

ArthroFreeTM

The Wireless Surgical Camera System

Instructions for Use, Cleaning, and Sterilization



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



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 the figures included herein.

Symbol Definitions

In addition to the symbols already listed, other 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 product.

TABLE 1: Symbols Associated with the ArthroFree Wireless Surgical Camera System		
Symbol	Meaning	Definition
	Caution	Indicates the need for the user to consult these instructions for important information such as warnings and cautions.
	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. Note: synonyms include "lot number" and "batch number."
	Catalog number	Indicates the manufacturer's catalog, reference, or reorder number for this specific device. Note: 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, the Instructions for Use (IFU).
	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 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	AF0001-101-11
ArthroFree Receiver	AF0002-101-10
ArthroFree Battery	AF0003-101-10
ArthroFree Battery Charger	AF0004-101-10
ArthroFree Sterilization Tray	AF0005-101-10

ArthroFree Wireless Camera Head

The Camera Head wirelessly transmits (1) live video, and (2) 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).

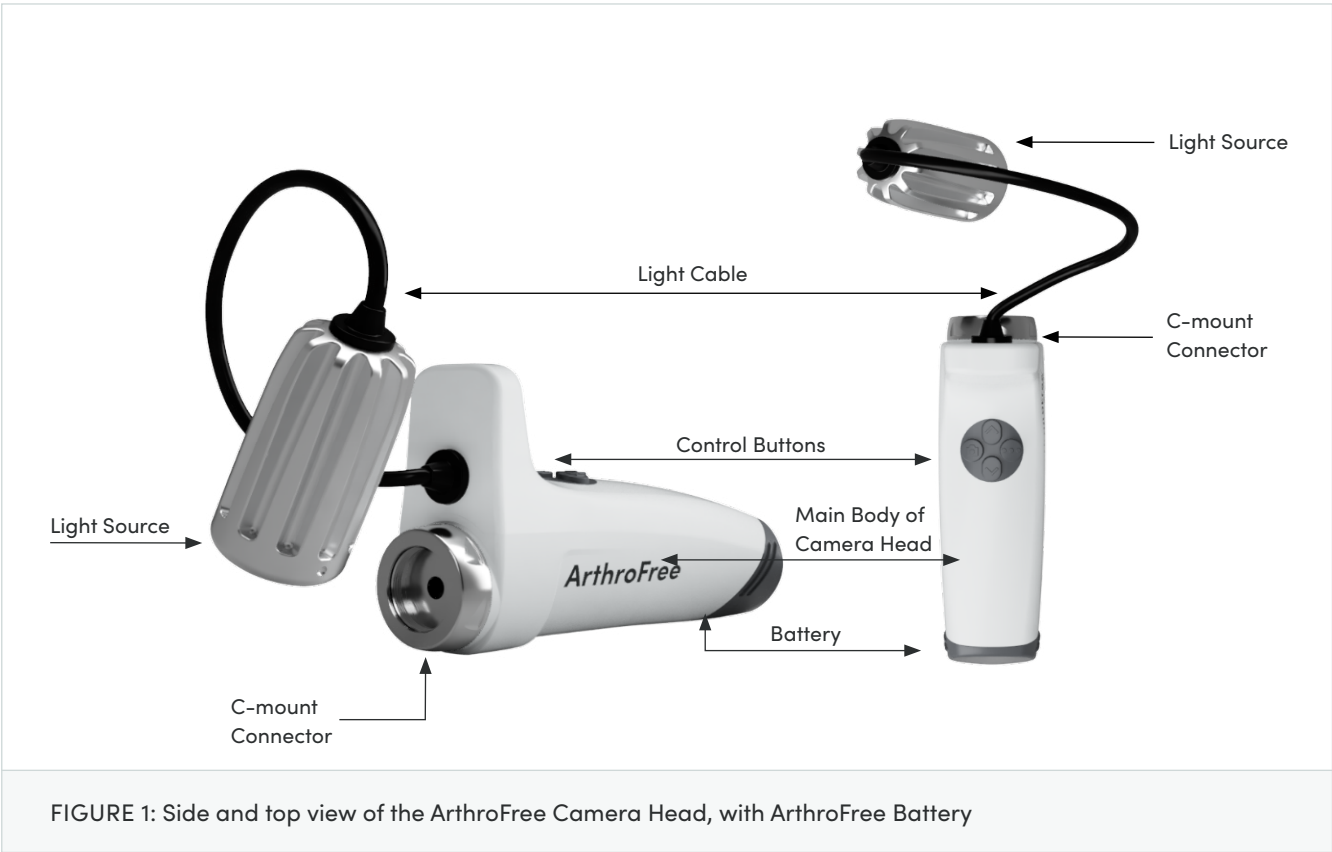


FIGURE 1: Side and top view of the ArthroFree Camera Head, with ArthroFree Battery

- 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 AMCI groove on the universal light post of an endoscope.



WARNING: The light source contains a Class 1 laser product. 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.

- 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.
- The control buttons manage brightness, digital zoom, and white balance. They enable still-image and video capture when connected to a compatible pre-existing capture system.
- The main body of the Camera Head is grasped during use.

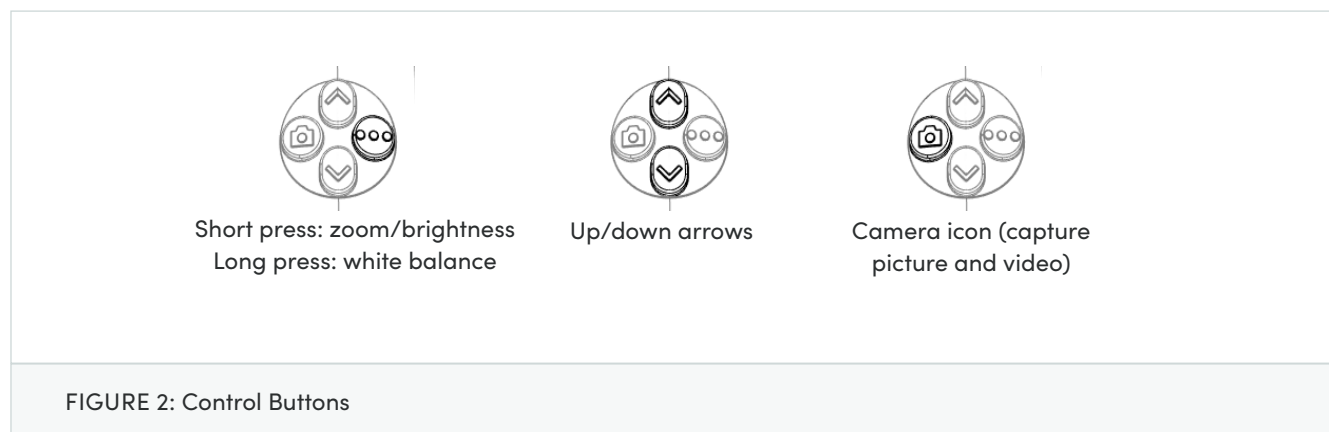


FIGURE 2: Control Buttons

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 on 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 Battery, or user injury. Failure to follow these instructions will void the warranty.



