LeMaitre® VASCULAR

AnastoClip GC® Closure System
Disposable (Single Use Only)
Sterile
Instructions for Use

AnastoClip GC® 血管及管状组织闭合系统
使用说明书

AnastoClip GC® Closure System

AnastoClip GC® Closure System

(Model Numbers 4007-06, 4007-07, 4007-08)

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

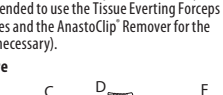
The AnastoClip GC is intended for use in the creation of everting anastomoses in blood vessels and other small tubular structures when tissue penetration is desired.

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. The AnastoClip GC applier consists of a rotating shaft and an integral cartridge containing titanium clips. The AnastoClip implantable clip is made of titanium and it is MRI-Conditional (up to 3 Tesla). 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).

Schematic View And Nomenclature

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



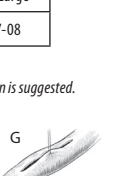
Designs available:

AnastoClip Applier	Medium	Large	Extra Large
3" (7.6 cm) Shaft	4007-06	4007-07	4007-08

Instructions For Use

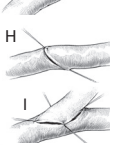
NOTE: It is recommended to wear loupes. A 2.5X magnification is suggested.

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.

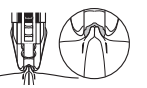
2. Symmetrically evert all tissue layers for secure nonpenetrating clip placement. Evert the tissue edges of the vessel with either design of tissue everting forceps. Ensure that all tissue edges are symmetrically everted prior to applying the clip. Failure to symmetrically evert the tissue edges properly can result in possible bleeding or leakage.



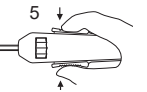
3. Inspect the tissue wall to ensure that the forceps do not damage tissue during manipulation.

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. If desired, the clip can be removed with the AnastoClip Remover and a new clip can be placed with the AnastoClip GC applier.
8. 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) 4007-06: 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.

B) 4007-08: 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.

C) 4007-09: Size XL

Approximate Span Before Closure	Approximate Overall Length	Clips Per Applier
2.5 mm	4.93 mm	25

The shape of the closed clip may vary according to tissue thickness.

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.
3. Place the clips in such a fashion that they are not "rocking" on their axis ("tips").
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

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. 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. LeMaitre Vascular makes no representation regarding the suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. 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.

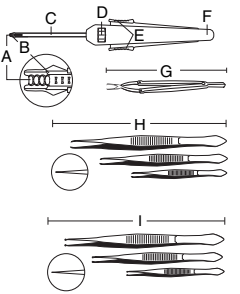
IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT 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.

AnastoClip GC® 血管及管状组织闭合系统
(型号 4007-06, 4007-07, 4007-08)
组织翻转镊和移除器
使用说明书

STERILE EO **Rx only**

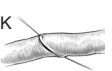
环氧乙烷灭菌
重要提示:
这本小册子只在使用AnastoClip GC®时实用的，在其它手术技术中不实用。
在使用产品前，请仔细阅读以下信息。
适用症
AnastoClip GC应用于以下情况：组织穿透时血管及其它小管状结构的翻转吻合。
组成
AnastoClip GC由一个可旋转的手柄和一个装有钛钉的完整的夹子组成。当闭合夹的闭合释放钮同时被紧握时，在组织边缘的钉子就闭合了。当松开闭合夹的闭合释放钮后，新的钉子将自动进入闭合夹的口端。我们建议，每次手术时，翻转组织边缘时使用组织翻转镊。该镊子具备两种长度。我们还建议，每次手术时，如果需要去除任何钉子时， 使用AnastoClip 移除器。



图解和命名
A) 钉子
B) 闭合夹口端
C) 工作杆
D) 方向旋钮
E) 闭合释放钮
F) 手柄
G) AnastoClip 移除器
H) 翻转镊
I) 无损伤翻转镊

