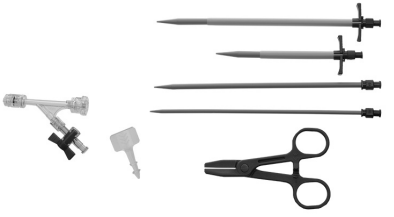
HeRO® GRAFT

ACCESSORY COMPONENT KIT



INSTRUCTIONS FOR USE

MERIT MEDICAL®

ENGLISH

INSTRUCTIONS FOR USE

℞ ONLY Federal (USA) law restricts this device to sale by or on the order of a physician.

Only qualified healthcare providers should place the device. Carefully read all instructions prior to use.

Not Made with Natural Rubber Latex.

Adhere to universal precautions when using the device.

STERILE (EO) – FOR SINGLE USE ONLY

The HeRO® Graft Accessory Component Kit is is provided double pouched with an outer sterile barrier and is EO sterilized.

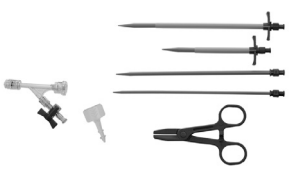
STORAGE

To provide maximum protection, store the HeRO® Graft Accessory Component Kit components in their original, unopened packages at room temperature. Keep dry and out of direct sunlight. The Accessory Component Kit must be used before the use by date printed on the label.

	Caution		Non-Pyrogenic
	Use-By Date		Do Not Resterilize
	Single Use		Manufacturer
	Sterilized Using Ethylene Oxide		Keep Dry
	Catalogue Number		Keep Away from Sunlight
	Batch Code		Do Not Use if Package is Damaged and Consult Instructions for Use
	Date of Manufacture: YYYY-MM-DD		Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within 7 calendar days, call U.S.A or E.U. Customer Service
	Single sterile barrier system with protective packaging inside		Medical Device
	Unique Device Identifier		

DEVICE DESCRIPTION

The HeRO® Graft Accessory Component Kit contains components that aid in the implantation of the HeRO® Graft (sold separately, refer to the HeRO® Graft IFU for a description of the device and its use). The components contained in the Accessory Component Kit are as follows: 20 French Peelable Sheath Introducer (long), 20 French Peelable Sheath Introducer (short), 12 French Dilator, 16 French Dilator, Hemostasis Y Valve with Stopcock, Disposable Clamp, and Hemostasis Plug.



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Kit Component	Sheath ID	Sheath Length	Dilator Length	Dilator OD	Guidewire Compatibility
20 Fr Peelable Sheath Introducer (Long)	20 Fr (6.7 mm)	14.8 cm	20 cm	6.7 mm	 0.035" (0.98 mm)
20 Fr Peelable Sheath Introducer (Short)	20 Fr (6.7 mm)	8 cm	12.1 cm	6.7 mm	 0.035" (0.98 mm)
12 Fr Dilator	NA	NA	20 cm	4.0 mm	 0.035" (0.98 mm)
16 Fr Dilator	NA	NA	20 cm	5.3 mm	 0.035" (0.98 mm)

Abbreviations: Fr = French (0.33 mm), ID = inner diameter, OD = outer diameter, mm = millimeter
NA = Not Applicable

INTENDED USE/INTENDED PURPOSE
The HeRO® Graft Accessory Component Kit is intended to aid in the implantation of the HeRO® Graft Venous Outflow Component.

INDICATIONS FOR USE
The HeRO Graft Accessory Component Kit is indicated for use in the placement of the HeRO Graft Venous Outflow Component in patients requiring hemodialysis who are catheter dependent or approaching catheter dependency.

CONTRAINDICATIONS
No known contraindications.

CLINICAL BENEFITS
The HeRO® Graft Accessory Component Kit provides indirect clinical benefits to the patient as it facilitates placement of the HeRO Graft Venous Outflow Component in patients receiving hemodialysis who have exhausted all other access options and are considered catheter dependent.

KEY PERFORMANCE CHARACTERISTICS
- Accessories are compatible with standard imaging modalities

WARNINGS
- **REUSE PRECAUTION STATEMENT**
  For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- **DO NOT attempt to use the HeRO® Accessory Component Kit in a target vessel that cannot be adequately dilated.**
- **DO NOT use the HeRO® Accessory Component Kit to place the HeRO® Graft in the same vessel as a catheter, defibrillator or pacemaker lead.**
- **DO NOT use product if package has been damaged, opened, or the use by date has passed, as sterility may be compromised.**

GENERAL CAUTIONS
- **The HeRO® Graft Accessory Component Kit is intended for use by physicians trained and experienced in endovascular and surgical interventions and techniques.**
- **Adhere to universal precautions when using the device.**
- **Monitor the patient for signs of arrhythmia throughout the procedure. To minimize the risk of arrhythmia, DO NOT place the tip of the guidewire into the right ventricle.**

POTENTIAL COMPLICATIONS
Potential perioperative complications for the HeRO® Graft Accessory Component Kit include the following:
- Allergic reaction
- Aneurysm
- Bleeding
- Cardiac arrhythmia
- Embolism
- Hematoma
- Hemorrhage
- Infection
- Site pain
- Trauma to major vasculature or nerves

PROCEDURE ACCESSORIES
In addition to the **Accessory Component Kit**, some vascular access surgical instruments may be required.

