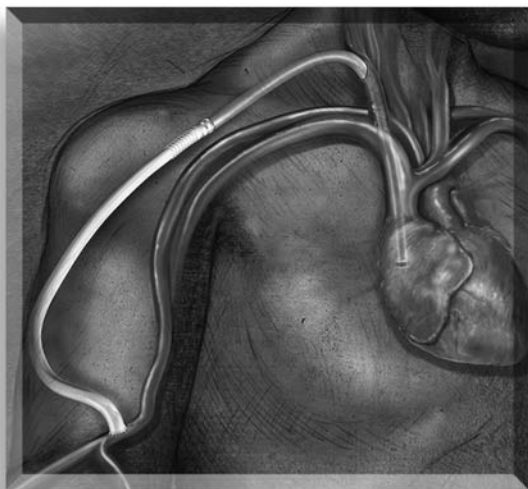
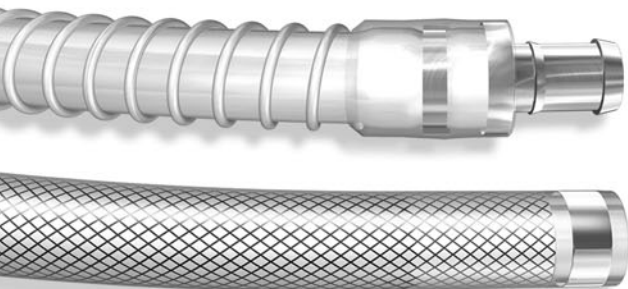


# Instructions for Use



**HeRO<sup>®</sup>**  
Vascular Access Device



**HeRO<sup>®</sup>**  
[Hemodialysis Reliable Outflow]  
**Vascular Access Device**

## 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® Vascular Access Device 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 accompanying documents



Use By Date



Single Use Only



Ethylene Oxide Sterilized



Product Number



Lot Number



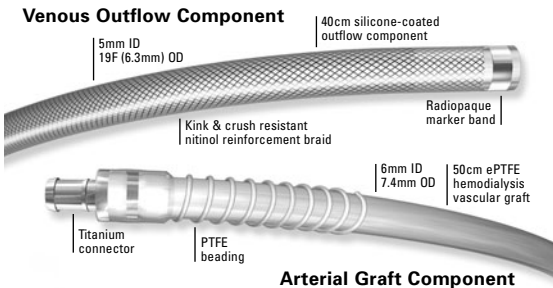
MRI Conditional



Non-Pyrogenic

## DEVICE DESCRIPTION

The HeRO® (**H**emodialysis **R**eliable **O**utflow) Vascular Access Device is a long-term permanent 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 platinum-iridium 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 proximal to 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® Vascular Access Device.

## INTENDED USE

The HeRO® Vascular Access Device 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® Vascular Access Device is indicated for end-stage renal disease (ESRD) patients on long-term hemodialysis who have exhausted all other peripheral access options.

## HeRO® PATIENT ELIGIBILITY

HeRO® eligible patients are readily identified per KDOQI Clinical Practice 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 for AV 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 vessel mapping.
- Are failing fistulas or grafts due to poor venous outflow as determined by access failure or vessel mapping.
- Have a compromised central venous system or central venous stenosis (CVS) as determined by history of previous access failures.

## CONTRAINDICATIONS

**Implantation of the HeRO® device is contraindicated if:**

- **The brachial artery 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.**

## POTENTIAL COMPLICATIONS

The HeRO® Vascular Access Device 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 10/25/2007)**

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>[3-4]</sup> Of the four (4) bleeding events in the graft study, two (2) were directly related to the HeRO® device implant and two (2) were related to the surgical procedure (elevated PTT and Heparin administrative error). The two (2) events directly related to the HeRO® device were in subjects that had a venous cut-down previously required for implantation of the larger 22F earlier generation HeRO® outflow component. 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>[3-4]</sup>

