



950-0068-01 Revision 0  
08/2020

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**AR-3210-0011**  
**4K Synergy<sup>UHD4™</sup> TRIMANO® Camera Holder**  
**User Manual**

**Endoscopic Accessories**

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R<sub>0</sub> ONLY

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## Packaging and Labeling

All of the symbols used on the labeling along with the title, description and standard designation number may be found on our website at [www.arthrex.com/symbolsglossary](http://www.arthrex.com/symbolsglossary).

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## Information

**In CE Accepting Countries:** Procedures carried out using these devices may be used on the general population.

**In CE Accepting Countries:** The clinical benefits associated with the use of these devices outweigh the known clinical risks.

**In CE Accepting Countries:** There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.

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## Warning and Cautions



**WARNING:** Read the user manual carefully for instructions on proper operation of the device and the accessories prior to use.



**WARNING:** Read the Arthrex Synergy<sup>UHD4™</sup> System [950-0047-XX] and TRIMANO<sup>®</sup> Support Arm AR-1640 user manuals carefully prior to use.



**WARNING:** Light sources emit large amounts of light energy and thermal energy. As a result:

- The Light Guide tip can get extremely hot as a result of high intensity light, giving rise to high temperatures in front of the light emission window which may cause severe burns. Always keep the light source in the STANDBY mode when not in use.
- Avoid prolonged exposure to intense illumination.

- Use the minimum level of illumination necessary to satisfactorily illuminate the target area.
- Do not place the Light Guide connector on the patient's skin, on flammable materials or on heat sensitive materials.
- Never look directly into the Light Guide's light output.
- Do not point Light Guide toward eyes.
- Federal law restricts this device to sale by or on the order of a physician.
- This device is intended to be used by a trained medical professional.
- Biohazard waste, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.
- Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.



**CAUTION:** Subjecting the 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder to excessive forces may result in damage. Risk of injury is possible during use if the 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder is damaged.

- Perform visual inspection and functional check prior to use (see “Visual Inspection & Functional Check” section on Page 15).

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## **Precautions**

Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.

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## Instructions for Use

### 1. About this Document

The current version of this document can be found on the internet at [www.arthrex.com](http://www.arthrex.com). You may also request this document from Arthrex.

Users of the 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder are encouraged to contact their representatives if, in their professional judgment, they require more comprehensive information on product use and care.

### 2. Device Description

The 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder is a sterilizable and reusable device designed to be a Synergy Camera Head accessory and used in a surgery environment.

### 3. Intended Use

This device is to be used with TRIMANO Support Arm and Arthrex Synergy Camera Head when viewing general surgical operations. This device enables the operating physician and/or third-party ease of positioning and holding camera in place for general surgery.

## 4. Contraindications

- Do NOT use the device for Endoscopic Surgery.
- Do NOT use the device if a compatible TRIMANO Support arm and/or Arthrex Synergy Camera Head is not available.
- Do not use the device if the environmental conditions for use do not meet the standards or regulations defined in the accompanying documents.

## 5. Safety Information

The 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder may only be used by trained medical professionals.

- To ensure assembly contains all required parts, refer to the “4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder Overview” section.
- Read instructions prior to use.
- Only use the Camera Holder according to the intended use stated in this user manual.

## 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder Overview

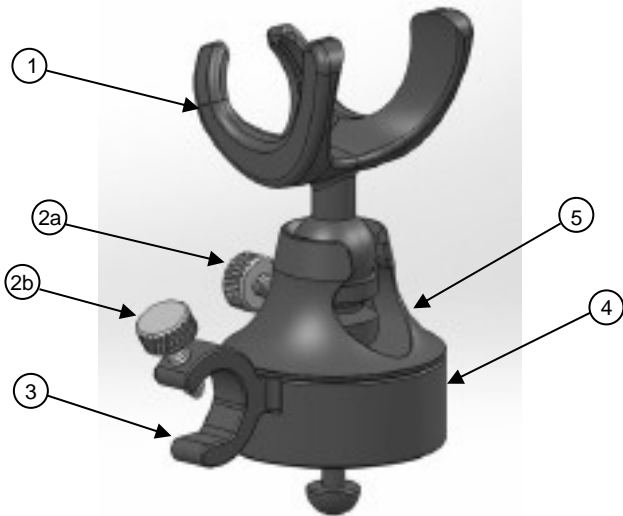
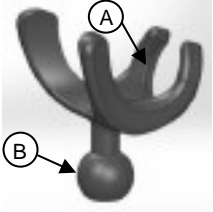




