INSTRUCTIONS FOR USE (REPROCESSING)

PENTAX VIDEO BRONCHOSCOPES

EB-1970TK
EB-1170K, EB-1570K
EB-1970K, EB-1575K
EB-1975K, EB-1990i
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 Lever; and air or fluids can be suctioned from the distal end of the endoscope by operating the Suction Control Valve.

Indication for Use
The PENTAX Video Bronchoscopes (EB Family) have been designed to be used with a PENTAX Video Processor (including Light Source), documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

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

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

Intended anatomical area: Airways and tracheobronchial tree

User: Medical doctors (expert 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 lever
• Remote control operation using remote buttons
• Suctioning function

Removable Components

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>OF-B179</td>
<td>Suction Control Valve</td>
</tr>
<tr>
<td>OF-B190</td>
<td>Inlet Seal</td>
</tr>
</tbody>
</table>

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 hyphen 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 Instructions 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
The endoscopes identified in this IFU are reusable semicritical devices. Since they are packaged non-sterile, they must be high-level disinfected or sterilized BEFORE initial 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
Throughout this IFU, the following conventions will be used to indicate a potentially hazardous situation which, if not avoided;

WARNING : could result in death or serious injury.

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

NOTE : 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”

Symbol for “DATE OF MANUFACTURE”

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

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マークは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标志意味着该类产品遵从欧洲共同体安全法规。
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Video Bronchoscopes
EB-1975K, EB-1990i

This symbol denotes an endoscope model's material compatibility with the STERRAD® NX™ system. (EB-1575K, EB-1975K, EB-1990i) Endoscopes that do not have this symbol are incompatible with the STERRAD® NX™ system. (EB-1170K, EB-1570K, EB-1970K, EB-1970TK)
Table of Minimum Instrument Channel Width

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Instrument Channel Width (I.D. φ mm)</td>
<td>1.2</td>
<td>2.0</td>
<td>2.8</td>
<td>3.2</td>
<td>2.0</td>
<td>2.8</td>
<td>1.2</td>
</tr>
</tbody>
</table>
Endoscope Components and Accessories

Endoscope Components

- Suction Valve (OF-B179)
- Inlet Seal (OF-B190)

Accessories

- Bite Bock (OF-Z5)
Accessories for Reprocessing

- PVE Soaking Cap (OE·C9)
- Ventilation Cap (OF·C5)
- Cleaning Adapter (OF·B155)
- Cleaning Brush (CS·C3S)
- Cleaning Brush (CS6002SN/CS6015ST/CS3010S)

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Appearance of Bristles</th>
<th>Length of Shaft</th>
<th>Diameter of Bristles</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS6002SN</td>
<td></td>
<td>20cm</td>
<td>φ 6mm</td>
</tr>
<tr>
<td>CS6015ST</td>
<td></td>
<td>150cm</td>
<td>φ 6mm</td>
</tr>
<tr>
<td>CS3010S</td>
<td></td>
<td>100cm</td>
<td>φ 3mm</td>
</tr>
</tbody>
</table>
Pre-Cleaning
- Preparation
- Wiping of insertion tube
- Aspiration of detergent solution through suction channel
- Transport to cleaning room

Leak Testing

Cleaning
- Preparation
- Cleaning of all external surfaces
- Brushing of suction channel
- Filling of detergent solution into suction channel
- Soaking in detergent solution
- Rinsing
- Drying

High-Level Disinfection
- Preparation
- Filling of disinfecting solution into suction channel
- Soaking in disinfecting solution
- Rinsing
- Drying

Optional Sterilization
Sterilization using STERRAD® NX™ system (EB-1575K, EB-1975K, EB-1990i only)
- Preparation
- Wrapping
- Sterilization Parameter Selection

⚠️ CAUTION
STERRAD® NX™ Validation data has not been generated for endoscope models in this manual other than EB-1575K, EB-1975K, and EB-1990i.
1-1. General

**NOTE**

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

1-1-1. Application

**WARNING**

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 Bronchoscopes

<table>
<thead>
<tr>
<th>TYPE</th>
<th>MODEL</th>
<th>Video Bronchoscopes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name</td>
<td>Number</td>
</tr>
<tr>
<td>Endoscope Component</td>
<td>Suction Control Valve OF-B179</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>Inlet Seal     OF-B190</td>
<td>Y</td>
</tr>
<tr>
<td>Accessory</td>
<td>Bite Block - Adult Size OF-Z5</td>
<td>Y</td>
</tr>
<tr>
<td>Reprocessing Accessory</td>
<td>PVE Soaking Cap OE-C9</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>Ventilation Cap OF-C5</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>Cleaning Adapter OF-B155</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>Cleaning Brush  CS6002SN</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>Cleaning Brush  CS6015ST</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td>Cleaning Brush  CS3010S</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td>Cleaning Brush  CS-C3S</td>
<td>Y</td>
</tr>
</tbody>
</table>

Y : YES  
N : NO
1-1-2. Important Instructions

**WARNING**

- **Reusable Medical Devices that are initially supplied 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 and 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 or 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 manufacturers. A list of legally marketed solutions/systems that have been determined to be compatible with PENTAX brand products is contained in this manual.
CAUTION

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 cable, use a slow back and forth motion to wipe them along the tube/cable. Never apply excessive force or torque to these strain reliefs or tubes/cables.

Do NOT Twist or Rotate  
Do NOT Bend

Figure 1.1

CAUTION

- EB-1575K, EB-1975K, EB-1990i can be sterilized using the STERRAD® NX™ system. For more detail, refer to sections 1-2-5-1 and 1-3-3-2 of this instruction for use.
- Video bronchoscopes other than EB-1575K, EB-1975K, EB-1990i are incompatible with sterilization using STERRAD® NX™ system.
- After every 100 cycles of STERRAD® NX™ exposure, the endoscope should be returned to an authorized PENTAX service facility for repair. Replacement of the insertion tube and bending section will be necessary and other components may also require service.
- Although STERRAD® NX™ compatible endoscopes are generally capable of withstanding up to 100 cycles of exposure to STERRAD® NX™, repair/replacement of components might be necessary prior to 100 cycles, depending upon the condition of the endoscope.
- Be sure to attach the ventilation cap (OF-C5) to the venting connector before performing STERRAD® NX™ sterilization.
NOTE

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 pre-cleaning step.
1-1-3. Internal Channels of Video Bronchoscopes

The following internal schematic 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.

