AtriCure®

AtriClip® FLEX-Mini LAA Exclusion System

INSTRUCTIONS FOR USE

#ACHM35, ACHM40, ACHM45, ACHM50

Rx ONLY MD

⚠**Caution:** Federal Law (US) restricts this device to sale by or on the order of a physician

FIGURE 1

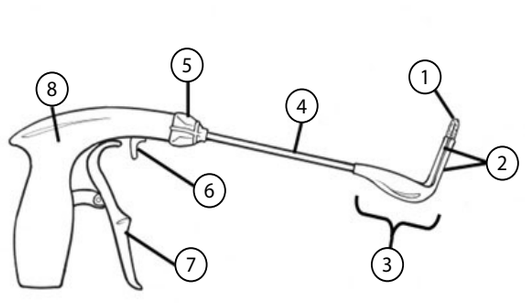


FIGURE 2

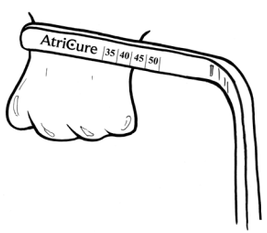


FIGURE 3

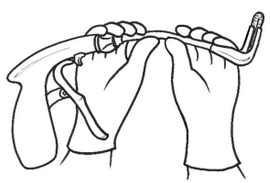
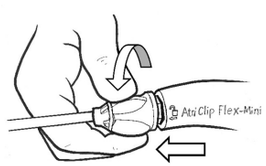


FIGURE 4



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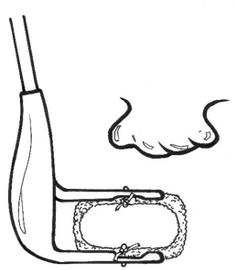

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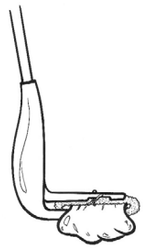


FIGURE 7

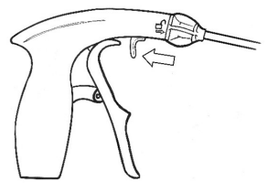
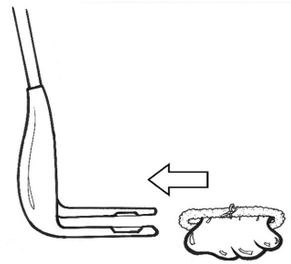


FIGURE 8



INSTRUCTIONS FOR USE (en)

AtriClip® LAA Exclusion System

INDICATION FOR USE

The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed 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 other appropriate viewing technologies.

CONTRAINDICATIONS

1. Do not use this device as a contraceptive tubal occlusion device.
2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy).
3. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in the presence of infected operating field.

SYSTEM DESCRIPTION

The AtriClip FLEX-Mini LAA Exclusion System contains an AtriClip Mini (Clip) for exclusion of the heart's left atrial appendage (LAA). Preclinical animal studies (Kamohara 2005, 2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical studies.

The AtriClip FLEX-Mini LAA Exclusion Systemis a delivery and deployment device preloaded with an AtriClip Mini. The AtriClip Mini is preloaded on a disposable Clip applier. The AtriClip Mini is a permanent implant; device lifetime is equal to patient lifetime. The Clip was determined to be "MR Conditional" per the requirements of standard ASTM F2503-23.

The AtriClip FLEX-Mini LAA Exclusion System is used to deliver a preloaded Clip to the target LAA site. The Clip is a sterile, permanent implant composed of Titanium (Ti64) beams, nitinol springs and covered in a knit-braided Polyethylene Terephthalate fabric that contains a small fraction of titanium dioxide. The AtriClip FLEX-Mini LAA Exclusion System is not made with natural rubber latex and does not contain phthalates. Detailed materials information for implanted AtriClip Mini sizes 35 mm to 50 mm is below.

