LeMaitre® VASCULAR

# TRIVEX® System Illuminator

**TRIVEX® System Illuminator**
Instructions for Use - English

**TRIVEX®** 系统照明棒
使用说明 – 简体中文

# TRIVEX® System Illuminator

(Model Number 7210351)
Instructions for Use - English

NON STERILE **Rx only**

**Description**
The LeMaitre Vascular TRIVEX® System Illuminator is used to instill tumescent solution and to transilluminate the targeted varicosities. The illuminator connects with fiber optic cables to the TRIVEX System to provide transillumination during endoscopic resection of superficial varicosities of the lower extremities.

**Indication for Use**
The TRIVEX System Illuminator is indicated for use in ambulatory phlebectomy procedures for resection and ablation of varicose veins.

**Contraindications**
None known.

**Warnings**
- This product is shipped non-sterile. It must be sterilized before the first use. It must be cleaned and sterilized before every subsequent use.
- The only method of sterilization appropriate for the illuminator is autoclave.
- Read these instructions and the TRIVEX System Operations/Service Manual (R2601) completely prior to use.
- Prior to use, the surgeon should become familiar with this surgical technique.
- The high energy radiated light emitted from the illuminating fiber at the distal end of the Illuminator may give rise to temperatures exceeding 106 °F (41° C) within an area of 8 mm in front of the Illuminator. Do not leave the tip of the Illuminator in direct contact with patient tissue or combustible materials or burns may result. Lower the light source output when working in close proximity to an object.
- As in conventional ambulatory phlebectomy procedures, bruising, hematoma, and hemosiderin deposits have been observed in clinical studies utilizing the TRIVEX System.
- To prevent a potential safety hazard to the patient caused by accidental loss of function of the device (i.e., front end damage by surgical instruments), it is recommended to have an additional sterile "stand-by" device during surgical procedures.

**Precautions**
1. United States Federal and other law restricts this device to sale on or by the order of a physician.
2. Prior to each use, inspect the device to ensure it is functioning properly and not damaged. Do not use a damaged device.
3. Prior to each use, the outer surface of the insertion portion of the Illuminator should be checked to ensure there are no rough surfaces, sharp edges, or protrusions.
4. Any foreign matter present on the surface after cleaning may tend to burn and discolor the surface when the high intensity lamp is in use.
5. Be aware that the TRIVEX System requires a special light guide adaptor (REF 7210375) for the light source end of the cable. Standard light guide adaptors will fit into the light source opening, but may not transmit adequate light from the lamp.

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

**Mechanical Assembly**
Place the correct adaptors on the fiber optic light post of the Illuminator and on the instrument end of the light guide. The light post threads may be lubricated as needed, being sure to remove any excess lubricant as required. Make sure that the fiberoptic surface remains free of foreign matter.
Adaptors can be used to fit most light guides. Simply attach the appropriate adaptor on or off the fiber optic light post to prepare the Illuminator for connection to light guides.

*CAUTION: Be aware that the TRIVEX System requires a special light guide adaptor (REF 7210375) for the light source end of the cable. Standard light guide adaptors will fit into the light source opening, but may not transmit adequate light from the lamp.*

**Attaching a Disposable Inflow Tube Set (REF 7209513) to the Irrigated Illuminator (REF 7210351)**
Follow operating room protocol for handling the tube set. Read the assembly instructions included with the Disposable Inflow Tube Set (R2593).

**Cleaning**

1. Clean the Illuminator thoroughly by washing with a soft brush and non-abrasive enzymatic detergent in hot water (140° F [60° C]), followed by repeated flushing to ensure that all surfaces and movable parts are clean.
2. The irrigation channel should be cleaned well with hot, soapy water and flushed repeatedly with clear running water.
3. After hot water washing, instruments should be thoroughly rinsed in warm water, and dried before being encased and sterilized for the next procedure.
4. The fiberoptic post and distal tip of the Illuminator must be cleaned and checked routinely to ensure maximum transmission of light. Both should be cleaned with warm water and mild soap. If stains are present, a mixture (1:1) of methyl alcohol and acetone may be used. A fine woven cloth or lens tissue should be used for cleaning. Dry with a soft, woven cloth.

*CAUTION: Any foreign matter present on the fiber surface after cleaning may tend to burn and discolor the surface when the high intensity lamp is in use.*

**Sterilization**

*WARNING: The only method of sterilization appropriate for the illuminator is autoclave.*

- Pre-Vacuum method at 270–275° F (132–135° C) for 4 minutes; or
- Gravity method at 270–275° F (132–135° C) for 10 minutes.

