

**VasoView™ 4 Uniport™ Endoscopic Vessel Harvesting System (EVH)
with VasoView™ Flexible Endoscopic Bipolar Scissors**

Information for Prescribers

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

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Important: Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

These Instructions for use are designed to assist in the use of the VasoView™ 4 Uniport™ Endoscopic Vessel Harvesting System (EVH) with VasoView™ Flexible Endoscopic Bipolar Scissors. They are not a reference to endoscopic surgery or techniques.

1.0 DEVICE DESCRIPTION

1.1 VasoView™ Uniport™ Plus Dissection Cannula

The VasoView™ Uniport™ Plus Dissection Cannula (Figure 1) is designed to be used in conjunction with the 5 mm Extended Length Endoscope. The cannula has a removable conical tip and four lumens to house the endoscope, vessel cradle/distal lens washer and a bipolar instrument for coagulation and division of vessel tributaries/branches. The vessel cradle/distal lens washer is independently controlled by a slider button on the handle of the device for retraction and blunt dissection of tissue as well as washing of the distal tip of the scope.

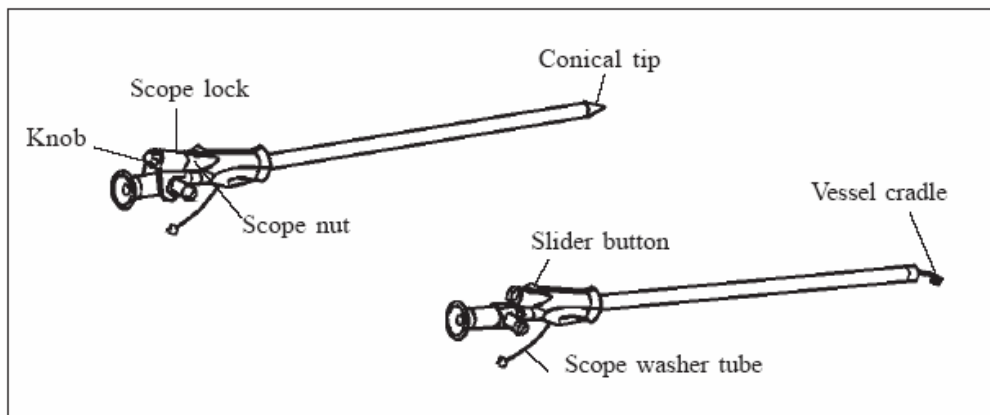


Figure 1

1.2 VasoView™ Flexible Endoscopic Bipolar Scissors

The VasoView™ Flexible Endoscopic Bipolar Scissors (Figure 2) are intended to be passed through a 5mm endoscopic cannula. Mechanical cutting and bipolar coagulation is achieved using electrosurgical energy under endoscopic visualization. This device is intended to be used with the bipolar outputs of compatible generators.

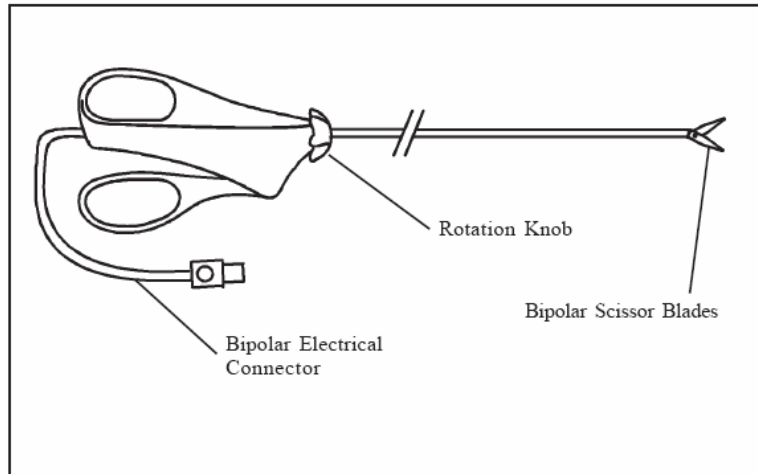


Figure 2

1.3 VasoView™ Short Port Blunt Tip Trocar (BTT)

The Short Port Blunt Tip Trocar (Figure 3) 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, a main seal on the proximal end, and an external port for gas insufflation. It may also include an alternate converter seal to allow insertion of smaller instruments. The balloon minimizes leakage and secures the port. A 30cc syringe is provided for inflation/deflation of the balloon.