Material	Mass (g)	CAS #
Titanium Ti64	0.76-1.07	Titanium, 7440-32-6 Aluminum, 7429-90-5 Vanadium, 7440-62-2
Polyethylene Terephthalate	0.14-0.18	25038-59-9
Nitinol	0.17-0.18	Nickel, 7440-02-0 Titanium, 7440-32-6
Titanium Dioxide	0.001	13463-67-7

ENVIRONMENTAL SPECIFICATIONS

Operating	Storage	Transit
Temperature: > 20°C (68°F)	Temperature: -29°C/ -20°F to 60°C/ 140°F	Temperature: -29°C/ -20°F to 60°C/ 140°F
Relative Humidity: N/A	Relative Humidity: 15% to 85%	Relative Humidity: 30% to 85%
Atmospheric Pressure: N/A	Atmospheric Pressure: N/A	Atmospheric Pressure: N/A

PACKAGE CONTENTS

1. One (1) AtriClip FLEX-Mini LAA Exclusion System
2. One (1) Implant Card and one (1) Implant Card Leaflet

The AtriClip FLEX-Mini LAA Exclusion System is supplied STERILE and NON-PYROGENIC in an unopened, undamaged package. For single use only. Do not re-sterilize. Do not re-use.

SYSTEM ACCESSORIES

Other devices, not included with the System, may be used in conjunction with the AtriClip FLEX-Mini LAA Exclusion System. These may include but are not limited to the following:

- Selection Guide (CGG100) (Guide) - Packaged Separately

ATRICLIP FLEX-MINI LAA EXCLUSION SYSTEM

NOMENCLATURE (SEE FIGURE 1)

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

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

⚠ WARNINGS⚠

Read all instructions carefully for the AtriClip LAA Exclusion System before use and use the device only as intended. Use of the AtriClip LAA Exclusion System should be limited to properly trained and qualified medical personnel. Improper use of this system may lead to device malfunction, failure to provide intended therapy, and/or serious injury to user or patient.

The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.

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.

Evaluate if thrombus is present in LAA. Management of thrombus is dependent on surgeon's standard of care. It is not recommended to place Clip on LAA if there is evidence of thrombus in LAA. Doing so may result in serious patient injury.

Do not use the Clip or applier to dissect tissue.

If there are concerns about the presence of adhesions on target anatomy in redo surgery, do not use device. Doing so may result in tissue damage.

⚠ WARNING ⚠

This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use this device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.

COMPLICATIONS

Potential complications which may be associated with the use of a left atrial appendage closure device or surgical procedure include but are not limited to:

- Air embolism
- Allergic reaction to anesthesia, anticoagulant, implant material
- Anaphylactic shock
- Anesthesia risks
- Aneurysm
- Angina
- Arrhythmia needing medical treatment (new onset)
- Arterial or venous dissection and/or perforation
- Arterial rupture
- Arterial spasm
- Arteriovenous fistula
- Atelectasis (major lung collapse with significant symptoms such as cyanosis, extreme shortness of breath, dyspnea, and/or stabbing pain on the affected side)
- Atrial rupture
- Atrio-esophageal fistula
- AV block requiring permanent pacemaker (new onset)
- Bleeding requiring intervention
- Blood vessel damage
- Cardiac perforation
- Cardiac tamponade
- Cardiac valve injury
- Cerebrovascular accident (CVA)/Transient Ischemic Attack (TIA)/stroke (ischemic or hemorrhagic)
- Chest pain/discomfort
- Compression of coronary artery
- Conduction disturbances
- Congestive heart failure (new onset or exacerbation)
- Coronary artery injury
- Death
- Device breakage/inability to remove
- Device-related death
- Diaphragmatic paralysis (unilateral or bilateral)
- Drug reaction (significant reaction to any procedure related medications requiring treatment, including allergic reaction and anaphylactic shock)
- Emergency during procedure requiring a change in planned access
- Empyema
- Endocarditis (bacterial)
- Esophageal injury
- Esophageal rupture
- Extension of cardiopulmonary/extracorporeal bypass
- Fever
- Gastric motility disorders
- Gastro-intestinal bleed
- Hematoma
- Hematuria
- Hemothorax
- Hypertension
- Hypotension
- Iatrogenic atrial flutter
- Iatrogenic lung injury (e.g., chest tube placement)
- Ischemia
- Kinking of coronary artery
- LAA dehiscence
- LAA tears
- Left atrial embolism
- Myocardial infarction (MI)
- Nerve injury (phrenic, laryngeal, thoracic, etc.)
- Pain/discomfort
- Pericardial effusion
- Pericarditis
- Permanent pacemaker
- Persistent chest pain (post discharge surgical incision pain, not angina)
- Phrenic nerve paralysis
- Pleural effusion
- Pneumonia
- Pneumothorax
- Postoperative embolic complications
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Renal insufficiency or failure
- Respiratory distress or failure (breathing problems)
- Sepsis
- Stenosis of left circumflex artery
- Sterility-related infection
- Superficial wound infection
- Surgical site infection
- Systemic adverse reaction due to device corrosion
- Thrombus and/or thromboembolism (including deep vein thrombosis)
- Tissue injury
- Tissue perforation
- Tracheal esophageal trauma
- Vascular access complications