Figure 1: Arthrex 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder, AR-3210-0011  
4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder



## Parts and Functions

	<p><b>1. Camera Mount-</b> Secures an Arthrex Camera Head via snap-fit feature, A. Mates with the Base and TRIMANO Attachment part to make up the ball-socket mechanism, B. The maximum service life of the Camera Mount is 100 uses.</p>
	<p><b>2a. Thumb Screw-</b> Intended to be twisted by hand, to lock and unlock the ball-socket positioning mechanism. The maximum service life of the Thumb Screw is 1156 uses.</p>
	<p><b>2b. Thumb Screw-</b> Intended to be twisted by hand, to lock and unlock the Light Guide from the assembly. The maximum service life of the Thumb Screw is 1156 uses.</p>



**3. Light Guide Holder-** Secures a compatible Light Guide in place using a thumb screw. Also mates to the TRIMANO Attachment via a puzzle piece feature, C. The maximum service life of the Light Guide Holder is 1156 uses.



**4. TRIMANO Attachment-** Connects and secures to TRIMANO Adapter. The maximum service life of the TRIMANO Attachment is 1156 uses.



**5. Base-** Intermediate part between the TRIMANO Attachment and the Camera Mount. The maximum service life of the Base is 1156 uses.

## Markings on the 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder

- Model Number
- CE Mark
- Arthrex Logo
- Component Lot Numbers
- Component Part Numbers
- Unique Device Identifier (UDI)

## Compatible Products

The 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder is intended to be used with the following instruments:

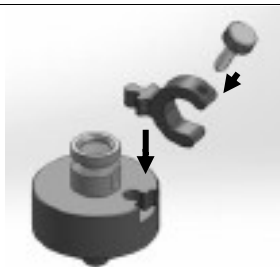
- AR-3210-0023  
(4K Synergy<sup>UHD4</sup> Camera Head, autoclavable)
- AR-3210-0025  
(4K Synergy<sup>UHD4</sup> C-Mount Camera Head, autoclavable)
- AR-3210-0028  
(4K Synergy<sup>UHD4</sup> C-Mount w/20 foot cable, autoclavable)
- AR-3240-3527  
(Fused Light Guide, Wolf, 3.5 mm x 274 cm)
- AR-3240-5027

- (Fused Light Guide, Wolf, 5 mm x 274 cm)
- AR-3240-5040  
(Fused Light Guide, Wolf, 5 mm x 406 cm)
- AR-1640 (TRIMANO Support Arm)
- AR-1641 (TRIMANO Adapter)

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## Assembly and Disassembly\*

**Step 1 (Optional):** Attach the Light Guide Holder to the TRIMANO Attachment via the puzzle slot. Thread the Thumb Screw into the Light Guide Holder.



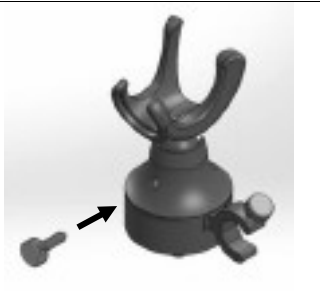
**Step 2:** Slide the Camera Mount into the Base and pull up to lock into place.



**Step 3:** Slide the Base onto the TRIMANO Attachment.



**Step 4:** Thread the Thumb Screw into the Base to lock the Camera Mount into position.



\*For disassembly repeat steps 1 through 4 in reverse.

**Note:** *The TRIMANO Attachment is a permanent assembly and is not intended to be disassembled.*

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## Preparation for Use

### Visual Inspection & Functional Check

- Perform a visual inspection of the device prior to initial use and each subsequent use as follows:
  - Inspect the entire Camera Holder for damage such as dents, cracks, bending and sharp edges. Do not use if the device exhibits any signs of damage.
- Perform a functional check of the device prior to use and each subsequent use as follows:
  - Lock and unlock the ball-socket and rotate the ball-socket mechanism. Do not use if the device fails any of the functional checks as described above.

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## Instructions for Use

### Installation of Camera Head



Figure 2: Installing Camera into Snap-Fit Camera Mount

- Place the Camera Head into the Camera Mount with the Camera Head cable positioned as shown above. Slide the Camera Head back (in the direction indicated by the arrow) until the snap feature engages with the groove in the back body of the Camera Head.



