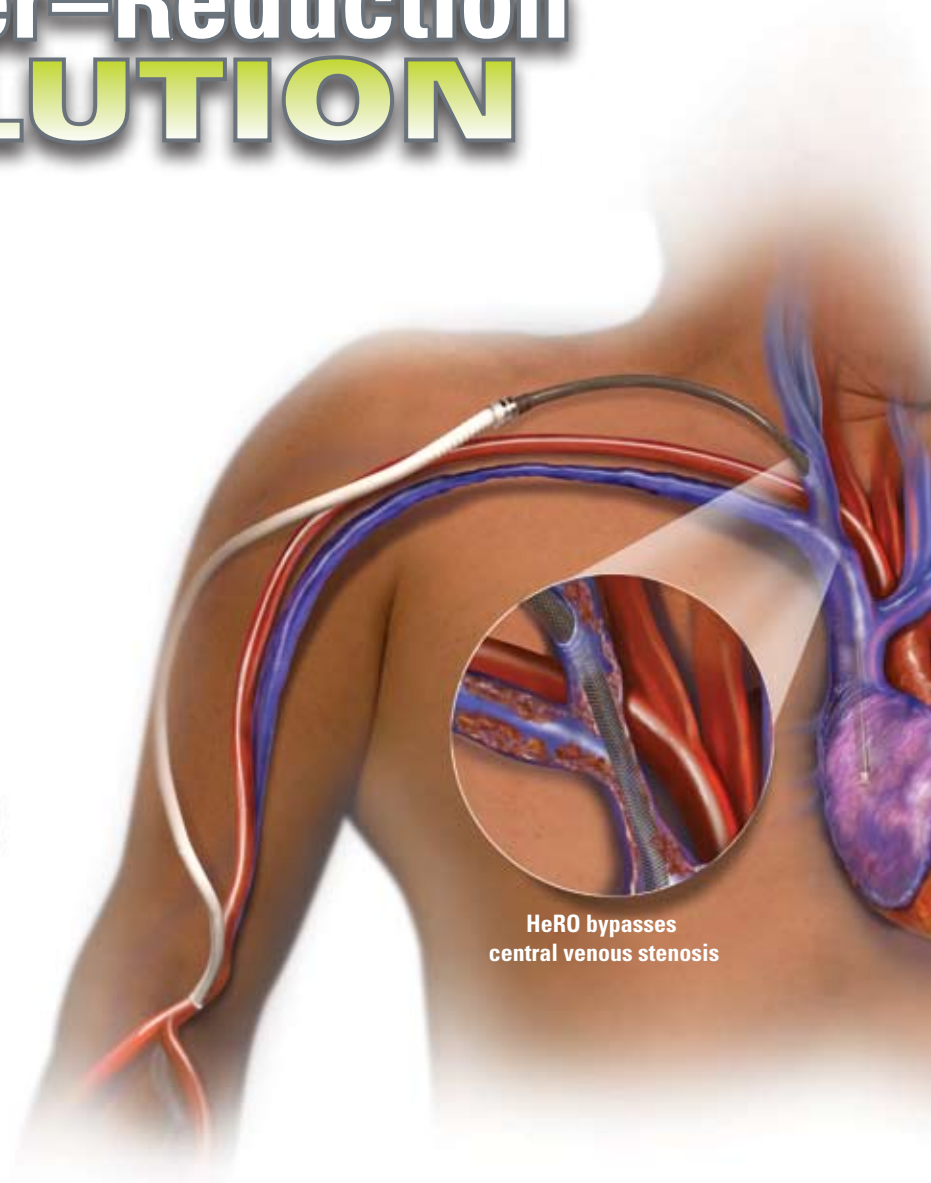
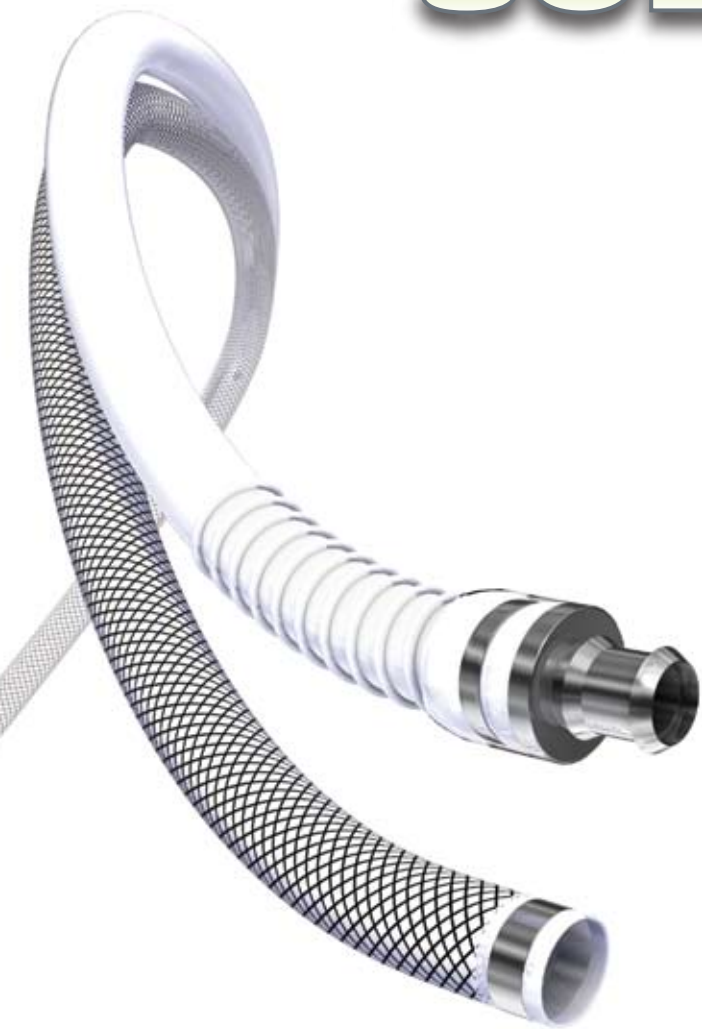




