INSTRUCTIONS FOR USE

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.

STERILE (EO) – FOR SINGLE USE ONLY

Each component of the HeRO Graft is provided in double sterile barrier packaging and is EO sterilized. DO NOT re-sterilize.

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.

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

Venous Outflow Component

- 5mm ID
- 19F (6.3mm) OD
- 40cm silicone-coated outflow component
- Radiopaque marker band
- Kink & crush resistant nitinol reinforcement braid

A or B:

A: The Adapter (with the Support Seal)
B: The Adapter (without the Support Seal)

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

NOTE: The clamshells are always on the inflow graft end of the Adapter.

Use-By Date
Do Not Re-Use
Sterilized Using Ethylene Oxide
Consult Instructions for Use
Manufacturers
Keep Dry
Keep Away from Sunlight
MR Condition
Non-Pyrogenic
Do Not Re-sterilize
Not Made with Natural Rubber Latex
Do Not Use if Package is Damaged
Catalogue Number
Batch Code
Graft Expander
Graft Expansion End
The FDA classification name for the HeRO Graft is vascular graft prosthesis.

The Accessory Component Kit (may not be included) 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

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 1.4.3

CONTRAINDICATIONS

Implantation of the HeRO Graft is contraindicated if:

• The patient has known or suspected systemic infection, bacteremia or septicemia.

• The patient has a topical or subcutaneous infection associated with the implantation site.

• The patient has an 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.

• Do not place the HeRO Graft in the same vessel as a catheter, defibrillator or pacemaker lead.

• 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.

• 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 Acuseal) 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.

• Grafts that were implanted previously should not be used with the Adapter. The Adapter should NOT be connected to any graft other than a new graft listed in Table 1 on page 2, 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.

• For tapered grafts, advance only the unmodified 6mm ID end of the graft onto the inflow graft end of the Adapter.

• Are receiving inadequate dialysis clearance (i.e., low Kt/V) via catheters. KDOQI guidelines recommend a minimum Kt/V of 1.4.3

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 reprocess or reuse any component.

• VECTOR® grafts should NOT be used with the Adapter.

• 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 a known or suspected allergy to device materials (i.e., ePTFE, silicone, titanium, nitinol).

• The HeRO Graft is a single use only product. DO NOT reprocess or reuse any component.

• 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 a known or suspected allergy to device materials (i.e., ePTFE, silicone, titanium, nitinol).

• The patient has a topical or subcutaneous infection associated with the implantation site.

• The patient has a known or suspected systemic infection, bacteremia or septicemia.

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 serrated vascular clamp (e.g., Kocher).

• Do not use mechanical/rotational thrombectomy devices (e.g., Arrow-TreTrol PD™) in the Venous Outflow Component and/or connector or the Adapter as internal damage may occur to these components.

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:
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 150cm 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
- 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 exclude in patients with:
   - A small brachial artery (e.g., 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 (i.e., cancer)
   - Insufficient antiembolization or non-compliance with antiembolization 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 (i.e., spring loaded hemostasis clamps)
   - A subsequent coagulopathy or infection

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 utilizing a surgical marker and draw the HeRO Graft routing path in a soft C configuration on the upper arm.
3. If choosing to utilize an existing tunneled catheter tract, use standard over-the-wire exchange techniques to remove catheter.
4. Open the Accessory Component Kit using aseptic technique.

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: Suturing 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: Use of the HeRO Graft was clinically studied utilizing 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
7. Using fluoroscopic guidance, advance a 0.035” guidewire, at least 150cm 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, utilize 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.

**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 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. Flush the assembly with heparinized saline, and close the stopcock 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, remove the dilator from the sheath and immediately insert the hemostasis plug into the sheath alongside the guidewire. Ensure both plug seal rings are fully seated within the sheath and 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) by using a twisting motion. Holding the delivery stylet fixed, 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 short 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 cap on the Y-adapter.

18. Prior to completing removal of the 10F delivery stylet from the Venous Outflow Component, clamp it at the incision site. Complete the removal of the delivery stylet from the guidewire.

**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 at the incision site and close the stopcock.

22. Return the patient to standard supine position.

23. Make the connector site incision at the deltopectoral groove (DPG).

24. Holding the Venous Outflow Component away from the incision sites, use heavy duty scissors to cut the silicone Luer End off and discard 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 IMPRA® 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 GORE® Tunneler or Bard® Bi-Directional Tunneler may be used. Consult manufacturer IFUs for proper utilization.

Proceed to the ASSEMBLING THE ADAPTER section.

