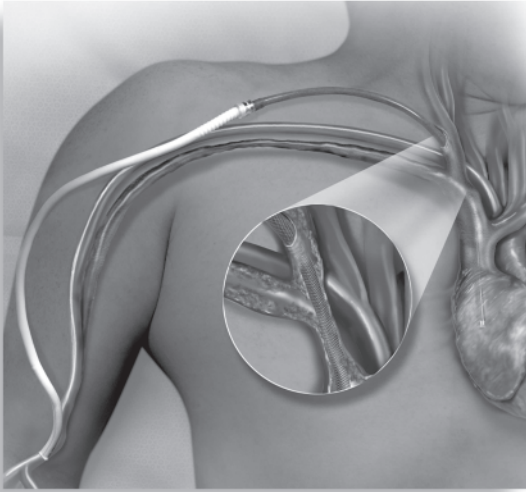
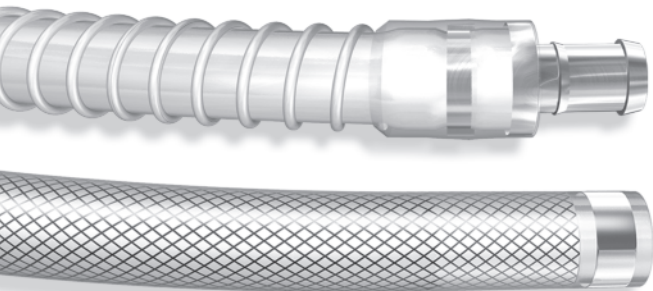


# Instructions for Use



**HeRO<sup>®</sup>**  
*Graft*



**HeRO<sup>®</sup>**  
[Hemodialysis Reliable Outflow]  
**Graft**

## 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, de-clot, 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 in accordance with ISO 11135.

**DO NOT** resterilize.

## STORAGE

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



Caution



Consult Instructions for Use



Use By



Do Not Reuse



Sterilized Using Ethylene Oxide



Product Code



Lot Number



MRI Conditional



Non-Pyrogenic



Do Not Resterilize

**LATEX FREE**

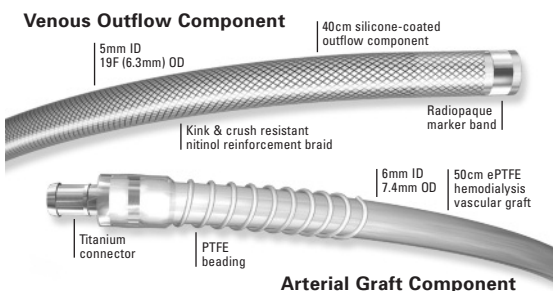
Latex Free



Manufacturer

## DEVICE DESCRIPTION

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



HeRO consists of two primary components:

- A proprietary **Venous Outflow Component**
- A proprietary ePTFE **Arterial Graft Component**

The HeRO **Venous Outflow Component** 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 distal tip.

The HeRO **Arterial Graft Component** has a 6mm ID, 7.4mm OD, and is 53cm long, inclusive of the connector. It consists of an ePTFE hemodialysis graft with PTFE beading to prevent kinking near the proprietary titanium connector. The titanium connector attaches the graft component to the outflow component. The HeRO graft component is cannulated using standard technique according to KDOQI guidelines.

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

The FDA regulation 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<sup>1</sup> 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.
- 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.<sup>22</sup>

## CONTRAINDICATIONS

**Implantation of the HeRO device 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 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 device 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 is a single use only product. DO NOT re-sterilize or reuse any component.**

## **GENERAL CAUTIONS**

- **Only qualified healthcare practitioners should place, manipulate, cannulate, de-clot, revise or explant the device.**
- **HeRO 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 device in the same vessel as a catheter, defibrillator or pacemaker lead.**
- **To avoid vessel damage, fluoroscopy must be used when inserting the HeRO device 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.**

