AtriCure®

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

(PRO235, PRO240, PRO245, PRO250)

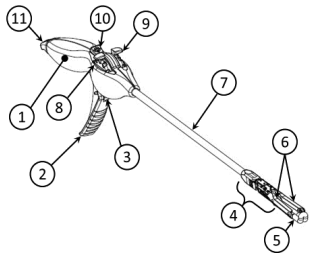
Instructions for Use

DESCRIPTION

The AtriClip LAA Exclusion System contains the Gillinov-Cosgrove LAA Clip (Clip) for exclusion of the heart's left atrial appendage (LAA). Preclinical animal studies (Kamohara 2005,2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA . A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical studies.

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



1. Handle
2. Activation Lever
3. Lever Release Trigger
4. End Effector
5. Gillinov–Cosgrove LAA Clip
6. Clip Opening Jaws
7. Shaft
8. Up/Down Articulation
9. Left/Right Articulation
10. Articulation Lock
11. Deployment Tab

⚠ 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

The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

CONTRAINDICATIONS

1. Do not use this device as a contraceptive tubal occlusion device.
2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy).

⚠ WARNINGS

1. **Do not attempt to reposition or remove the Clip after deployment. This may result in tissue damage or tearing.**
2. Use this device only as intended. Failure to do so may result in injury to the user or patient.
3. 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). Doing so may result in: tissue trauma, dehiscience, tissue tearing, displacement and/or exclusion.
4. Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Cosgrove-Gillinov Selection Guide Instructions for Use. Failure to correctly size or deploy the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement and/or exclusion.
5. Do not use on a LAA less than 29mm in width and 1.0mm wall thickness. Doing so may result in: tissue trauma, dehiscience, tissue tearing, displacement and/or exclusion.
6. Do not use on a LAA greater than 50mm when tissue is uncompressed. Doing so may result in incomplete occlusion of the structure.
7. Do not use this device if the patient has sensitivity to Nickel (nickel titanium alloy). This may result in an adverse user or patient reaction.
8. Visually check for rust on the Applier jaws prior to use. The Applier should not be used for durations longer than 1 hour to prevent the formation of rust.
9. The safety and effectiveness of this device is atrial rhythm control management, either alone or in combination with other ablative treatment, has not been established.
10. Atriclip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.

⚠ PRECAUTIONS

1. Read all instructions carefully for the AtriClip LAA Exclusion System. Failure to properly follow instructions may result in improper functioning of the device.
2. Use of the device should be limited to properly trained and qualified medical personnel.
3. Note that variations in specific procedures may occur due to individual physician techniques and patient anatomy.
4. 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.
5. DO NOT RESTERILIZE. The AtriClip LAA Exclusion System is provided STERILE and is intended for SINGLE use only. Re-sterilization may cause loss of function or injury to patient.
6. 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.
7. 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.
8. Do not kink or excessively bend the shaft as this may affect device performance.
9. 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.
10. Position and deploy Clip in a manner that provides clear visualization of all tissues being accessed. Poor visualization may result in suboptimal placement.
11. Take care to minimize manipulation of the LAA and Clip after Clip deployment.
12. It is recommended that the Clip be deployed in a dry field.
13. Do not use the Clip in temperatures below 20°C. Application of the Clip in temperatures below 20°C may affect device performance.
14. Do not attempt to articulate the End Effector while in the locked position. Force applied while in the locked position may cause damage to the device.

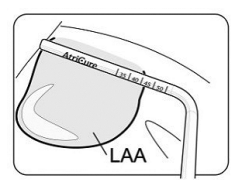
INSTRUCTIONS FOR USE

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

Clip Selection

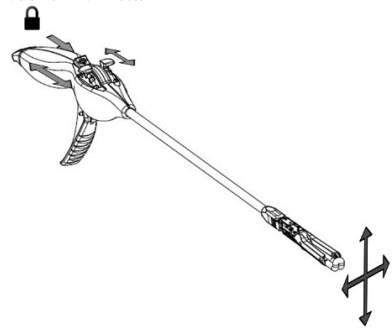
1. Using the Gillinov-Cosgrove Selection Guide, to determine correct selection of the Gillinov-Cosgrove LAA Clip. Clip sizes are located on the device package.

