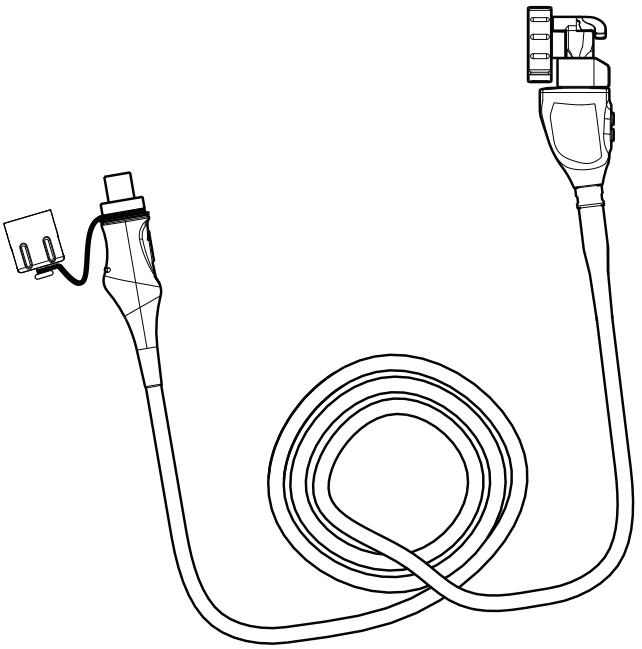
stryker®

1488 HD 3-Chip Pendulum Camera with Integrated Coupler

REF 1488310130



CE Rx ONLY

Contents

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.

A lightning bolt within a triangle is intended to warn of the presence of hazardous voltage. Refer all service to authorized personnel.

IMPORTANT SAFETY NOTICE: 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. Adjust the brightness level of the light source 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.

Warnings

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

1. Must be a qualified physician to use this equipment.
2. Carefully unpack this device and check if any damage occurred during shipment. If damage is detected, refer to the standard warranty.
3. Read this operating manual thoroughly, especially the warnings, and be familiar with its contents before connecting and using this device.
4. Before using this device, read Stryker operating manual P18966 or P18972 for warnings and other information about using the camera system.
5. Test this equipment prior to a surgical procedure. This unit was fully tested at the factory before shipment.
6. The camera head surface may exceed 41 °C (106 °F) in operating conditions with high ambient temperatures and should be handled with caution.
7. Pay close attention to the care, cleaning, disinfection, and sterilization instructions in this manual. Any deviation may cause damage.
8. Never use the camera system in the presence of flammable or explosive gases.
9. 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.
10. Do not disassemble any part of the camera head; doing so may break the seals, causing leakage and/or electric shock.
11. Attempt no internal repairs or adjustments not specifically detailed in this operating manual.
12. Ensure that readjustments, modifications, and/or repairs are carried out by persons authorized by Stryker Endoscopy.

The warranty is void if any of these warnings are disregarded.

Product Description and Intended Use

The Stryker 1488 HD 3-Chip Pendulum Camera Head with Integrated Coupler ("Pendulum Camera") is a high-definition camera used to produce still and video images of endoscopic surgical applications. It 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 1488 HD 3-Chip Camera Control Unit (1488010000 or 1488010001). For more information about the camera console, refer to Stryker user guide P18966 or P18972.

Indications/Contraindications

The 1488 HD 3-Chip 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.