FIGURE 3: ArthroFree Battery

ArthroFree Battery Charger

The Battery Charger can simultaneously recharge up to five Batteries. Each of the five battery bays include a 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. Failure to follow these instructions will void the warranty.

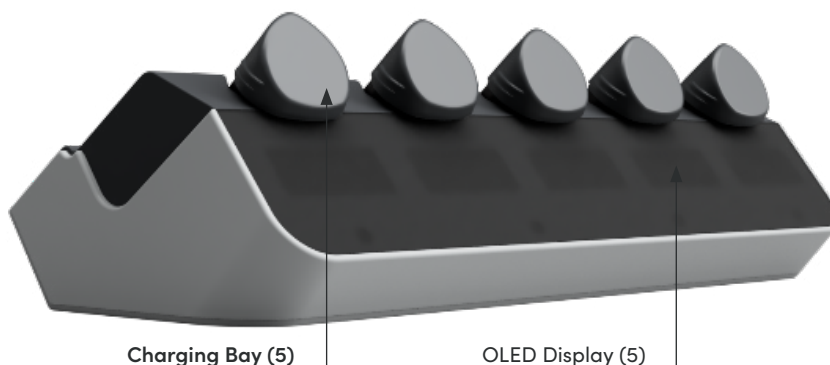


FIGURE 4: ArthroFree Battery Charger

Charge the Battery by inserting it completely into one of the five charging bays on the Battery Charger. While a Battery charges, the corresponding OLED display indicates its charging progress and the number of charging cycles completed. When a Battery is fully charged, the OLED display indicates “DONE CHARGING.” Batteries may be stored in the Charger.

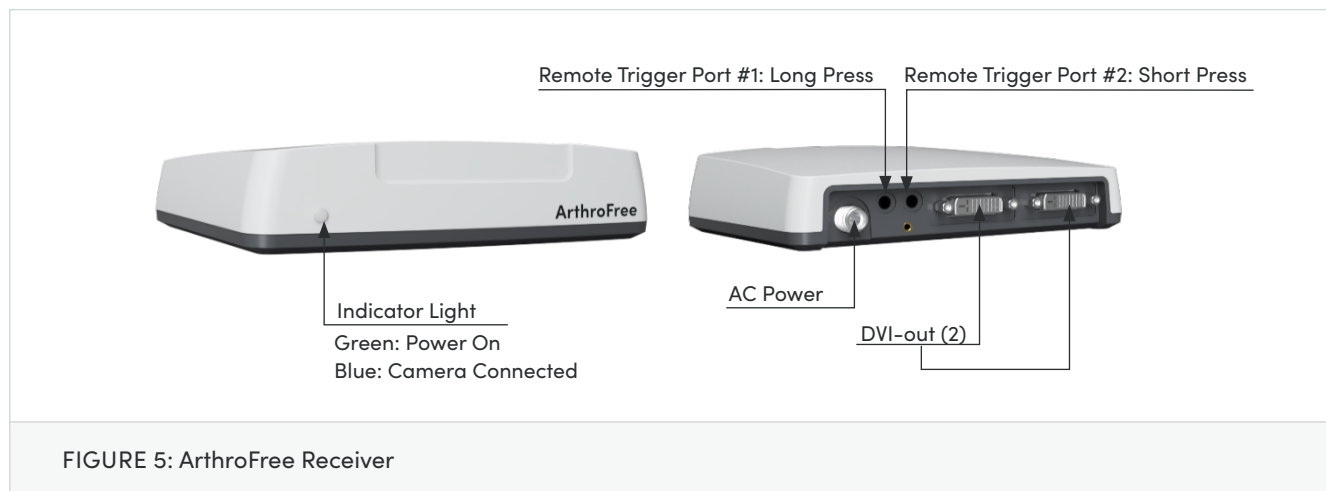
- To remove a Battery, pull it straight out of the charging bay, applying a small amount of force.
- Up to five Batteries can be charged at the same time in the Battery Charger.
- Lazurite (“Lazurite”) recommends Battery replacement after 300 charge cycles.

NOTE: Lazurite recommends using Batteries that have been charged within the last 30 days.

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 for initiation of still photo and video capture on an existing data console.



Sterilization Tray

When shipped as a kit or a set, the Camera Head and three Batteries are packed in the Sterilization Tray. The Components, though, are not shipped sterile. 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.

CAUTION: Do not pull on the light cable to remove the Camera Head and light source from the Sterilization Tray.

