

# Vasoview Hemopro

Endoscopic Vessel Harvesting System Training Manual



# Introduction

This training manual for endoscopic vessel harvesting (EVH), using the Vasoview Hemopro Endoscopic Vessel Harvesting System, is designed to provide the operator with step-by-step instructions for performing the EVH procedure.

Included in this document are preoperative considerations, intra-operative technique tips, post-operative recommendations, and troubleshooting suggestions. This document is not intended to replace the Instructions For Use and other labeling included with the product, and is not intended as a substitute for the healthcare professional's medical judgment.

### **Vasoview Hemopro Training Manual**

Getinge has a strong history of pioneering and advancing endoscopic vessel harvesting systems.

The Vasoview Hemopro Endoscopic Vessel Harvesting System is the product of multiple generations of learning and experience. Getinge combines leading-edge advances in product design with a solid history of surgical success to provide the most advanced and effective EVH solutions available. Vasoview products are supported by clinical trainers who have both hospital surgical experience and industry-leading training in EVH. The Vasoview System provides real options to cardiac surgeons and their surgical team and proven benefits to the patients they serve.

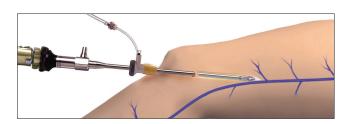
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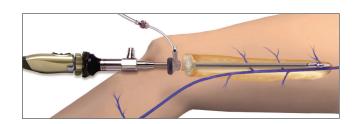
# **Endoscopic Vessel Harvesting**

## Saphenous Vein Procedure-at-a-Glance



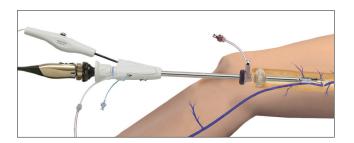
#### Incision

Create an incision in the area near the knee, over the greater saphenous vein. Attach the Dissection Tip to the end of the 7 mm Extended Length Endoscope. Insert the endoscope into the incision and visualize the vein and surrounding tissue on the video monitor.



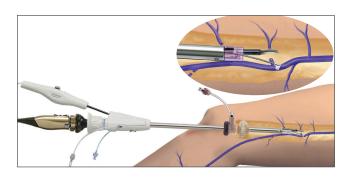
## Initiating CO, Insufflation

Advance the Short Port Blunt Tip Trocar (BTT) into position, and insufflate CO<sub>2</sub> gas to create a tunnel. Perform anterior, posterior and branch dissection with the Dissection Tip.



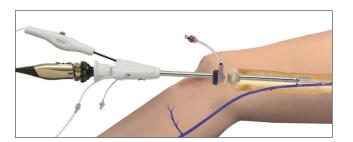
## **Sealing and Transecting Branches**

After removing the Dissection Tip from the endoscope, insert the endoscope into the Vasoview Hemopro Harvesting Cannula. Set the Vasoview Hemopro Power Supply on power setting between 2 and 3. Insert the cannula through the BTT. Use the Hemopro Harvesting Tool Jaws to engage the branch. Seal and transect the vessel branch in a single step by pulling the Activation Toggle back from the center position until a stop is noticed.



### **Enhanced Visualization**

For enhanced visualization during vessel branch sealing and transection, transfer the  $\mathrm{CO}_2$  source from the BTT  $\mathrm{CO}_2$  Insufflation Port to the Distal Insufflation  $\mathrm{CO}_2$  port on the Vasoview Hemopro Harvesting Cannula.



### **Running the Vessel**

Deploy the C-Ring from the Vasoview Harvesting Cannula. Engage the vein with the C-Ring and run the length of the vein to ensure that it is completely free and no branches remain.

#### **Transection and Retrieval**

Make a stab incision over the distal end of the tunnel. Clamp the saphenous vein, and externalize it through the stab incision. Transect the vein, and ligate the terminal end of the vein. Retrieve the harvested vein from the original incision at the knee.

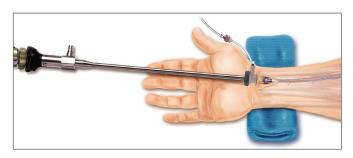
# **Endoscopic Vessel Harvesting**

## Radial Artery Procedure-at-a-Glance



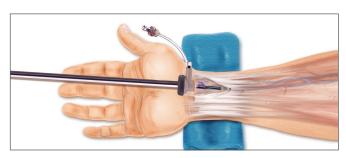
#### Incision

Beginning just proximal to the wrist crease, create a 2 cm longitudinal incision. Attach the Dissection Tip to the end of the 7 mm Extended Length Endoscope. Insert the 7 mm endoscope into the incision and visualize the radial artery and surrounding tissue on the video monitor.



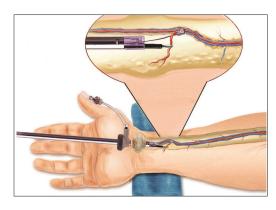
## Initiating CO<sub>2</sub> Insufflation

Insert the Short Port Blunt Tip Trocar (BTT) into position and begin CO<sub>2</sub> insufflation. Perform anterior, posterior, and lateral dissection of the radial artery pedicle using the Dissection Tip on the 7 mm endoscope.



### **Fasciotomy**

After removing the Dissection Tip from the endoscope, insert the endoscope into the Vasoview Hemopro Harvesting Cannula. Insert the Harvesting Cannula through the BTT. Using the Jaws of the Hemopro Harvesting Tool, release the fascia by cutting it from the distal to proximal forearm.

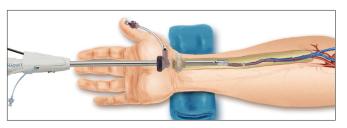


### **Sealing and Transecting Branches**

Use the C-Ring to protect the radial artery pedicle and expose the branches. Use the Hemopro Harvesting Tool Jaws to engage the branches. Seal and transect in one step by pulling the Activation Toggle back from the center position until a stop is noticed.



Deploy the C-Ring from the Vasoview Harvesting Cannula. Engage the radial artery with the C-Ring and run the length of the artery to ensure that it is completely free and that no intact branches remain.



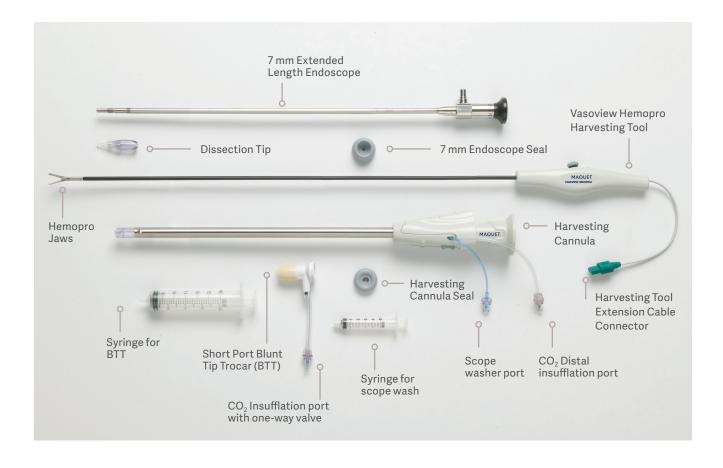
#### **Transection and Retrieval**

Make a stab incision near the elbow. Clamp the radial artery pedicle and externalize it through the stab incision. Transect the radial artery, and ligate the proximal radial artery stump. In retrograde fashion, retrieve the radial artery pedicle from the original incision at the wrist.

