

INSTRUCTIONS FOR USE (REPROCESSING)

PENTAX VIDEO COLONOSCOPES

EC-3890TLK
EC-2990Li, EC-3490Li
EC-3890Li, EC-3490TLi
EC-3490LK, EC-3890LK
EC-3890LZi, EC34-i10L
EC38-i10L

Product Overview

These instruments photograph the subject of observation using a solid-state image sensor located at the endoscope tip under the light transmitted from the processor/light source. The target of the observation is monitored by the physician using the endoscopic image displayed on the video monitor. The endoscopic procedure is performed by inserting biopsy forceps and other endoscopic accessories into the instrument channel inlet on the control body.

The bending section angulates in the intended direction and angle by operating the Angulation Control Knobs, air and water is fed from the distal end of the endoscope by operating the Air/Water Feeding Valve, and air or fluids can be suctioned from the distal end of the endoscope by operating the Suction Control Valve.

Indication for Use

This instrument is intended to be used with a PENTAX Video Processor (including light source), documentation equipment, Monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract including the anus, rectum, sigmoid colon, colon and ileocecal valve.

Application

Medical purpose: Provide images for optical visualization, recording, and/or diagnostic aid.

Patient populations: Adults and pediatrics who have been determined by the physician to be appropriate candidates for the use of these instruments.

Intended anatomical area: Lower gastrointestinal tract (rectum, sigmoid colon, colon and ileocecal valve)

User: Medical doctors (experts approved by the medical safety officer to perform endoscopic examinations at each medical facility)
Place of Use: Medical facility

Functions Used Frequently

The frequently used functions in these endoscope models are as follows:

- · Angulation capability using control knobs
- · Remote control operation using remote buttons
- · Air/Water feeding function
- · Suctioning function

Removable Components

OF-B118	Water Jet Connector Cap		
OF-B120	Suction Control Valve		
OF-B161	Suction Channel Selector (for EC-3890TLK only)		
OF-B188	Air/Water Feeding Valve		
OF-B190 Inlet Seal			
OE-C12 Water Jet Check Valve Adapter			

Notes

Read this Instructions for Use (IFU) before reprocessing the endoscope, and save this book for future reference. Failure to read and thoroughly understand the information presented in this IFU, as well as those developed for ancillary endoscopic equipment and accessories, may result in serious injury including infection by cross contamination to the patient and/or user. Furthermore, failure to follow the instructions in this IFU or the companion Instructions for Use (operation) may result in damage to, and/or malfunction of, the equipment.

It is the responsibility of each medical facility to ensure that only well-educated and appropriately trained personnel, who are competent and knowledgeable about the endoscopic equipment, antimicrobial agents/processes and hospital infection control protocol be involved in the use and the reprocessing of these medical devices. Known risks and/or potential injuries associated with flexible endoscopic procedures include, but are not limited to, the following: perforation, infection, hemorrhage, burns and electric shock.

This IFU describes the procedures for reprocessing and maintenance of the equipment after its use.

For inspection and preparation prior to its use, please refer to the separate Instruction for use (Operation).

The text contained in this IFU is common to various types/models of PENTAX endoscopes, and users must carefully follow only those sections and instructions pertaining to the specific instrument model in question.

If you have any questions regarding any of the information in this IFU or concerns pertaining to the safety and/or use of this equipment, please contact your local PENTAX representative.

Sterility Statement

These endoscopes identified in this IFU are reusable semicritical devices. Since they are packaged non-sterile, they must be high-level disinfected or sterilized BEFORE inital use. Prior to each subsequent procedure, they must be subjected to appropriate cleaning and either high-level disinfection or sterilization processes.

Contraindication

Please consult regional and national health authority recommendations and requirements regarding protocols to follow in order to reprocess and/or destroy endoscopes that will be used or have been determined to have been used (post procedure) on patients afflicted with Creutzfeldt-Jacob Disease (CJD or vCJD).

Conventions

Throuhghout this IFU, the following conventions will be used to indicate a potentially hazardous situation which, if not avoided;



: could result in death or serious injury.



: may result in minor or moderate injury or property-damage.



: may result in property-damage. Also advises owner/operator about important information on the use of this equipment.

Prescription Statement

Federal (U.S.A) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.

Symbols on Marking Symboles distinctifs



Symbol for "MANUFACTURER"



Attention, consult instructions for use Attention, consulter le manuel d'utilisation



Symbol for "DATE OF MANUFACTURE"



Type BF applied part (Safety degree specified by IEC 60601-1) Partie appliquée de type BF (niveau de sécurité spécifié par la norme CEI 60601-1)



Symbol for "Authorised Representative in the European Union"



このCEマーキングはEC指令への適合宣言マークです。

The CE marking assures that this product complies with the requirements of the EC directive for safety. Das CE Zeichen garantiert, daß dieses Produkt die in der EU erforderlichen Sicherheitsbestimmungen erfüllt. Le logo CE certifie que ce produit est conforme aux normes de sécurité prévues par la Communauté Européenne. Il marchio CE assicura che questo prodotto è conforme alle direttive CE relative alla sicurezza. La marca CE asegura que este producto cumple todas las directivas de seguridad de la CE.

CE 标志意味着保证该类产品遵从欧洲共同体安全法规。

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	4-1. PENTAX Medical Compatible Reprocessing Systems/Agents	

Reprocessing procedures of Video Colonoscopes can be classified into the following features of channel systems.

Classification of	Video Colonoscopes	Suction Channel		Air/Water	Water Jet
Channel Systems		Single	Two	Feeding Channel	Channel
Endoscopes with One Instrument Channel	EC-2990Li	Y	N	Y	Y
	EC-3490Li	Y	N	Y	Y
	EC-3890Li	Y	N	Y	Y
	EC-3490TLi	Y	N	Y	Y
	EC-3490LK	Y	N	Y	Y
	EC-3890LK	Y	N	Y	Y
	EC-3890LZi	Y	N	Y	Y
	EC34-i10L	Y	N	Y	Y
	EC38-i10L	Y	N	Y	Y
Endoscope with Two Instrument channels	EC-3890TLK	N	Y	Y	Υ

Y : YES N : NO General

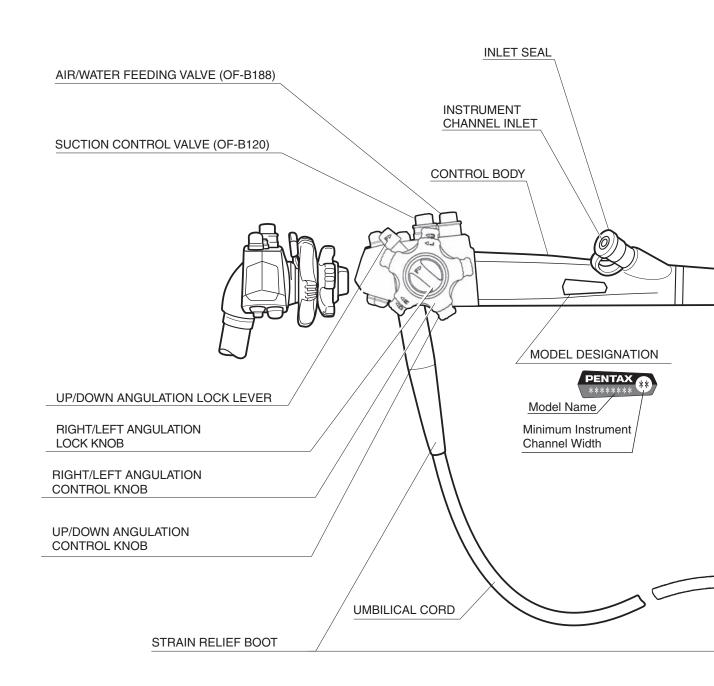
ndoscopes with one Instrument

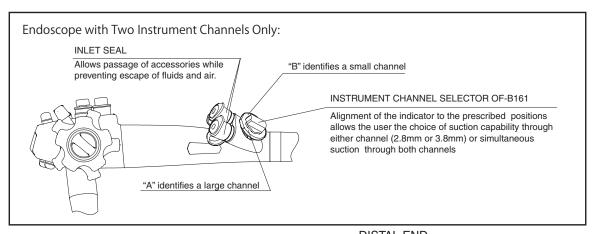
Endoscope with Two Instrument

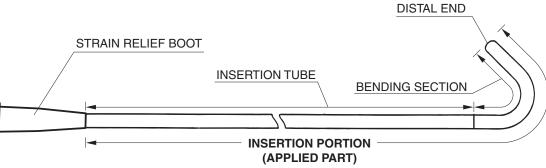
Accessory

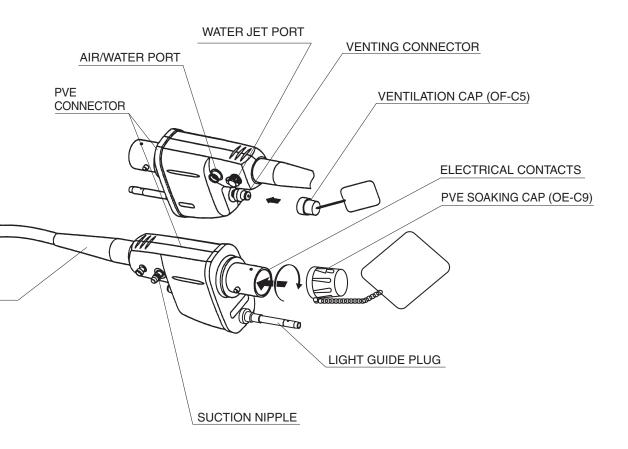
NOMENCLATURE

1. Video Colonoscopes (90K/90i Series) EC-3890TLK, EC-2990Li, EC-3490Li, EC-3890Li EC-3490TLi, EC-3490LK, EC-3890LK, EC-3890LZi



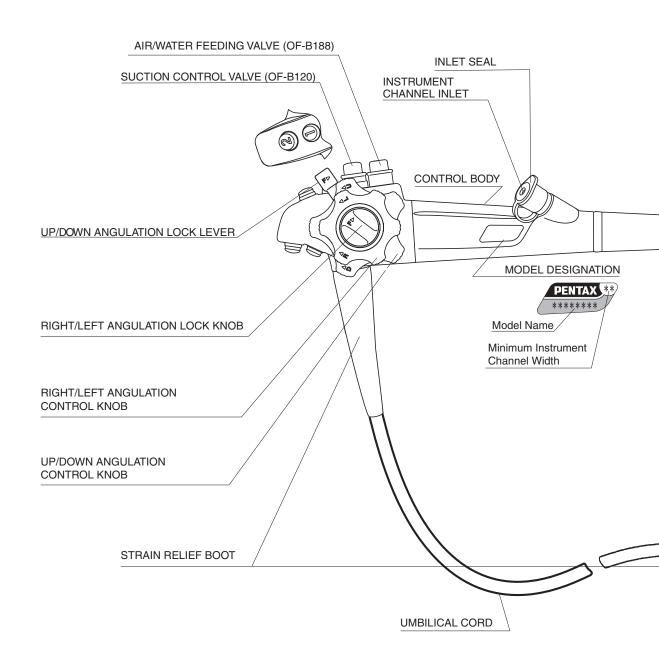


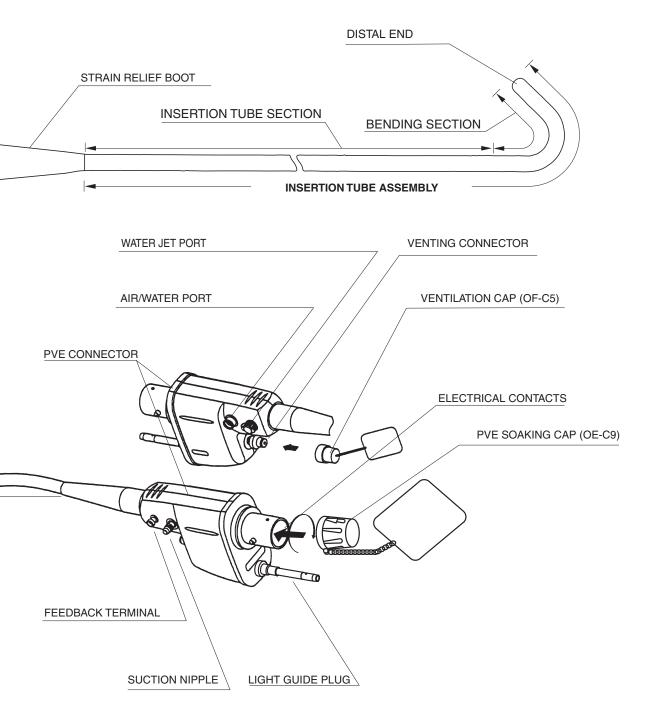




NOMENCLATURE

2. Video Colonoscopes (i10 Series) EC34-i10L, EC38-i10L





ENDOSCOPE REPROCESSING PROCEDURE FLOW

Pre-Cleaning

- Preparation
- Wiping of insertion tube
- Aspirating of detergent solution through suction channel
- Flushing of air/water channel with air
- Flushing of water jet channel with detergent solution
- Transport to cleaning room

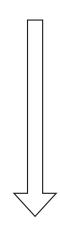


Leak Testing



Cleaning

- Preparation
- Cleaning of all external surfaces
- Brushing of suction channel, cylinder, port, and component
- Filling of detergent solution into channels
- Soaking in detergent solution
- Rinsing
- Drying





High-Level Disinfection

- Preparation
- Filling of disinfecting solution into channels
- Soaking in disinfecting solution
- Rinsing
- Drying

Optional Sterilization

1-1. General

NOTE)

This Instructions for Use (IFU) has been written having regard to 21CFR Part 801, ISO 17664, and national guidelines on reprocessing of medical products.

1-1-1. Application

General



Reprocessing may affect device functionality. Prior to use, always inspect the endoscope, components, and accessories for proper function to determine that they are appropriate for patient use.

Components and Accessories for Video Colonoscopes

MODEL					
			Endoscopes with	Endoscope with	
	Name	Number	One Instrument	Two Instrument	
			Channel	Channels	
			EC-2990Li		
			EC-3490Li		
			EC-3890Li		
			EC-3490TLi		
			EC-3490LK	K EC-3890TLK	
			EC-3890LK		
			EC-3890LZi		
			EC34-i10L		
			EC38-i10L		
	Suction Control Valve	OF-B120	Y	Y	
	Air/Water Feeding Valve	OF-B188	Y	Y	
Endoscope	Inlet Seal	OF-B190	Y	Y	
Component	Water Jet Check Valve Adapter	OE-C12	Y	Y	
	Water Jet Connector Cap	OF-B118		Y	
	Suction Channel Selector	OF-B161	N	Y	
Accessory	Irrigation Tube	OF-B113	Y	Y	
	PVE Soaking Cap	OE-C9		Y	
	Ventilation Cap	OF-C5	Y	Y	
	Cleaning Adapter	OF-B153	Y	Y	
Reprocessing	Cleaning Adapter	OF-G17	Y	Y	
Accessory	Cleaning Brush	CS-C9S	Y	Y	
	Cleaning Brush	CS6021T	Y	Y	
	Water Jet Channel Cleaning Adapter	OE-C20	Y	Y	

Y : YES N : NO

WARNING

• Reusable Medical Devices that are initially supplied as non-sterile require the end user to disinfect or sterilize them prior to initial use and to subsequently reprocess them after each subsequent use.

- Proper care of the device after each procedure is extremely important.
 Immediately (within one hour) after the completion of a procedure, the
 endoscope, its removable components, and accessories should be both
 pre-cleaned and mechanically cleaned with detergent solution. Generally,
 if these endoscopes and accessories are not precleaned within 15
 minutes and mechanically cleaned within one hour after the conclusion
 of the procedure, dried blood, mucus, or other patient debris may cause
 damage to the devices or interfere with the ability of the user to properly
 reprocess them.
- The use of detergent immediately after each procedure to dissolve and remove organic contaminants and proteinaceous debris is essential to the proper care and maintenance of the endoscope. Prior to disinfection or sterilization, all instruments and components must be meticulously cleaned. Failure to do so can result in incomplete or ineffective disinfection and sterilization.
- Always inspect reprocessed endoscopes and accessories prior to use according to their respective Instructions for Use (IFU).
- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- Contact the manufacturer and follow local regulations regarding safe use, appropriate handling, and disposal of cleaning and disinfection solutions, including alcohol and rinse water. Material Safety Data Sheets available from the cleaning and disinfection solution manufacturer should be consulted to provide guidance to end users about formulation, hazards, chemical and physical properties, first aid, handling and storage, stability, precautions, disposal, etc..

WARNING

Endoscopes are semicritical devices that require cleaning and at least high-level disinfection. Use only legally marketed solutions and/or automated endoscope reprocessors(AERs) for which validation testing with PENTAX products has been performed by their manufacturer. A list of legally marketed solutions/systems that have been determined to be compatible with PENTAX brand products is contained in this manual.

General

General



To avoid damaging the endoscope, do NOT twist, rotate or excessively bend any of the strain reliefs [(1), (2)] during inspection, clinical use, reprocessing, or any handling activity. Be particularly cautious regarding the insertion tube strain relief [(1)]. When wiping the insertion tube and the umbilical cord, use a slow back and forth motion to wipe them along the tube/cord. Never apply excessive force or torque to these strain reliefs or tubes/cords.

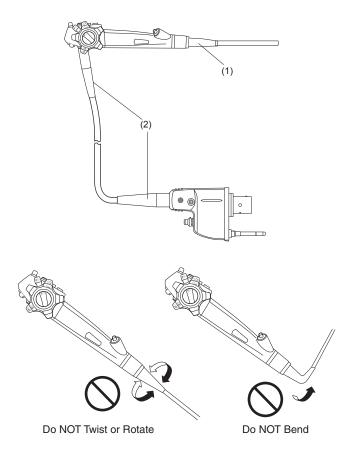


Figure 1.1.1

General

This IFU contains detailed recommendations on the manual reprocessing of PENTAX endoscopes using PENTAX supplied cleaning/disinfecting adapters. AERs may also be used to reprocess flexible endoscopes. However, only those AERs should be used whose manufacturers provide device-specific instructions and have validation data to support each AER claim with respect to PENTAX instruments. AER manufacturers should be consulted for their specific claims including, but not necessarily limited to:

- a) the ability of the AER to provide a cleaned and high-level disinfected (or sterilized) endoscope and endoscope components (e.g., valves),
- b) the identification of any special feature (internal channel) or endoscope component that cannot be reprocessed and therefore requires manual reprocessing,
- c) the microbial quality of the rinse water,
- d) the inclusion of an "automated" alcohol rinse cycle,
- e) the inclusion of a terminal drying cycle that removes the majority of water from within endoscope channels,
- f) maintenance procedures for water filter replacement and/or decontamination of the filtration system to ensure water of suitable quality,
- g) compliance with local regulations and/or guidelines.

NOTE |

PENTAX flexible endoscopes should not be exposed to temperatures in excess of 140°F (60°C) during either reprocessing or storage. During reprocessing, depending upon the detergent used, the endoscope may be damaged even if the temperature does not exceed 140°F (60°C). A list of detergents that are compatible with PENTAX endoscopes is contained in this manual.

NOTE]

All of the steps in the validated reprocessing protocol described in this manual are intended to be performed in rapid succession and as a single, continual procedure. There should be no breaks in between steps of the protocol that are of sufficient duration to permit the endoscope to dry to such an extent that dislodged debris and/or microbial contaminants would be permitted to dry onto any endoscope surface. In the event that drying of the endoscope occurs due to an excessive break in the reprocessing procedure, the procedure should be completely repeated, beginning with the first precleaning step.

