saphena medical

Venapax®

Endoscopic Vessel Harvesting System

Instructions for Use

English

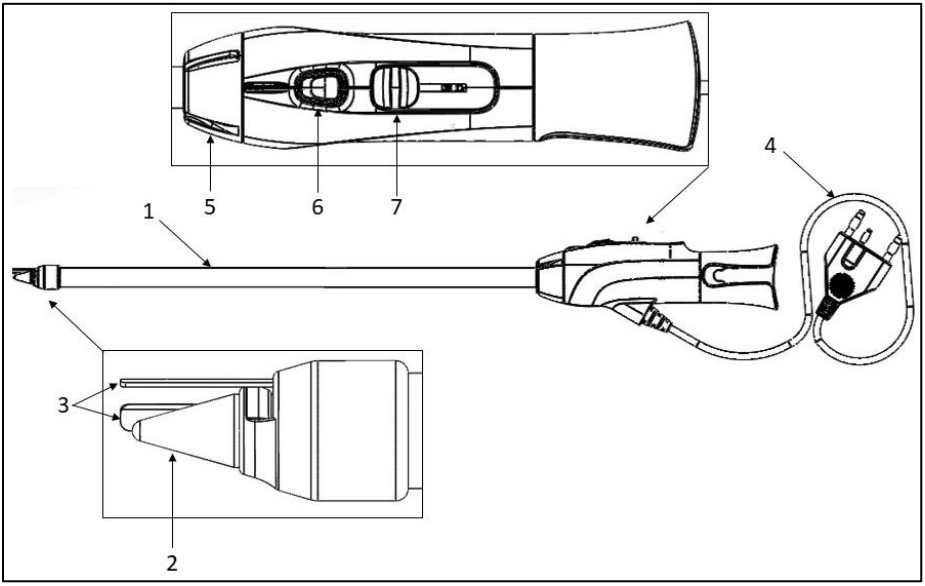
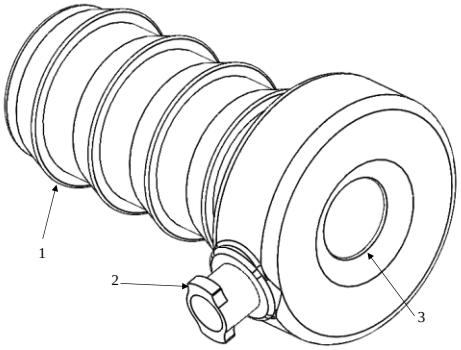


Figure 1: Venapax Endoscopic Vessel Harvesting System

1. Harvesting Cannula
2. Dissecting Tip
3. Bipolar Ligating Forceps
4. Electrical Connector
5. Forceps Rotator
6. Power Button
7. Forceps Slider

Figure 2: Short Port Blunt Tip Cannula (BTC)



1. Cannula Body
2. CO_2 Gas Port
3. Built-in Gas Seal

Read all information carefully before using.

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Important: These Instructions For Use are designed to assist in the use of Venapax Endoscopic Vessel Harvesting System. They are not a reference to endoscopic surgery or techniques.

DEVICE DESCRIPTION

Venapax Endoscopic Vessel Harvesting System

The Venapax Endoscopic Harvesting System is designed for use in conjunction with a Rigid Endoscope (not part of Venapax system). The Harvesting Cannula contains the Dissection Tip and one Bipolar Ligating Forcep. During dissection, the Forcep is fully retracted; during ligation and division of vessel branches, it is extended. The Forcep is extended and retracted using the Slider and rotated using the Rotator. Bipolar coagulation is achieved using electrosurgical energy. Transection is achieved through mechanical actuation of the Rotator. Positioning of the device, coagulation, and mechanical cutting are performed under endoscopic visualization. This device is intended for use with the bipolar outputs of compatible generators.

