1588 Pendulum Camera Head with Integrated Coupler

REF 1588-310-130
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Warnings and Cautions

Please read this manual and follow its instructions carefully. The words warning, caution, and note carry special meaning and should be carefully reviewed:

**Warning**
Indicates risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.

**Caution**
Indicates risks to the equipment. Failure to follow cautions may result in product damage.

**Note:** Clarifies the instructions or presents additional useful information.

An exclamation mark within a triangle is intended to alert the user to the presence of important operating and maintenance instructions in the manual.

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### Warnings

To avoid potential serious injury to the user and the patient and/or damage to this device, please note the following general warnings.

1. Must be a qualified physician to use this equipment.
2. Read this user manual thoroughly, especially the warnings, and be familiar with its contents before connecting and using this device.
3. Before using this device, read Stryker user manual P29923 (English) or P29924 (multilingual) for warnings and other information about using the camera system.
4. Test this equipment prior to a surgical procedure. This unit was fully tested at the factory before shipment.
5. The camera head surface may exceed 41 °C (106 °F) in operating conditions with high ambient temperatures and it should be handled with caution.
6. The device is shipped non-sterile. You must sterilize the devices before the first use and after each use. To prevent device damage and infection risk to the patient or user, follow all cleaning and sterilization instructions in this manual.
7. Never use the camera system in the presence of flammable or explosive gases.
8. Do not disassemble any part of the camera head; doing so may break the seals, causing leakage and/or electric shock.
9. Attempt no internal repairs or adjustments not specifically detailed in this user manual.
Cautions
To avoid potential damage to this device, please note the following cautions.

1. Carefully unpack this device and check if any damage occurred during shipment. If damage is detected, refer to the standard warranty.
2. Always treat the camera system with care. The camera system contains sensitive parts that are precisely aligned and may suffer damage if dropped or mistreated.
3. Ensure that readjustments, modifications, and/or repairs are carried out by persons authorized by Stryker Endoscopy.

Operating the Camera with a Light Source
Please note the following warnings to avoid user or patient injury or product damage when using the camera with a light source.

**IMPORTANT SAFETY NOTICE - HIGH TEMPERATURES:**
Before operating this device, please read this operating manual thoroughly and carefully. When using this device with a light source, fire and/or severe injury may result to the patient, user or inanimate objects if the instructions in this manual are not followed.

All light sources can generate significant amounts of heat (exceeding 41 °C/106 °F) at the scope tip, the scope light post, the light cable tip, and/or near the light cable adapter. Higher levels of brightness from the light source result in higher levels of heat. Always adjust the brightness level of the camera and the monitor before adjusting the brightness level of the light source. If the brightness level of the light source can be adjusted, set it to the minimum brightness necessary to adequately illuminate the surgical site.

In addition, adjust the internal shutter of the camera higher in order to run the light source at a lower intensity. Avoid touching the scope tip or the light cable tip to the patient, and never place them on top of the patient, as doing so may result in burns to the patient or user. In addition, never place the scope tip, the scope light post, the light cable adapter, or the light cable tip on the surgical drapes or other flammable material, as doing so may result in fire.

Always place the light source in standby mode whenever the scope is removed from the light cable or the device is unattended. The scope tip, scope light post, light cable adapter, and light cable tip will take several minutes to cool off after being placed in standby mode, and therefore may still result in fire or burns to the patient, user, or inanimate objects.

The warranty is void if any of the above warnings or cautions are disregarded.
Product Description and Intended Use

The Stryker 1588 Pendulum Camera Head with Integrated Coupler ("Pendulum Camera") is an endoscopic camera used to produce still and video images in the surgical field during surgical endoscopic procedures. The optical image is transferred from the surgical site to the camera head by a variety of rigid and flexible scopes which are attached to the camera head.

The Pendulum Camera is designed with a 90° angle between the camera head and the scope to allow for easier access during urology procedures. The Pendulum Camera also allows rotating the camera head 360° to properly orient the video image.

The Pendulum Camera is used in conjunction with the 1588 AIM Camera Control Unit (1588-010-000). For more information about the camera console, see Stryker user manual P29923 (English) or P29924 (multilingual).

**Note:** The Pendulum Camera is not compatible with Endoscopic Near-Infrared Visualization (ENV) mode on the 1588 AIM Camera Control Unit.
Indications
The 1588 Pendulum Camera Head with Integrated Coupler is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope/endoscope/arthroscope is indicated for use.