General

1-1-3. Internal Channels of Video Colonoscopes

The following internal schematic diagnosis is designed to help users better understand the intricate construction of PENTAX endoscopes. Please note that all solution entrance ports and flow pathways are illustrated below.

1-1-3-1. Endoscopes with One Instrument Channel

EC-2990Li, EC-3490Li, EC-3890Li, EC-3490TLi, EC-3490LK, EC-3890LK, EC-3890LZi, EC34-i10L, EC38-i10L

- (7) (6) (1) (3) (2) (4) (5) (10)(9)(11)(13)(12)
- (1) Water Nozzle
- (2) Air Nozzle
- (3) Air/Water Channel
- (4) Suction Channel
- (5) Water Jet Channel
- (6) Instrument Channel Inlet
- (7) Inlet Seal (OF-B190)
- (8) Cleaning Adapter (OF-B153)
- (9) Water Jet Channel Cleaning Adapter (OE-C20)
- (10) Cleaning Adapter (OF-G17)
- (11) PVE Soaking Cap (OE-C9)
- (12) Ventilation Cap (OF-C5)
- (13) Suction Nipple

Figure 1.1.2

1-1-3-2. Endoscope with Two Instrument Channels

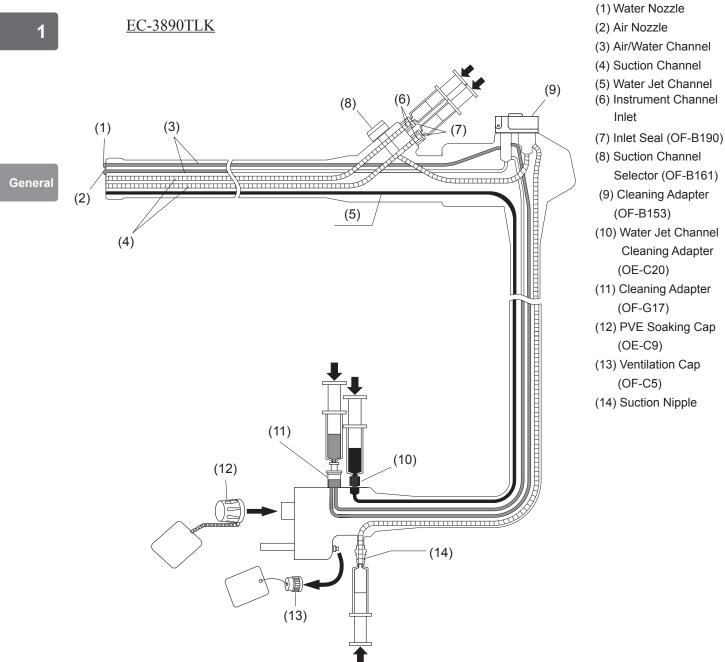


Figure 1.1.3

1-2. Endoscopes with One Instrument Channel

Video Colonoscopes with one instrument channel can be subjected to the following cleaning, disinfection, and optional sterilization processes.

	Cleaning		High-Level	Optional Sterilization	
Video Colonoscopes	Manual	Ultrasonic	Dinfection	Steam Sterilization	
EC-2990Li	Y	N	Y	N	
EC-3490Li	Υ	N	Υ	N	
EC-3890Li	Y	N	Y	N	
EC-3490TLi	Y	N	Y	N	
EC-3490LK	Y	N	Υ	N	
EC-3890LK	Υ	N	Υ	N	
EC-3890LZi	Υ	N	Y	N	
EC34-i10L	Y	N	Y	N	
EC38-i10L	Y	N	Y	N	



Endoscopes wit One Instrumen Channel

1-2-1. Pre-Cleaning

WARNING

- During reprocessing, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- Pre-cleaning is intended to remove visible debris from the endoscope immediately after its withdrawal from the patient, in order to increase the effectiveness of the subsequent cleaning procedure. Endoscopes that are retrieved from the patient are soiled with debris such as blood, tissues, and mucus. When such debris dries, it cannot be adequately removed in the subsequent cleaning procedure. It should be noted that pre-cleaning cannot substitute for the mechanical cleaning process. Always mechanically clean the endoscope after pre-cleaning.
- During pre-cleaning, never wipe the insertion tube with alcohol or disinfecting solution. These solutions may fix organic contaminants and proteinaceous debris to the instrument and have an adverse effect on endoscope functionality and proper reprocessing.
- When using detergent, use only legally marketed brands that have been tested and found to be compatible by PENTAX. A list of detergents that are compatible with PENTAX endoscopes is contained in this manual.
- When injecting detergent solution through an internal channels, ensure that detergent solution exits from the endoscope distal end. If not, the channel might be blocked. Never use an endoscope with a blocked channel. Contact your local PENTAX facility to arrange for repair of the device.

WARNING

• Please note that the forward water jet channel must undergo all steps of the endoscope reporocessing procedure, regardless of whether it was used during a clinical procedure.

Endoscopes with One Instrument • Immediately after use, the metal light guide plug and the electrical contacts/pins of the endoscope may be HOT. To avoid burns, do not touch these areas immediately after use. For safer handling after a procedure, grasp the PVE connector housing.

- In order to prevent damage the endoscope, do not place any objects other than Inlet Seal (OF-B190), Water Jet Check Valve Adapter (OE-C12), Irrigation Tube (OF-B113), Suction Control Valve (OF-B120), Air/Water Feeding Valve (OF-B188), and Water Jet Channle Cleaning Adapter (OE-C20) with the endoscope in the closed container used for transport to the reprocessing room.
- In order to avoid damaging the endoscope, never subject it to suction in excess of 66kPa.

NOTE

- If the use of detergent solution is not permitted in the procedure room, remove the endoscope from the procedure room and perform precleaning in another location.
- OE-C20 has been designed to leak slightly so as to insure contact between all cleaning fluids and the FWJ port on the scope.

1-2-1-1. Items required

Endoscope component

- Inlet seal (OF-B190)
- Suction control valve (OF-B120)
- Air/water feeding valve (OF-B188)

Reprocessing accessory

• Water jet channel cleaning adapter (OE-C20)

Other equipment

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Detergent solution, Endozime (Ruhof Corporation)
- Water bottle and Video processor
- · External suction source
- 500 mL basin
- Lint-free gauze
- 30 mL luer slip syringe

1-2-1-2. Preparation

- 1) Wear personal protective equipment.
- 2) Prepare a 500 mL basin with detergent solution per manufacturer's instructions (temperature, concentration). In the case of ENDOZIME, add 30 mL of ENDOZIME concentrate to 3.8 L (1 gallon) of clean potable water at 20°C~30°C (68°F~86°F).

1-2-1-3. Wiping the insertion tube

- 1) Turn off the lamp switch of the video processor.
- 2) Immediately after removing the endoscope from the patient, gently wipe the entire length of the insertion tube three times using lint-free gauze soaked with detergent solution.



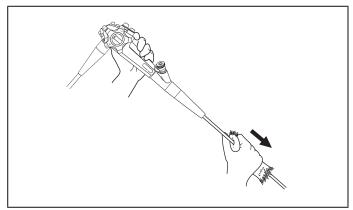


Figure 1.2.1

Endoscopes with One Instrument Channel

1-2-1-4. Aspirating detergent solution through the suction channel

- 1) Attach inlet seal (OF-B190) and suction control valve (OF-B120) to the endoscope.
- 2) Connect a suction tube from external suction source to the endoscope suction nipple.

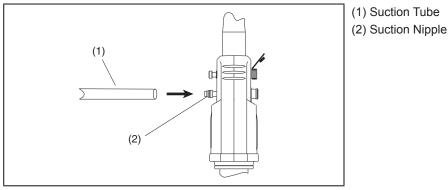


Figure 1.2.2

3) Turn on the external suction source.

Place the distal end of endoscope into a basin, and aspirate the detergent solution through the suction channel by pressing suction control valve (OF-B120) for 10 seconds.

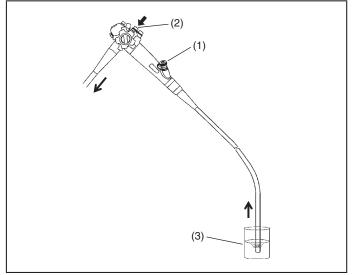


Figure 1.2.3

- Take the distal end out of the detergent solution, and aspirate air through the suction channel by pressing suction control valve (OF-B120) for 10 seconds.
- Turn off the external suction source. 6)
- 7) Disconnect tubing from the endoscope suction nipple.

1-2-1-5. Flushing the air/water channel with air

- Attach inlet seal (OF-B190) and air/water feeding valve (OF-B188) to the endoscope.
- 2) Connect the air/water feeding tube of the water bottle to the endoscope air/water port.

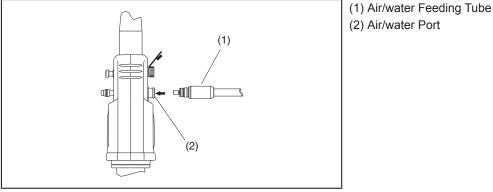


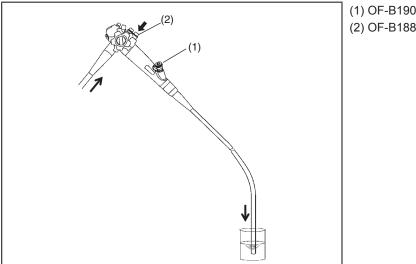
Figure 1.2.4

- Place the distal end of endoscope into a basin. 3)
- Set the lever on the water bottle to the drain position. 4)

(1) OF-B190

(3) Detergent Solution

With the air pump of video processor ON and set to the HIGHEST pressure setting, flush the air channel with air by covering the top of air/water feeding valve (OF-B188) for 10 seconds. Discharge all water in the water channel by pressing the button of OF-B188 for 10 seconds.



(2) OF-B188

Figure 1.2.5

Turn off the air pump of the video processor, and disconnect the air/water feeding tube of water bottle from the endoscope air/water port.

1-2-1-6. Flushing the water jet channel with detergent solution

Detach the Water Jet Check Valve Adapter (OE-C12) if it is attached, and attach the Water Jet Channel Cleaning Adapter (OE-C20) to the endoscope.

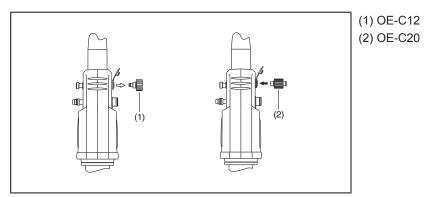


Figure 1.2.6

- 2) Place the distal end of endoscope into a basin.
- Attach a syringe filled with the detergent solution to the Water Jet Channel Cleaning Adapter (OE-C20), and flush the water jet channel with 10 mL of detergent solution. Ensure that a stream exits from the endoscope distal end.
- While the distal end of endoscope is still in a basin, using a syringe filled with air to flush the water jet channel with 30 mL of air to purge as much residual detergent solution as possible

1-2-1-7. Transport to cleaning room

- Turn off the power of the video proessor, and detach the endoscope PVE connector from the video processor.
- 2) Transport the pre-cleaned endoscope, detached OE-C12 and OF-B113 to the cleaning room in a closed container.

1-2-2. Leak Testing

Before reprocessing and/or immersion in any fluids, PENTAX endoscopes should be tested for the loss of integrity in their watertight construction by using a PENTAX brand leakage testers (SHA-P2 or SHA-P5). For specific details on PENTAX leak detection procedures, please refer to the instructions supplied with PENTAX leakage testers.

! CAUTION

Various types of endoscope leakage testers exist. Some are stand-alone units, and others may be integrated into an AER. PENTAX does not evaluate non-PENTAX leakage testers to verify their specific product claims with respect to their effectiveness to accurately detect leaks and/or their compatibility with PENTAX endoscopes. Insufficient pressures may reduce the likelihood for accurate leak detection, especially if the endoscope's distal bending section is not flexed during testing. Also, excessive pressures may adversely affect the endoscope, especially if pressurization occurs during automated reprocessing at elevated temperatures. PENTAX accepts no responsibility for use of non-PENTAX leakage testers. Users should check with the leakage tester manufacturer and confirm their specific product claims, including compatibility with PENTAX endoscopes at various temperatures and their ability to detect leaks with/without fluid immersion and with/without flexing of the endoscope's distal bending section.

Endoscopes with One Instrument Channel

WARNING

- During reprocessing, always wear protective equipment (e,g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- In order to ensure thorough cleaning, be sure to perform all cleaning steps. The effectiveness of each cleaning step will influence the effectiveness of subsequent steps. Failure to properly follow the cleaning steps described may result in incomplete or ineffective cleaning, disinfection and sterilization of endoscope, and may cause a crossinfection risk.
- Immediately (within one hour) after the completion of a procedure, the endoscope and its components should be thoroughly and carefully cleaned with detergent solution. If the endoscope and its components are left uncleaned for an excessive time after use, dried blood, mucus or other patient debris may cause damage or interfere with the ability of the user to properly reprocess the device.
- For cleaning, use only legally marketed detergents that have been tested according to the instructions of the manufacturer and found to be compatible by PENTAX. A list of detergents that are compatible with PENTAX endoscopes is contained in this manual.
- Fresh detergent solution must be used for each endoscope that is reprocessed.

!CAUTION

- <u>PVE soaking cap (OE-C9) must be properly secured over the electrical contacts.</u> Failure to do so can result in water invasion and damage to the endoscope. If an endoscope is cleaned **without** the PVE soaking cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.
- <u>Ventilation cap (OF-C5) must be taken OFF during reprocessing.</u> Failure to do so can result in damage to the endoscope. If an endoscope is cleaned **with** the ventilation cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.
- During cleaning, never twist, rotate, or bend the insertion portion, and umbilical cord excessively.
- Never subject the endoscope to ultrasonic cleaning methods.
- In order to prevent damage to the endoscope, do not place any objects other than the items the reprocessing accessories listed in section 1-2-3-1 of this Instructions for Use when immersing the endoscope in a cleaning basin.

NOTE

OE-C20 has been designed to leak slightly so as to insure contact between all cleaning fluids and the FWJ port on the scope.

Endoscopes with One Instrument

1-2-3-1. Items required

Endoscope component

• Inlet seal (OF-B190)

Reprocessing accessory

- PVE soaking cap (OE-C9)
- Cleaning brush (CS6021T)
- Cleaning brush (CS-C9S)
- Cleaning Adapter (OF-B153)
- Cleaning Adapter (OF-G17)
- Water jet channel cleaning adapter (OE-C20)

Other equipment

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Detergent solution, Endozime (Ruhof Corporation)
- · Clean potable water
- Basin sufficient in size to immerse the entire endoscope (at least 50 cm in width x 40 cm in depth x 15 cm in height)
- · Lint-free gauze
- 30 mL luer slip syringe
- 50 mL luer slip syringe

1-2-3-2. Preparation

- 1) Wear personal protective equipment.
- 2) Attach PVE soaking cap (OE-C9) to the endoscope.
- 3) Detach ventilation cap (OF-C5) from the endoscope.

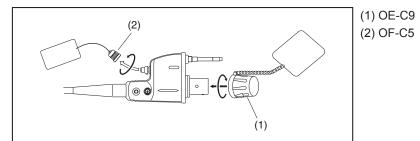


Figure 1.2.7

4) Fill a basin with a sufficient volume of detergent solution to completely immerse the endoscope. Prepare the detergent in accordance with the manufacturer's instructions (temperature, concentration). In the case of ENDOZIME, add 30 mL of ENDOZIME concentrate to 3.8 L (1 gallon) of clean potable water at 20°C~30°C (68°F~86°F).

! CAUTION

- Do not squeeze or severely bend the insertion tube.
- Do not use any abrasive materials.
- Be careful to avoid damage to the distal lenses.
- 1) Fully immerse the endoscope with the components attached in the detergent solution.
- 2) Detach inlet seal (OF-B190), suction control valve (OF-B120), air/water feeding valve (OF-B188), water jet channel cleaning adapter (OE-C20), and water jet connector cap (OF-B118) from the endoscope. Open the cap of OF-B190 in the detergent solution.

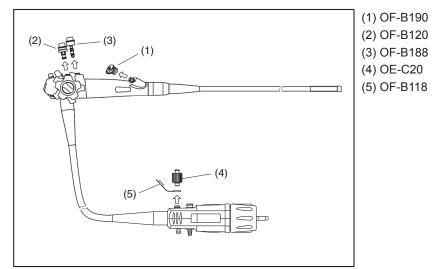


Figure 1.2.8

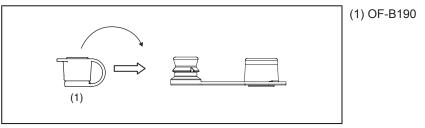


Figure 1.2.9

Endoscopes with One Instrument

One Instrument

3) OF-B190 and OE-C20 are reprocessed together with the endoscope, because they will be used for cleaning/disinfection of the endoscope. If these are to be reprocessed separately from the endoscope, follow the procedures described in the Section 1-4 "Endoscope components and accessories".

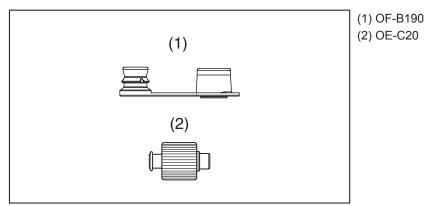


Figure 1.2.10

4) OF-B120, OF-B188, OF-B118, OE-C12, and OF-B113 are reprocessed separately from the endoscope, because these will be not used for cleaning/disinfection of the endoscope. (see Section 1-4 "Endoscope components and accessories")

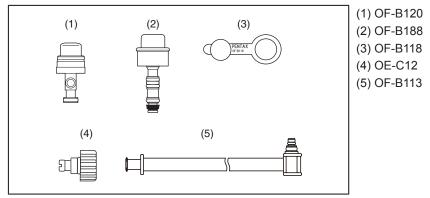


Figure 1.2.11

5) While still immersed in the detergent solution, wash the entire surface of endoscope three times with a lint-free gauze. Pay special attention to the distal end of the insertion tube by brushing it with the large brush head of cleaning brush (CS-C9S) until all soil has been removed. In similar fashion, use both brush heads of cleaning brush (CS-C9S) to remove soil from areas on the control body such as the grooved tips of the angulation knob spokes, areas behind and between the angulation knobs, area around the bases of the image control buttons, and the angulation lock lever and knob.

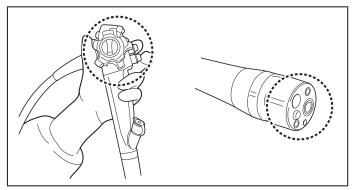


Figure 1.2.12

6) Wash the entire surface of OF-B190 and OE-C20 three times with a lint-free gauze.

1-2-3-4. Brushing suction channel, cylinder, port, and component

WARNING]

- Do not use cleaning brushes other than those are specified in this Instructions for Use. Failure to do so can result in endoscope damage or incomplete or ineffective cleaning.
- Cleaning brush (CS6021T) is provided non-sterile for one time use. Never reuse the brush on more than one instrument.
- Prior to use, ensure that cleaning brushes are not damaged (e.g., kinked shaft or bent or missing bristles).
- In order to prevent the reflux of patient debris left in the endoscope channel into the environment, always withdraw brushes slowly.