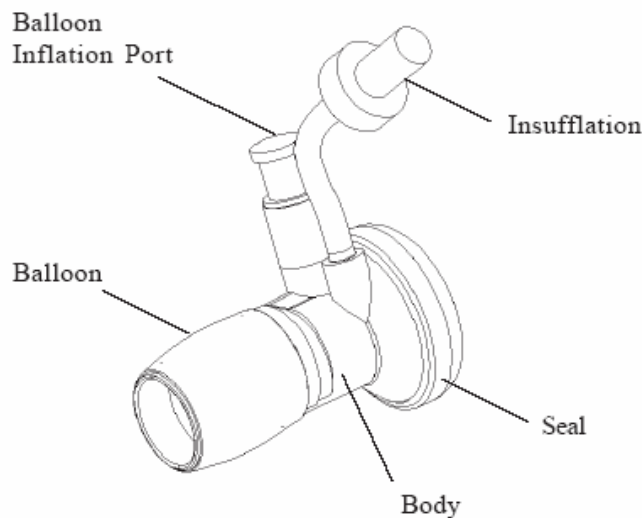


Figure 3

2.0 HOW SUPPLIED

The VasoView™ 4 Uniport™ Endoscopic Vessel Harvesting System (EVH) with VasoView™ Flexible Endoscopic Bipolar Scissors is supplied **STERILE** in an unopened and undamaged package. The VasoView™ 4 Uniport™ Endoscopic Vessel Harvesting System (EVH) with VasoView™ Flexible Endoscopic Bipolar Scissors has been sterilized using gamma irradiation and is for single use only. **DO NOT RESTERILIZE. DO NOT REUSE.**

Contents: One (1) VasoView™ Uniport™ Plus Dissection Cannula, One (1) VasoView™ Flexible Endoscopic Bipolar Scissor, One (1) 30 cc Syringe, One (1) 5 cc Syringe, One (1) Conical Tip, One (1) Tool Bridge, One (1) VasoView™ Short Port Blunt Tip Trocar (BTT).

3.0 INDICATIONS

3.1 VasoView™ Uniport™ Plus Dissection Cannula

The VasoView™ Uniport™ Plus Dissection Cannula 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 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 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 VasoView™ Flexible Endoscopic Bipolar Scissors

The VasoView™ Flexible Endoscopic Bipolar Scissors are indicated for endoscopic cutting and bipolar coagulation of tissue, including veins, arteries and other blood vessels.

3.3 VasoView™ Short Port Blunt Tip Trocar (BTT)

This product has applications for surgery in the leg or arm for establishment of a port of entry for endoscopic instruments.

4.0 CONTRAINDICATIONS

4.1 VasoView™ Uniport™ Plus Dissection Cannula

The device is contraindicated in situations where minimally invasive surgery is contraindicated.

4.2 VasoView™ Flexible Endoscopic Bipolar Scissors

The VasoView™ Flexible Endoscopic Bipolar Scissors are not intended for contraceptive coagulation of the fallopian tube but may be used to achieve hemostasis following transection of the tube.

4.3 VasoView™ Short Port Blunt Tip Trocar (BTT)

The device is contraindicated in situations in which minimally invasive surgery is contraindicated.

5.0 WARNINGS AND PRECAUTIONS

5.1 VasoView™ Uniport™ Plus Dissection Cannula

- 1) Read all instructions carefully. Failure to properly follow the instructions, warnings and cautions may lead to serious surgical consequences or serious injury to the patient.
- 2) Minimally invasive surgical procedures should be performed only by physicians having adequate training and familiarity with such surgical techniques. Consult medical literature regarding techniques, complications, and hazards prior to performance of these procedures.
- 3) Sterility: The product is sterile unless the package is opened or damaged. The product is designed for single use. **Do not reuse or resterilize.** The primary method of sterilization is irradiation.
- 4) Before endoscopic instruments and accessories from different manufacturers are employed in a procedure, verify compatibility and ensure that electrical isolation and grounding of these instruments is not compromised.
- 5) A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid shock and burn hazards to both the patient and operator(s) and damage to medical instrumentation.
- 6) Handle the endoscope carefully to avoid breakage. Regularly check the orientation of the camera before advancing.
- 7) Advance the cannula gently to avoid damage to delicate tissue.
- 8) Always advance the vessel cradle and bipolar instrument under endoscopic visualization. Ensure adequate visualization of bipolar instrument tips and surgical site prior to application of electrosurgical energy.

