



## Instructions for Use, Cleaning, Assembly, and Sterilization



AF0001-101-11  
AF0001-101-12

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

Proprietary & Confidential - Page 1 of 40 - Uncontrolled if Printed

R<sub>x</sub>only

## Contact Information

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

Lazurite Inc.  
4760 Richmond Road, Suite 400  
Cleveland, OH 44128  
United States of America

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## Important Safety Notice

This device must be operated only by personnel trained in minimally invasive surgical procedures and wireless medical video systems. Before operating this device, please read this manual thoroughly. When using this device, it may fail to perform as expected if the instructions in this manual are not followed. To prevent the device from powering down during use, keep additional Batteries available.

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

**"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, 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 figures included herein.

## System Compatibility

The ArthroFree System is compliant with recognized standards.

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 pre-existing surgical display (see [Operating Instructions](#)).

Should you experience problems, contact your Lazurite representative for technical assistance (see [Contact Information](#)).

## 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  | Definition  | Symbol  | Definition   |
|---|---|---|--|
|    | Caution (consult Instructions for Use)  |    | Storage humidity limitation  |
|    | Legal manufacturer  |    | Atmospheric pressure limitation  |
|    | Date of manufacture   |    | Type BF applied part   |
|    | Batch code  |   | Do not immerse in any liquid   |
|  | Product catalog number  |  | Temperature limit  |
|  | Serial number   |  | Consult Instructions for Use   |
|  | A Unique Identifier for a product or service that is used globally  |  | Fragile, handle with care  |
|  | Federal law (USA) restricts this device to use by, or on order of, a physician  |  | FCC marking  |
|  | Restriction of Hazardous Substances   |  | The marked item or its material is part of a recovery or recycling process |
|  | This product contains electronic equipment or may produce electrical waste. It must be collected separately and not be disposed of as unsorted municipal waste. |   |  |

## 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 in [TABLE 2](#) below.

**TABLE 2. ArthroFree Wireless Surgical Camera System Components**

| Component                                | Part No.             |
|--|----------------------|
| ArthroFree Wireless Camera Head          | AF0001-101-11 or -12 |
| ArthroFree Receiver                      | AF0002-101-11 or -12 |
| ArthroFree Battery                       | AF0003-101-10        |
| ArthroFree Battery Charger               | AF0004-101-10        |
| ArthroFree Sterilization Tray (with lid) | AF0005-101-10        |

AF0001-101-11 and AF0001-101-12 Camera Heads are only compatible with Receiver firmware versions as shown in [TABLE 3](#) below. Attempting to use these camera heads with incompatible Receiver firmware will result in failure to produce a video output on a connected Surgical Display.



**TABLE 3. ArthroFree Wireless Camera and Receiver Compatibility**

| Wireless Camera Head | Compatible Receiver | Firmware Version |
|----------------------|---------------------|------------------|
| AF0001-101-12        | AF0002-101-12       | 1.1.4+           |
| AF0001-101-11        | AF0002-101-11       | 1.1.3            |

## Determining the Version of the ArthroFree System

AF0001-101-11 and AF0001-101-12 Camera Heads and Receivers are visually distinguishable from each other by reference to the ArthroFree logos etched on each as shown in [TABLE 4](#) below.

**TABLE 4. ArthroFree Wireless Camera and Receiver Visually Distinguishing Markings**

|                 | Wireless Camera Head Visual Marking   | Compatible Receiver Visual Marking                              |   |
|-----------------|---|---|---|
| Icon & location |  <b>ArthroFree</b> <sup>®</sup><br>Both sides of Camera Head under control buttons | <b>ArthroFree</b> <sup>®</sup><br>Front panel, bottom left side |  <sup>®</sup><br>Front panel, right side |
| Color           | Light source and c-mount connector are anodized dark grey   |   |   |
| Icon & location | <b>ArthroFree</b> <sup>™</sup><br>Both sides of Camera Head under control buttons   | <b>ArthroFree</b> <sup>™</sup><br>Front panel, bottom left side |   |
| Color           | Light source and c-mount connector are bright silver  |   |   |

AF0001-11-12 Camera Heads and AF0002-11-12 Receivers may have updated Firmware versions, which can be verified upon Wireless Camera Head and Receiver pairing. The firmware version is displayed momentarily in the upper left-hand corner of the Surgical Display during initial system boot-up.

## 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 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).



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 of Wireless Camera Head AF0001-101-11 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.

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.

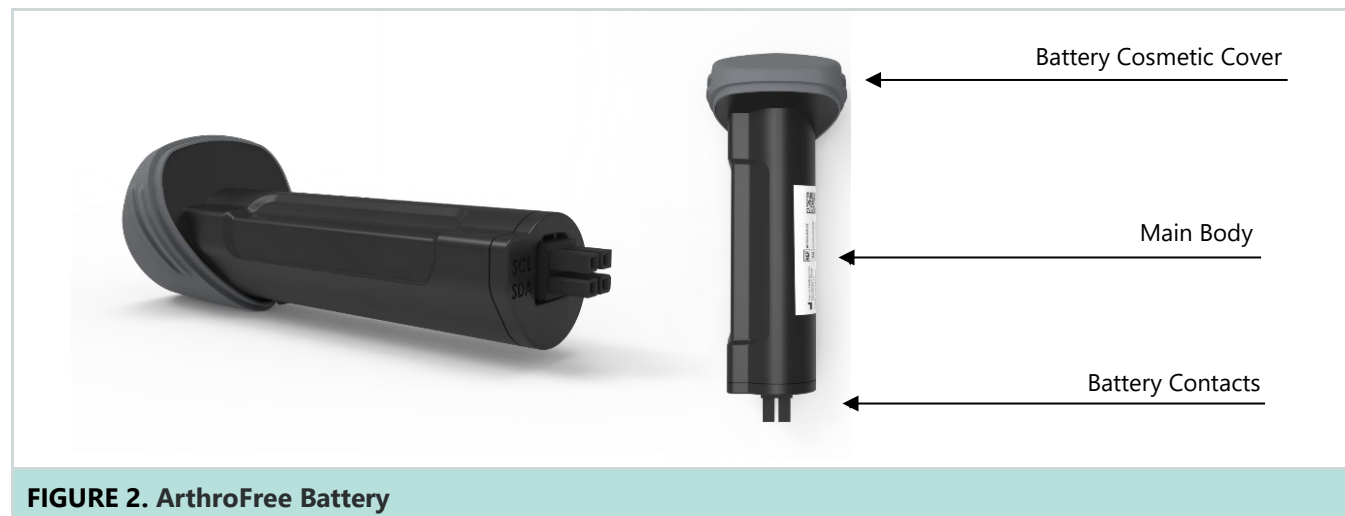


The control buttons allow a user to control brightness and digital zoom, and to conduct a white balance of the camera image. They also enable still-image and video capture when the Receiver is connected to a compatible, pre-existing patient data console.

