HeRO® GRAFT

SUPER HeRO® HeRO® ALLY

INSTRUCTIONS FOR USE

MERIT MEDICAL®

ENGLISH

INSTRUCTIONS FOR USE

℞ ONLY **Federal (USA) law restricts this device to sale by or on the order of a physician.**
Only qualified healthcare providers should place, manipulate, declot, revise or explant the device.

Carefully read all instructions prior to use.

Adhere to universal precautions when inserting, maintaining or explanting the device.

Not made with natural rubber latex.

STERILE (EO) – FOR SINGLE USE ONLY

Each component of the HeRO® Graft is provided double pouched with an outer sterile barrier and is EO sterilized.

STORAGE

To provide maximum protection, store the HeRO Graft components in their original, unopened packages at room temperature. Keep dry and out of direct sunlight. Each component must be used before the use by date printed on the individual labels.

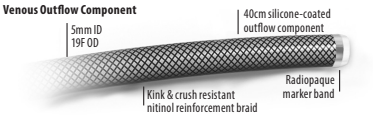
	Caution	MR	MR Conditional
	Use-By Date		Non-Pyrogenic
	Single Use	STERILIZE	Do Not Resterilize
STERILE EO	Sterilized Using Ethylene Oxide		Manufacturer
REF	Catalogue Number		Keep Dry
LOT	Batch Code		Keep Away from Sunlight
	Date of Manufacture: YYYY-MM-DD		Do Not Use if Package is Damaged and Consult Instructions for Use
	Single sterile barrier system with protective packaging inside		Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within seven calendar days, call U.S.A. or EU Customer Service.
UDI	Unique Device Identifier	MD	Medical Device

DEVICE DESCRIPTION

The HeRO (**He**modialysis **R**eliable **O**utflow) Graft is a long-term access solution for access-challenged and catheter-dependent patients. HeRO Graft is a fully subcutaneous surgical implant. It provides arterial venous (AV) access with continuous outflow into the central venous system. The HeRO Graft traverses central venous stenosis allowing for long-term hemodialysis access.

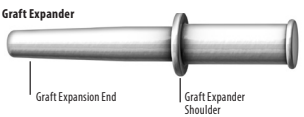
HeRO Graft consists of a proprietary **Venous Outflow Component** and the **Adapter**:

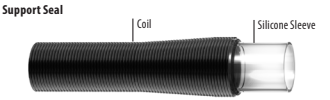
The **Venous Outflow Component** (may be included) has a 5mm inner diameter (ID), 19F outer diameter (OD), and is 40cm long. It consists of radiopaque silicone with braided nitinol reinforcement (for kink and crush resistance) and a radiopaque marker band at the tip. A 10 French Delivery Stylet is packaged with the Venous Outflow Component to aid in placement of the device.



The **Adapter** connects a 6mm ID vascular graft (not included in Merit packaging) to the **Venous Outflow Component**. The **Adapter** (titanium alloy) has a tapered ID (6mm to 5mm) to provide a smooth transition from a 6mm ID vascular graft to the 5mm ID **Venous Outflow Component**. A disposable **Graft Expander** is provided to aid in connecting a 6mm ID vascular graft to the **Adapter** . The **Support Seal** is only required for select grafts to provide seal reinforcement and kink resistance near the **Adapter** . See **ASSEMBLING THE ADAPTER** section or the **Graft Reference Card** for more details on grafts that require the **Support Seal**.

NOTE: To determine when the *Support Seal* is required, refer to Tables 1 and 2 in the ASSEMBLING THE ADAPTER section of the document as well as on the *Adapter* packaging.





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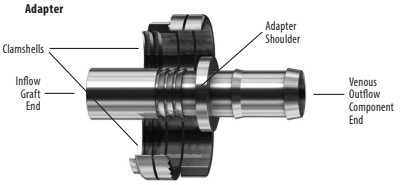


NOTE: The clamshells are always on the inflow graft end of the *Adapter*.
Option A or B:

A: The **Adapter** (with the **Support Seal**)

B: The **Adapter** (without the **Support Seal**)

The **Accessory Component Kit** provides instruments and accessories that may aid in the placement of the HeRO Graft.

The FDA classification name for the HeRO Graft is vascular graft prosthesis.

INTENDED USE/INTENDED PURPOSE

The HeRO Graft is intended for use in maintaining long-term vascular access for chronic hemodialysis patients who have exhausted peripheral venous access sites suitable for fistulas or grafts.

INDICATIONS FOR USE

The HeRO Graft is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the KDOQI guidelines as patients who:

- Have become catheter-dependent or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts).
- Are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or venography.
- Are failing fistulas or grafts due to poor venous outflow as determined by access failure or venography (e.g., fistula/graft salvage).
- Have poor remaining venous access sites for creation of a fistula or graft as determined by ultrasound or venography.
- Have a compromised central venous system or central venous stenosis (CVS) as determined by a history of previous access failures, symptomatic CVS (i.e., via arm, neck, or face swelling), or venography.
- Are receiving inadequate dialysis clearance (i.e., low Kt/V) via catheters. KDOQI guidelines recommend a minimum Kt/V of 1.4.

CONTRAINDICATIONS

Implantation of the HeRO Graft is contraindicated if:

- **The brachial or target artery inner diameter (ID) is less than 3mm.**
- **The internal jugular vein (IJV) or target vasculature cannot be dilated to accommodate the 19F HeRO Graft *Venous Outflow Component*.**
- **There is significant arterial occlusive disease that would preclude safe placement of an upper extremity hemodialysis access.**
- **There is known or suspected allergy to device materials (e.g., ePTFE, silicone, titanium alloys, nickel).**
- **The patient has a topical or subcutaneous infection associated with the implantation site.**
- **The patient has known or suspected systemic infection, bacteremia or septicemia.**

CLINICAL BENEFITS

The intended clinical benefit of the HeRO Graft System is to provide long-term vascular access (i.e., secondary patency) in end-stage renal disease patients on hemodialysis who have exhausted all other access options and are considered catheter dependent.

KEY PERFORMANCE CHARACTERISTICS

- Device allows for efficient dialysis
- Enables AV access in patients with central venous stenosis
- Amenable with complete or partial removal or revision
- Device and accessories are compatible with standard imaging modalities
- A summary of the endpoint and performance data from the U.S. Multi-center pivotal clinical trials is summarized in Table 3 - the performance data from the Clinical trials

GENERAL WARNINGS

- **REUSE PRECAUTION STATEMENT**
  For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- **Use of the HeRO Graft was clinically studied in the IJV. Implantation of the device in other vasculature has NOT been studied and may increase the risk of adverse events not encountered in the clinical trial.**
- **DO NOT use product if package has been damaged, opened, or the use by date has passed, as sterility may be compromised.**
- **The HeRO Graft is a single use only product. DO NOT resterilize or reuse any component.**
- **Vectra® grafts should NOT be used with the *Adapter*.**
- **Grafts containing reinforcement structures in the region that will interface with the *Adapter* should NOT be used.**
- **Grafts containing a coating/bonding (e.g., heparin, gels, carbon, etc.) on the inner and/or outer surfaces (with the exception of the GORE® ACUSEAL and GORE® PROPATEN® catalogue numbers listed in Tables 1 and 2) have not been tested in conjunction with the *Adapter* and should NOT be used.**
- **Grafts containing tissue have not been tested in conjunction with the *Adapter* and should NOT be used.**
- **Only grafts indicated for AV access should be used with the *Adapter*.**
- **The *Adapter* should only be used with the grafts listed in Tables 1 and 2. Use of other grafts not listed in Tables 1 or 2 may result in device failure and patient injury due to inadequate sealing or graft disconnection.**

- **In revision cases, previously implanted grafts should not be used with the *Adapter*. Only a new graft listed in Tables 1 and 2 should be attached to the *Adapter* as described under the ASSEMBLING THE ADAPTER section.**
- **During the assembly of the *Adapter*, ensure the *Support Seal* (if applicable) and the graft are flush with the shoulder of the *Adapter* prior to engaging the clamshells of the *Adapter*.**

