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

**INDICATION FOR USE**

This booklet is designed to assist in using this product. It is not a representation as to the performance characteristics of this product.

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 (LAA). Preclinical animal studies (Kamoshita 2005, 2006) demonstrate that complete exclusions with the Clip also result 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.

**WARNING**

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).
4. 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, dishiscence, tissue tearing, displacement and/or exclusion.
5. Do not use on a LAA less than 29mm in width and 1.0mm thickness. Doing so may result in: tissue trauma, dishiscence, 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 a known allergy to Nitinol (nickel titanium alloy).
8. The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with other ablative treatment, has not been established.
9. AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.
10. 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).
11. Do not use the Clip in temperatures below 20°C. Application of the Clip in temperatures below 20°C may affect device performance.
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 Deployment Loop 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, and on the deployment device handle.

**LAA Size Range**

<table>
<thead>
<tr>
<th>Clip Size</th>
<th>LAA Size Range</th>
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<tbody>
<tr>
<td>35 mm</td>
<td>29 – 35 mm</td>
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<tr>
<td>40 mm</td>
<td>34 – 40 mm</td>
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<tr>
<td>45 mm</td>
<td>39 – 45 mm</td>
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<tr>
<td>50 mm</td>
<td>44 – 50 mm</td>
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</tbody>
</table>

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.

**Articulation of End Effector**

4. By pressing the Articulation Release Button and pulling it backwards (proximal) into the locked position, the Deployment Loop of the AtriClip LAA Exclusion System may be manually articulated up and down, and side-to-side from 0° (inline – as supplied) to ±30° relative to the shaft to aid in the proper placement of the Gillinov-Cosgrove LAA Clip to take into account anatomical variations in the patient’s anatomy.
5. To lock the End-effector in position, disengage the Articulation Release Button by pushing down, forward and then releasing.
Clip Positioning

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

7. Gently open the Clip by squeezing the activation lever. **NOTE:** The Clip can be locked in the open position by means of a locking feature in the handle of the device. The lock will engage when the lever is activated and can be disengaged by gently pressing the lever release button.

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.

Deployment

13. After the Clip is positioned correctly, grasp the Activation Lever and depress the Lever Release Button and slowly release the Activation Lever allowing the Clip to close.

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

15. Following Clip deployment carefully squeeze the activation lever to retract the Pull Bar against the Loop of the Deployment Device to prevent unintentional tissue snags when removing the deployment loop.

16. Carefully remove the deployment loop 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 repositioned or re-used.

**RETURN OF USED PRODUCT**

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

2. 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.

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

**DISCLAIMER STATEMENTS**

Users must assume responsibility for approving the 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 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.

**REFERENCES**