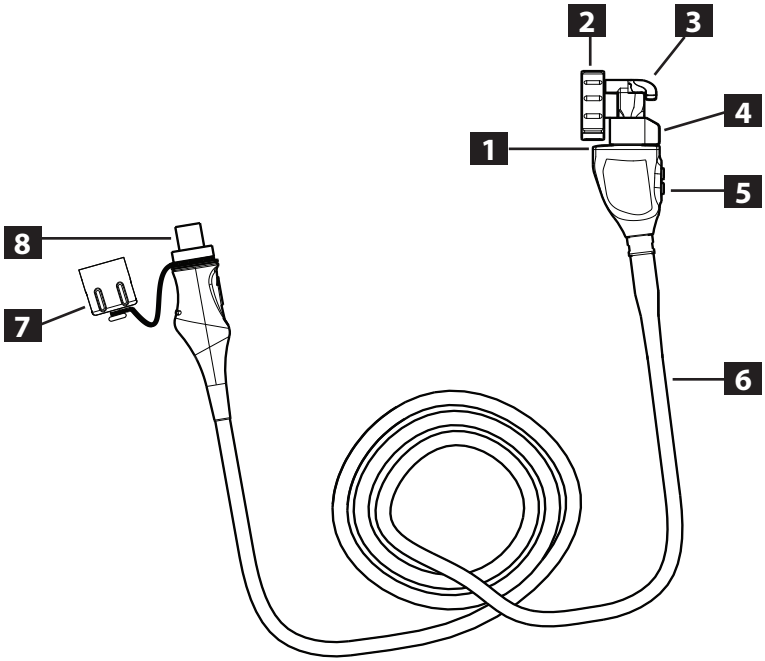
A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anterior spinal fusion, anterior cruciate ligament 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 and examination of the evacuated cardiac chamber during performance of valve replacement.

The users of the camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

There are no known contraindications.

Product Features

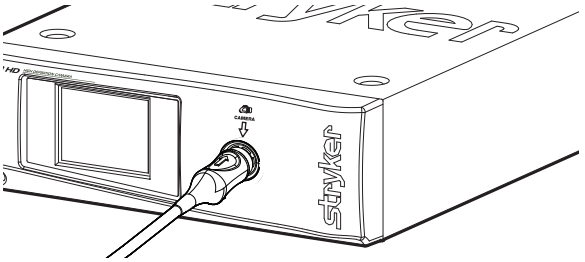
The Pendulum Camera connects to the camera console and produces video and photographic images, which it relays to the camera console. It features several controls that are accessible through a button keypad located on the top of the camera head (see the "Operation" section).



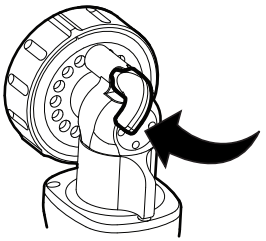
1.	**Image rotation joint**	Allows rotating the camera head 360° to reorient the video image as needed
2.	**Endobody clamp**	Secures the scope to the camera head
3.	**Endobody brake**	Prevents rotation of the scope
4.	**Focusing knob**	Adjusts the focus of the camera head
5.	**Camera head buttons**	Provide 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 1488 HD console according to the instructions provided in Stryker user manual P18966 or P18972.
2. Connect the Pendulum Camera to the console.
    - Unscrew the soaking cap from the cable connector if necessary.
    - Align the blue arrow on the cable connector with the blue 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.)

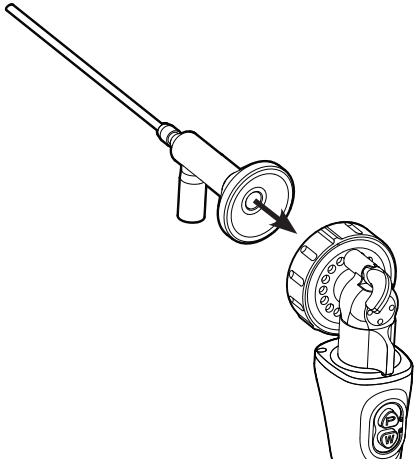


3. Attach an endoscope to the Pendulum Camera.
    - Remove the red dust cap if it is present.
    - Lock the endobody brake by pushing it to the left.

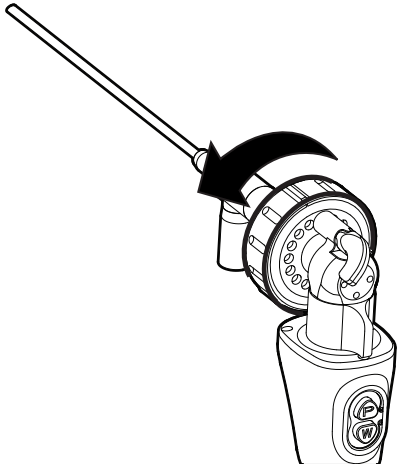


    - Twist the endobody clamp and hold it open.