GENERAL CAUTIONS

- **Only qualified healthcare practitioners should place, manipulate, cannulate, declot, revise or explant the device.**
- **The HeRO Graft is intended for use by physicians trained and experienced in endovascular and surgical interventions and techniques.**
- **Adhere to universal precautions when implanting, cannulating, maintaining or explanting the device.**
- **DO NOT place the HeRO Graft in the same vessel as a catheter, defibrillator or pacemaker lead.**
- **To avoid vessel damage, fluoroscopy must be used when inserting the HeRO Graft into the central venous system.**
- **Monitor the patient for signs of arrhythmia throughout the procedure. To minimize the risk of arrhythmia, DO NOT place the tip of the guidewire into the right ventricle.**
- **Caution should be used when placing or removing the *Venous Outflow Component* where stent contact may occur due to the potential for *Venous Outflow Component* or vessel damage.**
- **When connecting the *Venous Outflow Component* to the *Adapter*, verify the *Venous Outflow Component* is flush with the shoulder of the *Adapter*.**
- **The clamshells of the *Adapter* cannot be opened once closed; DO NOT close the *Adapter* clamshells prematurely.**
- **When assembling the *Adapter*, confirm full closure of the clamshells by firmly clamping with a straight serrated vascular clamp (e.g., Kocher).**
- **DO NOT clamp directly on the hinge of the *Adapter* clamshells.**
- **Do not use mechanical/rotational thrombectomy devices (e.g., Arrow-Trerotola PTD®) in the *Venous Outflow Component* and/or the *Adapter* as internal damage may occur to these components.**
- **In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.**

POTENTIAL COMPLICATIONS

The HeRO Graft provides an important means of treating patients requiring hemodialysis; however, the potential exists for serious complications including, but not limited to, the following:

Potential Vascular Graft & Catheter Complications	Potential Intraoperative & Post-Operative Complications
• Abnormal healing / skin erosion	• Allergic reaction
• Anastomosis or wound dehiscence	• Aneurysm
• Device kinking or compression	• Bleeding
• Device migration	• Cardiac arrhythmia
• Ectasia	• Cardiac tamponade
• Edema	• Death
• Foreign body reaction or rejection	• Embolism
• Graft extravasation	• Heart failure
• Bacteremia and non-bacteremic infection	• Hematoma
• Partial stenosis or full occlusion of prosthesis or vasculature	• Hemorrhage
• Prosthesis failure	• Hypotension / hypertension
• Pseudoaneurysm	• Myocardial infarction
• Seroma	• Pneumothorax / hemothorax / hydro-thorax
• Site pain	• Reactions to anesthesia
• Superior Vena Cava Syndrome	• Respiratory / cardiac arrest
• Vascular graft revision / replacement	• Sepsis
• Vascular insufficiency due to steal syndrome	• Trauma to major vasculature or nerves

PROCEDURE ACCESSORIES

In addition to the **Accessory Component Kit**, some vascular access surgical instruments may be required.

Vascular access surgical instruments including, but not limited to, the following:

- 5F micro-puncture set
- Various 0.035" guidewires at least 145cm in length
- Heavy duty scissors
- Heparinized saline
- 4 x 4 sterile gauze pads
- Various subcutaneous tissue & skin sutures
- Radiographic contrast fluid
- Tissue tunneler set with 6mm & 7mm bullet tips
- Various atraumatic vascular clamps
- Standard vessel loops
- Syringe & syringe adapter
- Sterile surgical lubricant
- Access needles
- Straight serrated vascular clamp

PATIENT SELECTION CONSIDERATIONS

The following patient considerations should be evaluated prior to initiating the implant procedure:

1. Ensure proper patient selection via vessel mapping.
   a) If vessel mapping indicates that a viable fistula or graft can be placed, consider these options first.
   b) The target artery must have an ID of at least 3mm to provide adequate arterial inflow to support the graft.
2. Verify the ejection fraction is greater than 20%.
3. Verify the systolic blood pressure is at least 100mmHg.
4. Obtain screening blood cultures to rule out asymptomatic bacteremia prior to HeRO Graft implant for any patient dialyzing on a catheter; treat patient with antibiotics per culture outcome and ensure infection is resolved prior to HeRO Graft implant procedure.
5. Swab the patient's nose prior to HeRO Graft implant for potential methicillin resistant staphylococcus aureus; treat accordingly.

6. As with conventional grafts, HeRO Graft may occlude in patients with:
   - A small brachial artery (i.e., ID less than 3mm)
   - Insufficient arterial inflow or inflow stenosis
   - A history of clotted accesses for unknown reasons
   - A coagulability disorder or medical condition that is associated with clotting (e.g., cancer)
   - Insufficient anticoagulation or non-compliance with anticoagulation medication
   - Systemic low blood pressure or severe hypotension following fluid removal post dialysis
   - A kinked graft
   - Incomplete thrombus removal in previous interventions
   - Intra-graft stenosis at site of multiple punctures
   - An event such as mechanical compression (e.g., spring loaded hemostasis clamps)

Thrombosis is the most common cause of vascular access dysfunction. Missed hemodialysis sessions are more likely to increase the number of thrombosis episodes in AVGs.[1]

HeRO GRAFT IMPLANT PROCEDURE

GAINING VENOUS ACCESS

1. Equip a standard operating room with fluoroscopic and ultrasound guidance and prep the patient according to standard surgical guidelines for a vascular access procedure.
2. Pre-plan the surgical implant using a surgical marker to indicate appropriate incisions and tunneling paths. Draw the HeRO Graft routing path in a soft C configuration on the upper arm.
3. If choosing to use an existing tunneled catheter tract, use standard over-the-wire exchange techniques to remove catheter.
4. Open the **Accessory Component Kit** using aseptic technique and prep the contents for use.

Caution: Use a separate tray for removal of the existing tunneled catheter to aid in sterile preservation. Culture any catheters removed at time of implant.

Caution: Suture the tract closed from the existing catheter to HeRO Graft tract.

Caution: Cover any catheter extensions with antimicrobial incise drape covering to protect the sterile area.

Caution: Plan for increased bacteremia risk after an ipsilateral HeRO Graft placement or with femoral bridging catheters and treat prophylactically with antibiotics knowing patients are at higher infection risk.

Caution: Apply antibiotic ointment to the bridging catheter exit site.

5. Prophylactically treat the patient in the peri-operative period with antibiotics based upon the patient's bacteremia history.
6. Using ultrasound guidance, gain percutaneous access to the venous system using a 5F micropuncture set and standard Seldinger technique.

Caution: Use of the HeRO Graft was clinically studied using the internal jugular vein. Central venous access through any other veins, for example the subclavian vein, has NOT been studied and may increase the risk of adverse events not encountered in the clinical trial. When using the subclavian vein for venous access, consideration should be made to follow these patients with clavicle imaging to monitor the potential of interaction of the clavicle and first rib with the *Venous Outflow Component*.[2]

7. Using fluoroscopic guidance, advance a 0.035" guidewire, at least 145cm in length, to the inferior vena cava (IVC).

Caution: Maintain wire placement throughout the implantation of the *Venous Outflow Component*.

8. If performing venography to diagnose venous anatomy, select an appropriately sized introducer sheath.
9. Create a small incision at the exit site of the guidewire to aid in placement of the introducer sheath.

IMPLANTING THE VENOUS OUTFLOW COMPONENT

1. For patients undergoing general anesthesia, consider Trendelenburg position. Additionally, anesthesia personnel should force a positive breath to reduce the potential for air embolus during implant.

NOTE: For conscious sedation patients, use the Valsalva maneuver to reduce air embolus potential.

2. Based upon venous anatomy, determine if serial dilation is required. If so, use the 12F and 16F dilators from the **Accessory Component Kit** as needed for pre-dilation of the venous tract prior to inserting the 20F introducer.

NOTE: Balloon angioplasty may also be required for severely stenosed anatomy.

NOTE: Do not bend introducer sheath or dilator or use them to bypass stenosis.

3. Insert the short 20F introducer from the **Accessory Component Kit** over the guidewire. The long 20F introducer may be used if needed for atypical accesses.

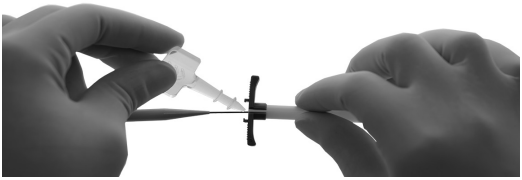
NOTE: Use of the shorter introducer may help prevent kinking since it cannot be advanced as far into the vessel.

4. Advance the dilator and sheath together over the guidewire into the vessel using a twisting motion.

NOTE: Do not insert the sheath/dilator too far. The tabs must extend well outside the body.

5. Using aseptic technique, open the **Venous Outflow Component**.
6. Flush the **Venous Outflow Component** with heparinized saline.
7. Apply sterile surgical lubricant to the 10F delivery stylet and advance through the silicone Luer end of the **Venous Outflow Component**.
8. Attach the Y-adapter onto the Luer end of the 10F delivery stylet and tighten the stopcock, if necessary.

