



AR-3210-0011

**4K Synergy UHD4 Trimano Camera Holder
User Manual**

Endoscopic Accessories



Arthrex, Inc.

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Naples, FL 34108, USA
(800)-934-4404

Device Symbols Used:



Manufacturer



Consult Instructions for Use



Authorized Representative in the European Community



Quantity



Lot Number



Catalog Number

R_x ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician



Non-sterile



Storage Humidity Range



Storage Pressure Range



Storage Temperature Range



Keep Dry



Fragile



CE Mark

IFU Symbols Used:



Do not use if damaged



WARNING: Instructions for preventing personal injury



CAUTION: Instructions for the intended use of the device. Damage to the equipment is possible if these instructions are not followed.



Instruction

Warning and Cautions



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



WARNING: Read the Arthrex Synergy^{UHD4} System [950-0047-00] and TRIMANO 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 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.



CAUTION: Subjecting the 4K Synergy UHD4 Trimano Camera Holder to excessive forces may result in damage. Risk of injury is possible during use if the 4K Synergy UHD4 Trimano Camera Holder is damaged.

- Perform visual inspection and functional check prior to use (see “Visual Inspection and & Functional Check” section on Page 13).

Instructions for Use

1. About this Document

The current version of this document can be found on the internet at www.arthrex.com. You may also request this document from Arthrex.

Users of the 4K Synergy UHD4 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 UHD4 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

- Device is NOT an Endoscopic Device/Accessory.
- 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 UHD4 Trimano Camera Holder may only be used by trained medical professionals.

- To ensure assembly contains all required parts, refer to the “4K Synergy UHD4 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 UHD4 Trimano Camera Holder Overview

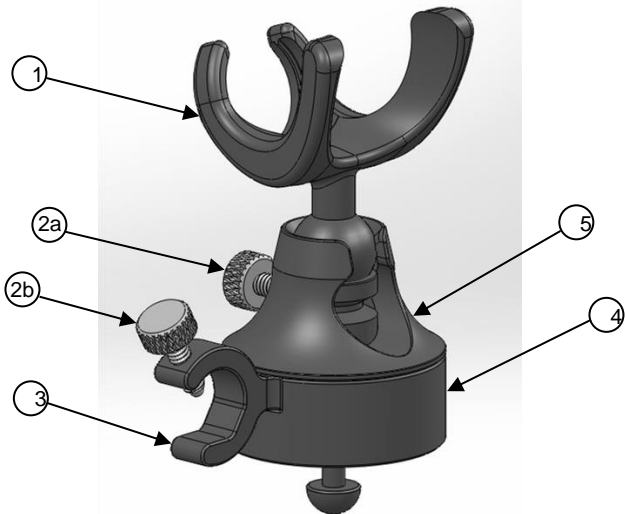
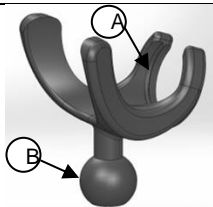
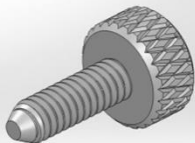


Figure 1: Arthrex 4K Synergy UHD4 Trimano Camera Holder, AR-3210-0011

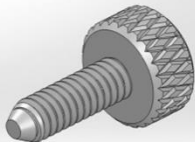
4K Synergy UHD4 Trimano Camera Holder Parts and Functions



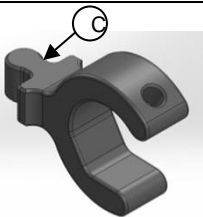
1. Camera Mount- Secures an Arthrex Camera Head via snap-fit feature, A. Mates with the Base and TRIMANO Attachment part to make up the ball-socket mechanism, B. The maximum service life of the Camera Mount is 100 uses.



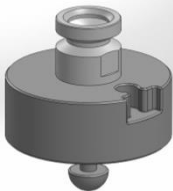
2a. Thumb Screw- Intended to be twisted by hand, to lock and unlock the ball-socket positioning mechanism. The maximum service life of the Thumb Screw is 1156 uses.



