

AtriClip LAA Exclusion System Special 510(k)	
Attachment L1 – Biocompatibility	
Description	Section No.
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Section I-6 – Biocompatibility Summary

All patient-contacting materials used in the AtriClip LAA Exclusion System have been tested, demonstrated to be biocompatible and met the acceptance criteria when evaluated in accordance with ISO 10993-1. There are no new risks or new issues of safety and effectiveness raised due to biocompatibility of the devices.

This ensures that the subject device, AtriClip LAA Exclusion System, is safe for intended use and does not introduce any evidence of toxicity.

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Delivery Directions

Please submit this eSTAR PDF for review using the [CDRH Portal](#) unless your medical device is regulated by the Center for Biologics Evaluation and Research (CBER) or is a combination product where CBER is the lead. You do not need to send any documentation in physical form using mail couriers.

For CBER-regulated medical devices or for combination products where CBER is the lead, please refer to [Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products](#) for information on how to submit to CBER through the [Electronic Submission Gateway](#).



September 29, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Division of Health Technology 2 B Circulatory Support, Structural and Vascular devices

RE: Special 510(k) for AtriClip LAA Exclusion System

AtriCure, Inc. is submitting a Special 510(k) for the AtriClip LAA Exclusion System. This Special 510(k) is based on the predicate AtriClip® LAA Exclusion System most recently cleared via K210293.

AtriCure is requesting clearance, via a Special 510(k) for updates to the AtriClip Instructions For Use and labels based on the following:

1. Intended use remains the same; The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures.
2. No changes were made to operating principle, and
3. No performance data was necessary to support the changes to the labels and Instructions For Use.

The information has been provided as one (1) electronic copy via Non-In Vitro Diagnostic eSTAR Template Version 4.

This submission contains trade secret and commercial or financial information that is exempt from disclosure under exemption 4 of the Freedom of Information Act (21 CFR 20.61), section 301(j) of the Federal Food, Drug, and Cosmetic Act, and 18 U.S. 1905.

Please do not hesitate to contact me via phone (513-341-0345) or email (shadnot@atricure.com) for any questions or points of clarification throughout the review of this Special 510(k) submission. If I am unavailable, please contact Jim Taufen, Director, Regulatory Affairs, at 952-314-1507 or jtaufen@atricure.com.

Thank you, and we look forward to your feedback.

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AtriClip LAA Exclusion System Special 510(k)	
Attachment D1 – Comprehensive Device Description and Principles of Operation	
Description	Section Number
AtriClip LAA Exclusion System Description	Section I-1
Administrative Comparison	Section I-2
AOD1, AOD2 Clip Description	Section I-3
LAAØ, ACH1, ACH2, PRO1, PRO2, PROV, ACHV Clip Applier Description	Section I-4

Section I-1 – AtriClip LAA Exclusion System Description

The AtriClip LAA Exclusion System (AtriClip) is a sterile, self-closing, implantable clip, preloaded on a single use applier along with a selection guide. It is utilized to secure and exclude the left atrial appendage during cardiac surgery. Multiple clip applier models (products LAAØ, ACH1, ACH2, ACHV, PRO1, PRO2, PROV) are offered for deployment of the implantable clip as noted in **Table 2-1**. These multiple clip applier models provide surgeons with varying options to accommodate differing body habitus, and various surgical approaches. The two implantable clip models are offered:

1. AOD1 AtriClip originally cleared under K093679 and supported by (b)(4)
2. AOD2 AtriClip originally cleared under K153500

The purpose of this Special 510(k) submission is to update the IFUs and labels for the AtriClip LAA Exclusion System devices (product codes LAAØ, ACH1, ACH2, ACHV, PRO1, PRO2, PROV, CGG100). The updates made are to align and comply with ISO 14971:2019 for risk management, ISO 15223-1:2021 for symbology, and ISTA3A for transit. These updates will align the AtriClip IFUs globally and are not associated with any adverse event reports. Additionally, this submission will include Letters to File that have been documented internally since the previous K210293 clearance. Please refer to **Attachment H1, Section I-5** for additional details regarding the Letters to File.

The following is an overview of the changes made to the IFUs. Refer to **Attachment H1, Section I-2** for additional details and rationale for the changes made.

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The proposed modifications do not change the fundamental technology of the device; there is no change to the indications for use of the device previously cleared and no performance data was necessary to support the change. Therefore, AtriCure believes this submission qualifies as a Special 510(k).

Device Name

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

Product Code / Model Number

LAA (Applier with Clip)

- LAAØ35 – 35 mm
- LAAØ40 – 40 mm
- LAAØ45 – 45 mm
- LAAØ50 – 50 mm

Clip / Applier Design

AOD1 (Clip)
LAAØ (Applier)

Accessories

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

ACH1 (Applier with Clip)

- ACH135 – 35 mm
- ACH140 – 40 mm
- ACH145 – 45 mm
- ACH150 – 50 mm

AOD1 (Clip)
ACH1 (Applier)

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

ACH2 (Applier with Clip)

- ACH235 – 35 mm
- ACH240 – 40 mm
- ACH245 – 45 mm
- ACH250 – 50 mm

AOD1 (Clip)
ACH2 (Applier)

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

PRO1 (Applier with Clip)

- PRO135 – 35 mm
- PRO140 – 40 mm
- PRO145 – 45 mm
- PRO150 – 50 mm

AOD1 (Clip)
PRO1 (Applier)

AtriClip Selection Guide (CGG100)

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

PRO2 (Applier with Clip)

- PRO235 – 35 mm
- PRO240 – 40 mm
- PRO245 – 45 mm
- PRO250 – 50 mm

AOD1 (Clip)
PRO2 (Applier)

AtriClip® PRO-V® LAA
Exclusion System

PROV (Applier with Clip)

- PROV35 – 35 mm
- PROV40 – 40 mm
- PROV45 – 45 mm
- PROV50 – 50 mm

AOD2 (Clip)
PROV (Applier)

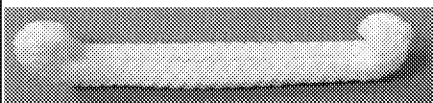
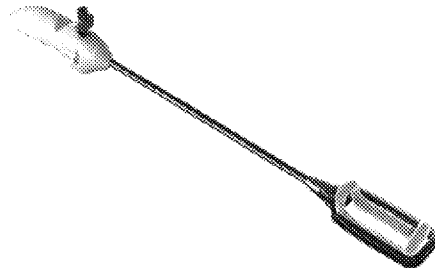
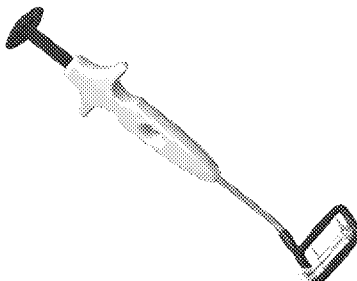
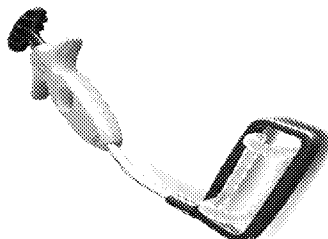
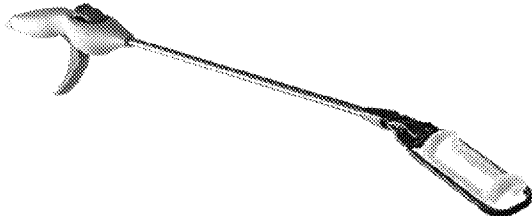
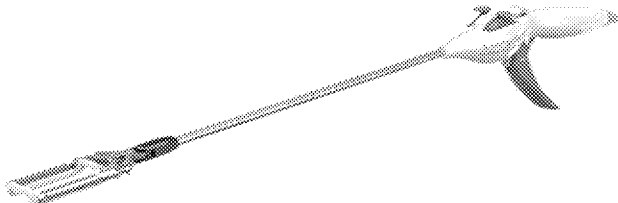
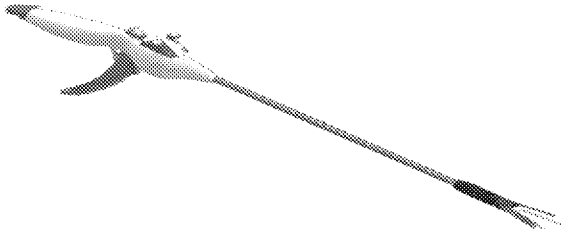
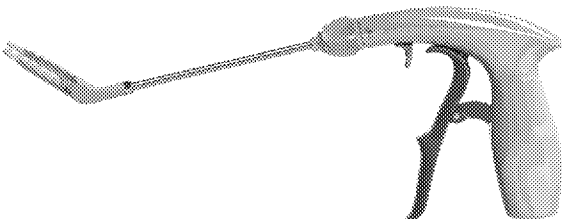
AtriClip® Flex-V® LAA Exclusion
System with Preloaded V Clip™

ACHV (Applier with Clip)

- ACHV35 – 35 mm
- ACHV40 – 40 mm
- ACHV45 – 45 mm
- ACHV50 – 50 mm

AOD2 (Clip)
ACHV (Applier)

Table 2-2 provides a visual representation of the AtriClip LAA Exclusion System Clip implant, and clip applicators with their respective original 510(k) clearance numbers. The most recent clearance for the AtriClip LAA Exclusion System is K210293.

Table 2-2: AtriClip LAA Exclusion System Clearance Summary		
Clip Implant		
Gillinov-Cosgrove Clip (K093679) (AOD1)		V Clip (K153500) (AOD2)
		
Clip Applicators (AOD1)		
LAAØ (K093679)	ACH1 (K122276)	ACH2 (K142120)
		
PRO1 (K122276)	PRO2 (K160454)	
		
Clip Applicators (AOD2)		
PROV (K153500)	ACHV (K180010)	
		

Section I-2 – Administrative Comparison

The AtriClip LAA Exclusion System contains the AtriClip utilized for exclusion of the heart's left atrial appendage. The AtriClip is preloaded on an applier and deployed around the appendage under direct visualization in conjunction with cardiac surgical procedures. Multiple clip applier models (product codes LAA0, ACH1, ACH2, ACHV, PRO1, PRO2, PROV) are offered for deployment of the implantable clip.

The proposed AtriClip LAA Exclusion System identifies the same as the predicate AtriClip LAA Exclusion System, as Class II, Implantable Clip and Clip Applier; per 21 CFR 878.4300, is proposed for review with the General and Plastic Surgery FDA Division, and identifies under FDA Product Code PZX.

Table 2-3 provides the administrative summary of the AtriClip LAA Exclusion System in comparison to the predicate.

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Section I-3 – AOD1, AOD2 Clip Description

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Section I-4 – LAAØ, ACH1, ACH2, PRO1, PRO2, PROV, ACHV Clip Applier Description

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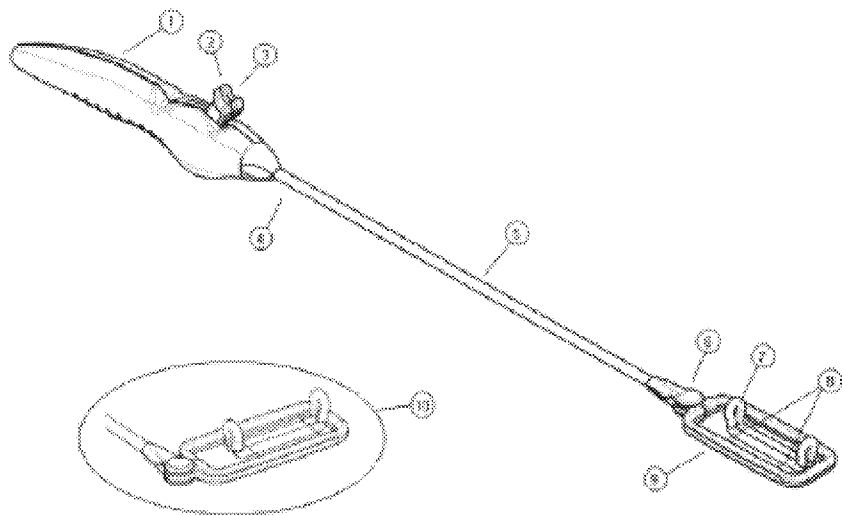


Figure 3: LAAØ35, LAAØ40, LAAØ45, LAAØ50 – AtriClip Long¹ Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	Handle	6	Articulation Clevis
2	Activation Lever	7	Gillinov-Cosgrove Clip
3	Suture Cutting Zone	8	Suture Anchors
4	Nose Cone with Clip Size Identifier	9	Deployment Loop
5	Malleable Shaft	10	Articulated Deployment Loop

¹The entire length of the AtriClip Long device's shaft is malleable.

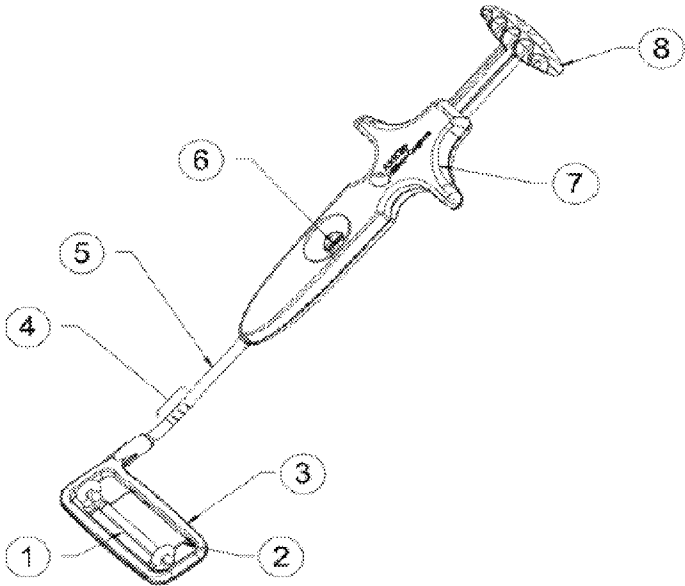


Figure 4: ACH135, ACH140, ACH145, ACH150 – AtriClip Standard Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	Gillinov-Cosgrove Clip	5	Shaft
2	Suture Anchors	6	Suture Cutting Zone
3	Deployment Loop	7	Handle
4	Malleable Zone ²	8	Plunger

²The AtriClip Standard device’s malleable zone is denoted by a set of slots on the shaft near the deployment loop. It is only intended for minor adjustments in the lateral (left/right) plane.

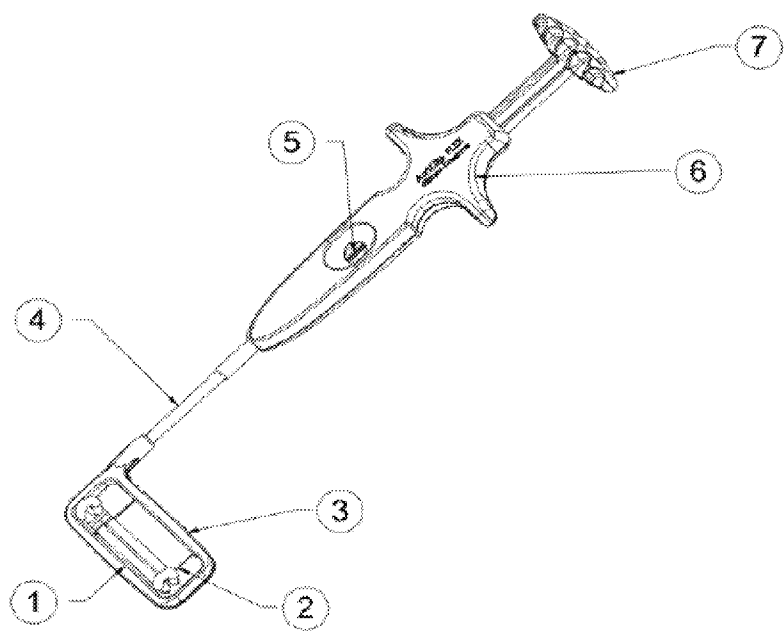


Figure 5: ACH235, ACH240, ACH245, ACH250 – AtriClip FLEX Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	Gillinov-Cosgrove Clip	5	Suture Cutting Zone
2	Suture Anchors	6	Handle
3	Deployment Loop	7	Plunger
4	Shaft ³		

³The entire length of the AtriClip FLEX device’s shaft is malleable. It is intended for adjustments up to 45° in all planes.

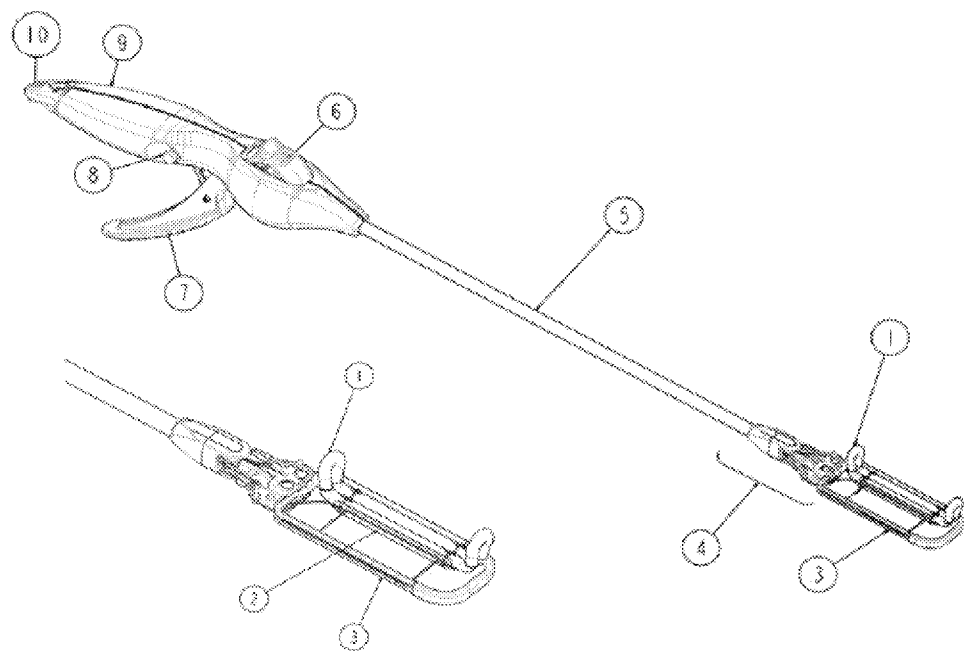


Figure 6: PRO135, PRO140, PRO145, PRO150 – AtriClip PRO Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	Gillinov-Cosgrove Clip	6	Articulation Release Button
2	Clip Pull Bar	7	Activation Lever
3	Deployment Loop	8	Lever Release Button
4	Articulation Joints	9	Handle
5	Shaft	10	Deployment Tab

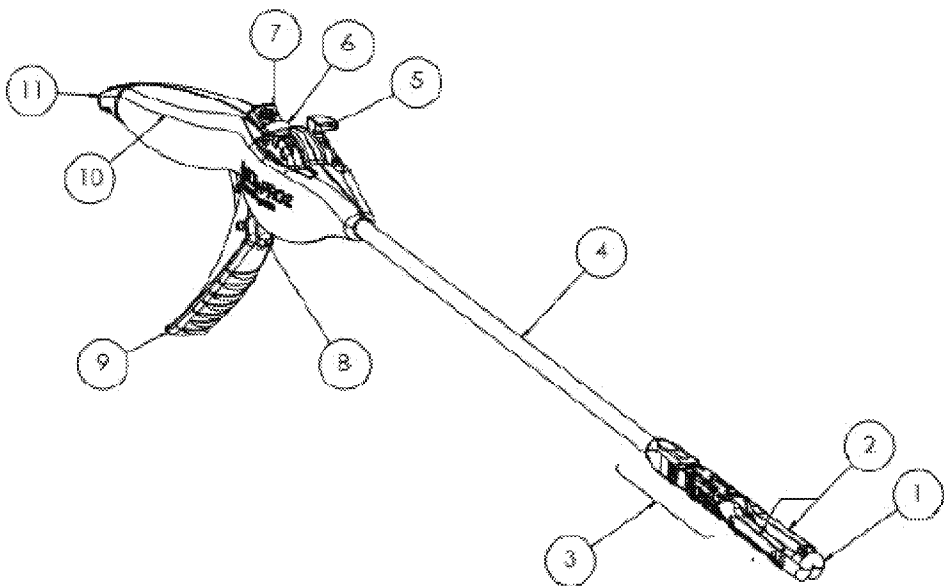


Figure 7: PRO235, PRO240, PRO245, PRO250 – AtriClip PRO2 Illustration and Nomenclature			
#	Feature Description	#	Feature Description
1	Gillinov-Cosgrove Clip	7	Articulation Lock
2	Clip Opening Jaws	8	Lever Release Trigger
3	End Effector	9	Activation Lever
4	Shaft	10	Handle
5	Left/Right Articulation	11	Deployment Tab
6	Up/Down Articulation		

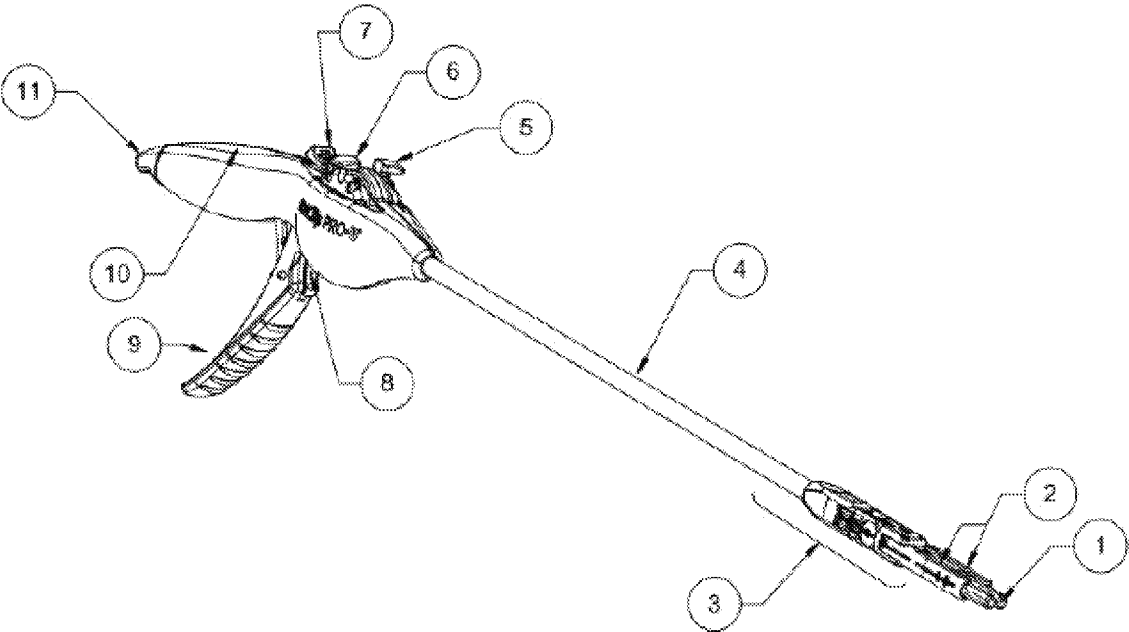


Figure 8: PROV35, PROV40, PROV45, PROV50 – AtriClip PROV Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	V Clip	7	Articulation Lock
2	Clip Opening Jaws	8	Lever Release Trigger
3	End Effector	9	Activation Lever
4	Shaft	10	Handle
5	Left/Right Articulation	11	Deployment Tab
6	Up/Down Articulation		

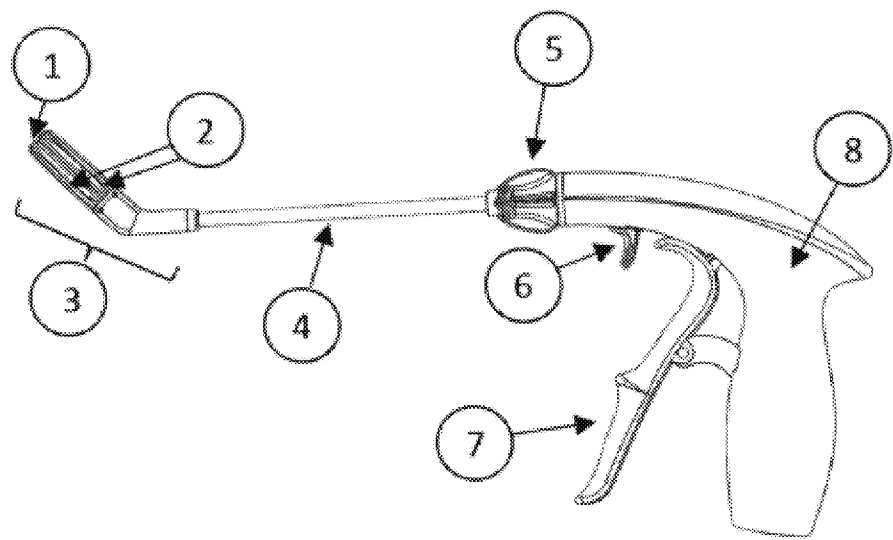


Figure 9: ACHV35, ACHV40, ACHV45, ACHV50 – AtriClip Flex-V Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	V Clip	5	Shaft Rotation Knob
2	Clip Opening Jaws	6	Deployment Trigger
3	End Effector	7	Activation Lever
4	Shaft ⁴	8	Handle

⁴The entire length of the shaft is malleable and intended for adjustments up to 45 degrees in any direction.

