprocessing area. Use a covered container to avoid environmental contamination if required by local policy.

■ *Transport the endoscope and accessories*

NOTE

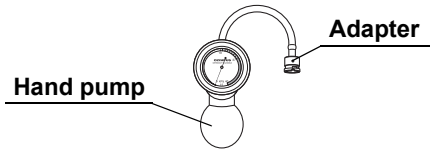
Refer to each instrument's instructions for reprocessing accessories.

Transport the endoscope to the reprocessing area. Use a covered container to avoid environmental contamination if required by local policy.

5.4 Leakage testing of the endoscope

■ Equipment needed

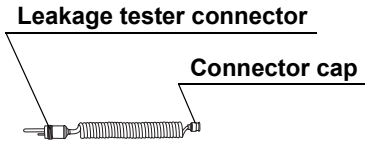
When performing a leakage test using WA23080A, prepare the following equipment.



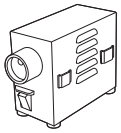
Leakage tester (WA23080A)
(Sold separately. See its instruction manual.)

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Water (See Section 3.5, "Water")**
- **Clean lint-free cloths**

When performing a leakage test using MB-155, prepare the following equipment.



Leakage tester (MB-155)
(Sold separately. See its instruction manual.)



Maintenance unit (MU-1)
(Sold separately. See its instruction manual.)

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Water (See Section 3.5, "Water")**
- **Clean lint-free cloths**

■ *Perform the leakage test*

CAUTION

- When attaching the connector cap of the leakage tester to the venting connector of the endoscope, 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 endoscope, 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.
- Do not attach/detach the leakage tester while immersed. Attaching/detaching under water could allow the water to enter the endoscope, resulting in endoscope damage.
- If you identify a leak during leakage testing, remove the endoscope from the water with both the venting connector and the leakage tester (WA23080A or MB-155) still attached. Contact Olympus regarding instructions for reprocessing a leaking endoscope in preparation for returning the endoscope to Olympus for repair.
- Detach the leakage tester (MB-155) from the maintenance unit (MU-1) before detaching the leakage tester from the venting connector on the endoscope. If the leakage tester is detached from the venting connector before detaching the leakage tester from the maintenance unit, the air pressure inside the endoscope will not vent properly. This may damage the endoscope.

Leakage testing with leakage tester (hand pump) (WA23080A)

CAUTION

- The leakage test pressure must not exceed 27 kPa (i.e., the pointer should remain within the “green area” on the pressure display). If the pressure increases so that the pointer moves into the red area on the display, the endoscope may be damaged. Press the pressure release lever to let the air escape.

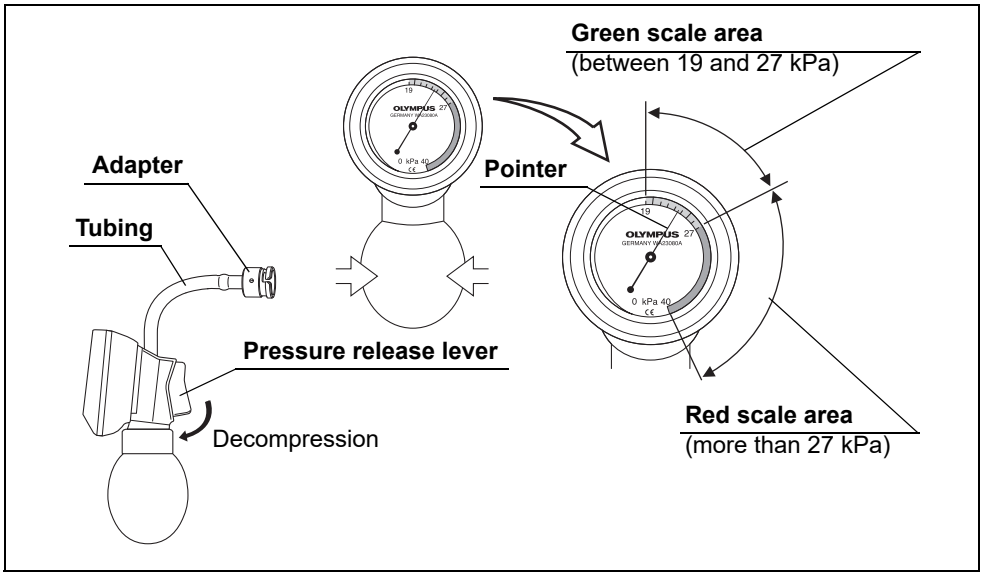


Figure 5.7

- Only the tubing and adapter of the leakage tester should be immersed. Other parts of the leakage tester could be damaged if immersed.
- Before detaching the adapter of the leakage tester from the venting connector, press the pressure release lever. Allow air to escape from the endoscope until 0 kPa is indicated on the display. Otherwise, the endoscope may be damaged.

1 Fill a clean, large basin with the water as described in Section 3.5, “Water”.

2 Confirm that both the inside of the adapter is dry. If not, dry it with clean lint-free cloths.

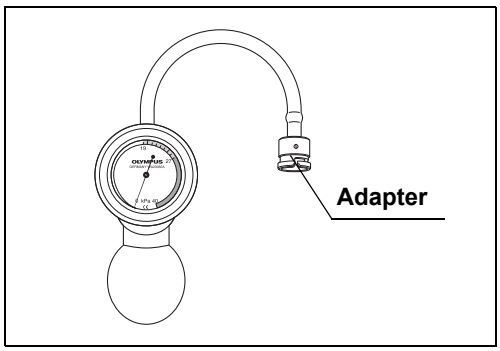


Figure 5.8

3 Confirm that the venting connector on the endoscope's light guide connector is dry. If not, dry it by wiping with clean lint-free cloths.

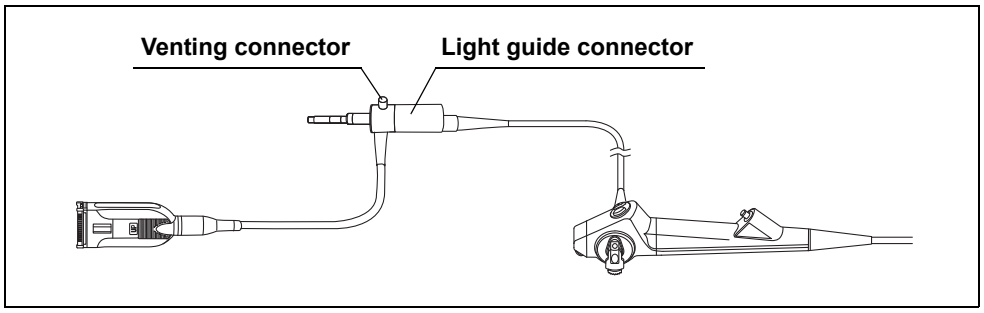


Figure 5.9

4 Attach the adapter of the leakage tester to the venting connector on the light guide connector as follows:

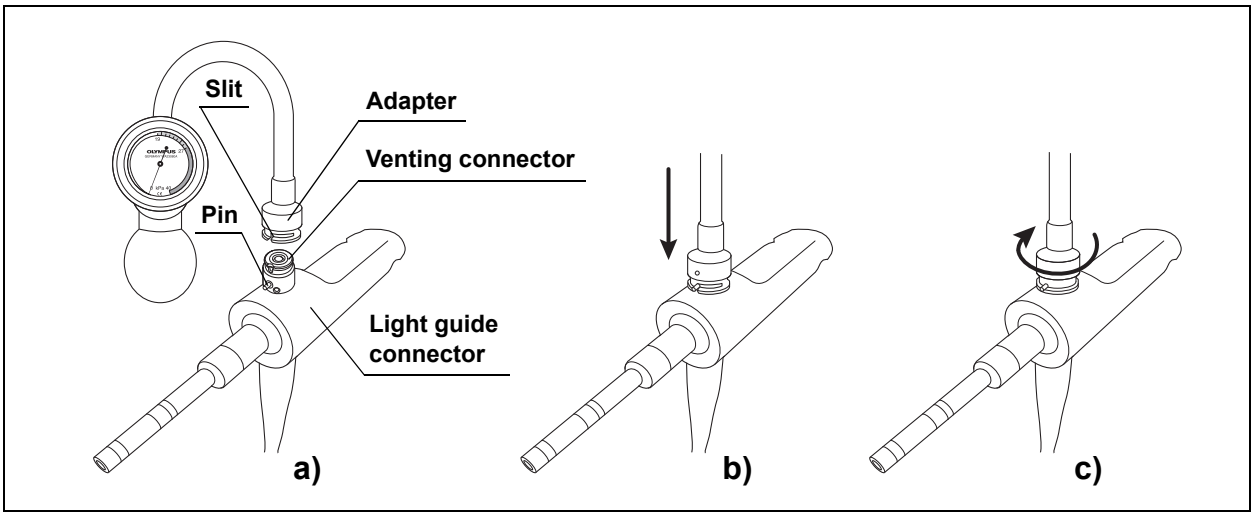


Figure 5.10

a) Align the pin on the venting connector with the slit on the adapter;

b) Push the adapter towards the light guide connector of the endoscope until it stops;

c) Rotate the adapter clockwise (approximately 90°) until it stops.

5 Grasp the hand pump until the pointer is in the green scale area (between 19 and 27 kPa) on the pressure display.

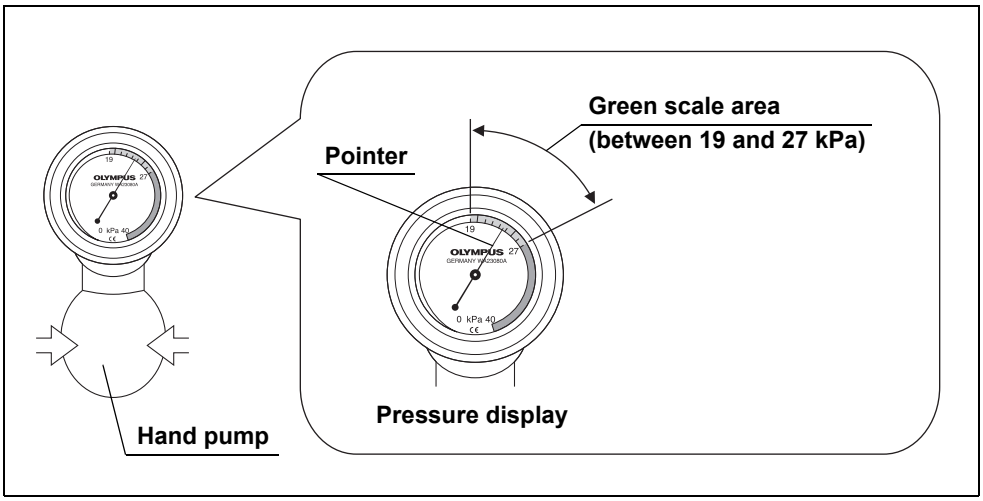


Figure 5.11

NOTE

To detect a slight water leakage, pressurize to near 27 kPa.

6 After several seconds, confirm that the pointer remains stable, and pressure is maintained.

CAUTION

If the pointer continues to fall towards 0 kPa, the endoscope might have a serious water leakage, or the leakage tester may be damaged. Stop the leakage test immediately. Water may enter the endoscope with no pressure inside if it is still immersed in water. As a result, severe damage may occur.

7 With the leakage tester attached, completely immerse all sections of the endoscope and the adapter of the leakage tester in the water. Keep the pressure display and the hand pump of the leakage tester out of the water.

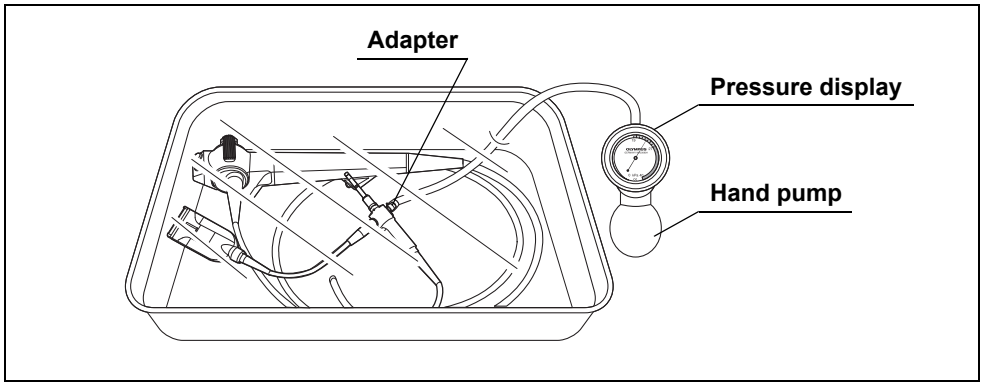


Figure 5.12

CAUTION

If continuous or intermittent air bubbles emerge from the adapter during leakage testing, the adapter might be damaged. For further details, contact Olympus.