Rigid Endoscope (not part of Venapax system)

The Rigid Endoscope is a reusable product which consists of a stainless-steel shaft housing, optical and illumination components. The proximal end has an eyepiece for camera adapter attachment, and a light post for light cable connection; the camera adapter and light cable are not included with the Venapax system. The Endoscope is designed to be used in conjunction with the Harvesting Cannula for blunt dissection of tissue and isolation of structures in the cavity as well as vessel ligation and division. The Rigid Endoscope is a reusable device and is supplied non-sterile. It must be cleaned and sterilized prior to each use according to the manufacturer's instructions.

The Venapax Endoscopic Vessel Harvesting system will function optimally with the use of the following rigid endoscopes:

Venapax Product Code	Compatible Rigid Endoscope	
	Part Number	**Description**
VPX3000	VH-1111	Maquet® 7mm Extended Length Endoscope
	MCENDO550	Terumo® Endoscope, 5.5mm
	502-205-010	Stryker® Ideal Eyes Bariatric 5mm 0 Degree A/C Laparoscope
VPX4000	26048ASA	Karl Storz® 5.5mm Hopkins II Autoclavable Laparoscope, 50cm (Angled Light Post)
	10320AA	Karl Storz® 5.5mm Hopkins II Autoclavable Laparoscope, 50cm (Straight Light Post)

Short Port Blunt Tip Cannula (BTC)

The Short Port Blunt Tip Cannula (BTC) is used to provide a port of access for insertion of endoscopic instruments in to an incision site. The device consists of a main body with a built-in seal for the Endoscope and Harvesting Cannula on the proximal end, and an external port for gas insufflation.

HOW SUPPLIED

The Venapax device is sterile unless the package is opened or damaged. The method of sterilization is gamma irradiation. The product is designed for single use. **Do not reuse or resterilize.** Contents of the Venapax Harvesting System: One (1) Venapax Endoscopic Vessel Harvesting Cannula, One (1) Short Port Blunt Tip Cannula (BTC).

INDICATIONS

Venapax Endoscopic Vessel Harvesting System

The Saphena Medical Venapax Endoscopic Vessel Harvesting System is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extra peritoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or radial artery for use in coronary artery bypass grafting. Thorascopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels, and other tissues of the chest wall.

CONTRAINDICATIONS

Venapax Endoscopic Vessel Harvesting System, and Short Port BTC are contraindicated in situations where minimally invasive surgery is contraindicated.

WARNINGS AND PRECAUTIONS

Venapax Endoscopic Vessel Harvesting System

1. Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious surgical consequences or serious injury to the patient.
2. Minimally invasive surgical procedures should be performed only by individuals adequately trained and familiar with such surgical techniques. Consult medical literature regarding techniques, complications, and hazards prior to performance of these procedures.
3. Sterility: The Venapax System is sterile unless the package is damaged or opened. The method of sterilization is gamma irradiation. The Venapax System is designed for single use. **Do not reuse or resterilize.**
4. Before endoscopic instruments and accessories from different manufacturers are employed in a procedure, verify compatibility and ensure that electrical isolation and grounding of these instruments is not compromised.
5. A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid shock and burn hazards to both the patient and operator(s) and damage to medical instrumentation.
6. The Venapax Endoscopic Vessel Harvesting System is for use with the bipolar outputs of electrosurgical generators only.
7. **FOR INTERMITTENT OPERATION ONLY:** Do not apply continuous cautery energy.
8. Do not exceed 25 watts in any mode.
9. Use only the generators listed and in the specified Mode and Setting Range only.
10. Handle the Endoscope carefully to avoid breakage. Regularly check the orientation of the camera before advancing.
11. To avoid damage to delicate tissue, advance the cannula gently.
12. Always advance the Bipolar Ligating Forceps under endoscopic visualization. Ensure adequate visualization of the ends and surgical site prior to application of electrosurgical energy.
13. Always inspect the surgical site for hemostasis. If hemostasis is not present, appropriate techniques should be applied to achieve hemostasis.
15. In endoscopic procedures which use gas insufflation, venous gas embolism is a very rare (approximately 1 in 10,000 cases) but potentially serious complication that may occur. Its occurrence is signaled by cardiovascular collapse (sudden, severe hypotension) and a precordial murmur. If gas embolism is suspected during a procedure, discontinue gas insufflation and place the patient in a left lateral and a slight Trendelenburg position.
16. When performing radial artery harvesting, the radial artery harvesting procedure should be performed prior to placing the patient on cardio pulmonary bypass.
17. Do not touch the coagulating surfaces while the device is activated. This may cause injury.
18. All exposed metal components at the distal end of the forceps may coagulate tissue.
19. Ensure that all exposed metal is within the field of vision and contacting the tissue intended for coagulation during the application of electrosurgical energy.
20. The cables to the device should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused product should be stored in a location that is isolated from the patient.
21. The use of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax, unless these agents are sucked away.
22. Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfection, or as solvents of adhesives, should be allowed to evaporate before the application of high frequency electrosurgery. There is a risk of pooling of flammable solutions under the patient or in body depressions. Any pooled fluid should be mopped up before high frequency electrosurgical equipment is used.
23. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool, and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the high frequency electrosurgical equipment.
24. Interference produced by the operation of high frequency electrosurgical equipment may adversely influence the operation of other electronic equipment.
25. Regularly inspect surgical accessories, particularly bipolar cables, for any possible damage or unintended rough surfaces, sharp edges, or protrusions.
26. Prior to the use of the device in patients who have cardiac pacemakers or electronic implants, consult the implant manufacturer's instructions.