## 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 2. 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.

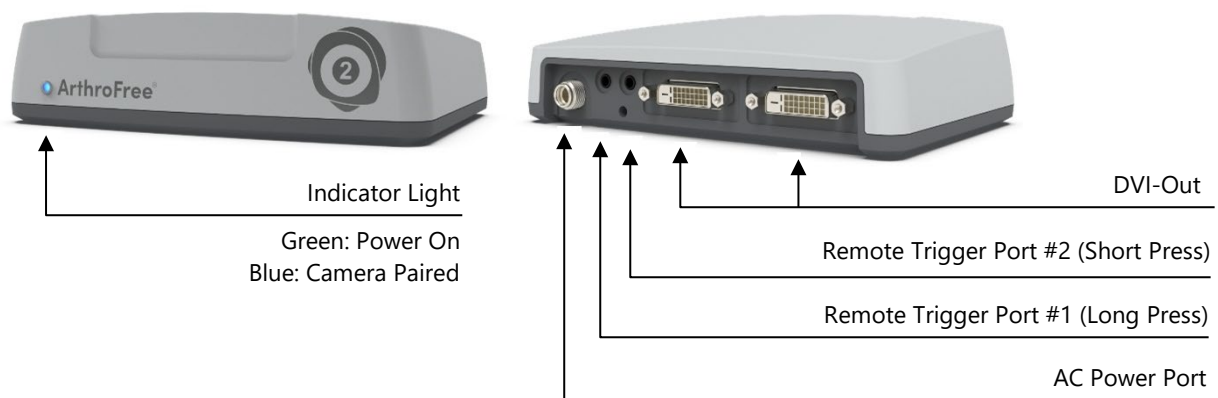


**FIGURE 3. ArthroFree Battery Charger**

## ArthroFree Receiver

The Receiver enables wireless transmission of the video signal from the Camera Head to a facility-installed 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](#)).

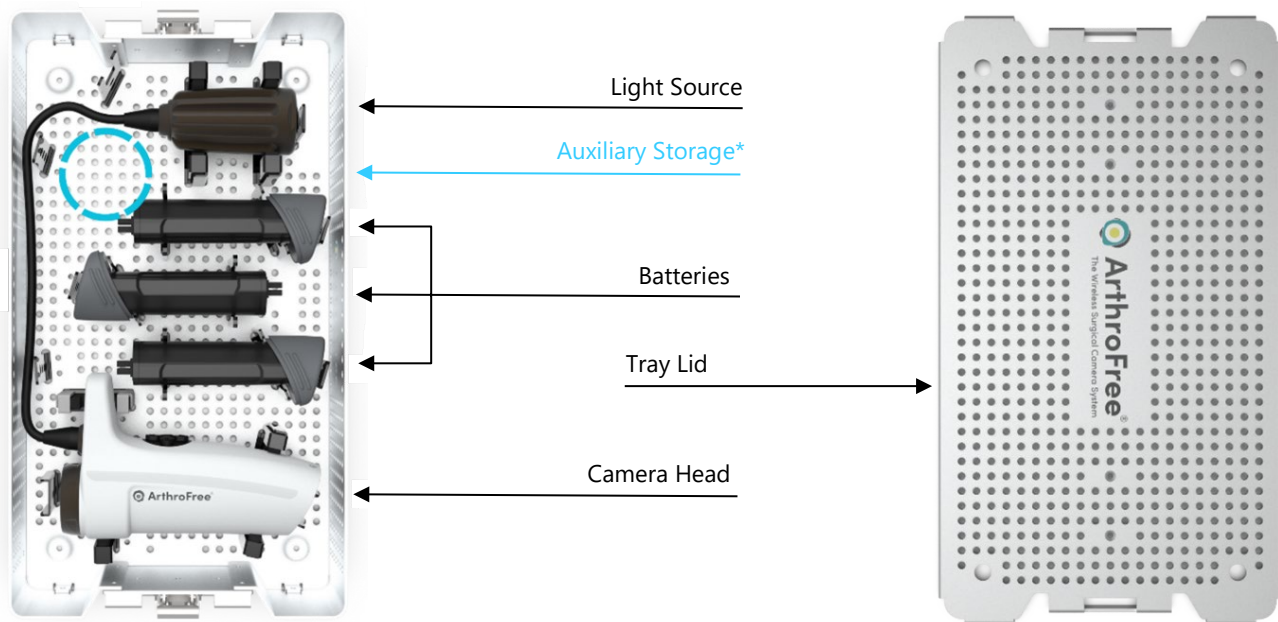
The Receiver utilizes two DVI-out ports, an AC power port, and two remote trigger ports.



**FIGURE 4. ArthroFree Receiver**

## ArthroFree Sterilization Tray

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



**FIGURE 5. ArthroFree Sterilization Tray**

*\*Lazurite has validated the use of this space to store and sterilize a c-mount endoscope coupler for use with the Camera Head. Storage and sterilization of other non-ArthroFree components in the auxiliary storage space may be possible and should be validated by the end-user.*

# 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 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 representative.

## Receiver Installation

Determine the best location in the installation location 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 the Receiver to the procedure location (e.g., on top of the connected surgical display or a nearby stable surface).

### Option A: Mounting the Receiver on the surgical display

1. Connect the provided VESA mounting bracket to the back of the surgical display using the provided screws. Refer to [FIGURE 6](#) for adjusting the bracket to match the VESA mounting pattern (100 mm or 200 mm).
2. Slide the Receiver mounting bracket onto the VESA bracket so it is flush with the front of the surgical display. Use the provided screws and nuts to secure it, and hand tighten to lock in place.
3. Slide the Receiver onto the Receiver mounting bracket. Secure it using the provided locking screw.

### Option B: Placing the Receiver on a Stable Surface

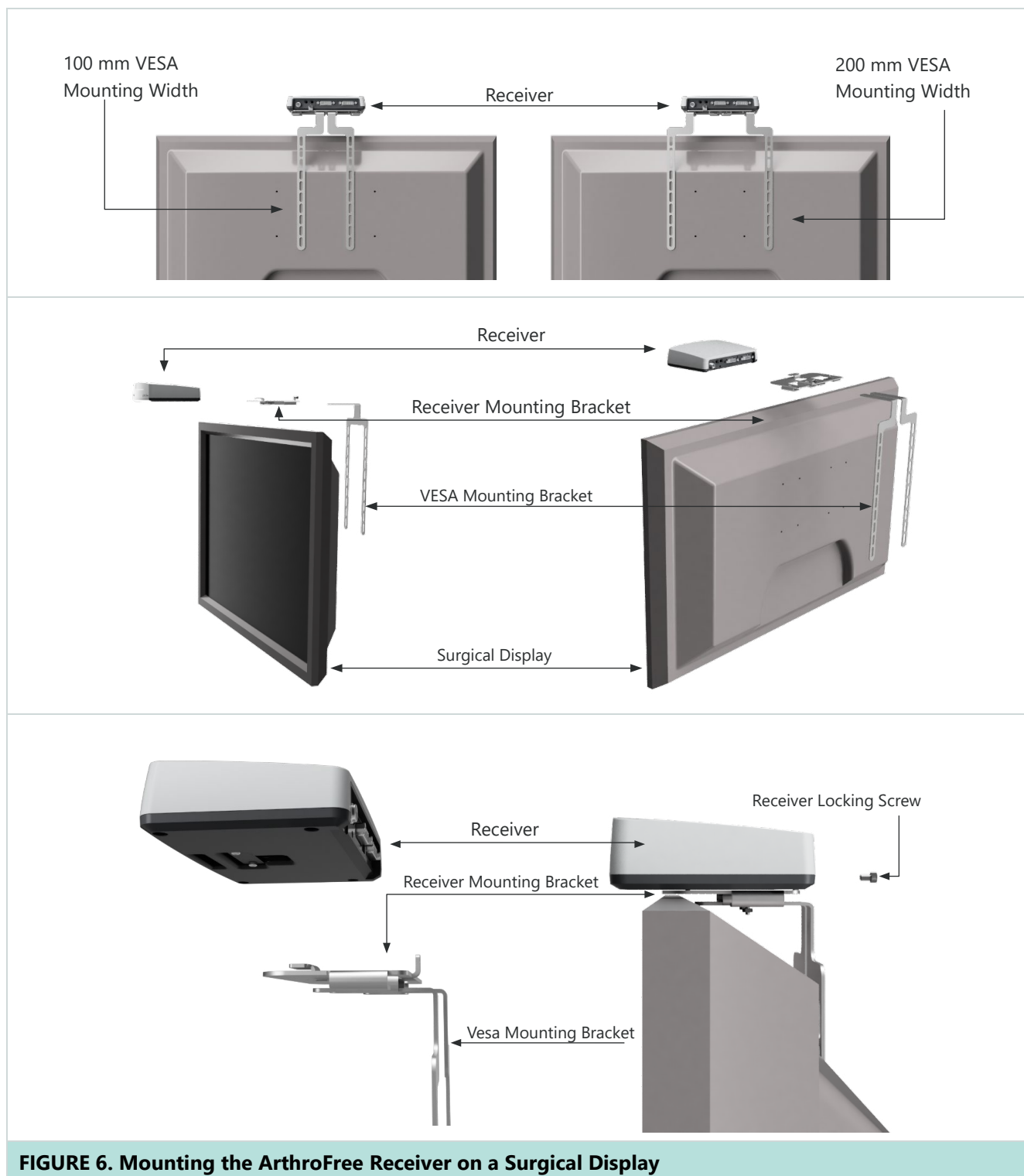
1. Choose a secure and stable location (e.g., tower shelf or boom arm mount) that allows the Receiver to directly face the procedure location where the Camera Head will be used.
2. Ensure that there is a clear, unobstructed line of sight between the Receiver and the Camera Head.