your
Catheter-Reduction
SOLUTION

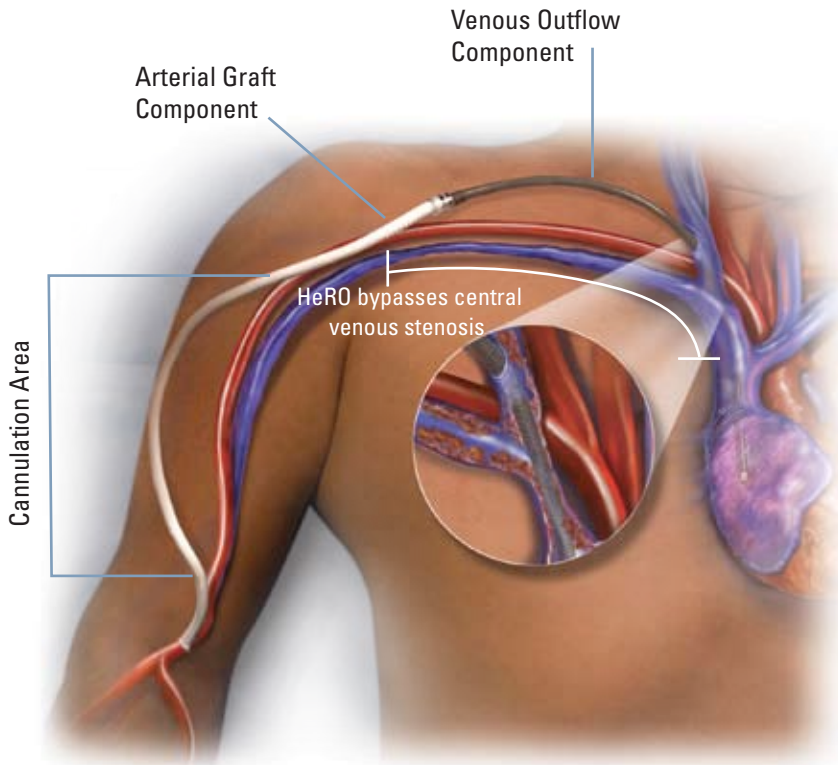


HeRO bypasses
central venous stenosis



hemosphere[®]
Restoring Lives. Revolutionizing Care.

