Arthrex Starfish Scope Rotation Attachment Insert Manual

Endoscopic Accessories

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1.0 Symbols Used:
1.1 Device Symbols:

- Manufacturer
- See Instructions for Use
- Authorized Representative in the European Community
- Quantity
- Lot Number
- Catalog Number
- 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
1.2 IFU Symbols:

⚠️ Warning: Instructions for preventing personal injury.

2.0 Warnings/Cautions:

2.1 Prior to use, read this manual carefully and become familiar with the operation of the device and the accessories before use during surgical procedures.

2.2 Prior to use, read the entire Arthrex Inc. Synergy\textsuperscript{HD3} System [950-0027-00] or Synergy\textsuperscript{UHD4} System [950-0047-00] video instruction manuals before use during surgical procedures.

2.3 Risk of injury due to faulty Starfish.

2.3.1 Carry out visual inspection and function check prior to each use.

2.3.2 Only use Starfish which are in perfect condition.
2.4 Starfish are delivered unsterile as reusable products. The state-of-the-art and national laws require the observance of validated processes. In general, users are responsible for the validation of their cleaning and sterilization processes. Ensure that the processing, material, and personnel are suitable for achieving the results necessary.

2.4.1 Observe any and all valid local operator regulations for all manual cleaning and drying processes.

2.4.2 Clean/disinfect and sterilize the Starfish prior to initial use, as well as each subsequent use.

2.4.3 Bring the Starfish to the decontamination area as soon as possible after use. Observe valid protective measures to prevent contaminating the environment.
3.0 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.
4.0 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.

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

5.1 After receipt of device(s), inspect the Starfish for completeness and damage.

5.2 Read, observe and store these instructions and any other applicable instructions.

5.3 Use Starfish only as intended.

5.4 For storage, transport and processing, ensure that the Starfish is not subjected to mechanical strain.
6.0 Inspection Handling & Maintenance

6.1 Inspect the Starfish for damage prior to use and at all stages of handling thereafter.

6.2 If damage is detected, do not use the Starfish prior to consulting the manufacturer for guidance.

6.3 Do not subject the Starfish to impact forces. Set the Starfish down carefully.

6.4 Do not bend the Starfish or use as a prying tool.
7.0 AR-3370-0006, Starfish Attachment Overview

7.1 Starfish Features:

7.1.1 **Scope Snap-Fit**: Accepts and locks into place a compatible scope.

7.1.2 **Light Post Snap-Fit**: Accepts and locks into place a compatible light post.

7.1.3 **Thumb Tabs**: Intended to be pushed by hand to rotate the scope.
7.2 Markings on the Starfish

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

7.3 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)
8.0 AR-3370-0008, C-Mount Starfish Attachment Overview:

8.1 C-Mount Starfish Features

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

Figure 8-1: AR-3370-0008 C-Mount Starfish Attachment
8.2 Markings on the C-Mount Starfish

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

8.3 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)
9.0 Preparation for Use

9.1 Visual Inspection & Function Check

⚠️ WARNING: Risk of injury due to faulty Starfish.

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

⚠️ WARNING: Do not bend the endoscope optics while installing or removing the Starfish. Handle the endoscope by the lightpost barrel and eyepiece only.
10.0 Installation

10.1 AR-3370-0006, Starfish

10.1.1 Press the Starfish Scope Snap-Fit onto a compatible endoscope such that the thumb tabs reach back towards the camera head.

Figure 10-1: Installing Scope Snap-Fit
10.1.2 Rotate the Starfish around the scope until the Light Post Snap-Fit engages the light post.

Figure 10-2: Installing Light Post Snap-Fit
10.2.1 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.

Figure 10-3: Installing Scope Snap-Fit
11.0 Operation

11.1 (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.

