



950-0036-02 Revision 0
09/2020

Arthrex Starfish™ Scope Rotation Attachment Insert Manual

Endoscopic Accessories



Rx ONLY

Arthrex, Inc.

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1.0 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.

2.0 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.

3.0 Warnings/Cautions:

- 3.1 Prior to use, read this manual carefully and become familiar with the operation of the device and the accessories before use during surgical procedures.
- 3.2 Prior to use, read the entire Arthrex Synergy^{HD3™} System [950-0027-XX] or Synergy^{UHD4™} System [950-0047-XX] video instruction manuals before use during surgical procedures.
- 3.3 Risk of injury due to faulty Starfish™.
 - 3.3.1 Carry out visual inspection and function check prior to each use.
 - 3.3.2 Only use Starfish which are in perfect condition.
- 3.4 Starfish are delivered non-sterile as reusable products. Ensure that the processing, material, and personnel are suitable for achieving the results necessary.
 - 3.4.1 Caution: Federal law restricts this device to sale by or on the order of a physician.
 - 3.4.2 This device is intended to be used by a trained medical professional.

- 3.4.3 Biohazard waste, such as explanted devices, needles and contaminated surgical equipment, should be safely disposed of in accordance with the institutions policy.
- 3.4.4 Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.
- 3.4.5 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.

4.0 About This Document

This document describes the correct handling, functioning, and reprocessing of the Arthrex Starfish Scope Rotation Attachments. This document may not be used to carry out examinations or surgeries, nor may it be used for training purposes.

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

Users of the Starfish attachments are encouraged to contact their representatives if, in their professional judgment, they require more comprehensive information on its use and care.

5.0 Intended Use

Arthrex Synergy Starfish Scope Rotation Attachments are used to rotate eye-coupler endoscopes during use. The Arthrex Synergy C-Mount Starfish Scope Rotation Attachment is used to rotate C-Mount arthroscopes during use. Both attachments will be referred to as the Starfish unless there is the need to differentiate between the two.

6.0 Safety Information

The Starfish may only be used by trained medical professionals in medical facilities.

- 6.1 After receipt of device(s), inspect the Starfish for completeness and damage.
- 6.2 Read, observe and store these instructions and any other applicable instructions.
- 6.3 Use Starfish only as intended.
- 6.4 For storage, transport and processing, ensure that the Starfish is not subjected to mechanical strain.

7.0 Inspection Handling & Maintenance

- 7.1 Inspect the Starfish for damage prior to use and at all stages of handling thereafter.
- 7.2 If damage is detected, do not use the Starfish prior to consulting the manufacturer for guidance.
- 7.3 Do not subject the Starfish to impact forces. Set the Starfish down carefully.
- 7.4 Do not bend the Starfish or use as a prying tool.

8.0 AR-3370-0006, Starfish Attachment Overview

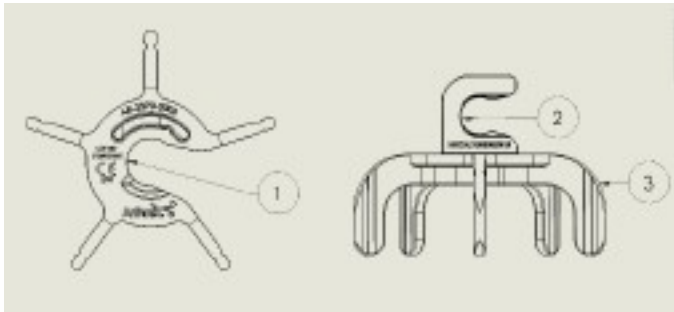


Figure 8-1: AR-3370-0006 Starfish Attachment

8.1 Starfish Features:

1. **Scope Snap-Fit:** Accepts and locks into place a compatible scope.
2. **Light Post Snap-Fit:** Accepts and locks into place a compatible light post.
3. **Thumb Tabs:** Intended to be pushed by hand to rotate the scope.