INSTRUCTIONS FOR USE

Surgeon judgment, with the assistance of the Guide, should determine what size Clip to apply.

This IFU is designed to assist in using this product. It is not a reference to surgical techniques.

CLIP SELECTION

⚠ WARNING ⚠

Carefully consider any presurgical treatment the patient may have undergone when selecting 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. Failure to correctly size the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, lack of desired hemostasis, and/or incomplete exclusion of the structure.

AtriCure®

1. Using the Guide, determine correct selection of the AtriClip Mini (See Figure 2). Clip sizes are located on the device package.

Labeled Clip Size	LAA Size Range
35 mm	29 – 35 mm (1.14 - 1.38 in)
40 mm	34 – 40 mm (1.34 - 1.57 in)
45 mm	39 – 45 mm (1.54 - 1.77 in)
50 mm	44 – 50 mm (1.73 - 1.97 in)

⚠ WARNINGS ⚠

Do not use on a compressed LAA less than 29 mm (1.14 in) in width and 1 mm (0.04 in) wall thickness. Doing so may result in: tissue in trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis.

Do not use on a compressed LAA greater than 50 mm (1.97 in). Doing so may result in incomplete exclusion of the structure.

2. Using sterile technique, remove the AtriClip FLEX-Mini LAA Exclusion System from its packaging.

⚠ WARNING ⚠

If the sterile package is damaged and/or the sterile barrier is breached, discard device and DO NOT USE to avoid the risk of patient infection.

⚠**CAUTION:** Do not drop the device as this may induce damage to the device. If the device is dropped, do not use. Replace with a new device.

3. Using the Activation Lever on the Handle, gently open and close the Clip to assure proper function.

SHAFT BENDING

⚠**CAUTION:** 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. The entire length of the Shaft is malleable and intended for adjustments up to 45° in any direction. 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.

4. The AtriClip FLEX-Mini contains a malleable Shaft that may be reshaped to aid in accessing the LAA. Apply gentle pressure to shape the device Shaft as required for anatomical variations (See Figure 3).

⚠**CAUTION:** 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.

SHAFT ROTATION

5. By pulling the Shaft Rotation Knob forward (distal) and twisting it to the left or right, the End Effector of the AtriClip FLEX-Mini 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 (See Figure 4).

⚠ **CAUTION:** Ensure the Shaft Rotation Knob is in the locked position before attempting to open the Clip.

6. To lock the End Effector in position, release forward pressure on the Shaft Rotation Knob and ensure that it is seated into position.

CLIP POSITIONING

⚠ WARNING ⚠

Take care not to damage surrounding structures when maneuvering and positioning the Clip.

