Summary of Safety and Clinical Performance (SSCP)

AtriClip LAA Exclusion System with Selection Guide

18 November 2022

REVISION B

OVERVIEW

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

INFORMATION INTENDED FOR USERS/ HEALTHCARE PROFESSIONALS:

Following this information there is a summary intended for patients.

1. Device Identification and General Information

Product name	AtriClip LAA Exclusion System with Selection Guide
Product group/family Basic UDI-DI	AtriClip LAA Exclusion System: 084014390000000000000016ZQ Selection Guide (CGG100): 084014390000000000000017ZS
Manufacturer legal name, address, and Single Registration Number (SRN)	AtriCure 7555 Innovation Way Mason, OH 45040 USA SRN: US-MF-000002974
EU Authorised Representative name, address, and Single Registration Number (SRN)	AtriCure Europe B.V. De entree 260 1101 EE Amsterdam NL SRN: NL-AR-000000165
European Medical Device Nomenclature (EMDN) code and description	ACH1: P070404 – Left Atrial Appendage Occluders ACH2: P070404 – Left Atrial Appendage Occluders PRO1: P070404 – Left Atrial Appendage Occluders PRO2: P070404 – Left Atrial Appendage Occluders PROV: P070404 – Left Atrial Appendage Occluders ACHV: P070404 – Left Atrial Appendage Occluders CGG100: Z12059099 – Various Instruments for Cardiology and Cardiac Surgery – Other
Product classification and rule (per MDR)	ACH1: Class III, Rule 8 ACH2: Class III, Rule 8 PRO1: Class III, Rule 8 PRO2: Class III, Rule 8 PROV: Class III, Rule 8 ACHV: Class III, Rule 8 CGG100: Class III, Rule 6

Year when the first certificate (CE) was issued covering the device	ACH1: 2010 ACH2: 2015 PRO1: 2012 PRO2: 2016 PROV: 2019 ACHV: 2019 CGG100: 2009
Notified Body Name, address, and number	BSI Say Building John M. Keynesplein 9 1066 EP Amsterdam NL +31 20 346 0780 CE 2797

2. Intended Use of the Device

2.1. Intended Purpose

The AtriClip LAA Exclusion System facilitates delivery and placement of AtriClip device for exclusion of the heart's left atrial appendage.

The AtriClip Selection Guide (Guide) is used to aid in the selection of the appropriate AtriClip size for exclusion of the left atrial appendage with the AtriClip LAA Exclusion System.

2.2. Indication(s) and target populations

Indications for Use:

The AtriClip LAA Exclusion System is indicated for use in patients at high risk of thromboembolism for whom left atrial appendage exclusion is warranted.

The AtriClip Selection Guide (Guide) is used to aid in the selection of the appropriate AtriClip size for exclusion of the left atrial appendage with the AtriClip LAA Exclusion System.

Target Patient Populations:

Patients at high risk of thromboembolism who are anatomically eligible for left atrial appendage exclusion.

2.3. Contraindications and/ or limitations

AtriClip LAA Exclusion System:

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). *[Note: This does not apply to PROV and ACHV.]*

Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field.

Selection Guide:

None known.

3. Device Description

3.1. Description of the device

Gillinov-Cosgrove LAA Clip (AOD1) Pre-Loaded Appliers: ACH1 (Figure 1), ACH2 (Figure 2), PRO1 (Figure 3), PRO2 (Figure 4):

The AtriClip LAA Exclusion System contains the Gillinov-Cosgrove LAA Clip (Clip) for exclusion of the heart's left atrial appendage (LAA). The Clip is preloaded on a disposable Clip applier. The AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip is not made with natural rubber latex or phthalates.

The AtriClip LAA Exclusion System is used to deliver a preloaded clip to the target LAA site. 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 a delivery and deployment device preloaded with a Gillinov-Cosgrove LAA Clip. 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.

Figure 1. AtriClip Standard LAA Exclusion System with Pre-Loaded Gillinov-Cosgrove Clip (ACH1)

Figure 2. AtriClip Flex LAA Exclusion System with Pre-Loaded Gillinov-Cosgrove Clip (ACH2)

Figure 3. AtriClip PRO LAA Exclusion System with Pre-Loaded Gillinov-Cosgrove Clip (PRO1)

Figure 4. AtriClip PRO2 LAA Exclusion System with Pre-Loaded Gillinov-Cosgrove Clip (PRO2)

PRO•V Pre-Loaded Clip Applier (Figure 5):

The AtriClip PRO•V LAA Exclusion System contains the V Clip (AOD2) for exclusion of the heart's left atrial appendage (LAA). The Clip is preloaded on a disposable Clip applier. The AtriClip PRO•V LAA Exclusion System with preloaded V Clip is not made with natural rubber latex or phthalates.

The AtriClip PRO•V LAA Exclusion System is used to deliver a preloaded clip to the target LAA site. The V 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 PRO•V LAA Exclusion System is a delivery and deployment device preloaded with a V clip. The Clip is a sterile, permanent implant composed of Grade 5 Titanium and covered in a knit, braided Polyethylene Terephthalate fabric that contains a small fraction of titanium dioxide.

Figure 5. AtriClip PRO•V LAA Exclusion System (PROV)

FLEX•V Pre-Loaded Clip Applier (Figure 6):

The AtriClip FLEX•V LAA Exclusion System contains a V Clip for exclusion of the heart’s left atrial appendage (LAA). The Clip is preloaded on a disposable Clip applier. The FLEX•V LAA Exclusion System with preloaded V Clip is not made with natural rubber latex or phthalates.

The AtriClip FLEX•V LAA Exclusion System is used to deliver a preloaded clip to the target LAA site. The V 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 FLEX•V LAA Exclusion System is a delivery and deployment device preloaded with a V Clip. The Clip is a sterile, permanent implant composed of Grade 5 Titanium and covered in a knit, braided Polyethylene Terephthalate fabric that contains a small fraction of titanium dioxide.

Figure 6. AtriClip FLEX•V LAA Exclusion System (ACHV)

AtriClip Selection Guide (CGG100; Figure 7):

The AtriClip Selection Guide is an accessory that works in conjunction with the AtriClip LAA Exclusion System. The AtriClip LAA Exclusion System is comprised of the AtriClip LAA Exclusion Device (Clip), the AtriClip Applier, and the Selection Guide.

The Selection Guide is a single patient use surgical instrument designed to assist in the selection of the appropriate Clip. The Selection Guide is malleable and may be placed directly adjacent to the Left Atrial Appendage (LAA) for sizing. The markings on the guide facilitate the evaluation of the structure and selection of the appropriate Clip size. The markings on the guide are 4 mm +/- 0.5 mm (0.16 in +/- 0.02 in) shorter than the clip nominal dimensions to approximate the appendage compression when the clip is applied. Tissue thickness, appendage geometry, and other factors can affect sizing decisions. Therefore, it is the physician's judgement to select the appropriate size.

The Selection Guide (CGG100) is a sterile accessory composed of aluminum and cured polyurethane ink. It does not contain latex and does not contain phthalates.

Figure 7. Selection Guide (CGG100)

3.2. A reference to previous generation(s) or variant(s) if such exist, and a description of the differences

The ACH1 Clip Applier preloaded with AOD1 was CE marked in 2010. ACH1 features design variations intended to provide an additional option for the surgeon, including a rigid shaft, a plunger style handle, and a non-articulating, hoop-shaped end effector that is fixed at a 90° angle relative to the shaft. The AOD1 clip is deployed manually by cutting the suture in the suture cutting zone on the ACH1 handle.

The PRO1 Clip Applier preloaded with AOD1 was CE marked in 2012. The PRO1 device was introduced as a design alternative intended to provide an additional option for the surgeon. PRO1 features an end effector that can be manually configured to ±30° both vertically and laterally, and which may be locked and unlocked. PRO1 features a lever on the handle that can open and lock the clip in the fully open position, as well as a button on the handle which unlocks and closes the clip. Like ACH1, the PRO1 device has a hoop-

shaped end effector. PRO1 includes a deployment tab that, when pulled, releases the AOD1 clip and attachment suture from the applier.

The ACH2 Clip Applier preloaded with AOD1 was CE marked in 2015. ACH2 was predicated by ACH1, with the purpose of providing an additional option to the surgeon. ACH2 has a malleable shaft. Like ACH1, the ACH2 has a plunger style handle, a non-articulating, hoop-shaped end effector, and manual deployment of the AOD1 clip by cutting the suture in the suture cutting zone.

The PRO2 Clip Applier preloaded with AOD1 was CE marked in 2016. PRO2 was predicated by the PRO1 device, with the purpose of providing an additional option to the surgeon. Like PRO1, the PRO2 device features an end effector that can be manually configured to ±30° both vertically and laterally, and which may be locked and unlocked. PRO2 includes active articulation levers on the handle to control the vertical and lateral articulation of the end effector. The end effector has an open-ended, hoopless design with a smaller diameter (12 mm) than the hoop-shaped end effector of PRO1. Like PRO1, PRO2 includes a deployment tab that, when pulled, releases the AOD1 clip and attachment suture from the applier.

The PROV Clip Applier preloaded with AOD2 was CE marked in 2019. PROV was predicated by PRO2, with the purpose of providing an additional option for the surgeon. The PROV end effector was designed to accommodate the V-shaped AOD2 clip. The AOD2 clip differs from the AOD1 clip in its shape (open-ended V-shape versus box/loop-shape, respectively). AOD2 is machined from a single piece of titanium as opposed to AOD1 being manufactured from two titanium beams covered by polyurethane and connected by Nitinol springs. AOD2 closes tip-first, whereas AOD1 closes uniformly in time along the entire length. Like PRO1 and PRO2, the PROV Clip Applier includes a deployment tab that, when pulled, releases the AOD2 clip and attachment suture from the applier.

The ACHV Clip Applier preloaded with AOD2 was CE marked in 2019. ACHV was predicated by ACH2, with the purpose of providing an additional option for the surgeon. ACHV has an end effector designed to rotate and articulate, a pistol-style grip to provide an alternative handle style option to the user, and a clip deployment trigger to release the AOD2 clip from the end effector.

Table 1 lists the changes to the AtriClip LAA Exclusion System since EU market introduction in 2009.

Table 1. Changes to the AtriClip LAA Exclusion System

Description of Change	Date of Change	Model(s) Impacted	Purpose of Change
Initial market release	September 2009	LAA0*; CGG100	Placed first AtriClip LAA Exclusion System with Selection Guide on the EU market.
Addition of ACH1 to System	December 2010	ACH1	Added ACH1 as an alternative option for users.
Addition of PRO to System	December 2012	PRO1	Added PRO1 as an alternative option for users.
Change of suture material	October 2014	LAA0*, ACH1, PRO1	Suture material changed from silk to polyester to match the raw material used in the knit-braided polyester covering of the

Description of Change	Date of Change	Model(s) Impacted	Purpose of Change
			AOD1 clips.
Lubricant added to end effector of PRO	October 2014	PRO1	Lubricant added to the end effector of PRO1 to reduce friction of the articulation joint
Change to inner tube diameter specification of the AOD1 Clip	October 2014	LAA0*, ACH1, PRO1	Inner tube diameter specification changed to avoid a possible interference with the Nitinol springs during assembly.
Addition of ACH2 to System	March 2015	ACH2	Added ACH2 as an alternative option for users.
Addition of PRO2 to System	June 2016	PRO2	Added PRO2 as an alternative option for users.
Design and components change to PRO2 applier	May 2017	PRO2	PRO2 applier underwent minor design and component changes.
Alternate supplier qualified for clip fabric and spring in the AOD1 Clip	May 2019	LAA0*, ACH1, ACH2, PRO1, PRO2	Added an alternate supplier for the clip fabric and spring.
Change in suture supplier, low-stretch suture introduced	May 2019	LAA0*, ACH1, ACH2, PRO1, PRO2	Suture supplier ceased operation, so a new suture supplier was qualified.
Change to articulation cable anchor design	May 2019	PRO1	The clamp plate and shrink tube design was changed to a clasp and washer design to secure the cables and to reduce the occurrence of cables slipping out of the anchor point.
Addition of PROV and ACHV to System	September 2019	PROV, ACHV	Added PROV and ACHV appliers (pre-loaded with AOD2 Clip) as alternative options for users.
Alternate supplier and processing changes qualified for the Clips: AOD1 titanium tubes and AOD2 fabric	November 2020	LAA0*, ACH1, ACH2, PRO1, PRO2, PROV, ACHV	Added alternate suppliers for two materials used for components of the implanted Clips (AOD1 titanium tubes and AOD2 fabric), which also included related component processing changes.
**LAA0 is not in scope of this Summary of Safety and Clinical Performance.*			

3.3. Description of any accessories which are intended to be used in combination with the device

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 12mm port *[Note: PRO2 and PROV only.]*

3.4. Description of any other devices and products which are intended to be used in combination with the device

None.

