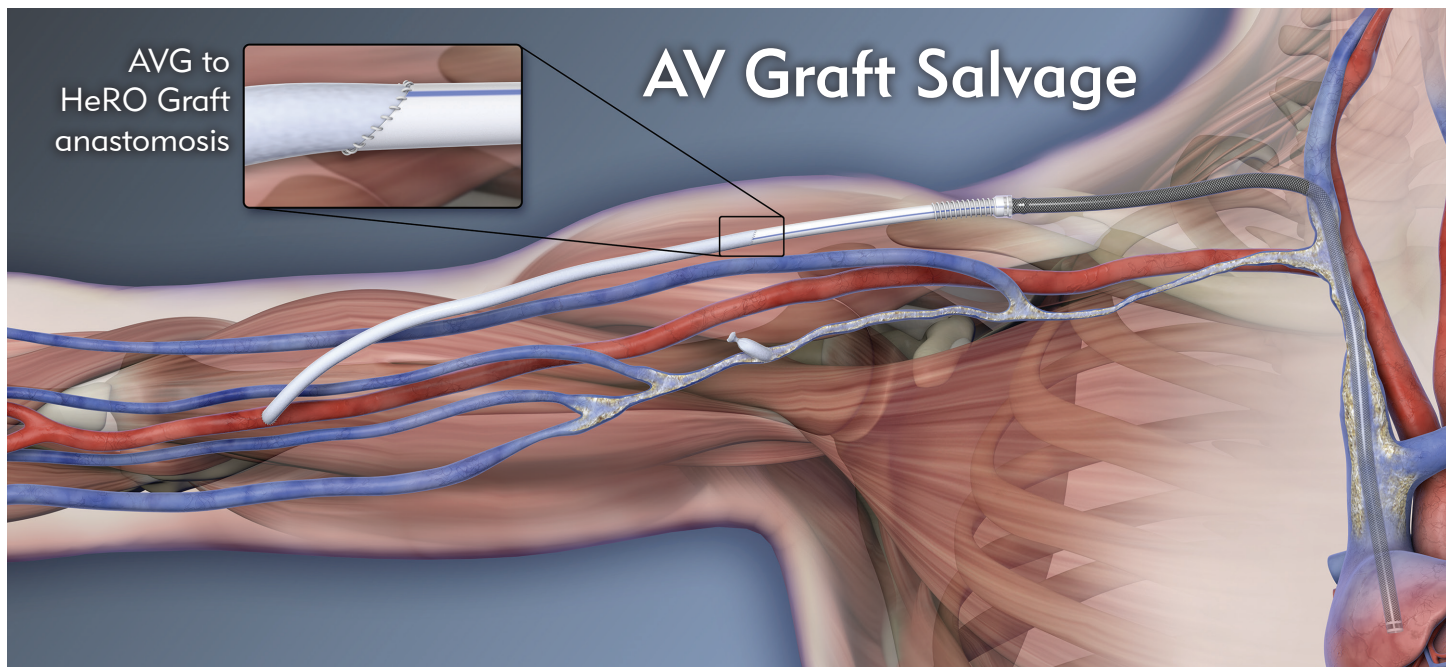
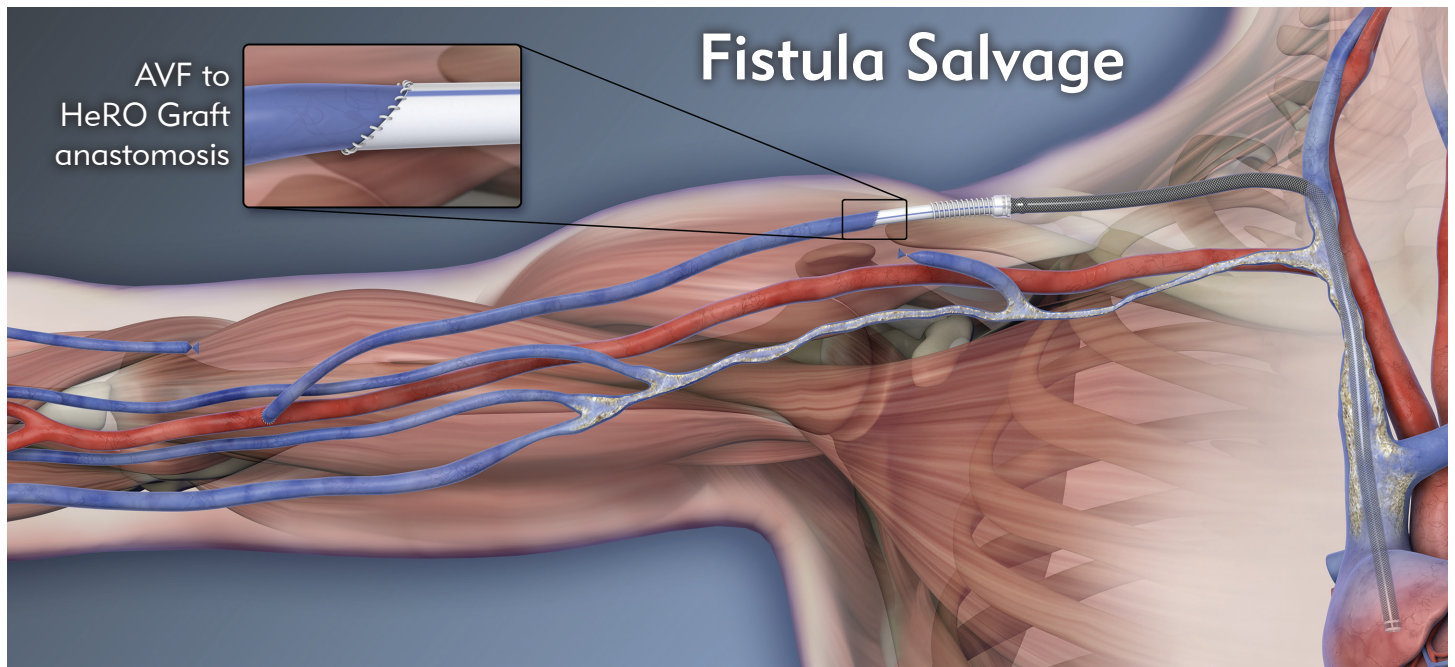