2b. Thumb Screw- 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.



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 UHD4 Trimano Camera Holder

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

Compatible Products

The 4K Synergy UHD4 Trimano Camera Holder is intended to be used with the following instruments:

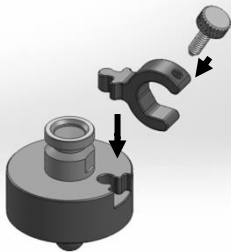
- AR-3210-0023
(4K Synergy UHD4 Camera Head, autoclavable)
- AR-3210-0025
(4K Synergy UHD4 C-Mount Camera Head, autoclavable)
- AR-3210-0028
(4K Synergy UHD4 C-Mount w/20 foot cable, autoclavable)
- AR-3240-3527
(Fused Light Guide, Wolf, 3.5 mm x 274 cm)

- 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)

Assembly and Disassembly*

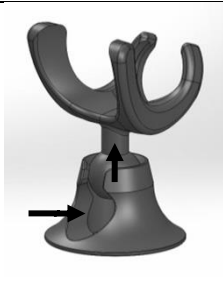
Step 1 (Optional):

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.



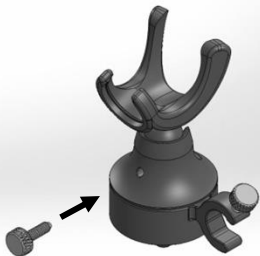
Step 3:

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.*

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.

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

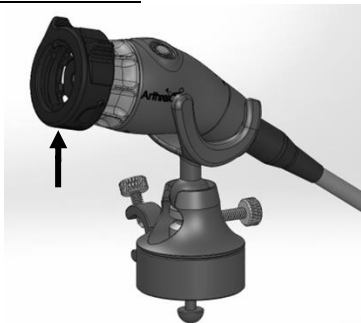


Figure 3: Removing camera from snap-fit Camera Mount

- 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 arrows 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.]

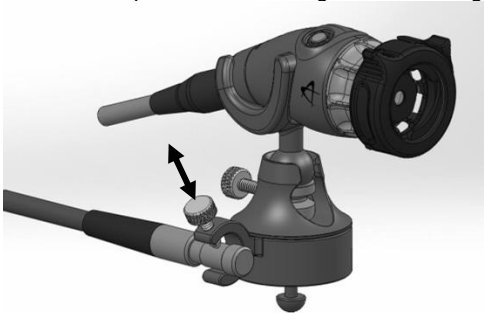


Figure 4: Installing Light Guide into Light Guide Holder

- 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.


Cleaning and Sterilization

Containment and Transportation

- Forward the Camera Holder to a decontamination station, immediately after use. Transport in a closed container to prevent propagation of biological contaminants.

Preparations for Cleaning and Sterilization

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

 CAUTION: Low acid or high alkaline solutions are not recommended as they corrode metal parts and anodized aluminum and compromise polymer plastics, such as FEP (Fluorinated ethylene propylene), ABS (Acrylonitrile Butadiene Styrene), Ultem™, Lexan™, and Cyclocac™.



WARNING: Wear protective gloves, clothing and face mask for cleaning of contaminated equipment.

- Follow the appropriate country-specific guidelines, standards and requirements for cleaning and sterilization.
- Clean and sterilize the Camera Holder prior to initial use, as well as after each subsequent use.
- Disassemble the camera holder prior to cleaning and sterilization.
- All cleaning should be performed with the appropriate cleaning solution. Cleaning solutions may include, but are not limited to ENZOL® enzymatic, Neodisher® Mediclean Forte, and Thermosept® alka clean.
- Repeated cleaning and sterilization does not adversely affect the Camera Holder.

