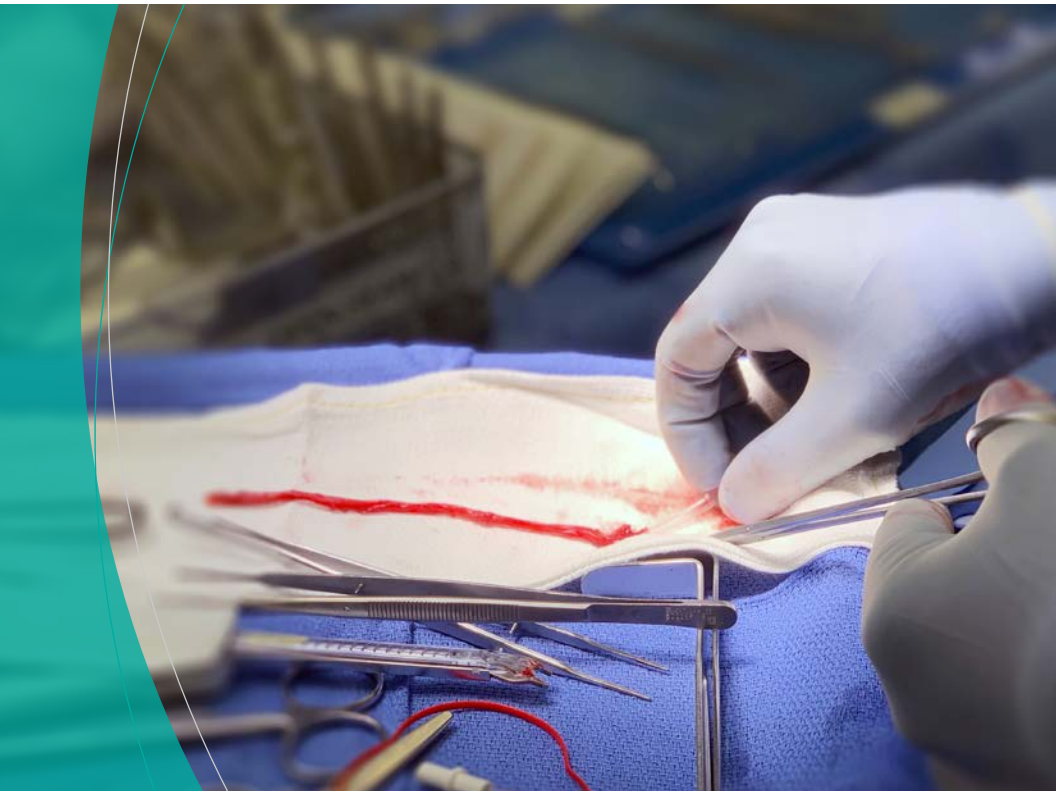
Clinician Training Workbook

VirtuoSaph® Plus Endoscopic Vessel Harvesting System

Endoscopic Radial Artery Harvesting



Technology inspired for life.™

TERUMO CARDIOVASCULAR

Learning Objectives

This manual is a comprehensive training tool designed to prepare you to better understand the endoscopic radial artery harvesting (ERAH) procedure and the VirtuoSaph® Plus Endoscopic Vessel Harvesting System. Upon completion of training, you will have successfully completed the following objectives and be able to understand or identify:

- Product features, benefits and functions
- Key anatomical landmarks of the arm
- Basic instrumentation
- ERAH procedure
- The procedure steps for the Terumo Technique

