HeRO Graft bypasses central venous stenosis

Reducing Catheter Dependency
HeRO Graft

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.

Key Benefits
- **Fewer Infections**: 69% reduced infection rate compared with catheters¹
- **Superior Dialysis Adequacy**: 1.7 Kt/V, a 16% to 32% improvement compared with catheters¹
- **High Patency Rates**: Up to 87% cumulative patency at 2 years¹,²
- **Cost Savings**: A 23% average savings per year compared with catheters³

HeRO Graft Candidates
- Catheter-dependent or approaching catheter-dependency
- Failing fistulas or grafts due to central venous stenosis

HeRO Graft vs. Catheter

<table>
<thead>
<tr>
<th>Key Features</th>
<th>Device</th>
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<tbody>
<tr>
<td>Infection rates</td>
<td>HeRO Graft</td>
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<tr>
<td>comparable to AVG¹</td>
<td>Catheter</td>
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<tr>
<td>Dialysis adequacy (Kt/V)</td>
<td>HeRO Graft</td>
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<tr>
<td>comparable to AVG¹</td>
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Treatment Algorithm

Failing AVF or AVG due to central venous stenosis

AVF

AVG

HeRO Graft

Catheter

HeRO Graft Candidates

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ePTFE Graft with Connector

- Beading (3-4cm) for kink resistance
- Orientation line on graft to guide placement during tunneling
- Titanium connector

Silicone-Coated Nitinol Component

- No venous anastomosis
- Reinforced 48 braid nitinol: kink & crush resistant
- Removable and replaceable
- Radiopaque band (at distal tip) integrated within the silicone

HeRO Graft is classified by the FDA as a vascular graft prothesis.
**Procedure Overview**

**Venous Outflow Component:** Utilizing percutaneous endovascular techniques, the Venous Outflow Component is placed in the central vein with the radiopaque distal tip in the mid to upper right atrium.

**Arterial Graft Component:** At the deltopectoral groove, the connector on the Arterial Graft Component is joined with the Venous Outflow Component. A standard arterial anastomosis is performed to attach the Arterial Graft Component to the target inflow artery.

**Implant Site Examples**

**Clinical Outcomes**

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<tbody>
<tr>
<td><strong>Bacteremia Rates</strong></td>
<td>0.14</td>
<td>0.72</td>
<td>0.70</td>
<td>2.3¹</td>
<td>0.11⁴</td>
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<td>(Infections/1,000 days)</td>
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<tr>
<td><strong>Adequacy of Dialysis</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>1.7</td>
<td>1.29-1.46³</td>
<td>1.37-1.62²</td>
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<td>(mean Kt/V)§</td>
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<tr>
<td><strong>Cumulative Patency</strong></td>
<td>91%</td>
<td>68%</td>
<td>72%¹</td>
<td>37%¹</td>
<td>65%¹</td>
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<td>(at 1 year)</td>
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<td><strong>Intervention Rate</strong></td>
<td>1.5</td>
<td>2.2</td>
<td>2.5</td>
<td>5.8¹</td>
<td>1.6-2.4¹</td>
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<td>(per year)</td>
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§ Note: Every 0.1 decrease in Kt/V increases 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

‡ 8.6 months

A full bibliography of over 150 HeRO Graft publications and presentations is available at www.Merit.com/hero.
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
- Is the measured Kt/V less than 1.4?  □ YES □ NO
- Has the flow rate dropped >20%?  □ YES □ NO
- Does the patient have swollen arms and/or distended collateral veins?  □ YES □ NO

If □ YES is checked for any box above, consider referring the 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 3
- Cost savings of over $3,100 (per patient/year) to the dialysis center when converting catheter-dependent patients to the HeRO Graft 9
- Reduces catheter-related infections and hospital admissions projected at $23k to $56k per stay 10, 11
- Lowers interventions and associated costs by more than 50% compared to catheters 1, 2

Impact of HeRO Graft in the Era of Dialysis Provider Bundling 9

Surgical Assessment

- Bilateral central venography to confirm central venous stenosis
- Vessel mapping to confirm artery ≥3mm for arterial anastomosis
- Medically-manage for hypercoagulation
- Infection-free
- Ejection fraction ≥20%
- Systolic blood pressure ≥100mmHg

Learn more at merit.com/hero

Product Code | Component | Diameter (ID) | Length
--- | --- | --- | ---
HeRO 1001 VOC | Venous Outflow Component | 5mm | 40cm (customizable)
HeRO 1002 | Arterial Graft Component | 6mm (ePTFE); 6mm - 5mm (connector) | 53cm (connector: 3cm)
HeRO 1003 | Accessory Component Kit | N/A | N/A

Learn more at merit.com/hero

References:
2. Gage et al., EJVES 2012
3. Dragofor et al., JSR 2012
4. Nassor et al., Semin Dial 2014
5. Data on file
6. Holger et al., Nephrology 2004
7. Dhingra et al., Kidney Int 2001
8. 2006 NKF KDOQI, Guideline 4
9. Yost and Dinwiddie, American Society of Nephrology (ASN), Nov 2010
10. Ramannathan et al., Infect Control Hosp Epidemiol 2007
11. O’Grady et al., The Centers for Disease Control 2002

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

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.