Figure 1.2

(1) Suction Channel
(2) Instrument Channel Inlet
(3) Inlet Seal (OF-B190)
(4) Suction Cylinder
(5) Cleaning Adapter (OF-B155)
(6) Ventilation Cap (OE-C5)
(7) PVE Soaking Cap (OE-C9)
1-1-4. Quick Reference of Injection Volumes for Internal Channel

The following table is designed to help users better understand the injection volumes for internal channel of video bronchoscopes.

**Cleaning Process**

<table>
<thead>
<tr>
<th>Video Bronchoscopes</th>
<th>Internal Channel</th>
<th>Maximum Volume Capacity (mL)</th>
<th>Detergent</th>
<th>Rinse Water</th>
<th>Air</th>
</tr>
</thead>
<tbody>
<tr>
<td>EB-1170K</td>
<td>Suction Channel</td>
<td>4 mL</td>
<td>①:25 mL</td>
<td>②:25 mL</td>
<td>①:35 mL</td>
</tr>
<tr>
<td>EB-1570K</td>
<td></td>
<td>6 mL</td>
<td>①:25 mL</td>
<td>②:25 mL</td>
<td>①:35 mL</td>
</tr>
<tr>
<td>EB-1970K</td>
<td></td>
<td>8 mL</td>
<td>①:25 mL</td>
<td>②:25 mL</td>
<td>①:35 mL</td>
</tr>
<tr>
<td>EB-1970TK</td>
<td></td>
<td>9 mL</td>
<td>①:25 mL</td>
<td>②:25 mL</td>
<td>①:35 mL</td>
</tr>
<tr>
<td>EB-1575K</td>
<td></td>
<td>6 mL</td>
<td>①:25 mL</td>
<td>②:25 mL</td>
<td>①:35 mL</td>
</tr>
<tr>
<td>EB-1975K</td>
<td></td>
<td>8 mL</td>
<td>①:25 mL</td>
<td>②:25 mL</td>
<td>①:35 mL</td>
</tr>
<tr>
<td>EB-1990i</td>
<td></td>
<td>4 mL</td>
<td>①:25 mL</td>
<td>②:25 mL</td>
<td>①:35 mL</td>
</tr>
</tbody>
</table>

- ① Injecting from suction nipple
- ② Injecting from inlet seal (OF-B190)

**High Level Disinfection Process**

<table>
<thead>
<tr>
<th>Video Bronchoscopes</th>
<th>Internal Channel</th>
<th>Maximum Volume Capacity (mL)</th>
<th>High Level Disinfection Injection Volumes (mL)</th>
<th>Alcohol Rinse Injection Volumes (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EB-1170K</td>
<td>Suction Channel</td>
<td>4 mL</td>
<td>①:25 mL</td>
<td>Alcohol: ①:15 mL, ②:35 mL</td>
</tr>
<tr>
<td>EB-1570K</td>
<td></td>
<td>6 mL</td>
<td>①:25 mL</td>
<td>Alcohol: ①:15 mL, ②:35 mL</td>
</tr>
<tr>
<td>EB-1970K</td>
<td></td>
<td>8 mL</td>
<td>①:25 mL</td>
<td>Alcohol: ①:15 mL, ②:35 mL</td>
</tr>
<tr>
<td>EB-1970TK</td>
<td></td>
<td>9 mL</td>
<td>①:25 mL</td>
<td>Alcohol: ①:15 mL, ②:35 mL</td>
</tr>
<tr>
<td>EB 1575K</td>
<td></td>
<td>6 mL</td>
<td>①:25 mL</td>
<td>Alcohol: ①:15 mL, ②:35 mL</td>
</tr>
<tr>
<td>EB-1975K</td>
<td></td>
<td>8 mL</td>
<td>①:25 mL</td>
<td>Alcohol: ①:15 mL, ②:35 mL</td>
</tr>
<tr>
<td>EB-1990i</td>
<td></td>
<td>4 mL</td>
<td>①:25 mL</td>
<td>Alcohol: ①:15 mL, ②:35 mL</td>
</tr>
</tbody>
</table>

- ① Injecting from suction nipple
- ② Injecting from inlet seal (OF-B190)
1-1-5. Inspection of Reprocessing Accessories

Before use, inspect reprocessing accessories according to the following procedure.

**WARNING**

- Replace reprocessing accessory with a new one when inspection of the device indicates that it is damaged or unable to function properly.

1-1-5-1. Inspection of PVE Soaking Cap (OE-C9)

1) Check that there is no cracking on the outer surface of the PVE Soaking Cap.
2) Check that there are no scratches, cracking, or chipping of the sealing surfaces inside the PVE Soaking Cap.

![Sectioned Drawing](image)

*Figure 1.3*

1-1-5-2. Inspection of Ventilation Cap (OF-C5)

1) Make sure that of the Locking Groove Potion of the Ventilation Cap is not deformed.
2) Check that there are no scratches, cracking, or chipping of the O-ring inside the Ventilation Cap.

![Diagram](image)

*Figure 1.4*
1-1-5-3. Inspection of Cleaning Adapter (OF-B155)

1) Check that there are no scratches, cracking, or chipping of the sealing surfaces inside the Cleaning adapter.

![Sectioned Drawing](image)

**Figure 1.5**

1-1-5-4. Inspection Cleaning Brushes (CS-C3S/CS6002SN/CS6015ST/CS3010S)

1) Make sure that there are no missing bristles on Cleaning Brushes.
2) Check that there is no kinking or bending of the Cleaning Brush Shaft.
1-2. Endoscope Reprocessing

Video bronchoscopes can be subjected to the following cleaning, disinfection, and optional sterilization process.

