

HeRO Graft bypasses
central venous stenosis

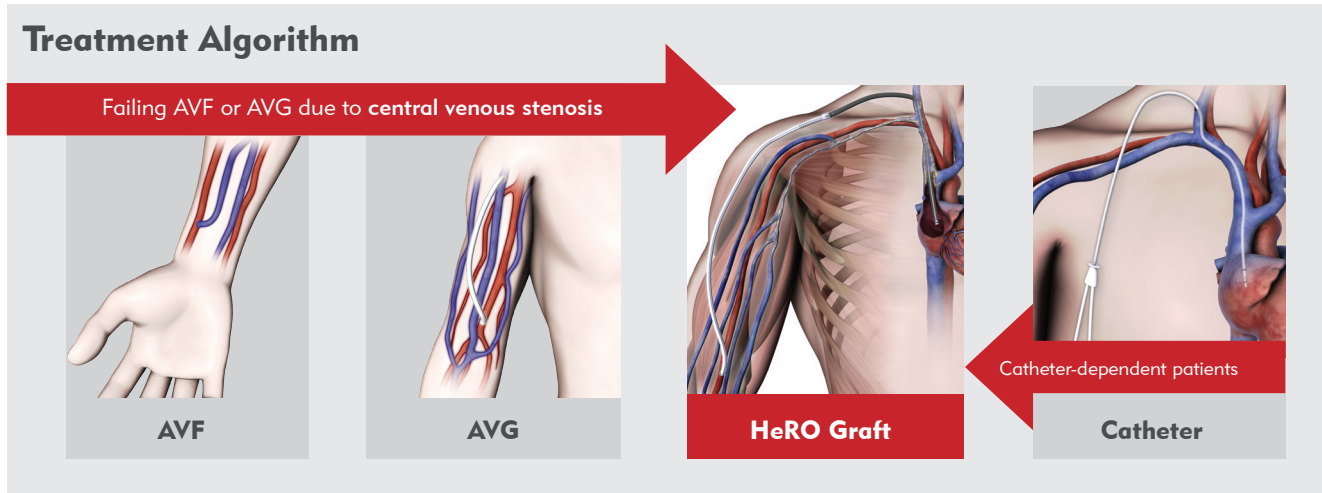
**Reducing
Catheter
Dependency**

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**.

HeRO Graft Candidates

- Catheter-dependent or approaching catheter-dependency
- 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

HeRO Graft vs. Catheter

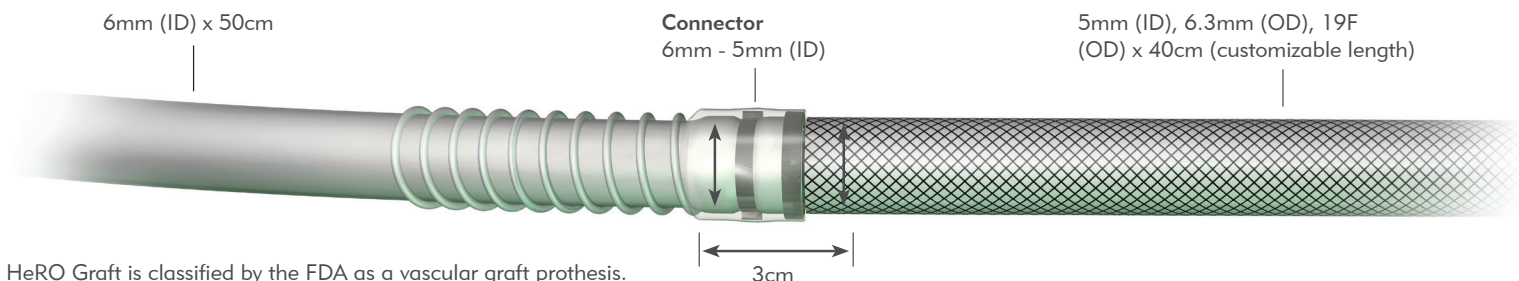
Key Features	Device	Yes	No
Infection rates comparable to AVG ¹	HeRO Graft	x	
	Catheter		x
Dialysis adequacy (Kt/V) comparable to AVG ¹	HeRO Graft	x	
	Catheter		x
Patency rates comparable to AVG ¹	HeRO Graft	x	
	Catheter		x

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)