! CAUTION

- In order to avoid damage to the endoscope distal end, never attempt to insert a cleaning brush into endoscope distal tip .
- Do not insert cleaning brush (CS6021T) into the suction control valve cylinder. The brush head of cleaning brush (CS6021T) could become stuck within the suction control valve cylinder.
- Never apply excessive pressure to introduce or withdraw the brush. This can result in damage to the endoscope and/or the brush.
- Some manufacturers' cleaning brushes/ devices have been found to damage PENTAX endoscopes and/or create the need for service, as they can become lodged ("stuck") inside various lumens of PENTAX endoscopes. The likelihood of endoscope damage or servicing increases if a cleaning device does not have a protective tip (or contains any sharpedged surface), if its flexible shaft uses a flimsy plastic material that is not firm enough to allow for easy accessory advancement, and/or if the proper sequence and/or direction of channel cleaning is not followed as described in PENTAX IFU.
- To prevent excessive friction between brush and channel, do NOT tightly coil the insertion tube and umbilical cord to a diameter of less than 30cm. NEVER attempt to pass the cleaning brush through a fully angulated endoscope. Failure to follow these instructions can result in endoscope or brush damage.

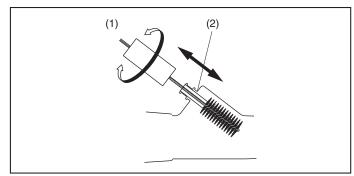
Endoscopes with One Instrument

1

One Instrument

Suction channel cleaning

Insert the large brush head of cleaning brush (CS-C9S) into the instrument channel inlet until it cannot be advanced further. Repetitively move the brush back and forth while twisting it left and right for one minute in order to scrub the entire inner surface of the instrument channel inlet.

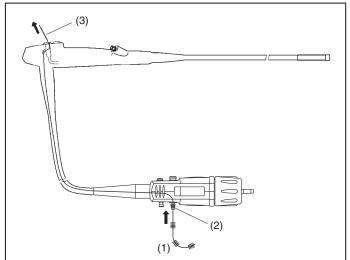


(1) CS-C9S

(2) Instrument Channel Inlet

Figure 1.2.13

- 2) Withdraw cleaning brush (CS-C9S) from the inlet, and clean the debris from the brush head by rubbing with fingers.
- 3) Repeat steps 1 and 2 three additional times.
- 4) Insert the blue tip of cleaning brush (CS6021T) into the opening of the suction nipple, and gently pass the brush until it appears in the suction cylinder.



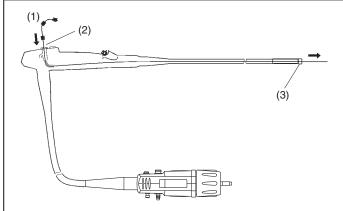
(1) CS6021T

- (2) Suction Nipple
- (3) Suction Cylinder

Figure 1.2.14

- 5) Grasp the blue tip of the brush shaft, and gently pull the brush from the suction cylinder until the brush heads exit the suction cylinder, and clean debris off the brush head by rubbing them with fingers.
- 6) Repeat the steps 4 and 5 three additional times.

7) Insert the blue tip of cleaning brush (CS6021T) into the opening at the bottom of the suction cylinder on the control head, and gently advance the brush until it exits the distal end of the endoscope.



| | Figure 1.2.15

- (1) CS6021T(2) Suction Cylinder
- (3) Distal End

(1) CS-C9S

(2) Suction Cylinder

Endoscopes wit One Instrumen Channel

- 8) Grasp the blue tip of the brush shaft, and gently pull the brush from the distal tip of the endoscope until it exits the distal end.
- 9) Repeat the steps 7 and 8 three additional times.

Cylinder cleaning

10) Insert the large brush head of cleaning brush (CS-C9S) into the suction cylinder until it cannot be advanced further. Repetitively move the brush back and forth while twisting it left and right for one minute in order to scrub the entire inner surface of the cylinder.

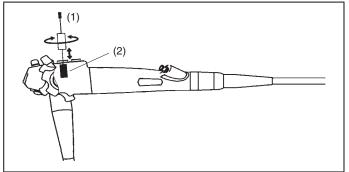


Figure 1.2.16

- 11) Withdraw the brush from the cylinder, and clean debris from the brush head by rubbing with fingers.
- 12) Repeat the steps 10 and 11 three additional times.



13) Insert the large brush head of cleaning brush (CS-C9S) into the air/water cylinder until it cannot be advanced further. Then repetitively move the brush back and forth while twisting it left and right for one minute in order to scrub the entire inner surface of the cylinder.

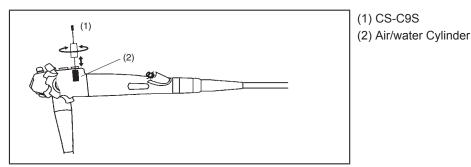


Figure 1.2.17

- 14) Withdraw the brush from the cylinder, and clean the debris from the brush head by rubbing with fingers.
- 15) Repeat steps 13 and 14 three additional times.

Water jet port cleaning

16) Insert the large brush head of cleaning brush (CS-C9S) into the water jet port until it cannot be advanced further, and rotate it for one minute to scrub the inner surfaces of the port.

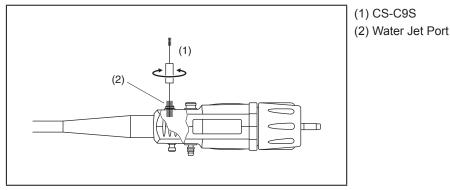


Figure 1.2.18

- 17) Withdraw the brush from the port, and clean the debris from the brush head by rubbing with fingers.
- 18) Repeat steps 16 and 17 three additional times.
- 19) After brushing the endoscope, dispose of CS6021T, which is a single-use accessory. Reprocess CS-C9S, which is a reusable accessory, according to Section 1-4 "Endoscope components and accessories".

1-2-3-5. Filling the channels with detergent solution

! WARNING

- While injecting detergent solution through the channels, avoid the introduction of air. The presence of air bubbles can prevent contact of the detergent solution with channel surfaces.
- Always fully immerse the endoscope while flushing detergent solution into the endoscope channel.
- It is imperative that the cleaning adapter (OF-B153) be securely attached to the endoscope. Failure to properly connect and secure the cleaning adapter can result in ineffective and incomplete reprocessing.

WARNING

 Please note that the forward water jet channel must undergo all steps of the endoscope reporocessing procedure, regardless of whether it used during a clinical procedure. Endoscopes wit One Instrumen Channel

1

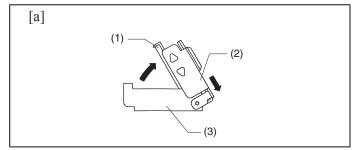
(CAUTION

In order to avoid damage to the endoscope, never apply excessive force if resistance is encountered while flushing the detergent solution into the channels.

Always immerse the endoscope, components, and accessories in the detergent solution during cleaning.

Attaching components and accessories to the endoscope

- According to the following procedure, attach cleaning adapter (OF-B153) to the air/ water cylinder and suction cylinder. This adapter caps (seals) off the air/water and suction cylinders to allow unidirectional flow of solution through these delivery/ aspiration systems.
 - [a] Raise the locking cap and slide the side covers (marked with \triangle) downward.
 - [b] Align the cylinder guide over the air/water and suction cylinder ports.
 - [c] Slide the OF-B153 forward.
 - [d] Holding the side covers (marked with \triangle), push down and slide the locking cap under the locking tab to secure.
 - [e] Secure the locking cap with the locking tab on the base.



- (1) Rubber Seal
- (2) Locking Cap
- (3) Base



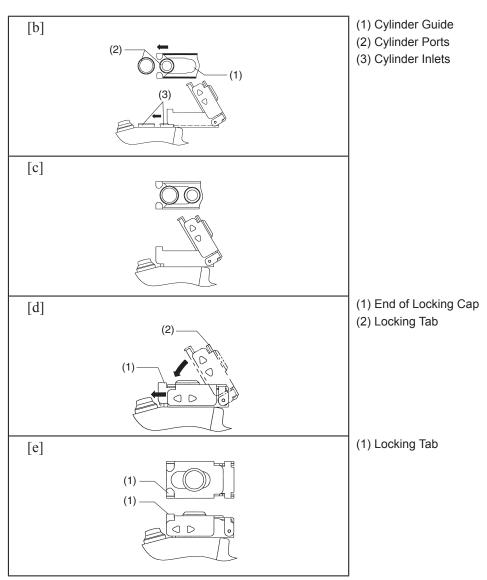


Figure 1.2.19

2) Attach the inlet seal (OF-B190), cleaning adapter (OF-G17), and water jet channel cleaning adapter (OE-C20) to the endoscope.

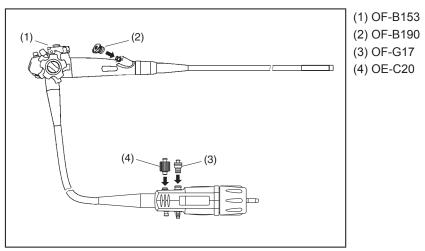


Figure 1.2.20

3) Attach a syringe filled with the detergent solution to OF-G17, and inject 30 mL of detergent solution into the air/water channel.

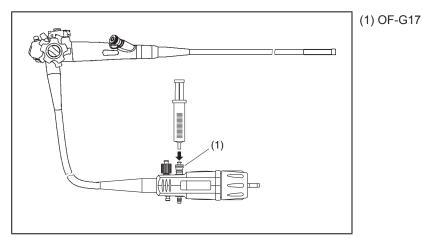


Figure 1.2.21

Endoscopes wi One Instrumer Channel

- 4) Check to confirm that detergent solution flows out from the air/water nozzle(s) on the distal end.
- 5) Attach a syringe filled with the detergent solution to the suction nipple, and inject 55 mL of the detergent solution into the suction channel.

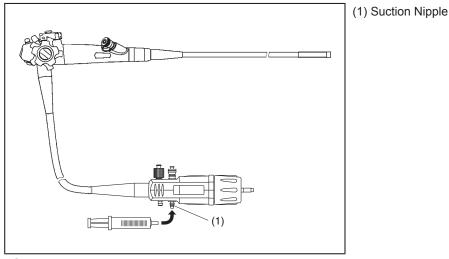


Figure 1.2.22

6) Check to confirm that detergent solution flows out from the suction channel opening on the distal end.

7) Insert a syringe filled with the detergent solution to OF-B190, and inject 55 mL of the detergent solution into the suction channel.

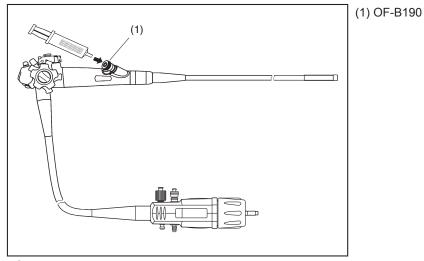


Figure 1.2.23

8) Attach syringe filled with detergent solution to OE-C20, and inject 15 mL of the detergent solution into the water jet channel.

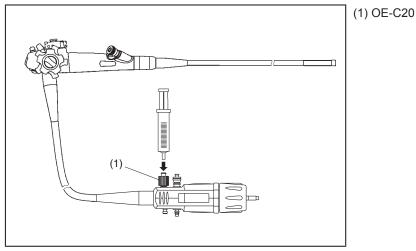


Figure 1.2.24

9) Check to confirm that the injected detergent solution flows out from the water jet channel opening on the distal end.

10) After injecting detergent solution into all channels, detach OF-B153, OF-B190, OF-G17, and OE-C20 from the endoscope, and leave them to soak along with the endoscope in the detergent solution until the next step. Open the cap of OF-B190.

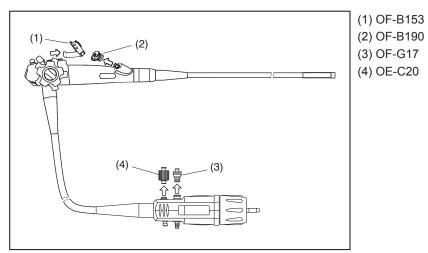


Figure 1.2.25

Channel

1-2-3-6. Soaking in detergent solution

WARNING

- The detergent solution must remain in contact with ALL internal channels, external endoscope surfaces, and components for the time period recommended by the manufacturer of the detergent.
- During immersion, detach all components and accessories (except the soaking cap) from the endoscope to ensure contact of all endoscope surfaces with the detergent solution.

! CAUTION

NEVER subject the endoscope to ultrasonic cleaning method.

1) While fully immersing the endoscope, inlet seal (OF-B190), and cleaning adapters (OE-C20, OF-B153, and OF-G17), ensure that there are no air bubbles on the endoscope surfaces, distal end, and accessories. If any air bubbles are detected, flush them away with detergent solution using a syringe.

2) Soak the endoscope, OF-B190, OE-C20, OF-B153, and OF-G17 under conditions (temperature, concentration, time) specified by the detergent manufacturer. In the case of Endozime, the soaking time is at three minutes.

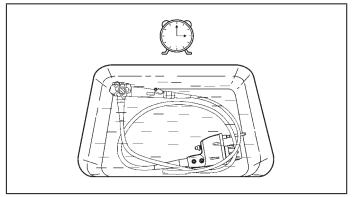


Figure 1.2.26

3) After soaking, ultrasonically clean OF-B190 according to Section 1-4 "Endoscope components and accessories".

Purging detergent solution from all channels

- 4) After ultrasonic cleaning, attach OF-B190, OE-C20, OF-B153, and OF-G17 to the endoscope.(see Figure 1.2.20, p27)
- 5) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air to purge as much residual detergent solution as possible. (see Figure 1.2.21, p28)
- 6) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 220 mL of air to purge as much residual detergent solution as possible. (see Figure 1.2.22, p28)
- 7) Insert a syringe filled with air to OF-B190, and flush the suction channel with 220 mL of air to purge as much residual detergent solution as possible. (see Figure 1.2.23, p29)
- 8) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air to purge as much residual detergent solution as possible. (see Figure 1.2.24, p29)
- 9) Take the endoscope with the components and accessories attached out of the detergent solution.

WARNING

It is important that all internal channels, external endoscope surfaces and components be thoroughly rinsed with clean water to remove residual detergent solution. Failure to do so can result in ineffective or incomplete disinfection and sterilization.

First rinse

- 1) Place the endoscope with the components and accessories attached into a basin of clean water that is of sufficient volume to completely immerse the endoscope.
- 2) Detach the inlet seal (OF-B190) and cleaning adapters (OE-C20, OF-B153, and OF-G17) from the endoscope. Open the cap of OF-B190. (see Figure 1.2.25, p30)
- 3) Wipe all exterior surfaces of the endoscope, OF-B190, OE-C20, OF-B153, and OF-G17 one time with lint-free gauze in order to remove residual detergent solution.
- While still completely immerse in water, grasp the distal end, control body of endoscope, and PVE connector with two hands, and agitate it under the water by moving it from side to side repeatedly for one minute.

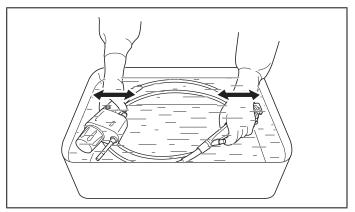


Figure 1.2.27

- 5) Similarity, grasp OF-B190, OE-C20, OF-B153, and OF-G17 with a hand, and agitate them under the water by moving them from side to side repeatedly for one minute.
- 6) Attach OF-B190, OE-C20, OF-B153, and OF-G17 to the endoscope. (see Figure 1.2.20, p27)
- 7) Attach a syringe filled with water to OF-G17, and flush the air/water channel with 90 mL of water. (see Figure 1.2.21, p28)
- 8) Attach a syringe filled with water to the suction nipple, and flush the suction channel with 220 mL of water. (see Figure 1.2.22, p28)
- 9) Insert a syringe filled with water to OF-B190, and flush the suction channel with 220 mL of water. (see Figure 1.2.23, p29)
- 10) Attach a syringe filled with water to OE-C20, and flush the water jet channel with 35 mL of water. (see Figure 1.2.24, p29)
- 11) Take the endoscope with the components and accessories attached out of the water.
- 12) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air. (see Figure 1.2.21, p28)
- 13) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 220 mL of air. (see Figure 1.2.22, p28)

One Instrument

- 14) Insert a syringe filled with air to OF-B190, and flush the suction channel with 220 mL of air. (see Figure 1.2.23, p29)
- 15) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air. (see Figure 1.2.24, p29)

Second rinse

16) Fill a basin with clean water, and repeat steps 1 - 15 in order to perform a second complete rinse.

Third rinse

17) Fill a basin with clean water, and repeat steps 1 - 15 in order to perform a third complete rinse.

Fourth rinse

- 18) Fill a basin with clean water, and repeat steps 1 15 in order to perform a fourth complete rinse.
- 19) Detach OF-B190, OE-C20, OF-B153, and OF-G17 from the endoscope. (see Figure 1.2.25, p30)

1-2-3-8. Drying

1) Gently wipe and dry all external surfaces of endoscope, components, and accessories with a new lint-free gauze.

1-2-4. High-Level Disinfection

Prior to high-level disinfection, the end user should confirm the minimum effective concentration (MEC) of reused disinfectant as per the manufacturer's instructions.

WARNING

- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- Prior to disinfection, it is imperative that any solutions previously used in the cleaning process be thoroughly rinsed and dried. Failure to do so can result in ineffective or incomplete disinfection.
- For high-level disinfection, use an appropriate disinfecting solution according to the instructions of the disinfectant manufacturer (temperature, concentration, time). Adhere to the instructions to accomplish effective and complete disinfection. The endoscope may be damaged if exposed to a disinfectant under conditions other than those specified by the disinfectant manufacturer.
- Use only a legally marketed disinfectant that has been tested according to the instructions provided by the manufacturer and found to be compatible by PENTAX. A list of disinfectants that are compatible with PENTAX endoscopes is contained in this manual.
- It is imperative that ALL internal channel surfaces of the channels be in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.
- Ideally, all final rinses should be performed with sterile water, or clean potable water, or the water that meets the requirements of the health care facility.
- Regardless of the quality of the rinse water used, it is essential to perform a final alcohol rinse followed by forced air in order to completely dry the endoscope channels and prevent bacterial colonization and/or infections associated with waterborne microorganisms.
- The basin that is used to perform disinfectant immersion should be thoroughly cleaned prior to filling it with disinfectant solution.

WARNING

• Please note that the forward water jet channel must undergo all steps of the endoscope reporocessing procedure, regardless of whether it was used during a clinical procedure.

Endoscopes with
One Instrument

 Prior to disinfection, attach PVE soaking cap (OE-C9). Failure to do so can result in water invasion and damage to the endoscope. If the endoscope is disinfected without the PVE soaking cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.

- Prior to disinfection, detach the ventilation cap (OF-C5). Failure to do so can result in damage to the endoscope. If the endoscope is disinfected with the ventilation cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.
- During disinfection, never twist, rotate or bend the insertion tube and umbilical cord excessively.
- In order to prevent damage to the endoscope, do not place any objects other than the reprocessing accessories described in section 1-2-4-1 of this Instructions for Use when immersing the endoscope in the disinfection basin.

NOTE]

OE-C20 has been designed to leak slightly so as to insure contact between all disinfecting fluids and the FWJ port on the scope.