11.2 During use, press the Thumb Tabs to rotate the scope.

11.3 Prepare the Starfish for reprocessing immediately after use to prevent surface damage.
12.0 Reprocessing

12.1 Limitations on Reprocessing

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

13.0 Containment & Transportation

13.1 It is recommended that the Starfish are reprocessed as soon as is reasonably practicable following use.

13.2 Instrument cases and trays are considered reusable devices. Trays should be inspected for visible soil and must be cleaned prior to use. Trays can be cleaned manually or in an automatic washer using a detergent.

13.3 Always store the Starfish securely and transport it to processing in a closed container to prevent damage to the Starfish and contamination of the environment.
14.0 Cleaning Instructions

⚠️ 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.

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

CAUTION: Wear protective gloves, clothing and face mask for cleaning of contaminated equipment.
14.1 Preliminary Cleaning:

When properly performed, cleaning, disinfection and/or sterilization do not compromise the use and mechanical performance of these devices. The Starfish are used with or on patients who may harbor both recognized and unrecognized infections. To prevent the spread of infection, Starfish must be thoroughly cleaned, disinfected, and sterilized after use on each patient.

14.1.1 Remove dried-on soil from Starfish, especially in areas such as joints and crevices, prior to washing. Clean the surfaces with a sponge or brush under cold running water until visible contamination has been removed. Pre-cleaning may also be completed utilizing an ultrasonic bath. If cleaning ultrasonically, place the device in the ultrasonic unit for a minimum of 10 minutes and process according to the ultrasonic unit’s directions.

14.1.2 Check Starfish for visible soil. Repeat pre-cleaning if soil is visible and re-inspect.
14.1.3 After the completion of preliminary cleaning, the end user has the option to perform either Manual Cleaning and Disinfection or Machine (Automatic) Cleaning and Thermal Disinfection.

14.2 Manual Cleaning and Disinfection
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.

14.2.1 Immerse the Starfish in an enzymatic or alkaline cleaning detergent solution. Cleaning solutions can include, but are not limited to: ENZOL® enzymatic, neodisher® Mediclean forte, and Thermosept® alka clean. Cleaning solutions should always be mixed to the manufacturer’s specification for concentration and cleaning shall be conducted at ambient temperature unless otherwise stated in the cleaning solution manufacturer’s instructions.

14.2.2 Scrub the Starfish with a soft brush, paying special attention to areas where debris might
accumulate. Always avoid any harsh materials that can scratch or mar the surface of the device. Immerse the Starfish in detergent, agitate and allow it to soak for at least one minute.

14.2.3 Rinse the Starfish thoroughly with cold distilled water for at least one minute following the cleaning process.

14.2.4 Immerse the Starfish in disinfection solutions for a minimum of 20 minutes. Suitable disinfection solutions can include, but are not limited to: CIDEX®, WAVICIDE®-01, Gigasept®, Kohrsolin®, and equivalent products. Use the supplier’s instructions for preparing the solution.

14.2.5 Disinfection solutions should always be mixed to the manufacturer’s specification for concentration.

14.2.6 After disinfection, the Starfish should be rinsed with cold distilled water or deionized sterile water.
14.2.7 Dry the Starfish thoroughly utilizing compressed air, wipes, or an oven.

14.2.8 Check the Starfish for visible soil. Repeat cleaning if soil is visible and re-inspect.

14.3 Machine (Automatic) Cleaning and Thermal Disinfection

Following preliminary cleaning, the instructions for Machine (Automatic) Cleaning and Thermal Disinfection may be followed as an alternative cleaning method to Manual Cleaning and Disinfection.