## 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:

<b>Potential Vascular Graft &amp; Catheter Complications</b>	<b>Potential Intraoperative &amp; Post-Operative Complications</b>
<ul style="list-style-type: none"> <li>• Seroma</li> <li>• Infection</li> <li>• Foreign body reaction or rejection</li> <li>• Vascular graft revision / replacement</li> <li>• Vascular insufficiency due to steal syndrome</li> <li>• Partial or full occlusion of prosthesis or vasculature</li> <li>• Prosthesis failure</li> <li>• Device kinking or compression</li> <li>• Site pain</li> <li>• Device migration</li> <li>• Anastomosis or wound dehiscence</li> <li>• Pseudoaneurysm</li> <li>• Edema</li> <li>• Ectasia</li> <li>• Abnormal healing / skin erosion</li> <li>• Graft extravasation</li> </ul>	<ul style="list-style-type: none"> <li>• Reactions to anesthesia</li> <li>• Respiratory / cardiac arrest</li> <li>• Myocardial infarction</li> <li>• Hypotension / hypertension</li> <li>• Death</li> <li>• Bleeding</li> <li>• Hematoma</li> <li>• Heart failure</li> <li>• Cardiac arrhythmia</li> <li>• Cardiac tamponade</li> <li>• Sepsis</li> <li>• Trauma to major vasculature or nerves</li> <li>• Embolism</li> <li>• Pneumothorax, hemothorax, or hydrothorax</li> <li>• Aneurysm</li> <li>• Allergic reaction</li> </ul>

## **SUMMARY OF HeRO CLINICAL EXPERIENCE (CLINICAL DATA AS OF 04/23/2008)**

The HeRO device 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 device was studied in two different patient populations. One was a prospective literature controlled study of HeRO device / implant procedure-related bacteremia rates in catheter-dependent subjects (the "bacteremia study"), and; the other was a randomized study of HeRO device 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 device. 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 1**.

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

The HeRO device 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 device and / or procedure-related adverse events by type are summarized in **Table 2**.

Device-related adverse events occurred at a frequency comparable to both the catheter and graft literature with the exception of bleeding.<sup>2,3</sup> Of the six (6) bleeding events in the patency study, two (2) were indirectly related to the HeRO device implant procedure; in the first patient, coagulopathy was caused by other conditions and bleeding was not unexpected, and in the second patient, a heparin administrative error occurred. Three (3) bleeding events were directly attributed to an earlier generation 22F HeRO Outflow Component, which required an internal jugular venous cut-down. The sixth bleeding event was related to a HeRO 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.<sup>2,3</sup>

**TABLE 1: Final HeRO Endpoint & Performance Data from (data as of 04/23/2008)**

		<b>HeRO Bacteremia Study (N=36)</b>	<b>HeRO Patency Study (N=50)</b>
<b>Device/Procedure- Related Bacteremia Rate/ 1,000 Days<sup>1</sup></b>		0.70/1,000 days (1.45 Upper Confidence Bound (UCB))	0.13/1,000 days (0.39 Upper Confidence Bound (UCB))
<b>Primary Patency at 6 Months % (n/N)</b>		47.2 (17/36)	48.0 (24/50)
<b>Assisted Primary Patency at 6 Months % (n/N)</b>		94.4 (34/36)	88.0 (44/50)
<b>Secondary Patency at 6 Months % (n/N)</b>		77.8 (28/36)	78.0 (39/50)
<b>Primary Patency at 12 Months % (n/N)</b>		33.3 (12/36)	36.0 (18/50)
<b>Assisted Primary Patency at 12 Months % (n/N)</b>		88.9 (32/36)	84.0 (42/50)
<b>Secondary Patency at 12 Months % (n/N)</b>		77.8 (28/36)	70.0 (35/50)
<b>Adequacy of Dialysis ±SD [Min, Max]</b>	<b>Kt/V</b>	1.7 ± 0.3 (N=24) [1.2,2.4]	1.6 ± 0.3 (N=33) [0.9,2.3]
	<b>URR</b>	74.3 ± 3.8 (N=24) [65.3,83.0]	72.8 ± 6.0 (N=21) [61.0,83.8]