8.2 Markings on the Starfish

- Article Number
- Lot Number
- CE Mark
- Arthrex Logo
- Unique Device Identifier (UDI)

8.3 Compatible Products

The Starfish is intended to be used with the following instruments:

- AR-3210-XXXX (Arthrex Synergy Camera Heads)
- AR-3350 4030 (4mm, 30° eyecup Arthroscope)
- AR-3350 4070 (4mm, 70° eyecup Arthroscope)
- AR-3350 5030 (Sheathless, 30° eyecup Arthroscope)
- AR-3350 5070 (Sheathless, 70° eyecup Arthroscope)

9.0 AR-3370-0008, C-Mount Starfish Attachment Overview:

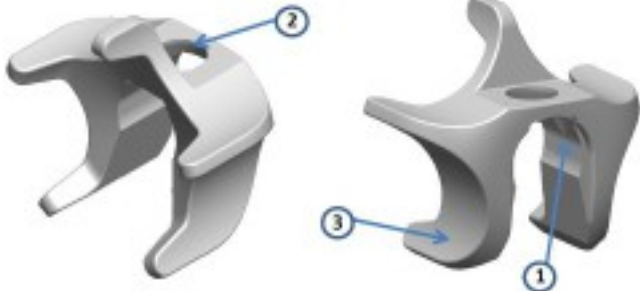


Figure 9-1: AR-3370-0008 C-Mount Starfish Attachment

9.1 C-Mount Starfish Features

1. **Scope Snap-Fit** — Accepts and locks into place a compatible scope.
2. **Light Post Alignment Hole** — Accepts and locks into place a compatible light post.
3. **Thumb Tabs** – Intended to be pushed by hand, to rotate the scope.

9.2 Markings on the C-Mount Starfish

- Article Number
- Lot Number
- CE Mark
- Arthrex Logo
- Unique Device Identifier (UDI)

9.3 Compatible Products

The C-Mount Starfish is intended to be used with the following instruments:

- AR-3210-XXXX (Arthrex Synergy^{HD3} and UHD4 C-Mount Camera Heads)
- AR-3355-3030 (C-Mount Arthroscope, 30°, 3x138mm, HD)
- AR-3355-3070 (C-Mount Arthroscope, 70°, 3x140mm, HD)
- AR-3355-4000 (C-Mount Endoscope, 0°, 4x152.5mm)
- AR-3355-4030 (C-Mount Arthroscope, 30°, 4x152.5mm)
- AR-3355-4030H (C-Mount Hip Arthroscope 30°, 3.5x 202mm)

- AR-3355-4030R (C-Mount Arthroscope, Reverse Light Post, 30°, 4x152.5mm)
- AR-3355-4070 (C-Mount Arthroscope, 70°, 4x156.5mm)
- AR-3355-4070H (C-Mount Hip Arthroscope 70°, 3.5x 204mm)
- AR-3355-5230 (4K C-Mount Arthroscope, 30°, 4.8x 152.5mm)
- AR-3355-5270 (4K C-Mount Arthroscope, 70°, 4.8x 156mm)
- AR-3355-5430 (4K C-Mount Sheathless Arthroscope, 30°, 5x160mm)
- AR-3355-5470 (4K C-Mount Sheathless Arthroscope, 70°, 5x162mm)

10.0 Preparation for Use

10.1 Visual Inspection & Function Check



WARNING: Risk of injury due to faulty Starfish.

- 10.1.1 Carry out visual inspection and function check prior to initial use and each subsequent use.
- 10.1.2 Only use Starfish which are in perfect condition.
- 10.1.3 Clean/Disinfect and sterilize the Starfish prior to initial use, as well as each subsequent use of the Starfish.
- 10.1.4 Ensure that there are no residual cleaning agents or disinfectants on the Starfish.
- 10.1.5 Inspect the entire Starfish for contaminants and damage of any type, such as dents, scratches, cracks, bending and/or sharp edges.



WARNING: Do not bend the endoscope optics while installing or removing the Starfish. Handle the endoscope by the light post barrel and eyepiece only.

11.0 Installation

11.1 AR-3370-0006, Starfish

1. Press the Starfish Scope Snap-Fit onto a compatible endoscope such that the Thumb Tabs reach back towards the camera head.



Figure 11-1: Installing Scope Snap-Fit

2. Rotate the Starfish around the scope until the Light Post Snap-Fit engages the light post.



Figure 11-2: Installing Light Post Snap-Fit

11.2 AR-3370-0008, C-Mount Starfish

Align the light post hole on the C-Mount Starfish to the light post on the scope. Press the Starfish Scope Snap-Fit onto a compatible C-Mount arthroscope such that the thumb tabs reach back towards the camera head.



