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HeRO Graft Introduction

- AV access graft with continuous outflow into the central venous system
- Unlike a traditional AV graft, HeRO Graft has no venous anastomosis
- Fully subcutaneous implant
- Traverses central venous stenosis allowing for long-term hemodialysis access
Product Overview

Arterial Graft Component
6mm (ID) x 50cm

Connector
6mm - 5mm (ID)

Venous Outflow Component
5mm (ID), 6.3mm (OD), 19F (OD) x 40cm (customizable length)

ePTFE Graft
• Beading (3-4cm) for kink resistance
• Orientation line on graft to guide placement during tunneling
• Connector

Silicone-Coated Nitinol Component
• No venous anastomosis
• Reinforced 48 braid nitinol: kink and crush resistant
• Removable and replaceable
• Radiopaque band (at distal tip)
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
- Catheter-dependent or approaching catheter dependency

1) HeRO Graft IFU.
HeRO Graft in ESRD Network’s “Catheter Reduction Toolkit”

- **HeRO Graft** referenced in Forum of ESRD Network’s Medical Advisory Council *Catheter Reduction Toolkit*¹

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¹ The National Forum of ESRD Networks’ Medical Advisory Council, Catheter Reduction Toolkit 2009; revised 2011, page 24
HeRO Graft in Update from National Kidney Foundation (NKF)

HeRO Graft is featured in NKF’s “Clinical Update on An Alternative Vascular Access for the Catheter-Dependent Hemodialysis Patient”

1) NKF Clinical Update, 12-10-4487_BBE.
HeRO Graft Key Benefits

- **Fewer Infections**: 69% reduced infection rate compared with catheters\(^1,2\)

- **Superior Dialysis Adequacy**: 1.7 Kt/V, a 16% to 32% improvement compared with catheters\(^1,2\)

- **23% average savings** per year with the HeRO Graft compared with catheters\(^2,3\)

- **Lower Intervention Rates**: 1.5 to 2.5 interventions per year compared with 5.8 per year with catheters (a 57% to 74% reduction)\(^1,2,4,5\)

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1) Katzman et al., J Vasc Surg 2009. Comparison to catheters data on file. 2) When used with HeRO 1001 and HeRO 1002. 3) Dageforde et al., JSR 2012. 4) Gage et al., EJVES 2012. 5) Nassar et al., Semin Dial 2014
# Key Features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Device</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection rates comparable to access grafts(^1)-(^3)</td>
<td>HeRO Graft</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Catheter</td>
<td></td>
<td>✗</td>
</tr>
<tr>
<td>Dialysis adequacy (Kt/V) comparable to access grafts(^1)-(^3)</td>
<td>HeRO Graft</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Catheter</td>
<td></td>
<td>✗</td>
</tr>
<tr>
<td>Patency rates comparable to access grafts(^1)-(^3)</td>
<td>HeRO Graft</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Catheter</td>
<td></td>
<td>✗</td>
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## Clinical Outcomes

<table>
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<tbody>
<tr>
<td><strong>Bacteremia Rates</strong> (Infections/1,000 days)</td>
<td>0.14</td>
<td>0.13</td>
<td>0.70</td>
<td>2.31¹,³,⁴</td>
<td>0.11²,⁴</td>
</tr>
<tr>
<td><strong>Adequacy of Dialysis</strong> (mean Kt/V)</td>
<td>NA</td>
<td>1.6</td>
<td>1.7</td>
<td>1.29 - 1.46⁴</td>
<td>1.37 - 1.62²-⁴</td>
</tr>
<tr>
<td><strong>Cumulative Patency at 1 Year</strong></td>
<td>91%</td>
<td>68%</td>
<td>72%^</td>
<td>37%¹,³,⁴</td>
<td>65%¹-⁴</td>
</tr>
<tr>
<td><strong>Intervention Rate</strong> (per year)</td>
<td>1.5</td>
<td>2.2</td>
<td>2.5</td>
<td>5.8¹,³</td>
<td>1.6 - 2.4¹,³</td>
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</tbody>
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¹Note: Every 0.1 decrease in Kt/V increases the mortality rate by 7%⁵ and is significantly (P<0.05) associated with 11% more hospitalizations, 12% more hospital days, and a $940 increase in Medicare inpatient expenditures.⁶

^8.6 months

150+ Publications & Presentations¹

- A bibliography of HeRO Graft publications and presentations is available at www.herograft.com.