**TABLE 1: HeRO® Endpoint & Performance Data (as of**

		<b>HeRO® Bacteremia Study</b>	<b>HeRO® Patency Study</b>
<b>Device/Procedure-Related Bacteremia Rate/ 1,000 Days<sup>II</sup></b> (UCB=Upper Confidence Bound)		0.00/1,000 (8.64 UCB) (N=2) Training Subjects	0.19/1,000 (0.70 UCB) (N=25) Training Subjects
		0.87/1,000 (1.80 UCB) (N=34) Treatment Subjects	0.11/1,000 (0.61 UCB) (N=25) Treatment Subjects
<b>Primary-Assisted Patency</b>		100% at 7.3 Months (2/2) [15.8,100.0] Training Subjects	76% at 12.3 Months (19/25) [54.9,90.6] Training Subjects
		91.2% at 7.3 Months (31/34) [76.3,98.1] Treatment Subjects	88% at 12.3 Months (22/25) [68.8,97.5] Treatment Subjects
<b>Primary Patency</b>		0% at 7.3 Months (0/2) [0,84.2] Training Subjects	28% at 12.3 Months (7/25) [12.1,49.4] Training Subjects
		47.1% at 7.3 Months (16/34) [29.8,64.9] Treatment Subjects	44% at 12.3 Months (11/25) [24.4,65.1] Treatment Subjects
<b>Secondary Patency</b>		100% at 7.3 Months (2/2) [15.8,100.0] Training Subjects	84% at 12.3 Months (21/25) [63.9,95.5] Training Subjects
		100% at 7.3 Months (34/34) [89.7,100.0] Treatment Subjects	72% at 12.3 Months (18/25) [50.6,87.9] Treatment Subjects
<b>Functional Patency<sup>III</sup></b>		50% at 7.3 Months (1/2) [1.3,98.7] Training Subjects	68% at 12.3 Months (17/25) [46.5,85.1] Training Subjects
		73.5% at 7.3 Months (25/34) [55.6,87.1] Treatment Subjects	44% at 12.3 Months (11/25) [24.4,65.1] Treatment Subjects
<b>Adequacy of Dialysis</b>	<b>Kt/V</b>	1.7 ± 0.3 (N=25) [1.2,2.4] Training and Treatment Subjects Combined	1.6 ± 0.3 (N=33) [0.9,2.3] Training and Treatment Subjects Combined
	<b>URR</b>	74.4 ± 4.1 (N=24) [65.3,84.5] Training and Treatment Subjects Combined	72.9 ± 6.2 (N=19) [61.0,83.8] Training and Treatment Subjects Combined

I. This table includes only subjects who received the HeRO® device.

II. 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

## 10/25/2007) Compared to Literature<sup>1</sup>

<b>Catheter Literature</b>	<b>ePTFE Graft Literature</b>	<b>KDOQI Adequacy of Hemodialysis Guidelines<sup>2</sup></b>
2.3/1,000 <sup>5</sup>	0.11/1,000 <sup>6</sup>	Not Applicable
92% at 6 months <sup>7</sup>	68% at 6 months <sup>7</sup>	Not Applicable
Not Reported	52% at 12 months <sup>7</sup>	
50% at 6 months <sup>7</sup>	58% at 6 months <sup>7</sup>	Not Applicable
36% at 12 months <sup>7</sup>	42% at 12 months <sup>7</sup>	
55% at 6 months <sup>7</sup>	76% at 6 months <sup>7</sup>	Not Applicable
37% at 12 months <sup>7</sup>	65% at 12 months <sup>7</sup>	
55% at 6 months <sup>7</sup>	76% at 6 months <sup>7</sup>	Not Applicable
37% at 12 months <sup>7</sup>	65% at 12 months <sup>7</sup>	
1.29-1.46 <sup>8</sup> Literature Range	1.37-1.62 <sup>8</sup> Literature Range	1.4 target <sup>2</sup>
65-70 <sup>9</sup> Literature Range	70-73 <sup>9</sup> Literature Range	70 target <sup>2</sup>

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.

