LeMaitre®

PhasTIPP® Illuminator Handpiece

PhasTIPP® Illuminator Handpiece

Instructions for Use - English

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(Model Number 5001-01)
Instructions for Use - English

Preface

The LeMaitre Vascular PhasTIPP Illuminator consists of the non-sterile Illuminator Handpiece and the sterile Disposable Illuminator. This manual contains information you need to operate and maintain the PhasTIPP Illuminator Handpiece. It is essential that you read and understand all of the information in this manual before using or maintaining the system.

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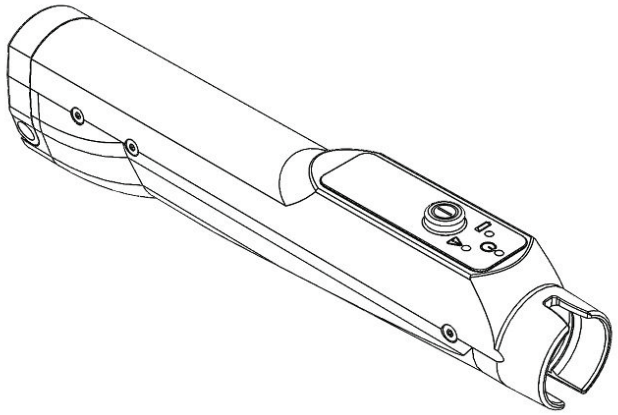
Device Description
The LeMaitre Vascular PhasTIPP Illuminator Handpiece is a reusable device that uses an LED (light emitting diode) to provide intense, white light during Trans Illuminated Powered Phlebectomy (TIPP) procedures. When connected to the PhasTIPP Disposable Illuminator and a peristaltic pump, the Illuminator Handpiece provides illumination and tumescent infusion to treatment sites during superficial varicose vein removal procedures. The distal stainless steel light shaft on the Disposable Illuminator is the applied part of the device and is intended for patient contact. The Illuminator Handpiece is provided non-sterile and must be covered with the microbial barrier sheath in the sterile field. The Illuminator Handpiece must not be sterilized or exposed to liquids.

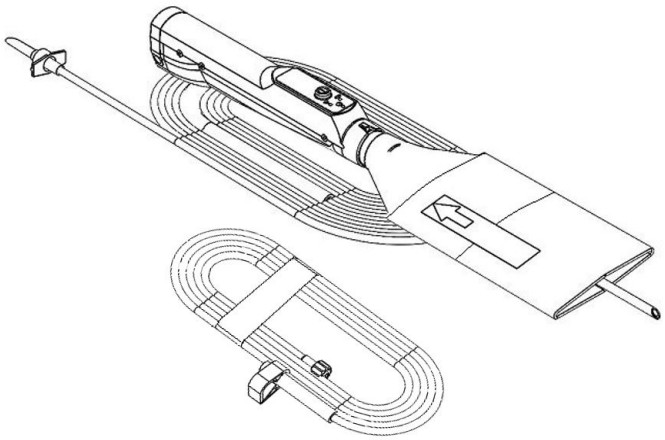
The Illuminator Handpiece is intended for use by vascular or general surgeons for treatment of patients of all ages and sexes. It is classified as a continuous use device, however, review the Warnings section for guidance on elevated temperatures prior to use (#15-18).

The Illuminator Handpiece can be used with the LeMaitre Vascular PhasTIPP Resector components for illumination in powered phlebectomy cases.

PhasTIPP Illuminator Handpiece



PhasTIPP Illuminator Handpiece attached to Disposable Illuminator



Indications 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.

Contraindications
None known.

Warnings
Please read this manual before using the PhasTIPP Illuminator Handpiece. These operating instructions will make the system easier to use and ensure optimal performance and reliable use. As with any surgical instrument, there are important health and safety considerations. These are listed below and reiterated within the text.

Following the maintenance recommendations and warnings outlined in this document are required to maintain safe and effective use.