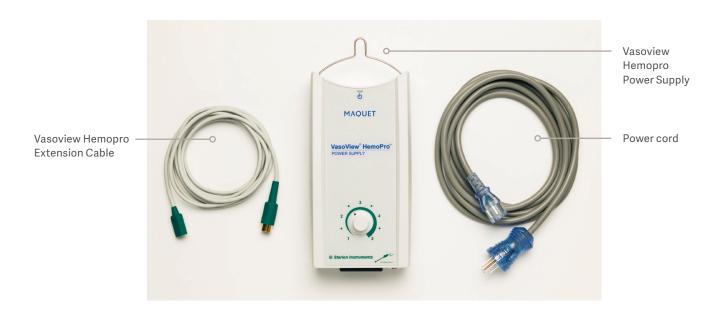
# **Operating Room**

## Instrumentation and Equipment

Vasoview Hemopro Endoscopic Vessel Harvesting System



## **Getinge Vasoview Hemopro Power Supply**



### **Video Equipment:**

- Camera Box
- Video Monitor
- Light Source
- Fiber Optic Cable with appropriate Scope Adaptor End (sterile)
- Camera compatible to Endoscope (sterile)
- Video Recorder (optional)
- Insufflator
- Insufflator Tubing (sterile)
- CO, Source

## **Additional Optional Items:**

- Anti-fog Solution
- Surgical Marking Pen
- · Instruments used for open harvest

# **Equipment Testing**

## **Tower and Insufflator Equipment**

- Prior to starting the EVH procedure, turn on all of the equipment on the video tower (video monitor, camera, light source, and insufflator). Be sure that the electric cords are attached to the back of each piece of equipment. Once all equipment checks are performed, turn the system completely off until the procedure begins.
- The monitor should show color bars until a camera head is plugged into the camera box. If the color bars are not balanced, press the reset button to bring them back to the factory setting.
- The camera head should be plugged into the camera box to check for a clear picture prior to sterilization (except in the case of terminal sterilization).
- The light source should be checked to ensure the light is coming from the unit. Do not look directly into the light.
- If the fiber optic light cable will be sterilized with the camera head, it should be checked for damaged fiber optics. To do this, hold one end toward a direct light source and look into the other end. If it illuminates with no more than one-third of the area grayed, the cable is in good order. If a significant portion of the cable does not illuminate (reflects a blackened area), use a different cable. If the fiber optic cables need to be terminally sterilized, this quality-control procedure should take place prior to sterilization.
- The endoscope should be checked in two ways prior to sterilization. First, look through the endoscope eyepiece and ensure the image is clear. Second, hold the light post up to a direct light source and look directly into the distal end of the endoscope. A complete circle of light should be visible around the distal tip.
- Turn the CO<sub>2</sub> gas tank to the open position. Ensure there is either a full tank of gas or an extra tank of CO<sub>2</sub> is available. Turn the insufflator to the "on" position. Set the insufflator settings to 3 5 L/min flow and 10 12 mmHg pressure. Ensure gas is flowing from the insufflator. Place the insufflator on "stand-by" until ready for use.

### **Power Supply and Extension Cable**

- The Power Supply should be tested prior to use.
- Plug the Power Cord into a grounded hospital grade receptacle.
- Turn the Power Supply on. A green power ON/OFF LED on the top of the front panel should illuminate. If not, check both power cord connections. If the LED still does not illuminate, replace the power cord.
- The Hemopro Extension Cable must be sterilized before each case. Open the sterile Hemopro Extension Cable onto the sterile field. Pass the circular end of the Extension Cable from the sterile field to the non-sterile field.
- Align the Extension Cable logo so that it faces the front of the Power Supply. Connect the Extension Cable to the Power Supply.
- Connect the portion of Extension Cable still in the sterile field to the Harvesting Tool Extension Cable Connector, ensuring correct orientation by aligning the triangular ends together.
- A green LED next to the Adapter Cable connector will now also illuminate indicating that the Power Supply recognized the complete connection between the Power Supply, and the Hemopro Extension Cable.
- Ensure the Power Supply knob is set between 2 and 3 when using the Vasoview Hemopro for optimal performance.

## **EVH Procedure**

## Saphenous Vein

## **Patient Positioning and Preparation**

#### **Patient Positioning**

Place the patient in a supine position. Externally rotate the leg with the knee flexed and with support behind the knee and the thigh. (Figure 1)

#### **Surgical Preparation and Vein Location**

Prior to the skin prep, assess the patient to select the incision site around the knee area. Once the intended incision site is identified, mark the area with a surgical marker.

The saphenous vein can usually be found by using anatomical landmarks. An ultrasonic doppler may be used to help locate the vein. If needed, use the doppler prior to the patient prep and then mark the site with a surgical marker. If appropriate, vein mapping may be performed preoperatively. Note that the saphenous vein lies fairly posterior in relationship to the patella. Perform skin prep according to hospital protocol.



Figure 1

#### **Product Assembly**

- Attach the 7 mm Extended Length Endoscope to the camera coupler. Attach the light cable to the post on the endoscope. Focus the endoscope on a gauze pad and white balance the video camera as described below. Ensure proper orientation of the camera head. It is important to maintain correct orientation throughout the endoscopic procedure.
- Thread the Dissection Tip onto the distal end of the endoscope until the proximal edge of the Dissection Tip lines up with the indicator etched on the endoscope shaft. (Figures 2 and 3)
- Insert the endoscope with attached Dissection Tip through the BTT. Ensure that the Endoscope Seal is on the BTT (it comes packaged with this seal attached). (Figure 4)

## **Proper White Balancing**

White balancing is the process by which the camera learns what "white" is. This process sets the full range of color through the camera.

- To white balance the camera, attach the camera head and fiber optic cables to the endoscope and hold a piece of white gauze approximately 1.5 inches from the distal end of the endoscope. (Figure 5)
- Focus the camera and ensure that only white is visible.
   Press the white-balance button from either the camera head or camera box, depending on the camera system.
   Hold the camera and endoscope still until the system indicates white balance is completed.

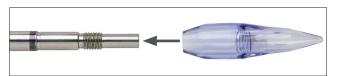


Figure 2



Figure 3



Figure 4



Figure 5

#### **Incision Site**

#### **Selecting the Incision Site**

There are several factors to consider when selecting the incision site, such as operator preference, number of grafts needed, and whether the upper or lower leg is used for the vein harvest.