<table>
<thead>
<tr>
<th>Video Bronchoscopes</th>
<th>Cleaning</th>
<th>High-Level Disinfection</th>
<th>Optional Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>EB-1170K</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>EB-1570K</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>EB-1970K</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>EB-1970TK</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>EB-1575K</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>EB-1975K</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>EB-1990i</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
</tbody>
</table>

Y : YES  
N : NO

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 withdrawal subsequent cleaning procedure. Endoscopes that are 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.

**CAUTION**

- 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.
- Prior to pre-cleaning the endoscope, leave the PVE connector attached to the video processor.
- In order to prevent damage to the endoscope, do not place any objects other than Inlet Seal (OF-B190) and Suction Control Valve (OF-B179) with the endoscope in the closed container used for transport to the reprocessing area.
CAUTION

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 pre-cleaning solution in another location.

1-2-1-1. Items required

- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- Detergent solution, Endozime (Ruhof Corporation)
- External suction source
- 500 mL basin
- Lint-free gauze
- 30 mL luer lock syringe
- Inlet seal (OF-B190)
- Suction control valve (OF-B179)

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 of 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 1.6
1-2-1-4. Aspiration of detergent solution through the suction channel

1) Connect inlet seal (OF-B190) and suction control valve (OF-B179) to the endoscope.
2) Connect a suction tube from an external suction source to the endoscope suction nipple.
3) Turn on the external suction source.
4) Place the distal end of the endoscope into a basin, and aspirate detergent solution through the suction channel by pressing suction control valve (OF-B179) for 10 seconds.

5) Take the distal end out of detergent solution, and aspirate air through the suction channel by pressing suction control valve (OF-B179) for 10 seconds.
6) Turn off the external suction source.
7) Disconnect tubing from the endoscope suction nipple.

1-2-1-5. Transport to cleaning room

1) Turn off the power to the video processor, and detach the PVE connector from the video processor.
2) Transport the pre-cleaned endoscope 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 leakage tester.

⚠️ CAUTION ⚠️

Various types of manual and automated endoscope leakage testers exist. Some manual and automated 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.
1-2-3. Cleaning

**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/or sterilization of endoscope, and may pose a cross-infection 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 uncleansed 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 endscope that is reprocessed.

**CAUTION**

- PVE soaking cap (OE-C9) must be properly secured over the electrical contacts. Failure to do so could result in water invasion and damage to the endoscope. If an endoscope is cleaned without the soaking cap attached, do not use the endoscope, and contact your local PENTAX service facility or sales representative.
- Ventilation cap (OF-C5) must be taken OFF during reprocessing. 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 cable 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 reprocessing accessories listed in section 1-2-3-1 of this instruction for use with the endoscope when immersing it in a cleaning basin.
1-2-3-1. Items required

Endoscope component
- Inlet seal (OF-B190)

Reprocessing accessory
- PVE soaking cap (OE-C9)
- Cleaning brush (CS6002SN)
- Cleaning brush (CS3010S) (EB-1170K and EB-1990i only)
- Cleaning brush (CS-C3S)
- Cleaning adapter (OF-B155)

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

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.

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).
1-2-3-3. Cleaning of all external surfaces

⚠️ 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 detergent solution.
2) Detach the inlet seal (OF-B190) and suction control valve (OF-B179) from the endoscope.

![Figure 1.9](image)

3) Open the cap of inlet seal (OF-B190) and place it in the detergent solution.

![Figure 1.10](image)

4) Reprocess suction control valve (OF-B179) separately from the endoscope. (see Section 1-3 “Endoscope components and accessories”)
5) While still immersed in detergent solution, wash the entire surface of the endoscope and OF-B190 three times with a lint-free gauze.
6) Visually inspect the entire surface of the endoscope to insure that no soil is present, paying special attention to areas such as the distal end, and control body, which are the most likely regions to retain visible soil.
7) If any soil is still present on the endoscope, remove it by wiping the area in question with lint-free gauze until it has been completely removed.
1-2-3-4. Brushing of the suction channel

**WARNING**

- Do not use cleaning brushes other than those that are specified in this instructions for use. Failure to do so could result in endoscope damage or incomplete or ineffective cleaning.
- Prior to use, ensure that cleaning brushes are not damaged (e.g., kinked shaft or bent or missing bristles).
- In order to prevent the dispersal of patient debris that might still be in the endoscope channel into the environment, always withdraw brushes slowly.

**CAUTION**

- In order to avoid damage to the endoscope, never attempt to insert a cleaning brush into the endoscope distal tip.
- Never apply excessive pressure to introduce or withdraw the brush. This can result in damage to the endoscope and/or the brush.

Always fully immerse the endoscope during brushing.

1) Insert cleaning brush (CS6002SN), into the opening of the suction nipple, and gently push it until it appears in the suction cylinder.

![Figure 1.11](image)

2) Gently withdraw the brush, and remove from debris from the brush head by rubbing it with gloved fingers.
3) Repeat steps 1 and 2 three additional times.
4) Insert cleaning brush (CS6002SN) into the opening at bottom of the suction cylinder and advance it for about 15 cm until resistance is felt. DO NOT USE EXCESSIVE FORCE.

![Figure 1.12](image)

5) Gently withdraw the brush, and remove debris from the brush head by rubbing it with gloved fingers.
6) Repeat steps 4 and 5 three additional times.
7) Insert cleaning brush (CS3010S for EB-1170K and EB-1990i/CS6015ST: for all other scopes) into the instrument channel inlet, and gently advance it until it exits the distal end of the endoscope.