A few examples of the more common endoscopic surgeries are listed below.

- laparoscopic cholecystectomy
- laparoscopic hernia repair
- laparoscopic appendectomy
- laparoscopic pelvic lymph node dissection
- laparoscopically assisted hysterectomy
- laparoscopic and thorascopic anterior spinal fusion
- anterior cruciate ligament reconstruction
- knee arthroscopy
- shoulder arthroscopy
- small joint arthroscopy
- decompression fixation
- wedge resection
- lung biopsy
- pleural biopsy
- dorsal sympathectomy
- pleurodesis
- internal mammary artery dissection for coronary artery bypass
- coronary artery bypass grafting where endoscopic visualization is indicated
- examination of the evacuated cardiac chamber during performance of valve replacement

The users of the 1588 Pendulum Camera Head with Integrated Coupler are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.
Device Features

The Pendulum Camera connects to the camera console and produces video and photographic images, which it relays to the camera console. Several controls are accessible through a button keypad located on the top of the camera head (see the Operation section).

1. **Image rotation joint**
   - Allows rotating the camera head 360° to reorient the video image as needed

2. **Endobody clamp**
   - Secures the scope to the camera head

3. **Endobody brake**
   - Prevents rotation of the scope

4. **Focusing knob**
   - Adjusts the focus of the camera head

5. **Camera head buttons**
   - Provide camera controls

6. **Camera cable**
   - The camera cable length is 10 feet (3.05 m)

7. **Soaking cap**
   - Protects the cable connector during cleaning, disinfection, and sterilization

8. **Cable connector**
   - Connects the camera head to the camera console
Setup

1. Set up the 1588 AIM console according to the instructions provided in Stryker user manual P29923 (English) or P29924 (multilingual).

2. Connect the Pendulum Camera to the console.
   - Unscrew the soaking cap from the cable connector if necessary.
   - Align the arrow on the cable connector with the arrow on the camera-connector port on the front console panel.
   - Push in the connector until it locks in place.
   - (To unplug the Pendulum Camera from the console, grasp the knobbed portion of the connector and pull straight out.)

3. Attach an endoscope to the Pendulum Camera.
   - Remove the red dust cap if it is present.
   - Lock the endobody brake by pushing it to the left.
   - Twist the endobody clamp and hold it open.
• Insert the endoscope into the endobody clamp.

• Release the endobody clamp. It will return to the original position and secure the endoscope. (Twisting the endobody clamp in the reverse direction can make it difficult to remove the endoscope.)

4. Attach a light cable from the light source to the light post on the endoscope.
Installing the Soaking Cap
Before reprocessing the camera head, the soaking cap must be installed to avoid damaging the cable connector.

Caution: Failure to properly tighten the soaking cap will corrode the connector pins and void the warranty.

- To install the soaking cap, screw the cap onto the threads of the cable connector until it forms a tight seal.
- To remove the soaking cap, unscrew the cap and pull it away from the cable connector.

Operation

Before using the Pendulum Camera in a surgical procedure, ensure all system components have been set up according to the instructions in the Setup section. Test all system components to ensure proper function. Ensure that a video image appears on all video monitors before beginning any procedure.

The operation instructions below describe the functions of the Pendulum Camera that are specific to the camera head. For instructions and troubleshooting about using the 1588 AIM Camera Control Unit, see user manual P29923 (English) or P29924 (multilingual).
Using the Camera Head Buttons

The camera head features a two-button keypad for controlling the Pendulum Camera. These buttons are labeled P and W.

P (Picture) Button

The P button controls up to two functions of a remote video accessory. Commonly this enables the user to capture images or start and stop video recording. See user manual P29923 (English) or P29924 (multilingual) for connection requirements.

- Press the P button for less than two seconds to select Remote 1. One beep will sound. When the camera is connected to a Stryker digital capture console, this will capture a photo.
- Press the P button for more than two seconds to select Remote 2. Two beeps will sound. When the camera is connected to a Stryker digital capture console, this will start or stop video recording.

W (White-Balance) Button

The W button activates the white-balance function or the zoom-cycle function.

