AtriCure®

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

# INSTRUCTIONS FOR USE

**(PRO235, PRO240, PRO245, PRO250)**

## DESCRIPTION

The AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip (hereafter: 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 Clip is pre-loaded on a disposable Clip applier. The AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip does not contain natural rubber latex components.

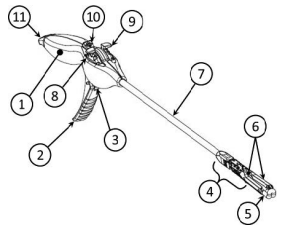
## PRODUCT COMPOSITION

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.

## TYPE AND SPECIFICATION

| Type | Clip Length(mm) |
|---|---|
| PRO235 | 35 |
| PRO240 | 40 |
| PRO245 | 45 |
| PRO250 | 50 |

## ATRICLIP LAA EXCLUSION SYSTEM ILLUSTRATION AND NOMENCLATURE




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

⚠BEFORE USING PRODUCT READ THE FOLLOWING INFORMATION THOROUGHLY

**IMPORTANT!**

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

## INDICATIONS FOR USE

The device is intended for atrial fibrillation patients who is undergoing left atrial appendage clipping through concurrent cardiac open chest surgery or minimally invasive surgery. The latter should be for atrial fibrillation patients who have failed to be treated by cardiology treatment and have been determined by a doctor to require left atrial appendage clipping.

## 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).

**⚠ WARNINGS ⚠**

1. Do not attempt to reposition or remove the Clip after deployment. This may result in tissue damage or tearing.
2. Use this device only as intended. Failure to do so may result in injury to the user or patient.
3. 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, dehiscience, tissue tearing, displacement and/or exclusion.

**⚠ WARNINGS ⚠**

4. Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Cosgrove-Gillinov Selection Guide Instructions for Use. Failure to correctly size or deploy the Clip may result in: tissue trauma, dehiscence, tissue tearing, displacement and/or exclusion.

5. Do not use on a LAA less than 29mm in width and 1.0mm wall thickness. Doing so may result in: tissue trauma, dehiscience, tissue tearing, displacement and/orexclusion.

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

7 Do not use this device if the patient has sensitivity to Nickel (nickel titanium alloy). This may result in an adverse user or patient reaction.

8. 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.

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

10. Atriclip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.

## ⚠PRECAUTIONS

1. Read all instructions carefully for the AtriClip LAA Exclusion System. Failure to properly follow instructions may result in improper functioning of the device.
2. Use of the device should be limited to properly trained and qualified medical personnel.
3. Note that variations in specific procedures may occur due to individual physician techniques and patient anatomy.
4. Do not drop or toss the device as this may induce damage to the device. If the device is dropped, do not use. Replace with a new device.
5. 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.
6. Carefully consider any pre-surgical treatment the patient may have undergone and in corresponding selection of 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.
7. Do not modify this instrument. Use of a modified device may result in improper instrument function. AtriCure, Inc. makes no claim or representation as to the performancecharacteristics of this product if any modifications have been made to the AtriClip LAA Exclusion System.
8. Do not kink or excessively bend the shaft as this may affect device performance.
9. Evacuate thrombus from the LAA prior to Clip application as with other conventional LAA occlusion surgical techniques. Evaluating for the presence of thrombus should be doneper the surgeon's discretion and standard of care.
10. Position and deploy Clip in a manner that provides clear visualization of all tissues being accessed. Poor visualization may result in suboptimal placement.
11. Take care to minimize manipulation of the LAA and Clip after Clip deployment.
12. It is recommended that the Clip be deployed in a dry field.
13. Do not use the Clip in temperatures below 20°C. Application of the Clip in temperatures below 20°C may affect device performance.
14. 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.

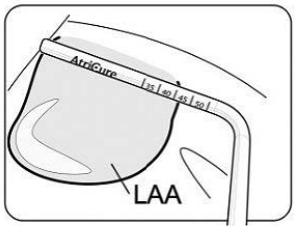
## INSTRUCTIONS FOR USE

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

### CLIP SELECTION

1. Using the Gillinov-Cosgrove Selection Guide, to determine correct selection of the Gillinov-Cosgrove LAA Clip. Clip sizes are located on the device package.

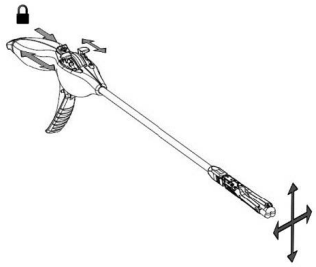
| Clip Size | LAA Size Range |
|---|---|
| 35 mm | 29-35 mm |
| 40 mm | 34-40 mm |
| 45 mm | 39-45 mm |
| 50 mm | 44-50 mm |




2. Using sterile technique, remove the AtriClip LAA Exclusion System from its packaging.
3. Using the activation lever on the handle, gently open and close the Clip to assure proper function.

