ArthroFree®

The Surgical Camera for the Wireless Era

Instructions for Use, Cleaning, Assembly, and Sterilization

WARNING: Before installing and using the ArthroFree System, read this manual thoroughly, especially the Warnings, Cautions, and Notes.

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Mar. 2024

Contact Information

For technical assistance or sales support, contact your Lazurite sales representative.
If you cannot reach your sales representative, contact Lazurite at 1.833.214.2324.

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Important Safety Notice

Before operating this device, please read this manual thoroughly. When using this device, the wireless transmission may fail if the instructions in this manual are not followed. Keep additional packaged Batteries charged and subsequently sterilized so a backup Battery is available when needed.

"WARNING" indicates risks to the safety of the patient, clinician, or user. Failure to follow Warnings may result in injury to the patient, clinician, or user.

"CAUTION" indicates risks to the equipment. Failure to follow Cautions may result in product damage.

"NOTE" indicates special information to clarify instructions or present additional information.

Warnings, Cautions, and Notes appear in many of the sections below.

To see the comprehensive list of Warnings, Cautions, and Notes in this manual, see the section Warnings, Cautions, and Notes.

Defined Terms

Capitalized terms in this document are defined either (1) in the text as offset by parentheses and quotation marks, or (2) as labeled items called out in bold text in the figures included herein.

Symbol Definitions

The symbols found on the ArthroFree Wireless Surgical Camera System and in this manual have specific meanings directing proper use and storage of the ArthroFree Wireless Surgical Camera System. Table 1 below defines the symbols associated with this device.

TABLE 1: Symbols Associated with the ArthroFree Wireless Surgical Camera System

Symbol	Meaning	Definition
	Risk of electric shock	Warns of electricity.
	Manufacturer	Indicates the medical device manufacturer.
	Date of manufacture	Symbol for date of manufacture; accompanied by a date.
	Batch code	Indicates the manufacturer's batch code, lot number, or batch number for this device. Synonyms include "lot number" and "batch number."
	Catalog number	Indicates the manufacturer's catalog, reference, or reorder number for this specific device. Synonyms include "reference number" and "reorder number."
	Serial number	Indicates the manufacturer's serial number for this specific device.
	Fragile: Handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	Storage humidity range	Indicates the humidity limits to which the medical device can be safely exposed.
	Atmospheric pressure	Indicates the pressure limits to which the medical device can be safely exposed.
	Type BF symbol	Identifies a type BF applied part complying with IEC 60601-1.
	Do not immerse in any liquid	Indicates that the appliance must not be immersed in liquid.
	Refer to IFU	Indicates that critical information can be found in this manual. Consult electronic instructions for use.
	Rx only	Indicates that the product is a medical device; US federal law restricts this device to sale to—or on the order of—a physician.
	FCC marking	Indicates that an electronic device sold in the United States is certified by, and that electromagnetic interference from the device is under the limits approved by, the US Federal Communications Commission ("FCC").
	Crossed-out trash can	Indicates that a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005.

Product Description and Intended Use

The ArthroFree Wireless Surgical Camera System ("ArthroFree System") is intended for use in endoscopic surgical procedures to transmit live video from a surgical site to a pre-existing patient data console or surgical display. The ArthroFree System also enables the capture of still images and video from the live video stream when connected to a pre-existing patient data console. The ArthroFree System neither stores data nor performs diagnoses. It is not intended to contact a patient or deliver any materials to a patient's body.

The ArthroFree System was designed to eliminate the hassle and risks associated with fiber-optic and power cables found in traditional endoscopic camera systems. It is designed to be drop-in compatible with most currently marketed patient data consoles and surgical displays, and with most endoscopes directly or by use of a pre-existing C-mount coupler.

CAUTION: Federal law in the United States of America ("US federal law") restricts this device to use by, or on the order of, a physician.

Indications

The ArthroFree System is indicated for use in arthroscopy, general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, plastic surgery, or wherever a laparoscope, endoscope, or arthroscope is indicated for use. The users of the camera include general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons, and urologists.

The ArthroFree System is indicated for use in diagnostic and operative endoscopic procedures, supplying illumination and visualization of an interior cavity of the body.

Examples of common general endoscopic surgeries are listed below.

- Laparoscopic cholecystectomy
- Laparoscopic hernia repair
- Laparoscopic appendectomy
- Laparoscopic pelvic lymph node dissection
- Laparoscopically assisted hysterectomy
- Laparoscopic and thoracoscopic 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 the performance of valve replacement

Contraindications

Do not use the ArthroFree System if endoscopic surgery is contraindicated.

Do not use the ArthroFree System if the environmental conditions for use do not meet the standards or regulations defined in this manual.

The ArthroFree Wireless Surgical Camera System

The components of the ArthroFree System ("Components") are listed below.

TABLE 2: ArthroFree Wireless Surgical Camera System Components

Component	Product No.
ArthroFree Wireless Camera Head	AF0001-101
ArthroFree Receiver	AF0002-101
ArthroFree Battery	AF0003-101
ArthroFree Battery Charger	AF0004-101
ArthroFree Sterilization Tray (with lid)	AF0005-101

ArthroFree Wireless Camera Head

The Camera Head wirelessly transmits live video, commands, and the status of the on-screen indicators to the Receiver. The Camera Head includes: control buttons, a light source connected by the light cable to the main body of the Camera Head, C-mount connector, battery bay, and Battery (when in use).

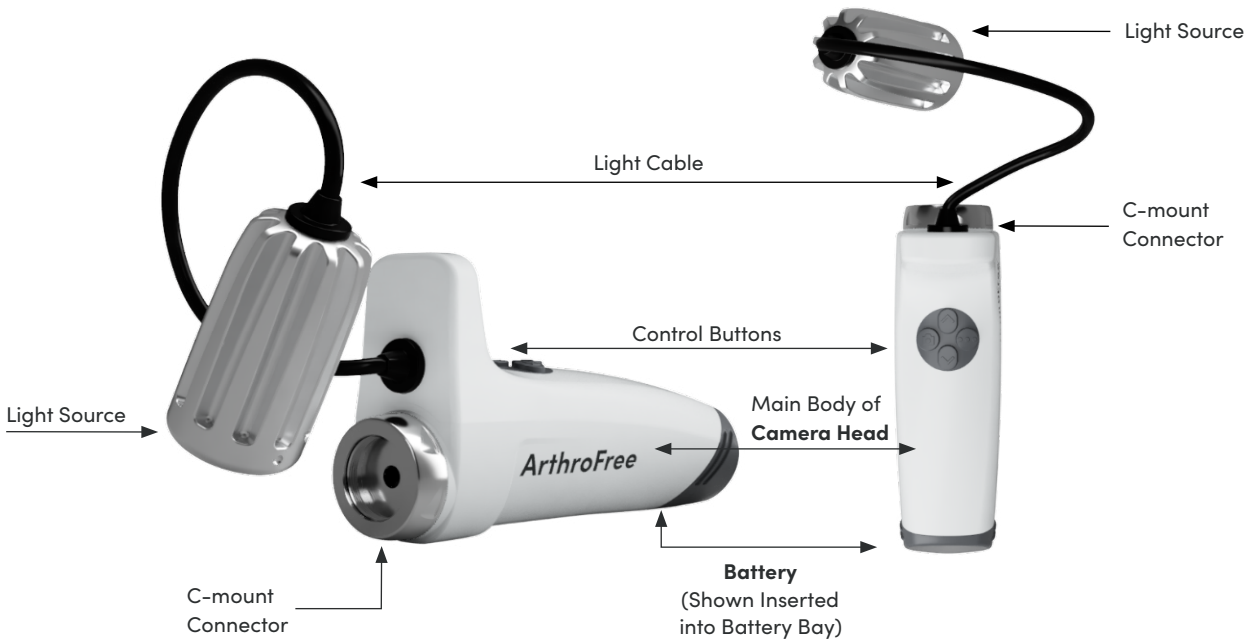


FIGURE 1: Profile View of the ArthroFree Camera Head

1. The light source is powered by Lazurite's Meridiem® light technology and is connected by the light cable to the main body of the Camera Head. The light source connects to the snap-in ACMI groove on the universal light post of an endoscope.

WARNING: The light source contains a Class 1 laser product. The external body of the light source is designed to prevent danger from the laser enclosed within it. Do not disassemble the light source. Use of the enclosed laser without the protective design is potentially hazardous. Do not look directly into the light source while disconnected or through a scope.

2. The C-mount connector allows for the mounting of a pre-existing C-mount endoscope or a pre-existing C-mount coupler and a scope.
3. The control buttons allow a user to control brightness and digital zoom, and to conduct a white balance of the camera image. They also enable still-image and video capture when the Receiver is connected to a compatible, pre-existing patient data console.