There are two commonly used incision sites: (Figure 6)

- Below the knee: Palpate along the tibia until reaching the medial tibial epicondyle. Make a 2 cm incision along the posterior border of the tibial epicondyle. (Figure 7)
- Above the knee: Make a 2 cm incision in the thigh where the vein lies in the groove between the sartorius and gracilis muscles. (Figure 8)

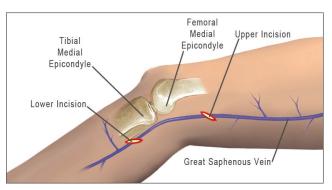
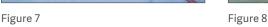


Figure 6

#### **Making the Incision**

- Once the incision site has been identified, make a 2 cm skin incision directly over the vein.
- A transverse, longitudinal or oblique incision may be used depending on operator preference.
- Under direct visualization, dissect the subcutaneous tissue to expose the greater saphenous vein.
- Continue dissection of the anterior surface of the vein in the direction of planned harvesting, creating a "hood". A hood is a small space within the subcutaneouse tissue created to ensure easy insertion of the BTT







## Inserting the 7 mm Endoscope with Attached Dissection Tip

- Under direct visualization, insert the Dissection Tip into the space created, and place it onto the anterior surface of the saphenous vein. (V) Note (on the video monitor) the color of the vein and the surrounding yellow fatty tissue. It is important to always identify the vein prior to advancement of the instrument. (Figure 9) If the vein is very superficial (adhered to the skin) or there is great resistance when advancing the Dissection Tip on the anterior surface of the vein, place the Dissection Tip on the posterior surface of the vein.
- Advance the endoscope approximately 4 cm, then slide the BTT through the incision site and into the previously dissected space. (Figures 10 and 11)

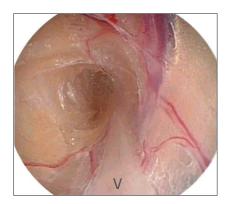


Figure 9



Figure 10

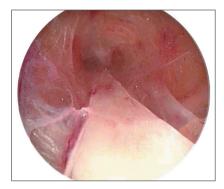


Figure 11

## CO<sub>2</sub> Insufflation

- Connect the CO<sub>2</sub> insufflation tubing to the clear flexible CO<sub>2</sub> Insufflation Port on the BTT and begin insufflation of CO<sub>2</sub>. Ensure the CO<sub>2</sub> Insufflator is set to the proper flow and pressure settings. CO<sub>2</sub> Flow: 3 5 L/min CO<sub>2</sub> Pressure: 10 12 mmHg
   The goal is to delineate a tissue plane for easier dissection and to maintain the tunnel.
- Once the CO<sub>2</sub> insufflation has begun, note the initial "webbing" effect or partial separation of tissues from the saphenous vein. (Figure 12)
- If desired pressure is not obtained in the tunnel, the slip tip syringe provided can be used to inflate the balloon on the BTT. Inflate the balloon with the minimal amount of air needed to create an adequate seal (0 – 25 cc's of air). If there is obvious leakage around the incision, use a purse-string suture to ensure a tight seal around the BTT.

#### **Technique Tips**

If partial separation of tissue from saphenous vein is not observed, check that the CO<sub>2</sub> is flowing, the pressure setting is 10 – 12 mmHg, and the tubing is connected properly to the BTT and the insufflator. Also check the CO<sub>2</sub> tank to ensure it is in the open position, with an adequate amount of CO<sub>2</sub>. (See Troubleshooting Section)

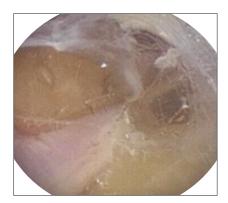


Figure 12

## **Endoscopic Dissection**

The endoscope with attachable Dissection Tip, is used to dissect surrounding subcutaneous and connective tissue from the saphenous vein and to dissect the branches. The atraumatic Dissection Tip performs the blunt dissection.  $CO_2$  insufflation aids the dissection by enabling constant visualization, reducing bleeding and helps to maintain a working space. Mastery of the dissection will enable clear exposure and easy access for branch sealing and transection.

The goal of dissection is to expose the vein so that it is suspended by its branches in the center of the working space. (Figures 13 and 14)

To ensure the best results, follow these basic three steps which are described on the following pages:

Step 1: Anterior Dissection Step 2: Posterior Dissection Step 3: Branch Dissection

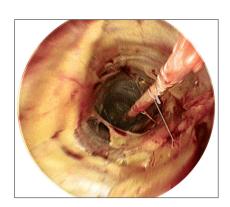


Figure 13

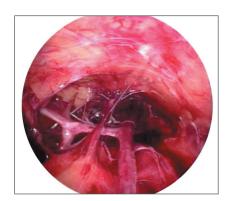


Figure 14

#### **Step 1: Anterior Dissection**

Position the Dissection Tip on the anterior surface of the vein. (Figure 15) Begin dissecting until you have reached the desired length of vein.

#### **Technique Tips**

- The Dissection Tip should be positioned between the vein surface and the surrounding fatty tissue.
- To ensure the maximum effect of the CO<sub>2</sub> insufflation and to create the optimal tunnel, it is important to keep the Dissection Tip close to the vein and not stray into the surrounding tissue. This helps to avoid creating multiple small spaces or pseudo-tunnels.
- Use smooth, controlled, short strokes when advancing the endoscope, allowing CO<sub>2</sub> to reach the tip and facilitate dissection.
- Use your dominant hand to guide the endoscope and your free hand on the external operative area to facilitate dissection with external manipulation. If tissue collects on the Dissection Tip, use the free hand on the outside of the leg to palpate the tip and dislodge the tissue. (Figure 16)
- Maintain the endoscope in a position parallel to the vein. This will help to avoid diving into the vein, thereby minimizing the risk of perforation. Correct camera orientation is necessary and should be maintained throughout the procedure.
- If at any point, the vein is no longer visible, retract the endoscope until the vein is again visualized, ensure proper camera orientation and proceed with the dissection.

#### **Preventing Avulsions or Perforations**

- A perforation may occur if the vein appears to surround the Dissection Tip. The video monitor may reveal a fine swirling or "halo" effect. If this occurs, stop advancing and withdraw the endoscope until the swirling effect disappears. Then continue dissection ensuring the endoscope is in the proper tissue plane.
- Watch for anterior branches and direct the Dissection
   Tip around them to prevent an avulsion.
- Some branches may require some dissection in order to allow easy passage around the branch while providing minimal branch tension.



Figure 15



Figure 16

#### **Step 2: Posterior Dissection**

Withdraw the endoscope to the tip of the BTT. Repeat dissection along the posterior aspect of the vein, using a gentle forward motion, until reaching the distal end of the tunnel. (Figure 17) Note the further benefit of  $\mathrm{CO}_2$  insufflation in separating tissue planes.

#### **Technique Tips**

- Maintain the Dissection Tip close to the posterior vein surface when dissecting the surrounding tissue.
- Advance the endoscope 180 degrees from the anterior dissection, which will help provide maximum dissection.
- Watch for posterior branches and direct the Dissection Tip around them to prevent an avulsion.