III. Loss of functional patency is defined as the time point at which the device can no longer be used for dialysis due to loss of secondary patency, infection, steal, patient or physician preference, etc.

**TABLE 2: Serious HeRO® Device and/or Procedure-Related Compared to the Literature<sup>1</sup>**

	Bacteremia Study # Events <sup>I</sup> / # Subject <sup>III</sup> (%) <sup>IV</sup>		Patency Study # Events/ # Subject (%)	
	Training N=2	Treatment N=36	Training N=25	Treatment N=27
<b>Bleeding, Hemorrhage or hematoma</b>	0/0 (0.0%)	1/1 (2.8%)	4/4 (16.0%)	1/1 (3.7%)
<b>Cardiac arrhythmia</b>	0/0 (0.0%)	1/1 (2.8%)	0/0 (0.0%)	0/0 (0.0%)
<b>Death</b>	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	1/1 (3.7%)
<b>Edema (includes edema and swelling)</b>	0/0 (0.0%)	1/1 (2.8%)	0/0 (0.0%)	0/0 (0.0%)
<b>Pulmonary embolism</b>	0/0 (0.0%)	1/1 (2.8%)	0/0 (0.0%)	1/1 (3.7%)
<b>Infection (non-bacteremia)</b>	0/1,000 days	0.1/1,000 days	1/1 (4.0%)	0/0 (0.0%)
<b>Stroke</b>	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	1/1 (3.7%)
<b>Vascular insufficiency due to steal syndrome (includes steal and ischemia)</b>	0/0 (0.0%)	1/1 (2.8%)	1/1 (4.0%)	1/1 (3.7%)
<b>Site pain</b>	0/0 (0.0%)	0/0 (0.0%)	1/1 (4.0%)	0/0 (0.0%)
<b>Trauma to major veins, arteries, nerves</b>	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	1/1 (3.7%)
<b>Wound problems (includes wound dehiscence)</b>	0/0 (0.0%)	1/1 (2.8%)	0/0 (0.0%)	0/0 (0.0%)
<b>Breakage or mechanical failure (prosthesis technical failure)</b>	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)	1/1 (3.7%)
<b>Other</b>	0/0 (0.0%)	1/1 (2.8%)	5/3 (12.0%)	3/2 (7.4%)

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

II. Total number of events.

III. Subjects with at least one event.

IV. Percent of subjects with at least one event.

V. Literature reports all deaths and not just device or procedure-related deaths.

VI. Graft literature reports all infections including bacteremia and sepsis.

## Adverse Events by Type (data as of 10/25/2007)

Catheter Literature <sup>3</sup>	ePTFE Graft Literature <sup>4</sup>
# Events/ # Subject, Catheter or Overall ESRD Population (%)	# Events/ # Subject or Overall ESRD Population (%)
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>v</sup> (249/1200)	18.6% <sup>v</sup> (327/1754)
5/86 (5.8%) per Catheter	32/222 (14.4%)
28/686 (4.1%) of ESRD subjects <sup>9</sup>	28/686 (4.1%) of ESRD subjects <sup>9</sup>
1.6/1,000 days	9.8% <sup>vi</sup> (260/2663)
0.08-0.088/per year in ESRD Subjects <sup>10</sup>	0.08-0.088/per year in ESRD Subjects <sup>10</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 Subject	Not Reported
Not Reported	Not Reported

In some instances, a direct comparison between the HeRO<sup>®</sup> 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.

'Other' serious device and/or procedure related events reported in the study were anticipated however not classified on the case report forms in pre-defined categories. These 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.

