LeMaitre®

PhasTIPP® Illuminator Injection Tubing

PhasTIPP® Illuminator Injection Tubing
Instructions for Use - English

PhasTIPP® Disposable Illuminator Injection Tubing

(Model Number 5003-01)

Instructions for Use - English

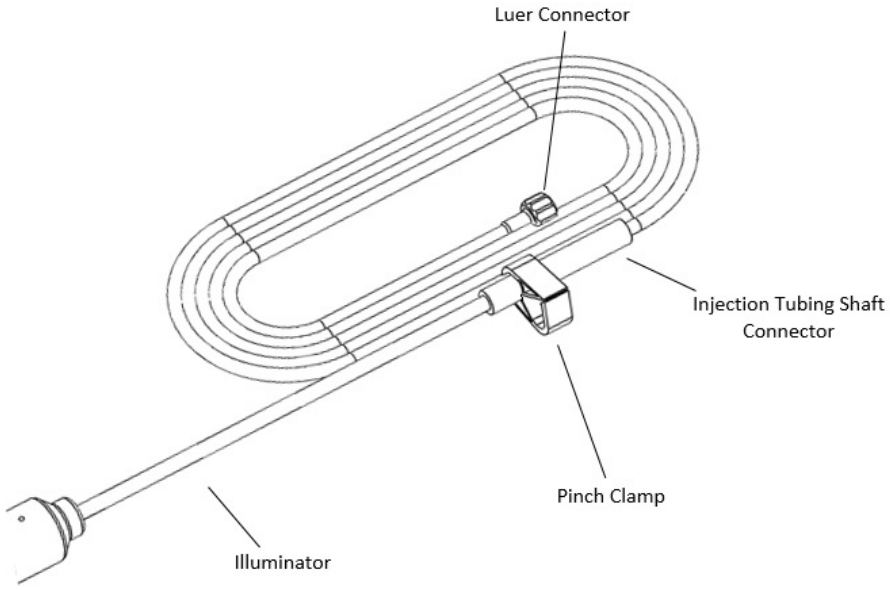
Please see the PhasTIPP Disposable Illuminator instructions for use (R3940).

Contents

1 ea. PhasTIPP Illuminator Injection Tubing

Description

The Illuminator Injection Tubing is an optional accessory device intended for use with the PhasTIPP system for the purpose of allowing the user to infuse directly via needle (needle not included).



Indication for Use

The PhasTIPP system is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins. The Illuminator is also indicated for use without the Resector for visualization of varicose veins and infusion of tumescent solution during an ambulatory phlebectomy case.

Warnings

1. 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. Battery is in a separate pouch marked non-sterile.
2. Prior to use, surgeons should become familiar with this surgical technique and PhasTIPP components. Read these instructions completely prior to use.

Contraindications

Please see the PhasTIPP Disposable Illuminator instructions for use (R3940).

Potential Complications

Please see the PhasTIPP Disposable Illuminator instructions for use (R3940).

Precautions

1. U.S. Federal law restricts this device to sale by or on the order of a physician.
2. Prior to use, inspect the product package for signs of damage or tampering. If damaged, do not use.
3. Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.

Instructions for Use

Fully attach disposable injection tubing (5003-01) to Disposable Illuminator (5001-03) and Illuminator Handpiece (5001-01). The Illuminator must already be set up per R3940 (Disposable Illuminator) and R3939 (Illuminator Handpiece).

1. Following aseptic procedure the non-sterile nurse opens the disposable pouch and offers the tubing to the sterile nurse. The sterile nurse removes the tubing from the pouch.
2. Sterile nurse discards the tubing sleeve and uncoils injection tubing on the sterile table.
3. Slide the larger diameter tube completely over the disposable illuminator distal shaft and clamp in place (see figure).
4. Select the desired injection needle (not included) and attach to the luer lock on the other end of the tubing.
5. The injection tubing may be connected and disconnected multiple times during a single case as needed.

Postoperative Procedure Instructions

1. Unclamp the tubing and discard in accordance with accepted medical practice and applicable local and national requirements as all disposable components are a potential biohazard.

Resterilization/Re-use

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.

Technical Specifications – PhasTIPP Illuminator Injection Tubing

Maximum Transit and Storage Temperature Limit: 60°C

Minimum Transit and Storage Temperature Limit: -29°C

Ordering Information – PhasTIPP Components and Accessories

REF	*DESCRIPTION*
5000-01	PhasTIPP Small Storage Case (handpieces only)
5000-02	PhasTIPP Medium Storage Case (handpieces & infusion pump)
5001-01	PhasTIPP Illuminator Handpiece
5001-02	PhasTIPP Illuminator Peristaltic Infusion Pump (optional)
5001-03	PhasTIPP Disposable Illuminator
5002-01	PhasTIPP Resector Handpiece
5002-45	4.5mm PhasTIPP Disposable Resector
5002-55	5.5mm PhasTIPP Disposable Resector
5003-01	PhasTIPP Illuminator Injection Tubing

Limited Product Warranty; Limitation of Remedies

LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device and that this device is suitable for the indication(s) expressly specified in these instructions for use. 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. 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.

Symbol Legend

Distributed By:	Rx only	REF	LOT	US		cm	STERILE EO			
Distributed By	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.	Catalog Number	Batch Code	Date/ Country of Manufacture	Manufacturer	Usable Length	Sterilized using ethylene oxide	Use-by date	Non-pyrogenic	Consult instructions for use

			UDI	
Do Not Use if Package is Opened or Damaged	Do not re-use	Do Not Resterilize	Unique Device Identifier	Single Sterile Barrier System

Distributed By:

LeMaitre Vascular, Inc.
Customer Service:
Tel: 781 221-2266
Fax: 781 221-2223

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