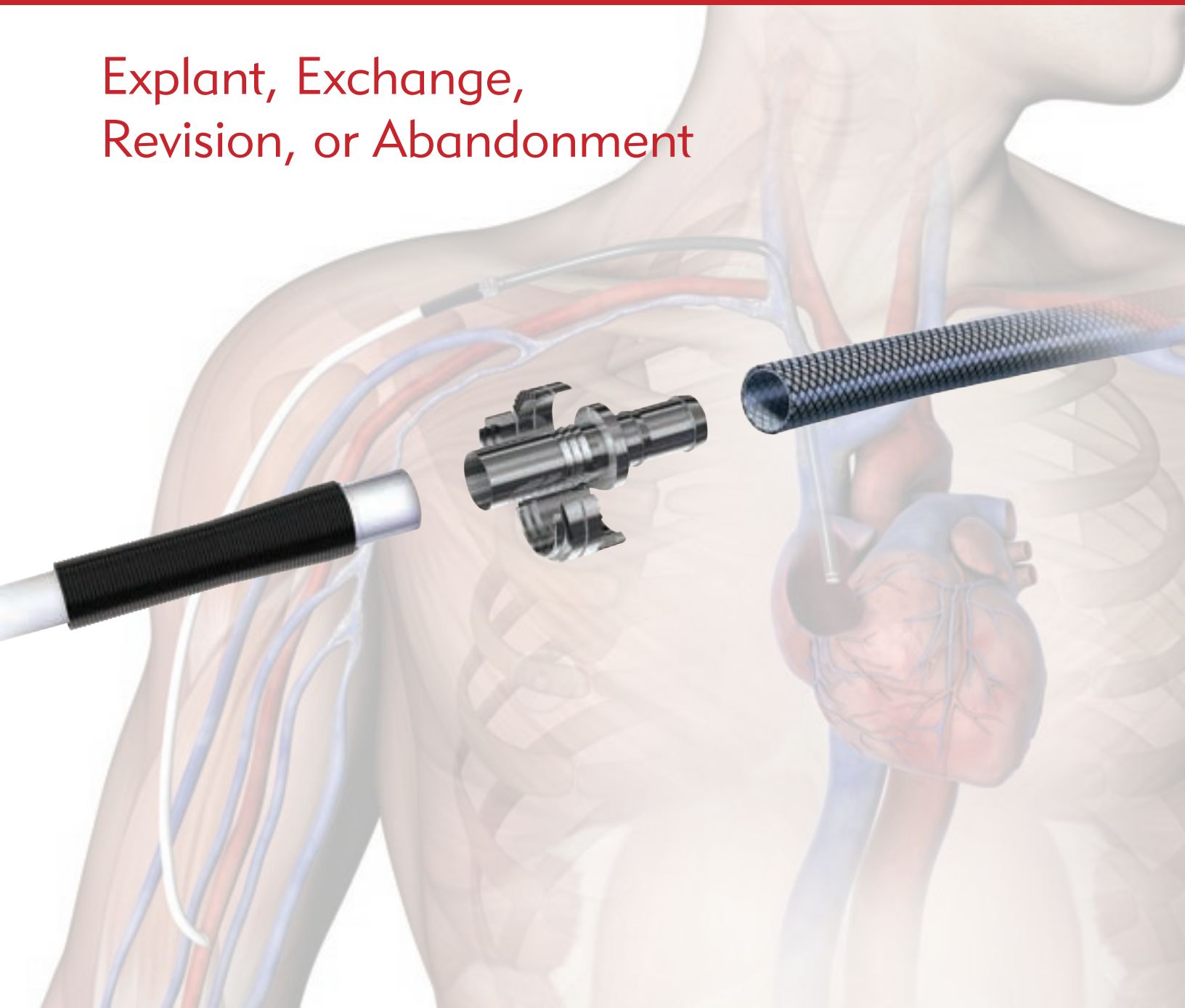
HeRO ALLY™

Frequently Asked Questions | FAQ's

Explant, Exchange, Revision, or Abandonment



Medical Professionals

HeRO Ally™
Revision Kit

Frequently Asked Questions | FAQ's

Explant, Exchange, Revision, or Abandonment

These FAQs are intended for:

- HeRO Graft with Arterial Graft Component (HERO 1002) and Venous Outflow Component(HERO 1001)
- HeRO Graft Adapter with or without the Support Seal™* (HERO 1006**), an ePTFE graft*, and Venous Outflow Component (HERO 1001)

* See the SuperHeRO or HeRO ALLY IFU for full details on when the Support Seal is required for use and on the ePTFE grafts that have been tested and are permitted for use with the Adapter.
** HeRO ALLY Revision Kit includes: Adapter, Support Seal, Vascular Clamps, 20cc Syringe.

Q

How is the HeRO Graft explant procedure performed?

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The Venous Outflow Component, Arterial Graft Component connector, and the Adapter do not incorporate into the surrounding tissue and may be removed using manual traction similar to a conventional hemodialysis catheter. 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 Graft Venous Outflow Component and Arterial Graft Component Connector or Adapter with or without the Support Seal:

1. Prep patient using aseptic surgical technique.
2. For the Arterial Graft Component, open the incision at the deltopectoral groove (DPG) and dissect to expose at least 5cm of the graft, including the connector and PTFE beading. For the Adapter with Support Seal, open the incision at the deltopectoral groove (DPG) and dissect to expose at least 5cm of the graft, including the Adapter and Support Seal. For the Adapter with an ePTFE graft, expose at least 5cm of the graft including the Adapter.
3. Carefully dissect the exposed graft and Arterial Graft Component connector or the Adapter to free the incorporated material for ease of revision.
4. For the Arterial Graft Component, ligate the graft approximately 1cm away from the PTFE beading.

NOTE: If the Adapter has been used, grafts that are permitted to be used with the device are not beaded. For the Adapter with an ePTFE graft, ligate the graft approximately 1cm away from the Adapter inflow graft end. For the Adapter with Support Seal, ligate the graft approximately 1cm away from the Support Seal coil.

5. For the Arterial Graft Component, cut the graft component between the ligation and the PTFE beading to separate the Venous Outflow Component. For the Adapter with the Support Seal, cut the graft portion between the ligation and the coil of the Support Seal to separate the Venous Outflow Component. For the Adapter with an ePTFE graft, cut the graft between the ligation and the Adapter inflow graft end to separate the Venous Outflow Component.
6. Gently twist to loosen the Venous Outflow Component with attached Arterial Graft Component connector or the Adapter. Using appropriate technique (i.e., syringe), apply negative pressure to remove potential intraluminal thrombus.
7. Pull gently using counter pressure applied at the original venous incision site until the Venous Outflow Component with the Arterial Graft Component connector or the Adapter is fully removed.

Caution: Upon removing the Venous Outflow Component and Arterial Graft Component connector or the Adapter, continue applying pressure at the original venous incision site to decrease risk of bleeding.

8. After removal of the components, close the DPG incision site.

General Cautions:

- **During removal of the Venous Outflow Component, special care should be used if there is a stent in the vessel. Use imaging (fluoroscopy) for visualization of the Venous Outflow Component and stent interaction to decrease the potential of Venous Outflow Component, stent, or vessel damage.**
- **Only qualified healthcare providers should explant the device.**
- **Adhere to universal precautions when explanting the device.**
- **The HeRO Graft 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 Merit Medical by contacting Merit Customer Service.**

Complete implant instructions are provided in the Instructions for Use manual available in the library at **www.merit.com/hero**.

Q A How is the Venous Outflow Component exchange procedure performed?

The Venous Outflow Component does not incorporate into venous anatomy and can be removed or exchanged. Fluoroscopy is required during insertion of a new Venous Outflow Component to avoid vessel damage and ensure proper placement. Due to the complexity and permutations of this procedure, exchanges should be attended by a Merit representative. Contact Customer Service for your local representative.