![Figure 1.13](image)

(1) CS3010S (for EB-1170K and EB-1990i)
CS6015T (for all other scopes)
(2) Instrument Channel Inlet

8) Remove debris from the brush head by rubbing it with gloved fingers and then gently withdraw the brush.
9) Repeat steps 7 and 8 three additional times.
10) Insert cleaning brush (CS-C3S) into the suction cylinder, and rotate it for 30 seconds. Do not insert the brush excessively.

![Figure 1.14](image)

(1) CS-C3S
(2) Suction Cylinder

11) Withdraw the brush. Remove debris from the brush head by rubbing it with gloved fingers.
12) Repeat steps 10 and 11 three additional times.
1-2-3-5. Filling the suction channel 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-B155) and Inlet Seal (OF-B190) be securely attached to the endoscope. Failure to properly mount and secure the cleaning adapter and inlet seal can result in ineffective and incomplete reprocessing.

**CAUTION**

In order to avoid damage to the endoscope, never apply excessive force if resistance is encountered while flushing detergent solution into channels. Do not use the endoscope, and contact your local PENTAX service facility or sales representative.

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

**Attaching components and accessories to the endoscope**

1) Attach inlet seal (OF-B190) and cleaning adapter (OF-B155) to the endoscope.

![Figure 1.15](image)

Filling the suction channel with detergent solution

2) Attach a 25 mL syringe filled with the detergent solution to the suction nipple, and inject 25 mL of detergent solution into the suction channel.

![Figure 1.16](image)
3) Check to confirm that detergent solution flows out from the suction channel opening on the distal end of the endoscope.

4) Insert a syringe filled with detergent solution to inlet seal (OF-B190), and inject 25 mL of detergent solution into the suction channel.

5) Detach the inlet seal cleaning adapter inlet seal (OF-B190), and cleaning adapter (OF-B155) from the endoscope, and leave them to soak along with the endoscope in detergent solution. Open the cap of inlet seal (OF-B190).

Figure 1.17

Figure 1.18
1-2-3-6. Soaking in detergent solution

**WARNING**

- The detergent solution must remain in contact with ALL internal channels and external endoscope surfaces for the time period recommended by the manufacturer of the detergent.
- Adhere to the conditions (temperature, concentration, time) specified by the detergent manufacturer to accomplish effective and complete cleaning. Use of the detergent solution under conditions that fall outside the manufacturer’s directions might damage the endoscope. Use of a timer or audible alarm is recommended in order not to exceed the recommended soaking time.
- During immersion, detach the cleaning adapter (OF-B155) and inlet seal (OF-B190) from the endoscope to ensure contact of all endoscope surfaces with the detergent solution.

**CAUTION**

Never subject the endoscope to ultrasonic cleaning methods.

1) While fully immersing the endoscope, inlet seal (OF-B190), and cleaning adapter (OF-B155), 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 30 mL syringe.

2) Soak the endoscope, inlet seal (OF-B190), and cleaning adapter (OF-B155) under conditions (temperature, concentration, time) specified by the detergent manufacturer. In the case of Endozime, the immersion time is 3 minutes.

![Figure 1.19](image)

3) After soaking, ultrasonically clean inlet seal (OF-B190), and cleaning adapter (OF-B155) according to Section 1-3 “Endoscope components and accessories”.

**Purging detergent solution the from suction channel**

4) After ultrasonic cleaning, attach inlet seal (OF-B190) and cleaning adapter (OF-B155) to the endoscope. (Figure 1.15, p23)

5) Attach a syringe filled with air to the suction nipple, and flush the suction channel with at least 35 mL of air to purge as much residual detergent solution as possible. (Figure 1.16, p23)

6) Insert a syringe filled with air to inlet seal (OF-B190), and flush the suction channel with at least 35 mL of air to purge as much residual detergent solution as possible. (Figure 1.17, p24)

7) Remove the endoscope (with inlet seal (OF-B190) and cleaning adapter (OF-B155) attached) from the detergent solution.
1-2-3-7. Rinsing

**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 inlet seal (OF-B190), and cleaning adapter (OF-B155) attached in a basin of clean water that is of sufficient volume to completely immerse the endoscope.

2) Detach inlet seal (OF-B190), and cleaning adapter (OF-B155) from the endoscope. Open the cap of inlet seal (OF-B190). (Figure 1.18, p24)

3) Wipe all exterior surfaces of the endoscope, inlet seal (OF-B190), and cleaning adapter (OF-B155) one time with a lint-free gauze in order to remove residual detergent solution.

4) While still completely immersed in water, grasp the distal end and control body of the scope and PVE connector with two hands, and agitate them under the water by moving them from side to side repeatedly for one minute.

5) Similarly, agitate inlet seal (OF-B190), and cleaning adapter (OF-B155) under the water by moving them from side to side repeatedly for at least one minute.

6) Attach inlet seal (OF-B190), and cleaning adapter (OF-B155) to the endoscope. (Figure 1.15, p23)

7) Attach a syringe filled with water to the suction nipple, and flush the suction channel with 35 mL of water. (Figure 1.16, p23)

8) Insert a syringe filled with water into inlet seal (OF-B190), and flush the suction channel with 35 mL of water. (Figure 1.17, p24)

9) Remove the endoscope with inlet seal (OF-B190), and cleaning adapter (OF-B155) attached from the water.

10) Attach a syringe filled with air to the suction nipple, and flush the suction channel with 35 mL of air to expel residual water. (Figure 1.16, p23)

11) Insert a syringe filled with air to the inlet seal, and flush the suction channel with 35 mL of air. (Figure 1.17, p24)
Second rinse
12) Fill a basin with clean water and repeat steps 1-11 to perform a second rinse.

Third rinse
13) Fill a basin with clean water and repeat steps 1-11 to perform a third rinse.

Forth rinse
14) Fill a basin with clean water and repeat steps 1-11 to perform a fourth rinse.
15) Detach inlet seal (OF-B190), and cleaning adapter (OF-B155) from the endoscope.
   (Figure 1.18, p24)

1-2-3-8. Drying

1) Gently wipe and dry all external surfaces of the endoscope, inlet seal (OF-B190), and cleaning adapter (OF-B155) with a new lint-free gauze.
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 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, clean potable water, or 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 must be thoroughly cleaned prior to filling it with disinfectant solution.
CAUTION

• 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 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 cable excessively.

