LeMaitre® VASCULAR

TRIVEX® System

TRIVEX® System

Operation/Service Manual - English

TRIVEX® 浅表静脉曲张动力去除系统

使用说明 – 简体中文

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PREFACE

This manual contains information you need to operate and maintain the LeMaitre Vascular TRIVEX® System. It is essential that you read and understand all the information in this manual before using or maintaining the system.

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DEVICE DESCRIPTION

The TRIVEX System provides controls for the operation of the light source for the Illuminator, the tumescent pump, the saline pump, and the mode and variable speed operation of the Resector Handpiece. The TRIVEX System uses a pair of peristaltic pumps to provide irrigation and tumescence anesthesia for the Transilluminated Powered Phlebectomy procedure. The left hand pump is dedicated to providing the tumescence anesthesia via the TRIVEX System Illuminator. The right hand pump is dedicated to providing saline to the TRIVEX Resector Handpiece for resector tip irrigation. The TRIVEX System uses a metal halide arc lamp to provide intense, white light via the TRIVEX System Illuminator for transillumination. The illuminator connects with fiber optic cables to the TRIVEX System to provide transillumination during endoscopic resection of superficial varicosities of the lower extremities. The Resector Handpiece drives the Resector and features push-button controls for Resector operation. The Cart provides a mobile base for the Control Unit and a mast for hanging the saline and tumescent solution irrigation bags. The Footswitch causes air pressure to activate a switch inside the Control Unit which turns on the tumescence pump.

The TRIVEX System is intended for use by vascular or general surgeons for treatment of patients of all ages and sexes that require removal of varicose veins.

INDICATIONS FOR USE

The TRIVEX System is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins.

CONTRAINDICATIONS

Use of the TRIVEX System is contraindicated in situations where ambulatory phlebectomy is contraindicated.

WARNINGS

Please read this manual before using the TRIVEX System. The brief operating instructions in this guide will make the system easier to use, while the recommended service and maintenance procedures will 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.

Prior to using the TRIVEX System, it is essential that all components of the system be inspected for damage that can negatively impact the equipment performance. The inspection should include all equipment to be used in surgery, including the illuminator, handpiece, cables, and accessories.

When removing the TRIVEX System and accessories from the shipping container, inspect contents to ensure that all components from the "Unpacking the Components" section are available.

Contact your LeMaitre Vascular Representative if damage is noted.

- Before using the TRIVEX System for the first time, you should review all available product information. Surgeons should become familiar with this surgical technique and the TRIVEX System. You should be experienced in ambulatory phlebectomy surgery using powered instruments. Healthy tissue can be injured by improper use of the TRIVEX System resector. Use every available means to avoid such injury.
- TRIVEX Resector Kits are packaged as a set. They must be used as supplied. Do not interchange resector components.
- Illuminator inflow tube sets and resector kits are provided STERILE and are for single use only. Do not reuse. Do not resterilize. Prior to use, inspect the product package for signs of damage or tampering. Discard any opened and unused product. Do not use after the expiration date.
- Resterilization and/or re-use of the Illuminator Tube Sets or Resector Kits may cause mechanical damage to these products. This may result in injury to the patient or user.
- The TRIVEX System pumps should not be running while setting up the tubing. Injuries to the operator's hands can occur.
- Work exclusively with sterile substances, sterile fluids, and sterile accessories.
- This system is intended only for use with flexible fluid containers and fluid bags. Glass containers or bottles may break, and there is a risk of implosion.
- Use of bags or containers not approved for this system, or large and/or lopsided loads, may cause the device to tip over.
- If visualization is lost during any point in the procedure stop resecting immediately.
- Excessive pressure of the TRIVEX resector against the vessel or prolonged activation of the TRIVEX resector in a stationary position may result in perforation of the resector through the limb surface.
- Do not hold the light source shutter open without a fiber optic cable in place. Failure to observe this precaution may result in eye injury.
- During procedure, avoid prolonged contact of the Illuminator tip to patient tissue or flammable materials. The Illuminator tip may reach high temperatures due to high-intensity light transmission.
- DANGER: Risk of explosion if used in the presence of flammable anesthetics.
- When the light source is turned on, do not look directly at the metal halide arc lamp without protective goggles.
- To prevent electrical shock, do not remove the TRIVEX System console cover. There are no user-serviceable components inside. Dismantling the equipment will void the warranty. Refer servicing to LeMaitre Vascular.
- To prevent electrical shock, connect the power cord to a properly-wired grounding receptacle only.
- To prevent electrical shock, unplug the unit from the electrical outlet before attempting to replace the fuses.
- Use extreme caution: The high internal pressure of the lamp may cause an explosion, regardless of whether the lamp is cold or hot. Always wear protective clothing and a face mask when handling the lamp.
- Hazardous high voltage and energy are present at the output and in the internal circuitry of this unit.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1, install an appropriately rated UL 60601-1/IEC 60601-1 approved isolation

transformer and retest the system.

- In some cases, high voltage may persist after the power has been removed. Only personnel qualified to service electronic equipment should operate or troubleshoot an "uncased" power supply.
- Dangerous voltages are present during leakage current testing. DO NOT TOUCH the TRIVEX System while power is applied.
- HIGH VOLTAGE (1500 VAC) is present during dielectric strength and Hi-Pot testing. Exercise extreme caution while operating the dielectric strength tester or the Hi-Pot tester to prevent personal injury from electrical shock or damage to the equipment. Ensure that only authorized personnel are in the test area during the tests.
- To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
    - Use of the accessory in the patient vicinity.
    - Evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601 Standard.

PRECAUTIONS

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Verify that the resector handpiece and its cable are sterile.
- Verify that the Illuminator, Light Guide and adaptors are sterile.
- Check to ensure that the resector(s) required for the procedure are available.
- Verify that the Preoperative Setup has been successfully completed.
- Only LeMaitre Vascular Disposable TRIVEX Resector Kits can be used with the TRIVEX System. Resectors used with the TRIVEX System are for single use only. Do not resterilize or lubricate the resectors. Dispose of the resectors after use.
- Use of reprocessed, single-use resectors may permanently damage, impede performance, or cause failure of your LeMaitre Vascular TRIVEX System. Use of such products may render any warranties null and void.
- Make sure the wheels on the TRIVEX System roller base are locked to prevent the system from rolling during setup and use.
- As in conventional ambulatory phlebectomy procedures, bruising, hematoma, and hemosiderin deposits have been observed in clinical studies utilizing the TRIVEX System.
- Disconnect power cord before cleaning the unit.
- Do not sterilize or immerse the TRIVEX System console in disinfectant.
- To prevent moisture from entering the handpiece cable during sterilization ensure that the protective cap is screwed on completely. Moisture can damage the cable or handpiece connectors.
- Do not allow the rotating portion of any resector to touch any metallic object such as the illuminator. Damage to both instruments is likely. Damage to the resector can range from a slight distortion or dulling of the resector edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures or dulling, or if you have any other reason to suspect a resector is damaged, replace it immediately.
- Excessive leverage on the resector does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.
- Do not cool the resector handpiece by immersing it in cold water.
- Do not operate the resector in the open air for an extended period.
- Use only the TRIVEX Light Source Adaptor (REF 7210375) with this system. Use of any other light source port adaptor may cause reduced light emission from the fiber optic cable.
- The power switch must be turned off, and the power cord disconnected from the power source, before attempting to replace the lamp.
- Replace the lamp only with an appropriate LeMaitre Vascular lamp (REF 7210115) as specified for the TRIVEX System. Use of any other lamp will void the warranty.
- Lamp may be very hot. Use protective eyewear and gloves when handling lamp.
- Do not leave the operating light cord without an Illuminator attached on the patient or surrounding materials. The light cord tip may reach a high temperature due to the high intensity light.
- 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.
- Do not operate at line voltage other than those stipulated on the back of the unit.
- Ensure that the available mains voltage matches the data listed on the label attached to the back of the control unit. Incorrect voltage can cause errors or malfunction, and may permanently harm the equipment.
- Handle the unit with care. If the unit is dropped or damaged in any way, it must be returned immediately for service.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- 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.
- 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.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- Equipment should be disposed of in accordance with local and/or federal codes and requirements.

SYSTEM COMPONENTS

The TRIVEX System consists of a variety of components:

- The TRIVEX System control unit provides controls for the mode and speed of the TRIVEX Resector, for activation and flow of the tumescence and saline pumps, and for operation of the light source for the TRIVEX System Illuminator.
- The console includes a display for resector speed and LED indicators for pump flow rate.
- The four control buttons (tumescence pump, lamp, resector mode, and saline pump) have lighted indicators above and below each push button. These indicate the status of each component by illuminating steady green, flashing green, steady orange, or flashing orange.
- The front of the control unit has ports for connecting the illuminator, two footswitches, and resector handpiece.
- The TRIVEX System stand provides a mobile base for the TRIVEX System control unit and an irrigation mast for the saline and tumescence solution irrigation bags.
- The 50 watt metal halide arc lamp provides intense, white light via the TRIVEX System Illuminator.
- The TRIVEX Resector Handpiece drives the LeMaitre Vascular 4.5 mm TRIVEX Resector (REF 7209514) and 5.5 mm TRIVEX Resector (REF 7209515), and features push-button controls for resector operation.

RESECTOR HANDPIECE

The TRIVEX Resector Handpiece is a hand-held motor drive that is electrically connected to the control unit via a 10 foot (3 meter) cable. The resector handpiece drives the disposable resectors.

The resector handpiece and its cable are autoclavable (see "CLEANING AND STERILIZATION").

TRIVEX SYSTEM ILLUMINATOR

The TRIVEX System Illuminator (REF 7210351) is used to instill tumescence solution and to transilluminate the targeted varicosities. Please see the TRIVEX System Illuminator Instructions for Use (R2596) for additional information.

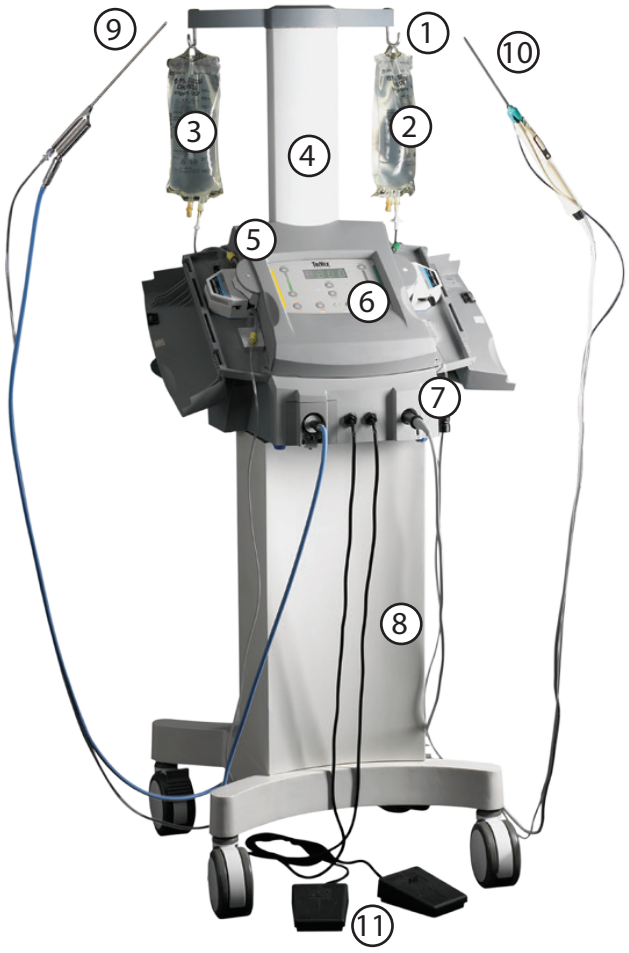


Figure 1: Component Identification

1. Fluid Bag Holder Hooks (x2)
2. Saline Solution Bag
3. Tumescence Solution Bag
4. Irrigation Mast
5. Control Unit
6. Control Unit Display
7. Connection Ports
8. TRIVEX System Stand
9. TRIVEX System Illuminator
10. TRIVEX System Resector Handpiece
11. Footswitch (x2)

UNPACKING THE COMPONENTS

Carefully unpack and inspect all components shipped with your LeMaitre Vascular TRIVEX System. If any parts are missing or damaged, contact your LeMaitre Vascular representative. Save the carton and packing materials in the event a component must be returned for repair.

ASSEMBLE CONTROL UNIT TO CART

1. Place the stand with roller base on a smooth level surface with the rear panel facing you.
2. Remove the 3/16" Allen wrench from the base of the irrigation mast. Using the Allen wrench, remove the four bolts securing the rear panel to the roller base.
3. Align the base of the control unit with the top of the roller base and lower the control unit straight down onto the roller base (figure 2).
4. For each of the four drawer latches located in the interior of the roller base: lift and engage the latch, then turn the latch key one half turn clockwise. Fold the latch key flat.
5. Replace the rear panel and reinsert the four bolts.

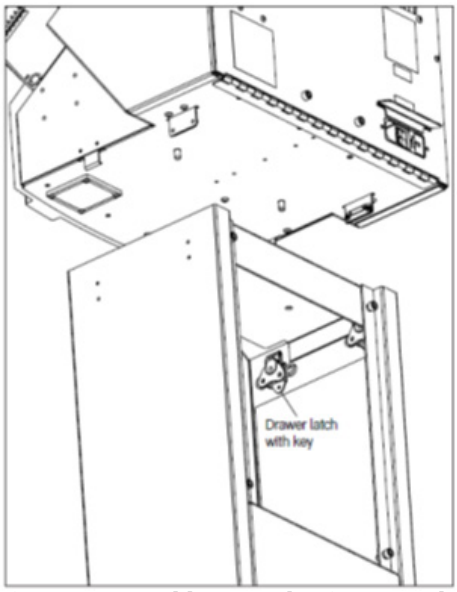


Figure 2: Assemble Control Unit to Stand

ASSEMBLE HANDLE TO MAST

6. Remove the four irrigation mast mounting bolts from the rear of the control unit.
7. Assemble the handle to the mast by: removing the two 1/4-20 x 5/8" socket head screws and washers from the handle using the 3/16" Allen wrench and then place the handle inside the box section of the mast weldment. Orient the handle so the threaded inserts align with the hole openings in the box section of the weldment. Secure the handle with the two, 1/4-20 x 5/8" socket head screws and washers.
8. Fit the irrigation mast with handle onto the rear of the control unit and secure it with the four irrigation mast mounting bolts.

CAUTION: Make sure the wheels on the TRIVEX System roller base are locked to prevent the system from rolling during setup and use.

TRIVEX SYSTEM CONTROL UNIT FRONT PANEL

CONTROL UNIT FRONT PANEL

1. Tumescence Pump Door – covers the tumescence pump hardware.
2. Saline Pump Door – covers the saline pump hardware.
3. TRIVEX System Display – contains the push buttons and displays for system operation.

FRONT PANEL CONNECTORS

There are four connectors on the front panel:

4. Fiber Optic Cable Connection Port – self-closing port designed to accept the TRIVEX Light Source Adaptor (REF 7210375).

CAUTION: Use of any other light source port adaptor may cause reduced light emission from the fiber optic cable or damage internal components, including the light source bulb.

