This instructions for use describes the recommended procedures for the reprocessing and maintenance of the duodenoscope after its use. For the inspection and directions for use, please refer to the separate operation instructions for use.
**Intended Use**
The ED-3490TK, Video Duodenoscope is intended to provide optical visualization (via a video monitor) of, and therapeutic access to, the Upper Gastrointestinal Tract and Biliary Tract. The Upper Gastrointestinal Tract and Biliary Tract includes but is not limited to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Common Bile Duct, Hepatic Duct and Cystic Duct. The instrument is introduced per orally when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

**Sterility Statement**
The endoscope identified in this IFU is a reusable semicritical device. Since the endoscope is packaged non-sterile, it must be cleaned and high-level disinfected or sterilized BEFORE initial use. Prior to each subsequent procedure, it 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).

**Notes**
Read this IFU before operating, 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 of the patient and/or user. Furthermore, failure to follow the instructions in this IFU and the companion IFU may result in damage to, and/or malfunction of, this equipment.

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

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 are involved in the reprocessing of these medical devices.

Current infection control guidelines require that G.I. endoscopes and other semi-critical medical devices that normally come into contact with intact mucus membranes, such as in the gastrointestinal tract, must at least be cleaned and high-level disinfected before patient use. Only the user can determine if an instrument has undergone appropriate infection control procedures prior to each clinical use. It must be recognized that infection control practices involve many complex and often controversial issues which are constantly evolving. PENTAX strongly recommends that user remain informed of the latest federal and local regulations, and it encourages users to follow infection control guidelines developed by various organizations for health care professionals.

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

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

- **WARNING**: could result in serious adverse reactions and potential safety hazards.

- **CAUTION**: may result in adverse reactions for safe and effective use of the device.

- **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” | Attention, consult instructions for use
| Symbol for “DATE OF MANUFACTURE” | Attention, consulter le manuel d’utilisation
| Symbol for “Authorised Representative in the European Union” | 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)

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。
Reprocessing procedures of Video Duodenoscope Model ED-3490TK address the following internal channel systems.

<table>
<thead>
<tr>
<th>Video Duodenoscopes</th>
<th>Suction Channel</th>
<th>Air/Water Feeding Channel</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED-3490TK</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

Y : YES  
N : NO
**NOMENCLATURE**

**Video Duodenoscopes**

**ED-3490TK**

<table>
<thead>
<tr>
<th>Model Name</th>
<th>Minimum Instrument Channel Width (IDømm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIR/WATER FEEDING VALVE (OF-B188)</td>
<td></td>
</tr>
<tr>
<td>SUCTION CONTROL VALVE (OF-B120)</td>
<td></td>
</tr>
<tr>
<td>BUTTON 1</td>
<td></td>
</tr>
<tr>
<td>BUTTON 2</td>
<td></td>
</tr>
<tr>
<td>UP/DOWN DEFLECTION LOCK</td>
<td></td>
</tr>
<tr>
<td>BUTTON 4</td>
<td></td>
</tr>
<tr>
<td>BUTTON 3</td>
<td></td>
</tr>
<tr>
<td>RIGHT/LEFT DEFLECTION LOCK</td>
<td></td>
</tr>
<tr>
<td>Functions similar to Up/Down lock</td>
<td></td>
</tr>
<tr>
<td>CANNULA/FORCEPS ELEVATOR</td>
<td></td>
</tr>
<tr>
<td>CONTROL KNOB</td>
<td></td>
</tr>
<tr>
<td>RIGHT/LEFT DEFLECTION CONTROL KNOB</td>
<td></td>
</tr>
<tr>
<td>UP/DOWN DEFLECTION CONTROL KNOB</td>
<td></td>
</tr>
<tr>
<td>STRAIN RELIEF BOOT</td>
<td></td>
</tr>
<tr>
<td>RUBBER INLET SEAL (OF-B190)</td>
<td></td>
</tr>
<tr>
<td>INSTRUMENT CHANNEL INLET</td>
<td></td>
</tr>
<tr>
<td>CONTROL BODY</td>
<td></td>
</tr>
<tr>
<td>MODEL DESIGNATION</td>
<td></td>
</tr>
</tbody>
</table>

**ED-3490TK Minimum Instrument Channel Width (ID ømm)**

<table>
<thead>
<tr>
<th>Video Duodenoscopes</th>
<th>ED-3490TK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Instrument</td>
<td>4.2</td>
</tr>
<tr>
<td>Channel Width (IDømm)</td>
<td></td>
</tr>
</tbody>
</table>
PROCEDURE FLOWCHART

**Pre-Cleaning**
- Preparation
- Wiping the insertion tube
- Aspiration of detergent solution through suction channel
- Flushing the air/water channel with air
- Transport to cleaning room

**Leak Testing**

**Cleaning**
- Preparation
- Cleaning all external surfaces
- Brushing the suction channel and cylinder
- Filling the suction channel with detergent solution
- Soaking entire scope in detergent solution
- Rinsing with clean potable water
- Drying by wiping with a new lint-free gauze

**High-Level Disinfection**
- Preparation
- Immersing the endoscope in disinfectant
- Filling channels with disinfectant
- Special disinfection handling procedure for elevator
- Soaking in disinfectant
- Rinsing
- Drying

**Sterilization**
1-1. General

NOTE

This Instructions for Use (IFU) has been written in accordance with 21CFR 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 according to their respective IFU for proper functionality to determine that they are appropriate for patient use.