1. When removing the Illuminator Handpiece from the shipping box, inspect contents to ensure that no damage is evident. Contact your LeMaitre Vascular representative if damage is noted.
2. Before using the Illuminator Handpiece for the first time, you should review all available product information. Surgeons should become familiar with this surgical technique and the PhasTIPP components. Surgeons should be experienced in ambulatory phlebectomy surgery using powered instruments.
3. The Illuminator Handpiece is only intended for use in a clinical environment.
4. The Illuminator Handpiece and the Disposable Illuminator are intended to be used together. They must be used as supplied. Do not interchange disposable components. Please read the PhasTIPP Disposable Illuminator Instructions for Use (R3940) before using these PhasTIPP devices.
5. **The outer surface of the Illuminator Handpiece should be isolated from the sterile field during clinical procedures. Prior to and after use, it should be wiped with liquid chemical disinfectants commonly used in healthcare facilities to clean plastic reusable medical devices.**
6. DO NOT STERILIZE – The PhasTIPP Illuminator Handpiece is provided non-sterile, and should never be subjected to sterilization (e.g. Autoclave). Mechanical and electrical damage will occur if the Illuminator Handpiece is subjected to chemical or pressurized steam (autoclave) sterilization. Sterilization will void the product warranty.
7. DO NOT SUBMERGE OR SPRAY – The PhasTIPP Illuminator Handpiece should never be submerged or sprayed with water or cleaning agents. Submerging or spraying the device with water will void the product warranty.
8. Do not allow any cleaning agent to drip into the battery compartment or the distal opening of the Illuminator Handpiece.
9. The suction source should not be running while setting up the tubing. Injuries to the operator's hands can occur.
10. This device is only for use with flexible fluid containers and fluid bags. Glass containers or bottles may break, and there is a risk of implosion.
11. If visualization is lost during any point when used with Resector components, stop resecting immediately.
12. **Do not stare directly into the light source or direct the light source toward other personnel.** Failure to observe this precaution may result in eye injury.
13. Use only the battery supplied with the PhasTIPP Disposable Illuminator to power the unit. Use of alternate batteries or other power sources may permanently damage the equipment, or cause errors or malfunction.
14. Do not store the device with batteries installed. Batteries must be discarded after a case is complete and new batteries loaded just prior to the next case.
15. **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.
16. **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).
17. **Due to potentially elevated temperatures, do not leave the light on and let the device rest on a table, particularly on it's side.**
18. No modification of this equipment is allowed. There are no serviceable components inside. Dismantling the equipment will void the warranty.
19. **DANGER:** Risk of explosion if used in the presence of flammable anesthetics.
20. The use of accessory equipment not complying with IEC 60601 or equivalent safety requirements may lead to a reduced level of safety of the PhasTIPP system.

21. Do not allow the battery or battery contacts to touch the patient and user simultaneously in order to prevent a conductive circuit between the patient, user, and device.
22. If defibrillation is necessary during procedure, stop the phlebectomy procedure and remove PhasTIPP components from patient and surgical table if possible. The PhasTIPP components are not defibrillation proof, so if they are contacting the patient or the surgical table, do not touch any of the PhasTIPP components during defibrillation.
23. If electrosurgery is necessary during procedure, use caution to prevent any emission effects via radiated and conducted current interference through the patient.
24. 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

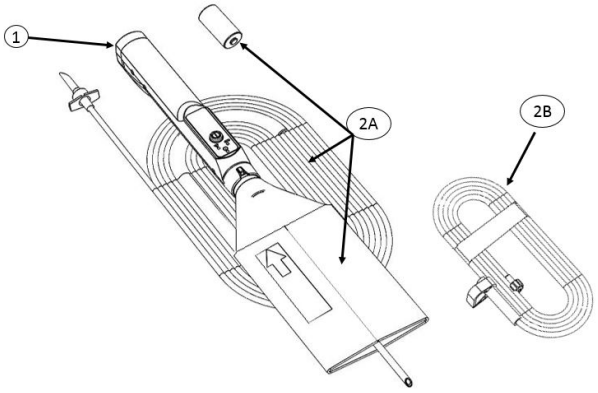
Precautions
1. U.S. Federal law restricts this device to sale by or on the order of a physician.
2. Only the LeMaitre Vascular PhasTIPP Disposable Illuminator can be used with the Illuminator Handpiece. The Disposable Illuminator is for single use only and must be disposed of after use. Do not resterilize the Disposable Illuminator.
3. Use of a resterilized Disposable Illuminator may permanently damage, impede performance, or cause failure of other PhasTIPP devices. Use of such products may render any warranties null and void.
4. This unit complies with IEC 60601-1. However, the user must be aware that this does not necessarily ensure protection of the unit against interference from other devices.
5. Handle the device with care. If the device is dropped or damaged in any way, it must be returned immediately for service.
6. This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:

a. Reorient or relocate this equipment, the other equipment, or both.

b. Increase the separation between the pieces of equipment.

c. Consult a biomedical engineer.

7. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.



