OLYMPUS®

REPROCESSING MANUAL

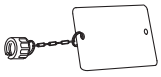
INSTRUCTIONS

RHINO-LARYNGO VIDEOSCOPE

OLYMPUS ENF-VH

Accessories:

- ETO cap (MB-156)



MB-156

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

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Chapter 1 General Policy

1.1 Instructions

- This manual contains the reprocessing methods recommended by Olympus for the endoscope and accessories listed on the front cover.
- This instruction manual contains essential information on reprocessing the endoscope 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:

AER is the abbreviation for Automated Endoscope Reprocessor, which is used for reprocessing the endoscopes and accessories.

Ch.1

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 healthcare facility
- 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. Also, a tap, basin, and/or nozzle of pharyngeal anesthetic spray 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), 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.
- Residual disinfectant solution may cause adverse reactions in patients. Therefore, rinse all external surfaces of the endoscope 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.
- 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.

WARNING

- Perform a leakage test on the endoscope after each precleaning procedure. Do not use the endoscope if a leak is detected. Use of an endoscope with a leak may cause a sudden loss of the endoscopic image, damage to the bending mechanism, or other malfunctions. Use of a leaking endoscope may also pose an infection control risk.

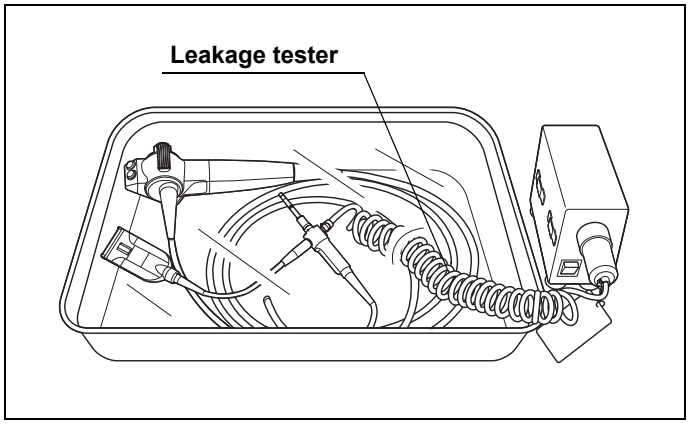


Figure 1.1

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

WARNING

- Only use the AER that meets the requirements of the relevant parts of EN ISO 15883 series in the member states of the EU.
- Before using an AER, confirm that it is capable of reprocessing the endoscope. 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 to reprocess the endoscope, contact the manufacturer of the AER 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.
- 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 chose to use a reprocessing method not recommended in this manual, the local institution and/or physicians must assume responsibility for its safety and efficacy. Make sure to carefully inspect each piece of endoscopic equipment for irregularities (damage) prior to each patient procedure. Do not use the equipment if any irregularity is found.
- Good quality control practices typically require appropriate documentation. Items such as local SOPs (Standard Operating Procedures), confirmation of operator training, routine testing of the disinfectant’s MEC (Minimal Effective Concentration), confirmation of the disinfectant’s use-life, etc. should be documented as performed.
- 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 ETO cap (MB-156) is not attached to the endoscope. If the ETO cap is attached, the reprocessing fluids will be able to penetrate the inside of the endoscope, and it can be damaged.
- 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 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.
- To maintain sterility of equipment following sterilization, use sterile packaging and wraps according to national guidelines.

WARNING

- 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.

1.7 Reprocessing before patient procedure

WARNING

- Improper storage practices, such as not thoroughly drying external surfaces 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 Accessory 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 ETO cap (MB-156)

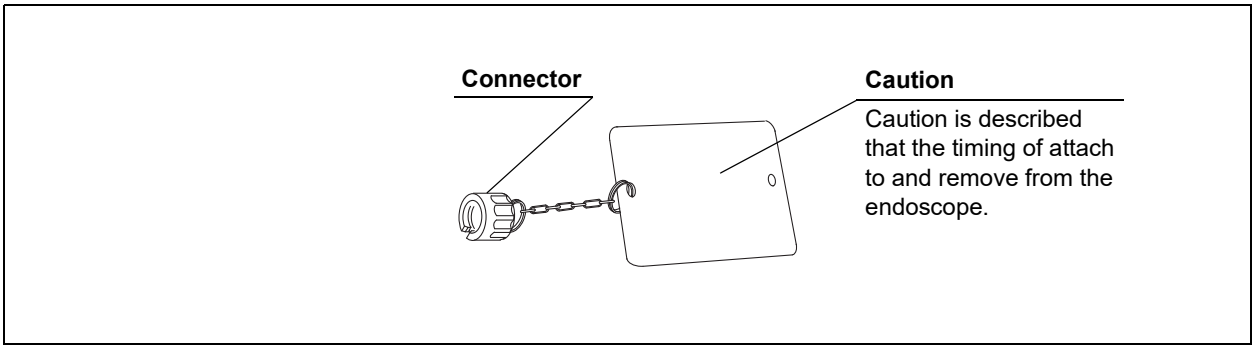


Figure 2.1

CAUTION

Failing to attach/remove the ETO 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 ETO 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.

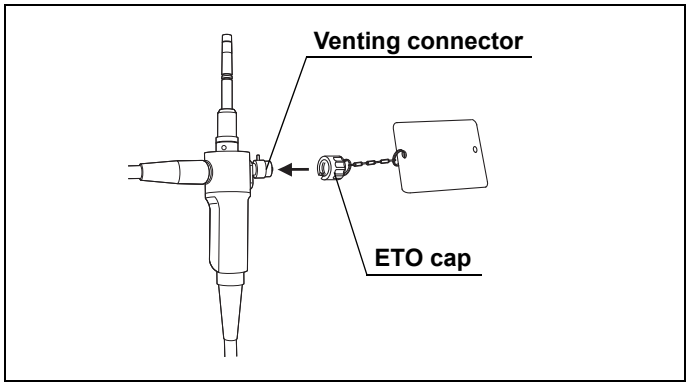


Figure 2.2

Inspection

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

Chapter 3 Compatible Reprocessing Methods and Chemical Agents

3.1 Compatibility summary

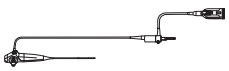
The endoscope and accessories are compatible with several methods of reprocessing. For information concerning the applicable reprocessing methods and parameters, refer to Section 3.2, “List of the compatible methods”. Additionally, some reprocessing methods may cause degradation of medical devices that shortens product life. For information concerning degradation of medical devices from reprocessing and its number of times, refer to Section 3.10, “Signs of degradation from reprocessing and its number of times”.
Follow the policies at your local institution when choosing which methods to employ.

CAUTION

- Methods listed as “compatible” in Table 3.1 are compatible for routine use only when used according to manufacturer’s instructions. Repeated use and reprocessing of endoscopes and accessories leads to gradual wear and tear. 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 accessory. For details on the chemicals and devices that can be used, refer to Section 3.3 and subsequent sections.