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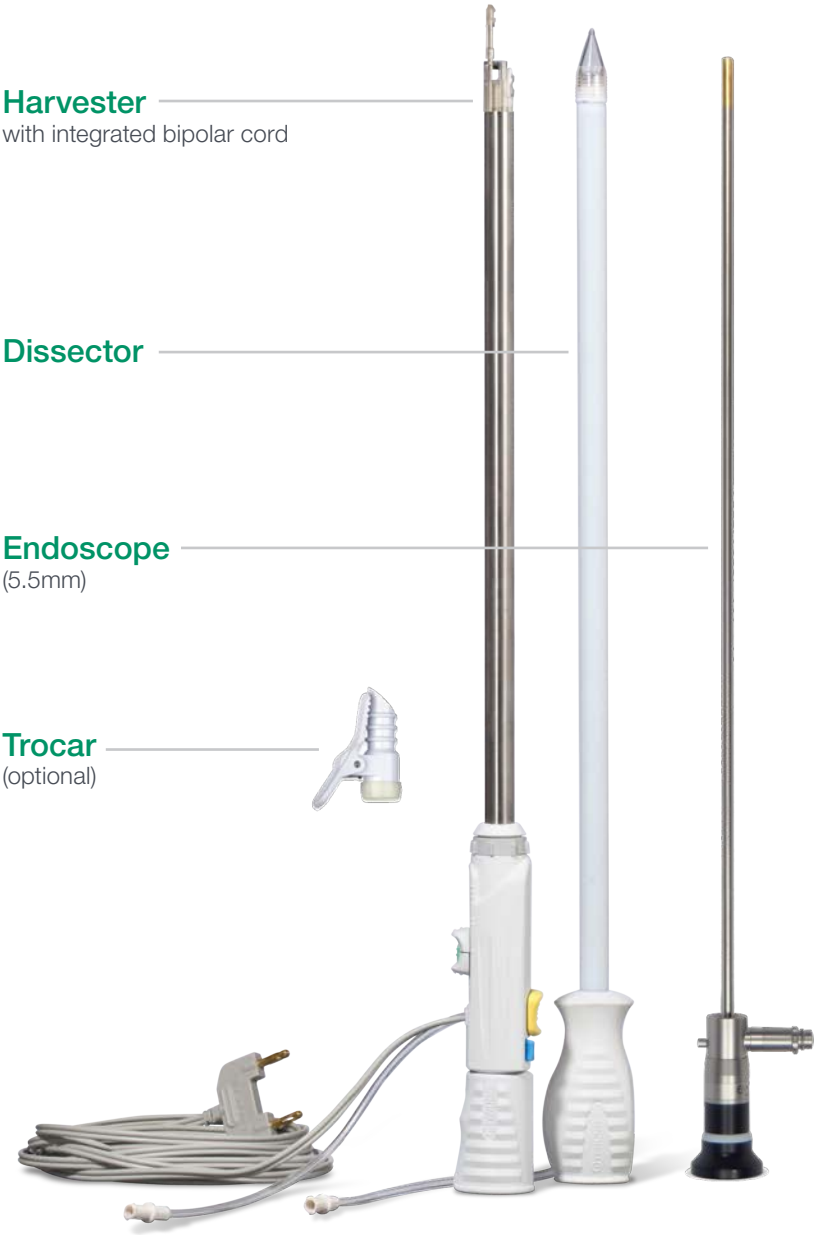
Overview

VirtuoSaph Plus Endoscopic Vessel Harvesting System



Key Benefits

VirtuoSaph Plus delivers consistent, successful vessel harvesting of both saphenous vein and radial artery for coronary and peripheral artery bypass grafting.

Designed for Efficiency

Engineered with a keen understanding of optimal functionality and everyday ease-of-use

- Patented PTFE-sheathed dissector has low coefficient of friction to reduce resistance and ease of dissection
- Unique wiper mechanism quickly clears and cleans the endoscope lens to improve procedural visibility without adding fluid in the cavity
- Integrated spot cautery with built-in safety switch activates in one simple step to control hemostasis when needed
- Less cumbersome design reduces the number of components, connections and procedural steps to improve efficiency in the OR
- Terumo Method is a two-pass dissection and one-pass harvesting technique specifically designed to minimize vessel manipulation and improve ergonomics