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

**U.S. Multi-Center Pivotal Clinical Trials**

<b>Catheter Literature</b>	<b>ePTFE Graft Literature</b>	<b>KDOQI Adequacy of Hemodialysis Guidelines</b>
2.3/1,000 <sup>4</sup>	0.11/1,000 <sup>5</sup>	Not Applicable
50% <sup>6-11</sup>	58% <sup>13</sup>	Not Applicable
92% <sup>12</sup>	68% <sup>14, 15</sup>	Not Applicable
55% <sup>6-11</sup>	76% <sup>13</sup>	Not Applicable
36% <sup>6-8, 10</sup>	42% <sup>13</sup>	Not Applicable
Not Reported	52% <sup>14, 15</sup>	Not Applicable
37% <sup>6-8, 10</sup>	65% <sup>13</sup>	Not Applicable
1.29 -1.46 <sup>16-19</sup>	1.37-1.62 <sup>16-19</sup>	1.4 target <sup>22</sup>
65-70 <sup>12, 17-21</sup>	70-73 <sup>17-21</sup>	70 target <sup>22</sup>

**TABLE 2: Final HeRO Serious Device and/or Implant Procedure-Clinical Trials (data as of 04/23/2008)**

	<b>HeRO Bacteremia Study # Events/ # Subject<sup>i</sup> (%)<sup>iii</sup> N = 38</b>	<b>HeRO Patency Study # Events/ # Subject (%) N = 52</b>
<b>Bleeding, hemorrhage or hematoma</b>	2/2 (5.3%)	6/6 (11.5%)
<b>Cardiac arrhythmia</b>	1/1 (2.6%)	0/0 (0.0%)
<b>Death</b>	0/0 (0.0%)	1/1 (1.9%)
<b>Edema (includes swelling)</b>	1/1 (2.6%)	0/0 (0.0%)
<b>Pulmonary embolism</b>	1/1 (2.6%)	1/1 (1.9%)
<b>Infection (non-bacteremia)</b>	1/1 (2.6%)	2/2 (3.8%)
<b>Stroke</b>	0/0 (0.0%)	1/1 (1.9%)
<b>Vascular insufficiency due to steal syndrome (includes ischemia)</b>	1/1 (2.6%)	2/2 (3.8%)
<b>Site pain</b>	0/0 (0.0%)	1/1 (1.9%)
<b>Trauma to major veins, arteries, nerves</b>	0/0 (0.0%)	1/1 (1.9%)
<b>Wound problems (includes wound dehiscence)</b>	1/1 (2.6%)	1/1 (1.9%)
<b>Breakage or mechanical failure (prosthesis technical failure)</b>	0/0 (0.0%)	2/1 (1.9%)
<b>Other<sup>vi</sup></b>	1/1 (2.6%)	8/5 (9.6%)

Literature rates are from references 2 or 3 unless otherwise denoted. This table includes all enrolled HeRO subjects including the 4 that did not receive the device.

- I. Total number of events
- II. Subjects with at least one event
- III. Percent of subjects with at least one event
- IV. Literature reports all deaths and not just device or procedure-related deaths.
- V. Graft literature reports all infections including bacteremia or sepsis.

## Related Adverse Events by Type from U.S. Multi-Center

Catheter Literature	ePTFE Graft Literature
79/4209 (1.9%) per Catheter	76/1587 (4.8%)
30/432 (6.9%) of ESRD subjects	30/432 (6.9%) of ESRD subjects
21% <sup>iv</sup> (249/1200)	18.6% <sup>iv</sup> (327/1754)
5/86 (5.8%) per Catheter	32/222 (14.4%)
28/686 (4.1%) of ESRD subjects <sup>23</sup>	28/686 (4.1%) of ESRD subjects <sup>23</sup>
1.6/1,000 days	9.8% <sup>v</sup> (260/2663)
0.08-0.088/per year in ESRD subjects <sup>24</sup>	0.08-0.088/per year in ESRD subjects <sup>24</sup>
Not Applicable	47/1229 (3.8%)
Not Reported	Not Reported
101/2823 (3.6%) per Catheter	7/93 (7.5%)
Not Reported	3/129 (2.3%)
278/2214 (12.6%) per subjects	Not Reported
Not Reported	Not Reported

VI. 'Other' serious device and/or procedure related events included right atrial clot, hypotension with fever, non-sustained mild and ventricular tachycardia, pneumonia, cardiogenic shock, hypoxia, hyperkalemia, hypoxemia, elevated white blood cell count.