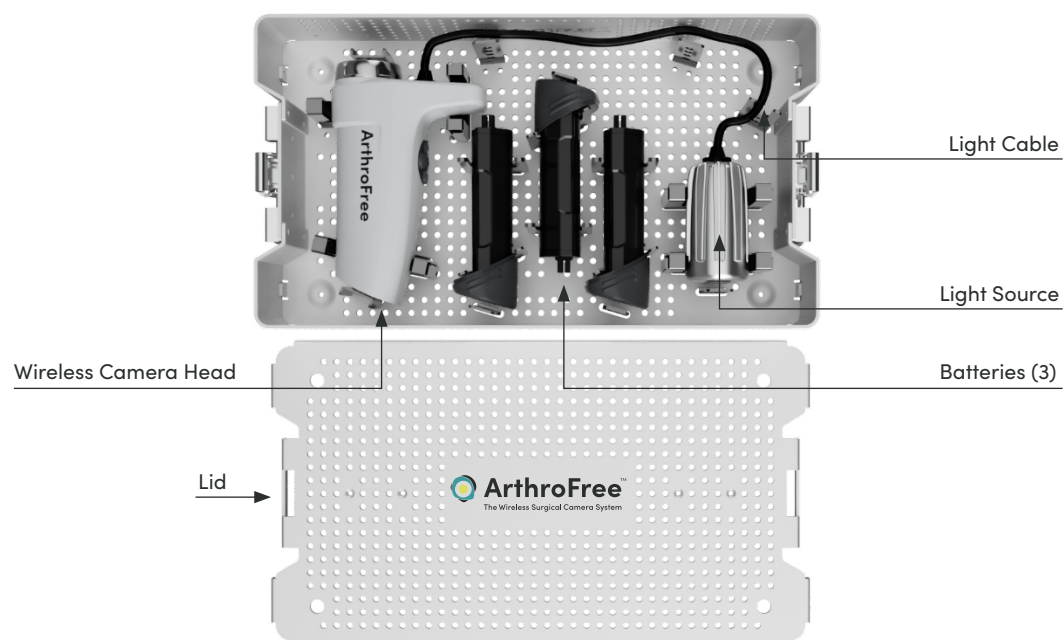


FIGURE 6: ArthroFree Sterilization Tray

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

WARNING: 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.

WARNING: 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 9, contact your Lazurite sales representative.

WARNING: The ArthroFree System is not shipped sterile. The Camera Head and Batteries must be properly sterilized prior to use in surgery (see Cleaning and Sterilization).

NOTE: For assistance with 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 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 (as shown in Figure 7) by:
 - a. First, connecting 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 pre-existing surgical display.
 - 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 and then use a 2.5mm hex key to tighten and lock into place. Do not overtighten.
 - c. Lastly, slide the Receiver onto the receiver mounting bracket and using the provided receiver locking screw and a 2.5mm hex key, secure the receiver in place. Do not overtighten.

OR place the Receiver in a secure and stable location and ensure that there are no obstructions between it and the operating table.

NOTE: The included receiver mounting bracket is compatible with a 100mm or 200mm VESA mounting pattern on a pre-existing surgical display. For technical support, please contact your Lazurite sales representative.

NOTE: The Receiver should be placed within ten feet of the location where the Camera Head will be used.

100mm VESA
Mounting Width

200mm VESA
Mounting Width

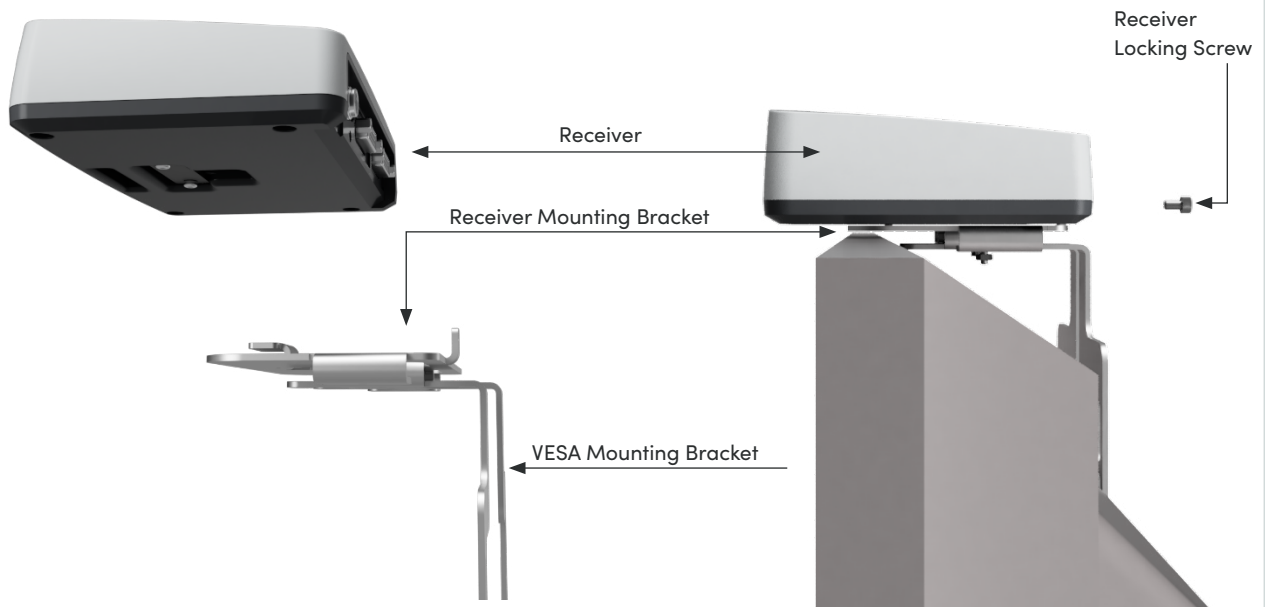
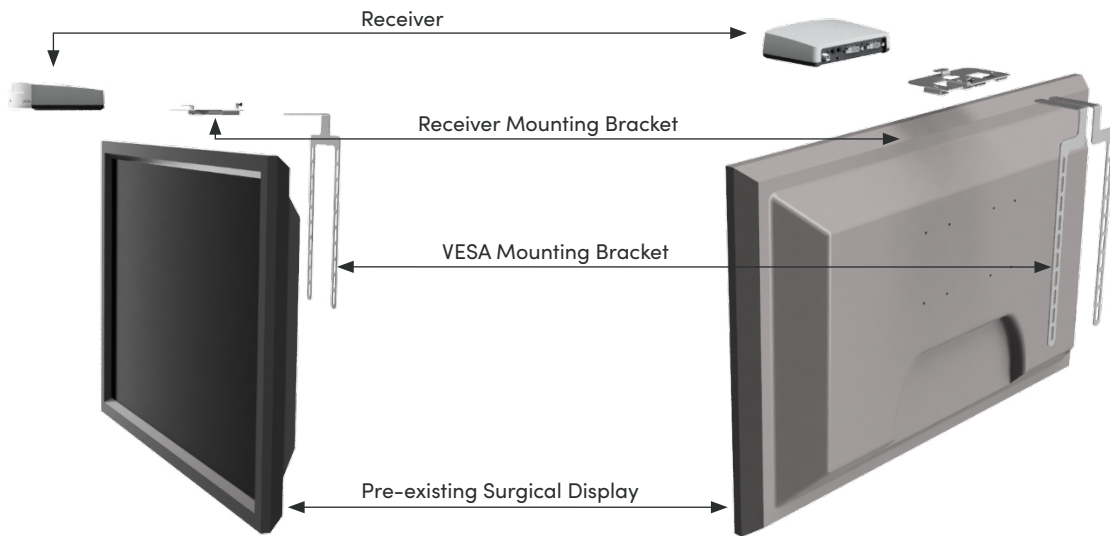
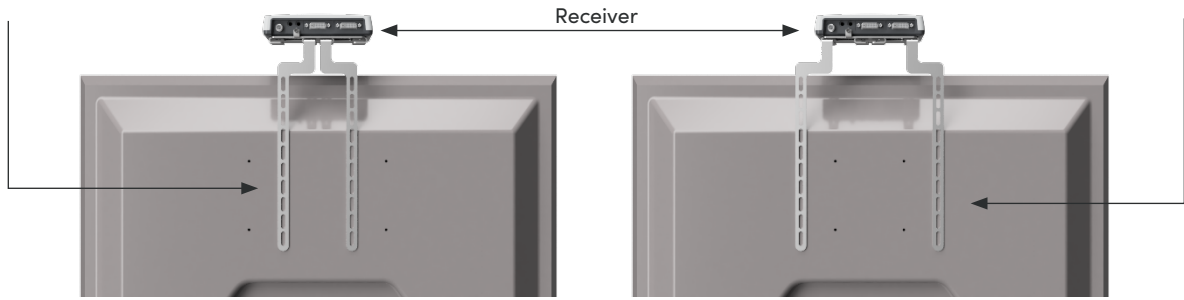