Short Port BTC

1. Sterility: The product is sterile unless the package is damaged or opened. The method of sterilization is gamma irradiation. The product is designed for single use. **Do not reuse or resterilize.**

INSTRUCTIONS FOR USE

The following instructions are recommended for proper function of the Venapax Endoscopic Vessel Harvesting System. It is not a reference for endoscopic surgery techniques.

Preparation of the Endoscope and Harvesting Cannula

1. Attach an appropriate light cable to the illumination port on the Endoscope until securely fastened. (When not attached to the scope, do not place the light cable on flammable materials such as surgical drapes or towels.) Attach the opposite end of the light cable to a Xenon light source (maximum 300W bulb).
2. Attach an appropriate camera adapter to the eyepiece of the Endoscope. Do not attempt to remove the eyepiece from the Endoscope. Attach the opposite end of the camera adapter cable to the appropriate port of the camera box.
3. Focus the image from the Endoscope using the focus ring on the camera adapter. Picture orientation can be corrected by rotating the camera adapter on the Endoscope Eyepiece to the appropriate position.
4. White balance the camera in accordance with the camera manufacturer's instructions for use.
5. Prior to each use, verify that image quality and light intensity are adequate to perform the procedure; if inadequate, remove the Endoscope from operation. Inspect the Endoscope for visible damage (e.g., cracks, loose components); if found, remove the Endoscope from operation.
6. Remove the Harvesting Cannula and BTC from the packaging.
7. Slide the Endoscope into the Harvesting Cannula from the proximal side. Align the illumination port on the Endoscope with the slot on the proximal end of the Harvesting Cannula. Advance the Endoscope until it snaps into place and is secured to the Harvesting Cannula.
8. Insert the Electrical Connector attached to the Harvesting Cannula into the bipolar port of the generator.
9. Turn on the generator to the recommended start setting and to the recommended mode listed on the generator chart.

   WARNING: DO NOT EXCEED 25 WATTS. If wattage setting is too high, tissue may dry out rapidly causing sticking and hemostasis may be compromised.
10. Pre-test the Venapax to verify complete electrical activity and generator setting:
    - Soak a sterile 4" x 4" (10.16 cm x 10.16 cm) gauze pad with saline.
    - Adjust electrodes to create a 2mm gap between the electrode tips.
    - Touch both electrodes against the soaked 4" x 4" (10.16 cm x 10.16 cm) gauze pad.
    - **WARNING: DO NOT TOUCH THE COAGULATING SURFACES WHILE THE DEVICE IS ACTIVATED. THIS MAY CAUSE INJURY.**
    - Activate the electrosurgical function by depressing the Power Button on the handle.
    - Steam generation from the soaked 4" x 4" (10.16 cm x 10.16 cm) gauze pad and the Electrodes indicates active power and a complete circuit.