- 9) Always inspect the surgical site for hemostasis. If hemostasis is not present, appropriate techniques should be applied to achieve hemostasis.
- 10) 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.
- 11) Remove and discard the Tool Bridge from the scope after use, prior to cleaning and sterilizing the scope.
- 12) When performing radial artery harvesting, the radial artery harvesting procedure should be performed prior to placing the patient on cardiopulmonary bypass.

5.2 VasoView™ Flexible Endoscopic Bipolar Scissors

- 1) Endoscopic procedures should be performed by physicians having adequate training and familiarity with endoscopic techniques. Consult medical literature regarding techniques, complications, and hazards prior to performance of any endoscopic procedure.
- 2) Sterility: The product is sterile unless the package is opened or damaged. The device is designed for one time use. **Do not reuse or resterilize.** The primary method of sterilization is irradiation.
- 3) Read all instructions carefully. Failure to properly follow the instructions, warnings, and cautions may lead to serious surgical consequences or injury to the patient.
- 4) For use with the bipolar outputs of electro-surgical generators only!
- 5) Do not exceed 35 watts in any mode.
- 6) Use generators listed in the required special mode setting only.
- 7) Do not use on Codman Mallis generators.
- 8) All exposed metal components at the distal end of the scissors may coagulate tissue. Ensure all exposed metal is within the field of vision and contacting tissue intended to be coagulated during the application of electro-surgical energy.
- 9) Device may not be compatible with some reusable trocars. Check instrument and trocar compatibility prior to use.

- 10) **WARNING:** Flexible scissors may not cut effectively if shaft is flexed excessively (approximately 45°).

5.3 VasoView™ Short Port Blunt Tip Trocar (BTT)

- 1) Read all instructions carefully. Failure to properly follow the instructions, warnings, and cautions may lead to serious surgical consequences.
- 2) Minimally invasive surgical procedures should be performed only by persons having adequate training and familiarity with such surgical techniques. Consult medical literature regarding techniques, complications, and hazards prior to performance of these procedures.
- 3) Sterility: The product is sterile unless the package is opened or damaged. The product is designed for single use. **Do not reuse or resterilize.** The primary method of sterilization is irradiation.
- 4) Before endoscopic instruments and accessories from different manufacturers are employed in a procedure, verify compatibility and ensure that electrical isolation and grounding of these instruments is not compromised.
- 5) A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid shock and burn hazards to both the patient and operator(s) and damage to medical instrumentation.
- 6) Balloon products must be treated with care. Damage to balloons by instruments used during insertion and in the course of a procedure may result in balloon rupture.
- 7) 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.
- 8) Over inflation of the BTT Port balloon may result in balloon rupture. Do not inflate more than 25 cc.
- 9) 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.

- 10) When performing radial artery harvesting, the radial artery harvesting procedure should be performed prior to placing the patient on cardiopulmonary bypass.

6.0 INSTRUCTIONS FOR USE

6.1 VasoView™ Uniport™ Plus Dissection Cannula

The following instructions are recommended for proper function of the VasoView™ Uniport™ Plus Dissection Cannula and the Blunt Tip Trocar (BTT) Port. It is not a reference to endoscopic surgery techniques.