- 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.

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.

Operating the Camera with a Light Source

IMPORTANT SAFETY NOTICE: 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.

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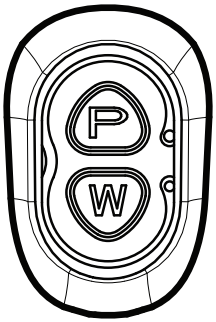
In addition, adjust the internal shutter of the camera higher in order to run the light source at a lower intensity. Avoid touching the scope tip or the light cable tip to the patient, and never place them on top of the patient, as doing so may result in burns to the patient or user. In addition, never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

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 Stryker user guide P18966 or P18972 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.

Using the Touchscreen Interface

The touchscreen interface on the camera console provides controls for adjusting or capturing the video image. The menus are described below.

Home Screen

The Home screen is the default screen. Use the buttons below to choose surgical specialties and operate the camera head.

Scroll through preset camera settings designed for **surgical specialties.** Choose from:

- Arthroscopy
- Cystoscopy
- ENT/Skull
- Flexi-Scope
- Hysteroscopy
- Laparoscopy
- Laser
- Microscope
- Standard

Press the camera button to **capture a photo.**

A single beep will sound to indicate that a signal for capture/record has been sent to the digital capture console.

Press the record button to **record a video.** Press again to stop recording.

A double beep will sound to indicate that a signal for capture/record has been sent to the digital capture console.

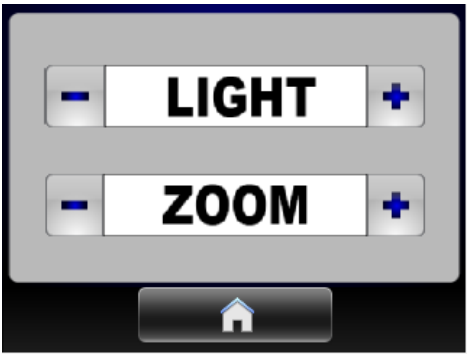
Press and hold the WB button for two seconds to activate **white balance**. See "Performing the White-Balance Test" below for more detail.

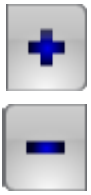
A checkmark will appear on the button after the white-balance test is complete.

Press the Menu button to navigate to the Menu screen.

Menu Screen

The Menu screen provides options for adjusting the camera picture.

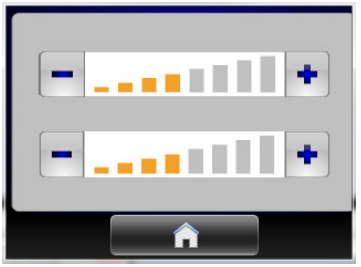




Press the plus or minus buttons to increase or decrease:

- **Light** (automatic-shutter light level)
- **Zoom** (magnification)

While adjusting Light or Zoom, a meter will briefly appear on the touchscreen to indicate each selection level.



Press the Home button to return to the Home screen.

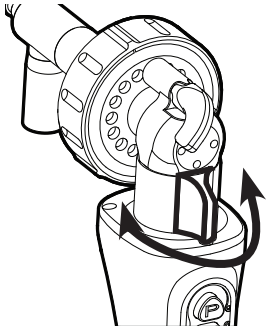
Performing the White-Balance Test

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, and that the camera, 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 video picture may change color. If you cannot achieve an acceptable white balance, refer to the "Troubleshooting" section in the camera console user guide P18966 or P18972.

