

AtriClip® Gillinov-Cosgrove Selection Guide™

INSTRUCTIONS FOR USE

(CGG100)

DESCRIPTION

The AtriClip Gillinov-Cosgrove Selection Guide (Guide) is an accessory that works in conjunction with the AtriClip LAA Exclusion System with Pre-Loaded Gillinov Cosgrove Clip (hereafter: AtriClip LAA Exclusion System). The AtriClip LAA Exclusion System is comprised of the AtriClip LAA Exclusion Device (Clip), the AtriClip Applier, and the Guide.

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

The Guide 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.

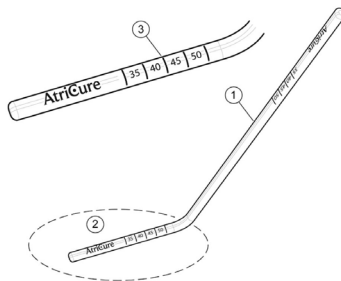
PART NAME

Selection Guide

TYPE AND SPECIFICATION

CGG100

ATRICLIP GILLINOV-COSGROVE SELECTION GUIDE ILLUSTRATION



- [1] Handle
- [2] Base
- [3] Indication Marks

⚠ 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 AtriClip Gillinov-Cosgrove™ Selection Guide (Guide) is intended to be used as an accessory to the AtriClip LAA Exclusion System.

CONTRAINDICATIONS

None known

⚠ WARNINGS ⚠

1. Do not use the Guide if the sterility barrier is breached. To avoid the risk of patient infection, inspect the product packaging prior to opening to ensure that the sterility barrier is not breached.
2. Do not apply excessive force when using the Guide. Using excessive force may cause tissue damage.

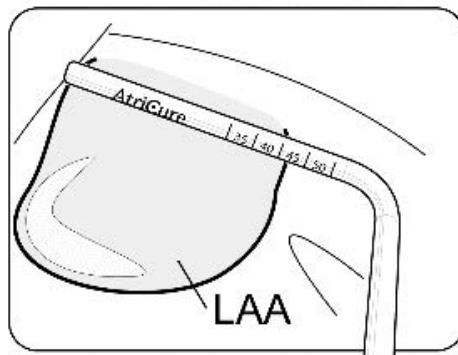
⚠ PRECAUTIONS

1. Carefully read all instructions for the AtriClip Gillinov-Cosgrove Selection Guide prior to using the device. Failure to properly follow instructions may lead to injury and/or may result in improper use of the device.
2. The AtriClip Gillinov-Cosgrove Selection Guide is to be used only to assist with selecting the appropriate Clip.
3. Use of the Guide should be limited to properly trained and qualified medical personnel.
4. To avoid damage to the device, do not drop or toss the Guide. If the Guide is dropped, do not use. Replace with a new Guide.
5. To avoid damage to the Guide, use caution when handling and interfacing with other devices.
6. Do not bend the guide in the area of the indication marks.
7. Do not re-sterilize or reuse the Guide. Single Patient use only.

INSTRUCTIONS FOR USE

1. Using sterile technique, remove the Guide from its packaging.
2. Align the Guide adjacent with the LAA.

NOTE: Evaluation should occur at the base of the appendage.



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

3. Evaluate the LAA and select the appropriate Clip size.
4. Discard the Guide after use. Follow the local governing ordinances and recycling plans regarding disposal or recycling of device components.

HOW SUPPLIED

The AtriClip Gillinov-Cosgrove Selection Guide is supplied as a STERILE instrument and is for single patient use only. Sterility is guaranteed unless the package is opened or damaged. Do not re-sterilize.

Do not use the Gillinov-Cosgrove Selection Guide after the expiration date indicated.

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.

⚠ CAUTION: It is the responsibility of the health care institution to adequately prepare and identify the product for shipment.












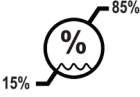
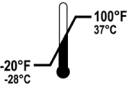
DISCLAIMER STATEMENTS

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.

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

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

	Non-pyrogenic		Use-by date
	Sterilized by Irradiation		Caution
	Single Use Only		Consult Instructions For Use
Rx ONLY	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner		Manufacturer
	Lot Number		Do not use if package is damaged
	Do not re-sterilize		Does Not Contain Natural Rubber Latex
 Humidity Limitation		 Temperature Limitation	

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. (爱创科技股份有限公司)

ADDRESS

7555 Innovation Way, Mason, Ohio 45040 USA

MANUFACTURING ADDRESS

7555 Innovation Way, Mason, Ohio 45040 USA

TELEPHONE

1-866-349-2342, 1-513-755-4100

LEGAL AGENT

AtriCure (Beijing) Medicine Information Consulting Service co Ltd.