⚠**Caution:** Do not open and close the Clip more than 3 times with the activation lever prior to deployment.

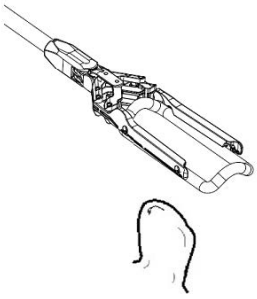
## ARTICULATION OF END EFFECTOR



4. By pushing down and pulling the Articulation Lock (10) backwards (proximal), the End Effector (4) 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 (5) and End Effector (4) can articulate 30° left or right and 30° up or down to take into account anatomical variations in the patient's anatomy.
5. To lock the End-Effector (4) in position, press the Articulation Lock (10) forward.

## CLIP POSITIONING

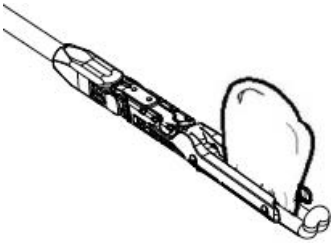
6. Maneuver the AtriClip LAA Exclusion System into the targeted dissection plane.



7. Gently open the Clip by squeezing the Activation lever (2).

**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 (3).

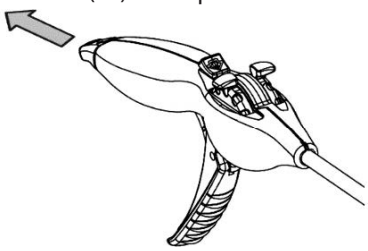
8. Orient the Clip applier with pre-loaded Clip at the tip of LAA with the loops at the ends of the Clip pointed away from the LAA.
9. Gently position the Clip at the base of the LAA.



10. Position the Clip in a manner that provides clear visualization of all tissues being accessed.
11. 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.
12. If the Clip is not placed correctly, gently open the Clip and reposition as needed.
13. After the Clip is positioned correctly, grasp the Activation Lever (2) and depress the Lever Release Trigger (3) and slowly release the Activation Lever allowing the Clip to close.

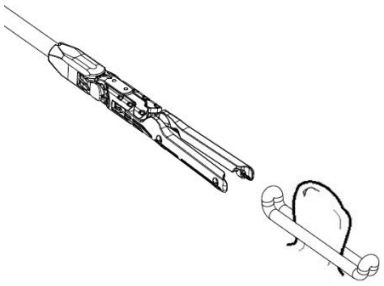
## DEPLOYMENT

14. Deploy the Clip by slowly pulling the Deployment Tab (11) at the proximal end of the handle.



**NOTE:** The Deployment Tab with steel cables may be completely removed from the end of the Handle.

15. Unlock the end effector articulation (10) and carefully remove it from the LAA as shown below leaving the Clip and attachment suture behind.



⚠**Caution:** After pulling the Deployment Tab, the AtriClip LAA Exclusion System cannot be used to reposition the Clip

16. Discard the deployment device after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

## 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 AtriClip 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
- Under the scan conditions defined for the AtriClip LAA Exclusion System Clip is expected to produce a maximum temperature rise of 2.9°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

### ARTIFACT INFORMATION

In non-clinical testing, the image artifact caused by the AtriClip LAA Exclusion System Clip extends approximately 10-mm from the AtriClip LAA Exclusion System Clip when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

### REFERENCES


1. Kamohara K, et al . A novel device for left atrial appendage exclusion. J Thorac Cardiovasc Surg 2005
2. Kamohara K, Fukamachi et al. Evaluation of a novel device for left atrial appendage exclusion: the second-generation atrial exclusion device. J Thorac Cardiovasc Surg 2006
3. Christoph T. Starck, 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)

## EXPLANATION OF SYMBOLS ON PACKAGE LABELING

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

| | |
|---|---|
|  | Non-pyrogenic |
|  | Sterilized by Irradiation |
|  | Single Use Only |
|  | Use-by date |
| Rx ONLY | Caution: Federal Law (US) restricts this device to sale by or on the order of a physician |
|  | Lot Number |
|  | Caution |
|  | Consult Instructions For Use |
|  | Manufacturer |
|  | Not made with natural rubber latex |
|  | MR Conditional |
|  | Do not re-sterilize |
|  | Do not use if package is damaged |