5. Two Footswitch Tubing Connection Ports – accept tubing for the TRIVEX System footswitches.
6. Resector Handpiece Cable Connection Port (accepts the Resector Handpiece cable)

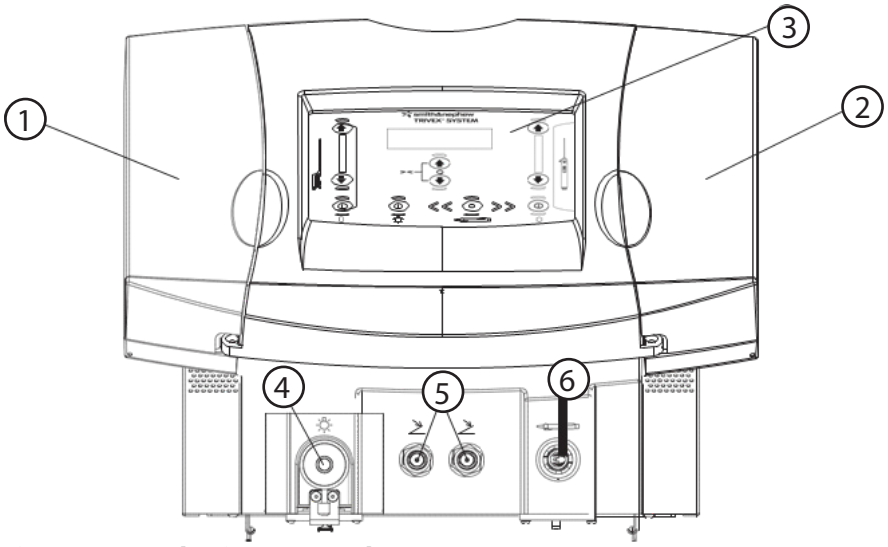


Figure 3: Control Unit Front Panel

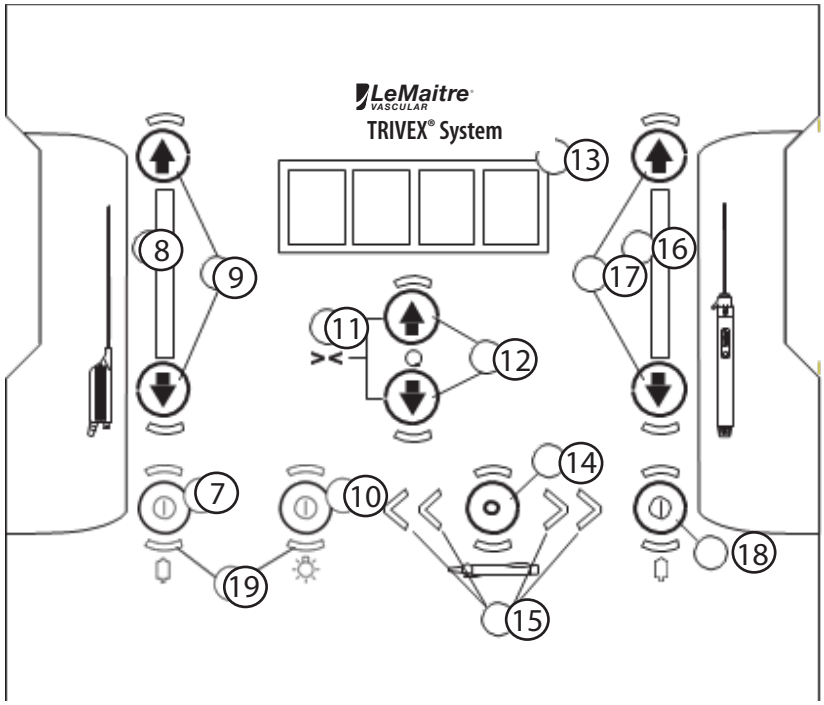


Figure 4: Control Unit Display

CONSOLE CONTROLS AND FUNCTIONS

7	Tumescence Pump ON/OFF Button	Turns the tumescence pump ON or OFF
8	Tumescence Pump Flow LED Indicators	Indicates the flow rate setting of the tumescence solution
9	Tumescence Pump Flow Increase / Decrease Buttons	Increase or decrease the flow rate of the tumescence pump. Each press of a button results in the flow rate increasing or decreasing by one level
10	Lamp ON / OFF Button	Turns the lamp ON or OFF
11	Window Lock Control	Holding down both Resector Speed Control increase/decrease buttons simultaneously engages the Window Lock function
12	Resector Speed Increase/ Decrease Buttons	Increase or decrease resector speed by 100 rpm with each button press
13	Resector Speed Display (rpm)	Displays the current speed of the resector incrementally in 100 rpm steps over a range of 100 rpm to 1500 rpm
14	Resector Mode Select Button	The Resector Mode button is used to change the resector direction between Oscillate, Forward, and Reverse
15	Resector Mode Indicators	When the resector is in Oscillate mode, a single arrow on each side of the Resector Mode Select button illuminates green (<>) When the resector is in Forward Mode, both right-side arrows illuminate green (>>) When the resector is in Reverse mode, both left-side arrows illuminate green (<<)
16	Saline Pump Flow LED Indicators	Indicates the flow rate setting of the Saline solution
17	Saline Pump Flow Increase / Decrease Buttons	Increase or decrease the flow rate of the Saline pump. Each press of a button results in the flow rate increasing or decreasing by one level
18	Saline Pump ON/OFF Button	Turns the Saline pump ON or OFF
19	Status Indicators	These indicators are located above and below the control buttons for the Tumescence Pump, Lamp, Resector Mode, and Saline Pump. They indicate the component's status by illuminating steady green, flashing green, steady orange, or flashing orange

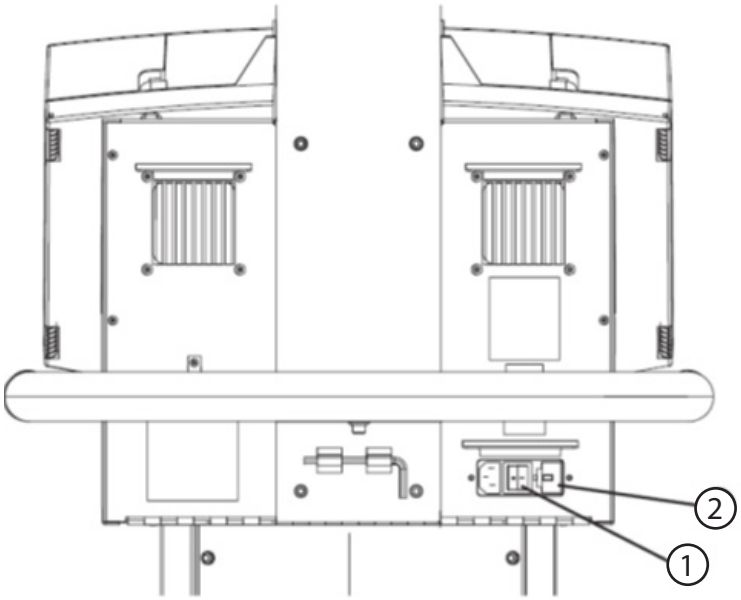


Figure 5: Control Unit Rear Panel

POWER SWITCH

The green rocker switch on the right side is the power ON/OFF switch for the entire system (1).
The switch is illuminated when the system is ON.
The three-prong electrical connector allows connection of the system to any 100 to 240 volt AC (50/60 Hz) source using the power cord supplied with the system.
The system power supply automatically detects the local power standard and adapts the system to that standard

FUSE PANEL

The control unit is protected by dual, 6.3 amp/250 volt time delay fuses mounted on the rear panel to the right of the green power switch (2).
NOTE: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

PREOPERATIVE SETUP FOR USE IN A SURGICAL PROCEDURE

⚠ WARNING: Work exclusively with sterile substances, sterile fluids, and sterile accessories.
There are five main steps for preparing the TRIVEX System for use in a surgical procedure:

1. Power up - turn the TRIVEX System on and check for faults.
2. TRIVEX System Illuminator Tumescence supply setup - prepare the Tumescence solution and tubing.
3. Resector Handpiece saline supply setup - prepare the saline irrigation and tubing.
4. Resector Handpiece setup - connect the Resector Handpiece and verify operation.
5. Connect the TRIVEX System Illuminator and Tumescence Pump footswitches and verify operation.

POWER UP

CAUTION: Ensure that the available mains voltage matches the data listed on the label attached to the back of the control unit. Incorrect voltage can cause errors or malfunction, and may destroy the equipment.
WARNING: To prevent electrical shock, connect the power cord to a properly- wired grounding receptacle only.

1. Plug the unit power cord into the rear panel connector and a grounded AC power source. The control unit power supply automatically detects the local power standard and adapts the system to that standard.
2. Push the power switch on the rear panel to the ON (I) position.
3. The TRIVEX System will start up with these defaults:

- Tumescence pump flow set to level four which corresponds to approximately 450 ml/min flow. Tumescence pump is OFF and Pump ON/OFF button is lit steady orange.
- Saline pump flow is set to level one. Saline pump is OFF and pump ON/OFF button is lit steady orange.
- Resector Mode is set to Oscillate (<>). The Resector Mode button will be lit steady orange if no Resector Handpiece is connected. The button will be lit steady green if a Resector Handpiece is connected.
- Resector Speed is set to 500 rpm.
- Lamp is OFF. Lamp ON/OFF button is lit steady orange.

NOTE: If the Resector Mode Select Button is flashing green or orange see "TROUBLESHOOTING".
NOTE: If the Lamp ON/OFF Button is flashing orange see "TROUBLESHOOTING".

TUMESCENCE SUPPLY SETUP

⚠ WARNINGS:

- This system is intended only for use with flexible fluid containers and fluid bags. Glass containers or bottles may break, and there is a risk of implosion.
- Use of bags or containers not approved for this system, or large and/or lopsided loads, may cause the device to tip over.

1. Hang the tumescence solution bag from the left hand arm of the TRIVEX System irrigation mast.

NOTE: Fluid bags must only be hung on the bag holder hooks. Hang only one bag per hook. Maximum allowable volume is 3 liters.

2. Open the Tumescence Pump Door.
3. Move the Tumescence Pump Handle to the open position to allow loading of the tubing into the Tumescence Pump.
4. Insert the tumescence solution tubing into the Tumescence Pump, and snap the yellow tubing fittings into the corresponding yellow brackets. Ensure that the tubing rests securely in the tubing forks.

CAUTION: Use only the TRIVEX System Illuminator Inflow Tube Set (REF 7209513).

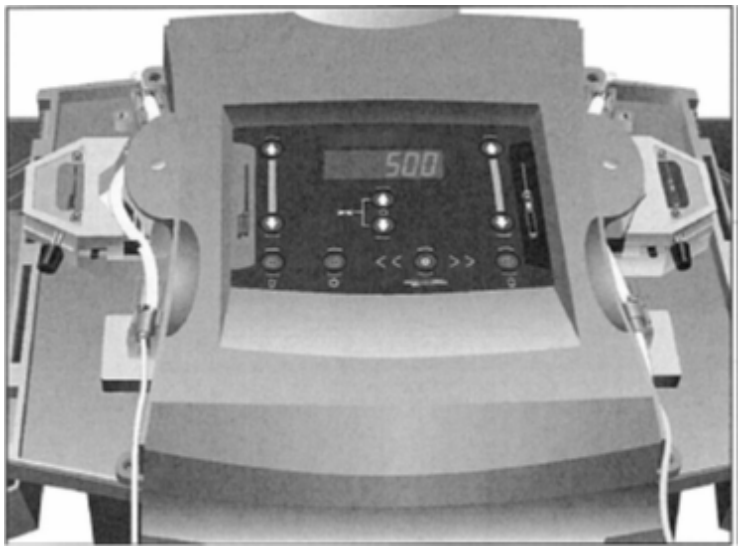


Figure 6: Tubing Connections

⚠ WARNINGS:

- The Tumescence Pump should not be running while setting up the tubing. Injuries to the operator's hands can occur.
- Tube sets are provided STERILE and are for single use only. Do not reuse. Do not resterilize. Prior to use, inspect the product package for signs of damage or tampering. Discard any opened and unused product.

5. Close the Tumescence Pump using the Tumescence Pump Handle. Make sure the tubing forks do not pierce the tumescence solution tubing.
6. Connect the tubing to the Tumescence solution bag.

NOTE: The Tumescence Solution tubing should only be connected to the TRIVEX System Illuminator.

7. Close the Tumescence Pump Door.

RESECTOR HANDPIECE SALINE SUPPLY SETUP

1. Hang the Saline solution bag from the right hand arm of the TRIVEX System irrigation mast.
2. Open the Saline Pump Door.
3. Move the Saline Pump Handle to the open position to allow loading of the tubing into the Saline Pump.
4. Insert the Saline solution tubing into the Saline Pump, and snap the green tubing fittings into the corresponding green brackets. Ensure that the tubing rests securely in the tubing forks.

CAUTION: Use only TRIVEX System Resector Kit tube sets (REF 7209514 or 7209515).

⚠ WARNING: The Saline pump should not be running while setting up the tubing. Injuries to the operator's hands can occur.

⚠ WARNING: Tube sets are provided STERILE and are for single use only. Do not reuse. Do not resterilize. Prior to use, inspect the product package for signs of damage or tampering. Discard any opened and unused product.

5. Close the Saline Pump using the Saline Pump Handle. Make sure the tubing forks do not pierce the saline solution tubing.
6. Connect the tubing to the Saline solution bag.

NOTE: The Saline Solution tubing should only be connected to the Resector Handpiece.

7. Close the Saline Pump Door.

CONNECTING THE RESECTOR HANDPIECE AND RESECTOR

CAUTION: Make sure the wheels on the TRIVEX System roller base are locked to prevent the system from rolling during setup and use.

1. Unscrew the protective cap from the connector end of the resector handpiece cable.
2. Connect the resector handpiece cable to the connection port on the front panel as follows: Orient the handpiece cable connector by aligning the white double arrows on the connector with the white dot on the connection port. The handpiece cable is fully engaged when the white arrows and the white dot are almost touching. Make certain the handpiece cable is fully inserted into the connection port.
3. Press and hold the Run button on the resector handpiece to confirm operation. The resector handpiece motor action can be observed by looking inside the distal end of the resector handpiece.
4. Remove the resector from the sterile package and insert the resector into the resector handpiece per the TRIVEX Resector Instructions for Use (R2590).
5. Press the Run button and observe the resector action to verify that it is properly installed.
6. Set the window lock position as described in the Operation section of this manual.

NOTE: The default directional mode setting for the resector handpiece is Oscillate.

7. Use the Resector Mode Select Button on the console to verify Forward and Reverse modes.

NOTE: If the Resector Mode Select Button is flashing green or orange, there is a problem with the resector handpiece. See the Troubleshooting section.

8. Connect the saline supply line from the Saline Pump to the inflow portal on the TRIVEX System resector.
9. Connect the suction by sliding the suction tubing onto the outflow portal on the proximal end of the resector handpiece.

NOTE: It is recommended that suction of -600 mm Hg be used for optimal resection performance.

CONNECTING THE ILLUMINATOR

⚠ WARNING: Do not hold the shutter open without a fiber optic cable in place. Failure to observe this precaution may result in eye injury.

1. Check the fiber optic cable for damage. Cuts, abrasions, or tears in the silicone sheath covering the fiber optic cable will reduce overall light transmission.
2. While aiming one end of the cable toward a bright light, inspect the other end for damaged fibers, e.g., black dots or dark areas (Figure 7). Excessive numbers of broken fibers in the cable will result in reduced light transmission.
3. Connect the TRIVEX System Illuminator to the instrument end of the fiber optic cable using the ACMI® instrument end adaptor (REF 2141) included with the TRIVEX System.
4. Attach the TRIVEX Light Source adaptor (REF 7210375) to the system end of the fiber optic cable. Press the shutter button and insert the light source end of the fiber optic cable into the light source port. To remove the cable, press the shutter button and then withdraw the cable.

CAUTION: Use only the TRIVEX Light Source adaptor (REF 7210375) with this system. Use of any other light source port adaptor may cause reduced light emission from the fiber optic cable and may cause damage to the system light bulb.

5. Connect the Tumescence inflow tubing to the Illuminator.
6. Connect the Tumescence Pump Footswitches to the Footswitch connectors.