1-2-4-1. Items required

Endoscope component

• Inlet seal (OF-B190)

Reprocessing accessory

- PVE soaking cap (OE-C9)
- Cleaning adapter (OF-B153)
- Cleaning adapter (OF-G17)
- Water jet channel cleaning adapter (OE-C20)

Other equipment

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Disinfecting solution, Cidex Activated Dialdehyde Solution (Johnson & Johnson)
- Sterile water (preferred) or clean potable water
- 70-90% medical grade ethyl or isopropyl alcohol
- Basin to immerse the entire endoscope (at least 50 cm in width x 40 cm in depth x 15 cm in height)
- Sterile gauze
- 30 mL luer slip syringe
- 50 mL luer slip syringe

1-2-4-2. Preparation

- 1) Wear personal protective equipment.
- 2) Attach PVE soaking cap (OE-C9) to the endoscope.
- 3) Ensure that the ventilation cap (OF-C5) is detached from the endoscope.

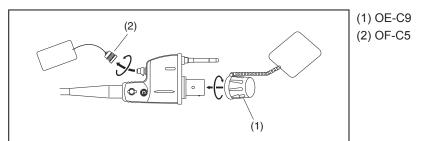


Figure 1.2.28

4) Prepare a basin with a sufficient volume of disinfecting solution to completely immerse the endoscope.

Endoscopes wi One Instrumer Channel

1-2-4-3. Filling the channels with disinfecting solution

WARNING

- When filling endoscope channels with disinfectant, avoid the introduction of air. The presence of air bubbles can prevent contact of the disinfectant with channel surfaces.
- Always immerse the endoscope while filling endoscope channels with disinfectant.

Always immerse the endoscope, components, and accessories in disinfecting solution during disinfection.

Attaching components and accessories to the endoscope

- 1) Fully immerse the endoscope in the disinfecting solution.
- 2) Attach the air/water/suction channel cleaning adapter (OF-B153), inlet seal (OF-B190), cleaning adapter (OF-G17), and water jet adapter (OE-C20) to the endoscope.

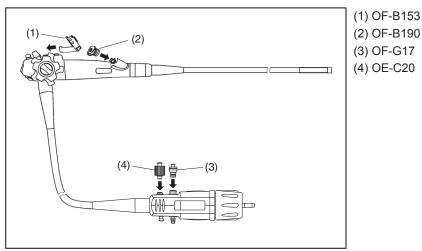


Figure 1.2.29

Attach a syringe filled with the disinfecting solution to OF-G17, and inject 30 mL of the disinfecting solution into the air/water channel.

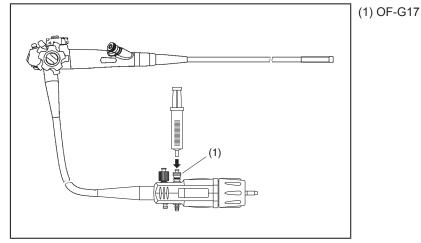


Figure 1.2.30

- Check to confirm that disinfecting solution flows out from the air/water nozzle(s) on the distal end.
- Attach a syringe filled with the disinfecting solution to the suction nipple, and inject 5) 55 mL of disinfecting solution into the suction channel.

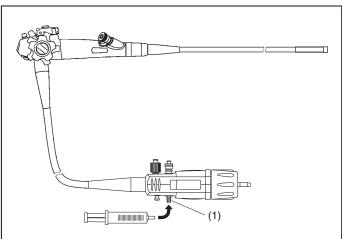
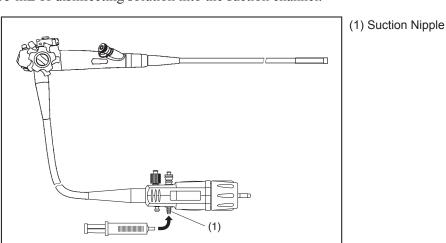


Figure 1.2.31

Check to confirm that the disinfecting solution flows out from the suction channel opening on the distal end.



Insert a syringe filled with the detergent solution to OF-B190, and inject 55 mL of the disinfecting solution into the suction channel.

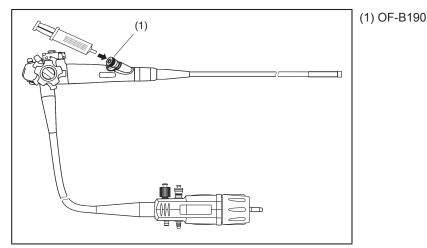


Figure 1.2.32

Endoscopes with One Instrument Channel

8) Attach a syringe filled with disinfecting solution to OE-C20, and inject 15 mL of disinfecting solution into the water jet channel.

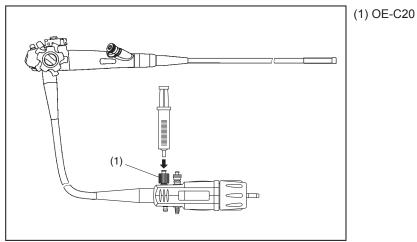


Figure 1.2.33

- 9) Check to confirm that disinfecting solution flows out from the water jet channel opening on the distal end.
- 10) After injecting disinfecting solution into all channels, detach OF-B153, OF-B190, OF-G17, and OE-C20 from the endoscope, and leave them to soak along with the endoscope until the next step. Open the cap of OF-B190.

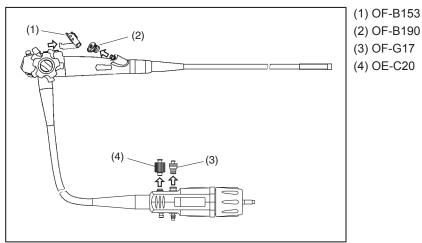


Figure 1.2.34

WARNING

- The disinfecting solution must remain in contact with ALL internal channels, external endoscope surfaces and components for the time period recommended by the disinfectant manufacturer.
- Adhere to the conditions (temperature, concentration, time) specified by the disinfectant manufacturer to accomplish effective and complete disinfection. Disinfectant solution use under conditions that fall outside the manufacturer's directions might damage the endoscope.
- During immersion, detach all components and accessories (except the soaking cap) from the endoscope to ensure contact of all endoscope surfaces with the disinfecting solution.
- 1) While fully immersed ensure that the endoscope, inlet seal (OF-B190), and cleaning adapters (OE-C20, OF-B153, and OF-G17) do not have air bubbles on their surfaces. If any air bubbles are detected, flush them away with disinfecting solution using a syringe.
- 2) Soak the endoscope, OF-B190, OE-C20, OF-B153, and OF-G17 under the conditions (temperature, concentration, time) specified by the disinfectant manufacturer. In the case of Cidex Activater Diadehyde Solution, the soaking time is 45 minutes at 25°C.

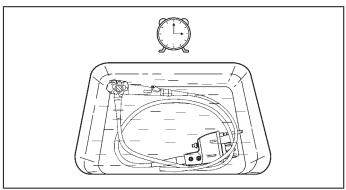


Figure 1.2.35

Purging disinfecting solution from all channels

- 3) After soaking, attach OF-B190, OE-C20, OF-B153, and OF-G17 to the endoscope. (see Figure 1.2.29, p36)
- 4) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air to purge as much residual disinfecting solution as possible. (see Figure 1.2.30, p37)
- 5) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 220 mL of air to purge as much residual disinfecting solution as possible. (see Figure 1.2.31, p37)
- 6) Insert a syringe filled with air to OF-B190, and flush the suction channel with 220 mL of air to purge as much residual detergent solution as possible. (see Figure 1.2.32, p38)
- 7) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air to purge as much residual disinfecting solution as possible. (see Figure 1.2.33, p38)
- 8) Take the endoscope with the components and accessories attached out of the disinfecting solution.



WARNING

- Ideally, all final rinses should be performed with sterile water. However, if sterile water is not used, use potable water or the water that meets the requirements of the health care facility.
- The basin that is used to perform rinsing of the endoscope and accessories should be thoroughly cleaned prior to filling it with rinse water.
- The rinse volumes recommended for removing residual disinfectant from channels are sufficient for 14-day glutaraldehydes (Cidex Activated Dialdehyde Solution). If extended shelf-life glutaraldehydes are used, consult with the disinfectant manufacturer for details regarding recommended rinse water volumes.

One Instrume

First rinse

- 1) Place the endoscope with components and accessories attached into a basin of sterile water that is of sufficient volume to completely immerse the endoscope.
- 2) Detach the inlet seal (OF-B190), and cleaning adapters (OE-C20, OF-B153, and OF-G17) from the endoscope. Open the cap of OF-B190. (see Figure 1.2.34, p38)
- 3) Wipe all exterior surfaces of the endoscope OF-B190, OE-C20, OF-B153, and OF-G17 two times with sterile gauze in order to remove residual disinfecting solution.
- 4) While still completely immerse in water, grasp the distal end and control body of the scope and PVE connector with two hands, and agitate it under the water by moving it from side to side repeatedly for one minute.

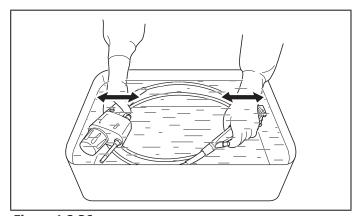


Figure 1.2.36

- 5) Similarity, grasp OF-B190, OE-C20, OF-B153, and OF-G17 with a hand, and agitate them under the water by moving them from side to side repeatedly for one minute.
- 6) Attach OF-B190, OE-C20, OF-B153, and OF-G17 to the endoscope. (see Figure 1.2.29, p36)
- 7) Attach a syringe filled with water to OF-G17, and flush the air/water channel with 90 mL of water. (see Figure 1.2.30, p37)
- 8) Attach a syringe filled with water to the suction nipple, and flush the suction channel with 220 mL of water. (see Figure 1.2.31, p37)

One Instrument

- 9) Insert a syringe filled with water to OF-B190, and flush the suction channel with 220 mL of water. (see Figure 1.2.32, p38)
- 10) Attach a syringe filled with water to OE-C20, and flush the water jet channel with 35 mL of water. (see Figure 1.2.33, p38)
- 11) Take the endoscope with the components and reprocessing accessories attached out of the water.
- 12) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air. (see Figure 1.2.30, p37)
- 13) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 220 mL of air. (see Figure 1.2.31, p37)
- 14) Insert a syringe filled with air to OF-B190, and flush the suction channel with 220 mL of air. (see Figure 1.2.32, p38)
- 15) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air. (see Figure 1.2.33, p38)

Second rinse

16) Fill a basin with clean water, and repeat steps 1 - 15 in order to perform a second complete rinse.

Third rinse

17) Fill a basin with clean water, and repeat steps 1 - 15 in order to perform a third complete rinse.

Fourth rinse

18) Fill a basin with clean water, and repeat steps 1 - 15 in order to perform a fourth complete rinse.

1-2-4-6. Drying

WARNING

Regardless of the quality of the rinse water used, it is essential to perform a final alcohol rinse followed by forced air in order to completely dry the endoscope channels and prevent bacterial colonization and/or infections associated with waterborne microorganisms.

Flushing all channels with alcohol

- 1) Attach a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to cleaning adapter (OF-G17), and flush the air/water channel with 35 mL of alcohol. (see Figure 1.2.30, p37)
- 2) Attach a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to the suction nipple, and flush the suction channel with 80 mL of alcohol. (see Figure 1.2.31, p37)
- 3) Insert a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to the inlet seal (OF-B190), and flush the suction channel with 80 mL of alcohol. (see Figure 1.2.32, p38)
- 4) Attach a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to water jet channel cleaning adapter (OE-C20), and flush the water jet channel with 15 mL of alcohol. (see Figure 1.2.33, p38)

Flushing all channels with air

- 5) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air to remove residual alcohol. (see Figure 1.2.30, p37)
- 6) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 220 mL of air to remove residual alcohol. (see Figure 1.2.31, p37)
- 7) Insert a syringe filled with air to OF-B190, and flush the suction channel with 220 mL of air. (see Figure 1.2.32, p38)
- 8) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air to remove residual alcohol. (see Figure 1.2.33, p38)
- 9) Ensure that no alcohol exits the endoscope tip.
- 10) Detach OF-B190, OE-C20, OF-B153, and OF-G17 from the endoscope. (see Figure 1.2.34, p38)

Drying of all external surfaces

11) Gently dry all external surfaces of the endoscope, components, and accessories with a sterile gauze.

ndoscopes with ne Instrument

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! WARNING

- Please note that PENTAX Medical has not validated any steam sterilization methods for flexible endoscopes.
- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- After sterilization, ensure that the package is intact. If there are any signs of abnormalities such as stains, tears or any other indications that the packaging has been damaged or opened, repeat the sterilization with new packaging.
- Sterilization efficacy and material compatibility depend on the following factors.
 - thorough cleaning of the device
 - load of the devices to be sterilized
 - wrapping of the devices to be sterilized
 - sterilizer cycle parameters
 - quality of rinse water
- Prior to sterilization, clean and dry the endoscope thoroughly. Failure to do so can result in ineffective or incomplete sterilization.
- Use a chemical indicator (CI) and/or biological indicator (BI) to control the sterilization process and ensure sterilization efficacy.
- The manufacturer of the sterilizer should be consulted to confirm that test data exists to substantiate that no harmful levels of any residues (active/inert ingredients, their by-products or derivatives of the processed devices) remain on any instrument that may pose a risk to patients and users.
- After sterilization, ensure that the package is intact. If there are any indications that the integrity of the package has been compromised, repeat the sterilization process with new packaging.

! CAUTION

- Due to the heat sensitive nature and/or the specific biocompatible materials used in the construction of flexible endoscopes, some sterilization systems/processes/solutions may have detrimental effects on flexible endoscopes. To avoid the potential for instrument damage and/or endoscope failure, confirm the compatibility of such systems/ solutions with your local PENTAX dealer prior to use with any PENTAX products. Also, confirm the specific claim(s) of any sterilization methods/ processes with the sterilizer manufacturer to ensure manufacturer that they have performed microbiological validation studies to support their claims of achieving sterilization of device specific flexible endoscopes models and endoscope components.
- NEVER place the endoscope in a steam sterilizer !

1-3. Endoscope with Two Instrument Channels

A Video Colonoscope with two-channels can be subjected to the following cleaning, disinfection, and optional sterilization process.

Video Colonoscopes	Cleaning		High-Level	Optional Sterilization
	Manual	Ultrasonic	Dinfection	Steam Sterilization
EC-3890TLK	Y	N	Y	N

Y : Yes N : No

1-3-1. Pre-Cleaning

WARNING

- During reprocessing, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- Pre-cleaning is intended to remove visible debris from the endoscope immediately after its withdrawal from the patient, in order subsequent cleaning procedure. Endoscopes that are withdrawn from the patient are soiled with debris such as blood, tissues, and mucus. When such debris dries, it cannot be adequately removed in the subsequent cleaning procedure. It should be noted that pre-cleaning cannot substitute for the mechanical cleaning process. Always mechanically clean the endoscope after pre-cleaning.
- During pre-cleaning, never wipe the insertion tube with alcohol or disinfecting solution. These solutions may fix organic contaminants and proteinaceous debris to the instrument and have an adverse effect on endoscope functionality and proper reprocessing.
- When using detergent, use only legally marketed brands that have been tested and found to be compatible by PENTAX. A list of detergents that are compatible with PENTAX endoscopes is contained in this manual.
- When injecting detergent solution through an internal channel, ensure that detergent solution exits from the endoscope distal end. If not, the channel might be blocked. Never use an endoscope with a blocked channel. Contact your local PENTAX facility to arrange for repair of the device.

WARNING

• Please note that the forward water jet channel must undergo all steps of the endoscope reporocessing procedure, regardless of whether it was used during a clinical procedure.

 Immediately after use, the metal light guide plug and electrical contacts/ pins of the endoscope may be HOT. To avoid burns, do not touch these areas immediately after use. For safer handling after a procedure, grasp the PVE connector housing.

- In order to prevent damage to the endoscope, do not place any objects other than Inlet Seal (OF-B190), Water Jet Check Valve Adapter (OE-C12), Irrigation tube (OF-B113), Suction Control Valve (OF-B120), Air/Water Feeding Valve (OF-B188), and Water Jet Channel Cleaning Adapter (OE-C20) with the endoscope in the closed container used for transport to the reprocessing room.
- In order to avoid damaging the endoscope, never subject it to suction in excess of 66kPa.

NOTE]

- If the use of detergent solution is not permitted in the procedure room, remove the endoscope from the procedure room and perform precleaning in another location.
- OE-C20 has been designed to leak slightly so as to insure contact between all cleaning fluids and the FWJ port on the scope.

1-3-1-1. Items required

Endoscope component

- Inlet seal (OF-B190)
- Suction control valve (OF-B120)
- Air/water feeding valve (OF-B188)
- Suction channel selector (OF-B161)

Reprocessing accessory

• Water jet channel cleaning adapter (OE-C20)

Other equipment

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Detergent solution, Endozime (Ruhof Corporation)
- Water bottle and Video processor
- External suction source
- 500 mL basin
- · Lint-free gauze
- 30 mL luer slip syringe

Endoscope with Two Instrument

1-3-1-2. Preparation

- 1) Wear personal protective equipment.
- 2) Prepare a 500 mL basin with detergent solution per manufacturer's instructions (temperature, concentration). In the case of ENDOZIME, add 30 mL of ENDOZIME concentrate to 3.8 L (1 gallon) of clean potable water at 20°C~30°C (68°F~86°F).

1-3-1-3. Wiping the insertion tube

- 1) Turn off the lamp switch of the video processor.
- 2) Immediately after removing the endoscope from the patient, gently wipe the entire length of the insertion tube three times using lint-free gauze soaked with the detergent solution.

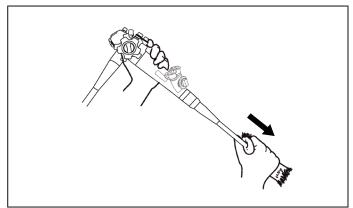


Figure 1.3.1

1-3-1-4. Aspirating detergent solution through the suction channel

- 1) Attach inlet seal (OF-B190), suction control valve (OF-B120), and suction channel selector (OF-B161) are attached to the endoscope.
- 2) Connect a suction tube from external suction source to the endoscope suction nipple.

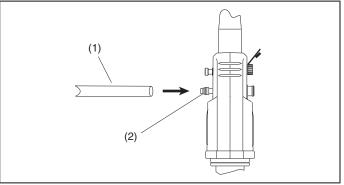


Figure 1.3.2

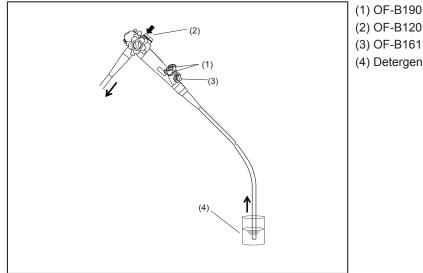
3) Turn on the external suction source.

(1) Suction Tube

(2) Suction Nipple



Place the distal end of endoscope into a basin. Align the suction channel selector knob (OF-B161) to the "A" indicator, and aspirate the detergent solution through the suction channel by pressing suction control valve (OF-B120) for 10 seconds.



- (2) OF-B120
- (3) OF-B161
- (4) Detergent Solution

Figure 1.3.3

- Take the distal end out of the detergent solution, and aspirate air through the suction channel by pressing suction control valve (OF-B120) for 10 seconds.
- 6) Place the distal end of endoscope into a basin. Align suction channel selector knob (OF-B161) to the "B" indicator, and aspirate the detergent solution through the suction channel by pressing suction control valve (OF-B120) for 10 seconds.
- Take the distal end out of the detergent solution, and aspirate air through the suction 7) channel by pressing OF-B120 for 10 seconds.
- 8) Turn off the external suction source.
- 9) Disconnect the suction tube from the endoscope suction nipple.