4. Risks and warnings

4.1. Residual risks and undesirable effects

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

Table 2. Potential Complications

Potential Complication	Residual Risk: Probability of Occurrence within 30 Days[1]	
Air embolism	≤5%; ≤5 out of 100 people	Rare
Allergic reaction to anesthesia, anticoagulant, implant material	≤5%; ≤5 out of 100 people	Rare
Anaphylactic shock[2]	<0.1%; <1 out of 1000 people	Improbable
Anesthesia risks	≤5%; ≤5 out of 100 people	Rare
Aneurysm	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Angina	≤5%; ≤5 out of 100 people	Rare
Arrhythmia needing medical treatment (new onset)	≤5%; ≤5 out of 100 people	Rare
Arterial or venous dissection and/or perforation	≤5%; ≤5 out of 100 people	Rare
Arterial rupture	≤5%; ≤5 out of 100 people	Rare
Arterial spasm	≤5%; ≤5 out of 100 people	Rare
Arteriovenous fistula	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Atelectasis (major lung collapse with significant symptoms such as cyanosis, extreme shortness of breath, dyspnea, and/or stabbing pain on the affected side)	≤5%; ≤5 out of 100 people	Rare
Atrial rupture	≤5%; ≤5 out of 100 people	Rare

Potential Complication	**Residual Risk: Probability of Occurrence within 30 Days[1]**	
Atrio-esophageal fistula[3]	≤0.5%; ≤5 out of 1000 people	Extremely Rare
AV block requiring permanent pacemaker (new onset)	≤5%; ≤5 out of 100 people	Rare
Bleeding requiring intervention	≤5%; ≤5 out of 100 people	Rare
Blood vessel damage	≤5%; ≤5 out of 100 people	Rare
Cardiac perforation	≤5%; ≤5 out of 100 people	Rare
Cardiac tamponade	≤5%; ≤5 out of 100 people	Rare
Cardiac valve injury	≤5%; ≤5 out of 100 people	Rare
Cerebrovascular accident (CVA)/TIA/stroke (ischemic or hemorrhagic)	≤5%; ≤5 out of 100 people	Rare
Chest pain/discomfort[4]	≤50%; ≤50 out of 100 people	Very common
Compression of coronary artery[2]	<0.1%; <1 out of 1000 people	Improbable
Conduction disturbances	≤5%; ≤5 out of 100 people	Rare
Congestive heart failure (new onset or exacerbation)	≤5%; ≤5 out of 100 people	Rare
Coronary artery injury	≤5%; ≤5 out of 100 people	Rare
Death	≤5%; ≤5 out of 100 people	Rare
Device breakage/inability to remove	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Device-related death	<0.1%; <1 out of 1000 people	Improbable
Diaphragmatic paralysis (unilateral or bilateral)	≤5%; ≤5 out of 100 people	Rare
Drug reaction (significant reaction to any study related medications requiring treatment, including allergic reaction and anaphylactic shock)	≤5%; ≤5 out of 100 people	Rare
Emergency during procedure requiring a change in planned access	≤5%; ≤5 out of 100 people	Rare
Empyema[5]	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Endocarditis (bacterial)	≤5%; ≤5 out of 100 people	Rare

Potential Complication	**Residual Risk: Probability of Occurrence within 30 Days[1]**	
Esophageal injury[6]	<0.1%; <1 out of 1000 people	Improbable
Esophageal rupture	≤5%; ≤5 out of 100 people	Rare
Extension of cardiopulmonary/extracorporeal bypass	≤5%; ≤5 out of 100 people	Rare
Fever	≤5%; ≤5 out of 100 people	Rare
Gastric motility disorders	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Gastro-intestinal bleed	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Hematoma	≤5%; ≤5 out of 100 people	Rare
Hematuria	≤5%; ≤5 out of 100 people	Rare
Hemothorax	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Hypertension	≤5%; ≤5 out of 100 people	Rare
Hypotension	≤5%; ≤5 out of 100 people	Rare
Iatrogenic atrial flutter[2]	<0.1%; <1 out of 1000 people	Improbable
Iatrogenic lung injury (e.g., chest tube placement)	≤5%; ≤5 out of 100 people	Rare
Ischemia	≤5%; ≤5 out of 100 people	Rare
Kinking of coronary artery[2]	<0.1%; <1 out of 1000 people	Improbable
LAA dehiscence[2]	≤0.5%; ≤5 out of 1000 people	Extremely Rare
LAA tears[2]	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Left atrial embolism[2]	<0.1%; <1 out of 1000 people	Improbable
Myocardial infarction (MI)	≤5%; ≤5 out of 100 people	Rare
Nerve injury (phrenic, laryngeal, thoracic, etc.)	≤5%; ≤5 out of 100 people	Rare
Pain/discomfort	≤20%; ≤20 out of 100 people	More common
Pericardial effusion	≤20%; ≤20 out of 100 people	More common

Potential Complication	**Residual Risk: Probability of Occurrence within 30 Days[1]**	
Pericarditis	≤20%; ≤20 out of 100 people	More common
Permanent pacemaker[7]	≤10%; ≤10 out of 100 people	Somewhat common
Persistent chest pain (post discharge surgical incision pain, not angina)	≤20%; ≤20 out of 100 people	More common
Phrenic nerve paralysis	≤5%; ≤5 out of 100 people	Rare
Pleural effusion	≤5%; ≤5 out of 100 people	Rare
Pneumonia[8]	≤5%; ≤5 out of 100 people	Rare
Pneumothorax	≤5%; ≤5 out of 100 people	Rare
Postoperative embolic complications	≤5%; ≤5 out of 100 people	Rare
Pseudoaneurysm	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Pulmonary edema	≤5%; ≤5 out of 100 people	Rare
Pulmonary embolism	≤5%; ≤5 out of 100 people	Rare
Renal insufficiency or failure	≤5%; ≤5 out of 100 people	Rare
Respiratory distress or failure (breathing problems)	≤5%; ≤5 out of 100 people	Rare
Sepsis	≤5%; ≤5 out of 100 people	Rare
Stenosis of left circumflex artery[2]	<0.1%; <1 out of 1000 people	Improbable
Sterility-related infection[2]	≤0.5%; ≤5 out of 1000 people	Extremely Rare
Superficial wound infection[9]	≤5%; ≤5 out of 100 people	Rare
Surgical site infection[10]	≤5%; ≤5 out of 100 people	Rare
Systemic adverse reaction due to device corrosion[2]	<0.1%; <1 out of 1000 people	Improbable
Thrombus and/or thromboembolism (including deep vein thrombosis)	≤5%; ≤5 out of 100 people	Rare
Tissue injury	≤5%; ≤5 out of 100 people	Rare
Tissue perforation[2]	≤0.5%; ≤5 out of 1000 people	Extremely Rare

Potential Complication	**Residual Risk: Probability of Occurrence within 30 Days[1]**	
Tracheal esophageal trauma	≤5%; ≤5 out of 100 people	Rare
Vascular access complications[11]	≤20%; ≤20 out of 100 people	More common

[1] Unless otherwise indicated, the residual risk probabilities were sourced from AtriCure's LeAAPS Clinical Trial informed consent form, which reflects the cumulative effect of the device, implantation, and concomitant procedural risks.
[2] Residual risk probability sourced from AtriCure's risk management files. This is based on commercial complaint rates, which may be underreported.
[3] Source for probability: Han et al. (2017). Circ Arrhythm Electrophysiol. 10(11), e005579.
[4] Sources for probability: Guimarães-Pereira et al. (2017). Pain. 158(10):1869–85.
Gimpel et al. (2019). BMJ (Clinical research ed.). 365:l1303.
[5] Source for probability: Grijalva et al. (2011). Thorax. 66(8):663–8.
[6] Source for probability: Piercy et al. (2009). J Cardiothorac Vasc Anesth. 23(1):62-5.
[7] Sources for probability: Jilaihawi et al. (2012). Catheter Cardiovasc Interv. 80(1):128-38.
Worku et al. (2011). Ann Thorac Surg. 92(6):2085-9.
Toledano et al. (2016). Interact Cardiovasc Thorac Surg. 23(6):861-8.
Emkanjoo et al. (2008). Indian Pacing Electrophysiol J. 8(1):14-21.
[8] Sources for probability: Kilic et al. (2016). Thorac Cardiovasc Surg. 151(5):1415-20.
Ailawadi et al. (2017). J Thorac Cardiovasc Surg. 153(6):1384-91.
[9] Sources for probability: Montrief et al. (2018). AJEM. 36(12):2289–97.
Lemaignen et al. (2015). Clin Microbiol Infect. 21(7):674.e11-8.
[10] Sources for probability: Montrief et al. (2018). AJEM. 36(12):2289–97.
Lepelletier et al. (2005). Infect Control Hosp Epidemiol, 26(5):466-72.
[11] Source for probability: Mach et al. (2021). J Clin Med. 10(21):5046.

4.2. Warnings and precautions

Warnings: ACH1/ACH2

- 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.
- AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.
- 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 exclusion of the structure.
- The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.
- The ACH1 devices contain small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.
- The ACH2 devices contain small amounts of Nickel (CAS# 7440-02-0). Do not use the device if the patient has sensitivity to Nickel as this may result in an adverse patient reaction.
- 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.
- Do not use on a LAA less than 29mm (1.14 in) in width and 1.0mm (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 50mm (1.97 in) when tissue is uncompressed. Doing so may result in incomplete exclusion of the structure.
- 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.
- Do not open and close the Clip more than 3 times with the plunger prior to deployment. This may lead to incomplete exclusion of the structure.
- 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.
- 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.

Cautions: ACH1/ACH2

- 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.
- Do not kink or excessively bend the shaft as this may affect device performance.
- Do not grasp the Deployment Loop to apply bend to shaft, as this may result in damage to the device. Apply bend by gently concentrating force under both thumbs. Excessive bending or kinking of the shaft may affect device performance. Do not attempt to twist the Deployment Loop, as this may cause damage to the device.

- Take care to minimize manipulation of the LAA and Clip after Clip deployment.

Warnings: PRO1

- 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 individuals 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.
- AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.
- 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 exclusion of the structure.
- The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.
- This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.
- 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.
- Do not use on a LAA less than 29 mm (1.14 in) in width and 1.0 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.
- 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.
- 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.
- 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 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.

- 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.

Cautions: PRO1

- 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.
- Do not kink or bend the shaft as this may affect device performance.
- 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.
- Take care to minimize manipulation of the LAA and Clip after Clip deployment.

Warnings: PRO2

- 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 individuals 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.
- AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.
- 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 exclusion of the structure.
- The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.
- This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.
- 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.
- Do not use on a LAA less than 29mm (1.14 in) in width and 1.0mm (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 50mm (1.97 in) when tissue is uncompressed. Doing so may result in incomplete exclusion of the structure.
- 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.
- 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.
- 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.
- 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.

Cautions: PRO2

- 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.
- Do not kink or bend the shaft as this may affect device performance.
- 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.
- Take care to minimize manipulation of the LAA and Clip after Clip deployment.

Warnings: PROV

- 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.
- The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.
- AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.
- 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.
- This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.
- 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.
- Do not use on a LAA less than 29mm (1.14 in) in width and 1.0mm (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 50mm (1.97 in) when tissue is uncompressed. Doing so may result in incomplete exclusion of the structure.
- 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.
- 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.
- 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.

Cautions: PROV

- 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.
- Do not kink or bend the shaft as this may affect device performance.
- 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.
- Take care to minimize manipulation of the LAA and Clip after Clip deployment.

Warnings: ACHV

- 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.
- The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.
- AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.
- 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.
- This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.
- 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.
- Do not use on LAA less than 29mm (1.14 in) in width and 1.0mm (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 50mm (1.97 in) when tissue is uncompressed. Doing so may result in incomplete exclusion of the structure.
- 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.
- 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 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.
- 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.

Cautions: ACHV

- 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.

- Do not grasp 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 shaft is malleable and intended for adjustments up to 45 degrees 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.
- Do not attempt to rotate the device End Effector without pulling it out of the locked position. Force applied while in the locked position may cause damage to the device.
- Take care to minimize manipulation of the LAA and Clip after Clip deployment.

Warnings: Selection Guide

- If the sterile package is damaged and/or the sterile barrier is breached, discard the device and DO NOT USE to avoid the risk of patient infection.
- Do not apply excessive force when using the Guide. Using excessive force may cause tissue damage.
- Read all instructions for the Guide before use and use the device only as intended. Use of the Guide should be limited to properly trained and qualified medical personnel. Improper use of this device may lead to device malfunction, failure to provide intended therapy, and/or serious injury.
- Do not bend the Guide in the area of the indication marks. This may lead to incorrectly determining corresponding AtriClip size. Failure to correctly size the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis.
- DO NOT RESTERILIZE. The Guide is provided STERILE and is intended for SINGLE use only. Re-sterilization may cause injury to the patient.
- Use caution when using the Guide to determine the corresponding AtriClip size. Failure to correctly size the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis.
- This device contains small amounts of Nickel (CAS# 7440-02-0). Do not use the device if the patient has sensitivity to Nickel as this may result in an adverse patient reaction.