			Endoscope 	ETO cap (MB-156) 
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)		
		ETD4 (Peracetic acid)		
		ETD4 (Glutaraldehyde)		
		OER-AW*2 (Peracetic acid)*3		
	WD (alkaline detergent, thermal disinfection)			
Sterilization	Hydrogen perioxide *6	V-PRO® maX (Non Lumen cycle, Flexible cycle)		*4*5
		STERRAD® NX® with ALLClear™ Technology (Standard cycle, Advanced cycle)		*4*5
		STERRAD® NX® (Standard cycle, Advanced cycle)		*4*5
		STERRAD® 100NX® with ALLClear™ Technology (Duo cycle)		*5
		STERRAD® 100NX® (Duo cycle)		*5
		STERRAD® 100S (Long cycle with booster)		
		STERRAD® 100S (Short cycle, Long cycle)		*4*5
	Steam (autoclaving)			
	Ethylen oxide gas			
	Low Temperature steam and formaldehyde (LTSF)			

compatible not compatible

Table 3.1

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

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

*3 ACECIDE disinfectant solution, which is peracetic acid, is execlusively 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 of the endoscope, and may impair effective cleaning.
- Do not reuse detergent solution.

Use a neutral (20 – 45°C) or alkaline (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

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 3.9, “Hydrogen peroxide sterilization”.

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

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

■ 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 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.

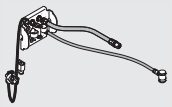
Model name	Accessories when ETD Double or ETD4 is used		
	Adapter 	Basket 	Configuration 
ETD Double	Olympus 1 (WD00120A)	(WD00117A)	Olympus 1-1
ETD4	–	E603 (E0425553)	–

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

3.8 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 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 3.7.

	OER-AW
ENF-VH	Group2

Table 3.7

3.9 Hydrogen peroxide sterilization

WARNING

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

CAUTION

- When performing STERRAD® 100S/NX® (with/without ALL Clear Technology) /100NX® (with/without ALL Clear Technology) sterilization, the ETO cap (MB-156) must be attached to the venting connector in order to avoid rupture of the bending section.

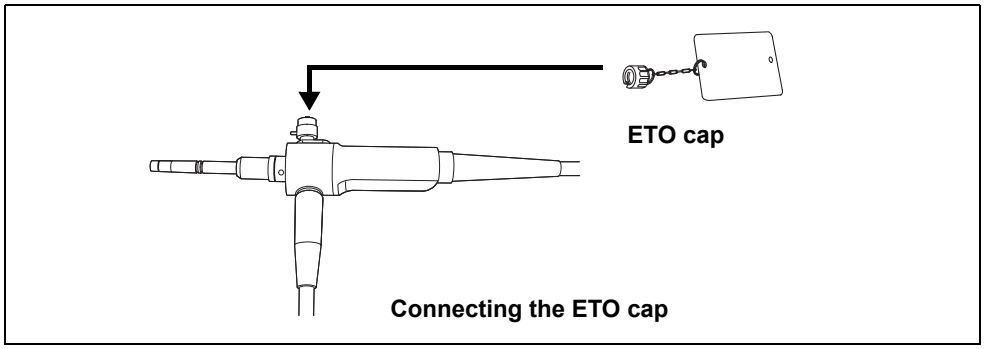


Figure 3.1

- Sterrad® may cause degradation. Please refer to Section 3.10 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 ETO cap (MB-156) must be attached to the venting connector in order to avoid rupture of the bending section. (See Figure 3.1)
- V-PRO® may cause degradation. Please refer to Section 3.10 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.

3.10 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.
  - Pitted, cracked, peeled or discolored adhesives at either end of the bending section shown as Figure 3.2.
  - Abnormal bulges or swelling, scratches and holes in the bending section
  - Swelling 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 Section Figure 3.2 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 3.2, insertion section or universal cord.

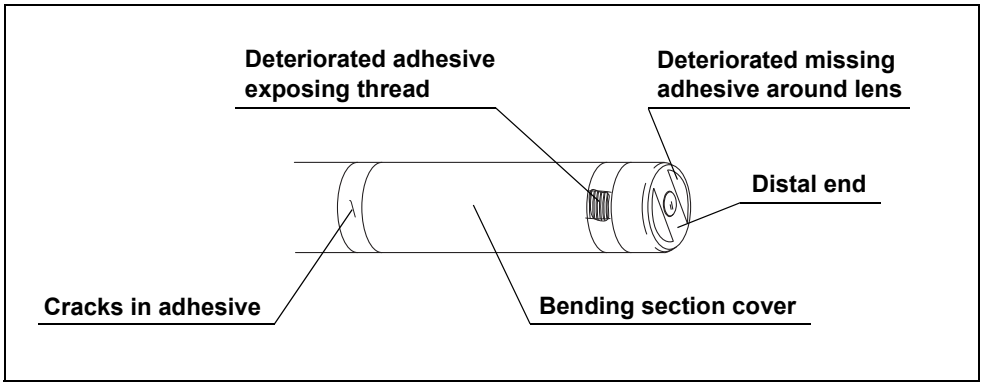


Figure 3.2

❍ Accessory (MB-156)

- Reprocessing may cause the above accessories to be pitted, cracked and discoloration. If you notice any of these signs of deterioration, discard and replace this accessory.

Reprocessing method			ETO cap (MB-156)
Manual cleaning	Alkaline enzymatic detergent		300 times
	Neutral enzymatic detergent		300 times
Manual disinfection	Peracetic acid		300 times
	Glutaraldehyde		300 times
Drying	Alcohol		Not Compatible
Automatic cleaning and disinfection	AER	ETD Double (Peracetic acid)	300 times
		OER-AW*1 (Peracetic acid)	–
	WD (Alkaline detergent, thermal disinfection)		Not Compatible
Sterilization	Hydrogen peroxide	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)		Not compatible
	Ethylene oxide gas		50 times

Table 3.8

*1 This product is not available in the member states of the EU.