- Press the W button for less than two seconds to activate the zoom-cycle function. Each press will raise the zoom level in eight steps. When the zoom level has reached its maximum, pressing the button again will cycle the level back to the lowest setting.
- Press the W button for more than two seconds to activate the white-balance function. White balancing will correct slight color differences that exist between different light sources or endoscopes. See “Performing the White-Balance Test” below.
Performing the White-Balance Test

Before each surgical procedure, perform the white-balance test to adjust the camera’s perception of white so it can display other colors correctly.

1. Ensure that a scope and light source are attached to the camera system, and that the console, light source and monitor are powered on.
2. Point the scope tip at several stacked white gauze pads, a white laparoscopic sponge, or any clean white surface.
3. Look at the monitor and make sure there is no visible glare off of the white surface of the image.
4. Press and hold the camera head W button (or “WB” on the touchscreen) until the monitor displays the message “WHITE BALANCE IN PROGRESS.”
5. Continue pointing the scope at the white surface until the video monitor displays the message “WHITE BALANCE COMPLETE.” The image may change color. If you cannot achieve an acceptable white balance, refer to the Troubleshooting section.

Adjusting the Focus

Slide the focusing knob 1 to the left or right to adjust the focus.
Rotating the Image

Rotate the camera head at the image rotation joint 1 to reorient the image as needed. The camera head will rotate 360° independently of the scope.

To allow rotation of the scope inside the endobody clamp, release the endobody brake 2 by pushing it to the right. To prevent the scope from rotating inside the endobody clamp, lock the endobody brake by pushing it to the left.
Reprocessing

These reprocessing instructions are provided in accordance with ISO 17664, AAMI TIR12, AAMI TIR30, AAMI ST79, and AAMI ST81. The instructions have been validated by Stryker as being capable of preparing the device for re-use. To achieve the desired result, the processor shall ensure that the following instructions are performed as written in their entirety and as appropriate in the processor’s facility. This normally requires routine monitoring and validation of the facility’s reprocessing procedures. Stryker recommends users observe these standards when reprocessing medical devices.

Overview

Reprocessing the camera head involves manual or automated cleaning with two different detergents, optional disinfection, and sterilization.

- **Step 1** (required): Cleaning with Enzymatic Detergent
- **Step 2** (required): Cleaning with Non-Enzymatic Detergent
- **Step 3** (optional): Disinfection
- **Step 4** (required): Sterilization

Warnings

- This device must be cleaned and sterilized prior to the first use and after every subsequent use.
- Separate the camera head and scope prior to cleaning, disinfection, or sterilization. Failure to follow this instruction will render the devices non-sterile. (Refer to the scope product manual for reprocessing instructions for that device.)
- Wear appropriate protective equipment: gloves, eye protection, etc.
- To avoid health risks from aerosol contamination, brush the device only when it is submerged in liquid.
- Use only the sterilization cycles outlined in this document. Using unspecified sterilization cycles may damage the device or result in incomplete sterilization.
- Sterilize only one camera head per tray, or incomplete sterilization may result. Follow any instructions provided with the sterilization tray or system regarding tray setup and other devices that may be sterilized within the same tray.
Cautions

• Always install the soaking cap prior to processing the camera. Failure to properly tighten the soaking cap will corrode the connector pins and void the warranty. Refer to the Installing the Soaking Cap section for more detail about installing the cap.
• Inspect the camera cable for cuts and breaks before soaking in any fluid. Return any damaged camera to Stryker for service.
• Never soak the camera in the same tray with sharp instruments.
• Do not use brushes or pads with metal or abrasive tips during manual cleaning, as permanent scoring or damage could result.
• To minimize galvanic corrosion, avoid soaking dissimilar metals in close proximity.
• The device cannot withstand an automated disinfection method.
• The 1588 Pendulum Camera Head is not autoclavable. Steam sterilizing camera heads that are not marked AUTOCLAVE will result in product damage.
• Allow the camera head to cool before connecting it to the console. Connecting the camera head while it is hot may result in system error.
• When using Steris® liquid chemical sterilization, remove the camera head from the chamber once sterilization is complete, or moisture may condense inside the camera head and cause display defects.

Limitations on Reprocessing

• Do not cross-sterilize the device. Using multiple sterilization methods may significantly reduce the performance of the device.
• Repeated sterilization via Ethylene Oxide or Sterrad® 100NX® can degrade the product’s cosmetic appearance.
• Do not leave the device in solutions longer than necessary. This may accelerate normal product aging.
• Damage caused by improper processing is not covered by the warranty.