8 While keeping all sections of the endoscope under the water for approximately 30 seconds, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

9 While deflecting the bending section of the endoscope by moving the endoscope's UP/DOWN angulation control lever in the water, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

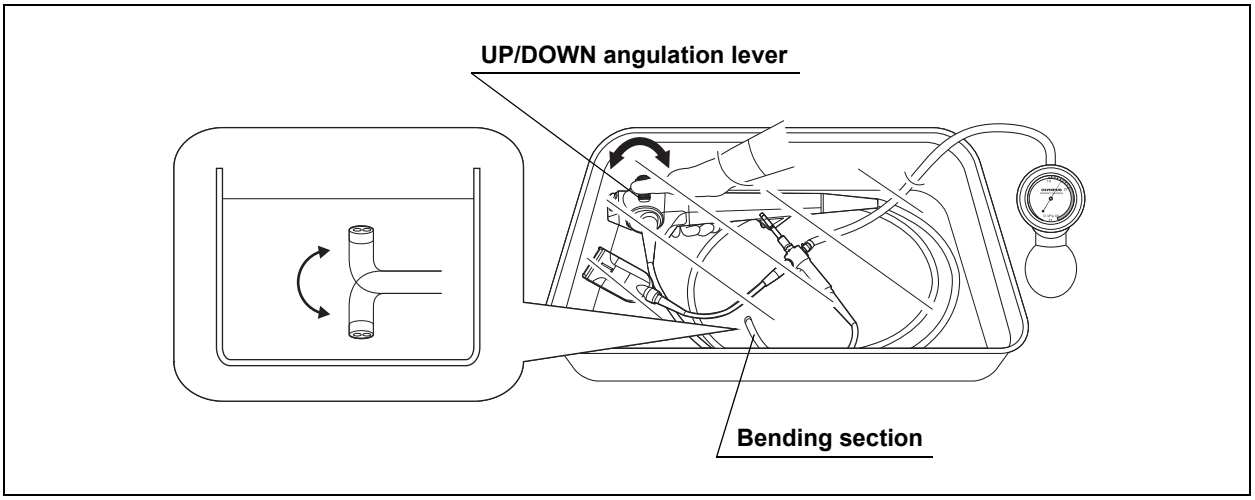


Figure 5.13

NOTE

- Air bubbles emerging continuously or intermittently from any location on the endoscope indicate a leak at that location. If there is a leak in the instrument channel of the endoscope, air bubbles will emerge continuously or intermittently from one or more channel openings (e.g., distal end, instrument channel port) on the immersed endoscope.

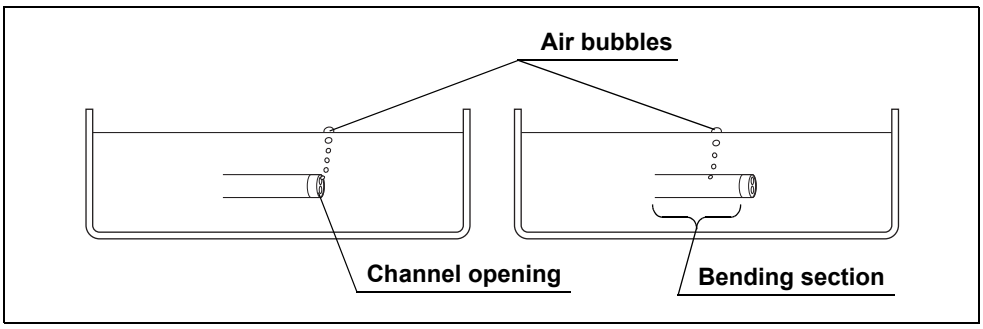


Figure 5.14

- During the leakage test, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

10 Remove the endoscope attached with the leakage tester from the water.

11 Reconfirm that the pointer remains in the green scale area (between 19 and 27 kPa) on the pressure display. If not, repeat Step 5 through 11.

NOTE

If the pointer is not in the green scale area, the pressure release lever may have been pressed unintentionally.

12 Press the pressure release lever until 0 kPa is indicated on the display to let the air escape from the endoscope.

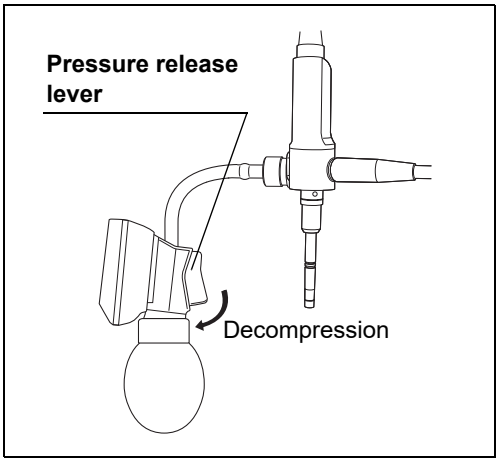


Figure 5.15

13 Detach the leakage tester from the venting connector of the endoscope by turning the adapter counterclockwise.

14 Thoroughly dry the leakage tester using clean lint-free cloths.

❍ Leakage testing with leakage tester (MB-155)

1 Fill a clean, large basin with the water as described in Section 3.5, “Water”.

2 Attach the leakage tester connector of the leakage tester (MB-155) to the output socket of the maintenance unit (MU-1).

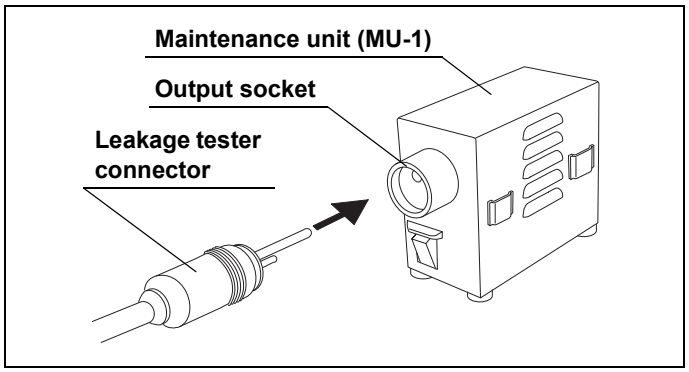


Figure 5.16

3 Turn the maintenance unit ON.

4 Depress the pin located inside the connector cap of the leakage tester and confirm that air is emitted from the connector cap with a whoosh sound.

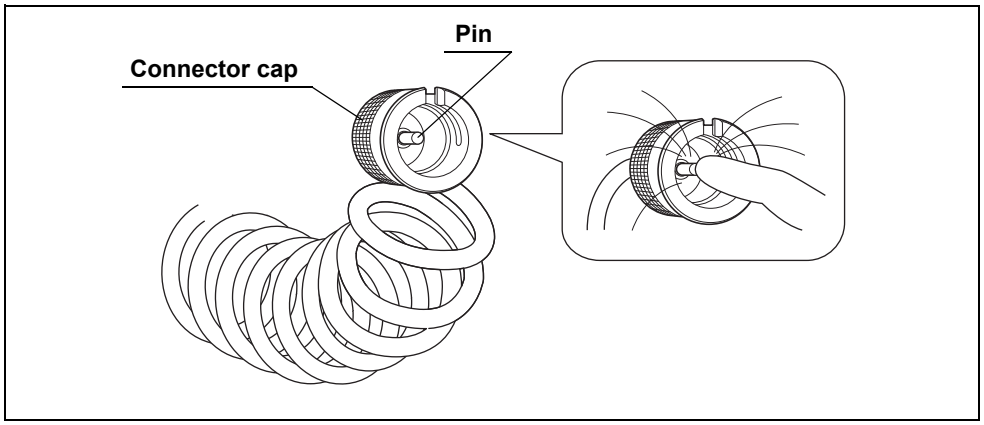


Figure 5.17

5 Confirm that the inside of the connector cap of the leakage tester is dry. If not, dry it by wiping with clean lint-free cloths.

6 Confirm that the venting connector on the endoscope’s light guide connector is dry. If not, dry it by wiping with clean lint-free cloths.

7 Attach the connector cap of the leakage tester to the venting connector on the light guide connector as follows:

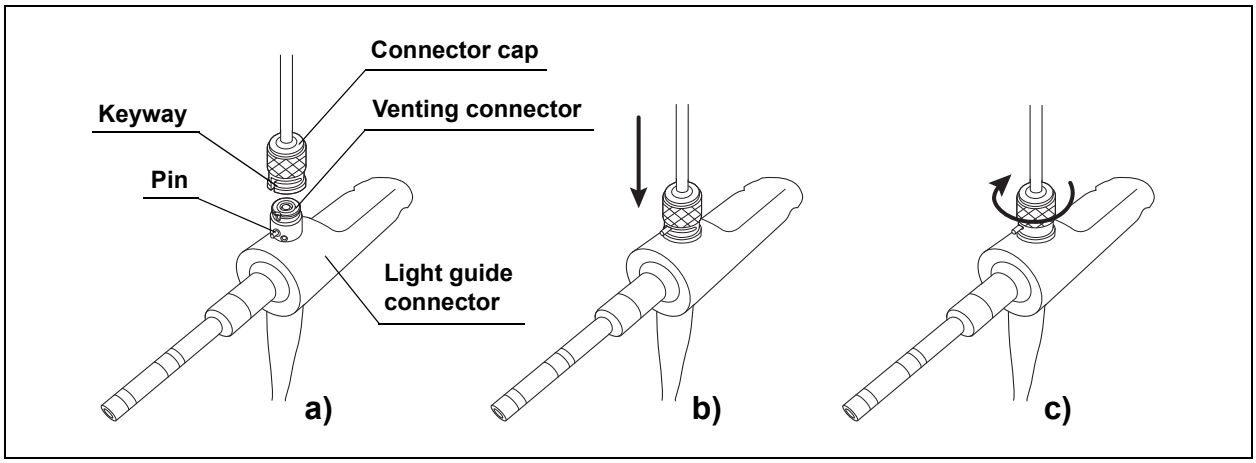


Figure 5.18

a) Align the pin on the venting connector with the keyway on the connector cap;

b) Push the connector cap towards the light guide connector of the endoscope until it stops;

c) Rotate the connector cap clockwise (approximately 90°) until it stops.

8 With the leakage tester attached, completely immerse all sections of the endoscope and the connector cap of the leakage tester in the water.

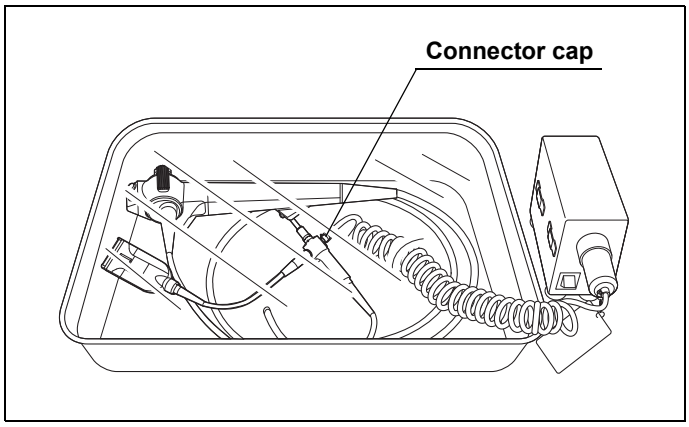


Figure 5.19

CAUTION

If continuous or intermittent air bubbles emerge from the adapter during leakage testing, the connector cap might be damaged. For further details, contact Olympus.