NOTE: The TRIVEX System starts up with the Tumescence pump OFF. The Tumescence Pump must be turned on using the Tumescence Pump ON/OFF button before the footswitches will work.

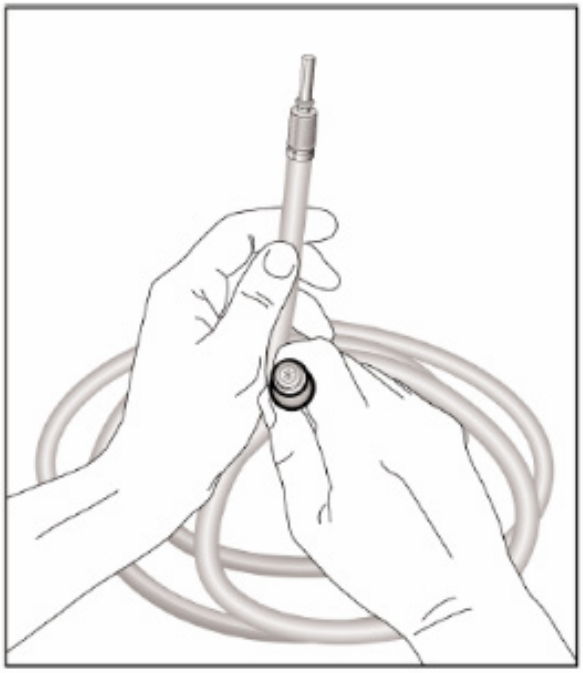


Figure 7: Fiber Optic Cable Inspection

⚠ WARNING: Possible explosion hazard if used in the presence of flammable anesthetics.

OPERATION

CAUTIONS

- Before using the TRIVEX System for the first time, you should review all available product information.
- Verify that the resector handpiece and its cable are sterile.
- Verify that the illuminator and the light guide cable are sterile.
- Check to ensure that the resector(s) required for the procedure are available.
- Verify that the Preoperative Setup has been successfully completed.
- Only LeMaitre Vascular Disposable TRIVEX Resector Kits can be used with the TRIVEX System Control Unit. The resectors are intended for single use only. Do not resterilize. Do not lubricate resectors. Discard the devices after use.
- Make sure the wheels on the TRIVEX System roller base are locked to prevent the system from rolling during setup and use.

RESECTOR CONTROL

There are two button controls on the Resector Handpiece (Figure 8). Press and hold the Run button to start the resector. The resector will run in the selected mode (Forward, Reverse, or Oscillate) until the button is released.

On startup, the TRIVEX System will default to Oscillate mode. The Resector Mode Select button indicator will glow green when a resector handpiece is connected.

For problem conditions with the Resector Handpiece the TRIVEX System will light the indicator bracketing the Resector Mode Select button. There are three possible indicators: a flashing orange light indicates a stalled motor or high current condition; a steady orange light indicates the TRIVEX System cannot detect a Handpiece; and a flashing green light indicates a problem with the Handpiece itself. (See "TROUBLESHOOTING" for additional information.)

The Window Lock function determines the stop position of the inner resector relative to the

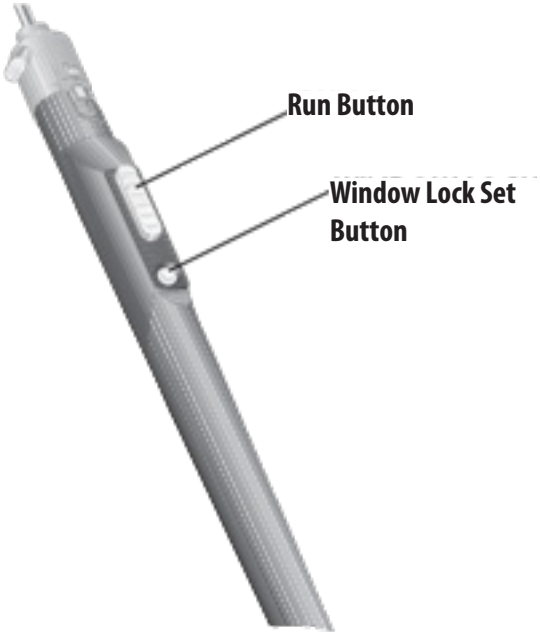


Figure 8: Resector Handpiece Controls

opening in the outer resector. Press and hold the Window Lock Set button to set the Window Lock. The Window Lock will rotate while the button is pressed. Release the button when the Window Lock has reached the desired position.

NOTE: The Resector Window Lock can also be set from the TRIVEX System control console unit console by pressing and holding the Resector Speed Increase and Decrease buttons simultaneously.

RESECTOR HANDPIECE IRRIGATION CONTROL

Turn the Saline Pump on using the Saline Pump ON/OFF Button. The TRIVEX System defaults to a Saline Pump Flow setting level of one on startup. This is approximately 50 ml/min. The Saline Pump will only run while the Resector Handpiece Run button is held down.

The Saline Pump Flow can be increased or decreased by pressing the Flow Increase or

Flow Decrease buttons located above and below the Saline Pump Flow Display. The Saline Pump has five Flow settings. The approximate flow rates for the pump fall between 50 ml per minute and 175 ml per minute.

NOTE: The Saline Pump ON/OFF Button glows orange when the pump is off and glows green when the pump is on.

NOTE: While operating the Resector Handpiece be sure that the saline pump is turned ON.

RESECTOR SPEED

The resector speed display indicates the current speed of the resector in rpm. When the TRIVEX System is turned on, the system is set to a default resector speed of 500 rpm. Use the increase and decrease push-buttons below the console display to set the actual speed of the resector. Pressing the increase and decrease buttons simultaneously will enable the Window Lock function.

Each press of a button will increase or decrease the speed of the resector by 100 rpm. The Resector speed can be set to any 100 rpm increment between 100 rpm and 1500 rpm.

The Forward (>>) and Reverse (<<) arrows that bracket the Resector Mode Select button indicate the resector direction.

CAUTION: Do not allow the rotating portion of the resector to touch any metallic object such as the illuminator. Damage to both instruments is likely. Damage to the resector can range from a slight distortion or dulling of the resector edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures or dulling, or if you have any other reason to suspect a resector is damaged, replace it immediately.

CAUTION: Excessive leverage on the resector does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.

CUTTING

Cutting takes place when the resector edge of the inner tube rotates across the resector's outer window. The resector action alternately opens and closes the window to modulate the suction flow.

WINDOW LOCK

With the Window Lock feature, the resector handpiece can be set to stop the resector in a specific position. The window can be fully opened or closed, or somewhere in between, depending on the technique requirement. Pressing the Window Lock button on the resector handpiece, or pressing the increase and decrease buttons on the console simultaneously will engage the Window Lock function.

CAUTION: Do not operate the resector in the open air for an extended period, as the lack of irrigation may cause the resector to overheat and seize.

TRIVEX SYSTEM ILLUMINATOR IRRIGATION

Turn the Tumescence Pump on using the Tumescence Pump ON/OFF Button. The TRIVEX System defaults to a Tumescence Pump Flow setting level of four on startup approximately 450 ml/min.

The Tumescence Pump Flow can be increased or decreased by pressing the Flow Increase or Flow Decrease buttons located above and below the Tumescence Pump Flow Display. The Tumescence Pump has five Flow settings. The approximate flow rates for the pump fall between 300 ml per minute and 500 ml per minute.

NOTE: The Tumescence Pump ON/OFF Button glows orange when the pump is off and glows green when the pump is on.

Press and hold either footswitch to start the Tumescence Pump. Release the footswitch to stop the pump.

NOTE: The TRIVEX System starts up with the Tumescence pump OFF. The Tumescence Pump must be started using the Tumescence Pump ON/OFF button before the footswitches will work.

TRIVEX SYSTEM ILLUMINATOR CONTROL

Turn the illuminator lamp on using the Lamp ON/OFF Button. When the TRIVEX System lamp is first turned on the button will flash green for 10 seconds while the system does a lamp check.

When the lamp is off the Button glows orange. Each time the lamp is turned off, it will enter a 30-second cool-down cycle. This 30-second cycle is in addition to the 10-second lamp check cycle. As a result, the lamp button can flash green for up to 40 seconds before switching to a steady green glow.

In the event that the lamp does not light after the self-check cycles, the lamp button will flash orange.

CLEANING AND STERILIZATION

RESECTOR HANDPIECE

Follow these steps after each procedure to sterilize the resector handpiece:

1. Dispose of the resector and tube set used during the procedure following standard protocols for disposal of biohazardous waste.

CAUTION: Resectors and tube sets used with the TRIVEX System are for single use only. Do not resterilize. Discard after use.

2. Disconnect the resector handpiece cable from the front panel. Screw the protective cap on to the connector end of the cable.

CAUTION: Do not disconnect the cable from the handpiece.

CAUTION: To prevent moisture from entering the handpiece cable during sterilization ensures that the protective cap is screwed on completely. Moisture can damage the cable or handpiece connectors.

3. Set the suction to fully open by releasing the pinch valve on the suction tube.
4. Clean the unit thoroughly with soapy water **by hand only**. The unit may be immersed.

CAUTION: Do not use ultrasonic cleaners or automated washers to clean the handpiece.

5. Clean the drain tube with a brush. Rinse the unit thoroughly with water. Do not use saline or solvents such as alcohol or acetone.
6. Thoroughly dry the unit using compressed air to evacuate water out of crevices.
7. Sterilize the handpiece using one of the following methods:

- Steam, pre-vacuum, wrapped at 270° F to 275° F (132° C to 135° C) for four minutes.
- Steam, gravity method, wrapped at 270° F to 275° F (132° C to 135° C) for ten minutes.

CAUTION: Do not cool the resector handpiece by immersing it in cold water.

TRIVEX SYSTEM CONTROL UNIT AND FOOTSWITCHES

The TRIVEX System control unit operates outside of the sterile field and does not require sterilization. Sterilization and/or disinfection procedures will damage the product and void the warranty. Follow these steps after each procedure to clean the control unit:

1. Disconnect the TRIVEX System from the electrical source.
2. Wipe the console with a clean damp cloth and mild germicide or isopropyl alcohol.

CAUTION: Do not sterilize or immerse the TRIVEX System console in disinfectant.

Wipe the footswitches and footswitch cables with a clean damp cloth.

FIBER OPTIC CABLE

See the Fiber Optic Cable Instructions for Use (R2603) for proper cleaning and sterilization procedures.

TRIVEX SYSTEM ILLUMINATOR

See the TRIVEX System Illuminator Instructions for Use (R2596) for proper cleaning and sterilization procedures.

MAINTENANCE

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.
- Connect the pieces of equipment into different outlets or circuits.
- Consult a biomedical engineer.

ENVIRONMENTAL PROTECTION

CAUTION: 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.

PREVENTATIVE MAINTENANCE

Recommended Electrical Safety Checks

Three safety tests are conducted on each unit during factory acceptance testing:

- Dielectric Strength Test
- Ground Continuity Test
- Leakage Current Test

LeMaitre Vascular recommends that these tests be performed regularly to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications IEC 60601-1.

CAUTION: Electrical safety testing should be performed by a biomedical engineer or other qualified person.

WARNING: HIGH VOLTAGE is present during electrical safety testing. Exercise extreme caution to prevent personal injury from electrical shock, or damage to the equipment. Ensure that only authorized personnel are in the test area during the tests.

Recommended Periodic Cleaning

LeMaitre Vascular recommends periodic cleaning of the fan screens on the rear panel of the TRIVEX System control unit. Use a soft brush to loosen and remove any dirt that may have collected on the fan screens.

CAUTION: Excessive dirt buildup may reduce air flow from the fans and cause overheating.

SERVICE

Appropriate servicing of the TRIVEX System involves field replacement of fuses, the lamp damaged or worn handpiece cable, fiber optic cable, or damaged or worn power cord. All other repairs should be performed by LeMaitre Vascular.

See "ORDERING INFORMATION" for a list of replacement parts.

SERVICE PHILOSOPHY

There are no user serviceable components inside the TRIVEX System Control Unit. Repairs and adjustments are to be performed only by LeMaitre Vascular service centers.

If service becomes necessary, 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. Daily rentals are available as needed. A replacement program is available, contact your LeMaitre Vascular representative for details.

NOTE: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or sterilized with a sterilization method other than one approved by LeMaitre Vascular will incur additional costs, regardless of warranty status.

REPLACING THE LAMP

WARNING: Do not touch the lamp with bare hands. Use gloves to avoid skin oils that will harm the lamp.

1. Pull knob on Lamp assembly drawer down and pull drawer out.
2. Disconnect Lamp
3. Using provided screwdriver, remove circuit boards (as necessary) and unlatch lamp.
4. Replace Lamp
5. Latch brackets, connect lamp, and reinstall circuit boards (as necessary)

CAUTION: Replace the lamp only with an appropriate LeMaitre Vascular Replacement Lamp (REF 7210115) as specified for the TRIVEX System. Use of any other lamp will void the warranty.

CAUTION: Lamp may be very hot. Use protective eyewear/gloves when handling the lamp.

TRIVEX SYSTEM FUSES

The control unit is protected by dual, 6.3 amp/250 volt time delay fuses mounted on the rear panel to the right of the three- pronged electrical connector. If the control unit fails to power-up when properly connected to a 100–240 volt (±10%) AC power source, check the fuses in the rear panel.

To replace the rear panel fuses:

⚠ *WARNING: To prevent electrical shock, unplug the unit from the electrical outlet before attempting to replace the fuses.*

1. Disconnect the unit from the power source.
2. Locate the fuse tray just to the right of the power cord.
3. Use a slotted screwdriver to press the tab on the side of the fuse holder in, toward the center of the fuse tray.
4. Slide the fuse tray out.
5. Replace the fuses with 6.3 amp/250 volt time delay fuses.

⚠ *WARNING: To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.*

6. Insert the tray into the holder until the tab click into place.
7. Reapply power to the unit.

NOTE: Blown fuses usually indicate a short circuit or a failed component. Make sure components are properly interconnected. If the problem persists, contact LeMaitre Vascular Customer Service for troubleshooting assistance.

RETURNING THE TRIVEX SYSTEM CONTROL UNIT

In the event of a System Error code or some other failure of the TRIVEX System Control Unit, remove the unit from its stand and ship it back to LeMaitre Vascular in its original box.

1. Unplug and remove the power cord from the TRIVEX System Control Unit.
2. Remove the footswitch connectors, fiber optic cable and adaptor, resector handpiece cable, and all tube sets.
3. Using the 3/16" Allen wrench located at the base of the irrigation mast, remove the four mounting bolts and detach the irrigation mast.

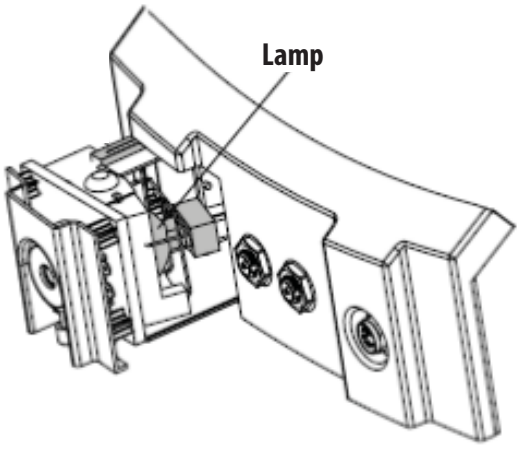


Figure 11: Lamp

4. Using the 3/16" Allen wrench, remove the four bolts securing the rear panel to the roller base. Remove the rear panel.
5. Locate the four drawer latches on the upper- interior of the roller base. For each of the four drawer latches: Lift the latch key and turn it one-half turn counterclockwise. Then lift and disengage the keeper.
6. Lift the TRIVEX Control Unit straight up from the roller base.
7. Repack the TRIVEX Control Unit in its original carton and ship back per instructions provided by LeMaitre Vascular.