Multifunction Button
Short Press: Zoom/Brightness
Long Press: White Balance

Up/Down Arrows

Camera Button
Short Press: Capture Picture
Long Press: Capture Video

FIGURE 2: Control Buttons

ArthroFree Battery

The Battery provides power to the Camera Head. It features a completely sealed case fit for vaporized hydrogen peroxide sterilization, which is not modifiable by the user. The Battery fits into the battery bay of the Camera Head.

WARNING: Do not short-circuit Batteries by bridging terminals with conductive materials, or open, crush, or incinerate Batteries. Doing so may lead to shock, burn, damage to the Battery, or user injury.

FIGURE 3: ArthroFree Battery

ArthroFree Battery Charger

The Battery Charger can simultaneously recharge up to five Batteries. Each of the five charger bays includes an OLED display of battery charge status (see Operating Instructions).

WARNING: Only charge the Battery with the Battery Charger. Failure to follow these instructions may result in damage to the Battery; damage to the Battery Charger; a fire or explosion; and/or injury to the patient, surgeon, or user.

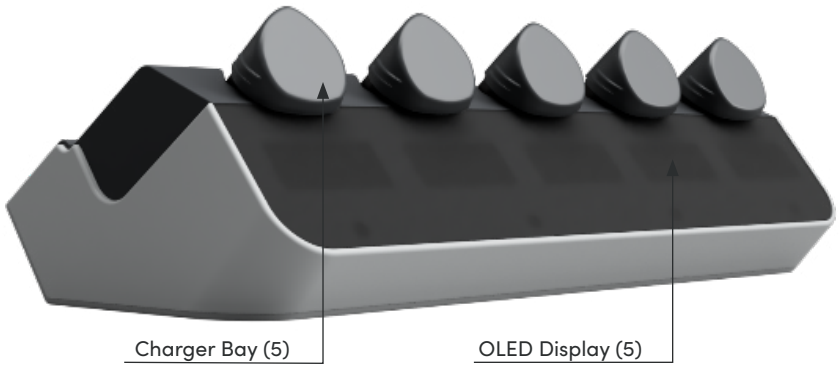


FIGURE 4: ArthroFree Battery Charger

ArthroFree Receiver

The Receiver enables wireless transmission of the video signal from the Camera Head to a pre-existing surgical display and patient data console equipped to display and store images and video. When a Battery is inserted to power on the Camera Head, the Receiver automatically pairs with the Camera Head, initiating wireless video transmission (see Operating Instructions).

The Receiver utilizes two DVI-out ports, an AC power port, and two remote trigger ports.

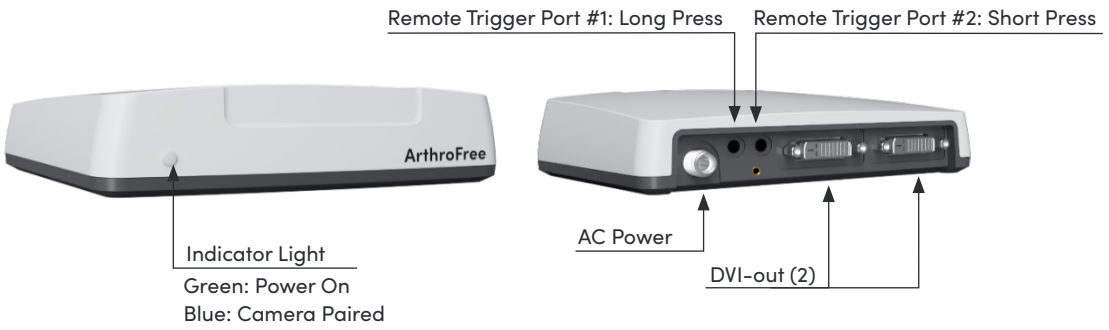


FIGURE 5: ArthroFree Receiver

ArthroFree Sterilization Tray

The ArthroFree Sterilization Tray has guides to snugly hold a Camera Head, three Batteries, and a lid.

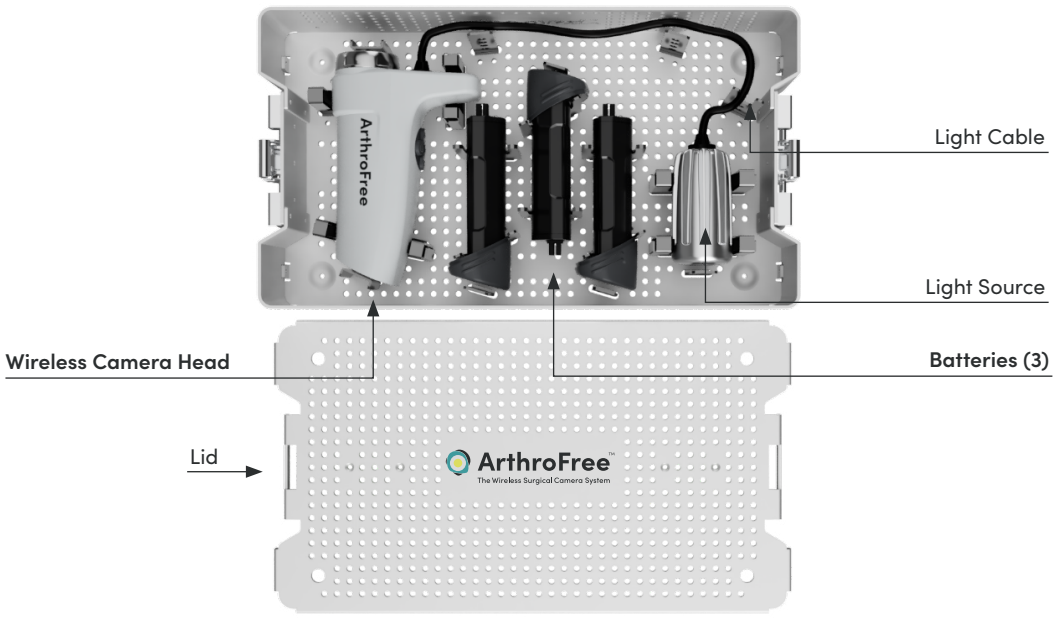


FIGURE 6: ArthroFree Sterilization Tray

System Compatibility

The ArthroFree System is standards compliant.

The compatibility of the ArthroFree System with surgical tower Components must be validated in clinical practice prior to first use. To validate, display a test image on the surgical display (see Operating Instructions).

Should you experience problems, contact your Lazurite sales representative (see Contact Information).

System Setup

Installation and Connection

WARNINGS

- Carefully unpack all ArthroFree Components and verify that no damage occurred during shipment. Verify that all parts are present and match items noted on the packing list.
- If the packaging of the ArthroFree System (1) is damaged in any way prior to receipt by the customer, (2) has been opened prior to receipt by the customer, or (3) has been exposed to environmental conditions outside of those specified in Figure 12, contact your Lazurite sales representative before using.
- The ArthroFree System is not shipped sterile. The Camera Head and Batteries must be properly sterilized prior to use in surgery (see Cleaning, Assembly, and Sterilization).

NOTE: For assistance with the installation and setup of the ArthroFree System, please contact your Lazurite sales representative.

Receiver Installation

Determine the best location in the operating room for the placement of the Receiver. For optimal signal strength and image quality, choose a location that allows for a direct line of sight from Receiver to operating table (e.g., on top of the main surgical display or the surgical tower).

1. **EITHER** place the Receiver on top of the pre-existing surgical display (see Figure 7) by:

    a. First, connect the provided VESA mount bracket to the back of the surgical display using appropriate screws for the pre-existing surgical display. Refer to Figure 7 for adjusting to the size of the VESA mount bracket.

    b. Then, slide the provided receiver mounting bracket flush onto the VESA mounting bracket. Using the provided screws and nuts, set the receiver mounting bracket so that it is flush with the front of the surgical display. Hand tighten to lock into place.

    c. Lastly, slide the Receiver onto the receiver mounting bracket. Use the provided receiver locking screw to secure the Receiver in place.

    OR place the Receiver in a secure and stable location and ensure that the front of the receiver is squarely facing the surgical field and the receiver is angled vertically on its tower or boom arm mount to optimize line-of-sight connectivity to a Camera Head being used in the surgical field. Ensure that there are no obstructions between it and the operating table.

NOTES

- The included receiver mounting bracket is compatible with a 100 mm or 200 mm VESA mounting pattern on a pre-existing surgical display. For technical support, please contact your Lazurite sales representative.
- The Receiver should be placed within 10 feet of the location where the Camera Head will be used.