3.10 Signs of degradation from reprocessing and its number of times

Chapter 4 Reprocessing Workflow for the Endoscope and Accessories

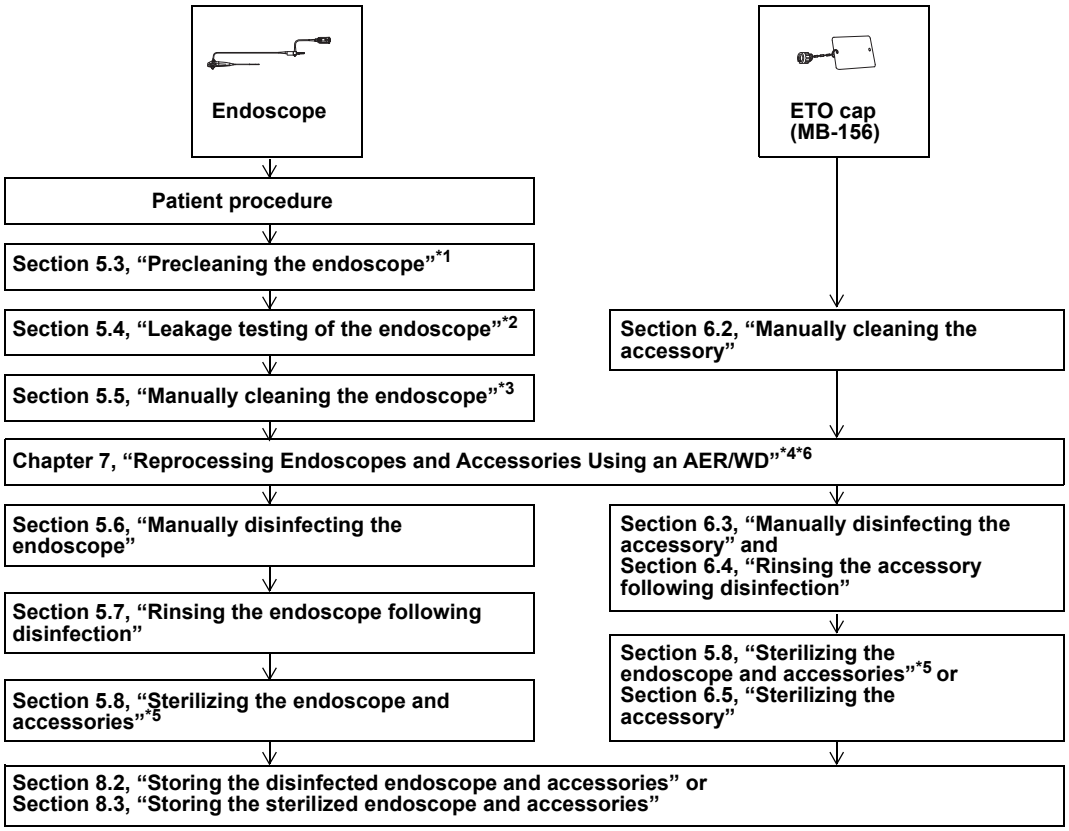
4.1 Summary of reprocessing workflow

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 the endoscope



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

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

*3 Depending upon the model of the AER/WD, you may be able to simplify the standard manual cleaning procedure. Refer to the instruction manual for the AER/WD.

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

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

*6 When the accessories are disinfected using AER, sterilization of the accessories is not required.

Chapter 5 Reprocessing the Endoscope (and related reprocessing accessories)

5.1 Summary of reprocessing the endoscope

The steps for reprocessing the endoscope are explained in this chapter.

The reprocessing workflow of all accessories is outlined in Chapter 4, “Reprocessing Workflow for the Endoscope 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 to contact the bending section. Such improper handling may damage the covering and cause the endoscope to leak.

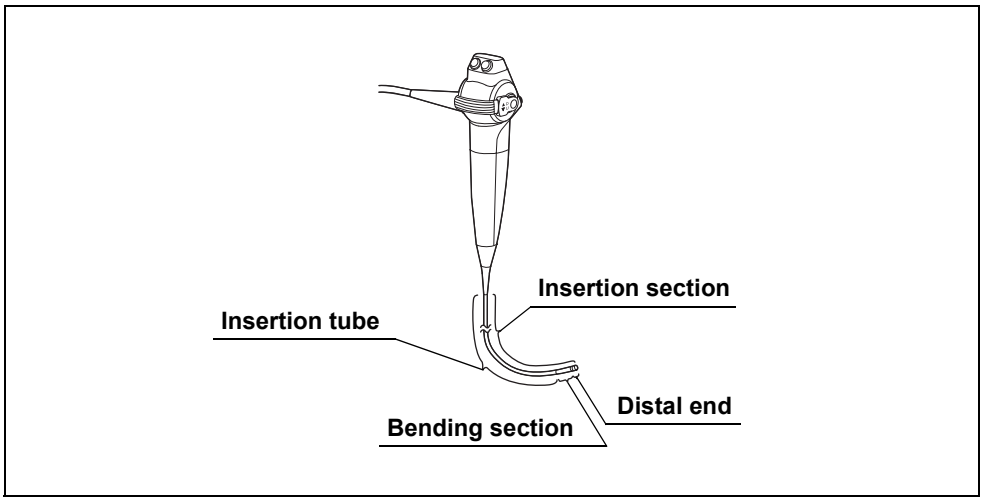


Figure 5.1

- 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.

CAUTION

- To prevent damage, do not coil the insertion tube or the universal cord of the endoscope with a diameter less than 10 cm.

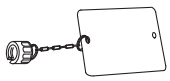
Use sterile equipment, such as sterile cloths, for all reprocessing steps occurring after immersion of the endoscope in disinfectant solution.

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

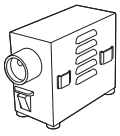


ETO cap (MB-156)

❍ Accessories and equipment for leakage test

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

+



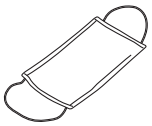
Maintenance unit (MU-1) (Sold separately. See its instruction manual.)

or

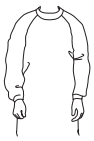
Leakage tester (WA23080A) (Sold separately.See its instruction manual.)

❍ Personal protective equipment (e.g.)

Eyewear



Face mask



Moisture-resistant clothing

Chemical-resistant gloves[*1]

❍ Other

- **Clean lint-free cloths[*2]**
- **Clean sponge(s)**
- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Water (See Section 3.5, "Water")**
- **Disinfectant solution (See Section 3.4, "Disinfectant solution for manual disinfection")**
- **Sterile lint-free cloths[*2]**
- **Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Sterile, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Detergent solution (See Section 3.3, "Detergent solution for manual cleaning")**
- **Rinse water (See 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. If gauze is used to reprocess the endoscope, ensure that fibers do not get caught on or remain trapped by protruding components.

5.3 Precleaning the endoscope

WARNING

If the endoscope used in the patient procedure is 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 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 sponge(s)**
- **Water (See Section 3.5, “Water”)**

■ 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.

Turn the video system center and light source OFF.

■ *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.

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

5.4 Leakage testing of the endoscope

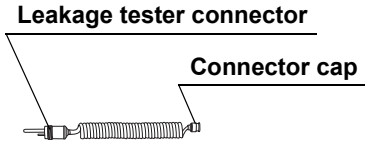
■ *Equipment needed*

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

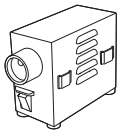
Leakage tester (WA23080A)
(Sold separately. See its instruction manual.)

- **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**

■ *Detach the endoscope from the video system center*

Detach the video connector from the video system center by pushing the locking lever down on the video system center.

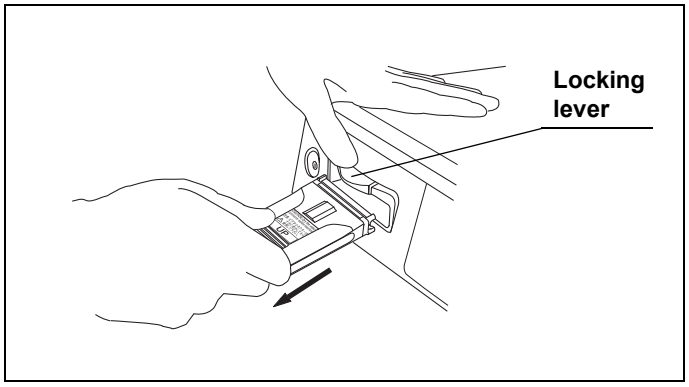


Figure 5.2

■ *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.

■ *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.