¹ Data on file.
# Identifying a HeRO Graft Candidate

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
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</thead>
<tbody>
<tr>
<td>Is the patient currently catheter dependent or approaching catheter dependency?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Is the patient failing a fistula or AV graft?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does the patient have a record of central venous stenosis?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does the patient have swollen arms and/or distended collateral veins?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Has the patient had multiple interventions (e.g. angioplasty)?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Is the measured Kt/V less than 1.4?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Has the flow rate dropped &gt;20%?</td>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>

If ☑ YES is checked for any box above, consider referring patient for a surgical assessment.
HeRO Graft Patients Will Have Three Incision Sites

1. Venotomy
2. Connector
3. Arterial anastomosis

1) Care & Cannulation Guide, L7159
Identification Card is Provided for Every Patient

Patient Identification Wallet Card

- Designed to be carried with the patient and shown to the dialysis center care team
- Identifies the patient has a HeRO Graft
Timing of Cannulation

• Assess the HeRO Graft to evaluate for first cannulation approximately two to four weeks post implant.¹,²

• The implanting surgeon may use a HeRO Graft component that allows for a different ePTFE graft to be used with the HeRO Graft than what is provided by CryoLife.¹
  
  • In these cases, consult the graft manufacturer Instructions for Use for more information regarding the cannulation of the other commercially available grafts selected for use with the HeRO Graft.¹

• Follow standard facility protocol for care and cannulation.

Arterial Graft Component Physical Assessment: Look, Listen, & Feel

Look
- Uniform sized graft
- No irregular areas or pseudoaneurysm formations
- Organized cannulation site rotation

Listen
- Low pitch continuous diastolic and systolic sound
- HeRO Graft bruit may be slightly softer due to absence of venous anastomosis

Feel
- Thrill and/or pulse strongest at the arterial anastomosis but should be felt over the course of the entire graft
- HeRO Graft thrill may also be less prominent
- Easy to compress

Cannulate HeRO Graft Using KDOQI Guidelines

- Aseptic technique should be used for all cannulation
- Swelling should have subsided so that palpation of the course of the graft can be performed
- Rotation of cannulation sites is needed to avoid pseudoaneurysm formation

• Palpate to confirm connector location

• A light tourniquet may be used to dilate the graft

• Stay at least 3” (8 cm) from the connector to avoid graft rings
HeRO Graft Cannulation Considerations (continued)¹

- Follow dialysis unit protocol for cannulation distance from the arterial anastomosis incision.
- If cannulating towards the arterial anastomosis incision, stay at least the length of the fistula needle from the incision site.

¹ Care & Cannulation Guide, L7159
HeRO Graft Cannulation Considerations (continued)\textsuperscript{1,2}

- Never cannulate the Venous Outflow Component
- Avoid the use of fistula clamps for hemostasis
- Remove bridging catheter (if applicable) as soon as possible after successful HeRO Graft cannulation

A HeRO Graft patient who has been cannulated in the Arterial Graft Component for hemodialysis.

\textsuperscript{1} HeRO Graft IFU.  \textsuperscript{2} Care & Cannulation Guide, L7159.
*If AVF is matured or AVG is incorporated when the HeRO Graft is implanted for a salvage procedure, the AVF or AVG may be cannulated immediately.

Follow your dialysis facility protocol for care and cannulation.
HeRO Graft Patients’ Feedback

With the HeRO Graft, I no longer have catheter tubes exposed outside my body that are a constant risk and worry of infection.
- Kaaren

“It gave me another chance at life.”
- Stewart

“Consider the HeRO Graft! Yes, there are needles involved, but the risk of infection is far less than a catheter and that is worth it to me.”
- Kay
Cost Benefits: Dialysis Center

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

Cost savings of over **$3100** (per patient/year) to the dialysis center when converting catheter-dependent patients to the HeRO Graft

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1) Yost and Dinwiddie, American Society of Nephrology (ASN), Nov 2010.
Dialysis Centers Reaching QIP Goals

• **HeRO Graft** is a totally subcutaneous vascular graft that bypasses central venous stenosis and may be a possible solution for reducing catheter rates in your dialysis center.

• Dialysis clinics with high catheter rates could face reimbursement penalties up to 2%.¹

• Would you consider the HeRO Graft to help reduce your catheter rates and reach your Quality Incentive Program (QIP) goals?

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.