LeMaitre®

PhasTIPP® Disposable Illuminator

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Instructions for Use - English

PhasTIPP® Disposable Illuminator
(Model Number 5001-03)
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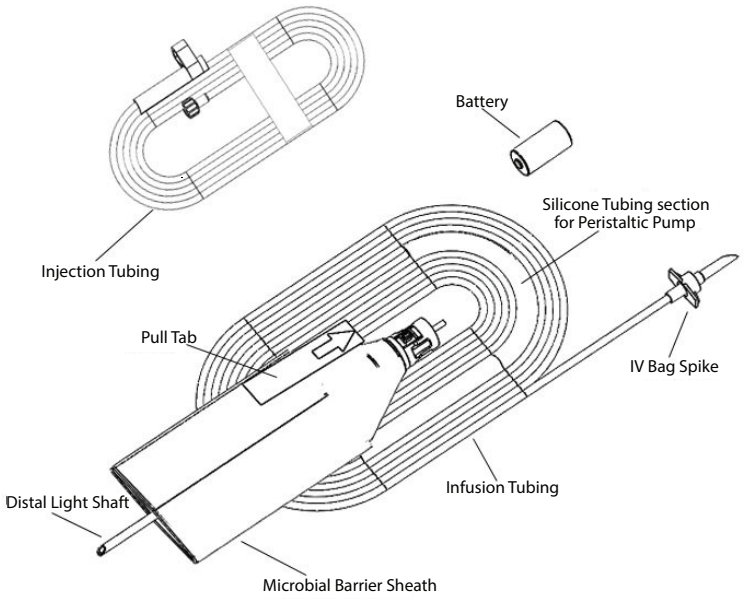
Contents
1 ea. PhasTIPP Disposable Illuminator with attached microbial barrier sheath
1 ea. CR123a Battery (CR-123A, 3V Lithium Ion), Non-Sterile

Description
The LeMaitre Vascular PhasTIPP Disposable Illuminator is used to infuse tumescent fluid and to trans-illuminate targeted varicosities during trans-illuminated powered phlebectomy (TIPP) procedures. The PhasTIPP Disposable Illuminator connects with the reusable Illuminator Handpiece and a tumescent fluid IV bag (not included). Pressurized flow is delivered by a peristaltic pump from the IV bag and through the Illuminator assembly to provide subcutaneous tumescent fluid infusion during procedures. The Illuminator Injection Tubing accessory (REF 5003-01) is also available for infusion via needle (needle not included).

Illumination is provided through the Illuminator assembly from an integrated battery-powered LED within the Illuminator Handpiece. The Illuminator components are utilized, along with PhasTIPP Resector components, to enable resection of superficial varicosities. The PhasTIPP Disposable Illuminator is supplied sterile per ethylene oxide (EO) sterilization.



Indication for Use
The PhasTIPP Disposable Illuminator is indicated for use in ambulatory phlebectomy procedures for 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.

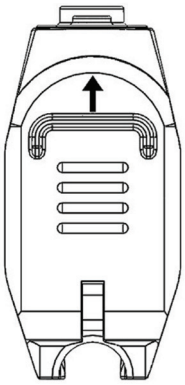
WARNING: No modification of this equipment is allowed.

Contraindications
None known.

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.
3. **The Illuminator Handpiece uses a high intensity LED which can cause the front sides of the handpiece to become hot if left on and stationary for longer than 15 minutes.** The maximum temperature the handpiece may exhibit is 152.4F (66.9C). If heat is detected, move hands further back on the handle to a cooler zone.
4. **Due to potentially elevated temperatures, do not allow the handle of the Illuminator Handpiece to make direct contact with the patient** (the Disposable Illuminator shaft, which is the applied part of the device, does not exhibit elevated temperatures).
5. **Due to potentially elevated temperatures, do not leave the light on and let the device rest on a table, particularly on its side.**
6. Do not allow the Illuminator shaft to touch the rotating portion of the PhasTIPP Disposable Resector. Damage to both instruments is likely. If you have any reason to suspect the device is damaged, replace it immediately.
7. Use caution when handling the device and sheath. If there is any reason to suspect that the microbial barrier sheath is damaged or compromised, immediately stop and replace the Disposable Illuminator.
8. Do not use the Illuminator as a leveraging tool. It is not intended to manipulate the tissue or withstand significant bending force. If lighting is not in the correct position, instead remove the device and reinsert in the correct direction.

