INSTRUCTIONS FOR USE
**INSTRUCTIONS FOR USE**

**R 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.

---

**DEVICE DESCRIPTION**

The HeRO (Hemodialysis Reliable Outflow) 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**:

- **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.

- **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 of the document as well as the Adapter packaging.

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

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 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 who have exhausted all other access options and are considered catheter dependent.

INDICATIONS FOR USE

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

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 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

- DO NOT use product if package has been damaged, opened, or the use by date has passed, as sterility may be compromised.
- 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.
- 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.
- Contamination of the device may lead to injury, illness or death of the patient.
- 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.
Potential Vascular Graft & Catheter Complications
- Abnormal healing / skin erosion
- Anastomosis or wound dehiscence
- Device kinking or compression
- Device migration
- Ectasia
- Edema
- Foreign body reaction or rejection
- Graft extravasation
- Bacteremia and non-bacteremic infection
- Partial stenosis or full occlusion of prosthesis or vasculature
- Prosthesis failure
- Pseudoaneurysm
- Seroma
- Site pain
- Superior Vena Cava Syndrome
- Vascular graft revision / replacement
- Vascular insufficiency due to steal syndrome

Potential Intraoperative & Post-Operative Complications
- Allergic reaction
- Aneurysm
- Bleeding
- Cardiac arrhythmia
- Cardiac tamponade
- Death
- Embolism
- Heart failure
- Hematoma
- Hemorrhage
- Hypotension / hypertension
- Myocardial infarction
- Pneumothorax / hemothorax / hydro-thorax
- Reactions to anesthesia
- Respiratory / cardiac arrest
- Sepsis
- 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:
- SF 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 atrumatic 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.  

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.

5. Ensure the valve on the stopcock is in the open position and flush with heparinized saline, then close the valve.

6. Open the Accessory Component Kit using aseptic technique and prep the contents for use.

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

7. Prophylactically treat the patient in the peri-operative period with antibiotics based upon the patient’s bacteremia history.

8. Attach the Y-adapter onto the Luer end of the 10F delivery stylet and tighten the stopcock, if necessary.

9. Create a small incision at the exit site of the guidewire to aid in placement of the introducer sheath.

10. If performing venography to diagnose venous anatomy, select an appropriately sized introducer sheath.

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.

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

9. If performing venography to diagnose venous anatomy, select an appropriately sized introducer sheath.

4. Open the Accessory Component Kit using aseptic technique and prep the contents for use.

5. Using aseptic technique and prep the contents for use.

6. Apply sterile surgical lubricant to the 10F delivery stylet and advance through the silicone Luer end of the 10F delivery stylet.

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

8. Ensure the valve on the stopcock is in the open position and flush with heparinized saline, then close the valve.

9. 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.

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 Vascular Grafts (qualified for use with the Adapter)

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Catalogue Number*</th>
<th>Support Seal Required for HeRO Graft Adapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLIXENE® Standard Wall</td>
<td>Atrium Medical Corp.</td>
<td>23053</td>
<td>NO</td>
</tr>
<tr>
<td>GORE® ACUSSEAL</td>
<td>W.L. Gore &amp; Associates</td>
<td>ECHO60010A</td>
<td>NO</td>
</tr>
</tbody>
</table>

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 Vascular Grafts (qualified for use with the Adapter and Support Seal)

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Catalogue Number*</th>
<th>Support Seal Required for HeRO Graft Adapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMPRA®</td>
<td>C.R. Bard</td>
<td>05050</td>
<td>YES</td>
</tr>
<tr>
<td>GORE-TEX®</td>
<td>W.L. Gore &amp; Associates</td>
<td>V06010A</td>
<td>YES</td>
</tr>
<tr>
<td>GORE-TEX® Stretch</td>
<td>W.L. Gore &amp; Associates</td>
<td>50001</td>
<td>YES</td>
</tr>
<tr>
<td>GORE® PROPATEN®</td>
<td>W.L. Gore &amp; Associates</td>
<td>H060010A</td>
<td>YES</td>
</tr>
</tbody>
</table>

IMPRRA 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.
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.

