LeMaitre® VASCULAR

# TRIVEX® Illuminator Inflow Tube Set

**TRIVEX® Illuminator Inflow Tube Set**
Instructions for Use - English

**TRIVEX®** 照明棒灌注路
使用说明 – 简体中文

**TRIVEX® Illuminator Inflow Tube Set**
(Model Number 7209513)
Instructions for Use - English

STERILE EO Rx only

*Please see the TRIVEX System Illuminator instructions for use (R2596).*

**Indications for Use**
See the TRIVEX System Illuminator instructions for use (R2596).

**Contraindications**
See the TRIVEX System Illuminator instructions for use (R2596).

**Warnings**
- Do not resterilize. This product is provided sterile, for single use only. Do not reuse. Do not use after the expiration date. Prior to use, inspect the product package for structural integrity. Discard any opened and unused product. 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.
- As in conventional ambulatory phlebectomy procedures, bruising, hematoma, and hemosiderin deposits have been observed in clinical studies utilizing the TRIVEX system.

**Precautions**
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Prior to use, surgeons should become familiar with this surgical technique and the TRIVEX system.

**Instructions for Use**

Attaching disposable inflow tube set (ref 7209513) to irrigated illuminator (ref 7210351)
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 illuminator inflow port by inserting female luer fitting into male luer fitting and turning clockwise.
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**

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.

**TRIVEX®** 照明棒灌注管路
(型号 7209513)
使用说明 – 简体中文

**STERILE EO** **Rx only**

请参阅《*TRIVEX* 系统照明棒使用说明 (R2596)》。

适应症
请参阅《TRIVEX 系统照明棒使用说明 (R2596)》。

禁忌症
请参阅《TRIVEX 系统照明棒使用说明 (R2596)》。

警告
- 请勿重复灭菌。本产品以无菌方式提供，仅供一次性使用。请勿重复使用。失效日期之后，请勿使用。使用前，请检查产品包装的结构是否完整。对于任何打开但未用过的产品，请丢弃处理。客户购买指示为“一次性使用”、“在一次手术中多次使用”、“请勿重复灭菌”或有类似标注的任何产品，即表示客户同意根据这些明确的指示使用该产品。
- 与传统的静脉曲张切除术一样，在使用 TRIVEX 系统的临床研究中发现有擦伤、血肿和血铁质沉淀的现象。

注意事项
- 根据美国联邦法律规定，该设备需由医师销售或在医师的指导下进行销售。
- 使用前，外科医生应熟悉此外科技术和 TRIVEX 系统。

使用说明

将一次性灌注管路（产品号 7209513）连接到照明棒（产品号 7210351）
请遵循手术室操作规程来使用灌注管路。以下提供的说明仅供参考。
1. 当班护士
   - 将包装好的器械提供给手术助理护士。
2. 手术助理护士
   - 从包装中取出管路。
   - 将母鲁尔管接头插入到公鲁尔管接头并按顺时针方向旋转，使管路与照明棒流入端口连接。
3. 当班护士
   - 闭合管路上的弹簧夹。
   - 刺穿液体袋。
4. 手术助理护士
   - 打开管组夹使液体流动。
   - 要调节液体流，请参阅《TRIVEX 系统操作/服务手册 (R2601)》中的详细使用说明。

有限产品质保；有限产品赔偿
LeMaitre Vascular, Inc. 保证已在本装置的生产过程中为保证产品质量作出必要的努力。除非此处明确规定，否则不管是由于法律原因还是其他原因所致，LEMAITRE VASCULAR（在本文中，这一名称指 LEMAITRE VASCULAR, INC.、其合作联盟及其各自的员工、高级职员、主管、经理和代理）不对该设备做任何明示或默示担保（包括但不限于针对特定用途的适销性和适用性所做的任何暗示担保），并且不承担任何责任。LeMaitre Vascular 不对本设备的特殊治疗用途的适用性做任

何表示，购买方对其适用性负有唯一责任。此有限产品质保不适用于购买者或任何第三方滥用或误用本产品，或未能正确保存该产品的情况。此有限质保的唯一例外赔偿是，按照购买者退还给 LeMaitre Vascular 的设备情况进行更换或按设备的购买价格退款（由 LeMaitre Vascular 单方面决定）。此有限质保将于该设备的有效日期后终止。

在任何情况下，LEMAITRE VASCULAR 均不负责任何直接、间接、后果性、特殊的、惩罚性或惩戒性的赔偿。然而，不管在任何情况下，LEMAITRE VASCULAR 就任何责任条款（不管是合同、侵权行为、严格责任还是其他条款）而应对本设备承担的全部责任不应超过一千美元 (US$1,000)，不论是 LEMAITRE VASCULAR 已经被告知这种损失的可能性，还是未能达到赔偿的基本目标。这些限制适用于任何第三方声明。

这些说明的修订或发布日期包含在使用说明的最后一页，以供参考。如果使用本产品时距此日期已超过二十四 (24) 个月，则用户应联系 LeMaitre Vascular，了解是否可有更多产品信息。

更多信息

如需有关本产品的更多信息，请致电 1-800-628-9470 联系美国的 LeMaitre Vascular 客户服务部门，或者联系您的授权代表。

**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. |
| 简体中文 | 符号图例 | 经销商 | 小心：根据美国联邦法律和其他法律规定，该设备需由医师销售或在医师的指导下进行销售。 |

| | REF | LOT | STERILE EO | |
|---|---|---|---|---|
| English | Catalog Number | Batch Code | Sterilized with etylene oxide | Do not re-use |
| 简体中文 | 型号规格 | 批号 | 环氧乙烷灭菌 | 不可重复使用 |

| | | # | |
|---|---|---|---|
| English | Use-by Date | Quantity | Do not use if package is damaged |
| 简体中文 | 失效日期 | 数量 | 如果包装受损或被打开,请勿使用. |

| | | | |
|---|---|---|---|
| English | Do not resterilize | Date of Manufacture | Manufacturer |
| 简体中文 | 不可重复灭菌 | 生产日期 | 制造商 |

LeMaitre®
VASCULAR

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EC REP

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R2593-01 Rev. E 03/18

CE 0088