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

## PROCEDURE ACCESSORIES

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

<b>Vascular access surgical instruments including, but not limited to, the following:</b>	
<ul style="list-style-type: none"><li>• 5F micro-puncture set</li><li>• Various 0.035" guidewires at least 150cm in length</li><li>• Heavy duty scissors</li><li>• Heparinized saline</li><li>• 4 x 4 sterile gauze pads</li><li>• Various subcutaneous tissue &amp; skin sutures</li></ul>	<ul style="list-style-type: none"><li>• Radiographic contrast fluid</li><li>• Kelly-Wick tunneler set with 6mm &amp; 7mm bullet tips</li><li>• Various atraumatic vascular clamps</li><li>• Standard vessel loops</li><li>• Syringe &amp; syringe adapter</li><li>• Sterile Surgical Lubricant</li></ul>

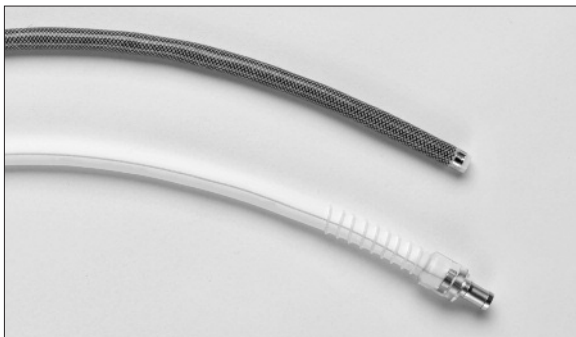


## PATIENT SELECTION CONSIDERATIONS

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 implant for any patient dialyzing on a catheter; treat patient with antibiotics per culture outcome and ensure infection is resolved prior to HeRO implant procedure.

5. Swab the patient's nose prior to HeRO implant for potential methicillin resistant staphylococcus aureus; treat accordingly.



6. As with conventional grafts, HeRO 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.<sup>25</sup>

## 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 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 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 and prep the contents for use.
  - ⚠ **Use a separate tray for removal of the existing tunneled catheter to aid in sterile preservation. Culture any catheters removed at time of implant.**
  - ⚠ **Suture the tract closed from the existing catheter to HeRO tract.**
  - ⚠ **Cover any catheter extensions with antimicrobial incise drape covering to protect the sterile area.**
  - ⚠ **Plan for increased bacteremia risk after an ipsilateral HeRO placement or with femoral bridging catheters and treat prophylactically with antibiotics knowing patients are at higher infection risk.**
  - ⚠ **Apply antibiotic ointment to the bridging catheter exit site or antimicrobial bridging catheter lock.**
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 placement
6. Using ultrasound guidance, gain percutaneous access to the venous system utilizing a 5F micro-puncture set and standard Seldinger technique.
  - ⚠ **Use of the HeRO device 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 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 outflow component.<sup>26</sup>**

7. Using fluoroscopic guidance, advance a 0.035" guidewire, at least 150cm in length, to the inferior vena cava (IVC).

**⚠️ Maintain wire placement throughout the implantation of the 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 Trendelenberg position. Additionally, anesthesia personnel should force a positive breath to reduce the potential for air embolus during implant.

