

AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip

Instructions for Use

PRO235, PRO240, PRO245, PRO250

MD

CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician.

MISE EN GARDE: En vertu de la loi fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.

FIGURE 1

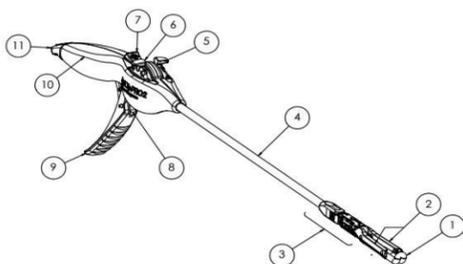


FIGURE 2

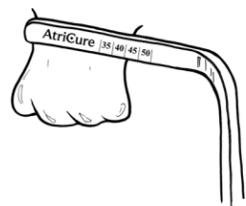


FIGURE 4

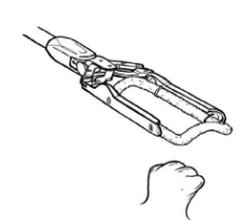


FIGURE 6

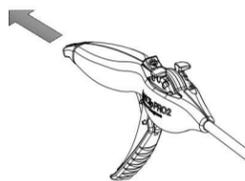


FIGURE 3



FIGURE 5

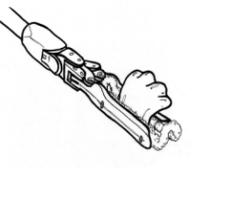
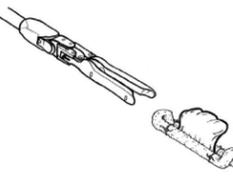


FIGURE 7



INSTRUCTIONS FOR USE

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AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip

INDICATION FOR USE

The AtriClip LAA Exclusion System is indicated for the occlusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other open cardiac surgical procedures.

CONTRAINDICATIONS

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

SYSTEM DESCRIPTION

The AtriClip LAA Exclusion System contains the Gillinov-Cosgrove LAA Clip (Clip) for occlusion of the heart's left atrial appendage (LAA).

The AtriClip LAA Exclusion System is a delivery and deployment device preloaded with a Gillinov-Cosgrove LAA Clip. The Clip is preloaded on a disposable Clip applicator. The Gillinov-Cosgrove Clip 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 F2503-20.

The AtriClip LAA Exclusion System is used to deliver a preloaded clip to the target LAA site. The Clip is a sterile, permanent implant composed of Grade 2 Titanium and Polyurethane beams, Nitinol springs, and covered in a knit-braided Polyethylene Terephthalate fabric that contains a small fraction of titanium dioxide. The AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip is not made with natural rubber latex and does not contain phthalates. Detailed materials information for implanted Clip sizes 35 mm to 50 mm are below:

Material	Mass (g)	CAS #
Titanium Grade 2	0.51 to 0.72	7440-32-6
Polyurethane	0.52 to 0.68	9009-54-5
Nitinol	0.27 to 0.39	Nickel, 7440-02-0 Titanium, 7440-32-6
Polyethylene Terephthalate	0.35 to 0.39	25038-59-9
Titanium Dioxide	0.001 to 0.002	13463-67-7

ENVIRONMENTAL SPECIFICATIONS

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

PACKAGE CONTENTS

- One (1) AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip
- One (1) Implant Card and (1) Implant Card Leaflet

The AtriClip LAA Exclusion System is supplied STERILE and NON-PYROGENIC in 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 LAA Exclusion System. These may include but are not limited to the following:

- Selection Guide (CGG100) (Guide)—Packaged Separately
- Minimum 12 mm port

ATRICLIP LAA EXCLUSION SYSTEM

NOMENCLATURE (SEE FIGURE 1)

- | | |
|-----------------------------|---------------------------|
| [1] Gillinov-Cosgrove Clip | [7] Articulation Lock |
| [2] Clip Opening Jaws | [8] Lever Release Trigger |
| [3] End Effector | [9] Activation Lever |
| [4] Shaft | [10] Handle |
| [5] Left/Right Articulation | [11] Deployment Tab |
| [6] Up/Down Articulation | |

⚠ 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.

Do not use on tissue which, in the opinion of the surgeon, would not be able to tolerate conventional suture materials or conventional closure techniques (such as surgical stapling). Doing so may result in: tissue trauma, dehiscence, tissue tearing, displacement and/or lack of desired hemostasis.

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 in temperatures below 20°C (68°F). Application of Clip in temperatures below 20°C (68°F) may affect device performance and result in incomplete occlusion of the structure.