9 While keeping all sections of the endoscope under the water for approximately 30 seconds, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

10 While deflecting the bending section of the endoscope by moving the endoscope's UP/DOWN angulation control lever in the water, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

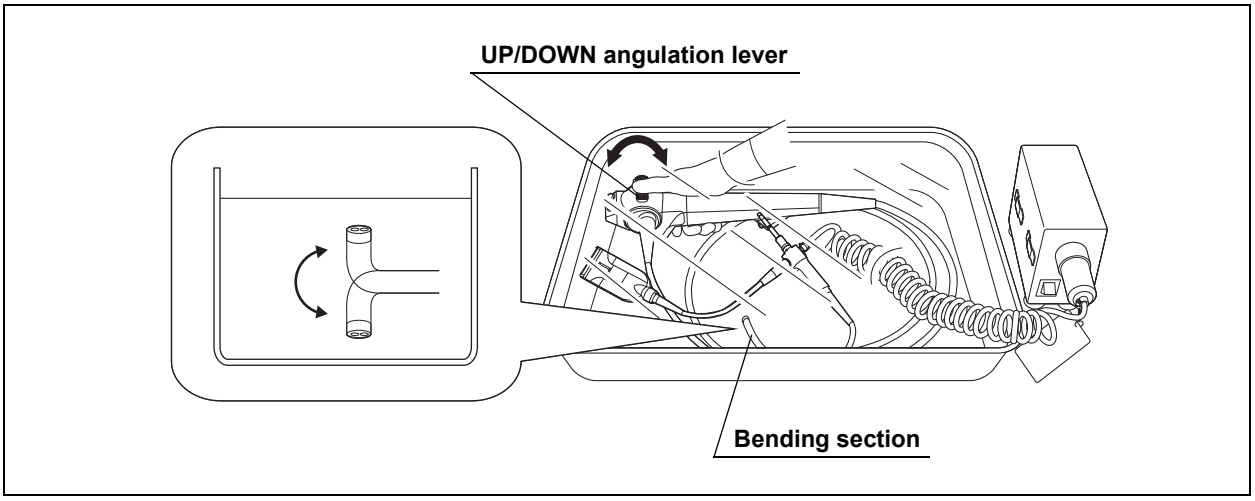


Figure 5.20

NOTE

- Air bubbles emerging continuously or intermittently from any location on the endoscope indicate a leak at that location. If there is a leak in the instrument channel of the endoscope, air bubbles will emerge continuously or intermittently from one or more channel openings (e.g., distal end, instrument channel port) on the immersed endoscope.

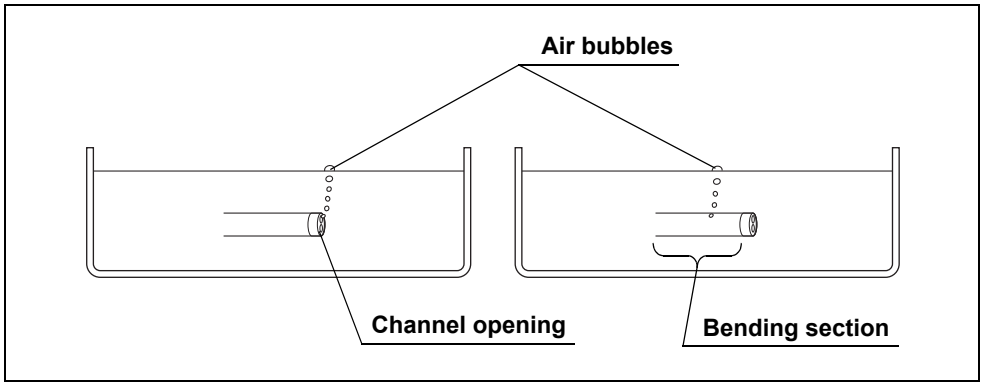


Figure 5.21

- During the leakage test, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

11 Remove the endoscope attached with the leakage tester from the water.

12 Turn the maintenance unit OFF.

13 Detach the leakage tester connector from the maintenance unit.

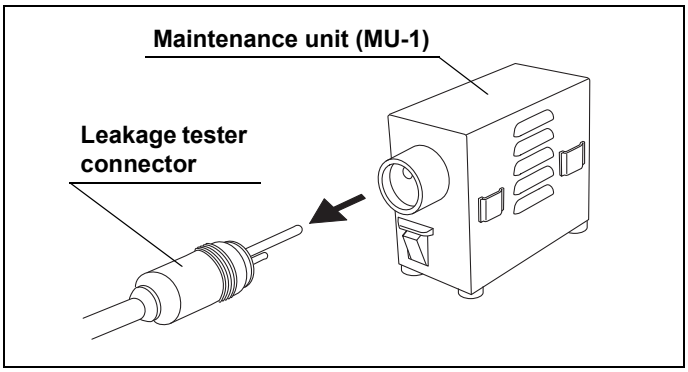


Figure 5.22

14 Wait 30 seconds or until the covering of the bending section contracts to its pre-expansion size.

15 Detach the leakage tester from the venting connector of the endoscope by turning the connector cap counterclockwise.

16 Thoroughly dry the leakage tester using clean lint-free cloths.

5.5 Manually cleaning the endoscope and accessories

If manual cleaning could not be performed within 1 hour after the patient procedure or if you are not sure whether manual cleaning could be performed within 1 hour, presoak the endoscope in the detergent solution to loosen debris that has dried and hardened as described in Section 5.9, “Presoaking the endoscope” before manually cleaning the endoscope.

CAUTION

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

■ Equipment needed

Prepare the following equipment.

Single use combination cleaning brush (BW-411B)

- **Clean lint-free cloths**
- **Clean sponges**
- **Water (Refer to Section 3.5, “Water”)**
- **70% ethyl or 70% isopropyl alcohol (Refer to Section 3.7, “Alcohol”)**
- **Clean 30 ml (30 cc) syringes**
- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Detergent solution (Refer to Section 3.3, “Detergent solution for manual cleaning”)**

■ *Clean the external surfaces*

❍ Preparation

1 Fill a clean, large basin with the detergent solution at the temperature and concentration recommended by the detergent manufacturer.

2 Completely immerse the entire endoscope in the detergent solution.

❍ Clean the external surfaces of the video connector, the video cable, the light guide connector, and the universal cord

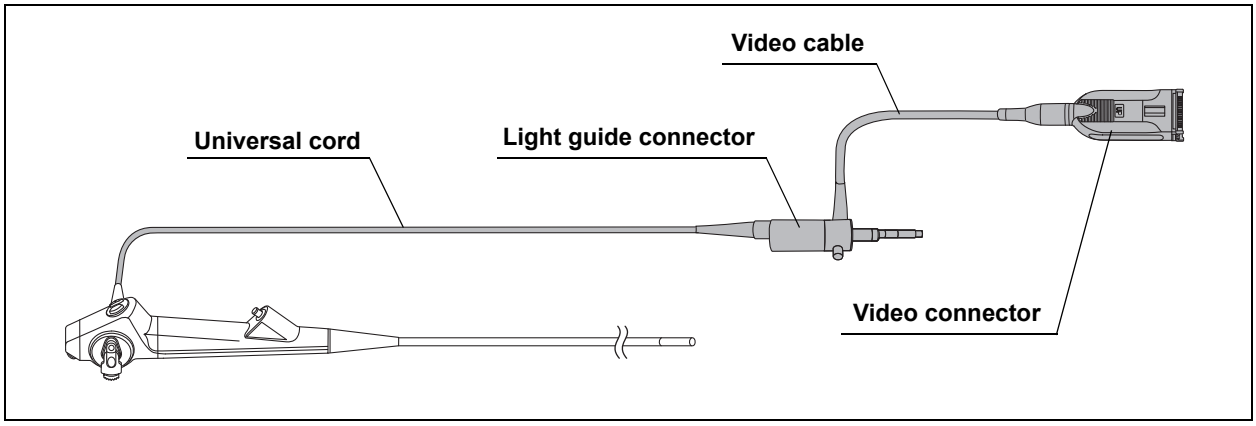


Figure 5.23

1 While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the video connector, the video cable, the light guide connector, and the universal cord, using clean lint-free cloths, sponges or brushes.

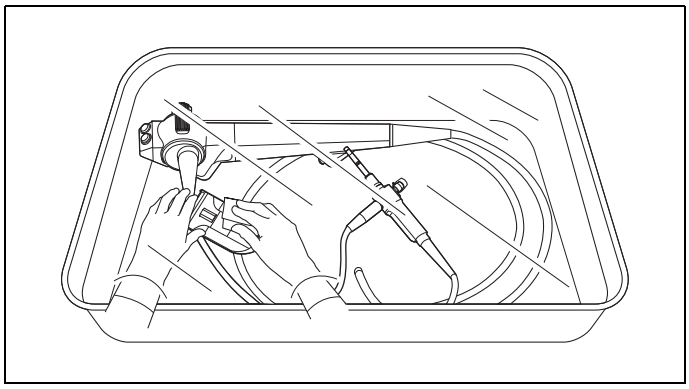


Figure 5.24

2 Take the video connector, the video cable, the light guide connector, and the universal cord out of the detergent solution.

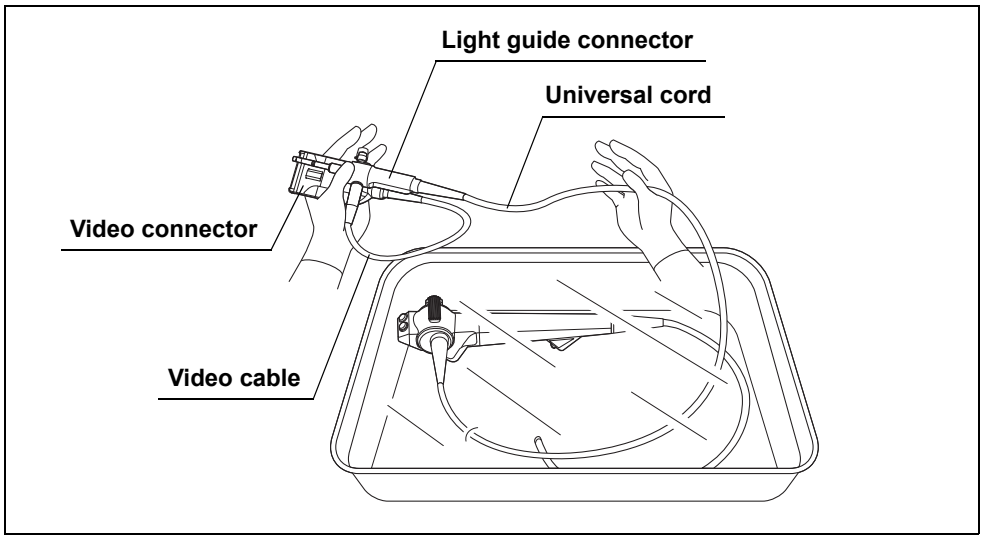


Figure 5.25

3 Confirm that no debris remains on all their external surfaces.

4 If any debris remains, repeat Step 1 through 3 until no debris is observed.

5 When all debris is removed, put back the video connector, the video cable, the light guide connector, and the universal cord in the detergent solution.

❍ Clean the external surfaces of the control section and its surrounding parts

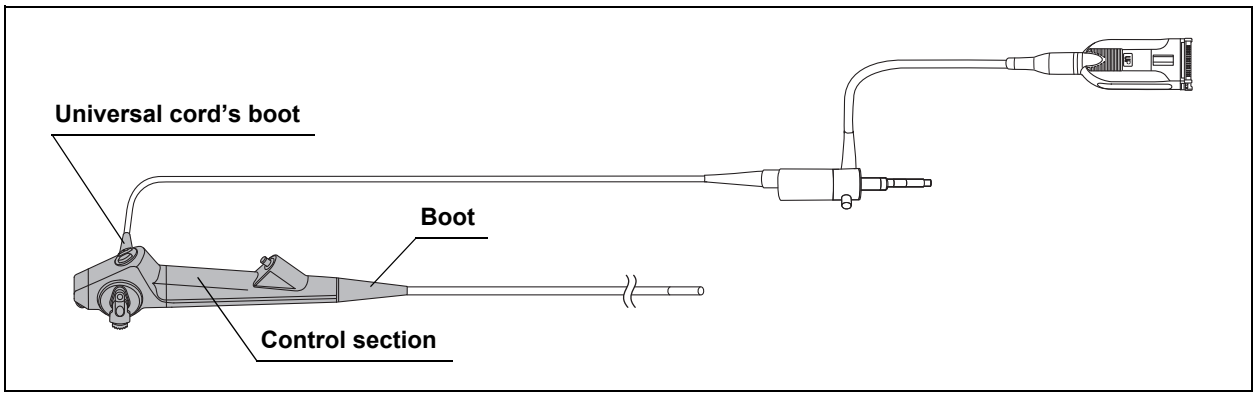


Figure 5.26

1 While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the universal cord's boot, the control section, and the boot, using clean lint-free cloths, sponges or brushes.