## 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" / 180cm guidewires</li><li>• Indeflator</li><li>• Assorted angioplasty balloons</li><li>• Heavy duty scissors</li><li>• Heparinized saline</li><li>• 4 x 4 sterile gauze pads</li></ul>	<ul style="list-style-type: none"><li>• Various subcutaneous tissue &amp; skin sutures</li><li>• Radiographic contrast fluid</li><li>• Kelly-Wick tunneler set with 6mm &amp; 8mm bullet tips</li><li>• Various atraumatic vascular clamps</li><li>• Standard vessel loops</li><li>• Syringe &amp; syringe adapter</li></ul>

## HeRO® VASCULAR ACCESS DEVICE

### 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 be 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 in advance of the procedure to rule out existing systemic infection. In the event blood cultures are positive, postpone implant of the HeRO® device pending antibiotic treatment and confirmation of infection resolution.

## HeRO® VASCULAR ACCESS IMPLANT PROCEDURE

### GAINING VENOUS ACCESS

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

2. Pre-plan the surgical implant utilizing the surgical marker provided in the **Accessory Component Kit** to indicate appropriate incisions and tunneling paths. Draw the HeRO® graft routing path in a soft C configuration on the upper arm.
3. Utilizing a standard operating room, equipped with fluoroscopic and ultrasound guidance, prep the patient according to standard surgical guidelines.
4. If choosing to utilize an existing tunneled catheter tract, use standard over-the-wire exchange techniques to remove. Consider administration of Vancomycin and Gentamycin.

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

5. Prophylactic intra-operative antibiotics are recommended (e.g., Ancef).
6. Using ultrasound guidance, gain percutaneous access to the venous system utilizing a 5F micro-puncture set and standard Seldinger technique.
7. Using fluoroscopic guidance, advance a 0.035" / 180cm guidewire 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 diagnostic sheath.
9. Create a small venotomy at the exit site of the guidewire to aid in placement of the introducer sheath .

## **IMPLANTING THE OUTFLOW COMPONENT**

1. For patients receiving conscious sedation, place the patient into Trendelenberg position and utilize the Valsalva maneuver to reduce the potential for air embolus during exchanges.
2. For patients undergoing general anesthesia, also consider Trendelenberg position. Additionally, anesthesia personnel should force a positive breath to reduce the potential for air embolus during exchanges.
3. 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 sheath.

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

4. Select the appropriate 20F introducer sheath (long or short) from the **Accessory Component Kit** and insert over the guidewire.
5. Open the **Venous Outflow Component** using aseptic technique and prep the contents for use.
6. Flush the outflow component with heparinized saline.
7. Wet the 10F delivery stylet and advance through the silicone Luer end of the outflow component.
8. Attach the Y-adapter onto the Luer end of the 10F delivery stylet.
9. Tighten the stopcock on the Y-adapter, if necessary.
10. Ensure the valve on the stopcock is in the open position and flush with heparinized saline, then close the valve.
11. To ease insertion into the sheath, apply sterile surgical lubricant to the exterior surface of the outflow component.
12. 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.
13. Insert the outflow component and delivery stylet assembly over the guidewire and advance up to the 20F peel away sheath.
14. Quickly exchange the hemostasis plug for the outflow component.
- ⚠ **DO NOT advance the tip of the delivery stylet into the right atrium.**
15. 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.
16. Confirm proper outflow component tip placement in the mid to upper right atrium.
17. Peel away the 20F sheath.

18. Remove the guidewire and close the cap on the Y-adapter.
19. Prior to complete removal of the 10F delivery stylet, clamp the outflow component at the venotomy site, and then fully remove the delivery stylet.
- ⚠ **To avoid potential damage to the outflow component, use only the atraumatic clamp provided in the Accessory Component Kit. To ensure full occlusion, place the outflow component near the clamp hinge.**
20. Detach the Y-adapter from the delivery stylet. Open the stopcock and attach the Y-adapter to the silicone Luer on the outflow component.
21. 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.
22. Attach a syringe with heparinized saline. Open the stopcock, remove the clamp and flush the outflow component. Reclamp the device at the venotomy site and close the stopcock.
23. Return the patient to standard supine position.
24. Make the connector site incision at the delto-pectoral groove (DPG).
25. Holding the outflow component away from the incision sites, use heavy duty scissors to cut the proximal end of the outflow component just distal to the silicone Luer. 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.**
26. Utilizing a standard Kelly-Wick tunneler with a 6mm bullet tip, tunnel from the DPG to the venotomy incision site.
27. Insert the 6mm bullet tip into the end of the outflow component and pull through the tunnel to the DPG.
28. 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 visually verify that it 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 3mm or greater may result in improved blood flow compared to a brachial artery of less than 3mm.**
3. Utilizing a standard Kelly-Wick tunneler with an 8mm 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 8mm bullet tip from the Kelly-Wick tunneler and reattach the 6mm bullet tip.
  5. Attach the proximal 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 blue line 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.
- ⚠ DO NOT test fit the outflow component onto the titanium connector as it can not be removed once connected.**

