AtriCure®

AtriClip® Flex•V™ LAA Exclusion System with Preloaded V•Clip

(ACHV35, ACHV40, ACHV45, ACHV50)

Instructions for Use

PACKAGE CONTENTS

AtriClip Flex•V LAA Exclusion System
V Clip

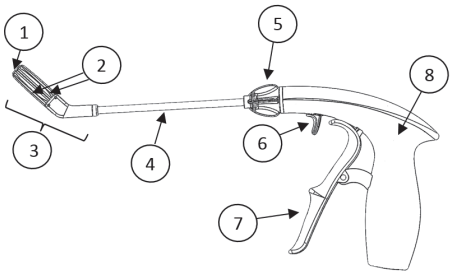
RECOMMENDED ACCESSORIES

Gillinov-Cosgrove™ Selection Guide

DESCRIPTION

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

AtriClip Flex•V LAA Exclusion System ILLUSTRATION AND NOMENCLATURE



1. V Clip
2. Clip Opening Jaws
3. End Effector
4. Shaft[1]
5. Shaft Rotation Knob
6. Deployment Trigger
7. Activation Lever
8. Handle

[1]The entire length of the shaft is malleable and intended for adjustments up to 45 degrees in any direction.

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 occlusion of the heart's left atrial appendage, 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 any other viewing technology.

CONTRAINDICATIONS

Do not use this device as a contraceptive tubal occlusion device.

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, dehiscence, tissue tearing, displacement and/or lack of desired homeostasis.
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, dehiscence, tissue tearing, displacement and/or lack of desired homeostasis.
5. Do not use on a LAA less than 29mm in width and 1.0mm wall thickness. Doing so may result tissue in: trauma, dehiscence, tissue tearing, displacement and/or lack of desired homeostasis.
6. Do not use on a LAA greater than 50mm when tissue is uncompressed. Doing so may result in incomplete occlusion of the structure.

PRECAUTIONS

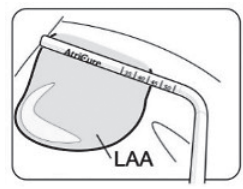
1. Federal Law (USA) restricts this device to sale by or on the order of a physician.
2. Use of the device should be limited to properly trained and qualified medical personnel.
3. Read all instructions carefully for the AtriClip Flex•V LAA Exclusion System. Failure to properly follow instructions may result in improper functioning of the device.
4. Note that variations in specific procedures may occur due to individual physician techniques and patient anatomy.
5. 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.
6. 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.
7. 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.
8. 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 Flex•V ™ LAA Exclusion System.
9. Do not grasp device end effector to apply bend to shaft, as this may result in damage to the device. Excessive bending or kinking of the shaft may affect device performance. Do not attempt to twist the device end effector, as this may cause damage to the device.
10. 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.
11. Position and deploy Clip in a manner that provides adequate visualization of all tissues being accessed. Poor visualization may result in suboptimal placement.
12. Take care to minimize manipulation of the LAA and Clip after Clip deployment.
13. It is recommended that the Clip be deployed in a dry field.
14. Do not attempt to rotate the End Effector without pulling it out of the locked position. Force applied while in the locked position may cause damage to the device.
15. Only pull the deployment trigger when the clip is properly positioned over the LAA. Pulling the Deployment Trigger permanently releases the Clip from the applier.

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 LAA Clip. Clip sizes are located on the device package.

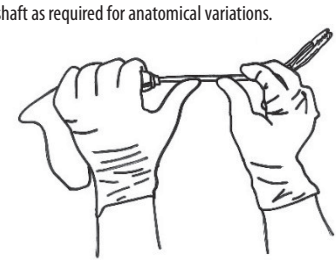


Clip Size	LAA Size Range
35 mm	29 – 35 mm
40 mm	34 – 40 mm
45 mm	39 – 45 mm
50 mm	44 – 50 mm

2. Using sterile technique, remove the AtriClip Flex•V LAA Exclusion System from its packaging.
3. Using the Activation Lever on the handle, gently open and close the Clip to assure proper function.

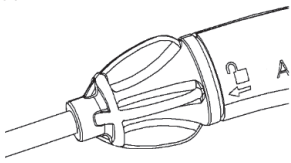
Shaft Bending

4. The AtriClip Flex•V contains a malleable shaft of that may be reshaped to aid in accessing the LAA. Apply gentle pressure to shape the device shaft as required for anatomical variations.



Precaution: Do not grasp device end effector 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 device end effector, as this may cause damage to the device.

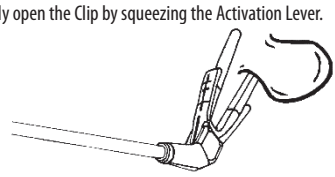
Shaft Rotation



5. By pulling the Rotation Knob forward (distal) and twisting it to the left or right, the End Effector of the Flex•V LAA Exclusion System may be manually rotated side-to-side. The Clip and End Effector can rotate 90° left or right in 45° increments to account for user preference or variations in the patient's anatomy.
6. To lock the End-Effector in position, release forward pressure on the knob and ensure that it is seated into position.

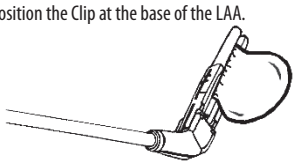
Clip Positioning

7. Maneuver the AtriClip Flex•V LAA Exclusion System into the targeted dissection plane.
8. Gently open the Clip by squeezing the Activation Lever.



NOTE: Maintain pressure on the Activation Lever in order to hold the Clip open. This device does not contain an automatic locking function.

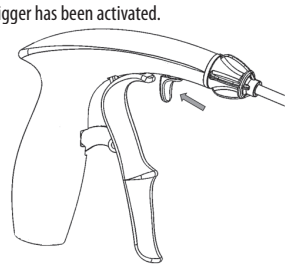
9. Gently position the Clip at the base of the LAA.



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. After the Clip is positioned correctly, slowly release the Activation Lever allowing the Clip to close.
13. If the Clip is not placed correctly, gently open the Clip and reposition as needed.

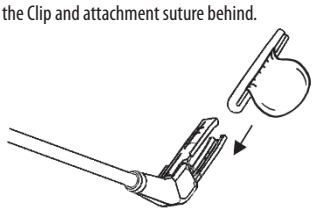
Deployment

14. Deploy the Clip by pulling the Deployment Trigger at the nose of the handle. NOTE: An audible "click" will be heard when the Deployment Trigger has been activated.



Precaution: Only pull the deployment trigger when the clip is properly positioned over the LAA. Pulling the Deployment Trigger permanently releases the Clip from the applier.

15. Carefully remove the End Effector from the LAA as shown below leaving the Clip and attachment suture behind.



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 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: V Clip

MRI Information

MRI Safety Information

MR Conditional

Non-clinical testing demonstrated that the A0D2 (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 A0D2 Clip is expected to produce a maximum temperature rise of 3.1°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information

In non-clinical testing, the image artifact caused by the A0D2 Clip extends approximately 20-mm from the A0D2 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
STERILE R	Sterilized by Gamma Radiation
	Single Use Only
	Expiration Date
Rx ONLY	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
LOT	Lot Number
	Attention, consult accompanying documents
	Follow Instructions for Use
	Manufactured By
LATEX	Not made with Natural Rubber Latex
MR	MR Conditional

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1-513-755-4100 (phone)