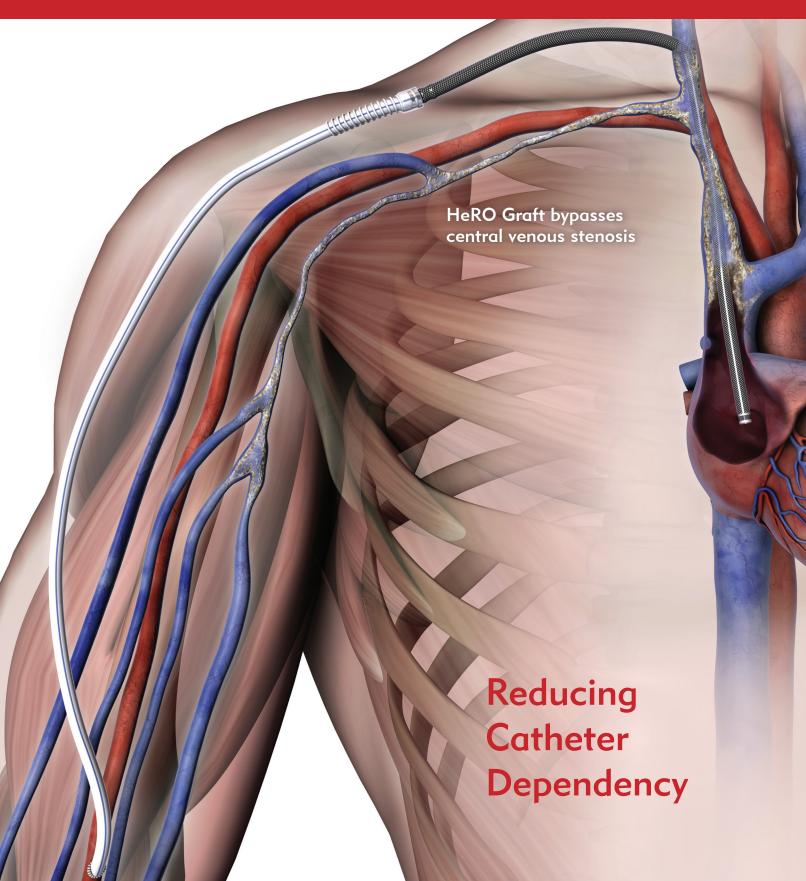




PERIPHERAL INTERVENTION



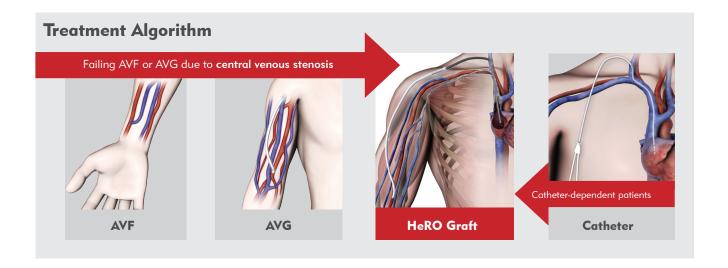


HeRO Graft

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**.

HeRO Graft Candidates

- Catheter-dependent or approaching catheterdependency
- Failing fistulas or grafts due to 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 years^{1,2}
- Cost Savings: A 23% average savings per year compared with catheters³

ePTFE Graft with Connector

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

6mm (ID) x 50cm

HeRO Graft vs. Catheter

Key Features	Device	Yes	No	
Infection rates	HeRO Graft	х		
comparable to AVG ¹	Catheter		Х	
Dialysis adequacy (Kt/V)	HeRO Graft	х		
comparable to AVG ¹	Catheter		Х	
Patency rates	HeRO Graft	х		
comparable to AVG ¹	Catheter		Х	

Silicone-Coated Nitinol Component

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





Procedure Overview

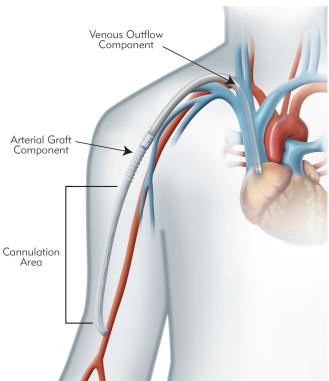
Venous Outflow Component:

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.

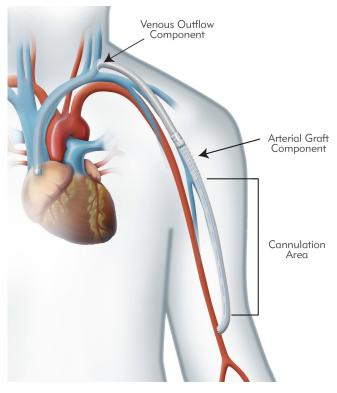
Arterial Graft Component:

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







Left Side Access

Clinical Outcomes

	HeRO Graft Gage, et al. EJVES ²	HeRO Graft Nassar, et al Semin Dial ⁴	HeRO Graft Katzman, et al. JVS ¹	Catheter Literature	ePTFE Graft Literature
Bacteremia Rates (Infections/1,000 days)	0.14	0.72	0.70	2.31	0.116
Adequacy of Dialysis (mean Kt/V) [§]	N/A	N/A	1.7	1.29-1.465	1.37-1.625
Cumulative Patency (at 1 year)	91%	68%	72% [‡]	37%1	65% ¹
Intervention Rate	1.5	2.2	2.5	5.81	1.6-2.41

[§] Note: Every 0.1 decrease in Kt/V increases the mortality rate by 7%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



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

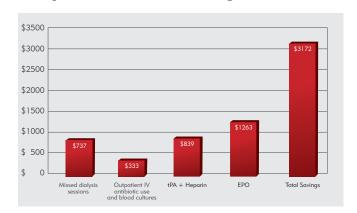
Cost Benefits

- 23% average savings per year with the HeRO Graft compared with catheters³
- Cost savings of over \$3,100 (per patient/year) to the dialysis center when converting catheter-dependent patients to the HeRO Graft9
- 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 catheters1,2

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

Impact of HeRO Graft in the Era of Dialysis Provider Bundling⁹



Product Code	Component	Diameter (ID)	Length
HeRO 1001	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

References

- 1) Katzman et al., J Vasc Surg 2009.
- 2) Gage et al., EJVES 2012. 3) Dageforde et al., JSR 2012
- 4) Nassar et al., Semin Dial 2014
- 5) Data on file.
- 6) Hajjar et al., Nephrologie 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) Ramanathan 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.

Learn more at www.MeritEMEA.com/hero



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