- 1) Insert the 5 mm Extended Length Endoscope into the VasoView™ Uniport™ Plus cannula and attach by turning the scope nut clockwise until it is snug. Ensure the conical tip is secured in the clear hood on the distal end of the device. Slip the scope lock over the scope's proximal end and secure by turning the knob clockwise until snug.
- 2) Make an initial 2 cm incision and locate the vessel. Slide the BTT Port over the entire length of the cannula. Insert the cannula into the subcutaneous space anterior to the vessel and advance the conical tip along the vessel until 3-4 cm of vessel is dissected. Insert the BTT Port into the incision and inflate the port's balloon with up to 25 cc of air. Insufflate the operative tunnel under low pressure after attaching the gas line to the port's one-way valve.
- 3) Continue advancing the cannula along the anterior aspect of the vessel, until the desired vessel length is captured. Monitor progress of dissection via the endoscope. Withdraw the cannula tip back to the BTT and then advance the cannula long the posterior aspect, dissecting gently and thoroughly around vessel branches as they are encountered.
- 4) After dissection of the vessel, withdraw the cannula from the tunnel. Remove the scope lock from the device handle by unscrewing the knob on the lock. Next, remove the conical tip from the cannula by fully withdrawing its flexible shaft from the lumen. Insert the VasoView™ Flexible Endoscopic Bipolar Scissors into the lumen with tips pointed left, Uniport™ Plus handle with slider button on top, and vessel cradle retracted.

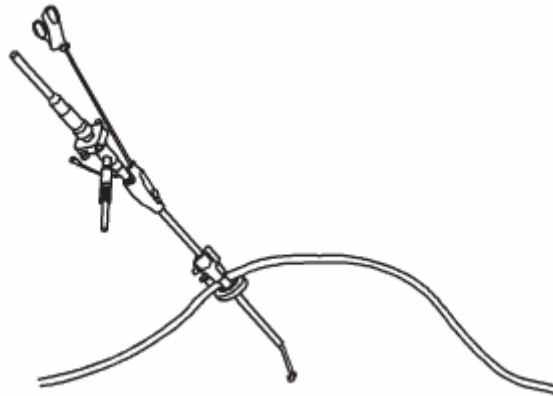


Figure 4

If desired, a water soluble lubricant may be used on the bipolar instrument shaft before insertion into VasoView™ Uniport™ Plus Dissection Cannula. If desired, snap the Tool Bridge over the back of the Endoscope (Figures 5 and 6), and rest the bipolar instrument shaft in the cutout of the Tool Bridge.

- 5) Insert the VasoView™ Uniport™ Plus Dissection Cannula back through the BTT Port (Figure 4). Move the distal end of the cannula to the target location.

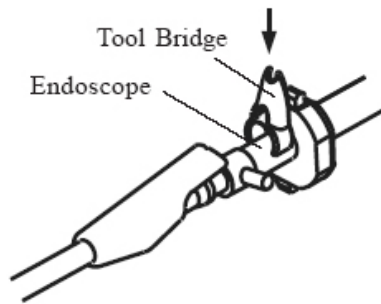


Figure 5

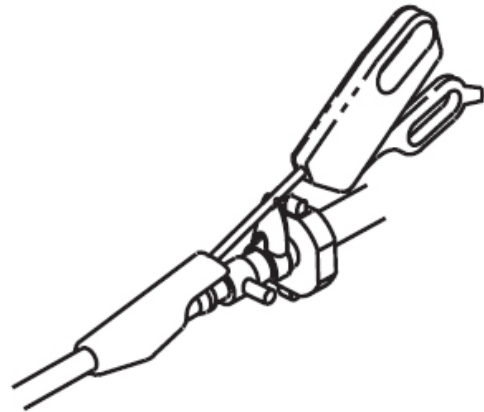


Figure 6

- 6) If the distal lens of the scope becomes obscured by blood or fat, advance the vessel cradle button to the mark on the handle to position the distal lens washer. Attach the 5 cc syringe of saline and squeeze the syringe to spray saline and clean the scope lens.
- 7) Under endoscopic visualization, advance the vessel cradle to the targeted tissue and apply short, axial strokes to dissect tissue, as needed. The vessel cradle may also be positioned by rotating the cannula around the endoscope.

- 8) Advance the bipolar instrument to the target location. If desired, use the vessel cradle to retract the main trunk of the vessel to expose the vessel tributaries/branches for coagulation and division.
- 9) The vessel cradle and bipolar instrument should be withdrawn back into the cannula when removing the device from the endoscopic port.
- 10) Always inspect the surgical site for hemostasis. If hemostasis is not present, appropriate techniques should be applied to achieve hemostasis.