Tools Required:

- HERO 1001 Venous Outflow Component
- HERO 1003 Accessory Component Kit
- 0.035" guidewire at least 150cm in length

Recommended Accessories:

- Stiffened 5F Micropuncture® Introducer Set (such as Merit Medical MAK501NPD-E)
- Heavy duty scissors, such as Vantage® Iris Scissors 4-1/8 Ref#V95-304

Venous 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 0.014" 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 Arterial Graft Component connector or the Adapter. For the Arterial Graft Component, open the deltopectoral groove (DPG) incision to expose the PTFE graft rings, the connector, and at least 5cm of the Venous Outflow Component. For the Adapter with Support Seal, open the deltopectoral groove (DPG) incision to expose the coil portion of the Support Seal, the Adapter and at least 5cm of the Venous Outflow Component. For the Adapter, open the deltopectoral groove (DPG) incision to expose the Adapter and at least 5cm of the Venous Outflow Component.
4. Clamp the graft with an atraumatic vascular clamp near the PTFE graft beading (Arterial Graft Component) or at least 1 cm distal to the Adapter or end of the Support Seal. Inject the graft with heparinized saline to maintain patency.

Caution: Do not clamp the PTFE beading of the Arterial Graft Component or the Support Seal of the Adapter as damage to the beading or Support Seal/Graft may result. If damage occurs to the PTFE beading, replacement of the Arterial Graft Component is recommended. Do not clamp the Support Seal of the Adapter as damage to the device may result. If damage occurs to the Support Seal of the Adapter, replace the entire Adapter, Support Seal, and ePTFE graft segment.

5. Palpate the venous access site to confirm location of the Venous Outflow Component. Open the previous incision and expose the Venous Outflow Component nearest the point it enters/exits the vein.
6. Create a purse string suture at the venous access site and clamp the Venous Outflow Component nearest the point it enters/exits the vein.
7 Place 4x4 gauze under the connector or Adapter to prevent debris from contaminating the incision site.
8. Ensure both clamps are secure and cut the Venous Outflow Component with a pair of heavy duty scissors approximately 3cm from the Arterial Graft Component connector or the Adapter.
9. Using the heavy duty scissors, cut the remainder of the Venous Outflow Component from the Arterial Graft Component connector or the Adapter starting at the Arterial Graft Component connector shoulder or the Adapter shoulder and working toward the cut end.

Caution: Cutting through the nitinol braiding of the Venous Outflow Component may be difficult. Do not damage the barbs on the Arterial Graft Component connector or Adapter. If damage occurs, replacement of the Arterial Graft Component or Adapter with a new Arterial Graft Component or Adapter with a new ePTFE graft* is recommended.

* See the SuperHeRO or HeRO ALLY IFU for full details on the ePTFE grafts that have been tested and are permitted for use with the Adapter and whether the Support Seal is required for the graft that is selected.

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 Venous Outflow Component until it can be removed from the Arterial Graft Component connector or Adapter without cutting. This may be a slow and time-consuming process.

Caution: Do not crush or otherwise damage the beading on the Arterial Graft Component. If damage occurs, replacement of the Arterial Graft Component is recommended. Do not damage the Support Seal of the Adapter. If damage occurs to the Support Seal, replace the entire Adapter, Support Seal, and ePTFE graft segment.

NOTE: If the Adapter has been used, grafts that are permitted to be used with the device are not beaded.

11. At the venous access site, gently pull the Venous Outflow Component through the tunneled tract. Do not move or displace the distal tip of the Venous Outflow Component in the right atrium.
12. Insert the assembled 5F sheath into the exposed end of the Venous Outflow Component. Ensure that the hub is securely seated in the Venous 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 Venous 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 Venous Outflow Component, to flush the Venous Outflow Component through the Y-adapter.
18. Advance the Venous Outflow Component over the guidewire. Remove the hemostasis plug and advance the Venous Outflow Component into the 20F sheath. Use fluoroscopy to advance the Venous 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 Venous Outflow Component in the mid to upper right atrium and use fluoroscopy to confirm proper tip placement. Remove stiffening stylet and wire.
20. Peel away the 20F sheath. Clamp the Venous Outflow Component with the disposable clamp.