• To prevent damaging the endoscope, do not place any objects other than the reprocessing accessories described in section 1-2-4-1 with the endoscope when immersing the endoscope in the disinfection basin.

1-2-4-1. Items required

Endoscope component

• Inlet seal (OF-B190)

Reprocessing accessory

• PVE soaking cap (OE-C9)

• Cleaning adapter (OF-B155)

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 sufficient in size 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
1-2-4-2. Preparation
1) Wear personal protective equipment.
2) Attach the PVE soaking cap (OE-C9) to the endoscope.
3) Ensure that the ventilation cap (OF-C5) is detached from the endoscope.

![Figure 1.21](image)

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

1-2-4-3. Filling the suction channel 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.
- It is imperative that cleaning adapter (OF-B155) and Inlet Seal (OF-B190) be securely attached to the endoscope. Failure to properly mount and secure the cleaning adapter and inlet seal can result in ineffective and incomplete reprocessing.

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

Attaching components and accessories to the endoscope
1) Fully immerse the endoscope in disinfecting solution, and attach inlet seal (OF-B190) and cleaning adapter (OF-B155) to the endoscope.

![Figure 1.22](image)
Filling the suction channel with disinfecting solution

2) Attach a syringe filled with disinfecting solution to the suction nipple, and inject 25 mL of disinfecting solution into the suction channel.

3) Confirm that disinfecting solution flows out from the suction channel opening on the distal end.

4) Insert a syringe filled with disinfecting solution into inlet seal (OF-B190), and inject 25 mL of disinfecting solution into the suction channel.

5) After injecting disinfecting solution into the suction channel, detach inlet seal (OF-B190), and cleaning adapter (OF-B155) from the endoscope, and leave them with the endoscope in the disinfecting solution. Open the cap of inlet seal (OF-B190).
1-2-4-4. Soaking in disinfecting solution

**WARNING**

- The disinfecting solution must remain in contact with ALL internal channels and external endoscope surfaces 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. Use of a timer or audible alarm is recommended in order not to exceed the recommended soaking time.
- During immersion, detach the cleaning adapter (OF-B155) and inlet seal (OF-B190) from the endoscope to ensure contact of all endoscope surfaces with the disinfecting solution.

1) Fully immerse the endoscope, inlet seal (OF-B190), and cleaning adapter (OF-B155) to 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 disinfecting solution using a syringe.

2) Soak the endoscope, inlet seal (OF-B190), and cleaning adapter (OF-B155) under the conditions (temperature, concentration, time) specified by the disinfectant manufacturer. In the case of Cidex Activated Dialdehyde Solution, the immersion time is 45 minutes at 25°C.

![Figure 1.26](image)

**Figure 1.26**

Purging of disinfecting solution from suction channel

3) After soaking, attach inlet seal (OF-B190) with the cap closed, and cleaning adapter (OF-B155) to the endoscope. (Figure 1.22, p30)

4) Attach a syringe filled with air to the suction channel, and flush the suction channel with at least 35 mL of air to purge as much residual disinfecting solution as possible. (Figure 1.23, p31)

5) Insert a syringe filled with air to inlet seal (OF-B190), and flush the suction channel with at least 35 mL of air to purge as much residual disinfecting solution as possible. (Figure 1.24, p31)

6) Remove the endoscope with inlet seal (OF-B190) and cleaning adapter (OF-B155) attached from the disinfecting solution.
1-2-4-5. Rinsing

**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 must 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 or other FDA-cleared, commercially available high level disinfectants are used, consult with the disinfectant manufacturer for details regarding recommended rinse water volumes.

First rinse

1) Place the endoscope with the inlet seal (OF-B190) and cleaning adapter (OF-B155) attached in a basin of sterile water that is of sufficient volume to completely immerse the endoscope.
2) Detach inlet seal (OF-B190), and cleaning adapter (OF-B155) from the endoscope. Open the cap of inlet seal (OF-B190).
3) Wipe all exterior surfaces of the endoscope, inlet seal (OF-B190), and cleaning adapter (OF-B155) at least two times with a sterile gauze in order to remove residual disinfecting solution.
4) While still completely immersed in water, grasp the distal end and control body of the scope and PVE connector with two hands, and agitate them under the water by moving them from side to side repeatedly for at least one minute.

5) Similarly, grasp inlet seal (OF-B190) and cleaning adapter (OF-B155) and agitate them under water by moving them from side to side for at least one minute.
6) Attach inlet seal (OF-B190) and cleaning adapter (OF-B155) to the endoscope. (Figure 1.22, p30)
7) Attach a syringe filled with water to the suction nipple, and flush the suction channel with at least 35 mL of water. (Figure 1.23, p31)
8) Insert a syringe filled with water to inlet seal (OF-B190) and flush the suction channel with at least 35 mL of water. (Figure 1.24, p31)
9) Take the endoscope with inlet seal (OF-B190) and cleaning adapter (OF-B155) attached out of the water.

10) Attach a syringe filled with air to the suction nipple, and flush the suction channel with at least 35 mL of air to expel residual water. (Figure 1.23, p31)

11) Insert a syringe filled with air into the inlet seal, and flush the suction channel with 35 mL of air. (Figure 1.24, p31)

Second rinse

12) Fill a basin with sterile water and repeat steps 1-11 in order to perform a second rinse.

Third rinse

13) Fill a basin with sterile water and repeat steps 1-11 in order to perform a third rinse.

Forth rinse

14) Fill a basin with sterile water and repeat steps 1-11 to perform a fourth rinse.

15) Remove the endoscope and its component from the basin of water and place them on a clean, dry, lint-free cloth.