AtriClip LAA Exclusion System Special 510(k)	
Attachment D2 – Device Pictures	
Description	Document Number
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AtriClip LAA Exclusion System Special 510(k)	
Attachment D3 – Device Packaging	
Description	Document Number
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AtriClip LAA Exclusion System Special 510(k)	
Attachment D4 – Accessories List	
Description	Section Number
Selection Guide Device Description	Section I-1

Section I-1 – Selection Guide Device Description

The AtriClip LAA Exclusion System utilizes a Selection Guide to aid in appropriate Clip size selection. The Selection Guide was originally cleared per K093679, and is used for each of the AtriClip devices previously cleared by FDA. To evaluate the LAA, the Selection Guide is aligned adjacent with the LAA at the base of the appendage. Indication marks on the Selection Guide indicate the appropriate Clip size when the device is aligned with the LAA. Please refer to **Attachment D5** for pictures of the Selection Guide.

AtriClip LAA Exclusion System Special 510(k)	
Attachment D5 – Accessory Pictures	
Description	Section Number
CGG100 Device Assembly	Section I-1
CGG100 Packaged Assembly (Pouch)	Section I-2
CGG100 Packaged Assembly (Carton)	Section I-3

Section I-1 – CGG100 Device Assembly

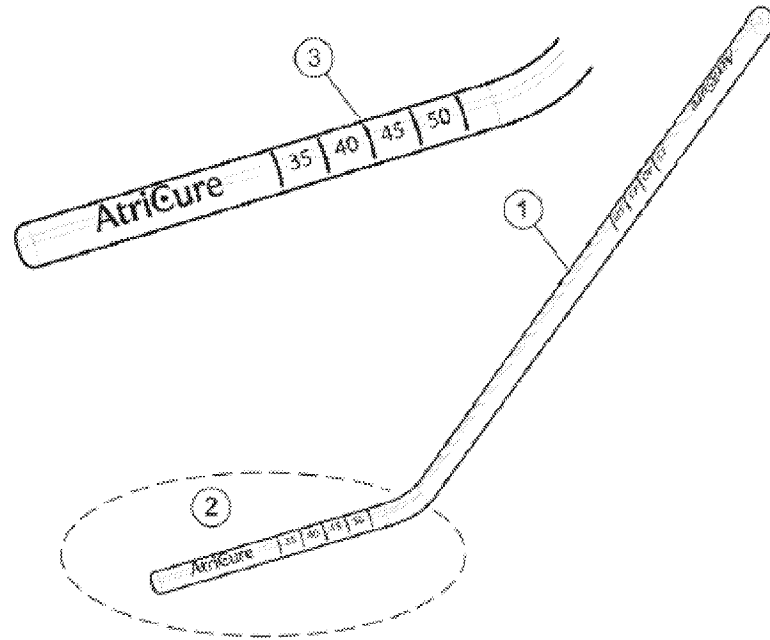


Figure 1: CGG100 – AtriClip Selection Guide Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	Handle	3	Indication Marks
2	Base		

Section I-2 – CGG100 Packaged Assembly (Pouch)

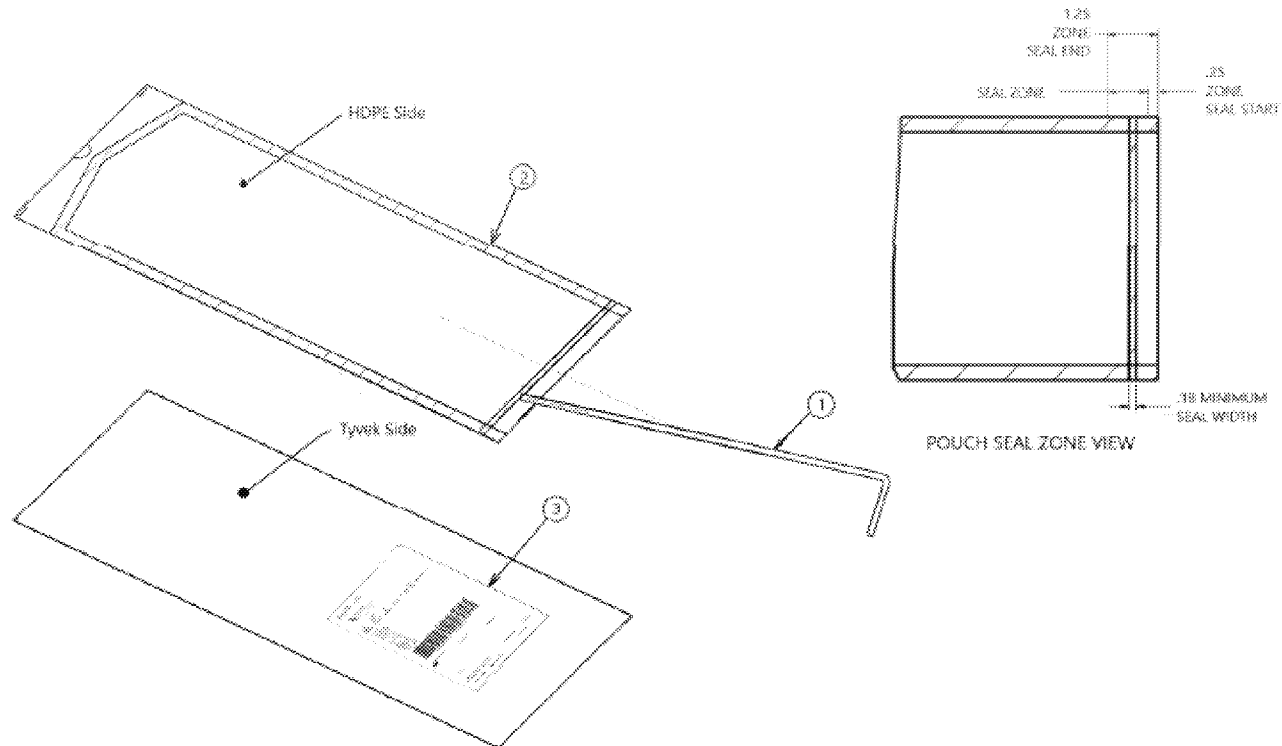


Figure 2: CGG100 – AtriClip Selection Guide Packaged Assembly (Pouch) Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	Selection Guide	3	Label
2	Pouch		

Section I-3 – CGG100 Packaged Assembly (Carton)

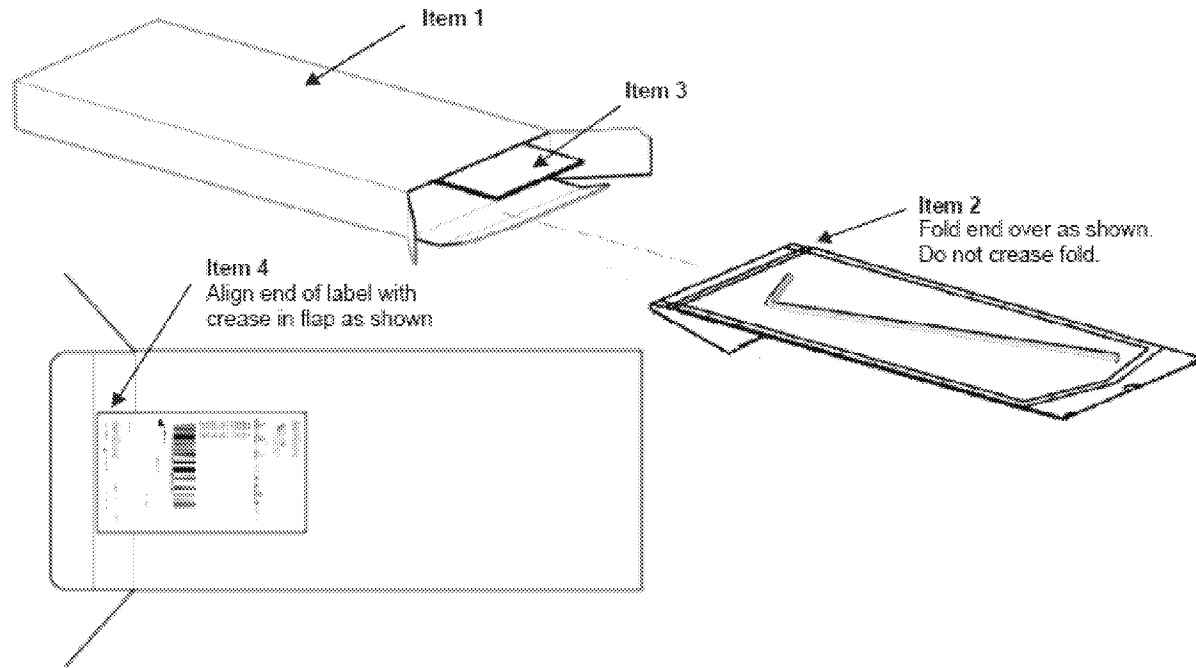


Figure 3: CGG100 – AtriClip Selection Guide Packaged Assembly (Carton) Illustration and Nomenclature

#	Feature Description	#	Feature Description
1	Carton	3	IFU
2	Packaged Selection Guide	4	Label

AtriClip LAA Exclusion System Special 510(k)	
Attachment H1 – Substantial Equivalence Comparison	
Description	Section Number
(b)(4)	

Section I-1 – Comparison to Predicate

This section provides an overview of the proposed changes as compared to the previously cleared AtriClip LAA Exclusion System (K210293). The modification in this Special 510(k) includes the updates to the AtriClip IFUs and labels (**Section I-2**) and minor modifications as documented per letters to file since the latest clearance (**Section I-5**), which are included for reference.

The intended use, overall design, operating principles, and function of the devices remain the same as the previously cleared 510(k).

Section I-2 – Proposed Modifications Compared to Predicate

This change is to the IFUs and labels of the AtriClip LAA Exclusion System. The updates made are to align and comply with ISO 14971:2019 for risk management, ISO 15223-1:2021 for symbology, and ISTA 3A for transit. These updates will align the AtriClip IFUs globally and are not associated with any adverse event reports.

The following is an overview of the changes made to the IFUs.

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Refer to **Tables 1 – 12** below for additional details and rationale for the changes made. Refer to **Attachment J2** for the proposed IFUs.

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The labels for the AtriClip LAA Exclusion System devices were updated to include symbology associated with ISO 15223-1:2021. Refer to **Attachment J1** for images of the LAA Exclusion System labels.

LAA0/ACH1/ACH2 IFU Changes (b)(4)

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PRO1 IFU Changes (b)(4)

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PRO2 IFU Changes (b)(4)

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PROV IFU Changes (b)(4)

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ACHV IFU Changes (b)(4)

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CGG100 IFU Changes (b)(4)

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Section I-3 – Substantial Equivalence Comparison

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Section I-4 – Substantial Equivalence Summary

The comparisons provided in **Table 13** establish that the proposed AtriClip LAA Exclusion System and the previously cleared AtriClip LAA Exclusion System are equivalent because:

- The devices have the same intended use.
- No changes were made in operating principle.
- No changes to the overall design or function of the devices.

Section I-5 – Minor Modifications Documented Internally Since Clearance

Since the most recent AtriClip LAA Exclusion System clearance K210293, cleared on March 3, 2021, AtriCure has made four device modifications. These modifications were deemed minor in nature and were documented internally via letter to file. The letters to file are provided in **Sections I-6 – I-9**. A summary of the internally documented changes is provided in **Table 14**.

Table 14: Device Modifications Documented Internally

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Section 1-6 -

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AtriCure Regulatory Affairs Change Assessment	
Document Type	AtriCure Letter to File Assessment
Document Number	(b)(4)
Date	8/29/2022
Product(s)	ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250 LAA035, LAA040, LAA045, LAA050 PRO135, PRO140, PRO145, PRO150 PRO235, PRO240, PRO245, PRO250 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50
Clearance(s)	K210293
Subject	(b)(4)

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Section I-7 – (b)(4)



Records processed under FOIA Request 2024-4617; Released by CDRH on 10-10-2024

AtriCure Regulatory Affairs Change Assessment		
Document Type	AtriCure Letter to File Assessment	
Document Number	(b)(4)	
Date	2/10/2023	
Product(s)	ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250	
Clearance(s)	K210293	
Subject	(b)(4)	

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Section I-8 – (b)(4)



AtriCure Regulatory Affairs Change Assessment	
Document Type	AtriCure Letter to File Assessment
Document Number	(b)(4)
Date	3/20/2023
Product(s)	ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250
Clearance(s)	K210293
Subject	(b)(4)

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AtriClip LAA Exclusion System Special 510(k)	
Attachment I1 – Design Control Activities	
Description	Section Number
(b)(4)	

Section I-1 – Design Control Activities

Per AtriCure's Quality System, Risk Analysis was performed for the proposed AtriClip LAA Exclusion System. The Risk Analysis methods include a Risk Benefit Analysis and Failure Mode Effects Analysis (FMEA).

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Attachment I2

Design Verification and Validation Activities

To the best of my knowledge, the verification and validation activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Signature: (b)(6)

Date: Sep 29, 2023

Robert Cantu
Vice President of Quality

7555 Innovation Way
Mason, Ohio 45040
www.atricure.com

(b)(4)



Attachment I3

Compliance Letter

The manufacturing facility, AtriCure, located in Mason, OH is in compliance and not currently in violation with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review upon request.

Signature: _____

(b)(6)

Date: Sep 29, 2023

Robert Cantu

Vice President of Quality

7555 Innovation Way
Mason, Ohio 45040
www.atricure.com

(b)(4)

AtriClip LAA Exclusion System Special 510(k)	
Attachment I4 – Verification and Validation Summary Table	
Description	Section Number
Verification and Validation Testing	Section I-1

Section I-1 – Verification and Validation Testing

(b)(4)

(b)(4)

(b)(4)

AtriClip LAA Exclusion System Special 510(k)	
Attachment J1 – Package Labeling	
Description	Section Number
LAAØ Sterile Barrier UDI Label	Section I-1
LAAØ Sterile Barrier Product Label	Section I-2
LAAØ Sales Unit UDI Label	Section I-3
LAAØ Sales Unit Product Label	Section I-4
ACH1 Sterile Barrier UDI Label	Section I-5
ACH1 Sterile Barrier Product Label	Section I-6
ACH1 Sales Unit UDI Label	Section I-7
ACH1 Sales Unit Product Label	Section I-8
ACH2 Sterile Barrier UDI Label	Section I-9
ACH2 Sterile Barrier Product Label	Section I-10
ACH2 Sales Unit UDI Label	Section I-11
ACH2 Sales Unit Product Label	Section I-12
PRO1 Sterile Barrier UDI Label	Section I-13
PRO1 Sterile Barrier Product Label	Section I-14
PRO1 Sales Unit UDI Label	Section I-15
PRO1 Sales Unit Product Label	Section I-16
PRO2 Sterile Barrier UDI Label	Section I-17
PRO2 Sterile Barrier Product Label	Section I-18
PRO2 Sales Unit UDI Label	Section I-19
PRO2 Sales Unit Product Label	Section I-20
PROV Sterile Barrier UDI Label	Section I-21
PROV Sterile Barrier Product Label	Section I-22
PROV Sales Unit UDI Label	Section I-23
PROV Sales Unit Product Label	Section I-24
ACHV Sterile Barrier UDI Label	Section I-25
ACHV Sterile Barrier Product Label	Section I-26
ACHV Sales Unit UDI Label	Section I-27
ACHV Sales Unit Product Label	Section I-28
CGG100 Sterile Barrier UDI Label	Section I-29
CGG100 Sales Unit UDI Label	Section I-30

Section I-1 – LAAØ Sterile Barrier UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAAØ35

REF A000644-8SB

●

○

○

2026-09-01

LOT 1234567890

35

UDI

AtriCure®

(01) 1 0840143 91186 6 (17) 260901 (10) 1234567890

AtriClip® # LAAØ35  LOT 1234567890

UDI

AtriCure®

(01) 1 0840143 91186 6 (17) 260901 (10) 1234567890

AtriClip® # LAAØ35  LOT 1234567890

UDI

AtriCure®

(01) 1 0840143 91186 6 (17) 260901 (10) 1234567890

AtriClip® # LAAØ35  LOT 1234567890

UDI

AtriCure®

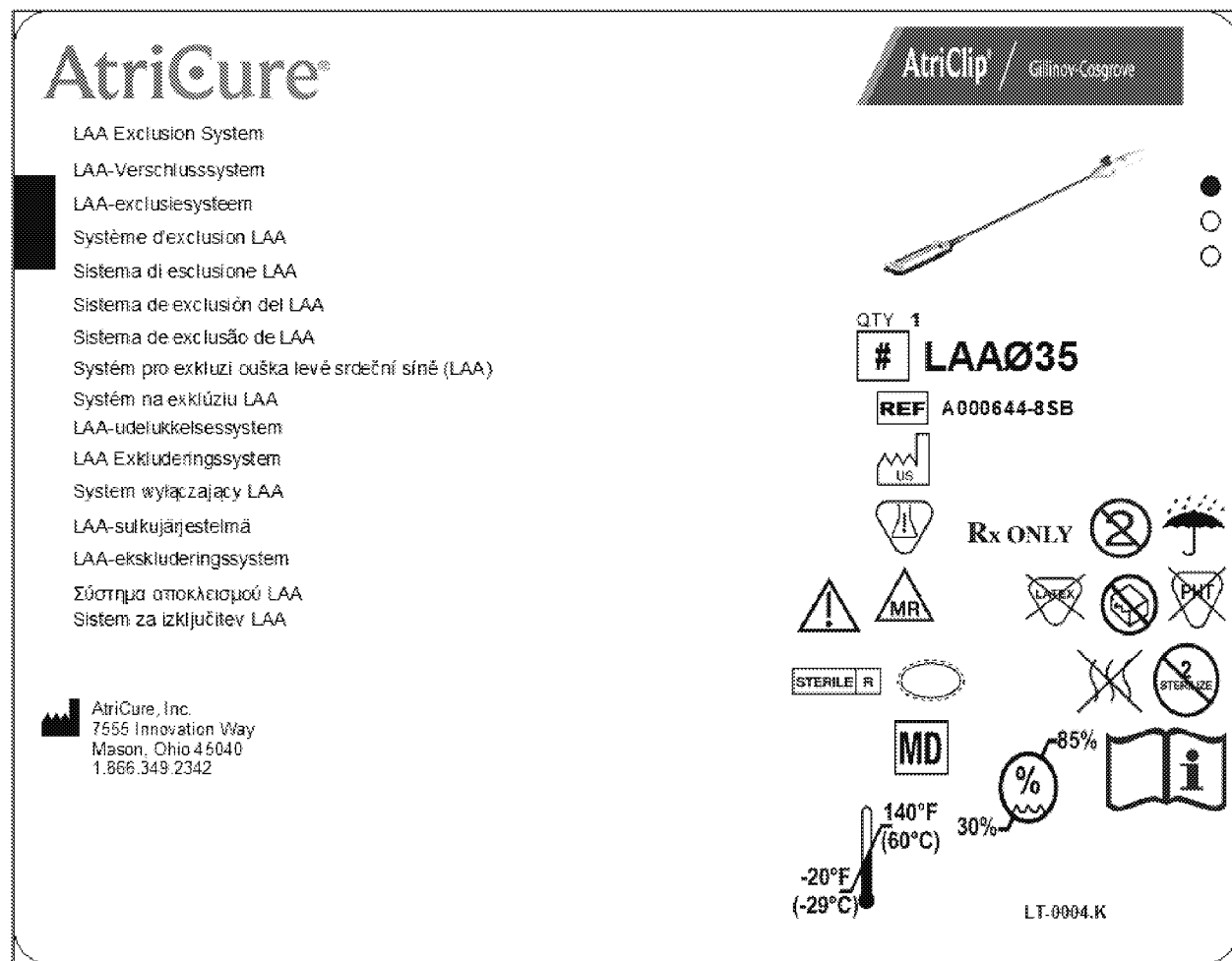
(01) 1 0840143 91186 6 (17) 260901 (10) 1234567890