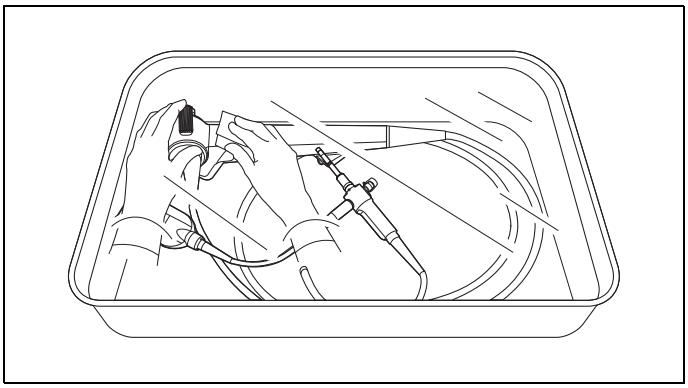


Figure 5.27

2 Take the universal cord's boot, the control section, and the boot out of the detergent solution.

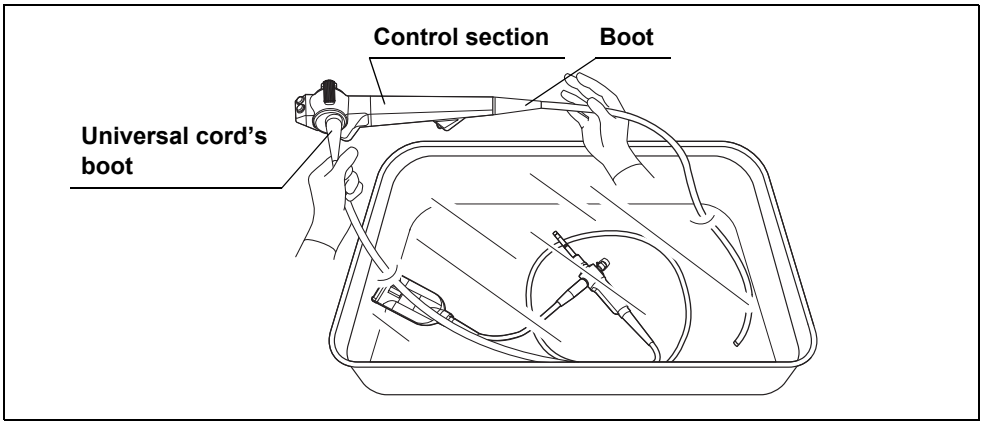


Figure 5.28

3 Confirm that no debris remains on all their external surfaces.

4 If any debris remains, repeat Step 1 through 3 until no debris is observed.

5 When all debris is removed, put back the universal cord's boot, the control section, and the boot in the detergent solution.

❍ Clean the external surfaces of the insertion section

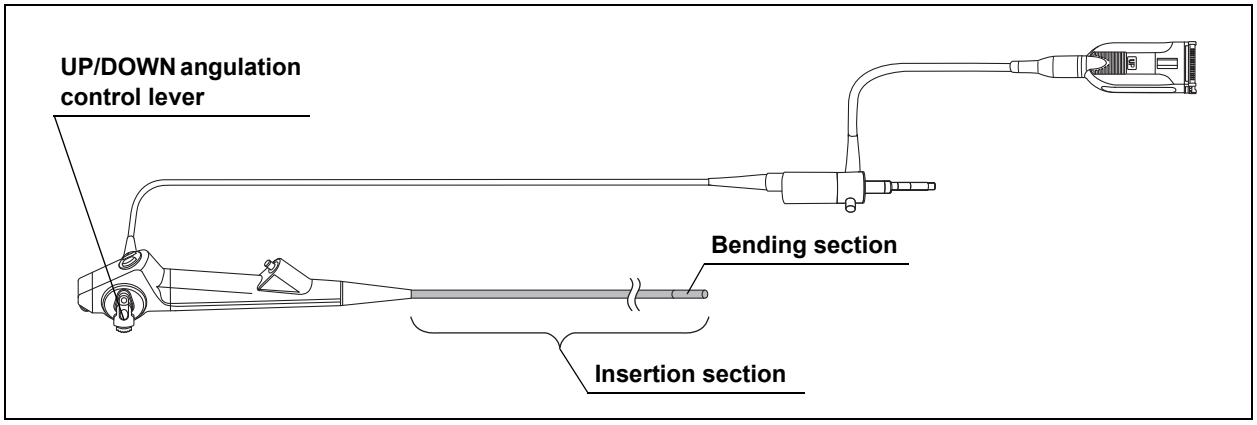


Figure 5.29

1 Straighten the bending section by use of endoscope's UP/DOWN angulation control lever.

2 While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the insertion section, using clean lint-free cloths, sponges or brushes.

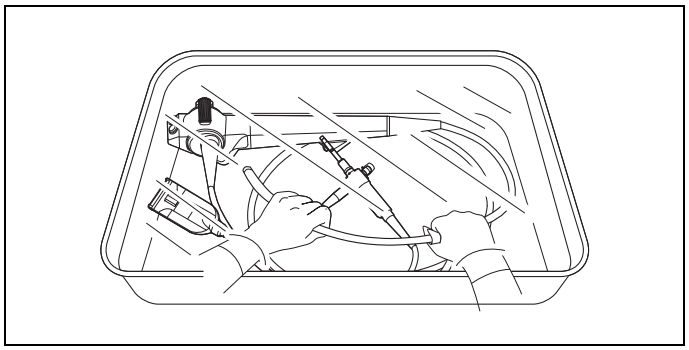


Figure 5.30

3 Take the insertion section out of the detergent solution.

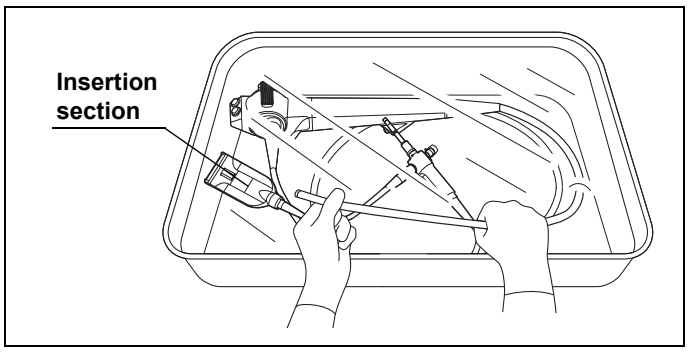


Figure 5.31

4 Confirm that no debris remains on all its external surfaces, particularly the objective lens on the distal end.

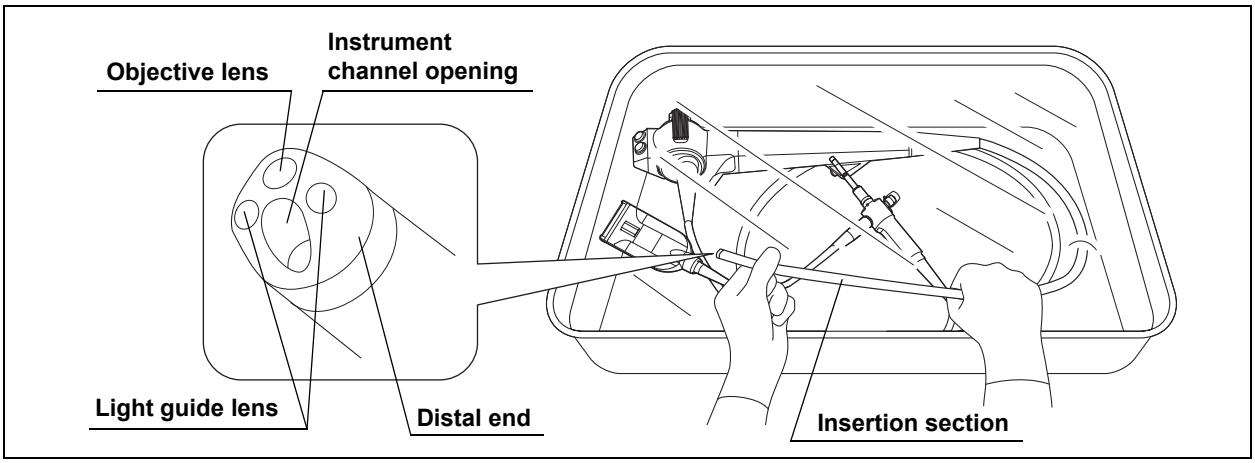


Figure 5.32

5 If any debris remains, repeat Step 2 through 4 until no debris is observed.

6 When all debris is removed, put back the insertion section in the detergent solution.

■ *Brush the channel*

WARNING

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

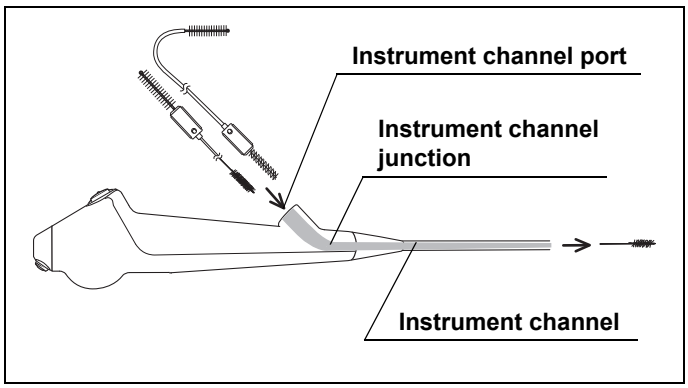


Figure 5.33

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

WARNING

- The single use combination cleaning brush (BW-411B) are for single use. Repeated usage of the brush may cause the brush head to become bent or kinked, which could cause it to come off during use. Before and after use, confirm that the brush is free from any damage or other irregularities. If a piece of the brush comes off inside the endoscope channel, immediately retrieve it. Confirm that no parts remain inside the instrument channel of the endoscope by carefully passing a new brush through the channel. Any part left in the channel 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 single use combination cleaning brush backwards – i.e. by inserting the brush directly into the instrument channel outlet at the distal end of the endoscope's insertion section. It may get caught, making retrieval impossible.

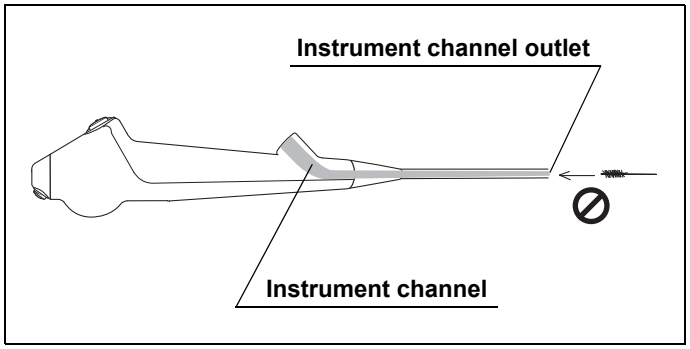


Figure 5.34

- Do not coil the insertion section 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 channel.

Brush the instrument channel

1 Straighten the bending section by use of endoscope's UP/DOWN angulation control lever.

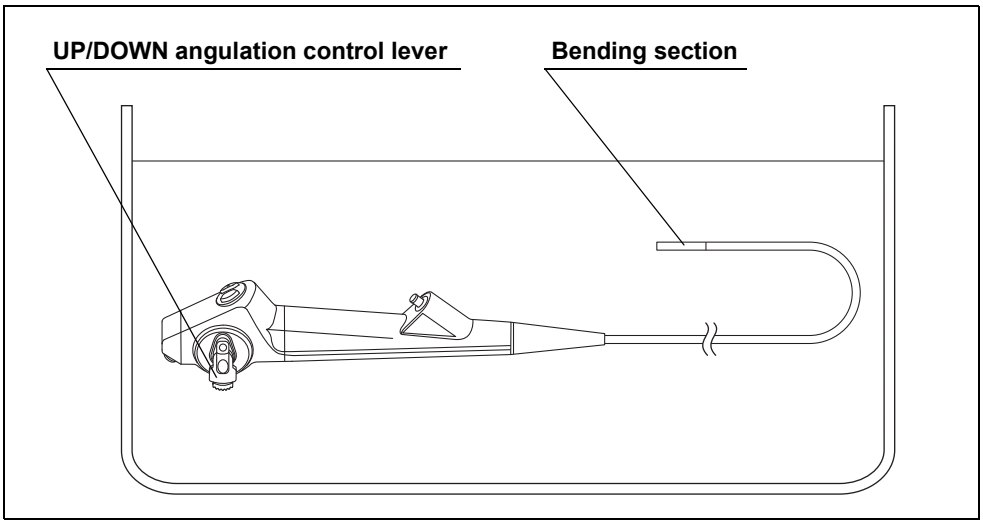


Figure 5.35

2 Grip the shaft of the single use combination cleaning brush (BW-411B) at a point 3 cm from the bristles of the channel cleaning brush part.