6.2 VasoView™ Flexible Endoscopic Bipolar Scissors

- 1) Carefully remove the device from its shipping package. Inspect to ensure no damage has occurred during transit. Do not use if opened or damaged. Remove tip protector if present.
- 2) Insert the electrical connector into the appropriate extension cord.
- 3) Pre-test device to verify complete electrical activity and generator setting:
 - a. Soak a sterile 4" x 4" (10.6 cm x 10.6 cm) gauze pad with saline.
 - b. Touch both exterior blade surfaces against the 4" x 4" (10.6 cm x 10.6 cm).
 - c. CAUTION: DO NOT TOUCH THE COAGULATING SURFACES WHILE THE DEVICE IS ACTIVATED. THIS MAY CAUSE INJURY.
 - d. Activate the electrosurgical function by depressing the COAG pedal on the footswitch.
 - e. Steam generation from the 4" x 4" (10.6 cm x 10.6 cm) and the coagulating surfaces indicates active power and a complete circuit.
- 4) If there is no steam during the Pre-test:
 - a. Add more saline to the pad.
 - b. Ensure that both coagulating surfaces are in contact with saline-soaked pad.
 - c. Verify that the electrosurgical generator power switch is ON, and in the foot switching mode.
 - d. Verify proper connection of the electrical connector on the Bipolar Scissors to the extension cord, and the extension cord to the generator.
 - e. Check generator function and setting. For power settings, see Table 1 – Generator Settings.
 - f. Turn power up in small increments.
 - g. Decrease the amount of pad surface contacting the coagulating surfaces.
 - h. If steam is still not observed, DO NOT use the device and call Guidant Customer Service.

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

- 5) Ensure power is off and device is closed prior to insertion and withdrawal through cannula. Advance the device through the endoscopic cannula until it exits the cannula and is in view.
- 6) Turn on generator to the recommended starting setting and to the recommended mode listed in Table 1 – Generator Settings. Optimum usage is 25 to 30 watts.

Warning: DO NOT EXCEED 35 WATTS!

Note: If wattage setting is too high, tissue may dry out rapidly causing sticking and hemostasis may be compromised.

- 7) Ensure tips are fully closed when inserting into and removing from appropriate cannula. If desired, Surgilube (or another water-soluble lubricant) may be used on the scissor shaft.
- 8) For flexible scissors, hold the scissors shaft approximately 6" (or 15 cm) from the tips while inserting into the endoscopic cannula handle.
- 9) Position the device as desired for cutting.

Note: Scissors may not open until extended to an adequate length.

Note: Scissor tips should be in view when cutting or coagulating, per standard endoscopic technique.

- 10) Activate the electrosurgical unit via the footswitch, while slowly cutting with scissors. Coagulating effect will occur between blades as tissue is cut. The slower the cut the more coagulation is effected. To use as a spot coagulator, close the blades and contact tissue with blade tips or blade edges if a larger coagulation area is desired. Both exterior blade surfaces should be in equal contact with tissue for optimum coagulation.

Warning: Flexible scissors may not cut effectively if shaft is flexed excessively (approximately 45°).

- 11) To clean the coagulating surfaces, use a 4" x 4" (10.6 cm x 10.6 cm) gauze pad soaked with saline solution to remove the debris. For optimum performance; keep blade surface free of debris.

6.3 Generator Settings for the VasoView™ Flexible Endoscopic Bipolar Scissors

NOTE: The Wolf generators is are compatible with Guidant connector cable #01837. All other generators listed are compatible with Guidant connector cable #01838.

Table 1. Generator Settings

| Generator | Model | Mode | Setting Range |
|------------------|----------------|-------------------------|----------------------|
| ValleyLab | Force 2 | Bipolar | 25-35 watts |
| ValleyLab | Force 4 | MicroBipolar Precise | 25-35 watts |
| ValleyLab | Force 30 | Bipolar | 25-35 watts |
| ValleyLab | Force 40 | Bipolar | 25-35 watts |
| ValleyLab | SSE2L | Bipolar Coag | 5-6 |
| ValleyLab | Force 4B | Precise Bipolar | 25-35 watts |
| Valley Lab | Force FX | Standard | 25-35 watts |
| Conmed | Excalibur | Bipolar Coag | 25-35 watts |
| Conmed | Excalibur Plus | Bipolar Coag | 25-35 watts |
| Conmed | Bistat | General | 25-35 watts |
| Conmed | Sabre 180 | Bipolar Coag | 25-35 watts |
| Conmed | Sabre 2400 | Bipolar Coag | 25-35 watts |
| Davol (Bard) | 5000 | Bipolar Cut Cut | 25-35 watts |
| Wolf | 2075 U | Bipolar— — — | 4-5 |
| Wolf | 2085 | Bipolar— — — | 4-5 |
| Wolf | 2352 | Bipolar— — — | 25-35 watts |
| Erbe | ICC 350 | Auto Bipolar | 25-35 watts |
| Ethicon | Pegasys | Bipolar | 25-35 watts |