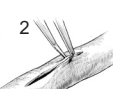
翻转镊尺寸和款式

长度	无损伤翻转镊
18 cm (7.0")	✓



注：无损伤组织翻转镊旨在减少潜在或者其它小管状结构的危害。

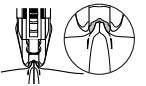
使用说明：
注：建议配戴2.5X倍放大率的小型放大镜。
1. 在使用组织翻转镊前，必须清洗和消毒!(参考清洗和消毒方法)。
   建议的准备工作如下：
J) 动脉或静脉切开术：可选择在中部切口留缝。
K) 端端缝合术： 在3点和9点钟方向的水平式缝合。



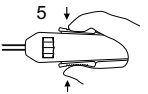
L) 端侧缝合术：头部和尾部的水平式缝合，在3，9点钟方向留缝。

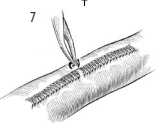
M) 侧侧缝合术：在6点和12点方向的水平式缝合：在3，9点钟方向留缝。

注:为了能对称外翻，可以根据缝合长度额外增加缝合点。

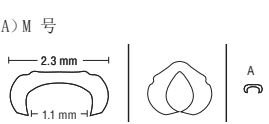


2. 为了能固定非穿透性钉，请对称地翻转组织层。用组织翻转镊，翻转组织的边缘。用该镊子确保所有的边缘组织是对称翻转的。不对称的翻转边缘组织可能会导致出血或者渗漏。
3. 检查血管壁，确保在操作过程中，镊子没有损坏血管。
   注意：无创伤性组织翻转镊是为了尽量减少潜在的损害血管或其他小管状结构而设计的。
4. 把器械的闭合夹口端放在翻转组织的边缘，以便使他们吻合。确保组织与闭合夹口端刚好相吻合，否则禁止使用该器械。
5. 捏压闭合释放钮，直到感到咔嗒一下。，当紧捏闭合释放钮，钉会被稳固在闭合夹口端并闭合组织边缘。钉的排序应该尽可能紧凑，不能超过0.5mm（参见图7）.
   注意：如果不能完全紧捏闭合释放钮，则可能导致组织出血或者渗漏。
6. 松开闭合释放钮，钉会从**AnastoClip**闭合夹上脱离出来，然后移开**AnastoClip**闭合夹（钉会由闭合夹口端自动脱落）。**AnastoClip**闭合夹会自动把下一个钉顶至最前端。
7. 检查夹子的稳固性。如果需要，可以使用**AnastoClip**移除器拆卸旧钉，然后通过**AnastoClip**闭合夹重新装上一个新钉。拆卸旧钉时，将**AnastoClip**移除器放置于底端并穿过已经闭合的旧钉子。然后紧握**AnastoClip**移除器的手柄，从而将钉从组织移开。
8. 在吻合术完成后，如果有必要的话，多添加一个或者更多的钉，和/或缝合点，可以用来控制出血。





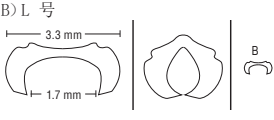
A）M 号



钉在闭合之前的跨度（近似值）	总长度（近似值）	钉数
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。

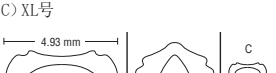
B）L 号



钉在闭合之前的跨度（近似值）	总长度（近似值）	钉数
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

C）XL号



钉在闭合之前的跨度（近似值）	总长度（近似值）	钉数
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。