Components and Accessories for Video Duodenoscopes

<table>
<thead>
<tr>
<th>TYPE</th>
<th>MODEL</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscope Component</td>
<td>Suction Control Valve</td>
<td>OF-B120</td>
<td>Y</td>
</tr>
<tr>
<td>Endoscope Component</td>
<td>Air/Water Feeding Valve</td>
<td>OF-B188</td>
<td>Y</td>
</tr>
<tr>
<td>Endoscope Component</td>
<td>Inlet Seal</td>
<td>OF-B190</td>
<td>Y</td>
</tr>
<tr>
<td>Accessory</td>
<td>Bite Block</td>
<td>OF-Z5</td>
<td>Y</td>
</tr>
<tr>
<td>Reprocessing Accessory</td>
<td>PVE Soaking Cap</td>
<td>OE-C9</td>
<td>Y</td>
</tr>
<tr>
<td>Reprocessing Accessory</td>
<td>Ventilation Cap</td>
<td>OF-C5</td>
<td>Y</td>
</tr>
<tr>
<td>Reprocessing Accessory</td>
<td>Cleaning Adapter</td>
<td>OF-B153</td>
<td>Y</td>
</tr>
<tr>
<td>Reprocessing Accessory</td>
<td>Cleaning Adapter</td>
<td>OF-G17</td>
<td>Y</td>
</tr>
<tr>
<td>Reprocessing Accessory</td>
<td>Cleaning Brush</td>
<td>CS-C9S</td>
<td>Y</td>
</tr>
<tr>
<td>Reprocessing Accessory</td>
<td>Cleaning Brush</td>
<td>CS6021T</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 high level disinfect or sterilize them prior to initial use and to reprocess them correctly according to this IFU after each subsequent use.

- Proper care of the device after each clinical diagnostic or therapeutic procedure is extremely important. Immediately (within one hour) after the completion of a procedure, the endoscope, its removable components, and accessories should be precleaned and mechanically cleaned with a detergent solution specified in this IFU. Generally, if they 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).

**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 efficacy validation testing including rinsing validation testing after high level disinfection with PENTAX products has been performed by their manufacturer. A list of legally marketed solutions/systems that have been determined to be materially compatible with PENTAX brand products is contained in this manual.
- CAUTION -

- 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. Safety Data Sheets available from the cleaning and disinfection solution manufacturers 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.

- To avoid damaging the endoscope, do NOT twist, rotate or excessively bend 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, never apply excessive force or torque to the strain reliefs, the insertion tube, or the umbilical cord.

![Figure 1.1.1](image-url)

**Figure 1.1.1**
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.

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 Duodenoscope

The following internal schematic diagram 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 1.1.2**

- **(1)** Air/Water Nozzle
- **(2)** Water Feeding Channel
- **(3)** Air Feeding Channel
- **(4)** Inlet Seal
- **(5)** Instrument Channel Inlet
- **(6)** Cleaning Adapter OF-B153
- **(7)** Suction Channel
- **(8)** Air/Water Cylinder
- **(9)** Suction Cylinder
- **(10)** PVE Soaking Cap (ATTACH)
- **(11)** Ventilation Cap (REMOVE)
- **(12)** Luer-Slip Syringe with Cleaning/Disinfecting Solution
- **(13)** Suction Nipple
- **(14)** Cleaning Adapter OF-G17

**NOTE**

- The elevator wire/channel is completely sealed and therefore not exposed to potential contaminants and/or patient debris.
- Since the elevator wire/channel is fully enclosed and not exposed to patient material, it does not require special reprocessing. However, the actual elevator mechanism (front, back and base) must be cleaned and thoroughly reprocessed.
- Be aware that all recessed areas around the elevator mechanism must be thoroughly cleaned using detergent solution and a cleaning brush (CS-C9S). Cleaning instructions are provided within this IFU.
1-2. Endoscope

Video Duodenoscope ED-3490TK can be subjected to the following cleaning, disinfection, and sterilization process.

<table>
<thead>
<tr>
<th>Duodenoscope Model</th>
<th>Cleaning</th>
<th>High-Level Disinfection</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Manual</td>
<td>Ultrasonic</td>
<td></td>
</tr>
<tr>
<td>ED-3490TK</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 increase the effectiveness of the subsequent cleaning procedure. Endoscopes are generally soiled with debris such as blood, tissues, and mucus when they are withdrawn from a patient. 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 materially compatible by PENTAX (see APPENDIX).
- When injecting detergent solution through an internal channel, ensure that the solution exits freely 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.

**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.
- In order to prevent damage to the endoscope, do not place any removable components other than the items described in section 1-2-1-1 of this Instructions for Use in the container used to transport the endoscope.
- In order to avoid damaging the endoscope, never subject it to suction in excess of 66kPa (9.57psi).
NOTE

If the use of detergent solution is not permitted in the clinical procedure room, remove the endoscope from the procedure room and perform pre-cleaning immediately in the reprocessing area.

1-2-1-1. Items required

Endoscope component

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

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
- 50 mL luer slip plastic syringe

1-2-1-2. Preparation

1) Wear personal protective equipment.
2) Prepare and fill a 500 mL basin with 400 mL - 450 mL 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).

1-2-1-3. Wiping the insertion tube and flushing the elevator

The term “Lower Position” used in this document is depicted in Figure 1.2.1 Always be sure to visually check elevator positioning. Do not depend solely upon the operation and/ or position of the elevator control lever.

![Lower Position](image-url)
1) Turn off the lamp switch of the processor used for the duodenoscope.
2) Set the elevator to “Lower Position” by operating the elevator control lever on the control body.
3) Immediately after removing the endoscope from the patient, gently wipe the entire length of the insertion tube from control body to distal end three times using lint-free gauze soaked with detergent solution.

4) Place the distal end of endoscope into a basin.
5) While the elevator is lowered, using a 50 mL syringe filled with detergent, spray 50 mL of detergent onto the rear of the elevator chamber.

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 suction tube from external suction source to the endoscope suction nipple.
3) Turn on the external suction source.
4) 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 1.2.5](image)

5) Remove the distal end from the detergent solution, and press the suction control valve (OF-B120) for 10 seconds.
6) Turn off the external suction source.
7) Disconnect the suction tube from the endoscope suction nipple.

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

1) 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 1.2.6](image)

3) Place the distal end of endoscope into a basin.
4) 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. Then, discharge all water in the water channel by pressing the button of air/water feeding valve (OF-B188) for 10 seconds.

![Diagram showing OF-B190 and OF-B188](image)

Figure 1.2.7

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

1-2-1-6. **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 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 either PENTAX brand leakage testers (SHA-P2 or SHA-P5) or a leakage tester that is sold by PENTAX. For specific details on PENTAX leak detection procedures, please refer to the instructions supplied with PENTAX leakage testers or a leakage tester that is sold by PENTAX.