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 ePTFE vascular grafts in Tables 1 and 2. Vectra® grafts should not be used with the Adapter. Grafts containing a coating/bonding (e.g., heparin, gels, carbon, etc.) on the inner and/or outer surfaces (with the exception of Acuseal) 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.

**Table 1: US/EU Marketed 6mm ID Vascular Grafts (tested with Adapter)**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Diameter</th>
<th>Length</th>
<th>Wall</th>
<th>Catalogue Number US / EU</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>6mm</td>
<td>10cm</td>
<td>SW</td>
<td>25053, 25142, 25052</td>
<td>NO</td>
</tr>
<tr>
<td>GORE® ACUSEAL®</td>
<td>W.L. Gore &amp; Associates</td>
<td>6mm</td>
<td>40cm</td>
<td>-</td>
<td>ECH060040A - US ECH060040 - EU</td>
<td>NO</td>
</tr>
</tbody>
</table>

**Table 2: US/EU Marketed Vascular Grafts (permitted for use)**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Diameter</th>
<th>Length</th>
<th>Wall</th>
<th>Catalogue Number US / EU</th>
<th>Support Seal Required for HERO Graft Adapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>GORE-TEX®</td>
<td>W.L. Gore &amp; Associates</td>
<td>6mm</td>
<td>10cm</td>
<td>SW</td>
<td>V06010L V06020L V06030L V06040L V06050L</td>
<td>YES</td>
</tr>
<tr>
<td>IMPRA®</td>
<td>C.R. Bard</td>
<td>6mm</td>
<td>10cm</td>
<td>SW</td>
<td>10506 20506 30506 40506 50506</td>
<td>YES</td>
</tr>
</tbody>
</table>

**SW = Standard Wall**

GENERAL WARNINGS:

Caution: Grafts that were implanted previously should not be used with the Adapter. The Adapter should NOT be connected to any graft other than a new graft listed in Table 1 and 2. For questions, contact customer service at 1-800-356-3748 or your local Merit Representative.

Caution: For tapered grafts, advance only the unmodified 6mm ID end of the graft onto the inflow graft end of the Adapter.

Caution: Assembly of the Adapter, Support Seal 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 from Table 1 and deliver to the sterile field.
3. Remove all the parts from the Adapter pouch insert card.

**NOTE:** Assembly of the Adapter may be better facilitated by performing the procedure over a flat sterile surface.
4. Based on Table 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. 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 10 cm from the 6 mm ID end of the graft.

7. Using dry gloves, insert the tapered end of the Graft Expander into the 6 mm ID graft end that will interface with the Adapter. Advance the graft as much as possible up to the Graft Expander shoulder to expand the end of the graft. 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.

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

**NOTE:** If advancement of the graft is difficult, expansion of the end of the graft can be repeated as needed using the Graft Expander.

10. 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 required) are fully advanced up to the shoulder of the Adapter.

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

**NOTE:** If using the Support Seal, verify that no portion of the Support Seal coil is under the clamshell halves while the silicone sleeve is flush with the shoulder of the Adapter.

11. Pinch the clamshells of the Adapter between the thumb and index fingers of both hands as tightly as possible.
12. To ensure complete closure of the Adapter clamshells, firmly clamp with a serrated vascular clamp.  

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

**NOTE:** Ensure the hinge of the clamshells is facing the hinge of the serrated vascular clamp as shown above.  

**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.  

13. The Adapter with graft assembly is now ready for implant.  

**IMPLANTING THE GRAFT**  
1. Make an incision at the selected arterial anastomosis site. Expose the artery, verify patency and verify the ID is greater than 3mm in size.  

**Caution:** Use of the HeRO Graft was clinically studied utilizing 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.  

**ATTENTION:**  
1. For ePTFE grafts that are used with the Adapter, consult the manufacturer Instructions for Use for proper tunneling and implantation.  
2. Leave approximately 8cm of the graft exposed at the DPG incision site.  
3. Cut the graft from the tunneler.  

**CONNECTING THE HeRO GRAFT**  
1. Place a sterile 4x4 gauze pad between the Venous Outflow Component and the DPG incision site.  
2. Determine the required Venous Outflow Component length and squarely cut it to the desired length.  

**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 the barbs of the Adapter's Venous Outflow Component end and up to the connector or Adapter shoulder.  