Withdraw the endoscope to the tip of the BTT. Begin dissecting along the lateral aspect of the vein removing any remaining tissue that is still adhered. (Figure 18) When a branch is encountered, dissect it with the Dissection Tip using short, controlled gentle probes. Continue until all branches are adequately exposed to facilitate later sealing and transection of the vessel branches. (Figure 19)

#### **Technique Tips**

- Be sure to expose each branch adequately, enabling easy access when using the Vasoview
   Hemopro Harvesting Tool. A thorough dissection is recommended in order to maximize the sealing capability of the Harvesting Tool and to minimize the sealing time.
- Larger branches may require additional dissection to achieve adequate branch length.
- Until experience is gained, be careful not to advance the endoscope too quickly when dissecting around branches. External manipulation with your free hand will aid dissection by bringing the tissue or branches to the Dissection Tip. As experience level increases, this will become even more beneficial.

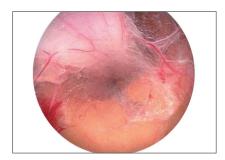


Figure 17



Figure 18



Figure 19

## Use of the Vasoview Hemopro Harvesting Tool

#### Overview

The Vasoview Hemopro Endoscopic Vessel Harvesting System seals and transects vessel branches in a single step, providing a high level of hemostasis. (Figure 20)

The C-Ring, extends from the Harvesting Cannula by adjusting the C-Ring Slider. (Figure 21) The C-Ring is used to protect the main vessel and to expose branches. The Hemopro Harvesting Tool is inserted through the Tool Adapter Port on the Vasoview Hemopro Harvesting Cannula. The Activation Toggle controls the Jaws of the Hemopro Harvesting Tool and the activation of the Power Supply. Pushing the Activation Toggle forward will open the Jaws. (Figure 22) Moving the Activation Toggle to the center position will close the Jaws. (Figure 23) Pulling back on the Toggle until a stop is noticed activates the Jaws of the Harvesting Tool. (Figure 24) The Power Supply will emit an intermittent tone during activation.

### Detailed steps are as follows:

- Ensure proper setup and testing of the Vasoview Hemopro Power Supply. See the Equipment Testing section of this Training Manual for instructions on proper set-up. (Page 8)
- After dissection of the vein with the 7 mm Extended Length Endoscope is complete, withdraw the endoscope from the tunnel, leaving the BTT in place. Remove the Dissection Tip from the endoscope. Remove the Endoscope Seal from the BTT and replace it with the Cannula Seal.
- Apply anti-fog solution to the distal end of the endoscope if desired.
- Insert the endoscope into the bell handle of the Vasoview Hemopro Harvesting Cannula. The Endoscope is secured with an audible "click," locking it into place.
- Attach the Extension Cable to the Extension Cable Connector on the Vasoview Hemopro Harvesting Tool. Ensure that the Extension Cable is properly connected to the Harvesting Tool, matching the triangular notches on the end. (Figure 25)



Figure 20



Figure 23



Figure 21

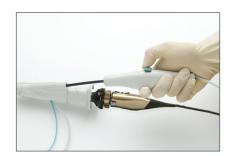


Figure 24



Figure 22



Figure 25

- Ensure that the Extension Cable is securely connected to the Power Supply. Always use the Power Supply setting between 2 and 3 when using Vasoview Hemopro Endoscopic Vessel Harvesting System. (Figure 26)
- Pre-test the Harvesting Tool to verify electrical activity prior to beginning the procedure. Soak a sterile gauze pad with normal saline, and place the soaked pad between the Vasoview Hemopro Jaws. Activate the Vasoview Hemopro Jaws. The Power Supply will emit an intermittent tone indicating application of energy and that the device is active. Steam generation from the soaked gauze pad indicates activation of the Harvesting Tool. (Figure 27)
- Close the Vasoview Hemopro Jaws prior to insertion of the Harvesting Tool through the Harvesting Cannula Tool Adapter Port. Hold the cannula with

- the Tool Adapter Port on top. Insert the Harvesting Tool through the Tool Adapter Port of the Harvesting Cannula by holding the Harvesting Tool approximately 6 inches (15 cm) from the tip of the Jaws and with the concave side of the Jaws or tips of the Jaws pointing up during insertion. (Figure 28)
- Ensure that the Hemopro Harvesting Tool and C-ring are fully retracted into the Harvesting Cannula. Insert the Harvesting Cannula through the BTT. Advance the Harvesting Cannula to the most distal portion of the tunnel, maintaining a central position to avoid injury to the main vessel and vessel branches and to avoid endoscope sliming. Always maintain correct orientation of the camera.
- Attach the CO<sub>2</sub> tubing to the Distal Insufflation Port on the Harvesting Cannula. Infuse CO<sub>2</sub> gas at a flow rate of 3 – 5 L/min and a pressure of 10 – 12 mmHg.







Figure 26 Figure 27

Figure 28

- Use the C-Ring Slider to advance the C-Ring and cradle the vein. (Figure 29) Using the incision as the point of reference, moving distal to proximal, retract the Harvesting Cannula down the tunnel. Always maintain correct orientation of the camera.
- Once a branch is encountered, keep the C-Ring distal to the branch and advance the Vasoview Hemopro Harvesting Tool into the tunnel and into the visual field.
   Open the Jaws of the Harvesting Tool to engage the vessel branch by moving the Activation Toggle on the Harvesting Tool Handle to the forward most position. (Figures 30 and 31)
- Always position the Harvesting Tool Jaws on the vessel branch with the concave side of the Jaws toward the main vessel. (Figure 31)
- Secure the branch by closing the Jaws. This is performed by pulling back on the Activation Toggle until mild resistence is met. (Figures 32 and 33)

- Apply energy by pulling the Activation Toggle back from the center position until a stop is noticed. (Figure 34) Apply mild tension to the vessel branch during device activation by retracting or slightly rotating the jaws to aid branch transection.
- When separation of the branch tissue is noticed, open the Jaws.
- If cutting is incomplete, reapply the Jaws to the vessel branch. Repeat Jaw Activation to the portion of the branch which is not transected.
- Close the Jaws prior to retracting the Harvesting Tool into the Harvesting Cannula to avoid damage to the device.







Figure 29 Figure 30 Figure 31







19

Figure 32 Figure 33 Figure 34

VASOVIEW HEMOPRO TRAINING MANUAL

## Branch Sealing and Transection Using the "C.L.A.M.P." Method

When used correctly, the Vasoview Hemopro Endoscopic Vessel Harvesting System produces a high level of hemostasis. In order to realize the full benefit

portion of the procedure, may reduce tissue buildup.

from the Hemopro technology and to minimize damage to the device, be sure to follow the "C.L.A.M.P." method to produce proper branch sealing and transection.

