

VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System

Information for Prescribers

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

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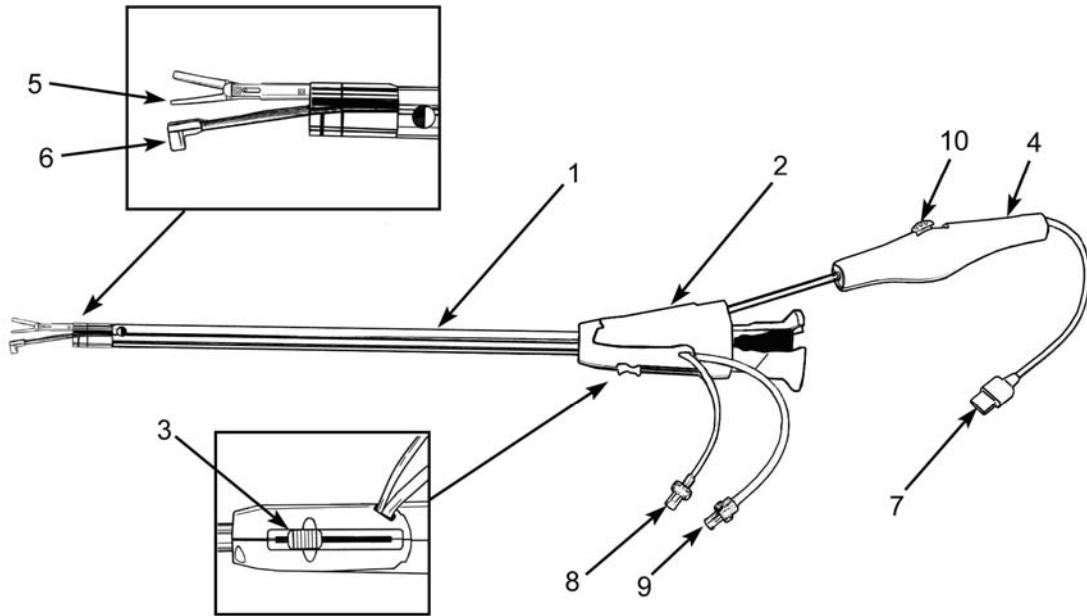


Figure 1: VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System.
1. Harvesting Cannula; 2. Tool Adapter Port; 3. C-Ring Slider; 4. VASOVIEW HEMOPRO Harvesting Tool; 5. VASOVIEW HEMOPRO Jaws; 6. C-Ring; 7. Harvesting Tool Extension Cable Connector; 8. Scope Washer Connector (blue); 9. Distal Insufflation Connector; 10. Activation Toggle

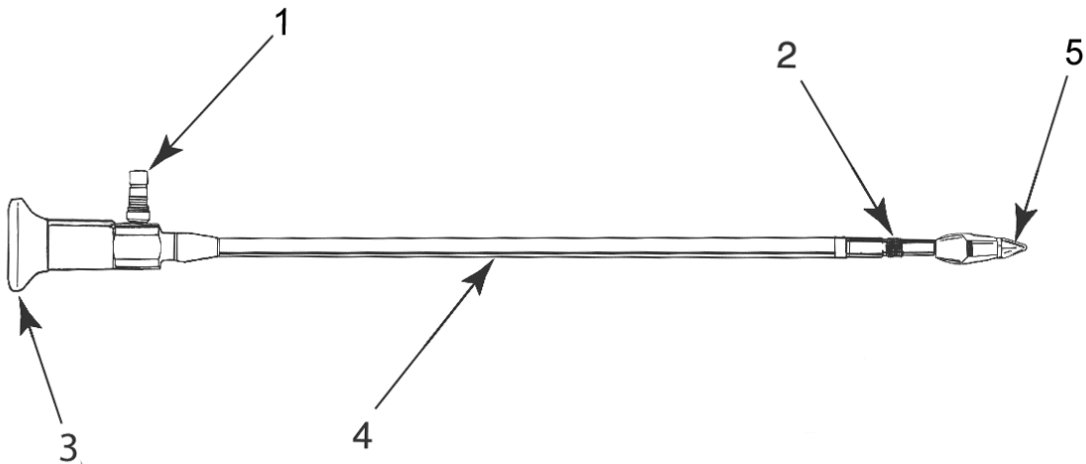


Figure 2: 7 mm Extended Length Endoscope and Dissection Tip
1. Illumination Port; 2. Indicator Band; 3. Eyepiece; 4. Shaft; 5. Dissection Tip

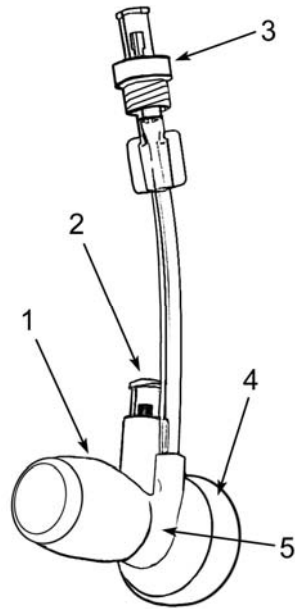


Figure 3: Short Port BTT

1. Balloon; 2. Balloon Inflation Port; 3. CO₂ Insufflation Port with one-way valve; 4. Endoscope Seal or Cannula Seal; 5. Body