AtriClip® # LAAØ35  LOT 1234567890

Label PN: LT-0006.K

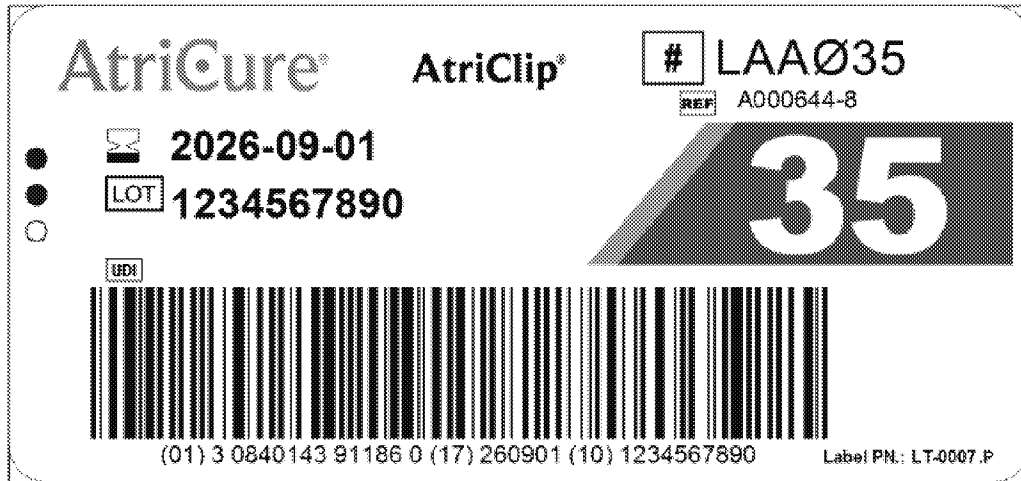
Section I-2 – LAAØ Sterile Barrier Product Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-3 – LAAØ Sales Unit UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-4 – LAAØ Sales Unit Product Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
LAA-Verschlussystem
LAA-exclusiesysteem
Système d'exclusion LAA
Sistema di esclusione LAA
Sistema de exclusión del LAA
Sistema de exclusão de LAA
Systém pro exkluzi ouška levé srdeční síně (LAA)
Systém na exklúziu LAA
LAA-udelukkelsessystem
LAA Ekskluderingsystem
System wyłączający LAA
LAA-sulkujärjestelmä
LAA-ekskluderingsystem
Σύστημα αποκλεισμού LAA
Sistem za izključitev LAA

 AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040
1.866.349.2342

AtriClip / Gillinov-Cosgrove



QTY 1

LAAØ35

REF A000644-8

US

Rx ONLY

MR

STERILE R

MD

140°F (60°C)

-20°F (-29°C)

30%

85%

LT-0004.K

Section I-5 – ACH1 Sterile Barrier UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure

ACH135

REF A000688-8SB

● 2026-09-01

○

○ LOT 1234567890

35

UDI

AtriCure

(01) 1 0840143 91190 3 (17) 260901 (10) 1234567890

AtriClip® # ACH135

MP

LOT 1234567890

UDI

AtriCure

(01) 1 0840143 91190 3 (17) 260901 (10) 1234567890

AtriClip® # ACH135

MP

LOT 1234567890

UDI

AtriCure

(01) 1 0840143 91190 3 (17) 260901 (10) 1234567890

AtriClip® # ACH135

MP

LOT 1234567890

UDI

AtriCure

(01) 1 0840143 91190 3 (17) 260901 (10) 1234567890

AtriClip® # ACH135

MP

LOT 1234567890

Label P/N: LT-0005.K

Section I-6 – ACH1 Sterile Barrier Product Label

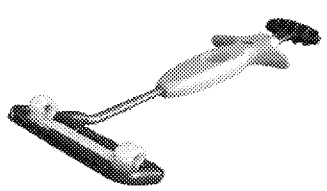
The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
LAA-Verschlussystem
LAA-exclusiesysteem
Système d'exclusion LAA
Sistema di esclusione LAA
Sistema de exclusión del LAA
Sistema de exclusão de LAA
Systém pro exkluzi ouška levé srdeční síně (LAA)
Systém na exklúziu LAA
LAA-udelukkelsessystem
LAA Exkluderingsystem
System wyłączający LAA
LAA-sulkujätjestelmä
LAA-ekskluderingsystem
Σύστημα αποκλεισμού LAA
Sistem za izključitev LAA

 AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040
1.866.349.2342

AtriClip® / Gillinov-Cosgrove

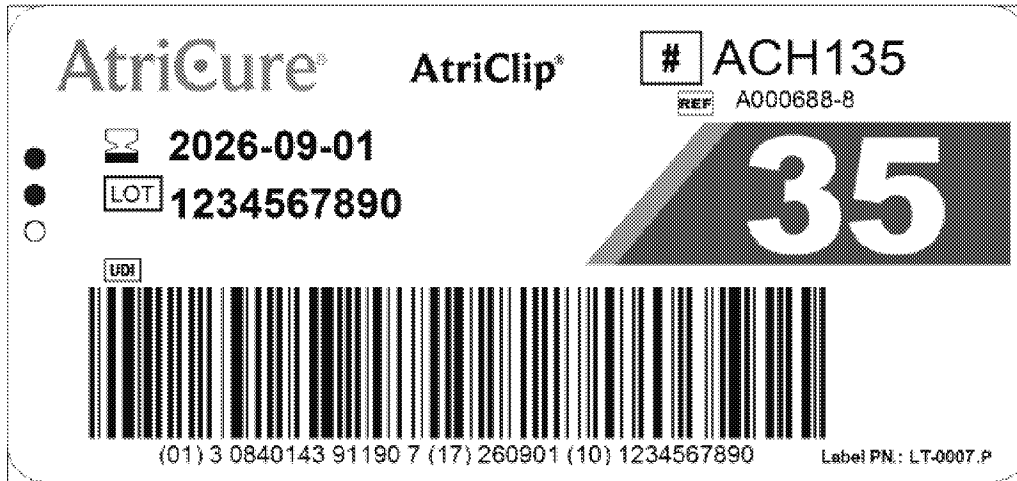


QTY 1
ACH135
REF A 000688-8 SB

 **Rx ONLY**  
    
STERILE   
MD  35%  30% 
-20°F (-29°C) 140°F (60°C)
LT-0004.K

Section I-7 – ACH1 Sales Unit UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-8 – ACH1 Sales Unit Product Label

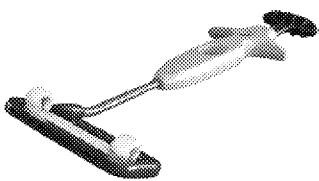
The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
 LAA-Verschlussystem
 LAA-exclusiesysteem
 Système d'exclusion LAA
 Sistema di esclusione LAA
 Sistema de exclusión del LAA
 Sistema de exclusão de LAA
 Systém pro exkluzi ouška levé srdeční síně (LAA)
 Systém na exklúziu LAA
 LAA-udelukkelsessystem
 LAA Ekskluderingsystem
 System wyłączający LAA
 LAA-sulkujajeselmä
 LAA-ekskluderingsystem
 Σύστημα αποκλεισμού LAA
 Sistem za izključitev LAA

 AtriCure, Inc.
 7555 Innovation Way
 Mason, Ohio 45040
 1.866.349.2342

AtriClip / Gillinov-Cosgrove



QTY 1

ACH135

REF A000688-8

US

Rx ONLY

MR

STERILE R

MD

140°F (60°C)

-20°F (-29°C)

85%

30%

LT-0004.K

Section I-9 – ACH2 Sterile Barrier UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®		#	ACH235	
		REF	A000916-8SB	
●		2026-09-01		
○				
○	LOT	1234567890		
		35		
UDI		AtriCure®		
				
(01) 1 0840143 91194 1 (17) 260901 (10) 1234567890				
AtriClip®		#	ACH235	LOT 1234567890
				
UDI		AtriCure®		
				
(01) 1 0840143 91194 1 (17) 260901 (10) 1234567890				
AtriClip®		#	ACH235	LOT 1234567890
				
UDI		AtriCure®		
				
(01) 1 0840143 91194 1 (17) 260901 (10) 1234567890				
AtriClip®		#	ACH235	LOT 1234567890
				
UDI		AtriCure®		
				
(01) 1 0840143 91194 1 (17) 260901 (10) 1234567890				
AtriClip®		#	ACH235	LOT 1234567890
				
Label PN: LT-0005 .IK				

Section I-10 – ACH2 Sterile Barrier Product Label

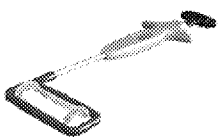
The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
 LAA-Verschlussystem
 LAA-exclusiesysteem
 Système d'exclusion LAA
 Sistema di esclusione LAA
 Sistema de exclusión del LAA
 Sistema de exclusão de LAA
 Systém pro exkluzi ouška levě srdeční síně (LAA)
 Systém na exklúziu LAA
 LAA-udelukkelsessystem
 LAA Ekskluderingsystem
 System wyłączający LAA
 LAA-sulkujärjestelmä
 LAA-ekskluderingsystem
 Σύστημα αποκλεισμού LAA
 Sistem za izključitev LAA

 AtriCure, Inc.
 7555 Innovation Way
 Mason, Ohio 45040
 1.866.349.2342

AtriClip® FLEX / Gillnet-Cosgrove



QTY 1
ACH235
REF A000916-8SB

 **Rx ONLY**      

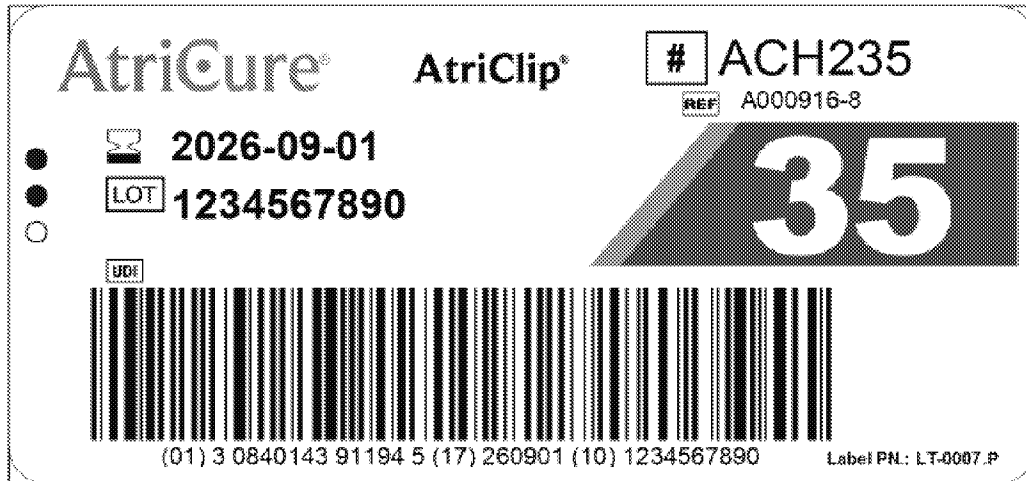
      

 140°F
 (60°C)
 -20°F
 (-29°C)

LT-0004.K

Section I-11 – ACH2 Sales Unit UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-12 – ACH2 Sales Unit Product Label

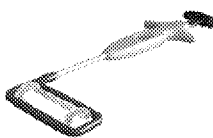
The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure[®]

LAA Exclusion System
 LAA-Verschlussystem
 LAA-exclusiesysteem
 Système d'exclusion LAA
 Sistema di esclusione LAA
 Sistema de exclusión del LAA
 Sistema de exclusão de LAA
 Systém pro exkluzi ouška levé srdeční síně (LAA)
 Systém na exklúziu LAA
 LAA-udelukkelsessystem
 LAA Exkluderingsystem
 System wyłączaący LAA
 LAA-sulkujärjestelmä
 LAA-ekskluderingsystem
 Σύστημα αποκλεισμού LAA
 Sistem za izključitev LAA

 AtriCure, Inc.
 7555 Innovation Way
 Mason, Ohio 45040
 1.866.349.2342

AtriClip FLEX / Gilino-Cosgrove



QTY 1
ACH235
REF A000916-8

 US



LT-0004.K

Section I-13 – PRO1 Sterile Barrier UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®		#	PRO135	
		REF	A000824-8SB	
●	2026-09-01			
○				
○	LOT	1234567890		
		35		
UDI				
AtriCure®				
				
(01) 1 0840143 91202 3 (17) 260901 (10) 1234567890				
AtriClip®	#	PRO135	MR	LOT 1234567890
UDI				
AtriCure®				
				
(01) 1 0840143 91202 3 (17) 260901 (10) 1234567890				
AtriClip®	#	PRO135	MR	LOT 1234567890
UDI				
AtriCure®				
				
(01) 1 0840143 91202 3 (17) 260901 (10) 1234567890				
AtriClip®	#	PRO135	MR	LOT 1234567890
UDI				
AtriCure®				
				
(01) 1 0840143 91202 3 (17) 260901 (10) 1234567890				
AtriClip®	#	PRO135	MR	LOT 1234567890
Label PN: LT-0006 .K				

Section I-14 – PRO1 Sterile Barrier Product Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
 LAA-Verschlussystem
 LAA-exclusiesysteem
 Système d'exclusion LAA
 Sistema di esclusione LAA
 Sistema de exclusión del LAA
 Sistema de exclusão de LAA
 Systém pro exkluzi ouška levé srdeční síně (LAA)
 Systém na exklúziu LAA
 LAA-udelukkelsessystem
 LAA Ekskluderingsystem
 System wyłączający LAA
 LAA-sulkujätesselmä
 LAA-ekskluderingsystem
 Σύστημα αποκλεισμού LAA
 Sistem za izključitev LAA

AtriCure, Inc.
 7555 Innovation Way
 Mason, Ohio 45040
 1.866.349.2342

AtriClip PRO / Gilrau-Cosgrove

QTY 1
PRO135
REF A000824-8 SB

STERILE R

140°F
(60°C)

-20°F
(-29°C)

85%

30%

LT-0004.K

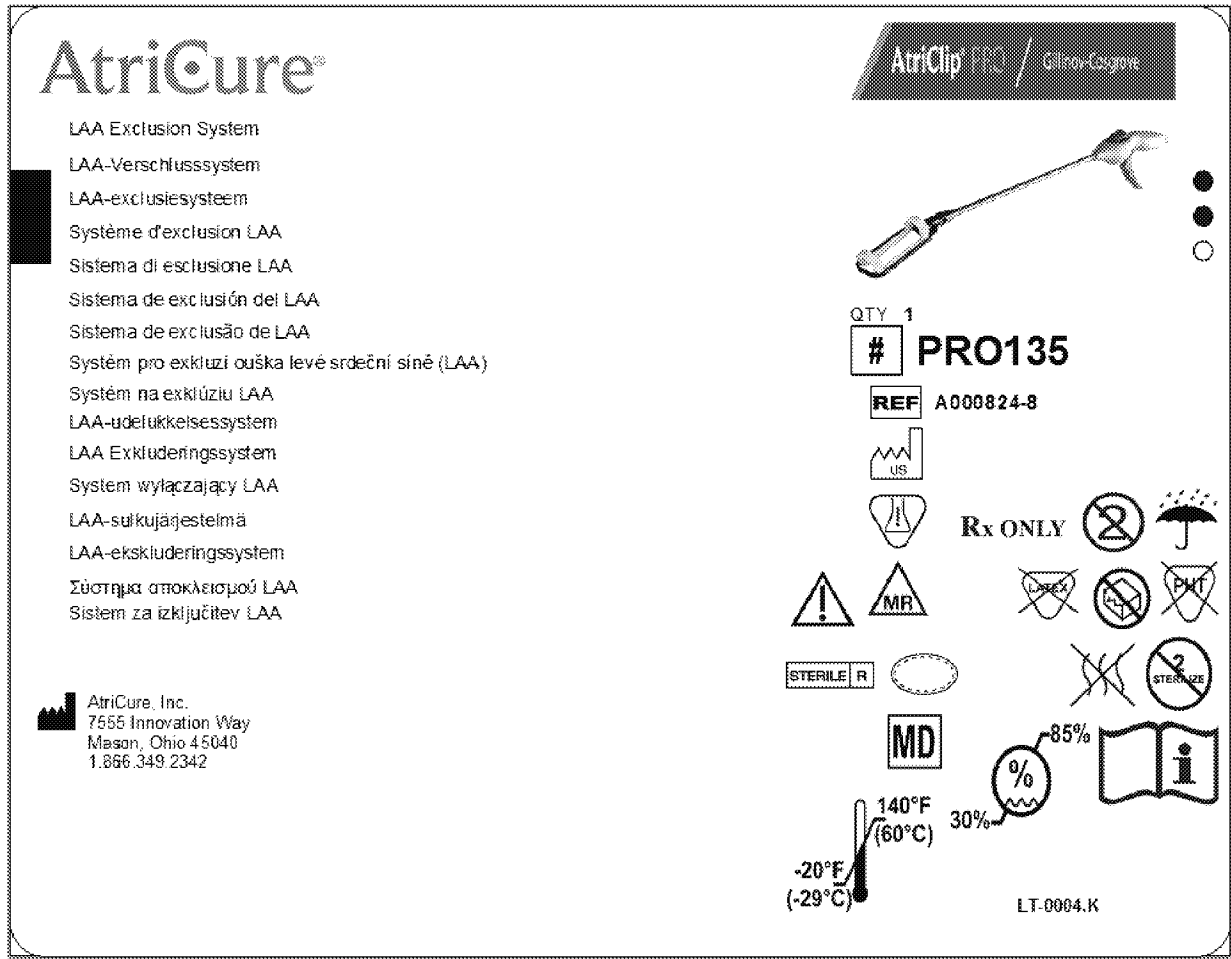
Section I-15 – PRO1 Sales Unit UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-16 – PRO1 Sales Unit Product Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



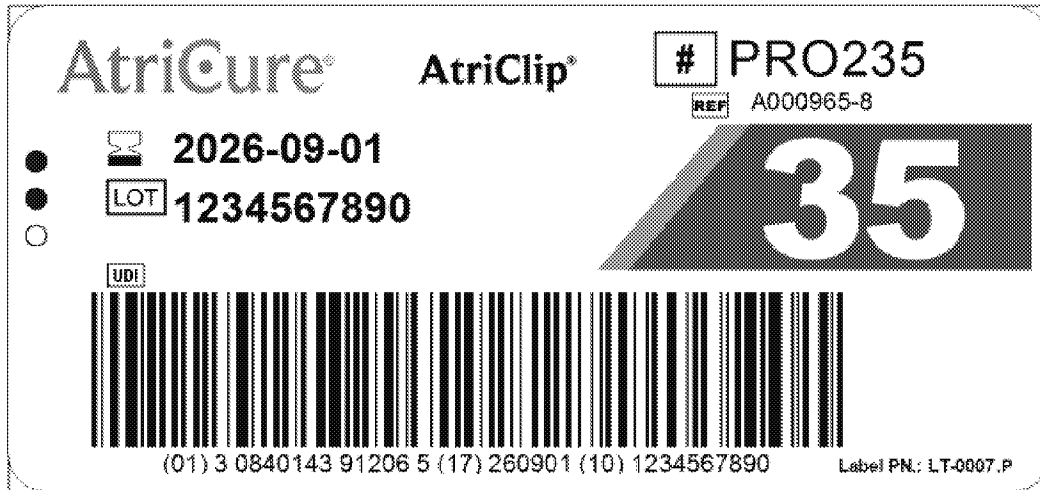
Section I-17 – PRO2 Sterile Barrier UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®		#	PRO235	
		REF	A000965-8SB	
●	2026-09-01			
○				
○	LOT	1234567890		
		35		
UDI AtriCure® (01) 1 0840143 91206 1 (17) 260901 (10) 1234567890 AtriClip® # PRO235 MR LOT 1234567890				
UDI AtriCure® (01) 1 0840143 91206 1 (17) 260901 (10) 1234567890 AtriClip® # PRO235 MR LOT 1234567890				
UDI AtriCure® (01) 1 0840143 91206 1 (17) 260901 (10) 1234567890 AtriClip® # PRO235 MR LOT 1234567890				
UDI AtriCure® (01) 1 0840143 91206 1 (17) 260901 (10) 1234567890 AtriClip® # PRO235 MR LOT 1234567890				
Label PN: LT-0005.K				

Section I-19 – PRO2 Sales Unit UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-20 – PRO2 Sales Unit Product Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
LAA-Verschlussystem
LAA-exclusiesysteem
Système d'exclusion LAA
Sistema di esclusione LAA
Sistema de exclusión del LAA
Sistema de exclusão de LAA
Systém pro exkluzi ouška levé srdce (LAA)
Systém na exklúziu LAA
LAA-udelukkelsessystem
LAA Ekskluderingsystem
System wyłączający LAA
LAA-sulkujärjestelmä
LAA-ekskluderingsystem
Σύστημα αποκλεισμού LAA
System za izključitev LAA

 AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040
1.866.349.2342

AtriClip® PRO2 / Gillinov-Cosgrove



QTY 1

#

PRO235

REF A000965-8

US

STERILE R

MD

Rx ONLY

-20°F
(-29°C)

140°F
(60°C)

30%

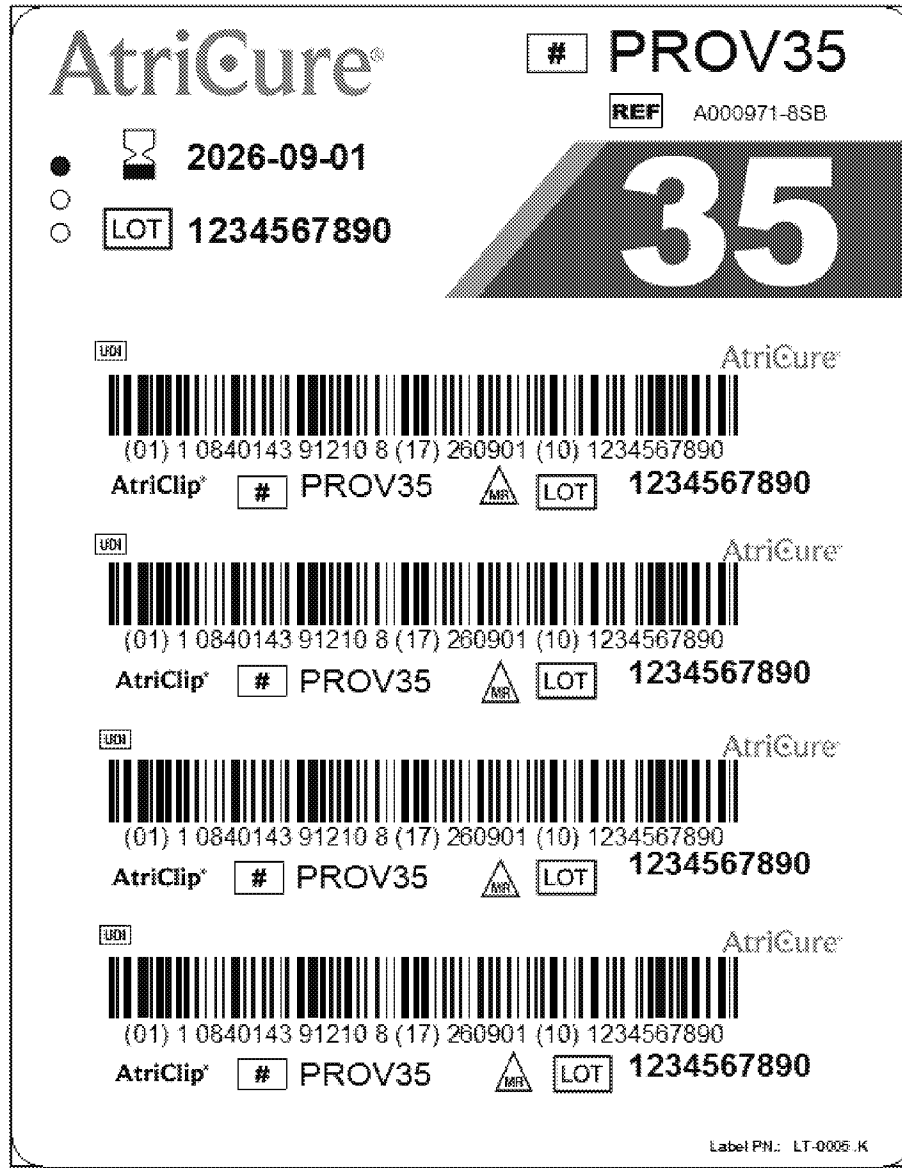
85%



LT-0004.K

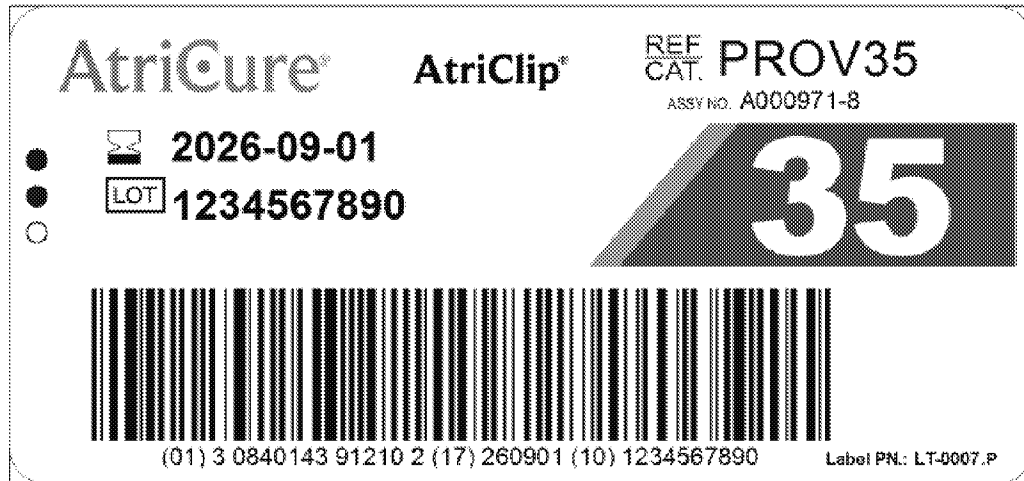
Section I-21 – PROV Sterile Barrier UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-23 – PROV Sales Unit UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-24 – PROV Sales Unit Product Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
 LAA-Verschlussystem
 LAA-exclusiesysteem
 Système d'exclusion LAA
 Sistema di esclusione LAA
 Sistema de exclusión del LAA
 Sistema de exclusão de LAA
 Systém pro exkluzi ouška levé srdeční síně (LAA)
 Systém na exklúziu LAA
 LAA-udelukkelsessystem
 LAA Ekskluderingsystem
 System wyłączający LAA
 LAA-sulkujärjestelmä
 LAA-ekskluderingsystem
 Σύστημα αποκλεισμού LAA
 Sistem za izključitev LAA