⚠️ CAUTION ⚠️

Various types of manual and automated endoscope leakage testers exist. Some are stand-alone units, and others may be integrated into an AER. PENTAX does not evaluate leakage testers that are not sold by PENTAX 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 of 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 leakage testers that it does not sell. 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 the endoscope and/or endoscope components and accessories, resulting in a potential risk of cross-contamination.**
- 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 materially compatible by PENTAX (see APPENDIX).
- Fresh detergent solution must be used for each endoscope that is reprocessed.
- After using operational/cleaning accessories (e.g., forceps, needles, snares, brushes etc.) with the endoscope, carefully check that all accessories are intact and that no parts have fallen off and become lodged within the endoscope's instrument/suction channel. Furthermore, ensure that any therapeutic devices (e.g., clips, stents, etc.) passed through the channel are accounted for after use. If the channel becomes blocked or clogged due to the accumulation of debris, an accessory that cannot be removed, or other cause, do NOT attempt to correct the blockage or continue to use the endoscope. In such a case, contact your local PENTAX Medical service facility to have the endoscope repaired.
- The use of an endoscope with a blocked internal channel may result in ineffective reprocessing and/or introduction of debris and/or device components into a patient during a subsequent procedure, posing a risk of cross-contamination.

**CAUTION**

- PVE soaking cap (OF-C9) must be properly secured over the electrical contacts. 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.
- The 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 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 reprocessing accessories listed in section 1-2-3-1 of this Instructions for Use with the endoscope when immersing the endoscope 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 (CS6021T)
- Cleaning brush (CS-C9S)
- Cleaning Adapter (OF-B153)
- Cleaning Adapter (OF-G17)

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 length x 40 cm in width x 15 cm in depth, or 19.7 inches in length x 15.8 inches in width x 5.9 inches in depth)
- Lint-free gauze
- 50 mL luer slip plastic 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 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.

The terms “Lower Position” and “Upper Position” used in this document are depicted in Figure 1.2.9. Always be sure to visually check elevator positioning. Do not depend solely upon the operation and/or position of the elevator control lever.

![Figure 1.2.9](image)

1) Fully immerse the endoscope with the components attached in the detergent solution.
2) Detach inlet seal (OF-B190), suction control valve (OF-B120), and air/water feeding valve (OF-B188) from the endoscope. Open the cap of inlet seal (OF-B190) in the detergent solution.

![Figure 1.2.10](image)

3) Suction control valve (OF-B120) and air/water feeding valve (OF-B188) are reprocessed separately from endoscope. (see Section 1-3 “Endoscope components and accessories”)
4) While still immersed in the detergent solution, wipe the entire surface of endoscope and inlet seal (OF-B190) two times in one direction with a lint-free gauze.
Brushing and flushing of Elevator

5) Set the elevator to the “Upper Position” by operating the elevator control lever on the control body.

6) Hold cleaning brush (CS-C9S) with fingers on brush shaft near the small brush head.

7) Perform steps a) through c) in order to brush the front of elevator chamber and elevator recess area with cleaning brush (CS-C9S). Repeat nine more times (total ten times).
   a) Place the smaller brush head of cleaning brush (CS-C9S) underneath the front opposite of lens side of the elevator chamber.
   b) Brush to the lens side.
   c) Brush to the front scraping out the debris in the lens side corner and wall of the elevator chamber.

8) Clean the debris from the brush head by rubbing with fingers.

9) Similarly perform step a) through c) in order to brush from the front lens side. Repeat nine more times. (total ten times)
   a) Place the smaller brush head of cleaning brush (CS-C9S) underneath the front lens side of the elevator chamber.
   b) Brush to the opposite of lens side.
   c) Brush to the front scraping out the debris in the front opposite of lens side corner and wall of the elevator chamber.

10) Clean the debris from the brush head by rubbing with fingers.
11) While the elevator is raised, place the smaller brush head of cleaning brush (CS-C9S) into the space behind the elevator. Brush to the front scraping out the debris in the back of the elevator. Repeat nine times. (total ten times)

![Figure 1.2.13]

12) Clean the debris from the brush head by rubbing with fingers.
13) While the elevator is raised, place the smaller brush head of cleaning brush (CS-C9S) into the front area of elevator chamber. Brush to the front scraping out the debris in the back of the front area of elevator chamber. Repeat nine times. (total ten times)

![Figure 1.2.14]

14) Clean the debris from the brush head by rubbing with fingers.
15) While the elevator is raised, using a 50 mL syringe filled with detergent solution without air, spray 50 mL of detergent onto the front of the Elevator Chamber.

![Figure 1.2.15]
16) Set the elevator to “Lower Position” by operating the elevator control lever on the control body.

17) Perform steps a) through c) in order to brush the back area of elevator chamber and elevator recess area with cleaning brush (CS-C9S). Repeat nine more times (total ten times).
   a) Place the smaller brush head of cleaning brush (CS-C9S) into the opposite side of lens side of the back area of elevator chamber.
   b) Brush to the lens side.
   c) Brush to the front scraping out the debris in the right corner of the back area of elevator chamber.

![Figure 1.2.16](image)

18) Similarly perform steps a) through c) in order to brush from the lens side. Repeat nine more times. (total ten times)
   a) Place the smaller brush head of cleaning brush (CS-C9S) underneath the lens side of the back of elevator chamber.
   b) Brush to the opposite of lens side.
   c) Brush to the front scraping out the debris in the opposite of lens side corner and wall of the back area of elevator chamber.

![Figure 1.2.17](image)
19) Place the smaller head of cleaning brush (CS-C9S) on the elevator. In order to clean the upper surface of the elevator, brush back and forth ten times.

![Figure 1.2.18](image)

20) While the elevator is lowered, using a syringe filled with detergent without air, spray 50 mL of detergent onto the rear of the elevator chamber.

![Figure 1.2.19](image)

21) 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, elevator, elevator chamber, and control body, which are the most likely regions to retain visible soil.

![Figure 1.2.20](image)

22) If any soil is still present on the distal end and control body, use cleaning brush (CS-C9S) to gently brush until all soil has been removed.

23) If any soil is still present on the elevator and elevator chamber, repeat steps 5-20 until all soil has been removed.
1-2-3-4. Brushing the suction channel and cylinder

⚠️ **WARNING**
- Do not use cleaning brushes other than those specified in this instruction 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 dissemination 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 the 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 sharp-edged 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 the 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.
Suction channel cleaning

1) 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 10 seconds in order to scrub the entire inner surface of the instrument channel inlet.