TROUBLESHOOTING

SERVICE INDICATIONS

During system operation, the TRIVEX System runs a concurrent diagnostic routine in the background, checking inputs from the attached components. When the system detects a condition that requires attention, an orange or green indicator light is lit on the front panel. In many cases, the system will continue to operate normally, but occasionally allowable resector speed will be reduced. If the procedures below do not resolve the problem, the unit should be referred to qualified personnel for service.

Symptom	Possible Cause	Remedy
The TRIVEX System fails to come on when power switch is pressed.	The unit is not connected to power.	Plug into a power outlet of suitable rating. Ensure that both ends of the power cord are properly connected.
	Lamp assembly drawer is not fully closed.	Check lamp drawer to be sure that it is fully seated into its housing.
Lamp ON/OFF button indicator light is flashing green.	Lamp self-test.	The lamp is running a self-test. Wait 10-40 seconds for self-test to finish.
Lamp ON/OFF button indicator light is flashing orange.	Defective lamp.	Replace the lamp. See Service/ Maintenance for instructions on replacing the lamp.
The light output is low.	The light cable is not in the light source adaptor correctly.	Reseat the fiber optic cable. Check to see if the light source adaptor is in the correct position.
	Illuminator defective.	Replace the illuminator.
	Defective lamp.	Replace the lamp module.
	Wrong light source portal adaptor attached to fiber optic cable.	Use only the TRIVEX System Light Source adaptor (REF 7210375).
Resector Mode Select button indicator light is flashing green.	Moisture in resector handpiece or resector cable connectors.	Disconnect the cable from the control unit. Check the cable connector for moisture. If wet, rinse the connector with distilled water and dry completely.
	There is a problem with the resector handpiece.	If the flashing green persists, the resector handpiece is damaged; contact your LeMaitre Vascular representative.
No light from light guide.	Light guide adaptor latch did not catch.	Check light guide adaptor to ensure that it is fully seated into console.
Resector Mode Select button is flashing orange while handpiece Run button is held down.	The resector handpiece motor has stalled.	Remove and inspect the resector. Replace with a new resector if damaged.
		Run the handpiece without a resector. If the handpiece is still stalled, use alternate handpiece and contact your LeMaitre Vascular representative.
Resector Mode Select button indicator light is flashing orange after handpiece Run button is released.	High current warning for resector handpiece.	Contact your LeMaitre Vascular representative.
Resector Handpiece will not run and Resector Mode Select button indicator light is green.	Bad handpiece connector cable.	Check cable connections. Make certain the handpiece cable is fully inserted into the port on the front panel.
Resector Mode Select button indicator light is steady orange.	Resector Handpiece not connected.	Connect a resector handpiece to the TRIVEX System.
Resector Speed Display reads E-01 through E-15.	System Error.	Note the error code and contact your LeMaitre Vascular representative.
Tubing appears to be creeping through the pump.	Tubing forks not tight enough.	Tighten the tubing forks by one notch until tubing is secure, or contact your LeMaitre Vascular representative for specific adjustment instructions.

No fluid flow from peristaltic pump.	Pump head is not latched.	Check black pump closing lever to be sure it is fully closed.
	Pump rollers have seized.	Call Customer Service for return authorization.

TECHNICAL SPECIFICATIONS

TRIVEX SYSTEM CONTROL UNIT (7210386)

Dimensions:	22.6″ wide x 24.2″ deep x 64.0″ high
Weight:	80 lbs
Power:	100–120/200–240 VAC 50/60 Hz, 350 VA
Equipment Classification:	Protection against electrical shock class 1 with BF type applied part. Protection against harmful ingress of water. (Ordinary equipment, none provided) Degree of safety of application in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide. (Not suitable)

FRONT PANEL

Lamp ON/OFF Button:	Turns the 50 Watt Metal Halide lamp On or Off and displays current lamp status.
Resector Speed Display:	4 character digital display–actual speed for installed resector.
Resector Mode Select Button:	Single momentary push button used to select the Resector Mode.
Resector Mode Display:	Two left-facing arrows and two right-facing arrows-display resector mode: Forward (>>), Reverse (<<), and Oscillate (<>).
Resector Speed Buttons:	Two momentary push buttons for increasing and decreasing speed settings.
Resector Window Lock Display:	Pressing and holding both the Resector Speed Buttons at the same time sets the Resector Window Lock.
Tumescence Pump Flow Buttons	Two momentary push buttons for increasing or decreasing Tumescence pump flow.
Saline Pump Flow Buttons:	Two momentary push buttons for increasing or decreasing Saline pump flow.
Pump ON/OFF Buttons:	Two momentary push buttons for starting or stopping the Saline pump or the Tumescence pump.
Connectors:	Light Source port, two Footswitch cable connectors, and a Resector Handpiece connector

REAR PANEL

Power ON/OFF:	Rocker switch
AC Power:	Detachable cord with a three-pin hospital-grade connector. Power input circuit automatically detects AC power standard.
Fuses:	Two 6.3 amp/250 volt time delay fuses (Littel Fuse, Inc., P/N 021806.3HXP).

TRIVEX RESECTOR HANDPIECE (REF 7210387)

Handpiece with push-button motor and window lock controls.

Length:	7.1″
Weight:	8.5 oz.

Equipped with 10-foot (3-meter) autoclavable, replaceable resector handpiece cable.

TRIVEX SYSTEM FOOTSWITCH (REF 7209791)

Two supplied.

ORDERING INFORMATION

TRIVEX SYSTEM COMPONENTS

REF	*DESCRIPTION*
2141	VERSITIP ACMI Adaptor
7205180	Gemini Universal Light Guide
7209791	TRIVEX System Footswitch
7210351	TRIVEX System Illuminator
7210375	VERSITIP , TRIVEX Adaptor
7210386	TRIVEX System Control Unit
7210387	TRIVEX System Resector Handpiece

7210414	TRIVEX System Cart
R2932	U.S. Power Cord
R2933	U.K. Power Cord
R2931	TUV/ EU Power Cord
R2927	China/ AUS Power Cord

TRIVEX SYSTEM DISPOSABLES/ACCESSORIES

REF	*DESCRIPTION*
7205683	Autoclavable Storage and Sterilization Tray
7209513	Illuminator Inflow Tubing
7209514	TRIVEX , 4.5 mm Blade and Tubing
7209515	TRIVEX, 5.5 mm Blade and Tubing
7210115	Replacement Lamp

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The LeMaitre Vascular TRIVEX System is intended for use in the electromagnetic environment specified below. The customer or the user of the LeMaitre Vascular TRIVEX System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The LeMaitre Vascular TRIVEX System 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 LeMaitre Vascular TRIVEX System 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
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LeMaitre Vascular TRIVEX System is intended for use in the electromagnetic environment specified below. The customer or the user of the LeMaitre Vascular TRIVEX System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic (ESD) Discharge IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile and the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<95% dip in UT for 1/2 cycle 60% dip in UT for 5 cycles 30% dip in UT for 25 cycles >95% dip in UT for 5 sec	<95% dip in UT for 1/2 cycle 60% dip in UT for 5 cycles 30% dip in UT for 25 cycles >95% dip in UT for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LeMaitre Vascular TRIVEX System requires continued operation during power mains interruptions, it is recommended that the LeMaitre Vascular TRIVEX System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the LeMaitre Vascular TRIVEX 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 LeMaitre Vascular TRIVEX System is used exceeds the applicable RF compliance level above, the LeMaitre Vascular TRIVEX System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LeMaitre Vascular TRIVEX System.

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

GUIDANCE FOR SEPARATION DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and the LeMaitre Vascular TRIVEX System

The LeMaitre Vascular TRIVEX System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the LeMaitre Vascular TRIVEX System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LeMaitre Vascular TRIVEX System 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.

HARDWARE (CONTROL UNIT AND MDU)- NEW:

If you purchased a new device, then the following warranty applies:
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 warranty applies to the original buyer of this device only. 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. Damage inflicted on this device by the user that renders it unsuitable for refurbishment may result in additional charges, regardless of warranty status. 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 twelve 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.

HARDWARE- REFURBISHED:

If you purchased a refurbished device, then the following warranty applies:
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 warranty applies to the original buyer of this refurbished device only. 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. Damage inflicted on this device by the user that renders it unsuitable for refurbishment may result in additional charges, regardless of warranty status. 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.

SERVICE REPLACEMENT UNITS WARRANTY

The TRIVEX System replacement units are warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

REPLACEMENT PROGRAM

LeMaitre Vascular offers a Replacement Program for TRIVEX System Control Units to minimize downtime in your operating room. With an active Replacement Agreement in place, a replacement TRIVEX System Control Unit will be shipped within 48-hours via next day delivery*. For a Return Goods Authorization (RGA) number or for additional information on this program, call Customer Service at 1-800-628-9470 in the U.S., or contact your LeMaitre Vascular representative.

*Next day delivery is not offered in all countries.

REPAIR SERVICE PROGRAM

For devices no longer under warranty, repairs can be made by LeMaitre Vascular. Non-warranty repairs will be made at the list price of replacement parts, plus labor. We will provide an estimate of repair cost and time required for the repair before any work is completed. Repair items should be carefully repackaged, marked with the Return Goods Authorization (RGA) number, and returned postpaid to the address provided by LeMaitre Vascular. LeMaitre Vascular Customer Service or your local representative can provide shipping information.

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), 855-673-2266 (Canada).

目录

前言

本手册提供操作和维护 LeMaitre Vascular TRIVEX® 浅表静脉曲张动力去除系统所需的信息。在使用或维护该系统之前，通读并理解本手册的所有信息非常重要。

目录

图

设备描述/适用范围/使用禁忌

设备描述
TRIVEX® 系统通过 TRIVEX 系统照明器使用金属
卤化物弧灯提供高强度白光透照。在下肢浅静脉曲张切除术期间，使用光导纤维光缆将照明器连接至 TRIVEX 系统以提供透照。

TRIVEX 系统使用一对蠕动式泵提供透照法曲张静 脉动力刨削术所需的灌注和肿胀麻醉。左侧泵专用通过 TRIVEX 系统照明器提供肿胀麻醉。右侧泵 专用于为 TRIVEX 切除器手持机提供生理盐水以进行切除器尖端灌注。

基本性能:
灌注泵的流量控制；切除器的转速控制；照明器的照明。

适用范围
TRIVEX 系统适用于在微创手术中下肢浅表曲张静脉的切除， 与旋切刀头组件和塑料灌注管路联合使用于临床。

使用禁忌
TRIVEX 系统禁忌用于静脉曲张微创手术 禁忌的情形。

警告
在使用 TRIVEX® 系统之前，请通读本手册。本手 册中的简明操作指导将使您使用系统更加容易，而执行建议的维修和维护步骤可确保系统发挥最佳性能并且多年操作稳定可靠。与任何手术设备一样，必须考虑健康和安全性因素。这些将在下文中列出并会在手册相应部分重述。

使用 TRIVEX 系统之前，必须检查系统的所有组 件是否存在对设备性能会产生不良影响的损坏迹 象。检查应包括手术中将使用的所有设备（包括 照明器、电缆和附件）。

从运输包装盒中取出 TRIVEX 系统和附件时，检查盒内物品并确保包含“拆开组件包装”部分的所有组件且均完好无损。

若发现部件损坏迹象，请与您的获授权 LeMaitre Vascular 代表联系

⚠ 警告

- 在第一次使用 TRIVEX 系统之前，您必须通读提 供的所有产品信息。医生必须熟悉此手术技术和 TRIVEX 系统的操作。请参阅《TRIVEX 手术技术指南》（参考编号2200026）。您应有在静脉曲张微创手术中使用电动 器械的临床经验。若 TRIVEX 系统切除器使用不当会损伤病人健康组织。因此应采取所有措施以避免此类 损伤。
- TRIVEX 切除器套件包成套提供。必须按供货原样 使用。切勿交换切除器组件。照明器吸入导管套件和切除器套件均以无菌 状态供货且仅限一次性使用。切勿重复使用。切勿重复灭菌。使用之前，应检查产品包装有无破损或撕裂迹象。应丢弃任何已打开包装且未使用过的产品。若已超过有效期，切勿使用。
- 重复灭菌或重复使用照明器导管套件和切除器套件 可能导致产品机械性损伤。由此对病人及操作员造成伤害。
- 在安装导管期间，TRIVEX 系统泵应处于非运行状 态。否则会对操作员的手造成伤害。
- 只可使用无菌物质、无菌液体和无菌附件。
- 配合本系统只能使用柔软的液体容器和液袋。玻璃容器或瓶子易碎，且存在内爆危险。
- 本系统上使用未经认证的的袋子或容器，或较大和/或不平衡的负载，可能会引起设备翻转。
- 如果手术期间的任何时间出现无法看见切除点，应立即停止手术。

- 若 TRIVEX 切除器对血管压力过大，或 TRIVEX 切除器在固定位置上激活时间过长，则可能导致切除器经四肢表面穿孔。
- 切勿在未正确连接光导纤维光缆的情况下即打开光源快门。若未遵照此注意事项则可能对眼睛造成损害。
- 手术期间，避免长时间将照明器头端与病人组织或易爆材料接触。由于高强度光传输，照明器头端可能达较高温度。
- 危险：若在存在易燃性麻醉剂的场所使用，则存在潜在爆炸危险。
- 当光源打开时，请勿在未戴防护眼镜的情况下直接观看金属卤化物弧灯。
- 为避免遭受电击，请勿拆卸 TRIVEX 系统控制台封盖。本设备中没有用户可维修的组件。若拆装本设备，将使其保修失效。维修工作将由获授权的LeMaitre Vascular 代表完成。
- 为避免遭受电击，只能将电源电缆连接到采用有线方式正确接地的供电插座中。
- 为避免遭受电击，在尝试更换保险丝之前应从电源插座中拔出设备电源电缆。
- 使用时请特别小心：无论灯处于冷或热状态，其内部高压均可能引起爆炸。在处理灯时，应始终穿着防护服并戴上保护面罩。
- 在本装置的输出端和内部电路中，存在危险高压和电能。
- 如果本装置配置为系统的一部分，则必须测试整个系统以确保符合 IEC 60601-1 标准。
- 如果配置后系统的总漏电电流超出 IEC 60601-1 标准规定的极限，则应安装一个相应额定值的、符合 UL 60601-1/IEC 60601-1 标准的绝缘变压器并重新测试系统。
- 某些情况下，即使关闭电源后高压仍可能继续存 在。只有合格的电气设备维修人员才可对“拆除外壳”的电源进行操作或故障排除。
- 泄漏电流测试期间存在危险电压。切勿触摸通电后的 TRIVEX®系统。
- 介电强度测试和高压绝缘电流泄漏测试期间存在高压 (1500 VAC)。操作介电强度测试器或高压绝缘电流泄漏测试器时应非常小心，以防电击造成人员受伤或损坏设备。测试期间应确保仅获授权人员在测试区内。
- 为免遭火灾，应只使用正确类型、额定电压和额定电流值的保险丝。
- TRIVEX 系统不应该与其工作频率相同或相近的其它设备接近或叠放使用，如果必须接近或叠放使用，则应观察验证在其使用的配置下能正常运行。
- 必须使用由本公司提供的电源电缆线及脚踏开关，设备所使用的电源线必须取得“CCC”认证且电源线长度应该小于3米。
- 除本公司提供的电源电缆线及脚踏开关外，使用其它的厂家附件可能导致 TRIVEX 系统发射的增加或抗扰度的降低。
- 配合本设备若使用未达到匹配安全性要求的附件设备，可能会导致最终系统的安全性级别降低。选择附件时应考虑的相关因素包括：
    - 附件将在病人附近使用。
    - 已按照相应的 IEC 60601标准执行了附件安全 性认证的验证。