## LICENSE NO.

国械注进20243130370

## PRODUCT TECHNICAL REQUIREMENT NO.

国械注进20243130370

## MANUFACTURING DATE

See Product Label

## EXPIRED DATE

See Product Label

## REGISTRANT/MANUFACTURER

AtriCure, Inc. (爱创科股份有限公司)

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AtriCure®

# 自闭合左心耳封闭系统

# 使用说明

**(PRO235, PRO240, PRO245, PRO250)**

## 描述

自闭合左心耳封闭系统包含用于闭合心脏左心耳 (LAA) 的可植入夹子。临床前动物研究 (Kamohara 2005,2006) 证明，使用夹子完全闭合左心耳也会使左心耳急性和慢性电隔离。一项人体临床研究 (Starck 2012) 已经证明了急性电隔离。尚未在人体临床研究中评价慢性电隔离。

可植入夹子预先安装在一次性输送系统上。自闭合左心耳封闭系统不含天然乳胶组件。

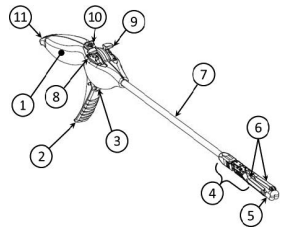
## 产品组成

自闭合左心耳封闭系统由一次性输送系统、预装在输送系统上的一次性无菌自闭合可植入夹子和测量尺组成。

## 型号和规格

| 型号 | 夹子长度 (mm) |
|---|---|
| PRO235 | 35 |
| PRO240 | 40 |
| PRO245 | 45 |
| PRO250 | 50 |

## 自闭合左心耳封闭系统图解和术语




[1] 手柄
[2] 夹子控制把手
[3] 把手锁定扳机
[4] 末端受动器
[5] 可植入夹子
[6] 夹子撑开钳口
[7] 连接杆
[8] 上下旋转控制
[9] 左右旋转控制
[10] 旋转锁定按钮
[11] 夹子释放拉钮

⚠使用该产品前，请先仔细阅读下列信息

**重要！**

**本手册旨在协助您使用本产品。而不用作手术技法的参考资料。**

## 适应症

该产品适用于通过合并同期心脏外科开胸手术或微创手术进行左心耳夹闭的房颤患者。其中后者需为心内科治疗房颤无效且经医生判定需要进行左心耳夹闭的房颤患者。

## 禁忌症

1. 本器械不能用作输卵管闭合避孕之用。
2. 如果患者已知对镍钛合金过敏，请勿使用本器械。

**⚠ 警告 ⚠**

1. 可植入夹子释放后请勿尝试重新定位或取出可植入夹子。这可能导致组织损伤或撕裂。

2. 仅按照预期用途使用本器械。否则可能会导致用户或患者受伤。

3. 根据外科医生的建议，请勿将本器械用于不适应常规缝合材料或常规封闭技术（例如外科缝合器缝合）的组织。否则可能导致：组织创伤、开裂、组织撕裂、位移和/或分离。

4. 请在放置可植入夹子之前仔细评估夹子的位置、组织厚度，以及组织宽度。如需确定适当的夹子尺寸，请参阅 测量尺使用说明。夹子尺寸不正确或释放不当可能导致：组织创伤、开裂、组织撕裂、位移和/或分离。

**⚠ 警告 ⚠**

5. 请勿将本器械用于宽度不足 29 mm 及壁厚不足 1.0 mm 的 LAA。否则可能导致：组织创伤、开裂、组织撕裂、位移和/或分离。
6. 请勿将本器械用于在未压缩时大于 50 mm 的 LAA。否则可能会导致闭合不完全。
7. 如果患者对镍（镍钛合金）过敏，请勿使用本器械。这可能会导致用户或患者出现不良反应。
8. 使用前，目视检查输送系统钳口是否生锈。为防止生锈，输送系统的使用时间不得超过 1 小时。
9. 该器械单独或与其他消融治疗联合用于房性节律控制管理的安全性和有效性尚未确定。
10. 允许血流进入 LAA 的夹子放置可能导致不会完全闭合和/或电隔离。

