LeMaitre®
VASCULAR

AnastoClip GC® Closure System

AnastoClip GC® Closure System
English — Instructions for Use

血管及管状组织闭合系统
使用说明书

AnastoClip GC® Closure System

(Model Numbers 4008-06, 4008-07, 4008-08, 4010-01, 4010-02, 4010-03)

STERILE EO Rx only

IMPORTANT!

This booklet is designed to assist in using the AnastoClip GC® Closure System with titanium clips. It is not a reference to surgical stapling techniques.

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

Indications

The AnastoClip GC is intended for use in the creation of everting anastomoses in blood vessels and other small tubular structures when tissue penetration is desired. The Applier is also intended for approximation of dural tissue/ durotomies following open craniotomy and open spinal laminectomy procedures. Dural approximation is only available in the United States.

Effects

The AnastoClip GC applier is available in three (3) clip sizes: medium-1.1 mm, large-1.7 mm and extra large-2.5 mm. They are available in two (2) lengths: 3 in. distal shaft and 6 in. distal shaft. The AnastoClip GC applier consists of a rotating shaft and an integral cartridge containing titanium clips.

As the levers of the applier are squeezed together, the clip is closed around the everted tissue edges. As the levers are released, a new clip is automatically loaded into the clip applier jaws. It is recommended to use the Tissue Everting Forceps to aid in the everting of the tissue edges and the AnastoClip Remover for the removal of any AnastoClip GC clips (if necessary).

MR Compatibility

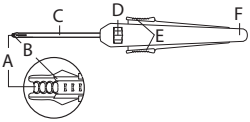
Non-clinical testing demonstrated that the AnastoClip GC Closure System is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the AnastoClip GC Closure System is expected to produce a maximum temperature rise of 1.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the AnastoClip GC Closure System extends approximately 4-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Schematic View And Nomenclature

A) Clips
B) Jaws
C) Shaft
D) Rotation Knob
E) Levers
F) Handle



Designs available:

AnastoClip Applier	Medium	Large	Extra Large
3" (7.6 cm) Shaft	4008-06	4008-07	4008-08
6" (15.2cm) Shaft	4010-01	4010-02	4010-03

How Supplied:

The applier is supplied sterile. The sterility of the device is assured as long as the packaging is not opened or damaged.

The entire device is considered to be non-pyrogenic for vascular applications.

The implantable clips, the stainless steel shaft and jaws of the applier are considered to be non-pyrogenic for dura applications. The plastic part of the applier (handle, levers and rotation knob) should not be in contact with cerebral spinal fluid.

Instructions For Use

NOTE: It is recommended to wear loupes. A 2.5X magnification is suggested.

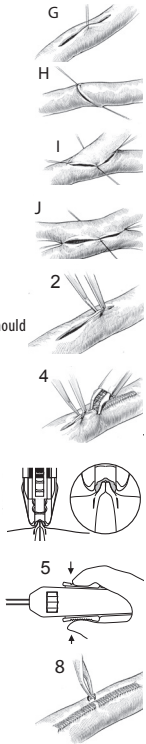
1. Preparation of tissues is recommended as follows:
   - G) ARTERIOTOMY OR VENOTOMY: One optional stay suture at mid-incision.
   - H) END-TO-END: Horizontal mattress sutures at 3 and 9 o'clock.
   - I) END-TO-SIDE: Horizontal mattress sutures heel and toe: stay sutures at 3 and 9 o'clock.
   - J) SIDE-TO-SIDE: Horizontal mattress sutures at 12 and 6 o'clock: stay sutures at 3 and 9 o'clock.

NOTE: Additional sutures may be placed depending on the length of the closure, in order to facilitate a symmetrical eversion.

2. Symmetrically evert all tissue layers for secure nonpenetrating clip placement. Evert the tissue edges of the vessel with either design of tissue everting forceps. Ensure that all tissue edges are symmetrically everted prior to applying the clip. Failure to symmetrically evert the tissue edges properly can result in possible bleeding or leakage.
3. Inspect the tissue wall to ensure that the forceps do not damage tissue during manipulation.

NOTE: Atraumatic Tissue Everting Forceps are designed to minimize potential damage to blood vessels or other small tubular structures.

4. Place the instrument jaws onto the everted tissue edges to be anastomosed, making certain that the tissue fits completely within the confines of the jaws. The tissue must comfortably fit within the confines of the jaws, or the use of the instrument is contraindicated.
5. Squeeze the levers together fully until a discernible click is felt. As the levers are squeezed, the clip is held firmly in the jaws and closed around the tissue. Clip placement should be as close as possible. There should not be more than 0.5 mm between clips (see illustration #7).