注意事项

- 美国联邦法律限制本装置只能由医生销售或根据其医嘱销售。
- 使用之前，应检验装置是否存在可能的损坏，以确保其正常发挥功能。若发现损坏切勿使用。
- 检查并确保切除器手持机及其电缆均为无菌状态。
- 检查并确保照明器和光导纤维光缆均为无菌状态。
- 检查并确保手术所需的切除器均已备妥。
- 检查并确保已成功完成手术前安装。
- 配合 TRIVEX 系统只能使用 LeMaitre Vascular 一次性 TRIVEX 切除器套件包。配合 TRIVEX 系统使用的切除器仅限一次性使用。切勿对切除器重复灭菌或润滑。使用后请丢弃切除器。
- 使用重新处理后的一次性切除器可能会对您的 LeMaitre Vascular TRIVEX 系统造成永久性损坏、降低其性 能或引起故障。此类产品使用可能导致任何相关产 品或所有产品的保修失效。
- 确保将 TRIVEX 系统滚轮底座上的轮子锁死，以防止在安装和使用期间系统意外滚动。
- 已在使用 TRIVEX 系统的临床研究中观察到在常规 静脉曲张微创显微手术中会出现青肿、血肿和含铁血黄素沉积。

- 在清洁本装置之前应先断开电源电缆。
- 切勿对 TRIVEX 系统控制台进行灭菌或将其浸入消毒剂中。
- 为了防止灭菌期间有潮气进入手持机电缆，应确保已 紧紧旋上防潮帽。否则潮气会损坏电缆或手持机的连接器。
- 请勿让任何切除器的旋转部分接触到任何金属物体 （如照明器）。否则可能对两者均造成损坏。人体内造成切除器的损坏从轻微的变形或切除器边缘变 钝到严重的端头部位断裂。若发生此类接触，请检
- 查端头部位。若发现裂纹、断裂或变钝，或者您 有任何其它理由怀疑切除器已受损，应立即更换。
- 切除器扭转力矩过大并不会提高切割性能，在极 端情况下反而可能引起内部组件磨损和性能降低。
- 请勿将切除器手持机浸入冷水中进行冷却。
- 请勿较长时间在暴露的空气中操作切除器。
- 配合本系统只能使用 TRIVEX® 光源适配器（参考编号 7210375）。使用任何其它光源端口适配器均可能减弱光导纤维光缆的光线辐射。
- 尝试更换灯之前，必须先关闭电源开关，并从电源插座上拔下电源电缆。
- 只能使用 LeMaitre Vascular 专为TRIVEX 系统生产的适当灯（参考编号 7210115）来更换本系统的灯。使用任何其它灯将导致产品保修失效。
- 灯可能非常灼热。处理此灯时，应戴上保护眼罩和手套。
- 照明器未在病人及其周围使用时不要放置手术灯线。高强光会使得灯线端达到很高的温度。
- 本装置符合 IEC 60601-1-2 标准。但是，用户必须意识到这并不保证本装置不会受到来自其它设备的干扰。
- 切勿将装置运行在其背面所示的线电压以外的范围 上。
- 确保所用的主电源电压与控制单元背面板标签上列示的数据一致。电源电压若不正确会引起错误或功能故障，并可能对设备造成永久性损坏。
- 处理本装置时应小心谨慎。如果本装置跌落或以任何方式损坏，必须立即退回进行维修。
- 电气安全测试必须由生物医学工程师或其他有资格的人员执行。
- 本设备含有印刷电路组件。在本设备的使用寿命结束时，应根据本国或管理机构适用的废弃电子设备管理法规进行处置和丢弃。
- 本设备经设计和检测，可确保对其它电气设备造成极小的干扰。但是，如果对其它设备造成干扰，可通过以下一种或多种方式予以纠正：
    - 改变本设备、其它设备或两者的方向或位置。
    - 增大设备之间的间距。
    - 将每个设备分别连接到不同的电源插座或电路上。
    - 咨询生物医学工程师寻求帮助。
- 旧的设备应按照本地和/或本国有关法规和规程进行处置和丢弃。

系统组件

TRIVEX® 系统包含各种不同组件：

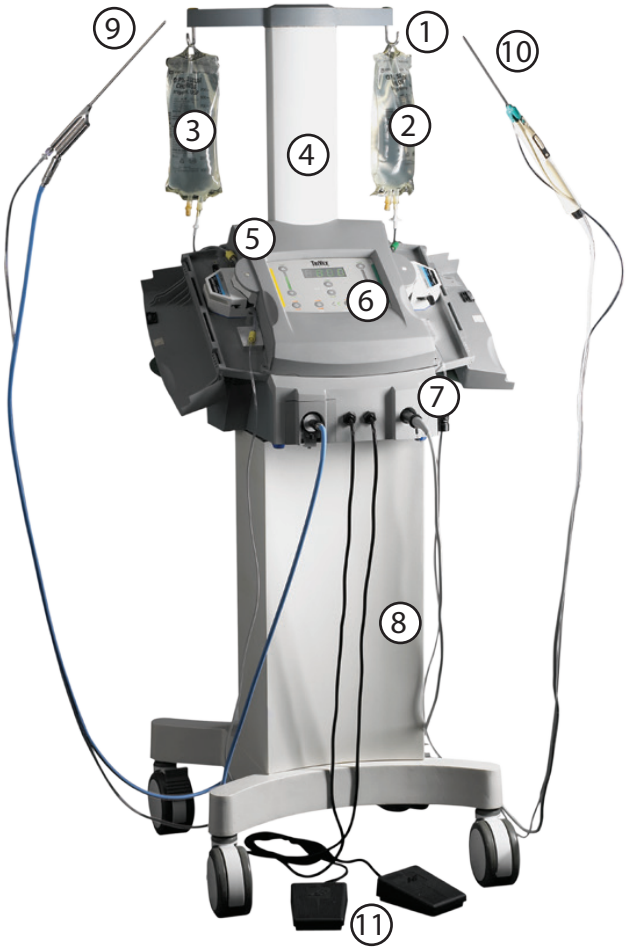
- TRIVEX 系统控制单元用于控制 TRIVEX 切除器的操作模式和速度、肿胀麻醉泵和生理盐水灌注泵的启动和流量、以及 TRIVEX 系统照明器的光源操作。
- 控制台包括一个显示屏，用于显示切除器速度；也包括几个 LED 指示灯，用于显示泵流速度。
- 四个控制按钮（肿胀麻醉泵、灯、切除器模式和生理盐水灌注泵）均在其上方和下方配有指示灯。这些指示灯以稳定绿色、闪烁绿色、稳定橙色或闪烁橙色等不同亮起方式指示每个组件的状态。
- 控制单元前面板上有连接照明器、两个脚踏开关和切除器的手持机。
- TRIVEX 系统支架提供用于TRIVEX 系统控制单元的移动式基座，及用于生理盐水和肿胀麻醉液灌注袋的灌注杆。
- 通过 TRIVEX 系统照明器，50 瓦金属卤化物弧灯提供高强度白光。
- TRIVEX 切除器手持机驱动 LeMaitre Vascular 4.5 厘米TRIVEX 切除器（参考编号 7209514）和 5.5 厘米TRIVEX 切除器（参考编号 7209515），通过按压式按钮控制切除器的操作。

切除器手持机

TRIVEX 切除器手持机是手持式电动机驱动装置，通过3 米电缆连接到控制单元。切除器手持机用于驱动一

次性切除器。
切除器手持机及其电缆为高温高压灭菌处理的（请参阅“清洁和灭菌”部分）。

TRIVEX 系统照明器
TRIVEX 系统照明器（参考编号 7210351）是一种附件，用于滴入肿胀麻醉液并透照目标静脉曲张部位。更详细信息，请参阅 TRIVEX 系统照明器使用说明（参考编号1059-00）。



组件识别
1. 液袋挂钩（2 个）
2. 生理盐水液袋
3. 肿胀麻醉液袋
4. 灌注杆
5. 控制单元
6. 控制单元显示器
7. 连接端口
8. 带滚轮底座的 TRIVEX系统支架
9. TRIVEX系统照明器
10. TRIVEX系统切除器手持机
11. 脚踏开关（2 个）

拆开组件包装
请小心拆开包装并检查随 LeMaitre Vascular TRIVEX® 系统附送的所有组件。如果发现任何部件缺失或损坏，请与您的获授权LeMaitre Vascular代表联系。请保留好外包装箱和包装材料，以备以后需退回组件进行修理时使用。

组装组件
将控制单元组装到支架

1. 将带滚轮的支架放到平坦的水平面上，让背面板朝向您。
2.从灌注杆底座上拆下 3/16 英寸内六角扳手。使用内六角扳手，拆下将背面板固定到滚轮底座的四条螺栓。
3.将控制单元的底座与滚轮底座的顶部对齐，将控制单元向下放在滚轮底座上（图 2）。
4.对位于滚轮底座内部的四个抽屉闩销：提起并啮合闩销，然后将闩销开关沿顺时针方向旋转半圈。折叠闩销开关使之收平。
5.重新装回背面板并重新插入四条螺栓。

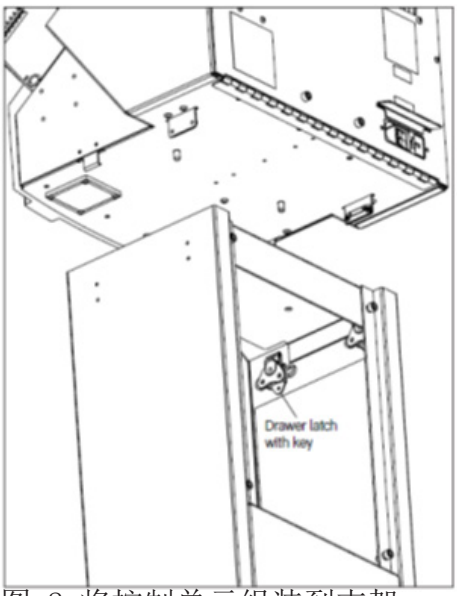


图 2.将控制单元组装到支架

将手柄组装到灌注杆
6. 从控制单元背面拆下四条灌注杆安装螺栓。
7. 执行以下步骤将手柄安装到灌注杆：使用 3/16 英寸内六角扳手从手柄上拆下两颗 1/4-20 x 5/8 英寸内六角螺钉和垫圈，然后将手柄放入灌注杆焊件的盒状部件内。调整手柄方向使螺纹插入端与焊件盒状部件的开口孔对齐。用两颗 1/4-20 x 5/8 英寸内六角螺钉和垫圈将手柄固定。
8. 将灌注杆安装到控制单元背面的手柄上，用四条灌注杆安装螺栓将其固定。

注意：确保将 TRIVEX 系统滚轮底座上的轮子锁死，以防止在安装和使用期间系统意外滚动。

TRIVEX® 系统控制单元前面板

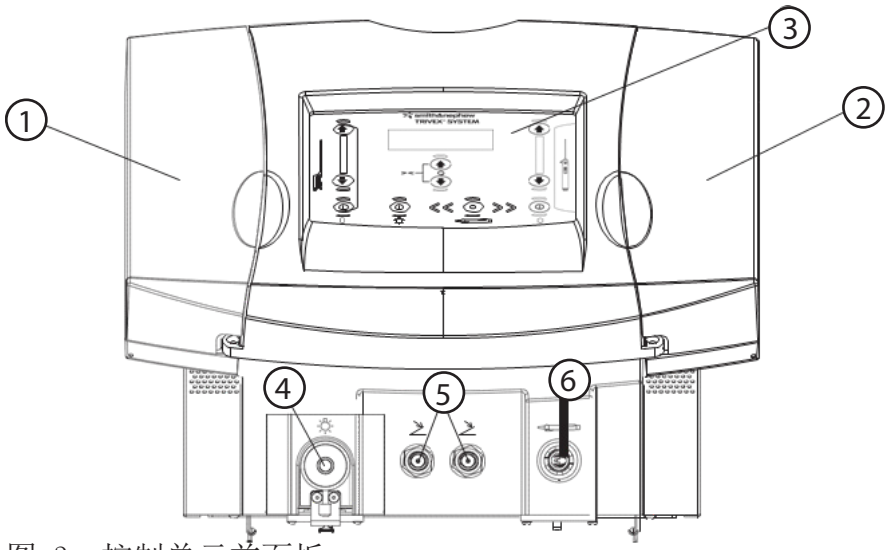


图 3. 控制单元前面板

控制单元前面板
1. 肿胀麻醉泵门 – 覆盖肿胀麻醉泵五金件。
2. 生理盐水灌注泵门 – 覆盖生理盐水灌注泵五金件。
3. TRIVEX 系统显示屏 – 包括控制系统操作的按压式按钮和显示屏。

前面板连接器
前面板上有四个连接器：
4. 光导纤维光缆连接端口 – 自闭合式端口，设计用于插接 TRIVEX 光源适配器（参考编号 7210375）。

注意：使用任何其它光源端口适配器均可能减弱光导纤维光缆的光线辐射或损坏包括光源灯泡在内的内部元件。

5. 两个脚踏开关导管连接端口 – 用于插接 TRIVEX 系统脚踏开关的导管。
6. 切除器手持机电缆连接端口 – 用于插接切除器手持机电缆。

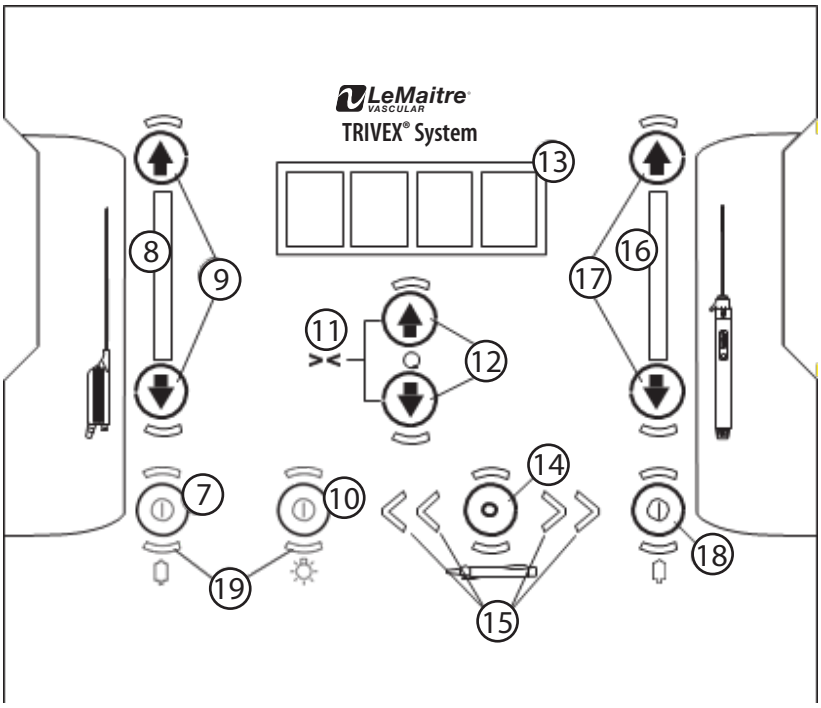


图 4. 控制单元显示器

控制台控制项和功能

	控制项	功能
7	肿胀麻醉泵开关按钮	打开或关闭肿胀麻醉泵电源。
8	肿胀麻醉泵流量 LED 指示灯	显示肿胀麻醉液的流速设置。
9	肿胀麻醉泵流量增大/减小按钮	增大或减小肿胀麻醉泵的流速。每按一下按钮会使流速增大或减小一个级别
10	灯开关按钮	打开或关闭灯电源。
11	窗锁定控制	同时按住切除器速度控制增大/减小按钮，以执行窗锁定功能
12	切除器速度增大/减小按钮	每按一下按钮，切除器转速会增大或减小 100 rpm。
13	切除器速度显示屏 (rpm)	显示切除器的当前转速，转速范围介于 100 rpm 至 1500 rpm 之间，增量为 100 rpm。
14	切除器模式选择按钮	切除器模式按钮用于在 Oscillate（振动）、Forward（正向）和 Reverse（反向）之间变换切除器刨削方向。
15	切除器模式指示灯	当切除器处于 Oscillate（振动）模式时，切除器模式选择按钮的每一侧会显示绿色的单箭头 (< >)。当切除器处于 Forward（正向）模式时，将显示绿色双向右箭头 (>>)。当切除器处于 Reverse（反向）模式时，将显示绿色双向左箭头 (<<)。
16	生理盐水灌注泵流量 LED 指示灯	显示生理盐水灌注液的流速设置。
17	生理盐水灌注泵流量增大/减小按钮	增大或减小生理盐水灌注泵的流速。每按一下按钮会使流速增大或减小一个级别。
18	生理盐水灌注泵开关按钮	打开或关闭生理盐水灌注泵电源
19	状态指示灯	这些指示灯位于肿胀麻醉泵、灯、切除器模式和生理盐水灌注泵的控制按钮上方和下方。这些指示灯以稳定绿色、闪烁绿色、稳定橙色或闪烁橙色等不同亮起方式指示相应组件的状态。