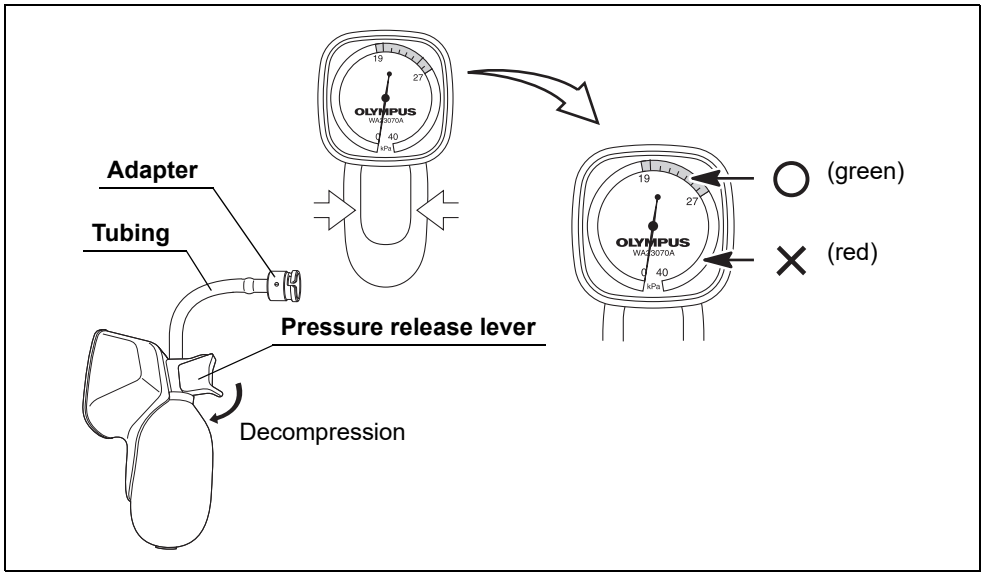


Figure 5.3

- 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, open the pressure release lever. Allow air to escape from the endoscope until 0 kPa is indicated on the display. 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 and the venting connector of the endoscope are dry. If not, dry with a clean, lint free cloth. Align the slit of the adapter with the pin of the venting connector on the endoscope. Push in the adapter and turn it clockwise until it stops.

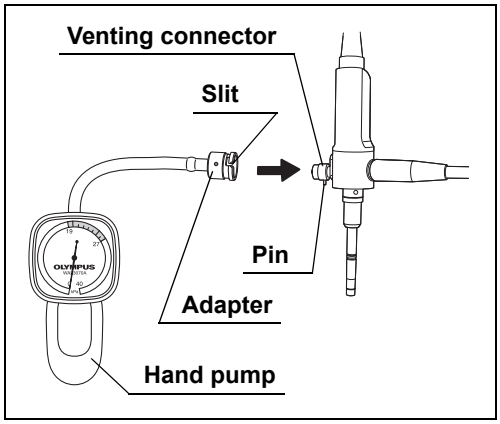


Figure 5.4

3 Confirm that the pressure release lever is closed.

4 Press the hand pump until a pressure between 19 and 27 kPa is indicated on the pressure display. The pointer must be within the “green area” on the pressure display. To detect a slight water leakage, pressurize to near 27 kPa. The pointer stabilizes several seconds after pressurization. Read the pressure when the pointer is stable.

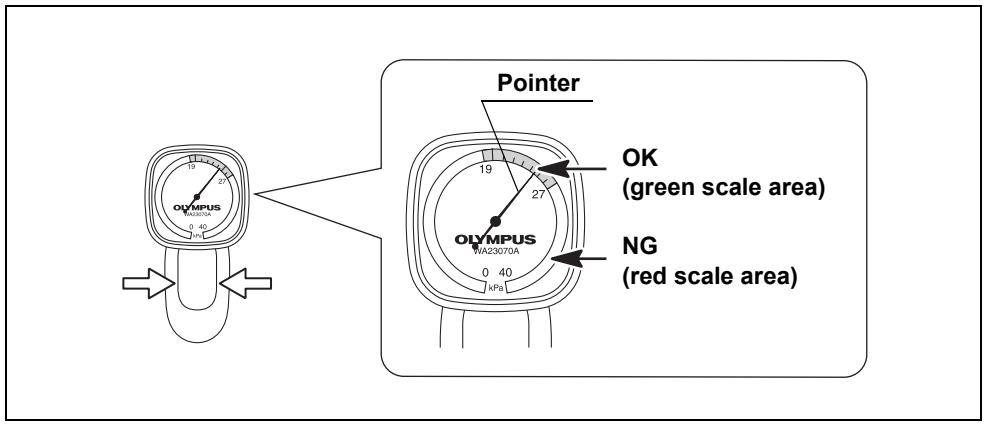


Figure 5.5

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 damages may occur.
- If continuous air bubbles emerge from the adapter during leakage testing, the adapter might be damaged. Repair the adapter as described in the instruction manual for the leakage tester.

5 Confirm that the pointer is stable. With the leakage tester attached, immerse the endoscope in the water and observe for approximately 30 seconds while deflecting the bending section of the endoscope by turning the endoscope's UP/DOWN angulation control lever. Confirm that there is no location on the endoscope from which a continuous series of air bubbles emerge.

NOTE

- A continuous series of air bubbles emerging from any location on the endoscope indicates a leak at that location.

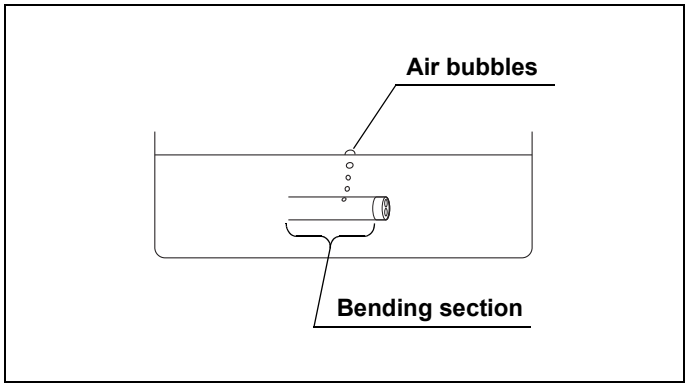


Figure 5.6

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

6 Remove the endoscope from the water with the leakage tester still attached.

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

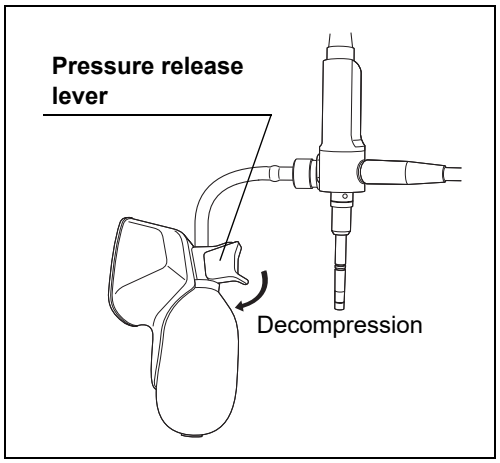


Figure 5.7

8 Detach the leakage tester from the endoscope's venting connector by turning the adapter counterclockwise.

9 Thoroughly dry the leakage tester using a clean lint free cloth.

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). Turn the maintenance unit ON.

3 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.