FAILURE TO COMPLETELY SQUEEZE THE LEVERS CAN RESULT IN CLIP MALFORMATION AND POSSIBLE BLEEDING OR LEAKAGE.

6. Release the levers to disengage the clip from the AnastoClip GC applier and remove the clip applier. (The closed clip is disengaged automatically from the jaws.) The applier automatically advances the next clip for successive applications.
7. Check tightness of clip placement. Tissue should completely fill clip opening and clip should not loosely rock side to side.
8. If desired, the clip can be removed with the AnastoClip Remover and a new clip can be placed with the AnastoClip GC applier.
9. After completion of the anastomosis, one or more clips, and/or sutures, may be used to control bleeding or leakage from the anastomotic site (if necessary.)

A) Size M

Approximate Span Before Closure	Approximate Overall Length	Clips Per Applier
1.1 mm	2.3 mm	35

The shape of the closed clip may vary according to tissue thickness.
The amount of Titanium that a patient is exposed to is 45 milligrams per Applier if the entire load of the applier is implanted.

B) Size L

Approximate Span Before Closure	Approximate Overall Length	Clips Per Applier
1.7 mm	3.3 mm	35

The shape of the closed clip may vary according to tissue thickness.
The amount of Titanium that a patient is exposed to is 92 milligrams per Applier if the entire load of the applier is implanted.

C) Size XL

Approximate Span Before Closure	Approximate Overall Length	Clips Per Applier
2.5 mm	4.9 mm	25

The shape of the closed clip may vary according to tissue thickness.
The amount of Titanium that a patient is exposed to is 140 milligrams per Applier if the entire load of the applier is implanted.

Warning

- SYMMETRICALLY EVERT ALL TISSUE EDGES
- PLACE CLIPS AS CLOSE AS POSSIBLE TO ONE ANOTHER
- AVOID USE ON VESSELS SEVERELY COMPROMISED DURING ENDARTERECTOMY

FAILURE TO OBSERVE THE ABOVE MAY CONTRIBUTE TO INTEROPERATIVE OR POST-OPERATIVE (SEVERAL DAYS) FAILURE OF ANASTOMOSIS RESULTING IN SERIOUS PATIENT INJURY.

Cautions

1. Squeeze the levers together fully until a discernible click is felt. Failure to squeeze the levers completely can result in clip malformation and possible bleeding or leakage.
2. Ensure that the tissue to be anastomosed fits completely within the confines of the jaws or bleeding and leakage may result. See figure below.
3. Place the clips in such a fashion that they are not "rocking" on their axis ("tips"). See figure below.

4. Inspect the anastomotic site to ensure proper application and that hemostasis has been achieved. If bleeding is observed after application, additional clips or placement of manual sutures may be necessary to complete hemostasis.
5. Do not evert the tissue by grasping one tissue edge with one pair of forceps and the other tissue edge with another pair of forceps and pulling them together to evert and apply the clips. This may result in asymmetrical eversion of tissue, which could result in possible bleeding or leakage.
6. Inspect the tissue wall to ensure that the forceps do not damage tissue during manipulation.
7. When using the AnastoClip GC applier with tissue, ensure that the total thickness of the everted tissue to be anastomosed does not exceed the total width of the clip being used (see tables A, B, and C).

Contraindications

1. Do not use the AnastoClip GC applier if tissue can not be properly everted due to the presence of arteriosclerotic or calcified material, or where the vessel has been severely compromised due to endarterectomy (e.g., carotid or any other artery in this condition).
2. The clips should not be more than 0.5 mm between one another. If this cannot be achieved, use of the AnastoClip GC applier is contraindicated.
3. Do not use the AnastoClip GC applier if all the tissue layers cannot be completely symmetrically everted prior to application of the clip.
4. Do not use the AnastoClip GC applier on tissue that is too friable for use of sutures.
5. The tissue must comfortably fit within the confines of the jaws, or use of the instrument is contraindicated.
6. The AnastoClip GC applier is not intended for use except as indicated. DISCARD AFTER USE. DO NOT RESTERILIZE.