- Clean the Jaws. Fat or tissue attached to the Harvesting Tool Jaws may impact visibility and result in sealing times that are longer than needed to seal a vessel branch. When excessive tissue adhesion is noticed, clean the Jaws of the device to enhance visualization and function. The use of distal CO<sub>2</sub> insufflation throughout the vessel branch transection portion of the procedure, and thorough dissection of tissue during the dissection
- Locate the vessel in the center of the Jaws for optimal performance and visualization. Keep the tips of the Jaws toward the main conduit. Tissue placed at the hinge of the Jaws may result in sticking or an incomplete cut. The rear of the Jaw does not seal and transect the tissue. (Figure 35) By placing the branch away from the hinge of the Jaws, sealing and transection is more complete. (Figure 36).
- Activate energy ONLY when material is placed between the Jaws for routine branch transection or tissue division. Once transection is complete, or if visualization is obstructed, STOP Jaw activation.
- Mild tension when sealing and transecting vessel branches. Apply mild tension on a vessel branch to enhance the "fall-away" effect once the cut is complete. Slight rotation or retraction of the C-Ring should be sufficient. Excess twisting or "pulling" of vessel branches with the Jaws may prevent optimal device performance and branch avulsion.
- Pull when cutting fascia. Dissect tissue by grasping the tissue with the Jaws and then pulling or rotating the Harvesting Tool while activating the device. Pulling applies tension while keeping view of the cut. More force can be applied when cutting fascia than when sealing and transecting vessel branches.







## **Optimizing Visualization**

- The Vasoview Hemopro Endoscopic Vessel Harvesting System provides distal insufflation at the site of branch sealing and transection. Remove the CO<sub>2</sub> source from the BTT CO<sub>2</sub> Insufflation Port; a one-way valve is designed to maintain the tunnel during this step. Attach the CO<sub>2</sub> source to the Distal Insufflation Port on the Harvesting Cannula. This will deliver CO<sub>2</sub> insufflation to the tip of the Harvesting Cannula.
- If the distal lens of the endoscope becomes obscured by blood or fat, use the integrated endoscope wash feature. Fill the 5 cc syringe with saline and attach it to the blue Scope Wash Port extending from the Harvesting Cannula handle. Extend the C-Ring slider to the optimal working distance and depress the syringe plunger slightly to wet the scope lens and clear obstructive debris or fluid. (Figure 37)
- Alternatively, the endoscope can be removed to clean the lens directly with a sterile gauze pad. Remove the endoscope from the bell handle leaving the Harvesting Cannula System in the tunnel to maintain surgical position. When the endoscope is cleaned, reinsert it back into the bell handle.
- The Vasoview Hemopro Harvesting Tool has vents in the distal portion of the shaft of the Harvesting tool which aids in the evacuation of any steam or smoke generated from branch sealing and transection or tissue cauterization.



Figure 37

## Guidelines for Safe and Effective Use of the Hemopro Harvesting Tool

- Always use the Power Supply setting between 2 and 3 when using the Vasoview Hemopro Endoscopic Vessel Harvesting System. Use of other settings may result in suboptimal sealing and transection.
- During Jaw activation, position the concave side of the Jaws towards the main vessel. (Figure 38)
- Activation of the Jaws without tissue between the Jaws should be avoided.
- Avoid placing vessel branches at the base of the Hemopro Jaws.
- Ensure adequate visualization of the Vasoview
   Hemopro Jaws and the surgical site prior to activation
   of the Jaws. If visualization of the surgical site is
   impaired, do not initiate or continue activation of
   energy.
- Use caution when placing the Vasoview Hemopro Jaws in contact or close proximity to flammable materials (surgical drapes, towels, alcohol, anesthetics, etc) or skin surfaces as an activated device may result in fire or burns
- Use caution when the target anatomy to be placed between the Vasoview Hemopro Jaws is located close to the skin surface. This situation may cause thermal injury to the skin surface and related structures.
- If the Vasoview Hemopro Harvesting Tool is active when not intended, retract the Harvesting Tool into the Harvesting Cannula and immediately disconnect the Harvesting Tool Extension Cable Connector from the Extension Cable. Use a new Hemopro Harvesting Tool to complete the procedure.

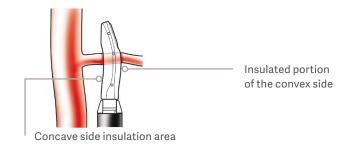


Figure 38

#### **Technique Tips**

- Use the internal diameter of the C-Ring (5 mm) as a guide for measuring distance.
- Advance the Harvesting Cannula to the distal end of the tunnel to begin vessel branch sealing and transection, working back towards the incision. If branches prohibit advancement of the Harvesting Cannula it may be less traumatic to the vein to perform vessel branch transection starting at the proximal end of the tunnel.
- Always ensure the C-Ring is behind the vessel branch that is being sealed and transected. (Figure 39)
- After branch sealing and transection, observe for bleeding. If bleeding is noted, use the Jaws to capture tissue on the tunnel walls and coagulate the bleeding.
- When sealing and transectiong branches, be sure to have the C-Ring as close to the vessel branch as possible before rotating. This will allow sealing and transecting to occur further away from the main vessel.
- When retracting the Harvesting Cannula with the vein in the C-Ring, if the vein appears to be turning (or snaking) around the instrument, rotate the Harvesting Cannula in the direction of the turning (or snaking).
   This most often indicates that a branch is going to be encountered.
- Always retract the Hemopro Harvesting Tool into the Harvesting Cannula when it is not in use.
- Try to keep the C-Ring with the vein in place in the center of the tunnel at all times. (Figure 40)



Figure 39



Figure 40

## **Running the Vein**

The purpose of running the vein is to identify any intact vessel branches or adherent tissue prior to distal ligation.

- Once all branches have been sealed and transected, run the C-Ring along the entire length of the vein from distal to proximal to ensure that all branches have been transected. (Figure 41)
- If needed, make a second pass with the C-Ring in the opposite orientation to ensure that all branches and connective tissue are free from the vessel. (Figure 42)
- Identify and seal and transect any connective tissue or branches that are still adhered to the vein.

### **Distal Transection and Ligation**

Distal ligation of the vein can be performed in various ways. A "stab and grab" approach is used to externalize the vein through a stab wound. The vessel is then transected externally. An "endoloop" approach divides the vein endoscopically and is the technique used by some experienced users.

#### "Stab and Grab"

- With the tunnel insufflated, make a small 1 3 mm stab wound with an 11 blade over the distal end of the tunnel. The distal end of the tunnel can be identified with external manipulation.
- Observe on the video monitor as a hemostat or similar small clamp is inserted through the stab wound and advanced into the tunnel. (Figure 43) Under endoscopic vision, place the clamp across the distal end of the vein. (Figure 44) Externalize the vein through the stab wound and transect it under direct vision per surgical protocol. (Figure 45)
- Ligate the terminal end of the vein stump per hospital protocol. Allow the ligated vein stump to retract back into the tunnel.

### **Endoloop Approach**

 This technique for performing distal ligation uses a knot pusher to pass a suture loop to the distal end of the tunnel. (Appendix A shows the steps for creating a ligation loop.)