FIGURE 7: Mounting the ArthroFree Receiver

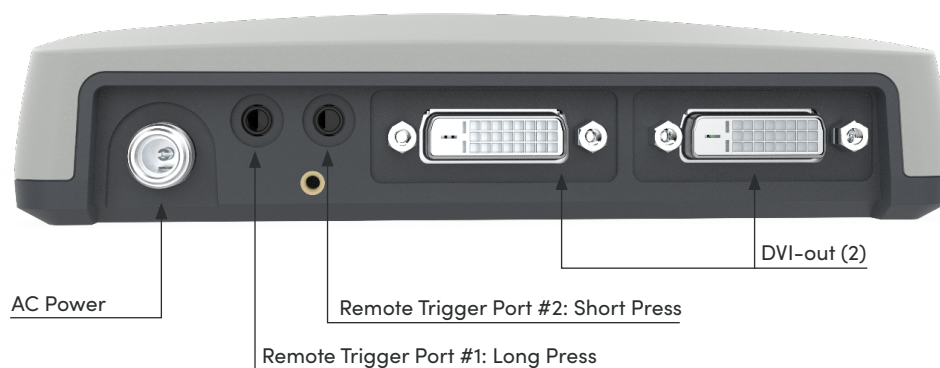


FIGURE 8: ArthroFree Receiver Connections

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 the pre-existing patient data console. If the Receiver is placed further than ten feet away from the pre-existing patient data console, use a longer DVI cable.
3. 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.
4. Connect the video trigger cable to remote trigger port #1 on the back of the Receiver and to the video remote trigger port on the pre-existing patient data console. After installation, test for video triggering and adjust port selection as necessary.
5. Connect the picture trigger cable to remote trigger port #2 on the back of the Receiver and to the picture remote trigger port on the pre-existing patient data console. After installation, test for picture triggering and adjust port selection as necessary.



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

CAUTION: The Receiver requires electricity via a hospital-grade electrical outlet. Position the Receiver so that the plug is easily accessible.

CAUTION: 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, secure, 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.



CAUTION: The Battery Charger requires electricity via a hospital-grade electrical outlet. Position the Battery Charger so that the plug is easily accessible.

CAUTION: 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



WARNING: 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.

WARNING: The ArthroFree user must be a qualified healthcare provider and must be familiar with the instructions for use of the equipment and any applicable surgical techniques.

CAUTION: 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.

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 the surgical display provides a live video with the correct image orientation.

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, 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 overtighten.

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 of the surgical image, damage to the Camera Head, or fluid accumulation that may obscure the image transmitted from the Camera Head to the surgical display. For C-mount scopes (i.e., those requiring no coupler), thread the endoscope directly onto the Camera Head until it forms a tight seal. Do not overtighten.

Connecting and Disconnecting the Light Source

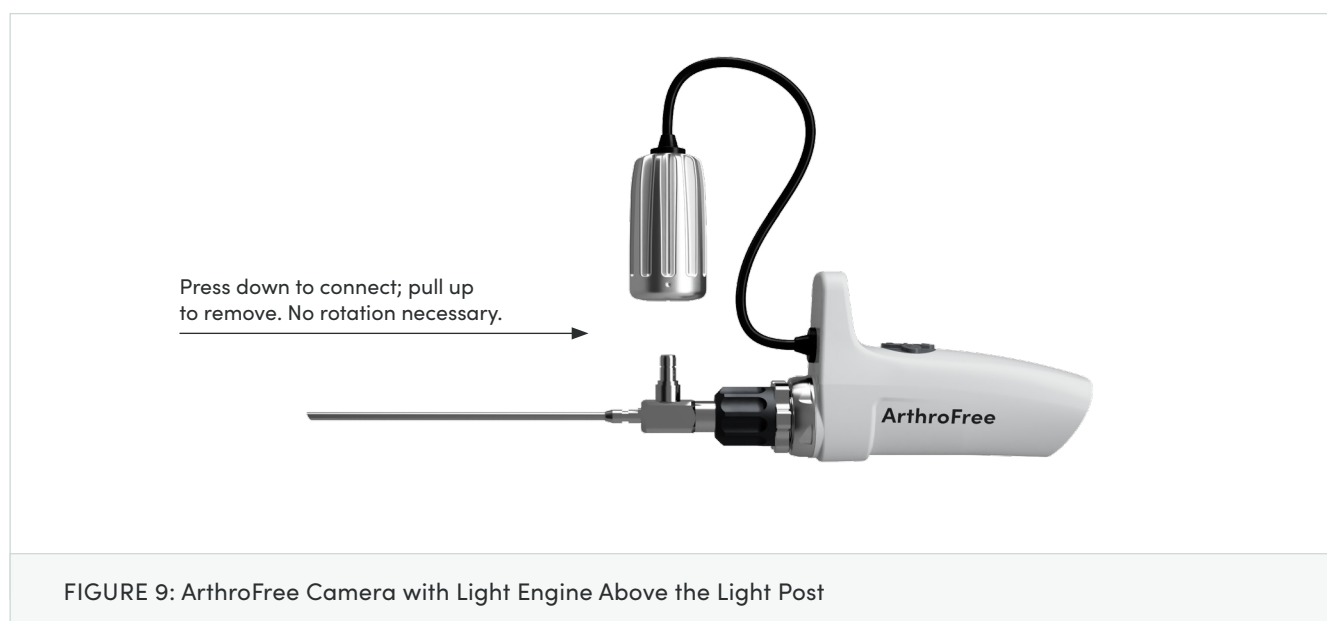
Gently press the light source onto the ACMI snap-in groove on the light post of the pre-existing endoscope until it clicks in.