Complications

- Infection
- Pain/swelling
- Tissue damage
- Blood leakage
- Hemorrhage
- Embolism
- Stenosis
- Intimal dissection
- Thrombosis/occlusion
- Anastomosis rupture
- Dehiscence
- Necrosis
- Seroma
- Anastomotic insufficiency
- Pseudoaneurysm
- Nerve injury
- Steal phenomenon
- Intimal hyperplasia
- Cerebrospinal fluid (CSF) leak
- Pseudomeningocele
- Neuropathic pain
- Spinal infarction

Resterilization/Re-use

This device is single-use only. Do not reuse, reprocess, or re-sterilize. The cleanliness and sterility of the re-processed device cannot be assured. Reuse of the device may lead to cross contamination, infection, or patient death. The performance characteristics of the device may be compromised due to reprocessing or re-sterilization since the device was only designed and tested for single use. The shelf life of the device is based on single use only.

Notices: Limited Product Warranty; Limitation Of Remedies

LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device and that this device is suitable for the indication(s) expressly specified in these instructions for use. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

血管及管状组织闭合系统
(型号、规格：4010-01, 4010-02, 4010-03)

STERILE EO **Rx only**

重要提示：
本册旨在辅助带有纯钛闭合夹的AnastoClip GC® 闭合系统的使用，不适用于在其他手术技术中使用。

在使用产品前，请仔细阅读以下信息。

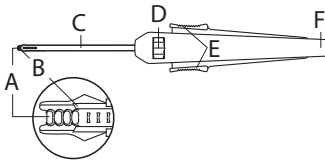
适用范围
AnastoClip GC产品适用于组织穿透时血管及其它小管状结构的翻转吻合。

结构与组成
该产品由闭合钉、手柄及移除器组成。闭合钉材料为纯钛。环氧乙烷灭菌，产品一次性使用。有效期5年。

作用
AnastoClip GC适用于以下种尺寸的闭合钉：中号-1.1mm，大号-1.7mm，超大号-2.5mm。AnastoClip GC是由一个旋转轴和一个装有闭合钉的完整的夹子组成。当闭合夹的控制杆同时被紧握时，在组织边缘的闭合钉即被闭合。当松开控制杆后，新的闭合钉将自动进入闭合夹的口端。我们建议使用翻转组织边缘时使用组织翻转镊，去除AnastoClip GC闭合钉时使用移除器（如需要）。

MR相容性
无临床试验表明AnastoClip AC对于MR适用是有条件的。带有闭合夹的病人在下述条件下可以适用MR进行安全的扫描。
仅1.5-Tesla和3-Tesla的静磁场条件下。
最大为2000 Gauss/cm （20-T/m）的空间磁场领域。
被报告的最大MR系统，正常操作模式下扫描15分钟（即每脉冲序列）整个身体平均的特定吸收率（SAR）为2-W/kg。
在被限定的扫描条件下，预期AnastoClip AC在连续扫描15分钟（即每脉冲序列）后的最大升温温度为1.5度。在非临床实验中，当使用梯度回波脉冲和3-Tesla MR系统成像时，AnastoClip AC引起大约4mm的图像伪影。

图解和命名
a. 闭合钉
b. 闭合夹口端
c. 工作杆
d. 方向旋钮
e. 闭合释放钮
f. 手柄

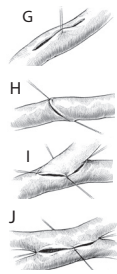


可使用的型号、规格：

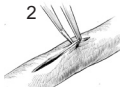
AnastoClip GC	中号	大号	超大号
15cm工作杆	4010-01	4010-02	4010-03

供应方式：
此器械为无菌供应。只要器械的包装没有打开或破损可认为此器械保持一直无菌。对于血管手术的应用整个器械是无热原的。

使用说明
注：建议配戴A2.5X倍放大率的小型放大镜。
1. 建议如下准备工作：
   g. 动脉或静脉切开术：可选择在中部切口留缝。
   h. 端端缝合术：在3点和9点钟方向的水平式缝合。
   i. 端侧缝合术：头部和尾部的水平式缝合，在3点和9点钟方向留缝。
   j. 侧侧缝合术：在6点和12点方向的水平式缝合：在3点和9点钟方向留缝。
   注：为了能对称翻转，可以根据缝合长度额外增加缝合点。
   注：无损伤组织镊旨在减少潜在或者其它小管状结构的危害。

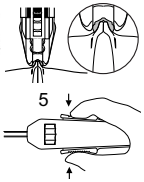


2. 为了能固定非穿透性闭合钉，请对称地翻转组织层。用组织翻转镊翻转组织的边缘。用该镊子确保所有的边缘组织是对称翻转的。不对称的翻转边缘组织可能会导致出血或渗漏。



3. 检查血管壁，确保在操作过程中，镊子没有损坏血管。
注意：无创伤性组织翻转镊是为了尽量减少潜在的损害血管及其他小管状结构而设计的。
4. 把器械的闭合夹口端放在翻转组织的边缘以便使他们吻合，确保组织与闭合夹口端刚好相吻合，否则禁止使用该器械。