Cautions: Selection Guide

- The Guide is to be used only to assist with selecting the appropriate Clip.
- 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.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

MRI Safety Information: Gillinov-Cosgrove Clip (Preloaded on ACH1, ACH2, PRO1, and PRO2)

- MR Conditional: Non-clinical testing demonstrated that the Gillinov-Cosgrove Clip is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:
    - Static magnetic field of 1.5-Tesla and 3-Tesla, only
    - Maximum spatial gradient magnetic field of 4,000 gauss/cm (40-T/m)

(extrapolated) or less

- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system.
- The scan conditions defined for the Gillinov-Cosgrove Clip are expected to produce a maximum temperature rise of 2.9°C (5.22°F) after 15-minutes of continuous scanning (i.e., per pulse sequence).

- Artifact Information: In non-clinical testing, the image artifact caused by the Gillinov-Cosgrove Clip extends approximately 10 mm (0.39 in) from the Gillinov-Cosgrove Clip when imaged using a gradient echo pulse sequence and a 3-Tesla MR System.

MRI Safety Information: V Clip (Preloaded on PROV and ACHV)

- MR Conditional: Non-clinical testing demonstrated that the V Clip is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:
  - Static magnetic field of 1.5-Tesla and 3-Tesla, only
  - Maximum spatial gradient magnetic field of 4,000 gauss/cm (40-T/m) (extrapolated) or less
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system.
  - The scan conditions defined for the V Clip are expected to produce a maximum temperature rise of 3.1°C (5.58°F) after 15-minutes of continuous scanning (i.e., per pulse sequence).
- Artifact Information: In non-clinical testing, the image artifact caused by the V Clip extend approximately 20 mm (0.79 in) from the V Clip when imaged using a gradient echo pulse sequence and a 3 Tesla MR System.

Recalls

- Since 01 January 2016, there have been two recalls for the AtriClip LAA Exclusion System. A recall initiated on 22 September 2016 impacted PRO2 devices sold in the EU and US. The reason for this recall was the deployment tool locking in the open position. The second recall also affected PRO2 devices in the EU and US. This recall, initiated on 30 November 2016, involved a complaint of the PRO2 jaw breaking prior to surgery being performed. Both recalls have since closed. There were no harms to patients as a result of these device issues.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

This section comprehensively summarises the clinical evaluation results and the clinical data forming the clinical evidence for the confirmation of conformity with relevant general safety and performance requirements, the evaluation of undesirable side-effects, and the acceptability of the benefit-risk ratio. It includes a summary of all clinical data, whether favourable, unfavourable, or inconclusive.

5.1. Summary of clinical data related to equivalent device, if applicable

The conformity of AOD2 (V Clip) and its preloaded appliers, PROV and ACHV, was assessed by the Notified Body on the basis of equivalence. AOD2 has been demonstrated as equivalent to AOD1 (Gillinov-Cosgrove clip), PROV has been demonstrated as equivalent to PRO2, and ACHV has been demonstrated as equivalent to ACH2. These products are all legacy devices in the European Union and are all in scope of this Summary of Safety and Clinical Performance. Clinical studies supporting these devices will be described in Section 5.2 below.

5.2. Summary of clinical data from conducted investigations of the device before the CE-Marking, if applicable

AtriCure has sponsored four completed clinical trials: Zurich Clinical Trial, EXCLUDE, Stroke Feasibility Study, and ATLAS. These clinical trials are summarised in the tables below.

Table 3. Zurich Clinical Trial Summary

Identity of the investigation/study	Zurich Clinical Trial[1] [NCT00567515 on clinicaltrials.gov]
Identity of the device	Gillinov-Cosgrove Clip with reusable deployment tool[2] and Selection Guide
Intended use of the device in the investigation	Exclusion of the heart's left atrial appendage (LAA) in patients with atrial fibrillation (AF) who are undergoing elective open heart surgery
Objectives of the study	• Acute and long-term safety of the AtriClip (30 days through 3 years follow-up) • Acute and long-term effectiveness of the AtriClip to exclude the LAA (3 months through 3 years follow-up)
Study design and duration of follow-up	Study Design: Single-arm, open-label, single-centre, prospective, first-in-human trial Duration of Follow-up: 3 months, 12 months, 24 months, 36 months
Primary and secondary endpoint(s)	Safety: The safety endpoint of the study was the occurrence of any of the following device-related complications: o Stroke or transient ischemic attack (TIA) o Device migration o Infection (local and generalized) o Major adverse cardiac event (MACE) o Adjacent tissue injury/erosions Performance: Efficacy endpoints for the study were the following hemodynamic parameters confirming absence of blood flow in the LAA: o Direct vision and pressure measurement (LAA) at implant (acute) o Intraoperative echocardiography (acute)

[1] Outcomes from the Zurich Clinical Trial are published. Early trial outcomes are published in *Salzberg et al. 2010. J Thorac Cardiovasc Surg, 139(5):1269-74.* Final trial outcomes are published in *Emmert et al. 2014. Euro J Cardiothorac Surg, 45(1):126-31.* Long-term follow-up for the 40 Zurich Clinical Trial patients and 251 institutional registry patients is published in *Caliskan et al. 2018. Europace, 20(7):e105-14.*

[2] The reusable deployment tool is a previous generation of the currently marketed AtriClip LAA Exclusion System. The reusable deployment tool is not in scope of this Summary of Safety and Clinical Performance.

<table>
<tr><td></td><td>o CT scan (3 months, 12 months, 24 months, 36 months)</td></tr>
<tr><td>Inclusion/exclusion criteria for subject selection</td><td>Inclusion Criteria:
o Documented history (paroxysmal, persistent, or permanent) of AF [one episode within the last 12 months of enrollment]
o Elective Maze procedure
o Suitable anatomy
o Able and willing to sign informed consent
o Age over 18 years

Exclusion Criteria:
o Patient from intensive care unit with:
▪ intra-venous catecholamines, or
▪ ventilator, or
▪ cardiac index <1.8 l/min.
o Re-operative cardiac surgery
o Systemic or inflammatory disease
o Dialysis
o Recent myocardial infarction (<21 days)
o History of pericarditis
o Patient taking part in any other device or drug study
o Patient with known sensitivity or allergy to any of the device components
o Pregnancy</td></tr>
<tr><td>Number of enrolled subjects</td><td>Forty-one (41) patients were enrolled in this trial and 40 were treated. Four of the treated patients experienced early mortality due to non-device-related causes. Thus, 36 patients were included in follow-up.</td></tr>
<tr><td>Study population</td><td>Baseline characteristics of the 41 enrolled patients are presented below.
<table>
<tr><th>Characteristic</th><th>Value</th></tr>
<tr><td>Male, n (%)</td><td>25 (61%)</td></tr>
<tr><td>Female, n (%)</td><td>16 (39%)</td></tr>
<tr><td>Average Age, years</td><td>69</td></tr>
<tr><td>Max Age, years</td><td>84</td></tr>
<tr><td>Min Age, years</td><td>44</td></tr>
</table></td></tr>
<tr><td>Summary of study methods</td><td>Patients eligible for this study were slated to undergo elective cardiac surgery during which an ablation procedure for AF of any type was planned. Patients who met the inclusion/exclusion criteria for the study were implanted with the AtriClip during the concomitant procedure and followed up to three years with physical examination, laboratory examinations, electrocardiogram, chest X-ray, and CT scans.

After routine preparation of the patient for the planned surgical procedure and before opening the chest, transesophageal echocardiogram (TEE) was performed to confirm the absence of thrombus in the LA or LAA. Once positioned properly, the Clip was closed, and the deployment tool was removed</td></tr>
</table>

<table>
<tr><td></td><td>from the Clip and taken out of the sterile field. Satisfactory Clip placement meant the Clip was as close to the base of the appendage as anatomically possible in a transverse orientation to the roof of the LA.

The Clip was applied prior to inserting the prosthesis when performing a mitral valve replacement. In all other cases done on cardiopulmonary bypass, the Clip was applied immediately prior to opening the aortic cross clamp. If the case was an off-pump coronary artery bypass, the Clip was applied after myocardial revascularization.</td></tr>
<tr><td>Summary of results</td><td><u>Surgical Success:</u>
○ There were no reports of repositioning of the Clips; all Clips were applied in a single attempt.

<u>Mortality:</u>
○ Early mortality was 10% (4 of 40 patients) due to non-device-related reasons. These included:
▪ iatrogenic lung bleed (postoperative day 1)
▪ acute postoperative hepatic failure (postoperative day 16)
▪ bleeding due to aortic tear at aortotomy suture line (postoperative day 20)
▪ over-anticoagulation-related tamponade (postoperative day 24)
○ Late mortality was 11.1% (4 of 36 patients) due to non-device-related reasons. These included:
▪ heart and renal failure (8 months post-operatively)
▪ pneumonia (22 months post-operatively)
▪ mitral valve endocarditis (28 months post-operatively)
▪ generalized cancer (32 months post-operatively)
○ None of these deaths were related to the device or study participation, as demonstrated by an independent autopsy report and Data Safety Monitoring Board review.

<u>Safety:</u>
○ There were no Clip or deployment tool-related adverse events during the trial.
○ Three-year mortality and major complications among N=36 patients included the following:
<table><tr><th>Safety Outcome</th><th>Number of Patients (n, % n/N)</th></tr><tr><td>Overall mortality</td><td>4 (10.8%)</td></tr><tr><td>Device-related mortality</td><td>0 (0%)</td></tr></table></td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td>Stroke</td><td>0 (0%)</td></tr>
<tr><td>Transient ischemic attack</td><td>1 (2.7%)</td></tr>
<tr><td>Myocardial infarction</td><td>1 (2.7%)</td></tr>
<tr><td>Heart failure</td><td>1 (2.7%)</td></tr>
<tr><td>Arrhythmia</td><td>1 (2.7%)</td></tr>
<tr><td>Endocarditis</td><td>1 (2.7%)</td></tr>
<tr><td>Renal failure</td><td>1 (2.7%)</td></tr>
<tr><td>Pulmonary failure</td><td>0 (0%)</td></tr>
<tr><td>Liver failure</td><td>1 (2.7%)</td></tr>
<tr><td>Pneumonia</td><td>2 (5.2%)</td></tr>
<tr><td>Malignancy</td><td>1 (2.7%)</td></tr>
</table>
<u>Performance:</u>
○ Chest X-rays prior to discharge demonstrated that the AtriClip was properly positioned and stable in all cases.
○ CT scans confirmed the positioning of AtriClip and showed complete exclusion in all CT scans performed (postoperative, 3 months, 12 months, 24 months, 36 months).
○ At 36 months, LAA exclusion was complete in all surviving patients (32 of 32, 100%) with no residual LAA perfusion.
○ At each follow-up visit, none of the patients had a residual LAA neck of >1 cm (postoperative, 3 months, 12 months, 24 months, 36 months).
○ Imaging follow-up through 36 months showed stability of the clip.
</td></tr>
<tr><td>Study Limitations</td><td>○ Single-arm study design
○ Single centre
○ Study only evaluated the AtriClip as a concomitant therapy option in patients undergoing cardiac surgery; the device was not evaluated in the setting of treatment of lone AF for stroke prevention.</td></tr>
<tr><td>Any device deficiency or device replacements related to safety or performance during the study</td><td>None reported.</td></tr>
</table>

Table 4. EXCLUDE Trial Summary

Identity of the investigation/study	EXCLUDE[3] [NCT00779857 on clinicaltrials.gov]
Identity of the device	Gillinov-Cosgrove Clip (with first-generation applier)
Intended use of the device in the investigation	In this trial, the Clip was intended only for open exclusion of the heart's left atrial appendage.
Objectives of the study	The objective of this study was to evaluate the acute safety and efficacy of the AtriClip LAA Exclusion Device during concomitant cardiac procedures in patients at high risk for stroke.