Cleaning Instructions

Ultrasonic Cleaning

- Disassemble the Camera Holder
- Place the Camera Holder in an ultrasonic cleaning unit for a minimum of 20 minutes and process in accordance with the equipment manufacturer's instructions.
- Rinse the Camera Holder thoroughly with water following the ultrasonic process.
- Check the Camera Holder for visible soil. Repeat cleaning if soil is visible.
- Ensure that there are no residual cleaning agents on the Camera Holder after cleaning.
- Visually inspect the Camera Holder for any signs of damage

Manual Cleaning

- Disassemble the Camera Holder
- Immediately rinse and clean the Camera Holder to effectively remove and prevent drying of adherent blood, mucus, etc.
- Scrub the Camera Holder with a soft brush, paying special attention to areas where debris might accumulate.
- Rinse the device thoroughly with water following the cleaning process.
- Check the Camera Holder for visible soil. Repeat cleaning if soil is visible.
- Ensure that there are no residual cleaning agents on the Camera Holder after cleaning.
- Visually inspect the Camera Holder for any signs of damage.

Automated Cleaning

- Disassemble the Camera Holder.
- Load the Camera Holder components in a washer such that all surfaces of the device are accessible to cleaning and appropriate draining
- Run the automatic wash cycle according to the following – minimum cycle parameters:
 - 2 minute cold prewash $68^{\circ}\pm 9^{\circ}\text{F}$ ($20^{\circ}\pm 5^{\circ}\text{C}$).
 - 3 minute cleaning wash (enzymatic or alkaline agent) at $140^{\circ}\pm 9^{\circ}\text{F}$ ($60^{\circ}\pm 5^{\circ}\text{C}$).
 - 15 second rinse at $140^{\circ}\pm 9^{\circ}\text{F}$ ($60^{\circ}\pm 5^{\circ}\text{C}$).
 - 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.
- Dry the Camera Holder with a soft cloth
- Visually inspect the Camera Holder for any signs of damage
- Ensure that there are no residual cleaning agents on the Camera Holder after cleaning.

Sterilization Instructions

- Prior to each sterilization cycle, the Camera Holder must be cleaned according to the cleaning instructions in this user manual.
- Ensure the Camera Holder is disassembled
- Sterilize the Camera Holder in suitable packaging to prevent subsequent contamination.
- Steam and STERRAD sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instruction.
- Cooling – The Camera Holder must be adequately cooled after removal from the sterilizer. It should not be handled during the cooling process. Do not place the device on a cold surface or immerse in a cold fluid.
- Visually inspect the Camera Holder for any signs of damage

STERRAD Sterilization Cycle Identification:

STERRAD Cycle Information	
Sterilization Protocol	Details
STERRAD System 100S/NX/100NX	The 4K Synergy UHD4 Trimano Camera Holder is validated for sterilization using the STERRAD 100S/NX/100NX cycles and following the STERRAD 100S/NX/100NX System Instructions.

Steam Sterilization Cycle Identification:

Follow your country- specific guidelines, standards, and requirements.

STERILIZATION PARAMETER: FOR THE USA ONLY:			
	Exposure	Exposure	Drying
	Temperature	Time	Time
Gravity- Displacement Steam Sterilization Cycle	121°C (250°F)	30 Minutes	15 to 30 Minutes
	132°C (270°F)	15 Minutes	15 to 30 Minutes
	135°C (275°F)	10 Minutes	30 Minutes
Pre-vacuum Cycle	132°C (270°F)	4 Minutes	20 to 30 Minutes
	135°C (275°F)	3 Minutes	16 Minutes
STERILIZATION PARAMETER: FOR OUSTIDE THE USA ONLY:			
	Exposure	Exposure	Drying
	Temperature	Time	Time
Gravity- Displacement Steam Sterilization Cycle	132°C - 135°C (270°F - 275°F)	15 Minutes	15 to 30 Minutes
	121°C (250°F)		
Pre-vacuum Cycle	132°C - 135°C (270°F - 275°F)	4 Minutes	20 to 30 Minutes

Storage & Transport

The 4K Synergy UHD4 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 UHD4 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.

Technical Support
1-800-391-8599



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