System Components
The PhasTIPP System consists of a variety of components.

1. Illuminator Handpiece, Non-Sterile

   The Illuminator Handpiece is a hand held battery operated device that provides on / off button control for the operation of the intense white light output from the Disposable Illuminator. It also provides LED indicator lights to display the status of the device. It is designed to be used along with a foot switch-operated peristaltic pump (not included) to provide control of the tumescent infusion flow rate.

2. Disposable Illuminator, Sterile

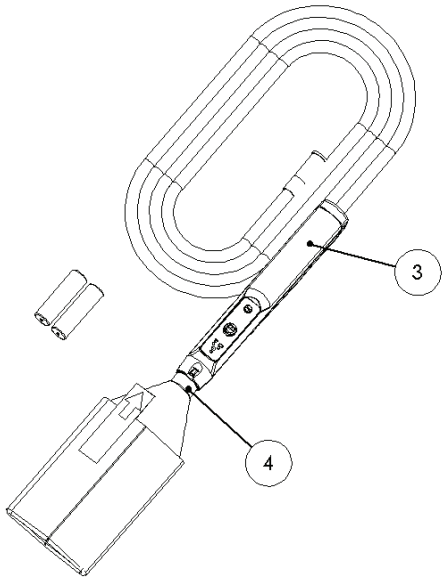
   The Disposable Illuminator (2A) provides a light shaft to connect to the Illuminator Handpiece in order to transilluminate the targeted varicosities. Also available as an accessory is the Illuminator Injection Tubing (REF 5003-01) (2B) to inject tumescent fluid from an IV bag (not included) via a needle (not included). A microbial barrier sheath covers the Illuminator Handpiece, and a non-sterile disposable battery for the Illuminator Handpiece. The hub on the Disposable Illuminator is a light teal color that matches a light teal stripe on the Illuminator Handpiece, which is intended to aid in connecting the correct disposable to the correct handpiece. Please see the PhasTIPP Disposable Illuminator Instructions for Use (R3940) for additional information.

3. Resector Handpiece, Non-Sterile

   The Resector Handpiece is a hand-held battery operated device that provides on / off button control for the operation of the oscillating motion of the Disposable Resector. It also provides a window lock button to control the position of the oscillating shaft when it stops and LED indicator lights to display the status of the device. Please see the PhasTIPP Resector Handpiece Instructions for Use (R3942) for additional information.

4. Disposable Resector, Sterile

   The PhasTIPP Disposable Resector includes a rotating distal shaft and suction tube that connects to the Resector Handpiece in order to remove the targeted varicosities. Also included with the Disposable Resector is a microbial barrier sheath to cover the Resector Handpiece and two non-sterile disposable batteries for the Resector Handpiece. The distal hub of the Disposable Resector is a dark teal color that matches a dark teal stripe on the Resector Handpiece, which is intended to aid in connecting the correct disposable to the correct handpiece. The Resector

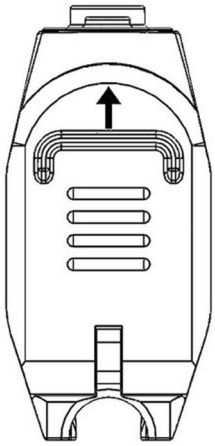


is available in two different shaft outer diameters (OD), and the proximal hub on these two sizes vary: 4.5mm OD (REF 5002-45, green) and 5.5mm OD (REF 5002-55, pink). Please see the PhasTIPP Disposable Resector Instructions for Use (R3941) for additional information.

Required accessories that may be purchased separately include a vacuum source, infusion pump, and storage cases.

Unpacking the Components

Carefully unpack and inspect all LeMaitre Vascular PhasTIPP components. If any parts are missing or damaged, contact your LeMaitre Vascular representative. Save the box and packing materials in the event a component must be returned for repair. When not in use, the Illuminator Handpiece should be stored in a LeMaitre Vascular PhasTIPP Storage Case (REF 5000-01 or -02).



To open: Slide battery door in direction of arrow

To close: Slide battery door against direction of arrow

PhasTIPP Illuminator Handpiece and Controls

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).

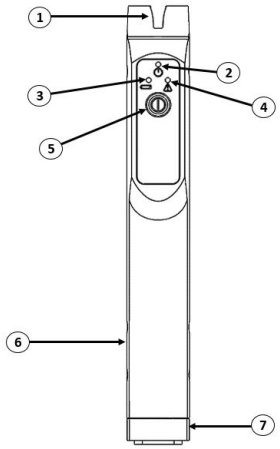
Preoperative Setup for Use in a Surgical Procedure

There are four main steps for preparing the PhasTIPP Illuminator Handpiece for use in a surgical procedure:

1. Prepare the tumescent fluid and setup pump flow to a level that corresponds to approximately 450ml/min flow.
2. 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 handpiece.