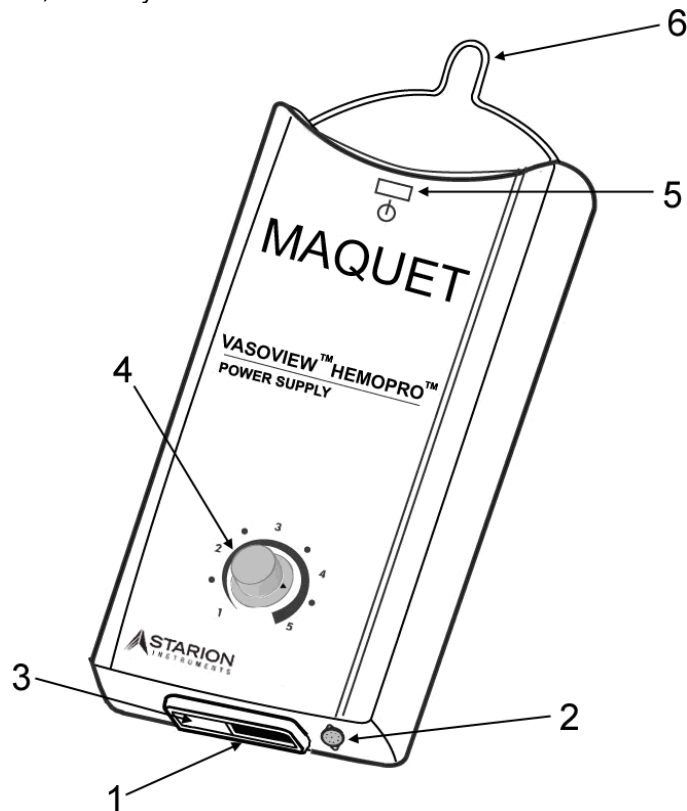


Figure 4: VASOVIEWHEMOPRO Power Supply

1. ON/OFF Switch; 2. Extension Cable Connector; 3. Power Cord Connector; 4. Power Setting Knob; 5. LED Power-On Indicator; 6. Hanger

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 the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System. They are not a reference to endoscopic surgery or techniques. Representative sources are listed in the bibliography section of these Instructions for Use.

1.0 DEVICE DESCRIPTION

1.1 VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System

The VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System is designed for use in conjunction with the 7 mm Endoscope. The Harvesting Cannula has four lumens which house the Endoscope, C-Ring, distal lens washer tube and VASOVIEW HEMOPRO Harvesting Tool for cutting and sealing of vessel branches. The C-Ring/distal lens washer is independently controlled by a C-Ring Slider on the handle of the device that retracts the vessel and washes the distal tip of the Endoscope. The Harvesting Tool can be extended/retracted from the main cannula by inserting it into the Tool Adapter Port, and rotated independently. The Harvesting Tool has two curved Jaws. One Jaw contains the heating elements for branch cutting and sealing; the second Jaw is longer and has a serrated inner edge. Cutting and sealing of vessel branches is achieved in two steps: (1) capture of the branch between the HEMOPRO Jaws, and (2) simultaneous coagulation and ligation of the branch with the Jaws using direct current. Both steps are achieved by mechanical application of the Activation Toggle. Positioning of the device, cutting, and sealing are performed under endoscopic visualization. This device is intended for specific use with the VASOVIEWHEMOPRO Power Supply.

1.2 VASOVIEW HEMOPRO Power Supply

The VASOVIEW HEMOPRO Power Supply is a reusable, AC-powered unit intended to be used only with the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System. The VASOVIEW HEMOPRO Power Supply is intended to be connected to AC power via a grounded hospital grade power cord and features an on/off switch and green power-on LED indicator. Output power is delivered to the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System when the Activation Toggle on the Harvesting Tool is pulled into its most proximal position. An intermittent tone indicates the Power Supply is activated. The level of power delivered to the VASOVIEW HEMOPRO Harvesting Tool is set by a knob on the Power Supply front panel; higher numbers indicate a higher level of energy. The Power Supply may be placed on a flat, non-sterile surface adjacent to the sterile field, or may be suspended from a nearby IV pole.

Compliance with Standards. The VASOVIEW HEMOPRO Power Supply complies with IEC60601-1 (UL 2601-1 and CAN/CSA-C22.2 No. 601.1-M90) requirements for type Class I, Type CF equipment, Type CF applied parts, and meets electromagnetic compatibility requirements of IEC-60601-1-2.

Electrical Requirements. Input: 100-240 VAC, 50/60 Hz, 80 W.
Maximum Output: 32 W, 6 V D.C.

1.3 VASOVIEW HEMOPRO Extension Cable

The VASOVIEW HEMOPRO Extension Cable is a reusable cable designed for use with the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System and the VASOVIEW HEMOPRO Power Supply. The Extension Cable is supplied non-sterile and must be sterilized prior to each use. The Extension Cable can withstand 20 sterilization cycles on average before replacement may be required.