A Unique Solution for Patients with Central Venous Stenosis



"I think this device saves lives for people who would otherwise be permanently catheter-dependent."

Jeffrey H. Lawson, MD, PhD
Vascular Surgery, Duke University, Durham, NC

Introducing the **HeRO**[®] Graft

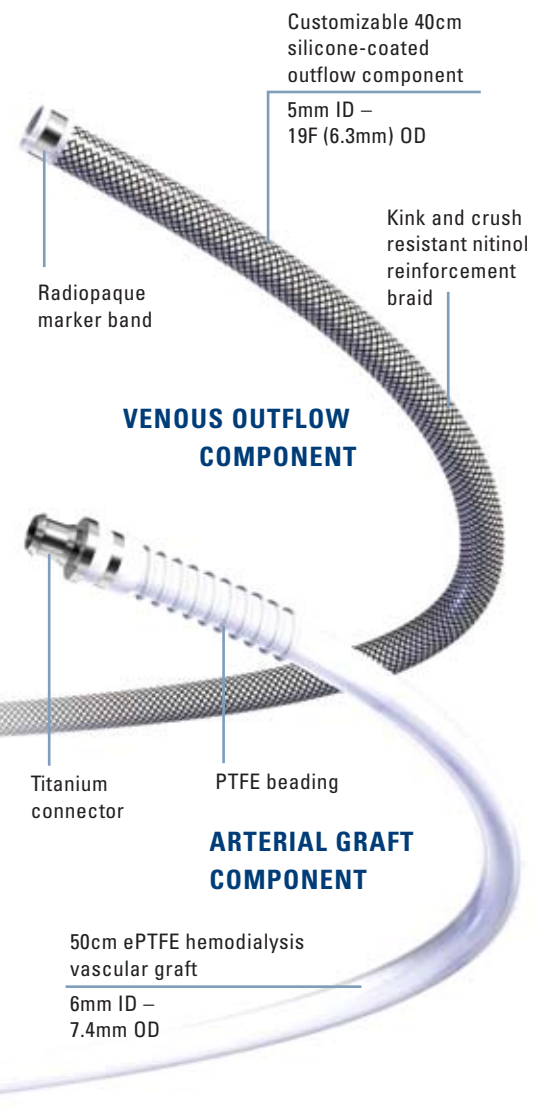
HeRO is the only fully subcutaneous AV access solution clinically proven to maintain long-term access for hemodialysis patients with central venous stenosis. HeRO is FDA classified as a graft.

Venous Outflow Component

Utilizing endovascular techniques, the venous outflow component is placed in the central venous vasculature with the radiopaque distal tip in the mid to upper right atrium.

Arterial Graft Component

At the deltopectoral groove, the proprietary titanium connector on the graft is joined with the venous outflow component. A standard arterial anastomosis is performed to attach the ePTFE graft to the target artery.



HeRO[®] Graft Demonstrates Clinical and Economic Benefits

Compared to published hemodialysis catheter data, the HeRO Graft:

- Reduced infection by **69%**
- Improved adequacy of dialysis (Kt/V = **1.7**)
- Demonstrated **patency** and **flow rates** comparable to grafts