![Figure 1.2.21](image)

2) Withdraw cleaning brush (CS-C9S) from the inlet, and clean the debris from the brush head by rubbing with fingers.

3) 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.

![Figure 1.2.22](image)

4) 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. Clean debris from the brush head by rubbing with fingers.
5) 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 1.2.23](image)

6) Grasp the blue tip of the brush shaft, and gently pull the brush from the distal end of the endoscope until the brush heads exits the distal end. Clean debris from the brush head by rubbing with fingers.

**Cylinder cleaning**

7) 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 10 seconds in order to scrub the entire inner surface of the cylinder.

![Figure 1.2.24](image)

8) Withdraw the brush from the cylinder, and clean debris from the brush head by rubbing with fingers.
9) Insert the large brush head of cleaning brush (CS-C9S) into the air/water cylinder until it cannot be advanced further. Repetitively move the brush back and forth while twisting it left and right for 10 seconds in order to scrub the entire inner surface of the cylinder.

![Figure 1.2.25](image)

10) Withdraw the brush from the cylinder, and clean debris from the brush head by rubbing with fingers.

11) After brushing the endoscope, dispose of cleaning brush (CS6021T), which is a single-use accessory.

1-2-3-5. Filling the 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-B153) be securely attached to the endoscope. Failure to properly connect and secure the cleaning adapter 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 the detergent solution into the channels.

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

1) Follow the steps below in order to attach cleaning adapter (OF-B153) to the air/water cylinder and suction cylinder. This adapter (seals) the air/water and suction cylinders to permit unidirectional flow of solution through these delivery/aspiration systems.

[a] Raise the locking cap and slide the side covers (marked with △) downward.
[b] Align the cylinder guide over the air/water and suction cylinder ports.
[c] Slide the cleaning adaptor (OF-B153) forward.
[d] Holding the side covers (marked with △), 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.

![Diagram A](image1)

![Diagram B](image2)

![Diagram C](image3)

![Diagram D](image4)

![Diagram E](image5)

Figure 1.2.26
2) Attach inlet seal (OF-B190) and cleaning adapter (OF-G17) to the endoscope.

![Figure 1.2.27](image)

**Figure 1.2.27**

**Filling channels with detergent solution**

3) Attach a 50 mL syringe filled with the detergent solution without air to cleaning adaptor (OF-G17), and inject 250 mL of the detergent solution into the air/water channel.

![Figure 1.2.28](image)

**Figure 1.2.28**

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

5) Attach a 50 mL syringe filled with detergent solution without air to the suction nipple, and inject 350 mL of the detergent solution into the suction channel.

![Figure 1.2.29](image)

**Figure 1.2.29**
6) Attach a 50 mL syringe filled with detergent solution without air to the inlet seal (OF-B190), and inject 50 mL of detergent solution into the suction channel.

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

8) After injecting detergent solution into all channels, detach inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) from the endoscope, and leave them to soak along with the endoscope in the detergent solution until the next step. Open the cap of inlet seal (OF-B190).
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.
- Avoid introduction of air during the flushing process. Confirm that no air bubbles exit from the channel openings at the endoscope distal tip. The presence of the air bubbles can prevent contact of the detergent with channel surfaces.

**CAUTION**

NEVER subject the endoscope to an ultrasonic cleaning method.

1) While fully immersing the endoscope, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17), ensure that there are no air bubbles on all external surfaces. If any air bubbles are detected, flush them away with detergent solution using a 50 mL syringe.

2) Soak the endoscope, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) under conditions (temperature, concentration, time) specified by the detergent manufacturer. In the case of Endozime®, the soaking time is 3 minutes.

3) After soaking, attach inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) to the endoscope, and close the cap of inlet seal (OF-B190). (see Figure 1.2.27, p27)

4) Attach a 50 mL syringe filled with air to cleaning adapter (OF-G17), and flush the air/water channel with 250 mL of air to purge residual detergent solution. (see Figure 1.2.28, p27)

5) Attach a 50 mL syringe filled with air to the suction nipple, and flush the suction channel with 350 mL of air to purge residual detergent solution. (see Figure 1.2.29, p27)

6) Attach a 50 mL syringe filled with air to the inlet seal (OF-B190), and flush the suction channel with 50 mL of air to purge residual detergent solution. (see Figure 1.2.30, p28)

7) Remove the endoscope (with inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) 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, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) into a basin of clean potable water that is of sufficient volume to completely immerse the endoscope.

2) Detach inlet seal (OF-B190) and cleaning adapters (OF-B153, and OF-G17) from the endoscope (see Figure 1.2.31, p28). Open the cap of inlet seal (OF-B190).

3) Wipe all exterior surfaces of the endoscope, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) two times with a lint-free gauze in order to remove residual detergent solution.

4) While still completely immersed in clean potable water, grasp the distal end, control body of endoscope, and PVE connector with two hands, and agitate it under the clean potable water by moving it from side to side repeatedly for 20 seconds.

5) Grasp inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) with a hand, and agitate them under the clean potable water by moving them from side to side repeatedly for 20 seconds.

6) Attach inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) to the endoscope, and close the cap of inlet seal (OF-B190). (see Figure 1.2.27, p27)

7) Attach a 50 mL syringe filled with clean potable water without air to cleaning adapter (OF-G17), and flush the air/water channel with 250 mL of water. (see Figure 1.2.28, p27)

8) Attach a 50 mL syringe filled with clean potable water without air to the suction nipple, and flush the suction channel with 350 mL of water. (see Figure 1.2.29, p27)

9) Attach a 50 mL syringe filled with clean potable water without air to the inlet seal (OF-B190), and flush the suction channel with 50 mL of water. (see Figure 1.2.30, p28)

10) Remove the endoscope (with inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) attached) from the clean potable water.
11) Attach a 50 mL syringe filled with air to cleaning adapter (OF-G17), and flush the air/water channel with 250 mL of air. (see Figure 1.2.28, p27)
12) Attach a 50 mL syringe filled with air to the suction nipple, and flush the suction channel with 350 mL of air. (see Figure 1.2.29, p27)
13) Attach a 50 mL syringe filled with air to the inlet seal (OF-B190), and flush the suction channel with 50 mL of air. (see Figure 1.2.30, p28)

Second rinse
14) Fill a basin with clean potable water, and repeat steps 1 - 13 in order to perform a second complete rinse.
15) Detach inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) from the endoscope. (see Figure 1.2.31, p28)

1-2-3-8. Drying
1) Gently wipe and dry all external surfaces of the endoscope, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) with a new lint-free gauze.

