AtriCure®

AtriClip® LAA Exclusion System with preloaded Gillinov-Cosgrove® Clip

(ACH135, ACH140, ACH145, ACH150)

(ACH235, ACH240, ACH245, ACH250)

Instructions for Use

⚠**CAUTION:** Investigational Device. Limited by Federal (United States) Law to Investigational Use. Exclusively for Clinical Investigation.

SURGICAL PROCEDURE INSTRUCTIONS

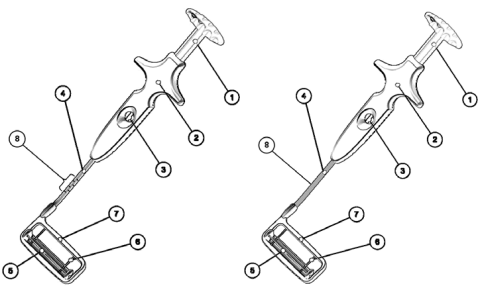
Please refer to the Clinical Study Protocol (CP2018-1) for these Instructions.

DESCRIPTION

The AtriClip LAA Exclusion System contains the Gillinov-Cosgrove LAA Clip (Clip) for occlusion of the heart's left atrial appendage (LAA). The Clip is pre-loaded on a disposable Clip applier. The AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip does not contain natural rubber latex components.

ATRICLIP LAA EXCLUSION SYSTEM

ILLUSTRATION AND NOMENCLATURE



(ACH135, ACH140, ACH145, ACH150) - AtriClip Standard[1]

(ACH235, ACH240, ACH245, ACH250) - AtriClip FLEX[2]

[1]	Plunger	[5]	Gillinov–Cosgrove Clip
[2]	Handle	[6]	Suture Anchors
[3]	Suture Cutting Zone	[7]	Deployment Loop
[4]	Shaft	[8]	Malleable Zone†

†Each AtriClip handpiece has a different malleable region.

[1]The AtriClip Standard device's malleable zone is denoted by a set of slots on the shaft near the deployment loop. It is only intended for minor adjustments in the lateral (left/right) plane.

[2]The entire length of the AtriClip FLEX device's shaft is malleable. It is intended for adjustments up to 45° in all planes.

⚠**CAUTION:** BEFORE USING PRODUCT READ THE FOLLOWING INFORMATION THOROUGHLY

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

INDICATION FOR USE

Please refer to the Clinical Study Protocol (CP2018-1) for these Instructions.

CONTRAINDICATIONS

- Please refer to the clinical study protocol (CP2018-1) for Exclusion Criteria.
- Do not use this device as a contraceptive tubal occlusion device.
- Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy).

⚠WARNINGS⚠

Do not attempt to reposition or remove the Clip after deployment. This may result in tissue damage or tearing.

Use this device only as intended.

Do not use on tissue which, in the opinion of the surgeon, would not be able to tolerate conventional suture materials or conventional closure techniques (such as surgical stapling).

Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Gillinov-Cosgrove Selection Guide Instructions for Use. Failure to correctly size or deploy the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement and/or lack of desired homeostasis.

Do not use on a LAA less than 29mm in width and 1.0mm wall thickness.

Do not use on a LAA greater than 50mm when tissue is uncompressed.

Do not use this device if the patient has sensitivity to Nickel (nickel titanium alloy).

⚠CAUTIONS

- Read all instructions carefully for the AtriClip LAA Exclusion System. Failure to properly follow instructions may result in improper functioning of the device.
- Use of the device should be limited to properly trained and qualified medical personnel.
- Note that variations in specific procedures may occur due to individual physician techniques and patient anatomy.
- Do not drop or toss the device as this may induce damage to the device. If the device is dropped, do not use. Replace with a new device.
- DO NOT RESTERILIZE. The AtriClip LAA Exclusion System is provided STERILE and is intended for SINGLE use only. Resterilization may cause loss of function or injury to patient.
- Carefully consider any pre-surgical treatment the patient may have undergone and in corresponding selection of Clip size. Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected Clip size.
- Do not modify this instrument. Use of a modified device may result in improper instrument function. AtriCure, Inc. makes no claim or representation as to the performance characteristics of this product if any modifications have been made to the AtriClip LAA Exclusion System.
- Do not kink or excessively bend the shaft as this may affect device performance.
- Evacuate thrombus from the LAA prior to Clip application as with other conventional LAA occlusion surgical techniques. Evaluating for the presence of thrombus should be done per the surgeon's discretion and standard of care.
- Position and deploy Clip in a manner that provides clear visualization of all tissues being accessed. Poor visualization may result in suboptimal placement.
- Take care to minimize manipulation of the LAA and Clip after Clip deployment.
- It is recommended that the Clip be deployed in a dry field.
- Do not use the Clip in temperatures below 20°C. Application of the Clip in temperatures below 20°C may affect device performance.

INSTRUCTIONS FOR USE

SURGICAL PROCEDURE INSTRUCTIONS

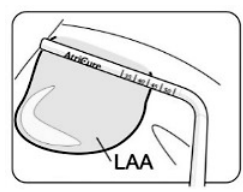
Please refer to the Clinical Study Protocol (CP2018-1) for these Instructions.

Surgeon judgment, with the assistance of the Gillinov-Cosgrove Selection Guide, should determine what size Clip to apply.