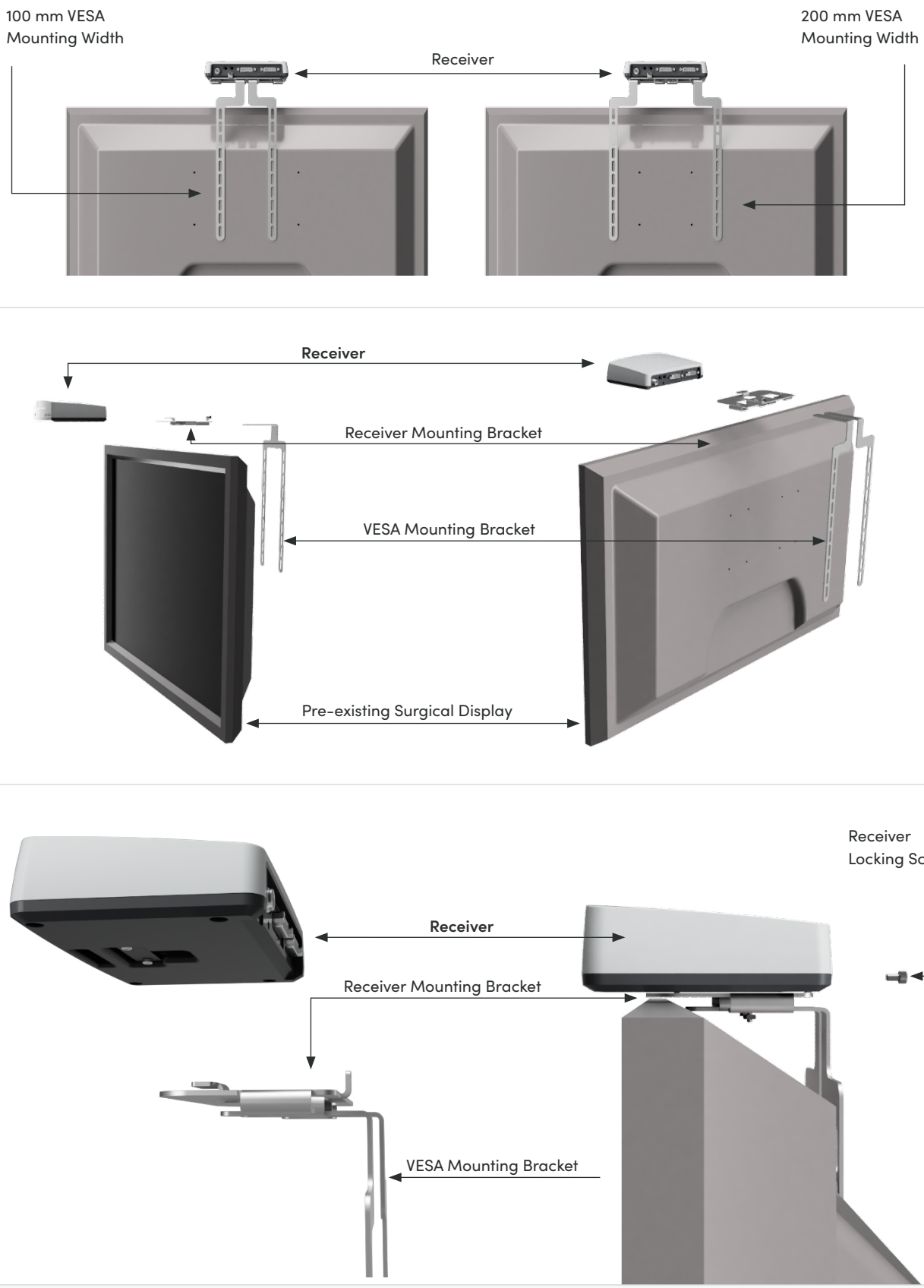


FIGURE 7: Mounting the ArthroFree Receiver on a Surgical Display

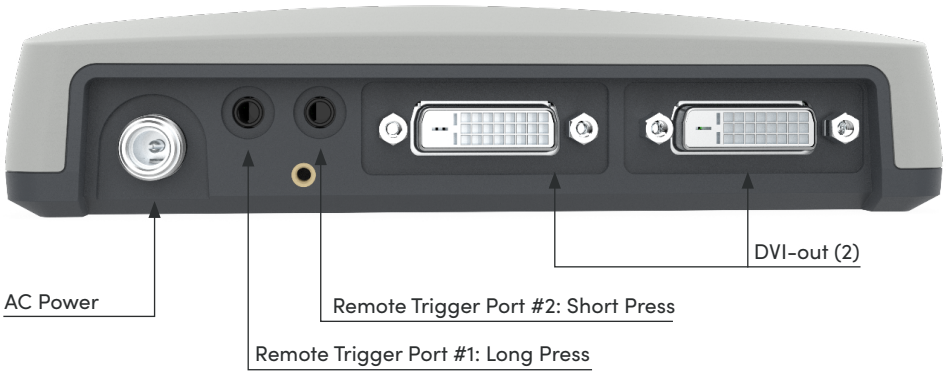


FIGURE 8: ArthroFree Receiver Connections

2. Once the Receiver is in place, connect at least one of the provided DVI cables to one of the DVI-out connections on the back of the Receiver and to a DVI input on a pre-existing patient data console.
3. Connect the video trigger cable to remote trigger port #1 on the back of the Receiver and to the video remote trigger port on a pre-existing patient data console. After installation, test for video triggering and adjust port selection as necessary.
4. Connect the picture trigger cable to remote trigger port #2 on the back of the Receiver and to the picture remote trigger port on a pre-existing patient data console. After installation, test for picture triggering and adjust port selection as necessary.
5. Connect the provided power cable to the AC power port on the back of the Receiver and plug in male end of power cord to a hospital-grade electrical outlet.

WARNING: Do not position the Receiver within the sterile field.

CAUTIONS

- The Receiver requires electricity via a hospital-grade electrical outlet. Position the Receiver so that the outlet is easily accessible.
- When setting up the Receiver, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions (see Technical Specifications: Electromagnetic Compatibility).

Battery Charger Installation

1. Place the Battery Charger on a flat and stable surface in a well-ventilated and secure location.
2. Ensure that there are no foreign substances in the charger bays.
3. Connect the AC power cord to a hospital-grade outlet. Ensure that this outlet is not being used for life-support equipment.
4. Each charger bay should now indicate “NO BATTERY” on its respective OLED display.

CAUTIONS

- The Battery Charger requires electricity via a hospital-grade electrical outlet. Position the Battery Charger so that the outlet is easily accessible.
- When setting up the Battery Charger, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions (see Technical Specifications: Electromagnetic Compatibility).

Operating Instructions

WARNINGS

- Before using the ArthroFree System in a surgical procedure, test all Components to ensure proper function. To test the Camera Head, power it on by inserting a Battery and then point it at an object. Ensure that a live video of that object appears on all connected surgical displays in the proper orientation.
- The ArthroFree user must be a qualified healthcare provider and must be familiar with the Instructions for Use of the equipment.

CAUTIONS

- Do not drop any Component of the ArthroFree System, including the Camera Head and Batteries. The Camera Head contains sensitive Components that are precisely aligned. Damage to the device may impair functionality, prevent proper sterilization, or both. The Battery contains lithium-ion cells that, if damaged, may result in a runaway reaction, causing smoke and fire.
- When removing the Components of the ArthroFree System from the Sterilization Tray, proper removal is critical. First remove the light source, then the main body of the Camera Head. Do not pull on the light cable to remove the Camera Head and light source from the Sterilization Tray.

NOTE: Before each use of the ArthroFree System, ensure that all Components are set up according to instructions in the System Setup section of this manual. Before each use, and after each Battery change, verify that a live video is displayed on the connected surgical monitor.

Charging the Battery

1. To insert a Battery, line up the Battery with an open charger bay and gently insert the Battery until the Battery stops.
2. Once inserted, the Battery will begin charging and its corresponding OLED display will indicate charging progress and the number of charge cycles completed.
3. Once the charging cycle is complete, the status display of the Battery Charger will indicate “DONE CHARGING.”
4. To remove a Battery, pull it straight out of the Battery Charger by applying a small amount of force.
5. Up to five Batteries can be charged at the same time using the provided Battery Charger.

WARNING: Do not position the Battery Charger within the sterile field.

CAUTION: Ensure that the Battery is disinfected, clean, and dry and that the charger bay of the Battery Charger is free of debris prior to inserting a Battery.

NOTES

- The Batteries will not charge if they are too warm: i.e., > 55°C (131°F). If a Battery will not charge and feels warm to the touch, allow the Battery time to cool and try to charge again.
- Lazurite recommends using Batteries that have been charged within the last 30 days and Battery replacement after 300 charge cycles.

Inspection of the Camera Head

Before each use, fully inspect all Components for signs of damage or wear. Any signs of damage—including cracking, hazing, chips, nicks, scratches, and abrasion on the Camera Head or battery housing—should be reported and immediately assessed to determine whether the ArthroFree System is suitable for use. The ArthroFree System is not designed to be field serviceable. If any Component is damaged or does not function properly, stop the use of the device and contact your Lazurite sales representative.

Endoscope Attachment

Attach a pre-existing C-mount endoscope or pre-existing C-mount coupler to the Camera Head.

EITHER

1. Screw a pre-existing C-mount endoscope clockwise onto the Camera Head until it forms a tight seal. Do not over tighten. **OR:**

2. Attach a pre-existing C-mount coupler to the Camera Head and then attach a compatible pre-existing endoscope.
    i. Screw the C-mount coupler clockwise onto the Camera Head until it forms a tight seal. Do not overtighten.
    ii. Open the endoscope clamp and insert the compatible endoscope into the scope end of the coupler.
    iii. Release the endoscope clamp.

