LeMaitre®

PhasTIPP® Disposable Resector

PhasTIPP® Disposable Resector
Instructions for Use - English

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(Model Number 5002-45, 5002-55)
Instructions for Use - English

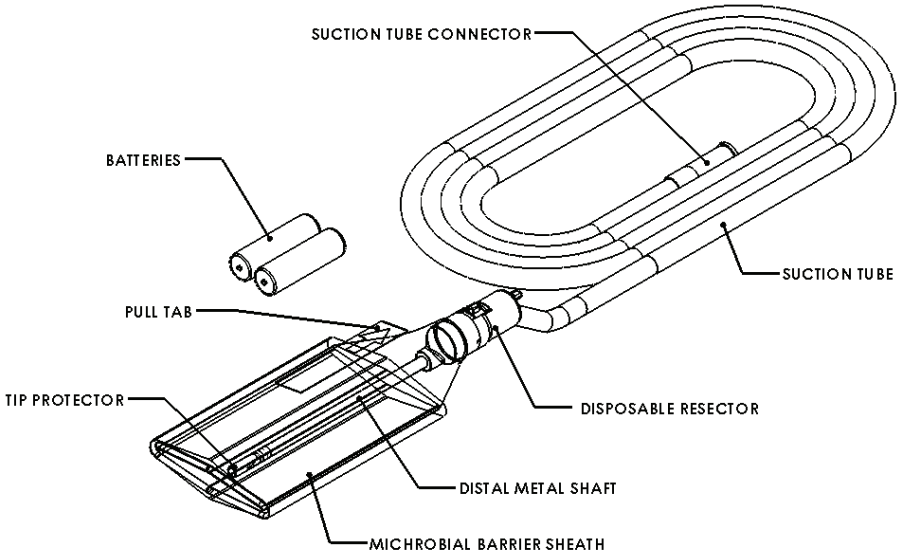
Contents

1 ea. PhasTIPP Disposable Resector with attached microbial barrier sheath and suction tubing
2 ea. Batteries (Tadiran TLM-1550HP, Lithium Ion 4V Battery), Non-Sterile

Description

The LeMaitre Vascular PhasTIPP Disposable Resector is used to morcellate and to remove targeted varicosities during trans-illuminated powered phlebectomy (TIPP) procedures. The Disposable Resector connects with the reusable Resector Handpiece and a vacuum source. The Resector Handpiece provides motor power to oscillate the Disposable Resector blades as it cuts tissue while the vacuum source provides suction to remove the morcellated tissue.

The PhasTIPP Resector components are utilized, along with the PhasTIPP Illuminator components, to enable endoscopic resection of superficial varicosities. The Disposable Resector is provided sterile per ethylene oxide (EO) sterilization. The Disposable Resector should only be used with the Resector Handpiece (REF 5002-01).



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.

Contraindications

Use of this device is contraindicated in situations where ambulatory phlebectomy is contraindicated.

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. Batteries are 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. Excessive pressure of the device against the vessel or prolonged activation in a stationary position may cause the blades to perforate the skin.
4. The distal end of the Resector shaft contains moving sharp blades. Use caution when operating the device so that the tip of the shaft is only exposed to areas where resection is desired. Do not attempt to clear debris from the blades by hand.
5. After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
6. Use caution when handling the device and microbial barrier sheath. If there is any reason to suspect that the sheath is damaged or compromised, immediately stop and replace the Resector.
7. Use of a resterilized Disposable Resector may permanently damage, impede performance, or cause failure of your other LeMaitre Vascular PhasTIPP devices. Use of such products may render any warranties null and void.

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. A vacuum suction of 500 mmHg or higher is recommended while the instrument is running.
3. Direct contact of the rotating cutting edge with metal (e.g., other surgical instruments) can cause damage to the instrument tip.
4. Excessive "side-loading" (aka extreme force to the side of the resector distal shaft) during clinical use does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.

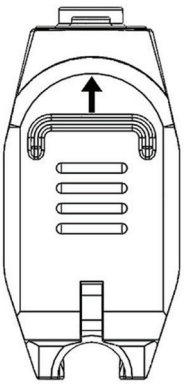
Instructions for Use

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.



To open: Slide battery door in direction of arrow

To close: Slide battery door against direction of arrow

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 Resector Handpiece should be cleaned per the PhasTIPP Resector Handpiece Instructions for Use (R3942). The non-sterile nurse opens box, removes the pouch, and removes batteries from external non-sterile pouch.

