ACCESS OPTIONS FOR PATIENTS WITH VENOUS OUTFLOW INSUFFICIENCY

MERIT IS COMMITTED TO DIALYSIS ACCESS
When end stage renal disease patients are catheter-dependent or are approaching catheter dependency, the HeRO Graft (Hemodialysis Reliable OutFlow) is the ONLY fully subcutaneous AV access solution clinically proven to maintain long-term access for hemodialysis patients with central venous stenosis. The HeRO Graft may be an option for patients with failing fistulas or grafts due to poor venous outflow as determined by access failure or venography.

Unlike a stent, HeRO Graft’s Venous Outflow Component (VOC) can be removed and replaced if necessary.

Benefits of the HeRO Graft compared to Long-Term Hemodialysis Catheters

**FEWER INFECTIONS**

69% reduced infection rate compared with catheters

**SUPERIOR DIALYSIS ADEQUACY**

1.6–1.7 Kt/V, a 10% to 44% improvement compared with catheters

**HIGH PATENCY RATES**

Up to 87% cumulative patency at two years

**COST SAVINGS**

A 23% average savings per year compared with catheters predicted by a US healthcare model for provision of dialysis access

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**IS YOUR PATIENT A CANDIDATE FOR THE HERO GRAFT?**

- Is the patient failing an AVF or AVG?
- Is the measured Kt/V less than 1.4?
- Has the flow rate dropped >20%?
- Is the patient catheter dependent or approaching catheter dependency?
- Does the patient have swollen arms and/or distended collateral veins?

If **YES** is answered for any of the questions above, consider referring patient for a central bilateral venogram for assessment of central venous stenosis.

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**CLINICAL OUTCOMES**

<table>
<thead>
<tr>
<th>Device/Procedure-Related Bacteremia Rate/1,000 Days</th>
<th>HeRO Graft Gage, et al. EJVES²</th>
<th>HeRO Graft Nassor, et al. Semin Dial¹</th>
<th>HeRO Graft Katzman, et al. JVS¹</th>
<th>Catheter Literature¹</th>
<th>ePTFE Graft Literature¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequacy of Dialysis (mean Kt/V)</td>
<td>N/A</td>
<td>1.6</td>
<td>1.7</td>
<td>1.18–1.46</td>
<td>1.37–1.62</td>
</tr>
<tr>
<td>Cumulative Patency (at 1 year)</td>
<td>91%</td>
<td>68%</td>
<td>72%¹</td>
<td>37%</td>
<td>65%</td>
</tr>
<tr>
<td>Intervention Rate (per year)</td>
<td>1.5</td>
<td>2.2</td>
<td>2.5</td>
<td>5.8</td>
<td>1.6–2.4</td>
</tr>
</tbody>
</table>

⁵ Note: Every 0.1 decrease in Kt/V is estimated to increase the mortality rate by 7% and is significantly (P<0.05) associated with 11% more hospitalizations, 12% more hospital days, and a $940 increase in Medicare inpatient expenditures.

‡ 8.6 months

¹ Procedure-related bacteremia was defined as any bacteremia seeded by the subject’s previous tunneled dialysis catheter (cultured at the time of HeRO Graft implant), any bacteremia that may have been seeded by a 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.
COMPONENTS OF THE HERO® GRAFT

ePTFE ARTERIAL GRAFT COMPONENT (HERO1002)

- ORIENTATION LINE ON GRAFT to guide placement during tunneling
- BEADING (3–4 cm) for kink resistance
- 6 mm ID x 50 cm
- 6.3 mm/19F OD
- 5 mm ID
- 40 cm customizable length

VENOUS OUTFLOW COMPONENT (HERO1001VOC)

- No venous anastomosis
- Removable and replaceable
- REINFORCED 48-BRAID NITINOL kink & crush resistant
- 6.3 mm/19F OD
- 5 mm ID
- 40 cm customizable length
- RADIOPAQUE MARKER BAND (1 mm) integrated within the silicone at the distal tip

ACCESSORY COMPONENT KIT (HERO1003)
Instruments and accessories to aid in the placement or revision of a HeRO system.