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 the channels with alcohol

1) Attach a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to the suction nipple, and flush the suction channel with 15 mL of alcohol. (Figure 1.23, p31)

2) Insert a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol into the inlet seal (OF-B190), and flush the suction channel with 15 mL of alcohol. (Figure 1.24, p31)

Purging of alcohol from channel

3) Attach a syringe filled with air to the suction nipple, and flush the suction channel 35 mL of air to expel residual alcohol. (Figure 1.23, p31)

4) Insert a syringe filled with air to inlet seal (OF-B190), and flush the suction channel with 35 mL of air to expel residual alcohol. (Figure 1.24, p31)

5) Ensure no alcohol exits the endoscope end. If any, repeat steps 3 and 4.

6) Detach inlet seal (OF-B190) and cleaning adapter (OF-B155) from the endoscope. (Figure 1.25, p31)

Drying of all external surfaces

7) Gently dry all external surfaces of the endoscope, inlet seal (OF-B190), and cleaning adapter (OF-B155) with a sterile gauze.
1-2-5. Optional Sterilization

**WARNING**

- Please note that PENTAX Medical has not validated any sterilization methods for flexible endoscopes other than STERRAD® NX™ system.
- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- 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 signs of abnormalities such as stains, tears, or any other indications that the packaging has been damaged or opened, 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 that they have performed microbiological validation studies to support their claims of achieving sterilization of device specific flexible endoscope models and endoscope components.
- NEVER place the endoscope in a steam sterilizer!

**CAUTION**

- PENTAX video bronchoscopes other than EB-1575K, EB-1975K, EB-1990i are incompatible with the STERRAD® NX™ system.
- When sterilizing the endoscope, do not place any objects other than inlet seal (OF-B 190) and suction control valve (OF-179) into the sterilization tray.
- After every 100 cycles of STERRAD® NX™ exposure, the endoscopes should be returned to an authorized PENTAX service facility for repair. Replacement of the insertion tube and bending section will be necessary, and other components may also require repair or replacement.
- Although STERRAD® NX™ compatible endoscopes are capable of withstanding STERRAD® NX™ sterilization for up to 100 cycles, repair/replacement of parts might be necessary prior to reaching 100 cycles, depending upon the condition of the endoscope.

1-2-5-1-1. Items required

- protective garments such as gloves, gowns, face masks, etc. to minimize the risk of cross contamination.
- APTIMAX Instrument Tray (270 mm in width, 576 mm in length, 100 mm in height)
- APTIMAX Instrument Tray Mat (254 mm in width, 546 mm in length)
- instrument wrap recommended by STERRAD® for use of STERRAD® NX™ system
- tape recommended by STERRAD® for use of STERRAD® NX™ system
- Ventilation cap (OF-C5)
1-2-5-1-2. Preparation

⚠️ WARNING ⚠️
Consult the manufacturer of the sterilization tray regarding its directions for use.

⚠️ CAUTION ⚠️
Prior to the sterilization using STERRAD® NX™ system, ensure that Ventilation cap (OF-C5) is attached to the scope. Failure to do so can result in bursting of the bending rubber.

1) Detach cleaning adapter (OF-B155) and the inlet seal (OF-B190) are detached from the scope.

![Figure 1.28](image)

2) Detach PVE soaking cap (OE-C9) from the scope.
3) Attach ventilation cap (OF-C5) to the scope

![Figure 1.29](image)

4) Lay the APTIMAX Instrument Tray Mat on APTIMAX Instrument Tray
5) Place the scope onto the mat as shown below

![Figure 1.30](image)

6) Cover the tray with the lid.
1-2-5-1-3. Wrapping

⚠️ WARNING

- Contact the manufacturer regarding directions for use of instrument wrap and tape.
- Scope components may be wrapped and sterilized together with the scope. However, do not attach any components other than the ventilation cap to the scope.
- Secure the wrapping with a length of tape that is sufficient to prevent the wrapping from peeling away from package. Failure to do so can result in removal of the tape and ineffective sterilization.

1) Wrap the tray containing the scope.
2) Apply the tape lengthwise across the three sides of the wrapped container.

1-2-5-1-4. Sterilization Parameter Selection

⚠️ WARNING

Contact Johnson & Johnson regarding directions for use of the STERRAD® NX™ system

1) Set the tray containing the scope into the sterilization chamber.

STERRAD® NX™:
Select "Advanced" cycle and operate the sterilizer according to the instructions supplied with the STERRAD® NX™.
# 1-3. Endoscope components and accessories

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

<table>
<thead>
<tr>
<th>Endoscope Component</th>
<th>Model</th>
<th>Cleaning</th>
<th>Optional Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name</td>
<td>Manual</td>
<td>Ultrasonic</td>
</tr>
<tr>
<td>Suction Control Valve</td>
<td>OF-B179</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Inlet Seal</td>
<td>OF-B190</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Accessory Bite Block</td>
<td>OF-Z5</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reprocessing Accessory</th>
<th>Name</th>
<th>Cleaning</th>
<th>Optional Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Model</td>
<td>Manual</td>
<td>Ultrasonic</td>
</tr>
<tr>
<td>PVE Soaking Cap</td>
<td>OE-C9</td>
<td>Y*</td>
<td>N</td>
</tr>
<tr>
<td>Ventilation Cap</td>
<td>OF-C5</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Cleaning Adapter</td>
<td>OF-B155</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Cleaning Brush</td>
<td>CS6002SN</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Cleaning Brush</td>
<td>CS6015ST</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Cleaning Brush</td>
<td>CS3010S</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Cleaning Brush</td>
<td>CS-C3S</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

**Y**: YES  
**N**: NO  

* : The PVE Soaking Cap (OE-C9) should be attached to the endoscope during cleaning and disinfection procedures.  
** : The ventilation cap (OF-C5) should be attached to the endoscope during the STERRAD® sterilization.

