



HeRO® Considerations to Reduce Risk of Movement of Outflow Component

HeRO 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 has no venous anastomosis. The tip of the Venous Outflow Component is located in the right atrium of the heart.

Since there is no venous anastomosis, the HeRO Outflow Component has freedom of movement. This movement could result in the tip not remaining in the right atrium of the heart. This may be more of a concern in:

- Left-sided implants
- Subclavian vein access (using extra caution due to the increased risk of patient complications)
- Morbidly obese patients
- Graft connector located lateral to the deltopectoral groove

Special consideration may be needed if an implant or revision is scheduled in a morbidly obese patient and/or a subclavian or left-sided HeRO implant. In an effort to reduce the amount of movement of the Venous Outflow Component, in these patients consider:

- Placing the tip of the HeRO Venous Outflow Component in the mid or lower right atrium
- Placing the HeRO connector medial (mid-clavicular) to the deltopectoral groove
- Suturing the HeRO connector to patient's fascia to hold it in place during the incorporation period
- Performing fluoroscopy of the HeRO tip while moving the patient's arm as much as possible (rotate at shoulder, adduct arm to side) after connecting the Graft and Outflow Component
- Obtaining an upright chest x-ray to verify location of the marker band at the tip of the HeRO in the patient's heart

HeRO may be at increased risk of occlusion in patients when the Venous Outflow Component is located outside the right atrium of the heart. Thrombosis is the most common cause of vascular access dysfunction. HeRO thrombosis rates are comparable to conventional grafts and are treated with similar methods.¹ Refer to the Thrombectomy Guidelines brochure for additional information at <http://www.heroaccess.com/procedures-physicians/declot-procedure-physicians>.

For additional information, please refer to the HeRO Instructions for Use or contact Hemosphere Customer Service at 888.313.8233

References:

1. Katzman HE, et al.: Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients. *J Vasc Surg* 50: 600-607, 2009.

The FDA regulation name for the HeRO Graft is vascular graft prosthesis.

INDICATIONS FOR USE: The HeRO Vascular Access Device is indicated for end-stage renal disease (ESRD) patients on long-term hemodialysis who have exhausted all other peripheral access options. Rx only.