- 10F Delivery Stylet
- 20F peel away sheath with dilator (long and short options)
- Y-adapter with 1-way stopcock
- Hemostasis Plug
- Vascular Clamp
- 12F and 16F Dilators
**HERO® GRAFT SYSTEM CONFIGURATIONS**

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**Early Cannulation Grafts**
Flixene® Standard Wall and Gore® Acuseal are qualified for use with the Adapter (Support Seal not needed).

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**Standard Wall Grafts**
Impra®, Gore-Tex®, Gor-Tex® Stretch, and Gore® Propaten® are qualified for use with the Adapter and Support Seal.

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**The Adapter has undergone successful in vitro testing with specific vascular grafts (see tables on next page).**

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**HERO1000**
Includes: Adapter, Support Seal, Graft Expander, Venous Outflow Component, Accessory Component Kit

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**HERO1006**
Includes: Adapter, Support Seal, Graft Expander, Vascular Clamp, Syringe

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**ADAPTER, SUPPORT SEAL, & GRAFT EXPANDER**

- Titanium Adapter connects VOC to other manufacturer grafts
- The Support Seal provides seal reinforcement and kink resistance.
- The Graft Expander aids in expanding a 6 mm ID vascular graft for connection to the Adapter.
### Table 1: Marketed 6 mm ID (qualified for use with the Adapter, Support Seal not needed)

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Catalog Number**</th>
<th>Support Seal Required for HeRO Graft Adapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLIXENE® Standard Wall</td>
<td>Atrium Medical Corp.</td>
<td>25053</td>
<td>25142</td>
</tr>
<tr>
<td>GORE® ACUSEAL</td>
<td>W.L. Gore &amp; Associates</td>
<td>ECH060010A</td>
<td>ECH060020A</td>
</tr>
</tbody>
</table>

### Table 2: Marketed 6 mm ID (qualified for use with the Adapter and Support Seal)

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Catalog Number**</th>
<th>Support Seal Required for HeRO Graft Adapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMPRA®</td>
<td>C.R. Bard</td>
<td>05S06</td>
<td>10S06</td>
</tr>
<tr>
<td>GORE-TEX® Stretch</td>
<td>W.L. Gore &amp; Associates</td>
<td>S0601</td>
<td>S0602</td>
</tr>
<tr>
<td>GORE® PROPATEN®</td>
<td>W.L. Gore &amp; Associates</td>
<td>H060010A</td>
<td>H060040A</td>
</tr>
</tbody>
</table>

The Adapter should NOT be connected to any graft other than a new graft listed in Tables 1 and 2.

* Refer to graft manufacturer Instructions for Use or website for indications and further information.

** Catalog numbers may contain identifiers that are not reflected on this table. Consult the graft manufacturer’s website to determine which equivalent catalog numbers are available in your region.

### COMMITTED TO DIALYSIS ACCESS

Merit Medical has a broad offering of dialysis access products, including hemodialysis and peritoneal dialysis catheters, balloons, and the HeRO graft. Contact your Merit Sales Professional or visit Merit.com/DialysisAccess to learn more about our products and our renowned physician training course, ThinkDialysisAccess.
## HERO GRAFT SYSTEM ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>HERO1000 (SUPER HERO)</td>
<td>Venous Outflow Component, Adapter, Support Seal, and Graft Expander, Accessory Component Kit</td>
</tr>
<tr>
<td>HERO1001VOC</td>
<td>Venous Outflow Component</td>
</tr>
<tr>
<td>HERO1002</td>
<td>Arterial Graft Component</td>
</tr>
<tr>
<td>HERO1003 (ACCESSORY COMPONENT KIT)</td>
<td>Accessory Component Kit</td>
</tr>
<tr>
<td>HERO1006 (HERO ALLY REVISION KIT)</td>
<td>Adapter, Support Seal, and Graft Expander, Vascular Clamp and Syringe</td>
</tr>
</tbody>
</table>

### References:
2. Gage et al., EJVES 2012.
3. Dageforde et al., JSR 2012.

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