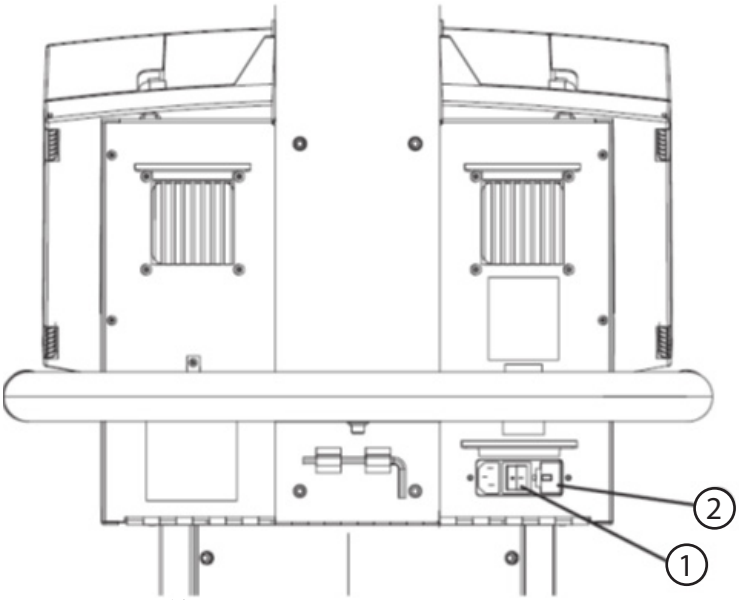


图 5. 控制单元背面板

电源开关

右侧的绿色摇摆式开关为整个系统 的电源开关。

当系统电源打开时，开关灯亮起。

三插脚电源连接器允许使用随系统附送的电源电缆将系统连接到任何 100-240 V 交流 (50/60 Hz) 电源上。系统电源自动检测当地电源标准，并调节系统适应该标准。

保险丝盖板

控制单元受 6.3 A/250 V 延时型双保险丝保护，保险丝位于背面板绿色开关 的右侧。

注释：如果系统因任何原因关闭，在重新打开电源之前，应等待至少 15 秒钟。

手术前安装

⚠ 警告：只可使用无菌物质、无菌液体和无 菌附件。

安装 TRIVEX® 系统准备执行外科手术

以下是准备 TRIVEX 系统以便执行外科手术的五个主要步骤：

1. 打开电源 - 打开 TRIVEX 系统电源并检查是否存在故障。
2. TRIVEX 系统照明器肿胀麻醉液供应安装 - 准备肿胀麻醉液和导管。
3. 切除器手持机生理盐水灌注液供应导管安装 - 准备生理盐水灌注液和导管。
4. 切除器手持机安装 - 连接切除器手持机并确认其操作。
5. 连接 TRIVEX 系统照明器和肿胀麻醉泵脚踏开关并确认其操作。

打开电源

注意：确保所用的主电源电压与控制单元背面板标签上列示的数据一致。电源电压若不正确会引起错误或功能故障，并可能毁坏设备。

⚠ 警告：为避免遭受电击，只能将电源电缆连接到采用有线方式正确接地的供电插座中。

1. 将设备电源电缆插入背面板电源连接器和接地的交流电供电插座中。控制单元电源自动检测当地电源标准，并调节系统适应该标准。
2. 将背面板的电源开关拨至打开 (I) 位置。

3. TRIVEX 系统启动并采用以下默认设置：
- 肿胀麻醉泵流量设置为 4 级，约相当于 450 毫升/分。肿胀麻醉泵处于关闭状态，且泵开关按钮指示灯以稳定橙色亮起。
- 生理盐水灌注泵流量设置为 1级。生理盐水灌注泵处于关闭状态，且泵开关按钮指示灯以稳定橙色亮起。
- 切除器模式设置为 Oscillate（振动）(<>)。如果未连接切除器手持机，切除器模式按钮将以稳定橙色亮起。如果已连接切除器手持机，按钮将以稳定绿色亮起。
- 切除器速度设置为 500 rpm。
- 灯处于关闭状态。灯开关按钮指示灯以稳定橙色亮起。

注释：如果切除器模式选择按钮指示灯以绿色或橙色闪烁，请参阅“故障排除”。
注释：如果灯开关按钮指示灯以橙色闪烁，请参阅“故障排除”。

肿胀麻醉液供应安装
警告
- 配合本系统只能使用柔性的液体容器和液袋。玻璃容器或瓶子易碎，且存在内爆危险。
- 本系统上使用未经认证的的袋子或容器，或较大和/或不平衡的负载，可能会引起设备翻转。

1. 将肿胀麻醉液袋挂在 TRIVEX 系统灌注杆的左臂挂钩上。

注释：只能将液袋挂在液袋挂钩上。一个挂钩只能挂一个液袋。最大允许体积为 3 升。

2. 打开肿胀麻醉泵门。
3. 将肿胀麻醉泵手柄移到打开位置，以允许导管装载到肿胀麻醉泵内。
4. 将肿胀麻醉液导管插入肿胀麻醉泵内，并将黄色导管接头卡入相应的黄色卡架内。确保将导管紧紧固定在导管叉架内。

注意：只能使用 TRIVEX 系统照明器流入导管 套件（参考编号 7209513）。

⚠ 警告：在安装导管期间，肿胀麻醉泵应处 于非运行状态。否则会对操作员的手造成伤害。

⚠ 警告：导管套件以无菌状态供货且仅限一次性使用。切勿重复使用。切勿重复灭菌。使用之前，应检查产品包装有无破损或撕裂 迹象。应丢弃任何已打开包装且未使用过的产品。

5. 使用肿胀麻醉泵手柄关闭肿胀麻醉泵。确保导管叉架不要刺破肿胀麻醉液导管。
6. 将导管连接到肿胀麻醉液袋。

注释：只能将肿胀麻醉液导管连接到 TRIVEX® 系统照明器。

7. 关闭肿胀麻醉泵门。

切除器手持机生理盐水灌注液供应导管安装
1. 将生理盐水灌注液袋挂在 TRIVEX 系统灌注杆的右臂挂钩上。
2. 打开生理盐水灌注泵门。
3. 将生理盐水灌注泵手柄移到打开位置，以允许导管装载到生理盐水灌注泵内。
4. 将生理盐水灌注液导管插入生理盐水灌注泵内，并将绿色导管接头卡入相应的绿色卡架内。确保将导管紧紧固定在导管叉架内。

注意：只能使用 TRIVEX 系统切除器导管套件
（参考编号 7209514 或 7209515）。

⚠ 警告：在安装导管期间，生理盐水灌注泵应处于非运行状态。否则会对操作员的手造成伤害。

⚠ 警告：导管套件以无菌状态供货且仅限一次性使用。切勿重复使用。切勿重复灭菌。使用之前，应检查产品包装有无破损或撕裂迹象。应丢弃任何已打开包装且未使用过的产品。

5. 使用生理盐水灌注泵手柄关闭生理盐水灌注泵。确保导管叉架不要刺破生理盐水灌注液导管。
6. 将导管连接到生理盐水灌注液袋。

注释：只能将生理盐水灌注液导管连接到切除器手持机。

7. 关闭生理盐水灌注泵门。

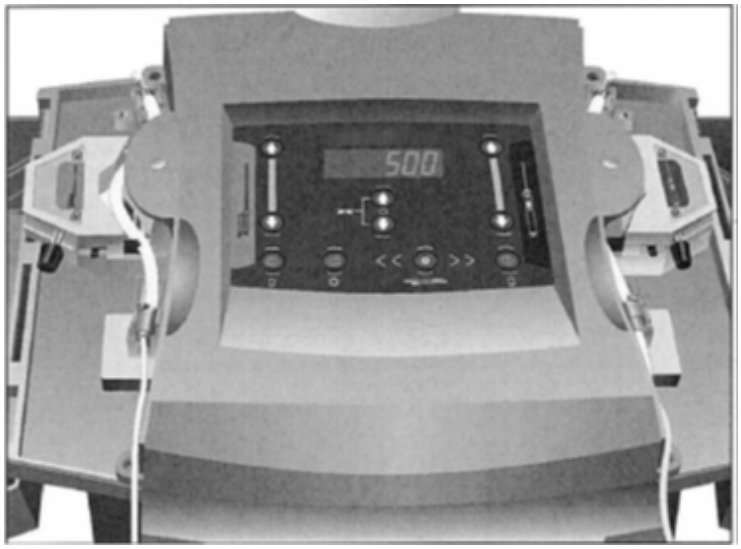


图 6. 导管连接

连接 TRIVEX®切除器手持机和切除器

注意：确保将 TRIVEX 系统滚轮底座上的轮子锁死，以防止在安装和使用期间系统意外滚动。

1. 将防潮帽从切除器手持机电缆的连接器端旋下。
2. 执行以下步骤将切除器手持机电缆连接到前面板连接端口：将连接器上的白色双箭头与连接器端口上的白点对齐，调整好手持机电缆连接器的方向。当白色箭头与白点几乎接触时，手持机电缆已完全卡扣啮合。确保已将手持机电缆完全插入连接端口内。
3. 按下并按住切除器手持机上的运行按钮以确认其操作。观察切除器手持机远端内部，检查切除器手持机的电动机操作。
4. 按照 TRIVEX 切除器使用说明（参考编号 1061199）的指导，从无菌包装中取出切除器，并将切除器插入切除器手持机。
5. 按下运行按钮并观察切除器的操作，以确认安装正确。
6. 按照本手册“操作”部分的描述设置窗锁定位置。

注释：切除器手持机的默认方向模式设置为 Oscillate（振动）。

7. 使用控制台上的切除器模式选择按钮以确认 Forward（正向）和 Reverse（反向）模式的操作。

注释：如果切除器模式选择按钮指示灯以绿色或橙色闪烁，则说明切除器手持机存在问题。请参阅“故障排除”部分。

8. 将生理盐水灌注液供应导管从生理盐水灌注泵连接到 TRIVEX 系统切除器的流入端口。
9. 将抽吸管滑动到切除器手持机近端的流出端口，连接好抽吸管。

注释：建议使用600毫米汞柱的吸力，以便获得最佳切除性能。

连接 TRIVEX® 系统照明器

⚠ 警告：切勿在未正确连接光导纤维光缆的 情况下即打开光源快门。若未遵照此注意事项则可能对眼睛造成损害。

1. 检查光导纤维光缆有无损坏。光缆硅酮外皮上若有切口、磨损或裂口，将会降低整体光传输质量。
2. 将光缆一端指向亮光，检查另一端是否有损坏的纤维，例如，是否可看到黑点或深灰色斑区（图 7）。光缆内若有过多断裂的光纤，将会导致光传输质量降低。
3. 使用随 TRIVEX 系统照明器附送的 ACMI® 仪器末端适配器（参考编号 2141），将 TRIVEX 系统照明器连接到光缆的仪器末端上。
4. 将 TRIVEX 光源适配器（参考编号 7210375）连接到光导纤维光缆的系统末端上。按快门按钮并将光导

纤维光缆的光源末端插入光源端口内。要拆除光缆，按快门按钮然后拔出光缆。

注意：配合本系统只能使用 TRIVEX 光源适配器（参考编号 7210375）。使用任何其它光源端口适配器均可能减弱光导纤维光缆的光线辐射并可能损坏系统灯泡。

5. 将肿胀麻醉液流入导管连接到照明器。
6. 将肿胀麻醉泵脚踏开关连接到脚踏开关连接器。

注释：TRIVEX 系统启动时，肿胀麻醉泵处于关闭状态。在可以使用脚踏开关之前，必须先使用肿胀麻醉泵开关按钮打开肿胀麻醉泵电源。

⚠ 警告：若在存在易燃性麻醉剂的场所使用，则存在潜在爆炸危险。

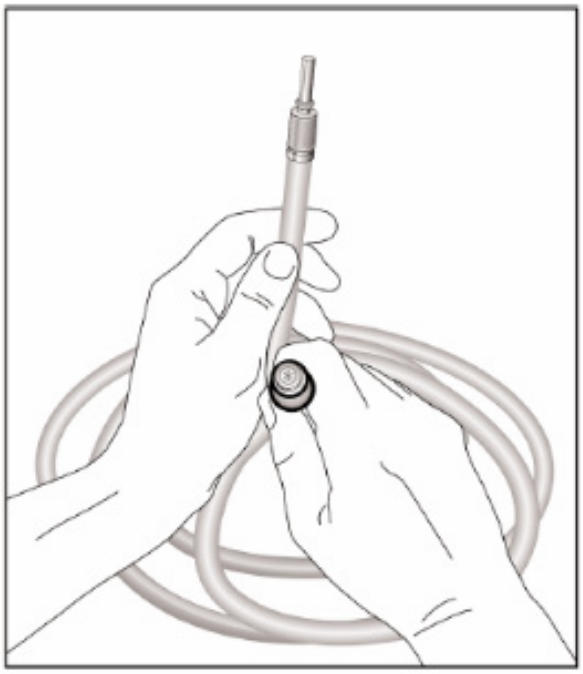


图 7. 光导纤维光缆检查

操作

注意

- 在第一次使用 TRIVEX®系统之前，您必须通读提供的所有产品信息。
- 检查并确保切除器手持机及其电缆均为无菌状态。
- 检查并确保照明器和光导向装置电缆均为无菌状态。
- 检查并确保手术所需的切除器均已备妥。
- 检查并确保已成功完成手术前安装。
- 配合 TRIVEX 系统控制单元只能使用 LeMaitre Vascular 一次性 TRIVEX 切除器套件包。这些切除器设计仅限一次性使用。切勿重复灭菌。请勿润滑切除器。使用后请丢弃设备。
- 确保将 TRIVEX 系统滚轮底座上的轮子锁死，以防止在安装和使用期间系统意外滚动。

切除器控制

切除器手持机上有两个控制按钮（图 8）。按下并按住运行按钮以启动切除器。切除器将在所选模式（Forward（正向）、Reverse（反向）或 Oscillate（振动））下运行，直到释放按钮。