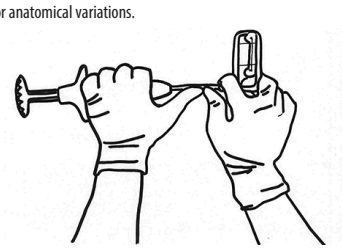
CLIP SELECTION

1. Use the Gillinov-Cosgrove Selection Guide, to determine correct selection of the Gillinov- Cosgrove LAA Clip. Clip sizes are located on the device package.

Clip Size	LAA Size Range
35 mm	29 – 35 mm
40 mm	34 – 40 mm
45 mm	39 – 45 mm
50 mm	44 – 50 mm



2. Using sterile technique, remove the AtriClip LAA Exclusion System from its packaging.
3. The malleable shaft of the AtriClip LAA Exclusion System may be reshaped to aid in accessing the LAA. Apply gentle pressure to shape the device shaft as required for anatomical variations.



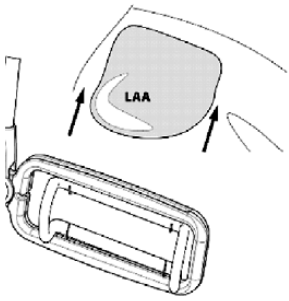
⚠**Caution:** Do not grasp deployment loop to apply bend to shaft, as this may result in damage to the device. Apply bend by gently concentrating force under both thumbs. Excessive bending or kinking of the shaft may affect device performance. Do not attempt to twist the deployment loop, as this may cause damage to the device.

4. Using the plunger on the handle, gently open and close the Clip to assure proper function.

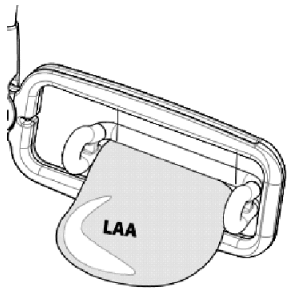
⚠**Caution:** Do not open and close the Clip more than 3 times with the plunger prior to deployment.

CLIP POSITIONING

5. Maneuver the AtriClip LAA Exclusion System into the targeted dissection plane.
6. Gently open the Clip by depressing the plunger.
7. Orient the Clip applier with pre-loaded Clip at the tip of LAA with the loops at the ends of the Clip pointed away from the LAA.



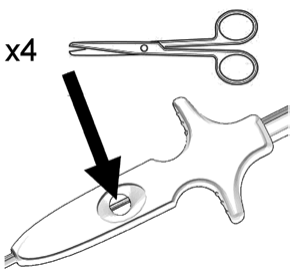
8. Gently position the Clip at the base of the LAA.



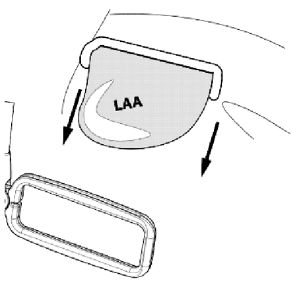
9. Position the Clip in a manner that provides clear visualization of all tissues being accessed.
10. While the Clip is still affixed to the Deployment Device, ensure that no surrounding structures interfere with or are damaged by the Clip, and that the Clip is placed correctly.
11. If the Clip is not placed correctly, gently open the Clip and reposition as needed.

DEPLOYMENT

12. After the Clip is positioned correctly, release the plunger allowing the Clip to close.
13. Deploy the Clip by manually cutting the suture at the designated cutting zone on the handle.

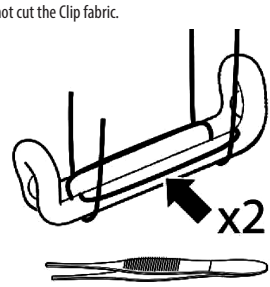


14. Providing counter pressure on the Clip, carefully remove the deployment loop from the LAA as shown below leaving the Clip and attachment suture behind.



⚠**Caution:** After manually cutting the sutures, the AtriClip LAA Exclusion System cannot be used to reposition the Clip.

15. After the Clip is deployed, remove the attachment sutures by gently pulling one at a time while providing counter traction on the Clip per the surgeon's discretion. Do not cut the Clip fabric.



16. Discard the deployment device after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

RETURN OF USED PRODUCT

If for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER STATEMENTS

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

HANDLING INFORMATION: GILLINOV- COSGROVE LAA CLIP

MRI SAFETY INFORMATION

MR CONDITIONAL

Non-clinical testing demonstrated that the AOD1 (Annular Occlusion Device) Clip is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system
- Under the scan conditions defined for the AOD1 Clip is expected to produce a maximum temperature rise of 2.9°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

ARTIFACT INFORMATION

In non-clinical testing, the image artifact caused by the AOD1 Clip extends approximately 10-mm from the AOD1 Clip when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

Refer to the outer package label to see which symbols apply to this product.

PYROGEN	Non-Pyrogenic		Caution
STERILE R	Sterilized with irradiation		Follow instructions for use
Rx ONLY	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician	LATEX	Not made with Natural Rubber Latex
LOT	Batch code		Manufacturer
	Used by date		Single Use Only
MR	Indicated MRI-Conditional		

Manufactured by:
AtriCure Incorporated
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1-866-349-2342 (toll free)
1-513-755-4100 (phone)