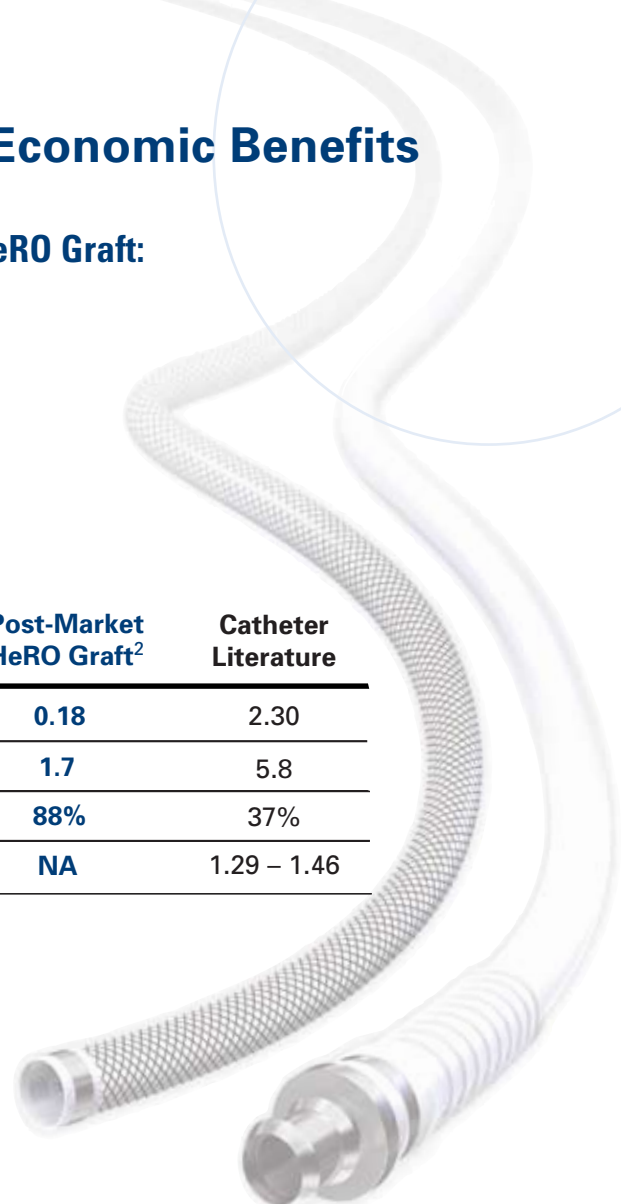
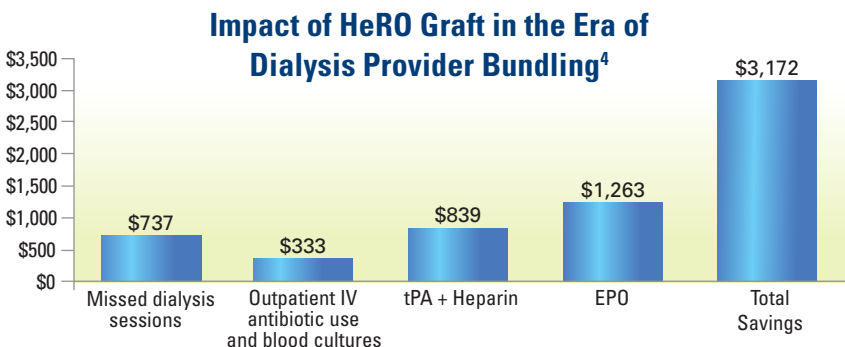
HeRO Clinical Outcomes Comparison

| Multi-Center Data | AVG Literature | FDA Clinical Trial HeRO Graft ¹ | Post-Market HeRO Graft ² | Catheter Literature |
|---|----------------|--|-------------------------------------|---------------------|
| Bacteremia Rates (Infections/1,000 days) | 0.11 | 0.70 | 0.18 | 2.30 |
| Intervention Rates (Per patient year) | 1.6 – 2.4 | 2.5 | 1.7 | 5.8 |
| 12 Month Secondary Patency Rates | 65% | 78% | 88% | 37% |
| Adequacy of Dialysis (mean Kt/V) | 1.37 – 1.62 | 1.70 | NA | 1.29 – 1.46 |

A full bibliography of over 70 HeRO publications and presentations is available on our website at www.herograft.com.