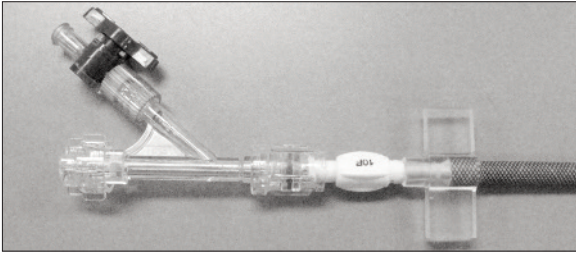
**NOTE:** For conscious sedation patients, utilize the Valsalva maneuver to reduce air embolus potential.

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

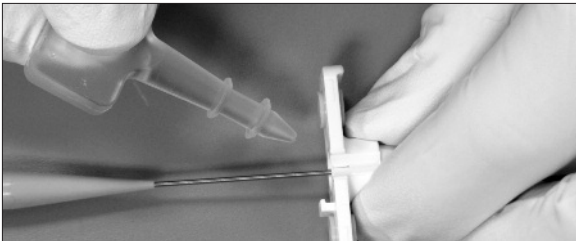
**NOTE:** Balloon angioplasty may also be required for severely stenosed anatomy.

3. Insert the short 20F introducer from the **Accessory Component Kit** over the guidewire. The long 20F introducer may be used if needed.
4. Open the **Venous Outflow Component** using aseptic technique.
5. Flush the outflow component with heparinized saline.
6. Apply sterile surgical lubricant to the 10F delivery stylet and advance through the silicone Luer End of the outflow component.

7. Attach the Y-adapter onto the Luer End of the 10F delivery stylet.



8. Tighten the stopcock on the Y-adapter, if necessary.
9. Ensure the valve on the stopcock is in the open position and flush with heparinized saline, then close the valve.
10. To ease insertion into the sheath, apply sterile surgical lubricant to the exterior surface of the 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.

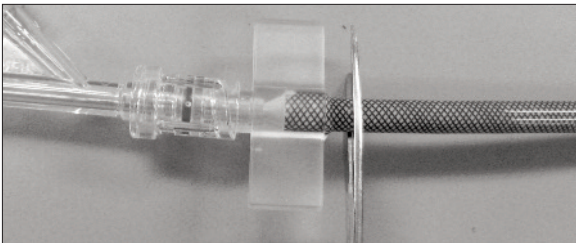


12. Insert the outflow component and delivery stylet assembly over the guidewire and advance up to the 20F peel away sheath.
  13. Quickly exchange the hemostasis plug for the outflow component.
- ⚠ DO NOT advance the tip of the delivery stylet into the right atrium.**
14. Under fluoroscopic guidance, advance the outflow component to the superior vena cava (SVC) by using a twisting or rotational motion. Holding the delivery stylet fixed, continue to advance the outflow component to the mid to upper right atrium.

15. Confirm proper outflow component tip placement in the mid to upper right atrium.
16. Peel away the 20F sheath.
17. Remove the guidewire and close the cap on the Y-adapter.
18. Prior to completing removal of the 10F delivery stylet from the outflow component, clamp the outflow component at the incision site to avoid loss of hemostasis. Complete the removal of the delivery stylet from the guidewire.

**⚠ To avoid potential damage to the 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 outflow component.
20. Attach a syringe to the stopcock and unclamp the outflow component. Aspirate the outflow component. Close the stopcock, reclamp the outflow component and remove the syringe.
21. Attach a syringe with heparinized saline. Open the stopcock, remove the clamp and flush the outflow component. Reclamp the device 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 outflow component away from the incision sites, use heavy duty scissors to cut the silicone Luer off of the outflow component. The end of the outflow component should be cut straight across ensuring the cut is square to the outflow component. Discard unused portion.