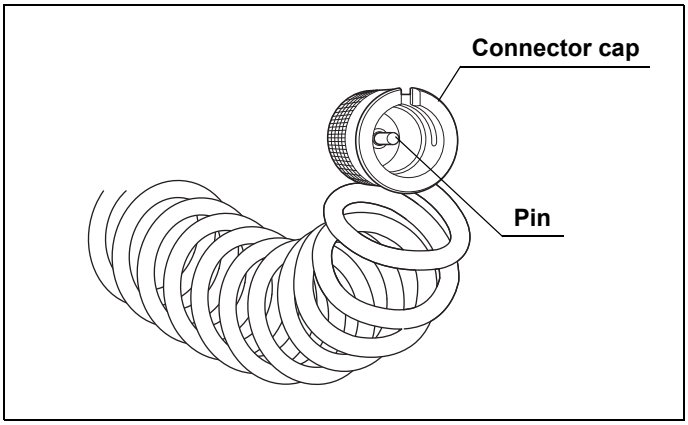


Figure 5.8

4 Confirm that both the connector cap of the leakage tester and the venting connector of the endoscope are dry. If not, dry with a clean, lint free cloth. Attach the connector cap to the venting connector by pushing on and rotating clockwise until it stops.

5 With the leakage tester attached, immerse the endoscope in the water and observe for approximately 30 seconds while deflecting the bending section of the endoscope by turning the endoscope’s UP/DOWN angulation control lever. Confirm that there is no location on the endoscope from which a continuous series of air bubbles emerges.

NOTE

- A continuous series of air bubbles emerging from any location on the endoscope indicates a leak at that location.

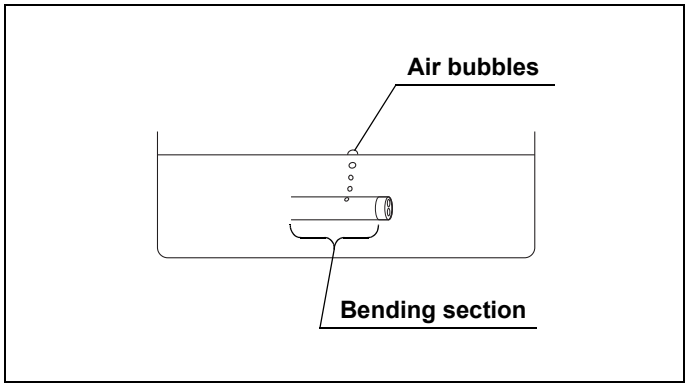


Figure 5.9

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

6 Remove the endoscope from the water with the leakage tester still attached.

7 Turn the maintenance unit OFF.

8 Detach the leakage tester from the maintenance unit.

9 Wait 30 seconds, or until the covering of the bending section contracts to its pre-expansion size. Detach the leakage tester from the venting connector.

10 Thoroughly dry the leakage tester using a clean lint-free cloth.

5.5 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.

- **Clean lint-free cloths**
- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Detergent solution (See Section 3.3, "Detergent solution for manual cleaning")**
- **Clean sponge(s)**
- **Water (See Section 3.5, "Water")**

■ Clean the external surface

❍ 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 endoscope in the detergent solution.

CAUTION

Do not use a stiff brush to clean the external surfaces of the endoscope. The endoscope may be damaged.

❍ Clean the external surfaces of the insertion section

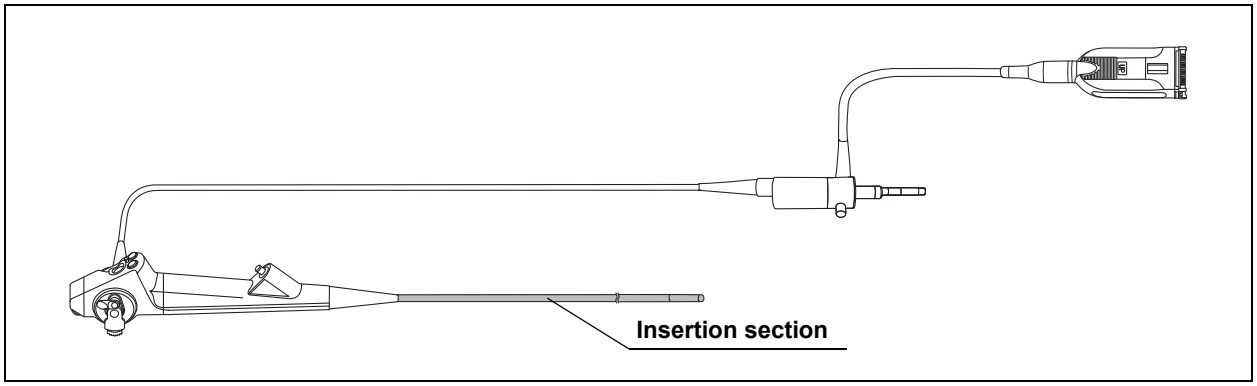


Figure 5.10

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

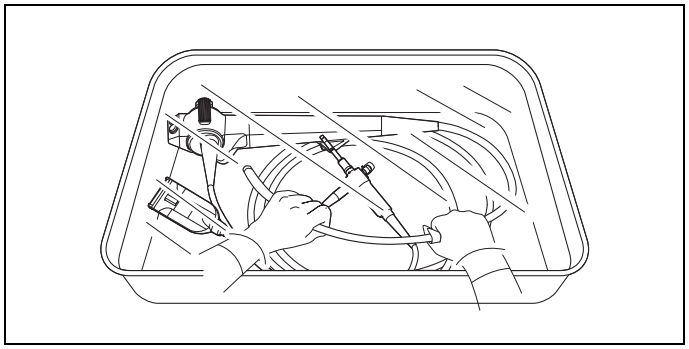


Figure 5.11

2 Take the insertion section out of the detergent solution and confirm that no debris remains on all its external surfaces, particularly the objective lens on the distal end.