9. Ensure the valve on the stopcock is in the open position and flush with heparinized saline, then close the valve.
10. To ease insertion into the sheath, apply sterile surgical lubricant to the exterior surface of the **Venous Outflow Component.**
11. While stabilizing the guidewire and 20F sheath, begin removing the dilator from the sheath. As soon as the dilator tip has exited the sheath, immediately insert the hemostasis plug by grasping the grip between the thumb and index finger. Firmly insert the hemostasis plug into the sheath alongside the guidewire. Ensure both plug seal rings are fully seated within the sheath. Fully remove the dilator over the guidewire.



12. Insert the **Venous Outflow Component** and delivery stylet assembly over the guidewire and advance up to the 20F sheath.
13. Quickly exchange the hemostasis plug for the **Venous Outflow Component**.

Caution: DO NOT advance the tip of the delivery stylet into the right atrium.

14. Under fluoroscopic guidance, advance the **Venous Outflow Component** to the superior vena cava (SVC) using a twisting motion. Holding the delivery stylet fixed, continue to advance the **Venous Outflow Component** to the mid to upper right atrium.

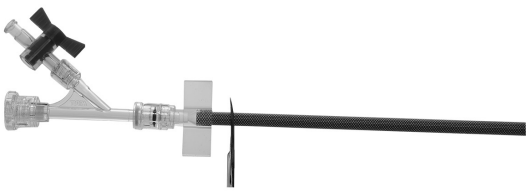
NOTE: If resistance is felt, determine the cause before continuing to advance the **Venous Outflow Component**. Keep the sheath straight to prevent it from kinking. If the sheath is bent, remove it and replace it with a new 20F sheath.

15. Confirm proper **Venous Outflow Component** tip placement in the mid to upper right atrium.
16. Gently pull up while peeling away the 20F sheath. Do not peel the sheath close to the incision site; only peel the sheath as it exits the incision site. Verify that the sheath has been completely removed and that the tip of the **Venous Outflow Component** is in the correct location via fluoroscopy.
17. Remove the guidewire and close the hemostasis valve on the Y-adapter.
18. Begin withdrawal of the 10F delivery stylet while maintaining **Venous Outflow Component** position. Prior to complete removal of the delivery stylet from the Luer, clamp the **Venous Outflow Component** at the incision site.

NOTE: Be careful not to overclamp (i.e., do not advance past the locking tab on the clamp handle).

Caution: To avoid potential damage to the *Venous Outflow Component*, use only the atraumatic clamp provided in the *Accessory Component Kit*.

19. Detach the Y-adapter from the delivery stylet. Open the stopcock and attach the Y-adapter to the silicone Luer on the **Venous Outflow Component**.
20. Attach a syringe to the stopcock and unclamp the **Venous Outflow Component**. Aspirate and close the stopcock. Reclamp the **Venous Outflow Component** and remove the syringe.
21. Attach a syringe with heparinized saline. Open the stopcock, remove the clamp and flush the **Venous Outflow Component.** Reclamp the **Venous Outflow Component** at the incision site and close the stopcock.
22. Return the patient to standard supine position.
23. Make the **Adapter** site incision at the deltopectoral groove (DPG).
24. Holding the **Venous Outflow Component** away from the incision sites, use heavy duty scissors to make a straight cut and remove the silicone Luer. Discard the unused portion.



Caution: Avoid displacing the *Venous Outflow Component* tip during manipulation.

Caution: The cut end of the *Venous Outflow Component* may have sharp edges. Avoid glove contact to prevent puncture.

25. Using a standard Bard® Kelly-Wick tunneler with a 6mm bullet tip, tunnel from the DPG to the venous incision site.
26. Insert the 6mm bullet tip into the end of the **Venous Outflow Component**, pull through the tunnel to the DPG and remove the bullet tip.

Caution: DO NOT bend the *Venous Outflow Component* beyond a 2.5cm diameter anywhere along its length to prevent kinking.

NOTE: Alternatively, a Bard Bi-Directional Tunneler may be used. Consult manufacturer IFUs for proper utilization.

ASSEMBLING THE ADAPTER

ATTENTION: The clamshells cannot be opened once closed; do NOT close the clamshells prematurely.

The **Adapter** has undergone successful in vitro testing with the following vascular grafts in Tables 1 and 2.

Table 1: Marketed 6mm ID Early Cannulation[I] Vascular Grafts (qualified for use with the *Adapter*)

Trade Name	Manufacturer	Catalogue Number[II]	Support Seal Required for HeRO Graft *Adapter*
FLIXENE® Standard Wall	Atrium Medical Corp.	25053 25142 25052	NO
GORE® ACUSEAL	W.L. Gore & Associates	ECH060010A ECH060020A ECH060040A ECH060050A	NO

FLIXENE is a registered trademark of Atrium Medical Corporation.
GORE is a registered trademark of W.L. Gore and Associates.

I. Refer to graft manufacturer Instructions for Use or website for indications and further information; II. Catalogue numbers may contain identifiers that are not reflected on this table. Consult the graft manufacturer's website to determine which equivalent catalog numbers are available in your region.

Table 2: Marketed 6mm ID Standard Wall[I] Vascular Grafts (qualified for use with the *Adapter* and *Support Seal*)

Trade Name	Manufacturer	Catalogue Number[II]	Support Seal Required for HeRO Graft *Adapter*
IMPRA®	C.R. Bard	05S06 | 10S06 | 20S06 | 30S06 | 40S06 | 50S06 60S06 | 70S06 | 80S06 | 90S06	YES
GORE-TEX®	W.L. Gore & Associates	V06010L | V06020L | V06030L | V06040L V06050L | V06070L | V06080L	YES
GORE-TEX® Stretch	W.L. Gore & Associates	S0601 | S0602 | S0603 | S0604 | S0605 S0607 | S0608 | S0609	YES
GORE® PROPATEN®	W.L. Gore & Associates	H060010A | H060040A | H060060A | H060080A	YES

IMPRA is a registered trademark of C.R. BARD, Inc.
GORE-TEX, GORE, and PROPATEN are registered trademarks of W.L. Gore and Associates.

I. Refer to graft manufacturer Instructions for Use or website for indications and further information; II. Catalogue numbers may contain identifiers that are not reflected on this table. Consult the graft manufacturer's website to determine which equivalent catalog numbers are available in your region.

GENERAL WARNINGS:

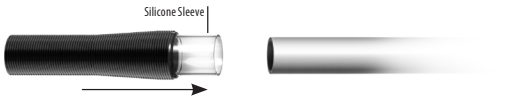
Caution: The *Adapter* should only be used with the grafts listed in Tables 1 and 2. Use of other grafts not listed in Tables 1 or 2 may result in device failure and patient injury due to inadequate sealing or graft disconnection.

Caution: Assembly of the *Adapter, Support Seal* (if applicable) and selected graft from Table 1 and 2 should be done using powder free, clean and dry gloves.

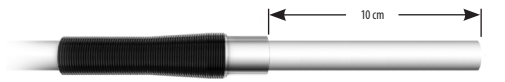
1. Select a new graft from Table 1 or 2.
2. Using aseptic technique, open the **Adapter** package and the selected graft and deliver to the sterile field.
3. Remove all the parts from the **Adapter** pouch insert card.
4. Based on Tables 1 and 2, determine if the graft chosen requires the use of the **Support Seal**. If the graft requires the **Support Seal**, proceed to the next step. If the graft does NOT require the **Support Seal**, proceed to step 7.

NOTE: Assembly of the **Adapter and Support Seal** (if applicable) may be better facilitated by performing the procedure over a flat sterile surface.

5. If using a graft from Table 2, insert the graft into the silicone sleeve end of the **Support Seal**. Some resistance may occur with the silicone sleeve. However, the **Support Seal** should still be advanced onto the graft in these instances.



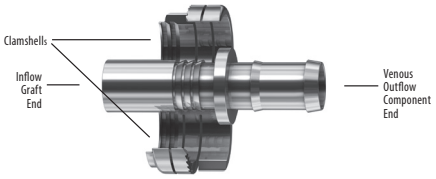
6. Advance the **Support Seal** down the majority of the graft length, stopping approximately 10cm from the end of the graft that will interface with the **Adapter**.



7. Insert the tapered end of the **Graft Expander** into the graft end that will interface with the **Adapter**. Advance the graft as much as possible up to the **Graft Expander** shoulder. Leave the **Graft Expander** in the end of the graft and prepare the **Adapter** for assembly.

NOTE: Inadequate expansion of the graft may make assembly of the graft and the **Adapter** more difficult. A back and forth twisting motion may help to advance the graft.