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.

NOTE: No rotation is necessary when attaching the light source. The light source will rotate freely even after it is secured onto the light post.

NOTE: 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.



Battery Insertion, Removal, and Replacement

1. To insert the Battery, place it completely 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 inserted, the Camera Head will automatically connect to the nearest unpaired and powered on Receiver.
3. With the Battery inserted, visually confirm signal strength on the pre-existing and connected surgical display.
4. To ensure that the pre-existing endoscope is properly attached to the Camera Head, perform a motion image check: move the scope to verify that the video on the surgical display continually corresponds with the object the Camera Head is pointing at.
5. To remove the Battery, pull it straight out of the Camera Head, applying a small amount of force to the battery end cap.

NOTE: If the Battery is removed or becomes depleted during surgery, the Camera Head will turn off and the connected surgical display will appear black and revert to the startup image. In this event, immediately cease operation of any surgical instruments, and remove instruments and scope from the patient. Replace the depleted Battery with a fully charged Battery and wait for the Camera Head to reconnect to the Receiver before resuming the procedure. The Camera Head will automatically reconnect to the Receiver and a video will appear to the connected surgical display when a fully charged Battery is inserted.

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

Charging the Battery

Charge the Battery by inserting it completely into one of the charger bays on the Battery Charger. While a Battery is charging, the corresponding OLED display indicates its charging progress and the number of charging cycles completed. Once the charging cycle is complete, the status display of the Battery Charger will indicate "DONE CHARGING." The Battery can be stored in the Battery Charger for as long as required.

1. To insert a Battery, line up the Battery with an open charging bay and gently insert the Battery fully until the Battery stops.
2. Once inserted, the Battery will automatically begin charging and its corresponding OLED display will indicate charging progress and the number of charge cycles completed.
3. To remove a Battery, pull it straight out of the Battery Charger by applying a small amount of force.
4. 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 bay of the Battery Charger is free of debris prior to inserting a Battery.

Connecting to the Receiver

Ensure that the Receiver has been installed and is powered on. See Receiver Installation for instructions. The powered-on Receiver will automatically and wirelessly connect to the Camera Head when the Camera Head is powered on.

Powering On and Off the Camera Head

1. To power on the Camera Head, insert a fully charged Battery into its battery bay.
2. To power off the Camera Head, remove the Battery by pulling it straight out of the battery bay.

WARNING: Do not power on more than one Camera Head within range of a single Receiver.

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.

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. Look at the monitor and confirm that no glare is visible off the white surface.
3. Press and hold the multifunction button (see Figure 2) until the white balance icon (see Icons) appears on the video monitor and an audible beep sound is made.
4. Release the button. A second beep will sound, and the white balance icon will disappear.

Using the Control Buttons

The Camera Head features a four-control button keypad to control the functions of the ArthroFree System. The control buttons (see Figure 2) are labeled with a camera icon, three linear dots (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 short press of the camera button will activate remote trigger port #1 on the Receiver—typically causing the capture of a still image of the displayed video.
- A long press and release of the camera button will activate remote trigger port #2 on the Receiver—typically causing the start of a recording of the displayed video. Press and hold the button to finish the recording.

The multifunction button is labeled with three linear dots and, depending on the length of depression, activates the white balance function or switches between the digital zoom and brightness functions.

- To initiate the white balance function, press and hold the multifunction button until a beep sounds. The white balance function will then automatically be performed.
- To switch between 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 wraparound if the user attempts to increase or decrease a level beyond the maximum or minimum level.

Icons

The following icons may be displayed on the connected and pre-existing 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 Battery to be at maximum charge level.
	Battery charge (2 segments)	Indicates Battery is about 2/3 of maximum charge level.
	Battery charge (1 segment)	Indicates Battery is about 1/3 of maximum charge level.
	Battery charge (0 segments)	Indicates Battery is below 1/3 of the maximum charge level. Replace with a fully charged Battery. The icon flashes when the Battery reaches a critically low charge level.
	Wireless signal (4 segments)	Indicates maximum wireless signal strength between Camera Head and Receiver (level does not impact image quality or device performance).
	Wireless signal (3 segments)	Indicates strong wireless signal strength between Camera Head and Receiver (level does not impact image quality or device performance).
	Wireless signal (2 segments)	Indicates an adequate wireless signal strength between Camera Head and Receiver (level does not impact image quality or device performance).
	Wireless signal (1 segment)	Indicates wireless signal strength between Camera Head and Receiver is low. Adjust position of Camera Head to improve signal strength (level does not impact image quality or device performance).

Wireless Visualization

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

NOTE: The ArthroFree System is designed to provide a live video within ten feet of the Receiver with a clear line of sight between the Receiver and Camera Head.

NOTE: 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.

Cleaning and Sterilization

The cleaning and sterilization instructions in this manual are made available in accordance with Reference AAMI TIR30. These instructions have been validated and must be followed in their entirety. Routine monitoring of an individual facility's processes and equipment, including validation, remains a requirement. Follow the instructions in this section to clean and sterilize the Camera Head and Batteries. As the Battery Charger and Receiver are maintained outside the sterile field, follow these instructions to clean the Battery Charger and Receiver.

WARNING: Always follow the cleaning instructions in this manual. Any deviation may damage the device and/or create health hazards for the patient, clinician, or user.

