AtriCure®

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

## INSTRUCTIONS FOR USE

**(ACH235, ACH240, ACH245, ACH250)**

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

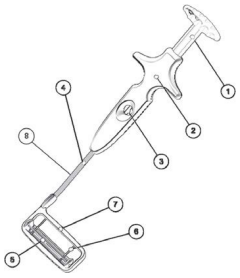
## PRODUCT COMPOSITION

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) |
|---|---|
| ACH235 | 35 |
| ACH240 | 40 |
| ACH245 | 45 |
| ACH250 | 50 |

## ATRICLIP LAA EXCLUSION SYSTEM ILLUSTRATION AND NOMENCLATURE



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

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

⚠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.

**⚠ WARNINGS ⚠**

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).

4. Carefully evaluate Clip position, tissue thickness, and tissue width prior to Clip deployment. To determine appropriate Clip size, refer to the Gillinov-Cosgrove 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.

6. Do not use on a LAA greater than 50mm when tissue is uncompressed.

7. Do not use this device if the patient has sensitivity to Nickel (nickel titanium alloy).

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

9. 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. Resterilization may cause loss of function orinjury to patient.
6. Carefully consider any pre-surgical treatment the patient may have undergone and in corresponding selection of Clip size. Preoperative radiotherapy mayresult 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 tothe performance characteristics 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 ofthrombus should be done per 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.

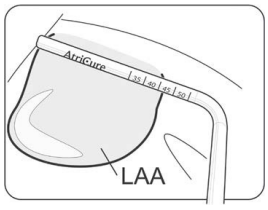
## INSTRUCTIONS FOR USE

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

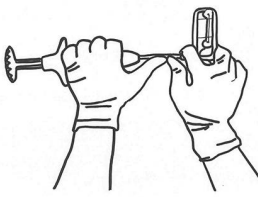
### CLIP SELECTION

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. 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 asrequired for anatomical variations.



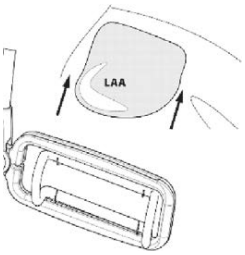
⚠**Caution:** Do not grasp deployment loop to apply bend to shaft, as this may result in damage to the device. Apply bend by gently concentrating force under both thumbs. Excessive bending or kinking of the shaft may affect device performance. Do not attempt to twist the deployment loop, as this may cause damage to the device.

4. Using the plunger, gently open and close the Clip to assure proper function.

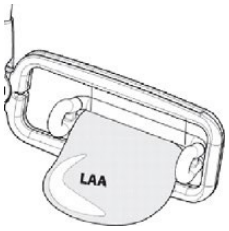
⚠**Caution:** Do not open and close the Clip more than 3 times with the plunger prior to deployment.

## CLIP POSITIONING

5. Maneuver the AtriClip LAA Exclusion System into the targeted dissection plane.
6. Gently open the Clip by depressing the plunger.
7. 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.



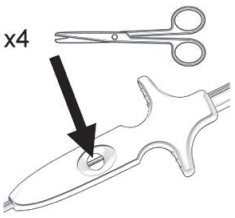

8. Gently position the Clip at the base of the LAA.



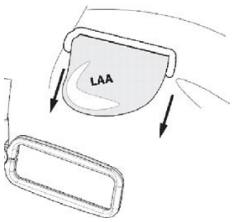

9. Position the Clip in a manner that provides clear visualization of all tissues being accessed.
10. While the Clip is still affixed to the Deployment Device, ensure that no surrounding structures interfere with or are damaged by the Clip, and that the Clip is placed correctly.
11. If the Clip is not placed correctly, gently open the Clip and reposition as needed.

## DEPLOYMENT

12. After the Clip is positioned correctly, release the plunger allowing the Clip to close.
13. Deploy the Clip by manually cutting the suture at the designated cutting zone on the handle.

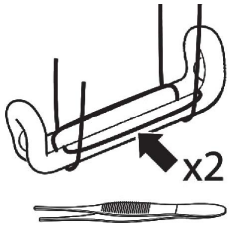



14. Providing counter pressure on the Clip, carefully remove the deployment loop from the LAA as shown below leaving the Clip and attachment suture behind.



⚠**Caution:** After manually cutting the sutures, the AtriClip LAA Exclusion System cannot be used to reposition the Clip.

15. After the Clip is deployed, remove the attachment sutures by gently pulling one at a time while providing counter traction on the Clip per the surgeon'sdiscretion. Do not cut the Clip fabric.