### Cable Connections and Power Setup

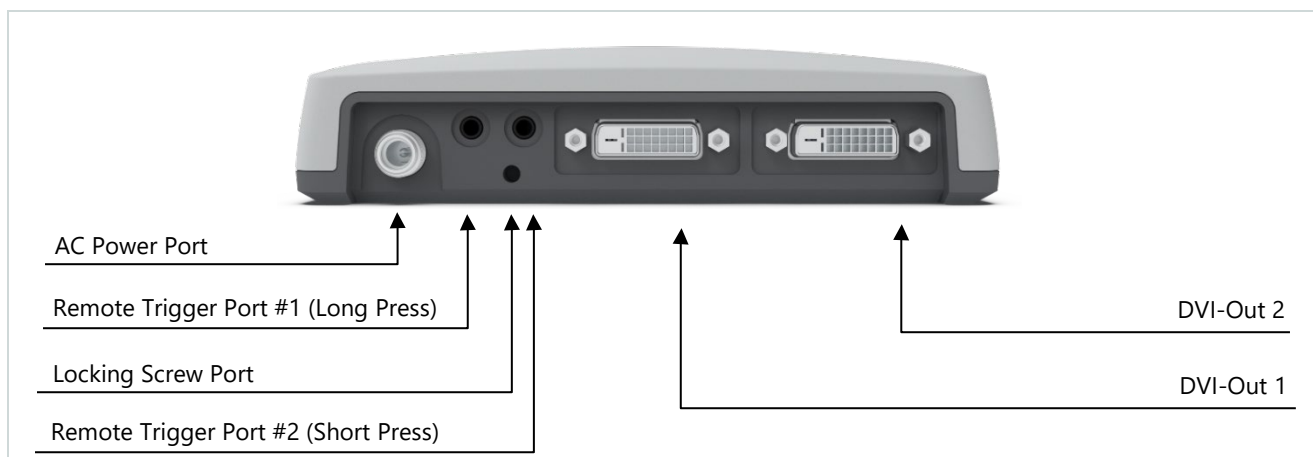
1. Connect the Receiver power cable to the AC power port on the back of the Receiver, then plug the other end into a hospital-grade electrical outlet.
2. Connect at least one of the provided DVI cables from a DVI-Out port on the back of the Receiver to a DVI input on the surgical display or patient data console.
3. On the surgical display, select the corresponding DVI input source to ensure the video from the Receiver is shown correctly. Refer to the display's user manual if necessary.
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 patient data console. Test video triggering and adjust the input port as needed.
5. Connect the picture trigger cable to remote trigger port #2 on the back of the Receiver and to the picture trigger port on the data console. Test picture capture functionality and adjust port selection as necessary.

## NOTES

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



**FIGURE 6. Mounting the ArthroFree Receiver on a Surgical Display**



**FIGURE 7. ArthroFree Receiver Connections**

1. 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 patient data console.
2. 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 patient data console. After installation, test for video triggering and adjust port selection as necessary.
3. 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 patient data console. After installation, test for picture triggering and adjust port selection as necessary.
4. 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 installing the Receiver, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions (see [Electromagnetic Compatibility](#)).

### Battery Charger Installation

1. Place the empty 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 installing the Battery Charger, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions (see [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 elements 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. Line up the Battery with an open charger bay and gently insert the Battery until the Battery stops. Once inserted, the Battery will begin charging and its corresponding OLED display will indicate charging progress, and the number of charge cycles completed.
2. Once the charging cycle is complete, the status display of the Battery Charger will indicate "DONE CHARGING."
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 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.,  $> 55^{\circ}\text{C}$  ( $131^{\circ}\text{F}$ ). If a Battery will not charge and feels warm to the touch, allow the Battery time to cool and try to charge again.
- To maintain optimal performance, Batteries should be charged within the last 30 days. Batteries should be replaced after 300 charge cycles.



## Inspection of the Camera Head and Battery

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

## Endoscope Attachment

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

**EITHER:** Screw a C-mount endoscope clockwise onto the Camera Head until it forms a tight seal. Do not overtighten.

**OR:**

1. Attach a C-mount coupler to the Camera Head and then attach a compatible endoscope.
2. Screw the C-mount coupler clockwise onto the Camera Head until it forms a tight seal. Do not overtighten.
3. Open the endoscope clamp and insert the compatible endoscope into the scope end of the coupler.
4. 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 between the components could occur that may obscure the image transmitted from the Camera Head to the connected surgical display.

## Connecting and Disconnecting the Light Source

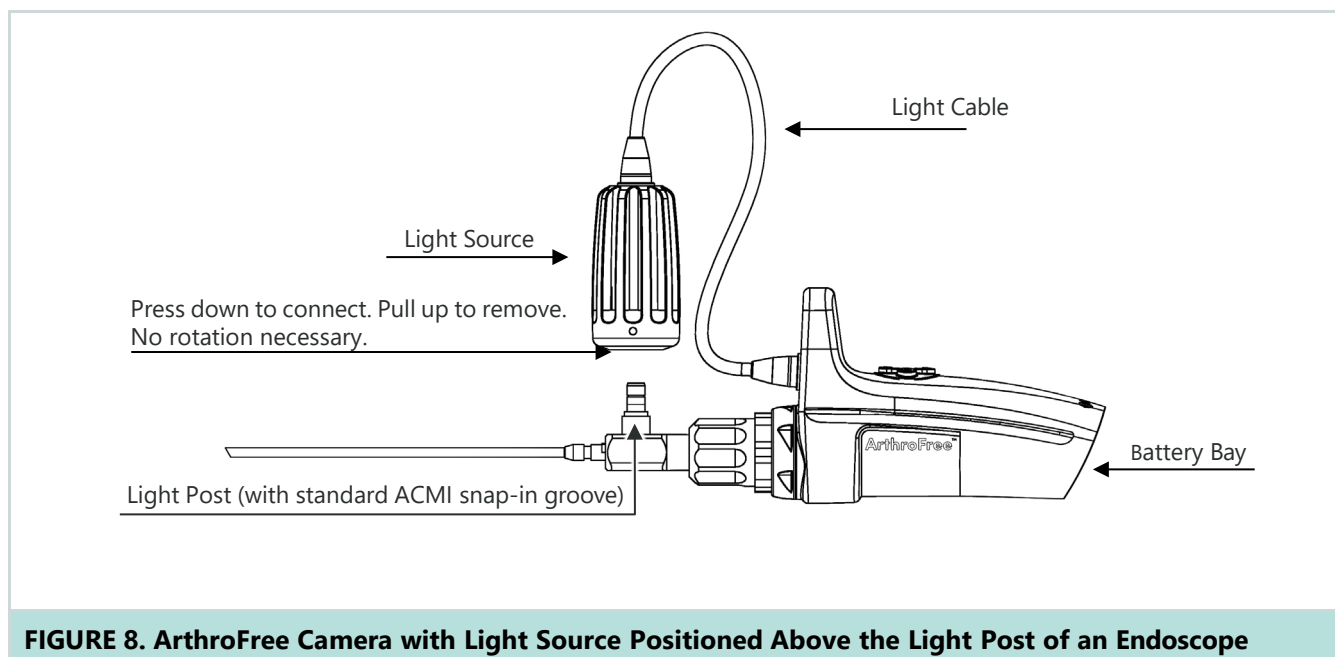
Gently press the light source onto the ACMI snap-in groove on the light post of the pre-existing endoscope until it clicks in.

