Adapter

More Graft Options**

- GORE® ACUSEAL
- FLIXENE® Standard Wall

* See Instructions for Use (IFU) for more details.
**Graft is not included with the Adapter. See Instructions for Use (IFU) for more details on the grafts permitted for use with the HeRO Graft Adapter.
What is the Adapter?

- The first product of its kind in vascular surgery
- The Adapter is a coupling device that allows for more graft options* to be used with HeRO Graft
- The Adapter has a 6mm to 5mm ID and connects:
  - ePTFE vascular graft (6mm ID)^
  - Venous Outflow Component (5 mm ID)^

*See IFU for more details on the grafts permitted for use with the HeRO Graft Adapter.
^Graft and Venous Outflow Component are not included with the Adapter.
Procedural Overview

See IFU for full details.
Implant Venous Outflow Component (VOC)

Utilizing endovascular techniques, the Venous Outflow Component is placed in the central venous vasculature to the opening of the right atrium.¹

¹ HeRO Graft IFU.
Adapter Assembly: Step 1

1. Select a new graft (not included) from Table 1.¹

Table 1: US Marketed Vascular Grafts (tested with the Adapter)

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Diameter</th>
<th>Length</th>
<th>Wall</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>GORE® ACUSEAL²</td>
<td>W.L. Gore &amp; Associates</td>
<td>6mm</td>
<td>40cm</td>
<td>-</td>
<td>ECH060040A</td>
</tr>
<tr>
<td>FLIXENE® Standard Wall³</td>
<td>Atrium Medical Corporation</td>
<td>6mm</td>
<td>10cm 30cm 50cm</td>
<td>SW</td>
<td>25053 25142 25052</td>
</tr>
</tbody>
</table>

GENERAL WARNINGS:¹
- The Adapter should NOT be connected to any graft other than a new graft listed above.
- Grafts that were implanted previously should not be used with the Adapter.

¹) HeRO Graft IFU.
Adapter Assembly: Step 2

2. Insert Graft Expander into graft. Advance graft up to shoulder as much as possible and leave in place.¹
Adapter Assembly: Step 3

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

**ATTENTION:** The clamshells CANNOT be opened once closed. Do NOT close prematurely.\(^1\)
Adapter Assembly: Step 4

4. Remove Graft Expander, slide graft onto the Adapter and advance graft to shoulder.¹

¹ HeRO Graft IFU.
Adapter Assembly: Step 5

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.¹
Adapter Assembly: Step 6

6. Ready for implant. See Instructions for Use (IFU) for full instructions.\(^1\)

1) HeRO Graft IFU.
Connect the VOC to the Adapter

- At the deltopectoral groove, the Adapter is joined to the Venous Outflow Component.¹

- Remove the clamp, check the device patency and verify there is no leakage at the Venous Outflow Component connection site and graft connection site with the Adapter using angiography.¹
Implant the Graft

• **ATTENTION:** For ePTFE grafts that are used with the Adapter, consult the graft manufacturer’s IFU for proper tunneling and implantation.¹

¹ HeRO Graft IFU.
A standard arterial anastomosis is performed to attach the ePTFE graft to the target inflow artery (>3mm).\textsuperscript{1}
Post-Implant View

- ADAPTER, (INCISION SITE)
- VENOUS OUTFLOW COMPONENT
- VENOTOMY, (INCISION SITE)
- ePTFE GRAFT, CANNULATION AREA
- ARTERIAL ANASTOMOSIS, (INCISION SITE)

*See IFU for more details on the grafts permitted for use with the HeRO Graft Adapter. Graft and Venous Outflow Component are not included with the Adapter.
**Fistula Salvage**

- AVF to HeRO Graft anastomosis
- Cannulation Area Immediately After AVF Salvage*
- Adapter
- HeRO Graft Venous Outflow Component
- Stenosed & Ligated AVF Venous Outflow
- Radiopaque Marker Band
- ePTFE Graft**

**AVG Graft Salvage**

- AVG to HeRO Graft anastomosis
- Cannulation Area Immediately After AVG Salvage*
- Adapter
- HeRO Graft Venous Outflow Component
- Stenosed & Ligated AVG Venous Outflow
- Radiopaque Marker Band
- ePTFE Graft**

*If AVF is matured or AVG is incorporated. Follow your dialysis facility protocol for care and cannulation.

**See IFU for more details on the grafts permitted for use with the HeRO Graft Adapter. Graft and Venous Outflow Component are not included with the Adapter.