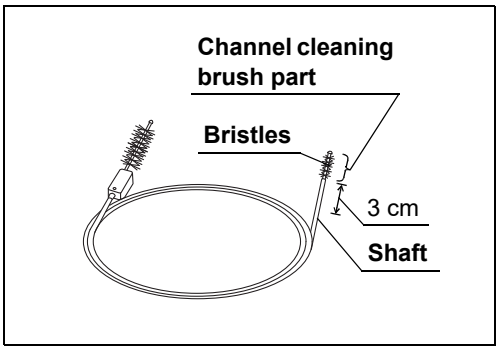


Figure 5.36

3 While immersing the entire endoscope completely in the detergent solution, insert the brush straight into the opening of the instrument channel port. Using short strokes, feed the brush through the instrument channel until it emerges from the distal end of the endoscope.

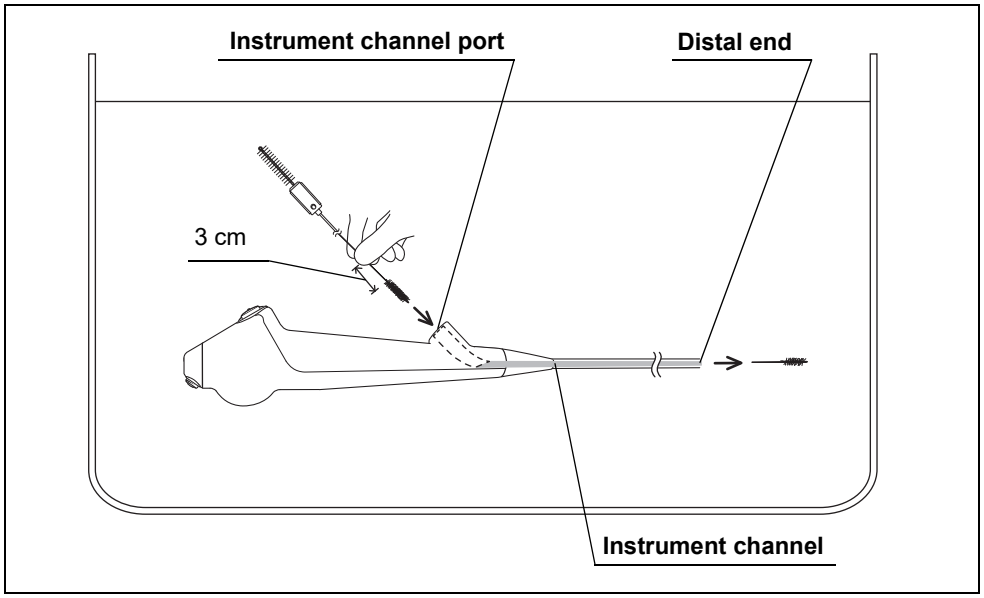


Figure 5.37

4 Inspect whether there is debris on the bristles when the brush emerges from the distal end of the endoscope.

5 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

6 While immersing the entire endoscope completely in the detergent solution, carefully pull the brush through the instrument channel and out of the instrument channel port.

7 Inspect whether there is debris on the bristles when the brush emerges from the instrument channel port.

8 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

9 Repeat Step 2 through 8 two additional times.

10 If any debris remains, repeat Step 2 through 8 until no debris is observed.

❍ Brush the instrument channel port

1 Grip the handle of the single use combination cleaning brush (BW-411B).

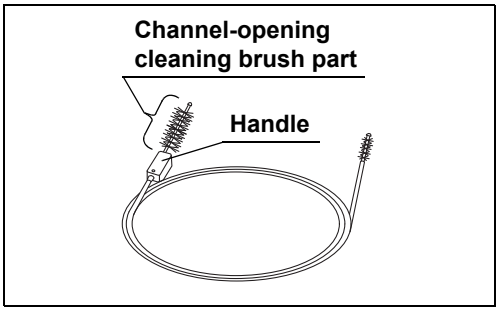


Figure 5.38

2 While immersing the entire endoscope completely in the detergent solution, insert the channel-opening cleaning brush part of the single use combination cleaning brush into the instrument channel port until the brush handle touches the channel opening.

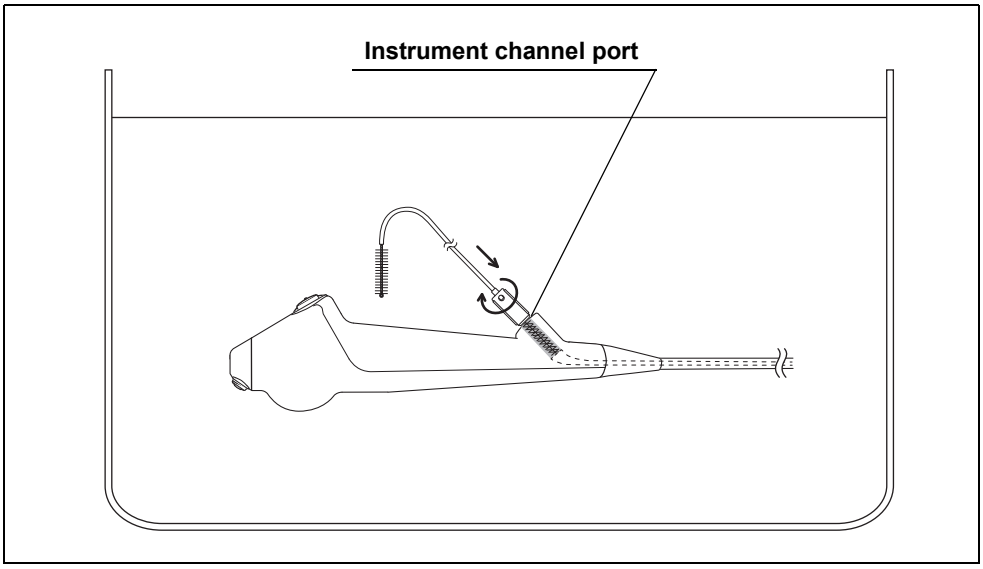


Figure 5.39

3 While immersing the entire endoscope completely in the detergent solution, rotate the inserted brush one full revolution.

4 While immersing the entire endoscope completely in the detergent solution, pull the brush out of the instrument channel port.

5 Inspect whether there is debris on the bristles when the brush emerges from the instrument channel port.

6 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

7 Repeat Step 1 through 6 two additional times.

8 If any debris remains, repeat Step 1 through 6 until no debris is observed upon inspection of the brush.

9 Dispose of the single use combination cleaning brush as described in Section 8.4, “Disposal”.

■ *Flush the instrument channel with detergent solution*

1 Completely immerse the entire endoscope in the detergent solution.

2 Fill a clean 30 ml syringe with the detergent solution.

3 While immersing the entire endoscope completely in the detergent solution, attach the syringe to the instrument channel port.

4 While immersing the entire endoscope completely in the detergent solution, flush the channel with 30 ml of the detergent solution.

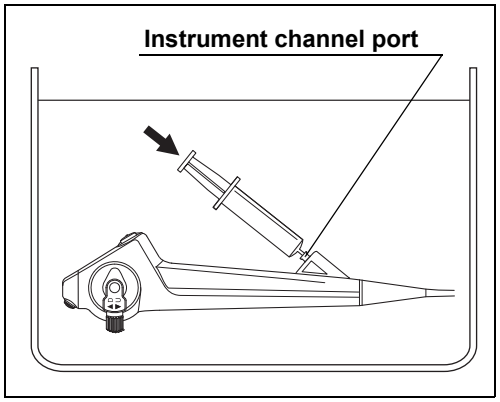


Figure 5.40

5 While immersing the entire endoscope completely in the detergent solution, detach the syringe from the endoscope.

6 Repeat Step 2 through 5 two additional times.

■ *Immerse the endoscope in detergent solution*

1 While immersing the entire endoscope completely in the detergent solution, wipe or brush all external surfaces of the endoscope to remove debris, using clean lint-free cloths, sponges or brushes.

2 Leave the endoscope completely immersed in the detergent solution during the recommended contact time according to the instructions of the detergent manufacturer.

3 Remove the endoscope from the detergent solution.

4 Place the endoscope in a clean, large basin.

■ *Remove detergent solution from the channel*

1 Fill a clean, large basin with the water as described in Section 3.5, “Water”.

2 Completely immerse the entire endoscope in the water.

3 Gently sway the endoscope to thoroughly rinse it.

4 Fill a clean 30 ml syringe with the water.

5 Attach the syringe to the instrument channel port.

6 Flush the channel with 30 ml of the water.

7 Detach the syringe from the endoscope.

8 Repeat Step 4 through 7 two additional times.

9 Remove the endoscope from the water.

10 Place the endoscope in a clean, large basin.

11 Fill a clean 30 ml syringe with air.

12 Attach the syringe to the instrument channel port.

13 Cover the distal end of the endoscope with clean lint-free cloths to prevent splashing from the channel opening.

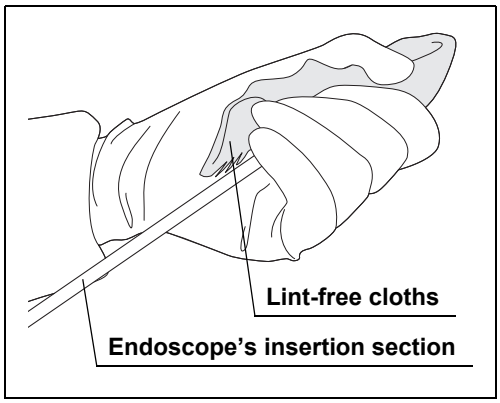


Figure 5.41

14 Flush the channel with 30 ml of air.

15 Detach the syringe from the endoscope.

16 Repeat Step 11 through 15 two additional times.

17 Remove the cloths from the endoscope.

■ *Dry external surfaces*

1 Dry the external surfaces of the endoscope by wiping with clean lint-free cloths.

2 Inspect all items for residual debris. If any debris remains, return to the beginning of Section 5.5, “Manually cleaning the endoscope and accessories” and repeat the entire cleaning procedure until all debris is removed.

■ *(Optional) Alcohol flush*

WARNING

To reduce the risk of residual alcohol by contacting patient’s mucosa and by electrosurgical procedures, remove residual alcohol from the endoscope channel by inspecting the irrigation function before each patient procedure, according to the procedures described in the operation manual of the endoscope.

If the endoscope will be disinfected (with manually) after cleaning, this step may be skipped.

1 Fill a sterile 30 ml syringe with the alcohol as described in Section 3.7, “Alcohol”.

2 Attach the syringe to the instrument channel port.

3 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing alcohol from the channel opening.

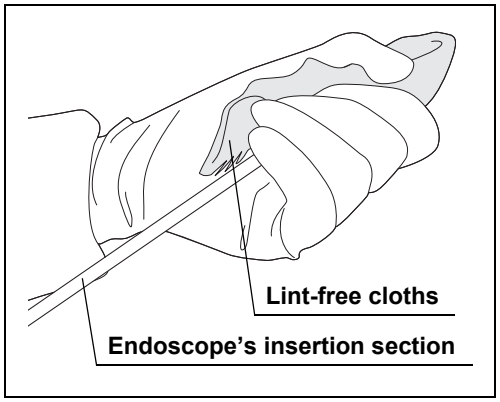


Figure 5.42

4 Flush the channel with 30 ml of the alcohol.

5 Detach the syringe from the endoscope.

6 Remove the cloths from the endoscope.

7 Fill a sterile 30 ml syringe with air.

8 Attach the syringe to the instrument channel port.

9 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing alcohol from the channel opening.

10 Flush the channel with 30 ml of air to expel all alcohol.

11 Detach the syringe from the endoscope.

12 Remove the cloths from the endoscope.

■ *Dry the endoscope*

If the endoscope will be disinfected (with manually) after cleaning, this step may be skipped.

CAUTION

When aerating the endoscope channels, the air pressure should be set 0.2 MPa or more but less than 0.3 MPa (≥2 and <3 kgf/cm^2, ≥29 and <43 psig). High pressure may cause damage to the endoscope.