1-3-1-5. Flushing the air/water channel with air

- Attach that inlet seal (OF-B190) and air/water feeding valve (OF-B188) are attached.
- 2) Connect that air/water feeding tube of water bottle is connected to the endoscope air/ water port.

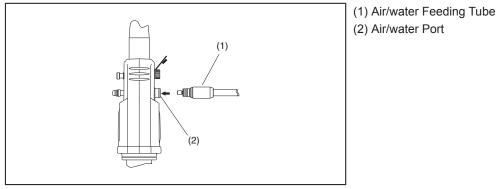


Figure 1.3.4

- Place the distal end of the endoscope into a basin. 3)
- Set the lever on the water bottle to the drain position.

5) With the air pump of video processor ON and set to the HIGHEST pressure setting, flush the air channel with air by covering the top of air/water feeding valve (OF-B188) for 10 seconds. Discharge all water in the water channel by pressing the button of OF-B188 for 10 seconds.

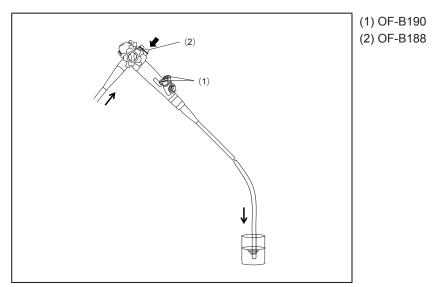


Figure 1.3.5

Endoscope with Two Instrument

6) Turn off the air pump of the videoprocessor, and disconnect the air/water feeding tube of water bottle from the endoscope air/water port.

1-3-1-6. Flushing the water jet channel with detergent solution

1) Detach the water jet check valve adapter (OE-C12) if it is attached, and attach the water jet channel cleaning adapter (OE-C20) to the endoscope.

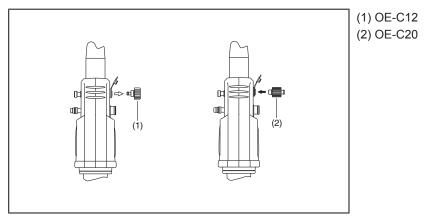


Figure 1.3.6

- 2) Place the distal end of endoscope into a basin.
- 3) Attach a syringe filled with the detergent solution to OE-C20, and flush the water jet channel with 15 mL of detergent solution. Ensure that detergent solution exits from the endoscope distal end.
- 4) While the distal end of endoscope is still in a basin, use a syringe filled with air to flush the water injection channel with 35 mL of air to purge as much residual detergent solution as possible

1-3-1-7. Transport to cleaning room

- 1) Turn off the power of the video processor, and detach the endoscope PVE connector from the video processor.
- 2) Transport the endoscope, detached OE-C12, and OF-B113 to the cleaning room in a closed container.

1-3-2. Leak Testing

Before reprocessing and/or immersion in any fluids, PENTAX endoscopes should be tested for the loss of integrity in their watertight construction by using a PENTAX brand leakage testers (SHA-P2 or SHA-P5). For specific details on PENTAX leak detection procedures, please refer to the instructions supplied with PENTAX leakage testers.

! CAUTION

Various types of endoscope leakage testers exist. Some are stand-alone units, and others may be integrated into an AER. PENTAX does not evaluate non-PENTAX leakage testers to verify their specific product claims with respect to their effectiveness to accurately detect leaks and/or their compatibility with PENTAX endoscopes. Insufficient pressures may reduce the likelihood for accurate leak detection, especially if the endoscope's distal bending section is not flexed during testing. Also, excessive pressures may adversely affect the endoscope, especially if pressurization occurs during automated reprocessing at elevated temperatures. PENTAX accepts no responsibility for use of non-PENTAX leakage testers. Users should check with the leakage tester manufacturer and confirm their specific product claims, including compatibility with PENTAX endoscopes at various temperatures and their ability to detect leaks with/without fluid immersion and with/without flexing of the endoscope's distal bending section.

Two Instrument

WARNING

- During reprocessing, always wear protective equipment (e,g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- In order to ensure thorough cleaning, be sure to perform all cleaning steps. The effectiveness of each cleaning step will influence the effectiveness of subsequent steps. Failure to properly follow the cleaning steps described may result in incomplete or ineffective cleaning, disinfection and sterilization of endoscope, and may cause a crossinfection risk.
- Immediately (within one hour) after the completion of a procedure, the endoscope and its components should be thoroughly and carefully cleaned with detergent solution. If the endoscope and its components are left uncleaned for an excessive time after use, dried blood, mucus or other patient debris may cause damage or interfere with the ability of the user to properly reprocess the device.
- For cleaning, use only legally marketed detergents that have been tested according to the instructions of the manufacturer and found to be compatible by PENTAX. A list of detergents that are compatible with PENTAX endoscopes is contained in this manual.
- Fresh detergent solution must be used for each endoscope that is reprocessed.

Endoscope with Two Instrument Channels

(CAUTION

- <u>PVE soaking cap (OE-C9) must be properly secured over the electrical contacts.</u> Failure to do so can result in water invasion and damage to the endoscope. If an endoscope is cleaned **without** the PVE soaking cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.
- <u>Ventilation cap (OF-C5) must be taken OFF during reprocessing.</u> Failure to do so can result in damage to the endoscope. If an endoscope is cleaned **with** the ventilation cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.
- During cleaning, never twist, rotate, or bend the insertion portion, and umbilical cord excessively.
- Never subject the endoscope to ultrasonic cleaning methods.
- In order to prevent damage to the endoscope, do not place any objects other than the items the reprocessing accessories listed in section 1-3-2-1 of this Instructions for Use when immersing the endoscope in a cleaning basin.

NOTE

OE-C20 has been designed to leak slightly so as to insure contact between all cleaning fluids and the FWJ port on the scope.

Endoscope with Two Instrument

1-3-3-1. Items required

Endoscope component

- Inlet seal (OF-B190)
- Suction channel selector (OF-B161)

Reprocessing accessory

- PVE soaking cap (OE-C9)
- Cleaning brush (CS6021T)
- Cleaning brush (CS-C9S)
- Cleaning Adapter (OF-B153)
- Cleaning Adapter (OF-G17)
- Water jet channel cleaning adapter (OE-C20)

Other equipment

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Detergent solution, Endozime (Ruhof Corporation)
- · Clean potable water
- Basin sufficient in size to immerse the entire endoscope (at least 50 cm in width x 40 cm in depth x 15 cm in height)
- · Lint-free gauze
- 30 mL luer slip syringe
- 50 mL luer slip syringe

1-3-3-2. Preparation

- 1) Wear personal protective equipment.
- 2) Attach PVE soaking cap (OE-C9) to the endoscope.
- 3) Detach the ventilation cap (OF-C5) from the endoscope.

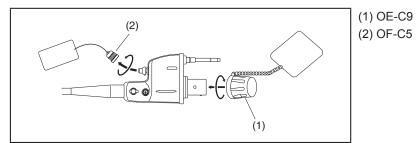


Figure 1.3.7

Fill a basin with a sufficient volume of detergent solution to completely immerse the endoscope. Prepare the detergent in accordance with the manufacturer's instructions (temperature, concentration). In the case of ENDOZIME, add 30 mL of ENDOZIME concentrate to 3.8 L (1 gallon) of clean potable water at 20°C~30°C (68°F~86°F).

! CAUTION

- Do not squeeze or severely bend the insertion tube.
- Do not use any abrasive materials.
- Be careful to avoid damage to the distal lenses.
- 1) Fully immerse the endoscope with the components attached in the detergent solution.
- 2) Detach the inlet seal (OF-B190), suction control valve (OF-B120), air/water feeding valve (OF-B188), suction channel selector (OF-B161), water jet channel cleaning adapter (OE-C20), and water jet connector cap (OF-B118) from the endoscope. Open the cap of OF-B190 in the detergent solution.

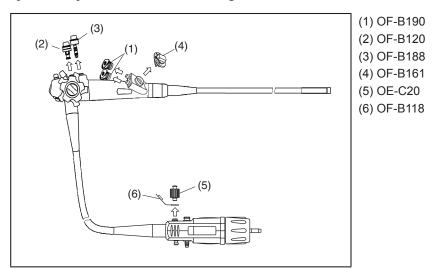


Figure 1.3.8

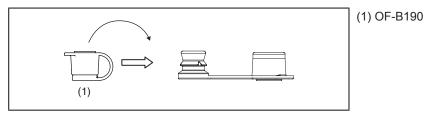
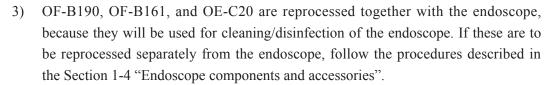


Figure 1.3.9

Endoscope with Two Instrument



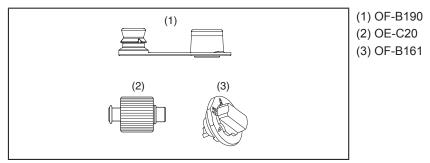


Figure 1.3.10

4) OF-B120, OF-B188, OF-B118, OE-C12, and OF-B113 are reprocessed separately from the endoscope, because these will be not used for cleaning/disinfection of the endoscope. (see Section 1-4 "Endoscope components and accessories")

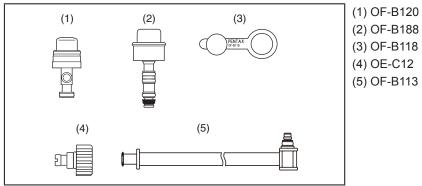


Figure 1.3.11

5) While still immersed in the detergent solution, wash the entire surface of endoscope three times with a lint-free gauze. Pay special attention to the distal end of the insertion tube by brushing it with the large brush head of cleaning brush (CS-C9S) until all soil has been removed. In similar fashion, use both brush heads of cleaning brush (CS-C9S) to remove soil from areas on the control body such as the grooved tips of the angulation knob spokes, areas behind and between the angulation knobs, area around the bases of the image control buttons, and the angulation lock lever and knob.

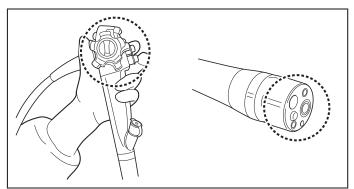


Figure 1.3.12

Wash the entire surface of OF-B190, OE-C20, and OF-B161 three times with a lint-free gauze.

1-3-3-4. Brushing of suction channel, cylinder, port, and component

WARNING

- Do not use cleaning brushes other than those are specified in this Instructions for Use. Failure to do so can result in endoscope damage or incomplete or ineffective cleaning.
- Cleaning brush (CS6021T) is provided non-sterile for one time use. Never reuse the brush on more than one instrument.
- Prior to use, ensure that cleaning brushes are not damaged (e.g., kinked shaft or bent or missing bristles).
- In order to prevent the reflux of patient debris left in the endoscope channel into the environment, always withdraw brushes slowly.

! CAUTION

- In order to avoid damage to the endoscope distal end, never attempt to insert a cleaning brush into endoscope distal tip.
- Do not insert cleaning brush (CS6021T) into the suction control valve cylinder. The brush head of Cleaning brush (CS6021T) could become stuck within the suction control valve cylinder.
- Never apply excessive pressure to introduce or withdraw the brush. This can result in damage to the endoscope and/or the brush.
- Some manufacturers' cleaning brushes/ devices have been found to damage PENTAX endoscopes and/or create the need for service, as they can become lodged ("stuck") inside various lumens of PENTAX endoscopes. The likelihood of endoscope damage or servicing increases if a cleaning device does not have a protective tip (or contains any sharpedged surface), if its flexible shaft uses a flimsy plastic material that is not firm enough to allow for easy accessory advancement, and/or if the proper sequence and/or direction of channel cleaning is not followed as described in PENTAX IFU.
- To prevent excessive friction between brush and channel, do NOT tightly coil the insertion tube and umbilical cord to a diameter of less than 30cm. NEVER attempt to pass the cleaning brush through a fully angulated endoscope. Failure to follow these instructions can result in endoscope or brush damage.

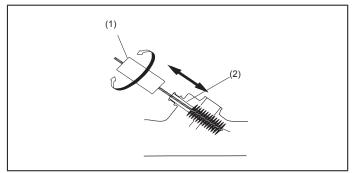
Endoscope with Two Instrument Channels

1

Endoscope with

Suction channel cleaning

Insert the large brush head of cleaning brush (CS-C9S) into the instrument channel inlet "A" until it cannot be advanced further. Repetitively move the brush back and forth while twisting it left and right for one minute in order to scrub the entire inner surface of the instrument channel inlet.

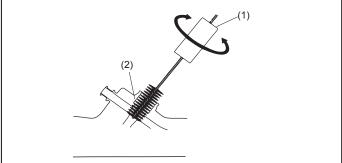


(1) CS-C9S

(2) Instrument Channel Inlet "A" and "B"

Figure 1.3.13

- 2) Withdraw cleaning brush (CS-C9S) from the inlet, and clean the debris from the brush head by rubbing with fingers.
- 3) Repeat steps 1 and 2 three additional times.
- 4) Repeat steps 1-3 with instrument channel inlet "B".
- 5) Insert the large brush head of cleaning brush (CS-C9S) into the selector cylinder, and rotate it for one minute.



(1) CS-C9S

(2) Selector Cylinder

Figure 1.3.14

- 6) Withdraw CS-C9S from the inlet, and clean the debris from the brush head by rubbing with fingers.
- 7) Repeat steps 5 and 6 three additional times.

Insert the blue tip of cleaning brush (CS-6021T) into the opening of the suction 8) nipple, and gently pass the brush until it appears in the suction cylinder.

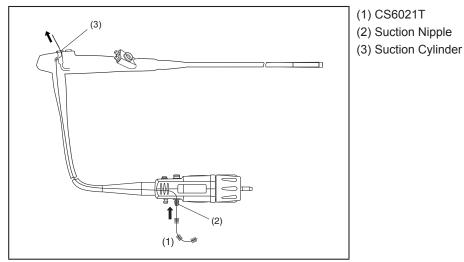


Figure 1.3.15

- Grasp the blue tip of the brush shaft, and gently pull the brush from the suction cylinder until it exits the suction cylinder. Clean debris from the brush heads by rubbing with fingers.

- 10) Repeat steps 8 and 9 three additional times.
- 11) Using cleaning brush (CS6021T), insert the blue tip of the brush into the opening at the bottom of the suction cylinder on the control head, and gently advance the brush until it exits the selector cylinder.

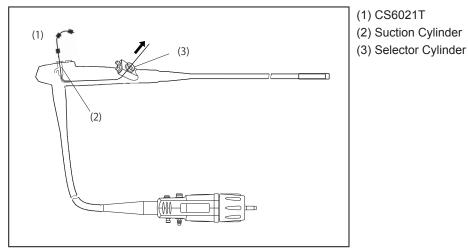
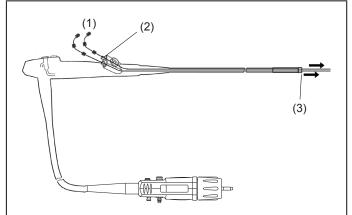


Figure 1.3.16

- 12) Grasp the blue tip of the brush shaft, and gently pull the brush until the brush heads exit the selector cylinder.
- 13) Repeat steps 11 and 12 three additional times.

14) Using cleaning brush (CS6021T), insert the blue tip of the brush into instrument channel inlet "A", and gently advance the brush until it exits the distal end of endoscope.



(1) CS6021T

- (2) Instrument Channel Inlet "A" and "B"
- (3) Distal End

Figure 1.3.17

- 15) Grasp the blue tip of the brush shaft, and gently pull the brush from the distal tip of the endoscope until the brush heads exit the distal end.
- 16) Repeat steps 14 and 15 three additional times.
- 17) Repeat steps 14 16 with the instrument channel inlet "B".

Cylinder cleaning

18) Insert the large brush head of cleaning brush (CS-C9S) into the suction cylinder until it cannot be advanced further. Repetitively move the brush back and forth while twisting it left and right for one minute in order to scrub the entire inner surface of the cylinder.

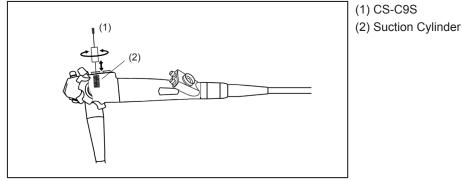
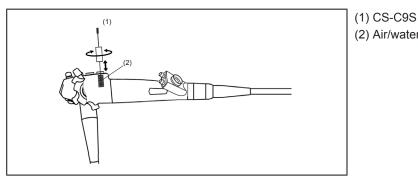


Figure 1.3.18

- 19) Withdraw the brush from the cylinder, and clean debris from the brush head by rubbing with fingers.
- 20) Repeat steps 18 and 19 three additional times.

21) Insert the large brush head of cleaning brush (CS-C9S) into the air/water cylinder until it cannot be advanced further. Then repetitively move the brush back and forth while twisting it left and right for one minute in order to scrub the entire inner surface of the cylinder.



(2) Air/water Cylinder

Figure 1.3.19

- 22) Withdraw the brush from the cylinder, and clean the debris from the brush head by rubbing with fingers.
- 23) Repeat steps 21 and 22 three additional times.

Water jet port cleaning

24) Insert the large brush head of cleaning brush (CS-C9S) into the water jet port until it cannot be advanced further, and rotate it for one minute to scrub the inner surfaces of the port. Do not insert the brush excessively.

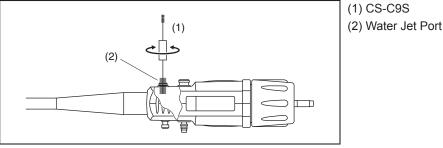


Figure 1.3.20

- 25) Withdraw the brush from the port, and clean the debris from the brush head by rubbing with fingers.
- 26) Repeat steps 24 and 25 three additional times.
- 27) After brushing the endoscope, dispose of CS6021T, which is a single-use accessory. Reprocess CS-C9S, which is a reusable accessory, according to Section 1-4 "Endoscope components and accessories".

WARNING

- While injecting detergent solution through the channels, avoid the introduction of air. The presence of air bubbles can prevent contact of the detergent solution with channel surfaces.
- Always fully immerse the endoscope while flushing detergent solution into the endoscope channel.
- It is imperative that the cleaning adapter (OF-B153) be securely attached to the endoscope. Failure to properly connect and secure the cleaning adapter could result in ineffective and incomplete reprocessing.

WARNING

 Please note that the forward water jet channel must undergo all steps of the endoscope reporocessing procedure, regardless of whether it was used during a clinical procedure.

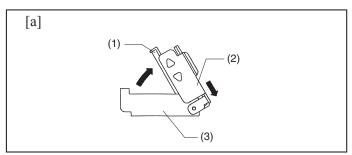
! CAUTION

In order to avoid damage to the endscope, never apply excessive force if resistance is encountered while flushing the detergent solution into the channels.

Always immerse the endoscope, components, and accessories in the detergent solution during cleaning.

Attaching components and accessories to the endoscope

- According to the following procedure, attach cleaning adapter (OF-B153) to the air/water cylinder and suction cylinder. This adapter caps (seals) off the air/water and suction cylinders to allow unidirectional flow of solution through these delivery/aspiration systems.
 - [a] Raise the locking cap and slide the side covers (marked with \triangle) downward.
 - [b] Align the cylinder guide over the air/water and suction cylinder ports.
 - [c] Slide the OF-B153 forward.
 - [d] Holding the side covers (marked with \triangle), push down and slide the locking cap under the locking tab to secure.
 - [e] Secure the locking cap with the locking tab on the base.