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 on the main body of the light source.



**FIGURE 8. ArthroFree Camera with Light Source Positioned Above the Light Post of an Endoscope**

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

1. Obtain and use proper personal protective equipment ("PPE") prior to use. Maintain gloved hands throughout operation.
2. 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.
3. Once the Battery is fully inserted, the Camera Head will automatically connect to an unpaired Receiver powered on and 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.
4. Visually confirm signal strength on the connected and powered on surgical display.
5. To power the Camera Head off, remove the Battery by pulling it straight out of the Camera Head. Apply only a small amount of force to the cosmetic cover of the Battery.

### NOTES

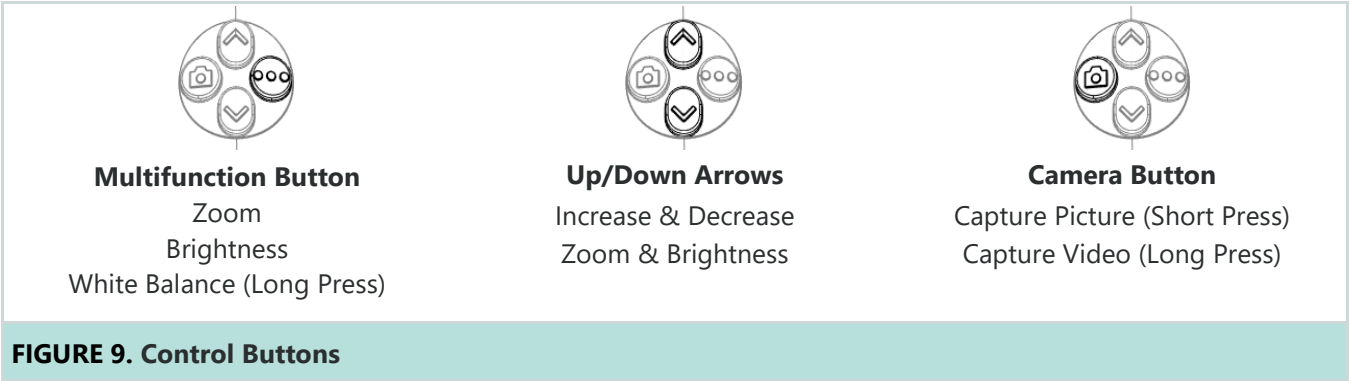
- Cameras and Receivers will only pair with matching version levels (See [TABLE 3](#) and [TABLE 4](#)). Attempting to pair different versions will not succeed.
- Do not forcibly insert the Battery into the battery bay, including not smacking or hitting the end of the Battery to fully seat it in the 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.
- The surface temperature of the Camera Head and light source may become warm to touch, i.e.,  $>55^{\circ}\text{C}$  ( $131^{\circ}\text{F}$ ), during use or if left powered on and unattended for an extended period of time. If, due to the warmth of the components, they become uncomfortable to hold for an extended time, the user should shift his/her grip on the Camera Head and/or light source.

**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, regardless of version (AF0001-101-11 or -12) within range of a single Receiver (see [Receiver Installation](#)).

## Using the Control Buttons

The Camera Head features a keypad to control the functions of the ArthroFree System. The control buttons (see Error! Reference source not found.) are labeled with a camera icon, three linear dots (the multifunction button), and up and down arrows.



The multifunction button allows the user to switch between the Zoom, Brightness, and White Balance functions.

- To switch functions, quickly press and release the multifunction button.

The up and down buttons are used to increase or decrease the Brightness or 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.

The camera button is labeled with a camera icon and is used to trigger the capture of images or to begin or end video recording.

- 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.

# White Balancing

**NOTE:** Perform a White Balance check before every 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 endoscope, and the Camera Head is powered on and transmitting video to the connected Surgical Display (see [FIGURE 9](#)).

1. Point the endoscope at a stack of white gauze pads, a white laparoscopic sponge, or any clean, white non-reflective surface (the target). Make certain that the white balance target material takes up the entire display.
2. Shade the target from excess ambient light by hand or with an opaque material preventing interference from ambient light sources.
3. Confirm that the image is clear and the image on the connected surgical display is in focus.
4. Look at the monitor and confirm that no glare is visible off the white surface.
5. Press and hold the multifunction button until the white balance icon (see [FIGURE 9](#)) appears on the video monitor in the lower right corner, and an audible beep sound is made.
6. 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 5. 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<br>(3 Segments)           | Indicates the Battery charge level is above 75% charge.  |
|    | Battery Charge<br>(2 Segments)           | Indicates the Battery charge level is between 51% and 75%.   |
|   | Battery Charge<br>(1 Segment)            | Indicates the Battery charge level is between 26% and 50%.   |
|  | Battery Charge<br>(0 Segments)           | Solid: Indicates the Battery charge level is between 10% and 25%.<br>Flashing: Indicates the Battery has less than 10% charge remaining.<br>Immediately replace with a fully charged Battery.  |
|  | Wireless Signal<br>(4 Segments)          | Indicates high signal strength between the Camera Head and Receiver. This level provides full image quality and device performance.  |
|  | Wireless Signal<br>(3 Segments)          | Indicates strong signal strength between the Camera Head and Receiver. This level provides full image quality and device performance.  |
|  | Wireless Signal<br>(2 Segments)          | Indicates adequate signal strength between the Camera Head and Receiver. This level provides full image quality and device performance.  |
|  | Wireless Signal<br>(1 Segment, blinking) | 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.