1.4 7 mm Extended Length Endoscope and Dissection Tip

The 7 mm 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 7 mm Endoscope.

The 7 mm Endoscope is designed to be used in conjunction with the removable Dissection Tip for blunt dissection of tissue and isolation of structures in the cavity. The Dissection Tip attaches to the distal end of the 7 mm Endoscope, and consists of a clear, blunt-tipped cone at the distal end for tissue dissection and visualization, and a larger bulb at the proximal end for dilation of the cavity.

1.5 Short Port Blunt Tip Trocar (BTT)

The Short Port Blunt Tip Trocar (BTT) is used to provide a port of access for insertion of endoscopic instruments into an incision site. The device consists of a main body with a Balloon on the distal end, a Balloon Inflation Port, an Endoscope Seal on the proximal end, and an external port with a one-way valve for gas insufflation. It also includes a Cannula Seal to allow insertion of the Harvesting Cannula. The Balloon minimizes leakage and secures the port. A 30 cc syringe is provided for inflation/deflation of the Balloon.

2.0 HOW SUPPLIED

VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System - The VASOVIEW HEMOPRO System 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, VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System: One (1) Harvesting Cannula, One (1) Harvesting Tool, One (1) 5 cc Syringe, One (1) Short Port Blunt Tip Trocar (BTT) with Endoscope Seal, One (1) Harvesting Cannula Seal, One (1) 30 cc Syringe, One (1) Dissection Tip.

VASOVIEW HEMOPRO Power Supply - The Power Supply is non-sterile. Contents of the Power Supply: One (1) Power Supply device, One (1) power cord.

VASOVIEW HEMOPRO Extension Cable - The Extension Cable is non-sterile. Contents of the Extension Cable: One (1) Extension Cable.

7 mm Extended Length Endoscope - The 7 mm Endoscope (sold separately) is a reusable device and is supplied non-sterile. It must be cleaned and sterilized prior to each use. Contents of the 7 mm Extended Length Endoscope: One (1) 7 mm Extended Length Endoscope.

3.0 INDICATIONS

3.1 VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System

The VASOVIEW HEMOPRO 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 extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or the radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

3.2 7 mm Extended Length Endoscope and Dissection Tip

The 7 mm Extended Length Endoscope with Dissection Tip is indicated for visualization of a surgical cavity and dissection in endoscopic procedures and other minimally invasive surgical procedures allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic vessel harvesting for arterial bypass. It is indicated for patients requiring endoscopic tissue separation of the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection / vessel harvesting 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. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels, and other tissues of the chest wall.

3.3 Short Port BTT

The Short Port BTT has applications for surgery in the saphenous vein or radial artery for establishment of a port of entry for endoscopic instruments.

4.0 CONTRAINDICATIONS

The VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System, 7 mm Extended Length Endoscope and Dissection Tip, and Short Port BTT are contraindicated in situations where minimally invasive surgery is contraindicated.

5.0 WARNINGS AND PRECAUTIONS

5.1 VASOVIEW HEMOPRO 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 VASOVIEW HEMOPRO System is sterile unless the package is damaged or opened. The method of sterilization is gamma irradiation. The VASOVIEW HEMOPRO 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 surgical procedures using electricity in a body is essential to avoid shock and burn hazards to both the patient and operator(s) and damage to medical instrumentation.
6. The VASOVIEW HEMOPRO System is for use with the VASOVIEW HEMOPRO Power Supply only!
7. FOR INTERMITTENT OPERATION ONLY: Do not apply continuous energy.
8. Do not apply energy to the VASOVIEW HEMOPRO Jaws without material between the Jaws of the tool, as this may damage the device. Once tissue has been transected, stop application of energy, as material is no longer between the Jaws.
9. To avoid damage to delicate tissue, advance the cannula gently.
10. Always advance the C-Ring and Harvesting Tool under endoscopic visualization.
11. Ensure adequate visualization of the HEMOPRO Jaws and the surgical site prior to application of energy. If visualization of the surgical site is impaired, do not initiate or continue activation of energy to the HEMOPRO Jaws.
12. Always inspect the surgical site for hemostasis. If hemostasis is not present, appropriate techniques should be applied to achieve hemostasis.
13. 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.
14. When performing radial artery harvesting, the radial artery harvesting procedure should be performed prior to placing the patient on cardiopulmonary bypass.
15. Do not touch the HEMOPRO Jaw surfaces while the device is activated. This may cause injury.

16. Close the HEMOPRO Jaws when inserting or retracting the Tool through the Harvesting Cannula.
17. The Power Supply emits an intermittent tone when activated, signaling application of energy to the HEMOPRO Jaws (i.e. the HEMOPRO Harvesting Tool is active).
 - If the HEMOPRO Harvesting Tool is active when not intended, retract the Tool into the Harvesting Cannula and immediately disconnect the Harvesting Tool Extension Cable Connector from the Extension Cable.
 - It is important to verify the position of the Activation Toggle on the Harvesting Tool and move the Toggle away from the most proximal position if necessary.
18. Use caution when placing the HEMOPRO jaws in contact or close proximity to flammable materials (surgical drapes, towels, alcohol, anesthetics, etc) or skin surface as an activated device may result in fire or burns.
19. Use caution when the target anatomy to be placed between the HEMOPRO jaws is located close to the skin surface as this situation may cause thermal injury to the skin surface and related structures.