8. Ensure the clamshells are open and centered around the base of the **Adapter**.



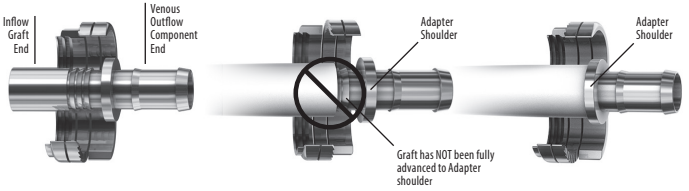
9. Grasp the graft near the shoulder of the **Graft Expander** and remove the **Graft Expander** from the graft.

10. Slide the expanded end of the graft onto the inflow end of the **Adapter** and advance the graft to the shoulder of the **Adapter**.

NOTES: If removal of the graft is difficult, it may help to gently pull the graft near the end of the **Graft Expander**.

Expansion can be repeated as needed using the **Graft Expander**.

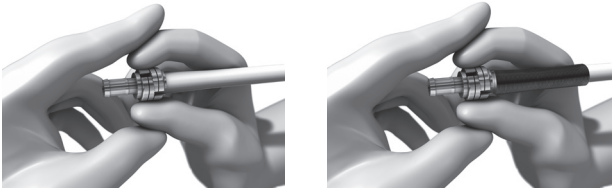
ATTENTION: The clamshells cannot be opened once closed; do NOT close the clamshells prematurely.



11. If using the **Support Seal**, advance the silicone sleeve of the **Support Seal** up to the **Adapter** shoulder ensuring it is flush with both the graft and the shoulder of the **Adapter**.

NOTE: Prior to closing the clamshells, verify that both the graft and the **Support Seal** (if applicable) are fully advanced to the shoulder of the **Adapter** and that no portion of the **Support Seal** coil is under the clamshells.

12. Pinch the clamshells of the **Adapter** between the thumb and index fingers of both hands as tightly as possible.



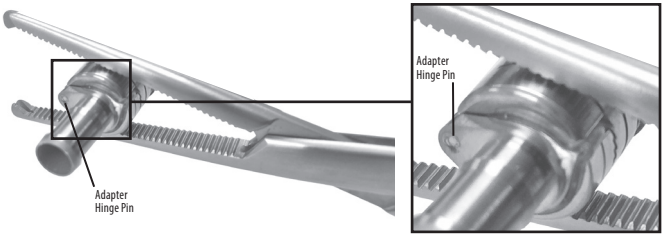
13. To ensure complete closure of the **Adapter** clamshells, firmly clamp with a straight serrated vascular clamp (see image below).

NOTE: Ensure the hinge of the clamshells is facing away from the hinge of the straight serrated vascular clamp (see image below).

Caution: Do NOT lock the straight serrated vascular clamp on the *Adapter*.

Caution: The *Adapter* should be placed at the center of the serrated jaws to avoid accidental locking of the clamps.

Caution: Do not clamp directly on the hinge of the *Adapter* clamshells.



WARNING: There is a risk of device failure if the clamshells are not fully closed. Be sure to deliberately clamp the clamshells tightly to ensure full closure.

14. The **Adapter** with graft assembly is now ready for implant.

IMPLANTING THE GRAFT

1. Make an incision at the selected arterial anastomosis site. Using a standard vessel loop, expose the artery and verify the ID is greater than 3mm in size. Verify patency via Doppler or tactile feel.

Caution: Use of the HeRO Graft was clinically studied using the brachial artery. Arterial implantation of the device to other arteries has NOT been studied and may increase the risk of adverse events not encountered in the clinical trial. However, identification of an alternative artery with an ID of 3mm or greater may result in improved blood flow compared to a brachial artery with an ID of less than 3mm.

2. For grafts that are used with the **Adapter** and **Support Seal** (if applicable), consult the manufacturer Instructions for Use for proper tunneling and implantation.

3. Leave approximately 8cm of the graft exposed at the DPG incision site to facilitate the connection from the graft to the **Venous Outflow Component**.

4. Cut the graft from the tunneler and use a standard vascular clamp to occlude the graft at the anastomosis site.

CONNECTING THE HeRO GRAFT

1. Place a sterile 4x4 gauze pad between the **Venous Outflow Component** and the DPG incision site to prevent debris from contaminating the incision.

2. Determine the **Venous Outflow Component** length required to make the connection to the graft at the final DPG location. Make a straight cut using heavy duty scissors.

Caution: DO NOT test fit the *Venous Outflow Component* onto the *Adapter's* Venous Outflow Component end as it was designed not to separate once connected.

3. Hold the **Venous Outflow Component** 2cm from the cut end and advance it over both barbs and up to the **Adapter** shoulder.

NOTE: Avoid kinking or compressing the coil portion of the **Support Seal** during connection.

Caution: The HeRO Graft *Venous Outflow Component* was designed to engage both barbs of the connector tightly so that the pieces do not separate. If separation is necessary, a new straight cut should be made to the *Venous Outflow Component* near the *Adapter.* Special care should be taken when trimming and removing the excess *Venous Outflow Component* piece from the *Adapter.* Clean the *Adapter* of any material or residue. If damage occurs to the *Adapter* during separation, a new device should be used. Use fluoroscopy to recheck radiopaque tip placement after any adjustment is made.

Caution: DO NOT grasp, peel, or otherwise damage the *Support Seal* as this may adversely impact the integrity of the graft. It is important during device connection to avoid contact with the *Support Seal*. Ensure the *Support Seal* is not crushed or damaged.

Caution: If damage to the *Support Seal* is noted during implant, new components should be used.

Caution: A damaged *Support Seal* may lead to flow disruption within the HeRO Graft, and may contribute to early device occlusion and/or repeated occlusion.

4. Verify the **Venous Outflow Component** is fully advanced onto the **Adapter** and flush with the **Adapter** shoulder.

5. After the connection is made, verify radiopaque tip placement in the mid to upper right atrium using fluoroscopy.

6. Carefully position the **Adapter** in the soft tissue at the DPG. Reposition the graft from the arterial end to remove excess material.

7. Remove the clamps at the **Venous Outflow Component** and arterial anastomosis sites to backbleed the entire HeRO Graft.

8. Reclamp the graft while avoiding the **Support Seal**.

9. Attach a syringe with heparinized saline to the graft using a syringe adapter. Remove the clamp and flush the entire HeRO Graft. Verify there is no leakage at the connection sites and reclamp the graft.

Caution: If leakage is observed, check for proper connection. If there is a leak at the *Adapter* site, attempt to further tighten the clamshells and verify the *Venous Outflow Component* was connected appropriately (See: CONNECTING THE HeRO GRAFT and ASSEMBLING THE ADAPTER sections). If a leak persists after following the previously stated troubleshooting steps, consider one of the following two options to implant the HeRO Graft.

OPTION 1: Remove and Replace *Adapter* and *Support Seal* (if applicable)

1. Using scissors, make a straight cut to the graft close to the inflow graft end of the **Adapter** (Fig. 1 and 2) or the **Support Seal** coil (if applicable, Fig. 3 and 4).

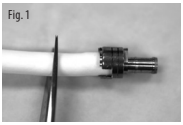
Fig. 1


Fig. 2


Fig. 3


Fig. 4


2. Using heavy duty scissors, make a straight cut to the **Venous Outflow Component** near the Venous Outflow Component end of the **Adapter** (Fig. 5 and 6) or **Adapter** with **Support Seal** (if applicable, Fig. 7 and 8).

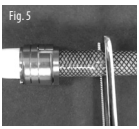
Fig. 5


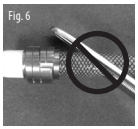
Fig. 6


Fig. 7


Fig. 8


3. Remove the **Adapter**, **Support Seal** (if applicable) and the cut portions of the graft and **Venous Outflow Component** (that are attached to the **Adapter**). Contact Customer Service at 1-800-356-3748 for returning the removed product.
4. Deliver a new **Adapter**, **Support Seal** (if applicable) and **Graft Expander** to the sterile field using aseptic technique.
5. Attach the new **Adapter** and **Support Seal** (if applicable) to the implanted graft at the DPG site by following the **ASSEMBLING THE ADAPTER** section.
6. Attach the **Venous Outflow Component** to the **Adapter** by following the **CONNECTING THE HeRO GRAFT** section.
7. Using fluoroscopy, reposition the assembled **Adapter** (as necessary) and verify that the radiopaque tip of the **Venous Outflow Component** is positioned in the mid to upper right atrium.
8. Proceed to the **GRAFT AND ARTERY CONNECTION** section.