[3] The EXCLUDE trial outcomes were published in *Ailawadi et al. 2011. JTCVS, 142(5):1002–9.*

Study design and duration of follow-up	Study Design: Prospective, single-armed, multi-centre, non-randomized study Duration of Follow-up: Primary safety endpoint through 30 days; primary efficacy endpoint evaluated at 3 months; general health and cardiac status, medications, NYHA classification, and adverse events documented through 24 months.
Primary and secondary endpoint(s)	Safety: ○ The primary safety endpoint was the rate of device-related serious adverse events (such as LAA tears, tissue injury, or bleeding which required intervention) within 30 days post-procedure or hospital discharge, whichever was later. Performance: ○ The primary efficacy endpoint for this study was the percent of patients with complete exclusion of the LAA as determined intraoperatively by TEE and at 3-months post-procedure on CT. Complete exclusion was defined as no fluid communication between the LA and the LAA. If the LAA cavity remained in communication with the LA, the primary efficacy endpoint was not achieved, and the patient was classified as a treatment failure. Intraoperative verification of completeness of LAA exclusion was also performed visually by the Investigator. If the LAA cavity was not totally excluded on visual exam, the primary efficacy endpoint was not achieved, and the patient was classified as a treatment failure. ○ Secondary endpoints to assess device performance included: ▪ Device placement success: The ability to successfully implant the device to the target location. ▪ Patient technical success: The ability to implant an AtriClip successfully in a patient. ▪ Intra-procedural success: The exclusion of the LAA assessed intra-procedurally by visual assessment as well as TEE. ▪ Three-month success: The exclusion of the LAA as assessed by a core lab review of a CT angiogram or based on TEE (assessed at the site by an echocardiographer not involved in the EXCLUDE trial) performed in the cases where CT was not feasible due to elevated creatinine or contrast allergy.
Inclusion/exclusion criteria for subject selection	Inclusion Criteria: ○ ≥18 years of age

	○ One of the following risk factors and 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 ○ Scheduled to undergo elective non-endoscopic cardiac surgical procedure(s) including cardiac surgery for one or more of the following: ▪ Mitral valve repair or replacement ▪ Aortic valve repair or replacement ▪ Tricuspid valve repair or replacement ▪ Coronary artery bypass procedures ▪ Concomitant surgical (ablation or cut-and-sew) Maze procedure ▪ Patent foramen ovale (PFO) closure ▪ Atrial septal defect (ASD) repair with the device deployed while on or prepared for cardio-pulmonary bypass support ○ Willing and able to provide written informed consent ○ Life expectancy of ≥2 years ○ Willing and able to return for scheduled follow-up visits <u>Exclusion Criteria:</u> ○ Previous cardiac surgery ○ Thrombus in the LAA/LA which cannot be evacuated prior to placement of the Clip ○ Patients requiring surgery other than CABG, and/or cardiac valve surgery, and/or surgical maze procedure (ablation or cut-and-sew), and/or PFO closure, and/or ASD repair ○ NYHA Class IV heart failure symptoms ○ Need for emergent cardiac surgery (i.e., cardiogenic shock) ○ Creatinine >200 µmol/L ○ LAA is not appropriate for exclusion based on intraoperative evaluations. ○ Current diagnosis of active systemic infection ○ Renal failure requiring dialysis or hepatic failure ○ A known drug and/or alcohol addiction ○ Mental impairment or other conditions which may not allow the subject to understand the nature, significance, and scope of the study ○ Pregnancy or desire to get pregnant within 12-months of the study treatment ○ Preoperative need for an intra-aortic balloon pump or intravenous ionotropes ○ Patients who have been treated with thoracic radiation

	○ Patients in current chemotherapy ○ Patients on long term treatment with oral or injected steroids (not including intermittent use of inhaled steroids for respiratory diseases) ○ Patients with known connective tissue disorders
Number of enrolled subjects	Seventy-one (71) subjects from 7 investigative centres in the United States were initially enrolled in the study. One patient was excluded after enrollment due to an LAA that was too small and did not meet eligibility criteria. AtriClip was implanted in 70 patients.
Study population	Patient Demographics (N=71) ○ Median Age: 74 years (range 48-87) ○ Male: 67.6% (48/71) ○ Female: 32.4% (23/71) ○ White: 97.2% (69/71) ○ Black:1.4% (1/71) ○ Hispanic: 1.4% (1/71) ○ Median Ejection Fraction: 55% (range 20-90%) ○ Median Left Atrial Size: 4.6 cm (range 1.9-6.5 cm) ○ History of AF: 47.9% (34/71) ○ CHADS Score >2: 38% (27/71) ○ Age >75 years: 46.5% (33/71) ○ Hypertension and Age >65 years: 77.5% (55/71) ○ Previous Stroke: 8.5% (6/71) Surgical Procedure (N=71) ○ CABG: 77.5% (55/71) ○ Mitral Valve Repair: 16.9% (12/71) ○ Mitral Valve Replacement: 7.0% (5/71) ○ Tricuspid Valve Repair: 5.6% (4/71) ○ Aortic Valve Replacement: 40.8% (29/71) ○ Atrial Septal Defect or Patent Foramen Ovale Closure: 0% (0/71) ○ Surgical (Ablation or Cut-and-Sew) Maze Procedure: 35.2% (25/71)
Summary of study methods	Before sternotomy, the LAA was assessed by intraoperative echocardiography to ensure no evidence of intra-atrial thrombus. After sternotomy, device insertion was performed at any point during the operation before, during, or without cardiopulmonary bypass and was based on surgeon preference. The base of the LAA was measured and the appropriate size clip was selected. The heart was rotated to the right such that the LAA was brought into view. The clip was placed at the base of the appendage avoiding the circumflex and pulmonary

	arteries. If the location of the clip was not satisfactory, the clip was repositioned before deployment. Once the clip was in optimal position, it was closed and released from the deployment tool manually. Successful LAA exclusion was assessed intraoperatively by TEE. The primary safety end point was device-related adverse events (AEs) at 30 days. The primary efficacy end point of successful LAA exclusion was a composite of intraprocedural TEE exclusion of flow to the LAA and exclusion assessed at 3-month follow-up by computed tomography angiography (CTA). Patients who could not receive intravenous contrast for CTA because of allergy or poor renal function underwent assessment by TEE. Efficacy of appendage exclusion was adjudicated by an independent core laboratory.
Summary of results	<u>Intraoperative Safety:</u> Among the 70 patients treated with the AtriClip, there were no instances of damage to the appendage, circumflex artery, or pulmonary artery. No patients experienced bleeding from the appendage and no patients required repair sutures. <u>Intraoperative Performance:</u> The clip did not migrate post-deployment in any of the 70 patients, and none of the patients required removal of the clip or LAA. Intraoperatively, 67 of 70 patients (95.7%) had successful exclusion of the LAA as assessed by postoperative TEE. A residual small stump was apparent in the remaining 3 patients. <u>Primary Safety Endpoint (30-Day Adverse Events):</u> The number and percent of patients (out of 70) who experienced an event within 30 days of the procedure are listed below. No events were attributable to the LAA exclusion or the AtriClip device. o AF: 2.9% (2/70) o Atrioventricular block: 10.0% (7/70) o Cardiac failure congestive: 4.3% (3/70) o Gastrointestinal haemorrhage: 1.4% (1/70) o Incision site infection: 1.4% (1/70) o Pneumonia: 1.4% (1/70) o Operative haemorrhage: 4.3% (3/70) o Postprocedural haemorrhage: 5.7% (4/70) o Ejection fraction decreased: 0.0% (0/70) o Renal failure: 4.3% (3/70) o Pleural effusion: 7.1% (5/70) o Pulmonary embolism: 1.4% (1/70) o Deep vein thrombosis: 1.4% (1/70) o Hypotension: 2.9% (2/70)

	○ Device-related serious AE: 0.0% (0/70) ○ Clip placement procedure-related serious AE: 0.0% (0/70) <u>Primary Efficacy Endpoint (3-Month LAA Exclusion Success)</u>: The number and percent of patients (out of 61) with complete exclusion of the LAA as determined at 3-months post-procedure by CT or TEE is described below. ○ 3-month success by CT evaluation by core laboratory: 98.2% (55/56) ○ 3-month success by TEE evaluation by site: 100% (5/5) The primary efficacy end point of composite intraprocedural exclusion by TEE and exclusion by CTA or TEE at 3 months was 95.1% (58/61). <u>Additional Safety Reporting (6-Month Adverse Events)</u>: The number and percent of patients (out of 70) who experienced an event within 6 months of the procedure are listed below. No events were attributable to the LAA exclusion or the AtriClip device. ○ AF: 2.9% (2/70) ○ Atrioventricular block: 10.0% (7/70) ○ Cardiac failure congestive: 5.7% (4/70) ○ Gastrointestinal haemorrhage: 1.4% (1/70) ○ Incision site infection: 1.4% (1/70) ○ Pneumonia: 1.4% (1/70) ○ Operative haemorrhage: 4.3% (3/70) ○ Postprocedural haemorrhage: 5.7% (4/70) ○ Ejection fraction decreased: 2.9% (2/70) ○ Renal failure: 5.7% (4/70) ○ Pleural effusion: 8.6% (6/70) ○ Pulmonary embolism: 1.4% (1/70) ○ Deep vein thrombosis: 1.4% (1/70) ○ Hypotension: 2.9% (2/70) ○ Device-related serious AE: 0.0% (0/70) ○ Clip placement procedure-related serious AE: 0.0% (0/70)
Study Limitations	○ Imaging follow-up is short-term (3 months), although clinical follow-up extends to 12 months. ○ Small cohort of patients (N=70). ○ Study not powered to assess reduction in stroke risk or to document efficacy of the AtriClip in stroke prophylaxis.
Any device deficiency or device replacements related to safety or performance during the study	In five cases it was deemed necessary by the operator to either remove or adjust the placement of the AtriClip to optimize results. In one situation the device selected was oversized and was therefore removed; a smaller device was successfully implanted. This occurred without any

	clinical sequelae, and the subject had a successful exclusion confirmed both intra-procedurally as well as at three months. In four cases it was deemed beneficial by the operator to adjust the placement of the AtriClip. The device had been placed, however, the physician felt it was not placed in an optimal position, so the physician adjusted the device location on the LAA. The subjects all had successful exclusion of the LAA without any clinical sequelae. Although this practice is considered a protocol deviation and is not recommended, it was performed successfully to achieve optimal results for the patients.

Table 5. Stroke Feasibility Study Summary

Identity of the investigation/study	AtriCure Stroke Feasibility Study [NCT01997905 on clinicaltrials.gov]
Identity of the device	PRO135, PRO140, PRO145, PRO150
Intended use of the device in the investigation	In this trial, the device was intended for exclusion of the heart's left atrial appendage (LAA), with delivery by a minimally invasive surgical procedure. The proposed indication for use was: *The AtriClip is intended to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation in whom long term oral anticoagulation therapy is medically contraindicated.*
Objectives of the study	The objective of this feasibility study was to evaluate the initial procedural safety and efficacy of the AtriClip for stroke prophylaxis (i.e., prevention of stroke) in patients with non-valvular atrial fibrillation, assessed at 3 months post-implant, in whom long term oral anticoagulation therapy was medically contraindicated.
Study design and duration of follow-up	Study Design: Prospective, multi-centre, single-arm, feasibility study Duration of Follow-up: Patients were assessed prior to hospital discharge, and at 30 days, 3 months, and 6 months post-index procedure.
Primary and secondary endpoint(s)	Primary Safety Endpoint: The primary safety endpoint consisted of the following serious adverse events within 30 days post-index procedure: ○ Serious injury to the cardiac structure or other body structure deemed to be related to the delivery or placement of the Clip ○ Cardiac-related death ○ Myocardial infarction ○ Ischemic stroke

	○ Major bleeding (defined as requiring re-operation and/or transfusion of >2 units packed red blood cells) within any 24-hour period during the first 2 days post-index procedure or at any time point if attributed to the device Secondary Safety Endpoints: ○ Overall serious device- or procedure-related adverse event rate: ▪ Incidence of all serious device- or procedure-related adverse events observed through the 3-month and 6-month follow-up assessments. ○ Overall serious adverse event (SAE) rate: ▪ Incidence of all SAEs regardless of attribution, observed through the 3-month and 6-month follow-up assessments. ○ Overall adverse event (AE) rate: ▪ Incidence of all device- or procedure-related AEs or any neurological related AEs, regardless of attribution, observed through the 3-month and 6-month follow-up assessments. Primary Efficacy Endpoint: The efficacy of the AtriClip LAA Exclusion System was defined as the success of the placement of the device and its performance in excluding the LAA. The primary efficacy endpoint was a success/failure endpoint with success requiring all the following: ○ Patient technical success: ▪ The ability to successfully implant an AtriClip device at the LAA in a patient. ○ Intra-procedural complete exclusion of the LAA: ▪ The complete exclusion of the LAA was defined by lack of fluid communication (<3 mm residual communication with LAA and <10 mm residual pocket) between the LA and LAA, assessed intra-procedurally by TEE. ○ Three-month follow-up complete exclusion of the LAA: ▪ The complete exclusion of the LAA was defined by lack of fluid communication (<3 mm residual communication with LAA and <10mm residual pocket) between the LA and LAA at ≥3-month TEE or CTA evaluation. Secondary Efficacy Endpoint:

	○ Composite of the following events within 3-months and 6-months post-index procedure: ▪ Stroke (ischemic) ▪ Non-central nervous system systemic embolism
Inclusion/exclusion criteria for subject selection	Inclusion Criteria: ○ Patient is ≥18 years and ≤80 years of age. ○ Patient has electrocardiographically confirmed non-valvular atrial fibrillation (paroxysmal, persistent, or longstanding persistent AF). ○ $CHADS_2$ or CHA_2DS_2-VASc score ≥2. ○ Patient has medical contraindication to long term anticoagulant therapy (OAC), defined as one or more of the following: ▪ History of intracranial bleeding (e.g., due to amyloid angiopathy or other condition) which renders patient unsafe for OAC ▪ History of gastrointestinal, genitourinary, or respiratory tract bleeding due to permanent condition which renders patient unsafe for OAC ▪ HAS-BLED Score ≥3 ○ Patient is considered an acceptable surgical candidate, including use of general anesthesia. ○ Female patients must be of non-childbearing potential or have a negative pregnancy test within 7 days prior to index procedure. Exclusion Criteria: ○ Stroke within 30 days prior to index procedure or TIA within 3 days prior to index procedure. ○ Documented medical history of any penetrating trauma to thorax, or blunt trauma to thorax which resulted in a left pneumothorax or left hemothorax. ○ Myocardial infarction within 60 days prior to index procedure. ○ NYHA Class IV heart failure. ○ Ejection fraction <40% (based on baseline transthoracic echocardiography (TTE)). ○ Prior attempted obliteration of left atrial appendage (percutaneous or open cardiac surgery). ○ Previous catheter ablation with perforation or complication. ○ Prior open cardiac surgery, or percutaneous coronary intervention with associated unintended cardiac perforation, or pericardial adhesions are suspected. ○ History of pericarditis or pericardiocentesis. ○ Active infection, septicemia, or fever of unknown origin.

