AtriClip® Left Atrial Appendage Exclusion System

THE MOST WIDELY PLACED LAA EXCLUSION DEVICE IN THE WORLD

WWW.ATRICURE.COM
Why the AtriClip® Left Atrial Appendage Exclusion System by AtriCure®?

1 / LAA ISOLATION

In preclinical and clinical studies, the AtriClip device securely sealed the LAA orifice resulting in a smooth endothelial tissue surface within 90 days.\(^1\)\(^,\)\(^2\)\(^,\)\(^3\)

2 / NON-PIERCING

Non-piercing application occludes the LAA. Woven polyester fabric covering promotes tissue ingrowth and promotes complete encapsulation in 90 days from implant, without erosion of adjacent structures.\(^1\)\(^,\)\(^4\)

3 / EXCLUDE - SAFETY

The AtriClip device provides safe and atraumatic exclusion of the LAA during open cardiac surgery.\(^5\)

4 / CUSTOM FIT TO SPECIFIC ANATOMY

AtriClip\(^®\) devices are custom fitted to the LAA anatomy and are available in four sizes, including 35 mm, 40 mm, 45 mm and 50 mm.\(^5\)

DEVICE DEPLOYMENT OPTIONS

- **AtriClip® FLEX**  
  (figure 3)  
  - Flexible shaft (6cm)  
  - Plunger grip

- **AtriClip® PRO**  
  (figure 4)  
  - Quick deploy feature  
  - Head articulation ±30° omnidirectional with lock feature  
  - Rigid shaft (25 cm)

- **AtriClip® Long**  
  (figure 5)  
  - Head articulation ±90° lateral  
  - Malleable shaft (25 cm)

- **AtriClip® Standard**  
  (figure 6)  
  - Stiff shaft (6 cm)  
  - Plunger grip  
  - Head articulation
AtriCure, Inc. is a medical device company providing innovative atrial fibrillation (Afib) solutions designed to produce outcomes that reduce the economic and social burden of atrial fibrillation. AtriCure’s Synergy™ Ablation System is the first and only surgical device approved for the treatment of persistent and longstanding persistent forms of Afib in patients undergoing certain open concomitant procedures. AtriCure’s AtriClip™ left atrial appendage management (LAAM) exclusion device is the most widely sold device worldwide that’s indicated for the occlusion of the left atrial appendage. AtriCure recently acquired nContact, a leader in minimally invasive technology for epicardial ablation. nContact’s mission is to transform the underserved arrhythmia population through a multidisciplinary epicardial-endocardial ablation approach. Afib affects more than 33 million people worldwide. For more information visit AtriCure.com or follow us on Twitter @AtriCure.
Products

**ATRICLIP® PRO LAA EXCLUSION SYSTEM**
- 35 mm AtriClip PRO 135
- 45 mm AtriClip PRO 145
- 40 mm AtriClip PRO 140
- 50 mm AtriClip PRO 150

**ATRICLIP® FLEX LAA EXCLUSION SYSTEM**
- 35 mm AtriClip ACH 235
- 45 mm AtriClip ACH 245
- 40 mm AtriClip ACH 240
- 50 mm AtriClip ACH 250

**ATRICLIP® LAA EXCLUSION SYSTEM, LONG**
- 35 mm AtriClip LAA 035
- 45 mm AtriClip LAA 045
- 40 mm AtriClip LAA 040
- 50 mm AtriClip LAA 050

**ATRICLIP® LAA EXCLUSION SYSTEM, STANDARD**
- 35 mm AtriClip ACH 135
- 45 mm AtriClip ACH 145
- 40 mm AtriClip ACH 140
- 50 mm AtriClip ACH 150
EXCLUDE Trial (#G080095)\(^7\)

- FDA trial to evaluate the safety and efficacy of the AtriClip\(^\text{®}\) LAA Exclusion System for the exclusion of the LAA via epicardial tissue approximation
- Prospective, non-randomized (N=70 patients)/open chest during concomitant cardiac surgery/Multi-Center (7)
- Definition of Exclusion: Complete exclusion of the LAA is defined as no communication (blood flow) between the LAA and LA as evidenced by contrast-enhanced CT scan at three months post implant.

**INCLUSION CRITERIA FOR EXCLUDE TRIAL**

Subject has any one of the following risk factors and is thought to benefit from LAA exclusion:
- CHADS score > 2
- Age > 75 years
- Hypertension and age > 65 years
- History of Atrial Fibrillation (any classification)
- Previous Stroke

Concomitant Cardiac Surgery

**OUTCOMES (N = 70)**

- 52.1% of subjects had no history of AF
- 70/70 clips placed successfully
- 69/70 complete exclusion confirmed by intra-op TEE
- 60/61 exclusion confirmed by 3 month CT Scan
- No device or clip procedure-related adverse events reported in the study

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**FIGURE 5. CONSISTENT FORCE**

*The AtriClip\(^\text{®}\) device securely seals the LAA orifice resulting in a smooth endothelial tissue surface.*

Become a MAZE IV trained surgeon with the Isolator® Synergy™ Ablation System, the only FDA-approved surgical device to treat Afib. Visit www.atricure.com/atrial-fibrillation/training to learn more.

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Please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events prior to using these devices.

US Only: AtriCure Synergy™ OLL2/OSL2 clamps are approved to ablate cardiac tissue for the treatment of PAF or LSP Afib in patients who are undergoing open concomitant CABG and/or valve replacement or repair. AtriCure Coolrail® linear pen, Synergy Access® and Synergy EMR2/EML2 clamps are cleared for cardiac tissue ablation. The AtriCure Isolator® multifunctional pen and Isolator® linear pen are cleared to both diagnose cardiac arrhythmias and ablate cardiac tissue. ACC2 and CryoICE® BOX devices, manufactured by AtriCure, are cleared for the treatment of cardiac arrhythmias. The AtriClip® LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

Europe Only: AtriCure clamps are approved for the treatment of Afib. The Isolator pen and Isolator Synergy Access are cleared to ablate soft tissue. The Isolator linear pen is cleared to ablate cardiac tissue and temporarily pace, sense, record and stimulate during evaluation of cardiac arrhythmias. ACC2 and CryoICE BOX devices, manufactured by AtriCure, are cleared for the treatment of cardiac arrhythmias. The AtriClip LAA Exclusion System is used for open occlusion of the heart’s left atrial appendage.

Non-European International: See www.atricure.com or Instructions for Use for a full listing of indications.

Rx Only.

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