## ⚠注意事项

1. 仔细阅读 自闭合左心耳封闭系统的所有说明。未正确遵照说明可能导致器械功能失常。
2. 仅经过适当培训且具有资格的医务人员方可使用本器械。
3. 请注意，由于医生技术和患者解剖结构的差异，具体程序可能有所变化。
4. 请勿掉落或投掷本器械，否则可能会导致器械损坏。如果器械掉落，请勿继续使用。应更换新的器械。
5. 切勿重复灭菌。自闭合左心耳封闭系统以无菌形式提供，仅供一次性使用。重复灭菌可能导致功能丧失或患者受伤。
6. 仔细考虑患者可能接受的任何术前治疗，并相应地选择可植入夹子尺寸。术前放疗可能会导致组织发生变化。例如，这些变化可能会使组织厚度超过所选可植入夹子尺寸的适用范围。
7. 请勿改装本器械。使用改装过的器械可能会导致仪器工作失常。对于任何改装后 自闭合左心耳封闭系统的性能特征，AtriCure, Inc. 不做出任何声明或陈述。
8. 请勿扭结或过度弯曲连接杆，因为这可能影响器械性能。
9. 与其他常规 LAA 闭合手术技术一样，在使用夹子之前也应清除来自 LAA 的血栓。应按照外科医生的判断和标准护理评估是否存在血栓。
10. 放置和释放夹子时应能清晰显示接触的所有组织。显示不清晰可能会导致夹子放置位置不佳。
11. 注意尽量在释放夹子后减少 LAA 和夹子操作。
12. 建议将夹子放置在干燥的部位。
13. 请勿在低于 20 °C 的温度下使用夹子。在低于 20 °C 的温度下使用夹子可能影响器械性能。
14. 在处于锁定位置时，请勿尝试旋转末端受动器。当在锁定位置施加外力可能会导致器械损坏。

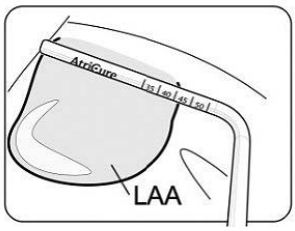
## 使用说明

借助于测量尺，外科医生判断确定适用的可植入夹子尺寸。

### 可植入夹子选择

1. 使用 测量尺来选择正确的 可植入夹子。夹子尺寸见器械包装。

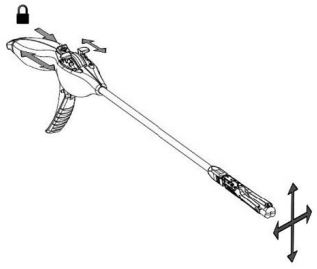
| 夹子尺寸 | LAA 尺寸范围 |
|---|---|
| 35 mm | 29-35 mm |
| 40 mm | 34-40 mm |
| 45 mm | 39-45 mm |
| 50 mm | 44-50 mm |




2. 使用无菌技术将 自闭合左心耳封闭系统从包装中取出。
3. 使用手柄上的夹子控制把手轻轻地打开和闭合夹子，以确保工作正常。

⚠**注意：**释放前，请勿用夹子控制把手打开和闭合夹子 3 次以上。

### 末端受动器旋转

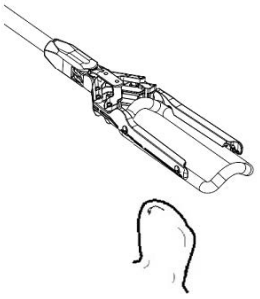


4. 通过向后（近端）下推和拉旋转锁定按钮 (10)，自闭合左心耳封闭系统的末端受动器 (4) 可以通过旋转控制或按下末端受动器进行手动上下和左右旋转。考虑到患者解剖结构的解剖变异，可植入夹子 (5) 和末端受动器 (4) 可向左或向右 30° 和上下 30° 转动。

5. 要将末端受动器 (4) 锁定到位，向前按下旋转锁定按钮 (10)。

## 放置夹子

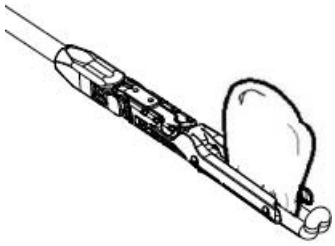
6. 操控 自闭合左心耳封闭系统进入目标解剖平面。



7. 通过握紧夹子控制把手 (2)，轻轻打开夹子。

**注意：**夹子通过器械手柄上的把手锁定扳机自动锁定在完全打开的位置。通过按下把手锁定扳机 (3) 可以解除锁定。

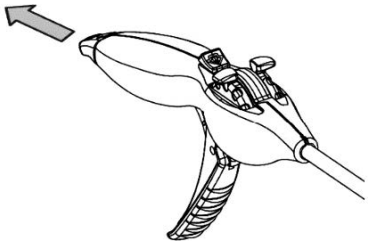
8. 将预装有夹子的输送系统定向在 LAA 尖端，夹子末端的环指向远离 LAA 的方向。
9. 轻轻将夹子放置于 LAA 的底部。