Materials and Equipment

All materials and equipment required to reprocess the camera head shall be supplied by the user unless otherwise noted

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>All phases</td>
<td></td>
</tr>
<tr>
<td>Gloves, eye protection, etc.</td>
<td>Wear protective equipment as required by the medical facility and procedure.</td>
</tr>
</tbody>
</table>
### Cleaning

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water basin</td>
<td>Large enough to accommodate camera head without excessive bending of cable</td>
</tr>
<tr>
<td>Enzymatic detergent(^1)</td>
<td>Used in cleaning solution to remove surgical debris</td>
</tr>
<tr>
<td>Tap water</td>
<td>To prepare cleaning solutions</td>
</tr>
<tr>
<td>Syringe(^2)</td>
<td>To inject detergent into hard-to-reach areas of device</td>
</tr>
<tr>
<td>Soft-bristle brush(^3)</td>
<td>To clean exterior of device or hard-to-reach areas of device</td>
</tr>
<tr>
<td>Reverse osmosis/deionized water(^4)</td>
<td>To rinse device</td>
</tr>
<tr>
<td>Clean cloth or filtered pressurized air (≤40 psi)</td>
<td>To assist with drying</td>
</tr>
<tr>
<td>Non-enzymatic detergent(^5)</td>
<td>Used in cleaning solution to remove surgical debris</td>
</tr>
<tr>
<td>Automated washer</td>
<td>For using the automated cleaning procedure</td>
</tr>
</tbody>
</table>

\(^1\) Cleaning was validated using ENZOL\(^\circ\) Enzymatic Detergent at 1 oz/gal. at 35 °C.

\(^2\) Cleaning was validated using a 50 mL syringe.

\(^3\) Recommend to clean with an M16 soft-bristle brush.

\(^4\) Cleaning was validated using reverse osmosis/deionized (RO/DI) water.

\(^5\) Cleaning was validated using Prolystica\(^\circ\) 2x Neutral Detergent at 1/8 oz/gal at 35 °C.

### Disinfection

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water basin</td>
<td>Large enough to accommodate camera head without excessive bending of cable</td>
</tr>
<tr>
<td>Disinfecting solution(^6)</td>
<td>≥ 2.4% glutaraldehyde</td>
</tr>
<tr>
<td>Tap water</td>
<td>To prepare disinfecting solution</td>
</tr>
<tr>
<td>Reverse osmosis/deionized water(^4)</td>
<td>To rinse the device</td>
</tr>
<tr>
<td>Clean cloth or filtered pressurized air (≤40 psi)</td>
<td>To assist with drying</td>
</tr>
</tbody>
</table>

\(^6\) Disinfection was validated using CIDEX\(^\circ\) Activated at 25 °C with a soaking time of 45 minutes.

### Sterilization

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization system(^7)</td>
<td>• Sterrad 100S, 200, NX(^\circ), or 100NX</td>
</tr>
<tr>
<td></td>
<td>• Steris/Amsco(^\circ) V-PRO(^\circ) 1, V-PRO 1 Plus, or V-PRO maX</td>
</tr>
<tr>
<td></td>
<td>• Steris System 1(^\circ), System 1E(^\circ), System 1 Plus, or System 1 Express</td>
</tr>
<tr>
<td></td>
<td>• Ethylene Oxide (EO)</td>
</tr>
<tr>
<td>Sterilization wrap(^8,9)</td>
<td>To maintain sterile barrier</td>
</tr>
<tr>
<td>Sterilization tray(^9)</td>
<td>Optional. Must be compatible with sterilization method.</td>
</tr>
</tbody>
</table>

\(^7\) Steris System 1, System 1 Plus, and System 1 Express are not intended for use in the United States.

\(^8\) For United States users: when sterilizing the device, use only sterilization wraps and sterilization trays that have been cleared by the FDA to use with the selected sterilization cycle.
## Instructions for Reprocessing

### Point of Use
- Disconnect the scope from the camera head. Twist the endobody clamp to hold it open, and remove the scope from the integrated coupler.
- Wipe any excess soil from the device using a clean sterile cloth.
- If an automated reprocessing method will be used, rinse any hard-to-reach areas in the device with 50 mL of sterile distilled water immediately after use.