警告

- 必须对称地翻转组织边缘
- 放置钉时，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 放置钉子时，钉子之间的距离应该尽可能的近，不应该超过0.5mm。还应把钉子尽可能放在缝线近的地方。
2 要尽可能地同时紧捏闭合释放钮。不正确的操作可能导致钉变形或者组织出血。
3 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。
4 钉的放置方式应避免钉在缝合轴附近移动或晃动。
5 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，增加钉或缝合点，可以用来控制出血。
6 如果因为动脉硬化或钙化，组织不能很好的翻转，请不要使用该产品。
7 不要用一把组织镊翻转一侧组织，而用另一把组织镊翻转另一组织。这可能导致非对称地翻转，这样就可能会导致组织出血。
8 检查血管，确保在操作过程中没有损坏血管。
9 当组织翻转镊的两尖端在闭合时相互交叉，请不要使用该组织镊来翻转组织。
10 当使用组织翻转镊时，确保需闭合的组织厚度应不超过闭合钉宽度。（见表A、B、C）
11 该组织翻转镊为“非无菌”包装，所以在使用前应先清洗，消毒。
12 AnastoClip GC 闭合夹是无菌一次性使用的。
13 AnastoClip GC 移除器是无菌一次性使用的。

禁忌

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闭合夹。
2 AnastoClip GC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 闭合夹。
3 在钉子吻合之前，如果所有的组织层不能很好的对称翻转，请不要使用AnastoClip GC 闭合夹。
4 如果组织已脆弱到无法用线缝合时， 不可使用AnastoClip 闭

合夹。
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 闭合夹。
6 AnastoClip 闭合夹不适用于上述适应症以外的情况。使用后请销毁。不能重复灭菌。
7 当组织翻转镊的两尖端在闭合时相互交叉，请不要使用该组织翻转镊。

警告：为了在搬运过程中保护组织翻转镊，组织翻转镊的外面有保护套，在清洗，消毒及使用前，先拆下保护套。

组织翻转镊的清洗和消毒办法

警告：提供的组织翻转镊是“非灭菌”产品，在使用前应清洗和消毒。

清洗办法

用清洗的毛巾擦洗所有可见的污迹，准备制造商推荐的酶洗涤剂。将镊子放入酶清洗剂中至少一分钟。用软毛刷清除剩余的脏物，特别注意镊子内侧的铰链，锯齿状的夹具和头端。用清水或蒸馏水冲洗洗涤剂和痕迹。检查镊子是否清洗干净，是否被损坏，确保镊子在消毒之前能正常工作且洁净。

消毒杀菌

组织翻转镊可在常态或真空中消毒，在进行消毒杀菌时，建议按照以下时间和温度进行：

非真空蒸汽灭菌
被包裹的镊子
温度：270-275° F (132-135° C)
处理时间：10分钟

非真空蒸汽灭菌
未被包裹的镊子
温度：270-275° F (132-135° C)
处理时间：10分钟

真空蒸汽灭菌
被包裹的镊子
温度：270-275° F (132-135° C)
处理时间：4分钟

真空蒸汽灭菌
未被包裹的镊子
温度：270-275° F (132-135° C)
处理时间：4分钟

重复灭菌/重复使用

该器械(镊子除外)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。该器械的使用有效期是基于一次性使用。

注意：产品保证

LeMaitre Vascular公司认为，在生产该设备的过程中已经相当谨慎了。除明确规定外，LeMaitre Vascular（如用于在本条中，此类条款包括LeMaitre Vascular公司，及其关联公司及其各自的雇员，官员，董事，经理和代理商）不作任何关于这一装置明示或暗示保证，无论是通过法律或其他形式的方式，并谨此声明。本有限保证不适合于任何滥用或误用，或未能妥善贮存的任何买方或第三方。对于这一有限保修的唯一的补救方法是更换保修，或者是跟着买方退还设备，而退还货

Symbol Legend

				**Rx only**			
English	Symbol Legend	Distributed By	Quantity	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.	Do Not Use if Package is Opened or Damaged	Consult instructions for use	Non-pyrogenic
中文	符号	经销商	数量	提示:美国法律限制只有医生才可以购买此器械.	如果包装受损或被打开,请勿使用.	请参考电子版使用说明	无致热原

LeMaitre®
VASCULAR

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产品名称：血管及管状组织闭合系统
注册证编号：国械注进20173460176
注册产品标准编号：YZB/USA 0735-2013
注册人及生产企业名称：LeMaitre Vascular, Inc.
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EC REP

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