Designed for Patient Safety

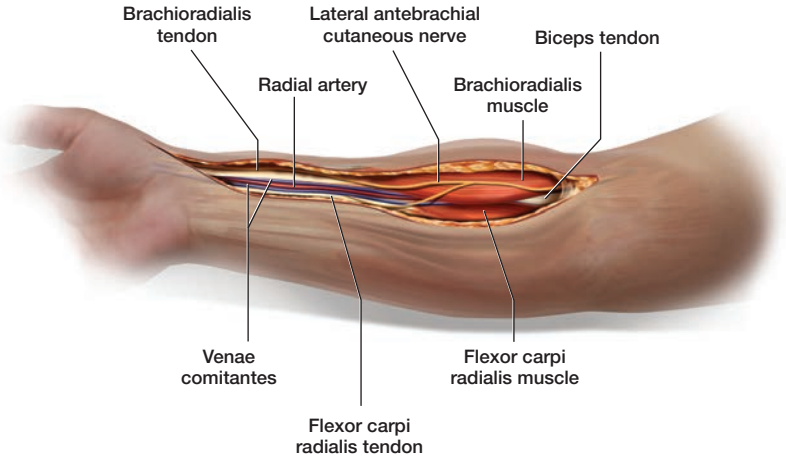
Open CO_2 system with distal insufflation reduces risk of CO_2 embolism and intraluminal thrombus

- Use of open CO_2 insufflation can lead to dramatic reductions in retained clots. Research has shown the frequent presence of intraluminal clots in vessels harvested endoscopically using a “closed” EVH system.[1-3] Two studies showed that CO_2 embolisms are noted about 4% to 17% of the time when using “closed” systems.[4]
- Distal insufflation minimizes the amount of CO_2 needed for tunnel maintenance and helps deliver a conduit that retains its native moisture

Anatomy

Key Anatomical Landmarks: *Two Muscles, Two Nerves, Two Branches*

- Two key muscles
  - Brachioradialis muscle
  - Flexor carpi radialis muscle
- Two key nerves run along the pedicle and are most prone to injury during ERAH. Knowledge of these will minimize risk of injury.
  - Superficial radial nerve
  - Lateral antebrachial cutaneous nerve
- Two key branches define proximal and distal limits of the radial artery harvest
  - Recurrent radial artery (proximal limit)
  - Superficial palmer artery (distal limit)
- The radial artery is bordered by two veins, venae comitantes
  - Constitutes the pedicle



Procedure Overview

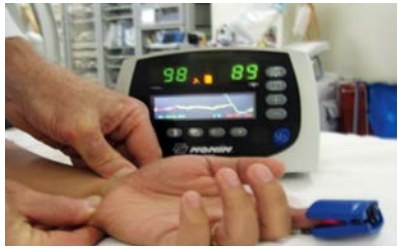
Pre-Op Supply List

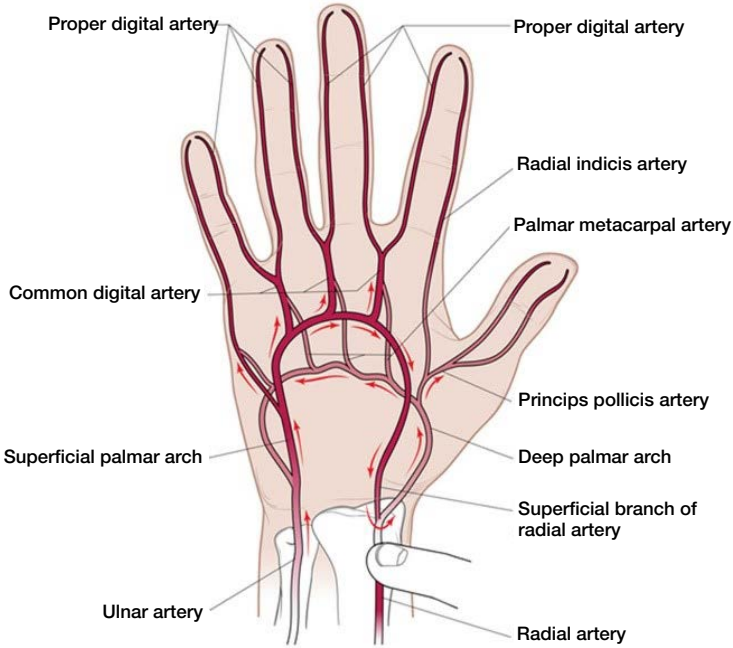
The following is a list of commonly used instruments for the procedure:

- Assorted forceps
- Metzenbaum scissors
- Two to three hemostats
- Tonsil or longer hemostat for stab and grab
- Small Weitlaner retractor
- Army navy retractor
- #3 knife handle with 10- and 11- blades
- Clip appliers per hospital protocol
- Three to four towel clips to secure arm to arm board
- Bovie
- Surgical skin marker
- Disposable pulse oximeter
- Syringe with vessel canulae for radial preparation.
- Tourniquet with cuff. Sterile or unsterile with Webril or stockinette padding. (Size 18 cuff most common.)
- Arm board (positioned at no more than 90 degrees to the operative table)
- Esmark bandage per hospital protocol
- Papaverine solution or hospital equivalent
- Rolled towels to hyper flex the wrist
- Proper draping material per hospital protocol
- Mammary bulldog for Allen's test
- Doppler
- Suture and/or ties to tie off radial stumps
- Wound dressings per hospital protocol
- Irrigation solution
- Terumo VirtuoSaph Plus (VSP) kit
- Terumo Endoscope
- VSP validated generator, foot pedal
- CO_2 tubing
- CPU and camera head cable
- Light source and light cable

Pre-Op Assessment Options

- Non-dominant arm is commonly selected
- Confirm diameter of radial is adequate for bypass; < 2 mm commonly avoided due to vasospasm concern
- Duplex examination and oximetry studies
  - Modified Allen's Test
  - Barbeau Test
  - Ultrasound assessment of ulnar flow and flow in deep palmer arch following occlusion of radial artery

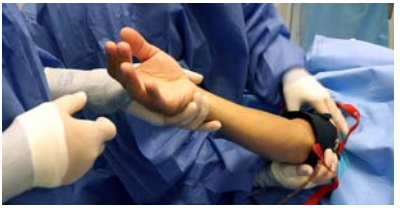


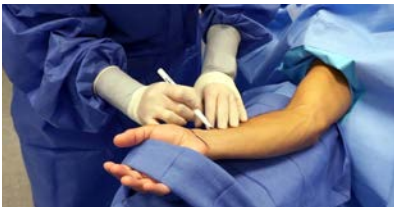


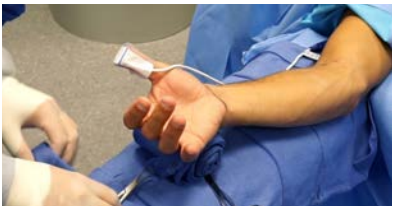
Arm Preparation

Place Tourniquet and Identify Landmarks

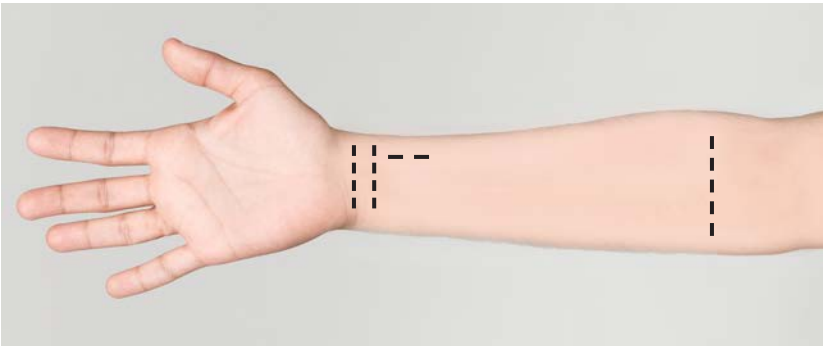
- Place Webril on upper arm followed by appropriately sized tourniquet
- Mark landmarks on arm: Major wrist crease, radial impulse/incision, antecubital fossa (two fingers breadth distal to crease)
- Prep arm circumferentially up to tourniquet
- Drape arm per hospital protocol
- Sterile skin marker to mark the incision site just above the radial styloid
- Recommend placing a sterile disposable pulse oximeter on the thumb