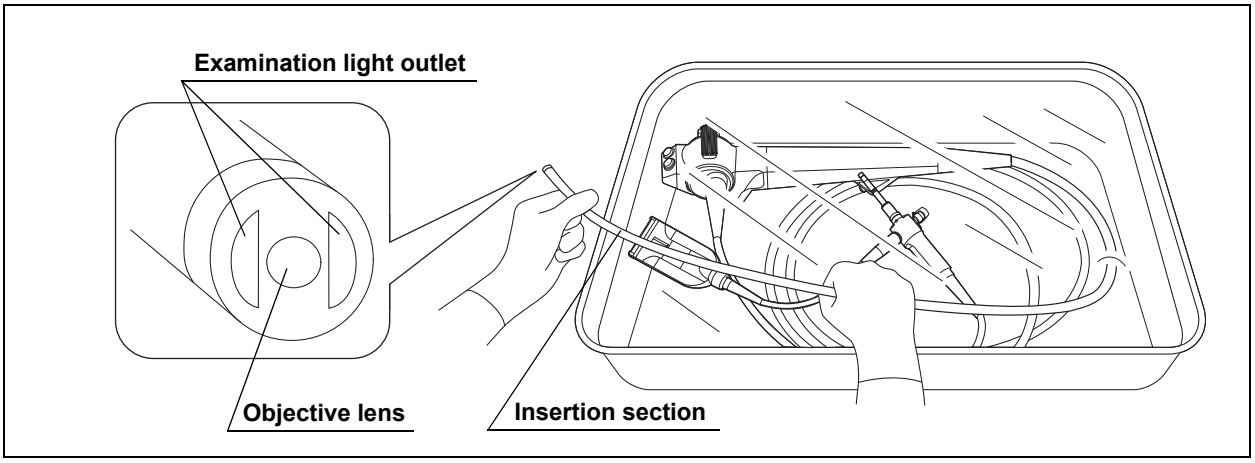


Figure 5.12

3 If any debris remains, repeat Step 1 and 2 until no debris is observed.

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

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

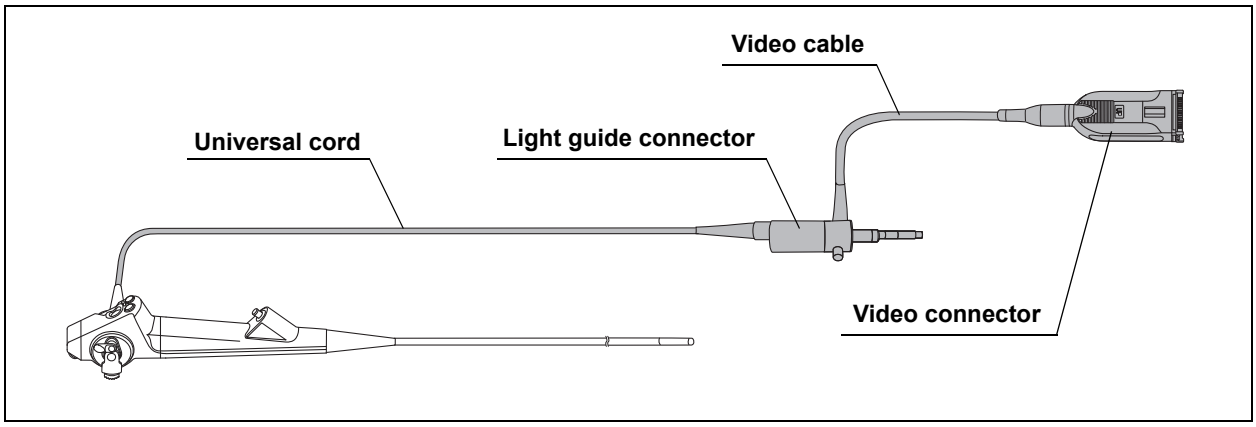


Figure 5.13

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

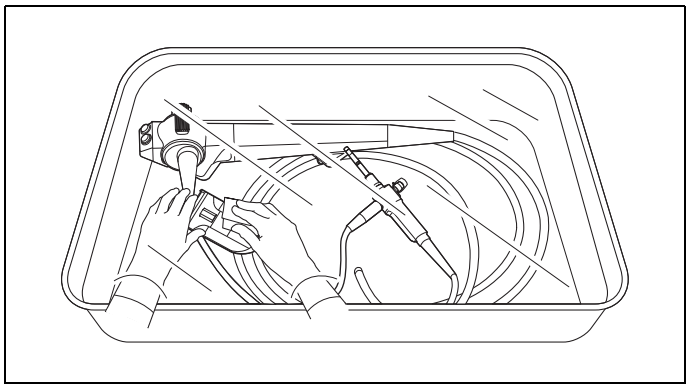


Figure 5.14

2 Take the light guide connector, the video connector, the universal cord, and the video cable out of the detergent solution and confirm that no debris remains on all their external surfaces.

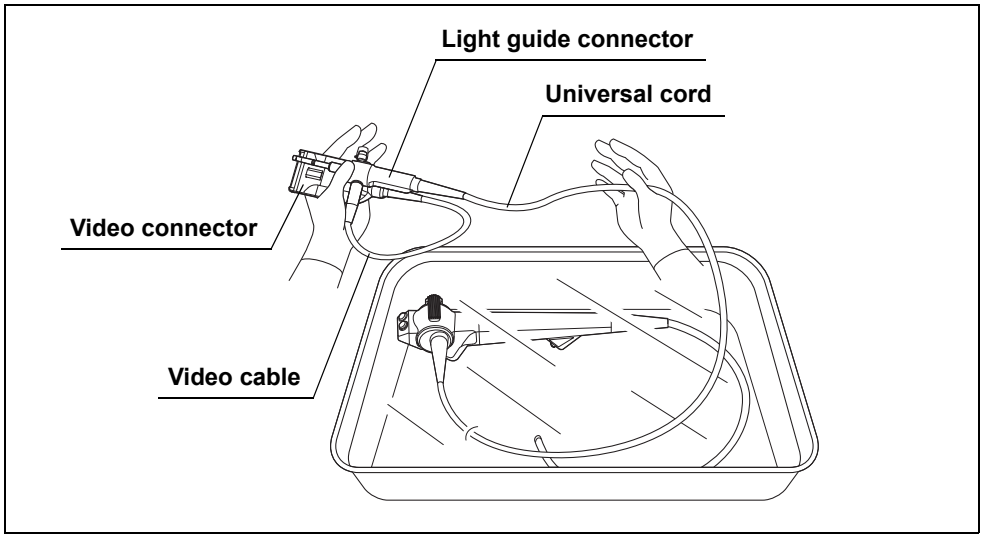


Figure 5.15

3 If any debris remains, repeat Step 1 and 2 until no debris is observed.

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

■ *Immerse the endoscope in detergent solution*

1 Leave the endoscope immersed in the detergent solution, according to the instructions of the detergent manufacturer.

2 Remove the endoscope from the detergent solution.

■ *Remove detergent solution from the endoscope*

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

2 Immerse the endoscope in the water and gently agitate them to thoroughly rinse.

3 Remove the endoscope from the water.

■ Dry the endoscope

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

5.6 Manually disinfecting the endoscope

■ Equipment needed

Prepare the following equipment.

- **Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Clean lint-free cloths**
- **Disinfectant solution (See Section 3.4, "Disinfectant solution for manual disinfection")**

■ 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.

■ *Immerse the endoscope in disinfectant solution*

WARNING

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

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 Immerse the endoscope in the disinfectant solution.

2 Confirm that the endoscope is completely immersed in the disinfectant solution.

3 Confirm that there are no air bubbles on the surfaces of the endoscope. If air bubbles adhere to the surfaces, wipe them away using your gloved finger or a clean lint-free cloth.

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

5 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.

■ *Remove the endoscope from disinfectant solution*

Remove the endoscope from the disinfectant solution.

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 channels of the endoscope and accessories. Otherwise, bacteria may proliferate in the channels 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, large basins**[*1] **(size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Rinse water (See Section 3.6, “Rinse water”)**

*1 Following disinfection, it is very important not to recontaminate the endoscope with potentially infectious microorganisms. When rinsing and drying the endoscope following disinfection, the use of sterile equipment (e.g., basin, cloths, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope 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. Immerse the endoscope in the rinse water.
3. Wipe all external surfaces of the endoscope, using a sterile lint-free cloth.
4. Remove the endoscope from the rinse water and place them in a sterile basin.
5. Repeat Step 1 through 4 for the necessary number of times described in the disinfectant manufacturer's instructions. If not specified, perform at least a total of two times.
6. Thoroughly dry the external surfaces of the endoscope by wiping with a sterile lint-free cloth(s).