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

21. Holding the Venous Outflow Component away from the incision sites, use heavy duty scissors to cut off 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 Venous Outflow Component at the venous incision site.
23. Unclamp the graft, confirm patency and reclamp.
24. For the Arterial Graft Component, grasp the silicone sleeve on the connector in one hand.

NOTE: If the Adapter has been used, it does not have a silicone sleeve.The Adapter may be grasped in one hand on the closed clamshells.

25. In the other hand, grasp the Venous Outflow Component 2cm back from the cut edge and push so it slides more easily over the first barb of the Adapter Venous Outflow Component end.
26. Continue to push the Venous Outflow Component onto the Adapter Venous Outflow Component end until the cut edge is past both barbs of the Adapter Venous Outflow Component end.
27. Verify the Adapter, and Support Seal if applicable, with an ePTFE graft and Venous Outflow Component are fully connected.

Caution: Do not peel or otherwise damage the graft beads as this may adversely impact the integrity of the graft. If damage occurs, replacement of the Arterial Graft Component is recommended. Do not damage the Support Seal of the Adapter. If damage occurs to the Support Seal, replace the entire Adapter, Support Seal, and ePTFE graft segment.

NOTE: If the Adapter has been used, grafts that are permitted to be used with the device are not beaded.

28. Verify Venous Outflow Component radiopaque tip placement in the mid to upper right atrium using fluoroscopy.
29. Gently tuck the connected device into the Arterial Graft Component connector or the Adapter site incision and return the patient to standard supine position.
30. Remove all clamps and confirm device patency before closing incisions. Return the explanted device to Merit Medical by contacting Merit Customer Service.

Complete implant instructions are provided in the Instructions for Use manual available in the library at **www.merit.com/hero**.

Q Are there any specific methods or training that must be used when performing a thrombectomy on HeRO Graft?

A For a HeRO Graft with the Arterial Graft Component or the Adapter with or without Support Seal and an ePTFE graft,*and Venous Outflow Component, a percutaneous or surgical technique may be used for a declot procedure. A surgical technique is recommended during the graft incorporation period to avoid risk of seroma or other complications. A percutaneous technique is recommended after the graft is completely incorporated using a rheolytic thrombectomy system, balloon maceration, or balloon-assisted aspiration. A 90cm rheolytic thrombectomy device or an 80cm soft compliant balloon is required to accommodate the entire length of the HeRO Graft. Do not use mechanical/rotational devices (e.g., Arrow-Trerotola PTD®) due to possible damage to the device.

After the thrombectomy procedure, administration of drugs such as tPA or urokinase to lyse any residual thrombus is recommended. A Thrombectomy Guidelines brochure can be found in the downloads section of the Library or watch the Thrombectomy Video located in the Videos section of the library at **www.merit.com/hero**.

*For ePTFE grafts permitted for use with the Adapter, see the ePTFE graft manufacturers' Instructions for Use for the full details for performing a thrombectomy.

Q How is HeRO Graft revision performed?

A The HeRO Graft Arterial Graft Component or the Adapter with or without Support Seal and an ePTFE graft 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. Follow the instructions for the jump graft procedure as detailed below.

If damage occurs to the PTFE beading on the existing Arterial Graft Component, replace the entire Arterial Graft Component including the connector. If damage occurs to the Support Seal of the Adapter, replace the entire Adapter, Support Seal, and ePTFE graft segment.

NOTE: If the Adapter has been used, grafts that are permitted to be used with the device are not beaded. Replacement of the Arterial Graft Component or Adapter (with or without Support Seal) will also require revision to the Venous Outflow Component and should be attended by a Merit representative. Contact Customer Service for further instructions and/or assistance.

To Revise the HeRO Graft Arterial Graft Component or the Adapter with or without Support Seal and ePTFE Graft:

1. Create incisions at the sites selected for the graft-to-graft anastomosis and dissect to expose the existing graft.

Caution: DO NOT peel or otherwise damage the graft beading of the Arterial Graft Component, as this may adversely impact the integrity of the existing graft.

NOTE: If the Adapter has been used, grafts that are permitted to be used with the device are not beaded. Do not damage the Support Seal of the Adapter. If damage occurs to the Support Seal of the Adapter, replace the entire Adapter, Support Seal, and ePTFE graft segment.