NOTE

Some national or professional guidelines recommend drying endoscope channel with compressed filtered air.

1 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel openings.

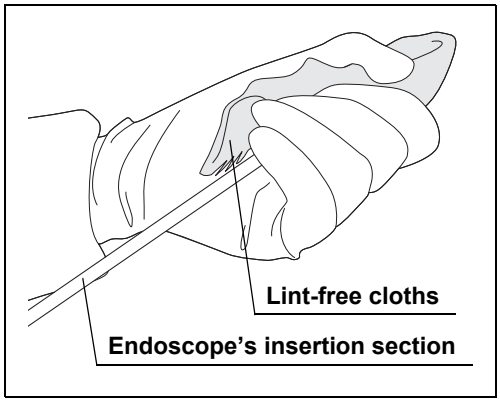


Figure 5.43

2 Feed instrument channel port with compressed filtered air of 0.2 – 0.3 MPa for 30 seconds.

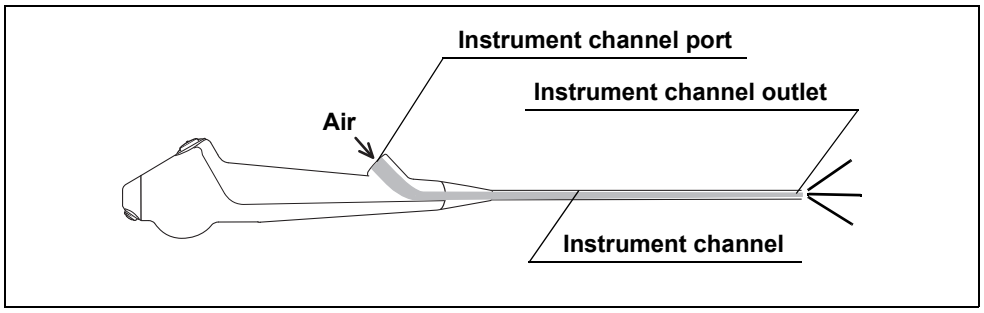


Figure 5.44

3 Remove the cloths from the endoscope.

4 Thoroughly dry the inside of the instrument channel port of the endoscope, using sterile cotton swabs.

5 Thoroughly dry the external surfaces of the endoscope by wiping with sterile lint-free cloths.

5.6 Manually disinfecting the endoscope

WARNING

The endoscope and accessories must be sterilized after using surgical operation. Refer to Section 5.8, “Sterilizing the endoscope”.

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

■ Equipment needed

Prepare the following equipment.

- **Clean lint-free cloths**
- **Clean 30 ml (30 cc)syringes**
- **Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Disinfectant solution (Refer to Section 3.4, “Disinfectant solution for manual disinfection”)**
- **Sterile lint-free cloths**[*1]
- **Sterile 30 ml (30 cc)syringes**[*1]
- **Sterile, large basins**[*1] **(size: 40 (W) × 40 (H) × 25 (D) cm or more)**

*1 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (basins, 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.

■ Preparation

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.

■ *Flush the channel with disinfectant solution*

WARNING

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

CAUTION

Do not immerse the endoscope 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.

NOTE

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

1 Completely immerse the entire endoscope in the disinfectant solution.

2 Fill a clean 30 ml syringe with the disinfectant solution.

3 While immersing the entire endoscope completely in the disinfectant solution, attach the syringe to the instrument channel port.

4 While immersed the entire endoscope completely in the disinfectant solution, flush the instrument channel with 30 ml of the disinfectant solution.

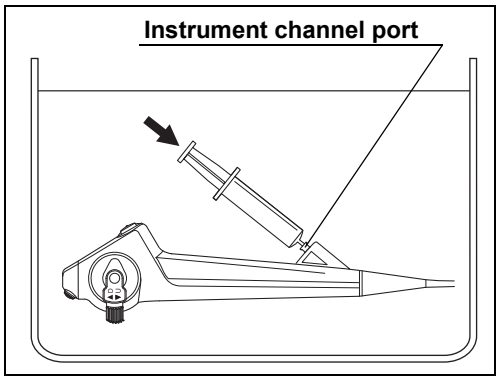


Figure 5.45

5 Repeat Step 2 through 4 two additional times.

6 Confirm that no air bubbles exit the distal end of the endoscope during the flush.

7 If air bubbles still exit during the flush, repeat Step 2 through 4 until no air bubbles exit.

8 While immersing the entire endoscope completely in the disinfectant solution, detach the syringe from the endoscope.

■ *Immerse the endoscope in the disinfectant solution*

WARNING

- During disinfection, keep the syringe detached from the endoscope. If the syringe remains attached to the endoscope during disinfection, the disinfectant solution cannot adequately contact the mated surfaces between the endoscope and the syringe.
- In addition, completely immerse the endoscope below the surface of the disinfectant solution so that all external surfaces of the endoscope contact the disinfectant solution. If the endoscope is not completely immersed, any protruding sections of this device will not be adequately disinfected.

CAUTION

Do not immerse the endoscope 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.

1 Confirm that the entire endoscope is completely immersed in the disinfectant solution.

2 Immerse clean lint-free cloths and then wring them out by hand until all trapped air bubbles are expelled in the disinfectant solution.

3 While completely immersing the entire endoscope in the disinfectant solution, wipe all external surfaces of the endoscope to remove air bubbles, using clean lint-free cloths.

4 While completely immersing the entire endoscope in the disinfectant solution, confirm that there are no air bubbles on all external surfaces of the endoscope.

5 If air bubbles adhere to the surfaces of the endoscope, wipe them away using your gloved fingertips or clean lint-free cloths.

6 Cover the basin of the disinfectant solution with a tight-fitting lid to minimize the diffusion of disinfectant vapors.

7 Leave the endoscope 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.

8 Remove the endoscope from the disinfectant solution.

9 Place the endoscope in a sterile, large basin.

■ *Remove disinfectant solution from the channel*

1 Fill a sterile 30 ml syringe with air.

2 Attach the syringe to the instrument channel port.

3 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

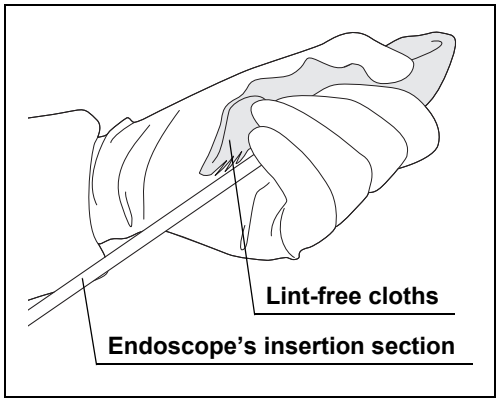


Figure 5.46

4 Flush the channel with 30 ml of air.

5 Detach the syringe from the endoscope.

6 Repeat Step 1 through 5 two additional times.

7 Remove the cloths from the endoscope.

5.7 Rinsing the endoscope following disinfection

This instruction manual describes procedures for rinsing the endoscope and accessories, and drying them following rinsing.

WARNING

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

CAUTION

Carefully dry the electrical contacts of the video connector after performing the procedure described in this section. Otherwise, equipment damage can result.

NOTE

Consult with your healthcare facility's infection control committee regarding rinse water quality as described in Section 3.6, “Rinse water”.

■ Equipment needed

Prepare the following equipment.

• **Sterile lint-free cloths**[*1]	• **Sterile cotton swabs**[*1]
• **Sterile 30 ml (30 cc) syringes**[*1]	• **Sterile, large basins**[*1] **(size: 40 (W) × 40 (H) × 25 (D) cm or more)**
• **Rinse water (See Section 3.6, “Rinse water”)**	• **70% ethyl or 70% isopropyl alcohol (See Section 3.7, “Alcohol”)**

*1 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (e.g., basins, 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*

Use appropriate rinse water as instructed in Section 3.6, “Rinse water”.

1 Fill a sterile, large basin with the rinse water as described in Section 3.6, “Rinse water”.

2 Completely immerse the entire endoscope in the rinse water.

3 While immersing the entire endoscope completely in the rinse water, wipe all external surfaces of the endoscope, using sterile lint-free cloths.

4 Fill a sterile 30 ml syringe with the rinse water.

5 While immersing the entire endoscope completely in the rinse water, attach the syringe to the instrument channel port.

6 While immersing the entire endoscope completely in the rinse water, flush the channel with 30 ml of the rinse water.

7 While immersing the entire endoscope completely in the rinse water, detach the syringe from the endoscope.

8 Repeat Step 4 through 7 two additional times.

9 Remove the endoscope from the rinse water and place them in a sterile basin.

10 Fill a sterile 30 ml syringe with air.

11 Attach the syringe to the instrument channel port.

12 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

13 Flush the channel with 30 ml of air.

14 Detach the syringe from the endoscope.

15 Repeat Step 10 through 14 two additional times.

16 Remove the cloths from the endoscope.

17 Repeat Step 1 through 16 above for the necessary number of times described in the disinfectant manufacturer's instruction. If not specified, perform at least a total of two times.

■ *(Optional) Alcohol flush*

Refer to “■ (Optional) Alcohol flush” on page 68 as the procedure is same.

■ *Dry the endoscope*

Refer to “■ Dry the endoscope” on page 69 as the procedure is same.

5.8 Sterilizing the endoscope

WARNING

The endoscope and accessories must be sterilized after using surgical operation.

■ Equipment needed

Prepare the following equipment.

Sterilization cap (MAJ-1538)

- **Sterilization wraps**
- **Instrument tray**
- **Sterilization pouches**
- **Sterile lint-free cloths**

■ STERRAD® 100S/NX®/100NX® sterilization of the endoscope

WARNING

- Thoroughly dry the endoscope and accessories before sterilization.
- All accessories must be removed from the endoscope prior to sterilization (except the sterilization cap (MAJ-1538)).
- Use only STERRAD® compatible instrument trays and sterilization wraps.

CAUTION

Attach the sterilization cap to the venting connector on the light guide connector prior to STERRAD® 100S/NX®/100NX® sterilization. If the sterilization cap is not attached to the venting connector during sterilization, the air inside the endoscope will expand and could rupture the bending section cover and/or damage the angulation mechanism.

1 Confirm that all external surfaces of the endoscope are thoroughly dry. If not, dry them as described in "■ Dry the endoscope" on page 69.

2 Dry the external surfaces of the sterilization cap by wiping with sterile lint-free cloths.

3 Attach the sterilization cap to the venting connector on the light guide connector as follows:

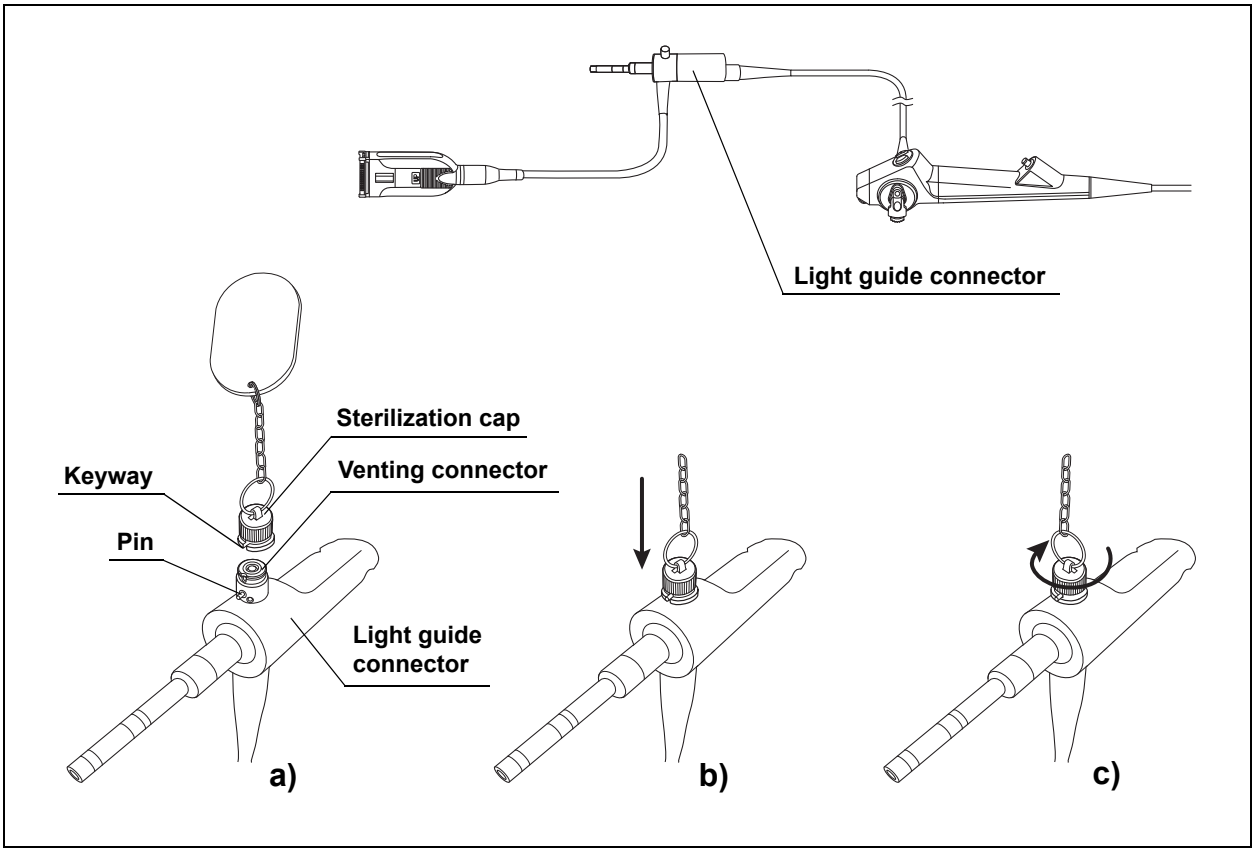


Figure 5.47

a) Align the pin on the venting connector with the keyway on the sterilization cap;

b) Push the sterilization cap towards the light guide connector of the endoscope until it stops;

c) Rotate the sterilization cap clockwise (approximately 90°) until it stops.