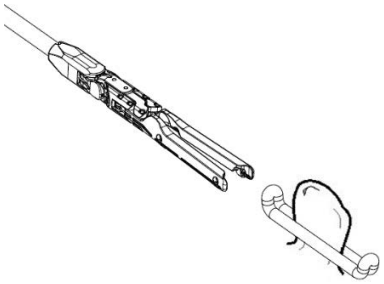
10. 放置可植入夹子时，周围邻近的所有组织应清晰可见。
11. 在可植入夹子仍附着于输送系统上时，确保周围不存在任何会干扰夹子或被夹子损坏的结构，并确保将夹子放置到位。
12. 如果夹子未放置到位，轻轻打开夹子并根据需要重新放置。
13. 在正确定位夹子后，抓住夹子控制把手 (2)，按下把手锁定扳机 (3)，缓慢松开夹子控制把手，使夹子闭合。

## 释放

14. 通过缓慢拉动手柄近端的夹子释放拉钮 (11)，释放夹子。**注意：** 可从手柄末端完全取出带有钢缆的夹子释放拉钮 (11)。



15. 解锁旋转锁定按钮 (10)，并如下图所示小心将其从 LAA 中取出，留下可植入夹子和附着的缝线。



**注意：** 拉动夹子释放拉钮后，自闭合左心耳封闭系统不能重新定位可植入夹子。

16. 使用后请丢弃释放器械。按照当地管理条例和回收计划处置或回收器械组件。

## 退回使用过的产品

如出于任何原因，必须将该产品退回给 AtriCure, Inc.，装运前，应先向 AtriCure, Inc. 索取退货授权 (RGA) 码。

如果该产品已经与血液或体液接触，包装前必须进行彻底清洗和消毒。为了避免运输过程中造成损坏，应将产品装进原包装纸箱或同等纸箱，并应适当粘贴 RGA 码和运输物品的生物危害性质说明标签。

有关清洁说明和材料，包括适当的运输包装箱、适当标签和 RGA 码，均可向 AtriCure, Inc 索取。

## 免责声明

用户必须负责在使用本产品之前核准产品的条件，并确保仅以这些使用说明中所述的方式使用本产品，包括但不限于确保本产品不被重复使用。

在任何情况下，对于因故意误用或重复使用本产品造成的任何偶然、特殊或间接损失、损坏或费用，包括与人身伤害或财产损坏相关的任何损失、损坏或费用，AtriCure, Inc. 概不负责。

## 处理信息：可植入夹子 **MRI** 安全性信息

### **MR** 条件限制

非临床试验证明 可植入夹子具有 MR 条件限制。在以下条件下，患者在置入本器械后能立即安全地在 MR 系统中接受扫描：

- 静态磁场强度仅为 1.5-Tesla 和 3-Tesla
- 最大空间梯度磁场强度 4,000-gauss/cm (40- T/m)（推测）或更小
- 所报告的最大 MR 系统，在 MR 系统操作的第一级受控操作模式中，15 分钟扫描（即每个脉冲序列）的全身平均比吸收率 (SAR) 为 4-W/kg
- 在给可植入夹子定义的扫描条件下，预期在持续扫描 15 分钟（即每个脉冲序列）后可植入夹子产生的最大温升为 2.9°C。

### 伪影信息

在非临床试验中，使用梯度回波脉冲序列和 3-Tesla 磁共振系统成像时，可植入夹子引起的图像伪影从 夹子延伸大约 10 mm。

### 参考资料


1. Kamohara K, et al . A novel device for left atrial appendage exclusion. J Thorac Cardiovasc Surg 2005
2. Kamohara K, Fukamachi et al. Evaluation of a novel device for left atrial appendage exclusion: the second-generation atrial exclusion device. J Thorac Cardiovasc Surg 2006
3. Christoph T. Starck, 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)

## 包装标签上的符号说明

请参考外包装标签，查看哪些符号适用于本产品。

| | |
|---|---|
|  | 无热原 |
|  | 经辐照灭菌 |
|  | 仅供一次性使用 |
|  | 有效期 |
| Rx ONLY | 注意：联邦法律 (US) 规定本器械只能由医生销售或遵医嘱销售 |
|  | 批号 |
|  | 注意 |
|  | 查阅使用说明 |
|  | 制造商 |
|  | 不含天然乳胶 |
|  | MR 条件限制 |
|  | 切勿重复灭菌 |
|  | 如包装破损，请勿使用 |

## 医疗器械注册证编号：

国械注进20243130370

## 产品技术要求编号：

国械注进20243130370

## 生产日期

见产品标签

## 失效日期

见产品标签

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