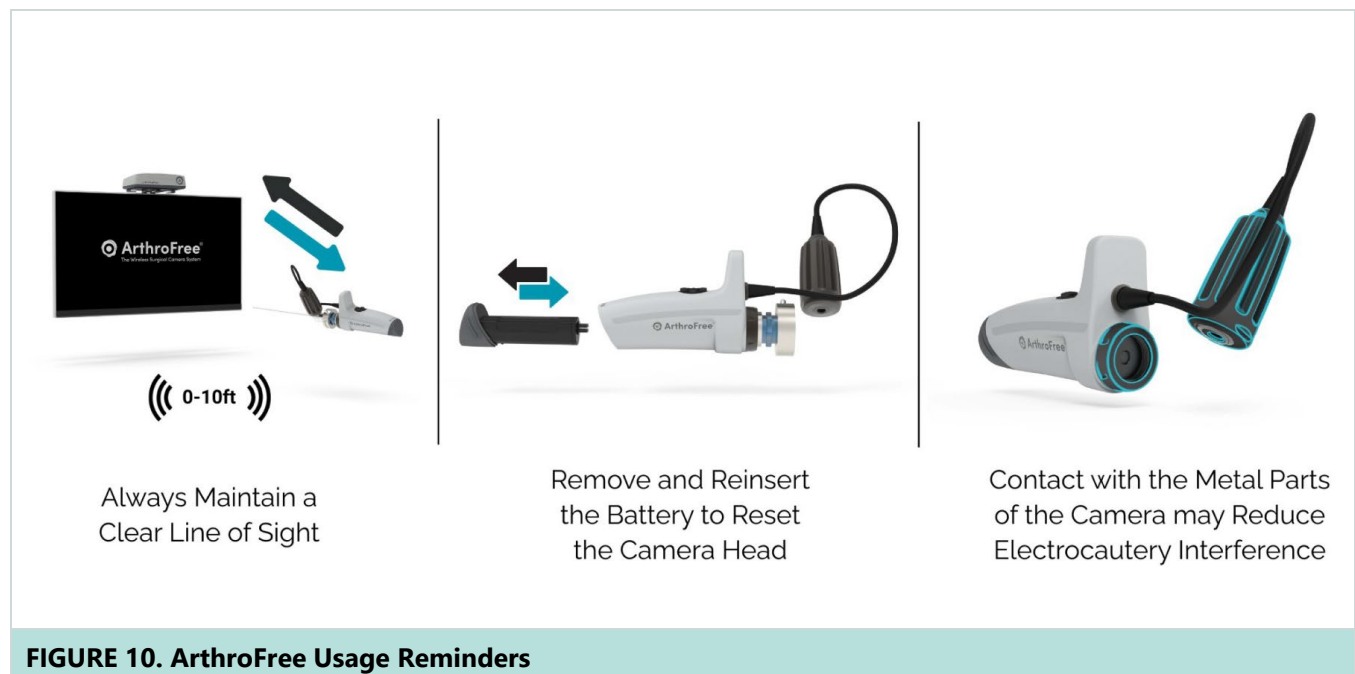
### NOTES

- 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 indicate the strength of the wireless signal between the Camera Head and Receiver. While the ArthroFree System functions across all signal levels, optimal performance is supported by minimizing the distance between the Camera Head and Receiver. Maintain the shortest practical distance during use to ensure signal reliability.

## Usage Reminders

For optimal performance of your ArthroFree system:

- Always ensure an unobstructed Line of Sight (LOS) between the Camera Head and Receiver and a maximum working distance of 10 ft.
- Remove and reinsert the Battery to reset the Camera Head.
- When using electrocautery devices with ArthroFree, maintaining hand contact with the metal parts of the Camera Head may reduce electrocautery interference.



## 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). The use of any other detergent must be validated independently by the end user.
- 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 6](#))

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

# Manual Cleaning, Containment, and Transportation

Point-of-use cleaning should occur immediately following use and before transportation.

## 1. Disassemble Components

- Disconnect the Camera Head light source from the endoscope light post.
- Unthread the endoscope or coupler from the Camera Head's C-Mount connector.
- Remove the Battery from the Camera Head by pulling it straight out of the battery bay.

## 2. Initial Cleaning

- Wipe all Components with a non-linting cloth moistened with enzymatic cleaner.
- Do not immerse Components. Prevent fluid entry into battery bay of the Camera Head or the battery contacts on the Batteries.

## 3. Packaging and Transport

- Place each component (Camera Head and Batteries) into appropriate closed containers or transport bins compliant with facility and regulatory guidelines.
- Do not stack items or compress Components during transport.
- Handle Components carefully to avoid impact or abrasion during transit.

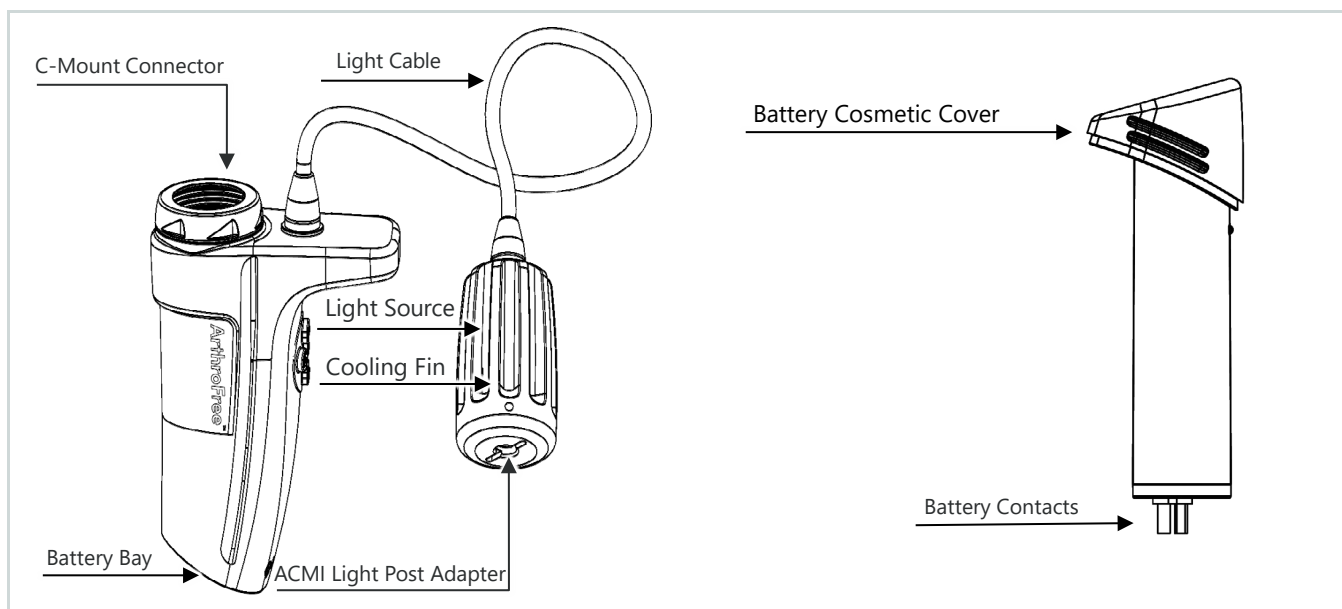
**WARNING:** Do not allow soil on devices to dry. Dried soil or tissue on the Camera Head or any of its subcomponents may make it more difficult to clean and/or sterilize the device. Any Components observed to be soiled at any point in their life or use cycle must be considered nonsterile and a potential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

# Decontamination

1. Remove all Components from the Sterilization Tray and set the Camera Head, Batteries, and Sterilization Tray separately into an empty wash basin, sink, or equivalent container.
2. Fill a *separate* wash basin, sink, or equivalent container with an appropriate level of water and enzymatic solution.
3. Using a non-linting cloth or equivalent, remove all visible debris (e.g., blood, tissue, or debris) from the Camera Head, Batteries and Sterilization Tray. For persistent debris, saturate a non-linting cloth with enzymatic cleaner and wrap it around heavily soiled areas. Ensure that excess solution does not seep into the battery bay of the Camera Head.
4. While holding the Camera Head with the battery bay 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 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.
5. 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 within the battery bay and battery contact.





