LeMaitre® VASCULAR

# Over-the-Wire LeMaitre® Valvulotome

Instructions for Use - English

Over-the-Wire LeMaitre® Valvulotome

**Over-the-Wire LeMaitre® Valvulotome** (Model Numbers 1005-00 and 1005-01)
Instructions for Use - English

**STERILE**

**Description**
The Over-the-Wire LeMaitre Valvulotome is a guidewire compatible device that cuts saphenous vein valves during bypass procedures. The Centering Hoops keep the head of the Over-the-Wire LeMaitre Valvulotome centered in the vessel and prevents the valve-cutting blades from damaging the vessel wall. The size of the Centering Hoops and Cutting Blades adjust to the internal diameter of the vein as the Over-the-Wire LeMaitre Valvulotome is being drawn through the vessel.

**Indication for Use**
The Over-the-Wire LeMaitre Valvulotome is indicated for cutting saphenous vein valves during in-situ bypass.

**Contraindications**
The Over-the-Wire LeMaitre Valvulotome is not recommended for the following:
1. pregnant women,
2. patients with allergy to any of the device materials,
3. endarterectomy procedures,
4. thrombolysis procedures,
5. vein stripping procedures,
6. embolectomy procedures, or
7. vessel dilation procedures.

**Warnings**
1. Do not use if the package or device is damaged.
2. Do not use if inner packaging is opened outside a sterile environment.
3. This device is to be used by a qualified physician.
4. Do not insert the device into a vessel or extract from a vessel in the open position.
5. Device must be used with an 0.035" Guidewire.
6. Do not open or close the device while in a coiled configuration.
7. Device must be flushed with saline or heparinized saline only.
8. Do not pass device through a vessel that has undergone synthetic grafting or contains implants.
9. Do not rotate the device in a vessel.

**Precautions**
1. United States Federal and other law restricts this device to sale on or by the order of a physician.
2. Do not use device past the expiration date printed on the labeling.
3. This device is single use only. Do not reuse, reprocess, or re-sterilize (reference "Re-sterilization/ Repackaging" section of this document for further details.
4. Keep any dissected portion of the vein straight and avoid twisting the vein during valvulotomy.
5. Use caution when advancing the guidewire past the proximal anastomosis.
6. Use caution when tracking the device in thrombophlebitic veins.
7. Do not advance the device with the blades in the open position.

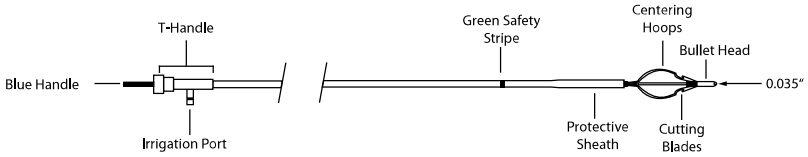
**Potential Complications**
- Vessel damage
- Vessel occlusion/ stenosis
- Hematoma
- Hemorrhage
- Thrombus formation
- Wound infections

- Erythema
- Myocardial infarction
- Amputation
- Death

**Additional Required Items**

1. .035" Guidewire
2. Radiopaque Tape

**Specifications**




| Catalog Number | Useable Length | Closed Catheter Outer Diameter | Maximum Open Cutting Blade Diameter | Maximum Open Centering Hoop Diameter |
|---|---|---|---|---|
| 1005-00 | 100 cm | 2.0 mm | 6.0 mm | 9.5 mm |

**To Open Package**

1. Open box and pull sealed tray out.
2. Slowly peel lid from tray and present product to personnel in sterile environment.

   ***Note:*** ***Device is contained in a single sterile barrier.***
3. Remove product by carefully dislodging Handle from tray, followed by the remainder of the catheter.
4. Place in basin filled with sterile, heparinized saline.

**Instructions for Use**

1. Perform an intra-operative venogram using Radiopaque Tape; mark the fistulae.
2. Excise the Sapheno-Femoral Complex.
3. Excise first valve set under direct vision using standard technique.
4. Perform the proximal anastomosis.
5. Ensure that the leg is fully extended and pass the 0.035" guidewire well beyond the treatment area.
6. With device in the open position, remove Irrigation Port cap, block guidewire lumen on the Blue Handle, and flush with sterile heparinized saline. Replace cap upon completion.
7. Sheath the Centering Hoops within the Protective Sheath by advancing the T-Handle until Cutting Blades are fully enclosed and a positive stop is detected.
8. Load the device over the guidewire carefully.
9. Advance into the saphenous vein to the treatment area; 2 cm to 3 cm distal to the anastomosis.
10. Expose the Cutting Blades and Centering Hoops by maintaining the position of the Blue Handle and retracting the T-Handle until a positive stop is detected.

    ***Note:*** ***Failure to maintain the position of the Blue Handle while exposing cutting blades may cause damage to the anastomosis.***
11. Slowly retract the device in the open position to disrupt valve sets.

    ***Warning:*** ***Do not rotate the device.***
12. When the Green Safety Stripe is visible, sheath the Cutting Blades and Centering Hoops into the Protective Sheath by maintaining the position of the Blue Handle and advancing the T-Handle.

    ***Warning:*** ***Failure to sheath Cutting Blades and Centering Hoops prior to retracting device from the***

***vessel may cause damage.***

***Note:*** ***If sheathing the Cutting Blades for vessel extraction leaves the most distal valve set intact, excise using standard technique.***

***Note:*** ***If device is set aside for further use within the same procedure, device must be stored in the open position in a basin of heparinized saline. Flush device as noted in step 6 prior to reintroduction.***

13. Ligate the venous tributaries previously located and marked.

    ***Note:*** ***Do not ligate the last major tributary until after the distal anastomosis is complete in order to allow blood run off.***

14. Pass the device through the vessel an additional 1-2 times after ligating the venous tributaries.
15. Steps 9 through 12 may be repeated as necessary.

    ***Warning:*** ***A maximum of 8 passes may be completed.***

16. Confirm free flow through saphenous vein using doppler.
17. Complete distal anastomosis to the appropriate arterial segment.
18. Perform a completion arteriogram using radiopaque tape to locate defects.

**Storage**
Store in a cool, dry place.

**Re-sterilization/Repackaging**
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. If for any reason this device must be returned to LeMaitre Vascular, place it in its original packaging and return it to the address listed on the box.

**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 TERMS INCLUDE 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**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Distributed By: | # | Rx only | | OD | cm | Do Not Open/Close Blades While Coiled | | |
| 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 | Outer Diameter | Usable Length | Attention: To avoid cutting blade retraction malfunction, do not open/close blades while coiled. | | After use, this product may be a potential biohazard. Handle and dispose of this product in accordance with acceptable medical practice and applicable laws and regulations |

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

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



CE 0088

R2242-00 Rev. B 12/11