FOR FISTULA OR GRAFT SALVAGE

Bypassing Venous Stenosis | Preserving the Access Site



HeRO Graft for AVF or AVG Salvage

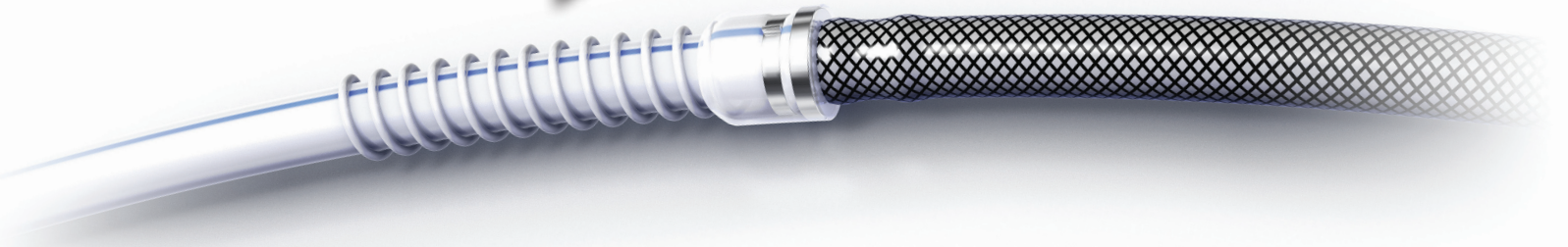
HeRO (Hemodialysis Reliable Outflow) Graft is a fully subcutaneous solution used to salvage a failing fistula or AV graft by bypassing central venous stenosis.

