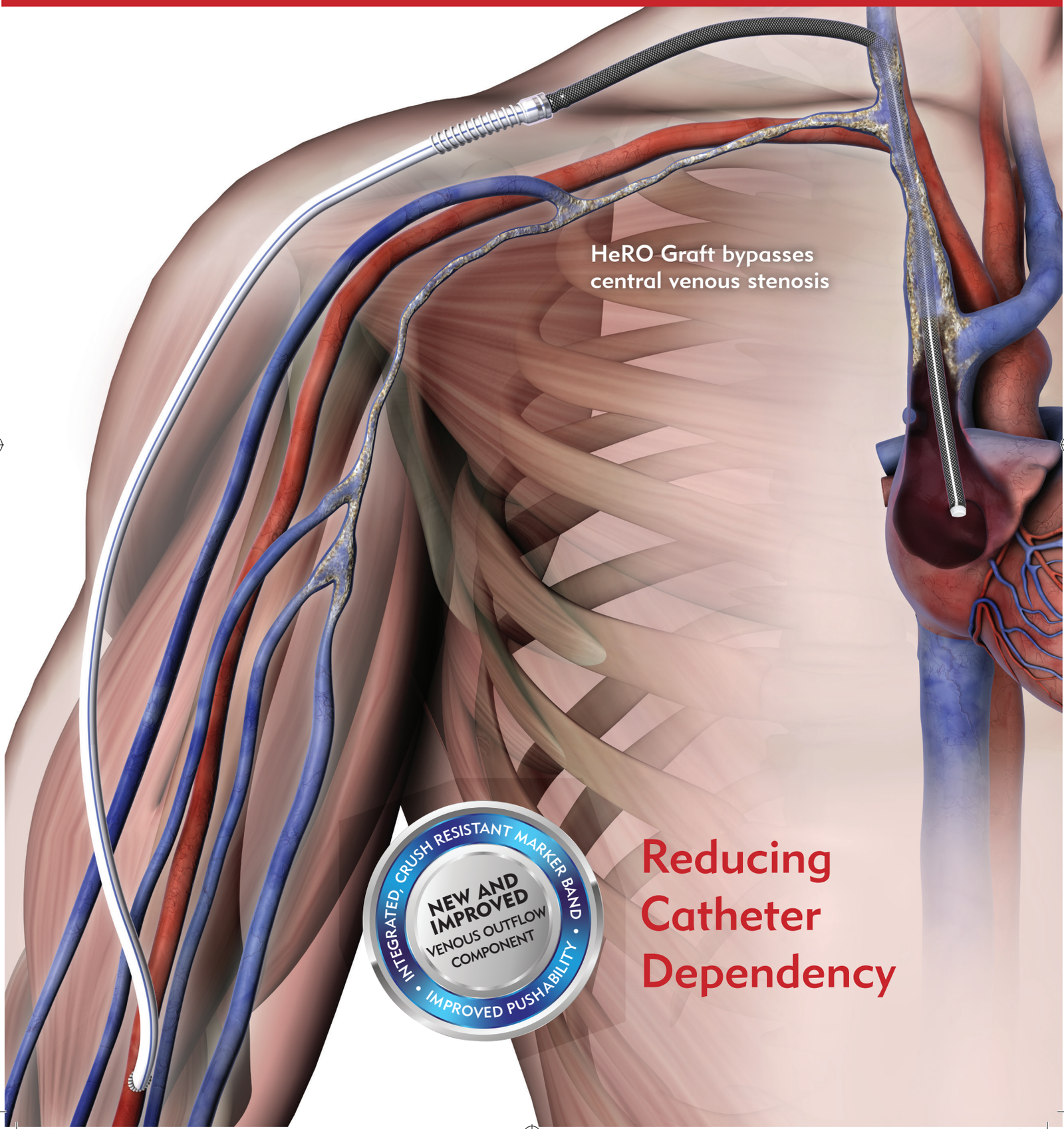
MERIT MEDICAL®

PERIPHERAL INTERVENTION

HeRO® GRAFT



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**.