**NOTE**

*Automated Endoscope Reprocessor (AER) manufacturers may not make specific claims or provide special instructions for reprocessing all of the removable endoscope components and accessories that are integral to the safe and effective operation of flexible endoscopes. Therefore, should the AER manufacturer’s instructions not specifically address reprocessing of any particular endoscope component (suction valve, inlet seal, etc.) reprocess those components manually as described in this manual. Prior to use, check with the AER manufacturer regarding their specific claims with respect to reprocessing individual endoscope components.*
1-3-1. 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.

1-3-1-1. Items required

- 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%)

1-3-1-2. Cleaning procedure

**Preparation**

1) Wear personal protective equipment.
2) Prepare a 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).
3) Fully immerse the components and accessories, and keep them immersed in detergent solution during the following cleaning procedure.
4) Open the cap of inlet seal (OF-B190) during cleaning.

![Figure 1.31](image)

**Cleaning of all external surfaces**

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

**Cleaning of brushes**

6) Wash the brush heads of cleaning brushes (CS6002SN, CS6015ST, CS3010S, CS-C3S) by rubbing them with gloved fingers for 30 seconds.

**Manipulating of valve mechanisms**

7) While fully immersed, manipulate the suction control valve (OF-B179) mechanism four times.

![Figure 1.32](image)

**Filling of lumens with detergent solution**

8) Using a syringe filled with detergent solution, inject 4 mL of the detergent solution directly into the lumen of the suction control valve (OF-B179).

![Figure 1.33](image)

**Soaking in detergent solution**

9) 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 detergent solution using a syringe.

10) Soak components and accessories in detergent solution according to the instructions (temperature, concentration, time) specified by the detergent manufacturer. In the case of Endozime, the immersion time is at 3 minutes.

11) Remove the components and accessories from the detergent solution.
1-3-1-3. Ultrasonic Cleaning

⚠️ WARNING

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

⚠️ CAUTION

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

1) Prepare 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) Using a syringe filled with detergent solution, inject detergent solution directly into each lumen of the suction control valve (OF-B179).
4) Perform ultrasonic cleaning under the following conditions:
   Frequency Range: 44 kHz +/- 6 %   Time: 5 minutes
5) After completion of the ultrasonic cleaning process, remove the components and accessories from the ultrasonic cleaner.

1-3-1-4. Rinsing

⚠️ WARNING

All residual detergent solution must be removed from the components and accessories. Residual detergent solution may interfere with subsequent disinfection and sterilization 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 at least two times with a lint-free gauze in order to remove residual detergent solution.
3) While still completely immersed in water, agitate them under the water by moving them from side to side for at least one minute.
4) Manipulate the suction control valve (OF-B179) mechanism at least four times in the water, and using a syringe filled with water, flush the lumen of the valve with at least 5 mL of water. (see Figure 1.32, p41 and Figure 1.33, p41)
5) Discard the water.

Second rinse
6) Fill a basin with clean water and repeat steps 2-5 to perform a second rinse.
Third rinse
7) Fill a basin with clean water and repeat steps 2-5 to perform a third rinse.

Forth rinse
8) Fill a basin with clean water and repeat steps 2-5 to perform a fourth rinse.
9) Remove all components and accessories from the water.

Purging of water from lumens
10) Using a syringe filled with air, flush the lumen of the suction valve (OF-B179) to purge residual water. (see Figure 1.33, p41)

1-3-1-5. Drying
1) Wipe all surfaces of components and accessories gently with a lint-free gauze.
1-3-2. High-Level Disinfection

**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, 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 that are compatible with PENTAX components and accessories is contained in this manual.
- Adhere to the instructions specified 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 must 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.

1-3-2-1. 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
1-3-2-2. 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 disinfecting solution during the following disinfection procedure.
4) Open the cap of inlet seal (OF-B190) and fully immerse it in disinfecting solution. (see Figure 1.31, p41)

Manipulating the valve mechanism
5) While fully immersed, manipulate the suction control valve (OF-B179) mechanism four times. (see Figure 1.32, p41)

Filling of disinfecting solution into the lumens
6) Using a syringe filled with disinfecting solution, inject at least 4 mL of the disinfecting solution directly into the lumen of suction control valve (OF-B179). (see Figure 1.33, p41)

Soaking in disinfecting solution
7) While fully immersed, ensure there are no air bubbles on the surfaces of components and accessories. If any air bubbles are detected, flush them away with disinfecting solution using a syringe.
8) Soak them in disinfecting solution according to the instructions (temperature, concentration, time) specified by the disinfectant manufacturer. In the case of Cidex Activated Dialdehyde Solution, the immersion time is 45 minutes at 25°C.
9) Remove the components and accessories from the disinfecting solution.

1-3-2-3. 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 at least two times with a sterile gauze in order to remove residual disinfecting solution.
3) While still completely immersed in water, agitate them under the water by moving them from side to side for at least one minute.
4) Manipulate the suction control valve (OF-B179) mechanism at least four times in the water, and using a syringe filled with water, flush the lumen of the valve with at least 5 mL of water. (see Figure 1.32, p41 and Figure 1.33, p41)
5) Discard the water.

Second rinse
6) Fill a basin with clean water and repeat steps 2-5 in order to perform a second rinse.

Third rinse
7) Fill a basin with clean water and repeat steps 2-5 in order to perform a third rinse.

Fourth rinse
8) Fill a basin with clean water and repeat steps 2-5 to perform a fourth rinse.
9) Remove all components and accessories from the water.
Purging of water from lumens
10) Using a syringe filled with air, flush the lumen of the suction valve (OF-B179) to purge residual water. (see Figure 1.33, p41)

1-3-2-4. 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 lumens of components and accessories, and prevent bacterial colonization and/or infections associated with waterborne microorganisms.