To protect common routes of infectious entry, use appropriate personal protective equipment ("PPE") when handling and processing Components of the ArthroFree System. Lazurite does not make recommendations on individual PPE needs. To determine proper PPE, please refer to the rules and regulations of your surgical facility and the Centers for Disease Control and Prevention website at www.cdc.gov/hai.



WARNING: Do not place any Component of the ArthroFree System in a moist heat sterilizer (autoclave) or automated washing device. Temperatures in these units may cause damage to sensitive electronics or the lithium-ion cell and, in turn, put the patient, clinician, or user at risk of serious injury.



CAUTION: 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 recommendations in this manual regarding cleaning and sterilization.

Materials and Equipment

For manual cleaning and subsequent sterilization, assemble the following materials and equipment

- PPE appropriate for universal precautions (bloodborne pathogen program)
- Washbasin
- Tap water
- Various soft bristle brushes
- Soft non-linting drying cloths or single use towelettes
- Distilled or deionized water
- An approved enzymatic solution (e.g., Steris® Prolystica 2X Concentrate¹)
- A sterilization system (e.g., Sterrad® 100NX Standard Cycle²)
- The Sterilization Tray included in the ArthroFree System



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 as appropriate.

² The use of equivalent systems or cycles must be validated independently by the end user as appropriate.

Reprocessing

The ArthroFree System is not intended to come into contact with patients. However, the Camera Head and Batteries should be cleaned and sterilized between each use.

Manual Cleaning

Camera Head and Battery

WARNING: Surgical procedures expose the Camera Head and Battery to patient tissue. Such tissue may contain viral agents (such as hepatitis and HIV), other pathogenic microorganisms, or etiologic agents. To avoid spread of any potential agents, always employ standard universal precautions when handling the Camera Head and Battery.

To clean the Camera Head and Battery manually:

1. Separate the pre-existing endoscope and C-mount coupler, if used, from the Camera Head by:
 - a. Disconnect the Camera Head light source from the endoscope's ACMI snap-in groove on the light post.
 - b. Then, unthread the endoscope or coupler from the C-mount connector on the Camera Head.
3. Separate the Battery from the Camera Head.
4. Remove all visible soil (e.g., blood, tissue, or debris) using a non-linting cloth or equivalent at the point of use or as soon as possible thereafter. Avoid letting soil or fluids dry on the Camera Head or Batteries.

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 recleaned and sterilized prior to use with a patient.

5. Place the Camera Head and one or more Batteries into an appropriate container. Apply an enzymatic cleaning agent as directed in this manual.



CAUTION: Do not immerse any ArthroFree Component in liquid. Doing so may irreparably damage the Component.

NOTE: When necessary, a non-linting cloth soaked in enzymatic cleaner may be wrapped around heavily soiled areas to allow proper contact between the enzymatic cleaner and the Camera Head or Battery surface.

6. Use a soft bristle brush, appropriate cloth, or suitable alternative soaked in an enzymatic cleaner to gently scrub the exterior of the Camera Head and Battery. Pay close attention to threaded mating surfaces or any areas where soil may have accumulated. If necessary, gently flush difficult-to-access or heavily soiled areas with additional enzymatic cleaner. Do not allow detergent to enter the battery bay or come into contact with the electrical connections. Do not immerse any ArthroFree Component in liquid.
7. Perform a final wipe of the Camera Head and Battery, using distilled or deionized water and a non-linting cloth to remove any residual cleaner.
8. Carefully dry the Camera Head and Battery using a non-linting cloth or single-use towelette. The Camera Head may be allowed to air dry.
9. Inspect the Camera Head and Battery for signs of damage or wear that may impair operation. If the

Camera Head or any Battery indicates damage or wear beyond that of normal usage, discontinue use and contact your Lazurite sales representative.

10. Repeat any cleaning and rinsing steps as needed.

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 warranty.



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

CAUTION: Never clean the charging contacts on the Battery Charger with liquid cleaners. Remove any dust with dry compressed air.

CAUTION: Never sterilize the Battery Charger or Receiver or immerse in liquid, as this will damage the units and void the warranty.

Sterilization

To sterilize the Camera Head and Battery:

1. Inspect the Sterilization Tray to ensure all components are present, including all guides and device holders.
2. Place the Camera Head and up to three Batteries into the Sterilization Tray in the locations visually indicated by the image in the base of the Sterilization Tray.
3. Wrap the Sterilization Tray in a double layer of sterilization wrap.³
4. Use a pre-existing, low-temperature hydrogen peroxide plasma sterilization system on its standard cycle setting. Lazurite recommends use of the Sterrad® NX or 100NX standard cycle, or the Steris V-Pro® platform standard cycle. Use of any other cycle, equipment, or parameters must be validated independently by the end user.



CAUTION: Following sterilization, ensure that the Camera Head and any sterilized Batteries are dry and have returned to ambient temperature before use.

Lazurite does not recommend placing any Components of the ArthroFree System into a moist heat (steam) sterilizer or an ethylene oxide sterilizer. These sterilization methods may cause irreparable damage to the ArthroFree System or result in severe bodily injury. Use of a sterilization method other than a low-temperature hydrogen peroxide plasma will void the warranty.



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.

³ Lazurite recommends Halyard Health ONE-STEP H600 double-layer sterilization wrap. The use of any other wrap must be validated independently by the end user as appropriate.