5.8 Sterilizing the endoscope and accessories

■ *STERRAD® 100S/NX®/100NX® sterilization of the endoscope and accessories*

WARNING

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

CAUTION

Attach the ETO cap (MB-156) to the venting connector of the endoscope prior to STERRAD® 100S/NX®/100NX® sterilization. If the ETO 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. Thoroughly dry all external surfaces of the endoscope and accessories by wiping with sterile lint-free cloths.

2 Dry the external surfaces of the ETO cap (MB-156) by wiping with sterile lint-free cloths.

3 Attach the ETO cap (MB-156) to the venting connector on the control section as follows:

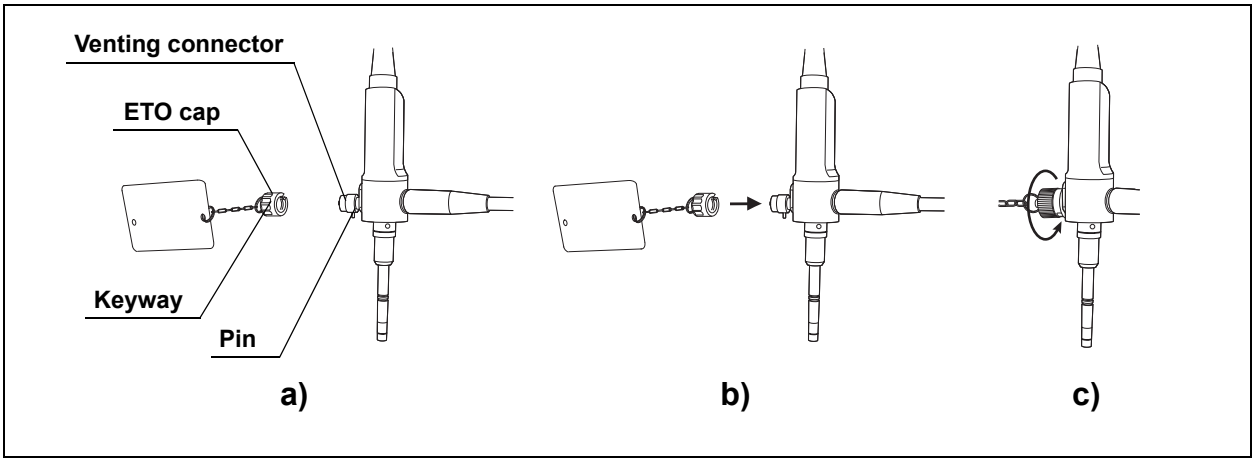


Figure 5.16

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

b) Push the ETO cap towards the control section of the endoscope until it stops;

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

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

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

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

WARNING

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

CAUTION

Attach the ETO cap (MB-156) to the venting connector on the light guide connector prior to V-PRO® maX sterilization. If the ETO 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 Thoroughly dry all external surfaces of the endoscope and accessories by wiping with sterile lint-free cloths.

2 Dry the external surfaces of the ETO cap (MB-156) by wiping with sterile lint-free cloths.

3 Attach the ETO cap (MB-156) to the venting connector on the control section as follows:

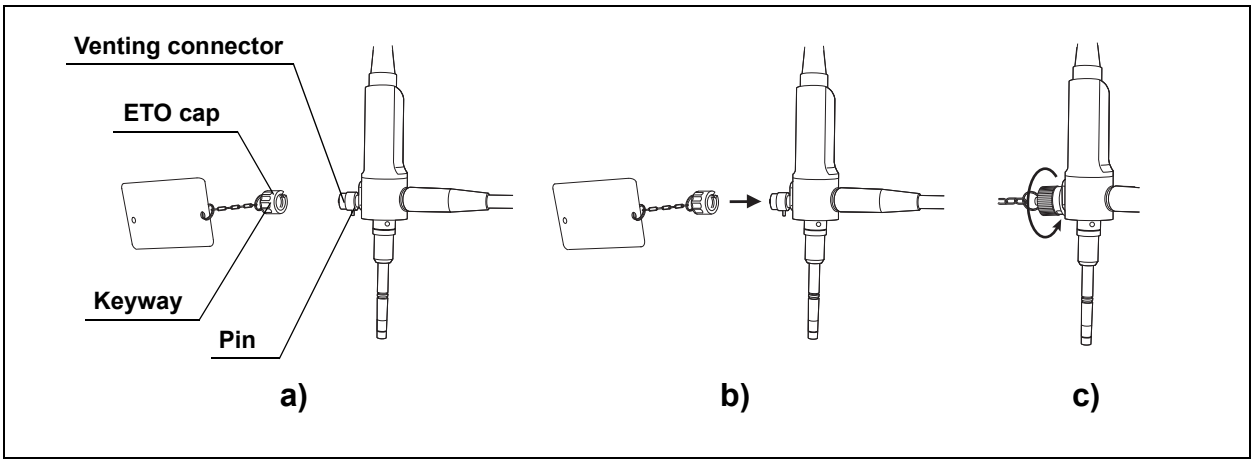


Figure 5.17

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

b) Push the ETO cap towards the control section of the endoscope until it stops;

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

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

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

5.9 Presoaking the endoscope

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

■ Equipment needed

Prepare the following equipment.

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

CAUTION

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

1. 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 at the temperature and concentration recommended by the detergent manufacturer.
3. Completely immerse the endoscope in the detergent solution.
4. Allow the endoscope to soak completely in the detergent solution for more than 0.5 hour. Do not immerse the endoscope for more than 1 hour.
5. Remove the endoscope from the detergent solution.
6. Return to Section 5.5, "Manually cleaning the endoscope" and reprocess according to the procedure. Even when using AER, perform all procedures according to Section 5.5 after presoaking.

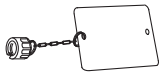
Chapter 6 Reprocessing the accessory

6.1 Summary of reprocessing the accessory

WARNING

All accessories (except single-use accessories) must be reprocessed after each use to prevent an infection control risk.

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



ETO cap (MB-156)

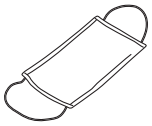
Use sterile equipment, such as sterile syringes and cloths, for all reprocessing steps occurring after immersion of the accessory in the disinfectant solution.

■ *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**
- **Sterile lint-free cloths[*2]**
- **Sterile 30 ml (30 cc) syringes[*2]**
- **Clean basins or containers**
- **Sterile basins or containers[*2]**
- **Detergent solution (Refer to Section 3.3, "Detergent solution for manual cleaning")**
- **Rinse water (Refer to Section 3.6, "Rinse water")**
- **Clean sponge**
- **Clean 30 ml (30 cc) syringes**
- **Sterile, small basins or containers[*2]**
- **Clean basin or container with tight-fitting lids**
- **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 Following disinfection, it is very important not to recontaminate the accessory with potentially infectious microorganisms. When rinsing and drying the accessory 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 accessory with potentially infectious microorganisms. Consult with your healthcare facility'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 accessory because the effectiveness of reprocessing is not guaranteed.