NOTE: 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: 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.

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).

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).

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).

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:
   - DRL (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 fluorescopy, 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 KDQI 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 venous anastomosis.

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.

EXPLAIN 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.

6. 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.

7. 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" stiffer guidewire at least 150cm in length

Recommended Accessories:
- Stiffened SF 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 Trendelenburg 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 SF 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 deltoidectomy 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 anatraumatic vascular clamp near the PTFE graft leading. Inject the graft with heparinized saline to maintain patency.

Caution: Do not clamp the PTFE leading as damage to the leading 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 leading 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 SF 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 SF 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 clip included in the Accessory Component Kit. **NOTE:** Be careful not to overlap (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 2 cm back from the cut edge and advance it over both bars 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 radioopaque 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. **NOTE:** 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 described below. If damage occurs to the PTFE branching 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 clamp 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. 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.
4. Reinflate the balloon once the balloon has passed through the connector and resides within the arterial graft.
5. Extract clot at the introducer site.
6. 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”); 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”).

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. 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 administration error occurred. Three (3) bleeding events were directly attributed to an earlier generation ZF 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.

<table>
<thead>
<tr>
<th>TABLE 3: Final HeRO Graft Endpoint &amp; Performance Data from U.S. Multi-Center Pivotal Clinical Trials</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device/Procedure-Related Bacteremia Rate</strong> (#/1,000 Days)</td>
<td><strong>HeRO Graft</strong></td>
</tr>
<tr>
<td><strong>Primary Patency at 6 Months (%) (N=50)</strong></td>
<td>70/4209 (1.9%)</td>
</tr>
<tr>
<td><strong>Secondary Patency at 6 Months (%) (N=50)</strong></td>
<td>2/38 (5.3%)</td>
</tr>
<tr>
<td><strong>Primary Patency at 12 Months (%) (N=50)</strong></td>
<td>77.8 (28/36)</td>
</tr>
<tr>
<td><strong>Secondary Patency at 12 Months (%) (N=50)</strong></td>
<td>33.3 (12/36)</td>
</tr>
<tr>
<td><strong>Adenopathy of Dialysis ±SD</strong></td>
<td><strong>HeRO Graft</strong></td>
</tr>
<tr>
<td><strong>Kt/V</strong></td>
<td>1.7 ± 0.3 (N=25)</td>
</tr>
<tr>
<td><strong>URR</strong></td>
<td>72.8 ± 6.0 (N=21)</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>70.0 (35/50)</td>
</tr>
<tr>
<td><strong>Primary Patency at 6 Months (%) (N=50)</strong></td>
<td>78.0 (39/50)</td>
</tr>
<tr>
<td><strong>Secondary Patency at 6 Months (%) (N=50)</strong></td>
<td>36.0 (18/50)</td>
</tr>
<tr>
<td><strong>Primary Patency at 12 Months (%) (N=50)</strong></td>
<td>78.0 (39/50)</td>
</tr>
<tr>
<td><strong>Secondary Patency at 12 Months (%) (N=50)</strong></td>
<td>36.0 (18/50)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th><strong>Adverse Events by Type from U.S. Multi-Center Pivotal Clinical Trials</strong></th>
<th><strong>HeRO Graft</strong></th>
<th><strong>ePTFE Graft</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bleeding, hemorrhage or hematoma</strong></td>
<td>3/18 (5.3%)</td>
<td>74/823 (9.1%)</td>
</tr>
<tr>
<td><strong>Cardiac arrhythmia</strong></td>
<td>1/8 (0.0%)</td>
<td>76/1587 (4.8%)</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>0/8 (0.0%)</td>
<td>30/423 (0.9%)</td>
</tr>
<tr>
<td><strong>Edema (includes swelling)</strong></td>
<td>1/8 (0.0%)</td>
<td>32/222 (14.4%)</td>
</tr>
<tr>
<td><strong>Pneumonia</strong></td>
<td>1/8 (0.0%)</td>
<td>28/686 (4.1%)</td>
</tr>
<tr>
<td><strong>Incontinence (non-bacteremia)</strong></td>
<td>1/8 (0.0%)</td>
<td>28/686 (4.1%)</td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>0/8 (0.0%)</td>
<td>3/18 (5.3%)</td>
</tr>
<tr>
<td><strong>Vascular insufficiency due to steal syndrome (includes ischemia)</strong></td>
<td>1/8 (0.0%)</td>
<td>74/823 (9.1%)</td>
</tr>
<tr>
<td><strong>Sino-pain</strong></td>
<td>0/8 (0.0%)</td>
<td>3/18 (5.3%)</td>
</tr>
<tr>
<td><strong>Trauma to major veins, arteries, nerves</strong></td>
<td>1/8 (0.0%)</td>
<td>1/8 (0.0%)</td>
</tr>
<tr>
<td><strong>Wound problems</strong></td>
<td>1/8 (0.0%)</td>
<td>3/18 (5.3%)</td>
</tr>
<tr>
<td><strong>Renal mechanical failure (preclinical technical failure)</strong></td>
<td>0/8 (0.0%)</td>
<td>27/2314 (1.2%)</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>1/8 (0.0%)</td>
<td>5/12 (0.0%)</td>
</tr>
</tbody>
</table>