3. Press fit the cut end of the outflow component onto the titanium connector.
  - ⚠ **The outflow component must be advanced past both barbs to seat flush against the shoulder of the connector to ensure the graft and outflow component do not separate post implant.**
  - ⚠ **DO NOT peel or otherwise damage the graft beads as this may adversely impact the integrity of the graft.**
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 venotomy and arterial anastomosis sites to back-bleed the entire HeRO® system.
6. Reclamp the proximal end of the 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 observed, check for proper connection of the graft to the outflow component.**

## **GRAFT AND ARTERY CONNECTION**

1. Proximal to the clamp, cut the graft to length, avoiding excessive tension or redundant 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. Duplex the distal arteries to check for signs of steal syndrome.
  - ⚠ **If the patient exhibits signs of steal syndrome, consider a graft banding procedure.**
6. Close all three incision sites.
7. Remove the plastic cover on the temporary surgical tattoo and place it paper side up on the outer wrist of the implant arm. Wet paper for 30 seconds and gently peel away paper backing.

## 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.
- 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 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® Cannulation & Care Guide in the patient information or review online at [www.heroaccess.com](http://www.heroaccess.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.heroaccess.com](http://www.heroaccess.com).

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

The HeRO® Venous Outflow Component 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.heroaccess.com](http://www.heroaccess.com).

## MRI INFORMATION

The HeRO® Vascular Access Device 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® Vascular Access device 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

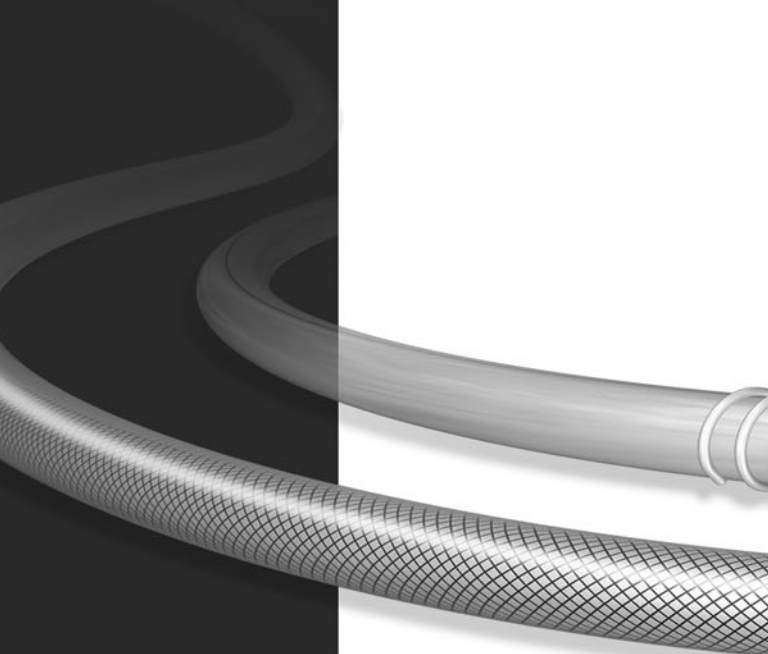
**[www.heroaccess.com](http://www.heroaccess.com)**

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