**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 repair or replacement of 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 date that is three months from the date of invoice for such 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.

# **TRIVEX**® 系统照明棒

(型号 7210351)

使用说明 – 简体中文

NON STERILE **Rx only**

描述

LeMaitre Vascular TRIVEX® 系统照明棒用于缓慢灌注肿胀麻醉液，并透光显示静脉曲张的位置。照明棒通过光纤电缆连接到 TRIVEX 系统，在切除下肢浅表静脉曲张手术中提供透射照明。

适应症

TRIVEX 系统照明棒专用于静脉曲张微创手术以进行曲张静脉的切除和消融。

禁忌症

未知。

警告

- 本产品以非无菌方式提供。在第一次使用之前必须进行灭菌。在以后每次使用之前，必须进行清洗和灭菌。
- 唯一适合照明棒灭菌的方法是高压灭菌。
- 在使用之前，必须完整阅读这些说明和 TRIVEX 系统操作/服务手册 (R2601)。
- 使用前，外科医生应熟悉此外科技术。
- 从照明棒尖端的照明光纤发射出来的高强度辐射光可导致照明棒尖端前面 8 毫米区域内的温度超过 41° C (106° F)。请勿让照明棒尖端直接接触患者的组织或可燃材料，否则可能导致烧伤。
- 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了擦伤、血肿和血铁质沉淀的现象。
- 为了防止因照明棒功能意外丧失（即照明棒尖端被其他手术器械损坏）而给患者带来潜在的安全风险，建议您在外科手术时准备另外一个无菌照明棒以“备用”。

注意事项

1. 美国联邦法律和其他法律规定，该器械需由医师销售或在医师的指导下进行销售。
2. 在每次使用前，检查器械以确保其正常运转且未损坏。请勿使用损坏的器械。
3. 在每次使用前，应检查照明棒插入部分的外表面以确保没有粗糙表面、锐边或突出。
4. 清洗之后表面上存在任何异物都可能在使用高强度灯时造成表面烧焦和褪色。
5. 请注意，TRIVEX 系统要求光导纤维光缆的近源端使用特殊的光源适配器（产品号 7210375）。 其他标准光源适配器可以装入光源开口，但可能无法从光源传输出充足的光强度。

使用说明

请遵循手术室的操作规程来使用管路。提供的说明书仅供参考。

机械组装

将正确的适配器放在照明棒的光纤接口上和光导纤维光缆的近光源端。根据需要可以对接口的螺纹进行润滑，但务必按照要求擦掉多余的润滑剂。请确保光纤表面没有异物。适配器可以用来配接大多数光导纤维光缆。只需将适当的适配器连接到光导纤维光缆的接口上，即可准备好将照明棒连接到光源上。

将一次性灌注管路（产品号 **7209513**）连接到照明棒（产品号 **7210351**）

请遵循手术室的操作规程来使用管路。请阅读一次性灌注管路(R2593) 随附的组装说明。

清洗

1. 使用软刷和非磨损性加酶洗涤剂在热水 (60° C [140° F]) 中彻底清洗照明棒，然后反复冲洗，确保所有表面和活动部件干净。
2. 灌注管腔应使用热肥皂水妥善清洗，然后用清水反复冲洗干净。
3. 用热水清洗之后，应在温水中彻底漂清器械，并在封装之前干燥，然后进行灭菌，以供下次手术时使用。
4. 必须定期清洗和检查照明棒的光纤接口和尖端以确保最大程度传导灯光。两个位置都应使用温水和柔性肥皂进行清洗。如有污点，可使用甲醇和丙酮混合液 (1:1) 清洗。应使用细织布或镜头纸进行清洁。使用软布擦干。

灭菌

警告：唯一适合照明棒灭菌的方法是高压灭菌。

- 在 132–135° C (270–275° F) 下采用预真空法灭菌 4 分钟；或
- 在 132–135° C (270–275° F) 下采用重力法灭菌 10 分钟。

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 的设备情况进行维修或更换（由 LeMaitre Vascular 单方面决定）。此质保将于该设备的发票日期起三个月之后后终止。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

| | |  |  |  |  |  |  |  | **Rx only** |
|---|---|---|---|---|---|---|---|---|---|
| English | Symbol Legend | Catalog Number | Batch Code | Serial Number | Manufacturer | Date of Manufacture | Caution | 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 | 型号规格 | 批号 | 序号 | 制造商 | 生产日期 | 注意 | 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。 |

LeMaitre®
VASCULAR

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