### Containment and Transportation
- Reprocess the device as soon as reasonably practical following use.
  
  **Note:** Cleaning was validated with a 30 minute wait time.
- Transport the device in a tray to avoid damage. Follow the facility’s internal procedures for the transportation of contaminated surgical instruments and devices.

### Cleaning

#### Manual Cleaning

**Note:** For necessary materials and equipment, see the Materials and Equipment table.

1. **Soak**
   - Disconnect the scope from the camera head.
   - Ensure the soaking cap is installed. Refer to the Installing the Soaking Cap section for more detail about installing the cap.
   - Prepare an enzymatic detergent according to the manufacturer instructions.
   - Use a clean cloth to wipe the entire device with the detergent.
   - Fully immerse the device in the detergent. Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces to remove loose debris.
   - Soak the device in the detergent for 15 minutes.
2. **Brush**
   - Thoroughly brush the exterior of the device with a soft-bristle brush for 90 seconds, focusing on any mated or rough surfaces.
   - Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces 5 times.
   - Brush between all gaps and crevices while twisting the endobody clamp to open it. Continue brushing all gaps and crevices while releasing the clamp to the initial position.

3. **Rinse**
   - Remove the device from the prepared detergent. Rinse the device with reverse osmosis/deionized water at ambient temperature for 90 seconds or until all visible detergent residue is removed.
   - Flush any crevices and mated surfaces 5 times. After all visible detergent residue is removed, continue to rinse for 30 seconds.
   - Drain excess water from the device and dry it with a clean cloth or filtered pressurized air.
   - Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1–3.

4. **Soak**
   - Prepare a non-enzymatic detergent according to the manufacturer instructions.
   - Fully immerse the device in the detergent. Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces.
   - Soak the device in the detergent for 15 minutes.

5. **Brush**
   - Thoroughly brush the exterior of the device with a soft-bristle brush for 90 seconds, focusing on any mated or rough surfaces.
   - Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces 5 times.
   - Brush between all gaps and crevices while twisting the endobody clamp to open it. Continue brushing all gaps and crevices while releasing the clamp to the initial position.
6. **Rinse**
   - Remove the device from the prepared detergent. Rinse the device with reverse osmosis/deionized water at ambient temperature for 90 seconds or until all visible detergent residue is removed.
   - Flush any crevices and mated surfaces 5 times. After all visible detergent residue is removed, continue to rinse for 30 seconds.
   - Drain excess water from the device and dry it with a clean cloth or filtered pressurized air.
   - Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1–6.

---

**Automated Cleaning**

**Note:** For necessary materials and equipment, see the Materials and Equipment table.

1. **Soak**
   - Disconnect the scope from the camera head.
   - Ensure the soaking cap is installed. Refer to the Installing the Soaking Cap section for more detail about installing the cap.
   - Prepare an enzymatic detergent according to the manufacturer instructions.
   - Use a clean cloth to wipe the entire device with the detergent.
   - Fully immerse the device in the detergent. Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces to remove loose debris.
   - Soak the device in the detergent for 15 minutes.

2. **Brush**
   - Thoroughly brush the exterior of the device with a soft-bristle brush for 90 seconds, focusing on any mated or rough surfaces.
   - Use a syringe to inject 50 mL of the detergent into any crevices and mated surfaces 5 times.
   - Brush between all gaps and crevices while twisting the endobody clamp to open it. Continue brushing all gaps and crevices while releasing the clamp to the initial position.
3. **Rinse**
   - Remove the device from the prepared detergent. Rinse the device with reverse osmosis/deionized water at ambient temperature for 90 seconds or until all visible detergent residue is removed.
   - After all visible detergent residue is removed, continue to rinse for 30 seconds.

4. **Automated Wash**
   - Place the device in the washer on an incline to facilitate drainage.
   - Program the washer using the following parameters:

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<tbody>
<tr>
<td><strong>Pre-Wash</strong></td>
<td></td>
</tr>
<tr>
<td>Recirculation Time</td>
<td>2 min</td>
</tr>
<tr>
<td>Water Temperature</td>
<td>Cold tap water</td>
</tr>
<tr>
<td>Detergent Type</td>
<td>n/a</td>
</tr>
</tbody>
</table>

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<table>
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<tbody>
<tr>
<td><strong>Enzyme Wash</strong></td>
<td></td>
</tr>
<tr>
<td>Recirculation Time</td>
<td>2 min</td>
</tr>
<tr>
<td>Water Temperature</td>
<td>Hot tap water</td>
</tr>
<tr>
<td>Detergent Type</td>
<td>Enzymatic detergent</td>
</tr>
</tbody>
</table>