4 When sterilizing with the STERRAD® 100S Sterilization System, depending on the inner diameter/length of channel, it is necessary to attach the booster (REF15400) to instrument channel of the endoscope according to the instructions of the sterilizer manufacturer.

5 Place the endoscope upon an instrument tray and double wrap the tray with sterilization wraps. Use a STERRAD® compatible instrument tray and sterilization wraps.

6 Sterilize the packaged endoscope, according to the instructions of the sterilizer manufacturer.

■ *V-PRO® maX sterilization of the endoscope*

WARNING

- Thoroughly dry the endoscope and accessories before sterilization.
- All accessories must be removed from the endoscope prior to sterilization (except the sterilization cap (MAJ-1538)).
- Use only V-PRO® maX compatible instrument trays and sterilization wraps.

CAUTION

Attach the sterilization cap to the venting connector on the light guide connector prior to V-PRO® maX sterilization. If the sterilization cap is not attached to the venting connector during sterilization, the air inside the endoscope will expand and could rupture the bending section cover and/or damage the angulation mechanism.

1 Confirm that all external surfaces of the endoscope are thoroughly dry. If not, dry them as described in “■ Dry the endoscope” on page 69.

2 Dry the external surfaces of the sterilization cap by wiping with sterile lint-free cloths.

3 Attach the sterilization cap to the venting connector on the light guide connector as follows:

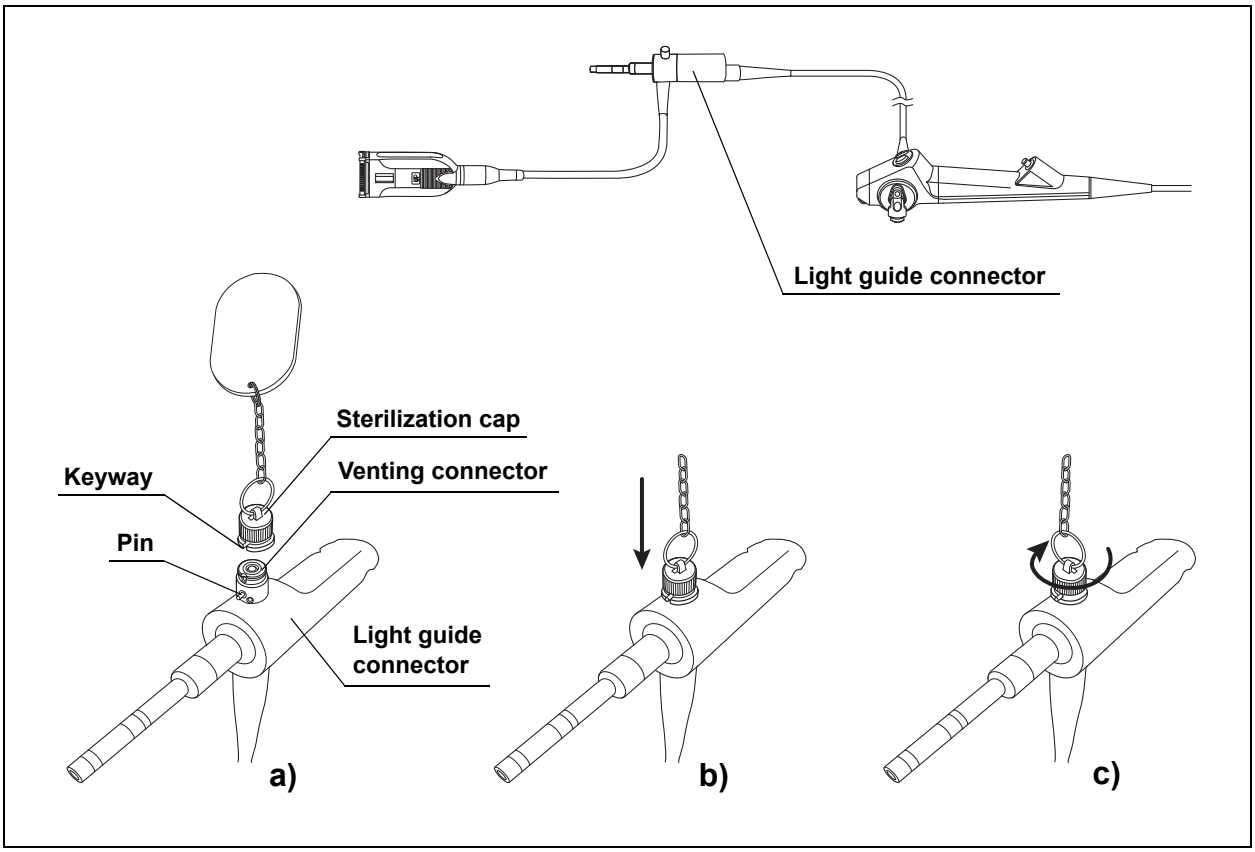


Figure 5.48

a) Align the pin on the venting connector with the keyway on the sterilization cap;

b) Push the sterilization cap towards the light guide connector of the endoscope until it stops;

c) Rotate the sterilization cap clockwise (approximately 90°) until it stops.

4 Place the endoscope upon an instrument tray and double wrap the tray with sterilization wraps. Use a V-PRO® maX compatible instrument tray and sterilization wraps.

5 Sterilize the packaged endoscope, according to the instructions of the sterilizer manufacturer.

5.9 Presoaking the endoscope

If manual cleaning could not be performed within 1 hour after the patient procedure or if you are not sure whether manual cleaning could be performed within 1 hour, 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.

WARNING

- If manual cleaning could not be performed within 24 hours after the patient procedure or if you are not sure whether manual cleaning could be performed within 24 hours, dried debris may not be removed and reprocessing of the endoscope may not be performed effectively.
- Do not reuse the detergent solution used for presoak. If performing manual cleaning with the detergent solution used for presoak, reprocessing of the endoscope may not be performed effectively.

CAUTION

Presoak the endoscope only if manual cleaning of the endoscope was delayed for more than 1 hour or if you are not sure whether manual cleaning could be performed within 1 hour. Unnecessary long-term immersions should be avoided. Consecutive reprocessing sessions using extended immersion may damage the endoscope.

■ Equipment needed

Prepare the following equipment.

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Detergent solution containing enzymes (Refer to Section 3.3, "Detergent solution for manual cleaning")**
- **Clean 30 ml (30 cc) syringes**

■ *Presoak the endoscope*

1 If a leakage test has not been performed, perform a leakage test according to Section 5.4, “Leakage testing of the endoscope”.

2 Fill a clean, large basin with the detergent solution containing enzymes at the temperature and concentration recommended by the detergent manufacturer.

3 Completely immerse the entire endoscope in the detergent solution.

4 Fill a clean 30 ml syringe with the detergent solution.

5 While immersing the entire endoscope completely in the detergent solution, attach the syringe to the instrument channel port.

6 While immersing the entire endoscope completely in the detergent solution, flush the channel with 30 ml of the detergent solution.
Confirm that air bubbles exit from the distal end of the endoscope during the flush to make sure that the instrument channel is not clogged.

7 When air bubbles did not exit from the distal end of the endoscope in Step 6, immerse the endoscope in the detergent solution for 30 minutes. And then repeat Step 4 through 6 to perform additional flushes of the instrument channel port.

8 While immersing the entire endoscope completely in the detergent solution, detach the syringe from the endoscope.

9 Allow the endoscope to soak completely in the detergent solution for 0.5 to 1 hour. Do not immerse the endoscope for more than 1 hour. Use a clock or timer to accurately measure the immersion time.

10 Remove the endoscope from the detergent solution.

11 Return to Section 5.5, “Manually cleaning the endoscope and accessories” and reprocess according to the procedure. Use the detergent solution containing enzymes in manual cleaning. Even when AER, perform all procedures according to Section 5.5 after presoaking.

Chapter 6 Reprocessing the Accessories

6.1 Summary of reprocessing the accessories

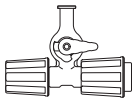
WARNING

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

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

Sterilization cap (MAJ-1538)

Luer-Split (MAJ-2092)



Forceps/irrigation plug (isolated type) (MAJ-891) (Sold separately.)

■ Reprocessing the luer-split (MAJ-2092)

Reprocess the luer-split as described in the luer-split instruction manual.

■ Reprocessing the forceps/irrigation plug (isolated type) (MAJ-891)

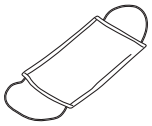
Reprocess the forceps/irrigation plug as described in the forceps/irrigation plug (isolated type) instruction manual.

■ *Equipment needed*

Prepare the following equipment.

❍ Personal protective equipment (e.g.)

Eyewear



Face mask

Moisture-resistant clothing

Chemical-resistant gloves[*1]

❍ Other

- **Clean lint-free cloths[*2]**
- **Sterile lint-free cloths[*2, *3]**
- **Clean basins or containers with tight-fitting lids**
- **Sterilization pouches**
- **Detergent solution (Refer to Section 3.3, "Detergent solution for manual cleaning")**
- **Rinse water (Refer to Section 3.6, "Rinse water")**
- **Clean sponges**
- **Clean basins or containers**
- **Sterile basins or containers[*3]**
- **Water (Refer to Section 3.5, "Water")**
- **Disinfectant solution (Refer to Section 3.4, "Disinfectant solution for manual disinfection")**

*1 Gloves are recommended to be long enough so that your skin is not exposed.

*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 channel. There is the potential for lint or cloth fibers to lodge in channel. If gauze is used to reprocess the endoscope, ensure that fibers do not get caught on or remain trapped by protruding components.

*3 Following disinfection, it is very important not to recontaminate the accessories with potentially infectious microorganisms. When rinsing and drying the accessories after disinfection, the use of sterile equipment (e.g., basins, 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.

6.2 Manually cleaning the accessory

If manual cleaning could not be performed within 1 hour after the patient procedure or if you are not sure whether manual cleaning could be performed within 1 hour, dispose of the accessories because the effectiveness of reprocessing is not guaranteed.

CAUTION

Make sure that the item immersed in detergent solution does not contact another.

■ Equipment needed

Prepare the following equipment.

- **Clean lint-free cloths**
- **Clean basins or containers**
- **Detergent solution (Refer to Section 3.3, "Detergent solution for manual cleaning")**
- **Clean sponges**
- **Water (Refer to Section 3.5, "Water")**

■ Manually cleaning the accessory

1. Fill a clean basin with the detergent solution at the temperature and concentration recommended by the detergent manufacturer.
2. Completely immerse the sterilization cap (MAJ-1538) in the detergent solution.
3. While immersing the sterilization cap completely in the detergent solution, wipe and clean the external surfaces of the sterilization cap using clean lint-free cloths or sponges.
4. Leave the sterilization cap immersed in the detergent solution, according to the instructions of the detergent manufacturer.
5. Remove the sterilization cap (MAJ-1538) from the detergent solution and check them for debris. If debris remains on any accessory, repeat Step 3 until all debris is removed.
6. Fill a clean basin with the water as described in Section 3.5, "Water" and immerse all accessories in the water.
7. Gently sway the sterilization cap (MAJ-1538) in the water.
8. Remove the sterilization cap (MAJ-1538) from the water.