	○ Concomitant elective surgical procedure (in addition to AtriClip placement) at the time of index procedure. ○ Planned atrial arrhythmia ablation procedure within six months following index procedure. ○ Underlying structural heart disease requiring planned surgical treatment within six months following the index procedure. ○ Cardiac or thoracic surgical procedure within the thirty days prior to index procedure. ○ Anticoagulation therapy for other medical condition (i.e., deep vein thrombosis) is required. ○ Patient unable to discontinue thienopyridines (e.g., clopidogrel) or non-ASA antiplatelet agents 4 days pre-operatively and abstain for at least 2 days post-operatively. ○ Renal Failure as defined by creatinine >2.0 mg/dl (>152.5 µmol/L) and/or need for dialysis. ○ Known carotid artery diameter stenosis greater than 80%. ○ Patient has symptomatic or high-grade carotid disease (>70% bilaterally). ○ Patient unable or unwilling to undergo transesophageal echocardiography (TEE). ○ Presence of thrombus in the left atrium or LAA, as determined by baseline TTE or Computed Tomography Angiogram (CTA). ○ Documented history of thrombophilic disorder, with diagnosis established via previous objective testing (e.g., familial screening for thrombophilia). ○ Moderate to Severe Chronic Obstructive Pulmonary Disease (FEV1 or VC<70% predicted) or intolerant of single lung ventilation. ○ History of hypercoagulopathy. ○ Body Mass Index (BMI) >35. ○ Other medical illness or comorbidity that may cause non-compliance with the protocol, confound data interpretation (e.g., severe dementia), or limited life expectancy (i.e., <3 months). ○ Enrolled in another investigational device or drug study at the time of enrollment and during the course of the study. ○ Psychiatric disorder which in the judgment of the investigator could interfere with informed consent, completion of tests, therapy, or follow-up. ○ Patient is pregnant or intends to become pregnant within 6-months post-index procedure.

	Intraoperative Exclusion Criteria: ○ Left atrial appendage width <29mm or >50mm, based on TEE imaging. ○ Presence of thrombus in the left atrium or LAA based on TEE imaging.
Number of enrolled subjects	A total of 13 subjects were enrolled from 4 sites. Of the 13 enrolled subjects, 10 were treated (defined as attempted surgery) with the investigational device.
Study population	The study population consisted of adult patients with non-valvular atrial fibrillation in whom oral anticoagulation is medically contraindicated. Demographic and baseline characteristics are available for 11 of the 13 subjects who were initially enrolled. Age (Years) N: 11 Mean (SD): 72.0 (8.85) Median: 74.0 Min, Max: 48, 80 Age Range 18-64 Years: 1 (9%) ≥65 Years of Age: 10 (91%) Gender (n, %) Female: 4, 36% Male: 7, 64% Race (n, %) American Indian or Alaska Native: 0, 0% Asian: 0, 0% Black or African American: 0, 0% Native Hawaiian or Other Pacific Islander: 0, 0% White: 11, 100% Other: 0, 0% Ethnicity (n, %) Hispanic or Latino: 1, 9% Non-Hispanic or Latino: 10, 91% NYHA Functional Class (n, %) I: 6, 60% II: 3, 30) III: 0, 0% IV: 0, 0% No Heart Block: 1, 10% $CHADS_2$ Score N: 10 Mean (SD): 2.9 (0.88) Median: 3.0 Min, Max: 2, 4 CHA_2DS_2-VASc Score N: 10 Mean (SD): 4.6 (0.84) Median: 5.0 Min, Max: 3, 6 HAS-BLED Score N: 10 Mean (SD): 3.6 (0.70)

	Median: 3.5 Min, Max: 3, 5
Summary of study methods	Four patients had totally thoracoscopic (TT) surgery, meaning the surgery was performed looking at the LAA through a scope. Five subjects had the surgery via Minimally Invasive Surgery (MIS) and had direct visualization wherein the surgeon was able to see the LAA without the use of imaging tools. Exclusion of the LAA was assessed intraprocedural by TEE and at 3-months by TEE or CTA evaluation.
Summary of results	Surgical Success: o The AtriClip was successfully placed in 9 patients. Safety: o Three cardiac disorder serious adverse events were reported (2 atrial fibrillation, 1 sick sinus syndrome), but all were adjudicated as pre-existing and unrelated to the procedure or device. o One patient died from a cause unrelated to the study and/or device. o There were no ischemic strokes or systemic embolisms reported in this feasibility study. Performance: o Intraoperatively, the sites reported that the LAA was fully excluded in all 9 (100%) patients. o At 3-months post-surgery, sites reported that the LAA was fully excluded in all 9 (100%) patients. However, following the adjudication of one subject, the independent adjudicator reported that his LAA was not fully excluded (residual communication of 5 mm). At 6-months post-surgery, the adjudicator and a third independent assessor concluded that the LAA was still not fully excluded, although the site maintained that the LAA was fully excluded. There were no protocol criteria deviations that could influence the effectiveness assessment.
Study Limitations	o No control group (single arm, not randomized) o Small sample size o Feasibility
Any device deficiency or device replacements related to safety or performance during the study	None reported.

Table 6. ATLAS Study Summary

Identity of the investigation/study	ATLAS[4] [NCT02701062 on clinicaltrials.gov]
Identity of the device	LAA035, LAA040, LAA045, LAA050, ACH135, ACH140, ACH145, ACH150, ACH235, ACH240, ACH245, PRO140 *Note: LAA0 devices are not part of this SSCP.*
Intended use of the device in the investigation	Exclusion of the heart's left atrial appendage (LAA)
Objectives of the study	○ Compare impact of post-operative AF (POAF) among two randomized treatment arms: patients with POAF and surgical LAA closure using the AtriClip LAA Exclusion System versus patients with POAF and no surgical LAA closure. ○ Evaluate long-term outcomes of LAA closure with the AtriClip in patients at risk of developing POAF.
Study design and duration of follow-up	Study Design: Prospective, multi-centre, randomized (2:1), unblinded pilot study Duration of Follow-up: Through 365 days post index procedure
Primary and secondary endpoint(s)	Primary Endpoint: ○ Number of perioperative complications associated with AtriClip placement. ▪ Timeframe: within any 24-hour period during the first 2 days post-index procedure ▪ Complications defined as: stroke, major bleeding that requires re-operation and/or transfusion of >2 U packed red blood cells, myocardial infarction, or death. Secondary Endpoints: ○ Number of subjects with intraoperative successful exclusion of LAA ▪ Timeframe: intraoperative period ▪ Successful exclusion of LAA defined as: no (0 mm) flow between LAA and <5 mm LAA remnant by intraoperative TEE with Doppler. ○ Composite event rates between subjects diagnosed with post-operative atrial fibrillation (POAF) ▪ Timeframe: through 365 days post-index procedure. ▪ Events to be evaluated include: thromboembolic and haemorrhagic events such as cerebrovascular accident

[4] The ATLAS trial outcomes were published in *Gerdisch et al. 2022. Innovations (Philadelphia, Pa.), 15569845221123796. Advance online publication. https://doi.org/10.1177/15569845221123796.*

<table>
<tr><td></td><td>(CVA), TIA, peripheral ischemia, haemorrhagic stroke, neurologic bleed, gastrointestinal bleeds, or other major bleeding event.</td></tr>
<tr><td>Inclusion/exclusion criteria for subject selection</td><td><u>Inclusion Criteria:</u>
Patients satisfying the following criteria were considered the screening population and were eligible for participation:
o Age >18 years, male or female.
o Scheduled for any non-mechanical valve and/or CABG (structural heart) procedure where direct access to the LAA is expected.
o No documented preoperative AF.
o CHA_2DS_2-VASc score of ≥2.
o HAS-BLED score of ≥2.
o Acceptable surgical candidate, including use of general anesthesia.
o Willing and able to provide written informed consent.

<u>Exclusion Criteria:</u>
Patients satisfying the following criteria were not eligible for participation:
o Redo cardiac surgery.
o Mechanical heart valve or other anticipated or current requirement for anticoagulation therapy during the post-operative (30-day) period.
o Hypercoagulability conditions that may confound the study.
o Ejection Fraction <30%.
o Left Atrium >6 cm.
o Severe Diastolic Dysfunction.
o Requires anticoagulation therapy.
o Patient had a stroke/CVA within previous 30 days prior to signing informed consent.

<u>Intra-Operative Exclusion Criteria</u>
o Presence of thrombus in the left atrium or LAA.
o LAA tissue is deemed friable or has significant adhesions (as evaluated by the surgeon) near or on the LAA making AtriClip placement overly risky.
o Left atrial appendage is outside the range of manufacturer's recommendations (width <29 mm or >50 mm).
o Direct visualization access is not available for AtriClip placement.</td></tr>
<tr><td>Number of enrolled subjects</td><td><u>AtriClip arm:</u> 376 patients
<u>No AtriClip arm:</u> 186 patients</td></tr>
<tr><td>Study population</td><td>
<table>
<tr><th>Characteristic</th><th>AtriClip (N=376)</th><th>No AtriClip (N=186)</th></tr>
<tr><td>Mean Age in Years (SD)</td><td>69.2 (7.8)</td><td>68.9 (8.7)</td></tr>
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</td></tr>
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	Female n, % n/N	113, 30.1%	50, 26.9%
	Male n, % n/N	263, 69.9%	136, 73.1%
	Hispanic or Latino Ethnicity n, % n/N	5, 1.3%	5, 2.7%
	Not Hispanic or Latino Ethnicity n, % n/N	370, 98.4%	180, 96.8%
	Unknown or Not Reported Ethnicity n, % n/N	1, 0.3%	1, 0.5%
	American Indian or Alaskan Native n, % n/N	0, 0%	1, 0.5%
	Asian n, % n/N	5, 1.3%	2, 1.1%
	Black or African American n, % m/N	13, 3.5%	7, 3.8%
	Native Hawaiian or Other Pacific Islander n, % n/N	0, 0%	1, 0.5%
	White n, % n/N	354, 94.1%	171, 91.9%
	Other Race n, % n/N	3, 0.8%	3, 1.6%
	More than One Race n, % n/N	1, 0.3%	1, 0.5%
	CHA_2DS_2-VASc Score Mean (SD)	3.4 (1.2)	3.4 (1.1)
	HAS-BLED Score Mean (SD)	2.8 (0.7)	2.9 (0.6)
Summary of study methods	All patients who were undergoing a valve or CABG (structural heart) procedure with direct visual access to the LAA were eligible to participate based upon consent and evaluation of the inclusion and exclusion criteria. The target patient population included patients at risk of POAF based on the CHA_2DS_2-VASc and HAS-BLED scoring. Patients were required to meet all inclusion/exclusion criteria (including intra-operative exclusion criteria) before enrolment or randomization. During the planned structural heart procedure, the intra-operative exclusion criteria were assessed. If any intra-operative exclusion criteria were met, the subject was a screen fail and was not enrolled or randomized. To execute randomization, at the time of enrolment, subjects were assigned a sequential identification number at each site and a corresponding sealed envelope which was opened		

	in the operating room to reveal the treatment group. Subjects were randomized 2:1 (2 with AtriClip to 1 with No AtriClip). Randomization sequences were generated by the AtriCure statistician and were stratified by site. Subject population was randomized using a blocking scheme for each surgeon to ensure equal and balanced treatment group allocations and to avoid bias with respect to known or unknown subject variables that could affect the outcome of the study. For subjects randomized to the No AtriClip arm, the left atrial appendage was left intact with no management. For subjects randomized to the AtriClip arm, the left atrial appendage was managed using the AtriClip LAA Exclusion System. Prior to and following deployment of the AtriClip, TEE with Doppler was performed to verify complete exclusion of the LAA and residual remnant less than 5 mm. Post-index procedure, all subjects were monitored per the hospital standard of care processes for POAF. Four (4) treatment arms resulted: o Surgery with AtriClip (POAF diagnosed / Institution Standard-of-Care anticoagulation therapy) o Surgery with AtriClip (no POAF) o Surgery with no AtriClip (POAF diagnosed / Institution Standard-of-Care anticoagulation therapy) o Surgery with no AtriClip (No POAF) Subjects were assessed for adverse events (AEs) related to the placement of the AtriClip and were instructed to notify the principal investigator of any AEs that occur during the study. All subjects that developed POAF during the hospital stay were followed for approximately 1 year (365 days) post-index procedure.
Summary of results	*Primary Endpoint (Safety):* There were no protocol-defined serious adverse events related to the device or application procedure. One (1) procedural serious adverse event (intraoperative torsion of the heart) (0.3%, 1/376) occurred but was resolved without sequalae; one (1) procedural non-serious adverse event occurred (post-pericardiotomy syndrome). Through 365-days follow-up, there were no thromboembolic events, hemorrhagic events, or deaths adjudicated as related to the AtriClip device or placement of the AtriClip.

