

 WARNINGS

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

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

- Using sterile technique, remove the AtriClip 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.

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

 WARNING

Do not open and close the Clip more than 3 times with the Activation Lever prior to deployment. This may lead to incomplete exclusion of the structure.

- By pressing the Articulation Release Button and pulling it backwards (proximal) into the unlocked position, the Deployment Loop of the AtriClip LAA Exclusion System may be manually articulated up and down and side-to-side from 0° (inline – as supplied) to ±30° relative to the shaft to aid in the proper placement of the AtriClip to take into account anatomical variations in the patient’s anatomy (See Figure 3).
- To lock the End Effector in position, disengage the Articulation Release Button by pushing down, forward and then releasing.

 **CAUTION:** Do not attempt to articulate the Deployment Loop while in the locked position. Force applied while in the locked position may cause damage to the device.

CLIP POSITIONING

 WARNING

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.

 **CAUTION:** Do not kink or bend the Shaft as this may affect device performance.

- Maneuver the AtriClip LAA Exclusion System into the targeted dissection plane.
- Gently open the Clip by squeezing the Activation Lever.

NOTE: The Clip can be locked in the open position by means of a locking feature in the Handle of the device. The lock will engage when the Activation Lever is activated and can be disengaged by gently pressing the Lever Release Button.

- Orient the Clip applicator with preloaded Clip at the tip of the LAA. Ensure the loops at the ends of the Clip are pointed away from the LAA (See Figure 4).
- Gently position the Clip at the base of the LAA (See Figure 5).
- Position the Clip in a manner that provides clear visualization of all tissues being accessed.
- 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.
- 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.

- After the Clip is positioned correctly, grasp the Activation Lever and depress the Lever Release Button. Slowly release the Activation Lever, allowing the Clip to close.
- Deploy the Clip by slowly pulling the Deployment Tab at the proximal end of the Handle.

NOTE: The Deployment Tab with steel cables may be completely removed from the end of the Handle (See Figure 6).

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

- Following Clip deployment carefully squeeze the Activation Lever to retract the Clip Pull Bar against the Deployment Loop of the Clip applicator to prevent unintentional tissue snags when removing the Deployment Loop.
- Carefully remove the Deployment Loop from the LAA leaving the Clip and attachment suture behind (See Figure 7).

NOTE: After pulling the Deployment Tab, the AtriClip 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

MRI SAFETY INFORMATION

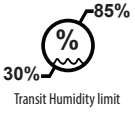
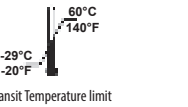


The AtriClip is MR Conditional. A patient with the AtriClip may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient:

- 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
- 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
	Does not contain phthalates		Contains hazardous substances
	Do not use if package is damaged		Non-pyrogenic
	Sterilized using irradiation		Consult Instructions For Use
	Do not re-use		Do not re-sterilize
	Not Made with natural Rubber Latex		Catalogue Number
	Model Number		Unique Device Identifier
	Lot Number		Use-by date
	Prescription Use Only		MR Conditional
	Country of Manufacture		Medical Device
	Keep dry	 85% 30% Transit Humidity limit	
 -29°C -20°F 60°C 140°F Transit Temperature limit			

REFERENCES

- Kamohara K, et al. A novel device for left atrial appendage exclusion. J Thorac Cardiovasc Surg 2005
- 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
- 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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