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. Using the Activation Lever 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 activation lever prior to deployment.

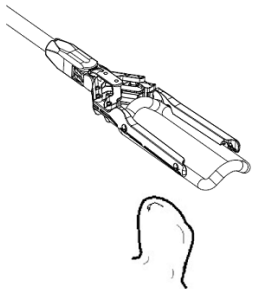
Articulation of End Effector



4. By pushing down and pulling the Articulation Lock (10) backwards (proximal), the End Effector (4) of the AtriClip LAA Exclusion System may be manually articulated up and down and side-to-side by either the articulation levers or pressing on the end effector. The Clip (5) and End Effector (4) can articulate 30° left or right and 30° up or down to take into account anatomical variations in the patient's anatomy.
5. To lock the End-Effector (4) in position, press the Articulation Lock (10) forward.

Clip Positioning

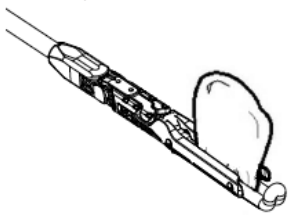
6. Maneuver the LAA Exclusion System into the targeted dissection plane.



7. Gently open the Clip by squeezing the Activation Lever (2).

NOTE: The Clip automatically locks in the fully open position by means of a Locking Trigger on the handle of the device. The lock can be disengaged by pressing the Lever Release Trigger (3).

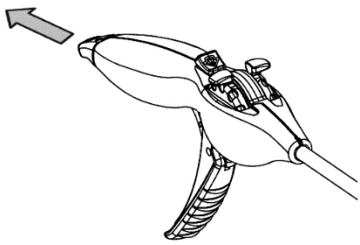
8. Orient the Clip applier with pre-loaded Clip at the tip of LAA with the loops at the ends of the Clip pointed away from the LAA.
9. Gently position the Clip at the base of the LAA.



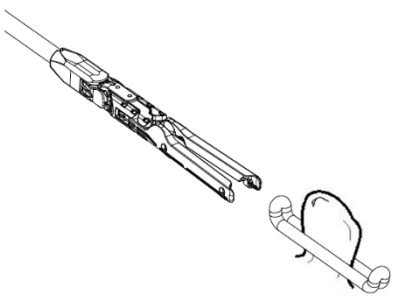
10. Position the Clip in a manner that provides clear visualization of all tissues being accessed.
11. While the Clip is still affixed to the Deployment Device, ensure that no surrounding structures interfere with or are damaged by the Clip, and that the Clip is placed correctly.
12. If the Clip is not placed correctly, gently open the Clip and reposition as needed.
13. After the Clip is positioned correctly, grasp the Activation Lever (2) and depress the Lever Release Trigger (3) and slowly release the Activation Lever allowing the Clip to close.

Deployment

14. Deploy the Clip by slowly pulling the Deployment Tab (11) at the proximal end of the handle. NOTE: The Deployment Tab (11) with steel cables may be completely removed from the end of the Handle.



15. Unlock the end effector articulation (10) and carefully remove it from the LAA as shown below leaving the Clip and attachment suture behind.



Caution: After pulling the Deployment Tab, the AtriClip LAA Exclusion System cannot be used to reposition the Clip.

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 LAA Exclusion System 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 LAA Exclusion System 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 LAA Exclusion System Clip extends approximately 10-mm from the LAA Exclusion System 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.

	Non-Pyrogenic
STERILE R	Sterilized by Irradiation
	Single Use Only
	Use-By Date
Rx ONLY	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician
LOT	Lot Number
	Caution
	Consult instructions for use
	Manufacturer
	Not made with Natural Rubber Latex
MR	MR Conditional
	Do Not Re-Sterilize
	Do Not use if the package is damaged.

REFERENCES

1. Kamohara K, et al . A novel device for left atrial appendage exclusion. J Thorac Cardiovasc Surg 2005
2. Kamohara K, Fukamachi et al. Evaluation of a novel device for left atrial appendage exclusion: the secondgeneration atrial exclusion device. J Thorac Cardiovasc Surg 2006
3. Christoph T. Starck, et al. Epicardial left atrial appendage clip occlusion also provides the electrical isolation of the left atrial appendage. Interactive CardioVascular and Thoracic Surgery 15 (2012)

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