5.2 VASOVIEW HEMOPRO Power Supply

1. Only use with the supplied regionally compatible Power Cord connected to a Hospital Grade receptacle.
2. Use only with the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System. Use with any other instrument may damage the instrument and/or the VASOVIEW HEMOPRO Power Supply and could prevent proper functioning during use.
3. Do not drop the Power Supply.
4. Do not sterilize the Power Supply. Follow recommended cleaning instructions as described in these Instructions for Use.
5. Do not use in the presence of flammable materials (e.g., alcohol, flammable anesthetics).
6. There are no risks associated with proper disposal of the Power Supply. Follow any local regulations regarding proper disposal of used electronic equipment.

7. Do not allow patient to contact grounded metal parts.
8. The safety and effectiveness of the Power Supply has not been fully evaluated in patients with cardiac pacemakers or metallic implants.
9. Inspect the Power Supply and all accessories, connections, and cords before each use, looking for damage and ensuring that casing is intact.
10. Do not immerse the Power Supply in liquids.
11. Check to make sure that there is no evidence of damage to the control knob on the Power Supply.
12. Inspect the on/off switch and power cord for evidence of rough handling, abrasion, kinks, or other signs of damage.
13. Inspect all labels and markings for legibility.
14. Check the condition of the housing, cover, handle, markings, and warning labels for evidence of damage.
15. Call Customer Service (888-880-2874 or 408-635-6800) if you discover any damage or situation that may jeopardize the safety and/or effectiveness of this device.
16. The Power Supply has no serviceable parts.

5.3 VASOVIEW HEMOPRO Extension Cable

1. The Extension Cable is a reusable instrument that is supplied non-sterile. Thoroughly clean and sterilize the Extension Cable prior to each use. Follow recommended sterilization and cleaning instructions as described in these Instructions for Use.
2. Inspect the VASOVIEW HEMOPRO Extension Cable prior to each use for any sign of damage. Immediately replace if there is any sign of damage.
3. Use the connector body when connecting/disconnecting the cable. Pulling by the cord may result in damage to the Extension Cable.
4. The Extension Cable must be fully seated to the Power Supply and to the Harvesting Tool to ensure proper function.
5. Avoid kinking or sharply bending the Extension Cable. Sharp bends or kinks may result in broken wires causing reduced performance or failure of the VASOVIEW HEMOPRO System.

5.4 7 mm Extended Length Endoscope and Dissection Tip

1. The Endoscope is a reusable instrument that is supplied non-sterile. Thoroughly clean and sterilize the Endoscope prior to each use. Follow recommended sterilization and cleaning instructions as described in these Instructions for Use.
2. The Endoscope is a fragile instrument. Handle carefully to avoid breakage. Bending of the Shaft or dropping the Endoscope may damage the optics or other internal components, making the Endoscope inoperable. Store in a protective tray whenever possible.
3. The Dissection Tip is sterile unless the package is opened or damaged. The Tip is designed for single use. **Do not reuse or resterilize the Dissection Tip.**
4. Whenever using endoscopic illumination equipment, ensure that the light cable connectors never rest on flammable materials such as surgical drapes, towels, etc.
5. If Prevacuum or Gravity steam sterilization (autoclave) is used, the Endoscope may have a shorter life due to harsher sterilization environment. Inspect the Endoscope after each steam sterilization cycle for damage.
6. Do not cool a hot Endoscope after sterilization by rapidly exposing it to air or liquid. Sudden temperature changes may cause glass components to crack.
7. Do not “flash” steam sterilize (autoclave) the Endoscope. Flash (i.e., unwrapped) steam sterilization cycles introduce sudden temperature changes, which may cause glass components to crack.

5.5 Short Port BTT

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.**
2. Balloon products must be treated with care. Damage to the Balloon by instruments used during insertion and in the course of a procedure may result in Balloon rupture.

3. The Short Port BTT balloon contains natural rubber latex that is encapsulated by a silicone coating such that latex is not intended to come in contact with the patient or the user. If the outer layer of the balloon on the Short Port BTT is damaged, natural rubber latex may be exposed. Natural rubber latex may cause allergic reactions.
4. Over inflation of the Short Port BTT Balloon may result in Balloon rupture. Do not inflate with more than 25 cc of air.

6.0 INSTRUCTIONS FOR USE

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

6.1 Preparation of the Endoscope and Dissection Tip

1. Remove the Endoscope from the packaging and discard the protective cap.
2. 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).
3. 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.
4. 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.
5. White balance the camera in accordance with the camera manufacturer's instructions for use.
6. 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.

7. Attach the removable Dissection Tip to the distal end of the Endoscope. Thread the Dissection Tip onto the Endoscope until the proximal edge of the Dissection Tip lines up with the Indicator Band on the Endoscope Shaft, and the Dissection Tip is securely attached to the Endoscope.