1-2-3-9. Visual inspection

**NOTE**

*Ideally, work surfaces used for inspection require 1,000 - 2,000 lux illumination (ANSI/AMMI ST79).*

1) Under adequate lighting, visually inspect the entire surface of the endoscope and accessories to insure that no debris is present, paying special attention to the surfaces of the duodenoscope elevator, recessed areas around the elevator, and the surfaces of the elevator chamber.

If any soil is still present on the duodenoscope and accessories, remove it by wiping and/or brushing the area(s) in question in detergent solution with lint-free cloths and/or the appropriate brush(es) specified in this IFU until it has been completely removed. After complete removal of residual soil has been attained, perform all rinsing steps that normally follow cleaning.
1-2-4. High-Level Disinfection

Prior to high-level disinfection, the end user should confirm that the high level disinfectant concentration is greater than the minimum effective concentration (MEC) of reused disinfectant as specified in 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’s 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 disinfectant manufacturer and found to be materially compatible by PENTAX.
- It is imperative that ALL internal surfaces of the channels be in contact with the disinfecting solution for the time period and at the temperature recommended by the manufacturer of the disinfectant.
- 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 should be thoroughly cleaned prior to filling it with disinfectant solution.
- Prior to disinfection, the endoscope and accessories must be meticulously cleaned. Failure to do so can result in incomplete or ineffective disinfection.

⚠️ CAUTION ⚠️

- Prior to high level 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 with the endoscope when immersing it 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-B153)
• Cleaning adapter (OF-G17)

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 length x 40 cm in width x 15 cm in depth, or 19.7 inches in length x 15.8 inches in width x 5.9 inches in depth).
• Sterile gauze
• 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 ventilation cap (OF-C5) is detached from the endoscope.

4) Prepare a basin of sufficient volume capacity to fully immerse the endoscope with CIDEX® Activated Dialdehyde Solution in accordance with the disinfectant manufacturer’s instructions for concentration and temperature.

1-2-4-3. Immersing the endoscope in disinfecting solution
1) Fully immerse the endoscope, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) in the disinfecting solution. Open the cap of inlet seal (OF-B190).
2) Wipe all external surfaces of the endoscope with a sterile gauze two times in order to thoroughly contact disinfecting solution to the surfaces. Ensure that all surfaces are in contact with disinfecting solution.
3) Lower the elevator by operating the elevator control lever on the control body.

1-2-4-4. Filling the 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.
- Avoid introduction of air during the flushing process. Confirm that no air bubbles exit from the channel openings at the endoscope distal tip. The presence of the air bubbles can prevent contact of the disinfectant with channel surfaces.
- Always immerse the endoscope while filling endoscope channels with disinfectant.

The terms “Lower Position”, “Middle Position”, and “Upper Position” used in this document are depicted in Figure 1.2.35. Always be sure to visually check elevator positioning. Do not depend solely upon the operation and/or position of the elevator control lever.

![Figure 1.2.35](image)

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

1) Attach inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) to endoscope, and close the cap of inlet seal (OF-B190).

![Figure 1.2.36](image)
2) Set the elevator to “Upper Position” by operating the elevator control lever on the control body.

3) Attach a 50 mL syringe filled with the disinfecting solution without air to cleaning adapter (OF-G17), and inject 250 mL of the disinfecting solution into the air/water channel.

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

5) Attach a 50 mL syringe filled with the disinfecting solution without air to the suction nipple, and inject 350 mL of disinfecting solution into the suction channel.

6) Attach a 50 mL syringe filled with disinfecting solution without air to the inlet seal (OF-B190), and inject 50 mL of disinfecting solution into the suction channel.
7) Check to confirm that the disinfecting solution flows out from the suction channel opening on the distal end.

8) After injecting disinfecting solution into all channels, detach inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) from the endoscope, and leave them to soak along with the endoscope until the next step. Open the cap of inlet seal (OF-B190).

1-2-4-5. Special handling of the elevator during disinfection

1) Raise and lower the elevator a total of 10 times by operating the elevator control lever on the control body.

2) Set the elevator to “Upper Position” by operating the elevator control lever on the control body.

3) Targeting the recessed area beneath the elevator, place the distal end of a 50 mL syringe filled with disinfecting solution without air as close as possible to the target area. Flush the target area with 50 mL of disinfecting solution.

4) Set the elevator to “Lower Position” by operating the elevator control lever on the control body.
5) Targeting the recessed area above the elevator, place the distal end of a 50 mL syringe filled with disinfecting solution without air as close as possible to the target area. Flush the target area with 50 mL of disinfecting solution.

![Figure 1.2.42](image1)

6) Set the elevator to “Middle Position” by operating the elevator control lever on the control body.

7) Targeting the recessed area beneath the elevator. Place the distal end of a 50 mL syringe filled with disinfecting solution without air as close as possible to the target area. Flush the target area with 50 mL of disinfecting solution.

![Figure 1.2.43](image2)

8) Targeting the recessed area above the elevator. Place the distal end of a 50 mL syringe filled with disinfecting solution without air as close as possible to the target area. Flush the target area with 50 mL of disinfecting solution.

![Figure 1.2.44](image3)

9) Repeat step 1 to 8 one additional time.
1-2-4-6. 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’s 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 (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) Ensure that the elevator is in the “Middle Position”.

3) Soak the endoscope, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) under the conditions (temperature, concentration, time) specified by the disinfectant manufacturer. In the case of CIDEX® Activated Diadehyde Solution, the soaking time is 45 minutes at 25°C.