OPTION 2: Remove the *Adapter, Support Seal* (if applicable) and Graft and Replace with HeRO Graft *Arterial Graft Component*

1. Using heavy duty scissors, make a straight cut to the **Venous Outflow Component** near the **Venous Outflow Component** end of the **Adapter** (Fig. 9 and 10) or **Adapter** with **Support Seal** (if applicable, Fig. 11 and 12).

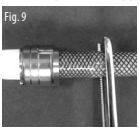
Fig. 9


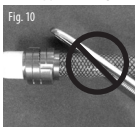
Fig. 10


Fig.11


Fig. 12


2. Remove the **Adapter**, **Support Seal** (if applicable), graft and cut portion of the **Venous Outflow Component** that are attached to the **Adapter**.
3. Deliver a HeRO Graft **Arterial Graft Component** to the sterile field using aseptic technique.
4. Use according to the instructions for use included with the HeRO Graft **Arterial Graft Component**.

GRAFT AND ARTERY CONNECTION

1. Cut the graft to length, avoiding excessive tension or excess material. Verify there are no kinks, twists, or bends in the graft.
2. Perform the arterial anastomosis using standard surgical techniques.

Caution: Use a small diameter tapered needle with a non-cutting edge to reduce the incidence of suture hole bleeding.

3. Remove the clamp, check the device patency using standard Doppler technique. Verify there is no leakage at the **Venous Outflow Component** and the graft connection sites using angiography. If there is a leak at either connection site, see **TROUBLESHOOTING FOR LEAKS** section.
4. Verify thrill and bruit.
5. Evaluate for steal syndrome during the implant procedure with Doppler of the radial and ulnar arteries. If steal syndrome symptoms occur, consider surgical interventions such as:
   - DRIL (distal revascularization-interval ligation) procedure
   - Banding, though this may reduce the flow in the HeRO Graft
   - Proximalization of the inflow

NOTE: Banding may reduce flow in the HeRO Graft.

6. Close all three incision sites.

NOTE: After use, the components used are a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

POST IMPLANT INFORMATION

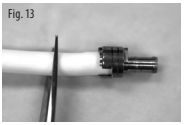
1. Complete the Implant Notification Fax Form in the Patient Information Pouch and fax the completed form to the patient's dialysis center.
2. The healthcare provider must place the peel tabs from the label of the implanted HeRO product(s), fill out the Patient name, Implant Date, implanting physician, hospital name and hospital address in the blanks on the card and supply the patient with the Patient Implant Card.
3. The healthcare provider is responsible for instructing the patient on proper postoperative care.
4. The healthcare provider shall inform the patient of the residual risks, contra-indications, undesirable side-effects, warnings and measures to be taken in the event of malfunction of the device. This should include information pertaining to the MRI safety information included in this IFU and also on the Patient Implant Card.

TROUBLESHOOTING FOR LEAKS

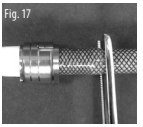
1. If there is a leak at the **Adapter** site, attempt to further tighten the clamshells and verify the **Venous Outflow Component** was connected appropriately (See: **CONNECTING THE HeRO GRAFT** and **ASSEMBLING THE ADAPTER** sections).
2. If a leak persists after following the previously stated troubleshooting steps, consider one of the following two options to implant the HeRO Graft.

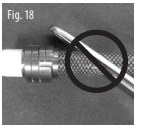
OPTION 1: Remove the *Adapter*, Anastomose an Interpositional Graft, and Attach a New *Adapter*

1. Using scissors, make a straight cut to the graft close to the inflow graft end of the **Adapter** (Fig. 13 and 14) or the **Support Seal** coil (if applicable, Fig. 15 and 16).



2. Using heavy duty scissors, make a straight cut to the **Venous Outflow Component** near the **Venous Outflow Component** end of the **Adapter** (Fig. 17 and 18) or **Adapter** with **Support Seal** (if applicable, Fig. 19 and 20).

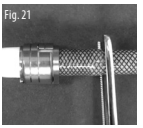


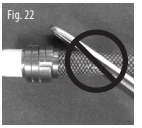


3. Remove the **Adapter**, **Support Seal** (if applicable) and the cut portions of the graft and **Venous Outflow Component** (that are attached to the **Adapter**). Contact Customer Service at 1-800-356-3748 for returning the removed product.
4. Measure the length that is required for the interpositional graft. The measured length should exceed the lengths of the cut portions of the graft, **Support Seal** (if applicable), and **Venous Outflow Component** that were removed during steps 1 and 2.
5. Deliver a new graft (from Table 1 or 2, **ASSEMBLING THE ADAPTER**) to the sterile field using aseptic technique.
6. Measure the precise length that is required for the interpositional graft and transversely cut the graft to length.
7. Using the new graft segment, sew an end-to-end anastomosis to the implanted graft at the DPG site.
8. Deliver a new **Adapter**, **Support Seal** (if applicable), and **Graft Expander** to the sterile field using aseptic technique.
9. Attach a new **Adapter** and **Support Seal** (if applicable) to the graft by following the **ASSEMBLING THE ADAPTER** section.
10. Attach the **Venous Outflow Component** to the **Adapter** by following the **CONNECTING THE HeRO GRAFT** section.
11. Using fluoroscopy, reposition the assembled **Adapter** (as necessary) and verify that the radiopaque tip of the **Venous Outflow Component** is positioned in the mid to upper right atrium.
12. Proceed to Step 3 of the **GRAFT AND ARTERY CONNECTION** section.

OPTION 2: Remove the *Adapter* and Graft and Replace with HeRO Graft *Arterial Graft Component*.

1. Using heavy duty scissors, make a straight cut to the **Venous Outflow Component** near the **Venous Outflow Component** end of the **Adapter** (Fig. 21 and 22) or **Adapter** with **Support Seal** (if applicable, Fig. 23 and 24).





2. Remove the **Adapter**, **Support Seal** (if applicable), graft, and cut portion of the **Venous Outflow Component** that are attached to the **Adapter**.
3. Deliver a HeRO Graft **Arterial Graft Component** to the sterile field using aseptic technique.
4. Follow the instructions for use included with the HeRO Graft **Arterial Graft Component.**

VASCULAR ACCESS CANNULATION

Follow KDOQI guidelines for graft assessment, preparation and cannulation.

NOTE: Consult the graft manufacturer's IFU for more information regarding the cannulation of the commercially available graft selected for use with the **Adapter** and **Support Seal** (if applicable).

- Swelling must subside enough to allow palpation of the entire graft.
- Rotation of cannulation sites is needed to avoid pseudoaneurysm formation.
- A light tourniquet may be used for cannulation as the thrill and bruit may be softer than a conventional ePTFE graft due to the elimination of the venous anastomosis.

Post-dialysis, and following needle removal, apply moderate digital pressure at the puncture site until hemostasis is achieved. To decrease the risk of an occlusion, do not use mechanical clamps or straps.

Caution: DO NOT cannulate the HeRO Graft within 8cm (3") of the DPG incision to avoid damage to the *Support Seal* (if applicable).

Caution: DO NOT cannulate the *Venous Outflow Component*.

Caution: Remove the bridging catheter as soon as possible once the HeRO Graft is ready to be cannulated to decrease the risk of an infection related to the bridging catheter.

Caution: All bridging catheters should be cultured upon explant. In the event catheter tip cultures are positive, treat the patient with appropriate antibiotics to decrease the risk of the HeRO Graft becoming infected.

For additional information refer to the HeRO Graft Care & Cannulation Guide or review it online at www.merit.com/hero.

EXPLANT PROCEDURE

If the patient moves to another form of Renal Replacement Therapy such as receiving a kidney transplant, it is recommended to remove the VOC and ligate the graft.

To Explant the HeRO Graft Venous Outflow Component and Arterial Graft Component Connector or Adapter:

1. Prep patient using aseptic surgical technique. Place the patient into Trendelenberg position to reduce the potential for air embolus during removal.
2. Open the incision at the deltopectoral groove (DPG) and dissect to expose at least 5cm of the graft, including the connector and PTFE beading (For **Arterial Graft Component**).
3. Carefully dissect the exposed graft and **Arterial Graft Component** connector or the **Adapter** to free the incorporated material for ease of revision.
4. For the **Arterial Graft Component**, ligate the graft approximately 1cm distal to the PTFE beading. NOTE : If the **Adapter** has been used, grafts that are permitted to be used with the device are not beaded . For the **Adapter** with an ePTFE graft, ligate the graft approximately 1cm away from the end of the Support Seal (if used) or the **Adapter** inflow graft end.
5. For the **Arterial Graft Component**, cut the graft component between the ligation and the PTFE beading to separate the **Venous Outflow Component**. For the **Adapter** with an ePTFE graft, cut the graft between the ligation and the end of the Support Seal (if used) or the **Adapter** inflow graft end to separate the **Venous Outflow Component**.
6. Gently twist to loosen the **Venous Outflow Component** with attached **Arterial Graft Component** connector or the **Adapter**. Using appropriate technique, (i. e., slip tip syringe) apply negative pressure to remove potential intraluminal thrombus.

