HeRO Graft for Fistula or Graft Salvage

The HeRO Graft Indications for Use includes fistula/graft salvage (see highlighted words below).

Indications for Use:
The HeRO Graft is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the KDOQI guidelines1 as patients who:

- Have become catheter-dependent or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts).
- Are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or venography.
- Are failing fistulas or grafts due to poor venous outflow as determined by access failure or venography (e.g. fistula/graft salvage).
- Have poor remaining venous access sites for creation of a fistula or graft as determined by ultrasound or venography.
- Have a compromised central venous system or central venous stenosis (CVS) as determined by history or previous access failures, symptomatic CVS (i.e., via arm, neck, or face swelling) or venography.
- Are receiving inadequate dialysis clearance (i.e., low Kt/V) via catheters. KDOQI guidelines recommend a minimum Kt/V of 1.4.2

Overview of the Procedure:
Typically a short segment of the ePTFE portion of HeRO Graft is connected to the existing vascular access in an end-to-end or end-to-side fashion. One advantage of this method is it eliminates the need for a bridging catheter, thus eliminating the infection risks associated with the use of tunneled dialysis catheters.

See page two for clinical summaries of HeRO Graft fistula/graft salvage.

KEY TAKEAWAYS:

- HeRO Graft Indications for Use have been updated to specify inclusion of Fistula & Graft Salvage
- Multiple publications describe this use and its advantages
- One key advantage is the elimination of the need for a bridging TDC

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The following are examples of clinical cases of HeRO Graft fistula (AVF) and graft (AVG) salvage:

**Fistula Salvage:**
  - 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.
  - Remains functional 6 months later and NO re-interventions were required.
  - 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.

**Graft Salvage:**
  - 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 months.
  - 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 to be used 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 months (AVG salvage patient) and 5 months (AVF salvage patient).
  - The HeRO Graft resolved one patient’s arm edema and pain due to central venous occlusive disease.