- (1) Rubber Seal
- (2) Locking Cap
- (3) Base

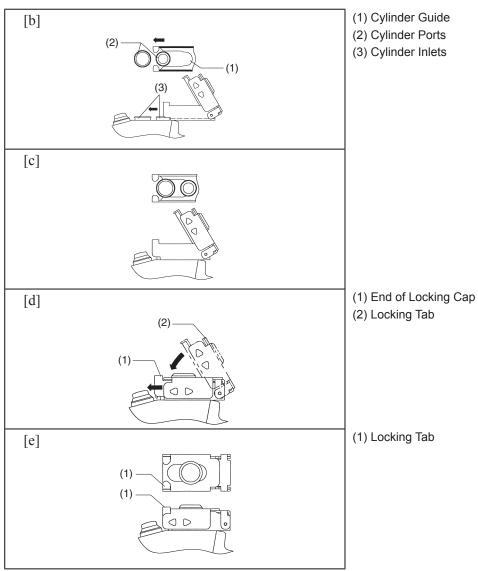


Figure 1.3.21

2) Attach inlet seal (OF-B190), suction channel selector (OF-B161), cleaning adapter (OF-G17), and water jet channel cleaning adapter (OE-C20) to the endoscope.

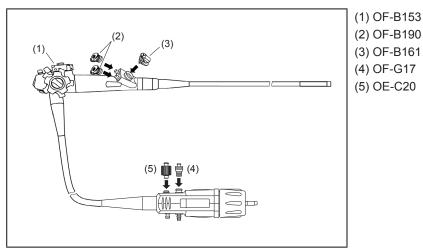


Figure 1.3.22

3) Attach a syringe filled with the detergent solution to OF-G17, and inject 30 mL of the detergent solution into the air/water channel.

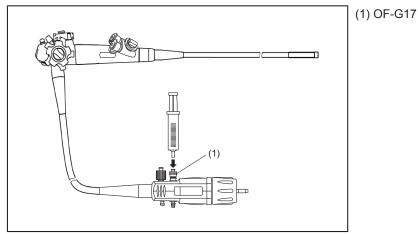


Figure 1.3.23

- 4) Check to confirm that detergent solution flows out from the air/water nozzle(s) on the distal end.
- 5) Attach a syringe filled with the detergent solution to the suction nipple, and inject 110 mL of detergent solution into the suction channel.

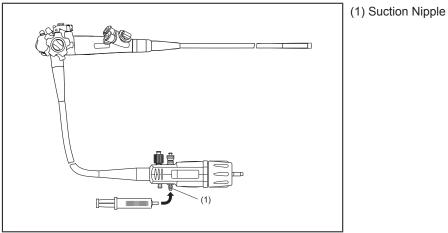


Figure 1.3.24

6) Check to confirm that detergent solution flows out from the suction channel opening on the distal end.



7) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with detergent solution to OF-B190 on the instrument channel inlet "A", and inject 110 mL of detergent solution into the suction channel.

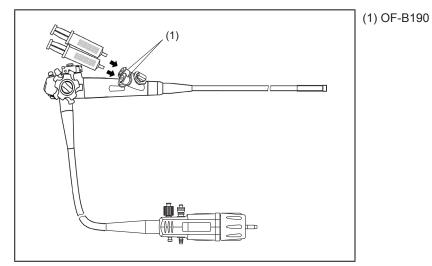


Figure 1.3.25

- 8) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with detergent solution to OF-B190 on the instrument channel inlet "B", and inject 110 mL of detergent solution into the suction channel.
- 9) Attach a syringe filled with detergent solution filled to OE-C20, and inject 15 mL of detergent solution into the water jet channel.

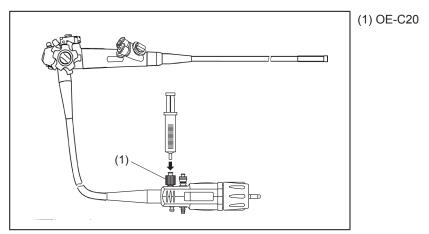


Figure 1.3.26

10) Check to confirm that the solution flows out from the water jet channel opening on the distal end.

Endoscope with Two Instrument 11) After injecting detergent solution into all channels, detach OF-B153, OF-B190, OF-B161, OF-G17, and OE-C20 from the endoscope, and leave them to soak along with the endoscope in the detergent solution until the next step. Open the cap of OF-B190.

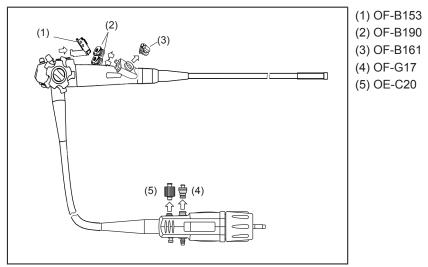


Figure 1.3.27

1-3-3-6. Soaking in detergent solution

WARNING

- The detergent solution must remain in contact with ALL internal channels, external endoscope surfaces, and components for the time period recommended by the manufacturer of the detergent.
- During immersion, detach all components and accessories (except the soaking cap) from the endoscope to ensure contact of all endoscope surfaces with the detergent solution.

!CAUTION

NEVER subject the endoscope to ultrasonic cleaning method.

While fully immersing the endoscope, inlet seal (OF-B190), cleaning adapters (OE-C20, OF-B153, and OF-G17), and suction channel selector (OF-B161), ensure that there are no air bubbles on the endoscope surfaces, distal end, and accessories. If any air bubbles are detected, flush them away with detergent solution using a syringe. 2) Soak the endoscope, OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 under conditions (temperature, concentration, time) specified by the detergent manufacturer. In the case of Endozime, the soaking time is at 3 minutes.

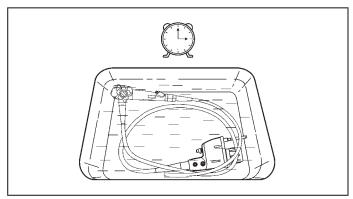


Figure 1.3.28

3) After soaking, ultrasonically clean OF-B190, and OF-B161 according to Section 1-4 "Endoscope components and accessories".

Purging detergent solution from all channels

- 4) After ultrasonic cleaning, attach OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 to the endoscope. (see Figure 1.3.22, p60)
- Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air to purge as much residual detergent solution as possible. (see Figure 1.3.23, p61)
- 6) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 110 mL of air to purge as much residual detergent solution as possible. (see Figure 1.3.24, p61)
- 7) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "A", and flush the suction channel with 110 mL of air to purge as much residual detergent solution as possible. (see Figure 1.3.25, p62)
- 8) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "B", and flush the suction channel with 110 mL of air to purge as much residual detergent solution as possible. (see Figure 1.3.25, p62)
- 9) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air to purge as much residual detergent solution as possible. (see Figure 1.3.26, p62)
- 10) Take the endoscope with the components and accessories attached out of the detergent solution.

Endoscope with Two Instrument Channels

! WARNING

It is important that all internal channels, external endoscope surfaces and components be thoroughly rinsed with clean water to remove residual detergent solution. Failure to do so can result in ineffective or incomplete disinfection and sterilization.

First rinse

- 1) Place the endoscope with the components and accessories attached into a basin of clean water that is of sufficient volume to completely immerse the endoscope.
- 2) Detach the inlet seal (OF-B190), cleaning adapters (OE-C20, OF-B153, and OF-G17), and suction channel selector (OF-B161) from the endoscope. Open the cap of OF-B190. (see Figure 1.3.27, p63)
- 3) Wipe all exterior surfaces of the endoscope, OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 two times with a lint-free gauze in order to remove residual detergent solution.
- 4) While still completely immerse in water, grasp the distal end, control body of endoscope, and PVE connector with two hands, and agitate it under the water by moving it from side to side repeatedly for one minute.

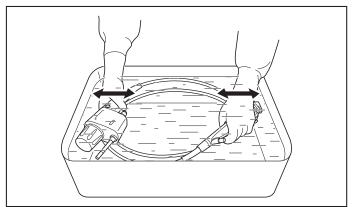


Figure 1.3.29

- 5) Similarity, grasp OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 with a hand, and agitate them under the water by moving them from side to side repeatedly for one minute.
- 6) Attach OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 to the endoscope. (see Figure 1.3.22, p60)
- 7) Attach a syringe filled with water to OF-G17, and flush the air/water channel with 90 mL of water. (see Figure 1.3.23, p61)
- 8) Attach a syringe filled with water to the suction nipple, and flush the suction channel with 440 mL of water. (see Figure 1.3.24, p61)
- 9) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with water to OF-B190 on instrument channel inlet "A", and flush the suction channel with 440 mL of water. (see Figure 1.3.25, p62)
- 10) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with water to OF-B190 on instrument channel inlet "B", and flush the suction channel with 440 mL of water. (see Figure 1.3.25, p62)

- 11) Attach a syringe filled with water to OE-C20, and flush the water jet channel with 35 mL of water. (see Figure 1.3.26, p62)
- 12) Take the endoscope with the components and accessories attached out of the water.
- 13) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air. (see Figure 1.3.23, p61)
- 14) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 110 mL of air. (see Figure 1.3.24, p61)
- 15) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "A", and flush the suction channel with 110 mL of air. (see Figure 1.2.25, p30)
- 16) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "B", and flush the suction channel with 110 mL of air. (see Figure 1.3.25, p62)
- 17) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air. (see Figure 1.3.26, p62)

Second rinse

18) Fill a basin with clean water, and repeat steps 1 - 17 in order to perform a second complete rinse.

Endoscope with Two Instrument Channels

Third rinse

19) Fill a basin with clean water, and repeat steps 1 - 17 in order to perform a third complete rinse.

Fourth rinse

- 20) Fill a basin with clean water, and repeat steps 1 17 in order to perform a fourth complete rinse.
- 21) Detach OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 from the endoscope. (see Figure 1.3.27, p63)

1-3-3-8. Drying

1) Gently wipe and dry all external surfaces of endoscope, components, and accessories with a new lint-free gauze.

1-3-4. High-Level Disinfection

Prior to high-level disinfection, the end user should confirm the minimum effective concentration (MEC) of reused disinfectant as per the manufacturer's instructions.

WARNING

- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- Prior to disinfection, it is imperative that any solutions previously used in the cleaning process be thoroughly rinsed and dried. Failure to do so can result in ineffective or incomplete disinfection.
- For high-level disinfection, use an appropriate disinfecting solution according to the instructions of the disinfectant manufacturer (temperature, concentration, time). Adhere to the instructions to accomplish effective and complete disinfection. The endoscope may be damaged if exposed to a disinfectant under conditions other than those specified by the disinfectant manufacturer.
- Use only a legally marketed disinfectant that has been tested according to the instructions provided by the manufacturer and found to be compatible by PENTAX. A list of disinfectants that are compatible with PENTAX endoscopes is contained in this manual.
- It is imperative that ALL internal channel surfaces of the channels be in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.
- Ideally, all final rinses should be performed with sterile water, or clean potable water, or the water that meets the requirements of the health care facility.
- Regardless of the quality of the rinse water used, it is essential to perform a final alcohol rinse followed by forced air in order to completely dry the endoscope channels and prevent bacterial colonization and/or infections associated with waterborne microorganisms.
- The basin that is used to perform disinfectant immersion should be thoroughly cleaned prior to filling it with disinfectant solution.

WARNING

 Please note that the forward water jet channel must undergo all steps of the endoscope reporocessing procedure, regardless of whether it was used during a clinical procedure.





- Prior to disinfection, attach PVE soaking cap (OE-C9). Failure to do so can result in water invasion and damage to the endoscope. If the endoscope is disinfected **without** the PVE soaking cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.
- Prior to disinfection, detach the ventilation cap (OF-C5). Failure to do so can result in damage to the endoscope. If the endoscope is disinfected with the ventilation cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.
- During disinfection, never twist, rotate or bend the insertion tube and umbilical cord excessively.
- In order to prevent damage to the endoscope, do not place any objects other than the reprocessing accessories described in section 1-3-3-1 of this Instructions for Use when immersing the endoscope in the disinfection basin.

NOTE]

OE-C20 has been designed to leak slightly so as to insure contact between all disinfecting fluids and the FWJ port on the scope.

Endoscope with Two Instrumer Channels

1-3-4-1. Items required

Endoscope component

- Inlet seal (OF-B190)
- Suction channel selector (OF-B161)

Reprocessing accessory

- PVE soaking cap (OE-C9)
- Cleaning adapter (OF-B153)
- Cleaning adapter (OF-G17)
- Water jet channel cleaning adapter (OE-C20)

Other equipment

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Disinfecting solution, Cidex Activated Dialdehyde Solution (Johnson & Johnson)
- Sterile water (preferred) or clean potable water
- 70-90% medical grade ethyl or isopropyl alcohol
- Basin to immerse the entire endoscope (at least 50 cm in width x 40 cm in depth x 15 cm in height)
- Sterile gauze
- 30 mL luer slip syringe
- 50 mL luer slip syringe

1-3-4-2. Preparation

- 1) Wear personal protective equipment.
- 2) Attach PVE soaking cap (OE-C9) to the endoscope.
- 3) Ensure that the ventilation cap (OF-C5) is detached from the endoscope.

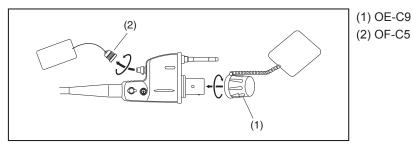


Figure 1.3.30

4) Prepare a basin with a sufficient volume of disinfecting solution to completely immerse the endoscope.

1-3-4-3. Filling the channels with disinfecting solution

WARNING

- When filling endoscope channels with disinfectant, avoid the introduction of air. The presence of air bubbles can prevent contact of the disinfectant with channel surfaces.
- Always immerse the endoscope while filling endoscope channels with disinfectant.

Always immerse the endoscope, components, and accessories in disinfecting solution during disinfection.

Attaching components and accessories to the endoscope

- 1) Fully immerse the endoscope in the disinfecting solution.
- 2) Attach the air/water/suction channel cleaning adapter (OF-B153), inlet seal (OF-B190), suction channel selector (OF-B161), cleaning adapter (OF-G17), and water jet channel cleaning adapter (OE-C20) to the endoscope.

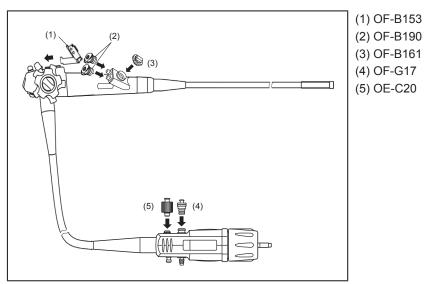


Figure 1.3.31

Endoscope with

3) Attach a syringe filled with the disinfecting solution to OF-G17, and inject 30 mL of the disinfecting solution into the air/water channel.

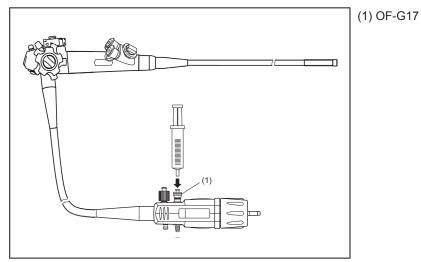


Figure 1.3.32

4) Check to confirm that disinfecting solution flows out from the air/water nozzle(s) on the distal end.

Endoscope with Two Instrumen Channels

5) Attach a syringe filled with disinfecting solution filled to the suction nipple, and inject 110 mL of disinfecting solution into the suction channel.

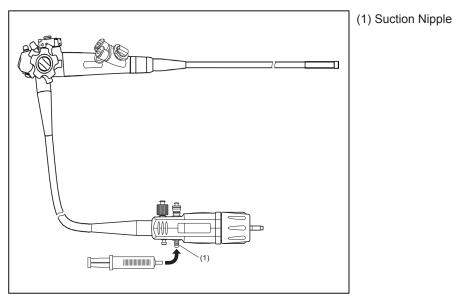


Figure 1.3.33

- 6) Check to confirm that disinfecting solution flows out from the suction
- 7) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with detergent solution to OF-B190 on instrument channel inlet "A", and inject 110 mL of disinfecting solution into the suction channel.

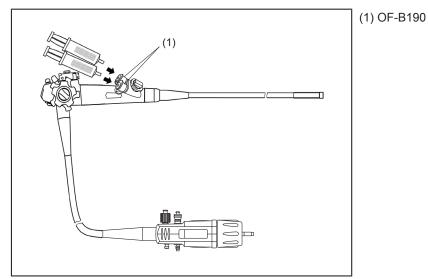


Figure 1.3.34

- 8) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with detergent solution to OF-B190 on the instrument channel inlet "B", and inject 110 mL of disinfecting solution into the suction channel.
- 9) Attach a syringe filled with disinfecting solution to OE-C20, and inject 15 mL of disinfecting solution into the water jet channel.

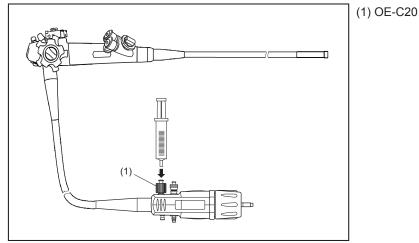


Figure 1.3.35

10) Check to confirm that disinfecting solution flows out from the water jet channel opening on the distal end.

11) After injecting disinfecting solution into all channels, detach OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 from the endoscope, and leave them to soak along with the endoscope in disinfecting solution until the next step. Open the cap of OF-B190.

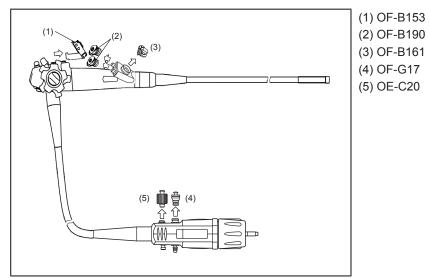


Figure 1.3.36

Endoscope with Two Instrumen

1-3-4-4. Soaking in disinfecting solution

WARNING

- The disinfecting solution must remain in contact with ALL internal channels, external endoscope surfaces and components for the time period recommended by the disinfectant manufacturer.
- Adhere to the conditions (temperature, concentration, time) specified by the disinfectant manufacturer to accomplish effective and complete disinfection. Disinfectant solution use under conditions that fall outside the manufacturer's directions might damage the endoscope.
- During immersion, detach all components and accessories (except the soaking cap) from the endoscope to ensure contact of all endoscope surfaces with the disinfecting solution.
- 1) While fully immersed ensure that the endoscope, inlet seal (OF-B190), cleaning adapters (OE-C20, OF-B152, and OF-G17), and suction channel selector (OF-B161) do not have air bubbles on their surfaces. If any air bubbles are detected, flush them away with disinfecting solution using a syringe.

2) Soak the endoscope, OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 under the conditions (temperature, concentration, time) specified by the disinfectant manufacturer. In the case of Cidex Activater Diadehyde Solution, the soaking time is 45 minutes at 25°C.