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 LAA Exclusion System Clip extends approximately 10-mm from the 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 |  | MR Conditional |
|  | Sterilized by irradiation |  | Caution |
| Rx ONLY | Caution: Federal Law (US) restricts this device to sale by or on the order of a physician |  | Consult Instructions For Use |
|  | Lot Number |  | Not made with natural rubber latex |
|  | Use-by date |  | Manufacturer |
|  | Do not re-sterilize |  | Single Use Only |
| | |  | 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

**(ACH235, ACH240, ACH245, ACH250)**

## 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。

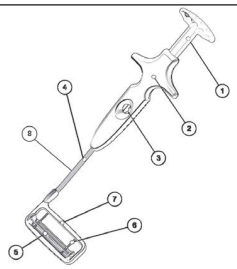
## 产品组成

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) |
|---|---|
| ACH235 | 35 |
| ACH240 | 40 |
| ACH245 | 45 |
| ACH250 | 50 |

## 自闭合左心耳封闭系统图解和术语



[1] 推杆
[2] 手柄
[3] 拉线切割区
[4] 连接杆
[5] 可植入夹子
[6] 拉线
[7] 夹子放置环
[8] 可塑区

**注意：**AtriClip FLEX 器械连接杆的整个连接杆身都是可塑的。预期可在所有平面上调整至 45°。

⚠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。
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。
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。夹子尺寸不正确或部署不当可能导致：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。
6. 请勿将本器械用于未压缩时大于 50 mm 的 LAA。
7. 如果患者对镍（镍钛合金）过敏，请勿使用本器械。
8. 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。
9. 允许血流进入 LAA 的 夹子置入可能导致不完全分离和/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设备工作失常。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，在施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. 注意尽量在部署夹子后减少 LAA 和夹子操作。
12. 建议将夹子释放在干燥的部位。
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。

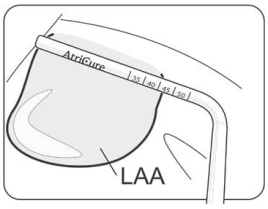
## 使用说明

借助于测量尺，外科医生判断确定适用的可植入夹子尺寸。

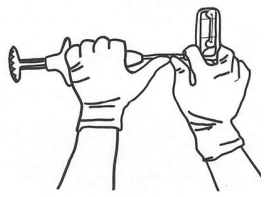
### 夹子选择

1. 使用 测量尺来选择正确的可植入夹子。夹子尺寸位于器械包装上。

| 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. 可对 自闭合左心耳封闭系统的可塑连接杆形状进行调整，以便接触 LAA。轻轻用力，根据解剖变异的需要调整器械连接杆的形状。



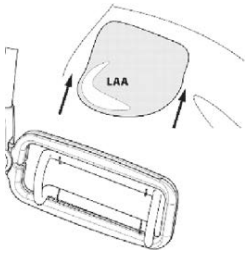
⚠**注意：**请勿抓握夹子放置环来弯曲连接杆，否则可能会损坏器械。通过轻轻在两个拇指下集中用力进行弯曲。连接杆过度弯曲或扭结可能会影响器械性能。请勿尝试扭曲夹子放置环，否则可能会损坏器械。

4. 使用推杆轻轻地打开和闭合夹子，以确保工作正常。

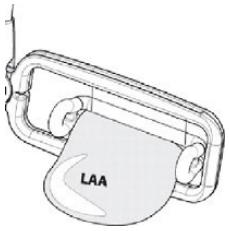
⚠**注意：**释放前，请勿用推杆打开和闭合夹子 3 次以上。

## 放置夹子

5. 操控 自闭合左心耳封闭系统进入目标解剖平面。
6. 通过按压推杆轻轻打开夹子。
7. 将预装有可植入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。



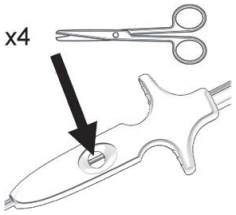

8. 轻轻将夹子放置于 LAA 的底部。




9. 放置夹子时，周围接近的所有组织应清晰可见。
10. 在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。
11. 如果夹子未放置到位，轻轻打开夹子并根据需要重新放置。

## 释放

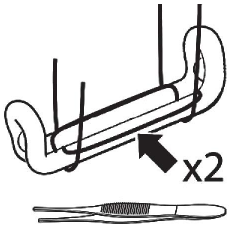
12. 将夹子放置到位后，松开推杆使夹子闭合。
13. 通过在手柄上的指定切割区手动切割拉线释放夹子。




14. 在夹子上施加反压，小心地从 LAA 中取出夹子放置环，如下图所示，留下夹子和附连拉线。

⚠**注意：**手动切断拉线后，自闭合左心耳封闭系统不能再重新定位夹子。

15. 释放可植入夹子后，根据外科医生的判断，在对夹子进行反向牵拉的同时，轻轻拉动一根，取出附连拉线。切勿切割夹子组织。




16. 使用后请丢弃输送系统。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

用户负责在使用本产品之前核准产品的可接受条件，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 LAA 分离系统夹具有 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 可植入夹子延伸大约 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 |  | MR 条件限制 |
|  | 经辐照灭菌 |  | 注意 |
| 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 |  | 查阅使用说明 |
|  | 批号 |  | 不含天然乳胶 |
|  | 有效期 |  | 制造商 |
|  | 切勿重复灭菌 |  | 仅供一次性使用 |
| | |  | 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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