6.2 Patient Preparation

1. Prepare the patient in accordance with standard surgical techniques.

6.3 Tunnel Dissection

1. Using an open technique, make an initial 2 cm incision and locate the vessel. Slide the Short Port BTT with Endoscope Seal up the Endoscope Shaft to the proximal hub of the Endoscope. 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 the anterior surface during the dissection process. Advance the instrument approximately 3 – 4 cm, and then slide the Short Port BTT into the incision. Inflate the BTT Balloon with up to 25 cc of air through the Balloon Inflation Port. Connect the gas line to the CO₂ Insufflation Port and infuse CO₂ gas at a low rate of 3 – 5 L/min and a pressure of 10 – 12 mm Hg. Gas insufflation holds the dissected tunnel open for improved visualization.
2. Continue advancing the Endoscope and Dissection Tip along the anterior aspect of the vessel, until the desired vessel length is dissected. Monitor progress of dissection via the Endoscope. Regularly check the orientation of the camera before advancing the Endoscope. Withdraw the Endoscope until the Dissection Tip is at the distal end of the Short Port BTT and then advance the Endoscope along the posterior aspect of the vessel, dissecting gently and thoroughly around vessel branches as they are encountered.

NOTE: A thorough dissection around vessel branches is recommended for optimal HEMOPRO performance.

3. Should the image become compromised, verify that all equipment is correctly connected to the Endoscope. If required, remove the Endoscope and Dissection Tip, 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.

4. Upon completion of tissue dissection, remove the Endoscope from the tunnel, and remove the Dissection Tip from the Endoscope.
5. The Harvesting Cannula may be used to complete isolation of the vessel. Upon completion of the endoscopic procedure, the working space may be quickly deflated by removing the Harvesting Cannula from the Short Port BTT.

6.4 Preparation of the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System and the VASOVIEW HEMOPRO Power Supply

1. Carefully remove VASOVIEW HEMOPRO System from its shipping package. Do not use if damaged or opened. Inspect to ensure no damage has occurred during transit.
2. Connect the Power Cord to the Power Supply.
3. Plug the Power Cord into a grounded Hospital Grade receptacle.
4. Connect the Extension Cable to the Power Supply.
5. Turn on the Power Supply. A green power on/off LED at the top of the front panel should illuminate. If not, check both power cord connections. If LED still does not illuminate, replace power cable. A green LED next to the Extension Cable connector should also illuminate indicating that the Power Supply recognized the VASOVIEW HEMOPRO Extension Cable.
6. Connect the Harvesting Tool Extension Cable Connector to the Extension Cable, ensuring correct orientation.
7. Pre-test the VASOVIEW HEMOPRO Harvesting Tool to verify complete electrical activity and Power Supply setting:
 - Set the Power Supply knob setting between 2 and 3.

NOTE: Any Power Supply setting may be used to perform tissue dissection and vessel harvesting. The setting between 2 and 3 is recommended for typical use.

 - Soak a sterile 4" x 4" (10.16 cm x 10.16 cm) gauze pad with saline.
 - Place the soaked 4" x 4" (10.16 cm x 10.16 cm) gauze pad between the Jaws of the Harvesting Tool. Secure the gauze pad by moving the Activation Toggle from the forward most position to the center position.

WARNING: DO NOT TOUCH THE JAW SURFACES WHILE THE DEVICE IS ACTIVATED. THIS MAY CAUSE INJURY.
WARNING: DO NOT PERFORM TESTING WITHOUT PLACING MATERIAL BETWEEN THE JAWS OF THE DEVICE.

- Activate the Harvesting Tool by pulling the Activation Toggle from the center to the proximal position. A discernable click indicates the application of energy.
- Steam generation from the soaked 4" x 4" (10.16 cm x 10.16 cm) gauze pad indicates active power and a complete circuit. The Power Supply will also emit an intermittent tone indicating that it is active.
- Deactivate the Harvesting Tool and open the Jaws by moving the Activation Toggle from the proximal position to the forward most position. The Power Supply tone will cease indicating that power is no longer active.

WARNING: IF THE HARVESTING TOOL WILL NOT DEACTIVATE, IMMEDIATELY DISCONNECT THE HARVESTING TOOL EXTENSION CABLE CONNECTOR FROM THE EXTENSION CABLE.

NOTE: If during the Pre-test there is no steam or a tone is not emitted from the Power Supply when the Activation Toggle is pulled to its most proximal position:

- Add more saline to the pad.
- Verify that the Power Supply power switch is ON.
- Verify proper connection of the Extension Cable on the Harvesting Tool to the Extension Cable, and the Extension Cable to the Power Supply.

If steam is still not observed, the Power Supply does not emit a tone when steam is observed, or the device will not deactivate. **DO NOT** use the device and call Customer Service at (888) 880-2874. For outside the United States, please call Customer Service at (408) 635-6800.

NOTE: Due to variations in individual patient anatomy and individual physician technique, the following steps may vary and should be considered recommendations only.

