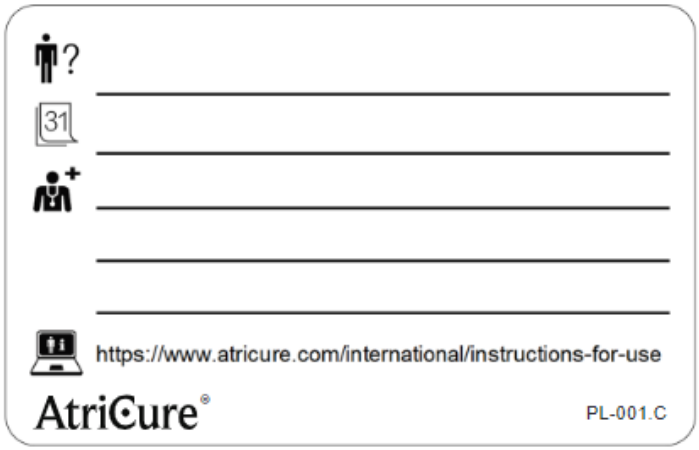
AtriCure®

MD

Patient Information Leaflet

AtriClip Left Atrial Appendage (LAA) Exclusion System



Front of the card - Figure 1

Back of the card – Figure 2

INSTRUCTIONS FOR COMPLETION of the Implant Card:
The following information should be completed by the healthcare institution/provider on the front of the implant card (See FIGURE 1).

	Patient Identification
	Procedure Date
	Name and Address of the Implanting Healthcare Institution/Provider

PATIENT INFORMATION:
The implant card serves as a record of the Atrial Closure implant you have received. The information on the implant card helps communicate information about this implant. It can be presented to physicians or airport security. The implant card should be presented anytime you are subject to a Magnetic Resonance Imaging (MRI) screening, as the information helps ensure the MRI does not interfere with the implanted device.

In the event you need to get a replacement card for your implant, you will need to have the UDI and lot information for your device off the rear of the card (See FIGURE 2). Contact the manufacturer to request a replacement card.

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In the unlikely event of any issues with the implant, the information on the implant card will ensure that your physician can inform you if you are impacted.

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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	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	

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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.

Manufacturing residuals have been assessed and do not pose a risk to the patient.

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.

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About Your Procedure

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/

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