7. Pull gently using counter pressure applied at the original venous incision site until the **Venous Outflow Component** with the **Arterial Graft Component** connector or the **Adapter** is fully removed and close previous entry site of **Venous Outflow Component** with purse string suture.

Caution: Upon removing the Venous Outflow Component and Arterial Graft Component connector or the Adapter, continue applying pressure at the original venous incision site to decrease risk of bleeding and air embolism.

8. After removal of the components, close the DPG incision site.

General Cautions:

- **During removal of the Venous Outflow Component, special care should be used if there is a stent in the vessel. Use imaging (fluoroscopy) for visualization of the Venous Outflow Component and stent interaction to decrease the potential of Venous Outflow Component, stent, or vessel damage.**
- **Only qualified healthcare providers should explant the device.**
- **Adhere to universal precautions when explanting the device.**

NOTE: The HeRO Graft has been in contact with body fluids and is a potential biohazard. Handle the device using acceptable medical practice and applicable local, state and federal laws and regulations.

EXCHANGE PROCEDURE FOR VENOUS OUTFLOW COMPONENT

If the **Venous Outflow Component** is not performing as expected, it can be removed or exchanged as it does not incorporate into venous anatomy. Potential reasons the **Venous Outflow Component** may need to be replaced may include but are not limited to; kinking, incorrect placement, patient injury/fall which dislodges the distal tip placement, infection, etc. Fluoroscopy is required during insertion of a new **Venous Outflow Component** to avoid vessel damage and ensure proper placement. Due to the complexity and permutations of this procedure, clinical support is available upon request. Contact Customer Service at 1-800-356-3748 or your local Merit representative.

Tools Required:

- **Venous Outflow Component**
- **Accessory Component Kit**
- 0.035"stiff guidewire at least 150cm in length

Recommended Accessories:

- Stiffened 5F Micropuncture Introducer Set (such as Merit P/N S-MAK501N)
- Heavy duty scissors

1. Prep the patient according to standard surgical guidelines. Place the patient into Trendelenberg position to reduce the potential for air embolus during exchanges. For patients undergoing general anesthesia, a positive breath can be forced during removal of the dilator from the sheath to prevent air induction.

2. Prepare the 5F microintroducer by removing the 0.018" wire-compatible dilator and securely attaching the sheath to the Y-adapter (from the **Accessory Component Kit**). Flush the sheath with heparinized saline via the Luer port.

3. Palpate to locate the **Arterial Graft Component** connector or the **Adapter**. Open the deltopectoral groove (DPG) incision to expose the PTFE graft rings (**Arterial Graft Component**) and at least 5cm of the **Venous Outflow Component**.

4. Clamp the graft with an atraumatic vascular clamp near the PTFE graft beading. Inject the graft with heparinized saline to maintain patency.

Caution: Do not clamp the PTFE beading as damage to the beading may result. If damage occurs, replacement of the Arterial Graft Component is recommended.

5. Palpate the venous access site to confirm location of the **Venous Outflow Component**. Open the previous incision and expose the **Venous Outflow Component** nearest the point it enters/exits the vein.

6. Create a purse string suture at the venous access site and clamp the **Venous Outflow Component** using the clamp in the **Accessory Component Kit** nearest the point it enters/exits the vein.

7. Place 4x4 gauze under the connector to prevent debris from contaminating the incision site.

8. Ensure both clamps are secure and cut the **Venous Outflow Component** with a pair of heavy-duty scissors approximately 3cm from the **Arterial Graft Component** connector or the **Adapter**.

9. Using the heavy-duty scissors, cut the remainder of the **Venous Outflow Component** from the **Arterial Graft Component** connector or the **Adapter** starting at the **Arterial Graft Component** connector shoulder or the **Adapter** shoulder and working toward the cut end.

Caution: Cutting through the nitinol braiding of the Venous Outflow Component may be difficult. Do not damage the barbs on the Arterial Graft Component connector or Adapter. If damage occurs, replacement of the Arterial Graft Component or Adapter with a new Arterial Graft Component or Adapter with a new ePTFE graft* is recommended.

***See Tables 1 and 2 in this Instructions for Use for full details on the ePTFE grafts that have been tested and are permitted for use with the Adapter.**

10. Once completed, remove the 4x4 gauze and inspect the wound for any potential debris left behind. Replace the gauze and continue the procedure.

NOTE: Alternately, it may be possible to twist and pull the **Venous Outflow Component** until it can be removed from the **Arterial Graft Component** connector or **Adapter** without cutting. This may be a slow and time-consuming process.

Caution: Do not crush or otherwise damage the beading on the Arterial Graft Component. If damage occurs, replacement of the Arterial Graft Component is recommended.

NOTE: If the **Adapter** has been used, grafts that are permitted to be used with the device are not beaded.

11. At the venous access site, gently pull the **Venous Outflow Component** through the tunneled tract. Do not move or displace the tip of the **Venous Outflow Component** in the right atrium .

12. Insert the assembled 5F sheath into the exposed end of the **Venous Outflow Component**. Ensure that the hub is securely seated in the **Venous Outflow Component** and remove the clamp.

13. Aspirate blood from the device. Under fluoroscopic guidance, advance the guidewire to the desired position in the inferior vena cava.

14. Maintaining guide wire position, gently remove the existing **Venous Outflow Component** over the wire. The purse string suture can help control bleeding at the venous access site.

15. Load the 20F peel away sheath onto the guidewire and use fluoroscopy to advance.

16. Flush the **Venous Outflow Component** with heparinized saline.

17. Apply sterile surgical lubricant to the 10F delivery stylet and advance through the silicone Luer end of the **Venous Outflow Component**.

18. Remove the Y-adapter from the 5F micropuncture assembly and attach to the Luer End of the delivery stylet placed within the new **Venous Outflow Component**.

19. Attach the stopcock to the Y-adapter and ensure the valve on the stopcock is in the open position and flush with heparinized saline, then close the valve.

20. To ease insertion into the sheath, apply sterile surgical lubricant to the exterior surface of the Venous Outflow Component.

21. While stabilizing the guidewire and 20F sheath, begin removing the dilator from the sheath. As soon as the dilator tip has exited the sheath, immediately insert the hemostasis plug by grasping the grip between the thumb and index finger. Firmly insert the hemostasis plug into the sheath alongside the guidewire. Ensure both plug seal rings are fully seated within the sheath. Fully remove the dilator over the guidewire. Avoid pinching or clamping the sheath.

22. Insert the **Venous Outflow Component** and delivery stylet assembly over the guidewire. Remove the hemostasis plug and quickly advance the **Venous Outflow Component** into the 20F sheath.

23. Under fluoroscopic guidance, advance the **Venous Outflow Component** to the superior vena cava . A twisting or rotational motion may be used to ease insertion. Holding the delivery stylet fixed, continue to advance the **Venous Outflow Component** to the mid to upper right atrium.

NOTE: If resistance is felt, determine the cause before continuing to advance the **Venous Outflow Component**. Keep the sheath straight to prevent it from kinking. If the sheath is bent, remove it and replace it with a new 20F sheath.

24. Confirm proper **Venous Outflow Component** tip placement in the mid to upper right atrium.

25. Gently pull up while peeling away the 20F sheath. Do not peel the sheath close to the incision site; only peel the sheath as it exits the incision site. Verify that the sheath has been completely removed and that the tip of the **Venous Outflow Component** is in the correct location via fluoroscopy.

26. Remove the guidewire and close the hemostasis valve on the Y-adapter.

27. Begin withdrawal of the 10F delivery stylet while maintaining **Venous Outflow Component** position. Prior to complete removal of the delivery stylet from the Luer, clamp the Venous Outflow Component at the incision site with the disposable clamp included in the **Accessory Component Kit**.

NOTE: Be careful not to overclamp (i.e., do not advance past the locking tab on the clamp handle)

28. Detach the Y-adapter from the delivery stylet. Open the stopcock and attach the Y-adapter to the silicone Luer on the **Venous Outflow Component**.

