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 resterilize.

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 longterm 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 only one of the following options:

• The Arterial Graft Component (not included)
• The Adapter (a separate commercially available 6mm ID vascular graft is not included with the Adapter)

NOTE: Only ONE of the following options should be used in conjunction with the Venous Outflow Component.

OPTION 1: Arterial Graft Component
The Arterial Graft Component has a 6mm ID, 7.4mm OD, and is 53cm long, inclusive of the connector. It consists of an expanded polytetrafluoroethylene (ePTFE) hemodialysis graft with PTFE beading to provide kink resistance near the titanium connector.

OPTION 2: The Adapter
The adapter connects a 6mm ID vascular graft (not included) to the Venous Outflow Component. The adapter (titanium) 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 Accessory Component Kit (not 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.

**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 (i.e., ePTFE, silicone, titanium, nitinol).
- The patient has a topical or subcutaneous infection associated with the implantation site.
- The patient has known or suspected systemic infection, bacteremia or septicemia.

**GENERAL WARNINGS**

- Use of the HeRO Graft was clinically studied in the IJV. Implantation of the device in other vasculature has NOT been studied and may increase the risk of adverse events not encountered in the clinical trial.
- DO NOT use product if package has been damaged, opened, or the use by date has passed, as sterility may be compromised.
- The HeRO Graft is a single use only product. DO NOT resterilize or reuse any component.
- Vectra® grafts should NOT be used with the Adapter.
- Grafts containing reinforcement structures in the region that will interface with the Adapter should NOT be used.
- Grafts containing a coating/bonding (e.g., heparin, gels, carbon, etc.) on the inner and/or outer surfaces (with the exception of Gore® 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.
- Only grafts indicated for AV access should be used with the Adapter.
- 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, under the ASSEMBLING THE ADAPTER section.
- During the assembly of the Adapter, ensure the graft is flush with the shoulder of the Adapter prior to engaging the clamshells of the Adapter.

**GENERAL CAUTIONS**

- Only qualified healthcare practitioners should place, manipulate, cannulate, declot, revise or explant the device.
- The HeRO Graft is intended for use by physicians trained and experienced in endovascular and surgical interventions and techniques.
- Adhere to universal precautions when implanting, cannulating, maintaining or explanting the device.
- DO NOT place the HeRO Graft in the same vessel as a catheter, defibrillator or pacemaker lead.
- To avoid vessel damage, fluoroscopy must be used when inserting the HeRO Graft into the central venous system.
• Monitor the patient for signs of arrhythmia throughout the procedure. To minimize the risk of arrhythmia, DO NOT place the tip of the guidewire into the right ventricle.

• Caution should be used when placing or removing the Venous Outflow Component where stent contact may occur due to the potential for Venous Outflow Component or vessel damage.

• When connecting the Venous Outflow Component and ePTFE graft to the Adapter, verify the Venous Outflow Component and ePTFE graft are flush with the shoulder of the Adapter.

• When connecting the Venous Outflow Component to the Arterial Graft Component, verify the Venous Outflow Component is flush with the connector shoulder.

• 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.

• Do not use mechanical/rotational thrombectomy devices (e.g., Arrow-Trerotola PTD®) 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:

- Thrombosis is the most common cause of vascular access dysfunction. Missed hemodialysis sessions significantly increase the number of thrombosis episodes in AVFs and AVGs.

- 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 and ePTFE graft to the Adapter, verify the Venous Outflow Component and ePTFE graft are flush with the shoulder of the Adapter.

- When connecting the Venous Outflow Component to the Arterial Graft Component, verify the Venous Outflow Component is flush with the connector shoulder.

- 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.

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

PROCEDURE ACCESSORIES

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

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

- 5F micro-puncture set
- Various 0.035" guidewires at least 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 atraumatic vascular clamps
- Standard vessel loops
- Syringe & syringe adapter
- Sterile surgical lubricant
- Access needles

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 (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 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 (i.e., spring loaded hemostasis clamps)

Thrombosis is the most common cause of vascular access dysfunction. Missed hemodialysis sessions significantly increase the number of thrombosis episodes in AVFs and 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: Suture the tract closed from the existing catheter to HeRO Graft tract.

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

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

5. Prophylactically treat the patient in the peri-operative period with antibiotics based upon the patient’s bacteremia history:
   • Ancef or combination Vancomycin and Gentamycin for native stick Venous Outflow Component placement
   • Vancomycin and Gentamycin for over-the-wire exchange of a tunneled cuffed dialysis catheter
   • Vancomycin and Gentamycin for femoral catheter placement and atypical HeRO Graft placement

6. Using ultrasound guidance, gain percutaneous access to the venous system utilizing a 5F micropuncture set and standard Seldinger technique.

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 clinical trial. When using the subclavian vein for venous access, a more lateral percutaneous approach might mitigate the risk of clavicle crush or occlusion of the Venous Outflow Component. Consideration should be made to follow these patients with clavicle imaging to monitor the potential of interaction of the clavicle and first rib with the Venous Outflow Component.

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 styelt 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, 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 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. 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.