Position and deploy Clip in a manner that provides direct visualization of all tissues being accessed. 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 other appropriate viewing technologies. Poor visualization may result in suboptimal placement and damage or obstruction of surrounding structures.

7. With the Clip in the closed position, maneuver the AtriClip FLEX-Mini LAA Exclusion System into the targeted dissection plane.
8. Gently open the Clip by squeezing the Activation Lever (See Figure 5). Ensure the Shaft Rotation Knob is in the locked position before attempting to open the Clip.

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 (See Figure 6).
10. Position the Clip in a manner that provides clear visualization of all tissues being accessed.
11. After the Clip is positioned correctly, slowly release the Activation Lever allowing the Clip to close.
12. 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.
13. If the Clip is not placed correctly, gently open the Clip and reposition as needed.

DEPLOYMENT

⚠ WARNINGS ⚠

Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the 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 hemostasis.

Unless medically necessary, do not attempt to reposition or remove the Clip after deployment. This may result in tissue damage or tearing.

14. Deploy the Clip by pulling the Deployment Trigger at the nose of the Handle (See Figure 7).

NOTE: 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.

NOTE: An audible "click" will be heard when the Deployment Trigger has been activated.

⚠**CAUTION:** Take care to minimize manipulation of the LAA and Clip after Clip deployment.

15. Carefully remove the End Effector from the LAA as shown in Figure 8, leaving the Clip and attachment suture behind.

NOTE: After pulling the Deployment Trigger, the AtriClip FLEX-Mini LAA Exclusion System cannot be used to reposition or remove the Clip.

DISPOSAL INFORMATION

After use, this device should be treated as medical waste and disposed of following hospital protocol.

SERIOUS INCIDENT

Any serious incident that has occurred in relation to this device should be reported to AtriCure.

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 assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

HANDLING INFORMATION: ATRICLIP MINI

MRI SAFETY INFORMATION

MR CONDITIONAL

The AtriClip Mini is MR Conditional. A patient with the AtriClip Mini may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient

- **Nominal Values of Static Magnetic Field:** 1.5-Tesla or 3.0-Tesla
- **Maximum Spatial Field Gradient:** 40 T/m (4,000 gauss/cm)
- **Type of RF Excitation:** Circularly Polarized (CP) (i.e., quadrature-transmission)
- **Transmit RF Coil Information:** There are no transmit RF coil restrictions. Accordingly, the following may be used: Body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
- **Operating Mode of MR System:** Normal Operating Mode
- **Maximum Whole Body Averaged SAR:** 2 W/kg (Normal Operating Mode)
- **Limits on Scan Duration:** Whole body averaged SAR of 2 W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
- **MR Image Artifact:** The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

SYMBOLS GLOSSARY

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

	Single sterile barrier system with protective packaging outside		Single sterile barrier system with protective packaging inside
	Manufacturer		Caution
PHT	Does not contain phthalates		Contains hazardous substances
	Do not use if package is damaged		Non-pyrogenic
STERILE R	Sterilized using irradiation		Consult Instructions For Use
	Do not re-use	STERILIZE	Do not re-sterilize
LATEX	Not Made with natural Rubber Latex	REF	Catalogue Number
#	Model Number	UDI	Unique Device Identifier
LOT	Lot Number		Use-by date
Rx ONLY	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician	MR	MR Conditional
US	Country of Manufacture	MD	Medical Device
	Keep dry		
60°C 140°F / -29°C -20°F	Transit Temperature limit	85% / 30%	Transit Humidity limit

REFERENCES

1. Kamohara K, et al. A novel device for left atrial appendage exclusion. J Thorac Cardiovasc Surg 2005
2. Kamohara K, Fukamachi et al. Evaluation of a novel device for left atrial appendage exclusion: the second-generation atrial exclusion device. J Thorac Cardiovasc Surg 2006
3. Starck C, et al. Epicardial left atrial appendage Clip occlusion also provides the electrical isolation of the left atrial appendage. Interactive CardioVascular and Thoracic Surgery 15 (2012)

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