    NOTE: If there is no steam during the Pre-test:
    - Add more saline to the pad.
    - Ensure that both electrodes are in contact with the saline-soaked pad.
    - Verify that the electrosurgical generator power switch is ON, and in the hand switching mode.
    - Verify proper connection of the Electrical Connector of the Venapax Endoscopic Vessel Harvesting System to the generator.
    - Check generator function and setting. For power settings, see enclosed chart.
    - Turn power up in small increments. Do not exceed 25 Watts.
    - Decrease the amount of pad surface contacting the coagulating surfaces.

    If steam is still not observed, **DO NOT** use the device and call Customer Service at (508)584-1596.

    NOTE: Due to variations in individual patient anatomy and individual physician technique, the following steps may vary and should be considered recommendations only to ensure adequate visualization of the tunnel:

- Confirm there is adequate gas in the CO_2 tank.
- Confirm the CO_2 tank valve is open.
- Confirm the CO_2 insufflator is turned on.
- Confirm the CO_2 tubing is properly connected.
- Confirm gas is present at the delivery end of the CO_2 tubing.
- Slowly withdraw the Harvesting Cannula back towards the Short Port Blunt Tip Cannula (BTC) until the tunnel re-expands.
- Perform blunt dissection or use Short Port Blunt Tip Cannula (BTC) to cut through the fascia to modify the tunnel size.
- Branch ligation may be done to increase tunnel size.

NOTE: If blood or other tissue obscures the Dissection Tip, apply light pressure to the outside of the leg such that the outer cavity wall makes contact with the Dissection Tip to clear the surface. Alternatively, the Endoscope can be removed and the distal lens cleared using a sterile 4" x 4" (10.16cmx10.16cm) gauze pad.

Patient Preparation

Prepare the patient in accordance with standard surgical techniques.

Tunnel Dissection

1. Using an open technique, make an initial 2cm incision and locate the vessel. Slide the Short Port BTC up the Harvesting Cannula shaft to the proximal hub of the Harvesting Cannula. Insert the Dissection Tip into the subcutaneous space anterior to the vessel. Advance the instrument toward the target tissue, keeping the tip in contact with anterior surface during the dissection process. Advance the instrument approximately 3–4cm, and then slide the Short Port BTC into the incision. Connect the gas line to the CO_2 Insufflation Port on the BTC and infuse CO_2 gas at a flow rate of 3–5L/min to a pressure of 10 –12mmHg. Gas insufflation holds the dissected tunnel open for improved visualization.
2. Continue advancing the Harvesting Cannula along the anterior aspect of the vessel, until the desired vessel length is dissected. Monitor progress of dissection via the Endoscope. Withdraw the Endoscope until the Dissection Tip is at the distal end of the Short Port BTC and then advance the Endoscope along the posterior aspect of the vessel, dissecting gently and thoroughly around vessel branches as they are encountered.
3. Should the image become compromised, verify that all equipment is correctly connected to the Endoscope. If required, remove the Harvesting Cannula, and carefully clean the distal tip of the Endoscope and/or the Dissection Tip. If the image is still unacceptable, remove the Endoscope from operation.