<p>| | |</p>
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<thead>
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</thead>
<tbody>
<tr>
<td><strong>Wash 1</strong></td>
<td></td>
</tr>
<tr>
<td>Recirculation Time</td>
<td>2 min</td>
</tr>
<tr>
<td>Water Temperature</td>
<td>Set point 66 °C</td>
</tr>
<tr>
<td>Detergent Type</td>
<td>Non-enzymatic detergent</td>
</tr>
</tbody>
</table>

<p>| | |</p>
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<tr>
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<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Rinse 1</strong></td>
<td></td>
</tr>
<tr>
<td>Recirculation Time</td>
<td>2 min</td>
</tr>
<tr>
<td>Water Temperature</td>
<td>Hot tap water</td>
</tr>
<tr>
<td>Detergent Type</td>
<td>n/a</td>
</tr>
</tbody>
</table>

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</tr>
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<tbody>
<tr>
<td><strong>Dry Phase</strong></td>
<td></td>
</tr>
<tr>
<td>Recirculation Time</td>
<td>7 min</td>
</tr>
<tr>
<td>Temperature</td>
<td>115 °C</td>
</tr>
<tr>
<td>Detergent Type</td>
<td>n/a</td>
</tr>
</tbody>
</table>

   - Filtered pressurized air can be used to aid in drying.
   - Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeats steps 1–4.
The device must be sterilized after disinfection. Failure to sterilize the device before reuse presents an acute infection control risk to the patient.

**Note:** For necessary materials and equipment, see the Materials and Equipment table.

The device can be disinfected using a disinfecting solution that has the following active ingredient: ≥ 2.4% glutaraldehyde at 25 °C.

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.
2. Prepare the disinfecting solution according to the manufacturer instructions.
3. Immerse the device in the solution, filling all mated surfaces and crevices.
4. Soak the device in the solution for 45 minutes.
5. Thoroughly rinse and flush the device with running, reverse osmosis/deionized water to remove the disinfectant.
6. Dry the device with a clean, lint-free cloth immediately after rinsing.
Sterilization

After performing the cleaning instructions specified above, perform one of the following sterilization cycles. **Note:** For necessary materials and equipment, see the Materials and Equipment table.

### Sterrad

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.
2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are compatible with Sterrad.
3. Double wrap the device (or tray) prior to sterilization.
4. Sterilize the device following the instructions of the manufacturer, using the Sterrad 100S, 200, NX, or 100NX Sterilization System. Select the standard cycle.
5. After sterilization, allow the device to cool to room temperature before reconnecting it to a scope or the console. Otherwise, the lens can fog during use or the console can produce a system error.

### Steris/Amsco V-PRO

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.
2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are approved for sterilization with V-PRO.
3. Double wrap the device (or tray) prior to sterilization.
4. Sterilize the device using one of the following V-PRO sterilization systems:
   - V-PRO 1 (Standard cycle)
   - V-PRO 1 Plus (Non-Lumen or Standard cycle)
   - V-PRO maX (Non-Lumen or Standard cycle)
5. After sterilization, allow the device to cool to room temperature before reconnecting it to a scope or the console. Otherwise, the lens can fog during use or the console can produce a system error.
Steris System 1 / 1E / 1 Plus / 1 Express

Note: Steris System 1, System 1 Plus, and System 1 Express are not intended for use in the United States.

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.

2. Following the instructions of the manufacturer, sterilize the device using one of the Steris systems below with the appropriate sterilant:
   • System 1 with Steris 20 Sterilant
   • System 1E with S40™ Sterilant
   • System 1 Plus with S40 Sterilant
   • System 1 Express with S40 Sterilant

3. Remove the device from the Steris chamber once sterilization is complete, or moisture may condense inside the device windows and cause fogging.

4. After sterilization, allow the device to completely dry and cool to room temperature before reconnecting it to a scope or the console. Otherwise, the lens can fog during use or the console can produce a system error.
**Ethylene Oxide (EO)**

1. Clean and prepare the device as recommended in this user manual. Ensure the soaking cap is installed.

2. If using a sterilization tray (optional), follow any additional instructions provided with the tray. Use only trays that are compatible with EO.