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

Procedure Overview

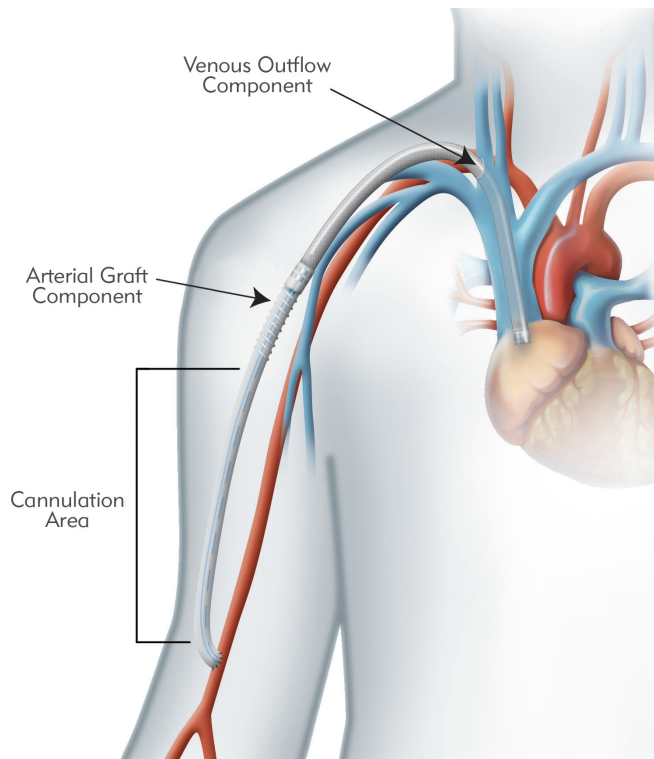
Venous Outflow Component:

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.

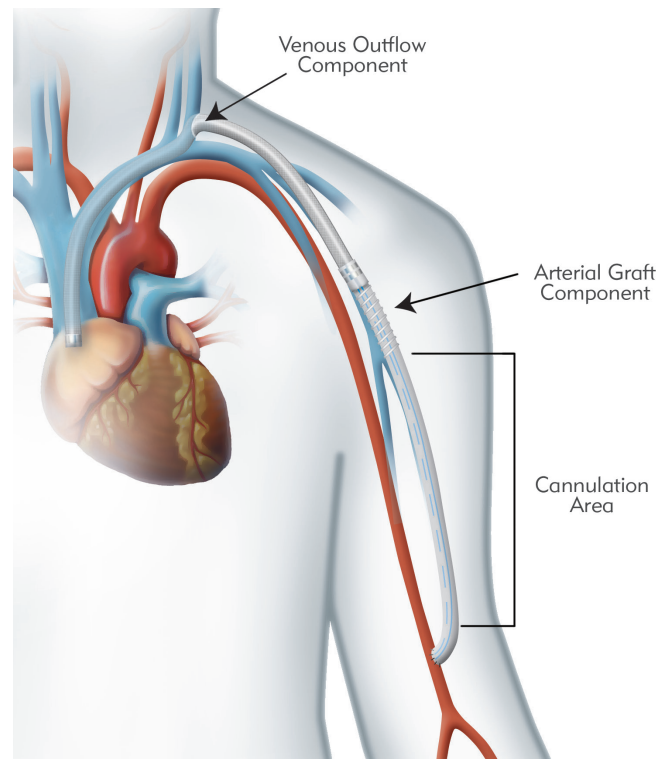
Arterial Graft Component:

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



Right Side Access



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	2.3 ¹	0.11 ⁶
Adequacy of Dialysis (mean Kt/V) [§]	N/A	N/A	1.7	1.29-1.46 ⁵	1.37-1.62 ⁵
Cumulative Patency (at 1 year)	91%	68%	72% [‡]	37% ¹	65% ¹
Intervention Rate (per year)	1.5	2.2	2.5	5.8 ¹	1.6-2.4 ¹

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

Cost Benefits

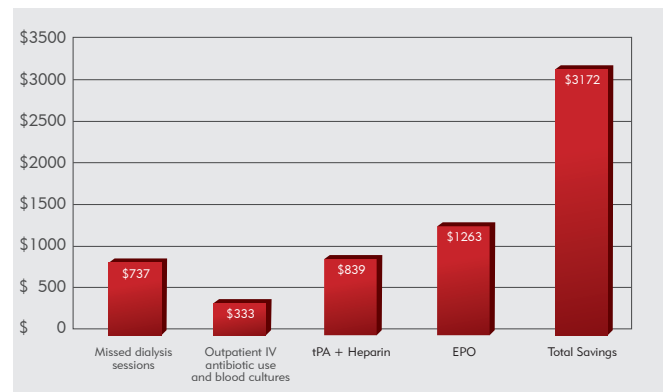
- **23% average savings** per year with the HeRO Graft compared with catheters³
- **Cost savings of over \$3,100** (per patient/year) to the dialysis center when converting catheter-dependent patients to the HeRO Graft⁹
- **Reduces** catheter-related infections and hospital admissions projected at \$23k to \$56k per stay^{10, 11}
- **Lowers interventions** and associated costs by more than 50% compared to catheters^{1, 2}

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

Surgical Assessment

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

Impact of HeRO Graft in the Era of Dialysis Provider Bundling⁹



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 Dirwiddie, 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.

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Learn more at www.Merit.com/hero



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