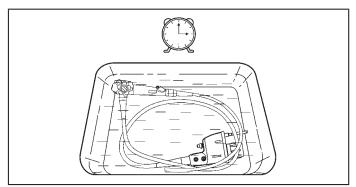


Figure 1.3.37

Purging of disinfecting solution from all channels

- 3) After soaking, attach OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 to the endoscope. (see Figure 1.3.31, p69)
- 4) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air to purge as much residual disinfecting solution as possible. (see Figure 1.3.32, p70)
- 5) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 110 mL of air to purge as much residual disinfecting solution as possible. (see Figure 1.3.33, p70)
- 6) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "A", and flush the suction channel with 110 mL of air to purge as much residual detergent solution as possible. (see Figure 1.3.34, p71)
- 7) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "B", and flush the suction channel with 110 mL of air to purge as much residual detergent solution as possible. (see Figure 1.3.34, p71)
- 8) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air to purge as much residual disinfecting solution as possible. (see Figure 1.3.35, p71)
- 9) Take the endoscope with the components and accessories attached out of the disinfecting solution.

WARNING

- Ideally, all final rinses should be performed with sterile water. However, if sterile water is not used, use potable water or the water that meets the requirements of the health care facility.
- The basin that is used to perform rinsing of the endoscope and accessories should be thoroughly cleaned prior to filling it with rinse water.
- The rinse volumes recommended for removing residual disinfectant from channels are sufficient for 14-day glutaraldehydes (Cidex Activated Dialdehyde Solution). If extended shelf-life glutaraldehydes are used, consult with the disinfectant manufacturer for details regarding recommended rinse water volumes.

First rinse

- 1) Place the endoscope with components and accessories attached into a basin of sterile water that is of sufficient volume to completely immerse the endoscope.
- 2) Detach the inlet seal (OF-B190), cleaning adapters (OE-C20, OF-B153, and OF-G17), and suction channel selector (OF-B161) from the endoscope. Open the cap of OF-B190. (see Figure 1.3.36, p72)
- 3) Wipe all exterior surfaces of the endoscope, OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 two times with sterile gauze in order to remove residual disinfecting solution.
- 4) While still completely immerse in water, grasp the distal end, control body of the scope, and PVE connector with two hands, and agitate it under the water by moving it from side to side repeatedly for one minute.

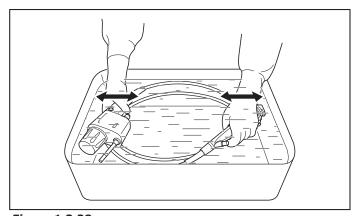


Figure 1.3.38

- 5) Similarity, grasp OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 with a hand, and agitate them under the water by moving them from side to side repeatedly for one minute.
- 6) Attach OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 to the endoscope. (see Figure 1.3.31, p69)
- 7) Attach a syringe filled with water to OF-G17, and flush the air/water channel with 90 mL of water. (see Figure 1.3.32, p70)
- 8) Attach a syringe filled with water to the suction nipple, and flush the suction channel with 440 mL of water. (see Figure 1.3.33, p70)

- 9) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with water to OF-B190 on instrument channel inlet "A", and flush the suction channel with 440 mL of water. (see Figure 1.3.34, p71)
- 10) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with water to OF-B190 on instrument channel inlet "B", and flush the suction channel with 440 mL of water. (see Figure 1.3.34, p71)
- 11) Attach a syringe filled with water to OE-C20, and flush the water jet channel with 35 mL of water. (see Figure 1.3.35, p71)
- 12) Take the endoscope with the components and reprocessing accessories attached out of the water.
- 13) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air. (see Figure 1.3.32, p70)
- 14) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 110 mL of air. (see Figure 1.3.33, p70)
- 15) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "A", and flush the suction channel with 110 mL of air. (see Figure 1.3.34, p71)
- 16) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "B", and flush the suction channel with 110 mL of air. (see Figure 1.3.34, p71)
- 17) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air. (see Figure 1.3.35, p71)

Second rinse

18) Fill a basin with clean water, and repeat steps 1 - 17 in order to perform a second complete rinse.

Third rinse

19) Fill a basin with clean water, and repeat steps 1 - 17 in order to perform a third complete rinse.

Fourth rinse

20) Fill a basin with clean water, and repeat steps 1 - 17 in order to perform a fourth complete rinse.

1-3-4-6. Drying

WARNING

Regardless of the quality of the rinse water used, it is essential to perform a final alcohol rinse followed by forced air in order to completely dry the endoscope channels and prevent bacterial colonization and/or infections associated with waterborne microorganisms.

Flushing all channels with alcohol

- 1) Attach a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to cleaning adapter (OF-G17), and flush the air/water channel with 35 mL of alcohol. (see Figure 1.3.32, p70)
- 2) Attach a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to the suction nipple, and flush the suction channel with 150 mL of alcohol. (see Figure 1.3.33, p70)

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- 3) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to inlet seal (OF-B190) on the instrument channel inlet "A", and flush the suction channel with 150 mL of alcohol. (see Figure 1.3.34, p71)
- 4) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to the inlet seal (OF-B190) on the instrument channel inlet "B", and flush the suction channel with 150 mL of alcohol. (see Figure 1.3.34, p71)
- 5) Attach a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to the water jet channel cleaning adapter (OE-C20), and flush the water jet channel with 15 mL of alcohol. (see Figure 1.3.35, p71)

Flushing all channels with air

- 6) Attach a syringe filled with air to OF-G17, and flush the air/water channel with 90 mL of air to remove residual alcohol. (see Figure 1.3.32, p70)
- 7) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 110 mL of air to remove residual alcohol. (see Figure 1.3.33, p70)
- 8) Align the suction channel selector knob (OF-B161) to the "A" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "A", and flush the suction channel with 110 mL of air. (see Figure 1.3.34, p71)
- 9) Align the suction channel selector knob (OF-B161) to the "B" indicator. Insert a syringe filled with air to OF-B190 on instrument channel inlet "B", and flush the suction channel with 110 mL of air. (see Figure 1.3.34, p71)
- 10) Attach a syringe filled with air to OE-C20, and flush the water jet channel with 35 mL of air to remove residual alcohol. (see Figure 1.3.35, p71)
- 11) Ensure no alcohol exits the endoscope tip. If any, repeat the step above.
- 12) Detach OF-B190, OE-C20, OF-B153, OF-B161, and OF-G17 from the endoscope. (see Figure 1.3.36, p72)

Drying of all external surfaces

13) Gently dry all external surfaces of the endoscope, components, and accessories with a sterile gauze.

Endoscope with Two Instrument

WARNING

- Please note that PENTAX Medical has not validated any steam sterilization methods for flexible endoscopes.
- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- After sterilization, ensure that the package is intact. If there are any signs of abnormalities such as stains, tears or any other indications that the packaging has been damaged or opened, repeat the sterilization with new packaging.
- Sterilization efficacy and material compatibility depend on the following factors.
 - thorough cleaning of the device
 - load of the devices to be sterilized
 - wrapping of the devices to be sterilized
 - sterilizer cycle parameters
 - quality of rinse water
- Prior to sterilization, clean and dry the endoscope thoroughly. Failure to do so can result in ineffective or incomplete sterilization.
- Use a chemical indicator (CI) and/or biological indicator (BI) to control the sterilization process and ensure sterilization efficacy.
- The manufacturer of the sterilizer should be consulted to confirm that test data exists to substantiate that no harmful levels of any residues (active/inert ingredients, their by-products or derivatives of the processed devices) remain on any instrument that may pose a risk to patients and users.
- After sterilization, ensure that the package is intact. If there are any indications that the integrity of the package has been compromised, repeat the sterilization process with new packaging.

(CAUTION

- Due to the heat sensitive nature and/or the specific biocompatible materials used in the construction of flexible endoscopes, some sterilization systems/processes/solutions may have detrimental effects on flexible endoscopes. To avoid the potential for instrument damage and/or endoscope failure, confirm the compatibility of such systems/ solutions with your local PENTAX dealer prior to use with any PENTAX products. Also, confirm the specific claim(s) of any sterilization methods/ processes with the sterilizer manufacturer to ensure manufacturer that they have performed microbiological validation studies to support their claims of achieving sterilization of device specific flexible endoscopes models and endoscope components.
- NEVER place the endoscope in a steam sterilizer !

Endoscope with

1-4. Endoscope components and accessories

Endoscope components and accessories can be subjected to the following cleaning, disinfection, and sterilization process.

	Model		Cleaning		High-level	Optional Sterilization
	Name	Number	Manual	Ultrasonic	Disinfection	Steam Sterilization
	Suction Control Valve	OF-B120	Y	Y	Y	Y
	Air/Water Feeding Valve	OF-B188	Y	Y	Y	Y
Endossono	Inlet Seal	OF-B190	Y	Y	Y	Y
Endoscope Component	Water Jet Check Valve Adapter	OE-C12	Y	Y	Y	Y
	Water Jet Connector Cap	OF-B118	Y	Y	Y	Y
	Suction Channel Selector	OF-B161	Y	Y	Y	Y
Accessory	Irrigation Tube	OF-B113	Υ	Y	Y	Y
	PVE Soaking Cap	OE-C9	Υ*	N	Υ*	N
Reprocessing Accessory	Water Jet Channel Cleaning Adapter	OE-C20	Y	Y	Υ	Y
	Ventilation Cap	OF-C5	N	N	N	N
	Cleaning Adapter	OF-B153	Y	Y	Y	Y
	Cleaning Adapter	OF-G17	Y	Y	Y	Y
	Cleaning Brush	CS-C9S	Y	Y	Y	Y
	Cleaning Brush	CS6021T	N	N	N	N

Accessory



^{* :} The PVE Soaking Cap (OE-C9) should be attached to the endoscope during cleaning and disinfection procedures.

1-4-1. Cleaning

WARNING

- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- Endoscope components and accessories should be thoroughly and carefully cleaned with detergent solution within one hour after the conclusion of an endoscopic procedure. If they are left uncleaned for greater than one hour after use, dried blood, mucus or other patient debris may cause damage to them or interfere with the ability of the user to properly reprocess them.
- For cleaning, use only legally marketed detergents which have been tested and found to be compatible by PENTAX. A list of detergents that are compatible with PENTAX components and accessories is contained in this manual.
- Fresh detergent solution must be used for each set of endoscope components and accessories.

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1-4-1-1. Items required

Reprocessing accessory

• Cleaning brush (CS-C9S)

Other equipment

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Detergent solution, Endozime (Ruhof Corporation)
- · Clean potable water
- Basin (at least 25 cm in width x 20 cm in depth x 15 cm in height)
- Lint-free gauze
- 10 mL luer slip syringe
- Ultrasonic cleaner (frequency range: 44 kHz +/-6%)

1-4-1-2. Cleaning procedure

Preparation

- 1) Wear personal protective equipment.
- 2) Prepare a basin of detergent solution per manufacturer's instructions (temperature, concentration). In the case of ENDOZIME, add 30 mL of ENDOZIME concentrate to 3.8 L (1 gallon) of clean potable water at 20°C~30°C (68°F~86°F).
- 3) Fully immerse the components and accessories, and keep them immersed in the detergent solution during the following cleaning procedure.
- 4) Open the cap of inlet seal (OF-B190).

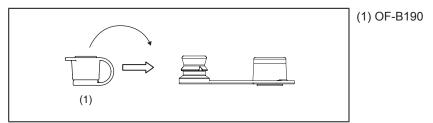


Figure 1.4.1

Cleaning external surfaces

5) Wash all entire surfaces of components and accessories three times with the lint-free gauze.

Cleaning brush

6) Wash the brush heads of the cleaning brush (CS-C9S) by rubbing them with fingers for 30 seconds.

Accessory

Brushing (Brush: small brush head of cleaning brush CS-C9S)

7) Brush all internal and external surfaces of the suction control valve (OF-B120) and air/water feeding valve (OF-B188). Brush them four times.

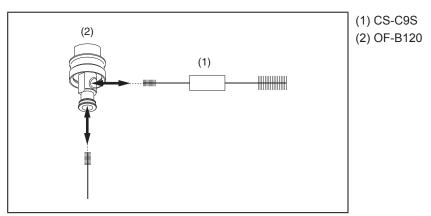


Figure 1.4.2

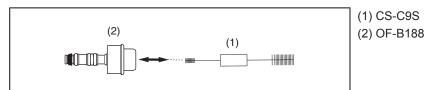


Figure 1.4.3

Detach check valve (OE-C14) from the water jet check valve adapter (OE-C12). While immersed in the detergent solution, brush all internal and external surfaces of OE-C12 and OE-C14 four times.

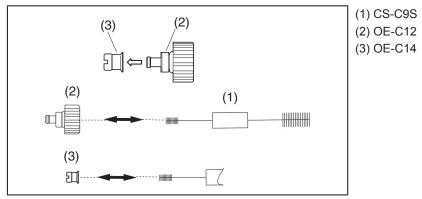


Figure 1.4.4

9) Brush all internal and external surfaces of suction channel selector (OF-B161).

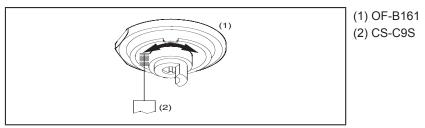


Figure 1.4.5

10) Insert the brush head into lumen of water jet channel cleaning adapter (OE-C20) from the lure lock side, and brush the entire length of the lumen back and forth for a total of 15 times.

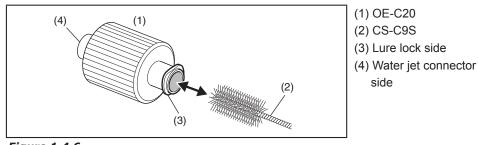


Figure 1.4.6

Brushing (Brush: large brush head of cleaning brush CS-C9S)

11) Brush the ridged portion of the water jet channel cleaning adapter (OE-C20) in the direction of the ridges for 40 seconds while simultaneously rotating the adapter so that its entire circumference is brushed.

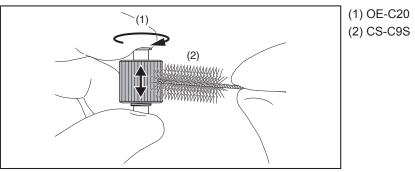


Figure 1.4.7

- 12) Brush the lure lock connector side of the water jet channel cleaning adapter (OE-C20) for 20 seconds while simultaneously rotating the adapter so that its entire circumference is brushed.
- 13) Turn the water jet channel cleaning adapter (OE-C20) upside down, and brush water jet connector side of the adapter for 20 seconds while simultaneously rotating the adapter so that its entire circumference is brushed.

Manipulating of valve mechanisms

14) While fully immersed, manipulate the suction control valve (OF-B120) mechanism and air/water feeding valve (OF-B188) mechanism four times.

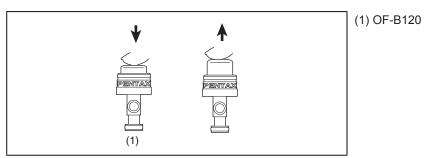


Figure 1.4.8

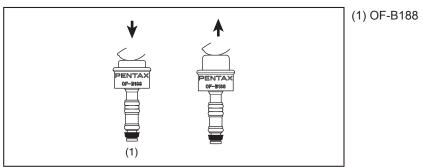


Figure 1.4.9

Filling lumens with detergent solution

15) Using a syringe filled with the detergent solution, inject 3 mL of detergent solution directly into each lumen of suction control valve (OF-B120) and air/water feeding valve (OF-B188).

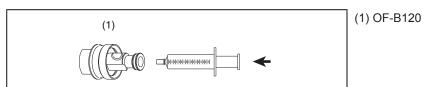


Figure 1.4.10

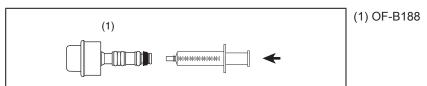


Figure 1.4.11

16) Using a syringe filled with the detergent solution, inject 3 mL of detergent solution directly into the lumen of the water jet check valve adapter (OE-C12).

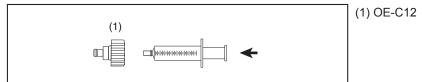


Figure 1.4.12

17) Using a syringe filled with the detergent solution, inject 10 mL of detergent solution directly into the lumen of the irrigation tube (OF-B113).

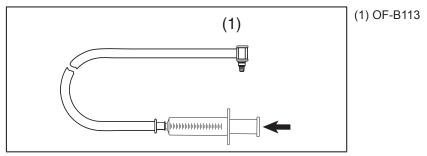


Figure 1.4.13

18) Using a syringe filled with the detergent solution, inject 10 mL of detergent solution directly into the lumen of the water jet channel cleaning adapter (OE-C20).

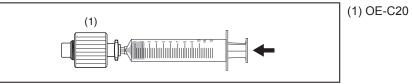


Figure 1.4.14

Soaking in detergent solution

- 19) While fully immersed, ensure there are no air bubbles on the surfaces of components and accessories. If any bubbles are detected, flush them away with the detergent solution using a syringe.
- 20) Soak them in the detergent solution according to the instructions (temperature, concentration, time) provided by the detergent manufacturer. In the case of Endozime, the immersion time is at 3 minutes
- 21) Remove the components from the detergent solution.

1-4-1-3. Ultrasonic Cleaning

! WARNING

All components and accessories must be ultrasonically cleaned prior to subsequent high-level disinfection or sterilization.

CAUTION

DO NOT use caustic or abrasive solutions in the ultrasonic cleaner.

- 1) Prepare the detergent solution per the manufacturer's instructions (temperature, concentration). In the case of ENDOZIME, add 30 mL of ENDOZIME concentrate to 3.8 L (1 gallon) of clean potable water at 20°C~30°C (68°F~86°F).
- 2) Immerse the components and accessories in detergent solution.
- 3) While fully immersed, ensure that there are no air bubbles on the surfaces of the components and accessories. If any bubbles are detected, flush them away with a syringe filled with detergent solution.
- 4) Perform ultrasonic cleaning under the following conditions:
 - Frequency Range: 44 kHz +/- 6 % Time: 5 minutes
- 5) After the completion of the ultrasonic cleaning process, remove the components and accessories from the ultrasonic cleaner.

Accessory

1-4-1-4. Rinsing

WARNING

All residual detergent solution must be removed from the components and accessories. Residual detergent solution may interfere with subsequent biocidal processes.

First rinse

- 1) Prepare a basin with clean water and fully immerse the components and accessories.
- 2) Wipe all exterior surfaces of the components and accessories three times with a lintfree gauze in order to remove residual detergent solution.
- 3) While still completely immersed in water, grasp them with a hand, agitate them under the water by moving them from side to side for a total one minute.
- 4) Manipulate the suction control valve (OF-B120) mechanism four times in the water. Using a syringe filled with water, flush the lumen of the valve with 5 mL of water. (see Figure 1.4.8, p82 and Figure 1.4.10, p82)
- 5) Manipulate the air/water feeding valve (OF-B188) mechanism four times in the water. Using a syringe filled with water, flush the lumen of the valve with 5 mL of water. (see Figure 1.4.9, p82 and Figure 1.4.11, p82)
- 6) Using a syringe filled with water, flush the lumen of the water jet check valve adapter (OE-C12) with 5 mL of water. (see Figure 1.4.12, p83)
- 7) Using a syringe filled with water, flush the lumen of the irrigation tube (OF-B113) with 15 mL of water. (see Figure 1.4.13, p83)

- 8) Using a syringe filled with water, flush the water jet channel cleaning adapter (OE-C20) with 10 mL of water. (see Figure 1.4.14, p83)
- 9) Discard the water.

Second rinse

10) Fill a basin with clean water, and repeat steps 2 - 9 in order to perform a second rinse.