The Clip contains nitinol, an alloy of nickel (CAS# 7440-02-0) and titanium (CAS# 7440-32-6). Persons with allergic reactions to nickel may suffer an allergic reaction to this implant. Prior to implantation, patients should be counselled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

COMPLICATIONS

Potential complications associated with the use of the AtriClip PRO2 LAA Exclusion System and procedure include, but are not limited to, those listed below:

- 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-related death
- Device breakage/inability to remove
- 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 occlusion of the structure.

- Using the Guide, determine correct selection of the LAA Clip (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 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 occlusion of the structure.

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

⚠ WARNINGS ⚠

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.
Visually check for rust on the Applier jaws prior to use. The Applier should not be used for durations longer than 1 hour to prevent the formation of rust. Failure to do so may result in a systemic adverse reaction.

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 occlusion of the structure.

ARTICULATION OF END EFFECTOR

- By pushing down and pulling the Articulation Lock backwards (proximal), the End Effector of the AtriClip LAA Exclusion System may be manually articulated up and down and side-to-side by either the articulation levers or pressing on the End Effector. The Clip and End Effector can articulate 30° left or right and 30° up or down to take into account anatomical variations in the patient's anatomy (See Figure 3).
- To lock the End-Effector in position, press the Articulation Lock forward.

CAUTION: Do not attempt to articulate the End Effector 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. 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 automatically locks in the fully open position by means of a Locking Trigger on the handle of the device. The lock can be disengaged by pressing the Lever Release Trigger.

- Orient the Clip applier 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.
- After the Clip is positioned correctly, grasp the Activation Lever, depress the Lever Release Trigger, and slowly release the Activation Lever to allow the Clip to close.

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.

- 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.

- Unlock the End Effector articulation and carefully remove it 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.

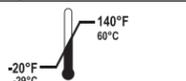
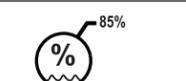
- Champ magnétique statique de 1,5 tesla et de 3 teslas, uniquement.
- Champ magnétique de gradient spatial maximal de 4 000 gauss/cm (40 T/m) (extrapolé) ou moins.
- Taux d'absorption spécifique (TAS) maximal, moyenné sur l'ensemble du corps, rapporté par le système RM, de 4 W/kg pour 15 minutes d'IRM (c'est-à-dire par séquence d'impulsions), en mode de fonctionnement contrôlé de premier niveau pour le système RM.
- Les conditions d'examen IRM définies pour l'agrafe Gillinov-Cosgrove devraient produire une augmentation de température maximale de 2,9 °C (5,22 °F) après 15 minutes d'IRM en continu (c'est-à-dire par séquence d'impulsions).

INFORMATION CONCERNANT LES ARTÉFACTS

Dans le cadre de tests non cliniques, l'artéfact provoqué par l'agrafe Gillinov-Cosgrove s'est étendu à environ 10 mm par rapport à l'agrafe Gillinov-Cosgrove, lors de séquences d'impulsion en écho de gradient avec un système RM de 3 teslas.

EN SYMBOLS GLOSSARY \ FR GLOSSAIRE DES SYMBOLES

en Refer to the outer package label to see which symbols apply to this product. \ fr Se reporter à l'étiquette de l'emballage extérieur pour consulter les symboles qui s'appliquent à ce produit.

	en Single Sterile Barrier System with protective packaging outside \ fr Système de barrière stérile simple avec emballage de protection à l'extérieur		en Single Sterile Barrier System with protective packaging inside \ fr Système de barrière stérile simple avec emballage de protection à l'intérieur
	en Manufacturer \ fr Fabricant		en Caution \ fr Mise en garde
	en No Phthalates \ fr Pas de phtalates		en Keep dry \ fr Conserver au sec
	en Do not use if package is damaged \ fr Ne pas utiliser si l'emballage est endommagé		en Non-pyrogenic \ fr Apyrogène
	en Sterilized by Gamma Radiation \ fr Stérilisé par rayonnement gamma		en Consult Instructions For Use \ fr Consulter le mode d'emploi
	en Do not re-use \ fr Ne pas réutiliser		en Do not re-sterilize \ fr Ne pas restériliser
	en Not Made with natural Rubber Latex \ fr Ne contient pas de latex de caoutchouc naturel		en Catalogue Number \ fr Référence catalogue
	en Model Number \ fr Numéro de modèle		en Unique Device Identifier \ fr Identifiant unique du dispositif (UDI)
	en Lot Number \ fr Numéro de lot		en Use-by date \ fr Date de péremption
	en For prescription use only \ fr Uniquement sur ordonnance		en MR Conditional \ fr Compatible avec l'IRM sous certaines conditions
	en Country And Date of Manufacture \ fr Pays et date de fabrication		en Medical Device \ fr Dispositif médical
 <p>en Transit Temperature limit \ fr Limite de température durant le transport</p>		 <p>en Transit Humidity limit \ fr Limite d'humidité durant le transport</p>	



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