ADAPTER

Featuring an early cannulation graft option*

More Graft Options**
- GORE® ACUSEAL
- FLIXENE® Standard Wall

*See inside and Instructions for Use (IFU) for more details.
**Graft is not included with the Adapter. See IFU for more details on the ePTFE grafts that have been tested and are permitted for use with the Adapter.
HeRO Graft

HeRO (Hemodialysis Reliable Outflow) Graft is the ONLY fully subcutaneous AV access solution clinically proven to maintain long-term access for hemodialysis patients with central venous stenosis.

Key Benefits

- **Superior Dialysis Adequacy:** 1.7 Kt/V, a 16% to 32% improvement compared with catheters
- **High Patency Rates:** Up to 87% cumulative patency at 2 years
- **Fewer Infections:** 69% reduced infection rate compared with catheters
- **Bridging Catheter Possibly Eliminated:** when using GORE ACUSEAL Vascular Graft, a bridging catheter may NOT be necessary when used with the Adapter and Venous Outflow Component

GORE ACUSEAL Vascular Graft:

- can be cannulated early (within 24 hours after implantation)
- Follow your facility’s protocol regarding care and cannulation

- See the next page or HeRO Graft Adapter IFU for full details on the ePTFE grafts that have been tested and are permitted for use with the HeRO Graft Adapter.

* When used with HeRO 1001 and HeRO 1002

Adapter

HeRO Graft Adapter connects a 6mm ID ePTFE vascular graft (not included) and the Venous Outflow Component (VOC, not included). The Adapter has a tapered ID (6mm to 5mm) to provide a smooth transition from the graft to the VOC.

Treatment Algorithm

Failing AVF or AVG due to central venous stenosis

AVF

AVG

HeRO Graft

Catheter-dependent patients

Catheter
Adapter Assembly Overview

1. Select a new graft (not included) from Table 1.

   **General Warning:** The Adapter should NOT be connected to any graft other than a new graft listed in Table 1.

2. Insert **Graft Expander** into graft. Advance graft up to shoulder as much as possible and leave in place.

3. Ensure clamshells are open and centered around the **Adapter** base.

   **ATTENTION:** The clamshells CANNOT be opened once closed. Do NOT close prematurely.

4. Remove **Graft Expander**, slide graft onto the **Adapter** and advance graft to shoulder.

5. Pinch the **Adapter** clamshells tightly between thumb and index fingers. Ensure full closure of clamshells using a serrated vascular clamp. Verify the hinge of clamshells is facing hinge of clamp per orientation shown below.

6. Ready for implant. See IFU for full instructions.

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### Table 1: US Marketed 6mm ID Vascular Grafts (Tested with Adapter)

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Length</th>
<th>Wall</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>GORE ACUSEAL⁴</td>
<td>W.L. Gore &amp; Associates</td>
<td>40cm</td>
<td>–</td>
<td>ECH060040A</td>
</tr>
<tr>
<td>FLIXENE Standard Wall⁵</td>
<td>Atrium Medical Corporation</td>
<td>10cm 30cm 50cm</td>
<td>SW</td>
<td>25053 25142 25052</td>
</tr>
</tbody>
</table>

**GW =** Standard Wall
Identifying a HeRO Graft Candidate

- Is the patient currently catheter-dependent or approaching catheter dependency? YES  NO
- Is the patient failing an AVF or AVG? YES  NO
- Does the patient have a record of central venous stenosis? YES  NO
- Does the patient have swollen arms and/or distended collateral veins? YES  NO
- Is the measured Kt/V less than 1.4? YES  NO
- Has the flow rate dropped >20%? YES  NO

If YES is checked for any box above, consider referring patient for a central bilateral venogram for assessment of central venous stenosis.

Cost Benefits

- 23% average savings per year with the HeRO Graft compared with catheters
- Cost savings of over $3,100 (per patient/year) to the dialysis center when converting catheter-dependent patients to the HeRO Graft
- Lowers interventions and associated costs by more than 50% compared to catheters

Impact of HeRO Graft in the Era of Dialysis Provider Bundling

<table>
<thead>
<tr>
<th>Missed dialysis sessions</th>
<th>Outpatient IV antibiotic use and blood cultures</th>
<th>tPA + Heparin</th>
<th>EPO</th>
<th>Total Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>$737</td>
<td>$333</td>
<td>$839</td>
<td>$1263</td>
<td>$3,172</td>
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</table>

Component Diameter (ID) Length Product Code

<table>
<thead>
<tr>
<th>Component</th>
<th>Diameter (ID)</th>
<th>Length</th>
<th>Product Code</th>
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<tbody>
<tr>
<td>Venous Outflow Component</td>
<td>5mm</td>
<td>40 cm (customizable)</td>
<td>HERO 1001</td>
</tr>
<tr>
<td>Accessory Component Kit</td>
<td>N/A</td>
<td>N/A</td>
<td>HERO 1003</td>
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<tr>
<td>Adapter</td>
<td>6mm - 5mm</td>
<td>2.48 cm</td>
<td>HERO 1004</td>
</tr>
</tbody>
</table>

Learn more at www.herograft.com Order at: 888-427-9654

References:
2) Data on file.
3) Gage et al., EJVES 2012.
7) Daggeforde et al., JSR 2012.
8) Yost and Dinwiddie, American Society of Nephrology (ASN), Nov 2010.

*When used with HeRO 1001 and HeRO 1002

HeRO Graft is classified by the FDA as a vascular graft prosthesis.

For the grafts permitted for use with the Adapter, refer to the graft manufacturers’ Instructions for Use.