Figure 41

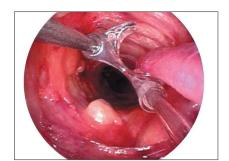


Figure 42



Figure 43

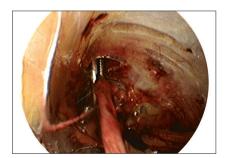


Figure 44



Figure 45

## **Vein Removal and Preparation**

- Turn off CO<sub>2</sub> insufflation. Deflate the BTT balloon if necessary and remove the BTT from the incision.
- Check for any branches and adherent tissue at the site of the BTT in the tunnel. These branches may be transected under direct vision.
- Remove the saphenous vein through the incision. Note the anatomical orientation of the vein for proper cannulation. Measure the vein to ensure adequate length for the bypass grafting. (Figure 46) If additional length is needed, further dissection can be carried out through the same incision, harvesting in the opposite direction.
- Flush and prepare the vein according to standard protocol.

## **Closing and Dressings**

Close incisions using hospital protocol. Apply dressings and wrap the leg according to standard procedure or operator preference.

#### **Technique Tips**

- Using a lap sponge, gently roll along the skin over the operative area, expressing any residual blood through the incision prior to closing.
- Irrigate the operative tunnel if desired. Roll out irrigant using the above technique.

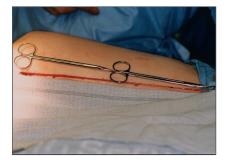


Figure 46

## **EVH Procedure**

## Radial Artery

## **Patient Positioning and Preparation**

#### **Preoperative Evaluation**

When harvesting the radial artery, typically the non-dominant arm is used. Confirm adequate collateral circulation through the use of the pulse-assisted Allen's test, Doppler evaluation, pulse oximetry, or a combination of these tests using hospital protocol. (Figure 47)

#### **Surgical Preparation**

Place the arm on a surgical board, positioning it at no more than a 90-degree angle. For procedures using a tourniquet, select an appropriately sized tourniquet and place the non-pressurized tourniquet high on the upper arm before the skin prep. Shave and prep the arm, using accepted hospital protocol. (Figure 48)

#### **Product Assembly**

For additional product assembly information, see the Product Assembly section of the Endoscopic Vessel Harvesting of the Saphenous Vein portion of this manual. (page 10)

- Attach the 7 mm Extended Length Endoscope to the camera coupler. Attach the light cable to the post on the endoscope. Focus the endoscope on a gauze pad and white balance the video camera. Ensure proper orientation of the camera head. It is important to maintain correct orientation throughout the endoscopic procedure.
- Thread the Dissection Tip onto the distal end of the endoscope until the proximal edge of the Dissection Tip lines up with the indicator etched on the endoscope shaft.
- Place the Dissection Tip on a gauze pad. Focus the video camera, ensuring that the image outside the Dissection Tip is clearly visualized.
- Insert the endoscope with attached Dissection Tip through the BTT. Ensure that the Endoscope Seal is on the BTT. (The BTT is packaged with the Endoscope Seal attached.) (Figure 49)
- Ensure proper set-up and testing of the Vasoview Hemopro Power Supply. See the Equipment Testing section of this Training Manual for instructions on proper set-up. (pages 17 and 18)







Figure 47

Figure 48

Figure 49

### **Incision and Tourniquet Deployment**

#### **Making the Incision**

Create a 2 – 3 cm longitudinal incision over the radial artery from the wrist crease proximally. (As a point of orientation, the elbow area will be referred to as proximal and the wrist area will be referred to as distal.) (Figure 50) Under direct vision, dissect locally through the lateral muscular fascia to identify the radial artery and venae comitantes. (Figure 51)

#### **Tourniquet Deployment**

In procedures using a tourniquet, wrap the arm tightly with an Esmark bandage from the fingers to the elbow. Inflate the tourniquet to 75 – 100 mmHg over systolic blood pressure, not exceeding 250 mmHg total. Remove the Esmark bandage. Extend the forearm, placing a rolled towel under the wrist. Note the time of tourniquet deployment. Generally tourniquet time is kept under one hour.

### **Endoscopic Dissection**

The radial artery is dissected as a pedicle with the accompanying venae comitantes. This technique is used to minimize contact with, and potential spasm of the radial artery. Advance the endoscope over the anterior surface of the radial artery, about 4 cm's, to allow insertion of the BTT. Insert the BTT into the incision. Attach the  $\rm CO_2$  insufflation tubing to the clear flexible  $\rm CO_2$  Insufflation Port on the BTT and begin  $\rm CO_2$  insufflation at  $\rm 10-12$  mmHg and a flow rate of  $\rm 3-5$  L/min. If desired pressure is not obtained in the tunnel, the syringe provided can be used to inflate the balloon on the BTT. Inflate the balloon with the minimal amount of air needed to create an adequate seal (0-25 cc's of air).

(Notice that you do not achieve the same sized tunnel that you see during saphenous vein harvesting, which is in part due to the fascia constraining the tunnel. Later in the procedure the fascia will be released, opening the tunnel.)

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Figure 51

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#### **Step 1: Anterior Dissection**

With the aid of CO<sub>2</sub>, advance the Dissection Tip along the pedicle veins on each side of the radial artery, avoiding any contact with the radial artery. (Figures 52 and 53) Dissect tissue and fascia away from the veins and radial artery, lifting the Dissection Tip in an upwards direction. The lifting motion transmits shear force against the lateral muscular fascia and not the radial artery. Continue anterior dissection to the level of the recurrent radial artery or venous plexus in the antecubital fossa. As branches are encountered, advance past them with as little displacement as possible.

#### **Step 2: Posterior Dissection**

Return the Dissection Tip back to the BTT port. (Figure 54) Carefully advance the endoscope posterior to the radial pedicle. Begin advancing the endoscope along the posterior aspect of the pedicle veins, again avoiding contact with the radial artery. Although anatomy varies from patient to patient, posterior branches are likely to be encountered midway up the forearm. When branches are encountered, free enough space around the branch to produce minimal stress to the branch as the Dissection Tip is advanced. Continue posterior dissection to the level of the recurrent radial artery. (Figure 55)

#### **Step 3: Lateral Dissection**

The purpose of lateral or branch dissection is to create "windows" in the tissue or to clear adjoining tissue from the pedicle. This is achieved by advancing the Dissection Tip through the targeted tissue.

To begin the lateral dissection, return the endoscope back to the BTT port. Larger branches may require creating a "window" through the tissue away from the pedicle to create improved exposure for later sealing. The final goal is obtaining a pedicle with both venae comitantes on each side of the radial artery. Therefore, avoid any dissection between these structures.



Figure 52



Figure 53



Figure 54

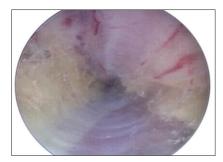


Figure 55

## **Fasciotomy**

The fasciotomy is performed to enhance visualization by opening up the tunnel. Additionally, it can reduce the risk of compartment syndrome if there is any bleeding post-operatively.

To begin, withdraw the endoscope from the tunnel, leaving the BTT in place. Remove the Dissection Tip from the end of the endoscope. Insert the endoscope into the Vasoview Hemopro Endoscopic Vessel Harvesting Cannula. Replace the Endoscope Seal with the Cannula Seal on the BTT.