   WARNING: The Illuminator Handpiece should never be subjected to sterilization (steam, chemical, or otherwise) and never submerged or sprayed with water or cleaning agents.
3. Open the battery door on the proximal end of the Illuminator Handpiece by sliding the door forward (the door will pop open automatically after unlatched). Load the battery from the PhasTIPP Disposable Illuminator package into the Illuminator Handpiece in the correct orientation and close battery door. Verify the green LED turns on.
4. Consult the PhasTIPP Disposable Illuminator Instructions for Use (R3940) for additional setup information related to the disposable.

   NOTE: Reference troubleshooting section if yellow or red indicator lights are on.



① Connection slot for the PhasTIPP Disposable Illuminator
② LED Status Indicator for Standby
③ LED Status Indicator for Low Battery
④ LED Status Indicator for System Fault
⑤ On / Off Control Button for illumination (click once to turn on, click again to turn off)
⑥ Tubing Channel (not visible, underneath)
⑦ Battery Door

Illuminator Control

Reference the Cautions section prior to operation.

Verify that the Preoperative Setup has been successfully completed.

There is one on/off control button on the Illuminator Handpiece. Press the button to turn on illumination. Illumination will remain on until the button is pressed again to turn it off. The green LED indicator light will remain on at all times when a battery is loaded and no faults are present.

If the yellow low battery indicator light is on obtain new batteries from a new PhasTIPP Disposable Illuminator.

If the red fault indicator light is on, contact LeMaitre Vascular for service (see "Repair Service Program" section).

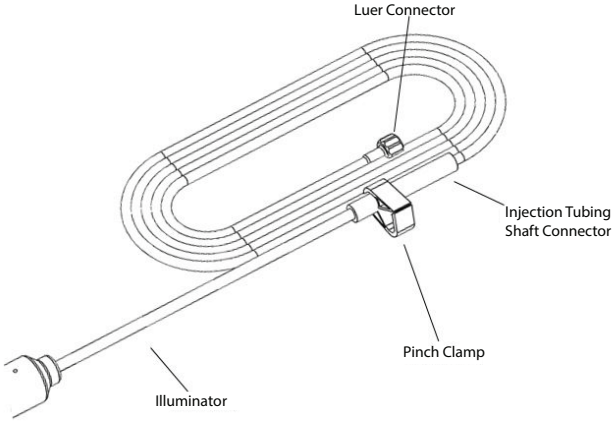
The non-sterile Illuminator Handpiece is designed to be isolated from the sterile field during clinical procedures by a plastic, see-through microbial barrier sheath that is deployed from the disposable component and over the Illuminator Handpiece. Operation of the Illuminator Handpiece control button and visibility of the LED indicators in the operating room (OR) is intended only through the plastic microbial barrier sheath.

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.

   CAUTION: The high intensity LED can cause the front sides of the handpiece to become hot if left on and stationary for longer than 15 minutes. Do not allow the handle of the Illuminator Handpiece to make direct contact with the patient. Do not leave the light on and let the device rest on a table, particularly on its side. If operator detects heat, move hands further back on the handle to a cooler zone.
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.)

Postoperative Procedure

Follow these steps after each procedure:

1. Disconnect and dispose of the Disposable Illuminator and tubing used during the procedure following standard protocols for disposal of biohazardous waste.

   CAUTION: Disposable Illuminator and tubing used with the Illuminator Handpiece are for single use only. Do not resterilize. Discard after use.
2. Open the battery door and dispose of the battery following standard protocols for battery waste. Close and secure battery door.
3. 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.

   WARNING: The Illuminator Handpiece should never be submerged or sprayed with water or cleaning agents.

   WARNING: The Illuminator Handpiece should never be subjected to sterilization (steam, chemical, or otherwise).
4. When not in use, store the Illuminator Handpiece in a PhasTIPP Storage Case (REF 5000-01 or -02).
5. This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment, it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Resterilization/Re-use

The PhasTIPP Illuminator Handpiece is a reusable device. It is supplied non-sterile and is not intended to be sterilized. During use it must be shielded from the sterile field by the sterile microbial barrier sheath attached to the Disposable Illuminator.