**NOTE:** Avoid excessive force on the Support Seal during connection.  

**Caution:** The HeRO Graft Venous Outflow Component was designed to engage both barbs of the connector tightly. If separation is necessary, a new straight cut should be made to the Venous Outflow Component near the Adapter's Venous Outflow Component end. Take special care when trimming and removing the excess Venous Outflow Component piece from the Adapter's Venous Outflow Component end. Clean the Adapter of any material or residue. If damage occurs to the Adapter's Venous Outflow Component end 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 the Support Seal. Ensure it is not crushed or damaged.  

**Caution:** If damage to the Support Seal is noted during implant, new components should be used. 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 clamp from the Venous Outflow Component and back-bleed.
8. Clamp 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 Venous Outflow Component connection site or at the inflow graft end connection site and then 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 section, step 1). 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 sterile scissors, make a transverse cut to the ePTFE 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 sterile scissors, make a transverse 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 ePTFE 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 ePTFE graft at the DPG site by following the ASSEMBLING THE ADAPTER section with steps 1 through 13.
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 ePTFE Graft and Replace with HeRO Graft Arterial Graft Component**

1. Using sterile scissors, make a transverse cut to the Venous Outflow Component near the Venous Outflow Component end of the Adapter.
2. Remove the Adapter, Support Seal (if applicable), ePTFE 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 and verify there is no leakage at the Venous Outflow Component connection site and graft connection site with the Adapter using angiography. If there is a leak at the Adapter site, see TROUBLESHOOTING FOR LEAKS section.
4. Verify thrill and bruit.
5. Evaluate for steal syndrome during the implant procedure.

**NOTE:** Banding may reduce flow in the HeRO Graft.
6. Close all three incision sites.

**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.

**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 section, step 1).
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 sterile scissors, make a transverse cut to the ePTFE graft close to the inflow graft end of the Adapter (Fig. 9 and 10) or the Support Seal coil (if applicable, Fig. 11 and 12).

**OPTION 2: Remove and Replace Adapter and Support Seal (if applicable)**

1. Using sterile scissors, make a transverse cut to the ePTFE 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 sterile scissors, make a transverse 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 ePTFE 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 ePTFE graft at the DPG site by following the ASSEMBLING THE ADAPTER section with steps 1 through 13.
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.
2. Using sterile scissors, make a transverse cut to the Venous Outflow Component near the Venous Outflow Component end of the Adapter (Fig. 13 and 14) or Adapter with Support Seal (if applicable, Fig. 15 and 16).

3. Remove the Adapter and cut portions of the ePTFE graft, Support Seal (if applicable), and Venous Outflow Component (that are attached to the Adapter).

4. Measure the length that is required for the interpositional ePTFE graft. The measured length should exceed the lengths of the cut portions of the ePTFE graft, Support Seal (if applicable), and Venous Outflow Component that were removed during steps 1 and 2.

5. Deliver a new ePTFE 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 ePTFE graft and transversely cut the graft to length.

7. Using the new ePTFE graft segment, sew an end-to-end anastomosis to the implanted ePTFE 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 ePTFE graft by following the ASSEMBLING THE ADAPTER section beginning with steps 1 - 11.

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 ePTFE Graft and Replace with HeRO Graft Arterial Graft Component.

1. Using sterile scissors, make a transverse 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).

2. Remove the Adapter, Support Seal (if applicable), ePTFE 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.

- 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 at www.merit.com/hero.

PERCUTANEOUS THROMBECTOMY

The HeRO Graft will require maintenance equivalent to conventional ePTFE grafts. The HeRO Graft can be up to 90cm long; thus requiring 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 Adapter as internal damage may occur to these components.

For specific thrombectomy instructions or guidance, please contact Customer Service at 1-800-356-3748 for a copy of the Thrombectomy Guidelines or it may also be found on www.herograft.com.

DEVICE EXPLANT, EXCHANGE, REVISION OR ABANDONMENT

The HeRO Graft, Adapter, Support Seal (if applicable), and Venous Outflow Component should be removed if the device will not be used for hemodialysis access. In situations where the HeRO Graft requires exchange, explant or revision, please contact Customer Service at 1-800-356-3748 for an instruction procedure and an Explant Return Kit. Instructions for use may also be found at www.merit.com/hero.

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.

NOTE: Consult the graft manufacturer’s IFU for more information regarding the cannulation of the commercially available graft selected for use with the Adapter.

- 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.
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- 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.
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The HeRO Graft has an associated safety profile that is comparable to existing grafts 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.10 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 hepatic arrestive error occurred. The (5) 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 events were directly attributed to an earlier generation 22F HeRO Graft Venous Outflow Component, which required an internal jugular venous cut-down.