 AtriCure, Inc.
 7555 Innovation Way
 Mason, Ohio 45040
 1.866.349.2342



QTY 1

PROV35

REF A000971-8

 US

 **Rx ONLY**

 MR

 **STERILE R**

 **MD**

 140°F
(60°C)
-26°F
(-29°C)

 85%
30%

 **i**

LT-0004.K

Section I-25 – ACHV Sterile Barrier UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®		#	ACHV35	
		REF	A001017-8SB	
●	2026-09-01			
○				
○	LOT	1234567890		
		35		
UDI				
AtriCure®				
				
(01) 1 0840143 91198 9 (17) 260901 (10) 1234567890				
AtriClip® # ACHV35  LOT 1234567890				
UDI				
AtriCure®				
				
(01) 1 0840143 91198 9 (17) 260901 (10) 1234567890				
AtriClip® # ACHV35  LOT 1234567890				
UDI				
AtriCure®				
				
(01) 1 0840143 91198 9 (17) 260901 (10) 1234567890				
AtriClip® # ACHV35  LOT 1234567890				
UDI				
AtriCure®				
				
(01) 1 0840143 91198 9 (17) 260901 (10) 1234567890				
AtriClip® # ACHV35  LOT 1234567890				
Label PN: LT-0005 JK				

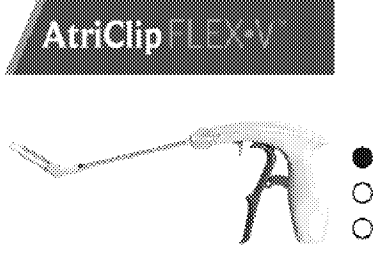
Section I-26 – ACHV Sterile Barrier Product Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
 LAA-Verschlussystem
 LAA-exclusiesysteem
 Système d'exclusion LAA
 Sistema di esclusione LAA
 Sistema de exclusión del LAA
 Sistema de exclusão de LAA
 Systém pro exkluzi ouška levé srdeční síně (LAA)
 Systém na exklúziu LAA
 LAA-udelukkelsessystem
 LAA Ekskluderingsystem
 System wyłączający LAA
 LAA-sulkujärjestelmä
 LAA-ekskluderingsystem
 Σύστημα αποκλεισμού LAA
 Sistem za izključitev LAA

 AtriCure, Inc.
 7555 Innovation Way
 Mason, Ohio 45040
 1.866.349.2342



QTY 1

ACHV35

REF A001017-8 SB

 US

STERILE R 

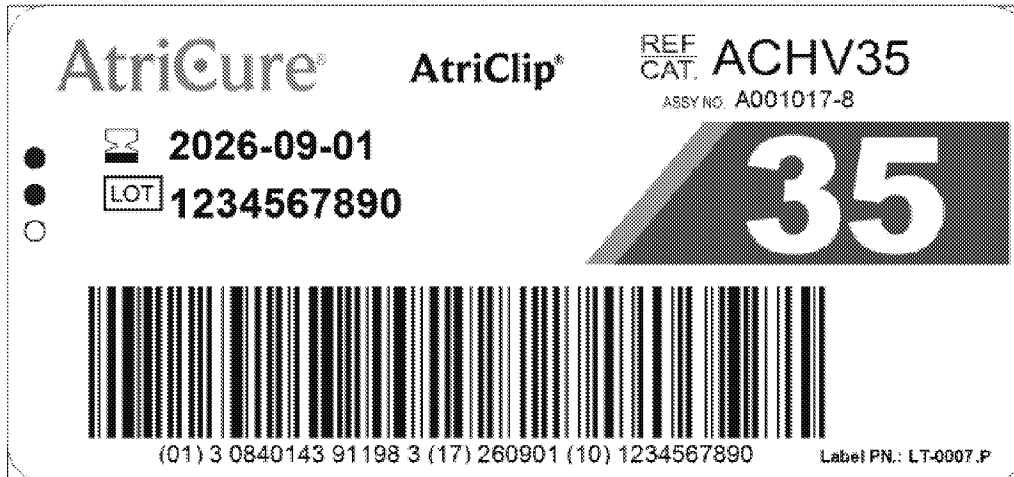
 140°F (60°C)
 -20°F (-29°C)

85% 30% 

LT-0004.K

Section I-27 – ACHV Sales Unit UDI Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.



Section I-28 – ACHV Sales Unit Product Label

The 35 mm label is representative of the 40 mm, 45 mm, and 50 mm.

AtriCure®

LAA Exclusion System
LAA-Verschlussystem
LAA-excludesysteem
Système d'exclusion LAA
Sistema di esclusione LAA
Sistema de exclusión del LAA
Sistema de exclusão de LAA
Systém pro exkluzi ouška levě srdeční síně (LAA)
Systém na exklúziu LAA
LAA-udelukkelsessystem
LAA Ekskluderingsystem
System wyłączający LAA
LAA-sulkujäjestelmä
LAA-ekskluderingsystem
Σύστημα αποκλεισμού LAA
Sistem za izključitev LAA

 AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040
1.866.349.2342

AtriClip FLEX-V™



QTY 1
ACHV35
REF A001017-8

 **Rx ONLY**   

STERILE R   

MD   

 140°F
(60°C)
-20°F
(-29°C)

LT-0004.K

Section I-29 – CGG100 Sterile Barrier UDI Label

AtriCure®

AtriClip®
Selection Guide

85%
30%

140°F
(60°C)

-20°F
(-29°C)

STERILE R

Selection Guide
 Selectiegid
 Auswahlhilfe
 Guide de sélection
 Guida alla selezione
 Guia de seleção
 Guía de selección
 Vodič pro výběr
 Pomůcka na výběr sroiek typu
 Størrelsesguide
 Markeringsguide
 Valintaohje
 Przymiar
 Οδηγός επιλογής

(01) 1 0840143 91214 6 (17) 260901 (10) 1234567890

AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040
1.866.349.2342

QTY 1

1234567890
 2026-09-01
 LT-0023 .R

CGG100
 A0-00349-3SB

Section I-30 – CGG100 Sales Unit UDI Label

Selection Guide

Selectiegids

Auswahlhilfe

Guide de sélection

Guida alla selezione

Guia de seleção

Guía de selección

Vodič pro výběr

Pomůcka na výběr srovnávek typu

Størrelsesguide

Markeringsguide

Valintahjain

Przymiar

Οδηγός επιλογής

(01) 1234567890 (17) 260901 (10) 1234567890

AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040
1.866.349.2342

QTY 3

LOT 1234567890 2026-09-01

CGG100

REF A000349-8

LT-0023 .R

AtriClip LAA Exclusion System Special 510(k)	
Attachment J2 – Package Instructions for Use	
Documents Enclosed	
Description	Document Number
LAAØ/ACH1/ACH2 Instructions For Use	P001352
PRO1 Instructions For Use	P001354
PRO2 Instructions For Use	P001355
PROV Instructions For Use	P001356
ACHV Instructions For Use	P001351
CGG100 Instructions For Use	P000224

Please see **Attachment H1, Section I-2** for the modifications made to the IFUs.

AtriCure

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

INSTRUCTIONS FOR USE

LAA035, LAA040, LAA045, LAA050
ACH135, ACH140, ACH145, ACH150
ACH235, ACH240, ACH245, ACH250

Rx ONLY MD

FIGURE 1 LAA

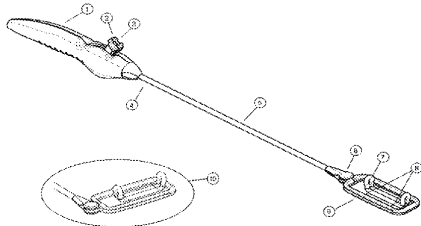


FIGURE 2 ACH1

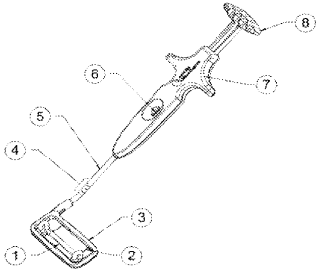


FIGURE 3 ACH2

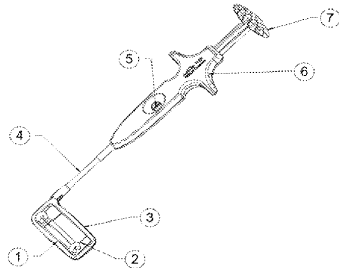


FIGURE 4

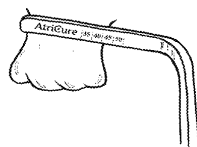


FIGURE 5

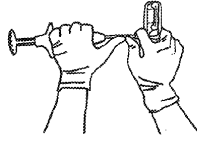


FIGURE 6

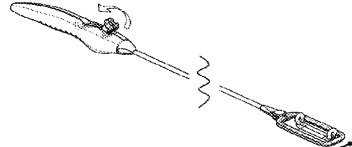


FIGURE 7

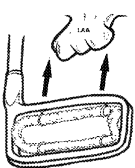


FIGURE 8

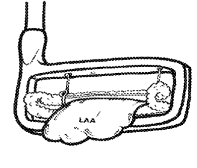


FIGURE 9

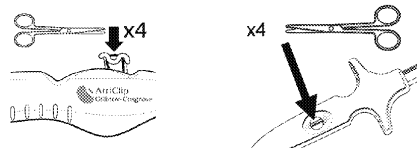


FIGURE 10

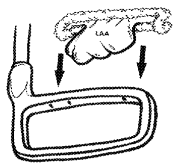
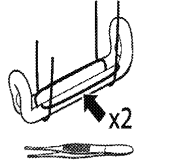


FIGURE 11



INSTRUCTIONS FOR USE

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

INDICATION FOR USE

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

CONTRAINDICATIONS

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

SYSTEM DESCRIPTION

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

The AtriClip LAA Exclusion System is a delivery and deployment device preloaded with a Gillinov-Cosgrove LAA Clip. The Clip is preloaded on a disposable Clip applicator. The Gillinov-Cosgrove Clip is a permanent implant device; device lifetime is equal to patient lifetime. The Clip was determined to be "MR Conditional" per the requirements of standard ASTM F2503-20.

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

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

ENVIRONMENTAL SPECIFICATIONS

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

PACKAGE CONTENTS

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

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

SYSTEM ACCESSORIES

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

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

ATRICLIP LAA EXCLUSION SYSTEM

(LAA035, LAA040, LAA045, LAA050) - ATRICLIP LONG

NOMENCLATURE (SEE FIGURE 1)

- | | |
|---|----------------------------------|
| [1] Handle | [6] Articulation Clevis |
| [2] Activation Lever | [7] Gillinov-Cosgrove Clip |
| [3] Suture Cutting Zone | [8] Suture Anchors |
| [4] Nose Cone with Clip size identifier | [9] Deployment Loop |
| [5] Malleable Shaft ¹ | [10] Articulated Deployment Loop |

¹The entire length of the LAA device's shaft is malleable.

(ACH135, ACH140, ACH145, ACH150) - ATRICLIP STANDARD

NOMENCLATURE (SEE FIGURE 2)

- | | |
|---------------------------------|-------------------------|
| [1] Gillinov-Cosgrove Clip | [5] Shaft |
| [2] Suture Anchors | [6] Suture Cutting Zone |
| [3] Deployment Loop | [7] Handle |
| [4] Malleable Zone ¹ | [8] Plunger |

¹The ACH1 device's malleable zone is denoted by a set of slots on the shaft near the deployment loop. It is only intended for minor adjustments in the lateral (left/right) plane.

(ACH235, ACH240, ACH245, ACH250) - ATRICLIP FLEX

NOMENCLATURE (SEE FIGURE 3)

- | | |
|----------------------------|-------------------------|
| [1] Gillinov-Cosgrove Clip | [5] Suture Cutting Zone |
| [2] Suture Anchors | [6] Handle |
| [3] Deployment Loop | [7] Plunger |
| [4] Shaft ¹ | |

¹The entire length of the ACH2 device's shaft is malleable. It is intended for adjustments up to 45° in all planes.

⚠ WARNINGS ⚠

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

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

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.

⚠ WARNINGS ⚠

The LAA and ACH1 devices contain small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use this device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.

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.

COMPLICATIONS

Potential complications associated with the use of the AtriClip LAA/ACH1/ACH2 LAA Exclusion System and procedure include, but are not limited to, those listed below:

- | | |
|---|--|
| <ul style="list-style-type: none">• Air embolism• Allergic reaction to anesthesia, anticoagulant, implant material• Anaphylactic shock• Anesthesia risks• Aneurysm• Angina• Arrhythmia needing medical treatment (new onset)• Arterial or venous dissection and/or perforation | <ul style="list-style-type: none">• Extension of cardiopulmonary/extracorporeal bypass• Fever• Gastric motility disorders• Gastro-intestinal bleed• Hematoma• Hematuria• Hemothorax• Hypertension• Hypotension |
|---|--|

AtriCure

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

INSTRUCTIONS FOR USE

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

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

CLIP SELECTION

⚠ WARNING ⚠

Carefully consider any presurgical treatment the patient may have undergone when selecting Clip size. Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected Clip size. Failure to correctly size the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, lack of desired hemostasis, and/or incomplete exclusion of the structure.

- Using the Guide, determine correct selection of the Gillinov- Cosgrove LAA Clip (See Figure 4). Clip sizes are located on the device package.

Labeled Clip Size	LAA Size Range
33 mm	29 – 33 mm (1.14 – 1.38 in)
40 mm	34 – 40 mm (1.34 – 1.57 in)
45 mm	39 – 45 mm (1.54 – 1.77 in)
50 mm	44 – 50 mm (1.73 – 1.97 in)

⚠ WARNINGS ⚠

Do not use on a LAA less than 29 mm (1.14 in) in width and 1 mm (0.04 in) wall thickness. Doing so may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis. Do not use on a LAA greater than 50 mm (1.97 in) when tissue is uncompressed. Doing so may result in incomplete exclusion of the structure.

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

⚠ WARNING ⚠

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

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

- The Malleable Shaft of the AtriClip LAA Exclusion System may be reshaped to aid in accessing the LAA. Apply gentle pressure to shape the device Shaft as required for anatomical variations (See Figure 5).

NOTE: LAA, ACH1, and ACH2 have a different malleable region.

NOTE: The ACH1 device's malleable zone is denoted by a set of slots on the Shaft near the deployment loop. It is only intended for minor adjustments in the lateral (left/right) plane.

NOTE: The entire length of the LAA and ACH2 devices' Shaft is malleable. The ACH2 Shaft is intended for adjustments up to 45° in all planes.

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

⚠ CAUTION: 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.

- Using the Plunger or Activation Lever on the Handle, gently open and close the Clip to ensure proper function.

⚠ WARNING ⚠

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

ARTICULATION OF END EFFECTOR- APPLIES TO LAA DEVICES

- The Deployment Loop of the AtriClip LAA Exclusion System may be manually articulated from 0° (inline - as supplied) to ±90° relative to the Shaft to aid in the proper placement of the Gillinov-Cosgrove LAA Clip to take into account anatomical variations in the patient's anatomy (See Figure 6).

CLIP POSITIONING

⚠ WARNING ⚠

Position and deploy Clip in a manner that provides direct visualization of all tissues being accessed. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies. Poor visualization may result in suboptimal placement and damage or obstruction of surrounding structures.

- Maneuver the AtriClip LAA Exclusion System into the targeted dissection plane.
- Gently open the Clip by moving the Activation Lever backwards or depressing the Plunger.

NOTE: The Clip can be locked in the open position by means of a locking feature in the handle of the device. The lock will engage when the lever is activated and can be disengaged by gently moving the lever to the left. Applies to LAA devices.

NOTE: Maintain pressure on the Plunger in order to hold the Clip open. This device does not contain an automatic locking function. Applies to the ACH1 and ACH2 devices.

- Orient the Clip applier with preloaded Clip at the tip of LAA. Ensure the loops at the ends of the Clip are pointed away from the LAA (See Figure 7).
- Gently position the Clip at the base of the LAA (See Figure 8).
- Position the Clip in a manner that provides clear visualization of all tissues being accessed.
- While the Clip is still affixed to the Deployment Device, ensure that no surrounding structures interfere with or are damaged by the Clip, and that the Clip is placed correctly.

- If the Clip is not placed correctly, gently open the Clip and reposition as needed.

DEPLOYMENT

⚠ WARNINGS ⚠

Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Guide Instructions for Use. Failure to correctly size or deploy the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis. Unless medically necessary, do not attempt to reposition or remove the Clip after deployment. This may result in tissue damage or tearing.

- After the Clip is positioned correctly, release the Activation Lever or Plunger to allow the Clip to close.
- Deploy the Clip by manually cutting the suture at the designated Suture Cutting Zone on the Lever or Handle (See Figure 9).

NOTE: After manually cutting the sutures, the AtriClip LAA Exclusion System cannot be used to reposition or remove the Clip.

- Providing countertraction on the Clip, carefully remove the Deployment Loop from the LAA. Leave the Clip and attachment suture behind (See Figure 10).

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

- After the Clip is deployed, remove the attachment sutures by gently pulling one at a time while providing countertraction on the Clip per the surgeon's discretion. Do not cut the Clip fabric (See Figure 11).

DISPOSAL INFORMATION

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

SERIOUS INCIDENT

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

RETURN OF USED PRODUCT

If, for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER STATEMENTS

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

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

HANDLING INFORMATION: GILLINOV- COSGROVE LAA CLIP

MRI SAFETY INFORMATION

⚠ 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.

SYMBOLS GLOSSARY

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

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

REFERENCES

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



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+1 513 755 4100 (phone)

AtriCure

AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip INSTRUCTIONS FOR USE

PRO135, PRO140, PRO145, PRO150

Rx ONLY MD

FIGURE 1

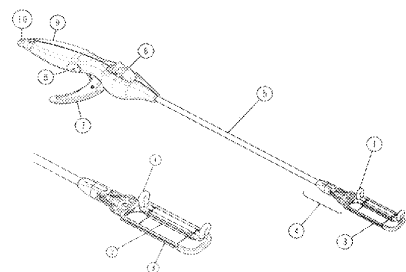


FIGURE 2

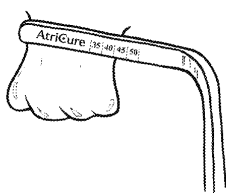


FIGURE 4

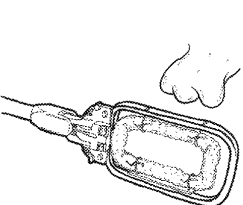


FIGURE 3

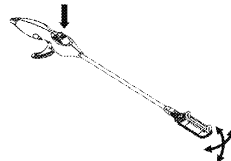


FIGURE 5

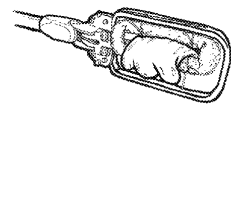
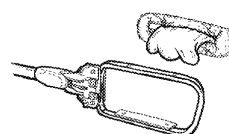


FIGURE 6



FIGURE 7



INSTRUCTIONS FOR USE

en

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

INDICATION FOR USE

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

SYSTEM DESCRIPTION

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

The AtriClip LAA Exclusion System is a delivery and deployment device preloaded with a Gillinov-Cosgrove LAA Clip. The Clip is pre-loaded on a disposable Clip applicator. The Gillinov-Cosgrove Clip is a permanent implant; device lifetime is equal to patient lifetime. The Clip was determined to be "MR Conditional" per the requirements of standard ASTM F2503-20.

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

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

ENVIRONMENTAL SPECIFICATIONS

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

PACKAGE CONTENTS

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

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

SYSTEM ACCESSORIES

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

- Selection Guide (CGG 100) (Guide)—Packaged Separately

ATRICLIP LAA EXCLUSION SYSTEM

NOMENCLATURE (SEE FIGURE 1)

[1]	Gillinov-Cosgrove Clip	[6]	Articulation Release Button
[2]	Clip Pull Bar	[7]	Activation Lever
[3]	Deployment Loop	[8]	Lever Release Button
[4]	Articulation Joints	[9]	Handle
[5]	Shaft	[10]	Deployment Tab

⚠ WARNINGS ⚠

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

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

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.

⚠ WARNING ⚠

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

COMPLICATIONS

Potential complications associated with the use of the AtriClip PRO1 LAA Exclusion System and procedure include, but are not limited to, those listed below:

- Air embolism
- Allergic reaction to anesthesia, anticoagulant, implant material
- Anaphylactic shock
- Anesthesia risks
- Aneurysm
- Angina
- Arrhythmia needing medical treatment (new onset)
- Arterial or venous dissection and/or perforation
- Arterial rupture
- Arterial spasm
- Arteriovenous fistula
- Extension of cardiopulmonary/extracorporeal bypass
- Fever
- Gastric motility disorders
- Gastro-intestinal bleed
- Hematoma
- Hematuria
- Hemothorax
- Hypertension
- Hypotension
- Iatrogenic atrial flutter
- Iatrogenic lung injury (e.g., chest tube placement)
- Ischemia

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

INSTRUCTIONS FOR USE

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

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

CLIP SELECTION

⚠ WARNING ⚠

Carefully consider any presurgical treatment the patient may have undergone when selecting Clip size. Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected Clip size. Failure to correctly size the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, lack of desired hemostasis, and/or incomplete exclusion of the structure.