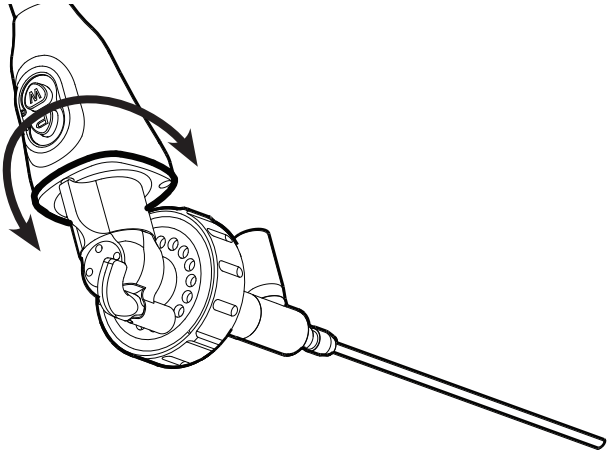
Adjusting the Focus

Slide the focusing knob to the left or right to adjust the focus.



Rotating the Image

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



Reprocessing and Maintenance

These reprocessing instructions are provided in accordance with ISO 17664, AAMI TIR12, AAMI ST79, and AAMI ST81. While they have been validated by Stryker as being capable of preparing the device for re-use, it remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Stryker recommends users observe these standards when reprocessing medical devices.

Warnings

- This device must be cleaned and sterilized prior to the first use and after every subsequent use.
- Use only the sterilization cycles outlined in this document. Using unspecified sterilization cycles may damage the device or result in incomplete sterilization.
- Separate the camera and scope prior to cleaning, disinfection, or sterilization.
- Wear appropriate protective equipment: gloves, eye protection, etc.

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.
- 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 Pendulum Camera 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.
- Prolonged sterilization via Ethylene Oxide or Sterrad® 100NX™ may degrade the product appearance.
- Do not leave the device in solutions longer than necessary. This may accelerate normal product aging.
- Proper processing has a minimal effect on this device. End of life is normally determined by wear and damage due to use.
- Only dry the device with the automated washing system parameters specified below. Additional drying time or other setups can cause product damage.
- Damage caused by improper processing is not covered by the warranty.

Instructions

Point of Use

- Wipe excess soil from the device using disposable paper towels.
- If an automated reprocessing method will be used, rinse any channels 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[1].
- Transport the device in a tray to avoid damage.

[1] A 30 minute wait time was used during cleaning validation.

Preparation for Cleaning

1. Disassemble the scope from the coupler and camera head.
2. Prepare an enzymatic detergent according to the manufacturer's recommendations (one ounce per gallon of tap water at 35–40 °C)[2].
3. Wipe the entire device with the detergent, using a clean cloth.
4. Immerse the device in the detergent. Using a syringe, inject any inside regions of the device with 50 mL of the detergent to ensure all parts of the device are reached.
5. Soak the device in the detergent for a minimum of 15 minutes.

[2] ENZOL® Enzymatic Detergent is validated for cleaning efficacy.

Cleaning: Manual

1. **Brush**
   - Prepare a fresh solution of enzymatic detergent according to the manufacturer's recommendations (one ounce per gallon of tap water at 35–40 °C).
   - Thoroughly brush the exterior of the device with a soft-bristled brush, focusing on any mated or rough surfaces.
   - Using a syringe, inject any lumen or mated surface a minimum of five times with 50 mL of the detergent.
   - Brush any lumens a minimum of five times from each end, using an appropriate bottle brush.
   - Brush any movable parts in all extreme positions.
2. **Rinse**
   - Rinse the device with reverse osmosis/de-ionized (RO/DI) water at ambient temperature until all detergent residue is removed. Flush any lumens or mated surfaces a minimum of five times. Once all detergent residue is removed, continue to rinse for a minimum of 30 seconds.
   - Drain excess water from the device and dry it using a clean cloth or pressurized air.
   - Visually inspect the device for cleanliness, paying close attention to hard-to-reach areas. If visible soil remains, repeat steps 1 and 2.
3. **Soak**
   - Prepare a non-enzymatic detergent according to the manufacturer's recommendations (0.125 ounces per gallon of tap water at 35–40 °C)[3].
   - Fully immerse the device and use a syringe to inject any lumens and mated surfaces with 50 mL of the detergent.
   - Soak the device for a minimum of 15 minutes.
4. **Brush**
   - Thoroughly brush the exterior of the device using a soft-bristled brush.
   - Using a syringe, inject 50 mL of the detergent into any cannulae, lumens, or mated surfaces a minimum of five times.
   - Brush any lumens a minimum of five times from each end, using an appropriate bottle brush.
   - Actuate the device, brushing around any movable parts in all extreme positions.

