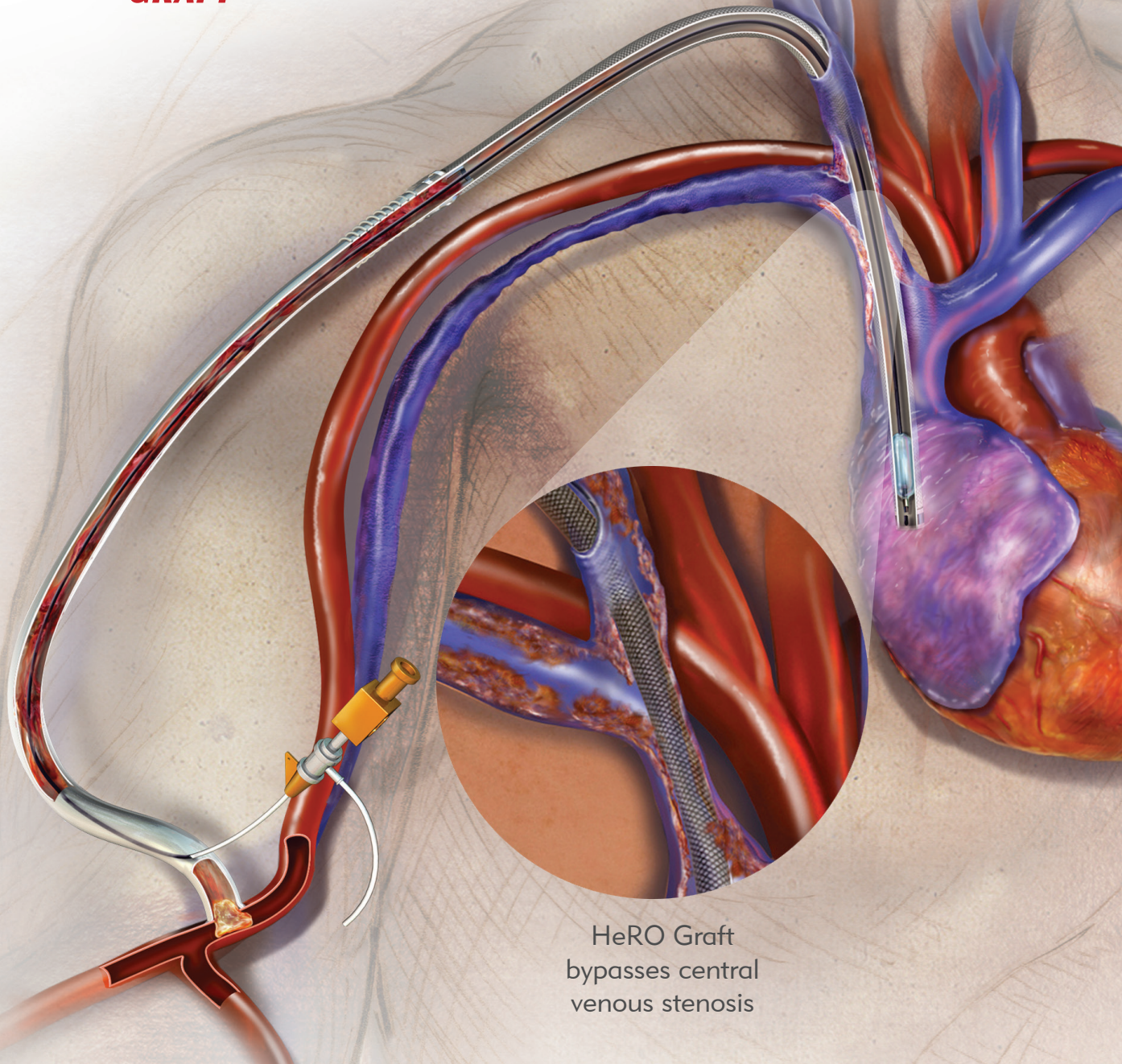


HeRO[®]
GRAFT



HeRO Graft
bypasses central
venous stenosis

Thrombectomy Guidelines

HeRO Graft

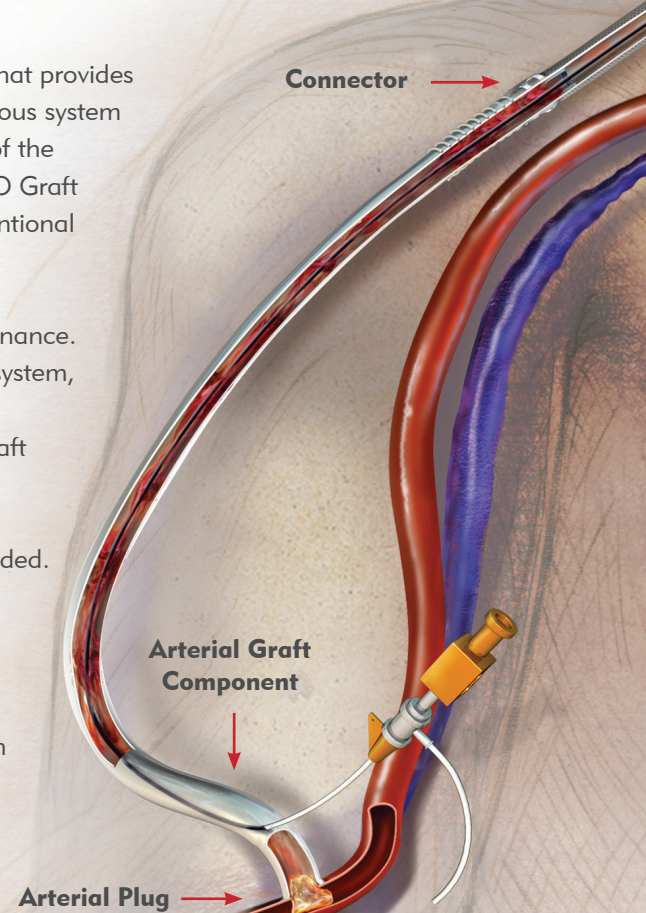
HeRO (Hemodialysis Reliable Outflow) Graft is a fully subcutaneous system that provides reliable, continuous blood flow directly from a target artery to the central venous system and into the heart. HeRO Graft has no venous anastomosis because the tip of the Venous Outflow Component is located in the mid to upper right atrium. HeRO Graft is FDA classified as a vascular graft prosthesis and is cannulated like a conventional ePTFE graft.

Like other specialized ePTFE grafts, HeRO Graft may require periodic maintenance. A percutaneous technique is recommended (e.g., a rheolytic thrombectomy system, balloon maceration, or balloon-assisted aspiration), after the ePTFE graft is completely incorporated. A surgical technique is recommended during the graft maturation period.