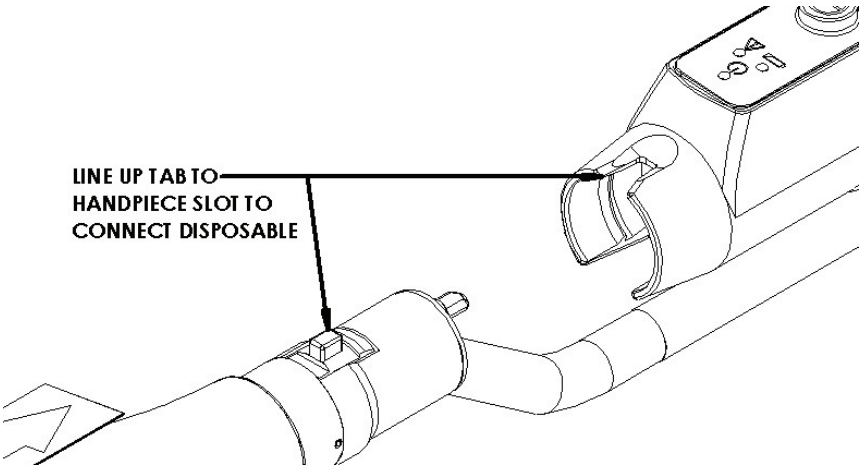
1. The non-sterile nurse sets up a vacuum source per the pump manufacturer's instructions.
2. The non-sterile nurse opens Resector Handpiece battery door, discards any existing batteries if present per local guidelines, and inserts new batteries in correct orientation per the markings on the handpiece). Then close the battery door and ensure it is fully latched.
3. The non-sterile nurse confirms that the green status indicator LED on Resector Handpiece is illuminated. See "Troubleshooting", section #1 if the green status indicator LED is not functioning.
4. The non-sterile nurse verifies operation by pressing and holding the power button on the Resector Handpiece to confirm the motor is functional and powered (internal motor rotations are audible and felt through the handle). See "Troubleshooting", section #5 if the motor is not functioning.

CAUTION: THE DISPOSABLE RECECTOR IS STERILE AND THE RESECTOR HANDPIECE IS NON-STERILE.

5. Following aseptic procedure the non-sterile nurse opens the disposable pouch and offers tray to the sterile nurse. The sterile nurse removes the tray from the pouch.
6. The sterile nurse, working on a sterile table, removes all components from the tray, discards the tray, and uncoils vacuum tubing.
7. Note that both Resector assemblies have a dark teal distal hub, but the 5.5mm Resector has a pink proximal hub and the 4.5mm Resector has a green proximal hub.

WARNING: STERILE NURSE MUST USE CAUTION NOT TO TOUCH NON-STERILE HANDPIECE

8. The non-sterile nurse holds the Resector Handpiece so that the control buttons are on top and the Resector connection point (opening) faces out. The sterile nurse holds the tapered end of the dark teal hub on the Disposable Resector. The sterile nurse inserts the hub into the Resector Handpiece held by the non-sterile nurse, so that the key on the Disposable Resector hub inserts into the slot on the Resector Handpiece (see figure). Both individuals should apply force until there is a discernable click. This ensures a positive lock between Resector Handpiece and Disposable Resector is obtained.
9. The non-sterile nurse inserts the suction tubing into the tubing channel on the bottom of the Illuminator Handpiece.
10. While the non-sterile nurse continues to hold the Resector Handpiece, the sterile nurse repositions to hold the distal shaft inside the folded microbial barrier sheath. The non-sterile nurse releases the Resector Handpiece while the sterile nurse supports the connected devices from the sterile end.



11. 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 sheath over the Resector Handpiece. Use care not to touch the non-sterile Resector Handpiece. Continue pulling the microbial barrier sheath until it is fully deployed and the teal hub on the Disposable Resector is no longer under the sheath. With the microbial barrier sheath in place, the entire device may now be placed in the sterile field.
12. The sterile nurse passes the connector end of the vacuum tubing to the non-sterile nurse to be connected to the non-sterile vacuum source.
13. Remove protective tip from the device and discard.
14. Confirm proper function of the device by pressing the power button and confirming the inner tube rotates. The device is ready to use. See "Troubleshooting", section #5 if the tube is not rotating.

Resector 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. For varicose vein removal a minimum of two incisions are required, one on either end of the varicosity (generally one distal and one proximal). One access point will be used for infusion/illumination and another for resection.
2. Insert the tip of the Illuminator into one incision at a shallow angle and use the foot pedal to deliver tumescent anesthesia into the surgical site through the peristaltic pump. Tumescent solution is recommended as it will create a fluid pocket around the target vein to aid in visualization and also cause the vein to spasm, pushing blood out of the vein to eases removal.
3. Insert the tip of the resector into the other incision in the subcutaneous space under or on the side of the vein. Skin over the varicosity should be held taut with an open hand. With the illuminator on, begin resecting the varicose vein by holding down the button on the resector hand piece and laterally moving the devices in sync, so that the varicosity and tip of the resector are always visible.

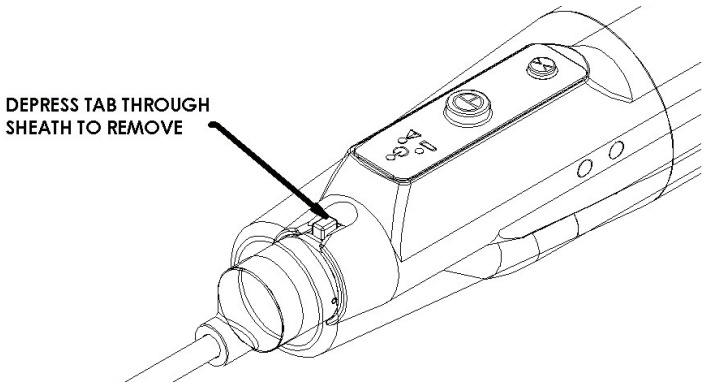
NOTE: Do not use a sweeping motion under the skin as it may increase bruising. Instead remove device completely and re-insert in a new direction.