NOTE: Always verify proper connection between the Camera Head and any applicable couplers and scopes. Failure to do so may result in loss or misalignment of the surgical image, reduced light or focal length, damage to the Camera Head, or fluid accumulation that may obscure the image transmitted from the Camera Head to the connected surgical display.

Connecting and Disconnecting the Light Source

Gently press the light source onto the ACMI snap-in groove on the light post of the pre-existing endoscope until it clicks in.

To remove the light source, pull on the main body of the light source with a small amount of pressure to disconnect it from the light post of the pre-existing endoscope.

NOTES

- No rotation is necessary when attaching the light source. The light source will rotate freely even after it is secured onto the light post.
- The light source is designed to connect to an ACMI snap-in groove on the light post. Any pre-installed light post adapters corresponding to other attachment standards should be removed prior to connecting the light source to a pre-existing endoscope.

CAUTION: Do not pull on the light cable to disconnect the light source from the light post of a pre-existing endoscope. Only pull from the main body of the light source.

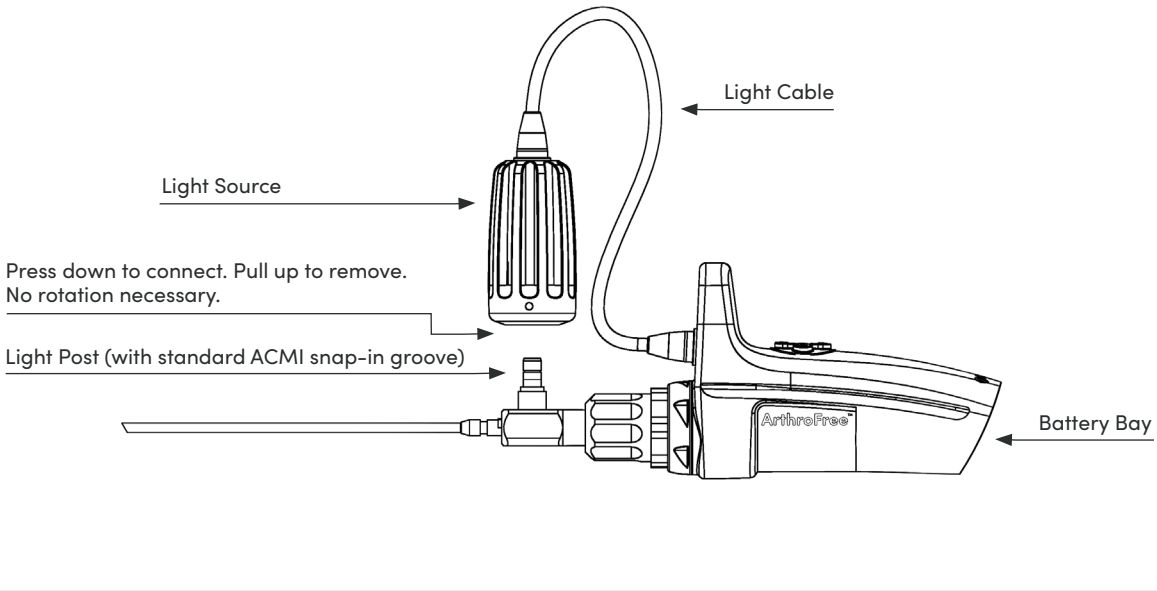


FIGURE 9: ArthroFree Camera Head with Light Source Positioned Above the Light Post of a Pre-existing Endoscope

Powering On and Off the Camera Head and Connecting to the Receiver

1. To power on the Camera Head, gently insert a fully charged Battery into the battery bay of the Camera Head, aligning it as indicated by the shape of the exterior housing of the main body of the Camera Head.
2. Once the Battery is fully inserted, the Camera Head will automatically connect to an unpaired and powered on Receiver located within its wireless signal range. The indicator light on the Receiver will change from green to blue to confirm connection with the Camera Head.
3. With the Battery inserted, visually confirm signal strength on the connected surgical display.
4. To remove the Battery, pull it straight out of the Camera Head, applying a small amount of force to the cosmetic cover of the Battery.

NOTES

- Do not forcibly insert the Battery into the battery bay, including not "smacking or hitting" the end of the Battery to fully seat it in the Camera Head. Doing so may damage the Battery, Camera Head, or both.
- When the Battery charge reaches 1%, the message "BATTERY LOW" and "PLEASE REPLACE BATTERY" will appear on the screen. When fully depleted, the Camera Head automatically turns off and the connected display returns to the startup image. In this event, immediately cease operation of any surgical instruments and remove instruments and scope from the patient. Insert a fully charged Battery and wait for the Camera Head to pair with the Receiver before resuming the procedure.

CAUTION: Ensure that the battery bay of the Camera Head is free of debris prior to inserting a Battery.

WARNING: Do not power on more than one Camera Head within range of a single Receiver. (See System Setup: Receiver Installation.)

Using the Control Buttons

The Camera Head features a keypad to control the functions of the ArthroFree System. The control buttons (see Figure 2) are labeled with a camera icon, three linear dots (the multifunction button), and up and down arrows.

The camera button is labeled with a camera icon and is used to enable a compatible pre-existing patient data console to capture images or record video of the wirelessly transmitted signal.

- A long press and release of the camera button activates remote trigger port #1 on the Receiver—starting a recording of the displayed video. Press, hold, and release the button a second time to end the recording.
- A short press and release of the camera button activates remote trigger port #2 on the Receiver—capturing a still image of the displayed video.

The multifunction button allows the user to switch between the zoom function and the brightness function.

- To switch between white balance, zoom, and brightness functions, quickly press and release the multifunction button.

The up and down buttons are used to increase or decrease the brightness or digital zoom level.

- To increase the zoom or brightness level by one increment, quickly press and release the up button.
- To decrease the zoom or brightness level by one increment, quickly press and release the down button.
- To continuously increase the zoom or brightness level, press and hold the up button.
- To continuously decrease the zoom or brightness level, press and hold the down button.

NOTE: Zoom and brightness levels will wrap around if the user attempts to increase or decrease a level beyond the maximum or minimum level.

White Balancing

NOTE: Perform a white balance check before every surgical procedure and after every Battery change.

Before checking or adjusting white balance, ensure that the Camera Head is attached to an endoscope, the light source is connected to the ACMI snap-in groove on the light post of the pre-existing endoscope, and the Camera Head is powered on and transmitting video to the connected surgical display. (See Figure 2: Control Buttons.)

1. Point the scope at a stack of white gauze pads, a white laparoscopic sponge, or any clean, white surface. Make certain that the white balance target material takes up the entire display.
2. Confirm that the image is clear and the scope is in focus.
3. Look at the monitor and confirm that no glare is visible off the white surface.
4. Press and hold the multifunction button until the white balance icon (see Table 3) appears on the video monitor and an audible beep sound is made.
5. Release the button. A second beep will sound, and the white balance icon will disappear.

Icons

The following icons may be displayed on the connected surgical display when using the ArthroFree System:

TABLE 3: Icons That Appear on the Surgical Display While the ArthroFree System is in Use

Symbol	Meaning	Definition
	White balance	Indicates Camera Head is adjusting the white balance.
	Brightness mode	Indicates Camera Head is in brightness adjust mode.
	Zoom mode	Indicates Camera Head is in zoom adjust mode.
	Battery charge (3 segments)	Indicates the battery is above 75% charge.
	Battery charge (2 segments)	Indicates the Battery charge level is between 51% and 75%.
	Battery charge (1 segment)	Indicates the Battery charge level is between 26% and 50%.
	Battery charge (0 segments)	Solid: Indicates the Battery charge level is between 10% and 25%. Flashing: Indicates the Battery has less than 10% charge remaining. Replace with a fully charged Battery.
	Wireless signal (4 segments)	Indicates high signal strength between the Camera Head and Receiver. This level provides full image quality and device performance.
	Wireless signal (3 segments)	Indicates strong signal strength between the Camera Head and Receiver. This level provides full image quality and device performance.
	Wireless signal (2 segments)	Indicates adequate signal strength between the Camera Head and Receiver. This level provides full image quality and device performance.
	Wireless signal (1 segment)	Indicates low signal strength between the Camera Head and Receiver. This level may impact the image quality or device performance. Reposition the Camera Head and Receiver and/or reduce the distance between the Camera Head and Receiver to improve signal strength.

Wireless Visualization

The ArthroFree System enables surgical visualization without wires or cables. Following all instructions in the System Setup section is critical for successful use of the ArthroFree System.

NOTES

- The ArthroFree System is designed to provide a live video within a range of 10 feet of the Receiver with a clear line of sight between the Receiver and Camera Head.
- Wireless icons are indicators of wireless signal strength only. There is no change in the performance of the ArthroFree System at any of the signal strength levels. While in use, maintain a minimum distance at any of the signal strength levels.