**⚠ Avoid displacing the outflow component tip during manipulation.**

**⚠ The cut end of the outflow component may have sharp edges. Avoid glove contact to prevent puncture.**

25. Utilizing a standard 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 outflow component and pull through the tunnel to the DPG.
  27. Remove the 6mm bullet tip from the outflow component.
- ⚠ **DO NOT bend the outflow component beyond a 2.5cm diameter anywhere along its length to prevent kinking.**

## **IMPLANTING THE ARTERIAL GRAFT COMPONENT**

1. Open the **Arterial Graft Component** using aseptic technique and prep the contents for use.
  2. Make an incision at the selected arterial anastomosis site. Utilizing a standard vessel loop, expose the artery and verify the ID is greater than 3mm in size. Verify patency via Doppler or tactile feel.
- ⚠ **Use of the HeRO device 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.**
3. Utilizing a standard Kelly-Wick tunneler with a 7mm bullet tip, follow the previously drawn soft C graft routing path to create a subcutaneous tunnel from the arterial incision site to the connector incision site at the DPG. Graft routing will vary depending on patient-specific anatomy.
  4. Remove the 7mm bullet tip from the Kelly-Wick tunneler and reattach the 6mm bullet tip.
  5. Attach the non-connector end of the graft onto the 6mm bullet tip and secure a tight connection with a suture(s).
  6. Gently pull the graft through the tunnel to the arterial incision site. Utilize the markings on the graft to verify the graft has not twisted.
  7. Leave approximately 8cm of the graft exposed at the DPG incision site to facilitate the connection from the graft to the outflow component.
  8. Cut the graft from the tunneler and use a standard vascular clamp to occlude the graft at the arterial anastomosis site.

## CONNECTING THE HeRO VASCULAR ACCESS SYSTEM

1. Place a sterile 4x4 gauze pad between the outflow component and the DPG incision site to prevent debris from contaminating the incision.
2. Determine the outflow component length required to make the connection to the graft component at the final DPG location. Utilizing a pair of heavy duty scissors, straight cut the outflow component to the desired length ensuring that the cut is square to the outflow component.

**⚠ DO NOT test fit the outflow component onto the titanium connector as it was designed not to separate once connected.**

3. Press the cut end of the outflow component onto the titanium connector. Connecting the two components is done by grasping the outflow component approximately 2cm back from the cut edge and pushing so it slides more easily over the first barb of the titanium connector. Continue to push the outflow component onto the connector until the cut edge is flush with the silicone sleeve hub past both barbs.

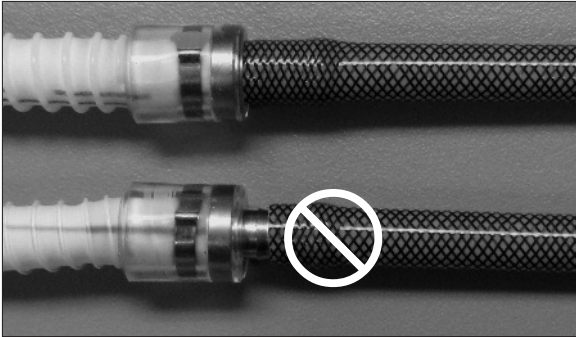


**⚠ The HeRO Venous Outflow Component was designed to engage both barbs of the titanium connector tightly so that the pieces do not separate. If separation is necessary, a new straight cut should be made to the outflow component. The new cut should be near the connector, and special care should be taken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

**⚠ DO NOT grasp, peel, or otherwise damage the graft beads as this may adversely impact the integrity of the graft. It is important during device connection to grasp the silicone sleeve of**

**the graft component and avoid contact with the graft beading. Ensure the beading is not crushed or damaged.**

- ⚠ **If damage to the graft beading is noted during implant, a new *Arterial Graft Component* should be used.**
- ⚠ **Damaged or crushed beading may lead to flow disruption within the device, and may contribute to early device occlusion and/or repeated occlusion.**



- ⚠ **Verify the graft component and outflow component are fully connected and that no portion of the titanium connector is exposed. After the connection is made, verify radiopaque tip placement in the mid to upper right atrium using fluoroscopy.**

4. Carefully position the titanium connector in the soft tissue at the DPG. Reposition the graft from the arterial end to remove excess graft material.
5. Remove the clamps at the outflow component and arterial anastomosis sites to back-bleed the entire HeRO system.
6. Reclamp the graft.