**6.5 VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System
Insertion**

1. After completing tunnel dissection, attach the Cannula Seal to the Short Port BTT.
2. Insert the 7 mm Endoscope into the VASOVIEW Harvesting Cannula until it snaps into place.
3. Ensure the HEMOPRO Jaws are closed prior to insertion through the VASOVIEW Harvesting Cannula. Hold the VASOVIEW HEMOPRO Harvesting Tool approximately 6" (or 15 cm.) from the tips before inserting through the Tool Adapter Port. If desired, Surgilube (or another water-soluble lubricant) may be used on the Harvesting Tool. Insert the Harvesting Tool through the Tool Adapter Port of the Harvesting Cannula, but do not advance the tip of the Harvesting Tool beyond the end of the Harvesting Cannula.

NOTE: The HEMOPRO Jaws have a protective coating to minimize tissue adhesion. In order to get the full benefit from the Tool, handle the device with care.

4. Slide the Harvesting Cannula through the Short Port BTT and into the harvesting space. Advance the distal end of the Cannula to the target location.

NOTE: To ensure minimal leakage through incision:

- Ensure the BTT port Balloon is inflated (up to 25 cc of air).
- Apply gentle backpressure to the Balloon to ensure the incision is sealed.
- If necessary, use suture to reduce the incision size.

5. Ensure the gas line is connected to the CO₂ Insufflation Port on the Short Port BTT or to the Distal Insufflation Connector on the Harvesting Cannula. Infuse with CO₂ gas at a flow rate of 3 – 5 L/min to a pressure of 10 – 12 mmHg. Gas insufflation holds the dissected tunnel open for improved visualization.

NOTE: To ensure adequate visualization of the tunnel:

- Confirm there is adequate gas in the CO₂ tank.
- Confirm the CO₂ tank valve is open.
- Confirm the CO₂ insufflator is turned on.
- Confirm the CO₂ tubing is properly connected.
- Confirm gas is present at the delivery end of the CO₂ tubing.

- Switch gas line to Distal Insufflation Connector if originally attached to the BTT Insufflation Port.
- Slowly withdraw the Harvesting Cannula back towards the BTT until the tunnel re-expands.
- Perform blunt dissection or use the Jaws to cut through the fascia to modify the tunnel size.

NOTE: When cutting fascia, apply mild tension by retracting or rotating the Harvesting Tool to ensure optimal visualization of the surgical site during transection.

NOTE: If blood or other tissue obscures the distal lens of the Endoscope, advance the C-Ring Slider to position the distal lens washer. Attach the 5 cc syringe of saline to the blue Scope Washer Connector and squeeze the syringe to spray saline and clean the Endoscope lens. Alternatively, the endoscope can be removed and the distal lens cleared using a sterile 4" x 4" (10.16 cm x 10.16 cm) gauze pad.

6. Confirm the VASOVIEW HEMOPRO Power Supply knob setting is between 2 and 3.

NOTE: Any Power Supply setting may be used to perform tissue dissection and vessel harvesting. The setting between 2 and 3 is recommended for typical use.

6.6 Vessel Harvesting

1. Under endoscopic visualization, extend the C-Ring to the targeted vessel by advancing the C-Ring Slider forward. The C-Ring may also be positioned by rotating the VASOVIEW Harvesting Cannula around the Endoscope. If desired, use the C-Ring to retract the main trunk of the vessel for additional exposure of the branches.

2. Extend the VASOVIEW HEMOPRO Harvesting Tool toward the targeted branch with the Jaws in the open position (Activation Toggle in the forward most position). Rotate the Harvesting Tool as necessary via mechanical rotation in order to position the Jaws to grasp the target vessel. Position the targeted branch within the HEMOPRO Jaws. Secure the branch by closing the Jaws, pulling back on the Activation Toggle until resistance is met. Apply mild tension to the branch by rotating or retracting the Harvesting Tool slightly, or by rotating the C-ring. Applying tension enhances visualization of tissue separation after transection.

NOTE: To avoid damage to delicate tissue, advance the Harvesting Cannula gently.

NOTE: Open the HEMOPRO Jaws when the tool is extended to an adequate length and viewable in the Endoscope. Avoid use when the Jaws are beyond the viewable area.

NOTE: The HEMOPRO Jaws should be in view when performing branch ligation, per standard endoscopic technique. **When activating energy to the device, visually ensure that material is between the Jaws.**

NOTE: Placing vessel branch at the base of the HEMOPRO Jaws may cause the branch to adhere to the Jaws. Place the vessel branch away from the hinge of the Jaws for optimal performance.

3. Apply energy to the VASOVIEW HEMOPRO System by pulling the Activation Toggle back from the center position until a discernable click is noticed. Cutting and sealing is simultaneous within the HEMOPRO Jaws. When separation of the branch tissue is noticed, open the Jaws and stop application of energy by pushing the Activation Toggle into the forward most position, and retract the Harvesting Tool slightly. If cutting is incomplete, reapply the Jaws to the branch and repeat activation of energy to the unseparated portion of the branch.