![Figure 1.2.45](image)

**Figure 1.2.45**

Purging disinfecting solution from all channels

4) After soaking, attach inlet seal (OF-B190) and cleaning adapters (OF-B153, and OF-G17) to the endoscope, and close the cap of inlet seal (OF-B190). (see Figure 1.2.36, p34)

5) Attach a 50 mL syringe filled with air to cleaning adapter (OF-G17), and flush the air/water channel with 250 mL of air to purge residual disinfecting solution. (see Figure 1.2.37, p35)

6) Attach a 50 mL syringe filled with air to the suction nipple, and flush the suction channel with 350 mL of air to purge residual disinfecting solution. (see Figure 1.2.38, p35)

7) Attach a 50 mL syringe filled with air to the inlet seal (OF-B190), and purge the suction channel with 50 mL of air to purge residual disinfectant solution. (see Figure 1.2.39, p35)

8) Remove the endoscope (with OF-B190, OF-B153, and OF-G17 still attached) from the disinfecting solution.
1-2-4-7. Rinsing

**WARNING**

- Ideally, all final rinses should be performed with sterile water. However, if sterile water is not used, use potable water or water that meets the requirements of the health care facility.
- The basin that is used to perform rinsing should be thoroughly cleaned prior to filling it with rinsing water.
- The rinse volumes recommended for removing residual disinfectant from internal channels are sufficient for 14-day glutaraldehydes (e.g., 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 OF-B190, OF-B153, and OF-G17 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 (OF-B153 and OF-G17) from the endoscope (see Figure 1.2.40, p36). Open the cap of inlet seal (OF-B190).
3) Wipe all exterior surfaces of the endoscope, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) two times with sterile gauze in order to remove residual disinfecting solution.
4) While still completely immersed in water, grasp the distal end, control body, and PVE connector with two hands, and agitate the scope under the water by moving it from side to side repeatedly for 20 seconds.

![Figure 1.2.46](image)

5) Grasp inlet seal (OF-B190), cleaning adapters (OF-B153 and OF-G17) with a hand, and agitate them under the water by moving them from side to side repeatedly for 20 seconds.
6) Attach inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) to the endoscope, and close the cap of inlet seal (OF-B190). (see Figure 1.2.36, p34)
7) Ensure that the elevator is in the “Middle Position”.
8) Attach a 50 mL syringe filled with water without air to cleaning adapter (OF-G17), and flush the air/water channel with 250 mL of water. (see Figure 1.2.37, p35)
9) Attach a 50 mL syringe filled with water without air to the suction nipple, and flush the suction channel with 350 mL of water. (see Figure 1.2.38, p35)
10) Attach a 50 mL syringe filled with water without air to the inlet seal (OF-B190), and flush the suction channel with 50 mL of water. (see Figure 1.2.39, p35)
11) Remove the endoscope (with OF-B190, OF-B153, and OF-G17 still attached) from the water.

12) Attach a 50 mL syringe filled with air to the cleaning adapter (OF-G17), and flush the air/water channel with 250 mL of air. (see Figure 1.2.37, p35)

13) Attach a 50 mL syringe filled with air to the suction nipple, and flush the suction channel with 350 mL of air. (see Figure 1.2.38, p35)

14) Attach a 50 mL syringe filled with air to the inlet seal (OF-B190), and flush the suction channel with 50 mL of air. (see Figure 1.2.39, p35)

Second rinse

15) Fill a basin with clean water, and repeat steps 1 - 14 in order to perform a second complete rinse.

Third rinse

16) Fill a basin with clean water, and repeat steps 1 - 14 in order to perform a third complete rinse.
1-2-4-8. 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 50 mL 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 1.2.37, p35)
2) Attach a 50 mL 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 1.2.38, p35)
3) Attach a 50 mL syringe filled with 70-90% medical grade ethyl or isopropyl alcohol to the inlet seal (OF-B190), and flush the suction channel with 35 mL of alcohol. (see Figure 1.2.39, p35)

Flushing all channels with air
4) Attach a 50 mL syringe filled with air to cleaning adapter (OF-G17), and flush the air/water channel with 250 mL of air to remove residual alcohol. (see Figure 1.2.37, p35)
5) Attach a 50 mL syringe filled with air to the suction nipple, and flush the suction channel with 350 mL of air to remove residual alcohol. (see Figure 1.2.38, p35)
6) Attach a 50 mL syringe filled with air to the inlet seal (OF-B190), and flush the suction channel with 35 mL of air to remove residual alcohol. (see Figure 1.2.39, p35)
7) Ensure that no alcohol exits the endoscope tip.
8) Detach inlet seal (OF-B190) and cleaning adapters (OF-B153 and OF-G17) from the endoscope. (see Figure 1.2.40, p36)

Drying of all external surfaces
9) Gently dry all external surfaces of the endoscope, inlet seal (OF-B190), and cleaning adapters (OF-B153 and OF-G17) with a sterile gauze.
1-2-5. Sterilization

**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 sterilization of the device with new packaging.
- Sterilization efficacy and material compatibility depend upon 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 biological indicator (BI) according to sterilizer labeling to monitor 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 byproducts, or derivatives of the processed devices) remain on any instrument or lumened surfaces that may pose a risk to patients and users.
- Prior to sterilization, the endoscope and accessories must be meticulously cleaned. **Failure to do so can result in incomplete or ineffective sterilization.**

**CAUTION**

- Due to the heat sensitive nature and/or the composition of 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 PENTAX prior to use with any PENTAX products. Also, before using any sterilization method/process other than the method/process described in this IFU, confirm with PENTAX that the specific method/process not in this IFU is acceptable for the PENTAX endoscope used in your healthcare facility.
- NEVER place the endoscope in a steam sterilizer!
1-2-5-1. Liquid Chemical Sterilization of ED-3490TK using the STERIS System 1E® Liquid Chemical Sterilant Processing System

Items required for STERIS System 1E Liquid Chemical Sterilization

- Personal Protective Equipment (e.g., gloves, gowns, face masks) to minimize the risk of cross contamination and protect personnel
- S40® Sterilant Concentrate (STERIS Corporation)
- C1160E Universal Flexible Processing Tray
- QPC1713E Quick Connect for System 1E Processor

PENTAX Duodenoscope Model ED-3490TK may undergo liquid chemical sterilization using the STERIS System 1E® Liquid Chemical Sterilant Processing System. Please consult the following documents for specific instructions:

- STERIS System 1E Liquid Chemical Sterilant Processing System Operator Manual – provides instructions for operation of the processor and the use of S40 Sterilant Concentrate
- C1160E Universal Flexible Processing Tray Processing Instructions – provides instructions for preparation of the universal flexible processing tray and tray placement into the STERIS System 1E Liquid Chemical Sterilant Processing System
- QPC1713E Quick Connect for System 1E Processor Processing Instructions – provides information on flow unit connection, adapter placement, and flow unit confirmation.

