

## Venous Outflow Component Exchange Procedure

The HeRO Venous Outflow Component does not incorporate into venous anatomy and can be removed or exchanged. Fluoroscopy is required during insertion of a new outflow component to avoid vessel damage and ensure proper placement.

Due to the complexity and permutations of this procedure, Hemosphere recommends that exchanges be proctored by a certified company representative. Contact Customer Service for your local representative.

### Tools Required:

- HERO 1001, Venous Outflow Component
- HERO 1003, Accessory Component Kit
- 0.035" x 180cm guidewire

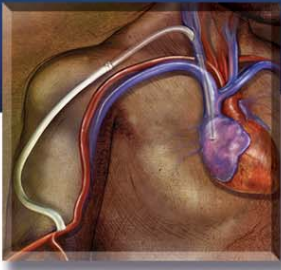
### Recommended Accessories:

- Stiffened 5 Fr Micropuncture<sup>®</sup> Introducer Set (Cook<sup>®</sup> Inc. MPIS-501-10.0-SC-NT-U)
- Vantage Iris Scissors 4-1/8 Ref#V95-304
- Hemosphere Explant Return Kit

### Outflow Component Exchange Procedure:

1. Prep the patient according to standard surgical guidelines. Place the patient into Trendelenberg position to reduce the potential for air embolus during exchanges. For patients undergoing general anesthesia, a positive breath can be forced during removal of the dilator from the sheath to prevent air induction.
2. Prepare the 5F microintroducer by removing the .014" wire-compatible dilator and securely attaching the sheath to the Y-adapter (from the Accessory Component Kit). Flush the sheath with heparinized saline via the Luer port.
3. Palpate to locate the device connector. Open the deltopectoral groove (DPG) incision to expose the PTFE graft rings and at least 5cm of the outflow component.
4. Clamp the graft with an atraumatic vascular clamp proximal to the PTFE graft beading. Inject the graft with heparinized saline to maintain patency.
5. Palpate the venous access site to confirm location of the outflow component. Open the previous incision and expose the outflow component nearest the point it enters/exits the vein.
6. Create a purse string suture at the venous access site and clamp the outflow component nearest the point it enters/exits the vein.
7. Place 4x4 gauze under the connector to prevent debris from contaminating the incision site.
8. Ensure both clamps are secure and cut the outflow component with a pair of heavy duty scissors approximately 3cm from the connector.
9. Using the Iris scissors, cut the remainder of the outflow component from the titanium connector starting at the connector shoulder and working toward the cut end.

**Caution:** Cutting through the nitinol braiding may be difficult. Do not damage the barbs on the titanium connector. If damage occurs, replacement of the connector with a new graft component is recommended.



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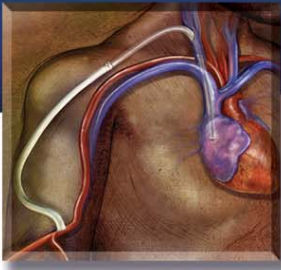
10. Once completed, remove the 4x4 gauze and inspect the wound for any potential debris left behind. Replace the gauze and continue the procedure.

**Note:** Alternately, it may be possible to twist and pull the outflow component until it can be removed from the titanium connector without cutting. This may be a slow and time-consuming process.

**Caution:** Do not crush or otherwise damage the beading on the graft component. If damage occurs, replacement of the graft component is recommended.

11. At the venous access site, gently pull the outflow component through the tunneled tract. Do not move or displace the distal tip of the outflow component in the right atrium.
12. Insert the assembled 5F sheath into the exposed end of the outflow component. Ensure that the hub is securely seated in the outflow component, and remove the clamp.
13. Aspirate blood from the device. Use fluoroscopy while advancing the guidewire to the desired position in the inferior vena cava.
14. Maintaining wire position, gently remove the existing outflow component over the wire. The purse string suture can help control bleeding at the venous access site.
15. Load the 20F peel away sheath onto the guidewire and use fluoroscopy to advance.
16. Withdraw the dilator and use the silicone hemostasis plug to occlude the sheath opening, leaving the guidewire in place. Ensure both plug seal rings are fully seated within the sheath. Avoid pinching or clamping the sheath.
17. Remove the Y adapter from the 5F micropuncture assembly and attach to the Luer end of the new outflow component.
18. Advance the outflow component over the guidewire. Remove the hemostasis plug and advance the outflow component into the 20F sheath. Use fluoroscopy to advance the outflow component to the superior vena cava. A twisting or rotational motion may be used to ease insertion. Surgical lubricant may be used, if necessary.
19. Place the radiopaque tip of the outflow component in the mid to upper right atrium and use fluoroscopy to confirm proper tip placement.
20. Peel away the 20F sheath. Clamp the outflow component with the disposable clamp using the hinge area to fully occlude the device.

**Caution:** Use only the disposable clamp included in the Accessory Component Kit. Use of other clamps may result in damage to the device.



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21. Holding the outflow component away from the incision sites, use heavy duty scissors to cut the proximal end, removing the silicone Luer and Y-adapter assembly. Discard unused portion. Tunnel through the existing tract to the connection site.
22. Remove the clamp and flush with heparinized saline. Reclamp the outflow component at the venotomy site.
23. Unclamp the graft, confirm patency and reclamp.
24. Grasp the silicone sleeve on the connector in one hand. In the other hand, grasp the outflow component 2cm back from the cut edge and push so it slides easily over the first barb of the titanium connector. Continue to push the outflow component onto the connector until the cut edge is flush with the silicone sleeve hub past both barbs. Verify the graft component and outflow component are fully connected and that no portion of the titanium connector is exposed.

**Caution:** Do not peel or otherwise damage the graft beads as this may adversely impact the integrity of the graft.

25. Verify radiopaque tip placement in the mid to upper right atrium using fluoroscopy.
26. Gently tuck the connected device into the connector site incision and return the patient to standard supine position.
27. Remove all clamps and confirm device patency before closing incisions.

**Return the explanted device to Hemosphere using the Explant Return Kit obtained from:**

Hemosphere, Inc.  
Customer Service  
888.313.8233  
[www.heroaccess.com](http://www.heroaccess.com)

### GENERAL CAUTIONS:

- Rx only. Only qualified healthcare providers should exchange or explant the device. Adhere to universal precautions.
- The HeRO outflow component has been in contact with body fluids and is a potential biohazard. Handle and dispose of the device using acceptable medical practice and applicable local, state and federal laws and regulations.