HeRO Graft bypasses central venous stenosis

Thrombectomy Guidelines

NOTE: The above image shows the placement of the HeRO Graft Venous Outflow Component and Arterial Graft Component. Other configurations of the HeRO Graft are possible based on the use of the Adapter. For alternative configurations, refer to the Instructions for Use.
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. For ePTFE grafts permitted for use with the Adapter, see the ePTFE graft manufacturers’ Instructions for Use for the full details for performing a thrombectomy.

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 Arterial Graft Component connector or the Adapter. 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 Arterial Graft Component connector or the Adapter.
- Pull balloon through the Arterial Graft Component connector or the Adapter and reinflate within the graft.
- Extract clot at the introducer site.
- Declot the full length of HeRO Graft prior to removing the arterial plug to decrease risk of pulmonary embolism.

*See the HeRO Graft Adapter IFU for full details on the ePTFE grafts that have been tested and are permitted for use with the Adapter.
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 Arterial Graft Component connector or the Adapter 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.

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

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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. HeRO Graft thrombosis rates are comparable to conventional grafts and are treated with similar methods.

- 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:

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

Learn more at www.herograft.com