■ Equipment needed

Prepare the following equipment.

- **Clean lint-free cloths**
- **Clean 30 ml (30 cc) syringes**
- **Water (Refer to Section 3.5, "Water")**
- **Clean sponges**
- **Clean basins or containers**
- **Detergent solution (Refer to Section 3.3, "Detergent solution for manual cleaning")**

■ Clean the external surfaces

1. Fill a clean basin with the detergent solution at the temperature and concentration recommended by the detergent manufacturer.
2. Completely immerse the accessory in the detergent solution.
3. While immersing the accessory completely in the detergent solution, Wipe and clean all external surfaces of the accessory, using clean lint-free cloths or sponges.
4. Take the accessory out of the detergent solution and confirm that no debris remains on all their external surfaces.
5. If any debris remains, repeat Step 3 and 4 until no debris is observed.
6. When all debris is removed, put the accessory in the detergent solution again.

■ *Immerse the accessory in detergent solution*

CAUTION

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

1. Leave the accessory completely immersed in the detergent solution, according to the instructions of the detergent manufacturer.
2. Remove the accessory from the detergent solution.
3. Confirm that all debris is removed from all surfaces of the accessory.
4. If debris remains on any accessory, return to the beginning of Section 6.2, “Manually cleaning the accessory” and repeat the applicable procedures until all debris is removed.

■ *Remove detergent solution from the accessory*

❍ Immerse the accessory in water

1. Fill a clean basin with the water as described in Section 3.5, “Water”.
2. Completely immerse the accessory in the water.
3. Gently sway the accessory while immersing them completely in the water.

■ *Dry the accessory*

If the accessory will be disinfected (with manually or WD) soon after cleaning, this step may be skipped.

1. Remove the accessory from the water.
2. Thoroughly dry the external surfaces of the accessory by wiping with clean lint-free cloth.
3. Inspect the accessory for residual debris. If debris is found on any accessory, return to the beginning of Section 6.2, “Manually cleaning the accessory” and repeat the cleaning procedure until all debris is removed.

6.3 Manually disinfecting the accessory

WARNING

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

■ Equipment needed

Prepare the following equipment.

• **Clean lint-free cloths**	• **Clean 30 ml (30 cc) syringes**
• **Clean basins or containers with tight-fitting lids**	• **Detergent solution (Refer to Section 3.3, "Detergent solution for manual cleaning")**

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 accessory in the disinfectant solution.
3. Wipe the external surfaces of the accessory while immersed in the disinfectant solution, using your gloved fingertips or clean lint-free cloths to dispel any attached air bubbles.
4. Confirm that the accessory are completely immersed 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 the accessory immersed in the disinfectant solution. Follow the instruction of the disinfectant manufacturer regarding contact time, temperature, and concentration.
7. Remove all other accessories from the disinfectant solution.

6.4 Rinsing the accessory following disinfection

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

WARNING

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

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, small basins or containers**[*1]
- **Clean basins or containers**
- **Rinse water (Refer to Section 3.6, "Rinse water")**
- **Sterile 30 ml (30 cc) syringes**[*1]
- **Sterile basins or containers**[*1]
- **Clean basin or container with tight-fitting lids**

*1 Following disinfection, it is very important not to recontaminate the accessory with potentially infectious microorganisms. When rinsing and drying the accessory 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 accessory with potentially infectious microorganisms. Consult with your healthcare facility's infection control committee regarding local policies or requirements regarding reprocessing equipment.

■ *Rinse the accessory*

1. Fill a sterile basin with the rinse water as described in Section 3.6, “Rinse water”.
2. Immerse the accessory in the rinse water.
3. Gently sway the accessory while immersed.
4. Wipe the external surfaces of the accessory in the water, using sterile lint-free cloths.
5. Remove all other accessories from the rinse water. Place the accessory in a sterile basin.
6. Wipe and thoroughly dry the external surfaces of the accessory, using sterile lint-free cloths.

■ *Dry the accessory*

Refer to “■ Dry the accessory” on page 52 as the procedure is same.

6.5 Sterilizing the accessory

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).

■ STERRAD® 100S/NX® sterilization

WARNING

- Thoroughly dry the accessory 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 accessory.

NOTE

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

1. Seal the accessory in an individual packaging appropriate for STERRAD® 100S/NX® sterilization according to your institution's protocol.
2. Sterilize the packaged accessories, according to the parameters described in "■ STERRAD® 100S/NX®/100NX® sterilization of the endoscope and accessories" on page 44. In addition, always follow the instructions of the sterilizer manufacturer.

■ *V-PRO® maX sterilization*

WARNING

- Thoroughly dry the accessory 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 accessory.

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

2 Sterilize the packaged accessories, according to the parameters described in "❍ V-PRO® maX" on page 19. In addition, always follow the instructions of the sterilizer manufacturer.

Chapter 7 Reprocessing Endoscopes and Accessories Using an AER/WD

7.1 Reprocessing endoscopes and accessories using an AER

Follow the workflow described in Section 4.2, “Workflow for reprocessing the endoscope” 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.

WARNING

When cleaning and disinfecting the endoscope in the OER-AW or OER-Pro, use connectors/adaptors that are compatible with the endoscope model. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope. The applicable connectors/adaptors for the endoscope model should be listed in the “List of Compatible Endoscopes/Connecting Tubes” for the OER-AW, OER-Pro.

CAUTION

After reprocessing the endoscope using an AER, dry the electrical contacts of the endoscope connector not by air-drying but by wiping with sterile lint-free cloths.

7.2 Reprocessing endoscope and accessory using an ETD

- When setting the endoscopes in the ETD, put the forceps elevator in intermediate position of the range of movement by moving the elevator control lever and refer to the instruction manual for the 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.

■ Dry the endoscope and accessory

Refer to "■ Dry the endoscope" on page 41 and "■ Dry the accessory" on page 52 as the procedure is same.

■ 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 setting the endoscopes in the ETD, put the forceps elevator in intermediate position of the range of movement by moving the elevator control lever and refer to the instruction manual for the 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.

7.3 Reprocessing endoscopes and accessory using an OER-AW

■ 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 3.8, “OER-AW (Olympus Endoscope Reprocessor)”.
- OER-AW is not available in the member states of the EU.

■ Dry the endoscope and accessories

Refer to “■ Dry the endoscope” on page 41 and “■ Dry the accessory” on page 52 as the procedure is 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 lock in the "F▼" (or free) position.

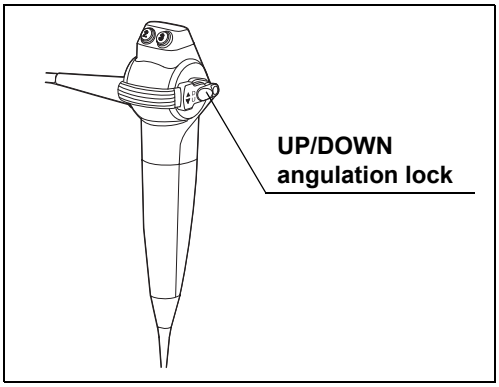


Figure 8.1

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.

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Date of Issue 2021-09-01
RC8203 02

Printed in Japan 20210830 *0000