4. Switch the illuminator and resector positions or make additional incisions as required to completely resect the varicose tissue. After the resecting is complete, turn off the illuminator and remove the devices from the surgical site at shallow angles.
5. Using a surgical punch, it is recommended that drainage holes be created around the surgical site. Use the Illuminator and tumescence to irrigate the surgical site until drainage holes run clear.
6. If the battery indicator turns on during use, stop resecting and obtain a new disposable. Repeat the pre-use instructions with new batteries and a new disposable (bat-

teries cannot be replaced without compromising sterility so a new disposable is required).

Resector Handpiece Suction Control

The PhasTIPP Resector components use standard hospital suction. For optimal resection, a suction pressure of 500 mm Hg or higher is recommended. Suction is connected to the Disposable Resector and removes fluid and debris drawn through the Disposable Resector tube.



Post-use instructions

1. Remove device from sterile field and disconnect tubing from vacuum source.
2. Push the microbial barrier sheath forward slightly to create some slack in the sheath near the connection between the Resector Handpiece and the Disposable Resector.
3. Through the microbial barrier sheath, depress the dark teal key on the Disposable Resector with your thumb or fingertip (see figure). Withdraw the Resector Handpiece from the sheath. Discard Disposable Resector (including sheath and infusion tubing).
4. Open Resector Handpiece battery door and discard batteries per local guidelines. Close and secure battery door.
5. Wipe down the outer surfaces of the Resector 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 Resector Handpiece. Refer to the PhasTIPP Resector Handpiece Instructions for Use for more detail (R3942).

WARNING: The Resector 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 Resector 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 Resector Handpiece and the green indicator LED will turn off. In some cases, the device will continue to operate normally, but in other cases it 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 batteries. • Confirm the battery door is latched closed. • Confirm proper orientation of the batteries. • Obtain a new set of batteries from a PhasTIPP Disposable Resector.
		The Resector Handpiece is defective.	• Return Resector Handpiece to LeMaitre Vascular for service or replacement.
2	The yellow 'Low Battery' LED indicator is on (solid).	The device does not have enough power.	• Obtain a new set of batteries from a PhasTIPP Disposable Resector.
		The Resector Handpiece is defective.	• Return Resector Handpiece to LeMaitre Vascular for service or replacement.
3	The yellow 'Low Battery' LED indicator is flashing.	The battery is critically low.	• Obtain a new set of batteries from a PhasTIPP Disposable Resector.
4	The red 'Fault' LED indicator is on (solid).	There is an issue with the battery power.	• Obtain a new set of batteries from a PhasTIPP Disposable Resector.
		The Resector Handpiece is defective.	• Return Resector Handpiece to LeMaitre Vascular for service or replacement.
5	The red 'Fault' LED indicator is flashing slowly.	The device is experiencing difficult to remove varicosities.	• Pull back and operate the Resector in a fluid pocket. • Slowly advance again using caution not to overload the device's power.
6	The resector stops responding to button presses and the red "Fault" LED indicator flashes quickly.	The Resector Handpiece is experiencing a hardware problem.	• If this occurs once and then operates normally, the Resector Handpiece may be used as usual.
			• If this occurs repeatedly, return Resector Handpiece to LeMaitre Vascular for service or replacement.

#	Symptom	Possible Cause	Remedy
7	Resector Handpiece will not run or runs erratically.	The PhasTIPP Disposable Resector is not properly connected.	• Replace the PhasTIPP Disposable Resector.
		The PhasTIPP Disposable Resector is defective.	
		The device does not have enough power.	• Obtain a new set of batteries from a PhasTIPP Disposable Resector.
		The Resector Handpiece is defective.	• Return Resector Handpiece to LeMaitre Vascular for service or replacement.
8	The Resector will not stop rotating.	The Resector Handpiece is defective.	• Press and hold both buttons to stop rotations. • Remove batteries to cut power to device. • Return Resector Handpiece to LeMaitre Vascular for service or replacement.
9	Miscellaneous Device Malfunction / Overheating	The Resector Handpiece is defective	• Press and hold both buttons to stop rotations. • Remove batteries to cut power to device. • Return Resector Handpiece to LeMaitre Vascular for service or replacement.

Technical Specifications – PhasTIPP Disposable Resector

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			-29°C 60°C		
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	Non-pyrogenic	Storage/ Transport Temperature Limit	Do Not Use if Package is Opened or Damaged	Do not re-use

STERILIZE	STERILE EO			OD	UDI	
Do Not Resterilize	Sterilized using ethylene oxide	Use-by date	Consult instructions for use	Outer Diameter	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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