AtriCure®
AtriClip Gillinov-Cosgrove™ LAA Clip
(GEC135, GEC140, GEC145, GEC150)

Instructions for Use

DESCRIPTION
The AtriClip Gillinov-Cosgrove™ LAA Clip (Clip) is a single patient use medical implant for open occlusion of the heart’s left atrial appendage (LAA). The AtriCure Reusable Clip Applier Gillinov-Cosgrove LAA Exclusion Device (Applier) facilitates placement of the AtriClip Gillinov-Cosgrove™ LAA Clip.

AtriClip Gillinov-Cosgrove™ LAA Clip
ILLUSTRATION AND NOMENCLATURE

1. Cartridge
2. Cartridge Rib
3. LAA Clip
4. Clip Clamp Member
5. Clip End Loop
6. Fabric covering

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 Gillinov-Cosgrove™ LAA Clip is used for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, without assistance from a camera, endoscope, etc., or any other viewing technology. This includes procedures performed by sternotomy (full or partial) as well as thoracotomy (single or multiple).

CONTRAINDICATION
1. Do not use this device as a controllable tubal occlusion device.
2. Do not use this device if the patient has a known allergy to Nickel or this device contains Nickel (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.
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 before releasing the Clip from the Clip Applier. To evaluate the LAA 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 closure techniques (such as surgical stapling).
5. Releasing the Clip Applier handle rings closes the Clip. Maintain a controlled closure of the Clip to ensure Clip engagement with the tissue.
6. Do not use on a LAA less than 29mm in width and 1.0 mm wall thickness when tissue is uncompressed.
7. Do not open and close the Clip more than 4 times prior to deployment.

PRECAUTIONS
1. Read all instructions carefully for the AtriClip Gillinov-Cosgrove™ LAA Clip. 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 closed or toss the device as this may induce damage to the tissue. If the device is dropped, do not use. Replace with a new device.
5. Do NOT RESTERILE. The AtriClip Gillinov-Cosgrove™ LAA Clip is provided STERILE and is intended for use in a SINGLE procedure only. Resterilization 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 affect tissue integrity.
7. Do not modify this device. Use of a modified device may result in improper device 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 Gillinov-Cosgrove™ LAA Clip.

8. Each AtriClip Gillinov-Cosgrove™ LAA Clip will fit and operate properly only in the Reusable Clip Applier. Attempting to use a AtriClip Gillinov-Cosgrove™ LAA Clip in any instrument other than that for which it has been designed will result in Clip malfunction.
9. Evacuate thrombus from the LAA prior to Clip application as with other conventional LAA occlusion surgical techniques. Evaluating for the presence of thrombus prior to LAA occlusion should be done per the surgeon’s discretion and standard of care.
10. Position and deploy Clip under direct visualization. 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. Avoid contact of electrical instruments with Clip and Applier.

INSTRUCTIONS FOR USE

Surgical 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, measure the LAA for correct selection of the AtriClip Gillinov-Cosgrove™ LAA Clip. Clip sizes are located on the device package.

2. Using sterile technique, remove the appropriate size AtriClip Gillinov-Cosgrove™ LAA Clip from its packaging. Note: the Clip is contained in a hard polymeric Cartridge for protection purposes. Only the AtriCure Reusable Clip Applier is to be used to remove the Clip from the Cartridge.
3. To load the Clip onto the Applier, refer to the Reusable Clip Applier Instructions for Use.

NOTE: Do not attempt to manually load the clip onto the Reusable Clip Applier should the clip become dislodged from Applier. Cartridge MUST be used to position clip properly on Applier in order to deploy clip.
4. Once the Clip is loaded onto the Reusable Clip Applier, by squeezing the Applier handle rings together the beam point apart and the Clip is opened. The opening stop limits the distance the clip may be opened.
5. Releasing the Clip Applier handle rings closes the Clip. Maintain a controlled closure of the Clip to ensure Clip engagement with the Applier.
6. Squeeze the Reusable Clip Applier handle rings, gently open and close the clip to assure proper function.

Clip Positioning
1. Maneuver the AtriClip Gillinov-Cosgrove™ LAA Clip into the targeted area over the LAA.
2. Gently open the Clip by squeezing the Reusable Clip Applier handle rings together.
3. Orient the Clip applier with the loaded clip at the tip of LAA. The Clip end loops will be positioned away from the heart.
10. Gently position the Clip at the base of the LAA.

11. Position the Clip in a manner that provides clear visualization of all tissues being accessed.

12. While the clip is still affixed to the Applier, check to ensure that no surrounding structures interfere with or are damaged by the Clip.

13. While the Clip is still affixed to the Applier, check to ensure that the Clip is placed correctly. The LAA should be centered along the length of the Clip clamp member.

14. If the Clip is not placed correctly, gently open the Clip and reposition as needed.

15. After the Clip is positioned correctly, gently release the Applier rings in a controlled manner allowing the Clip to close upon the LAA.

Deployment

16. After the Clip is positioned correctly, deploy by applying a light counterforce to the Clip, separating the Clip from the Applier.

17. After the Clip is deployed, gently open the Applier and carefully remove the Applier from the LAA as shown below.

18. Set the Applier aside after deploying the Clip. Follow the cleaning and sterilization procedure prior to Applier reuse; refer to the Reusable Clip Applier Instructions for Use.

19. After the Clip is deployed, do not attempt to reposition or remove the Clip.

20. After the Clip is deployed, do not attempt to reengage the Clip Applier with the Clip.

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 must assume responsibility for approving the condition of this product before it is used. AtriCure, Inc. cannot be held liable for any consequential damage, personal injury or damage to property nor for the misuse of this product.

AtriCure, Inc. will not be liable for any damage caused by the reuse of this product.

This Instruction for Use describes the procedures for proper use of the product. Any deviation from these procedures, which may compromise the function of the product, is the responsibility of the user.

HANDLING INFORMATION: Gillinov-Cosgrove™ clip

MRI Information

The Gillinov-Cosgrove™ Clip was determined to be MR-conditional (i.e., according to information provided in the following document: American Society for Testing and Materials (ASTM) International, Designation: F 2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428, 2005.)

Non-clinical testing has demonstrated that the Gillinov-Cosgrove™ Clip is MR Conditional. A patient with the Gillinov-Cosgrove™ Clip can be scanned safely under the following conditions:

- Spatial gradient field of 720-Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the Gillinov-Cosgrove™ Clip produced a temperature rise of less than 0.4°C at a maximum whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system (Excite, Software G3.0-052B, General Electric Medical Systems, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Gillinov-Cosgrove™ Clip.

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PYROGEN</td>
<td>Non-Pyrogenic</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>STERILE</td>
<td>Sterilized by Gamma Radiation</td>
</tr>
<tr>
<td>Rx ONLY</td>
<td>Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician</td>
</tr>
<tr>
<td>Single Use Only</td>
<td></td>
</tr>
<tr>
<td>Expired Date</td>
<td></td>
</tr>
<tr>
<td>Indicated MRI Conditional</td>
<td></td>
</tr>
<tr>
<td>Attention: See Instructions for Use</td>
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