Treatment Algorithm

Failing AVF or AVG due to central venous stenosis

Salvage Benefits

- **Access Site Preservation:** salvage a failing AVF or AVG to avoid using a new access site and bridging catheter¹
- **Removable & Replaceable:** unlike a stent, HeRO Graft's Venous Outflow Component can be removed & replaced if necessary



Clinical & Cost Benefits

- **Fewer Infections:** 69% reduced infection rate compared with catheters²
- **Superior Dialysis Adequacy:** 1.7 Kt/V, a 16% to 32% improvement compared with catheters²
- **High Patency Rates:** Up to 87% cumulative patency at two years^{2,3}
- **Cost Savings:** A 23% average savings per year compared with catheters⁴

Seizing the "Window of Opportunity"

Interdisciplinary Team (IDT) collaboration is essential to seize the "window of opportunity" in placing the HeRO Graft for AVF or AVG salvage before the AVF's or AVG's venous outflow occludes (Fig 1).⁵

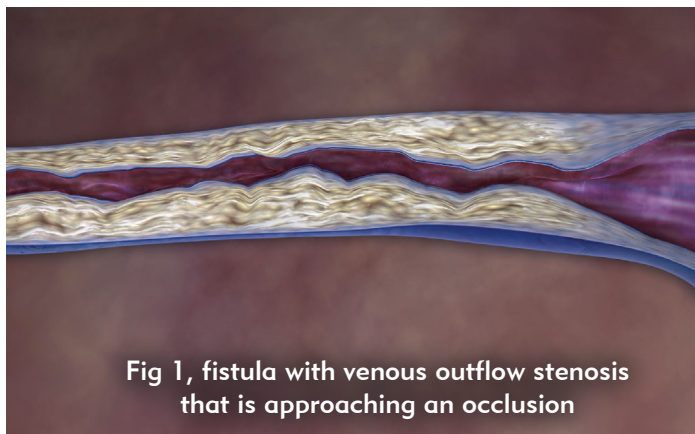


Fig 1, fistula with venous outflow stenosis that is approaching an occlusion

Identifying an AVF or AVG Salvage Candidate

- 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.

