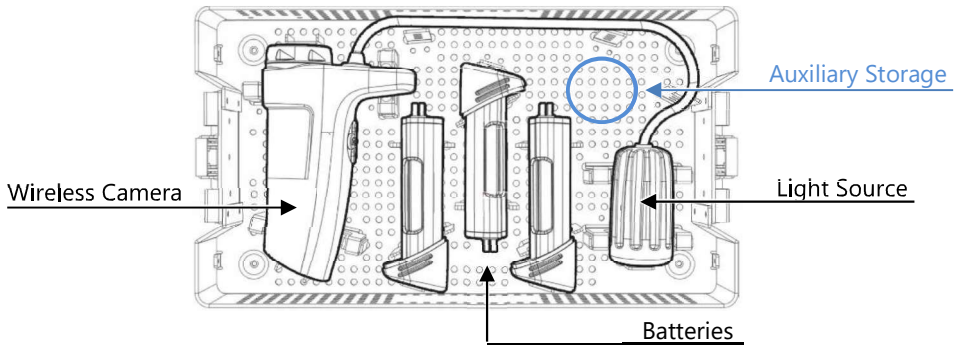
Validated Sterilization Equipment and Cycles (IFU, Table 4)

Steris	
Sterilization Method	**Cycle Time**
V-PRO® maX 2: Fast non lumen	16.5 minutes
V-PRO maX 2: Non lumen	28 minutes
V-PRO maX: Non lumen	28 minutes
V-PRO 60: Non lumen	28 minutes
V-PRO s2: Non lumen	28 minutes
V-PRO 1: Non lumen	28 minutes
V-PRO maX 2: Flexible	35 minutes
V-PRO maX: Flexible	35 minutes
V-PRO 60: Flexible	38 minutes
V-PRO s2: Flexible	38 minutes
V-PRO maX 2: Lumen	55 minutes
V-PRO maX: Lumen	55 minutes
V-PRO 1: Standard	55 minutes
V-PRO 1: Plus lumen	55 minutes
V-PRO 60: Lumen	60 minutes
V-PRO s2: Lumen	60 minutes
Sterrad	
Sterilization Method	**Cycle Time**
Sterrad NX: Standard	47 minutes
Sterrad 100NX: Standard	28 minutes
Plasmapp	
Sterilization Method	**Cycle Time**
STERLINK Plus: Chamber mode	36 minutes
STERLINK Mini: Chamber mode	18 minutes

Components in the Sterilization Tray



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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.

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

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.

CAUTIONS

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

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

Materials and Equipment

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

- Decontamination-appropriate PPE
- Wash basin or decontamination sink
- Utility water (as referenced in AAMI TIR-34)
- Various soft-bristle brushes
- Soft non-linting absorbent drying cloths or single-use towelettes
- Critical Water (as defined in AAMI TIR-34)
- An approved enzymatic solution (e.g., Steris® Prolystica 2X Concentrate[1])
- Sterilization wrap: dual layer with minimum dimensions of 30´´ by 30´´

For Full IFU:

qrco.de/bdEVcm

- The Sterilization Tray included with the ArthroFree System
- Vaporized hydrogen peroxide ("VHP") sterilization system: See Table 4

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

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

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Processing: Manual Cleaning

Containment and Transportation

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

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

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

Decontamination

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

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

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

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

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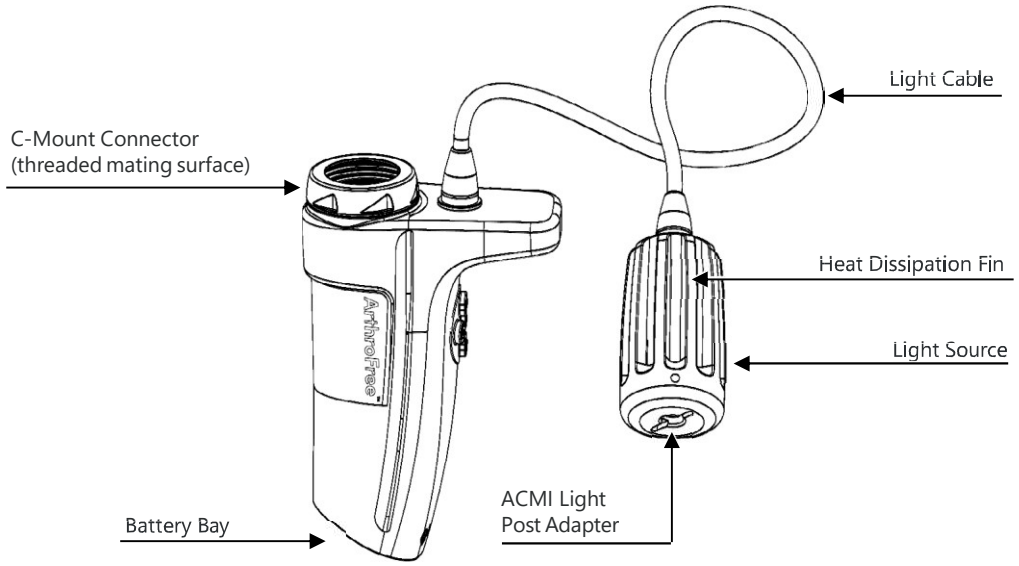
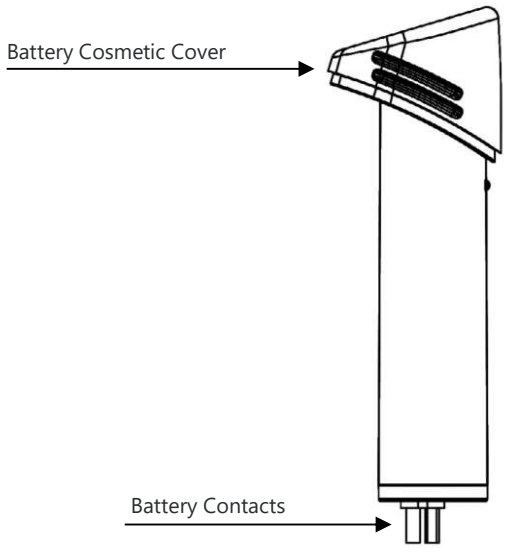


Proper Orientation of the Camera Head for Decontamination and Cleaning

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

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



Proper Orientation of the Battery for Decontamination and Cleaning

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

Battery Charger and Receiver

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

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

Inspection and Assembly

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

3. For use of the Plasmapp STERLINK Plus and STERLINK Mini systems, follow steps 3a through 3d below.
   a. Inspect the Camera Head for signs of trapped water, focusing on any ridges or recesses. Focus attention on the battery bay, including the insides of the female battery connector. Inspect the Batteries for trapped water, focusing on the male battery connector. Inspect the Camera Head and Batteries for signs of damage or wear that may impair operation.
   b. Obtain three charged Batteries. Remove the used Batteries and charge them per facility guidelines.
   c. Place the Camera Head in an appropriate Tyvek/plastic pouch and up to three charged Batteries in a second Tyvek/plastic pouch. Fill each pouch to a maximum of 75% of its packing volume, leaving space around the Camera Head or Batteries from all sides of the pouch. Seal each pouch.
   d. Utilize an appropriate chemical indicator for post-sterilization cycle monitoring.

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. Complete one of the sterilization cycles in the chart below.
3. Verify that the sterilization cycle has been successfully completed prior to use.

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

Reference: pp. 23-28 of the ArthroFree IFU 4.1

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