<table>
<tr><td></td><td>
Secondary Endpoints (Successful Exclusion and Composite Event Rates):
<table>
<tr><th>Parameter</th><th>AtriClip N=376</th></tr>
<tr><td colspan="2">Clip Placement Determination</td></tr>
<tr><td>Appendage suitable for exclusion with AtriClip device</td><td>99.2% (373/376)</td></tr>
<tr><td>Alternative method used to exclude appendage</td><td>0.0% (0/376)</td></tr>
<tr><td colspan="2">Intraoperative Exclusion Success (Per TEE with Doppler)</td></tr>
<tr><td>Total Patients, No Flow with Stump ≤5 mm [(95%CI) (n/N)]</td><td>95.4% [(92.7-97.3) (353/370)]</td></tr>
<tr><td>Total Patients, No Flow with Stump ≤10 mm [(95%CI) (n/N)]</td><td>98.9% [(97.3-99.7) (366/370)]</td></tr>
</table>

During the 365-days follow-up, the composite event rates between groups diagnosed with POAF were not statistically different (p=0.2593), but overall event rate trended lower in the AtriClip without OAC subgroup (10/122; 8.2%) compared to the Standard of Care with OAC subgroup (4/25; 16%) and the combined Standard of Care with or without OAC group (7/71; 9.9%).

When all subjects were combined, irrespective of POAF and irrespective of OAC use, the subjects that received the AtriClip trended towards lower composite event rate (25/376; 6.6%) than the Standard of Care (No AtriClip) group (14/186; 7.5%), but this was not statistically significant (p=0.222).
</td></tr>
<tr><td>Study Limitations</td><td>ATLAS was an exempt post-market study. Therefore, the use of oral anticoagulants could not be directed or standardized across the study sites. This led to a wide variation to the medical post-operative management in both the types of drugs used for oral anticoagulation and the dosages prescribed. Furthermore, the sample size for this feasibility study is relatively small, which limits the ability to make a definitive conclusion on the impact of LAA exclusion and thromboembolic events.</td></tr>
<tr><td>Any device deficiency or device replacements related to safety or performance during the study</td><td>Among the treated subjects in the AtriClip group, there were four device observations reported. At least one observation occurred at each phase of the device application: before placement (2), during placement (1), and post-placement but prior to discharge (1). There were no reports of left atrium or left atrial appendage injuries requiring intervention due to attempted device placement. In addition, there were no unintended or excessive trauma as a result of device usage. The</td></tr>
</table>

	observation reported post-placement was for the serious adverse event of torsion of the heart and was resolved before completion of the procedure by repositioning the clip. In each case, the subject was successfully implanted and continued until study completion.

5.3. Summary of clinical data from other sources, if applicable

PROV Post-Market Evaluation

A prospective, multi-centre, non-randomized, unblinded, post-market evaluation of the PROV LAA Exclusion System with Selection Guide was conducted by AtriCure in 2016 per Good Clinical Practice. The primary objective of this investigation was to demonstrate the efficacy of the PROV open-ended clip (AOD2) in patients undergoing concomitant cardiac surgery. The efficacy of the device was evaluated for its exclusion of the LAA and for its ability to maintain position once deployed. Fifty-one (51) devices were implanted in patients (N=51) at three sites. Patients who planned to undergo designated non-emergent, non-endoscopic cardiac surgical procedure(s) with direct visual access to the LAA were eligible to participate based upon the inclusion and exclusion criteria defined in the protocol. The duration of the study was approximately 30 days post-operatively (range: 30-44 days). The study is summarized below in **Table 7**.

Table 7. PROV Post-Market Clinical Evaluation Summary

Number of subjects	51
Number of sites	3
Surgical approach	Minimally invasive or open sternotomy
Acute performance endpoints	Intra-procedural complete exclusion of the LAA
Acute safety endpoints	Intra-procedural measurement of the LAA stump
Post-implantation performance endpoints	30-day follow-up complete exclusion of the LAA
Post-implantation safety endpoints	30-day follow-up measurement of the LAA stump
Number of serious adverse events	0 (1 death unrelated to the device)
Number of device observations	One device observation occurred. The observation occurred during the AtriClip placement and was related to the Applier. The PROV device did not close when the button to close the Clip was triggered. However, on second attempt the device closed. In addition, the surgeon saw a small area of metal protruding through the fabric at the cephalad end of the clip and manipulated the fabric to cover it as best as possible. This finding was further investigated by AtriCure engineering. This observation required no intervention, did not result in a serious adverse event, and prolonged the procedure by about five minutes.
Surgical approach	Right mini-thoracotomy (minimally invasive): 25 of 51 subjects Sternotomy (open): 21 of 51 subjects

	Other: 5 of 51 subjects (mini parasternal/partial sternotomy)
Results	○ Intra-operatively, the sites reported: ▪ No residual stump/pouch in 84.3% (43/51) [95% CI: 71.4%, 93.0%] of patients. ▪ No flow between the LAA and LA in 100% (51/51) [95% CI: 93.0%, 100%] of patients. The mean ± SD depth (mm) of patients with a residual stump was 4.88 ± 2.75 (range: 1 to 9). ○ At 30-day follow-up, the sites reported: ▪ No residual stump/pouch in 97.7% (43/44) [95% CI: 88.0%, 99.9%] of patients. ▪ No flow between the LAA and LA in 97.8% [95% CI: 88.2%, 99.9%] of patients.

Systematic Literature Review

The body of clinical literature describing safety and/or performance of the AtriClip LAA Exclusion System includes over 50 peer-reviewed publications. Collectively, these studies provide evidence that the AtriClip LAA Exclusion System is state-of-the-art for both safety and performance[5]. In clinical literature, incidence of adverse events related to the AtriClip device or implantation procedure within 30 days is less than 10.5%, and successful LAA exclusion intraoperatively or at follow-up is greater than 97%, which exceeds the clinical performance objective of 80%.

5.4. An overall summary of the clinical performance and safety

Safety

The clinical safety objective identified in the AtriClip LAA Exclusion System Clinical Evaluation Plan is as follows:

> *Incidence of adverse events (AEs) related to the device and/or implant procedure within 30 days of the index procedure shall be ≤10.5%.*

Adverse events included in this assessment included death, major bleeding (BARC 3[6] and above), surgical site infection, pericardial effusion requiring intervention, and clinical diagnosis of myocardial infarction.

To assess the safety of the AtriClip LAA Exclusion System in relation to the clinical safety objective, the five predefined adverse events (death, major bleeding, surgical site infection, pericardial effusion requiring intervention, and myocardial infarction) were compiled from all available sources of clinical evidence, which included a systematic literature review and AtriCure's completed clinical trials[7].

The total of all available sources of clinical evidence, irrespective of type of clip or applier and representing over 2400 patients, achieved the safety objective of adverse event rate ≤10.5%. As such, the totality of clinical evidence for the AtriClip LAA Exclusion System supports the safety and state-of-the-art use of these devices for their intended use.

Performance

[5] Systematic literature review sources are listed in the Bibliography (Section 10).
[6] BARC 3 refers to Bleeding Academic Research Consortium's Bleeding Type 3. Refer to *Mehran et al. 2011. Circulation, 123:2736-47*.
[7] Refer to the Bibliography (Section 10) for clinical trial publications and systematic literature review sources, which describe safety and/or performance outcomes for the AtriClip LAA Exclusion System.

The clinical performance objective identified in the AtriClip LAA Exclusion System Clinical Evaluation Plan is defined as:

> *Successful closure rate acutely (i.e., intraoperatively) or during follow-up ≥80%, with successful LAA closure defined as no residual flow/leak between the left atrial appendage and the left atrium.*

Compilation of study outcomes from a systematic literature review and from completed AtriCure-sponsored clinical trials demonstrated >97% successful LAA closure. Successful closure has been demonstrated acutely and long-term (up to 7 years)[8].

The clinical benefit of the AtriClip LAA Exclusion System is defined as:

> *Elimination of the left atrial appendage, a source of thrombus, resulting in reduction in thromboembolic events.*

Observed versus predicted thromboembolic event rates among AtriClip-treated patients in clinical literature support the clinical benefit[9]. Studies comparing thromboembolic event rates in patients with or without AtriClip implantation also support thromboembolic risk reduction among patients who receive LAA management with the AtriClip LAA Exclusion System[10].

5.5. Ongoing or planned post-market clinical follow-up

AtriCure is conducting the following clinical studies, which include endpoints that will address the safety and/or performance of the AtriClip LAA Exclusion System including Selection Guide:

- DEEP Pivotal (NCT02393885 on clinicaltrials.gov)
- CEASE AF (NCT02695277 on clinicaltrials.gov)
- ICE-AFIB (NCT03732794 on clinicaltrials.gov)
- VCLIP (post-market study)
- LeAAPS (NCT05478304 on clinicaltrials.gov)

Collectively, these studies will provide safety and performance data on over 6500 additional patients treated with the AtriClip LAA Exclusion System. These in-progress PMCF studies will continue to provide acute, medium-term, and long-term outcomes related to the safety and/or performance of the AtriClip LAA Exclusion System including Selection Guide. The information generated from these studies and post-market surveillance will be used to monitor and identify residual risks from use of the devices or performance-related impacts to the benefit-risk ratio.

6. Possible diagnostic or therapeutic alternatives

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia worldwide and an independent risk factor for stroke and systemic thromboembolism caused by thromboembolic events (Caliskan, et al., 2017). Atrial fibrillation increases a patient's risk of non-embolic stroke 1.56-fold and embolic stroke 5.8-fold (Yuan, et al., 1998). The left atrial appendage (LAA) is the primary source of thromboembolism in AF patients (Kong, Liu, Huang, Jiang, & Huang,

[8] Long-term LAA closure success has been assessed by TEE or CT imaging in multiple cohorts of patients, with results reported in publications such as Branzoli et al. 2020, Caliskan et al. 2019, Cartledge et al. 2022, Ellis et al. 2017, Emmert et al. 2014, Kiankhooy et al. 2022, Mokracek et al. 2015, Salzberg et al. 2010, and van Laar et al. 2018. Refer to the Bibliography (Section 10) of clinical trial publications and systematic literature review publications for study citations.

[9] Refer to Antaki et al. 2021, Branzoli et al. 2020, Cartledge et al. 2022, Fleerakkers et al. 2020, Franciulli et al. 2020, Smith et al. 2017, and Suwalski et al., 2015 in Bibliography (Section 10) of systematic literature review sources.

[10] Refer to Friedman et al. 2022, Soltesz et al. 2021, and Whitlock et al. 2021 in Bibliography (Section 10) of systematic literature review sources.

2015). The heavily trabeculated, pouch-like LAA is prone to hemostasis in AF patients, thus increasing risk of embolism.

First-line management for AF patients typically consists of pharmacological intervention to control heart rate, to control heart rhythm, and to provide oral anticoagulation (OAC). The European Society of Cardiology (ESC) 2020 Guidelines include a Class I, Level A recommendation of oral anticoagulation for stroke prevention in AF patients with CHA_2DS_2-VASc score ≥2 in men or ≥3 in women and a Class IIa, Level B recommendation that oral anticoagulation be considered among AF patients with CHA_2DS_2-VASc score of 1 in men or 2 in women (Hindricks, Potpara, Dagres, & Arbelo, 2020). Similarly, the American Heart Association/American College of Cardiology/Heart Rhythm Society 2019 update to the 2014 guideline for the management of patients with AF proffers a Class I, Level A recommendation that, "For patients with AF and an elevated CHA_2DS_2-VASc score of 2 or greater in men or 3 or greater in women, oral anticoagulants are recommended" (January, et al., 2019). Oral anticoagulation reduces risk of ischemic stroke and of LAA thrombus in patients with non-valvular AF, but poses risks for major bleeding events and drug interactions; efficacy of this therapy also requires patient compliance and frequent dose adjustments (Caliskan, et al., 2017; Murtaza, et al., 2020; Ueberham, Dagres, Potpara, Bollmann, & Hindricks, 2017).