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

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

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⚠ WARNINGS ⚠

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

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

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

⚠ WARNING ⚠

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

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

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

⚠ WARNING ⚠

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

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

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

CLIP POSITIONING

⚠ WARNING ⚠

Position and deploy Clip in a manner that provides direct visualization of all tissues being accessed. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies. Poor visualization may result in suboptimal placement and damage or obstruction of surrounding structures.

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

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

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

- Orient the Clip applier with preloaded Clip at the tip of the LAA. Ensure the loops at the ends of the Clip are pointed away from the LAA (See Figure 4).
- Gently position the Clip at the base of the LAA (See Figure 5).
- Position the Clip in a manner that provides clear visualization of all tissues being accessed.
- While the Clip is still affixed to the Deployment Device, ensure that no surrounding structures interfere with or are damaged by the Clip, and that the Clip is placed correctly.
- If the Clip is not placed correctly, gently open the Clip and reposition as needed.

DEPLOYMENT

⚠ WARNINGS ⚠

Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Guide Instructions for Use. Failure to correctly size or deploy the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis.

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

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

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

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

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

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

DISPOSAL INFORMATION

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

SERIOUS INCIDENT

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

RETURN OF USED PRODUCT

If, for any reason, this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER STATEMENTS

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

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

HANDLING INFORMATION: GILLINOV-COSGROVE LAA CLIP

MRI SAFETY INFORMATION

MR 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.

SYMBOLS GLOSSARY

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

	Single sterile barrier system with protective packaging outside		Single sterile barrier system with protective packaging inside
	Manufacturer		Caution
	Does not contain phthalates		Contains hazardous substances
	Do not use if package is damaged		Non-pyrogenic
	Sterilized using irradiation		Consult Instructions For Use
	Do not re-use		Do not re-sterilize
	Not Made with natural Rubber Latex		Catalogue Number
	Model Number		Unique Device Identifier
	Lot Number		Use-by date
	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician		MR Conditional
	Country of Manufacture		Medical Device
	Keep dry		
	Transit Temperature limit		

REFERENCES

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



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AtriCure

AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip INSTRUCTIONS FOR USE

PRO235, PRO240, PRO245, PRO250

Rx ONLY **MD**

FIGURE 1

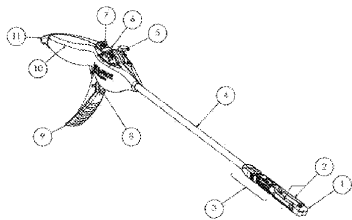


FIGURE 2

FIGURE 3

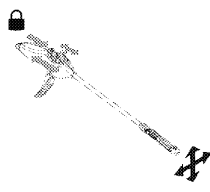
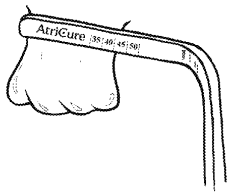


FIGURE 4

FIGURE 5

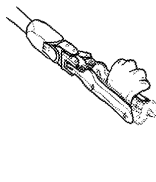
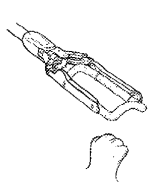
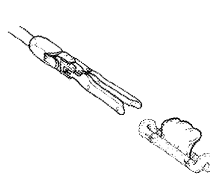
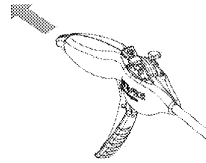


FIGURE 6

FIGURE 7



INSTRUCTIONS FOR USE

en

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

INDICATION FOR USE

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

CONTRAINDICATIONS

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

SYSTEM DESCRIPTION

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

The AtriClip LAA Exclusion System is a delivery and deployment device preloaded with a Gillinov-Cosgrove LAA Clip. The Clip is preloaded on a disposable Clip applicator. The Gillinov-Cosgrove Clip is a permanent implant; device lifetime is equal to patient lifetime. The Clip was determined to be "MR Conditional" per the requirements of standard ASTM F2503-20.

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

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

ENVIRONMENTAL SPECIFICATIONS

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

PACKAGE CONTENTS

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

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

SYSTEM ACCESSORIES

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

- Selection Guide (CGG 100) (Guide)—Packaged Separately
- Minimum 12 mm port

ATRICLIP LAA EXCLUSION SYSTEM

NOMENCLATURE (SEE FIGURE 1)

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

⚠ WARNINGS ⚠

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

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

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.

⚠ WARNING ⚠



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

COMPLICATIONS

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

- Air embolism
- Allergic reaction to anesthesia, anticoagulant, implant material
- Anaphylactic shock
- Anesthesia risks
- Aneurysm
- Angina
- Arrhythmia needing medical treatment (new onset)
- Arterial or venous dissection and/or perforation
- Arterial rupture
- Fever
- Gastric motility disorders
- Gastro-intestinal bleed
- Hematoma
- Hematuria
- Hemothorax
- Hypertension
- Hypotension
- Iatrogenic atrial flutter
- Iatrogenic lung injury (e.g., chest tube placement)

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

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

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

CLIP SELECTION

⚠ WARNING ⚠

Carefully consider any presurgical treatment the patient may have undergone when selecting Clip size. Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected Clip size. Failure to correctly size the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, lack of desired hemostasis, and/or incomplete exclusion of the structure.

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

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

AtriCure

⚠ WARNINGS ⚠

Do not use on a LAA less than 29 mm (1.14 in) in width and 1 mm (0.04 in) wall thickness. Doing so may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis. Do not use on a LAA greater than 50 mm (1.97 in) when tissue is uncompressed. Doing so may result in incomplete exclusion of the structure.

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

⚠ WARNINGS ⚠

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

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

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

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

⚠ WARNING ⚠

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

ARTICULATION OF END EFFECTOR

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

CAUTION: Do not attempt to articulate the End Effector while in the locked position. Force applied while in the locked position may cause damage to the device.

CLIP POSITIONING

⚠ WARNING ⚠

Position and deploy Clip in a manner that provides direct visualization of all tissues being accessed. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies. Poor visualization may result in suboptimal placement and damage or obstruction of surrounding structures.

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

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

NOTE: The Clip automatically locks in the fully open position by means of a Locking Trigger on the handle of the device. The lock can be disengaged by pressing the Lever Release Trigger.

- Orient the Clip applier with preloaded Clip at the tip of the LAA. Ensure the loops at the ends of the Clip are pointed away from the LAA (See Figure 4).
- Gently position the Clip at the base of the LAA (See Figure 5).
- Position the Clip in a manner that provides clear visualization of all tissues being accessed.
- While the Clip is still affixed to the Deployment Device, ensure that no surrounding structures interfere with or are damaged by the Clip, and that the Clip is placed correctly.
- If the Clip is not placed correctly, gently open the Clip and reposition as needed.
- After the Clip is positioned correctly, grasp the Activation Lever, depress the Lever Release Trigger, and slowly release the Activation Lever to allow the Clip to close.

DEPLOYMENT

⚠ WARNINGS ⚠

Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Guide Instructions for Use. Failure to correctly size or deploy the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis. Unless medically necessary, do not attempt to reposition or remove the Clip after deployment. This may result in tissue damage or tearing.

- Deploy the Clip by slowly pulling the Deployment Tab at the proximal end of the Handle.

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

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

- Unlock the End Effector articulation and carefully remove it from the LAA, leaving the Clip and attachment suture behind (See Figure 7).

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

DISPOSAL INFORMATION

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

SERIOUS INCIDENT

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

RETURN OF USED PRODUCT

If, for any reason, this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER STATEMENTS

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

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

HANDLING INFORMATION: GILLINOV-COSGROVE LAA CLIP

MRI SAFETY INFORMATION

⚠ 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.

SYMBOLS GLOSSARY

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

	Single sterile barrier system with protective packaging outside		Single sterile barrier system with protective packaging inside
	Manufacturer		Caution
	Does not contain phthalates		Contains hazardous substances
	Do not use if package is damaged		Non-pyrogenic
	Sterilized using irradiation		Consult Instructions For Use
	Do not re-use		Do not re-sterilize
	Not Made with natural Rubber Latex		Catalogue Number
	Model Number		Unique Device Identifier
	Lot Number		Use by date
	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician		MR Conditional
	Country of Manufacture		Medical Device
	Keep dry		
	Transit Temperature limit		

REFERENCES

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

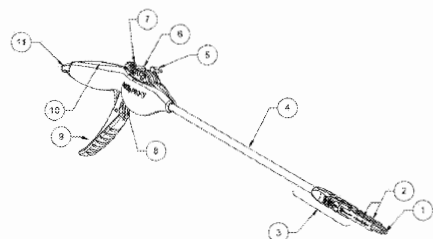
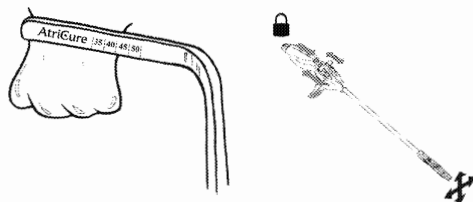
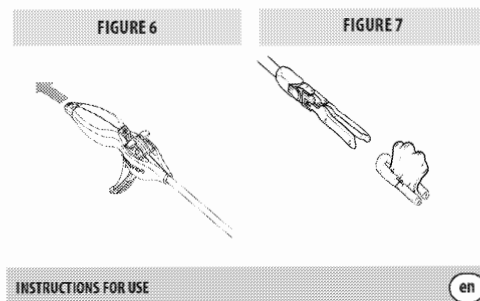
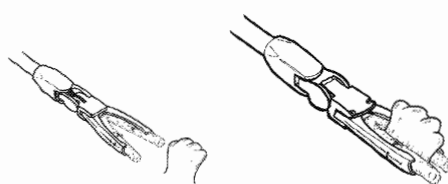


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AtriCure**AtriClip® PRO-V® LAA Exclusion System**
INSTRUCTIONS FOR USE

PROV35, PROV40, PROV45, PROV50

Rx ONLY MD

FIGURE 1**FIGURE 2****FIGURE 3****FIGURE 4****FIGURE 5****AtriClip® PRO-V® LAA Exclusion System****INDICATION FOR USE**

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

CONTRAINDICATIONS

1. Do not use this device as a contraceptive tubal occlusion device.
2. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in the presence of infected operating field.

SYSTEM DESCRIPTION

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

The AtriClip Pro-V LAA Exclusion System is a delivery and deployment device preloaded with a V Clip. The V Clip is pre-loaded on a disposable Clip applicator. 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 used to deliver a preloaded Clip to the target LAA site. 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. The Pro-V LAA Exclusion System with preloaded V Clip is not made with natural rubber latex and does not contain phthalates. Detailed materials information for implanted V Clip sizes 35 mm to 50 mm are below:

Material	Mass (mg)	CAS #
Titanium Grade 5	2.41 to 3.73	Titanium, 7440-32-6 Aluminum, 7429-90-5 Vanadium, 7440-62-2
Polyethylene Terephthalate	0.25 to 0.31	25038-59-9
Titanium Dioxide	0.001	13463-67-7

ENVIRONMENTAL SPECIFICATIONS

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

PACKAGE CONTENTS

1. One (1) AtriClip LAA Exclusion System with Preloaded V Clip
2. One (1) Implant Card and (1) Implant Card Leaflet

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

SYSTEM ACCESSORIES

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

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

ATRICLIP PRO-V LAA EXCLUSION SYSTEM**NOMENCLATURE (SEE FIGURE 1)**

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

⚠ WARNINGS ⚠

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

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

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.

⚠ WARNING ⚠

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

COMPLICATIONS

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

- Air embolism
- Allergic reaction to anesthesia, anticoagulant, implant material
- Anaphylactic shock
- Anesthesia risks
- Aneurysm
- Angina
- Arrhythmia needing medical treatment (new onset)
- Arterial or venous dissection and/or perforation
- Arterial rupture
- Arterial spasm
- Arteriovenous fistula
- Atelectasis (major lung collapse with significant symptoms such as cyanosis, extreme shortness of breath, dyspnea, and/or stabbing pain on the affected side)
- Extension of cardiopulmonary/extracorporeal bypass
- Fever
- Gastric motility disorders
- Gastro-intestinal bleed
- Hematoma
- Hematuria
- Hemothorax
- Hypertension
- Hypotension
- Iatrogenic atrial flutter
- Iatrogenic lung injury (e.g., chest tube placement)
- Ischemia
- Kinking of coronary artery
- LAA dehiscence
- LAA tears

- Atrial rupture
- Atrio-esophageal fistula
- AV block requiring permanent pacemaker (new onset)
- Bleeding requiring intervention
- Blood vessel damage
- Cardiac perforation
- Cardiac tamponade
- Cerebrovascular accident (CVA)/transient ischemic attack (TIA)/stroke (ischemic or hemorrhagic)
- Chest pain/discomfort
- Compression of coronary artery
- Conduction disturbances
- Congestive heart failure (new onset or exacerbation)
- Coronary artery injury
- Death
- Device breakage/inability to remove
- Device-related death
- Diaphragmatic paralysis (unilateral or bilateral)
- Drug reaction (significant reaction to any procedure related medications requiring treatment, including allergic reaction and anaphylactic shock)
- Emergency during procedure requiring a change in planned access
- Empyema
- Endocarditis (bacterial)
- Esophageal injury
- Esophageal rupture
- Left atrial embolism
- Myocardial infarction (MI)
- Nerve injury (phrenic, laryngeal, thoracic, etc.)
- Pain/discomfort
- Pericardial effusion
- Pericarditis
- Permanent pacemaker
- Persistent chest pain (post discharge surgical incision pain, not angina)
- Phrenic nerve paralysis
- Pleural effusion
- Pneumonia
- Pneumothorax
- Postoperative embolic complications
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Renal insufficiency or failure
- Respiratory distress or failure (breathing problems)
- Sepsis
- Stenosis of left circumflex artery
- Sterility-related infection
- Superficial wound infection
- Surgical site infection
- Systemic adverse reaction due to device corrosion
- Thrombus and/or thromboembolism (including deep vein thrombosis)
- Tissue injury
- Tissue perforation
- Tracheal/esophageal trauma
- Vascular access complications

INSTRUCTIONS FOR USE

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

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

CLIP SELECTION**⚠ WARNING ⚠**

Carefully consider any presurgical treatment the patient may have undergone when selecting Clip size. Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected Clip size. Failure to correctly size the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, lack of desired hemostasis, and/or incomplete exclusion of the structure.

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

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

⚠ WARNINGS ⚠

Do not use on a LAA less than 29 mm (1.14 in) in width and 1 mm (0.04 in) wall thickness. Doing so may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis. Do not use on a LAA greater than 50 mm (1.97 in) when tissue is uncompressed. Doing so may result in incomplete exclusion of the structure.

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

AtriCure

⚠ WARNINGS ⚠

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

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

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

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

ARTICULATION OF END EFFECTOR

⚠ CAUTION: Do not attempt to articulate the End Effector while in the locked position. Force applied while in the locked position may cause damage to the device.

- By pushing down and pulling the Articulation Lock backwards (proximal), the End Effector of the AtriClip LAA Exclusion System may be manually articulated up and down and side-to-side by either the articulation levers or pressing on the end effector. The Clip and End Effector can articulate 30° left or right and 60° up or down to take into account anatomical variations in the patient's anatomy (See Figure 3).
- To lock the End Effector in position, press the Articulation Lock forward.

CLIP POSITIONING

⚠ WARNING ⚠

Position and deploy Clip in a manner that provides direct visualization of all tissues being accessed. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies. Poor visualization may result in suboptimal placement and damage or obstruction of surrounding structures.

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

- With the Clip in the closed position, maneuver the AtriClip LAA Exclusion System into the targeted dissection plane.
- Gently open the Clip by squeezing the Activation Lever (See Figure 4).

NOTE: The Clip automatically locks in the fully open position by means of a Locking Trigger on the handle of the device. The lock can be disengaged by pressing the Lever Release Trigger.

- Gently position the Clip at the base of the LAA (See Figure 5).
- Position the Clip in a manner that provides clear visualization of all tissues being accessed.
- While the Clip is still affixed to the Deployment Device, ensure that no surrounding structures interfere with or are damaged by the Clip, and that the Clip is placed correctly.
- After the Clip is positioned correctly, grasp the Activation Lever and depress the Lever Release Trigger and slowly release the Activation Lever allowing the Clip to close.

DEPLOYMENT

⚠ WARNINGS ⚠

Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Guide Instructions for Use. Failure to correctly size or deploy the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis.

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

- If the Clip is not placed correctly, gently open the Clip and reposition as needed.
- Deploy the Clip by slowly pulling the Deployment Tab at the proximal end of the Handle.

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

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

- Unlock the End Effector and carefully remove it from the LAA, leaving the Clip and attachment suture behind (See Figure 7).

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

DISPOSAL INFORMATION

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

SERIOUS INCIDENT

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

RETURN OF USED PRODUCT

If, for any reason, this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER STATEMENTS

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

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

HANDLING INFORMATION- V CLIP

MRI SAFETY INFORMATION

⚠ 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 extends approximately 20 mm (0.79 in) from the V Clip when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

SYMBOLS GLOSSARY

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

	Single sterile barrier system with protective packaging outside		Single sterile barrier system with protective packaging inside
	Manufacturer		Caution
	Does not contain phthalates		Contains hazardous substances
	Do not use if package is damaged		Non-pyrogenic
	Sterilized using irradiation		Consult Instructions For Use
	Do not re-use		Do not re-sterilize
	Not Made with natural Rubber Latex		Catalogue Number
	Model Number		Unique Device Identifier
	Lot Number		Use by date
	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician		MR Conditional
	Country of Manufacture		Medical Device
	Keep dry		
	Transit Temperature limit		

REFERENCES

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



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AtriCure

AtriClip® Flex-V® LAA Exclusion System

with Preloaded V Clip™

INSTRUCTIONS FOR USE

ACHV35, ACHV40, ACHV45, ACHV50

Rx ONLY MD

FIGURE 1

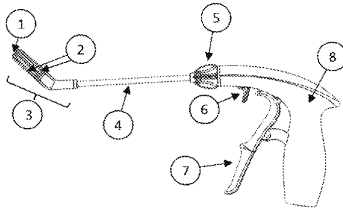


FIGURE 2

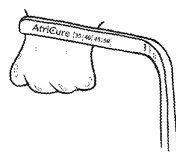


FIGURE 3

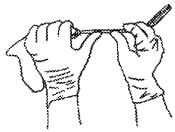


FIGURE 4

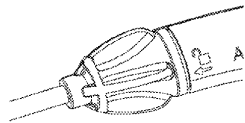


FIGURE 5

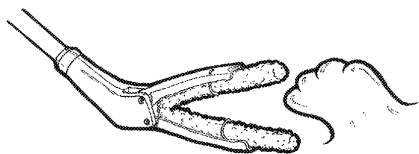


FIGURE 6

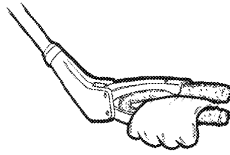


FIGURE 7

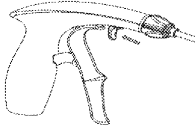
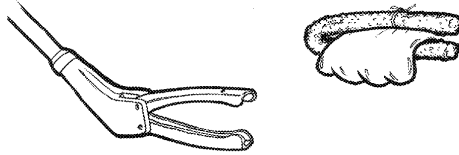


FIGURE 8



INSTRUCTIONS FOR USE

en

AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™

INDICATION FOR USE

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

CONTRAINDICATIONS

1. Do not use this device as a contraceptive tubal occlusion device.
2. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field.

SYSTEM DESCRIPTION

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

The AtriClip Flex-V LAA Exclusion System is a delivery and deployment device preloaded with a V Clip. The V Clip is preloaded on a disposable Clip applicator. 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 used to deliver a preloaded Clip to the target LAA site. 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. The Flex-V LAA Exclusion System with preloaded V Clip is not made with natural rubber latex and does not contain phthalates. Detailed materials information for implanted V Clip sizes 35mm to 50mm are below:

Material	Mass (mg)	CAS #
Titanium Grade 5	2.41 to 3.73	Titanium, 7440-32-6 Aluminum, 7429-90-5 Vanadium, 7440-62-2
Polyethylene Terephthalate	0.25 to 0.31	25038-59-9
Titanium Dioxide	0.001	13463-67-7

ENVIRONMENTAL SPECIFICATIONS

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

PACKAGE CONTENTS

1. One (1) AtriClip Flex-V LAA Exclusion System with Preloaded V Clip
2. One (1) Implant Card and (1) Implant Card Leaflet

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

SYSTEM ACCESSORIES

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

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

ATRICLIP FLEX-V LAA EXCLUSION SYSTEM

NOMENCLATURE (SEE FIGURE 1)

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

The entire length of the Shaft is malleable and intended for adjustments up to 45 degrees in any direction.

⚠ WARNINGS ⚠

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

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.

⚠ WARNING ⚠



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.

COMPLICATIONS

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

- Air embolism
- Allergic reaction to anesthesia, anticoagulant, implant material
- Anaphylactic shock
- Anesthesia risks
- Aneurysm
- Angina
- Extension of cardiopulmonary/extracorporeal bypass
- Fever
- Gastric motility disorders
- Gastro-intestinal bleed
- Hematoma
- Hematuria
- Hemothorax

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

INSTRUCTIONS FOR USE

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

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

CLIP SELECTION

⚠ WARNING ⚠

Carefully consider any presurgical treatment the patient may have undergone when selecting Clip size. Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected Clip size. Failure to correctly size the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, lack of desired hemostasis, and/or incomplete exclusion of the structure.

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

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

AtriCure

⚠ WARNINGS ⚠

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

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

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

⚠ WARNING ⚠

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

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

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

SHAFT BENDING

CAUTION: 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.

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

CAUTION: Do not attempt to rotate the device End Effector without juggling it out of the locked position. Force applied while in the locked position may cause damage to the device.

- By pulling the Shaft Rotation Knob forward (distal) and twisting it to the left or right, the End Effector of the Flex-V LAA Exclusion System may be manually rotated side-to-side. The Clip and End Effector can rotate 90° left or right in 45° increments to account for user preference or variations in the patient's anatomy (See Figure 4).
- To lock the End Effector in position, release forward pressure on the Shaft Rotation Knob and ensure that it is seated into position.

CLIP POSITIONING

⚠ WARNING ⚠

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.

- With the Clip in the closed position, maneuver the AtriClip Flex-V LAA Exclusion System into the targeted dissection plane.
- Gently open the Clip by squeezing the Activation Lever (See Figure 5).

NOTE: Maintain pressure on the Activation Lever in order to hold the Clip open. This device does not contain an automatic locking function.