1. 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 peri-operative 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 whenever the infection could be identified.

#### Table 4 Notes:
1. Total number of events, 8. Subjects with at least one event, 9. All subjects with at least one event.
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

ALTHOUGH THIS PRODUCT HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS WITH ALL REASONABLE CARE, MERIT MEDICAL SYSTEMS, INC. HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MERIT MEDICAL SYSTEMS, INC. THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. DESCRIPTIONS OR SPECIFICATIONS IN MERIT MEDICAL SYSTEMS, INC. PRINTED MATERIAL, INCLUDING THIS PUBLICATION, ARE MEANT SOLELY TO GENERALLY DESCRIBE THE PRODUCT AT THE TIME OF MANUFACTURE AND DO NOT CONSTITUTE ANY EXPRESS WARRANTIES. MERIT MEDICAL SYSTEMS, INC. SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MERIT MEDICAL SYSTEMS, INC. TO ANY REPRESENTATION, CONDITION, WARRANTY OR LIABILITY WITH RESPECT TO THE PRODUCT.

THE EXCLUSIONS AND LIMITATIONS SET OUT ABOVE ARE NOT INTENDED TO, AND SHOULD NOT BE CONSTRUED SO AS TO CONTRAVENE MANDATORY PROVISIONS OF APPLICABLE LAW. IF ANY PART OR TERM OF THIS WARRANTY DISCLAIMER IS HELD TO BE ILLEGAL, UNENFORCEABLE OR IN CONFLICT WITH APPLICABLE LAW BY A COURT OF COMPETENT JURISDICTION, THE VALIDITY OF THE REMAINING PORTIONS OF THIS WARRANTY DISCLAIMER SHALL NOT BE AFFECTED, AND ALL RIGHTS AND OBLIGATIONS SHALL BE CONSTRUED AND ENFORCED AS IF THIS WARRANTY DISCLAIMER DID NOT CONTAIN THE PARTICULAR PART OR TERM HELD TO BE INVALID AND THE INVALID PART OR TERM SHALL BE SUBSTITUTED BY A VALID PART OR TERM WHICH BEST REFLECTS MERIT MEDICAL SYSTEMS, INC.'S LEGITIMATE INTEREST IN LIMITING ITS LIABILITY OR WARRANTY.

In the event that such a disclaimer is found invalid or unenforceable for any reason: (i) any action for breach of warranty must be commenced within one year after any such claim or cause of action accrued and (ii) the remedy for such breach is limited to the replacement of the product. Prices, specifications and availability are subject to change without notice.

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
www.merit.com/hero

Authorized Representative:
Merit Medical Ireland Ltd
Parkmore Business Park West
Galway, Ireland
EC Customer Service +35 43 3588222
www.merit.com/hero

REFERENCES


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