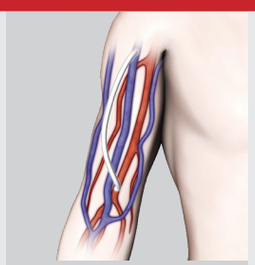
HeRO Graft Candidates

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

Treatment Algorithm

Failing AVF or AVG due to **central venous stenosis**

AVF



AVG

HeRO Graft

Catheter-dependent patients

Catheter

Key Benefits

- **Fewer Infections:** 69% reduced infection rate compared with catheters[1]
- **Superior Dialysis Adequacy:** 1.7 Kt/V, a 16% to 32% improvement compared with catheters[1]
- **High Patency Rates:** Up to 87% cumulative patency at 2 years[1,2]
- **Cost Savings:** A 23% average savings per year compared with catheters[3]

HeRO Graft vs. Catheter

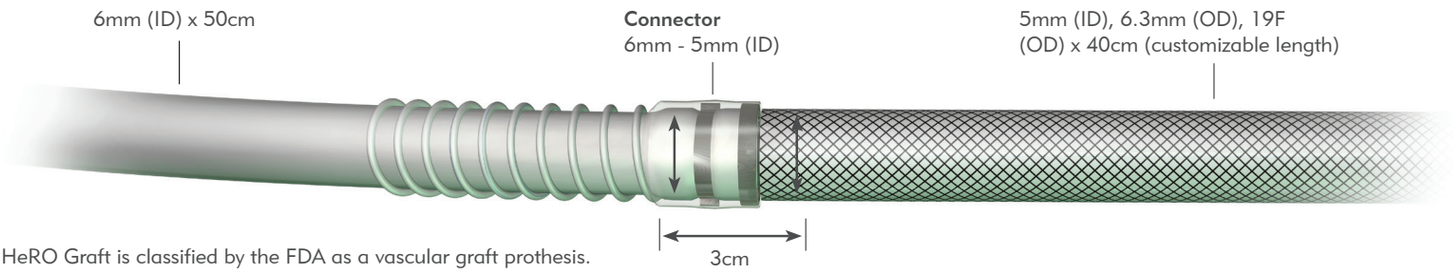
Key Features	Device	Yes	No
Infection rates comparable to AVG[1]	**HeRO Graft**	x	
	Catheter		x
Dialysis adequacy (Kt/V) comparable to AVG[1]	**HeRO Graft**	x	
	Catheter		x
Patency rates comparable to AVG[1]	**HeRO Graft**	x	
	Catheter		x

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) integrated within the silicone