For patients who are medically contraindicated to OAC therapy, interventions to occlude or exclude the LAA from circulation are recommended. The ESC 2020 Guidelines include a Class IIb, Level B recommendation that "LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment (e.g., intracranial bleeding without a reversible cause)" (Hindricks, Potpara, Dagres, & Arbelo, 2020). Further, the ESC guidelines include a Class IIb, Level C recommendation that "surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients with AF undergoing cardiac surgery." The American Heart Association/American College of Cardiology/Heart Rhythm Society 2019 update to the 2014 guidelines for the management of patients with AF proffers Class IIb, Level B recommendations that "percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation," and that "surgical occlusion of the LAA may be considered in patients with AF undergoing cardiac surgery, as a component of an overall heart team approach to the management of AF" (January, et al., 2019).

Various techniques to manage the LAA exist in the current era. Exclusion or excision of the LAA has been performed since the late 1940s, and includes such techniques as epicardial suture ligation, endocardial suture occlusion, stapling, and surgical excision. These surgical techniques are associated with incomplete LAA closure rates of 40% to 60%, and the technique can be difficult, adding significant cross clamp time (Caliskan, et al., 2017; Ueberham, Dagres, Potpara, Bollmann, & Hindricks, 2017; van Laar, et al., 2018). Left atrial appendage closure devices are an alternative to suturing, stapling, and/or pharmacological treatment. These devices occlude or exclude the LAA to prevent thrombus formation. Boston Scientific's WATCHMAN™ and Abbott's Amplatzer Amulet are LAA occluders that are positioned endocardially using a percutaneous delivery device. These devices demonstrate LAA closure rates between 90 and 100%, as defined by closure with less than 5 mm leak (Della Rocca, et al., 2022; Galea, et al., 2022; Garg, et al., 2021; Lakkireddy, et al., 2021; Qiao, et al., 2022). Major bleeding, device-related thrombus, vascular access complications, and pericardial effusion are among the most common procedural complications associated with the Amplatzer and WATCHMAN devices.

The decision to choose a technique for closure depends on patient characteristics which include: the anatomic dimensions of the LAA (which determine if the device can adequately be sized to fit the LAA); history of prior cardiothoracic surgery (which may preclude an epicardial approach); the need for concomitant cardiac surgery for other indications (which may favor a surgical approach for closure); and the inability to tolerate even short-term anticoagulation (which will preclude an endocardial approach) (Rajabali, Badhwar, & Lee, 2018).

7. Suggested profile and training for users

Licensed medical doctors who perform cardiac and/or thoracic procedures are qualified by training and education to use the AtriClip LAA Exclusion System. AtriCure offers additional comprehensive education and training on the use of these AtriCure devices per the device instructions for use. This training is available to the clinicians using the AtriClip LAA Exclusion System.

8. Reference to any harmonized standards and CS applied

Table 8. Compliance to Standards

Standard	Compliance: Full, Partial, or No	Justification if Partial or No
BS EN ISO 13485:2016+A11:2021 Medical devices — Quality management systems – Requirements for regulatory purposes	Full	N/A
BS EN ISO 14971:2019+A11:2021 Medical devices – Application of risk management to medical devices	Full	N/A
BS EN ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice	Full	N/A
BS EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Full	N/A
BS EN ISO 10993-3:2014 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Full	N/A
BS EN ISO 10993-4:2017 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	Full	N/A
BS EN ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Full	N/A
BS EN ISO 10993-6:2016 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	Full	N/A
BS EN ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization	Full	N/A
BS EN ISO 10993-11:2018 Biological evaluation of medical devices – Part 11: Test for systemic toxicity	Full	N/A
BS EN ISO 10993-12:2021 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Full	N/A
BS EN ISO 10993-17:2009 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances	Full	N/A
BS EN ISO 10993-18:2020 Biological evaluation of medical devices – Part 18:	Full	N/A

Standard	Compliance: Full, Partial, or No	Justification if Partial or No
Chemical characterization of medical device materials within a risk management process		
BS EN ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation	Full	N/A
ISTA 3A:2018 Performance testing of shipping containers and systems	Full	N/A
BS EN ISO 11137-1:2015+A2:2019 Sterilization of health care products. Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Full	N/A
BS EN ISO 11137-2:2015 Sterilization of health care products. Radiation – Part 2: Establishing the sterilization dose	Full	N/A
BS EN ISO 11607-1:2020+A11:2022 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems	Full	N/A
BS EN ISO 11607-2:2020+A11:2022 Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes	Full	N/A
BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	Full	N/A
BS EN ISO 20417:2021 Medical Devices – Information to be supplied by the manufacturer	Full	N/A
BS EN IEC 62366-1: 2015+A1:2020 Medical devices – Application of usability engineering to medical devices	Full	N/A
ASTM F1980-21:2021 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices	Full	N/A
ASTM F2052-21:2021 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	Full	N/A
ASTM F2213-17:2017 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	Full	N/A
ASTM F2182-19e2:2019 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	Full	N/A
ASTM F2503-20:2020 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic	Full	N/A

Standard	Compliance: Full, Partial, or No	Justification if Partial or No
Resonance Environment		
ASTM D2256/D2256M-21:2021 Standard Test Method for Tensile Properties of Yarns by the Single-Strand Method	Full	N/A
BS EN ISO 14644-1:2015 Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration	Full	N/A
BS EN ISO 14644-2:2015 Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)	Full	N/A

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Validated by Notified Body (Yes or No)	Validation Language
A	See AtriCure MasterControl	Initial Release	No	English
B	22Feb2024	Updated Revision to “B” on title page and document header. Consolidated Basic UDI-DI rows from multiple product codes into one common row for AtriClip LAA Exclusion System in Section 1 of both the User/Healthcare Professional and Patient portions of the SSCP. Corrected EU Authorized Representative address and BSI address from “The Netherlands” to “NL”. Updated device descriptions and figure captions in Section 3 of User/Healthcare Professional portion of SSCP. Corrected typographical errors in table in Patient Section 4.4. Listed “Yes” in “Validated by Notified Body” in Section 9 table.	Yes	English

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A summary of the safety and clinical performance of the device, intended for patients, is given below.

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INFORMATION INTENDED FOR PATIENTS:

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1. Device Identification and General Information

Product Name:	AtriClip LAA Exclusion System with Selection Guide
Product Group/Family Basic UDI-DI	AtriClip LAA Exclusion System: 08401439000000000000016ZQ Selection Guide (CGG100): 08401439000000000000017ZS
Manufacturer Legal Name and Address: Single Registration Number (SRN)	AtriCure 7555 Innovation Way Mason, OH 45040 USA SRN: US-MF-000002974
Year when the first certificate (CE) was issued covering the device:	ACH1: 2010 ACH2: 2015 PRO1: 2012 PRO2: 2016 PROV: 2019 ACHV: 2019 CGG100: 2009

2. Intended Use of the Device

2.1. Intended Purpose

The left atrial appendage (LAA) is a small sac about the size of your thumb that hangs off the left atrium of the heart. Blood can collect in the LAA in people with atrial fibrillation. Atrial fibrillation is an abnormal rhythm in the upper chambers of the heart. When blood pools in the LAA, it may form clots. The clots may be ejected from the LAA into the heart and blood stream. This can cause strokes, clogged arteries, and serious injury or death.

The AtriClip System is used to close off (i.e., exclude) the LAA from the rest of the heart using a metal clamping spring covered in fabric (the Clip). The only part of the AtriClip System that remains in your body after the LAA closure procedure is the Clip.

2.2. Indication(s) and intended patient groups

The AtriClip is indicated for use in patients who are at high risk of stroke and/or who a licensed medical doctor believes would be good candidates for permanent closure of the left atrial appendage. Patients may include those with atrial fibrillation who are medically contraindicated to taking oral anticoagulation or who are intolerant or unable to take oral

anticoagulation therapy long-term.

2.3. Contraindications

You may not receive the AtriClip as a contraceptive device. It is not indicated for use in permanent sterilization.

Certain models of the AtriClip contain Nitinol, which is a nickel titanium alloy. These models should not be used if you have an allergy to Nitinol or nickel. Inform your doctor if you have, or suspect you may have, allergy or sensitivity to nickel or other metals. Your doctor will help you determine if you are a candidate for other models of the AtriClip.

You may not receive the AtriClip if you have an infection in your bloodstream or if you have bacterial endocarditis (an infection of the inside of the heart).

3. Device Description

3.1. Device description and material/substances in contact with patient tissues

The AtriClip LAA Exclusion System includes: (1) a tool (called a Selection Guide) that helps your doctor determine the best-fitting clip size for you, and (2) an implantable Clip pre-loaded onto a delivery device.

The Selection Guide is a sterile accessory that is made of aluminum and has markings made with cured polyurethane ink. It does not contain latex or phthalates.

There are two different versions of the Clip, which come pre-loaded onto different delivery devices depending on the doctor's assessment. The delivery devices contain small amounts of Cobalt, and one of the delivery devices your doctor may use contains small amounts of nickel.

Both Clip versions are sterile, permanent implants that do not contain natural rubber latex or phthalates. One version of the Clip is shaped like a box and is composed of Titanium, Polyurethane, Nitinol, and knit-braided Polyethylene Terephthalate fabric that contains a small fraction of titanium dioxide. The other version of the Clip is shaped like the letter "V" and contains Titanium and knit-braided Polyethylene Terephthalate fabric, which contains a small fraction of titanium dioxide.

No materials or substances in the Clips have been found at levels that would pose a risk to the patient over the lifetime of the implant.

3.2. Information about medicinal substances in the device, if any

There are no medicinal substances in the devices.

3.3. Description of how the device is achieving its intended mode of action

The AtriClip closes the LAA off from the rest of the heart by securely and permanently clamping the walls of the LAA together to form a tight seal through which no blood or clots can pass.

3.4. Description of accessories, if any

The AtriClip comes with an accessory called the Selection Guide. Your doctor will use the Selection Guide to help him or her determine the appropriate size of the AtriClip to best fit your LAA size and shape. Once your doctor has selected the best AtriClip size for you, the Selection Guide will serve no additional function and will be disposed.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1. How potential risks have been controlled or managed

AtriCure has performed rigorous risk assessment and risk management activities for the AtriClip System. These activities are in accordance with AtriCure internal procedures and international standards. The complications that may happen with use of the AtriClip and LAA closure procedure are believed to be consistent with those for similar devices and procedures.

4.2. Warnings and precautions

The Clip delivery devices contain some stainless steel parts. Stainless steel contains some nickel and a small amount of cobalt. Some AtriClip models include a material called Nitinol, which contains nickel. You should discuss with your doctor if you have an allergy or sensitivity to nickel. Cobalt is considered a substance of concern.

The implantable Clip contains metals. You can be scanned safely in an MR system immediately after implantation with the Clip, but this has only been verified under certain conditions. Ask your doctor about the ability to undergo MR imaging after implantation with the Clip. You will be provided with an implant card, which will include more information on MRI safety post-implantation.

Other warnings and precautions for your doctor are listed in the Instructions for Use provided in every AtriClip System product package and in AtriClip System training.

4.3. Summary of any field safety corrective action, (FSCA including FSN) if applicable

In 2016, there were two recalls of the AtriClip System. One involved the PRO2 model of the delivery device locking in an open position. The other involved a component of the PRO2 model of the delivery device breaking prior to surgery being performed. Both recalls have since closed. There were no harms to patients as a result of these device issues.

4.4. Remaining risks and undesirable effects

The following risks and undesirable effects have been observed in clinical studies or in 'real-world' device use, or they can potentially occur with this type of procedure. Risks are like those of other cardiac surgeries.