启动时，TRIVEX 系统将默认为 Oscillate（振动）模式。当已连接切除器手持机时，切除器模式选择按钮指示灯将以绿色亮起。
如果切除器手持机存在故障状态，TRIVEX 系统将使包围切除器模式选择按钮的指示灯亮起。指示灯有三种可能亮起方式：以橙色闪烁表示电动机停止或电流较大；以稳定橙色亮起表示 TRIVEX 系统未能检测到手持机；以绿色闪烁表示手持机本身存在故障。（有关详情，请参阅“故障排除”部分。）
“窗锁定”功能确定相对于外部切除器开口的内部切除器停止位置。按下并按住窗锁定设置按钮以设置窗锁定。当按下此按钮时，窗锁定将旋转。当窗锁定到达所需位置时释放按钮。

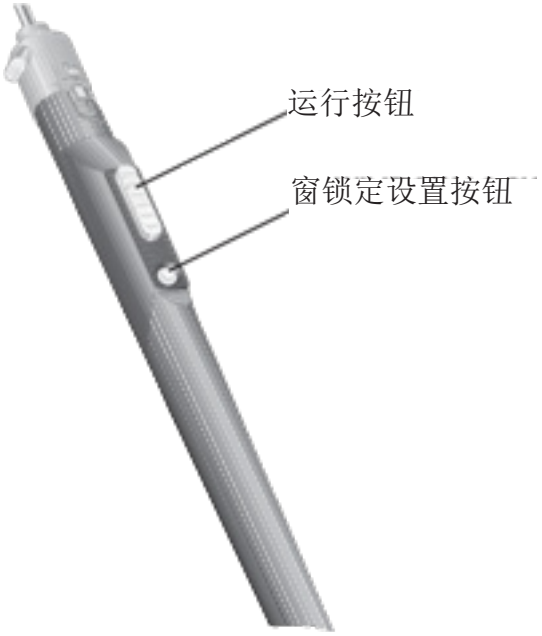


图 **8.** 切除器手持机控制

注释：切除器窗锁定也可在 TRIVEX 系统控制单元控制台上通过同时按下并按住切除器速度增大和减小按钮来设置。

切除器手持机抽吸控制

TRIVEX®系统采用标准医疗抽吸方式。推荐 600毫米汞柱作为最佳切除的吸入压力。 将抽吸管连接到切除器

手持机近端的端口上，以除去通过切除器窗吸聚的液体和碎屑。除了除去液体外，抽吸液还可冷却并润滑电动机驱动装置。

图 9. 切除器手持机抽吸控制杆完全打开

切除器手持机近端的控制杆用于控制抽吸流量。控制杆可从完全打开到完全闭合进行调节，提供抽吸速度的即刻手动控制。

1. 当控制杆与箭头指示符对齐（图 9）时，抽吸流速达到最大。
2. 当控制杆与箭头指示符垂直（图 10）时，抽吸流速归零。

切除器手持机灌注控制

使用生理盐水灌注泵开关按钮打开生理盐水灌注泵电源。启动时 TRIVEX 系统的生理盐水灌注泵默认流量设置为 1 级， 约为 50 毫升/分。仅在按住切除器手持机运行按钮时生理盐水灌注泵才会运行。

图 10. 切除器手持机抽吸控制杆完全闭合

按位于生理盐水灌注泵流量显示屏上方和下方的流量增大或流量减小按钮，可增大或减小生理盐水灌注泵流量。生理盐水灌注泵有五个流量级别设置。泵的流速约介于 50 毫升/分至 175 毫升/分之间。

注释：生理盐水灌注泵开关按钮指示灯将在泵关闭时以橙色亮起，在泵打开时以绿色亮起。

注释：操作切除器手持机时要确保生理盐水灌注泵已打开。

切除器速度

切除器速度显示屏上显示切除器的当前转速（单位：rpm）。当打开 TRIVEX® 系统时，系统将切除器转速默认设置为 500 rpm。使用控制台显示屏下方的增大和减小按钮，可以设置切除器的实际转速。同时按下增大和减小按钮将启动窗锁定功能。

每按一下按钮，会将切除器的转速增大或减小 100 rpm。切除器转速可设置为介于 100 rpm 与 1500 rpm 之间的设置，增量为 100 rpm。

包围切除器模式选择按钮的指示灯以 (>>)（正向）和 (<<)（反向）箭头显示切除器的刨削方向。

注意：请勿让切除器的旋转部分接触到任何金属物体（如照明器）。否则可能对两者均造成损坏。人体内造成切除器的损坏从轻微的变形或切除器边缘变钝到严重的端头部位断裂。若发生此类接触，请检查端头部位。若发现裂纹、断裂或变钝，或者您有任何其它理由怀疑切除器已受损，应立即更换。

注意：切除器扭转力矩过大并不会提高切割性能，在极端情况下反而可能引起内部组件磨损和性能降低。

切割

当内部导管的切除器边缘划过切除器外窗旋转时，便执行切割（刨削）操作。切割器操作会交替打开和关闭窗口以调节抽吸流量。

窗锁定

通过窗锁定功能，可设置切除器手持机在特定位置上停止。此窗可完全打开或关闭，或处于两者间的某个位置，根据技术要求而定。按下切除器手持机上的窗锁定按钮，或同时按下控制台上的增大和减小按钮都可启动窗锁定功能。

注意：请勿较长时间在暴露的空气中操作切除器，因为缺少灌注可能会引起切除器过热而被卡住。

TRIVEX 系统照明器灌注
使用肿胀麻醉泵开关按钮打开肿胀麻醉泵电源。启动时，TRIVEX 系统将肿胀麻醉泵流量默认设置为 4 级，约为 450 毫升/分。

按位于肿胀麻醉泵流量显示屏上方和下方的流量增大或流量减小按钮，可增大或减小肿胀麻醉泵流量。肿胀麻醉泵有五个流量级别设置。泵的流速约介于 300 毫升/分至 500 毫升/分之间。

注释：肿胀麻醉泵开关按钮指示灯将在泵关闭时
以橙色亮起，在泵打开时以绿色亮起。

踩下并压住任意一个脚踏开关可启动肿胀麻醉泵。释放脚踏开关以停止肿胀麻醉泵。

注释：TRIVEX 系统启动时，肿胀麻醉泵处于关闭状态。在可以使用脚踏开关之前，必须先使用肿胀麻醉泵开关按钮启动肿胀麻醉泵。

TRIVEX 系统照明器控制
使用灯开关按钮打开照明器。当第一次打开 TRIVEX 系统灯时，开关按钮指示灯将以绿色闪烁 10 秒钟，此时系统正在执行灯检查。

当灯关闭时，按钮指示灯以橙色亮起。每次将灯关闭后，将进入 30 秒的冷却循环。此 30 秒冷却循环独立于 10 秒灯检查循环。因此，在变换为稳定绿色之前，灯按钮指示灯会以绿色闪烁长达 40 秒。

如果在自检查循环后照明灯未亮，则灯按钮指示灯将以橙色闪烁。

清洁和灭菌

切除器手持机
每次手术后应按照下列步骤对切除器手持机进行灭菌：
1. 按照处置生物危害废弃物的标准程序处置并丢弃用过的切除器和导管套件。

注意：配合 TRIVEX® 系统使用的切除器和导 管套件仅限一次性使用。切勿重复灭菌。使用后请丢弃。

2. 从前面板上拔下切除器手持机电缆。请勿从手持机上断开电缆连接。
将防潮帽固定到电缆连接器末端上。

注意：为了防止灭菌期间潮气进入手持机电缆，应确保防潮帽已完全上紧。否则潮气会损坏电缆或手持机的连接器。

3. 让抽吸控制杆与双箭头对齐，将抽吸控制杆置于完全打开状态。

注释：如果拆下抽吸控制杆，注意不要丢失抽吸控制杆的 O 型环。

4. 用肥皂水彻底清洁设备。
可将设备浸泡漂洗。
5. 用刷子清洁排放管。用水彻底冲洗部件。切勿使用生理盐水或溶剂，如酒精或丙酮。
6. 使用以下方法之一对手持机进行灭菌：
- 预抽真空高温蒸汽灭菌法（包裹），在 132℃ 至 135℃下灭菌 4 分钟。
- 重力置换高温蒸汽灭菌法（包裹），在 132℃ 至 135℃ 下灭菌 10 分钟。

注意：请勿将切除器手持机浸入冷水中进行冷却。

TRIVEX 系统控制单元和脚踏开关
TRIVEX 系统控制单元在无菌区以外操作，且无需灭菌。灭菌和/或消毒步骤会损坏本产品，并使产品保修失效。每次手术后应按照下列步骤对控制单元进行清洁：
1. 从电源插座中拔出 TRIVEX 系统电缆。
2. 用干净布块蘸湿温和杀菌剂或异丙醇擦拭控制台。

注意：切勿对 TRIVEX 系统控制台进行灭菌或将其浸入消毒剂中。

用干净的湿布块擦拭脚踏开关及其电缆。脚踏开关（参考编号 7209791）具有 IPX8 级防水性能。

光导纤维光缆
有关正确的清洁和灭菌步骤，请参阅光导纤维光缆使用说明（参考编号10600351）。

TRIVEX 系统照明器
有关正确的清洁和灭菌步骤，请参阅 TRIVEX 系统照明器使用说明（参考编号1059-00）。

维护
电气干扰
注意：本设备经设计和检测，可确保对其它电气设备造成极小的干扰。但是，如果对其它设备造成干扰，可通过以下一种或多种方式予以纠正：
- 改变本设备、其它设备或两者的方向或位置。
- 增大设备之间的间距。
- 将每个设备分别连接到不同的电源插座或电路上。
- 咨询生物医学工程师寻求帮助。

环境保护
注意：本设备含有印刷电路组件。在本设备的使用寿命结束时，应根据本国或管理机构适用的废弃电子设备管理法规进行处置和丢弃。

预防性维护
建议电气安全性检查
在工厂验收测试期间，对每件装置均进行了三项安全性测试：
- 介电强度测试
- 接地持续性测试
- 泄漏电流测试

LeMaitre Vascular建议定期进行这些测试，以确保持续符合适用的安全性要求。这些测试应按照IEC 60601-1 标准所列的规格执行。
注意：电气安全测试必须由生物医学工程师或其他有资格的人员执行。

⚠ 警告：电气安全性测试期间存在高压。操作应非常小心，以防电击造成人员受伤或损坏设备。测试期间应确保仅获授权人员在测试区内。

建议定期清洁
LeMaitre Vascular 建议定期对 TRIVEX® 系统控制单元背面板上的风扇罩进行清洁。用软毛刷松动并除去任何聚积在风扇罩上的灰尘。
注意：聚积过多灰尘可能会降低风扇的送气流量并引起设备过热。

维修
TRIVEX® 系统的适当维修包括：现场更换保险丝、灯；现场更换损坏或磨损的手持机电缆、光导纤维光缆；

或现场更换损坏或磨损的电源电缆。所有其它修理只能在工厂进行或由 LeMaitre Vascular 授权的现场维修技术人员执行。
有关替换部件的列表，请参阅“订购信息”。

维修原则
TRIVEX 系统控制单元中没有用户可维修的组件。修理和调节只能由 LeMaitre Vascular 授权的维修中心执行。
如果需要进行维修，在退回本设备之前，请致电获授权的 LeMaitre Vascular 客户维修代表，并获取一个退还授权 (RA, Return authorization) 编号。您的代表会向您解释可用的更换服务和修理计划。
必须小心地将待维修部件包装好，并邮寄回LeMaitre Vascular。您的 LeMaitre Vascular 客户维修代表会提供其它相关指导。

注释：对于退回维修的产品，若发现在此之前产
品曾经由未获授权的第三方维修机构进行过维修，和/或曾经采用非 LeMaitre Vascular 许可的灭菌方法进行过灭菌，则无论产品保修是否已失效，您都需要支付相关的维修费用。
退回设备进行维修时，不必包括各附件（如电源电缆等）。

更换灯
请参阅随替换灯附送的更换灯指导说明（参考编号 1061448）。
注意：只能使用 LeMaitre Vascular 专为TRIVEX 系统生产的适当灯（参考编号 7210115）来更换本系统的灯。使用任何其它灯将导致产品保修失效。
注意：灯可能非常灼热。处理此灯时，应戴上保护眼罩和手套。

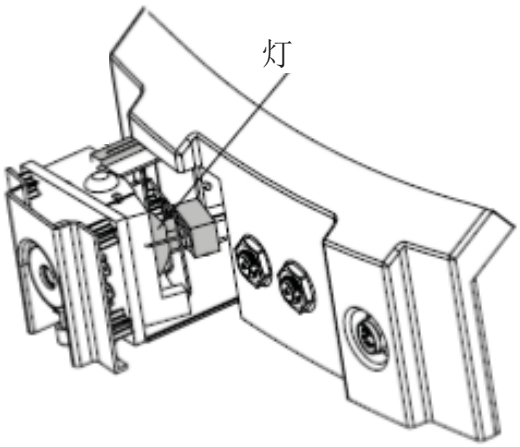


图 11. 灯

TRIVEX 系统保险丝
控制单元受 6.3 A/250 V 延时型双保险丝保护，保险丝位于背面板上三插脚电源连接器的右侧。

当控制单元正确连接到 100-240 V (±10%) 交流电源时若不能加电启动，应检查背面板内的保险丝。

更换背面板保险丝：

⚠ 警告：为避免遭受电击，在尝试更换保险丝之前应从电源插座中拔出设备电源电缆。
1. 从电源插座中拔下控制单元电源电缆。
2. 在紧靠电源电缆的右侧找到保险丝托盘。
3. 使用带槽口的螺丝刀向托盘中心方向按压保险丝架两侧的卡舌。
4. 将保险丝托盘滑出。
5. 使用 6.3 A/250 V 延时型保险丝更换保险丝。

⚠ 警告：为免遭火灾，应只使用正确类型、额定电压和额定电流值的保险丝。

6. 将托盘插入保险丝架，直到卡舌将其卡扣到位。
7. 重新接通装置电源。

注释：保险丝熔断通常表明存在短路或组件故障。确保组件间正确互连。若问题依然存在，请与 LeMaitre Vascular 客户服务部联系以寻求故障排除帮助。

退回 TRIVEX® 系统控制单元
如果 TRIVEX 系统控制单元出现系统错误代码或其它一些故障，应将其从支架上拆下，并用原始包装材料

包装后寄回LeMaitre Vascular。
1. 从 TRIVEX 系统控制单元上拔出并拆下电源电缆。
2. 拆下脚踏开关连接器、光导纤维光缆和适配器、切除器手持机电缆以及所有导管套件。
3. 使用灌注杆底座上的 3/16 英寸内六角扳手，拆下四条安装螺栓并分离灌注杆。
4. 使用 3/16 英寸内六角扳手，拆下将背面板固定到滚轮底座的四条螺栓。拆下背面板。
5. 找到滚轮底座内部上方的四个抽屉闩销。对四个抽屉闩销中的每个闩销：提起闩销开关并沿逆时针方向旋转半圈。然后提起并松脱挡板。
6. 从滚轮底座上垂直向上提起 TRIVEX 控制单元。

用原始包装箱将 TRIVEX 控制单元重新包装好并寄回LeMaitre Vascular。

故障排除
维修状态
系统操作期间，TRIVEX® 同时在后台运行诊断例程，检查来自相连组件的输入。当系统检测到需引起注意的状态时，前面板上的橙色或绿色指示灯会亮起。许多情况下，系统将继续正常操作，但偶尔切除器会减速。如果下列步骤未能解决您的问题，请将您的设备交由合格人员进行维修。

故障排除
维修状态
系统操作期间，TRIVEX® 同时在后台运行诊断例程，检查来自相连组件的输入。当系统检测到需引起注意的状态时，前面板上的橙色或绿色指示灯会亮起。许多情况下，系统将继续正常操作，但偶尔切除器会减速。如果下列步骤未能解决您的问题，请将您的设备交由合格人员进行维修。