**NOTE:** Avoid beaded region of graft.

7. Attach a syringe with heparinized saline to the graft using a syringe adapter. Remove the clamp and flush the entire HeRO system. Observe the DPG connection site for leakage. Reclamp the graft.

- ⚠ **If leakage is observed, check for proper connection of the graft to the outflow component.**

## GRAFT AND ARTERY CONNECTION

1. Cut the graft to length, avoiding excessive tension or excess graft material. Verify there are no kinks, twists, or bends in the graft material.
2. Perform the arterial anastomosis utilizing standard surgical techniques.  
**⚠ Use a small diameter tapered needle with a non-cutting edge to reduce the incidence of suture hole bleeding.**
3. Remove the clamp and check the device patency utilizing standard Doppler technique.
4. Verify thrill and bruit.
5. Evaluate for steal syndrome during the implant procedure with Doppler of the radial and ulnar arteries. If steal syndrome symptoms occur, consider surgical interventions such as:
  - DRIL (distal revascularization-interval ligation) procedure
  - Banding, though this may reduce the flow in the HeRO graft
  - Proximalization of the inflow
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**.
2. Provide the patient with the remaining items in the Patient Information Pouch.

## VASCULAR ACCESS CANNULATION

Follow KDOQI guidelines for graft assessment, preparation and cannulation.

- The graft requires 2-4 weeks to incorporate prior to cannulation.
- 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.

**⚠ DO NOT cannulate the HeRO graft within 8cm (3") of the DPG incision to avoid damage to the beaded section of the graft.**

**⚠ DO NOT cannulate the outflow component.**

**⚠ Remove the bridging catheter as soon as possible once the HeRO device is ready to be cannulated to decrease the risk of an infection related to the bridging catheter.**

**⚠ 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 device becoming infected.**

For additional information refer to the HeRO Care & Cannulation Guide in the patient information or review online at [www.herograft.com](http://www.herograft.com).

## **PERCUTANEOUS THROMBECTOMY**

The HeRO device will require maintenance equivalent to conventional ePTFE grafts. The HeRO device is approximately 90cm long; thus requiring a longer thrombectomy device to traverse the entire length of the device.

**⚠ Mechanical thrombectomy devices with rotational tips are not recommended due to possible damage to the device.**

For specific thrombectomy instructions or guidance, please contact Customer Service at **888.313.8233** for a copy of the Thrombectomy Brochure. Instructions may also be found on [www.herograft.com](http://www.herograft.com).

## **DEVICE EXPLANT, EXCHANGE, REVISION OR ABANDONMENT**

The HeRO **Venous Outflow Component** and connection portion should be removed if the device will not be used for hemodialysis access. In situations where the HeRO device requires exchange, explant or revision, please contact Customer Service at **888.313.8233** for an instruction procedure and an Explant Return Kit. Instructions may also be found on [www.herograft.com](http://www.herograft.com).

## MRI INFORMATION

The HeRO Graft was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing has demonstrated that the HeRO Graft is MR-conditional. 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

### MRI-Related Heating

In non-clinical testing, the device produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla / 128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.6°C.

Therefore, the MRI-related heating experiments for the device at 3-Tesla using a transmit / receive radiofrequency (RF) body coil at an MR system reported whole body averaged SAR of 3.0-W / kg (i.e., associated with a calorimetry measured value of 2.8-W / kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

### 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 device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size:	7,849mm <sup>2</sup>	295mm <sup>2</sup>	9,519mm <sup>2</sup>	1,273mm <sup>2</sup>
Plane Orientation:	Parallel	Perpendicular	Parallel	Perpendicular

## **WARRANTY DISCLAIMER**

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## **TECHNICAL SUPPORT**

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

**Hemosphere, Inc.**  
6545 City West Parkway  
Eden Prairie, MN 55344  
Customer Service: 888.313.8233  
Toll Free Fax: 888.313.9427

**[www.herograft.com](http://www.herograft.com)**

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11-0114 Rev. G 2011-11