**General Warnings**: Grafts that were implanted previously should not be used with the Adapter. Grafts containing tissue have not been tested in conjunction with the Adapter and should NOT be used. See IFU for full details.
Temporary Catheter
(during the bridging period if applicable)\textsuperscript{1}

- Consult the graft manufacturer's IFU for more information regarding the cannulation of the commercially available grafts selected for use with the Adapter.\textsuperscript{1}

- Cannulate ePTFE graft per your standard facility protocol.

1) HeRO Graft IFU.
Treatment Algorithm

Failing AVF or AVG due to central venous stenosis

Fistula  Graft  HeRO Graft  Catheter

HeRO Graft Candidates

- Failing fistulas or grafts due to central venous stenosis\(^1\)
- Catheter-dependent or approaching catheter dependency\(^1\)

1) HeRO Graft IFU.
Adapter Key Benefits: Early Cannulation

- The GORE® ACUSEAL Vascular Graft can be cannulated early (within 24 hours after implantation)\(^1,2\)

- When using GORE ACUSEAL Vascular Graft with the Adapter, a bridging catheter may NOT be necessary\(^1\)

2)  Follow your facility’s protocol regarding care and cannulation
Patient Benefits: GORE ACUSEAL*

- “Patients in need of hemodialysis who do not have a central venous catheter.”¹
- “Patients with a long-term central venous catheter that need a vascular graft.”¹
- “Patients who are prone to develop pseudoaneurysms in their vascular grafts or arteriovenous fistulas.”¹
- “Patients who have experienced seroma formation with other vascular grafts.”¹

¹ W. L. GORE, Care and Cannulation brochure, AP0064-EN2. 
http://www.goremedical.com/resources/downloads/featured/acusealvg/content/AP0064
EN2.HEMODIALYSIS.BRO.FNL.MR.pdf, downloaded 06/01/2015.

*See HeRO Graft IFU for more details on the grafts permitted for use with the HeRO Graft Adapter. Graft and Venous Outflow Component are not included with the Adapter.
Patient Benefits: FLIXENE SW*

“Tri-laminate construction reduces hydrostatic pressure eliminating weeping and/or blood strike-through, clinically demonstrated through minimizing associated complications such as seroma and pseudoaneurysm.”


*See HeRO Graft IFU for more details on the grafts permitted for use with the HeRO Graft Adapter. Graft and Venous Outflow Component are not included with the Adapter.
Adapter Packaging & Contents

Pouch Insert Card* with:
- Adapter
- Graft Expander
- Adapter Assembly Instructions**

* The Pouch Insert Card is double-pouched.
**See the IFU for full instructions.
Ordering: Adapter

- All the items in Table A are required for the HeRO Graft when using the Adapter (HERO 1004) and each are sold separately.¹

Table A

<table>
<thead>
<tr>
<th>PRODUCT PACKAGING</th>
<th>COMPONENT</th>
<th>PRODUCT CODE</th>
<th>Product Image</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Image" /></td>
<td>Venous Outflow Component</td>
<td>HERO 1001</td>
<td></td>
</tr>
<tr>
<td><img src="image2" alt="Image" /></td>
<td>Adapter</td>
<td>HERO 1004</td>
<td></td>
</tr>
<tr>
<td><img src="image3" alt="Image" /></td>
<td>Accessory Component Kit</td>
<td>HERO 1003</td>
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</tbody>
</table>

- Additionally, one of the ePTFE grafts ² that is permitted with the Adapter is required from Table B (NOT available from CryoLife³).

Table B: 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>
<th>Product Representative Image</th>
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<tbody>
<tr>
<td>GORE® ACUSEAL²</td>
<td>W.L. Gore &amp; Associates</td>
<td>40cm</td>
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<td>SW</td>
<td>25053, 25142, 25052</td>
<td></td>
</tr>
</tbody>
</table>

SW = Standard Wall

General Warnings: The Adapter should NOT be connected to any graft other than a new graft listed in Table B. Grafts that were implanted previously should not be used with the Adapter.

NOTE:
- The GORE ACUSEAL Vascular Graft is available through W.L. Gore & Associates.
- The FLIXENE Standard Wall Vascular Graft is available through Atrium Medical (Maquet Getinge Group).

¹) HeRO Graft IFU.
²) W.L. Gore & Associates. GORE ACUSEAL Vascular Graft Configurations. [Website Link], downloaded on 06/01/2015.
Surgical technique is at the discretion of the surgeon. Variations in technique and practices will inevitably and appropriately occur when clinicians take into account the needs of the individual patients, available resources, and limitations unique to an institution or type of practice.