NOTE: Moving the Activation Toggle into the proximal (or rear) position requires a small degree of force, intentionally provided to prevent accidental branch transection and sealing. To stop application of energy, release the Activation Toggle.

NOTE: When energy is activated, the VASOVIEW HEMOPRO Power Supply emits a tone until the Activation Toggle is released.

NOTE: If visualization is impaired, stop activation to the Jaws. Never perform endoscopic surgery without proper visualization.

NOTE: Once material has been transected, stop application of energy.

4. To clean the HEMOPRO Jaws, use 4" x 4" (10.16 cm x 10.16 cm) gauze pad(s) soaked with saline solution.

NOTE: For optimum performance, keep Jaw surfaces free of debris.

5. Upon completion of use of the VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System, turn the Power Supply OFF and ensure the HEMOPRO Jaws are closed prior to retracting the tool through the Tool Adapter Port. Then withdraw the C-Ring into the Harvesting Cannula before removing the device from the tunnel.

6. To remove the Short Port BTT, place the syringe in the Balloon Inflation Port with the plunger depressed. The Balloon will deflate, pushing the plunger out and filling the syringe. Remove the Short Port BTT.

7. 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.

7.0 HANDLING, STORAGE and CLEANING

7.1 VASOVIEW HEMOPRO Power Supply

1. Do not drop. Store in a cool, dry place. Avoid prolonged exposure to extreme temperatures.
2. Exterior of the VASOVIEW HEMOPRO Power Supply may be cleaned using a soft cloth moistened with a solution of water and hospital grade detergent or disinfectant. Gently wipe down all cords, switches, buttons, and device housing, taking special care not to get liquid into housing or electrical components. Gently dry the entire Power Supply, including cords.

Table 1. Recommended Environmental Conditions

	Transport	Storage	Operating
	-15°C to 50°C	15°C to 30°C	15°C to 30°C
	25 to 95	30 to 85	45 to 75
	700hPa to 1060hPa	700hPa to 1060hPa	700hPa to 1060hPa

7.2 VASOVIEW HEMOPRO Extension Cable

The VASOVIEW HEMOPRO Extension Cable must be thoroughly cleaned prior to re-sterilization.

1. Upon completion of a vessel harvesting procedure, cover the soiled Extension Cable with a towel moistened with distilled water, to prevent soil from drying out before cleaning.
2. Soak the Extension Cable in Steris Klenzyme™ enzymatic solution (prepared per manufacturer's instructions) for a minimum of 2 minutes. Rinse thoroughly with distilled water.
3. Manually clean the cable with Steris Manu-Klenz™ detergent (prepared per manufacturer's instructions). Use a soft, non-abrasive cloth or brush to clean the cable, especially grooves, and crevices, until no visible soil remains. Rinse thoroughly with distilled water.
4. Thoroughly dry the Extension Cable with clean, lint-free material.

7.3 7 mm Extended Length Endoscope

The Endoscope must be thoroughly cleaned prior to resterilization.

1. Upon completion of the procedure, cover the soiled Endoscope with a towel moistened with distilled water, to prevent soil from drying out before cleaning.
2. If present, remove the light cable adapter from the Endoscope.
3. Soak the Endoscope in Steris Klenzyme™ enzymatic solution (prepared per manufacturer's instructions) for a minimum of 2 minutes. Rinse thoroughly with distilled water.
4. Manually clean the Endoscope with Steris Manu-Klenz™ detergent (prepared per manufacturer's instructions). Use a soft, non-abrasive cloth or brush to clean the Endoscope, especially threads, grooves, and crevices, until no visible soil remains on the Endoscope. Rinse thoroughly with distilled water.
5. Thoroughly dry the Endoscope with clean, lint-free material.

8.0 STERILIZATION

8.1 VASOVIEW HEMOPRO Extension Cable

Use one of the methods listed below to sterilize the VASOVIEW HEMOPRO Extension Cable.

1. 100% Ethylene Oxide Sterilization per ANSI/AAMI/ISO 11135 with the following parameters:

Configuration: Wrapped with 2 ply muslin or equivalent
Preconditioning: 57°C (135°F) temperature, 70% relative humidity, 1-hour minimum exposure.

Conditioning and Sterilization: 57°C (135°F) temperature, 70% ± 5% relative humidity, 100% ethylene oxide (600 ± 25 mg/L concentration), 2 hour minimum exposure

Aeration: 57°C (135°F) temperature, 12-hour minimum aeration.

2. STERIS SYSTEM 1: sterilize per manufacturer's instructions.
3. STERRAD 100s, 50, 200: sterilize per manufacturer's instructions.

NOTE: Steam Sterilization is not recommended for sterilization of the VASOVIEW HEMOPRO Extension Cable.

VASOVIEW HEMOPRO Extension Cable: The Extension Cable will withstand an average of twenty sterilization cycles when cleaned and sterilized according to the criteria above. The maximum number of sterilization cycles is dependent on proper care and inspection of the device by your facility per the Instructions for Use.

8.2 7mm Extended Length Endoscope

Use one of the methods listed below to sterilize the 7 mm Extended Length Endoscope.