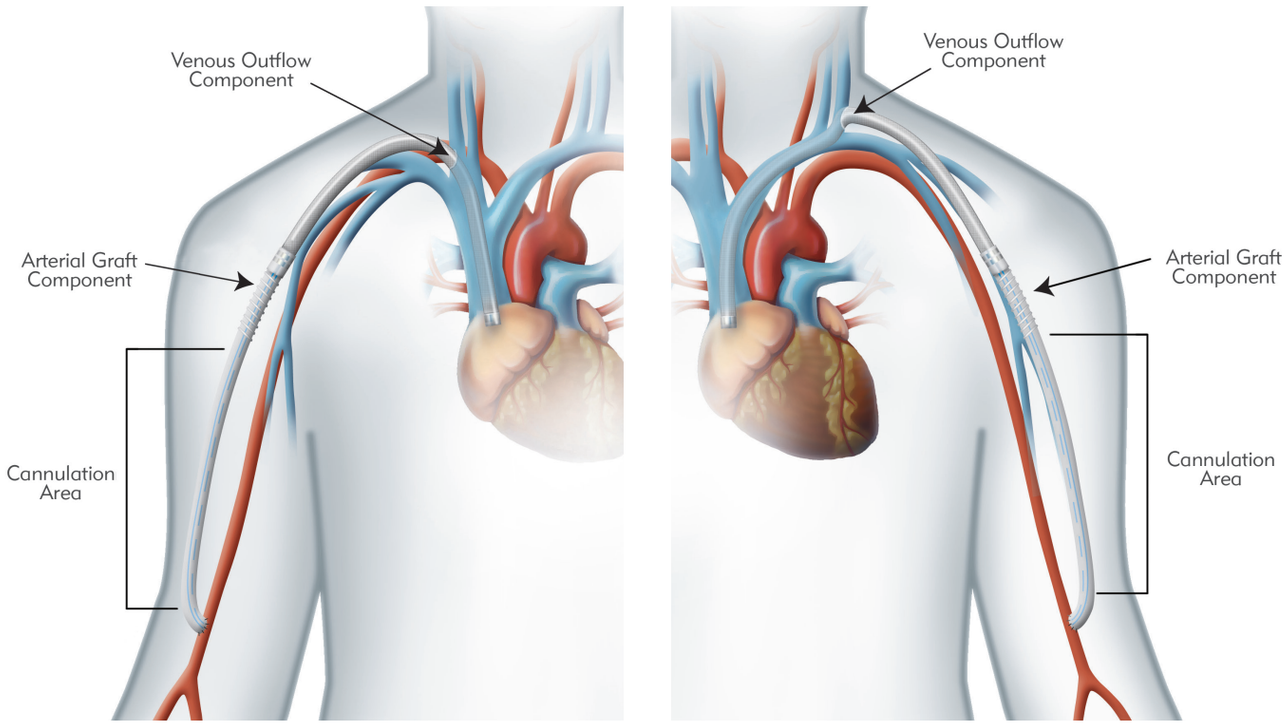
HeRO Graft is classified by the FDA as a vascular graft prothesis.

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



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

A full bibliography of over 150 HeRO Graft publications and presentations is available at **www.Merit.com/hero**.

HeRO® GRAFT

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.

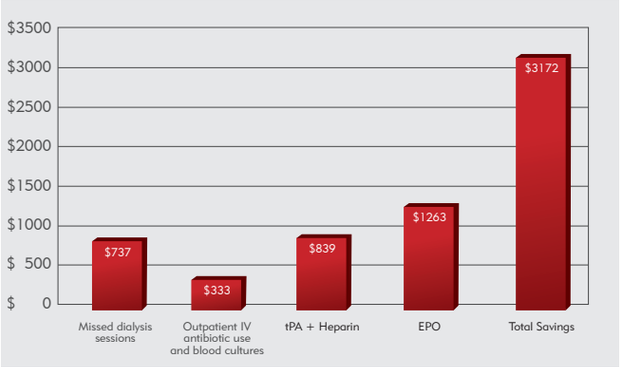
Cost Benefits

- **23% average savings** per year with the HeRO Graft compared with 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]

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 Bundling[9]



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

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 **merit.com/hero**

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

MERIT MEDICAL®

Understand. Innovate. Deliver.™

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
1.801.253.1600
1.800.35.MERIT

merit.com

Merit Medical Europe, Middle East, & Africa (EMEA)
Amerikalaan 42, 6199 AE Maastricht-Airport
The Netherlands
+31 43 358 82 22

Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland
+353 (0) 91 703 733

Australia
+61 (0) 3 8373 4943

Austria
0800 295 374

Belgium
0800 72 906 (Dutch)
0800 73 172 (Français)

Brazil
+55 11 4561 - 0062

Canada
1.800.364.4370

China
+86-10 8561 0788

Denmark
80 88 00 24

Finland
0800 770 586

France
0800 91 60 30

Germany
0800 182 0871

Hong Kong
+852-2207 6888

India
+91-80-41223376

Ireland (Republic)
1800 553 163

Italy
800 897 005

Luxembourg
8002 25 22

Netherlands
0800 022 81 84

Norway
800 11629

Portugal
308 801 034

Russia
+7 495 221 89 02

Singapore
+65 67536311

South Korea
+8210 2205 0707

Spain
+34 911238406

Sweden
020 792 445

Switzerland
(Deutsch)
+41 22 518 02 30

(Français)
+41 22 518 02 52

(Italiano)
+41 22 518 00 35

UK
0800 973 115

401512001/002 ID 022818