Cleaning, Assembly, and Sterilization

The cleaning, assembly, and sterilization instructions in this manual are made available in accordance with AAMI TIR: 30, AAMI ST: 79, and AAMI TIR: 34. These instructions are validated by the manufacturer and must be followed in their entirety. These instructions include how to clean, assemble, and sterilize the Camera Head, Batteries, and Sterilization Tray. The Battery Charger and Receiver are not to be sterilized. See Battery Charger and Receiver below.

CAUTIONS

- Use universal standard precautions at all times when handling the Camera Head, Batteries, and Sterilization Tray.
- The ArthroFree System may be damaged by the use of harsh oxidizing chemicals, the use of improper cleaning techniques or tools, or improper sterilization. Always follow the guidelines in this manual regarding cleaning, assembly, and sterilization.
- Do not immerse any ArthroFree Component in liquid. Doing so may irreparably damage the Component.

WARNING: Do not place any Component of the ArthroFree System in a moist heat sterilizer (autoclave) or automated washer disinfector. Temperatures in these units may cause damage to sensitive electronics or the lithium-ion battery cell. This could lead to serious injury of the patient, clinician, or end users.

Materials and Equipment

For manual cleaning, assembly, and subsequent sterilization, gather the following materials:

- Decontamination-appropriate PPE
- Wash basin or decontamination sink
- Utility water (as referenced in AAMI TIR-34)
- Various soft-bristle brushes
- Soft non-linting absorbent drying cloths or single-use towelettes
- Critical Water (as defined in AAMI TIR-34)
- An approved enzymatic solution (e.g., Steris® Prolystica 2X Concentrate[1])
- Sterilization wrap: dual layer with minimum dimensions of 30˝ by 30˝
- The Sterilization Tray included with the ArthroFree System
- Vaporized hydrogen peroxide ("VHP") sterilization system: See Table 4

CAUTION: To ensure proper cleaning of the Components of the ArthroFree System, always use a recommended enzymatic cleaning agent.

1. The use of any other detergent must be validated independently by the end user.

Processing: Manual Cleaning

Containment and Transportation

1. Point-of-use cleaning should occur in the operating room and the devices should be pre-cleaned prior to transportation.
    a. Follow these steps to disassemble the endoscope and from the Camera Head
        i. Disconnect the Camera Head light source from the light post on the endoscope.
        ii. Unthread the endoscope or coupler from the C-mount connector on the Camera Head.
    b. Separate the Battery from the Camera Head by pulling it directly out of the battery bay.
2. Clean Components at point-of-use and place them into the Sterilization Tray for storage, transportation, and sterilization of the ArthroFree System.

WARNING: Do not allow soil on devices to dry. Dried soil or tissue on the Camera Head or any of its subcomponents may make it more difficult to clean and/or sterilize the device. Any devices observed to be soiled at any point in their life or use cycle must be considered to be nonsterile and a potential source for disease transmission. Any visibly soiled articles should be re-cleaned and sterilized prior to use with a patient.

3. Process the Camera Head, Batteries, and Sterilization Tray as soon as reasonably practical following use.
4. Always transport the Camera Head and Batteries within the dedicated Sterilization Tray to avoid damage. Follow your facility's internal guidelines for handling and transport of soiled surgical instruments and devices.

Decontamination

1. Disassembly
    a. To clean and decontaminate the Camera Head, Battery (or Batteries), and Sterilization Tray:
        i. Remove all Components from the Sterilization Tray.
    b. Set the Camera Head, Batteries, and Sterilization Tray into an appropriate empty wash bin, sink, or equivalent container. Fill a separate empty wash basin, sink, or equivalent container with an appropriate level of water and enzymatic solution.

NOTE: When necessary, a non-linting cloth saturated with enzymatic cleaner may be wrapped around heavily soiled areas to allow proper contact between the enzymatic cleaner and the Camera Head, Battery, or Sterilization Tray surface. Ensure that no excess solution seeps into the battery bay of the Camera Head.

2. Remove all visible soil (e.g., blood, tissue, or debris) using a non-linting cloth or equivalent prior to decontamination.
3. Enzymatic cleaning
    a. Decontaminate the Camera Head by positioning the device with the battery bay facing down (see Figure 10). Use a soft bristle brush, non-linting cloth, or suitable alternative soaked in an enzymatic cleaner to gently scrub the exterior of the Camera Head. Pay close attention to threaded mating surfaces, the heat dissipation fins on the light source, or any areas where soil may have accumulated. If necessary, gently flush difficult-to-access or heavily soiled areas with additional enzymatic cleaner.
    b. Wipe the interior of the battery bay with a moistened cloth or towelette to remove any debris. Ensure that liquid does not fill or pool in the battery bay.

CAUTION: Do not allow any liquid to enter the battery bay of the Camera Head or come into contact with the electrical connections.

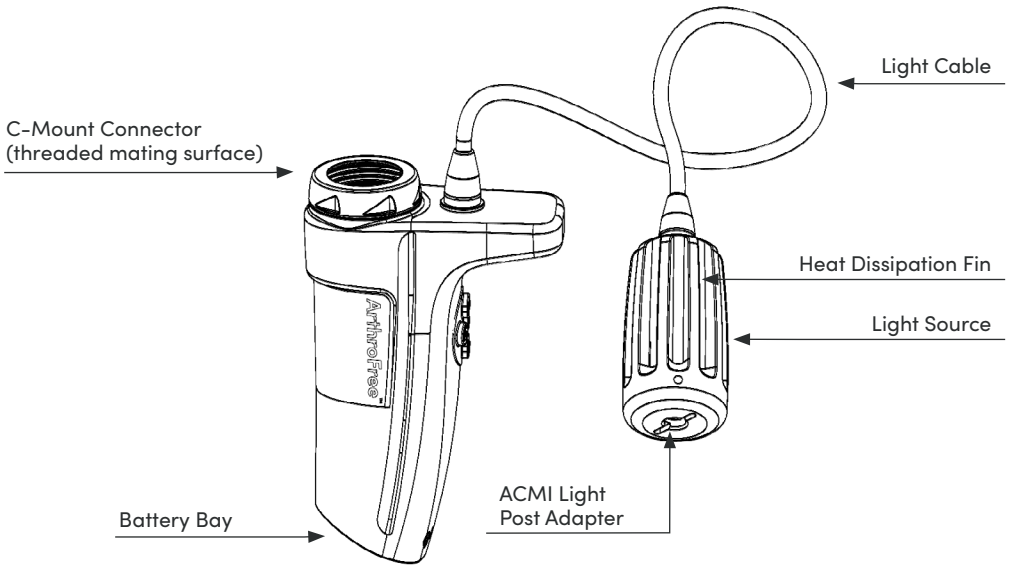


FIGURE 10: Proper Orientation of the Camera Head for Decontamination and Cleaning

c. Decontaminate one Battery at a time with the connectors facing down (see Figure 11). Use a soft bristle brush, non-linting cloth, or suitable alternative soaked in an enzymatic cleaner to gently scrub the exterior of each Battery. Pay close attention to the battery end cap or any areas where soil may have accumulated. If necessary, gently flush difficult-to-access or heavily soiled areas with additional enzymatic cleaner. Repeat until all Batteries have been decontaminated.

d. Decontaminate the Sterilization Tray by soaking it in enzymatic cleaner and use a soft bristle brush, non-linting cloth, or suitable alternative soaked in an enzymatic cleaner to gently scrub all surfaces of the Sterilization Tray.

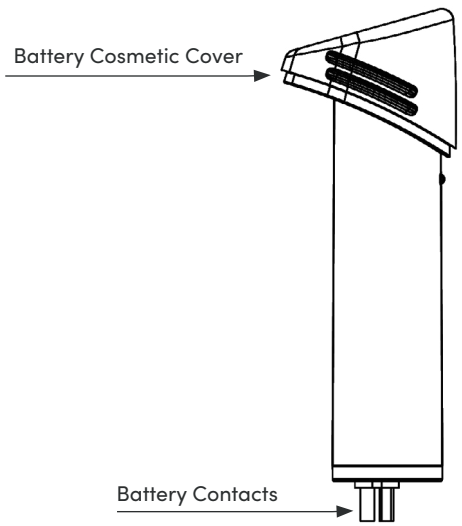


FIGURE 11: Proper Orientation of the Battery for Decontamination and Cleaning

4. Rinsing
    a. Rinse the enzymatic cleaner from the Camera Head with the open ends of the battery bay and light source pointing downward to prevent water entry. Perform a final wipe of the Camera Head using Critical Water and a non-linting cloth to remove any residual cleaner.
    b. Rinse the enzymatic cleaner from one Battery at a time with the connectors facing downward to prevent water entry. Perform a final wipe of each Battery using Critical Water and a non-linting cloth to remove any residual cleaner.
    c. Rinse the Sterilization Tray by soaking it in Critical Water, spraying it with Critical Water, or using Critical Water and a non-linting cloth to remove any residual cleaner.
5. Inspect the Components and repeat any cleaning and rinsing steps as needed.
6. Send the decontaminated Components to inspection and assembly area for next steps.