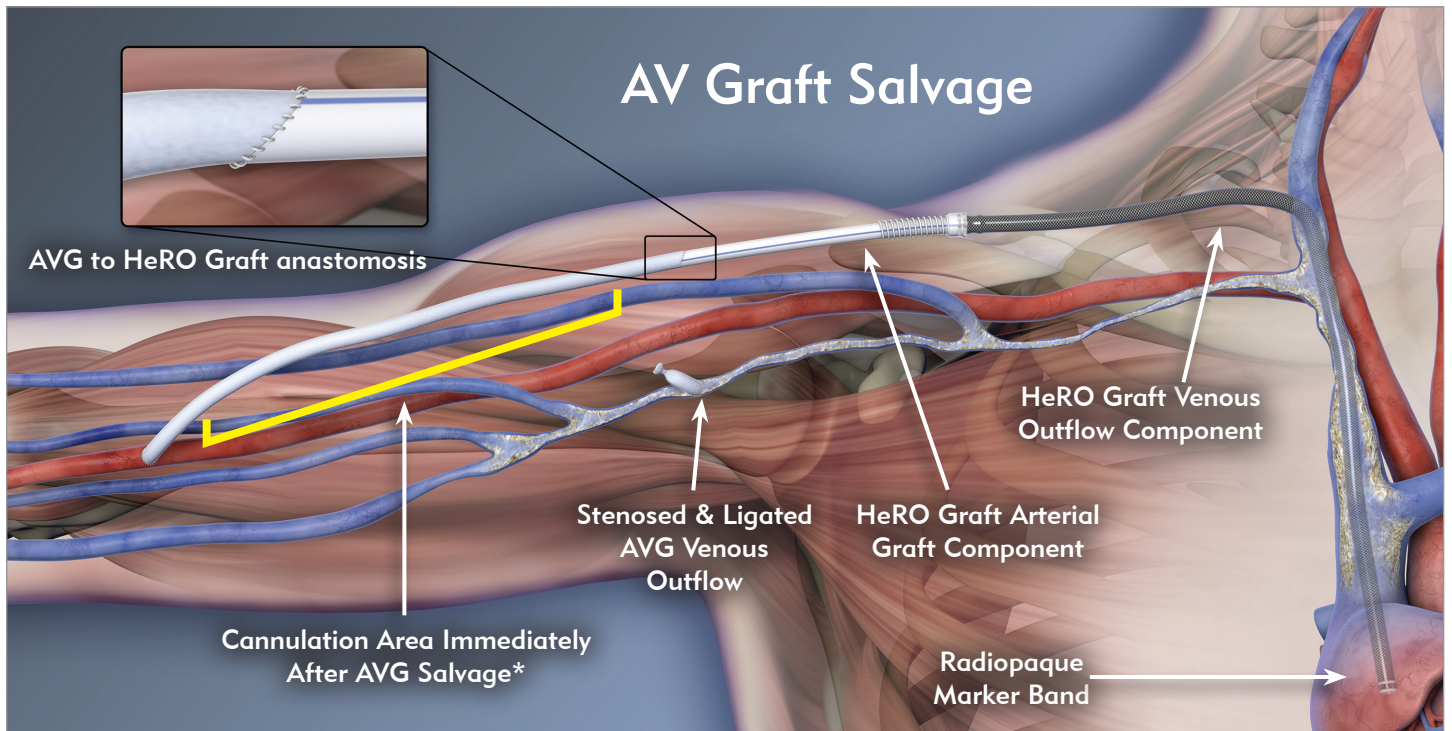
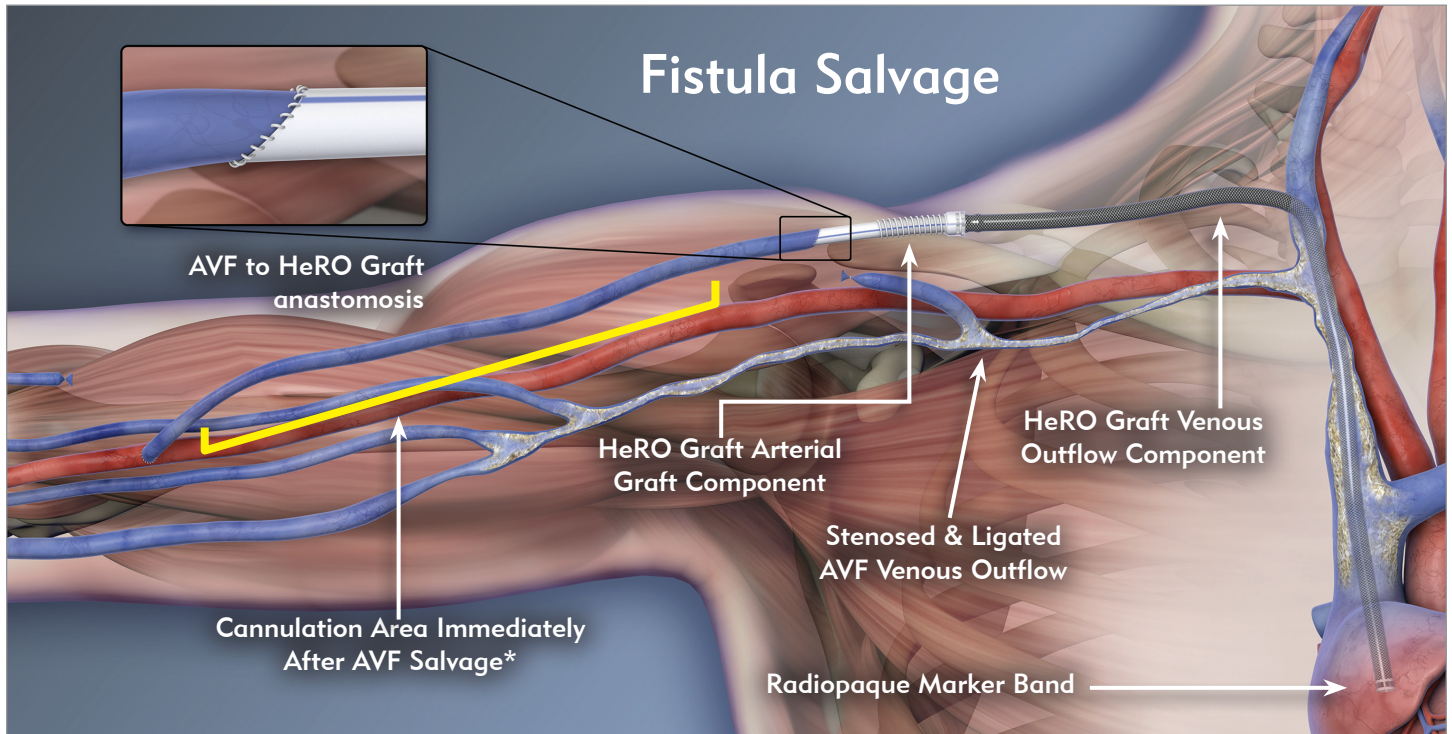