Third rinse

11) Fill a basin with clean water, and repeat steps 2 - 9 in order to perform a second rinse.

Four rinse

- 12) Fill a basin with clean water, and repeat steps 2 9 in order to perform a fourth rinse.
- 13) Take all components and accessories out of the water.

Purging of water from lumens

- 14) Using a syringe filled with air, flush the lumen of suction control valve (OF-B120) with air to purge residual water. (see Figure 1.4.10, p82)
- 15) Using a syringe filled with air, flush the lumen of air/water feeding valve (OF-B188) with air to purge residual water. (see Figure 1.4.11, p82)
- 16) Using a syringe filled with air, flush the lumen of water jet check valve adapter (OE-C12) with air to purge residual water. (see Figure 1.4.12, p83)
- 17) Using a syringe filled with air, flush the lumen of irrigation tube (OF-B113) with air to purge residual water. (see Figure 1.4.13, p83)
- 18) Using a syringe filled with air, flush the lumen of water jet channel cleaning adapter (OE-C20) with air to purge residual water. (see Figure 1.4.14, p83)

1-4-1-5. Drying

1) Wipe all surfaces of components and accessories gently with a lint-free gauze.



- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- Prior to disinfection, all components and accessories must be meticulously cleaned. Failure to do so can result in incomplete or ineffective disinfection.
- For high-level disinfection, use disinfecting solution according to instructions of the disinfectant manufacturer (temperature, concentration, time). Use only legally marketed disinfecting solutions that have been tested and found to be compatible by PENTAX. A list of disinfectant solutions compatible with PENTAX components and accessories is contained in this manual.
- Adhere to the instructions provided by the disinfectant manufacturer to accomplish effective and complete disinfection. Failure to do so may result in damage to the endoscope components and accessories.
- Ideally, all final rinses should be performed with sterile water. However, if sterile water is not used, use clean potable water that meets the requirements of the health care facility.
- Regardless of the quality of the rinse water used, it is essential
 to perform a final alcohol rinse followed by forced air in order to
 completely dry the lumens of components and accessories, and prevent
 bacteria colonization and/or infections associated with waterborne
 microorganisms.
- The basin that is used to perform disinfectant immersion should be thoroughly cleaned prior to filling it with disinfectant solution.
- Verification that the potency of the liquid chemical germicide is at or above its Minimum Effective Concentration (MEC) (using recommended test strips or similar methods) is required to ensure that high-level disinfection/sterilization can be achieved.

1-4-2-1. Items required

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Disinfecting solution, Cidex Activated Dialdehyde Solution (Johnson & Johnson)
- · Sterile water (preferred) or clean potable water
- 70-90% medical grade ethyl or isopropyl alcohol
- Basin (at least 25 cm in width x 20 cm in depth x 15 cm in height)
- Sterile gauze
- 10 mL luer slip syringe

1-4-2-2. Disinfection procedure

Preparation

- 1) Wear personal protective equipment.
- 2) Prepare a basin of disinfecting solution per manufacturer's instructions (temperature, concentration).
- 3) Fully immerse the components and accessories, and keep them immersed in the disinfecting solution during the following disinfection procedure.
- 4) Open the cap of inlet seal (OF-B190) in the disinfecting solution.

Manipulating of valve mechanisms

5) While fully immersed, manipulate the suction control valve (OF-B120) mechanism and air/water feeding valve (OF-B188) mechanism four times. (see Figure 1.4.8, p82 and Figure 1.4.9, p82)

Filling the lumens with disinfecting solution

- 6) Using a syringe filled with disinfecting solution, inject 3 mL of disinfecting solution directly into each lumen of suction control valve (OF-B120) and air/water feeding valve (OF-B188). (see Figure 1.4.10, p82 and Figure 1.4.11, p82)
- 7) Using a syringe filled with disinfecting solution, inject 3 mL of disinfecting solution directly into the lumen of water jet check valve adapter (OE-C12). (see Figure 1.4.12, p83)
- 8) Using a syringe filled with disinfecting solution, inject 10 mL of disinfecting solution directly into the lumen of the irrigation tube (OF-B113). (see Figure 1.4.11, p82)
- 9) Spray the outer surfaces of the connector portions of irrigation tube (OF-B113) with 10 mL of disinfecting solution. Rotate irrigation tube (OF-B113) in order to ensure that all connector surfaces are contacted.

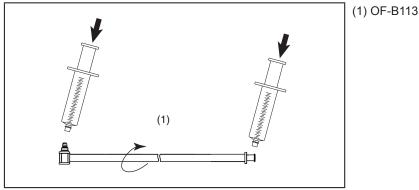


Figure 1.4.15

10) Using a syringe filled with the disinfecting solution, inject 10 mL of disinfecting solution directly into the lumen of the water jet channel cleaning adapter (OE-C20).

Soaking in disinfecting solution

- 11) While fully immersed, ensure there are no air bubbles on the surfaces of components and accessories. If any bubbles are detected, flush them away with disinfecting solution using a syringe.
- 12) Soak the items in disinfecting solution for the appropriate amount of time according to the instructions of disinfectant manufacturer. In the case of Cidex Activated Dialdehyde Solution, the immersion time is 45 minutes at 25°C.
- 13) Remove the items from the disinfecting solution.

1-4-2-3. Rinsing

First rinse

- 1) Prepare a basin with sterile water, and immerse the components and accessories.
- 2) Wipe all exterior surfaces of the components and accessories two times with lint-free gauze in order to remove residual disinfecting solution.
- 3) While still completely immersed in water, grasp them with a hand, and agitate them under the water by moving them from side to side for a total one minute.
- 4) Manipulate suction control valve (OF-B120) mechanism four times in the water. Using a syringe filled with water, flush the lumen of the valve with 5 mL of water. (see Figure 1.4.8, p82 and Figure 1.4.10, p82)
- 5) Manipulate the air/water feeding valve (OF-B188) mechanism four times in the water. Using a syringe filled with water, flush the lumen of the valve with 5 mL of water. (see Figure 1.4.9, p82 and Figure 1.4.11, p82)
- 6) Using a syringe filled with water, flush the lumen of water jet check valve adapter (OE-C12) with 5 mL of water. (see Figure 1.4.12, p83)
- 7) Using a syringe filled with water, flush the lumen of irrigation tube (OF-B113) with 15 mL of water. (see Figure 1.4.13, p83)
- 8) Using a syringe filled with water, flush the water jet channel cleaning adapter (OE-C20) with 10 mL of water. (see Figure 1.4.14, p83)
- 9) Discard the water.

Second rinse

10) Fill a basin with clean water, and repeat steps 2 - 9 in order to perform a second rinse.

Third rinse

11) Fill a basin with clean water, and repeat steps 2 - 9 in order to perform a third rinse.

Fourth rinse

- 12) Fill a basin with clean water, and repeat steps 2 9 in order to perform a fourth rinse.
- 13) Take all components and accessories out of the water.

Purging of water from lumens

- 14) Using a syringe filled with air, flush the lumen of suction control valve (OF-B120) with air to purge residual. (see Figure 1.4.10, p82)
- 15) Using a syringe filled with air, flush the lumen of air/water feeding valve (OF-B188) with air to purge residual water. (see Figure 1.4.11, p82)
- 16) Using a syringe filled with air, flush the lumen of water jet check valve adapter (OE-C12) with air to purge residual water. (see Figure 1.4.12, p83)
- 17) Using a syringe filled with air, flush the lumen of irrigation tube (OF-B113) with air to purge residual water. (see Figure 1.4.13, p83)
- 18) Using a syringe filled with air, flush the lumen of water jet channel cleaning adapter (OE-C20) with air to purge residual water. (see Figure 1.4.14, p83)

WARNING

Regardless of the quality of the rinse water used, it is essential to perform a final alcohol rinse followed by forced air in order to completely dry the lumens of components and accessories, and prevent bacteria colonization and/or infections associated with waterborne microorganisms.

Flushing lumens with alcohol

- Using a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol, flush the lumen of suction control valve (OF-B120) with 2 mL of alcohol. (see Figure 1.4.10, p82)
- Using a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol, 2) flush the lumen of air/water feeding valve (OF-B188) with 2 mL of alcohol. (see Figure 1.4.11, p82)
- Using a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol, flush the lumen of water jet check valve adapter (OE-C12) with 2 mL of alcohol. (see Figure 1.4.12, p83)
- Using a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol, flush the lumen of irrigation tube (OF-B113) with 5 mL of alcohol. (see Figure 1.4.11, p82)
- Using a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol, flush the lumen of water jet channel cleaning adapter (OE-C20) with 2 mL of alcohol. (see Figure 1.4.14, p83)

Purging alcohol from lumens

- Using a syringe filled with air, flush the lumen of suction control valve (OF-B120) with air to purge residual alcohol. (see Figure 1.4.8, p82)
- Using a syringe filled with air, flush the lumen of air/water feeding valve (OF-B188) with air to purge residual alcohol. (see Figure 1.4.9, p82)
- Using a syringe filled with air, flush the lumen of water jet check valve adapter (OE-C12) with air to purge residual alcohol. (see Figure 1.4.10, p82)
- Using a syringe filled with air, flush the lumen of irrigation tube (OF-B113) with air to purge residual alcohol. (see Figure 1.4.11, p82)
- 10) Using a syringe filled with air, flush the lumen of water jet channel cleaning adapter (OE-C20) with air to purge residual alcohol. (see Figure 1.4.14, p83)

Drying of all external surfaces

11) Gently dry all external surfaces of components and accessories with a sterile gauze moistened with 70-90% medical grade ethyl or isopropyl alcohol.

1-4-3. Optional Sterilization



- Please note that PENTAX Medical has not validated any sterilization methods for flexible endoscopes.
- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- After sterilization, ensure that the package is intact. If there are any indications that the integrity of the packaging has been compromised, repeat the sterilization with new packaging.
- Prior to sterilization, all instruments and components must be meticulously cleaned and dried. Failure to do so can result in incomplete or ineffective sterilization.
- Sterilization efficacy and material compatibility depend on the following factors:
 - thorough cleaning of the device
 - load of the devices to be sterilized
 - wrapping of the devices to be sterilized
 - sterilization cycle parameters
- Use a chemical indicator (CI) and/or biological indicator (BI) recommended by the manufacturer of the sterilizer to control the sterilization process and ensure sterilization efficacy.
- The manufacturer of the sterilizer should be consulted to confirm that test data exists to substantiate that no harmful residues (active/inert ingredients, their by-products, or derivatives of the processed devices) remain on any instrument that may pose a risk to patients and users.

ACAUTION

After sterilization, the components and accessories may be hot. To avoid burns, wait until they return to room temperature befor handling.

1-4-3-1-1. **Preparation**

1) Make sure that the cap of inlet seal (OF-B190) has been closed.

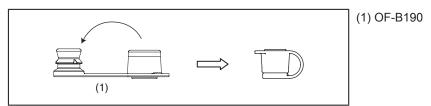


Figure 1.4.16

2) Attach check valve (OE-C14) to the water jet check valve adapter (OE-C12).

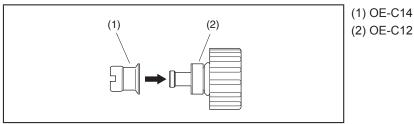


Figure 1.4.17

1-4-3-1-2. Wrapping

1) Prior to steam sterilization, wrap the components and accessories individually with two layers of one-ply Kinguard KC200 sterilization wrap (Kimberly-Clark) using sequential wrapping technique.

4

1-4-3-1-3. Parameters

Steam sterilization can be performed under the following conditions:

Sterilizer Type	Temperature	Exposure	Drying Time
Pre-vacuum	132°C	4 minutes	30 minutes
Pre-vacuum	135°C	3 minutes	16 minutes

NOTE

- Validation testing of these parameters was performed using two layers of one ply Kimberly Clark Wrap KC-200 Sterilization Wrap (Kimberly-Clark). Sequential wrapping technique was employed.
- Biological and/or chemical indicators used must be appropriate for the stated sterilization cycle parameters and cleared by FDA.

POST REPROCESSING AND STORAGE

WARNING

- Make sure that all removable components such as the air/water feeding valve, suction control valve, water jet components, inlet seal are detached from the endoscope. This will allow for better air circulation through the internal channels and permit thorough drying.
- NEVER store the endoscope, its components, and accessories in the carrying case, as this type of dark, humid, and unventilated environment is conducive to bacterial colonization, and increases the risk of cross contamination. These cases are intended for transportation of the instrument, not storage.

! CAUTION

- NEVER store the endoscope in areas of high humidity, high temperatures or in direct exposure to sunlight or X-rays.
- Avoid storage of the endoscope in cabinets, which have sharp edges, exposed nails/screws, etc. Contact with sharp objects can puncture, scratch or otherwise damage the endoscope.
- When utilizing heated disinfectants for reprocessing PENTAX endoscopes, the instruments should be allowed to return to room temperature prior to use and/or further handling.
- Following reprocessing, the endoscope may either be reused or placed in storage. 1)
- Prior to reuse, ensure that instrument has been properly inspected and fully prepared for the next clinical procedure.
- Prior to storage, ensure that all internal channels, endoscope components, instrument surfaces, and accessories are thoroughly dry.
- The endoscope should be hung in a clean, dry, well-ventilated storage cabinet at room temperature. The insertion tube and light guide cable should be hung and kept as straight as possible during storage.

3

WARNING

- Instrument repairs should only be performed by an authorized PENTAX service facility. PENTAX assumes no liability for any patient/user injury, instrument damage or malfunction, or reprocessing failure due to repairs made by unauthorized personnel.
- A list of "compatible" reprocessing agents with PENTAX endoscopes based upon material compatibility and functionality studies performed by PENTAX, Japan is contained in this manual. These tests apply only to genuine PENTAX parts, components and materials including proprietary adhesives, sealants, lubricants, etc. specifically selected for use in PENTAX endoscopes to satisfy their original design criteria. PENTAX manual reprocessing instructions supplied with each product have been validated for PENTAX endoscopes utilizing exclusive PENTAX parts/ materials and assembled based upon proprietary PENTAX manufacturing technologies and/or servicing techniques.
- Please note that PENTAX does not evaluate non-PENTAX parts, components, materials and/or servicing methods and therefore questions regarding material compatibility and/or functionality of PENTAX instruments repaired with these unauthorized, untested and unapproved items, materials, repair/assembly methods must be referred to the third party service organization and/or device remanufacturer. It is unknown to PENTAX if serviced or remanufactured instruments (performed by unauthorized PENTAX entities) which still bear a PENTAX label are within PENTAX device specifications and/or if unauthorized activities have significantly changed the instrument's performance, intended use, safety and/or effectiveness.
- Independent Service Organizations should confirm the ability of these serviced/remanufactured devices to be reprocessed safely and effectively with reprocessing agents/systems recognized as compatible by PENTAX for standard PENTAX products. These companies and/or remanufacturers should be consulted to confirm whether they have performed reprocessing validation studies on instrument models which they have serviced (or remanufactured) that support their cleaning, high-level disinfection and/or sterilization via the endoscope OEM reprocessing recommendations, standard AER device-specific instructions, and/or their own unique reprocessing recommendations.
- Ultimately, owners of these medical devices are responsible for selecting an appropriate service facility or vendor whose activities render an instrument to the same expectations and quality of a finished device supplied by the endoscope OEM.

Prior to returning any instrument for repair to PENTAX, the instrument should first undergo appropriate reprocessing/decontamination procedures for the purpose of infection control. Check with your local PENTAX service facility for more details.

- All instruments requiring repair should be shipped in the original carrying case with appropriate packing along with comments describing the instrument damage and complaint.
- 2) A repair purchase order number, contact name, and phone number of the individual responsible for authorizing repairs, as well as shipping address should be included.
- 3) The ventilation cap should be attached to the instrument if it will be shipped by air freight.
- 4) Any accessories and/or endoscope components potentially related to the endoscope damage or complaint should also be returned with the endoscope.
- 5) PVE soaking caps should also be returned with the endoscope to check/confirm the integrity of their watertight seal.
- 6) After servicing, all endoscopes must be reprocessed prior to patient use.
- 7) For disposal of instruments, follow local or country regulations.

4-1. PENTAX Medical Compatible Reprocessing Systems/Agents

The information below is based upon material compatibility and functionality studies performed by HOYA Corporation- PENTAX Medical Division, Japan. Reference to specific brand name products is not an endorsement of their efficacy. Tests have shown these solutions to be compatible with materials used in the construction of PENTAX Medical endoscopes, provided that the manufacturers' instructions for use are followed. This document has been prepared by PENTAX Medical Company for PENTAX Medical customers in the United States, Canada and Latin America.

Important

PENTAX Medical instructions for use contain detailed recommendations for the manual reprocessing of PENTAX Medical endoscopes using PENTAX Medical supplied cleaning accessories. Automated Endoscope Reprocessor (AER) product claims are the responsibility of the AER manufacturer, including but not limited to cleaning, disinfection, sterilization, rinsing, drying, biocompatibility, reprocessing instructions, required channel adapters, efficacy validation studies, and compliance with regulatory requirements and/or professional guidelines. Prior to reprocessing PENTAX Medical brand endoscopes in a specific model AER machine, contact the AER manufacturer to confirm the following:

- The AER efficacy claims have been validated for the specific PENTAX Medical model endoscopes in question.
- Instructions are available for the specific PENTAX Medical model endoscopes and endoscope components in question.

Enzymatic Detergents

Product Brand Name	Manufacturer	
Cidezyme® XTRA (used exclusively in EvoTech ECR)	- Advanced Sterilization Products (ASP)	
Enzol [®]		
Endozime [®]	Dubof Companylian	
Endozime® AW Plus	Ruhof Corporation	
Enzy-Clean	Care Fusion	
MetriZyme [®]	Metrex Research Corporation	
Tergal 800	Custom Ultrasonics	
ZymeX™ Enzymatic Cleaner Concentrate	Sultan Healthcare	

High Level Disinfectants

The following liquid chemical germicides have received FDA 510(k) clearance for claims of high level disinfection (HLD). Some HLD products may have multiple label claims and/or may be FDA-cleared only for use in a legally marketed AER machine that can attain specific use parameters (e.g., temperature).

Product Brand Name	Manufacturer
Cidex® OPA Cidex® OPA-C (used exclusively in EvoTech ECR) Cidex® Activated Dialdehyde Solution (14-Day Glutaraldehyde)	Advanced Sterilization Products
MetriCide® (Glutaraldehyde - may also be marketed as Omnicide NS or MaxiCide® NS)	Metrex Research Corporation
Sporicidin [®] (Glutaraldehyde)	Contec Incorporated
Rapicide® (Glutaraldehyde)	Medivators Inc.
Wavicide®-01 (Glutaraldehyde)	Medical Chemical Corporation

Sterilization Agents/Processes

The following agents/processes have received FDA 510(k) clearance for claims of sterilization:

Ethylene Ox	ide / Carbon Dioxide (80:20 gas mixture)
Ethylene Ox	ide / Carbon Dioxide (90:10 gas mixture)

NOTICE

These instruments are used with Class B Medical Equipment (specified CISPR11) and are intended for Hospitals, Ambulatory Surgery Centers, or Medical Clinics.

Together, these endoscopes and the compatible processor comply with EN 60601-1-2 for EU, IEC 60601-1-2 for other countries.

When used in clinical or residential areas near radio and TV receiver units, these instruments may cause radio interference.

To avoid and resolve adverse electromagnetic effects, do NOT operate these instruments near the radio frequency energy equipment.

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• Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

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