Use of fluoroscopy during any HeRO Graft intervention is strongly recommended.

Restoring Patency

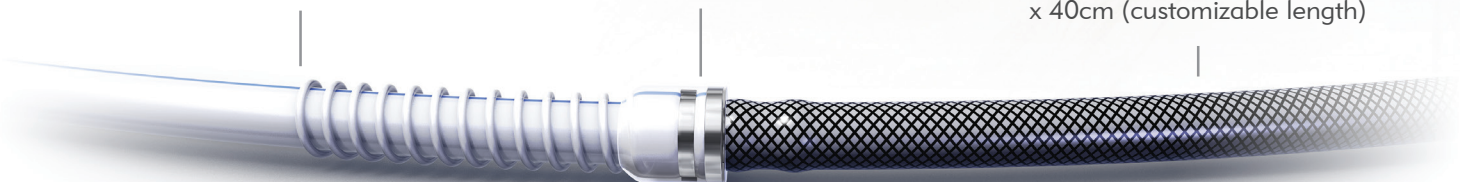
- Introduce a 7F short vascular sheath near the arterial anastomosis.
- Inflate a soft, compliant embolectomy balloon at the radiopaque marker band of the 5mm Venous Outflow Component. Do not advance the balloon beyond the radiopaque marker band to avoid dislodgment of the Venous Outflow Component.
- Pull balloon back to the connector. Apply positive aspiration while deflating the balloon by approximately 10%. Failure to deflate the balloon may result in balloon perforation as the catheter passes through the connector.
- Pull balloon through the connector and reinflate within the 6mm graft.
- Extract clot at the introducer site.
- Decloit the full length of HeRO Graft prior to removing the arterial plug to decrease risk of pulmonary embolism.

