LeMaitre®
VASCULAR

# AnastoClip® AC Closure System

**AnastoClip® AC Closure System**
English — Instructions for Use

# **AnastoClip®** AC Closure System

## Tissue Everting Forceps and Clip Remover

(Model Numbers 4012-01, 4012-02, 4012-03, 4013-00, 4013-01, e4012-01, e4012-02, e4012-03, 4013-00, e4013-00, e4013-01)
English — Instructions for Use

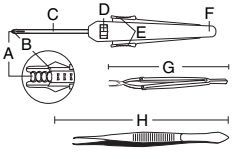
**STERILE EO Rx only**

**IMPORTANT!**
This booklet is designed to assist in using the AnastoClip® AC 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 applier has application in the repair of arteriovenous fistulae and the creation of everting anastomoses in blood vessels and other small tubular structures. The Applier is also intended for approximation of dural tissue (dural approximation only indicated for use with Medium, Large, and Extra Large appliers, not Small appliers).

**Effects**
The AnastoClip applier is available in four (4) clip sizes: small-0.9 mm, medium-1.4 mm, large-2.0 mm and extra large-3.0 mm. The AnastoClip applier is also available in three (3) lengths: 2 in distal shaft, 3 in. distal shaft and 6 in. distal shaft. The AnastoClip AC clip 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, with each procedure, to use the Tissue Everting Forceps to aid in the everting of the tissue edges. It is also recommended, with each procedure, to use the AnastoClip remover for the removal of any clips (if necessary). The remover is available in two (2) lengths.




**Schematic View And Nomenclature**

A) Clips
B) Jaws
C) Shaft
D) Rotation Knob
E) Levers
F) Handle
G) AnastoClip remover
H) Atraumatic Everting Forceps

Designs available:

| AnastoClip Applier | Small | Medium | Large | Extra Large |
|---|---|---|---|---|
| 2" (5 cm) Shaft | ✓ | | | |
| 3" (7.6 cm) Shaft | | ✓ | ✓ | ✓ |
| 6" (15.2 cm) Shaft | | ✓ | ✓ | ✓ |

| AnastoClip Remover | Usable Length | Width at rest | Application |
|---|---|---|---|
| Traditional | 4" (10cm) | >24mm (.9") | Shallow, wide access |
| Elongated | 6" (15cm) | >18mm (.7") | Deep, narrow access |

NOTE: Atraumatic Tissue Everting Forceps are designed to minimize potential damage to blood vessels or other small tubular structures.
NOTE: Usable Length on the Remover refers to the distance between the tips and the midpoint of the serrated region on the handle.

**Instructions For Use**
NOTE: It is recommended to wear loupes. A 2.5X magnification is suggested.
THE TISSUE EVERTING FORCEPS MUST BE CLEANED AND STERILIZED PRIOR TO USE! (REFER TO CLEANING AND STERILIZATION METHOD).

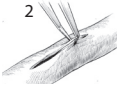
1. Preparation of tissues is recommended as follows:
   - I) ARTERIOTOMY OR VENOTOMY: One optional stay suture at mid-incision.
   - J) END-TO-END: Horizontal mattress sutures at 3 and 9 o'clock.
   - K) END-TO-SIDE: Horizontal mattress sutures heel and toe: stay sutures at 3 and 9 o'clock.
   - L) SIDE-TO-SIDE: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



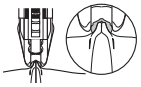




3. Inspect the tissue wall to ensure that the forceps do not damage tissue during manipulation. NOTE: Atraumatic Tissue Everting Forceps are designed to minimize potential damage to blood vessels or other small tubular structures.

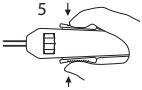

4. Place the instrument jaws onto the everted tissue edges to be anastomosed, making certain that the tissue fits completely within the confines of the jaws. The tissue must comfortably fit within the confines of the jaws, or the use of the instrument is contraindicated.

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).

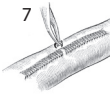


FAILURE TO COMPLETELY SQUEEZE THE LEVERS CAN RESULT IN CLIP MALFORMATION AND POSSIBLE BLEEDING OR LEAKAGE.