## Removal of Camera Head

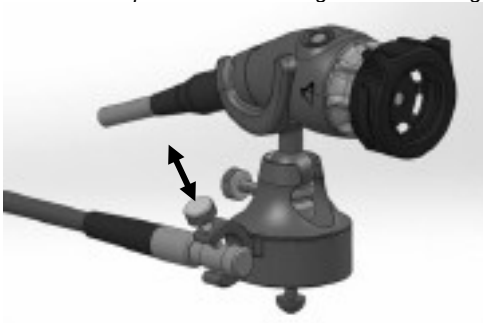


Figure 3: Removing camera from snap-fit Camera Mount

- To release the Camera Head from the Camera Mount, hold the Camera Mount arms securely and pull Camera Head up (in the direction of the arrow shown above). Push the Camera Head until it is released. Care should be taken to maintain a secure grip on the Camera Head to prevent accidental release or damage.

## Installation/ Removal of Light Guide

*[Optional attachment to provide additional light to the viewing area.]*



**Figure 4: Installing Light Guide into Light Guide Holder**

- To install the Light Guide, slide the Light Guide into the Light Guide Holder until the metal segment of the Light Guide is under the Thumb Screw (as shown). Twist the Thumb Screw to secure the Light Guide in place. To remove, loosen the Thumb Screw and remove the Light Guide.

## Installation/Removal to TRIMANO Arm

- Refer to the TRIMANO Support Arm Operating Instructions section “Mounting the quick change coupling with sterile cover” and “Removing the quick change coupling” for instructions on how to install and remove the Camera Holder to and from the TRIMANO Support Arm.

## Operation

- To adjust the position of the Camera Holder, loosen the Thumb Screw securing the ball-socket mechanism, position the Camera Head as desired, and re-tighten the Thumb Screw to lock into place.

## Inspection, Handling & Maintenance

- Inspect the Camera Holder for damage prior to use and at all stages of handling thereafter.
- Do not use the Camera Holder if it is damaged.
- Care should be taken when handling the Camera Holder.

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## **Cleaning and Sterilization**

Devices must be adequately cleaned and sterilized prior to use or re-use. All devices are to be cleaned and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile devices. Effective cleaning is an indispensable requirement for an effective sterilization of the devices.

### Point of Use Preparation, Containment, and Transportation

It is recommended that devices are reprocessed within a maximum of 2 hours of use. At point of use, soiled devices must be removed from trays and moistened to prevent debris from drying before transportation to the reprocessing area for cleaning procedures. Soaking in enzyme solutions facilitates cleaning, especially in devices with complex features and hard-to-reach areas (lumens, etc.). These enzyme solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on devices. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed. Devices

should be contained and transported in a closed, puncture-proof device to ensure safety.

### Detergent Selection

Consider the following points during selection of the cleaning detergent:

1. Suitability of the cleaning agent for ultrasonic cleaning (no foam development).
2. Compatibility of the cleaning agent with the devices. Arthrex recommends the use of neutral pH or enzymatic cleaning agents. Alkaline agents may be used to clean devices in countries where required by law or local ordinance, or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) or Creutzfeldt - Jakob disease (CJD) are a concern (applies only outside of the US). Arthrex does not recommend the use of a specific brand of cleaning agent. Enzol<sup>®</sup> and neodisher<sup>®</sup> MediClean forte were utilized during the validation of these instructions.  
**Caution: Low acid or alkaline solutions are not**

**recommended, as they corrode metal parts and compromise plastics.**

Follow the instructions of the detergent manufacturer regarding use concentration and temperature for either manual or automated cleaning. Please use only freshly prepared solutions as well as only purified (critical, e.g. RO or DI) water for final rinse.

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## **Cleaning Instructions**

The end user has the option to utilize either the Manual Cleaning procedure or the Automated Cleaning procedure. If possible, the Automated Cleaning procedure (Washer-Disinfector) should be used for cleaning. The Manual Cleaning procedure should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of the manual procedure should be considered. Manual cleaning may require onsite validation by the healthcare facility and appropriate procedures should be in place to avoid human factor variability.

## Manual Cleaning

- Disassemble the Camera Holder.
- Immediately rinse the Camera Holder under cool running utility water to remove gross soil.
- Scrub the Camera Holder with a soft-bristled brush, paying special attention to areas where debris might accumulate, to further remove gross soil.
- Rinse the device thoroughly with utility water.
- Prepare a detergent solution using utility water in an ultrasonic unit. Soak and sonicate for a minimum of 20 minutes.
- Remove the devices from the cleaning solution and rinse at least one minute with critical water.
- Check the Camera Holder for visible soil. Repeat cleaning if soil is visible and re-inspect.
- Dry the Camera Holder with a soft, low-linting cloth and/or filtered medical grade air.
- Proceed to Sterilization.