5. Rinse

- Thoroughly rinse the device with RO/DI water until all detergent residue is removed. Flush any lumens or crevices a minimum of five times. Once all detergent residue is removed, continue to rinse for a minimum of 30 seconds.
- Drain the excess water from the device and dry it using a clean cloth or pressurized air.

[3] Prolystica® 2x Neutral Detergent is validated for cleaning efficacy.

Cleaning: Automated

1. Brush

- Using a syringe, inject 50 mL of the enzymatic detergent (from the "Preparation for Cleaning" section) into any lumen and mated surface a minimum of one time.
- Brush from both ends of any lumens a minimum of five times, using an appropriate bottle brush.

2. Rinse

- Rinse the device with RO/DI water at ambient temperature until there is no visible detergent residue. Continue to rinse for a minimum of 30 seconds after all detergent residue has been removed.
- Place the device in the washer on an incline to facilitate drainage.

3. Automated wash

- Program the washer using the following parameters:

Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration (if applicable)
Pre Wash	2 minutes	Cold tap water	N/A
Enzyme Wash	2 minutes	Hot tap water	Enzymatic Detergent
Wash 1	2 minutes	Set point (66 ˚C)	Non-enzymatic Detergent[4]
Rinse 1	2 minutes	Hot tap water	N/A
Dry Phase	7 minutes	115 ˚C	N/A

- If necessary, use pressurized air to aid in drying. Visually inspect each device for cleanliness.

[4] Prolystica® 2x Neutral Detergent is validated for cleaning efficacy.

Low Level Disinfection (optional)

1. Clean and prepare the camera head and cable as recommended in this user guide. Ensure the soaking cap is installed.
2. Disinfect the device in a disinfecting solution that has one of the following active Ingredients:
   - ≥ 2.4% glutaraldehyde[5] with a minimum soaking time of 45 min at 25°C
   - ≥ 3.4% glutaraldehyde[6] with a minimum soaking time of 20 min at 25°C
   - ≥ 0.55% ortho-phthalaldehyde[7] with a minimum soaking time of 12 min at 25°C.
3. Prepare the disinfecting solution according to the manufacturer's instructions.
4. Per manufacturer's recommendations, immerse the device, filling all lumens, in the disinfecting solution for the required time at the appropriate temperature.
5. Dry all parts with a lint-free towel immediately after rinsing.

[5] CIDEX Activated® is validated for disinfection efficacy.
[6] CIDEX Plus® is validated for disinfection efficacy.
[7] CIDEX® OPA is validated for disinfection efficacy.

Drying

- For automated drying, use the drying cycle provided with the washer/disinfector.
- For manual drying, use a lint-free cloth.
- Dry any lumens with compressed air.

Maintenance, Inspection, and Testing

- Inspect the device on a continual basis. If a problem is observed or suspected, the device should be returned for repair.
- Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and disinfection procedures.
- Inspect the camera cable for cuts and breaks. Return any damaged camera to Stryker for service.

Packaging

N/A

Sterilization

After performing the cleaning instructions specified above, perform one of the following sterilization cycles.

Ethylene Oxide (EO)

1. Clean and prepare the camera head and cable as recommended in this user guide. 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 camera head and cable (or tray) prior to sterilization.
4. Sterilize the camera head and cable using the parameters below.
5. Allow the camera head, cable, coupler, and scope to completely dry before reassembly. Any moisture on the threads will cause the camera and coupler windows to fog during use.