NOTE: Methods other than Steam Sterilization are recommended for longer Endoscope life.

1. 100% Ethylene Oxide Sterilization per ANSI/AAMI/ISO 11135, with the following parameters:

Configuration: Wrapped with 2 ply muslin or equivalent

Preconditioning: 57°C (135°F) temperature, 70% relative humidity, 1-hour minimum exposure.

Conditioning and Sterilization: 57°C (135°F) temperature, 70% ± 5% relative humidity, 100% ethylene oxide (600 ± 25 mg/L concentration), 2 hour minimum exposure

Aeration: 57°C (135°F) temperature, 12-hour minimum aeration.

Note: Use a protective tray during sterilization and storage of the endoscope.

Note: Ethylene Oxide method is recommended for longer Endoscope life.

2. Prevacuum Steam Sterilization (Prevacuum Autoclave) with the following parameters:

Configuration: Wrapped with 2 ply muslin or equivalent

Exposure Time: 4 minutes

Temperature: 132°C (270°F)

Note: Use a protective tray during sterilization and storage of the endoscope.

3. Gravity Steam Sterilization (Gravity Autoclave) with the following parameters:

Configuration: Wrapped with 2 ply muslin or equivalent

Exposure time: 15 minutes

Temperature: 132°C (270°F)

Note: Use a protective tray during sterilization and storage of the endoscope.

4. STERIS SYSTEM 1 (liquid peracetic acid) compatible. Use STERIS 20 sterilent and C1200 or C1220 processing tray

Note: Use a protective tray during storage of the endoscope.

5. STERRAD 100s, 50, 200 compatible. Use STERRAD instrument tray. Double wrap with KIMGUARD sterile wrap or equivalent.

Note: Use a protective tray during storage of the endoscope.

9.0 ADDITIONAL INFORMATION

9.1 Radial Artery Harvesting Feasibility Study Results

Objective: To evaluate the safety of the VASOVIEW Endoscopic Vessel Harvesting System (VASOVIEW Uniport Plus Dissection Cannula) when used to harvest radial arteries in patients who undergo coronary artery bypass surgery.

Methods: Seven (7) patients undergoing CABG and meeting study criteria were enrolled and consented in a single-center feasibility study. Two patients were excluded from the primary endpoint analysis for meeting an exclusion criteria and enrolling under a previous protocol version. Data was collected at baseline, preoperatively, and post-operatively up to discharge and at 30 days.

Results: The radial artery was successfully harvested in all seven (7) patients with minor donor arm complications and patency was demonstrated for all five (5) patients who underwent angiography at 30 days. All 5 radial artery grafts were reported to be patent by the core lab. Minimal stenosis (25%) was found in all of the radial artery grafts at the anastomotic site with the average lesion length of 2.22 +/- 0.56 mm. TIMI 3 flow was reported for each radial artery graft with no calcification or tortuosity. One patient experienced stenosis of a native coronary artery which required PTCA with stenting. A summary of the feasibility study results is provided in Table 2.

Table 2. Radial Artery Harvesting Feasibility Study Results

Category Results	(N=7)
Age in years, mean (range)	57.8 (41-69)
Gender (% male)	86%
Primary Endpoint	
Patency (n)	100% (5/5)*
Secondary Endpoint	
Arm Complications	
Hand/thumb weakness	0
Dysesthesia/paresthesia	2
Motor deficit	0
Nerve damage	0
Hematoma	0
Infection/wound complication**	1
MACE	0
Stroke	0
Hemorrhage	0

*2 patients did not undergo angiogram

**erythema

10.0 BIBLIOGRAPHY
























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11.0 WARRANTY

MAQUET Cardiovascular LLC (MAQUET) 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, storage, cleaning and sterilization of this system, including any disposable components, power supply, capital equipment, or other components, as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond MAQUET's control directly affect the instrument and the results obtained from its use. MAQUET'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 MAQUET 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 MAQUET, at its option, to inspect the system and its components and the purchaser must reasonably cooperate with MAQUET 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 MAQUET, at its option, to repair or replace the affected component(s). Repairs must be made by an authorized MAQUET site or this warranty will be null and void. 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. MAQUET neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this system. **MAQUET 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 MAQUET 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 are protected under one or more of the following U.S. patents: 5,895,353; 6,176,825; RE36,043; 6,162,173; 5,993,384; 5,697,946; 6,406,425; 6,830,546.

12.0 GRAPHICAL SYMBOL DEFINITIONS

 Catalogue Number :	 Sterilization by Irradiation
 Lot Number:	 Authorized Representative in the European Community
 Serial Number:	 Non-Sterile
 Use By:	 Input
 Do Not Reuse	 Max. Output
 Manufacturer:	 Protective Earth Ground
 Date of Manufacture:	 Type CF Applied Part
 Contents (Numeral represents quantity of units inside)	 Relative Humidity
 Attention: See Instructions For Use	 Atmospheric Pressure
 Federal Law (USA) restricts this device to sale by or on the order of a physician.	 Temperature
 Requires Separate Collection For Electrical and Electronic Equipment	 Power OFF
	 Power ON

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EL2048114 Rev. K