Mark landmarks on the arm

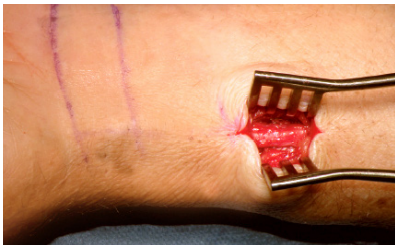


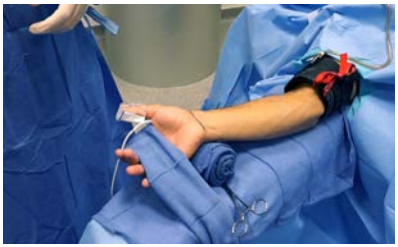
Mark the arm at the major wrist crease, radial impulse/incision, and antecubital fossa (two fingers breadth distal to crease).

Arm Preparation *continued*

Incision, Inflating Tourniquet, and Positioning Arm

- Make a 2 cm incision at pre-marked site
- Locate radial artery and venae comitantes under direct vision
- Occlude the radial artery, watching for changes in O_2 saturation with release of radial artery
- If O_2 saturations drop and do not return to baseline, the radial is considered not harvestable
- Raise the arm and use an Esmark bandage, starting at the fingertips, wrapping tightly all the way to the tourniquet. This creates a bloodless field.
- Inflate the tourniquet per hospital protocol (commonly 250 mmhg). Start and stop times of tourniquet inflation should be recorded. It is recommended to keep duration < 60 minutes.
- Once tourniquet is inflated, remove Esmark bandage and position arm for the procedure
- Place rolled sterile towels under the wrist. Place a towel over the fingers and secure to arm board with non-penetrating towel clips.