症状	可能原因	纠正方法
当按下电源开关时，TRIVEX 系统未启动	设备未插入电源插座。	将电源电缆插入供应适当额定值的电源插座。确保电源电缆的两端均正确连接。
	灯组件抽屉未完全关闭。	检查灯抽屉并确保其已完全固定在外壳内。
灯开关按钮指示灯以绿色闪烁。	灯自测试。	灯正在运行自测试。等待 10 至 40 秒使自测试结束。
灯开关按钮指示灯以橙色闪烁。	有缺陷的灯。	更换灯。有关更换灯的指导说明，请参阅“维修/维护”部分。
光输出较弱。	光缆未正确插入光源适配器。	重新插接光导纤维光缆。检查光源适配器是否处于正确位置。
	有缺陷的照明器。	更换照明器。
	有缺陷的灯。	更换灯模块。
	连接到光导纤维光缆的光源端口适配器不正确。	配合本系统只能使用 TRIVEX 系统光源适配器（参考编号 7210375）。
切除器模式选择按钮指示灯以绿色闪烁。	切除器手持机或切除器电缆连接器内有潮气。	从控制单元上拔下电缆。检查两个电缆连接器上是否存在潮气。如有潮湿，用蒸馏水彻底冲洗连接器并使其彻底干燥。
	切除器手持机出现问题。	如果持续闪烁绿灯，则表明切除器手持机已损坏，请与您的获授权 LeMaitre Vascular 代表联系。
光导向装置中无光发出。	光导向适配器插销未锁定。	检查光导向适配器并确保其已紧固固定在控制台上。
当按下手持机运行按钮时，切除器模式选择按钮指示灯以橙色闪烁。	切除器手持机失速。	拆下并检查切除器。如有损坏，应使用新切除器更换。
		在没有切除器的情况下运行手持机。如果手持机仍异常停止，应更换手持机。
当释放手持机运行按钮后，切除器模式选择按钮指示灯以橙色闪烁。	切除器手持机强电流报警。	请与您的 LeMaitre Vascular 代表联系。

切除器手持机不运行且切除器模式选择按钮指示灯以绿色亮起。	手持机连接器电缆故障。	检查电缆连接。确保已将手持机电缆完全插入前面板上的端口内。
切除器模式选择按钮指示灯以稳定橙色亮起。	未连接切除器手持机。	将切除器手持机连接到 TRIVEX® 系统。
切除器速度显示屏显示为 E-01 至 E-15。	系统错误。	记录下错误代码并与您的 LeMaitre Vascular 代表联系。
导管似乎在穿过泵微微蠕动。	导管叉架未足够固定。	通过凹口紧固导管叉架，或致电客户服务部了解具体调节说明。
蠕动式泵中无液流流出。	泵压头未锁定。	检查黑色泵闭合拉杆，确保其完全闭合。
	泵滚轮被卡死。	请致电客户服务部以获得退还授权。

技术规格
TRIVEX® 系统控制单元
（参考编号 7210386）
尺寸
57.4 厘米宽 x 61.47 厘米厚 x 162.56 厘米高

重量
36.29 千克

电源
100-120/200-240 V 交流，50/60 Hz，350 VA

设备分类
Class 1（I 类）防电击保护，Type BF（BF 型）
电气部件。

有害水侵入防护等级。

（普通设备，不提供防护级别。）

在存在易燃性麻醉剂与空气、氧气或一氧化二氮混合物的场合的电器安全性级别。
（不适合）

前面板
灯开关按钮
打开或关闭 50 瓦金属卤化物弧灯，并显示当前的灯状态。
切除器速度显示屏
4 字符数字显示屏 – 显示所安装切除器的实际转速。
切除器模式选择按钮
单个短暂按压式按钮，用于选择切除器
操作模式。
切除器模式显示屏
两个左向箭头和两个右向箭头 – 显示切除器模式：正向 (>>)、反向 (<<) 和振动 (<>)。
切除器速度按钮
两个短暂按压式按钮，用于增大和减小转速设置。
切除器窗锁定显示屏
同时按下并按住两个切除器速度按钮可设置切除器窗锁定。
肿胀麻醉泵流量按钮

两个短暂按压式按钮，用于增大或减小肿胀麻醉泵流量。
生理盐水灌注泵流量按钮
两个短暂按压式按钮，用于增大或减小生理盐水灌注泵流量。
泵开关按钮
两个短暂按压式按钮，用于启动或停止生理盐水灌注泵或肿胀麻醉泵。
连接
光源端口、两个脚踏开关电缆连接器和一个切除器手持机连接器。

背面板
电源开关
摇摆式开关。
交流电源
可拆卸软线，三导芯医用级连接器。电源输入电路自动检测交流电源标准。
保险丝
两条 6.3 A/250 V 延时保险丝（参考编号 8100305）。

TRIVEX 切除器手持机
（参考编号 7210387）
手持机，带按压式电动机和窗锁定控制按钮。
长度
18.03 厘米

重量
0.24 千克

配备 3 米可高压灭菌、可更换切除器手持机电缆。

TRIVEX 系统脚踏开关
（参考编号 7209791）
随系统提供两个脚踏开关。

尺寸
10.16 厘米宽 x 13.97 厘米厚 x 4.45 厘米高

重量
0.21 千克

订购信息

TRIVEX® 系统部件

参考编号	描述
2141	用于 TRIVEX 系统照明器的ACMI® 适配器
1061421	操作/维护手册
7205180	光导纤维光缆
7209513	照明器流入导管套件
7209514	4.5毫米TRIVEX 系统 100 SV 切除器套件
7209515	5.5 毫米TRIVEX 系统 200 LV 切除器套件
7209791	TRIVEX 系统脚踏开关
7210115	替换灯
7210351	TRIVEX 系统照明器

7210375 TRIVEX 系统光源适配器
7210386 TRIVEX 系统控制单元
7210387 带电缆的 TRIVEX 系统切除器手持机
7210414 TRIVEX 系统支架
8005600 美国规格电源电缆
8013378 英国规格电源电缆
8013380 国际规格电源电缆
1248-00 电源线(中国)

规范指南和制造商声明
电磁辐射

规范指南和制造商声明 - 电磁辐射		
LeMaitre Vascular TRIVEX® 系统设计用于下文指定的电磁环境。LeMaitre Vascular TRIVEX 系统的客户或用户应确保该系统是在这样的环境中使用。		
辐射测试	符合规范	电磁环境 - 规范指南
射频辐射 CISPR 11	1 组	LeMaitre Vascular TRIVEX 系统仅为其内部功能使用射频能量。因此，其射频辐射非常低，且不可能对附近的电子设备产生干扰。
射频辐射 CISPR 11	A 类	LeMaitre Vascular TRIVEX 系统适合在所有电路设施中使用，但民用电路设施和直接连接到公共低电压供电网（为民用用途建筑物供电）的电路设施除外。
谐波辐射 IEC 61000-3-2	A 类	
电压波动 / 闪变辐射 IEC 61000-3-3	符合规范	

规范指南和制造商声明 - 电磁抗扰度

规范指南和制造商声明 - 电磁抗扰度			
LeMaitre Vascular TRIVEX® 系统设计用于下文指定的电磁环境。LeMaitre Vascular TRIVEX 系统的客户或用户应确保该系统是在这样的环境中使用。			
抗扰度测试	IEC 60601 测试水平	符合 水平	电磁环境 - 规范指南
静电 放电 IEC 61000-4-2	+/- 6 kV（接触） +/- 8 kV（空气）	+/- 6 kV（接触） +/- 8 kV（空气）	地板应为木材、混凝土或陶瓷铺设，相对湿度至少达到30%。
快速瞬变脉冲 / 瞬爆 IEC 61000-4-4	供电线压 +/- 2 kV 输入 / 输出线压 +/- 1 kV	供电线压 +/- 2 kV 输入 / 输出线压 +/- 1 kV	所用主电源应为普通商用或医用电源。
电涌 IEC 61000-4-5	差动 模式 +/- 1 kV 共态 模式 +/- 2 kV	差动 模式 +/- 1 kV 共态 模式 +/- 2 kV	所用主电源应为普通商用或医用电源
电源输入线路上的电压瞬时跌落、短时断路和电压波动 IEC 61000-4-11	UT 上 <95% 的暂降持续 1/2 个周期 UT 上 60% 的暂降持续 5 个循环 UT 上 30% 的暂降持续 25 个循环 UT 上 >95% 的暂降持续 5 秒	UT 上 <95% 的暂降持续 1/2 个周期 UT 上 60% 的暂降持续 5 个循环 UT 上 30% 的暂降持续 25 个循环 UT 上 >95% 的暂降持续 5 秒	所用主电源应为普通商用或医用电源。如果 LeMaitre Vascular TRIVEX 系统的用户需要在电源中断期间继续操作，建议配备一只不间断电源或电池，以便为 LeMaitre Vascular TRIVEX 系统持续供电。

工频（50/60 Hz）磁场 IEC 61000-4-8	3 A/m	3 A/m	工频磁场水平应为普通商用或医用环境中普通地点的水平。
注释：UT 是应用测试级别前的交流主电源电压。			
传导射频 IEC 61000-4-6	3 Vrms 150 kHz 至 80 MHz	3 Vrms	勿在接近 LeMaitre Vascular TRIVEX 系统的任何位置（包括线缆附近）使用便携和移动式射频通信设备，而应在根据适用于发射机频率的等式计算出的建议间隔距离使用。 建议间隔距离 d=1.2 √(p) d=1.2 √(p) 80 MHz 至 800 MHz d=2.3 √(p) 800 MHz 至 2.5 GHz 其中，p 代表发射机制造商公布的发射机最大输出功率额定值，以瓦特（W）为单位；d 代表以米（m）为单位的建议间隔距离。
辐射射频 IEC 61000-4-3	3 V/m 80 MHz 至 2.5 GHz	3 V/m	执行电磁现场调查a 所获得的来自固定射频发射机的场强，应低于每一频率范围内的要求水平。b 在标有以下符号的设备附近可能会出现干扰： 
注释 1：在 80 MHz 至 800 MHz 频率下，适用较高的频率范围。 注释 2：这些使用指南可能并不适用于所有情况。电磁传播受设施建筑物、物体和人员的吸收和反射等特性影响 a 无法从理论上精确地预测来自固定发射机的场强，如无线电（手机 / 无绳电话）发射基站和地面移动无线电系统、业余无线电系统、调幅和调频无线电广播及电视广播等。要评价固定射频发射机所造成的电磁环境，应考虑进行电磁现场调查。如果在使用 LeMaitre Vascular TRIVEX 系统的位置测得的磁场强度超出以上适用的射频符合规范级别，则应观察 LeMaitre Vascular TRIVEX 系统以验证其是否正常操作。如果观察到不正常的性能，则可能需要采取其它措施，例如重新定向或重新放置 LeMaitre Vascular TRIVEX 系统。 b 在 150 kHz 至 80 MHz 频率范围内，场强应低于 3 V/m。			

间隔距离指南

便携式和移动式射频通信设备与 LeMaitre Vascular TRIVEX® 系统之间的建议间隔距离			
LeMaitre Vascular TRIVEX 系统设计用于射频干扰受控制的电磁环境。LeMaitre Vascular TRIVEX 系统的客户或用户可通过维持移动射频通信设备（发射机）与 LeMaitre Vascular TRIVEX 系统之间的最小距离（如下文根据通信设备的最大输出功率所建议），以帮助防止电磁干扰。			
发射机的额定最大输出功率（W）	Separation distance according to frequency of transmitter M		
	150 kHz 至 80 MHz d=1.2 √p	80 MHz 至 800 MHz d=1.2 √p	800 MHz 至 2.5 GHz d=2.3 √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
如果此处未列出发射机的额定最大输出功率，可使用适用于发射机频率的公式估算出建议间隔距离d （以米（m）为单位），其中p 指发射机制造商提供的发射机最大额定输出功率，以瓦（W）为单位。 注释 1：在 80 MHz 和 800 MHz 频率下，适用较高频率范围的间隔距离。 注释 2：这些使用指南可能并不适用于所有情况。电磁传播受设施建筑物、物体和人员的吸收和反射等特性影响。			

新产品保修
LeMaitre Vascular 产品自发票日期起，在特定产品的相应保修期内为用户提供免于材料和制造工艺缺陷的产品保修。有关特定产品的保修信息，请参阅最新的 LeMaitre Vascular 产品目录或与 LeMaitre Vascular 客户服务部联系查询。

此有限保修限于在保修期内发现的任何有缺陷的产品，由 LeMaitre Vascular 根据情况决定对产品进行修理或更换。若因用户原因而造成产品损坏从而使其不适合整修时，则无论其保修是否已失效，均将另外收取相应费用。所有保修仅限于产品的原始购买者。对于用户因
购买或使用任何产品而导致的任何关于预期收益、后续性损坏或花用时间补偿等损失。

除上述产品保修外，不提供任何其它明示或暗示保修。

维修更换部件保修
TRIVEX®系统更换部件自原始发票日期起 90 天内为用户提供免于材料和制造工艺缺陷的产品保修，当地法律规章另行规定者除外。

维修更换计划LeMaitre Vascular 为其产品提供 24 小时维修更换计划，确保将您的手术室停机时间降至最低。我们的目标是自您致电（正常上班时间）起 24 小时**内为您寄送出维修更换部件。有关退还授权 (RA) 编号或该计划的其它信息，请您联系美国客服1-800-628-9470 或与您当地的授权代表联系。

**并非对所有国家都提供 24 小时内寄出更换部件服务。

修理服务计划
对于已过保修期的设备，其修理必须由 LeMaitre Vascular 或其授权维修机构执行。不享受保修服务的设备修理，将按照更换部件的价目表价格加上工时费用收取。若客户提出请求，在进行任何修理之前可以先对修理所需费用和大概时间进行预估。必须小心地将待修理部件进行重新包装，标注退还授权 (RA) 编号，并支付邮费邮寄到相应的 LeMaitre Vascular 维修中心。LeMaitre Vascular 客户服务代表或您当地的授权代表可为您提供邮寄地址信息。

Symbol Legend

		Distributed By:	EC REP	Rx only													
English	Symbol Legend	Distributed By	European Representative	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.	On-Off push control	Mode select control	Speed control	Up and Down buttons	WARNING: HOT	Fluid bag	Lamp	Handpiece	Footswitch	Forward	DoNot Push	Read Manual
简体中文	符号图例	经销商	欧洲代表	注意 美国联邦法律限制本装置只能由医生销售或根据其医嘱销售	按压式开关控制	模式选择控制	速度控制	上调和下调按钮	警告：灼热	液袋	灯	手持机	脚踏开关	正向	勿推	请阅读手册

<<	< >	><		CE	I	O				~	REF	SN			
Reverse	Oscillate	Window Lock	US: Not for general waste	CE Mark	On (Toggle switch)	Off (Toggle switch)	Non-ionizing electromagnetic radiation	EQUIPMENT CLASSIFICATION—Type BF Applied Part	DANGEROUS VOLTAGE: Danger of Electric Shock	Alternating Current	Catalog Number	Serial Number	Fuse	UL Classification
反向	振动	窗锁定	美国：不同于一般废弃物处理	CE 标志	开（切换开关）	关（切换开关）	非电离电磁辐射	设备分类 — Type BF（BF 型）触身部件	危险电压：存在电击危险	交流电流	产品目录编号	序列号	保险丝	UL 分类

Keep dry	Fragile; Handle with Care	This way up
保持干燥	易碎，小心搬运	此端向上

LeMaitre® VASCULAR

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产品名称：浅表静脉曲张动力去除系统
注册证编号：国械注进20153213108
注册人及生产企业名称：LeMaitre Vascular, Inc.
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EC REP

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