5. 捏压闭合释放钮，直到感到咔嗒一下。当紧握闭合释放钮，闭合钉会被稳固在闭合夹口端并闭合组织边缘。闭合钉的排序应该尽可能紧凑，不能超过0.5mm（参见图7）。
如果不能完全紧捏闭合释放钮，则可能导致组织出血或者渗漏。



6. 松开闭合释放钮，使闭合钉会从AnastoClip GC上脱离出来，然后移开AnastoClip GC。（闭合的闭合钉会自动从闭合夹口端脱离。）AnastoClip GC会自动推上新的闭合钉以便连续使用。
7. 检测闭合钉放置的牢固度。组织应能被闭合钉完全闭合并且闭合钉不应松脱。
8. 如果需要，可以使用AnastoClip移除器拆卸旧闭合钉，然后通过AnastoClip GC重新放置一个新闭合钉。

9. 在吻合术完成后，如果有必要的话，多添加一个或者更多的闭合钉，和/或缝合点，可以用来控制出血或渗漏。

A）中号

闭合钉闭合前的跨度（近似值）	总长度（近似值）	闭合钉的数量
1.1mm	2.3mm	35

闭合钉的形状可能会随组织的厚度而有所变化。
如果一个完整AnastoClip GC的全部被植入的话，那么将有45毫克的钛暴露给病人。

B）大号

闭合钉闭合前的跨度（近似值）	总长度（近似值）	闭合钉的数量
1.7mm	3.3mm	35

闭合钉的形状可能会随组织的厚度而有所变化。
如果一个完整AnastoClip GC的全部被植入的话，那么将有92毫克的钛暴露给病人

C）超大号

闭合钉闭合前的跨度（近似值）	总长度（近似值）	闭合钉的数量
2.5mm	4.9 mm	25

闭合钉的形状可能会随组织的厚度而有所变化。
如果一个完整AnastoClip GC的全部被植入的话，那么将有140毫克的钛暴露给病人。

警告

- **必须对称地翻转组织边缘**
- **放置闭合钉时，闭合钉的排序要尽可能的紧凑**
- **避免使用于在动脉内膜切除术中严重受损的血管**
- **尽可能地紧捏闭合释放钮**

不遵守以上警告，可能导致吻合术失败及在术中或术后（若干天）对患者造成伤害。

注意事项

1. 要尽可能地同时紧捏闭合释放钮。不正确的操作可能导致闭合钉变形或者组织出血。
2. 确保组织刚好与闭合夹口端相吻合，否则可能会导致出血和渗漏。见下图。
3. 以下列的方式放置闭合钉，放置方式应避免钉在缝合轴附近移动或晃动。见下图。

4. 检查吻合后的部位，以达到完全吻合及止血的目的。如果吻合术后出现出血的情况，增加闭合钉或缝合点，可以用来控制出血。
5. 不要用一把组织镊翻转组织，而用另一把组织镊翻转另一侧组织。这可能导致非对称地翻转，从而可能导致组织出血。
6. 检查血管壁，确保在操作过程中没有损坏血管。
7. 当AnastoClip GC用于组织时，确保翻转的组织和移植物的总厚度与闭合夹刚好吻合（见表A，B和C）。

禁忌症

1. 如果由于动脉硬化或钙化而不能很好地翻转，或者组织（例如颈动脉或其他任何动脉）在动脉内膜切除术中受损，请不要使用AnastoClip GC。
2. 闭合钉之间的距离不应该超过0.5mm。如果无法达到，请不要使用AnastoClip GC。
3. 在闭合钉吻合之前，如果所有的组织层不能很好的对称翻转，请不要使用AnastoClip GC。
4. 如果组织已脆弱到无法用线缝合时，不可使用AnastoClip GC。
5. 组织应该刚好适合闭合夹口端的跨度，否则请不要使用AnastoClip GC。
6. AnastoClip GC不适用于上述适应症意外的情况。使用后请销毁。不可重复使用。

并发症

- 感染
- 疼痛/肿胀
- 组织坏死
- 漏血
- 出血
- 栓塞
- 狭窄
- 内膜分离
- 血栓/栓塞
- 吻合断裂
- 裂开
- 坏死
- 积液
- 吻合不充分
- 假动脉瘤
- 盗血
- 内膜增生

重复灭菌/重复使用

该器械是一次性使用，请不要重复使用，重复加工，或者重复灭菌。重复使用该器械可能导致交叉污染，感染，甚至患者死亡。由于该器械是为了一次性使用设计和测试的，如果重复加工或灭菌，可能导致该器件的性能受到影响。该器械的灭菌有效期是基于一次性使用。