Storage

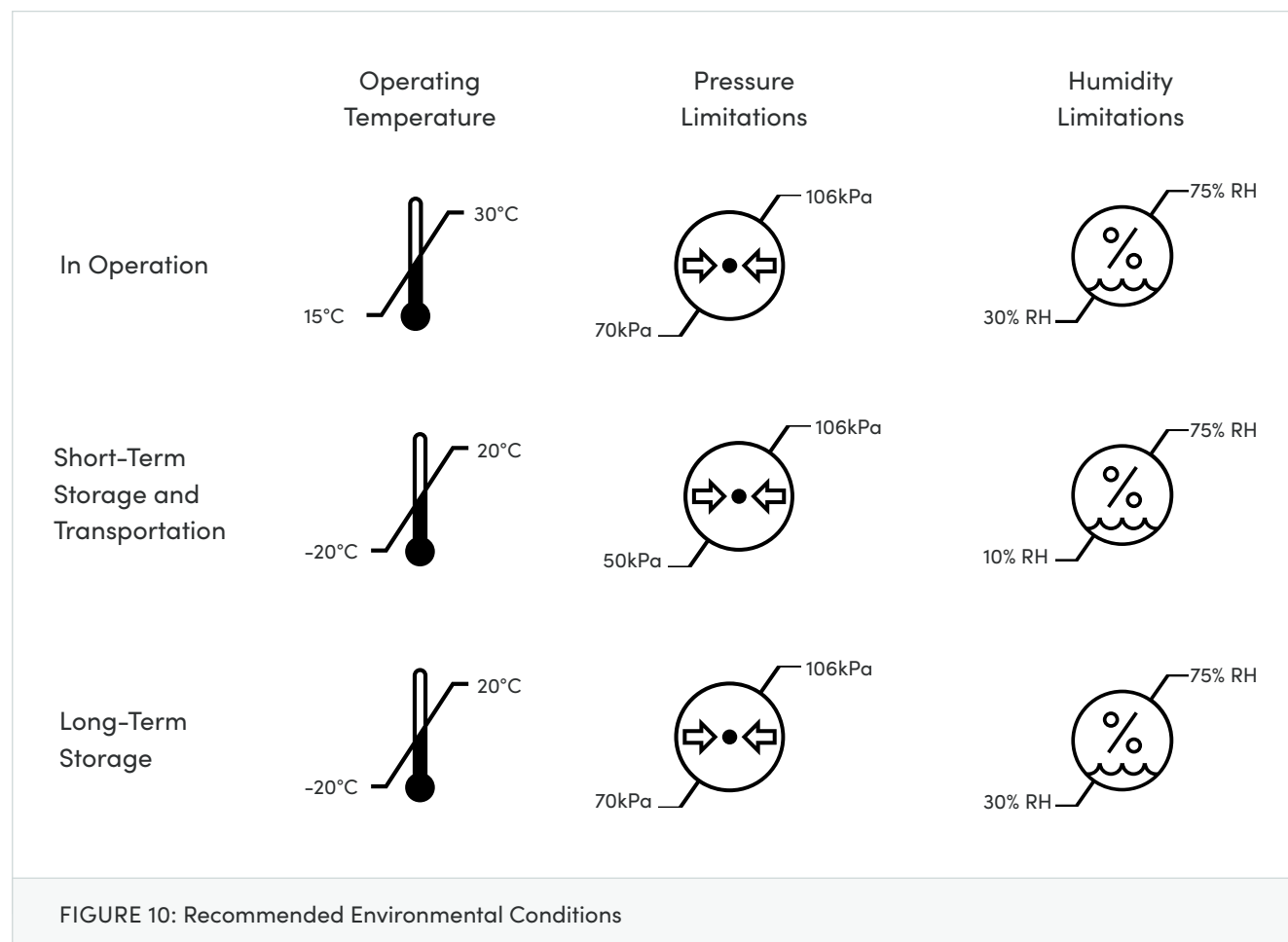
Following cleaning and sterilization, store the sterilized ArthroFree Components in the Sterilization Tray or sterilization wrap in which they were sterilized.

Except as noted herein, the maximum shelf life for storage of ArthroFree Components shall be defined by facility-specific rules and regulations.

Batteries stored longer than 30 days should be recharged and reprocessed prior to use.

Repeated cleaning and sterilization may impact the expected service life of ArthroFree Components. Inspect all Components prior to each use.

Environmental Conditions



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 number of times a Component in the ArthroFree System is used, cleaned, or sterilized. Actual service life is determined by factors such as handling, wear, sterilization methods, chemical exposure, and time between uses.

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

The Components of the ArthroFree System must be disposed of according to local laws and hospital 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. In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment, as amended, 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 4: Technical Specifications

	Camera Head	Receiver	Battery	Battery Charger	Sterilization Tray
Product #	AF0001-101-11	AF0002-101-10	AF0003-101-10	AF0004-101-10	AF0005-101-10
Imaging system	1/2.7" Progressive Scan CMOS High Definition 2MP	1080p @ 60 fps HD video	Not applicable	Not applicable	Not applicable
Output electrical ratings	Not applicable	Not applicable	3.6 V 2930mAh, 10.55Wh	12Vdc, 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	2x 3.5mm 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	4.1V max charging voltage	100–240 VAC, 50–60 Hz, XX A	Not applicable
Device weight	371g	294g	83g	800g	1400g
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

Electromagnetic Compatibility

To ensure electromagnetic compatibility ("EMC") with local devices, install the ArthroFree System according to instructions in this manual. 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.



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 Lazurite product is guaranteed to be free from defects in material and workmanship during its product warranty period. For specific warranty information, contact your Lazurite sales representative.

This limited warranty is restricted to repair or replacement by Lazurite, at its option, of any product found to be defective during the warranty period. Damage inflicted on a product by the user will result in additional charges and may void the warranty. This includes, but is not limited to, damage sustained during normal use, attempted repair by an unauthorized service provider, use of a sterilization method not approved by Lazurite, and use of the product in a way not intended by Lazurite.



CAUTION: Do not attempt any repairs or adjustments not specifically detailed in this manual. Doing so will damage the device and void the warranty.

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 in Table 4 below. The warranty is void if any warning is disregarded.

TABLE 5: 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 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 Battery, or user injury. Failure to follow these instructions will void the warranty.
	Only charge the Battery with the Battery Charger provided in the ArthroFree System. 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, clinician, or user. Failure to follow these instructions will void the warranty.
System Setup	Carefully unpack all ArthroFree Components and verify that no damage occurred during shipment. Verify that all parts are present and match those on the included 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 9, 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 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 and ensure that a video image of that object appears on all connected surgical displays.
	The ArthroFree user must be a qualified healthcare provider and must be familiar with the instructions for use of the equipment and any applicable surgical techniques.
	Do not position the Battery Charger within the sterile field.
	Do not power on more than one ArthroFree Camera Head within range of a single Receiver.