Additional information about the STERIS System 1E Sterilant Processing System may be obtained at www.steris.com or by contacting STERIS Customer Service at 1-800-548-4873.
1-3. Endoscope components and accessories

⚠️ WARNING

Current infection control guidelines require that biopsy forceps and similar endoscopic accessory instruments which enter sterile tissue or the vascular system or break the mucosal barrier must be sterilized before each patient use. For patient contact endoscopic accessories, follow the specific and detailed reprocessing instructions supplied with each product.

1-3-1. Cleaning

⚠️ CAUTION

Not all manufacturers of Automated Endoscope Reprocessors (AERs) /Washer-Disinfectors (WDs) make specific claims or provide special instructions for reprocessing all of the removable endoscope components that are integral to the safe and effective operation of flexible endoscopes. Therefore, should the AER/WD manufacturer’s instructions not specifically address reprocessing of any particular endoscope component (e.g., air/water feeding valve, suction control valve, inlet seal, irrigation tube, check valve, selector mechanism, etc.), then those components must be reprocessed manually as described in PENTAX instructions/labeling. Prior to use, check with each AER/WD manufacturer as to their specific claims with respect to reprocessing individual endoscope components.

⚠️ CAUTION

NEVER use ultrasonic cleaning methods on the endoscope itself.

1) Reusable endoscopic accessory instruments (EAIs) such as biopsy forceps and removable endoscope components such as valves should be cleaned immediately (at least within one hour) after each use, since dried blood, mucus, or other debris may cause damage to the instrument, render the mechanism inoperable, or interfere with the ability of the user to reprocess the device or component.

2) Place the EAIs and/or components in a basin with fresh cleaning detergent solution for the time period, concentration, and temperature recommended by the detergent manufacture, being careful not to tightly coil or kink the EAI.
3) Clean the handle and flexible shaft by gently wiping with a soft gauze or the like. The biopsy cups and pivot pin area should be carefully and gently cleaned with a soft brush. Removable components such as the air/water and suction control valves should be manipulated while in the detergent, with detergent injected directly into/onto component surfaces and then brushed clean.

3)-1 Scrub all internal and external surfaces of suction control valve OF-B120 using the smaller end of the cylinder cleaning brush (CS-C9S).

![Figure 1.3.1](1) CS-C9S
(2) OF-B120

3)-2 Remove the air/water feeding valve (OF-B188) from the endoscope. Scrub all internal and external surfaces of the valve using the smaller end of the cylinder cleaning brush (CS-C9S). Repeat several times OR until the bristles of the brush become visibly clean.

![Figure 1.3.2](1) CS-C9S
(2) OF-B188

4) Rinse all residual detergent from the air/water feeding valve (OF-B188) by completely immersing it under clean water and manipulating the handle and cup mechanism.

5) While fully immersed, manipulate valve mechanisms, and inject clean water into them using a syringe.

6) Ultrasonic cleaning of valves and similar accessories is recommended, provided the manufacturer’s instructions and the parameters below are followed: Heavily soiled and/or difficult-to-manually clean components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to subsequent high-level disinfection or sterilization.

- **Frequency Range**: 44 kHz ± 6%
- **Time**: 5 minutes

**CAUTION**

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

All detergent must be removed from the inner mechanisms of individual endoscope components.

Any detergent that remains after water evaporates may cause increased friction that may render the mechanism inoperable. Residual detergent may also reduce the effectiveness of the subsequent biocidal process.

7) After cleaning and thorough rinsing EAIs and components, dry them gently using a soft gauze or the like. Avoid tight coiling or kinking EAIs such as biopsy forceps, and do NOT put tension on the flexible shaft of the forceps and similar EAIs.

NOTE

Other PENTAX reusable accessories (e.g., channel cleaning adapters, cleaning brushes, bite block, etc.) and endoscope components (e.g., inlet seals, air/water and suction control valves, etc.) not specifically identified previously should be cleaned in a manner similar to that described previously. Ultrasonic cleaning methods are recommended for accessories and endoscope components whose entire surfaces are not easily accessible by manual cleaning. Heavily soiled components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to subsequent high-level disinfection or sterilization. For these specific items, please refer to their individual operation instructions for uses or instruction sheets.

NOTE

It is imperative that ultrasonic cleaning of the Endoscopic Accessory Instruments (EAIs) and other components be performed PRIOR to steam sterilization. Only those PENTAX accessories identified by their pink colored handle, labeled as being autoclavable, or identified below may be subjected to steam sterilization.

- PENTAX biopsy forceps
- PENTAX bite block (OF-Z5)
- PENTAX suction control valve (OF-B120)
- PENTAX A/W feeding valve (OF-B188)
- PENTAX inlet seal (OF-B190)
- PENTAX cleaning adapter (OF-G17)
- PENTAX cylinder cleaning brush (CS-C9S)
- PENTAX cleaning adapter (OF-B153)

Also, please refer to the instructions for use supplied with each accessory.
1-3-2. High-Level Disinfection

Before any attempt is made to disinfect endoscopic accessory instruments and/or scope components such as bite blocks, air/water and suction control valves, brushes, etc., the complete cleaning procedure described previously in this instructions for use must have been completed. Heavily soiled components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to high-level disinfection.