Close the Vasoview Hemopro Harvesting Tool Jaws. Holding the Harvesting Tool approximately 6 inches (15 cm) from the distal end of the Jaws and with the Jaw tips oriented upwards, insert the Harvesting Tool into the Harvesting Cannula through the Tool Adapter Port. (Figure 56)

Use the Power Supply setting between 2 and 3 with the Vasoview Hemopro Endoscopic Vessel Harvesting System. Use of other settings may result in sub-optimal cutting and sealing. Pre-Test the Harvesting Tool as described on page 18.

Perform the fasciotomy by advancing the Hemopro Harvesting Tool so the fascia is within the Jaws and applying energy from the Power Supply to cut the tissue. The fascia should be released from the distal forearm to the mid or proximal forearm. (Figure 57)

Recall the steps from the "C.L.A.M.P." method described earlier (page 20):

**P-Pull when cutting fascia.** Dissect tissue by grasping the tissue with the Jaws, apply energy while pulling or rotating the Harvesting Tool. Pulling applies tension while keeping view of the cut. More force can be applied when cutting fascia than when cutting vessels.

During fasciotomy, ensure that the tissue not intended to be cauterized is not within the Jaws.



Figure 56



Figure 57

## **Branch Sealing and Transection**

- Once the fasciotomy is complete, begin branch transection. Always use the Power Supply setting between 2 and 3 when using the Vasoview Hemopro Endoscopic Vessel Harvesting System.
- Use the C-Ring to protect the pedicle and to maintain a consistent distance between the pedicle and the Hemopro Harvesting Tool. Using the C-Ring can ensure that the integrity of the radial artery conduit is preserved by maintaining a distance of 3-5 mm between the pedicle and the Hemopro Harvesting Tool during branch transection. (Figure 59)
- Engage the branches with the Vasoview Hemopro
  Jaws by pulling the Activation Toggle into the center
  position. (Figures 58 and 59) Ensure the tips of the
  Jaws are towards the main vessel.
- Always ensure the C-Ring is behind the vessel branch or adhered tissue being transected. (Figure 59)

- Apply energy by pulling the Activation Toggle back from the center position until a stop is noticed. (Figure 60) The time of activation will depend on vessel branch size. Use the C-Ring to protect the vessel pedicle. (Figure 59)
- Recall the "C.L.A.M.P." method described earlier in the Branch Sealing and Transection section of the EVH procedure for saphenous vein. Those same steps apply to endoscopic radial artery harvesting. (Page 20)
- During branch transection, ensure that tissue not intended to be cauterized is not within the Jaws.
- When the branch has been divided, open the Vasoview Hemopro Jaws by moving the Activation Toggle into the forward position. (Figure 61)
- If cutting is incomplete, reapply the Jaws to the branch. Repeat the procedure to the portion of the branch which is not transected.



Figure 58



Figure 59



Figure 60



Figure 61

- Close the Jaws before retracting the Harvesting Tool into the Harvesting Cannula to avoid damage to the device.
- Work proximal to distal (elbow to wrist). The proximal end of the pedicle is indicated by the recurrent radial artery.
- Upon completion of the vessel branch sealing and transecting, use the C-Ring to run the pedicle, ensuring that all branches have been transected. (Figure 62)
- Inspect the sites of branch transection along the tunnel for hemostasis.



Figure 62

# Transection and Retrieval of the Radial Artery

The radial artery pedicle can be divided and ligated using either the "stab and grab" technique with an 11-blade as described in the Distal Transection and Ligation section of the EVH Procedure for saphenous vein (page 24), or with a vessel loop, as described in Appendix A.

For procedures not using a tourniquet, the radial artery pedicle should be clamped at the wrist with a soft bulldog-type clamp prior to proximal division. This is intended to keep the pedicle from back bleeding into the tunnel.

Once the radial artery pedicle has been transected and ligated, allow both vessel segments to retract back into the tunnel. Remove the BTT from the incision and withdraw the pedicle in a retrograde fashion externally through the incision. (Figure 63) Transect and ligate the radial artery at the wrist area using standard protocol. Note the anatomical orientation of the artery for proper cannulation of the artery.



Figure 63

## **Hemostasis and Conduit Preparation**

#### Procedure - Non-tourniquet Method

Once the radial artery has been transected and ligated at the wrist, place the BTT back into the incision. Place the Harvesting Cannula through the BTT to inspect the tunnel for hemostasis. If bleeding is noted, use the Jaws to capture tissue on the tunnel walls and coagulate the bleeding.

#### Procedure - Using a Tourniquet

Deflate the tourniquet and note the tourniquet time. Check pulse oximetry on the digits to ensure adequate perfusion to the hand.

#### **Conduit Preparation**

The radial artery is prepared in the usual fashion per hospital protocol and operator preference.

## **Closing and Dressings**

Close incisions using hospital protocol. Apply dressings and wrap the arm according to standard protocol or operator preference. (Figures 64-67)

### **Technique Tips**

- Using a lap sponge, gently roll along the skin over the operative area, expressing any residual blood out through the incision prior to closing. (Figure 64)
- Irrigate the operative tunnel, if desired. Roll out irrigation using the above technique.











Figure 67



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# **Nursing Considerations**

The OR staff plays an integral part in the endoscopic vessel harvesting procedure. It is crucial that the OR staff understands how the instrumentation and equipment are used, as well as the steps of the procedure, in order to create a cohesive team. The OR staff should be properly trained on the endoscopic vessel harvesting procedure as well as on the Vasoview Endoscopic Vessel Harvesting System being used. If the cardiovascular OR staff is not familiar with the videoscopic equipment, it is suggested that the manufacturer's local field representative also provide additional in-services. Equipment issues should not complicate the endoscopic procedure. All equipment should be tested and in good working condition prior to beginning the case.

As with any new procedure, patience is required during the learning phase. Allow extra time for the OR staff and the operator during the first several procedures.

#### **Circulating Nurse Responsibilities**

Knowing and understanding each component of the video setup is important for the circulating nurse, as the nurse is the primary troubleshooter once the procedure has begun. (See Troubleshooting Section, page 37)

Turn on all components to the video system, including those that may not be used. Once the various cords are handed off from the sterile field to the OR staff person in the non-sterile OR field, the following tasks are completed.

- Connect the camera cable to the camera box. The
  color bars are replaced by a clear image that is visible
  on the screen. Note that the light source settings—
  manual and automatic—correlate with the camera
  box settings, as do shutter controls and gain buttons.
  (Check with the video vendor for the proper settings.)
- Connect the fiber optic cable to the light source. Place the unit in the standby mode until the procedure begins. Be sure that the fiber optic cable is not resting against the patient or sterile drapes unless in the standby mode. There is potential for fire due to the intensity and heat of the light. During this procedure, it may be necessary to increase the light intensity. Frequently, the light source unit can be set to manual for adjustment of the light intensity. The "gain" button generally boosts the light even further.
- Connect the insufflation tubing to the unit, verify settings, and place in standby mode until CO<sub>2</sub> is needed.
- Connect the Hemopro Extension Cable to the Hemopro Power Supply and verify the setting is between 2 and 3.

