LeMaitre® VASCULAR

AnastoClip GC® Closure System

AnastoClip GC® Closure System
English — Instructions for Use

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

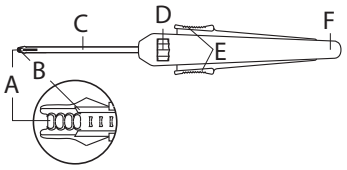
Non-clinical testing demonstrated that the AnastoClip GC Closure System is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- 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.

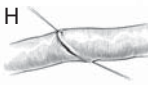
1. Preparation of tissues is recommended as follows:
   G) ARTERIOTOMY OR VENOTOMY: One optional stay suture at mid-incision.
   H) END-TO-END: Horizontal mattress sutures at 3 and 9 o'clock.
   I) END-TO-SIDE: Horizontal mattress sutures heel and toe: stay sutures at 3 and 9 o'clock.
   J) SIDE-TO-SIDE: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

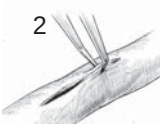
NOTE: Additional sutures may be placed depending on the length of the closure, in order to facilitate a symmetrical eversion.

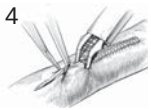
2. Symmetrically evert all tissue layers for secure nonpenetrating clip placement. Evert the tissue edges of the vessel with either design of tissue everting forceps. Ensure that all tissue edges are symmetrically everted prior to applying the clip. Failure to symmetrically evert the tissue edges properly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

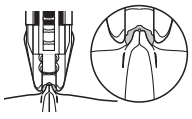
NOTE: Atraumatic Tissue Everting Forceps are designed to minimize potential damage to blood vessels or other small tubular structures.

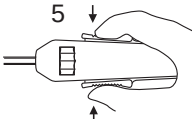
4. Place the instrument jaws onto the everted tissue edges to be anastomosed, making certain that the tissue fits completely within the confines of the jaws. The tissue must comfortably fit within the confines of the jaws, or the use of the instrument is contraindicated.
5. Squeeze the levers together 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).

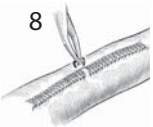








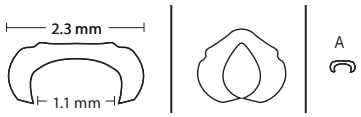




FAILURE TO COMPLETELY SQUEEZE THE LEVERS CAN RESULT IN CLIP MALFORMATION AND POSSIBLE BLEEDING OR LEAKAGE.

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

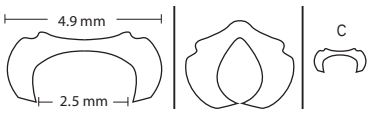
The shape of the closed clip may vary according to tissue thickness.

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.

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.

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. 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.

Symbol Legend

									Rx only
Distributed By	Authorized Representative in the European Community	Manufacturer	Catalogue Number	Batch Code	Use-by date	Date of Manufacture	Quantity	Usable Length	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.

						
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

LeMaitre® VASCULAR

Distributed By:

LeMaitre Vascular, Inc.
Customer Service:
Tel: 781 221-2266
Fax: 781 221-2223

LeMaitre Vascular GK
1F Kubodera Twin Tower Bldg.
2-9-4 Kudan-minami, Chiyoda-ku
Tokyo 102-0074, Japan
Tel: +81-(0)3-5215-5681

LeMaitre Vascular ULC
9135 Keele Street, Suite B6
Vaughan, Ontario
Canada L4K 0J4
Tel: 855-673-2266

EC REP

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts., Germany
Tel: +49-(0)6196-659230

LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803

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