LeMaitre® VASCULAR

# TRIVEX® System Disposable Resector Kit

**TRIVEX® System Disposable Resector Kit**
Instructions for Use - English

**TRIVEX® System Disposable Resector Kit**
(Model Numbers 7209514, 7209515)
Instructions for Use - English

STERILE EO Rx only

**Contents**
- 1 ea. Resector
- 1 ea. Inflow Tube Set

**Indications for Use**
The LeMaitre Vascular TRIVEX System Disposable Resector Kit is indicated for use in ambulatory phlebectomy procedures for resection and ablation of varicose veins.

**Contraindications**
Use of this device is contraindicated in situations where ambulatory phlebectomy is contraindicated.

**Warnings**
- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- Prior to use, surgeons should become familiar with this surgical technique and the TRIVEX System. Read these instructions completely prior to use.
- By purchasing any product designated for "single use," "multiple use in a single procedure," "do not resterilize," or the like, the customer agrees to limit that product's use in accordance with those express designations.
- Excessive pressure of the TRIVEX Resector against the vessel or prolonged activation of the TRIVEX Resector in a stationary position may result in perforation of the limb surface by the resector.
- As in conventional ambulatory phlebectomy procedures, bruising, hematoma and hemosiderin deposits have been observed in clinical studies utilizing the TRIVEX System.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

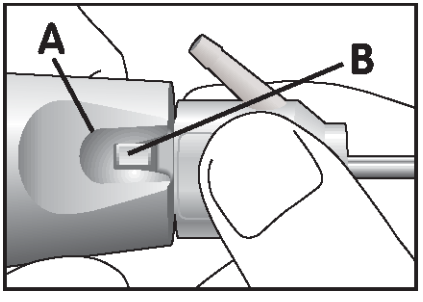
**Precautions**
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Prior to use, inspect the product package for signs of damage or tampering. If damaged, do not use.
- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Ensure that suction of 128 mmHg minimum is flowing while the instrument is running.
- Direct contact of the rotating cutting edge of resector with metal (e.g., other surgical instruments) can cause damage to the instrument tip.
- Excessive "side-loading" on the resector during use does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.

**Important**
All resectors are pre-assembled, packaged sterile and ready for use. To remove a TRIVEX System Disposable Resector Kit from its sterile package, peel the Tyvek seal off of the tray and proceed with the instructions in this document.

**Instructions for Use**

Resector Attachment and Removal

1. To insert a resector, orient the handpiece so that you can see the key slot (A) on the handpiece. Insert the resector into the handpiece so that the key (B) on the resector goes into the slot. The key should be pushed in proximally as far as possible for a positive lock.




2. To remove a resector, depress the key on the resector with your thumb or fingertip. Withdraw the resector from the handpiece.

*Note: Please see the TRIVEX System Operations/Service Manual (R2601) for detailed instructions for use.*

Disposable Inflow Tube Set Attachment

Follow operating room protocol for handling the tube set. Instructions are provided as reference only.

1. Circulator Nurse
   - Offer packaged contents to Scrub Nurse.
2. Scrub Nurse
   - Remove tube set from package.
   - Attach tube set to inflow port on resector.
3. Circulator Nurse
   - Close pinch clamps on tube set.
   - Spike fluid bag.
4. Scrub Nurse
   - Open tube set clamp to establish flow.
   - To regulate fluid flow please see the TRIVEX System Operations/Service Manual (R2601) for detailed instructions for use.

**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.

**For Further Information**

If further information on this product is needed, please contact LeMaitre Vascular Customer Service at 1-800-628-9470 in the U.S., or your authorized representative.

## Symbol Legend

| | | | |
|---|---|---|---|
| | | Distributed By: | **Rx only** |
| English | Symbol Legend | Distributed By | Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician. |

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
5915 Airport Road, Suite 608
Mississauga, Ontario
Canada L4V 1T1
Tel: +1 905 673-2266

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

R2590-01 Rev. B 07/14

CE 0088