Battery Charger and Receiver

If the Battery Charger or Receiver needs to be cleaned, wipe clean with standard approved hospital products and allow to air dry. At no point should the Battery Charger or Receiver be subjected to a sterilization process or immersed in liquid. Doing so will irreparably damage such units and their internal components and will void the product warranty.

CAUTION: Disconnect the Battery Charger and Receiver from the AC power source before cleaning.

Inspection and Assembly

1. Fully dry the Components using one or more of the following techniques:
    a. Use non-linting absorbable wipes to dry all Components.
    b. Air dry all Components at ambient temperature.
    c. Use AAMI-standard instrument grade compressed air to remove moisture. Do not exceed 30 psi.
    d. Air dry at elevated temperature in a drying cabinet that does not exceed 60°C (140°F).
2. For use of Steris and Sterrad systems, follow steps 2a through 2f below.
    a. Inspect the Camera Head for signs of trapped water, focusing on any ridges or recesses. Focus attention on the battery bay, including the insides of the female battery connector. Inspect the Batteries for trapped water, focusing on the male battery connector. Inspect the Sterilization Tray for trapped water focusing on guides, device holders, and air-flow perforations. If any water is observed, repeat step 1 above until all visible moisture is removed. Inspect the Camera Head and Batteries for signs of damage or wear that may impair operation.
    b. Inspect the Sterilization Tray to ensure all guides and device holders are present. If any have damage or wear beyond normal usage, discontinue use and contact your Lazurite sales representative.
    c. Obtain three charged Batteries. Remove the used Batteries and charge them per facility guidelines.
    d. Utilize an appropriate chemical indicator for post-sterilization cycle monitoring.
    e. Place the Camera Head and up to three charged Batteries into the Sterilization Tray within the locations visually indicated by the image on the inside bottom of the Sterilization Tray. Secure the Sterilization Tray lid in place using the incorporated latches.
    f. Wrap the Sterilization Tray in a double layer of sterilization wrap with minimal dimensions of 30´´ by 30´´.
3. For use of the STERLINK Plus system, follow steps 3a through 3d below.
    a. Inspect the Camera Head for signs of trapped water, focusing on any ridges or recesses. Focus attention on the battery bay, including the insides of the female battery connector. Inspect the Batteries for trapped water, focusing on the male battery connector. Inspect the Camera Head and Batteries for signs of damage or wear that may impair operation.
    b. Obtain three charged Batteries. Remove the used Batteries and charge them per facility guidelines.
    c. Place the Camera Head in an appropriate Tyvek/plastic pouch and up to three charged Batteries in a second Tyvek/plastic pouch. Fill each pouch to a maximum of 75% of its packing volume, leaving space around the Camera Head or Batteries from all sides of the pouch. Seal each pouch.
    NOTE: Do not use the ArthroFree Sterilization Tray in the STERLINK Plus sterilizer.
    d. Utilize an appropriate chemical indicator for post-sterilization cycle monitoring.

Sterilization

1. Utilize a biological test pack as appropriate for post-sterilization cycle monitoring.
2. Complete one of the sterilization cycles in the chart below.
3. Verify that the sterilization cycle has been successfully completed prior to use.

WARNING: Use only the sterilization cycles outlined in this document. The use of undefined sterilization cycles may damage the device or result in incomplete sterilization.

TABLE 4: Validated Sterilization Equipment and Cycles

Steris	
Sterilization Method	**Cycle Time**
V-PRO® maX 2: Fast non lumen	16.5 minutes
V-PRO maX 2: Non lumen	28 minutes
V-PRO maX: Non lumen	28 minutes
V-PRO 60: Non lumen	28 minutes
V-PRO s2: Non lumen	28 minutes
V-PRO 1: Non lumen	28 minutes
V-PRO maX 2: Flexible	35 minutes
V-PRO maX: Flexible	35 minutes
V-PRO 60: Flexible	38 minutes
V-PRO s2: Flexible	38 minutes
V-PRO maX 2: Lumen	55 minutes
V-PRO maX: Lumen	55 minutes
V-PRO 1: Standard	55 minutes
V-PRO 1: Plus lumen	55 minutes
V-PRO 60: Lumen	60 minutes
V-PRO s2: Lumen	60 minutes

Sterrad	
Sterilization Method	**Cycle Time**
Sterrad NX: Standard	47 minutes
Sterrad 100NX: Standard	28 minutes

STERLINK Plus	
Sterilization Method	**Cycle Time**
Chamber mode	36 minutes

Do not place any Components of the ArthroFree System into a moist heat sterilizer (autoclave) or an ethylene oxide sterilizer. These sterilization methods may cause damage to the Components, which could lead to serious injury of the patient, clinician, or end users.

CAUTION: Treat each of the Components of the ArthroFree System with care. Misuse or incorrect or improper sterilization of this device may damage its sensitive optical, electronic, and battery elements.

Storage

Following cleaning and sterilization, store the sterilized ArthroFree Components in the Sterilization Tray, PET/LLDPE-Tyvek™ pouches, or other sterilization wrap in which they were sterilized.

Except as noted herein, shelf-life for storage of ArthroFree Components shall be defined by facility-specific guidelines.

Batteries that have been sterilized and stored should be recharged and reprocessed if not used within 30 days.

Repeated cleaning and sterilization may impact the expected service life of ArthroFree Components. Inspect all Components prior to each use. (See Service Life below.)

Environmental and In-Use Conditions

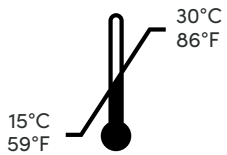
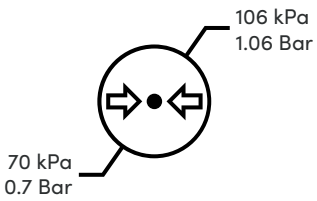
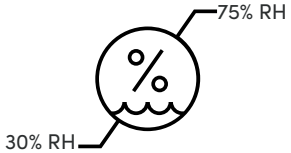
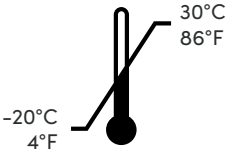
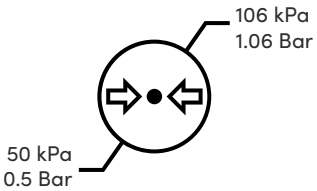
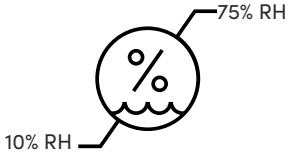
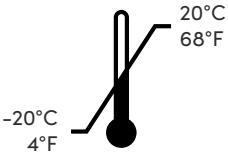
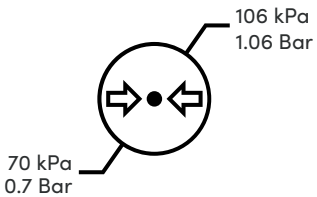
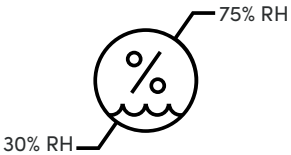
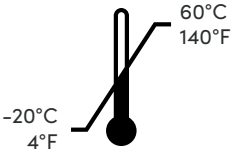
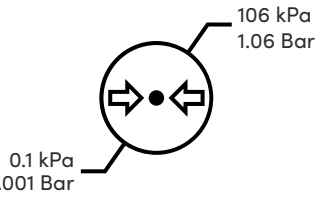
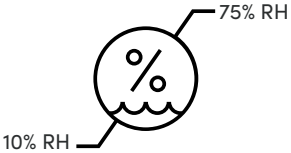
Temperature	Pressure	Humidity
		
In Operation (in use) Min and Max Temperature Range for the ArthroFree System	**In Operation (in use)** Min and Max Pressure Range for the ArthroFree System	**In Operation (in use)** Min and Max Humidity Range for the ArthroFree System
		
Short-term Storage and Transportation Min and Max Temperature Range for the ArthroFree System	**Short-term Storage and Transportation** Min and Max Pressure Range for the ArthroFree System	**Short-term Storage and Transportation** Min and Max Humidity for the ArthroFree System
		
Long-term Storage Min and Max Temperature Range for the ArthroFree System	**Long-term Storage** Min and Max Pressure Limits for the ArthroFree System	**Long-term Storage** Min and Max Humidity for the ArthroFree System
		
Sterilization and Stability Min and Max Temperature Range for the Camera Head and Battery	**Sterilization and Stability** Min and Max Pressure Limits for the Camera Head and Battery	**Sterilization and Stability** Min and Max Humidity for the Camera Head and Battery

Figure 12: Recommended Conditions for Use, Storage, and Transportation

Service Life

Excluding the Batteries, the Components of the ArthroFree System have an expected service life of five years. Each Battery has an expected service life of 300 charge/discharge cycles.