**FIGURE 11. Proper Orientation of the Camera Head and Battery for Decontamination and Cleaning**

6. Decontaminate one Battery at a time. With the battery contacts 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.
7. Soak the Sterilization Tray in enzymatic cleaner. 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.
8. 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.
9. Rinse the enzymatic cleaner from one Battery at a time with the battery contacts 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.
10. 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.
11. Inspect the Components for residual debris and repeat cleaning and rinsing steps as needed.
12. Use one or more of the following techniques to fully dry the Components.
  - Hand dry with non-linting absorbable wipes.
  - Let air dry at ambient temperature.
  - Blow dry using AAMI-standard instrument grade compressed air, not exceeding 30 psi.
  - Air dry in a drying cabinet at an elevated temperature, not exceeding 60°C (140°F).

# Inspection and Assembly

For Steris or Sterrad low temperature sterilization systems, following steps outlined below.

1. Inspect all Components for signs of trapped water, focusing on ridges or recesses. While inspecting the Batteries and battery bay, pay special attention to the battery connectors. Inspect the Sterilization Tray for trapped water focusing on guides, device holders, and air-flow perforations. If any water is observed, repeat Decontamination Step 7 until all visible moisture is removed.
2. Inspect all Components for signs of damage or wear that may impair operation. If any damage or wear beyond normal usage is observed, discontinue use and contact your Lazurite representative.
3. Charge used Batteries per facility guidelines and obtain charged Batteries for sterilization.
4. Place the Camera Head and charged Batteries into the Sterilization Tray within the locations visually indicated on the inside bottom of the tray. Secure the Sterilization Tray lid in place using the incorporated latches.
5. Wrap the Sterilization Tray in a double layer of sterilization wrap with minimal dimensions of 30''by 30''.

For Plasmapp STERLINK Plus and STERLINK Mini systems, follow the steps outlined below.

1. 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.
2. Inspect all Components for signs of damage or wear that may impair operation. If any damage or wear beyond normal usage is observed, discontinue use and contact your Lazurite representative.
3. Charge used Batteries per facility guidelines and obtain charged Batteries for sterilization.
4. 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 or STERLINK mini sterilizer.

## Sterilization

1. Utilize a biological test pack as appropriate for post-sterilization cycle monitoring.
2. Select and execute the appropriate sterilization cycle from the chart below.
3. Confirm that the sterilization cycle has been successfully completed.

**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 6. Validated Sterilization Equipment and Cycles**

The following cycles have been validated for AF0001-101-11 Camera Heads, AF0001-101-12 Camera Heads, AF0003-101-10 Batteries, and AF0005-101-10 Sterilization Trays as appropriate to provide a sterility assurance level (SAL) of  $10^{-6}$ .

| <b>Steris V-PRO Cycle Types and Times (min)</b> |                       |                  |                 |                       |
|---|-----------------------|------------------|-----------------|-----------------------|
| <b>System</b>                                   | <b>Fast Non Lumen</b> | <b>Non Lumen</b> | <b>Flexible</b> | <b>Lumen/Std/Plus</b> |
| V-PRO maX 2                                     | 16.5                  | 28               | 35              | 55                    |
| V-PRO maX                                       | –                     | 28               | 35              | 55                    |
| V-PRO 60  | –                     | 28               | 38              | 60                    |
| V-PRO s2  | –                     | 28               | 38              | 60                    |
| V-PRO 1   | –                     | 28               | –               | 55                    |

| <b>Sterrad Cycle Types and Times (min)</b> |                 | <b>Plasmapp Cycle Types and Times (min)</b> |                     |
|--|-----------------|---|---------------------|
| <b>System</b>                              | <b>Standard</b> | <b>System</b>                               | <b>Chamber Mode</b> |
| 100NX                                      | 28              | STERLINK Mini                               | 18                  |
| NX   | 47              | STERLINK Plus                               | 36                  |

**WARNING:** Do not place any Components of the ArthroFree System into a moist heat sterilizer (autoclave) or an ethylene oxide (ETO) 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, incorrect, or improper sterilization of this device may cause damage to the device.

## Battery Charger and Receiver

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

If the Battery Charger or Receiver becomes soiled, wipe clean with a standard approved medical grade cleaning product 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 units and void the product warranty.

## Storage

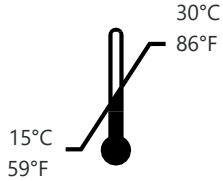
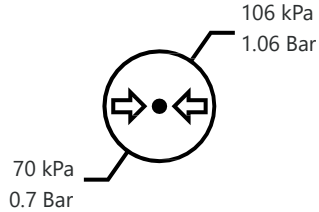
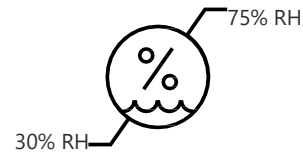
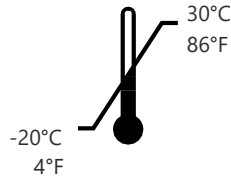
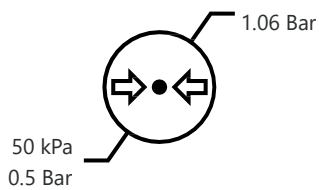
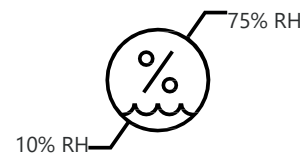
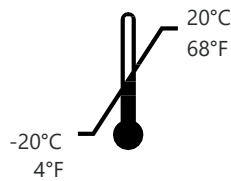
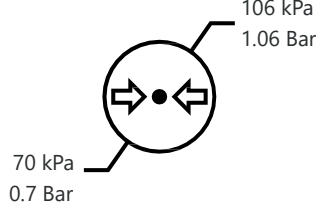
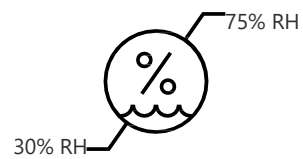
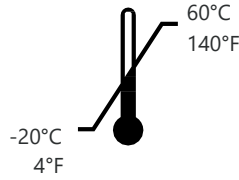
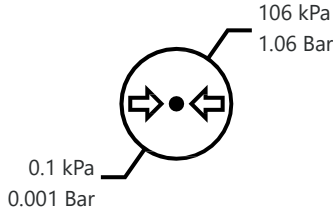
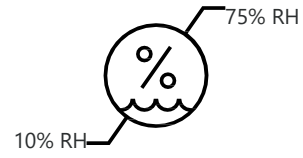
Following cleaning and sterilization, store the sterilized ArthroFree Components in the Sterilization Tray, PET/LLDPE-Tyvek™ pouches, or other sterilization wrap in which they were sterilized.

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   |
|---|--|--|
|  <p><b>In Operation (in use)</b><br/>Min and Max Temperature Range for the ArthroFree System</p>                 |  <p><b>In Operation (in use)</b><br/>Min and Max Pressure Range for the ArthroFree System</p>                 |  <p><b>In Operation (in use)</b><br/>Min and Max Humidity for the ArthroFree System</p>                 |
|  <p><b>Short-term Storage and Transportation</b><br/>Min and Max Temperature Range for the ArthroFree System</p> |  <p><b>Short-term Storage and Transportation</b><br/>Min and Max Pressure Range for the ArthroFree System</p> |  <p><b>Short-term Storage and Transportation</b><br/>Min and Max Humidity for the ArthroFree System</p> |
|  <p><b>Long-term Storage</b><br/>Min and Max Temperature Range for the ArthroFree System</p>                   |  <p><b>Long-term Storage</b><br/>Min and Max Pressure Limits for the ArthroFree System</p>                  |  <p><b>Long-term Storage</b><br/>Min and Max Humidity for the ArthroFree System</p>                   |
|  <p><b>Sterilization and Stability</b><br/>Min and Max Temperature Range for the Camera Head and Battery</p>   |  <p><b>Sterilization and Stability</b><br/>Min and Max Pressure Limits for the Camera Head and Battery</p>  |  <p><b>Sterilization and Stability</b><br/>Min and Max Humidity for the Camera Head and Battery</p>   |
| <b>FIGURE 12. Recommended Conditions for Use, Storage, and Transportation</b>   |  |  |

## Service Life

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

Expected Service Life is estimated based on the results of Lazurite's Service Life Assessment Study. This study used elevated temperature to simulate advanced aging of the ArthroFree System and assessed functionality at defined intervals.