Electrical Interference

CAUTION: This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment.
- Consult a biomedical engineer.

Environmental Protection

CAUTION: This equipment contains electronic printed circuit assemblies and lithium ion batteries. At the end of the useful life of the equipment, it should be disposed of in accordance with any applicable national or institutional policy relating to disposal of electronic equipment.

Service

All service and repairs should be performed by LeMaitre Vascular. Contact LeMaitre Vascular Customer Service prior to returning the device to request a Return Goods Authorization (RGA) number. Items to be serviced should be carefully repackaged and returned per instructions provided by LeMaitre Vascular Customer Service.

NOTE: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or damaged due to liquid or sterilization will incur additional costs, regardless of warranty status.

See the "Ordering Information" section for a list of replacement parts.

Troubleshooting and Service Indications

When in use, 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, and the green indicator LED on the Illuminator Handpiece will turn off. In some cases, the system will continue to operate normally, but in other cases the device will not function. If the procedures below do not resolve the problem, the unit 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.
7	Miscellaneous Device Malfunction / Overheating	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 Illuminator Handpiece

Dimensions:	1.0" wide x 1.8" deep x 7.0" long
Weight:	1 lb
Power:	CR-123A, Lithium 3V, Non-Rechargeable, Qty 1
Ambient Operating Temperature:	15°C ~ 30°C
Atmospheric Pressure:	70kPa - 106kPa
Environmental Humidity Range:	30-70% RH
Equipment Classification:	BF type applied part.
	The equipment is internally powered
	The Illuminator Handpiece is not rated for protection against harmful ingress of water.
	Do not use the Illuminator Handpiece in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide.

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The PhasTIPP Illuminator Handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the Illuminator Handpiece should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Illuminator Handpiece uses RF energy only for its internal functions. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Illuminator Handpiece is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The PhasTIPP Illuminator Handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the Illuminator Handpiece should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment –Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV 8kV contact ± 8kV 15kV air	± 6kV 8kV contact ± 8kV 15kV air	Floors should be wood, concrete or ceramic tile and the relative humidity should be between 30-70%.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	30 A/m	The power frequency magnetic field should be at levels
RFID Immunity 134.2kHz (IEC 61000-4-39)	65A/m	65A/m	Do not expose device above tested level
RFID Immunity 13.56MHz (IEC 61000-4-39)	7.5A/m	7.5A/m	Do not expose device above tested level
Electrosurgery Interference Susceptibility (IEC 60601-2-2 Annex BB.4)	Cutting and Coagulation	Cutting and Coagulation	User should mitigate emission effects when using in combination with HF surgical equipment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment –Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the LeMaitre Vascular PhasTIPP System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2 √(p..) d=1.2 √(p..) 80 MHz to 800 MHz d=2.3 √(p..) 800 MHz to 2.5 GHz Where "p" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a) Field strengths from fixed transmitters, such as base stations for radio, (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PhasTIPP device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PhasTIPP device.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note: The EMC performance is not affected by the connection of the infusion tube.

Guidance for Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and PhasTIPP Devices

The PhasTIPP Illuminator Handpiece is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Illuminator Handpiece can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PhasTIPP device(s) as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d=1.2\sqrt{p}$	80 MHz to 800 MHz $d=1.2\sqrt{p}$	800 MHz to 2.5 GHz $d=2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Warranty

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 date that is 12 months from the date of invoice for this device.

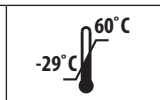
IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT 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.

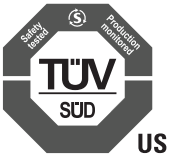
A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

Training Program

Training opportunities are available at Surgeon Training Centers. For next available dates please contact your local Sales Representative, email csus@lemaitre.com, or call LeMaitre Vascular at 800-628-9470 (US).

Symbol Legend

Distributed By:	Rx only							
Distributed By	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.	On-Off push control	Waste electrical and electronic equipment	Non-ionizing electro-magnetic radiation	Caution	Fragile, handle with care	Storage/ Transit Temperature Limit	Date/ Country of Manufacture

							
EQUIPMENT CLASSIFICATION — Type BF Applied Part	Catalog Number	Serial Number	Batch Code	TUVus SUD 60601 Safety Certification	Keep dry	Consult instructions for use	Non-sterile

							
Manufacturer	Do Not Autoclave	Not Disposable	System Fault	Battery Orientation	Standby	Low Battery	Unique Device Identifier

Distributed By:

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

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