安全处理与丢弃

在使用此器械过程中如有严重医疗事故发生，使用者需通知LeMaitre Vascular以及使用者所在国家的主管部门。

本产品不含有尖锐物、重金属或放射性同位素，并且无传染性或致病性。对于丢弃处理无特殊要求，请咨询当地管理部门以确认正确丢弃方式。

被移除AnastoClip的包装和运输

运输返还到LeMaitre Vascular要依据2个重要问题：

1. 在移除生物补片时，生物补片是来源于一个已知或假定致病性条件的病人吗？
2. 移除的生物补片是来源于一个具有已知治疗历史且在最近6个月内进行过放射性核素治疗的病人吗？

如果问题1或2是的回答是肯定的，LeMaitre Vascular不提供用于运输的适当指导。**在任何环境中，这些移除物不应被返还到LeMaitre Vascular。**在这种情况下，移除物应根据当地的法规要求进行丢弃。

移除物无致病性或放射性危害，请使用下述方法：

预移除：

LeMaitre Vascular可接受隐去病人匿名的临床信息。
LeMaitre Vascular要求的信息包括：

1. 导致使用植入物的原始诊断。
2. 涉及到植入物的病人的相关医疗历史，包括在哪个医院或诊所进行的移植。

3. 在植入物移除之前的病人的植入经历。
4. 在哪个医院或诊所进行的移除，以及移除日期。

移除：

1. 被移除的闭合夹应选用下列方法之一进行清洁：
    a. 使用大量水冲洗，然后放入70-80%的乙醇中，或
    b. 在异丙醇中清洗，并随后采用超声处理，或
    c. 在水解蛋白酶溶液中清洗，或
    d. 在次氯酸钠溶液（50-60mg/L）中清洗，或
    e. 使用3%的过氧化氢清洗。
2. 被移除的闭合夹应使用高压灭菌器处理样品或使用环氧乙烷气体净化样品。
3. 完全干燥后方可包装。

包装：

1. 移除物应采用密封并包装的这样一种方式，这种运输方式在运输过程中应可将破碎、环境污染或暴露包装的情况最小化。应采用吸收剂或缓冲器以隔离密封容器以便放入次级包装中。此后初级包装和次级包装必须要放在一个外层包装中。
2. 装有移除物的密封容器应贴有带有ISO 7000-0659生物危害符号的标签。次级包装盒外包装上同样也应贴有同样符号的标签。外包装上应有邮寄的名称、地址和电话号码，并且写明“如发现损坏或泄露，应将此包裹隔离并通知邮寄人”。
3. 对于外层运输包装容器的装运文件是不需要的。
4. 采用上述方式准备的包裹可邮寄至：

LeMaitre Vascular
63 Second Avenue, Burlington, MA 01803

是否清洗干净，是否被损坏，确保镊子在消毒之前能正常工作且洁净。

产品有效期限：5年。

医疗器械注册证编号：国械注进20173020176

产品技术要求编号：国械注进20173020176

注册人/生产企业：

名称：LeMaitre Vascular, Inc. 乐脉血管医疗器械股份有限公司
住所/生产地址：63 Second Avenue, Burlington, MA 01803, USA
电话：001-781-2212266
传真：001-781-2212223

代理人/售后服务单位：

名称：乐脉医疗科技（上海）有限公司
住所：上海市徐汇区宜山路407-1号809室
电话/传真：021- 64696919

中文说明书修订日期：

2022年02月

Symbol Legend

		Distributed By:	EC REP		REF	LOT			cm	Rx only
English	Symbol Legend	Distributed By	Authorized Representative in the European Community	Manufacturer	Catalogue Number	Batch Code	Use-by date	Date of Manufacture	Usable Length	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.
中文	符号	经销商	欧盟代表机构	制造商	注意	批号	失效日期	生产日期	可用长度	提示:美国法律限制只有医生才可以购买此器械.

	STERILE EO					Parts of the device	MR	MD
English	Sterilized using ethylene oxide	Do Not Use if Package is Opened or Damaged	Do not re-use	Do not resterilize	Consult instructions for use	Consult the How Supplied section of the instructions for use.	MR Conditional	Medical Device
中文	环氧乙烷灭菌	如果包装受损或被打开, 请勿使用.	不可重复使用	不可重复灭菌	请参考电子版使用说明	请参考使用说明书中产品提供部分	特定条件下核磁共振兼容	医疗器械

LeMaitre®
VASCULAR

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