HeRO[®] Graft Supports Catheter-Reduction Initiatives

- **Reduces** catheter-related infections and hospital admissions projected at \$23-45K per stay³
- **Lowens** interventions and associated costs by more than 50% compared to catheters^{1,2}
- **Savings** of over \$3000 per patient each year to the dialysis center when converting catheter-dependent patients to the HeRO Graft⁴



HeRO is clinically proven¹ to **reduce** catheter-related infections by **69%**

“The HeRO graft not only reduces catheter rates, life-threatening infections, and overall costs to the healthcare system; but my patients have a better quality of dialysis care and quality of life than catheters offer.”

Kim Carter-Birdsong, BSN, RN
South Fulton Dialysis Center, Atlanta, GA

How to Identify a **HeRO** Candidate

HeRO candidates are patients who are:

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

Dialysis Access Monitoring and Surveillance

- | | | |
|--|------------------------------|-----------------------------|
| Is patient currently catheter-dependent or approaching catheter dependency? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Is the current measured Kt/V less than 1.4? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Based on your monthly access surveillance, has the flow rate dropped by >20%? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Does the patient have a swollen arm, limb edema, or prominent chest wall collateral veins? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

If **YES** is checked for any box above, refer patient for a central venogram to assess for central venous stenosis

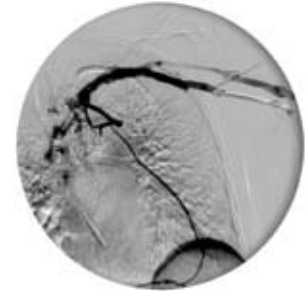
Surgical Assessment for HeRO Graft may include:

- Bilateral central venography to confirm central venous stenosis
- Vessel mapping to confirm artery $\geq 3\text{mm}$ for arterial anastomosis
- Medically-managed for hypercoagulation
- Ejection fraction $\geq 20\%$
- Blood pressure systolic $\geq 100\text{mmHg}$
- Infection -free

“Every time I discuss the HeRO option with a dialysis patient who has exhausted his or her upper extremity veins, I see a glimmer of hope in their eyes and eagerness to try it.”

George Nassar, MD

Nephrology, The Kidney Institute, Houston, TX



This patient presented with central venous occlusion caused by long term catheter use. The existing catheter was excised and HeRO was implanted over the wire.



Fluoroscopic image of the HeRO outflow component.

Treatment Algorithm



SCVS, 37th Annual Society for Clinical Vascular Surgery Meeting, Orlando, FL, March 2009, Christopher L. Stout, MD, Jean M. Panneton, MD, and Marc H. Glickman, MD, Division of Vascular Surgery, Eastern Virginia Medical School, Norfolk, VA

“HeRO is a unique new solution in the vascular access treatment algorithm that returns catheter-dependent patients (to) graft-like outcomes, and should be considered before a thigh graft.”

Howard E. Katzman, MD, FACS

Vascular Surgery, University of Miami, Miami, FL

REFERENCES: A full bibliography of HeRO publications, posters, and presentations is available online at www.heroaccess.com/news-publications. 1) Data from HeRO Bacteremia Study submitted for FDA Clearance published in Journal of Vascular Surgery (JVS), Sept 2009, Katzman, MD, et. al. Comparisons to AVG and catheters are from literature review on file at Hemosphere. 2) Data presented at American Society of Nephrology (ASN), Nov 2010 with data contributed by Duke University, University of Miami, Baylor Health Systems, and Bamberg County Hospital. 3) Ramanathan V. et. al.; Healthcare costs associated with hemodialysis catheter-related infections: a single center experience; Infect Control Hosp Epidemiol; 2007;4 28:606-9. 4) Data presented at American Society of Nephrology (ASN), Nov 2010 by Larry Yost, RPh and Lesley Dinwiddie, MSN, RN, FNP, CNN.

INDICATIONS FOR USE: The HeRO Graft is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. See Instructions for Use for full indication, contraindication and caution statements. Rx Only.

WARNINGS: Do not attempt intervention without device information. Do not place central lines or other medical devices on the same side as the HeRO device. © 2011 Hemosphere and HeRO are registered trademarks of Hemosphere, Inc.



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