1) The entire accessory or component should be immersed in disinfecting solution.
2) Accessory and component surfaces should remain in contact with the disinfecting solution for the time period and at the temperature recommended by the manufacturer of the solution. To ensure better contact, manipulate components such as valves while injecting disinfectant into/onto components surfaces, including all lumens.
   2)-1 While fully immersed, manipulate valve mechanisms, and inject disinfectant via syringe into/through removable endoscope components.
3) After the item has been in contact with the disinfecting solution for the appropriate amount of time, remove it from the disinfecting solution.
4) Rinse all residual disinfecting solution from the accessory/component by immersing it in sterile water.
   4)-1 While fully immersed, manipulate the mechanism of OF-B120 and OF-B188 two times.
   4)-2 Using a syringe filled with water, flush the each lumen of OF-B120 and OF-B188 with 2 mL of water.
5) After thoroughly rinsing, the items should be gently dried using a soft gauze or the like. Compressed air may also be used to facilitate drying.

**NOTE**

Ideally, all final rinses should be made with sterile water or bacteria-free water whose microbial quality has been confirmed via monitoring. After water rinsing, 70-90% medical grade ethyl or isopropyl alcohol should be flushed through lumens of the endoscopic instruments, as well as any removable scope components including valve mechanisms. Alcohol flushing should be followed by drying with compressed air at pressure not greater than 165kPa (24psi). External instrument and component surfaces can be dried by gently wiping them with a sterile gauze or lint-free cloth saturated with alcohol. Regardless of the quality of the rinse water used, a dry instrument is essential to prevent bacterial colonization and/or infections associated with waterborne microorganisms. Such infections are more likely to occur when wet/contaminated instruments are used on patients whose immune systems are compromised or suppressed or when they are used in sterile anatomical areas.
The addition of defoaming agents to the water supply and/or automated reprocessing system is NOT recommended. Due to their nature, these silicone-based agents cling tenaciously to surfaces. Unless they are rinsed very thoroughly, a "barrier" that can potentially reduce the effectiveness of the disinfection/sterilization process can be created. Additionally, repeated use of such defoamers can eventually lead to residual silicone accumulation, resulting in equipment malfunctions such as clogged air and water feeding channels. Similarly, silicone residues can deposit a "film" onto the distal objective lens, causing "blurry" endoscopic images.

1-3-3. Sterilization

WARNING

Current infection control guidelines require that biopsy forceps and similar accessories that enter sterile tissue or the vascular system, or that break the mucosal barrier must be sterilized before each patient use. For patient contact endoscopic accessories, follow the specific and detailed reprocessing instructions supplied with each product.

Before any attempt is made to sterilize accessories and/or individual endoscope components, the complete cleaning procedure previously described in this instructions for use must have been completed. Heavily soiled components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to sterilization.

CAUTION

Use only the type of packaging material and package configuration recommended by the manufacturer of the accessory. Use appropriate chemical indicators and/or biological monitor, as recommended by the manufacturer of the sterilizer.

NOTE

The following sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.
1-3-3-1. Steam Sterilization (Autoclaving) Recommended

1) Prior to steam sterilization, all autoclavable endoscopic accessory instruments and endoscopic components previously identified should be thoroughly cleaned using the manual and ultrasonic cleaning methods previously described in this instructions for use.

2) Autoclaving can be performed under the following conditions:

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

**NOTE**

Validation testing of these parameters was performed using Kimberly Clark Wrap KC-600.
POST REPROCESSING AND STORAGE

⚠️ WARNING ⚠️

- If the endoscope will be stored after reprocessing, detach removable valves, components, etc. All channels should be completely dry before storage.
- Make sure that all removable components such as the air/water feeding valve, suction control valve, and inlet seal are detached from the endoscope. This will allow for better air circulation throughout 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 that have any sharp edges, exposed nails/screws, etc. Contact with sharp objects can puncture, scratch, or otherwise damage the endoscope.
- When utilizing heated disinfectants to reprocess 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 in storage.
2) Prior to reuse, ensure that instrument has been properly inspected and fully prepared for the next clinical procedure.
3) Prior to storage, ensure that all internal channels, endoscope components, instrument surfaces and accessories are thoroughly dry.
4) 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.
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 method. Therefore, questions regarding material compatibility and/or functionality of PENTAX instruments repaired with these unauthorized, untested, and unapproved items, materials, and repair/assembly methods must be referred to the third party service organization and/or device remanufacturer. It is unknown to PENTAX whether serviced or remanufactured instruments from by unauthorized PENTAX entities that still bear a PENTAX label are within PENTAX device specifications, and/or whether 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 that they have serviced or remanufactured, as well as whether the instruments that they have serviced or remanufactured should be reprocessed using 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 be in compliance with the validated and regulatory authorized/approved design of 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.

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 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 that:

- 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>Ruhof Corporation</td>
</tr>
<tr>
<td>Endozime®</td>
<td>Ruhof Corporation</td>
</tr>
<tr>
<td>Endozime® AW Plus</td>
<td>Ruhof Corporation</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>

NOTE: The cleaning process for the endoscopes and accessories described in this IFU has been validated with Endozime® (Ruhof Corporation).
**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)*</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>

*Wavicide-01® may also be marketed as:  
  - MaxiCide® or MaxiCide NS® (Henry Schein)  
  - Acu-Sol® (Acuderm, inc.)  
  - Biocide G30® (Biotrol)  
  - TD-5® (CS Medical LLC)

NOTE: The manual high level disinfection process of the endoscopes and accessories described in this IFU has been validated with Cidex® Activated dialdehyde Solution (Advanced Sterilization Products). The listing of other high level disinfectant brands in the table above does not imply that PENTAX has validated manual high level disinfection with those products.
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, EC 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.

Manufacturer

HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo 160-0023 Japan

Distributors

PENTAX Medical Company
A Division of PENTAX of America, Inc.
3 Paragon Drive Montvale, New Jersey 07645-1782 USA
Tel: +1-201-571-2300 Toll Free: +1-800 431-5880
Fax: +1-201-391-4189

PENTAX Canada, Inc.
6715 Millcreek Drive, Unit 1 Mississauga, Ontario L5N 5V2 Canada
Tel: +1-905-286-5570
Fax: +1-905-286-5571

PENTAX Europe GmbH
Julius Vosseler Strasse 104, 22527 Hamburg, Germany
Tel: +49-40-561-920
Fax: +49-40-560-4213

Manufacturing Site

HOYA Corporation, PENTAX Miyagi Factory
30-2 Okada, Aza-Shimomiyano, Tsukidate, Kurihara-shi, Miyagi 987-2203 Japan

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