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

## Disposal

The Components of the ArthroFree System must be disposed of according to local laws and facility practices. Contact your Lazurite representative for instructions on returning components to Lazurite for disposal (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 equipment is decontaminated prior to recycling. Do not dispose of as unsorted municipal waste.

Ensure equipment is decontaminated prior to disposal.

Never dispose of any electronic ArthroFree component or accessory in an incinerator.

The ArthroFree System and its 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 7. Technical Specifications**

|                           | Camera Head                | Receiver                   | Battery                | Battery Charger                | Sterilization Tray |
|---------------------------|----------------------------|----------------------------|------------------------|--------------------------------|--------------------|
| Product #                 | AF0001-101-11/-12          | AF0002-101/-12             | AF0003-101             | AF0004-101                     | AF0005-101         |
| Imaging System            | 1/2.7" Pro. Scan CMOS 2 MP | 1080p @ 60fps HD video     | Not applicable         | Not applicable                 | Not applicable     |
| Output Electrical Ratings | Not applicable             | Not applicable             | 3.6V, 2930mAh, 10.55Wh | 12V DC, 1A                     | Not applicable     |
| Mounting                  | C-mount*                   | Top of Surgical Display**  | Not applicable         | Outside sterile field tabletop | Not applicable     |
| Auto Shutter Range        | 1/60 (1/50)–1/100,000 s.   | Not applicable             | Not applicable         | Not applicable                 | Not applicable     |
| Trigger Port(s)           | Not applicable             | 2 x 3.5 mm female (1/8")   | Not applicable         | Not applicable                 | Not applicable     |
| Input Electrical          | 3.6V DC                    | 100–240V AC, 50–60Hz, 0.6A | 4.1V max charging      | 100–240V AC, 50–60Hz, 0.6A     | Not applicable     |
| Device Weight             | 370g/372g                  | 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     |

\*C-mount Coupler or Endoscope. \*\*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.

**NOTE:** If interference occurs, increase the distance between the high-frequency device and the Camera Head or have the user make contact with a metal part of 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.

## 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.

## 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.

## Warnings, Cautions, Notes

Please ensure that all users 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 in the order of appearance in [TABLE 8](#), [TABLE 9](#), [TABLE 10](#).

### Warnings

To avoid potential serious injury to the patient, clinician, or other 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 product warranty is void if any Warning is disregarded.

**TABLE 8. Warnings**

| Section                              | Warning  |
|--------------------------------------|--|
| General Warnings                     | Before operating this device, please read this manual thoroughly. When using this device, it may fail to perform as expected if the instructions in this manual are not followed.  |
|                                      | To prevent the device from powering down during use, keep additional Batteries available.  |
| Product Description and Intended Use | The Light Source of Wireless Camera Head AF0001-101-11 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 <a href="#">FIGURE 12</a> , contact your Lazurite 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 <a href="#">Cleaning, Assembly, and Sterilization</a> ).  |
|                                      | 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.  |
|                                      | Do not power on more than one Camera Head, regardless of version (AF0001-101-11 or -12) within range of a single Receiver (see <a href="#">Receiver Installation</a> ).  |



|  |  |
|--|--|
| Cleaning,<br>Assembly,<br>and<br>Sterilization | Do not place any Component of the ArthroFree System in a moist heat sterilizer (autoclave) or automated washer disinfectant. 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 Components observed to be soiled at any point in their life or use cycle must be considered nonsterile and a potential source for disease transmission. Any visibly soiled Components 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.  |
|  | Do not place any Components of the ArthroFree System into a moist heat sterilizer (autoclave) or an ethylene oxide (ETO) sterilizer. These sterilization methods may cause damage to the Components, which could lead to serious injury of the patient, clinician, or end users.   |
| 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 ArthroFree System, follow the Cautions prescribed throughout this document and summarized below. The product warranty is void if any Caution is disregarded.

**TABLE 9. Cautions**

| Section                            | Caution   |
|------------------------------------|---|
| Product Description & 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 installing the Receiver, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions (see <a href="#">Electromagnetic Compatibility</a> ).   |
|                                    | The Battery Charger requires electricity via a hospital-grade electrical outlet. Position the Battery Charger so that the outlet is easily accessible.  |
|                                    | When installing the Battery Charger, use only supplied cables and accessories. Any other cables or accessories may result in increased EMC emissions (see <a href="#">Electromagnetic Compatibility</a> ).  |
| Operating Instructions             | Do not drop any Component of the ArthroFree System, including the Camera Head and Batteries. The Camera Head contains sensitive elements 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.   |

|                                       |  |
|---------------------------------------|--|
|                                       | 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 on 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 within the battery bay and battery contact.   |
|                                       | Treat each of the Components of the ArthroFree System with care. Misuse, incorrect, or improper sterilization of this device may cause damage to the device.   |
|                                       | Disconnect the Battery Charger and Receiver from its power source before cleaning.   |
| Disposal                              | 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 equipment is decontaminated prior to recycling. Do not dispose of as unsorted municipal waste. |
|                                       | Ensure equipment is decontaminated prior to disposal.  |
| EMC                                   | 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                              | Do not attempt any repairs or adjustments not specifically detailed in this manual.  |

## Notes

The Notes identified throughout this document contain special information intended to clarify the instructions in this manual, present additional information, or both. Notes are summarized in [TABLE 10](#) below.

**TABLE 10. Notes**

| Section      | Note  |
|--------------|---|
| System Setup | For assistance with the installation and setup of the ArthroFree System, please contact your Lazurite representative.   |
|              | The included Receiver mounting bracket is compatible with a 100 mm or 200 mm VESA mounting pattern on a surgical display. For technical support, please contact your Lazurite representative. |
|              | The Receiver should be placed within 10 feet of the location where the Camera Head will be used.  |
| Operating    | Before each use of the ArthroFree System, ensure that all Components are set up according   |

|                                     |   |
|-------------------------------------|---|
| Instructions                        | to instructions in the <a href="#">System Setup</a> 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.   |
|                                     | To maintain optimal performance, Batteries should be charged within the last 30 days. Batteries should be replaced 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 between the components could occur 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 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.  |
|                                     | Cameras and Receivers will only pair with matching version levels (See <a href="#">TABLE 3</a> and <a href="#">TABLE 4</a> ). Attempting to pair different versions will not succeed.   |
|                                     | 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. |
|                                     | The surface temperature of the Camera Head and Light Source may become warm to touch, i.e., >55°C (131°F), during use or if left powered on and unattended for an extended period of time. If, due to the warmth of the components, they become uncomfortable to hold for an extended time, the user should shift his / her grip on the Camera Head.  |
| Wireless Visualization              | 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 procedure and after every Battery change.  |
|                                     | 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.  |
| Cleaning Assembly and Sterilization | Wireless icons indicate the strength of the wireless signal between the Camera Head and Receiver. While the ArthroFree System functions across all signal levels, optimal performance is supported by minimizing the distance between the Camera Head and Receiver. Maintain the shortest practical distance during use to ensure signal reliability.   |
|                                     | Do not use the ArthroFree Sterilization Tray in the STERLINK Plus or STERLINK mini sterilizer.  |
| Technical Specifications            | If interference occurs, increase the distance between the high-frequency device and the Camera Head or have the user make contact with a metal part of the Camera Head while operating the interfering device.  |