ADDRESS

Room 418, Floor 4, Unit 2, Building 1, No. 3 Courtyard, Jinhang Middle Road,
Shunyi District, Beijing (Tianzhu Comprehensive Bonded Zone)

TELEPHONE

010-84554569

NAME OF AFTER-SALES SERVICE AGENT

AtriCure (Beijing) Medicine Information Consulting Service co Ltd.

ADDRESS OF AFTER-SALES SERVICE AGENT:

Room 418, Floor 4, Unit 2, Building 1, No. 3 Courtyard, Jinhang Middle Road, Shunyi District, Beijing (Tianzhu Comprehensive Bonded Zone)

TELEPHONE

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自闭合左心耳封闭系统
使用说明

测量尺:CGG100

描述

测量尺是与其配合使用的自闭合左心耳封闭系统的附件。自闭合左心耳封闭系统由可植入夹子、输送系统和测量尺组成。

测量尺是供单名患者使用的手术器械,旨在协助您选择适当的可植入夹子。测量尺具有可塑性,可直接放置在左心耳(LAA)附近进行测量。

测量尺上有标记,有助于评价结构和选择适当的可植入夹子尺寸。测量尺上的标记比可植入夹子标称尺寸短 4 mm +/-0.5 mm,以近似可植入夹子对左心耳的压缩。组织厚度、心耳几何形状和其他因素可能影响尺寸的确定,因此由医生决定选择适当的尺寸。

本测量尺不含天然乳胶组件。

产品组成

自闭合左心耳封闭系统由预装在一次性输送系统上的一次性无菌可植入夹子和测量尺组成。

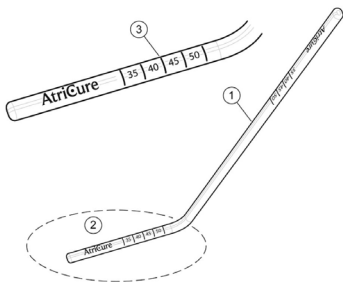
部件名称

测量尺

型号和规格

CGG100

测量尺图解



- [1] 手柄
- [2] 头部
- [3] 指示标记

⚠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

测量尺旨在用作自闭合左心耳封闭系统的附件

禁忌症

尚未发现

⚠警告⚠

1.

如果无菌屏障破损,请勿使用该测量尺。为避免患者感染风险,打开前检查产品包装,以确保无菌屏障未破损。

2.

使用测量尺时,请勿过度用力。用力过大可能导致组织损伤。

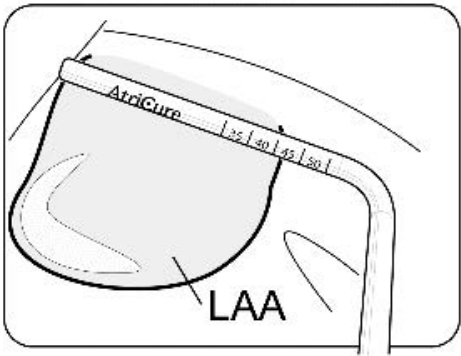
⚠️ 注意事项

- 1. 在使用该器械之前,仔细阅读 测量尺 的所有说明。未能正确遵循使用说明可能导致损伤和/或可能导致器械使用不当。
- 2. 测量尺 仅用于协助选择适当的夹子。
- 3. 仅经过适当培训且具有资格的医务人员方可使用本测量尺。
- 4. 为避免器械损坏,请勿掉落或投掷该测量尺。如果测量尺掉落,请勿继续使用。应更换新的测量尺。
- 5. 为避免测量尺损坏,搬运和连接其他器械时应小心。
- 6. 请勿弯曲测量尺的指示标记区域。
- 7. 切勿重复灭菌或反复使用测量尺。仅供单名患者使用。

使用说明

- 1. 采用无菌技术,从包装中取出测量尺。
- 2. 将测量尺与 LAA 相邻对齐。

注意:应在附件底部进行评价。



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

- 3. 评估 LAA 并选择适当的可植入夹子尺寸。
- 4. 使用后丢弃测量尺。按照当地管理条例和回收计划处置或回收器械组件。

供应方式

测量尺 以无菌器械形式提供,仅供单名患者使用。除非包装打开或破损,否则可保证无菌性。切勿重复灭菌。
在指定的失效日期后,请勿使用 测量尺。

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。

⚠️ 注意:医疗卫生机构负责充分准备和识别待装运的产品。

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失相关的任何损失、损坏或费用,AtriCure, Inc. 概不负责。

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		有效期
	经辐照灭菌		注意
	仅供一次性使用		查阅使用说明
Rx ONLY	注意:美国联邦法律规定 本器械只能由医生或其他 执业医师销售或遵医嘱 订购		制造商
	批号	 湿度限制	
	如包装破损,请勿使用	 温度限制	
	切勿重复灭菌		不含天然乳胶

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

注册人/生产企业名称

AtriCure, Inc. (爱创科股份有限公司)

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代理人住所

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电话

010-84554569

售后服务机构名称

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售后服务机构住址

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