Potential Complications
- Bruising
- Hematoma
- Hemosiderin deposits

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.



To open: Slide battery door in direction of arrow

To close: Slide battery door against direction of arrow

Instructions for Use

To Open Battery Door

1. Slide the battery cover in the direction of the arrow (see figure).
2. The door will pop open.

To Close Battery Door

1. Fully extend the battery cover.
2. Close the battery cover against the handpiece.
3. Slide the battery cover in the direction opposite of the arrow on the battery door (see figure).

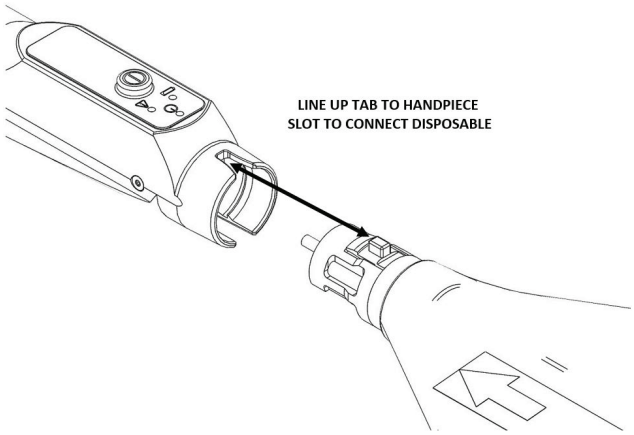
Pre-use instructions

NOTE: Prior to setup, the Illuminator Handpiece should be cleaned per the PhasTIPP Illuminator Handpiece Instructions for Use (R3939).

1. The non-sterile nurse sets up a peristaltic pump per the pump manufacturer's instructions.
2. The non-sterile nurse opens the box, removes the pouch, and removes the battery from external non-sterile pouch.
3. The non-sterile nurse opens the Illuminator Handpiece battery door, discards any existing battery if present per local guidelines, and inserts the new battery in the correct orientation (per the markings on the handpiece). Then close the battery door and ensure it is fully latched.
4. The non-sterile nurse confirms that the green status indicator LED on the Illuminator Handpiece is illuminated. See "Troubleshooting", section #1 if the green status indicator LED is not functioning.
5. The non-sterile nurse points the Illuminator Handpiece towards the floor and presses the power button to confirm that the illumination LED is operational. The power button is then pressed again to turn illumination LED off. See "Troubleshooting", section #5 if the illuminator LED is not functioning.

   CAUTION: THE DISPOSABLE ILLUMINATOR IS STERILE AND ILLUMINATOR HANDPIECE IS NON-STERILE.
6. Following aseptic procedure the non-sterile nurse opens the disposable pouch and offers the tray to the sterile nurse. The sterile nurse removes the tray from the pouch.
7. The sterile nurse, working on a sterile table, removes all components from the tray, discards the tray, and uncoils infusion tubing.

   WARNING: STERILE NURSE MUST USE CAUTION NOT TO TOUCH NON-STERILE HANDPIECE
8. The non-sterile nurse holds the Illuminator Handpiece so that the control buttons are on top and the Illuminator connection point (opening) faces out. The sterile nurse holds the tapered end of the light teal hub on the Disposable Illuminator. The sterile nurse inserts the hub into the Illuminator Handpiece held by the non-sterile nurse, so that the key on the Disposable Illuminator hub inserts into the slot on the Illuminator Handpiece (see figure above). Both individuals apply force until there is a discernable click. This ensures a positive lock between Illuminator Handpiece and Disposable is obtained.