## **Case Setup**

Day before procedure: Determine the best location for OR equipment (OR tables, perfusion and anesthesia equipment) the day before the case to eliminate confusion on the day of surgery. The videoscopic tower is best positioned across from the harvester.

**Day of procedure:** Begin with a Mayo stand or an area of the back table that can be devoted to the Vasoview products. The advantage of a separate Mayo stand is that it can be removed from the field once the vessel harvesting is completed and to simplify the general setup.

#### Sterile items:

- Components of the Vasoview Hemopro Endoscopic Vessel Harvesting System kit:
  - Vasoview Hemopro Harvesting Cannula, Hemopro Harvesting Tool
  - Short Port BTT with 7 mm Endoscope Seal, Harvesting Cannula Seal and Dissection Tip
- Vasoview Hemopro Extension Cable
- · Camera head (or camera cover)
- 7 mm Extended Length Endoscope
- · Fiber optic light cable
- CO<sub>2</sub> insufflation tubing
- Anti-fog solution (optional)
- Scalpel handle
- #11 blade, #10 blade
- Army/Navy retractor
- 6-inch or 7-inch right-angle hemostat
- 6-inch or 7-inch Crile or Kelly Clamp
- Ligature (manual clips, small and medium, with appliers or suture)
- Items available but not opened:
  - Minor instrument set
  - Sterile 7 mm Extended Length Endoscope

#### Non-sterile items:

 Endoscopic video tower (video monitor, camera, light source, and insufflator)

- Vasoview Hemopro Power Supply
- Vasoview Hemopro Power Cord
- CO<sub>2</sub> Source

# **Postoperative Procedures**

For the most part, the postoperative procedures will remain consistent with those practiced for other harvesting techniques.

#### Suggestions

- Care must be taken when handling the 7 mm Extended Length Endoscope; it is especially long and more fragile than shorter or larger-diameter endoscopes. It is recommended that the endoscopes be kept in the instrument tray available through Getinge. More detailed instructions can be found in the Instructions For Use.
- Create a Vasoview Hemopro Endoscopic Vessel Harvesting System supply cart. Keep all related supplies on the cart, including back-up kit components. It is easy for something to fall on the floor or become contaminated.
- · Designate someone to restock the cart.
- Consider making one person the resident expert with the Vasoview Endoscopic Vessel Harvesting System.

# **Troubleshooting**

Occasionally, the operator may encounter problems while performing the endoscopic vessel harvesting procedure. Most situations can be managed easily with a quick check of the equipment. If problems arise, stop the procedure and check these items.

#### No Tunnel/No CO,

- CO<sub>3</sub> tank is full and opened.
- CO<sub>2</sub> tubing is connected to the BTT and the insufflator.
- Flow and pressure settings on insufflator (3 5 L/mm and 10 – 12 mmHg).
- CO<sub>2</sub> leaking around incision.
- Ensure BTT has been inserted correctly into the tunnel.
- CO<sub>2</sub> tubing is not connected to BTT Balloon Port or Washer Port on the Harvesting Cannula.

#### No Power Supply Activation

- · Hemopro Power Supply is plugged in.
- Hemopro Power Supply is turned on and LED light is lit.
- Ensure Extension Cable is properly connected to the Harvesting Tool.
- Ensure that the Extension Cable is properly connected to the Hemopro Power Supply.

#### **Endoscope "Sliming"**

- When advancing instruments, ensure that they are maintained in a central position in the tunnel.
- Ensure that tissue is not on the C-Ring before withdrawing it into the Harvesting Cannula.
- Attempt to clean the endoscope lens on tunnel wall.
- Remove the scope and clean it externally.
- Use the scope washer within the Harvesting Cannula to clean the lens.

#### **Endoscope Fogging**

- Use anti-fog solution on the end of the endoscope (only with the Harvesting Cannula). Do not use antifog solution on the lens prior to placement of the Dissection Tip.
- Withdraw the distal tip of the endoscope back to the BTT, keeping the instrument in the tunnel. Hold in place for about 10 seconds. This allows cold CO<sub>2</sub> to infuse directly over the tip of the endoscope and clears the fogging (similar to using air conditioning in a car to clear a fogged windshield).

#### Picture of the Tunnel is Too Dark

- Light cable is connected to the endoscope and the light source.
- · Re-white balance the endoscope.
- Increase the gain on the camera.
- Increase the light intensity.
- Change the light cable.
- Blood absorbs light; if blood is in tunnel, try rolling it out through the incision.
- Position the operative lights over the external working area of the leg to transilluminate the tunnel.
- Try replacing the endoscope and check the fiber optics of endoscope after the procedure is completed.

#### **Blood in the Tunnel**

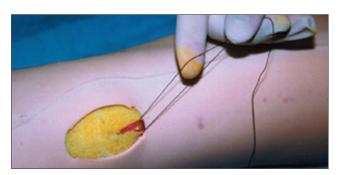
- Remove the BTT. Using a lap sponge, gently roll along the tunnel toward the incision, expressing blood through the incision.
- Remove the BTT. Insert a Yankauer suction into the incision and suction pooled blood from the tunnel.
- Remove the BTT. Irrigate with non-heparinized normal saline. Roll the tunnel externally to remove irrigation and re-insert the BTT and continue with insufflation.

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VASOVIEW HEMOPRO TRAINING MANUAL

# **Appendix A: Endoloop Approach**

# Eight Steps for Tying a Ligation Loop



## Step 1:

Using a monofilament suture, grasp both suture ends between the thumb and index finger as shown.



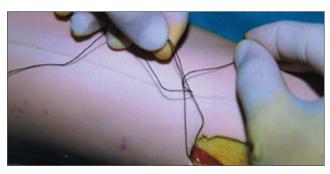
#### Step 2:

Take the shortest suture tail in front of the 2 sutures, forming a complete circle around the index finger.



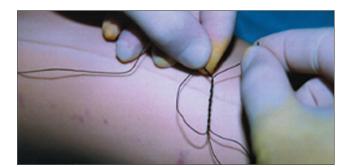
#### Step 3:

Take the shortest suture strand in back of the 2 suture strands and pass the short strand through the circle.



#### Step 4

Grasp the short strand and pull through the circle and begin process over, wrapping short strand a total of 5 times in the circle.

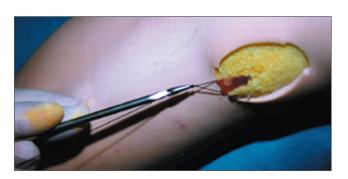


**Step 5:** Pull short and long strand to tighten knot.



Pull short strand and one of the 2 strands to tighten knot securely. Remember, one of the strands will tighten the knot and one will advance the knot.





**Step 7:** Once the knot is secure, cut the short tail, leaving 2 to 3 mm of suture. Do not cut right next to the knot.



Step 8:
Thread the knot pusher and advance knot and knot pusher into insufflated tunnel. (Push the knot to the ligation point and cinch the suture around the vein. The suture is secure and tight when the vein has an hourglass appearance.)





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