



HeRO[®] VASCULAR ACCESS DEVICE EXPLANT PROCEDURE

OVERVIEW:

Management of the HeRO Arterial Graft Component and removal of the HeRO Venous Outflow Component are required if the device is abandoned, or will not be used for hemodialysis access.

Arterial Graft Component: In the absence of infection, the graft portion of the device may not require removal, and may be ligated and left in place similar to a conventional ePTFE graft.

Venous Outflow Component (OC) and Connector: The OC and connector do not incorporate into the surrounding tissue and may be removed using manual traction similar to a conventional hemodialysis catheter. Image the device prior to explant using appropriate vascular imaging to determine if thrombus is present in, or on, the OC. If thrombus is present, it may be dislodged during the explant procedure and therefore should be treated using a thrombolytic agent, or other appropriate therapy, prior to performing the explant procedure.

TO EXPLANT THE HERO OUTFLOW COMPONENT AND CONNECTOR:

1. Prep patient using aseptic surgical technique.
 2. Open the incision at the deltopectoral groove (DPG) and dissect to expose at least 5cm of the graft, including the connector and PTFE beading.
 3. Carefully dissect the exposed graft and connector to free the incorporated material for ease of revision.
 4. Ligate the graft approximately 1cm proximal to the PTFE beading.
 5. Cut the graft component between the ligation and the PTFE beading to separate the OC.
 6. Gently twist to loosen the OC with attached connector. Using appropriate technique, (i.e., syringe) apply negative pressure to remove potential intraluminal thrombus.
 7. Pull gently using counter pressure applied at the original venotomy site until the OC and connector is fully removed.
- CAUTION: UPON REMOVING THE OC AND CONNECTOR, CONTINUE APPLYING PRESSURE AT THE ORIGINAL VENOTOMY SITE TO DECREASE RISK OF BLEEDING.**
8. After removal of the components, close the DPG incision site.

GENERAL CAUTIONS:

- During removal of the Outflow Component, special care should be used if the Outflow Component may come into contact with a stented vessel. Use imaging (fluoroscopy) for visualization of the Outflow Component and stent interaction to decrease the potential of Outflow Component, stent, or vessel damage.
- Only qualified healthcare providers should explant the device.
- Adhere to universal precautions when explanting the device.
- The HeRO device has been in contact with body fluids and is a potential biohazard. Handle the device using acceptable medical practice and applicable local, state and federal laws and regulations. Return the explanted portion of the device to Hemosphere using the Explant Return Kit obtained from Customer Service.

Hemosphere, Inc.
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