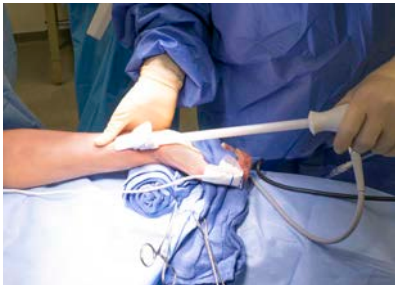


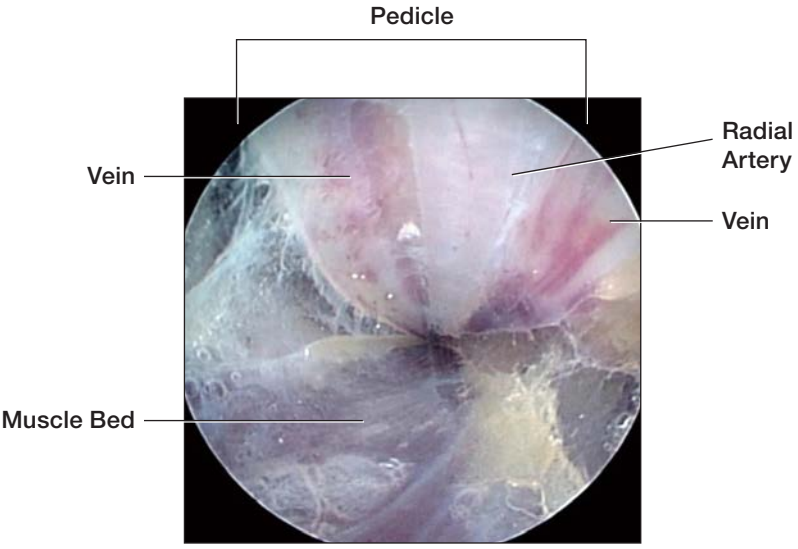


Dissection

Dissector

- Load dissector onto Terumo endoscope and ensure camera, light cord, and gas insufflation are connected
- Locate venae comitantes on both sides of the radial artery which constitute the pedicle
- With the radial artery pedicle in view, carefully insert your dissector to create a tunnel (trocar is optional)
- Dissect lateral and medial along venae comitantes. Clear tissue around branches to free radial pedicle circumferentially. Minimize contact with radial artery to reduce spasm or injury.
- Use caution as you arrive at the venous plexus of the antecubital fossa. Do not push dissector into the fat pad, bleeding could occur.
- Once dissection is complete, remove dissector and insert trocar (if not previously inserted)





Harvesting

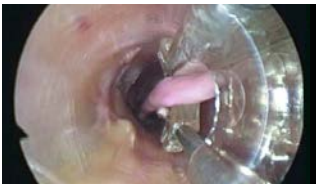
Fasciotomy* and Capture of Radial Artery Pedicle

**Fasciotomy is recommended to help avoid compartment syndrome post-operatively, to create a working tunnel, and to reduce direct pressure on the radial artery.*

- Load harvester onto Terumo endoscope and ensure camera, light cord, and gas insufflation are connected
- Verify foot pedal and harvester are connected to a validated generator
- Insert the harvester, taking note to position the V-Keeper for easy entry into the tunnel

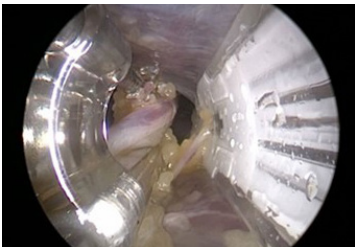
- Pause briefly upon entry to allow the tunnel to insufflate
- Activate the V-Cutter to separate fascia while traveling down the tunnel. Avoid arterial branches. It is common to separate fascia at least two thirds the length of the arm.

- Following fasciotomy, advance harvester to the tunnel end
- Rotate the open harvester to capture the entire pedicle (include radial artery and the venae comitantes) within the V-Keeper