# Troubleshooting

**TABLE 11. Troubleshooting**

| Symptom  | Possible Cause  | Recommended Action   |
|--|---|--|
| No video appears on connected surgical display | <ul style="list-style-type: none"> <li>Receiver or Camera not powered or paired</li> <li>Incorrect input source</li> <li>Hardware connection issue</li> <li>Incompatible Camera/Receiver model or firmware</li> </ul> | <ul style="list-style-type: none"> <li>Ensure the surgical display power is ON</li> <li>Ensure the main power on tower or boom is ON</li> <li>Confirm the Receiver is powered ON (green light)</li> <li>Confirm the Camera Head is paired (blue light)</li> <li>Check Receiver-to-display connection and input source</li> <li>Remove and reinsert Battery</li> <li>Verify Camera model: <ul style="list-style-type: none"> <li>AF0001-101-11 = ArthroFree</li> <li>AF0001-101-12 = ArthroFree 2</li> </ul> </li> <li>Verify Receiver firmware: <ul style="list-style-type: none"> <li>ArthroFree 1 - v1.1.3</li> <li>ArthroFree 2 - v1.1.4+</li> </ul> </li> </ul> <p>Contact Lazurite representative if issue persists</p> |
| Incorrect picture color                        | <ul style="list-style-type: none"> <li>Improper white balance</li> <li>Incorrect color settings</li> <li>Brightness too low/high</li> <li>Damaged endoscope or coupler</li> </ul>                                     | <ul style="list-style-type: none"> <li>Perform the white balance procedure (see <a href="#">White Balancing</a>).</li> <li>Use compatible lighting (e.g., LED, xenon, metal-halide); avoid fluorescent or reflective white surfaces.</li> <li>Adjust color settings on the surgical display</li> <li>Set the brightness level at 3 to 4 bars</li> <li>Check endoscope and/or coupler for damage</li> </ul> <p>Contact Lazurite representative if issue persists</p>  |
| Picture is too dark                            | <ul style="list-style-type: none"> <li>Camera or display brightness set too low</li> </ul>  | <ul style="list-style-type: none"> <li>Increase brightness by quickly pressing and releasing the multifunction button on the Camera Head until the brightness icon is displayed</li> <li>Press and release the up button until the desired brightness is achieved</li> <li>Check the brightness settings on the surgical display</li> </ul> <p>Contact Lazurite representative if issue persists</p>   |

|  |  |   |
|--|--|---|
| Picture is too bright                          | <ul style="list-style-type: none"> <li>• Camera or display brightness set too high</li> </ul>  | <ul style="list-style-type: none"> <li>• 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 the desired brightness is achieved</li> <li>• Check the brightness settings on the Surgical Display</li> </ul> <p>Contact Lazurite representative if issue persists</p>   |
| Poor white balance quality                     | <ul style="list-style-type: none"> <li>• Incorrect brightness setting</li> <li>• Improper lighting conditions</li> <li>• Camera not balanced under appropriate conditions</li> </ul>                         | <ul style="list-style-type: none"> <li>• Refer to solutions for "Picture is too dark" and "Picture is too bright"</li> <li>• Set the brightness level at 3 to 4 bars</li> <li>• With the light source connected to the endoscope, perform the white balance procedure (see <a href="#">White Balancing</a>) using LED, metal-halide, or xenon lighting. Avoid fluorescent lighting and reflective white surfaces.</li> </ul> <p>Contact Lazurite representative if issue persists</p>   |
| No light is coming out of the endoscope        | <ul style="list-style-type: none"> <li>• Camera Head not powered</li> <li>• Battery depleted</li> <li>• Light source not connected or damaged</li> <li>• Scope light path is blocked or defective</li> </ul> | <ul style="list-style-type: none"> <li>• Confirm that the Camera Head is turned on (see <a href="#">Powering the Camera Head On and Off and Connecting to the Receiver</a>)</li> <li>• Ensure the light source is properly connected to the endoscope light post</li> <li>• Replace the Battery with one that is fully charged</li> <li>• Inspect the light source and cable for visible damage</li> <li>• Check the scope's illumination path: point the distal tip at a ceiling light and observe the light post port. If it remains dark, replace the scope</li> <li>• Change endoscopes</li> <li>• If actions do not resolve symptom, <ul style="list-style-type: none"> <li>◦ Contact your endoscope provider for repair/replacement if scope fails light transmission, then if unresolved</li> </ul> </li> </ul> <p>Contact Lazurite representative if issue persists</p> |
| Camera Head takes a video instead of a picture | <ul style="list-style-type: none"> <li>• Trigger cables are reversed</li> </ul>  | <ul style="list-style-type: none"> <li>• Reverse the trigger cables and try again</li> </ul> <p>Contact Lazurite representative if issue persists</p>   |

|   |  |   |
|---|--|---|
| Image is lost during surgery                                  | <ul style="list-style-type: none"> <li>• Battery failure</li> <li>• Camera-Receiver pairing lost</li> <li>• Obstruction or interference</li> </ul>         | <ul style="list-style-type: none"> <li>• Immediately stop using surgical instruments</li> <li>• Remove endoscope and instruments from patient</li> <li>• Ensure the light engine is fully connected to the scope</li> <li>• Replace the Battery and allow Camera Head to re-pair with Receiver</li> <li>• Maintain clear line of sight between Camera Head and Receiver</li> </ul> <p>Contact Lazurite representative if issue persists</p> |
| Battery fails to charge or is not detected by Battery Charger | <ul style="list-style-type: none"> <li>• Charging bay malfunction</li> <li>• Overheated Battery</li> <li>• Battery failure</li> </ul>                      | <ul style="list-style-type: none"> <li>• Place Battery into a different charging bay</li> <li>• If Battery is warm, allow it to cool before reattempting charge</li> </ul> <p>Contact Lazurite representative if issue persists</p>   |
| The Receiver indicator light is off                           | <ul style="list-style-type: none"> <li>• Power switch off</li> <li>• Power cable disconnected or damaged</li> <li>• Power not reaching Receiver</li> </ul> | <ul style="list-style-type: none"> <li>• Check power switch if applicable</li> <li>• Ensure Receiver power cable is fully connected at both ends</li> <li>• Confirm power adapter and cable are securely connected</li> <li>• Verify Receiver is receiving power (green = power, blue = pairing)</li> <li>• Inspect cable/adaptor for damage</li> </ul> <p>Contact Lazurite representative for cable replacement if damaged</p>             |

Featuring our patented ArthroFree® and Meridiem® technologies.

See [www.lazurite.co/patents](http://www.lazurite.co/patents) for more details.

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# 19-005D ArthroFree System IFU v5.0 (DOC-1222) Ver. 0

**Approved By:**

[\(CO-228\) 19-005D v5.0](#)

**Description**

19-005D ArthroFree System IFU v4.1 to v5.0 release

**Justification**

19-005D ArthroFree System IFU v5.0 Final

| Assigned To:   | Initiated By:  | Priority: | Impact: |
|----------------|----------------|-----------|---------|
| Patrick Polito | Patrick Polito | High      | Major   |

**Version History:**

| Author         | Effective Date            | CO#                    | Ver. | Status    |
|----------------|---------------------------|------------------------|------|-----------|
| Patrick Polito | July 30, 2025 3:58 PM EDT | <a href="#">CO-228</a> | 0    | Published |