A patient who has central venous stenosis and collateral veins that are distended.

Procedure Overview

Typically, a short segment of the ePTFE portion of HeRO Graft is anastomosed to an arteriovenous fistula (AVF) or arteriovenous graft (AVG).

One advantage of this method, if the existing AVF is matured or AVG is incorporated, is that the access can be cannulated immediately. This eliminates the need for a bridging catheter. The benefit of not needing a bridging dialysis catheter is avoiding its associated risks for infection.



*If AVF is matured or AVG is incorporated. Follow your dialysis facility protocol for care and cannulation.

Clinical Data

The following clinical cases involve HeRO Graft for the purpose of AVF or AVG salvage:

AVF Salvage

Chen G, et al. *EJVES Extra*. 2011; 22(4):e37-39.

- Case report of patient with functioning AVF who developed arm edema due to occluded central venous system refractory to repeated endovascular treatment including two stent placements over two years.
- Arm swelling resolved and AVF could be used immediately after being connected to HeRO Graft.
- Remained functional 6 months later and no re-interventions were required.

Bowers V, et al. *VASA*; 2010 Las Vegas, NV. *J Vasc Access*, 2010; 11(S2):S26-27. Lin J, et al. *ASDIN*; 2010 Orlando, FL.

- Case report of two patients who had HeRO Graft to salvage failing AVF due to central venous stenosis.
- The HeRO Graft implants avoided the need for use of bridging catheters.
- Also highlighted value of collaborative team effort, credited IDT approach with timely communication resulting in saving an AVF.

AVG and AVF SALVAGE

Gage S, et al. *Ann Vasc Surg* 2011; 25(3):387.e1-5.

- Case report of two patients with arm edema due to occluded central venous system: one with functioning AVF, one with functioning AVG.
- Both patients underwent multiple interventions, including angioplasty and stenting, yet symptoms recurred.
- Rather than abandoning functioning vascular access, the HeRO Graft was implanted which resolved the patients arm edema and saved the access.
- HeRO Graft has continued to function for twenty-one (21) months.

Allan B, et al. *J Vasc Surg* 2012; 56(4):1127-1129.

- Two case studies describing use of HeRO Graft to salvage failing AVG and AVF due to occluded subclavian vein and failed attempts at recanalization of the subclavian vein.
- The salvaged portion of the AVG or AVF was able for use for dialysis the next day with flow rates of 420-450 ml/min.
- The patients' HeRO Grafts have continued to function at time of publication for fourteen (14) months (AVG salvage patient) and five (5) months (AVF salvage patient).
- The HeRO Graft resolved one patient's arm edema and pain due to central venous occlusive disease.

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

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

References:

1) Gage S, et al. *Ann Vasc Surg* 2011. 2) Katzman et al., *J Vasc Surg* 2009. 3) Gage et al., *EJVES* 2012. 4) Dageforde et al., *JSR* 2012. 5) Lin J, et al. *ASDIN*; 2010 Orlando, FL.

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