14.3.1 Load the Starfish in the washer such that all its 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).

14.3.2 Run the automatic wash cycle. The minimum cycle parameters are listed below:
### Minimum Washing Cycle Parameters

<table>
<thead>
<tr>
<th>Phase</th>
<th>Recirculation Time</th>
<th>Temperature</th>
<th>Detergent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold Pre-Wash</td>
<td>3 Minutes</td>
<td>20 ± 5°C (68 ± 9°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Cleaning Wash</td>
<td>10 Minutes</td>
<td>65.5 ± 5°C (150 ± 9°F)</td>
<td>Enzymatic or alkaline agent</td>
</tr>
<tr>
<td>Rinse 1</td>
<td>3 Minutes</td>
<td>50 ± 5°C (122 ± 9°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Rinse 2</td>
<td>3 Minutes</td>
<td>50 ± 5°C (122 ± 9°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Thermal</td>
<td>5 Minutes</td>
<td>90 ± 5°C (194 ± 9°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Drying</td>
<td>6 Minutes</td>
<td>115°C (239°F)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

14.3.3 Automatic wash cleaning solutions can include, but are not limited to: neodisher® Mediclean forte, Thermosept® alka clean, Prolystica® Ultra Concentrate Enzymatic Cleaner, and ProKlenz NpH Neutral Detergent.

14.3.4 Check the Starfish for visible soil. Repeat cleaning if soil is visible and re-inspect.
14.4 Sterile Packaging

**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.

**Sets**: Where appropriate, cleaned, disinfected and inspected devices should be placed into trays/cases as provided or in general-purpose sterilization trays; **do not exceed 8.5 Kgs./18.7 lbs. per tray**. 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.
15.0 Sterilization

Prior to each sterilization cycle, the Starfish must be cleaned and disinfected according to the methods in these cleaning instructions.

15.1 Sterilize Starfish in suitable packaging to prevent subsequent contamination.

15.2 Comply with specified process parameters. The parameters stipulated have been validated to ensure the sterility of the Starfish. Sterilization may be performed using Moist Heat Sterilization or STERRAD.

15.3 Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer’s instructions.

15.4 Follow your country-specific guidelines, standards, and requirements.
### Steam Sterilization or Moist Heat

#### Sterilization Parameters: For USA Only

<table>
<thead>
<tr>
<th>Gravity Displacement Steam Sterilization Cycle</th>
<th>Exposure Temperature</th>
<th>Exposure Time</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>121°C (250°F)</td>
<td>30 minutes</td>
<td>15 to 30 minutes</td>
</tr>
<tr>
<td></td>
<td>132°C (270°F)</td>
<td>15 minutes</td>
<td>15 to 30 minutes</td>
</tr>
<tr>
<td></td>
<td>135°C (275°F)</td>
<td>10 minutes</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Pre-Vacuum Cycle</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
<td>20 to 30 minutes</td>
</tr>
<tr>
<td></td>
<td>135°C (275°F)</td>
<td>3 minutes</td>
<td>16 minutes</td>
</tr>
</tbody>
</table>

#### Sterilization Parameters: For Outside the USA Only

<table>
<thead>
<tr>
<th>Gravity Displacement Steam Sterilization Cycle</th>
<th>Exposure Temperature</th>
<th>Exposure Time</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>132 - 135°C (270°F - 275°F)</td>
<td>18 minutes</td>
<td>15 to 30 minutes</td>
</tr>
<tr>
<td></td>
<td>121°C (250°F)</td>
<td>30 minutes</td>
<td>15 to 30 minutes</td>
</tr>
<tr>
<td>Pre-Vacuum Cycle</td>
<td>132 - 135°C (270°F - 275°F)</td>
<td>4 minutes</td>
<td>20 to 30 minutes</td>
</tr>
</tbody>
</table>
15.5.1 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.

15.6 STERRAD

<table>
<thead>
<tr>
<th>System</th>
<th>Cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>STERRAD®</td>
<td>STERRAD® System 100S</td>
</tr>
<tr>
<td></td>
<td>STERRAD® System NX</td>
</tr>
<tr>
<td></td>
<td>STERRAD® System 100NX</td>
</tr>
</tbody>
</table>

15.7 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.
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.

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:

16.3.1 Avoid direct sunlight;

16.3.2 Store Starfish either in the original packaging or in a screen tray/container;
16.3.3 Ensure that the Starfish is stored securely;

16.3.4 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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