Vessel Harvesting

1. Under endoscopic visualization, extend the Bipolar Ligating Forceps to the targeted vessel by advancing the Slider forward.
2. Engage the target vessel between the electrodes by using the Rotator to position the targeted vessel in between the Forceps electrodes. Manually rotate the Rotator until the target position is reached.
3. Activate the electrocautery by pressing the Power Button. **Note: For safety purposes, power will not engage unless the Slider is advanced fully distally.** Coagulation occurs between the non-insulated surfaces of the electrodes. Electrode surfaces should be in contact with tissue for optimum coagulation. Be sure the electrodes are not in contact with each other as this will bypass the electrical energy away from the tissue. Tissue dehydration and blanching should indicate successful coagulation. To use as a spot coagulator, contact the tissue with the electrodes. After coagulation, remove electrocautery energy by releasing the Power Button. Continue the rotation of the Rotator until the electrodes make contact, transecting the coagulated tissue. Gently remove device from tissue after cutting. The Bipolar Ligating Forceps should be in view when cutting or coagulating per standard endoscopic technique.

   NOTE: If desired, apply gentle tension on the vessel by twisting the Bipolar Ligating Forceps while the electrodes have engaged the target vessel may facilitate cautery and transection.
4. To clean the cutting and coagulating surfaces, use 4" x 4" (10.16 cm x 10.16 cm) gauze pad(s) soaked with saline solution. For optimum performance, keep the blade and electrode surfaces free of debris.
5. Upon completion of use of the Harvesting Cannula, turn electrocautery power OFF. Then retract the Bipolar Ligating Forceps into the Harvesting Cannula using the Slider before removing the device from the tunnel.
6. Upon completion of the endoscopic procedure, the working space may be quickly deflated by removing the Harvesting Cannula from the Short Port Blunt Tip Cannula (BTC).
7. Disconnect CO_2 gas and remove the Short Port BTC.
8. Remove harvested vessel per standard procedure.

   NOTE: Always inspect the surgical site for hemostasis. If hemostasis is not achieved, appropriate techniques should be applied to control bleeding.

Generator Settings

Table 1. Generator Settings

Generator	Model	Mode	Setting Range
ValleyLab	ForceFX	Standard Medium Bipolar	15-25 watts

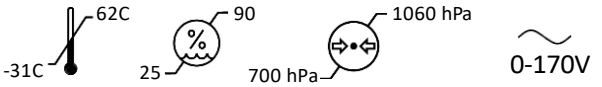
WARNING: DO NOT EXCEED 25 WATTS IN ANY GENERATOR SETTING!

CAUTION: This device should not be used with any generator not shown in Table 1.

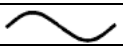
WARRANTY

Saphena Medical warrants that reasonable care has been used in the design and manufacture of this system and its individual components. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling and storage, of this system as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Saphena's control directly affect the instrument and the results obtained from its use. Saphena's obligation under this warranty is limited to the repair or replacement of this system and its components for a period of one year from the date of purchase with respect to parts and labor, and Saphena shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this system. In the event of a warranty claim, the purchaser must allow Saphena, at its option, to inspect the system and its components and the purchaser must reasonably cooperate with Saphena with respect to verifying the warranty claim of the purchaser. In the event that a warranted defect is discovered, the sole remedy available to purchaser will be for Saphena, at its option, to repair or replace the affected component(s).
This Warranty applies only to products that are defective and does not cover failures or damages due to normal wear, abuse, misuse, tampering, lack of proper maintenance, and force majeure. Saphena neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this system. **Saphena assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.** With regard to Saphena products that are labeled **FOR SINGLE USE ONLY** or **DO NOT REUSE**, this warranty is null and void following the single use of such products.

This product and/or its use may be covered by the following US patent: 9,498,246; 9,814,481; 9,943,328



Symbol Legend:

REF	Catalog Number
	Use By
LOT	Lot Number
SN	Serial Number
	Consult Instructions for Use
R_X ONLY	Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Do Not Resterilize
	Do Not Reuse
	Do Not Use if package opened or damaged
STERILE R	Sterilization by Irradiation
	Pressure Environment
	Humidity Environment
	Temperature Environment
	Type BF Applied Part
	Alternating Current (AC)
	Power On/Off
EC REP	Authorized Representative in the European Community
	Manufacturer
	Date of Manufacture

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