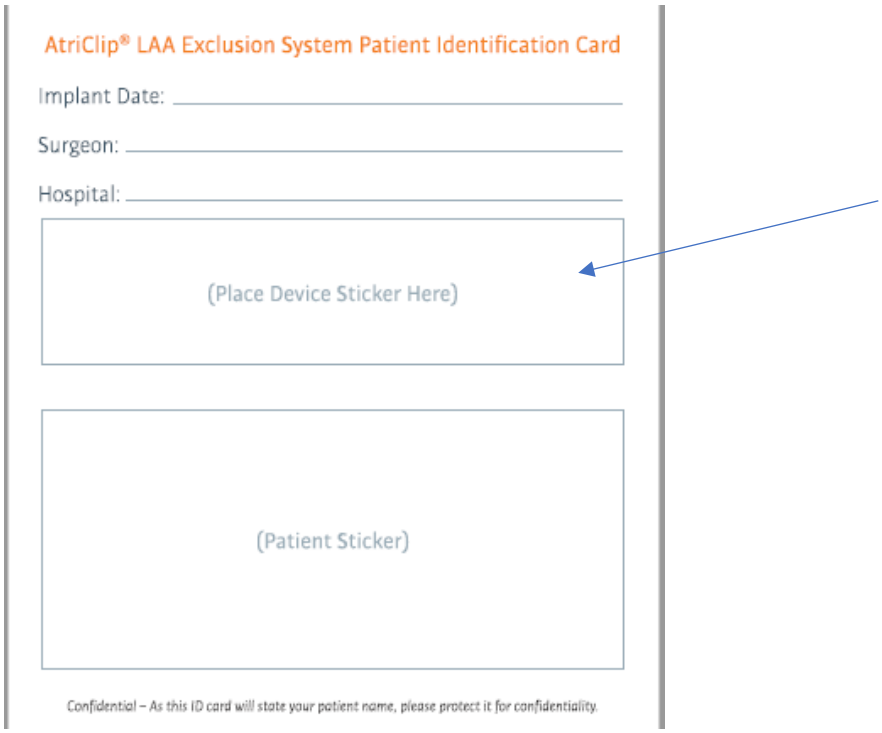
Patient Leaflet

IFU-0049.A

Instructions for completion:

Physician/healthcare provider to fill out required information and to apply device label, from the Tyvek on the sterile barrier, to the patient card in the example location identified below, prior to giving this leaflet and the implant card to the patient/care giver.



Patient Information Leaflet

AtriClip Left Atrial Appendage (LAA) Exclusion System

Product Name/Description	Pre-loaded Clip	Product Code	Picture
AtriClip Application Devices			
AtriClip FlexV	V-clip	ACHV35 ACHV40 ACHV45 ACHV50	
AtriClip Flex	Gillinov-Cosgrove clip	ACH235 ACH240 ACH245 ACH250	

AtriClip PRO Devices			
AtriClip PRO	Gillinov-Cosgrove clip	PRO135 PRO140 PRO145 PRO150	
AtriClip PRO2	Gillinov-Cosgrove clip	PRO235 PRO240 PRO245 PRO250	
AtriClip PRO•V	V-clip	PROV35 PROV40 PROV45 PROV50	

Product Description:

The AtriClip Left Atrial Appendage (LAA) Exclusion Systems are indicated for the occlusion of the heart's LAA.

The intended population of patients are those patients who are eligible for LAA exclusion. The Gillinov-Cosgrove clip devices should not be used if you have a known allergy to nickel.

The AtriClip LAA Exclusion Systems are composed of a single-use, self-closing implantable Clip preloaded onto a sterile, single-use applier. They are designed to completely exclude blood flow between the LAA and the left atrium during cardiac surgery. The Clip is an implant that permanently excludes the LAA. There are two different AtriClip designs of the implantable component (the AtriClip). The traditional, Gillinov-Cosgrove clip and the V-clip (see images below). Following the procedure, refer to your Patient ID Card to see which AtriClip model was selected for your surgery.

The traditional, Gillinov-Cosgrove LAA Exclusion Systems include the ACH2, PRO1, and PRO2; only the appliers are different. The V-Clip LAA Exclusion Systems include the ACHV and PROV with identical clip components, only differing in the clip appliers.

The traditional, Gillinov-Cosgrove AtriClip consists of two Nitinol (nickel titanium) springs and two titanium tubes which are covered with a knit braided polyester fabric, composed entirely of polyethylene terephthalate (PET). The device contains no microbial, animal or medicinal components.

The AtriClip V-Clip consists of a single titanium core with a set of opposing springs, covered with a knit braided polyester fabric, composed entirely of PET. The device contains no microbial, animal or medicinal components.

Gillinov-Cosgrove Clip: ACH2, PRO1, PRO2

V-Clip: PROV, ACHV

Reasons for needing the device:

Your healthcare provider team has recommended that your LAA be closed with an AtriClip as part of your cardiac surgery procedure. The AtriClip will remain on the LAA of your heart to ensure it remains closed.

Side effects:
There are no side effects associated with the implant of the AtriClip; however, your surgeon will inform you of potential adverse effects from your heart procedure.

Contact your doctor if you experience unexpected side effects after your procedure or have questions about your implant.

Warnings/Precautions:

MRI- Magnetic resonance imaging (MRI) is a medical imaging technique that uses magnetic fields to create images of the body. The AtriClip device is MR conditional, so you can be scanned safely in an MR system immediately after placement. You should still talk to your doctor if you need imaging studies to discuss the specific conditions of your imaging study. Showing your patient information card (PIC) may be helpful as the PIC specifies your implanted device.

The AtriClip device will become fully encapsulated in the surrounding tissues while remaining implanted for the patient lifetime.

Precautions:

You should follow and comply with all physician recommendations, precautions, and post-surgical medical appointments.

<u>About Your Procedure</u>

Pre-operative Screening:
During the preoperative screening phase (before the surgery is performed) the following evaluations may be reviewed or performed:

- A physical exam
- Blood tests to rule out infection and to check for a normal red blood cell count and platelet count

The following tests may also be completed during this visit:

- A urine pregnancy test
- A Transthoracic (across the chest) Echocardiogram (TTE) will be performed at this visit if one is not already documented in your recent medical history. This is used to produce images and sounds that can be used by the physician to detect damage and disease, and the size and function of your heart.

Intra-operative (day of surgery):

The following will occur during your surgical procedure:
• A Transesophageal Echocardiogram (TEE) probe will be used to confirm that there are no clots in your atria (the upper chambers of your heart), and to assess the function and size of your heart. This procedure requires a probe to be inserted down your throat into the esophagus (the organ that connects the throat to the stomach). You will be under anesthesia while this study is performed. This procedure is a standard part of the surgery.
• The heart surgery required to correct your heart problem (if applicable). During the surgery, your surgeon will use the AtriClip device to close off the LAA of your heart.
• The TEE will be used to confirm that your LAA is completely closed off by the AtriClip. You will still be under anesthesia while this happens.

Post-Operative (prior to discharge):
The following procedures will be performed:
• A physical exam, including a review of any complications you experienced during your hospital stay
• A review of all medications you have taken while in the hospital prior to discharge
• Blood tests to assure a stable blood volume, that you do not have an infection, and that your liver and kidneys are functioning properly.

Any serious incidents occurring in relation to the device should be reported to the Manufacturer (AtriCure, Inc. 7555 Innovation Way, Mason, OH 45040 USA 1-866-349-2342) and the Therapeutic Goods Administration at https://www.tga.gov.au/

7555 Innovation Way
Mason, OH 45040 USA
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