**Align light post
hole with light
post and snap
together**

Figure 11-3: Installing Scope Snap-Fit

12.0 Operation

- 12.1 (AR-3370-0006 Starfish only) When using the Starfish attachment in conjunction with a camera head, allow the camera head's scope mount to spring closed around the scope automatically. Do not manually adjust the tightness of the scope mount.
- 12.2 During use, press the Thumb Tabs to rotate the scope.
- 12.3 Prepare the Starfish for reprocessing immediately after use to prevent surface damage.

13.0 Reprocessing Limitations

Repeated processing has minimal effect on the Starfish. End of life is normally determined by wear and damage due to intended use.

14.0 Cleaning and Disinfection

Devices must be adequately cleaned and sterilized prior to use or re-use. All devices are to be cleaned, disinfected, 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 effective sterilization of the devices.

CAUTION: If the Starfish is cracked or damaged, properly dispose of the device.

14.1 Point-of-Use Preparation, Containment, and Transportation

14.1.1 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.

14.2 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[®] and neodisher[®] 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.

14.3 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.

14.4 Preliminary Cleaning

- Remove excess soil from devices, especially in areas such as joints and crevices, by cleaning the surfaces with a sponge or brush under cold running water or with a non-shedding disposable wipe for a minimum of 1 minute.
- Rinse the devices at least 1 minute under running utility water (temperature < 35°C/95°F). Special attention should be given to lumens, joint, crevices, and other hard-to-reach areas.
- Immerse the devices in cleaning solution inside an ultrasonic bath. While immersed in solution,

brush the devices for 2 minutes using a soft-bristled brush. Special attention should be given to lumens, joints, crevices, and other hard-to-reach areas. Lumens should be brushed with appropriate diameter and length bristle sizes for the particular lumen. Actuate movable parts at least (5) times during soaking, as applicable.

- After brushing, turn on ultrasonic power and soak and sonicate for 10 minutes at a minimum of 40 ± 5 kHz. Ensure devices are in the open position and that lumens have complete contact with cleaning solution during soaking.
- Remove the devices from the cleaning solution and rinse at least 1 minute with utility water. Thoroughly and aggressively rinse lumens, joints, crevices, and other hard-to-reach areas.
- After the completion of preliminary cleaning, the end user has the option to perform either Manual Cleaning and Disinfection **or** Machine (Automated) Cleaning and Thermal Disinfection (preferred).

14.5 Manual Cleaning and Disinfection

- 14.5.1 Following preliminary cleaning, the instructions for Manual Cleaning and Disinfection may be followed as an alternative cleaning method to Machine (Automatic) Cleaning and Thermal Disinfection.
- 14.5.2 After preliminary cleaning is complete, repeat steps 1-5 provided in the Preliminary Cleaning section of this DFU, including rinsing, immersion and sonication, and post-rinsing. Final rinsing should be completed with purified (critical, e.g. RO or DI) water.
- 14.5.3 Check devices for visible soil. Repeat cleaning if soil is visible and re-inspect.
- 14.5.4 Soak the devices for the given soaking time (provided by the disinfectant manufacturer) in disinfectant solution so that the devices are sufficiently covered. Make sure that there is no contact between the devices. Ensure that the device is in the open position during soaking. Actuate movable parts at least five times during disinfection, as applicable.

14.5.5 Remove the devices from the disinfectant solution and rinse per disinfectant manufacturer's instructions.

14.5.6 Dry devices thoroughly utilizing filtered medical grade air or a soft, clean, and low-linting cloth. Proceed to Sterilization section.

14.6 Machine (Automatic) Cleaning and Thermal Disinfection

Considerations for the selection of the washer-disinfector:

- Capable of providing an approved program for thermal disinfection (appropriate exposure time and temperature according to A_0 concept)
- Final rinse completed with purified (critical, e.g. RO or DI) water and utilizes only filtered air for drying

14.6.1 Load the Starfish in the washer-disinfector such that all design features are accessible to cleaning and such that design features that might retain liquid can drain (hinges should be open and cannulations/holes positioned to drain).

14.6.2 If using alkaline cleaning agents, a neutralization step should be utilized as appropriate.

14.6.3 Run an automated wash cycle with fundamentally approved efficiency of the washer-disinfector (for example, CE marking according to EN ISO 15883 or FDA approval/clearance/registration).

14.7 The following minimum recommended wash cycle parameters were utilized by Arthrex during the validation of these instructions.