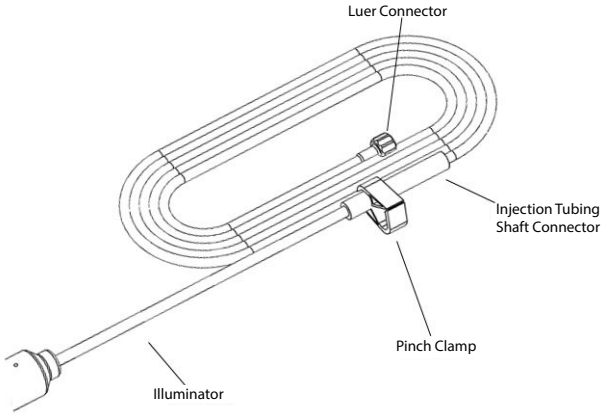


9. While the non-sterile nurse continues to hold the Illuminator Handpiece, the sterile nurse repositions to hold the distal shaft inside the folded sheath. The non-sterile nurse releases the Illuminator Handpiece while the sterile nurse supports the connected devices from the sterile end.
10. Position the device to hold the shaft up and the handle down. While continuing to hold the shaft with one hand, the sterile nurse uses another hand to gently apply tension to the pull tab to deploy the microbial barrier over the non-sterile Illuminator Handpiece. Use care not to touch the non-sterile Illuminator Handpiece. Continue pulling the sheath until it is fully deployed and the teal hub on the Illuminator Disposable is no longer under the sheath. With the microbial barrier in place, the entire device may now be placed in the sterile field.
11. The sterile nurse, through the sheath, inserts the infusion tubing into the tubing channel on the bottom of the Illuminator Handpiece.
12. The sterile nurse passes the connector end of the infusion tubing to the non-sterile nurse to be connected to non-sterile peristaltic pump and IV bag (not included).
13. The non-sterile nurse positions the silicone tubing section within peristaltic pump head (the silicone tubing is the short section of tubing roughly in the center of the tubing set).

14. The non-sterile nurse then inserts tubing spike into suspended tumescent fluid IV bag.
15. Proper device function is confirmed by pointing the Illuminator towards the floor and pressing the power button on the Illuminator Handpiece to verify that the illumination LED is operational. The power button is pressed again to turn illumination LED off. Device is ready to use. See "Troubleshooting", section #5 if the illuminator LED is not functioning.
16. Point the distal end of the Disposable Illuminator toward an absorbent surface. Actuate the peristaltic pump via the foot pedal and continue until tumescent fluid is expelled in a steady stream. This indicates that the infusion line is fully primed.

Illuminator Clinical Use Instructions

1. Make vertical incisions of 2-3mm in length strategically around surgical site. Use the minimum number of incisions to gain access.
2. Insert the tip of the Illuminator into the incision at a shallow angle to enter the subcutaneous region.
3. Turn on the LED to illuminate as needed by pressing the power button on the hand piece.
   Note: Light is designed to illuminate out and upward from the tip of the illuminator shaft, not down (up aligns with the button on the handpiece). Therefore, rotation of the device may be necessary to obtain best visualization of the surgical site.
4. Tumescent may be delivered through the tip of the illuminator by pressing on the foot pedal to actuate the peristaltic pump.
5. When illumination is no longer required, turn off the light by pressing the power button on the hand piece and remove the illuminator from the incision at a shallow angle.
6. Also available as an accessory is the Illuminator Injection Tubing (REF 5003-01). The larger diameter tube at one end may be directly connected to the illuminator shaft and clamped in place (see figure). The male luer lock on the other end of the tubing can be connected to any needle for subdermal infusion via needle.



7. If the battery indicator turns on during use, stop procedure and obtain a new disposable. Follow Disposable Resector Postoperative Procedure Instructions to disconnect devices and Preoperative Setup Instructions with a new battery and disposable (batteries cannot be replaced without compromising sterility so a new disposable is required.)