6. Release the levers to disengage the clip from the AnastoClip 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 applier. To remove the clip, place the AnastoClip remover underneath and through the apex of the already placed clip. Squeeze the handles of the AnastoClip remover together. This process will open the clip and allow for the clip to be removed from the tissue.




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) Size S**


| Approximate Span Before Closure | Approximate Overall Length | Clips Per Applier |
|---|---|---|
| 0.9 mm | 1.4 mm | 40 |

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

**B) Size M**


| Approximate Span Before Closure | Approximate Overall Length | Clips Per Applier |
|---|---|---|
| 1.4 mm | 2.3 mm | 35 |

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

**C) Size L**


| Approximate Span Before Closure | Approximate Overall Length | Clips Per Applier |
|---|---|---|
| 2.0 mm | 3.3 mm | 35 |

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

**D) Size XL**


| Approximate Span Before Closure | Approximate Overall Length | Clips Per Applier |
|---|---|---|
| 3.0 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**
- **SQUEEZE THE APPLIER HANDLES AS FAR AS THEY WILL GO**

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

**Cautions**

1. The levers must be squeezed together firmly as far as they will go. 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 AnastoClips 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 applier with tissue or prosthetic graft material (e.g., Meadox, knitted polyester) ensure that the total thickness of the everted tissue and graft material to be anastomosed does not exceed 1.0 mm for the medium 1.4 mm clip applier, 1.6 mm for the large 2.0 mm clip applier and 1.8 mm for the extra large 3.0 mm clip applier.
8. When using the AnastoClip S-0.9 mm clip applier on tissue, ensure that the total thickness of the everted tissue does not exceed 0.5 mm.
9. The tissue everting forceps are packaged NONSTERILE and must be cleaned and sterilized prior to use.
10. The AnastoClip applier is provided STERILE and is intended for use in a SINGLE procedure only.
11. The AnastoClip remover is provided STERILE and is intended for use in a SINGLE procedure only.

**Contraindications**

1. Do not use the AnastoClip 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 AnastoClips should not be more than 0.5 mm between one another. If this cannot be achieved, use of the AnastoClip applier is contraindicated.
3. Do not use the AnastoClip applier if all the tissue layers cannot be completely symmetrically everted prior to application of the clip.
4. Do not use the AnastoClip 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. Do not use the AnastoClip S-0.9 mm clip applier on any prosthetic graft material.
7. Do not use the tissue everting forceps if the tips scissor when they are closed.

NOTE: The tissue everting forceps are packaged with instrument guards to protect the tip of the forceps during shipment. Remove the protective guard prior to cleaning, sterilization and use.

CLEANING AND STERILIZATION METHOD: TISSUE EVERTING FORCEPS:

Caution: The tissue everting forceps are packaged NONSTERILE and must be cleaned and sterilized prior to use.

**Cleaning**

Using a clean towel, wipe all visible soil from the forceps. Prepare an enzymatic detergent per the manufacturer's recommendations. Allow the forceps to soak in the enzymatic detergent for a minimum of one minute. Using a soft bristled brush remove any remaining soil paying particular attention to the inside of the forceps hinge, serration grips and pin. Thoroughly rinse in fresh running water and/or distilled water to remove all traces of detergents and soil. Forceps should be inspected for cleanliness and damage, ensure they function correctly and are clean prior to sterilization.

**Sterilization**

The tissue everting forceps may be steam sterilized in a gravity displacement or prevacuum autoclave). ] It is recommended that the tissue everting forceps be sterilized in accordance with one of the following sterilization times and temperatures:

Gravity-Displacement Steam Sterilization
Wrapped Forceps
Temperature: 270-275°F (132-135°C)
Exposure Time: 10 minutes

Gravity-Displacement Flash Cycle
Unwrapped Forceps
Temperature 270-275°F (132-135°C)
Exposure Time: 10 minutes

Pre-Vacuum Steam Sterilization
Wrapped Forceps
Temperature: 270-275°F (132-135°C)
Exposure Time: 4 minutes

Pre-Vacuum Flash Cycle
Unwrapped Forceps
Temperature 270-275°F (132-135°C)
Exposure Time: 4 minutes

**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 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

| | |  |  |  |  |  |  |
|---|---|---|---|---|---|---|---|
| English | Symbol Legend | Distributed By | Quantity | Usable Length | 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: https://eifu.lemaitre.com |

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