9 Wipe and dry the external surfaces of the sterilization cap (MAJ-1538), using clean lint-free cloths.

10 Inspect the sterilization cap (MAJ-1538) for residual debris. If debris is found on any accessory, repeat the cleaning procedure until all debris is removed.

6.3 Manually disinfecting the accessory

WARNING

The endoscope and accessories must be sterilized after using surgical operation. Refer to Section 6.5, “Sterilizing the accessories”.

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

■ Equipment needed

Prepare the following equipment.

- **Clean lint-free cloths**
- **Disinfectant solution (Refer to Section 3.4, “Disinfectant solution for manual disinfection”)**
- **Clean basins or containers with tight-fit lids.**

■ *Immerse the accessory in the disinfectant solution*

WARNING

Make sure that the disinfectant solution contacts all external surfaces of the accessory. If the accessories are not completely immersed, any protruding section(s) of the device(s) will not be adequately disinfected. Always confirm that the accessories are completely below the surface of the disinfectant solution.

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 sterilization cap (MAJ-1538) in the disinfectant solution.

3 Wipe the external surfaces of the sterilization cap (MAJ-1538) while immersed in the disinfectant solution, using your gloved fingers or clean lint-free cloths to dispel any attached air bubbles.

4 Confirm that the sterilization cap (MAJ-1538) is completely immersed in the disinfectant solution and free from air bubbles.

5 Cover the basin of the disinfectant solution with a tight-fitting lid to minimize the diffusion of disinfectant vapors.

6 Leave all accessories immersed in the disinfectant solution. Follow the instruction of the disinfectant manufacturer regarding contact time and concentration.

7 Remove the sterilization cap (MAJ-1538) from the disinfectant solution.

6.4 Rinsing the accessory following disinfection

This section describes procedures for rinsing the accessory. and drying it following rising.

WARNING

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

■ Equipment needed

Prepare the following equipment.

- **Sterile lint-free cloths**[*1]
- **Sterile basins or containers**[*1]
- **Rinse water**
  (Refer to Section 3.6, “Rinse water”)

*1 Following disinfection, it is very important not to recontaminate the accessories with potentially infectious microorganisms. When rinsing and drying the accessories following disinfection, the use of sterile equipment (basins, 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.

■ Rinse the accessory including drying

Use appropriate rinse water as instructed in Section 3.6, “Rinse water”.

1. Fill a sterile basin with the rinse water as described in Section 3.6, “Rinse water”.
2. Completely immerse the sterilization cap (MAJ-1538) in the rinse water.
3. Gently sway the sterilization cap while immersed.
4. While completely immersed in the rinse water, wipe the external surfaces of the sterilization cap using sterile lint-free cloths.
5. Remove the sterlization cap from the rinse water. Place it in a sterile basin.
6. Wipe and thoroughly dry the external surfaces of the sterilization cap, using sterile lint-free cloths.
7. Repeat Step 1 through 6 above for the necessary number of times described in the rinse water manufacturer's instruction. If not specified, perform at least a total of two times.

6.5 Sterilizing the accessories

This section describes the methods for sterilizing those accessories that are listed in Table 3.1 as being compatible with hydrogen peroxide sterilization or steam sterilization (autoclaving).

■ Steam sterilization (autoclaving)

WARNING

- Thoroughly dry the accessories before sterilization.
- 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 it, seal it in new sterile packaging, and sterilize it again.
- Inspect each equipment package for openings, tears, or other damage. If the equipment package is open or damaged, seal the equipment in a new package and resterilize it as described below.

CAUTION

- Exceeding the recommended sterilization parameters may cause damage to the accessories.
- After steam sterilization (autoclaving), let all components gradually cool down to room temperature. Sudden changes in temperature may damage the accessories.

1 Seal the accessories in an individual packaging appropriate for steam sterilization, according to your institution's protocol.

2 Sterilize the packaged accessories, according to the parameters described in Section 3.12, "Steam sterilization (autoclaving)". In addition, always follow the instructions of the sterilizer manufacturer.

■ *STERRAD® 100S/NX® sterilization*

WARNING

- Thoroughly dry the accessories before sterilization.
- Inspect each equipment package for openings, tears, or other damage. If the equipment package is open or damaged, seal the equipment in a new package and resterilize it as described below.

CAUTION

Exceeding the recommended sterilization parameters may cause damage to the accessories.

NOTE

Sterilization of the accessories alone is not applicable to STERRAD 100NX(DUO cycle). When using STERRAD 100NX, place the accessories on the instrument tray containing the endoscope described in Section 5.8 to sterilize.

1 Seal the accessories in an individual packaging appropriate for STERRAD® 100S/NX® sterilization according to your institution's protocol.

2 Sterilize the packaged accessories, according to the instructions of the sterilizer manufacturer.

■ *V-PRO® maX sterilization*

WARNING

- Thoroughly dry the accessories before sterilization.
- Inspect each equipment package for openings, tears, or other damage. If the equipment package is open or damaged, seal the equipment in a new package and resterilize it as described below.

CAUTION

Exceeding the recommended sterilization parameters may cause damage to the accessories.

1 Seal the accessories in an individual packaging appropriate for V-PRO® maX sterilization according to your institution's protocol.

2 Sterilize the packaged accessories, according to the instructions of the sterilizer manufacturer.

Chapter 7 Reprocessing Endoscopes and Accessories Using an AER/WD

7.1 Reprocessing endoscope and accessories using an AER

Follow the workflow described in Section 4.2, “Workflow for reprocessing endoscopes and accessories” when reprocessing endoscopes and accessories with an 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 any endoscopes and accessories that are not compatible with the AER.

7.2 Reprocessing endoscope and accessories using an ETD

When using the ETD, conduct all steps of precleaning and manual cleaning as instructed in this manual before setting the endoscope in the ETD.

■ ETD

- Reprocess the endoscope using the standard cycle in the ETD.
- For the information concerning the details of the reprocessing steps required, please refer to the instruction manual for the ETD before putting this endoscope into the ETD.
- Make sure to use the correct adapters for this endoscope according to the instruction manual for the ETD.

WARNING

When using the ETD, conduct all steps of precleaning and manual cleaning as instructed in this manual before setting the endoscope in the ETD.

■ (Optional) Alcohol flush

Refer to “■ (Optional) Alcohol flush” on page 68 for the accessories as the procedures are same.

■ Dry the endoscope and accessories

Refer to “■ Dry the endoscope” on page 69 for the accessories as the procedures are same.

7.3 Reprocessing endoscope and accessories using an OER-AW

- Reprocess the endoscope using the OER-AW.
- For the information concerning the details of the reprocessing steps required, please refer to the instruction manual for the OER-AW before putting this endoscope into the OER-AW.
- Make sure to use the correct adapters for this endoscope according to the instruction manual for the OER-AW or Section 3.9, “OER-AW(Olympus Endoscope Reprocessor)”.
- OER-AW is not available in the member states of the EU.

■ (Optional) Alcohol flush

Refer to “■ (Optional) Alcohol flush” on page 68 for the accessories as the procedures are same.

■ Dry the endoscope and accessories

Refer to “■ Dry the endoscope” on page 69 for the accessories as the procedures are same.

7.4 Accessories using a WD

Follow the workflow described in Section 4.2, “Workflow for reprocessing endoscopes and accessories” when reprocessing accessories with a WD.
Be sure to attach all required connectors to the accessories. For details concerning appropriate connectors, refer to the instructions of the WD manufacturer.
Manually clean and disinfect any accessories that are not compatible with the WD.

NOTE

Lumens must be connected to the WD so that they will be rinsed through and all inner and outer surfaces come in contact with chemicals.

■ Washer-Disinfector

For the information concerning the details of the reprocessing steps required before putting accessories into WD, please refer to the instruction manual for WD and chemicals.

■ Dry the endoscope and accessories

Refer to “■ Dry the endoscope” on page 69 for the accessories as the procedures are same.

Chapter 8 Storage and Disposal

8.1 Precaution of 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, ultraviolet rays, or ozone.
- To prevent damage, do not store the endoscope and/or accessories with chemicals or in a gas-generating area.
- Do not coil the endoscope's insertion tube or universal cord with a diameter of less than 10 cm. Such improper storage may damage the endoscope.

NOTE

Some national or professional guidelines recommend checking the quality of the final drying and if necessary, drying endoscopes manually with compressed filtered air before storage.

8.2 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.

NOTE

- Some professional guidelines as well as Olympus recommend storing endoscopes in an endoscope storage cabinet with the insertion tube and the universal cord hanging vertically.
- Storing time for disinfected endoscopes varies depending on the method to keep aseptic state, storing method, environmental condition, and handling condition. The maximum period disinfected endoscopes can be stored until the next use should be determined at each medical facility.

1 Confirm that all surfaces of the endoscope and accessories are dry.

2 Place the endoscope's angulation locks in the "F▼" (or free) position.

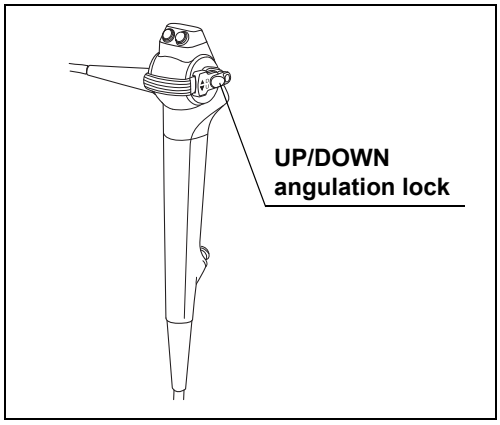


Figure 8.1

3 Store the disinfected endoscope and accessories properly.

8.3 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.
- Storing time for sterile endoscopes varies depending on the method to keep aseptic state, storing method, environmental condition, and handling condition. The maximum period sterilized endoscopes can be stored until the next use should be determined at each medical facility.

8.4 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.

OLYMPUS

Manufactured by

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
Fax: (042)646-2429 Telephone: (042)642-2111

Distributed by

OLYMPUS AMERICA INC.
3500 Corporate Parkway, P.O. Box 610, Center Valley, PA
18034-0610, U.S.A.
Fax: (484)896-7128 Telephone: (484)896-5000

OLYMPUS LATIN AMERICA, INC.
5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2097, U.S.A.
Fax: (305)261-4421 Telephone: (305)266-2332

EC REP **OLYMPUS EUROPA SE & CO. KG**
(Premises/Goods delivery) Wendenstrasse 20, 20097 Hamburg, Germany
(Letters) Postfach 10 49 08, 20034 Hamburg, Germany
Fax: (040)23773-4656 Telephone: (040)23773-0

KEYMED (MEDICAL & INDUSTRIAL EQUIPMENT) LTD.
KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom
Fax: (01702)465677 Telephone: (01702)616333

OLYMPUS MOSCOW LIMITED LIABILITY COMPANY
Elektrozavodskaya str. 27 bld.8, 107023 Moscow, Russia
Fax: (7)495-926-7072 Telephone: (7)495-926-7077

OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.
A8F, Ping An International Financial Center, No. 1-3, Xinyuan South Road,
Chaoyang District, Beijing, 100027 P.R.C.
Fax: (86)10-5976-1299 Telephone: (86)10-5819-9000

OLYMPUS KOREA CO., LTD.
(Seocho-dong, Majestar City Tower One), 2F & 3F, 12, Seocho-daero 38-gil, Seocho-gu,
Seoul, 06655, Republic of Korea
Fax: (02)6255-3210 Telephone: 1544-3200

OLYMPUS SINGAPORE PTE LTD
438B Alexandra Road #03-07/12, Alexandra Technopark Blk B, Singapore 119968
Fax: 6834-2438 Telephone: 6834-0010

OLYMPUS AUSTRALIA PTY LTD
3 Acacia Place, Notting Hill, VIC 3168, Australia
Fax: (03)9543-1350 Telephone: (03)9265-5400

Date of Issue 2022-02-14
RC7852 05

Printed in Japan 20220209 *0000