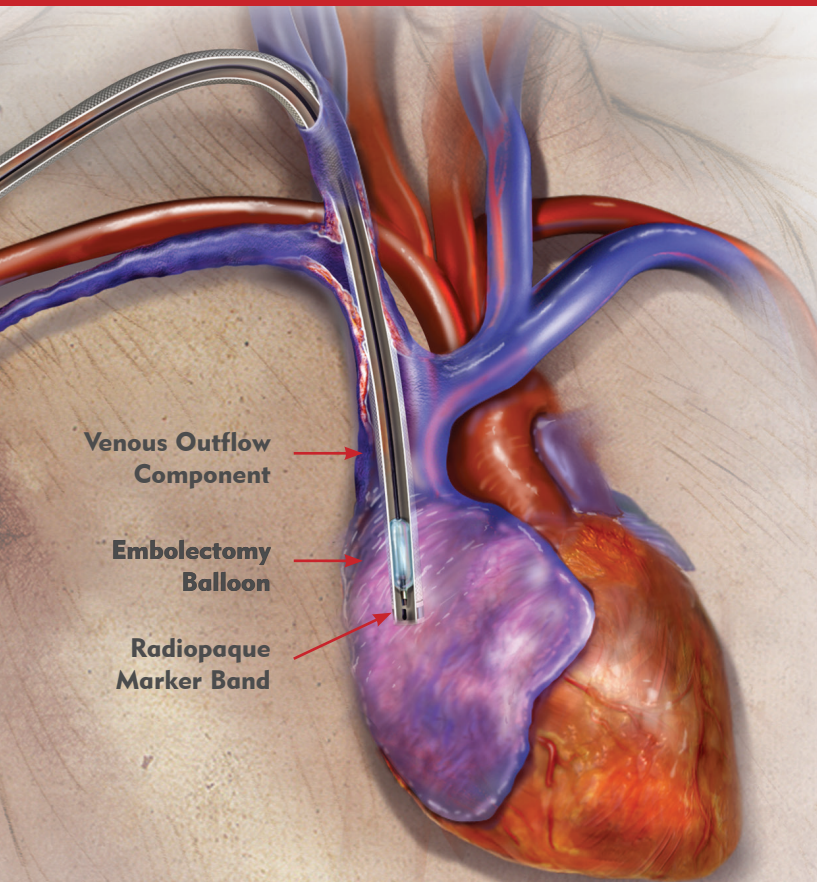


Arterial Graft Component
6mm (ID) x 50cm

Connector
6mm - 5mm (ID)