- Gently position the Clip at the base of the LAA (See Figure 6).
- Position the Clip in a manner that provides clear visualization of all tissues being accessed.
- While the Clip is still affixed to the Deployment Device, ensure that no surrounding structures interfere with or are damaged by the Clip, and that the Clip is placed correctly.
- After the Clip is positioned correctly, slowly release the Activation Lever to allow the Clip to close.
- If the Clip is not placed correctly, gently open the Clip and reposition as needed.

DEPLOYMENT

⚠ WARNING ⚠

Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Guide Instructions for Use. Failure to correctly size or deploy the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement, and/or lack of desired hemostasis.

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

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

NOTE: Only pull the Deployment Trigger when the Clip is properly positioned over the LAA. Pulling the Deployment Trigger permanently releases the Clip from the applicator.

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

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

- Carefully remove the End Effector from the LAA leaving the Clip and attachment suture behind (See Figure 8).

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

DISPOSAL INFORMATION

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

SERIOUS INCIDENT

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

RETURN OF USED PRODUCT

If, for any reason, this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER STATEMENTS

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

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

HANDLING INFORMATION: V CLIP

MRI SAFETY INFORMATION

MR 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 extends approximately 20 mm (0.79 in) from the V Clip when imaged using a gradient echo pulse sequence and a 3 Tesla MR System.

SYMBOLS GLOSSARY

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

	Single sterile barrier system with protective packaging outside		Single sterile barrier system with protective packaging inside
	Manufacturer		Caution
	Does not contain phthalates		Contains hazardous substances
	Do not use if package is damaged		Non-pyrogenic
	Sterilized using irradiation		Consult Instructions For Use
	Do not re-use		Do not re-sterilize
	Not Made with natural Rubber Latex		Catalogue Number
	Model Number		Unique Device Identifier
	Lot Number		Use-by date
	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician		MR Conditional
	Country of Manufacture		Medical Device
	Keep dry		
	Transit Temperature limit		

REFERENCES

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



AtriCure Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
Customer Service:
+1 866 349 2342 (toll free)
+1 513 755 4100 (phone)

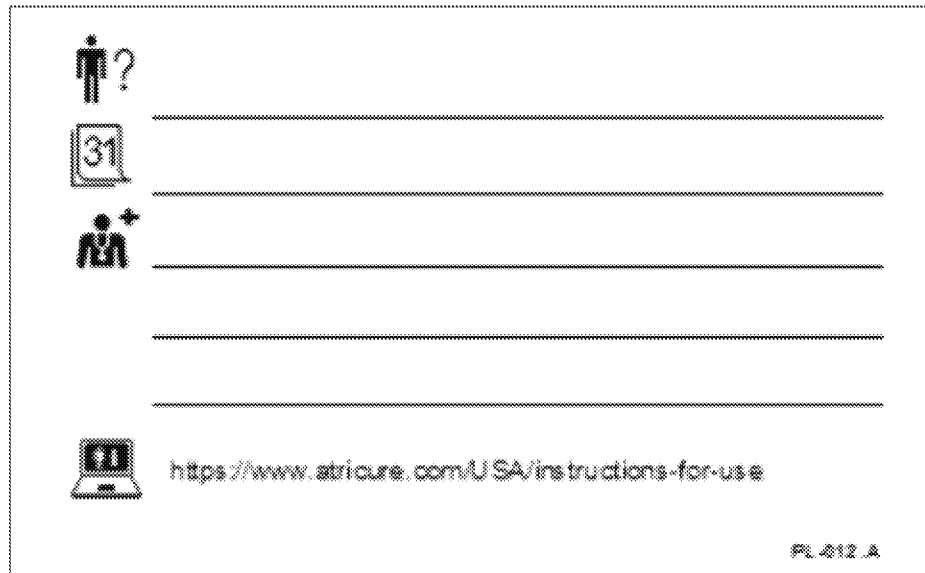
[illegible]

AtriClip LAA Exclusion System Special 510(k)	
Attachment J3 – Other Labeling	
Documents Enclosed	
Description	Section Number
Implant Card	Section I-1
Implant Card Leaflet	Section I-2

Section I-1 – Implant Card

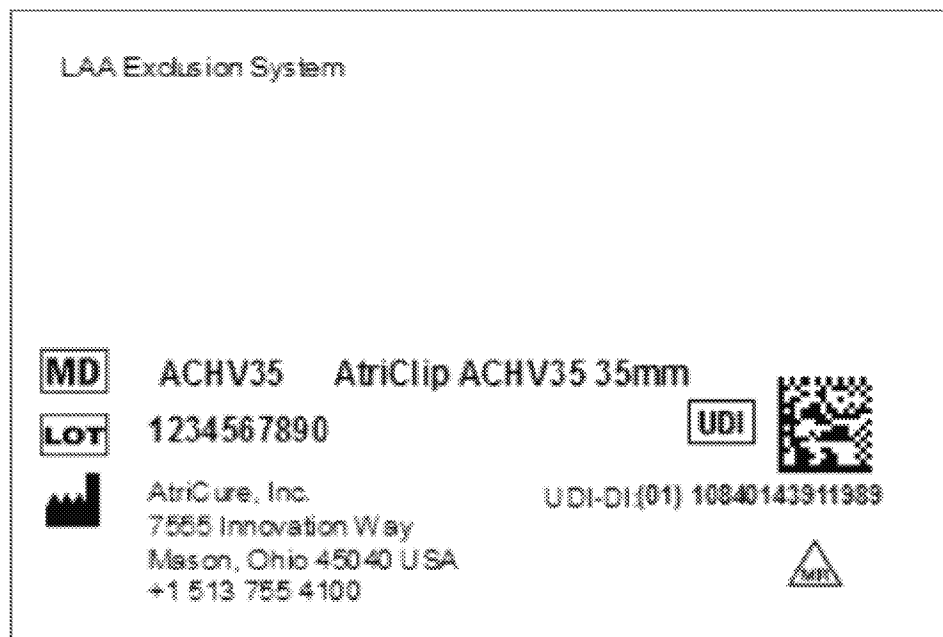
The AtriClip LAA Exclusion System devices (LAA0, ACH1, ACH2, PRO1, PRO2, PROV, ACHV) contain an Implant Card. There are no differences in the implant card content between clip sizes or applicator models. The Implant Card is included in the 1-up sales unit package of each AtriClip device.

Figure 1 – Front of Implant Card



The front of the implant card features a dotted border and several fields for handwritten information. On the left side, there are four icons: a person with a question mark, a box containing the number 31, a person with a plus sign, and a laptop. To the right of these icons are four horizontal lines for writing. Below the laptop icon, the URL <https://www.atricure.com/USA/instructions-for-use> is printed. In the bottom right corner, the text "FL 212_A" is visible.

Figure 2 – Back of Implant Card



The back of the implant card has a dotted border and contains the following information:

- LAA Exclusion System** (at the top)
- MD** (Medical Device icon) **ACHV35** **AtriClip ACHV35 35mm**
- LOT** (Lot icon) **1234567890**
- UDI** (UDI icon) **UDI-DI(01) 10840143911383**
- AtriCure, Inc.**
7555 Innovation Way
Mason, Ohio 45040 USA
+1 513 755 4100
- UDI-DI(01) 10840143911383** (next to a QR code)
- MT** (triangle icon)

Section I-2 – Implant Card Leaflet

The AtriClip LAA Exclusion System devices (LAA0, ACH1, ACH2, PRO1, PRO2, PROV, ACHV) contain an Implant Card Leaflet describing how to use the Implant Card. The Implant Card Leaflet is included in the 1-up sales unit package of each AtriClip device.

IMPLANT CARD LEAFLET

R_x ONLY



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

FIGURE 1

 ? _____
 _____
 _____

 <https://www.etracore.com/USA/instructions-for-use>
 PL-012.R

FIGURE 2

LAA Exclusion System

MD ACHM35 AtriClip ACHM35 35mm

LOT 1234567890

UDI 

 AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
+1 513 755 4109

UDI-DI (51) 10840143911774



PATIENT INFORMATION:

processed under FOIA Request 2024-4617. Released by CDRH on 08/20/2024.

In the event you need to get a replacement card for your implant, you will need to have the UDI and lot information for your device off the rear of the card (**See FIGURE 2**). Contact the manufacturer to request a replacement card.

In the unlikely event of any issues with the implant, the information on the implant card will ensure that your physician can inform you if you are impacted.

Device lifetime is equal to patient lifetime.



MR CONDITIONAL

Non-clinical testing demonstrated that the LAA Exclusion System 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 LAA Exclusion System Clip are expected to produce a maximum temperature rise of 2.9°C (5.22°F) for Gillinow-Cosgrove Clip (LAA, ACH1, ACH2, PRO1, PRO2 devices) and 3.1°C (5.58°F) for V Clip (FLEX-V, PRO-V devices) after 15-minutes of continuous scanning (i.e., per pulse sequence).

DEVICE CONTAINS	
CGG CLIP	VCLIP
Titanium Grade 2	Titanium Grade 5
Polyurethane	Polyethylene Terephthalate
Nitinol	Titanium Dioxide
Polyethylene Terephthalate	
Titanium Dioxide	

SYMBOLS GLOSSARY			
	Medical Device		Unique Device Identifier
	Batch Code		MR Conditional
	Manufacturer		Healthcare center or doctor
	Procedure Date		Patient Identification
		Patient Information Website	
Rx ONLY		Caution: Federal (US) law restricts this device to sale by or on the order of a physician or other licensed practitioner.	

IMPLANT CARD LEAFLET

en

INSTRUCTIONS FOR COMPLETION:

The following information should be completed by the healthcare institution/provider on the front of the implant card. (See **FIGURE 1**).

	Patient Identification
	Procedure Date
	Name and Address of the Implanting Healthcare Institution/Provider

Once the implant card is populated with information above, give both implant card leaflet and implant card to patient.

AtriClip LAA Exclusion System
Special 510(k) Submission

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

AtriCure Confidential

AtriClip LAA Exclusion System Special 510(k)	
Attachment K1 – Sterilization	
Description	Section Number
Sterilization Assessments for Changes Documented Internally	Section I-1
Pyrogenicity Testing	Section I-2

Section I-1 – Sterilization Assessments for Changes Documented Internally

(b)(4)

(b)(4)

Section I-2 – Pyrogenicity Testing

(b)(4)

Attachment S1 EXECUTIVE SUMMARY

AtriClip LAA Exclusion System Devices Special 510(k) Executive Summary

The AtriClip LAA Exclusion System was previously cleared per K210293.

The purpose of this submission is to update the IFUs and labels for the AtriClip LAA Exclusion System. The updates made are to align and comply with ISO 14971:2019 for risk management, ISO 15223-1:2021 for symbology, and ISTA 3A for transit. These updates will align the AtriClip IFUs globally and are not associated with any adverse event reports. Additionally, this submission will include Letters to File that have been documented internally since the previous K210293 clearance. Please refer to **Attachment H1, Section I-5** for additional details regarding the Letters to File.

The following is an overview of the changes made to the IFUs. Please refer to **Attachment H1, Section I-2, Tables 1 – 12** for additional details and rationale for the proposed changes. The proposed IFUs are included in **Attachment J2**.

(b)(4)

(b)(4)

The Intended Use for the AtriClip LAA Exclusion System devices is not changing as the AtriClip devices continue to be indicated for the exclusion of the left atrial appendage. The currently marketed product has the following Indication for Use statement:

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

The Intended Use for the device, design, materials, operating principles, and function of the subject device remain the same as the predicate 510(k), K210293. Based on the technological characteristics comparisons, the proposed labeling for the AtriClip LAA Exclusion System devices have been shown to be appropriate for its indication for use and is considered to be substantially equivalent to the previously cleared predicate, K210293.

510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ATRICURE INC 7555 Innovation Way Mason OH 45040 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0305	2. CONTACT NAME Jim Taufen 2.1 E-MAIL ADDRESS jtaufen@atricure.com 2.2 TELEPHONE NUMBER (include Area code) 612-804-7968 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 513-6444753
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) <u>Select an application type:</u> ☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice ☐ De Novo Request 3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☒ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☒ YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.) ☐ NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) ☐ YES ☒ NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118	

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

15-Sep-2023

Form FDA 3601 (07/22)

"Close Window" Print Cover sheet

510(k) Summary

I. Applicant Information

Manufacturer: AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040

Contact Person: Stephanie Hadnot
Senior Regulatory Affairs Specialist
P: 513-341-0345

Alternate Contact: Jim Taufen
Director, Regulatory Affairs
P: 952-314-1507

Date Prepared: 09/29/2023

II. Device Information

Proprietary Name: AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip
(LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

Common Name: Implantable Clip and Clip Applier

Classification: Implantable Clip and Clip Applier
Regulatory Class: Class II; per 21 CFR 878.4300
Product Code: PZX
Classification Panel: Cardiovascular

Predicate Device: The device proposed for modification in this submission is the AtriClip LAA Exclusion System cleared via K210293 on March 3, 2021.

III. Device Description

The AtriClip LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a Single Use Clip Applier along with a selection guide. When closed, the Clip applies uniform pressure over the length of the Clip to ensure consistent, reproducible, and secure exclusion of the left atrial appendage (LAA). The Clip is then deployed and is left as a permanent implant and excludes the LAA resulting in electrical isolation of the LAA. Preclinical animal studies (Kamohara 2005,2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical

studies. The Clip is available in the following lengths to accommodate difference sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm. The Clip Appliers are disposable devices with a handle, shaft, suture anchors, articulation controls, and deployment loop/jaws which contain the Clip.

Intended Use/ Indications for Use

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

The indications for use are identical to the predicate device.

IV. Comparison of Technological Characteristics with the Predicate Device (AtriClip LAA Exclusion System – K210293)

#	Feature	Predicate (K210293) AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
1	Proprietary Name	AOD1: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AOD2: AtriClip LAA Exclusion System with Preloaded V Clip	AOD1: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AOD2: AtriClip LAA Exclusion System with Preloaded V Clip	Same
2	Clip Applier Product Code(s)	LAA035, LAA040, LAA045, LAA050 ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250 PRO135, PRO140, PRO145, PRO150 PRO235, PRO240, PRO245, PRO250 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50	LAA035, LAA040, LAA045, LAA050 ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250 PRO135, PRO140, PRO145, PRO150 PRO235, PRO240, PRO245, PRO250 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50	Same
3	Selection Guide Product Code	CGG100	CGG100	Same
4	Device Classification	21 CFR 878.4300, product code: PZX	21 CFR 878.4300, product code: PZX	Same
5	Regulatory Class	Class II	Class II	Same
6	FDA Division	Cardiovascular	Cardiovascular	Same
7	Performance Standards	No performance standards applicable to this product have been promulgated by FDA	No performance standards applicable to this product have been promulgated by FDA	Same
8	Intended Use	The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see	The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see	Same

#	Feature	Predicate (K210293) AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
		the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	
9	Contraindications	LAA0, ACH1, ACH2, PRO1, PRO2: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy). PROV, ACHV: 1. Do not use this device as a contraceptive tubal occlusion device.	LAA0, ACH1, ACH2, PRO1, PRO2: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy). 3. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field. PROV, ACHV: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field.	Similar – Contraindication added to emphasize standard surgical practice and possible limited use of devices.
10	Software	This product does not contain software.	This product does not contain software.	Same
11	Shelf Life	3 years	3 years	Same
12	Biocompatibility	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Same
13	Sterilization	Gamma Irradiation	Gamma Irradiation	Same
14	Sterility Assurance Level	10 ⁻⁶ SAL	10 ⁻⁶ SAL	Same
15	Pyrogen	Non-Pyrogenic	Non-Pyrogenic	Same
Clip				
16	Suture Material	Polyethylene Terephthalate	Polyethylene Terephthalate	Same
17	Preloaded Clip	AOD1: Preloaded Gillinov-Cosgrove Clip AOD2: Preloaded V Clip	AOD1: Preloaded Gillinov-Cosgrove Clip AOD2: Preloaded V Clip	Same
18	Clip Opening	AOD1: Opens 12.5mm ± 1.5mm as measured between the beams of the AOD1 clip. AOD2: Opens AOD2 Clip to a minimum of 12mm at the distal end and 4mm at the proximal end of the clip.	AOD1: Opens 12.5mm ± 1.5mm as measured between the beams of the AOD1 clip. AOD2: Opens AOD2 Clip to a minimum of 12mm at the distal end and 4mm at the proximal end of the clip.	Same
19	Biocompatibility	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Same
20	Sterilization	Gamma Irradiation	Gamma Irradiation	Same

- The devices have the same intended use.
- No changes were made in operating principle.
- No changes to the overall design or function of the devices.

Performance Data

A review of the risk analysis concluded there is no overall change to the risk profile of the proposed AtriClip LAA Exclusion System versus the previously cleared AtriClip LAA Exclusion System as the modifications to the proposed AtriClip LAA Exclusion System do not add or remove any features of the device or change the clinical application.

The proposed changes do not include any change to design or performance specifications of the AtriClip LAA Exclusion System. Additionally, the proposed changes did not modify the intended use, therefore the previously submitted bench and animal data remain valid for the AtriClip LAA Exclusion System.

V. Conclusions

AtriCure has demonstrated that the modifications made to the AtriClip LAA Exclusion System are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the previously cleared AtriClip LAA Exclusion System per K210293.

October 19, 2023</br></br>

Review Assignment Notification

<p>I am the lead reviewer assigned to your submission K233407. Your file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 B. The first line supervisor is the Assistant Director of Cardiac Occluders and Hemostasis Devices.</p>

<p>I will contact you should any additional information be required during the course of the review of your submission. You may contact me at any point during the review if you have questions or concerns. FDA aims to apply the least burdensome principles when requesting additional information. </p>

<p>You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.</p>

<p>If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.</p>

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U.S. FOOD & DRUG
ADMINISTRATION

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AtriCure, Inc.
Stephanie Hadnot
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K233407

Trade/Device Name: AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (LAA0);
AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH1);
AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH2);
AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO1);
AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO2);
AtriClip PRO-V LAA Exclusion System (PROV); AtriClip Flex-V LAA
Exclusion System with preloaded V Clip (ACHV)

Regulation Number: 21 CFR 878.4300

Regulation Name: Implantable Clip

Regulatory Class: Class II

Product Code: PZX

Dated: September 29, 2023

Received: October 5, 2023

Dear Stephanie Hadnot:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**LETTER SHOULD BE DATED BEFORE SIGNING,
AND MUST BE SIGNED OUT OF CTS ON THE
DATE INDICATED ON THE LETTER.**

Rachel Neubrander

K233407 - Stephanie Hadnot

Page 3

Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Hi Stephanie,

Thanks for introducing yourself. We have just about wrapped up our review of K233407, but we have some comments regarding the (b)(4). Please see the attached pdf for highlighted points of edit, also summarized below:

(b)(4)

Best,

Victor

Victor A. Mondine

Biomedical Engineer, Cardiac Occluders & Hemostasis Devices Team

DHT2B: Division of Circulatory Support, Structural, & Vascular Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality | CDRH

Tel: 240-402-2693

victor.mondine@fda.hhs.gov<mailto:victor.mondine@fda.hhs.gov>

[cid:image001.png@01DA0D89.E27797A0]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0D89.E27797A0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0D89.E27797A0]<https://twitter.com/US_FDA>

[cid:image004.jpg@01DA0D89.E27797A0]<<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA0D89.E27797A0]<<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01DA0D89.E27797A0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

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From: Stephanie Hadnot <SHadnot@atricure.com>

Sent: Wednesday, November 1, 2023 10:45 AM

To: Mondine, Victor <Victor.Mondine@fda.hhs.gov>

Subject: [EXTERNAL] RE: [External Sender]: K233407 Review Assigned

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Victor,

Please feel free to reach out to me if you have any questions or need anything for the AtriClip LAA Exclusion System Special 510(k), K233407.

Thanks,

Stephanie Hadnot

Senior Regulatory Affairs Specialist | AtriCure

O. 513-644-4239

M. 513-341-0345

E. SHadnot@AtriCure.com<<mailto:SHadnot@AtriCure.com>>

Twitter @AtriCure

From: Victor Mondine [VICTOR.MONDINE]
<victor.mondine@fda.hhs.gov<<mailto:victor.mondine@fda.hhs.gov>>>

Sent: Thursday, October 19, 2023 9:24 AM

To: Stephanie Hadnot <SHadnot@atricure.com<<mailto:SHadnot@atricure.com>>>

Cc: Victor Mondine [VICTOR.MONDINE]
<victor.mondine@fda.hhs.gov<<mailto:victor.mondine@fda.hhs.gov>>>

Subject: [External Sender]: K233407 Review Assigned

You don't often get email from victor.mondine@fda.hhs.gov<<mailto:victor.mondine@fda.hhs.gov>>. Learn why this is important<<https://aka.ms/LearnAboutSenderIdentification>>

October 19, 2023

Review Assignment Notification

I am the lead reviewer assigned to your submission K233407. Your file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 B. The first line supervisor is the Assistant Director of Cardiac Occluders and Hemostasis Devices.

I will contact you should any additional information be required during the course of the review of your submission. You may contact me at any point during the review if you have questions or concerns. FDA aims to apply the least burdensome principles<<https://www.fda.gov/media/73188/download>> when requesting additional information.

You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory<<https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>>.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov<<mailto:OPEQSubmissionSupport@fda.hhs.gov>>.

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November 2, 2023</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Victor Mondine.</p>

<p>*** This is a system-generated email notification ***</p>



U.S. FOOD & DRUG
ADMINISTRATION

November 2, 2023

AtriCure, Inc.
Stephanie Hadnot
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K233407

Trade/Device Name: AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip
(LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

Regulation Number: 21 CFR 878.4300

Regulation Name: Implantable Clip

Regulatory Class: Class II

Product Code: PZX

Dated: September 29, 2023

Received: October 5, 2023

Dear Stephanie Hadnot:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine N. Trivedi
-S 

for Rachel Neubrander
Assistant Director

K233407 - Stephanie Hadnot

Page 3

DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

(b)(4)

Indications for Use

510(k) Number (if known)
K233407

Device Name

AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip (LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

Indications for Use (Describe)

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. Applicant Information

Manufacturer: AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040

Contact Person: Stephanie Hadnot
Senior Regulatory Affairs Specialist
P: 513-341-0345

Alternate Contact: Jim Taufen
Director, Regulatory Affairs
P: 952-314-1507

Date Prepared: 09/29/2023

II. Device Information

Proprietary Name: AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip
(LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

Common Name: Implantable Clip and Clip Applier

Classification: Implantable Clip and Clip Applier
Regulatory Class: Class II; per 21 CFR 878.4300
Product Code: PZX
Classification Panel: Cardiovascular

Predicate Device: The device proposed for modification in this submission is the AtriClip LAA Exclusion System cleared via K210293 on March 3, 2021.

III. Device Description

The AtriClip LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a Single Use Clip Applier along with a selection guide. When closed, the Clip applies uniform pressure over the length of the Clip to ensure consistent, reproducible, and secure exclusion of the left atrial appendage (LAA). The Clip is then deployed and is left as a permanent implant and excludes the LAA resulting in electrical isolation of the LAA. Preclinical animal studies (Kamohara 2005,2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical

studies. The Clip is available in the following lengths to accommodate difference sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm. The Clip Appliers are disposable devices with a handle, shaft, suture anchors, articulation controls, and deployment loop/jaws which contain the Clip.