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 it has not twisted.
4. Use a standard vascular clamp to occlude the existing graft near 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 next 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.

If explanting a segment of the device, please return the explant by contacting Merit Customer Service.

Complete implant instructions are provided in the Instructions for Use manual available in the downloads section of the library at **www.merit.com/hero**.

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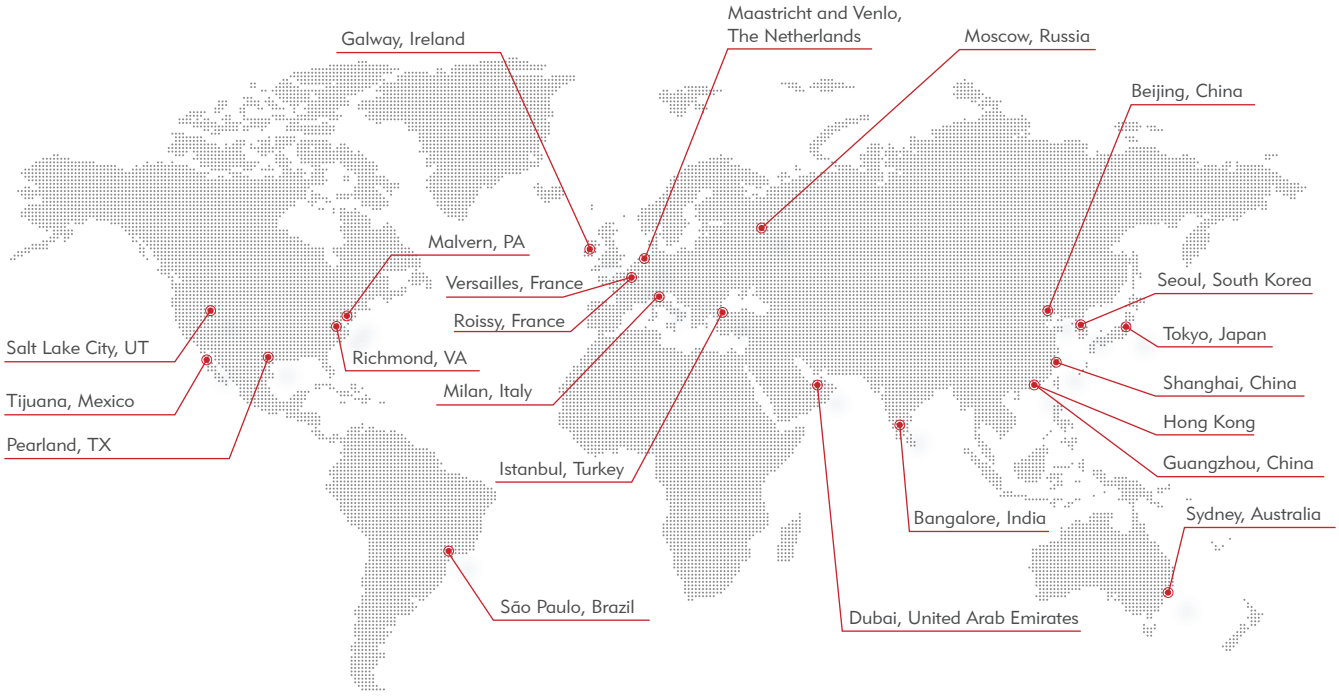
In what situations will the HeRO Graft be removed?

If the HeRO Graft is abandoned for any reason, we recommend removal of the Venous Outflow Component. The ePTFE graft portion of the Arterial Graft Component or the Adapter and Support Seal would typically not be removed due to maturation/incorporation of surrounding tissue into the material. It can be ligated and left in place similar to conventional AV grafts.

Learn more at Merit.com/hero
Contact your local Sales Representative for more details.

OUR VISION

Our vision is to be the most customer-focused company in healthcare. Each day we are determined to make a difference by understanding our customers' needs through innovation and by delivering a diverse range of products that improve the lives of people, families, and communities throughout the world.



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