



Endovascular Considerations

The HeRO Graft (Hemodialysis Reliable Outflow) is a fully subcutaneous AV access solution, clinically proven to maintain long-term access for hemodialysis patients with venous outflow obstruction. Only qualified healthcare providers should place, manipulate, de-clot, revise or explant the device. Consider a consult or assistance from an interventional radiologist or interventional nephrologist regarding central venous access in patients with severe stenosis, occlusion or tortuous vessels.

Complications may occur at any time during or after the endovascular portion of the procedure. Possible complications include, but are not limited to:

- Bleeding
- Embolism
- Hematoma
- Infection
- Trauma to major vasculature
- Cardiac arrhythmia

To avoid vessel or heart damage or cardiac arrhythmia, special care must be taken with:

- Guidewire
 - Assure correct location of the guidewire tip in the inferior vena cava throughout the entire procedure using fluoroscopy
 - Stabilize the guidewire in the IVC while advancing the dilator sheath
 - Use of stiff guidewires requires extra care to prevent perforation during advancement and manipulation
- Dilators
 - Use care when using the dilators
 - Consider balloon angioplasty for serial dilation
- Delivery Stylet
 - The stylet is not visible under fluoroscopy
 - DO NOT advance the tip of the delivery stylet into the right atrium
 - DO NOT advance the delivery stylet independently of the Outflow Component

To reduce the risk of complications, perform vessel mapping in advance to ensure appropriate vessel size and location when determining an optimum strategy for treatment. Be aware that cannulation of the LEFT internal jugular vein (IJV) **may increase** the risk of complications when compared to the right IJV.¹

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

References:

1. Sulek CA, Blas ML, Lobato EB. A randomized study of left versus right internal jugular vein cannulation in adults. J Clin Anesth. 2000 Mar; 12(2):142-5.

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.