Cleaning and Sterilization	Always follow the care and cleaning instructions in this manual. Any deviation may damage the device and/or create health hazards for the patient, clinician, or user.
	To protect common routes of infectious entry, appropriate PPE should always be worn when handling and processing Components of the ArthroFree System. Lazurite does not make recommendations on individual PPE needs. To determine proper PPE, please refer to the rules and regulations of your surgical facility and the Centers for Disease Control and Prevention website at www.cdc.gov/hai .
	Do not place any Component of the ArthroFree System in a moist heat sterilizer (autoclave) or automated washing device. Temperatures in these units may cause damage to sensitive electronics or the lithium-ion cell and, in turn, put the patient, clinician, or user at risk of serious injury.
	Surgical procedures expose the Camera Head and Battery to patient tissue. Such tissue may contain viral agents (such as hepatitis and HIV), other pathogenic microorganisms, or etiologic agents. To avoid spread of any potential agents, always employ standard universal precautions when handling the Camera Head and Battery.
	Do not allow soil on devices to dry. Dried soil or tissue on the ArthroFree 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 recleaned and sterilized prior to use with a patient.
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 potentially damaging the Components of the ArthroFree System, please take note of the **CAUTIONS** identified throughout this document as summarized below. The warranty is void if any caution is disregarded.

TABLE 6: Cautions	
Section	Caution
	US federal law restricts this device to use by, or on the order of, a physician.
Product Description and Intended Use	Do not pull on the light cable to remove the Camera Head and light source from the Sterilization Tray.
System Setup	The Receiver requires electricity via a hospital-grade electrical outlet. Position the Receiver so that the plug 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 plug 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 and/or prevent proper sterilization. The battery contains lithium-ion cells that, if damaged, may result in a runaway reaction, causing smoke and fire.
	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.
	Ensure that the battery bay of the Battery Charger is free of debris prior to inserting a Battery.
Cleaning and Sterilization	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 recommendations in this manual regarding cleaning and sterilization.
	To ensure proper cleaning of the Components of the ArthroFree System, always use a recommended enzymatic cleaning agent.
	Do not immerse any ArthroFree Component in liquid. Doing so may irreparably damage the Component.
	Disconnect the Battery Charger and Receiver from the AC power source before cleaning.
	Never clean the charging contacts on the Battery Charger with liquid cleaners. Remove any dust with dry compressed air.
	Never sterilize the Battery Charger or Receiver or immerse in liquid, as this will damage the units and void the warranty.
	Following sterilization, ensure that the Camera Head and any sterilized Batteries are dry and have returned to ambient temperature before use.
	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 cabled 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. Doing so will damage the device and void the warranty.

Notes

The **NOTES** identified throughout this document and summarized in Table 6 below contain special information intended to clarify the instructions in this manual and/or present additional information.

TABLE 7: Notes	
Section	Note
Product Description and Intended Use	Lazurite recommends using Batteries that have been charged within the last 30 days.
System Setup	For assistance with installation and setup of the ArthroFree System, please contact your Lazurite sales representative.
	The Receiver should be placed within ten feet of the location where the Camera Head will be used.
	The included mounting equipment is compatible with a 100mm or 200mm VESA mounting pattern on a pre-existing surgical display. Contact your Lazurite sales representative.
Operating Instructions	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 the surgical display provides a live video with the correct image orientation.
	Always verify proper connection between the Camera Head and any applicable couplers and scopes. Failure to do so may result in loss of the surgical image, damage to the Camera Head, or fluid accumulation that may obscure the image transmitted from the Camera Head to the surgical display. For C-mount scopes (i.e., those requiring no coupler), thread the endoscope directly onto the Camera Head until it forms a tight seal. Do not overtighten.
	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.
	If the Battery is removed or becomes depleted during surgery, the Camera Head will turn off and the connected surgical display will appear black and revert to the startup image. In this event, immediately cease operation of any surgical instruments, and remove instruments and scope from patient. Replace the depleted Battery with a fully charged Battery and wait for the Camera Head to reconnect to the Receiver before resuming the procedure. The Camera Head will automatically reconnect to the Receiver and a video will appear to the connected surgical display when a fully charged Battery is inserted.
	Perform a white balance check before every surgical procedure and after every battery change.
	Zoom and brightness levels will wraparound if the user attempts to increase or decrease a level beyond the maximum or minimum level.
Wireless	The ArthroFree System is designed to provide a live video within ten feet of the Receiver with a clear line of sight between the Receiver and Camera Head.
	While wireless icons seen on the pre-existing surgical display are indicators of wireless signal strength, there is no change in the performance of the ArthroFree System at any of the signal strength levels.
Cleaning and Sterilization	When necessary, a non-linting cloth soaked in enzymatic cleaner may be wrapped around heavily soiled areas to allow proper contact between the enzymatic cleaner and the Camera Head or Battery surface.

Troubleshooting

TABLE 8: Troubleshooting

Problem	Possible solution
No video picture when the wireless connection is active	<ul style="list-style-type: none"> • Confirm that the Camera Head is paired with the Receiver. • Confirm that the Receiver is powered on. • Confirm that the Receiver is securely connected to the surgical display. • Confirm that the Receiver cables are securely connected and that 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	<ul style="list-style-type: none"> • Perform the white balance procedure (see White Balance). • Check color settings on the visual display. • Check endoscope and/or coupler for damage. • If the problem persists, contact your Lazurite sales representative.
Poor white balance quality	<ul style="list-style-type: none"> • See the solution for "Picture is too dark." • See the solution for "Picture is too bright." • With the light source connected to the scope, perform the white balance procedure (see White Balance) under metal-halide, xenon, or LED lighting. Avoid fluorescent lighting. • If the problem persists, contact your Lazurite sales representative.
Picture is too dark	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.
No light is coming out of the endoscope head	<ul style="list-style-type: none"> • 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. • 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	<ul style="list-style-type: none"> • Reverse the trigger cables and try again. • If the problem persists, contact your Lazurite sales representative.

Image is lost during surgery	<ul style="list-style-type: none"> • Immediately cease operation of any surgical instruments. • Remove instruments and scope from patient. • Replace the Battery and wait for the Camera Head to reconnect before restarting surgery.
Battery fails to charge or is not detected	<ul style="list-style-type: none"> • Place Battery into different charger bay. • Replace Battery.
The Receiver indicator light is off	<ul style="list-style-type: none"> • Check that power is being delivered to the Receiver. • Check that the power cable is connected to the power adapter. • Check for signs of damage to the power adapter or cable. If damaged, contact your Lazurite sales representative for replacement cables.

Featuring our patented Meridiem™ and ArthroFree™ technologies.

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

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