



HeRO[®] VASCULAR ACCESS DEVICE ARTERIAL GRAFT REVISION PROCEDURE

OVERVIEW:

The HeRO[®] Arterial Graft Component can be revised if necessary via a jump graft procedure.

If graft revision is necessary due to infection, resection and removal of the infected portion of the graft is required prior to completing the jump graft procedure. Return the excised portion of the graft to Hemosphere. Follow the instructions for the jump graft procedure as detailed below.

If damage occurs to the PTFE beading on the existing graft, Hemosphere recommends replacement of the entire Arterial Graft Component including the proprietary connector. Replacement of the Arterial Graft Component will also require revision to the HeRO Venous Outflow Component and should be proctored by a certified Hemosphere representative. Contact Customer Service at **888.313.8233** or visit **www.heroaccess.com** for further instructions and/or assistance.

TO REVISE THE HERO ARTERIAL GRAFT COMPONENT:

1. Create incisions at the sites selected for the graft-to-graft anastomosis and dissect to expose the existing graft.
2. Create a subcutaneous tunnel from new inflow incision site to the new outflow incision site circumventing the existing graft. Graft routing may vary depending on patient-specific anatomy and the placement of the existing graft.
3. Using standard graft tunneling techniques, gently pull the jump graft through the new tunnel. Utilize markings on the graft to verify the graft has not twisted.
4. Use a standard vascular clamp to occlude the existing graft proximal to the new inflow anastomosis site.
5. Perform a standard graft-to-graft anastomosis.
6. Remove the clamp, bleed the jump graft segment to remove air, and then reclamp the jump graft segment just proximal to the new outflow anastomosis site.
7. Cut the graft to length, avoiding excessive tension or redundant graft material, and perform the outflow anastomosis of the jump graft to the existing graft using standard technique.
8. Remove the clamp and check the device patency, utilizing standard Doppler technique.
9. Close both incisions.

GENERAL CAUTIONS:

- Federal (USA) law restricts these devices to sale by or on the order of a physician.
- Only qualified healthcare providers should replace or revise the device.
- Adhere to universal precautions when revising the device.
- Carefully read the graft implant instructions prior to use.
- 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. If explanting a segment of the device, return using the Explant Return Kit obtained from:

Hemosphere, Inc.
Customer Service
888.313.8233
www.heroaccess.com