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





Venous Outflow Component

Embolectomy Balloon

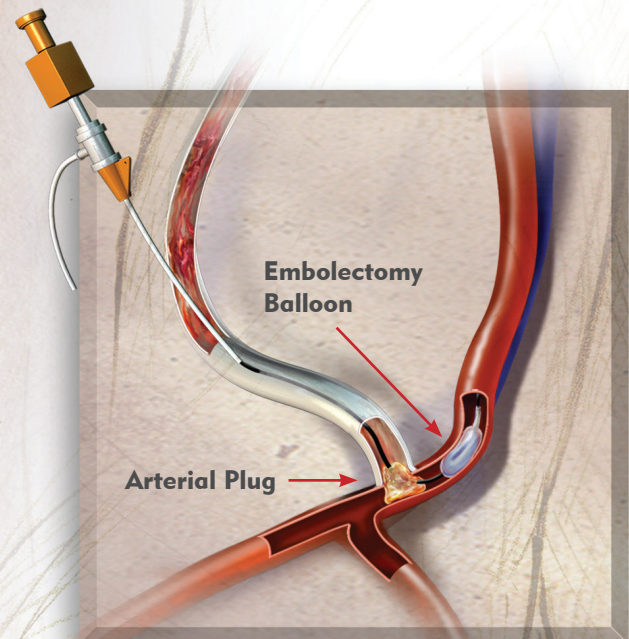
Radiopaque Marker Band

Arterial Plug Removal

- Choose a Fogarty embolectomy balloon sized for the artery (3-4mm) and insert past the arterial plug.
- Inflate the balloon, “pop” the arterial plug, then pull back to the introducer site.
- Extract the arterial plug, then confirm flow and patency throughout the device. Ultrasound may be used to assess flow.
- Reconfirm placement of the connector and Venous Outflow Component tip via fluoroscopy.

Tips for Successful Outcomes

- Percutaneous or surgical technique may be used to declot HeRO Graft. A surgical technique is recommended during the graft incorporation period to avoid risk of seroma or other complications.
- A 90cm rheolytic thrombectomy device or an 80cm soft compliant embolectomy balloon is required to accommodate the entire length of the HeRO Graft.
- Administration of drugs such as TPA or urokinase to lyse the thrombus is recommended.
- Thrombus may be soft or gelatinous in nature and is likely to be present throughout the entire HeRO Graft.



Embolectomy Balloon

Arterial Plug

CAUTION: Do not use mechanical/rotational devices (e.g., Arrow-Terrotola PTD®) in the Venous Outflow Component and/or connector as internal damage may occur to these components.



CLINICAL OUTCOMES

	HeRO Graft Patency Study ¹	HeRO Graft Bacteremia Study ¹	Catheter Literature	ePTFE Graft Literature
Bacteremia Rates (Infections/1,000 days)	0.13	0.70	2.3 ²	0.11 ³
Adequacy of Dialysis (mean Kt/V) [†]	1.6	1.7	1.29-1.46 ¹	1.37-1.62 ¹
Cumulative Patency (at 1 year)	70%	78%	37% ²	65% ²

[†] Note: Every 0.1 decrease in Kt/V increases the mortality rate by 7%⁴ and is significantly (P<0.05) associated with 11% more hospitalizations, 12% more hospital days, and a \$940 increase in Medicare inpatient expenditures.⁵

TROUBLESHOOTING THROMBOSIS

Thrombosis is the most common cause of vascular access dysfunction. Missed hemodialysis sessions significantly increase the number of thrombosis episodes in AVFs and AVGs.⁶ HeRO Graft thrombosis rates are comparable to conventional grafts and are treated with similar methods.¹

- Test for coagulability disorders after repeated clotting episodes.
- After a clotting episode, thoroughly image the inflow artery all the way to the shoulder and throughout the entire HeRO Graft, including the Venous Outflow Component tip, to identify root causes.
- Consider prescribing an anticoagulant in patients with repeated clotting episodes.
- During dialysis treatment, closely monitor the patient for hypotensive events. A clinical evaluation of prescribed hypertensive medication may be necessary.
- Avoid using fistula clamps after a dialysis session.

References:

- 1) Data on file.
- 2) Katzman et al., J Vasc Surg 2009.
- 3) Hajjar et al., Nephrologie 2004.
- 4) Dhingra et al., Kidney Int 2001.
- 5) 2006 NKF KDOQI, Guideline 4.
- 6) Shah et al., Clin Nephrol 2011.

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

Learn more at Merit.com/hero



Understand. Innovate. Deliver.™

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
+1 801-208-4300
+1 800 35 MERIT

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

Merit.com

Austria
0800 295 374

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

Denmark
80 88 00 24

Finland
0800 770 586

France
0800 91 60 30

Germany
0800 182 0871

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

Spain
+34 911238406

Sweden
020 792 445

Switzerland
(Deutsch)
+41 225180252
(Français)
+41 225948000
(Italiano)
+41 225180035
UK
0800 973 115