Expected service life is based on our Service Life Assessment Study, which used elevated temperature to simulate advanced aging of the ArthroFree System while assessing functionality at defined intervals.

Always fully inspect all Components of the ArthroFree System prior to use. Assess whether the ArthroFree System is suitable for the anticipated procedure. If there are any concerns about the use of the device, contact your Lazurite sales representative.

Disposal

Return Components of the ArthroFree System to Lazurite for disposal. Contact Lazurite for a shipping label and instructions.

The Components of the ArthroFree System must be disposed of according to local laws and facility practices. If no guidance is provided, please contact Lazurite for more information (see Contact Information).

When disposing of Batteries, please reference local, state, and federal regulations regarding the safe disposal of lithium-ion batteries. Do not disassemble or incinerate Batteries or dispose of them in municipal waste.

CAUTION: Dispose of Batteries in accordance with all applicable state and local regulations.

The Camera Head, Receiver, and Battery Charger contain electronic equipment. Such Components must not be disposed of as unsorted municipal waste. Components should be collected separately for recycling. Ensure infected equipment is decontaminated prior to recycling. Do not dispose of as unsorted municipal waste.

Never dispose of any electronic ArthroFree Component or accessory in an incinerator. The ArthroFree System and its associated Components contain no user-serviceable parts.

WARNING: The Components of the ArthroFree System are not serviceable by the user. Do not open or disassemble any part of the ArthroFree System. Doing so may cause leakage, damage to electronics, sterilization failure, and/or electric shock.

Technical Specifications

TABLE 5: Technical Specifications

	Camera Head	Receiver	Battery	Battery Charger	Sterilization Tray
Product #	AF0001-101	AF0002-101	AF0003-101	AF0004-101	AF0005-101
Imaging system	1/2.7" Progressive Scan CMOS High Definition 2 MP	1080p @ 30 fps HD video	Not applicable	Not applicable	Not applicable
Output electrical ratings	Not applicable	Not applicable	3.6 V 2930 mAh, 10.55 Wh	12 Vdc, 1A	Not applicable
Mounting	C-mount coupler or C-mount endoscope	Top of surgical display*	Not applicable	Outside sterile field tabletop	Not applicable
Auto shutter range	1/60 (1/50)–1/100,000 second	Not applicable	Not applicable	Not applicable	Not applicable
Trigger port(s)	Not applicable	2 x 3.5 mm mono (1/8”) female	Not applicable	Not applicable	Not applicable
Input electrical ratings	3.6 VDC	100–240 VAC, 50–60 Hz, 0.6 A	4.1 V max charging voltage	100–240 VAC, 50–60 Hz, 0.6 A	Not applicable
Device weight	371 g	294 g	83 g	800 g	1400 g
Classification	Class II equipment	Class II equipment	Class II equipment	Unclassed	Class II equipment
Applied part	Type BF	Not applicable	Not applicable	Not applicable	Not applicable

*Or other secure location outside sterile field.

Electromagnetic Compatibility

To ensure electromagnetic compatibility (“EMC”) with local devices, install the ArthroFree System according to instructions in this manual and test prior to use. All medical electrical devices require special precautions to minimize risk to surrounding equipment.

The ArthroFree System has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

Do not use this equipment in the radio frequency shielded room of a medical electrical system for magnetic resonance imaging, where there are intense electromagnetic fields.

The Camera Head and Receiver are unlikely to receive interference from local high-frequency surgical devices. If interference occurs, increase the distance between the high-frequency device and the Camera Head or have the user touch the exterior of C-mount connector on the Camera Head while operating the interfering device.

CAUTION: When setting up the Receiver or Battery Charger, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions.

Warranty

Every Component of the ArthroFree System will materially conform to the specifications set forth in these Instructions for Use during its product warranty period. For specific warranty information, review the Terms of Use or contact Lazurite at 1.833.214.2324. The Warranty shall be void if the ArthroFree System: (1) is not installed, used, or maintained in accordance with these Instructions for Use, (2) is not purchased or procured from Lazurite or an approved distributor of the ArthroFree System, or (3) is repaired by or attempted to be repaired by an unauthorized repair service provider.

CAUTION: Do not attempt any repairs or adjustments not specifically detailed in this manual.

Federal Communications Commission ID

This device contains FCC ID: 2AZYQ-01A
This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warnings, Cautions, and Notes

Please ensure that all staff and medical professionals using this equipment read and understand this manual thoroughly. Failure to do so may result in incorrect operation and lead to patient harm.

Warnings, Cautions, and Notes are listed here in the order they appear above.

Warnings

To avoid potentially serious injury to the patient, clinician, or user and to reduce the risk of damage to the ArthroFree System, please take note of the Warnings identified throughout this document as summarized below. The warranty is void if any Warning is disregarded.

TABLE 6: Warnings

Section	Warning
General Warnings	Before installing and using the ArthroFree System, read this manual thoroughly, especially the Warnings, Cautions, and Notes.
Product Description and Intended Use	The light source contains a Class 1 laser product. The external body of the light source is designed to prevent danger from the laser enclosed within it. Do not disassemble the light source. Use of the enclosed laser without the protective design is potentially hazardous. Do not look directly into the light source while disconnected or through a scope.
	Do not short-circuit Batteries by bridging terminals with conductive materials, or open, crush, or incinerate Batteries. Doing so may lead to shock, burn, damage to the Battery, or user injury.
	Only charge the Battery with the Battery Charger. Failure to follow these instructions may result in damage to the Battery; damage to the Battery Charger; a fire or explosion; and/or injury to the patient, surgeon, or user.
System Setup	Carefully unpack all ArthroFree Components and verify that no damage occurred during shipment. Verify that all parts are present and match items noted on the packing list.
	If the packaging of the ArthroFree System (1) is damaged in any way prior to receipt by the customer, (2) has been opened prior to receipt by the customer, or (3) has been exposed to environmental conditions outside of those specified in Figure 12, contact your Lazurite sales representative before using.
	The ArthroFree System is not shipped sterile. The Camera Head and Batteries must be properly sterilized prior to use in surgery (see Cleaning, Assembly, and Sterilization).
	Do not position the Receiver within the sterile field.
Operating Instructions	Before using the ArthroFree System in a surgical procedure, test all Components to ensure proper function. To test the Camera Head, power it on by inserting a Battery and then point it at an object. Ensure that a live video of that object appears on all connected surgical displays in the proper orientation.
	The ArthroFree user must be a qualified healthcare provider and must be familiar with the Instructions for Use of the equipment.
	Do not position the Battery Charger within the sterile field.

Operating Instructions	Do not power on more than one Camera Head within range of a single Receiver. (See System Setup: Receiver Installation.)
Cleaning, Assembly, and Sterilization	Do not place any Component of the ArthroFree System in a moist heat sterilizer (autoclave) or automated washer disinfector. Temperatures in these units may cause damage to sensitive electronics or the lithium-ion battery cell. This could lead to serious injury of the patient, clinician, or end users.
	Do not allow soil on devices to dry. Dried soil or tissue on the Camera Head or any of its subcomponents may make it more difficult to clean and/or sterilize the device. Any devices observed to be soiled at any point in their life or use cycle must be considered to be nonsterile and a potential source for disease transmission. Any visibly soiled articles should be re-cleaned and sterilized prior to use with a patient.
	Use only the sterilization cycles outlined in this document. The use of undefined sterilization cycles may damage the device or result in incomplete sterilization.
Disposal	The Components of the ArthroFree System are not serviceable by the user. Do not open or disassemble any part of the ArthroFree System. Doing so may cause leakage, damage to electronics, sterilization failure, and/or electric shock.

Cautions

To avoid potential damage and maintain the integrity and functionality of the Components of the ArthroFree System, follow the prescribed Cautions throughout this document and summarized below. The warranty is void if any Caution is disregarded.

TABLE 7: Cautions

Section	Caution
Product Description and Intended Use	Federal law in the United States of America ("US federal law") restricts this device to use by, or on the order of, a physician.
System Setup	The Receiver requires electricity via a hospital-grade electrical outlet. Position the Receiver so that the outlet is easily accessible.
	When setting up the Receiver, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions (See Technical Specifications: Electromagnetic Compatibility).
	The Battery Charger requires electricity via a hospital-grade electrical outlet. Position the Battery Charger so that the outlet is easily accessible.
	When setting up the Battery Charger, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions (See Technical Specifications: Electromagnetic Compatibility).
Operating Instructions	Do not drop any Component of the ArthroFree System, including the Camera Head and Batteries. The Camera Head contains sensitive Components that are precisely aligned. Damage to the device may impair functionality, prevent proper sterilization, or both. The Battery contains lithium-ion cells that, if damaged, may result in a runaway reaction, causing smoke and fire.