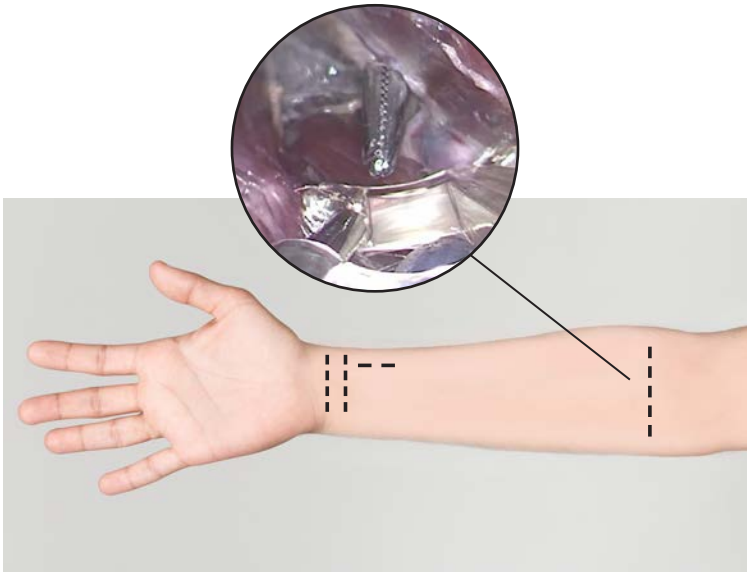
Dividing Branches

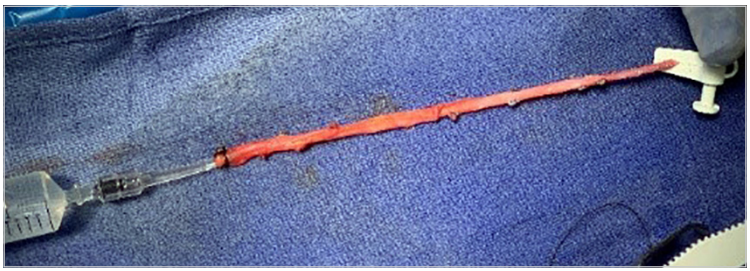
- Gently withdraw the harvester, while dividing branches toward the incision. Avoid avulsing branches.
- Follow Terumo Technique for each branch division. Be sure to ground device against tunnel wall.
- Once single-pass harvest is complete, return to the end of the tunnel



Retrieving the Radial Artery

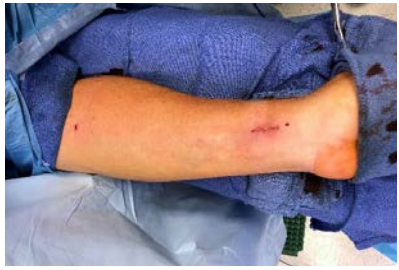
- Make a stab wound near the antecubital fossa (two fingers breadth distal to crease) *shown below*
- Insert a hemostat and elevate the radial artery pedicle through the incision. Grasp the entire radial pedicle to prevent damage to the conduit.
- Cut the radial artery pedicle and ligate the proximal stump. Drop radial artery pedicle back into the tunnel.
- Withdraw radial artery pedicle from wrist incision and ligate the distal stump
- Cannulate and flush radial artery per hospital protocol





Hemostasis and Closure

- Reintroduce harvester to the end of the tunnel
- Release tourniquet and confirm stump is secure
- Withdraw scope, examining tunnel for any bleeding as arm reperfuses. Use spot cautery as needed.
- Once hemostasis is confirmed, disconnect or remove tourniquet per hospital protocol. Note tourniquet time.
- Close incision per hospital protocol and apply sterile dressings as appropriate



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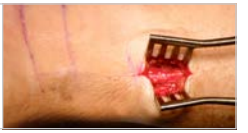
Procedure at a Glance

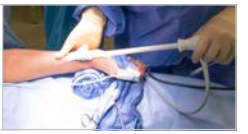
1 **Pre-operative**: Assess arm. Place tourniquet. Prepare arm.

2 **Incision**: Proximal to wrist crease. Confirm collateral flow.



3 **Exsanguinate**: Inflate tourniquet.

4 **Dissect**: Medial and lateral dissection with CO_2 insufflation. Maintain sight of venae comitantes.



5 **Fasciotomy**: Activate V-Cutter to release fascia in 2/3 of lower arm.

6 **Harvest**: Capture pedicle. Carefully separate branches in single pass.

7 **Separation**: Stab and grab pedicle. Ligate stump at both ends.

8 **Conclusion**: Deflate tourniquet. Verify hemostasis. Prepare and close per hospital protocol. Remove tourniquet.

9 **Conduit is ready for handoff.**

FOOTNOTES

1. Brown et al. Strategies to reduce intraluminal clot formation in endoscopically harvested saphenous veins. *J Thorac Cardiovasc Surg* 2007;134:1259-1265.
2. Burris et al. Incidence of residual clot strands in saphenous vein grafts after endoscopic harvest. Innovations: *Technology & Techniques in Cardiothorac & Vasc Surg* 2006;1(6):323-327.
3. Burris et al. Catheter-based infrared light scanner as a tool to assess conduit quality in coronary artery bypass surgery. J Thorac Cardiovasc Surg 2007;133:419-42. 4 Chiu et al. Reduction of carbon dioxide embolism for endoscopic saphenous vein harvesting. *Ann Thorac Surg* 2006;81:1697-1699.
4. Lin et al. Carbon dioxide embolism during endoscopic saphenous vein harvesting in coronary artery bypass surgery. *J Thorac Cardiovasc Surg* 2003;126:2011-2015.

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