Intended Use/ Indications for Use

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

The indications for use are identical to the predicate device.

IV. Comparison of Technological Characteristics with the Predicate Device (AtriClip LAA Exclusion System – K210293)

#	Feature	Predicate (K210293) AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
1	Proprietary Name	AOD1: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AOD2: AtriClip LAA Exclusion System with Preloaded V Clip	AOD1: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AOD2: AtriClip LAA Exclusion System with Preloaded V Clip	Same
2	Clip Applier Product Code(s)	LAA035, LAA040, LAA045, LAA050 ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250 PRO135, PRO140, PRO145, PRO150 PRO235, PRO240, PRO245, PRO250 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50	LAA035, LAA040, LAA045, LAA050 ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250 PRO135, PRO140, PRO145, PRO150 PRO235, PRO240, PRO245, PRO250 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50	Same
3	Selection Guide Product Code	CGG100	CGG100	Same
4	Device Classification	21 CFR 878.4300, product code: PZX	21 CFR 878.4300, product code: PZX	Same
5	Regulatory Class	Class II	Class II	Same
6	FDA Division	Cardiovascular	Cardiovascular	Same
7	Performance Standards	No performance standards applicable to this product have been promulgated by FDA	No performance standards applicable to this product have been promulgated by FDA	Same
8	Intended Use	The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see	The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see	Same

#	Feature	Predicate (K210293) AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
		the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	
9	Contraindications	LAA0, ACH1, ACH2, PRO1, PRO2: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy). PROV, ACHV: 1. Do not use this device as a contraceptive tubal occlusion device.	LAA0, ACH1, ACH2, PRO1, PRO2: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy). 3. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field. PROV, ACHV: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field.	Similar – Contraindication added to emphasize standard surgical practice and possible limited use of devices.
10	Software	This product does not contain software.	This product does not contain software.	Same
11	Shelf Life	3 years	3 years	Same
12	Biocompatibility	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Same
13	Sterilization	Gamma Irradiation	Gamma Irradiation	Same
14	Sterility Assurance Level	10 ⁻⁶ SAL	10 ⁻⁶ SAL	Same
15	Pyrogen	Non-Pyrogenic	Non-Pyrogenic	Same
Clip				
16	Suture Material	Polyethylene Terephthalate	Polyethylene Terephthalate	Same
17	Preloaded Clip	AOD1: Preloaded Gillinov-Cosgrove Clip AOD2: Preloaded V Clip	AOD1: Preloaded Gillinov-Cosgrove Clip AOD2: Preloaded V Clip	Same
18	Clip Opening	AOD1: Opens 12.5mm ± 1.5mm as measured between the beams of the AOD1 clip. AOD2: Opens AOD2 Clip to a minimum of 12mm at the distal end and 4mm at the proximal end of the clip.	AOD1: Opens 12.5mm ± 1.5mm as measured between the beams of the AOD1 clip. AOD2: Opens AOD2 Clip to a minimum of 12mm at the distal end and 4mm at the proximal end of the clip.	Same
19	Biocompatibility	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Same
20	Sterilization	Gamma Irradiation	Gamma Irradiation	Same

- The devices have the same intended use.
- No changes were made in operating principle.
- No changes to the overall design or function of the devices.

Performance Data

A review of the risk analysis concluded there is no overall change to the risk profile of the proposed AtriClip LAA Exclusion System versus the previously cleared AtriClip LAA Exclusion System as the modifications to the proposed AtriClip LAA Exclusion System do not add or remove any features of the device or change the clinical application.

The proposed changes do not include any change to design or performance specifications of the AtriClip LAA Exclusion System. Additionally, the proposed changes did not modify the intended use, therefore the previously submitted bench and animal data remain valid for the AtriClip LAA Exclusion System.

V. Conclusions

AtriCure has demonstrated that the modifications made to the AtriClip LAA Exclusion System are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the previously cleared AtriClip LAA Exclusion System per K210293.

Indications for Use

(b)(4)

Hi Stephanie,

Thanks for introducing yourself. We have just about wrapped up our review of K233407, but we have some comments regarding the **(b)(4)** Please see the attached pdf for highlighted points of edit, also summarized below:

(b)(4)

Please provide a final pdf with the edits by the end of the day today or early tomorrow, so we can complete a timely review. If you have any questions or concerns, feel free to reach out.

Best,
Victor

Victor A. Mondine

Biomedical Engineer, Cardiac Occluders & Hemostasis Devices Team

DHT2B: Division of Circulatory Support, Structural, & Vascular Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality | CDRH

Tel: 240-402-2693

victor.mondine@fda.hhs.gov



x > x x v

Excellent customer service is important to us. Please take a moment to provide feedback [here](#) regarding the customer service you have received.

From: Stephanie Hadnot <SHadnot@atricure.com>
Sent: Wednesday, November 1, 2023 10:45 AM
To: Mondine, Victor <Victor.Mondine@fda.hhs.gov>
Subject: [EXTERNAL] RE: [External Sender]: K233407 Review Assigned

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Victor,

Please feel free to reach out to me if you have any questions or need anything for the AtriClip LAA Exclusion System Special 510(k), K233407.

Thanks,

Stephanie Hadnot

Senior Regulatory Affairs Specialist | AtriCure

O. 513-644-4239

M. 513-341-0345

E. SHadnot@AtriCure.com

Twitter @AtriCure

From: Victor Mondine [VICTOR.MONDINE] <victor.mondine@fda.hhs.gov>
Sent: Thursday, October 19, 2023 9:24 AM
To: Stephanie Hadnot <SHadnot@atricure.com>
Cc: Victor Mondine [VICTOR.MONDINE] <victor.mondine@fda.hhs.gov>
Subject: [External Sender]: K233407 Review Assigned

You don't often get email from victor.mondine@fda.hhs.gov. [Learn why this is important](#)

tober 19, 2023

Review Assignment Notification

I am the lead reviewer assigned to your submission K233407. Your file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 B. The first line supervisor is the Assistant Director of Cardiac Occluders and Hemostasis Devices.

I will contact you should any additional information be required during the course of the review of your submission. You may contact me at any point during the review if you have questions or concerns. FDA aims to apply the least burdensome principles when requesting additional information.

You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the [CDRH Management Directory](#).

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

*** This is a system-generated email notification ***



510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hi Victor,

Thank you for your feedback and review of K233407. I have (b)(4) per your requests below. Please let me know if any further updates are required!

(b)(4)

Thanks,

Stephanie Hadnot
Senior Regulatory Affairs Specialist | AtriCure

O. 513-644-4239
M. 513-341-0345
E. SHadnot@AtriCure.com
Twitter [@AtriCure](https://twitter.com/AtriCure)

From: Mondine, Victor <Victor.Mondine@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sent: Thursday, November 2, 2023 12:45 PM
To: Stephanie Hadnot <SHadnot@atricure.com>
Cc: k233407@docs.fda.gov
Subject: K233407 510(k) Summary Edits - Response Requested ASAP
Importance: High

You don't often get email from victor.mondine@fda.hhs.gov. Learn why this is important

Stephanie,

Thanks for introducing yourself. We have just about wrapped up our review of K233407, but we have some comments regarding the (b)(4) Please see the attached pdf for highlighted points of edit, also summarized below:

(b)(4)

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Best,
Victor

Victor A. Mondine
Biomedical Engineer, Cardiac Occluders & Hemostasis Devices Team

DHT2B: Division of Circulatory Support, Structural, & Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality | CDRH

Tel: 240-402-2693
victor.mondine@fda.hhs.gov



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From: Stephanie Hadnot <SHadnot@atricure.com>
Sent: Wednesday, November 1, 2023 10:45 AM
To: Mondine, Victor <Victor.Mondine@fda.hhs.gov>
Subject: [EXTERNAL] RE: [External Sender]: K233407 Review Assigned

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Victor,

Please feel free to reach out to me if you have any questions or need anything for the AtriClip LAA Exclusion System Special 510(k), K233407.

Thanks,

Stephanie Hadnot
Senior Regulatory Affairs Specialist | AtriCure

O: 513-644-4239
M: 513-341-0345
E: SHadnot@AtriCure.com
Twitter: [@AtriCure](#)

From: Victor Mondine [VICTOR.MONDINE] <victor.mondine@fda.hhs.gov>
Sent: Thursday, October 19, 2023 9:24 AM
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Cc: Victor Mondine [VICTOR.MONDINE] <victor.mondine@fda.hhs.gov>
Subject: [External Sender]: K233407 Review Assigned

You don't often get email from victor.mondine@fda.hhs.gov. Learn why this is important

October 19, 2023

Review Assignment Notification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

I am the lead reviewer assigned to your submission K233407. Your file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 B. The first line supervisor is the Assistant Director of Cardiac Occluders and Hemostasis Devices.

I will contact you should any additional information be required during the course of the review of your submission. You may contact me at any point during the review if you have questions or concerns. FDA aims to apply the least burdensome principles when requesting additional information.

You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

*** This is a system-generated email notification ***



K233407

AtriCure

FDA/CDRH/DCC

September 29, 2023

OCT 05 2023

RECEIVED

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Division of Health Technology 2 B Circulatory Support, Structural and Vascular devices

RE: Special 510(k) for AtriClip LAA Exclusion System

AtriCure, Inc. is submitting a Special 510(k) for the AtriClip LAA Exclusion System. This Special 510(k) is based on the predicate AtriClip® LAA Exclusion System most recently cleared via K210293.

AtriCure is requesting clearance, via a Special 510(k) for updates to the AtriClip Instructions For Use and labels based on the following:

1. Intended use remains the same; The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures.
2. No changes were made to operating principle, and
3. No performance data was necessary to support the changes to the labels and Instructions For Use.

The information has been provided as one (1) electronic copy via Non-In Vitro Diagnostic eSTAR Template Version 4.

This submission contains trade secret and commercial or financial information that is exempt from disclosure under exemption 4 of the Freedom of Information Act (21 CFR 20.61), section 301(j) of the Federal Food, Drug, and Cosmetic Act, and 18 U.S. 1905.

Please do not hesitate to contact me via phone (513-341-0345) or email (shadnot@atricure.com) for any questions or points of clarification throughout the review of this Special 510(k) submission. If I am unavailable, please contact Jim Taufen, Director, Regulatory Affairs, at 952-314-1507 or jtaufen@atricure.com.

Thank you, and we look forward to your feedback.

(b)(6)

Stephanie Hadnot
Senior Regulatory Affairs Specialist
AtriCure, Inc.
P: 513-341-0345
E: shadnot@atricure.com

7555 Innovation Way
Mason, Ohio 45040
www.atricure.com



U.S. FOOD & DRUG
ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIB
WO66 RM2554
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-2693

Premarket Notification 510(k) Review

Date: November 1, 2023

Reviewer: Victor Mondine

510(k)# K233407 **Subject:** Special

Applicant: AtriCure, Inc.

Device Trade Name: AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (LAA0); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH1); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH2); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO1); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO2); AtriClip PRO-V LAA Exclusion System (PROV); AtriClip Flex-V LAA Exclusion System with preloaded V Clip (ACHV)

Contact Name: Stephanie Hadnot

Contact Title: Senior Regulatory Affairs Specialist

Correspondent Firm: AtriCure, Inc.

Phone: (513) 341-0345 **Email:** shadnot@atricure.com

Received Date: October 5, 2023

Due Date: November 4, 2023

Pro Code(s): PZX **Class:** II **Reg #:** 878.4300

Reg Name: Implantable Clip

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K210293	PZX	AtriClip LAA Exclusion System	AtriCure, Inc.

(b)(5)

Review Team

Lead Reviewer

Victor Mondine (CDRH/OPEQ/OHTII/DHTIIB)

(b)(5)

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.16.03)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

For each of the specific issues identified in the recommended requests to the applicant above, I and/or if applicable contributing consulting reviewer(s) (and or supervisors), have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability for requests: add all relevant numbers here, else delete that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s).

I also confirm, if applicable, that contributing consulting reviewers (and or supervisors) have provided the above attestation.

Reviewer Sign-Off

Victor Mondine-S 2023.11.01 23:07:36
-04'00'



U.S. FOOD & DRUG
ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIB
WO66 RM2554
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-2693

Premarket Notification 510(k) Review

Date: November 1, 2023

Reviewer: Victor Mondine

510(k)# K233407 **Subject:** Special

Applicant: AtriCure, Inc.

Device Trade Name: AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (LAA0); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH1); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH2); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO1); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO2); AtriClip PRO-V LAA Exclusion System (PROV); AtriClip Flex-V LAA Exclusion System with preloaded V Clip (ACHV)

Contact Name: Stephanie Hadnot

Contact Title: Senior Regulatory Affairs Specialist

Correspondent Firm: AtriCure, Inc.

Phone: (513) 341-0345 **Email:** shadnot@atricure.com

Received Date: October 5, 2023

Due Date: November 4, 2023

Pro Code(s): PZX **Class:** II **Reg #:** 878.4300

Reg Name: Implantable Clip

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K210293	PZX	AtriClip LAA Exclusion System	AtriCure, Inc.

(b)(5)

Review Team

Lead Reviewer

Victor Mondine (CDRH/OPEQ/OHTII/DHTIIB)

(b)(5)

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(b)(5)

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 10/5/2023 6:37:10 PM
To: shadnot@atricure.com; jtaufen@atricure.com
CC: DCCLetters@fda.hhs.gov
Subject: K233407 Acknowledgement Letter
Attachments: K233407-Acknowledgement Letter.pdf

October 5, 2023

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

The CDRH Portal is now available:

Instead of shipping your submissions to us, you can now upload them at our [CDRH Portal](#).

*** This is a system-generated email notification ***



**U.S. FOOD & DRUG
ADMINISTRATION**

Acknowledgement Letter

10/05/2023

Stephanie Hadnot, Senior Regulatory Affairs Specialist
AtriCure, Inc.
7555 Innovation Way
Mason, OH 45040
UNITED STATES

Dear Stephanie Hadnot:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K233407

Received: 10/05/2023

Applicant: AtriCure, Inc.

Device: AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (LAA0); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH1); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (ACH2); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO1); AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip (PRO2); AtriClip PRO-V LAA Exclusion System (PROV); AtriClip Flex-V LAA Exclusion System with preloaded V Clip (ACHV)

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health



electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices

Version 4.0 (2023-06-12)

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

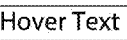
Key

A Red Bar indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

 Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

 Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?

A: For technical issues or bug reports please email eSubPilot@fda.hhs.gov.

For regulatory process or content questions please email:

USFDA: DICE@fda.hhs.gov

Health Canada: meddevices-instrumentsmed@hc-sc.gc.ca

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?

A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type, attachment name, or size restriction?

A: Unacceptable attachment types and names are automatically prevented. If an attachment is great than 1 GB,

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g. 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g. 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

4.0 (2023-06-12): Software section updated according to FDA Software Guidance document. Fixed bug in EMC questions. Contact FDA/CDRH/OCE/DMA at CDRH-FOI@FDA.HHS.gov or 301-796-6118

Application/Submission Type

Application Jurisdiction

☒ US FDA☐ Health Canada ?

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose

☒ Premarket Notification 510(k)☐ De Novo☐ Premarket Application PMA ?

Show Application Introduction

Application Type

(Choose Abbreviated if you are submitting a Safety & Performance based submission.)

☐ Traditional☐ Abbreviated☒ Special

Show Application Type Introduction

Since you indicated this is a Special 510(k), only those sections that were affected by the modifications in comparison to your predicate device need to be submitted. Ensure the sections that were affected by the modifications in comparison to your original 510(k) are checked, and uncheck those that were not affected. The Device Description section, as well as other sections not listed here, will always be present. If the changes are not appropriate for a Special 510(k), or you uncheck a section that was affected by a modification, the review time-line of your submission WILL be negatively impacted.

☐ Reprocessing☒ Sterility☐ Shelf-Life☒ Biocompatibility☐ Software☐ Cybersecurity☐ EMC☐ Wireless Technology

Application Sub-Type

(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)

☒ New Application/Submission☐ Additional Information ?

Cover Letter / Letters of Reference

Add Attachment

Attach your Cover Letter

?

Open Attachment

Attachment B1 - Cover Letter.pdf

Delete Attachment

Add Attachment

Attach any Letters of Reference

?

Applicant Information

?

Contact

Title Mrs.

Last Name Hadnot

First Name Stephanie

Email shadnot@atricure.com

Phone Number 513-341-0345

Occupation Title Senior Regulatory Affairs Specialist

Company

Company Name AtriCure, Inc.

Address - Line 1 7555 Innovation Way

Address - Line 2

City Mason

State OH

Zip 45040

Country/Region United States

Add Correspondent/Consultant

Primary Correspondent/Consultant Information

Contact

Title Mrs.

Last Name Hadnot

First Name Stephanie

Email shadnot@atricure.com

Phone Number 513-341-0345

Occupation Title Senior Regulatory Affairs Specialist

Company

Company Name AtriCure, Inc.

Address - Line 1 7555 Innovation Way

Address - Line 2

City Mason

State OH

Zip 45040

Country/Region United States

Add Correspondent/Consultant

Delete Correspondent/Consultant

Correspondent/Consultant Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

Contact

Title	Mr.	Last Name	Jim	First Name	Taufen
Email	jtaufen@atricure.com			Phone Number	952-314-1507
Occupation Title	Director, Regulatory Affairs				

Company

Company Name	AtriCure, Inc.				
Address - Line 1	7555 Innovation Way				
Address - Line 2					
City	Mason	State	OH	Zip	45040
Country/Region	United States				

Add Correspondent/Consultant

Delete Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)? ?

Standards ?

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. A recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators request standards information be attached, see help text.

ISO	14971 Third Edition 2019-12	5-125	Delete Standard
Medical devices - Application of risk management to medical devices			

Are you using this standard for general use, or are you declaring conformity to it?

 ?

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2 ?

Add Standard

ISO	15223-1 Fourth edition 2021-07	5-134	Delete Standard
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements			

Are you using this standard for general use, or are you declaring conformity to it?

 ?

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2 ?

Add Standard

ISO	10993-1 Fifth edition 2018-08	2-258	Delete Standard
-----	-------------------------------	-------	-----------------

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

Add Standard

ISO

10993-2 Second edition 2006-07-15

2-222

Delete Standard

Biological Evaluation of medical devices - Part 2: Animal welfare requirements

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

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Add Standard

ISO

10993-3 Third edition 2014-10-1

2-228

Delete Standard

Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

Add Standard

ISO

10993-5 Third edition 2009-06-01

2-245

Delete Standard

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

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Add Standard

ISO

10993-6 Third edition 2016-12-01

2-247

Delete Standard

Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

Add Standard

ISO

10993-10 Third Edition 2010-08-01

2-174

Delete Standard

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

Add Standard

ISO

10993-11 Third edition 2017-09

2-255

Delete Standard

Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

Add Standard

ISO

10993-12 Fifth edition 2021-01

2-289

Delete Standard

Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

Add Standard

ISO

10993-23 First edition 2021-01

2-291

Delete Standard

Biological evaluation of medical devices - Part 23: Tests for irritation

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

Add Standard

ISO

10993-17 First edition 2002-12-01

2-237

Delete Standard

Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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Add Attachment

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

Add Standard

ISO

10993-18 Second edition 2020-01

2-276

Delete Standard

Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a r

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTAT@fda.hhs.gov or 301-796-8118

[Add Attachment](#)

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

[Add Standard](#)

ISO

11137-1 First edition 2006-04-15

14-528

[Delete Standard](#)

Sterilization of health care products - Radiation - Part 1: Requirements for development validation and routine con

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

[Add Standard](#)

ISO

11137-2 Third edition 2013-06-01

14-409

[Delete Standard](#)

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

Are you using this standard for general use, or are you declaring conformity to it?

General Use

?

[Add Attachment](#)

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

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[Add Standard](#)

ISO

11737-1 Third edition 2018-01

14-514

[Delete Standard](#)

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorg

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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[Add Attachment](#)

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

?

[Add Standard](#)

ISO

11607-1 Second edition 2019-02

14-530

[Delete Standard](#)

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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[Add Attachment](#)

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

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[Add Standard](#)

ISO

11607-2 Second edition 2019-02

14-531

[Delete Standard](#)

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assem

Are you using this standard for general use, or are you declaring conformity to it?

General Use

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[Add Attachment](#)

Standards Details / Supplemental Documentation per ISO/IEC 17050-2

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[Questions? Contact FDA/CDRH/OCE/Dockets at \[DATUS@fda.hhs.gov\]\(mailto:DATUS@fda.hhs.gov\) or 301-796-8118](#)

ISTA	3A 2018	Records processed under FOIA Request 2024-4617; Released by CDRH on 5/12/2024	Delete Standard
Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less			
Are you using this standard for general use, or are you declaring conformity to it?		General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2		?
Add Standard			

Device Description

Listing of Device(s)

Add Device

Provide the Product Trade Name and (optionally) Model Number/Name

AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip

LAA0

Delete Device

AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip

ACH1

Delete Device

AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip

ACH2

Delete Device

AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip

PRO1

Delete Device

AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip

PRO2

Delete Device

AtriClip PRO-V LAA Exclusion System

PROV

Delete Device

AtriClip Flex-V LAA Exclusion System with preloaded V Clip

ACHV

Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?

No

Are there any direct or indirect tissue contacting components?

Yes

• Is the device or a component an implant?

Yes

Does the device use software/firmware?

No

Is the device or a component packaged as sterile?

Yes

The device/system uses or is... (choose all that apply)

- ☒ a single use device(s), non-sterile or packaged as sterile
☐ a single use device(s), terminal/end user sterilized
☐ a reusable single patient use device(s)
☐ a reusable multi-patient use device(s)

The environment of use of the device/system includes... (choose all that apply)

- ☒ Professional Healthcare Facility
☐ Home Environment
☐ Magnetic Resonance (MR) Environment
☐ Transport (Ambulatory) Environment
☐ Other Environment

Is the device a combination product or does a Request For Designation (RFD) / pre-RFD exist for the product?

No (most common)

Is the device electrical (battery or wall powered)?

No, the device is not electrical

Please check the attributes that are applicable to your device. If none apply, keep all unchecked.

- ☐ Medical Counter Measures Device
☐ Nanotechnology
☐ Reprocessed Single Use Device
☐ Animal-Derived Material(s)
☐ Predetermined Change Control Plan

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The AtriClip LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a Single Use Clip Applier along with a selection guide. When closed, the Clip applies uniform pressure over the length of the Clip to ensure consistent, reproducible, and secure exclusion of the left atrial appendage (LAA). Preclinical animal studies (Kamohara 2005,2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical studies.

The Clip is available in the following lengths to accommodate difference sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm. The Clip Appliers are disposable devices with a handle, shaft, suture anchors, articulation controls, and deployment loop/jaws which contain the Clip.

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	Attachment D1 - Comprehensive Device Description.pdf	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	Attachment D2 - Device Pictures.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	Attachment D3 - Device Packaging.pdf	Delete Attachment

System/Kit Components and Accessories

Is the device intended to be marketed with multiple system/kit components or accessories?

Yes

?

Under section 513(f)(6), are you requesting risk-based classification of an accessory that is not explicitly identified in a classification regulation, or has not been included in a cleared 510(k), approved PMA, or granted De Novo request?

No

?