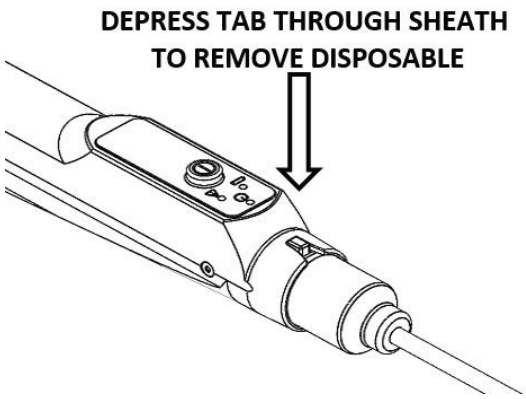
Post-use instructions

1. Depress power button to turn off illumination.
2. Remove device from sterile field and disconnect tubing from IV bag and peristaltic pump.
3. Remove infusion line from Illuminator Handpiece channel.
4. Push the microbial barrier sheath forward slightly to create some slack in the sheath near the connection between the Illuminator Handpiece and the Disposable Illuminator.
5. Through the microbial barrier sheath, depress the light teal key on the Disposable Illuminator hub with thumb or fingertip. Withdraw the Illuminator Handpiece from the sheath. Discard Disposable Illuminator (including sheath and infusion tubing) in accordance with accepted medical practice and applicable local and national requirements as all disposable components are a potential biohazard.
6. Open Illuminator Handpiece battery door and discard battery per local guidelines.
7. Wipe down the outer surfaces of the Illuminator Handpiece with a disposable chemical disinfectant wipe or a with a clean damp cloth and mild germicide commonly used in health care facilities to clean plastic reusable medical devices. Do not allow any cleaning agent to drip into the battery compartment or the distal opening of the Illuminator Handpiece. Refer to the Illuminator Handpiece Instructions for Use for more detail (R3939).

WARNING: The Illuminator Handpiece should never be subjected to sterilization (steam, chemical, or otherwise) and never submerged or sprayed with water or cleaning agents.

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.



Troubleshooting and Service Indications

During system operation, the PhasTIPP Illuminator Handpiece runs a diagnostic routine in the background, checking for power level from the battery and any other system faults. When the system detects a condition that requires attention, the yellow or red indicator LED will become illuminated on the Illuminator Handpiece and the green indicator LED will turn off. In some cases, the device will continue to operate normally, but in other cases the Illuminator LED will not function. If the procedures below do not resolve the problem, the device should be returned to LeMaitre Vascular for service.

#	Symptom	Possible Cause	Remedy
1	The green 'Standby' LED indicator fails to turn on.	The device does not have enough power.	• Confirm presence of a battery. • Confirm the battery door is latched closed. • Confirm proper orientation of the battery. • Obtain a new set of batteries from a PhasTIPP Disposable Illuminator.
		The Illuminator Handpiece is defective.	• Return Illuminator Handpiece to LeMaitre Vascular for service or replacement.
2	The yellow 'Low Battery' LED indicator is on.	The device does not have enough power.	• Obtain a new set of batteries from a PhasTIPP Disposable Illuminator.
		The Illuminator Handpiece is defective.	• Return Illuminator Handpiece to LeMaitre Vascular for service or replacement.
3	The red 'Fault' LED indicator is on.	There is an issue with the battery power.	• Obtain a new set of batteries from a PhasTIPP Disposable Illuminator.
		The Illuminator Handpiece is defective.	• Return Illuminator Handpiece to LeMaitre Vascular for service or replacement.
4	The Illuminator light output is low.	The Illuminator light guide is not properly seated in the Illuminator Handpiece	• Disconnect and reconnect the PhasTIPP Disposable Illuminator.
		The Illuminator light guide is defective.	• Replace PhasTIPP Disposable Illuminator.
		The Illuminator Handpiece is defective.	• Return Illuminator Handpiece to LeMaitre Vascular for service or replacement.
5	No light from Disposable Illuminator.	The Illuminator light guide is defective.	• Replace PhasTIPP Disposable Illuminator.
		The Illuminator Handpiece is defective.	• Return Illuminator Handpiece to LeMaitre Vascular for service or replacement.
6	The illuminator light output will not turn off.	The Illuminator Handpiece is defective.	• Remove batteries to cut power to device. • Return Illuminator Handpiece to LeMaitre Vascular for service or replacement.

Technical Specifications – PhasTIPP Disposable Illuminator

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

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		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	Sterilized using ethylene oxide	Use-by date	Non-pyrogenic	Caution

			STERILIZE	60°C -29°C	UDI	
Consult instructions for use	Do Not Use if Package is Opened or Damaged	Do not re-use	Do Not Resterilize	Storage/Transport Temperature Limit	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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Burlington, MA 01803, USA

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