Potential Complication and Definition	Chance of Occurrence	
Air embolism *Air bubble blocking a vessel, potentially leading to heart attack, stroke, or death*	May occur in 5 or less people out of 100	Rare
Allergic reaction to anesthesia, anticoagulant, implant material *Rash or trouble breathing due to allergy*	May occur in 5 or less people out of 100	Rare
Anaphylactic shock *Severe allergic reaction that can affect blood pressure and breathing*	May occur in less than 1 person out of 1000	Improbable
Anesthesia risks *Risks may include nausea, confusion, sore throat, and other side effects*	May occur in 5 or less people out of 100	Rare
Aneurysm *Weakening of part of an artery wall which causes the artery to widen abnormally, balloon out, leak, and/or rupture*	May occur in 5 or less people out of 1000	Extremely Rare
Angina *Chest pain caused by reduced blood flow to the heart*	May occur in 5 or less people out of 100	Rare

Potential Complication and Definition	Chance of Occurrence	
Arrhythmia needing medical treatment (new onset) *Change from the normal heartbeat pattern*	May occur in 5 or less people out of 100	Rare
Arterial or venous dissection and/or perforation *Tear or puncture in the inside wall of an artery or vein, creating a weak spot which may lead to a life-threatening leak*	May occur in 5 or less people out of 100	Rare
Arterial rupture *A complete tear in the wall of an artery*	May occur in 5 or less people out of 100	Rare
Arterial spasm *Temporary tightening/narrowing of the muscles in the wall of an artery, which may slow or stop blood flow*	May occur in 5 or less people out of 100	Rare
Arteriovenous fistula *Abnormal connection or passageway between an artery and a vein, which may be acquired during medical procedures in which a cardiac catheter is used*	May occur in 5 or less people out of 1000	Extremely Rare
Atelectasis *Partial or complete collapse of the lung*	May occur in 5 or less people out of 100	Rare
Atrial rupture *Rupture of one of the upper chambers of the heart, which may leak blood into the sac that surrounds the heart*	May occur in 5 or less people out of 100	Rare
Atrio-esophageal fistula *Often fatal injury to the esophagus, usually thermal in nature*	May occur in 5 or less people out of 1000	Extremely Rare
AV block requiring permanent pacemaker (new onset) *Block in the normal electrical signals that stimulate the heart to beat at a normal pace, leading to implantation of a cardiac pacing device*	May occur in 5 or less people out of 100	Rare
Bleeding requiring intervention *Excessive loss of blood that requires transfusion of 2 or more units of blood*	May occur in 5 or less people out of 100	Rare
Blood vessel damage *Damage to an artery or vein*	May occur in 5 or less people out of 100	Rare
Cardiac perforation *Puncture, tear, or hole in the heart*	May occur in 5 or less people out of 100	Rare
Cardiac tamponade *Blood or fluid collecting in the sac around the heart*	May occur in 5 or less people out of 100	Rare
Cardiac valve injury *Damage to a heart valve, a tissue flap that controls the direction of blood flow through the chambers of the heart*	May occur in 5 or less people out of 100	Rare

Potential Complication and Definition	Chance of Occurrence	
Cerebrovascular accident (CVA)/TIA/stroke (ischemic or hemorrhagic) *CVA refers to a stroke that causes sudden damage to the brain when the blood flow to the brain is impaired.* *TIA refers to a mini-stroke, which is a passing episode of neurologic dysfunction caused by loss of blood flow without tissue death or other problems with the nerves, spinal cord, or brain function.* *Ischemic stroke refers to sudden damage to the brain caused by a clot or blockage in the brain that blocks off blood supply, causing a lack of oxygen to those cells.* *Hemorrhagic stroke refers to sudden damage to the brain caused by swelling and pressure when there is a leak or rupture in a weakened blood vessel in the brain.*	May occur in 5 or less people out of 100	Rare
Chest pain/discomfort	May occur in 50 or less people out of 100	Very common
Compression of coronary artery *Narrowing of the coronary artery, which may damage the artery wall and reduce blood flow through the artery*	May occur in less than 1 person out of 1000	Improbable
Conduction disturbances *Disruption to the electrical impulses that control the beating of the heart*	May occur in 5 or less people out of 100	Rare
Congestive heart failure (new onset or exacerbation) *Chronic condition in which the heart does not pump blood as well as it should*	May occur in 5 or less people out of 100	Rare
Coronary artery injury *Tear in one of the arteries that supply blood to the heart, causing blood to flow between the layers*	May occur in 5 or less people out of 100	Rare
Death	May occur in 5 or less people out of 100	Rare
Device breakage/inability to remove	May occur in 5 or less people out of 1000	Extremely Rare
Device-related death	May occur in less than 1 person out of 1000	Improbable
Diaphragmatic paralysis (unilateral or bilateral) *Loss of control of the diaphragm due to injury to, or disease of, the nerves controlling its motion*	May occur in 5 or less people out of 100	Rare

Potential Complication and Definition	Chance of Occurrence	
Drug reaction *Significant reaction to any study related medications requiring treatment, including allergic reaction and anaphylactic shock*	May occur in 5 or less people out of 100	Rare
Emergency during procedure requiring a change in planned access *An emergency that could potentially require the surgeon change to a full sternotomy*	May occur in 5 or less people out of 100	Rare
Empyema *The collection of pus in a cavity of the body, such as the area around the heart or lungs*	May occur in 5 or less people out of 1000	Extremely Rare
Endocarditis (bacterial) *Bacterial infection causing inflammation of the innermost layer of the tissue that lines the chambers of the heart*	May occur in 5 or less people out of 100	Rare
Esophageal injury *Damage to the esophagus*	May occur in less than 1 person out of 1000	Improbable
Esophageal rupture *Puncture, tear, or hole in the esophagus*	May occur in 5 or less people out of 100	Rare
Extension of cardiopulmonary/extracorporeal bypass *Prolonged time during which the heart is on bypass, in which the blood is diverted from the heart*	May occur in 5 or less people out of 100	Rare
Fever	May occur in 5 or less people out of 100	Rare
Gastric motility disorders *Disorder of the movement of food through the digestive system*	May occur in 5 or less people out of 1000	Extremely Rare
Gastro-intestinal bleed *Bleeding in any part of the digestive tract*	May occur in 5 or less people out of 1000	Extremely Rare
Hematoma *Collection of blood outside of a blood vessel*	May occur in 5 or less people out of 100	Rare
Hematuria *Presence of blood in the urine*	May occur in 5 or less people out of 100	Rare
Hemothorax *Collection of blood in the space between the chest wall and the lung*	May occur in 5 or less people out of 1000	Extremely Rare
Hypertension *High blood pressure*	May occur in 5 or less people out of 100	Rare
Hypotension *Low blood pressure*	May occur in 5 or less people out of 100	Rare

Potential Complication and Definition	Chance of Occurrence	
Iatrogenic atrial flutter *Atrial flutter, a type of heart rhythm disorder in which the atria beat too fast, caused by a medical treatment*	May occur in less than 1 person out of 1000	Improbable
Iatrogenic lung injury (e.g., chest tube placement) *Injury to the lung caused by a medical treatment, such as during placement of a chest tube*	May occur in 5 or less people out of 100	Rare
Ischemia *Decreased oxygen in a tissue, usually because of decreased blood flow*	May occur in 5 or less people out of 100	Rare
Kinking of coronary artery *Sharp, angular turn in the path of a coronary artery, which can damage the artery wall and restrict blood flow*	May occur in less than 1 person out of 1000	Improbable
LAA dehiscence *Splitting open of the left atrial appendage*	May occur in 5 or less people out of 1000	Extremely Rare
LAA tears *Tear in the tissue of the left atrial appendage*	May occur in 5 or less people out of 1000	Extremely Rare
Left atrial embolism *Blood clot in the left atrium of the heart*	May occur in less than 1 person out of 1000	Improbable
Myocardial infarction (MI) *Heart attack – the death of heart muscle*	May occur in 5 or less people out of 100	Rare
Nerve injury (phrenic, laryngeal, thoracic, etc.) *Injury or damage to a nerve caused by pressure, stretching, or cutting of the nerve*	May occur in 5 or less people out of 100	Rare
Pain/discomfort	May occur in 20 or less people out of 100	More common
Pericardial effusion *Abnormal accumulation of fluid in the sac that surrounds the heart*	May occur in 20 or less people out of 100	More common
Pericarditis *Inflammation of the pericardium (the sac around the heart), which may cause sharp pain or stabbing sensation*	May occur in 20 or less people out of 100	More common
Permanent pacemaker *Permanent implantation of a cardiac pacing device*	May occur in 10 or less people out of 100	Somewhat common
Persistent chest pain *Includes post-discharge surgical incision pain, not angina*	May occur in 20 or less people out of 100	More common
Phrenic nerve paralysis *Paralysis of a nerve that may cause elevation of one side of the diaphragm, which may present as difficulty breathing*	May occur in 5 or less people out of 100	Rare

Potential Complication and Definition	Chance of Occurrence	
Pleural effusion *Abnormal accumulation of fluid in the space that surrounds the lungs*	May occur in 5 or less people out of 100	Rare
Pneumonia *Infection that inflames the air sacs in one or both lungs*	May occur in 5 or less people out of 100	Rare
Pneumothorax *Collection of air in the space between the chest wall and the lung*	May occur in 5 or less people out of 100	Rare
Postoperative embolic complications *Complications caused by a blocked artery*	May occur in 5 or less people out of 100	Rare
Pseudoaneurysm *A false aneurysm – a collection of blood that forms as the result of a leaking hole in an artery*	May occur in 5 or less people out of 1000	Extremely Rare
Pulmonary edema *Too much fluid in the lungs, making it difficult to breathe*	May occur in 5 or less people out of 100	Rare
Pulmonary embolism *Blockage in one of the pulmonary arteries in the lungs, often caused by a blood clot*	May occur in 5 or less people out of 100	Rare
Renal insufficiency or failure *Poor function or failure of the kidneys, possibly requiring dialysis or kidney transplant*	May occur in 5 or less people out of 100	Rare
Respiratory distress or failure (breathing problems) *Inability or difficulty breathing*	May occur in 5 or less people out of 100	Rare
Sepsis *Life-threatening complication of an infection, which can lead to multi-organ failure*	May occur in 5 or less people out of 100	Rare
Stenosis of left circumflex artery *Narrowing of the left circumflex artery, which is an artery that runs near the base of the LAA*	May occur in less than 1 person out of 1000	Improbable
Sterility-related infection *An infection caused by a non-sterile instrument or procedure*	May occur in 5 or less people out of 1000	Extremely Rare
Superficial wound infection *An infection in the area of skin where the surgical incision was made*	May occur in 5 or less people out of 100	Rare
Surgical site infection *An infection that occurs after surgery in the part of the body where the surgery took place*	May occur in 5 or less people out of 100	Rare
Systemic adverse reaction due to device corrosion *Inflammation in multiple organs or throughout the body caused by exposure to deteriorated materials of the device*	May occur in less than 1 person out of 1000	Improbable

Potential Complication and Definition	Chance of Occurrence	
Thrombus and/or thromboembolism (including deep vein thrombosis) *Obstruction of a blood vessel*	May occur in 5 or less people out of 100	Rare
Tissue injury	May occur in 5 or less people out of 100	Rare
Tissue perforation *Puncture or hole in tissue*	May occur in 5 or less people out of 1000	Extremely Rare
Tracheal esophageal trauma *Traumatic injury to the trachea (the windpipe)*	May occur in 5 or less people out of 100	Rare
Vascular access complications *Complications like thrombosis, infection, bleeding, or punctures associated with access to the blood vessels*	May occur in 20 or less people out of 100	More common

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Clinical background of the device

The AtriClip LAA Exclusion System was first CE marked in 2009. Between 2010 and 2019, the current generations of the devices were approved for sale on the EU market. These devices have a proven clinical track record of safety and performance.

5.2. The clinical evidence for the CE-marking

AtriCure has completed four clinical trials to study the safety and performance of the AtriClips. These included the Zurich first-in-human trial, the EXCLUDE trial, the Stroke Feasibility Trial, and the ATLAS trial.

The first-in-human trial established the AtriClip as a safe device, as there were no device-related complications among 40 treated patients. CT scans of the trial participants three months after AtriClip implantation also showed that the device was stable and effective at closing the LAA, with all patients' scans showing complete closure.

The EXCLUDE trial included 70 patients implanted with the AtriClip. No adverse events caused by the AtriClip were reported by any of the 70 patients. Among this group of patients, more than 95% had complete LAA closure three months after the procedure.

AtriCure tested the AtriClip in a small study to assess the safety and performance of the device for stroke prevention. Ten patients underwent the procedure and nine successfully had the Clip implanted. None of the patients experienced adverse effects from the device itself or the implantation procedure. Three months later, all nine patients had complete LAA closure.

The ATLAS trial was the largest of AtriCure's trials using the AtriClip. This trial included 376 patients who received the Clip. There were no reports of stroke, major bleeding, heart attack, or death in the short-term following the operation. More than 99% of the patients had successful closure outcomes by traditional definitions.

AtriCure also tracks clinical studies performed by others and reviews study publications for safety and performance information for the AtriClip devices. Many institutions have published studies on patients treated with the AtriClip. These publications report rare incidence of device-related adverse events occurring among patients implanted with the Clip. The publications demonstrate consistently high rates of successful LAA closure with the AtriClip, with more than 97% of patients having complete closure.

5.3. Safety

AtriCure and doctors who are experts in LAA closure have reviewed the clinical data on the safety of the AtriClip. They have concluded that the AtriClip is safe and performs appropriately when used properly by trained doctors. AtriCure has identified actual and potential risks for patients who are treated with the AtriClip. These risks have been reduced as much as possible. AtriCure also has a robust surveillance program that collects information on the use of the AtriClip. This information includes complaints, device recalls, service and repair information, additional 'real-world' use in patients, and ongoing clinical studies. More safety data will be collected in AtriCure's ICE-AFIB and LeAAPs clinical trials, AtriCure's VCLIP post-market study, and investigator-sponsored research studies.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can consider your individual situation.

There are other ways to provide LAA closure. Other devices can be placed inside or outside of the heart to close off the LAA. The LAA can also be closed surgically.

7. Suggested training for users

AtriCure provides comprehensive training and continuing education to doctors who use the AtriClip System. All doctors who want to use the AtriClip System will be offered an initial training session before using the AtriClip System.