## Automated Cleaning

- Disassemble the Camera Holder.
- Load the Camera Holder components in a washer-disinfector such that all surfaces of the device are accessible to cleaning and appropriate draining.
- Run an automated wash cycle with fundamentally approved efficiency of the washer-disinfector (for example, CE marking according to ISO 15883 or FDA approval/clearance/registration).  
Recommended Washing Cycle Parameters:
  - 2 minute cold utility water pre-wash
  - 3 minute detergent wash (enzymatic or alkaline agent) at detergent manufacturer's temperature recommendation
  - 15 second rinse with hot utility water
  - 1 minute thermal rinse at  $176^{\circ}\pm 9^{\circ}\text{F}$  ( $80^{\circ}\pm 5^{\circ}\text{C}$ ).
  - 6 minute drying phase at high temperature.
- Check the Camera Holder for visible soil. Repeat cleaning if soil is visible and re-inspect.
- Dry the Camera Holder with a soft, low-linting cloth and/or filtered medical grade air.
- Proceed to Sterilization.



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## Sterilization Instructions

### Sterile Packaging

**Singly:** Single devices should be packed as to ensure that the pack is large enough to contain the device without stressing the seals. Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. If a wrap is utilized, it should be completed following AAMI double-wrap or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body).

**Sets:** Where appropriate, cleaned and inspected devices should be placed into trays/cases as provided or in general-purpose sterilization trays. The total weight of trays/cases should not exceed 11.4 kg/25 lbs. (other local limits below 11.4 kg/25 lbs. may apply). Trays/Cases should be double wrapped following AAMI or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body).

## Sterilization

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

<b>RECOMMENDED STEAM STERILIZATION PARAMETERS</b>			
<b>Cycle</b>	<b>Minimum Exposure Temperature</b>	<b>Minimum Exposure Time</b>	<b>Minimum Drying Time</b>
<b>Gravity-Displacement</b>	121°C (250°F)	30 Minutes	30 Minutes
	132°C (270°F)	15 Minutes	30 Minutes
<b>Pre-vacuum</b>	132°C (270°F)	4 Minutes	30 Minutes

Drying times vary according to load size and should be increased for larger loads.



**PRECAUTION:** After sterilization, ensure that the devices are allowed to adequately cool before attaching to another device.

<b>HYDROGEN PEROXIDE STERILIZATION METHODS</b>	
<b>System</b>	<b>Cycles</b>
Steris® Systems	<ul style="list-style-type: none"><li>• V-PRO® 1 Low Temperature Sterilization System [Standard Cycle]</li><li>• V-PRO® 1 Plus Low Temperature Sterilization System [Lumen and Non-lumen Cycles]</li><li>• V-PRO® maX Low Temperature Sterilization System [Lumen, Non-lumen and Flexible Cycles]</li><li>• V-PRO® 60 Low Temperature Sterilization System [Lumen and Non-lumen Cycles]</li></ul>

## HYDROGEN PEROXIDE STERILIZATION METHODS

System	Cycles
STERRAD® Systems	<ul style="list-style-type: none"><li>• Sterrad® System 100S [Short Cycle]</li><li>• Sterrad® System NX [Standard Cycle]</li><li>• Sterrad® System 100NX [Standard Cycle]</li></ul>

### Material Compatibility

In addition to the Sterilization chemicals listed above, the Camera Holders are material compatible with Cidex OPA. No SAL claims are made with Cidex OPA.



**WARNING: Use of Sterilants or Chemicals other than those listed in the Cleaning and Sterilization section may result in the compromise of the device's safety and effectiveness. Use of Sterilants or Chemicals other than those listed in the Cleaning and Sterilization section shall void the product's warranty.**

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## Storage & Transport

The 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder is manufactured from non-degradable materials and therefore does not have a limited shelf life when stored in a clean dry environment.

The following storage recommendations apply when the 4K Synergy<sup>UHD4</sup> TRIMANO Camera Holder is stored in a non-sterile condition within its original packaging:

Temperature: -40°F - 122°F [-40°C - 50°C]

Humidity: 10% - 90%, non-condensing

Pressure: 500hPa – 1060hPa

## Additional Storage Requirements

- Avoid direct sunlight
- Store the Camera Holder in its original packaging or in a screen tray/container.
- Ensure that the Camera Holder is stored securely
- Apply the appropriate national provisions when storing in a sterile condition.

## Disposal

- Observe country-specific regulations and laws for the disposal of medical products.

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## Technical Support

1-800-391-8599



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