Operating Instructions	When removing the Components of the ArthroFree System from the Sterilization Tray, proper removal is critical. First remove the light source, then the main body of the Camera Head. Do not pull on the light cable to remove the Camera Head and light source from the Sterilization Tray.
	Ensure that the Battery is disinfected, clean, and dry and that the charger bay of the Battery Charger is free of debris prior to inserting a Battery.
	Do not pull on the light cable to disconnect the light source from the light post of a pre-existing endoscope. Only pull from the main body of the light source.
	Ensure that the battery bay of the Camera Head is free of debris prior to inserting a Battery.
Cleaning, Assembly, and Sterilization	Use universal standard precautions at all times when handling the Camera Head, Batteries, and Sterilization Tray.
	The ArthroFree System may be damaged by the use of harsh oxidizing chemicals, the use of improper cleaning techniques or tools, or improper sterilization. Always follow the guidelines in this manual regarding cleaning, assembly, and sterilization.
	Do not immerse any ArthroFree Component in liquid. Doing so may irreparably damage the Component.
	To ensure proper cleaning of the Components of the ArthroFree System, always use a recommended enzymatic cleaning agent.
	Do not allow any liquid to enter the battery bay of the Camera Head or come into contact with the electrical connections.
	Disconnect the Battery Charger and Receiver from the AC power source before cleaning.
	Treat each of the Components of the ArthroFree System with care. Misuse or incorrect or improper sterilization of this device may damage its sensitive optical, electronic, and battery elements.
Disposal	Dispose of Batteries in accordance with all applicable state and local regulations.
Technical Specifications	When setting up the Receiver or Battery Charger, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions.
	Do not attempt any repairs or adjustments not specifically detailed in this manual.

Notes

The Notes identified throughout this document and summarized below contain special information intended to clarify the instructions in this manual, present additional information, or both.

TABLE 8: Notes

Section	Note
System Setup	For assistance with the installation and setup of the ArthroFree System, please contact your Lazurite sales representative.
	The included receiver mounting bracket is compatible with a 100 mm or 200 mm VESA mounting pattern on a pre-existing surgical display. For technical support, please contact your Lazurite sales representative.
	The Receiver should be placed within 10 feet of the location where the Camera Head will be used.
Operating Instructions	Before each use of the ArthroFree System, ensure that all Components ore set up according to instructions in the System Setup section of this manual. Before each use, and after each Battery change, verify that a live video is displayed on the connected surgical monitor.
	The Batteries will not charge if they are too warm: i.e., > 55°C (131°F). If a Battery will not charge and feels warm to the touch, allow the Battery time to cool and try to charge again.
	Lazurite recommends using Batteries that hove been charged within the last 30 days and Battery replacement after 300 charge cycles.
	Always verify proper connection between the Camera Head and any applicable couplers and scopes. Failure to do so may result in loss or misalignment of the surgical image, reduced light or focal length, damage to the Camera Head, or fluid accumulation that may obscure the image transmitted from the Camera Head to the connected surgical display.
	No rotation is necessary when attaching the light source. The light source will rotate freely even after it is secured onto the light post.
	The light source is designed to connect to on ACMI snap-in groove on the light post. Any pre-installed light post adapters corresponding to other attachment standards should be removed prior to connecting the light source to a pre-existing endoscope.
	Do not forcibly insert the Battery into the battery bay, including not “smacking or hitting” the end of the Battery to fully seat it in the Camera Head. Doing so may damage the Battery, Camera Head, or both.
	When the Battery charge reaches 1%, the message “BATTERY LOW” and “PLEASE REPLACE BATTERY” will appear on the screen. When fully depleted, the Camera Head automatically turns off and the connected display returns to the startup image. In this event, immediately cease operation of any surgical instruments and remove instruments and scope from the patient. Insert a fully charged Battery and wait for the Camera Head to pair with the Receiver before resuming the procedure.

Operating Instructions	Zoom and brightness levels will wrap around if the user attempts to increase or decrease a level beyond the maximum or minimum level.
	Perform a white balance check before every surgical procedure and after every Battery change.
Wireless Visualization	The ArthroFree System is designed to provide a live video within a range of 10 feet of the Receiver with a clear line of sight between the Receiver and Camera Head.
	Wireless icons are indicators of wireless signal strength only. There is no change in the performance of the ArthroFree System. While in use, maintain a minimum distance at any of the signal strength levels.
Cleaning Assembly and Sterilization	When necessary, a non-linting cloth saturated with enzymatic cleaner may be wrapped around heavily soiled areas to allow proper contact between the enzymatic cleaner and the Camera Head, Battery, or Sterilization Tray surface. Ensure that no excess solution seeps into the battery bay of the Camera Head.
	Do not use the ArthroFree Sterilization Tray in the STERLINK Plus sterilizer.

Troubleshooting

TABLE 9: Troubleshooting

Problem	Possible solution
No video appears on connected surgical display	• Ensure the surgical display power is on. • Ensure the main power on tower or boom is on. • Confirm that the Receiver is powered on and the Camera Head is paired with the Receiver. (A green indicator light confirms the Receiver is powered on. A blue indicator light confirms that the Camera Head is paired with the Receiver.) • Confirm that the Receiver is securely connected to the surgical display. Ensure that the connectors do not have broken pins or obstructions. • Remove and reinsert the Battery. • If the problem persists, contact your Lazurite sales representative.
Incorrect picture color	• Perform the white balance procedure (see White Balancing). • Check color settings on the surgical display. • Set the brightness level at 3 to 4 bars. • Check endoscope and/or coupler for damage. • If the problem persists, contact your Lazurite sales representative.
Picture is too dark	• Increase brightness by quickly pressing and releasing the multifunction button on the Camera Head until the brightness icon is displayed, then quickly press and release the up button until desired brightness is achieved. • If the problem persists, contact your Lazurite sales representative.
Picture is too bright	• Decrease brightness by quickly pressing and releasing the multifunction button on the Camera Head until the brightness icon is displayed, then quickly press and release the down button until desired brightness is achieved. • If the problem persists, contact your Lazurite sales representative.
Poor white balance quality	• See the solution for "Picture is too dark." • See the solution for "Picture is too bright." • Set the brightness level at 3 to 4 bars. • With the light source connected to the scope, perform the white balance procedure (see White Balancing) under metal-halide, xenon, or LED lighting. Avoid fluorescent lighting and reflective white surfaces. • If the problem persists, contact your Lazurite sales representative.
No light is coming out of the endoscope	• Confirm that the Camera Head is turned on (see Powering On and Off the Camera Head). • Make sure the light source is properly connected to the endoscope light post. • Replace the current Battery with one that is confirmed to be fully charged. • Inspect the light source and cable for visible damage. • Check that the illumination path of the scope transmits light. Point the distal tip of the scope at a bright ceiling light and look at the light post port. If the scope is working properly, the light post port of the scope should glow. If the light post port remains dark/black, switch to a new scope. Contact your scope provider for repair/replacement options. • If the problem persists, contact your Lazurite sales representative.

Camera Head takes a video, instead of a picture, when the camera button is quickly pressed and released	• Reverse the trigger cables and try again. • If the problem persists, contact your Lazurite sales representative.
Image is lost during surgery	• Immediately cease operation of all surgical instruments. • Remove instruments and scope from patient. • Make sure that the light engine is fully connected to the scope. • Replace the Battery and wait for the Camera Head to pair with Receiver before restarting surgery. • Ensure an unobstructed line of sight between the Camera Head and Receiver. Reposition the Camera Head, Receiver, or any obstruction, as necessary. • If the problem persists, contact your Lazurite sales representative.
Battery fails to charge or is not detected by Battery Charger	• Place Battery into a different charging bay. • If a Battery will not charge and feels warm to the touch, allow the Battery time to cool and try to charge again. • Replace Battery. • If the problem persists, contact your Lazurite sales representative.
The Receiver indicator light is off	• Check that the receiver power cable is securely plugged into an outlet on one end and securely connected to the Receiver on the other end. • Check that the two parts of the receiver power cable—cable and power adapter—are securely connected. • Check that power is being delivered to the Receiver. (A green indicator light confirms the Receiver is powered on. A blue indicator light confirms that the Camera Head is paired with the Receiver.) • Check for signs of damage to the power adapter or cable. If damaged, contact your Lazurite sales representative for replacement cables.
Image latency, stuttering, freezing, tearing, or decreased clarity	• Ensure an unobstructed line of sight between the Camera Head and Receiver. Reposition the Camera Head, Receiver, or any obstruction, as necessary. • Confirm all installation cable connectors are securely attached. • Check for and replace faulty installation cables. Do not use cables or accessories other than those provided with the ArthroFree System. Use of aftermarket cables or accessories may result in increased electromagnetic emissions or decreased immunity to such emissions. • If electrocautery or radio frequency (RF) devices are in use: ◦ Physically separate the Camera Head and scope from the electrocautery device. ◦ Reposition or re-secure the electrocautery grounding pad on the patient. ◦ Touch and maintain contact with the Camera Head's C-mount connection while using electrocautery or RF devices.

Featuring our patented ArthroFree® and Meridiem® technologies.

See www.lazurite.co/patents for more details.

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