Flushing of lumens with alcohol
1) Using a syringe filled with 70-90% medical grade ethyl or isopropyl alcohol, flush the lumen of the suction valve (OF-B179) with 2 mL of alcohol. (see Figure 1.33, p41)

Purging of alcohol from lumens
2) Using a syringe filled with air, flush the lumen of the suction valve (OF-B179) with air to purge residual alcohol. (see Figure 1.33, p41)

Drying of all external surfaces
3) Gently dry all external surfaces of components and accessories with a sterile gauze moistened with 70-90% medical grade ethyl or isopropyl alcohol.
1-3-3. Optional sterilization

**WARNING**

- Please note that PENTAX Medical has not validated any sterilization methods for flexible endoscopes other than steam sterilization and the STERRAD® NX™ system.
- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross contamination.
- 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.
- After sterilization, ensure that the package is intact. If there are any signs of abnormalities such as stains, wetness, tears, or any other indications that the packaging has been damaged or opened, repeat the sterilization process with new packaging.

1-3-3-1. Steam Sterilization

**CAUTION**

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

1-3-3-1-1. Preparation

1) Make sure that the cap of the inlet seal (OF-B190) is closed when packaged for sterilization.

![Figure 1.34](image_url)
1-3-3-1-2. Wrapping

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

1-3-3-1-3. Parameters

Steam sterilization can be performed under the following conditions:

<table>
<thead>
<tr>
<th>Sterilizer Type</th>
<th>Temperature</th>
<th>Exposure</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>132°C</td>
<td>4 minutes</td>
<td>30 minutes</td>
</tr>
<tr>
<td></td>
<td>135°C</td>
<td>3 minutes</td>
<td>16 minutes</td>
</tr>
</tbody>
</table>

**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.

1-3-3-2. Sterilization using STERRAD® NX™ system

The suction control valve (OF-B179) and the inlet seal (OF-B190) can be sterilized using the STERRAD® NX™ sterilization.

1-3-3-2-1. Items required

- protective garments such as gloves, gowns, face masks, etc., to minimize the risk of cross contamination.
- APTIMAX Instrument Tray (270 mm in width, 576 mm in length, 100 mm in height)
- APTIMAX Instrument Tray Mat (254 mm in width, 546 mm in length)
- instrument wrap recommended by STERRAD® for use of STERRAD® NX™ system
- tape recommended by STERRAD® for use of STERRAD® NX™ system
1-3-3-2-2. Preparation

⚠️ WARNING

Contact the manufacturer of the tray regarding directions for use of the tray.

1) Lay APTIMAX Instrument Tray Mat on APTIMAX Instrument Tray.
2) Place the suction control valve (OF-B179) and the inlet seal (OF-B190).
3) Cover the tray with the lid.

1-3-3-2-3. Wrapping

⚠️ WARNING

- Contact the manufacturer regarding directions for use of the wrap and tape.
- The suction control valve (OF-B179) and the inlet seal (OF-B190) may be wrapped and sterilized together with the endoscope. In this case, do not attach any components other than the ventilation cap (OF-C5) to the endoscope.
- The ventilation cap (OF-C5) must be attached to the endoscope when performing sterilization using STERRAD® NX™ system.
- Secure the wrapping with a length of tape that is sufficient to prevent the wrapping from peeling away from package. Failure to do so could result in removal of the tape and ineffective sterilization.

1) Wrap the tray containing the components.
2) Apply the tape lengthwise across the three sides of the container.

1-3-3-2-4. Parameter

⚠️ WARNING

Contact Johnson & Johnson regarding directions for use of STERRAD® NX™ system.

Set the tray containing the components into the sterilization chamber.

STERRAD®NX™:
Select "Advanced" cycle and operate the sterilizer according to the instructions supplied with the STERRAD® NX™.
# POST REPROCESSING AND STORAGE

## WARNING

- Make sure that all removable components such as the suction control valve, rubber inlet seal, etc., are detached from the endoscope. This will allow for better air circulation through the internal channels and permit thorough drying. All channels should be completely dry before storage.
- Never store the endoscope, its components, or 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 only for transportation of the instrument, not storage.

## CAUTION

- Never store the endoscope in areas of high humidity, high temperature, or in direct exposure to sunlight or X-rays.
- Avoid storage of the endoscope in cabinets that 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.

1) Following reprocessing, the endoscope may either be reused or placed into storage.
2) Prior to storage, ensure that all internal channels, endoscope components, instrument surfaces, and accessories are thoroughly dry.
3) The endoscope should be hung vertically 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.
4) Prior to reuse, ensure that instrument has been properly inspected and fully prepared for the next clinical procedure.
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. 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 will render an instrument equivalent to the expectations and quality of a finished device supplied by the endoscope OEM.

CAUTION

Never drop this equipment or subject it to severe impact, as it can compromise the functionality and/or safety of the unit. Should this equipment be mishandled or dropped, do not use it. Return it to an authorized PENTAX service facility for inspection or repair.
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.

1) 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 (OF-C5) 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 cap (OE-C9) should also be returned with the endoscope to check/confirm the integrity of its watertight seals.

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

<table>
<thead>
<tr>
<th>Product Brand Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cidezyme® XTRA (used exclusively in EvoTech ECR)</td>
<td>Advanced Sterilization Products (ASP)</td>
</tr>
<tr>
<td>Enzol®</td>
<td></td>
</tr>
<tr>
<td>Endozime®</td>
<td>Ruhof Corporation</td>
</tr>
<tr>
<td>Endozime® AW Plus</td>
<td></td>
</tr>
<tr>
<td>Enzy-Clean</td>
<td>Care Fusion</td>
</tr>
<tr>
<td>MetriZyme®</td>
<td>Metrex Research Corporation</td>
</tr>
<tr>
<td>Tergal 800</td>
<td>Custom Ultrasonics</td>
</tr>
<tr>
<td>ZymeX™ Enzymatic Cleaner Concentrate</td>
<td>Sultan Healthcare</td>
</tr>
</tbody>
</table>
**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).

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

**Sterilization Agents/Processes**

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

<table>
<thead>
<tr>
<th>Ethylene Oxide / Carbon Dioxide (80:20 gas mixture)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene Oxide / Carbon Dioxide (90:10 gas mixture)</td>
</tr>
</tbody>
</table>
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.