25. Using a standard IMPRA® Kelly-Wick tunneler with a 6mm bullet tip, tunnel from the DPG to the venous incision site. 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.

If using the Arterial Graft Component, proceed to the IMPLANTING THE GRAFT section. If not, 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 6mm ID ePTFE vascular grafts in Table 1. 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 GORE® 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.

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<th>Trade Name</th>
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<th>Length</th>
<th>Wall</th>
<th>Catalogue Number</th>
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<td>10cm</td>
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<td>W.L. Gore &amp; Associates</td>
<td>40cm</td>
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</table>

**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. For questions, contact customer service at 770-419-3355 or your local CryoLife Representative.

Caution: Assembly of the Adapter and selected graft from Table 1 should be done using powder free, clean and dry gloves.

1. Select a new graft from Table 1.
2. Using aseptic technique, open the Adapter package and verify the selected graft from Table 1 and deliver to the sterile field.
3. Remove all 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. Using dry gloves, 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 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 end may make assembly of the graft and the Adapter more difficult.

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

6. 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 graft end using the Graft Expander can be repeated as needed.

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

8. To ensure complete closure of the Adapter clamshells, firmly clamp with a serrated vascular clamp (e.g., Kocher). 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 (e.g., Kocher) 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.

9. The Adapter assembly is now ready for implant.

**IMPLANTING THE GRAFT**

**NOTE:** Using aseptic technique, open the Arterial Graft Component if being used.
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: For ePTFE grafts that are used with the Adapter, consult the manufacturer Instructions for Use for proper tunneling and implantation.

2. For the Arterial Graft Component, use a standard tunneler with a 7mm bullet tip to create a tunnel from the arterial incision site to the DPG. Graft routing will vary depending on patient-specific anatomy.

3. Replace the 7mm bullet tip with the 6mm bullet tip.

4. Attach the non-connector end of either the Arterial Graft Component or the Adapter assembly onto the 6mm bullet tip and secure a tight connection with a suture(s).

5. Gently pull the graft through the tunnel to the arterial incision site. Graft markings should be used to verify it has not twisted.

6. Leave approximately 8cm of the graft exposed at the DPG incision site.

7. 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 connector or the Adapter 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 connector or the Adapter Venous Outflow Component end and up to the connector or Adapter shoulder.

NOTE: Avoid excessive force on the graft beading 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 connector or the Adapter Venous Outflow Component end. Take special care when trimming and removing the excess Venous Outflow Component piece from the connector or the Adapter Venous Outflow Component end. Clean the connector or the Adapter Venous Outflow Component end of any material or residue. If damage occurs to the connector or 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 graft beading as this may adversely impact the integrity of the graft. It is important during device connection to avoid contact with the beading. Ensure neither are crushed or damaged.

Caution: If damage to the beading is noted during implant, new components should be used. Damaged or crushed beading 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 connector or Adapter and flush with the connector or 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 connector or 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 beading.

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 and graft connection site with the Adapter, 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 section, steps 1 through 4). 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 Adapter and Replace with a New Adapter

1. Using sterile scissors, make a transverse cut to the ePTFE graft close to the inflow graft end of the Adapter.
1. Using sterile scissors, make a transverse cut to the Venous Outflow Component near the Venous Outflow Component end of the Adapter.

2. Using sterile scissors, make a transverse cut to the Venous Outflow Component near the Venous Outflow Component end of the Adapter.

3. Remove the Adapter and the cut portions of the ePTFE graft and Venous Outflow Component (that are attached to the Adapter). Contact Customer Service at 770-419-3355 for an instruction procedure for returning the removed product and to receive an Explant Return Kit.

4. Deliver a new Adapter to the sterile field using aseptic technique.

5. Attach the new Adapter to the implanted ePTFE graft at the DPG site by following the ASSEMBLING THE ADAPTER section beginning with steps 3 through 8.

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 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, 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 from the IMPLANTING THE GRAFT and CONNECTING The HeRO GRAFT sections.

**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 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 and Venous Outflow Component that were removed during steps 1 and 2.

5. Deliver a new ePTFE graft (from Table 1, 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 to the sterile field using aseptic technique.

9. Attach a new Adapter to the ePTFE graft by following the ASSEMBLING THE ADAPTER section beginning with steps 3 through 8.

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.

**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. Provide the patient with the remaining items in the Patient Information Pouch.

**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, steps 1 through 4).

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.

2. Using sterile scissors, make a transverse cut to the Venous Outflow Component near the Venous Outflow Component end of the Adapter.

3. Remove the Adapter and the cut portions of the ePTFE graft 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 and Venous Outflow Component that were removed during steps 1 and 2.

5. Deliver a new ePTFE graft (from Table 1, 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 to the sterile field using aseptic technique.

9. Attach a new Adapter to the ePTFE graft by following the ASSEMBLING THE ADAPTER section beginning with steps 3 through 8.

10. Attach the Venous Outflow Component to the Adapter by following the CONNECTING THE HeRO GRAFT section.
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.

2. Remove the Adapter, 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 from the IMPLANTING THE GRAFT AND CONNECTING THE HeRO GRAFT sections.