Recommended Washing Cycle Parameters

Phase	Recirculation Time	Temperature	Detergent
Pre-Wash	3 Minutes	Cold Water	N/A
Cleaning Wash	10 Minutes	Follow detergent manufacturer's recommendation	Enzymatic or alkaline agent
Neutralization Rinse (optional)	2 Minutes	Follow detergent manufacturer's recommendation	Neutralizing agent (as needed)
Rinse	3 Minutes	Cold Water	N/A
Thermal Rinse	5 Minutes	90°C (194°F)	N/A
Drying	Minimum 6 Minutes or until visibly dry	Minimum 100°C (212°F)	N/A

14.7.1 Remove the devices from the washer-disinfector following the completion of the program and check devices for visible soil. Repeat cleaning if soil is visible and re-inspect; otherwise, proceed to Sterilization section.

15.0 Sterilization

Sterilization is to be performed following cleaning, disinfection, and sterile packaging prior to use.

15.1 Sterile Packaging

- 15.1.1 **Singly:** Single devices should be packed as to ensure that the pack is large enough to contain the Starfish without stressing the seals. Packaging should be completed utilizing a pouch or wrap, which conforms to the recommended specifications for steam sterilization as outline above. If a wrap is utilized it should be completed following AAMI or equivalent guidelines with an appropriate wrap. An appropriate wrap is one that, for example, is cleared by the FDA or the local governing body at the point of use.
- 15.1.2 **Sets:** Where appropriate, cleaned, disinfected 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. An appropriate wrap is one that, for example, is cleared by the FDA or the local governing body at the point of use.

15.2 Steam Sterilization

15.2.1 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.

Recommended Steam Sterilization Parameters			
Cycle Type	Minimum Exposure Temperature	Minimum Exposure Time	Minimum Drying Time¹
Gravity-Displacement	132°C (270°F)	15 minutes	30 minutes
US Pre-Vacuum	132°C (270°F)	4 minutes	30 minutes
UK Pre-Vacuum	134°C (273°F)	3 minutes	30 minutes

¹Drying times vary according to load size and should be increased for larger loads.

15.2.2 Cooling – The Starfish must be adequately cooled, after being removed from the sterilizer. It should not be touched during the cooling process. Do not place the Starfish on a cold surface or immerse in a cold fluid.

15.3 Hydrogen Peroxide Sterilization

The Starfish can be sterilized by the following Hydrogen Peroxide methods:

System	Cycles
STERRAD®	STERRAD® System 100S, Short Cycle STERRAD® System NX, Standard Cycle STERRAD® System 100NX, Standard Cycle

15.4 Material Compatibilities

In addition to the Sterilization chemicals listed above, the AR-3370-0006 and the AR-3370-0008 Starfish attachments 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 sections 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 sections shall void the product's warranty.

16.0 Storage & Transport

16.1 Non-sterile devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not raise any question of device stability when stored under recommended conditions. It is the responsibility of the end-user to ensure devices, once sterilized, are stored in such a way as to maintain the sterility of the device until use. Sterile, packaged devices should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, and temperature/humidity extremes. Sterile device packages should be carefully examined prior to opening to ensure that package integrity has not been compromised. Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, shows any evidence of tampering, or has been exposed to moisture, the device or set must be cleaned, repackaged, and sterilized.

16.2 As long as the Starfish is stored non-sterile in the original packaging, the following storage conditions apply:

- Temperature: -40°F - 122°F [-40°C - 50°C];
- Humidity: 10% - 90%, non-condensing;
- Pressure: 500hPa – 1060hPa

16.3 Additional Storage Requirements:

- Avoid direct sunlight;
- Store Starfish either in the original packaging or in a screen tray/container;
- Ensure that the Starfish is stored securely;
- Apply the respective valid national provisions when storing in a sterile condition.

17.0 Disposal

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

18.0 Special Precaution: Transmissible Spongiform Encephalopathy Agents

It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy Agents.

The agents for transmission of Creutzfeldt-Jakob disease (CJD) are believed to be resistant to normal processes of disinfection and sterilization and therefore the normal processing methods of decontamination and sterilization as described above may not be appropriate where CJD transmission is a risk.

In general, the tissues that come into contact with orthopedic surgical instruments are those of low TSE infectivity. However, particular precautions should be taken when handling instruments that have been used on known, suspected, or at-risk patients.

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