3. Double wrap the device (or tray) prior to sterilization.

4. Sterilize the device using the parameters below.

<table>
<thead>
<tr>
<th><strong>Preconditioning</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapping</td>
<td>Double</td>
</tr>
<tr>
<td>Temperature</td>
<td>55 °C (131 °F)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>70%</td>
</tr>
<tr>
<td>Vacuum Set Points</td>
<td>1.3 psia</td>
</tr>
<tr>
<td>Preconditioning Time</td>
<td>30 min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Exposure</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>55 ± 2 °C (131 ± 5 °F)</td>
</tr>
<tr>
<td>Chamber Humidity</td>
<td>70% RH (50–80%) ± 5%</td>
</tr>
<tr>
<td>Concentration (100% EO)</td>
<td>725 mg/L</td>
</tr>
<tr>
<td>Time</td>
<td>1 hour</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Aeration</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Aeration Time</td>
<td>12 hours</td>
</tr>
<tr>
<td>Temperature</td>
<td>35–39 °C (95–102 °F)</td>
</tr>
</tbody>
</table>

5. After sterilization, allow the device to cool to room temperature before reconnecting it to a scope or the console. Otherwise, the lens can fog during use or the console can produce a system error.
User Maintenance

Inspection
• Inspect the device on a continual basis for unacceptable deterioration such as (but not limited to) corrosion, discoloration, pitting, cracked seals, or abnormal noises. If a problem is observed or suspected, the device should be returned for service.
• Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and sterilization procedures.
• Inspect the camera cable for cuts and breaks. Return any damaged camera to Stryker for service.

Using Sterile Drapes
Using sterile drapes will ensure maximum longevity of the device. For best results, follow the instructions provided by the drape manufacturer.

Storage
Store the device in a dry, clean, and dust-free environment at room temperatures.

Expected Service Life
When the device is sterilized with V-PRO, Sterrad, or Steris System 1/1E/1 Plus/1 Express, the expected service life is 280 reprocessing cycles (two years based on 140 cycles per year).

When the device is sterilized with Ethylene Oxide, the expected service life is 140 reprocessing cycles (two years based on 70 cycles per year).

Disposal and Recycling Information
This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately in accordance with applicable national or institutional related policies relating to obsolete electronic equipment.

Dispose of the camera system according to local laws and hospital practices. Refer to the diagram below to identify components that must be recycled.
## Recycling Diagram

<table>
<thead>
<tr>
<th>Item</th>
<th>Material</th>
<th>Qty.</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Camera Head Enclosure (PC Boards)</td>
<td>1</td>
<td>The camera head enclosure that contains PC Boards is sealed and cannot be dismantled without special equipment and training.</td>
</tr>
<tr>
<td>2</td>
<td>Cable</td>
<td>1</td>
<td>—</td>
</tr>
</tbody>
</table>
# Technical Specifications

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Imaging System</strong></td>
<td>1/3” Progressive Scan CMOS High Definition</td>
</tr>
</tbody>
</table>
| **Operating Conditions**        | Temperature: 10–30 °C  
Relative Humidity: 25–75%                                                |
| **Transport and Storage**       | Conditions                                                              |
|                                 | Temperature: -18–60 °C  
Relative Humidity: 15–90%                                                |
| **Device Weight**               | 1.0 lb (0.5 kg) (approximate weight)                                    |
| **Dimensions**                  | Camera Head Cable: 10 ft (3.05 m) sealed cable                           |
| **Classification**              | Type BF Applied Part  
Ingress Protection, IPX7—Protected against the effects of temporary immersion in water |
Symbol Definitions

This device and its labeling contain symbols that provide important information for the safe and proper use of the device. These symbols are defined below.

- **Rx only**
  - Federal law (USA) restricts this device to use by, or on order of, a physician

- **Caution (consult instructions for use)**
  - Consult instructions for use

- **Made in USA**
  - Product is manufactured in the USA

- **Date of manufacture**

- **Legal manufacturer**

- **Non sterile and must be sterilized before use**

- **Product catalog number**

- **Serial number**

- **Ce**
  - The device meets requirements for safety and effectiveness set forth in MDD 93/42/EEC

- **EC REP**
  - Stryker European representative

- **Type BF applied part**

- **Device recycling code (applicable in China)**
  - This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately.
  - Rotate endobody clamp in indicated direction to detach endoscope