LeMaitre® VASCULAR

TRIVEX® System Illuminator

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Instructions for Use - English

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(Model Number 7210351)
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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.

Symbol Legend

		Distributed By:	**Rx only**
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LeMaitre®
VASCULAR

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