WARNING: DO NOT EXCEED 35 WATTS IN ANY GENERATOR SETTING!

CAUTION: This device should not be used with generators that have bipolar outputs greater than 1000 volts max (peak to peak).

NOTE: If you have an unlisted generator, please call Customer Service.

6.4 VasoView™ Short Port Blunt Tip Trocar (BTT)

The following instructions are recommended for proper use of the Short Port Blunt Tip Trocar (BTT). They are not a reference to endoscopic surgery techniques.

- 1) Prepare the patient in accordance with standard surgical techniques.
- 2) Using an open technique make an initial cutdown and identify the structure of interest. Insert the Dissection Cannula through the BTT Port. If a Conical Dissection Cannula is used, replace the main seal with the alternate seal (marked "CDC") prior to insertion. Then grasp the Dissection Cannula handle and place the tip of the cannula into the subcutaneous space.
- 3) Advance the cannula toward the target tissue, keeping the tip in contact with the anterior surface during the dissection process. Advance the cannula for approximately 4 cm, then slide the BTT Port 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 insufflation port and infuse CO₂ gas at a low rate of 3-5 L/min to a pressure of 10-12 mmHg. Gas insufflation holds the dissected tunnel open for improved visualization.
- 4) Once the space is created, remove the cannula from the BTT Port. If present, remove the CDC seal from the port and replace with the main seal. The VasoView™ Uniport™ Plus Dissection Cannula may be used to complete the isolation of the vessel.

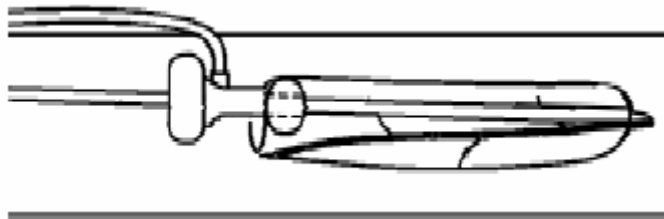


Figure 7

- 5) Upon completion of the endoscopic procedure, the working space may be quickly deflated by removing the instrument from the BTT Port.
- 6) To remove the BTT Port, 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 BTT Port.

6.5 Radial Artery Harvesting Feasibility Study Results

Objective: To evaluate the safety of the VasoView™ 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, perioperatively, 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 1 below.






Table 2. Radial Artery Harvesting Feasibility Study Results

| Category Result | (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 | |

7.0 WARRANTY

GUIDANT CORPORATION (GUIDANT) warrants that reasonable care has been used in the design and manufacture of this instrument. **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 instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond GUIDANT's control directly affect the instrument and the results obtained from its use. GUIDANT's obligation under this warranty is limited to the repair or replacement of this instrument and GUIDANT shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. GUIDANT neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **GUIDANT 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.**

8.0 GRAPHICAL SYMBOL DEFINITIONS

| | |
|---|---|
| REF Model Number: |  Contents (Numeral represents quantity of units inside) |
| LOT Lot Number: |  Read instructions WWW.GUIDANT.COM/IFU U.S. Only |
|  Use By: | |
| STERILE R Sterilization by irradiation |  Federal Law (USA) restricts this device to sale by or on the order of a physician. |
|  Do Not Reuse | |

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The VasoView™ Flexible Endoscopic Bipolar Scissors are manufactured for Guidant.

Guidant Corporation, Cardiac Surgery

170 Baytech Drive

San Jose, CA. 95134 USA

US Toll-free Tel: (888) 880-2874 Tel: (408) 635-6800

US Toll-free Fax: (888) 899-2874 Fax: (408) 635-6801

<http://www.guidant.com/>

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