Add Attachment	If the device is intended to be marketed as a kit, for the purposes of this premarket notification [510(k)], please attach your signed kit certification statement and please identify all the kit components included in your kit certification. For more information, including the text of the kit certification statement, see FDA's guidances, "Kit Certifications for 510(k)s" and "Convenience Kits Interim Regulatory Guidance." If you cannot make the kit certification statement for each component of your kit, you must provide a list of these excluded components in the requested attachment below.	
Add Attachment	Please attach a list of all the system/kit components and accessories that are part of this submission. Please also include the submission number if the system/kit component or accessory received marketing authorization. For 510(k)s, only include kit components here that are not part of the kit certification statement if this certification was provided (see help text). If you only have kit components that are part of the kit certification statement, please provide an attachment here that states this.	?
Open Attachment	Attachment D4 - Accessories List.pdf	Delete Attachment
Add Attachment	Please attach System/Kit Component and/or Accessory Pictures, Illustrations, Schematics, and/or Diagrams	
Open Attachment	Attachment D5 - Accessory Pictures.pdf	Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

N/A

Indications for Use

(b)(4)

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450).

Medical Specialty

Regulation

Product Code

Associated Product Code(s)

Record released under FOIA Request #2025-0457 Released by CDRH on 10-01-2025

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?

No

Predicate Submission Number (e.g., K210001)

K210293

Predicate Device Trade Name

AtriClip LAA Exclusion System

Predicate Device Primary Product Code

Medical Specialty General & Plastic Surgery

Regulation 878.4300 - Implantable clip

Product Code PZX (Class 2) - Left Atrial Appendage Clip, Implantable

Add Predicate/Reference Device

Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

**ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW.
CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).**

Indications for use are the same.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

**ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW.
CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

There are no design changes between the proposed AtriClip LAA Exclusion System and the previously cleared AtriClip LAA Exclusion System. The devices have the same intended use, no changes were made to the operating principle, and no changes were made to the overall design or function of the devices. Please see Attachment H1, Section I-3 for a substantial equivalence comparison.

Add Attachment

Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s).
If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.

Open Attachment

Attachment H1 - Substantial Equivalence Comparison.pdf

Delete Attachment

Benefits, Risks, and Mitigation Measures

Design Control Activities

Please attach a concise summary of the design control activities. This summary should include the following:

- Identification of the risk analysis method(s) used to assess the impact of the change on the device and the results of the analysis;
- Identification of the device change(s);
- Identification of all risks associated with each device change, including identification of risks that are considered new because of the change; and
- Risk control measures to mitigate identified risks (e.g., labeling, verification).

Please attach a signed statement by the manufacturer's designated individual(s) responsible for design control activities that includes:

- A statement that, as required by the risk analysis, all design verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and
- A statement that the submitter has complied and is not currently in violation of the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review, upon request.

For more information, please refer to the Special 510(k) Program Guidance Document.

Add Attachment	Please attach a concise summary of the design control activities.	
Open Attachment	Attachment I1 - Design Control Activities.pdf	Delete Attachment
Add Attachment	Please attach a signed statement that, as required by the risk analysis, all design verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.	
Open Attachment	Attachment I2 - Verification and Validation Statement - Signed.pdf	Delete Attachment
Add Attachment	Please attach a signed statement that the submitter has complied and is not currently in violation of the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review, upon request.	
Open Attachment	Attachment I3 - Compliance Letter - Signed.pdf	Delete Attachment

Verification and/or Validation

Based on the risk analysis, please include an identification of the verification and/or validation activities required to comply with 21 CFR 820.30 in an attachment below. This attachment should include a summary of test methods, acceptance criteria, and results, and why each is adequate to establish SE. If unchanged from a previous premarket submission, the applicant can reference the location of protocols and acceptance criteria by providing a submission and section numbers. When the results are quantitative in nature, the submission should include basic descriptive statistics, such as the mean, standard deviation, and range of the data. Protocol deviations observed during testing should be provided and justified, if applicable.

For more information regarding the content for standardized and non-standardized test methods, please refer to the Special 510(k) Program Guidance Document.

Add Attachment	Please attach your Verification and Validation. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118	
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Open Attachment

Attachment 14 - Verification and Validation Summary Table.pdf
Records processed under FOIA Request 2024-0101, Released by CDRH on 09/10/2024

Delete Attachment

Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).

Attachment J2 – Pages 3, 5, 7, 9, 11, 13

What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?

MR Conditional

If the device(s) contains a static/permanent magnet, please specifically cite the attachment and page number where labeling includes a statement and/or contraindication regarding the risk of magnet use within 6 inches of other magnetically susceptible medical devices. Type "N/A" if not applicable.

N/A

Package Labeling

Add Attachment

Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.

Open Attachment

Attachment J1 - Package Labeling.pdf

Delete Attachment

Package Insert / Instructions for Use

Add Attachment

Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.

Open Attachment

Attachment J2 - Package Instructions for Use.pdf

Delete Attachment

Other Labeling

Add Attachment

Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

Other Labeling and Promotional Material

Open Attachment

Attachment J3 - Other Labeling.pdf

Delete Attachment

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.

Attachment J2 – Pages 2-13
Attachment J1 – Pages 3, 5, 7, 9,

Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.

Attachment J2 – Pages 2, 4, 6, 8, 10, 12

Questions? Contact FDA/CDRH/OC/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.

Attachment J2 – Pages 3, 5, 7, 9, 11, 13
Attachment J1 – Pages 3, 5, 7, 9,

Are all of the changes in the proposed labeling resulting from device modification(s) highlighted or prominently identified?

Yes

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Labeling. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

N/A

Reprocessing, Sterility, and Shelf-Life

Based on the answers provided in the Device Description section, sterility information, but no reprocessing information, is needed. Based on the answer provided in the Application/Submission Type section, no shelf-life information is needed.

Sterility

(b)(4)

What is the Sterility Assurance Level (SAL)?

10⁻⁶

If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?

(b)(4)

For devices labeled "Non-Pyrogenic", be sure to provide the documentation described in the Sterilization Guidance document in Part V(A)(4). This documentation can be attached in the "Reprocessing, Sterilization and Shelf-Life Documentation" section.

Please provide a description of the packaging, the materials used, and a description of the package test methods.

(b)(4)

Sterilization Method 2

Identify the device(s) / accessory(ies) / component(s) that is sterilized.

AtriClip LAA Exclusion System (PRO1, PRO2, PROV, ACHV)

What is the Sterilization Method?

Radiation (Est A)

?

(b)(4)

If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?

(b)(4)

For devices labeled "Non-Pyrogenic", be sure to provide the documentation described in the Sterilization Guidance document in Part V(A)(4). This documentation can be attached in the "Reprocessing, Sterilization and Shelf-Life Documentation" section.

Please provide a description of the packaging, the materials used, and a description of the package test methods.

(b)(4)

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Reprocessing or Sterility. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment

Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.

?

Other

Open Attachment

Attachment K1 - Sterilization.pdf

Delete Attachment

Biocompatibility

?

Based on the answer provided in the Device Description section, biocompatibility information is needed.

(b)(4)

(b)(4)

Cytotoxicity	Sensitization	Irritation	Acute Systemic & Pyrogenicity	Subacute/Subchronic
Genotoxicity	Implantation	Chronic	Carcinogenicity	
Cytotoxicity Testing				

(b)(4)

(b)(4)

Close Tab

Sensitization Testing

(b)(4)

(b)(4)

(b)(4)

Close Tab

Irritation Testing

(b)(4)

(b)(4)

Acute Systemic Toxicity Testing & Material Mediated Pyrogenicity Testing

Acute Systemic Toxicity Testing

(b)(4)

Close Tab

Subacute/Subchronic Toxicity Testing

(b)(4)

(b)(4)

Genotoxicity Testing

Was Genotoxicity Toxicity testing conducted?

Yes

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Genotoxicity Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-3 and ISO/TR 10993-33. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

Genotoxicity testing were conducted per the standard. A summary of the testing is provided in Attachment L1 (Biocompatibility), Section I-4.

Close Tab

Implantation Testing

Was Implantation Toxicity testing conducted?

Yes

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Implantation Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-6. You may also like to consult ASTM F981-04, F1408-97, F1983-99, and F763-05 for more information, as well as the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

Implantation testing were conducted per the standard. A summary of the testing is provided in Attachment L1 (Biocompatibility), Section I-4.

Close Tab

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-6118

(b)(4)

Carcinogenicity Assessment

(b)(4)

(b)(4)

(b)(4)

Cytotoxicity

Sensitization

Irritation

Acute Systemic & Pyrogenicity

Cytotoxicity Testing

(b)(4)

Results

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Close Tab

Sensitization Testing

(b)(4)

(b)(4)

(b)(4)

Close Tab

Irritation Testing

(b)(4)

(b)(4)

Close Tab

Acute Systemic Toxicity Testing & Material Mediated Pyrogenicity Testing

Acute Systemic Toxicity Testing

(b)(4)

Specific questions for these tests do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Acute Systemic Toxicity and and Material Mediated Pyrogenicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11 for Acute Systemic Toxicity and per ISO 10993-11 and USP <151> for Material Mediated Pyrogenicity. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

Acute systemic toxicity testing and material mediated pyrogenicity testing were conducted per the standard. A summary of the testing is provided in Attachment L1 (Biocompatibility), Section I-5.

Close Tab

(b)(4)

(b)(4)

Cytotoxicity

Sensitization

Irritation

Acute Systemic & Pyrogenicity

Cytotoxicity Testing

(b)(4)

Results

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Close Tab

Sensitization Testing

(b)(4)

(b)(4)

(b)(4)

Close Tab

Irritation Testing

(b)(4)

(b)(4)

Close Tab

Acute Systemic Toxicity Testing & Material Mediated Pyrogenicity Testing

Acute Systemic Toxicity Testing

Was Acute Systemic Toxicity testing conducted? Yes ?

Material Mediated Pyrogenicity Testing

Was Material Mediated Pyrogenicity testing conducted? Yes ?

Specific questions for these tests do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Acute Systemic Toxicity and and Material Mediated Pyrogenicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11 for Acute Systemic Toxicity and per ISO 10993-11 and USP <151> for Material Mediated Pyrogenicity. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

Acute systemic toxicity testing and material mediated pyrogenicity testing were conducted per the standard. A summary of the testing is provided in Attachment L1 (Biocompatibility), Section I-5.

Close Tab

Biocompatibility Reports and Documentation

Add Attachment

Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.

Open Attachment

Attachment L1 - Biocompatibility.pdf

Delete Attachment

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, no software, cybersecurity, or interoperability information is needed.

EMC, Wireless, Electrical, Mechanical, and Thermal Safety

Records processed under FOIA Request # 2025-0615, Released by CDRH on 10/11/2025

Based on the answers provided in the Device Description section, no EMC or wireless technology information is needed. You should still address Mechanical and Thermal safety testing in the textbox below.

Electrical, Mechanical, and Thermal Safety Summary

Please summarize the Electrical, Mechanical and Thermal Safety Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).

The AtriClip LAA Exclusion System is not an electrical device, therefore electrical, mechanical, and thermal safety testing was not required.

EMC, Wireless, & EMT Documentation

Add Attachment

Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.

References

Is literature referenced in the submission?

No

?

Administrative Documentation

Add Attachment

General Summary of Submission/Executive Summary

Open Attachment

Attachment S1 - Executive Summary.pdf

Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(l)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.

Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.

Add Attachment

510(k) Summary or Statement

Open Attachment

Attachment S2 - 510(k) Summary.pdf

Delete Attachment

Add Attachment

Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.

Open Attachment

Attachment S3 - FDA User Fee Form.pdf

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Please enter in the User Fee Payment Identification Number.

Show User Fee Introduction

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(l)]

I certify that, in my capacity as **Senior Regulatory Affairs Specialist** of AtriCure, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Date Signed: 2023-10-05

510(k)#: (b)(4) For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Verification

The following sections are complete:

- Application/Submission Type
- Cover Letter / Letters of Reference
- Administrative Information
- Device Description
- Indications for Use
- Classification
- Predicates and Substantial Equivalence
- Benefits, Risks, and Mitigation Measures
- Labeling
- Reprocessing, Sterility, and Shelf-Life
- Biocompatibility
- Software/Firmware & Cybersecurity/Interoperability
- EMC, Wireless, Electrical, Mechanical, and Thermal Safety
- References
- Administrative Documentation

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.
Admin Functions	FOR ADMINISTRATOR USE ONLY

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

Please submit this eSTAR PDF for review using the CDRH Portal unless your medical device is regulated by the Center for Biologics Evaluation and Research (CBER) or is a combination product where CBER is the lead. You do not need to send any documentation in physical form using mail couriers.

For CBER-regulated medical devices or for combination products where CBER is the lead, please refer to Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products for information on how to submit to CBER through the Electronic Submission Gateway.



U.S. FOOD & DRUG
ADMINISTRATION

November 2, 2023

AtriCure, Inc.
Stephanie Hadnot
Senior Regulatory Affairs Specialist
7555 Innovation Way
Mason, Ohio 45040

Re: K233407

Trade/Device Name: AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip
(LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

Regulation Number: 21 CFR 878.4300

Regulation Name: Implantable Clip

Regulatory Class: Class II

Product Code: PZX

Dated: September 29, 2023

Received: October 5, 2023

Dear Stephanie Hadnot:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine N. Trivedi
-S

for Rachel Neubrander
Assistant Director

K233407 - Stephanie Hadnot

Page 3

DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233407

Device Name

AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip (LAA0, ACH1, ACH2, PRO1, and PRO2)

AtriClip® PRO-V® LAA Exclusion System (PROV)

AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

Indications for Use (Describe)

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Applicant Information

Manufacturer: AtriCure, Inc.
7555 Innovation Way
Mason, Ohio 45040

Contact Person: Stephanie Hadnot
Senior Regulatory Affairs Specialist
P: 513-341-0345

Alternate Contact: Jim Taufen
Director, Regulatory Affairs
P: 952-314-1507

Date Prepared: 09/29/2023

II. Device Information

Proprietary Name: AtriClip® LAA Exclusion System with Preloaded Gillinov-Cosgrove® Clip
(LAA0, ACH1, ACH2, PRO1, and PRO2)
AtriClip® PRO-V® LAA Exclusion System (PROV)
AtriClip® Flex-V® LAA Exclusion System with Preloaded V Clip™ (ACHV)

Common Name: Implantable Clip and Clip Applier

Classification: Implantable Clip and Clip Applier
Regulatory Class: Class II; per 21 CFR 878.4300
Product Code: PZX
Classification Panel: Cardiovascular

Predicate Device: The device proposed for modification in this submission is the AtriClip LAA Exclusion System cleared via K210293 on March 3, 2021.

III. Device Description

The AtriClip LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a Single Use Clip Applier along with a selection guide. When closed, the Clip applies uniform pressure over the length of the Clip to ensure consistent, reproducible, and secure exclusion of the left atrial appendage (LAA). The Clip is then deployed and is left as a permanent implant and excludes the LAA resulting in electrical isolation of the LAA. Preclinical animal studies (Kamohara 2005,2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical

studies. The Clip is available in the following lengths to accommodate difference sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm. The Clip Appliers are disposable devices with a handle, shaft, suture anchors, articulation controls, and deployment loop/jaws which contain the Clip.

Intended Use/ Indications for Use

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

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.

The indications for use are identical to the predicate device.

IV. Comparison of Technological Characteristics with the Predicate Device (AtriClip LAA Exclusion System – K210293)

#	Feature	Predicate (K210293) AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
1	Proprietary Name	AOD1: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AOD2: AtriClip LAA Exclusion System with Preloaded V Clip	AOD1: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip AOD2: AtriClip LAA Exclusion System with Preloaded V Clip	Same
2	Clip Applier Product Code(s)	LAA035, LAA040, LAA045, LAA050 ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250 PRO135, PRO140, PRO145, PRO150 PRO235, PRO240, PRO245, PRO250 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50	LAA035, LAA040, LAA045, LAA050 ACH135, ACH140, ACH145, ACH150 ACH235, ACH240, ACH245, ACH250 PRO135, PRO140, PRO145, PRO150 PRO235, PRO240, PRO245, PRO250 PROV35, PROV40, PROV45, PROV50 ACHV35, ACHV40, ACHV45, ACHV50	Same
3	Selection Guide Product Code	CGG100	CGG100	Same
4	Device Classification	21 CFR 878.4300, product code: PZX	21 CFR 878.4300, product code: PZX	Same
5	Regulatory Class	Class II	Class II	Same
6	FDA Division	Cardiovascular	Cardiovascular	Same
7	Performance Standards	No performance standards applicable to this product have been promulgated by FDA	No performance standards applicable to this product have been promulgated by FDA	Same
8	Intended Use	The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see	The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see	Same

#	Feature	Predicate (K210293) AtriClip™ LAA Exclusion System	Modified AtriClip™ LAA Exclusion System	Equivalence Comparison
		the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.	
9	Contraindications	LAA0, ACH1, ACH2, PRO1, PRO2: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy). PROV, ACHV: 1. Do not use this device as a contraceptive tubal occlusion device.	LAA0, ACH1, ACH2, PRO1, PRO2: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if the patient has a known allergy to Nitinol (nickel titanium alloy). 3. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field. PROV, ACHV: 1. Do not use this device as a contraceptive tubal occlusion device. 2. Do not use this device if evidence of systemic infection, bacterial endocarditis, or in presence of infected operating field.	Similar – Contraindication added to emphasize standard surgical practice and possible limited use of devices.
10	Software	This product does not contain software.	This product does not contain software.	Same
11	Shelf Life	3 years	3 years	Same
12	Biocompatibility	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Same
13	Sterilization	Gamma Irradiation	Gamma Irradiation	Same
14	Sterility Assurance Level	10 ⁻⁶ SAL	10 ⁻⁶ SAL	Same
15	Pyrogen	Non-Pyrogenic	Non-Pyrogenic	Same
Clip				
16	Suture Material	Polyethylene Terephthalate	Polyethylene Terephthalate	Same
17	Preloaded Clip	AOD1: Preloaded Gillinov-Cosgrove Clip AOD2: Preloaded V Clip	AOD1: Preloaded Gillinov-Cosgrove Clip AOD2: Preloaded V Clip	Same
18	Clip Opening	AOD1: Opens 12.5mm ± 1.5mm as measured between the beams of the AOD1 clip. AOD2: Opens AOD2 Clip to a minimum of 12mm at the distal end and 4mm at the proximal end of the clip.	AOD1: Opens 12.5mm ± 1.5mm as measured between the beams of the AOD1 clip. AOD2: Opens AOD2 Clip to a minimum of 12mm at the distal end and 4mm at the proximal end of the clip.	Same
19	Biocompatibility	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices.	Same
20	Sterilization	Gamma Irradiation	Gamma Irradiation	Same

- The devices have the same intended use.
- No changes were made in operating principle.
- No changes to the overall design or function of the devices.

Performance Data

A review of the risk analysis concluded there is no overall change to the risk profile of the proposed AtriClip LAA Exclusion System versus the previously cleared AtriClip LAA Exclusion System as the modifications to the proposed AtriClip LAA Exclusion System do not add or remove any features of the device or change the clinical application.

The proposed changes do not include any change to design or performance specifications of the AtriClip LAA Exclusion System. Additionally, the proposed changes did not modify the intended use, therefore the previously submitted bench and animal data remain valid for the AtriClip LAA Exclusion System.

V. Conclusions

AtriCure has demonstrated that the modifications made to the AtriClip LAA Exclusion System are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the previously cleared AtriClip LAA Exclusion System per K210293.

Hi Victor,

Thank you for your feedback and review of K233407. I have updated the (b)(4) per your requests below. Please let me know if any further updates are required!

(b)(4)

Thanks,

Stephanie Hadnot

Senior Regulatory Affairs Specialist | AtriCure

O. 513-644-4239

M. 513-341-0345

E. SHadnot@AtriCure.com<mailto:SHadnot@AtriCure.com>

Twitter @AtriCure

From: Mondine, Victor <Victor.Mondine@fda.hhs.gov>

Sent: Thursday, November 2, 2023 12:45 PM

To: Stephanie Hadnot <SHadnot@atricure.com>

Cc: k233407@docs.fda.gov

Subject: K233407 (b)(4) Edits - Response Requested ASAP

Importance: High

You don't often get email from

victor.mondine@fda.hhs.gov<mailto:victor.mondine@fda.hhs.gov>. Learn why this is important<<https://aka.ms/LearnAboutSenderIdentification>>

Hi Stephanie,

Thanks for introducing yourself. We have just about wrapped up our review of K233407, but we have some comments regarding the (b)(4). Please see the attached pdf for highlighted points of edit, also summarized below:

(b)(4)

Best,

Victor

Victor A. Mondine

Biomedical Engineer, Cardiac Occluders & Hemostasis Devices Team

DHT2B: Division of Circulatory Support, Structural, & Vascular Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality | CDRH

Tel: 240-402-2693

victor.mondine@fda.hhs.gov<mailto:victor.mondine@fda.hhs.gov>

[cid:image001.png@01DA0D94.703FA0F0]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0D94.703FA0F0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0D94.703FA0F0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01DA0D94.703FA0F0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA0D94.703FA0F0] <<http://www.flickr.com/photos/fdaphotos/>>

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From: Stephanie Hadnot <SHadnot@atricure.com<mailto:SHadnot@atricure.com>>

Sent: Wednesday, November 1, 2023 10:45 AM

To: Mondine, Victor <Victor.Mondine@fda.hhs.gov<mailto:Victor.Mondine@fda.hhs.gov>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Subject: [EXTERNAL] RE: [External Sender]: K233407 Review Assigned

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Victor,

Please feel free to reach out to me if you have any questions or need anything for the AtriClip LAA Exclusion System Special 510(k), K233407.

Thanks,

Stephanie Hadnot

Senior Regulatory Affairs Specialist | AtriCure

O. 513-644-4239

M. 513-341-0345

E. SHadnot@AtriCure.com<<mailto:SHadnot@AtriCure.com>>

Twitter @AtriCure

From: Victor Mondine [VICTOR.MONDINE]
<victor.mondine@fda.hhs.gov<<mailto:victor.mondine@fda.hhs.gov>>>

Sent: Thursday, October 19, 2023 9:24 AM

To: Stephanie Hadnot <SHadnot@atricure.com<<mailto:SHadnot@atricure.com>>>

Cc: Victor Mondine [VICTOR.MONDINE]
<victor.mondine@fda.hhs.gov<<mailto:victor.mondine@fda.hhs.gov>>>

Subject: [External Sender]: K233407 Review Assigned

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important<<https://aka.ms/LearnAboutSenderIdentification>>

October 19, 2023

Review Assignment Notification

I am the lead reviewer assigned to your submission K233407. Your file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 B. The first line supervisor is the Assistant Director of Cardiac Occluders and Hemostasis Devices.

I will contact you should any additional information be required during the course of the review of your submission. You may contact me at any point during the review if you have questions or concerns. FDA aims to apply the least burdensome principles<<https://www.fda.gov/media/73188/download>> when requesting additional information.

You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory<<https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>>.

If you have general questions about the review process for your submission, you should

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-4617; Released by CDRH on 10-10-2024
contact OPEQSubmissionSupport@fda.hhs.gov<<mailto:OPEQSubmissionSupport@fda.hhs.gov>>.

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(b)(4)