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

<table>
<thead>
<tr>
<th>Device/Procedure-Related Factor</th>
<th>HeRO Graft Patency Study (N = 50)</th>
<th>HeRO Graft Endpoint &amp; Performance Data (N = 38)</th>
<th>Catheater Literature</th>
<th>ePTFE Graft Literature</th>
<th>KDOQI Adequacy of Hemodialysis Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Days % (n/N)</td>
<td>77.8 (28/36)</td>
<td>72.8 ± 0.0 (N = 21)</td>
<td>76 (75/100) (9.4 %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Patency at 6 Months % (n/N)</td>
<td>50.0 (18/36)</td>
<td>70.0 ± 0.0 (N = 30)</td>
<td>37% (12/32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary Patency at 12 Months % (n/N)</td>
<td>36.0 (13/36)</td>
<td>65.0 ± 0.0 (N = 26)</td>
<td>70 - 75%</td>
<td></td>
<td>70 ± 17%</td>
</tr>
<tr>
<td>Adaptable to放宽 (n/Ma)</td>
<td>84 ± 9</td>
<td>74.3 ± 3.8 ± (N = 24)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Months % (n/N)</td>
<td>47.2 (17/36)</td>
<td>71.8 ± 0.0 (N = 21)</td>
<td>76 ± 30% (9.4 %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant procedure-related bacteremia</td>
<td>1.9 % (1/52)</td>
<td>47% (1/2214 ± 12.6 %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vascular access-related bacteremia</td>
<td>2.6% (1/38)</td>
<td>28/686 (4.1 %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac arrhythmia</td>
<td>1/1 (2.6%)</td>
<td>1/1 (2.6%)</td>
<td>30/432 (6.9 %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0/0 (0 %)</td>
<td>0/0 (0 %)</td>
<td>1/1 (2.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin complications</td>
<td>1/1 (2.6%)</td>
<td>1/1 (2.6%)</td>
<td>32/222 (14.4 %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>1/1 (2.6%)</td>
<td>1/1 (2.6%)</td>
<td>28/686 (4.1 %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>1/1 (2.6%)</td>
<td>1/1 (2.6%)</td>
<td>28/686 (4.1 %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>0/0 (0 %)</td>
<td>0/0 (0 %)</td>
<td>1/1 (2.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vascular insufficiency due to intimal factor (includes ischemia)</td>
<td>1/1 (2.6%)</td>
<td>1/1 (2.6%)</td>
<td>32/222 (14.4 %)</td>
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<td>Trauma to major veins, arteries, nerves</td>
<td>0/0 (0 %)</td>
<td>0/0 (0 %)</td>
<td>1/1 (2.6%)</td>
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<td></td>
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<tr>
<td>Blood pressure (includes wound dehiscence)</td>
<td>1/1 (2.6%)</td>
<td>0/0 (0 %)</td>
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<tr>
<td>Breakage or mechanical failure (prosthesis technical failure)</td>
<td>0/0 (0 %)</td>
<td>1/1 (2.6%)</td>
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<td></td>
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<tr>
<td>Other</td>
<td>0/0 (0 %)</td>
<td>0/0 (0 %)</td>
<td>32/222 (14.4 %)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Table 4 illustrates 1 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/or just device or procedure-related deaths. V Graft literature reports all infections including bacteria or sepsis. VI Other v device-related and/or procedure-related events included right atrial cath, hypotension with pressure, non-sustained mild and ventricular tachycardia, pneumonia, cardiacogenic shock, hypoglycemia, hypotension, cerebrospinal fluid infected.

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

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<td></td>
</tr>
<tr>
<td>Bleeding, hemorrhage or hematoma</td>
<td>2/2 (10%)</td>
<td>6/6 (11.1 %)</td>
<td>78/429 (19.1 %) per ESRD subjects</td>
<td>1/12 (8.3 %) per ESRD subjects</td>
</tr>
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</tr>
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MR Implant-related complications. In non-clinical testing, the HeRO Graft produced the following temperature rises during MRI performed for 15-min of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA, software Numaris/4, Version Syngo MR 2002B DHHS Active-shield, horizontal field scanner) and 3-Tesla (3-Tesla/128-MHz, Excite, HDx, software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI systems:

- 1.5-Tesla 3-Tesla
- MR system reported, whole body averaged SAR 2.9-W/kg 2.9-W/kg
- Calorimetry measured values, whole body averaged SAR 2.3-W/kg 2.7-W/kg
- Highest Temperature change +2.4ºC +2.9ºC

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.
REFERENCES


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