VASCULAR ACCESS CANNULATION

Follow KDQOI guidelines for graft assessment, preparation and cannulation.

• The ePTFE of the Arterial Graft Component requires 2-4 weeks to incorporate prior to cannulation.

NOTE: Consult the graft manufacturer's IFU for more information regarding the cannulation of the other commercially available grafts 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 graft beading of the Arterial Graft Component.

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

For specific thrombectomy instructions or guidance, please contact Customer Service at 770-419-3355 for an instruction procedure and an Explant Return Kit. Instructions may also be found in the Frequently Asked Questions section of www.herograft.com.

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/or connector or the Adapter as internal damage may occur to these components.

For specific thrombectomy instructions or guidance, please contact Customer Service at 770-419-3355 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 Arterial Graft Component connector, Adapter, and Venous Outflow Component should be removed if the device will not be used for hemodialysis access. In situations where the HeR,O Graft requires exchange, explant or revision, please contact Customer Service at 770-419-3355 for an instruction procedure and an Explant Return Kit. Instructions may also be found in the Frequently Asked Questions section of www.herograft.com.

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"),4 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").5 6

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 2.

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 that reported in the literature for conventional ePTFE grafts. HeRO Graft patency and adequacy of dialysis are significantly improved compared to that reported in the literature for conventional ePTFE grafts.

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 3.

Device-related adverse events occurred at a frequency comparable to both the catheter and graft literature with the exception of bleeding.4 5 6 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 22F HeRO Graft Venous Outflow Component, which required an internal jugular venous cut-down. The sixth bleeding event was related to a HeRO Graft explant procedure. There was one (1) device-related death in the patency study due to device-related sepsis complications, a known vascular access complication reported in the literature.4 6

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Note: The text above includes technical medical information that may require specific knowledge to understand fully. The document appears to be a guideline for the use of a medical device, specifically the HeRO Graft, and includes instructions for cannulation, maintenance, and removal. It also references studies and literature regarding the device's performance and safety profile.
These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

<table>
<thead>
<tr>
<th>Device/Procedure-Related Bacteremia Rate/1,000 Days</th>
<th>HeRO Graft Bacteremia Study (N=36)</th>
<th>HeRO Graft Patency Study (N=50)</th>
<th>Catheter Literature</th>
<th>ePTFE Graft Literature</th>
<th>KDOQI Adequacy of Hemodialysis Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>70,000 days (1.45 Upper Confidence Bound (UCB))</td>
<td>0.25% (1/40)</td>
<td>0.00% (0/50)</td>
<td>48% (18/38)</td>
<td>2.7±1.6/1,000</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Primary Patency at 6 Months % (n/N)</td>
<td>44.1% (19/43)</td>
<td>36% (18/50)</td>
<td>21% (3/14)</td>
<td>3.0/1,000</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Secondary Patency at 6 Months % (n/N)</td>
<td>65.6% (28/43)</td>
<td>58% (29/50)</td>
<td>25% (4/16)</td>
<td>0.13/1,000</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Primary Patency at 12 Months % (n/N)</td>
<td>73.7% (32/43)</td>
<td>60% (30/50)</td>
<td>34% (5/15)</td>
<td>0.13/1,000</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Secondary Patency at 12 Months % (n/N)</td>
<td>87.0% (36/43)</td>
<td>70% (35/50)</td>
<td>37% (5/14)</td>
<td>0.13/1,000</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

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

Table 3: Final HeRO Graft Serious Device and/or Implant Procedure-Related Adverse Events by Type from U.S. Multi-Center Clinical Trials

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

Table 3 Footnotes:
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 not just device or procedure-related deaths; V. Graft literature reports all infections including bacteremia or sepsis; VI ‘Other’ serious device and/or procedure related events included the overall ESRD population vs specific catheter or graft populations. Additionally, some catheter literature data is only appropriate to report per catheter rather than per subject such as procedure related adverse events.

MRI INFORMATION
Non-clinical testing has demonstrated that the HeRO Graft is MR-conditionable. A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient magnetic field of 720-Gauss / cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) Normal Operating Mode of operation for the MR system

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) Normal Operating Mode of operation for the MR system

<table>
<thead>
<tr>
<th>MRI System</th>
<th>Temperature Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5-Tesla</td>
<td>+2.4°C</td>
</tr>
<tr>
<td>3-Tesla</td>
<td>+2.9°C</td>
</tr>
</tbody>
</table>

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.
Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the HeRO Graft. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of this implant. The lumen of this device cannot be visualized on the pulse sequences used for this evaluation.

Pulse Sequence | T1-SE | T1-SE | GRE | GRE
---|---|---|---|---
Signal Void Size: | 7,899mm² | 501mm² | 8,929mm² | 1,530mm²
Plane Orientation: | Parallel | Perpendicular | Parallel | Perpendicular

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

CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144 • United States
Customer Service: 770-419-3355
Fax: 770-590-3753
www.herograft.com

REFERENCES

A bibliography of HeRO Graft publications and presentations is available at www.herograft.com.