29. Attach a syringe to the stopcock and unclamp the **Venous Outflow Component**. Aspirate and close the stopcock. Reclamp the **Venous Outflow Component** and remove the syringe.

30. Attach a syringe with heparinized saline. Open the stopcock, remove the clamp and flush the **Venous Outflow Component**. Reclamp the **Venous Outflow Component** at the incision site and close the stopcock.

31. Holding the **Venous Outflow Component** away from the incision sites, use heavy duty scissors to make a straight cut and remove the silicone Luer and Y-adapter assembly. Discard unused portion . Tunnel through the existing tract to the connection site.

32. Remove the clamp from the **Venous Outflow Component** and flush with heparinized saline. Reclamp the **Venous Outflow Component** at the venous incision site.

33. Unclamp the graft, confirm patency and reclamp.

34. For the **Arterial Graft Component**, grasp the silicone sleeve on the connector in one hand. NOTE: If the **Adapter** has been used, it does not have a silicone sleeve. It may be grasped in one hand on the closed clamshells. In the other hand, grasp the **Venous Outflow Component** 2cm back from the cut edge and advance it over both barbs and up to the connector shoulder of the **Arterial Graft Component** or **Adapter** shoulder.

Verify the **Arterial Graft Component** or the **Adapter** with an ePTFE graft and **Venous Outflow Component** are fully connected .

Caution: Do not peel or otherwise damage the graft beads as this may adversely impact the integrity of the graft. If damage occurs, replacement of the Arterial Graft Component is recommended.

NOTE: If the **Adapter** has been used, grafts that are permitted to be used with the device are not beaded.

35. Verify radiopaque tip placement in the mid to upper right atrium using fluoroscopy.

36. Gently tuck the connected device into the **Arterial Graft Component** or the **Adapter** site incision and return the patient to standard supine position.

37. Remove all clamps and confirm device patency before closing incisions.

NOTE: The HeRO Graft has been in contact with body fluids and is a potential biohazard. Handle the device using acceptable medical practice and applicable local, state and federal laws and regulations.

If the device was removed due to performance issues, return the explanted portion of the device to Merit Medical Systems by contacting Customer Service at 1-800-356-3748.

REVISE THE HERO GRAFT ARTERIAL GRAFT COMPONENT OR THE HERO ADAPTER WITH AN ePTFE GRAFT:

If the HeRO Graft is no longer able to provide adequate dialysis it can be revised or replaced due to potential reasons such as but not limited to; adequacy of dialysis (Kt/V), stenosis, increased pressures during dialysis, excessive bleeding at graft cannulation sites, swelling of the limb, edema around graft site, etc.,

The HeRO Graft **Arterial Graft Component** or the **Adapter** with an ePTFE graft can be revised if necessary via a jump graft procedure. If graft revision is necessary due to infection, resection and removal of the infected portion of the graft is required prior to completing the jump graft procedure. Return the excised portion of the graft to Merit Medical Systems, Inc. by contacting Customer Service at 1-800-356-3748. Follow the instructions for the jump graft procedure as detailed below. If damage occurs to the PTFE beading on the existing **Arterial Graft Component**, replace the entire **Arterial Graft Component** including the connector. NOTE: If the **Adapter** has been used, grafts that are permitted to be used with the device are not beaded. Replacement of the **Arterial Graft Component** will also require revision to the **Venous Outflow Component**. Due to the complexity and permutations of this procedure, clinical support is available upon request. Contact Customer Service at 1-800-356-3748 or your local Merit representative.

1. Create incisions at the infection free sites selected for the graft-to-graft anastomosis and dissect to expose the existing graft.

Caution: DO NOT peel or otherwise damage the graft beading as this may adversely impact the integrity of the existing graft.

NOTE: If the **Adapter** has been used, grafts that are permitted to be used with the device are not beaded.

2. Create a subcutaneous tunnel from new inflow incision site to the new outflow incision site circumventing the existing graft. Graft routing may vary depending on patient-specific anatomy and the placement of the existing graft.

3. Using standard graft tunneling techniques, gently pull the jump graft through the new tunnel. Utilize markings on the graft to verify it has not twisted.

NOTE: If replacing the entire Arterial Graft Component, connect the Venous Outflow Component to the connector of the Arterial Graft Component.

4. Use a standard vascular clamp to occlude the existing graft near the new inflow anastomosis site.

5. Perform a standard graft-to-graft anastomosis.

6. Remove the clamp, bleed the jump graft segment to remove air, and then reclamp the jump graft segment next to the new outflow anastomosis site.

7. Cut the graft to length, avoiding excessive tension or redundant graft material, and perform the outflow anastomosis of the jump graft to the existing graft using standard technique.

8. Remove the clamp and check the device patency, utilizing standard Doppler technique.

9. Close both incisions.

NOTE: The HeRO Graft has been in contact with body fluids and is a potential biohazard. Handle the device using acceptable medical practice and applicable local, state and federal laws and regulations.

If the device was removed due to performance issues, return the explanted portion of the device to Merit Medical Systems by contacting Customer Service at 1-800-356-3748.

If the HeRO Graft is abandoned for any reason, we recommend removal of the **Venous Outflow Component**. The ePTFE graft portion of the **Arterial Graft Component** or the **Adapter** would typically not be removed due to maturation/ incorporation of surrounding tissue into the ePTFE graft material. It can be ligated and left in place similar to conventional AV grafts.

PERCUTANEOUS THROMBECTOMY

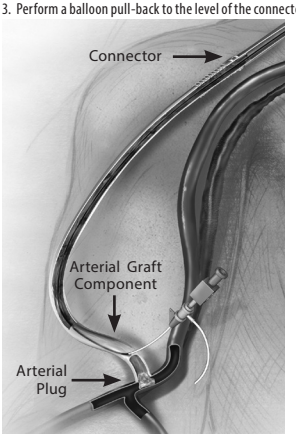
Similar to conventional arteriovenous grafts or fistulas, the HeRO Graft System will require intervention such as thrombectomy to maintain graft patency. The HeRO Graft System is up to 130 cm in length, and therefore requires a longer thrombectomy device to traverse the entire length of the device.

Caution: Do not use mechanical/rotational thrombectomy devices (e.g., Arrow-Trerotola PTD®) in the Venous Outflow Component and/or connector as internal damage may occur to these components.

Use of fluoroscopy is recommended for all HeRO Graft System interventions. The following outlines the general procedural steps involved with a percutaneous thrombectomy procedure:

PERCUTANEOUS THROMBECTOMY (DECLOTTING) THE HERO GRAFT SYSTEM

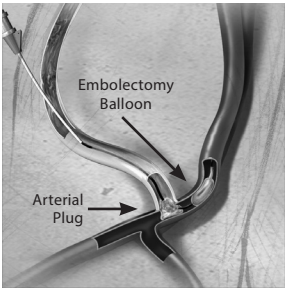
1. Introduce a 7 Fr short vascular sheath near the arterial anastomosis.
2. Inflate a soft, compliant embolectomy balloon at the distal radiopaque marker band of the **Venous Outflow Component**. To avoid dislodging the **Venous Outflow Component**, the balloon should not be advanced distally beyond the radiopaque marker band.
3. Perform a balloon pull-back to the level of the connector.



4. At the level of the connector, aspirate while deflating the balloon by approximately 10%. Failure to deflate the balloon may result in balloon perforation as the catheter passes through the connector.
5. Reinflate the balloon once the balloon has passed through the connector and resides within the arterial graft.
6. Extract clot at the introducer site.
7. Declot the full length of HeRO Graft prior to removing the arterial plug to decrease risk of pulmonary embolism.

ARTERIAL PLUG REMOVAL

1. Choose a Fogarty embolectomy balloon sized for the artery (3-4mm) and insert past the arterial plug.



2. Inflate the balloon, "pop" the arterial plug, and pull the balloon back to the introducer site.
3. Extract the arterial plug, then confirm flow and patency throughout the device. Ultrasound may be used to assess flow.
4. Reconfirm placement of the connector and **Venous Outflow Component** tip via fluoroscopy.
5. Proceed with correcting any lesions in the graft as you routinely would.

SUMMARY OF HeRO GRAFT CLINICAL EXPERIENCE

The HeRO Graft was evaluated in a prospective clinical study to demonstrate that the device raises no new concerns of safety and effectiveness when used as indicated in patients requiring long-term hemodialysis.

The HeRO Graft was studied in two different patient populations. One was a prospective literature controlled study of HeRO Graft / implant procedure-related bacteremia rates in catheter-dependent subjects (the "bacteremia study"),[3] and the other was a randomized study of HeRO Graft patency in upper arm graft-eligible subjects compared to subjects receiving an ePTFE control graft (the "patency study").[3]

Fourteen (14) institutions treated 86 subjects with the HeRO Graft. Subjects were required to return for post-operative evaluation at three-month intervals for a minimum of 12 months. Endpoint and performance results are summarized in **Table 3**.