Preconditioning parameters	
Temperature	55 °C (131 °F)
Chamber Humidity	70% RH
Vacuum Set Points	1.3 psia
Time	30 minutes
Exposure	
Concentration (100% EO)	725 mg/L
Temperature	55 ± 2 °C (131 ± 5 °F)
Time	1 hour
Chamber Humidity	70% RH (50–80%) ± 5%
Aeration parameters	
Aeration Time	12 hours
Temperature	35–54 °C (95–129 °F)

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 camera head and cable as recommended in this user guide. Ensure the soaking cap is installed.
2. Following the instructions of the manufacturer, sterilize the camera head and cable using one of the Steris systems below with the appropriate sterilant:
    - System 1 with Steris 20 Sterilant
    - System 1E® with S40™ Steris Sterilant
    - System 1 Plus with S40 Sterilant
    - System 1 Express with S40 Sterilant
3. Remove the camera head and cable from the Steris chamber once sterilization is complete, or moisture may condense inside the camera head and cause display defects.
4. Allow the camera head, cable, coupler, and scope to completely dry before reassembly. Any moisture on the threads will cause the camera and coupler windows to fog during use.

Steris/Amsco V-PRO

1. Clean and prepare the camera head and cable as recommended in this user guide. 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 Steris/Amsco® V-PRO®.
3. Double wrap the camera head and cable (or tray) prior to sterilization.
4. Sterilize the device using the V-PRO maX Sterilizer (Non-Lumen or Standard cycle), the V-PRO 1 Plus Sterilizer (Non-Lumen or Standard cycle), or the V-PRO 1 Sterilizer (Standard cycle).
5. Allow the camera head, cable, coupler, and scope to completely dry before reassembly. Any moisture on the threads will cause the camera and coupler windows to fog during use.

Sterrad

1. Clean and prepare the camera head and cable as recommended in this user guide. 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.

Not all sterilization trays are compatible with Sterrad systems. Using an incompatible tray may result in incomplete device sterilization. Consult the instructions that came with your sterilization tray to determine which sterilization method is compatible with your tray and devices. If a compatible tray is not available, the devices can be double wrapped prior to using the Sterrad system.

3. Double wrap the camera head and cable (or tray) prior to sterilization.
4. Sterilize the camera head and cable following the instructions of the manufacturer, using the Sterrad 100S, NX™, or 100NX Sterilization System. Select the standard cycle.
5. Allow the camera head, cable, coupler, and scope to completely dry before reassembly. Any moisture on the threads will cause the camera and coupler windows to fog during use.

Storage

Never store the device in a non-ventilated, humid environment such as a carrying case. This may present an infection control risk.

Using Sterile Drapes

Using sterile drapes will ensure maximum longevity of your 1488 HD Camera Head. For best results, follow the instructions provided by the drape manufacturer.

Disposal

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.

The 1488 HD must be disposed of according to local laws and hospital practices.

Technical Specifications

Imaging System	1/3″ Progressive Scan CMOS High Definition
Operating Conditions	Temperature: 10–30 °C Relative Humidity: 25–75%
Transport and Storage Conditions	Temperature: -18–60 °C Relative Humidity: 15–90%
Total Shipping Weight	1.5 lb (0.680 kg)
Dimensions	Camera Head Cable: 10.3 ft (3.15 m) sealed cable 20.7 ft (6.30 m) cable extension available
Classification	Type BF Applied Part Ingress Protection, IPX7—Protected against the effects of temporary immersion in water

Please contact your local Stryker Endoscopy sales representative for information on changes and new products.

Symbol Definitions

In addition to the cautionary symbols already listed, other symbols found on the 1488 HD Camera and in this manual have specific meanings that clarify the proper use and storage of the 1488 HD Camera. The following list defines the symbols associated with this product:

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

Caution (consult instructions for use)

Rotate endobody clamp in indicated direction to detach endoscope

Product is manufactured in the USA

Date of manufacture

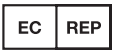
Legal manufacturer

Device is shipped non-sterile and must be sterilized before use

Product catalog number

Serial number

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



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.

Temperature limitation

Relative humidity limitation

stryker®

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U.S. Patents: www.stryker.com/patents

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WCR: None