The study results show that the rate of device / procedure-related bacteremia associated with the HeRO Graft is statistically lower than reported in the literature for tunneled catheters and comparable to that reported in the literature for conventional ePTFE grafts. HeRO Graft patency and adequacy of dialysis are significantly improved compared to catheter literature and comparable to graft literature.

The HeRO Graft has an associated safety profile that is comparable to existing graft and catheters used for hemodialysis. In this study, no new concerns of safety and effectiveness for a long-term vascular access device were observed. There were no unanticipated events. Serious HeRO Graft and / or procedure-related adverse events by type are summarized in **Table 4**.

Device-related adverse events occurred at a frequency comparable to both the catheter and graft literature with the exception of bleeding.[4,5] Of the six (6) bleeding events in the patency study, two (2) were indirectly related to the HeRO Graft implant procedure; in the first patient, coagulopathy was caused by other conditions and bleeding was not unexpected, and in the second patient, a heparin administrative error occurred. Three (3) bleeding events were directly attributed to an earlier generation 22F HeRO Graft Venous Outflow Component, which required an internal jugular venous cut-down. The sixth bleeding event was related to a HeRO Graft explant procedure. There was one (1) device-related death in the patency study due to device-related sepsis complications, a known vascular access complication reported in the literature.[4,5]

TABLE 3: Final HeRO Graft Endpoint & Performance Data from U.S. Multi-Center Pivotal Clinical Trials

		HeRO Graft Bacteremia Study (N=36)[3]	HeRO Graft Patency Study (N=50)[3]	Catheter Literature	ePTFE Graft Literature	KDOQI Adequacy of Hemodialysis Guidelines
Device/Procedure-Related Bacteremia Rate/1,000 Days [I]		0.70/1,000 days (1.45 Upper Confidence Bound (UCB))	0.13/1,000 days (0.39 Upper Confidence Bound (UCB))	2.3/1,000[6]	0.11/1,000[7]	Not Applicable
Primary Patency at 6 Months % (n/N)		47.2 (17/36)	48.0 (24/50)	50%[6]	58%[6]	Not Applicable
Assisted Primary Patency at 6 Months % (n/N)		94.4 (34/36)	88.0 (44/50)	92%[6]	68%[6]	Not Applicable
Secondary Patency at 6 Months % (n/N)		77.8 (28/36)	78.0 (39/50)	55%[6]	76%[6]	Not Applicable
Primary Patency at 12 Months % (n/N)		33.3 (12/36)	36.0 (18/50)	36%[6]	42%[6]	Not Applicable
Assisted Primary Patency at 12 Months % (n/N)		88.9 (32/36)	84.0 (42/50)	Not Reported	52%[6]	Not Applicable
Secondary Patency at 12 Months % (n/N)		77.8 (28/36)	70.0 (35/50)	37%[6]	65%[6]	Not Applicable
Adequacy of Dialysis ±SD [Min,Max]	**Kt/V**	1.7 ± 0.3 (N=25) [1.2,2.4]	1.6 ± 0.3 (N=33) [0.9,2.3]	1.29 -1.46[3]	1.37-1.62[6]	1.4 target
	URR	74.3 ± 3.8 (N=24) [65.3,83.0]	72.8 ± 6.0 (N=21) [61.0,83.8]	65-70[3]	70-73[6]	70 target

I. Procedure-related bacteremia was defined as any bacteremia seeded by the subject's previous tunneled dialysis catheter (cultured at the time of HeRO Graft implant), any bacteremia that may have been seeded by a pre-existing infection elsewhere in the subject's body possibly making the subject more susceptible to bacteremia in the peri-operative period, or where there is no other source for the bacteremia identified other than the implant procedure. Bacteremia was categorized as device-related when no other source for the infection could be identified.

TABLE 4: Final HeRO Graft Serious Device and/or Implant Procedure-Related Adverse Events by Type from U.S. Multi-Center Clinical Trials

	HeRO Graft Bacteremia Study # Events[I] / # Subject[II] (%)[III] (N = 38)[3]	HeRO Graft Patency Study # Events/ # Subject (%) (N = 52)[3]	Catheter Literature[3]	ePTFE Graft Literature[3]
Bleeding, hemorrhage or hematoma	2/38 (5.3%)	6/52 (11.5%)	79/4209 (1.9%) per Catheter	76/1587 (4.8%)
Cardiac arrhythmia	1/38 (2.6%)	0/52 (0.0%)	30/432 (6.9%) of ESRD subjects	30/432 (6.9%) of ESRD subjects
Death	0/38 (0.0%)	1/52 (1.9%)	21%[IV] (249/1200)	18.6%[IV] (327/1754)
Edema (includes swelling)	1/38 (2.6%)	0/52 (0.0%)	5/86 (5.8%) per Catheter	32/222 (14.4%)
Pulmonary embolism	1/38 (2.6%)	1/52 (1.9%)	28/686 (4.1%) of ESRD subjects	28/686 (4.1%) of ESRD subjects
Infection (non-bacteremia)	1/38 (2.6%)	2/52 (3.8%)	1.6/1,000 days	9.8%[V] (260/2663)
Stroke	0/38 (0.0%)	1/52 (1.9%)	0.08-0.088/per year in ESRD subjects	0.08-0.088/per year in ESRD subjects
Vascular insufficiency due to steal syndrome (includes ischemia)	1/38 (2.6%)	2/52 (3.8%)	Not Applicable	47/1229 (3.8%)
Site pain	0/38 (0.0%)	1/52 (1.9%)	Not Reported	Not Reported
Trauma to major veins, arteries, nerves	0/38 (0.0%)	1/52 (1.9%)	101/2823 (3.6%) per Catheter	7/93 (7.5%)
Wound problems (includes wound dehiscence)	1/38 (2.6%)	0/52 (0%)	Not Reported	3/129 (2.3%)
Breakage or mechanical failure (prosthesis technical failure)	0/38 (0.0%)	1/52 (1.9%)	278/2214 (12.6%) per subjects	Not Reported
Other[VI]	1/38 (2.6%)	5/52 (9.6%)	Not Reported	Not Reported

This table includes all enrolled HeRO Graft subjects including the 4 that did not receive the device.

Table 4 Footnotes: I. Total number of events; II. Subjects with at least one event; III. Percent of subjects with at least one event; IV. Literature reports all deaths and not just device or procedure-related deaths; V. Graft literature reports all infections including bacteremia or sepsis; VI 'Other' serious device and/or procedure related events included right atrial clot, hypotension with fever, non-sustained mild and ventricular tachycardia, pneumonia, cardiogenic shock, hypoxia, hyperkalemia, hypoxemia, elevated white blood cell count.

In some instances, a direct comparison between the HeRO Graft data and the literature cannot be made because the only literature data available is reported per the overall ESRD population vs specific catheter or graft populations. Additionally, some catheter literature data is only appropriate to report per catheter rather than per subject such as procedure related adverse events.

MRI Safety Information

Non-clinical testing has demonstrated that the HeRO Graft System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the HeRO Graft System is expected to produce a maximum temperature rise of 4.8ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 10mm from the HeRO Graft System when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

WARRANTY DISCLAIMER

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TECHNICAL SUPPORT

To obtain additional information on the HeRO Graft, including questions on infection control procedures, contact the customer service department at:

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A. Customer Service 1-800-356-3748
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REFERENCES

1. Shah, et al., 2011. Vascular access thrombosis and interventions in patients missing hemodialysis sessions. Clin Nephrol, Dec 2011; 76(6): 435-9
2. Illig KA. Management of Central Vein Stenosis and Occlusions: The Critical Importance of the Costoclavicular Junction. Semin Vasc Surg 24:113-118, 2011.
3. Data on file.
4. Lucas, George F. 2007. Scientific Review of Adverse Events related to the use of Chronic Hemodialysis Catheters (not including infections). Data on file.
5. Lucas, George F. 2007. Scientific Review of Adverse Events in Hemodialysis Grafts. Data on file.
6. Katzman H. (2009). Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients. Journal Vascular Surgery, 600-607.
7. Hajjar J, Girard R, Marc JM, et al. [Surveillance of infections in chronic hemodialysis patients (Article in French)]. Nephrologie 2004;25:133-40.

A bibliography of HeRO Graft publications and presentations is available at www.merit.com/hero.

www.merit.com/hero

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