Vascular access surgical instruments including, but not limited to, the following:
- 5F micro-puncture set
- Various 0.035" guidewires at least 145cm in length
- Heavy duty scissors
- Heparinized saline
- Radiographic contrast fluid
- Sterile surgical lubricant
- Access needles
- Syringes

HeRO GRAFT IMPLANT PROCEDURE

GAINING VENOUS ACCESS

1. Equip a standard operating room with fluoroscopic and ultrasound guidance and prep the patient according to standard surgical guidelines for a vascular access procedure.
2. If choosing to use an existing tunneled catheter tract, use standard over-the-wire exchange techniques to remove catheter.
3. Open the **Accessory Component Kit** using aseptic technique and prep the contents for use.
4. Using ultrasound guidance, gain percutaneous access to the venous system using a 5F micropuncture set and standard Seldinger technique.
5. Using fluoroscopic guidance, advance a 0.035" guidewire, at least 145cm in length, to the inferior vena cava (IVC).
   Caution: Maintain wire placement throughout the implantation of the Venous Outflow Component.
6. Create a small incision at the exit site of the guidewire to aid in placement of the introducer sheath.

IMPLANTING THE VENOUS OUTFLOW COMPONENT

1. For patients undergoing general anesthesia, consider Trendelenburg position. Additionally, anesthesia personnel should force a positive breath to reduce the potential for air embolus during implant.

NOTE: For conscious sedation patients, use the Valsalva maneuver to reduce air embolus potential.

2. Based upon venous anatomy, determine if serial dilation is required. If so, use the 12F and 16F dilators as needed for pre-dilation of the venous tract prior to inserting the 20F introducer.

NOTE: Do not bend introducer sheath or dilator or use them to bypass stenosis.

3. Insert the short 20F introducer over the guidewire. The long 20F introducer may be used if needed for atypical accesses.

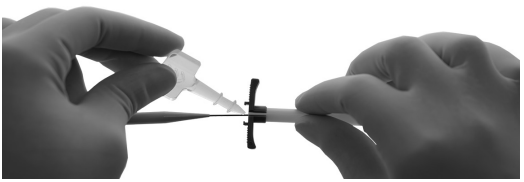
NOTE: Use of the shorter introducer may help prevent kinking since it cannot be advanced as far into the vessel.

4. Advance the dilator and sheath together over the guidewire into the vessel using a twisting motion.

NOTE: Do not insert the sheath/dilator too far. The tabs must extend well outside the body.

5. Using aseptic technique, open the **Venous Outflow Component** with 10 French Delivery Stylet (sold separately).
6. Flush the **Venous Outflow Component** with heparinized saline.
7. Apply sterile surgical lubricant to the 10F delivery stylet and advance through the silicone Luer end of the **Venous Outflow Component**.
8. Attach the Y-adapter onto the Luer end of the 10F delivery stylet and tighten the stopcock, if necessary.

9. Ensure the valve on the stopcock is in the open position and flush with heparinized saline, then close the valve.
10. To ease insertion into the sheath, apply sterile surgical lubricant to the exterior surface of the **Venous Outflow Component.**
11. While stabilizing the guidewire and 20F sheath, begin removing the dilator from the sheath. As soon as the dilator tip has exited the sheath, immediately insert the hemostasis plug by grasping the grip between the thumb and index finger. Firmly insert the hemostasis plug into the sheath alongside the guidewire. Ensure both plug seal rings are fully seated within the sheath. Fully remove the dilator over the guidewire.



12. Insert the **Venous Outflow Component** and delivery stylet assembly over the guidewire and advance up to the 20F sheath.
13. Quickly exchange the hemostasis plug for the **Venous Outflow Component**.

Caution: DO NOT advance the tip of the delivery stylet into the right atrium.

14. Under fluoroscopic guidance, advance the **Venous Outflow Component** to the superior vena cava (SVC) by using a twisting motion. Holding the delivery stylet fixed, continue to advance the **Venous Outflow Component** to the mid to upper right atrium.

NOTE: If resistance is felt, determine the cause before continuing to advance the **Venous Outflow Component**. Keep the sheath straight to prevent it from kinking. If the sheath is bent, remove it and replace it with a new 20F sheath.

15. Confirm proper **Venous Outflow Component** tip placement in the mid to upper right atrium.

16. Gently pull up while peeling away the 20F sheath. Do not peel the sheath close to the incision site; only peel the sheath as it exits the incision site. Verify that the sheath has been completely removed and that the tip of the **Venous Outflow Component** is in the correct location via fluoroscopy.
17. Remove the guidewire and close the hemostasis valve on the Y-adapter.
18. Begin withdrawal of the 10F delivery stylet while maintaining **Venous Outflow Component** position. Prior to complete removal of the delivery stylet from the Luer, clamp the **Venous Outflow Component** at the incision site site using the disposable clamp from the **Accessory Component Kit**.

NOTE: Be careful not to overclamp (i.e., do not advance past the locking tab on the clamp handle).

Caution: To avoid potential damage to the Venous Outflow Component, use only the atraumatic clamp provided in the *Accessory Component Kit*.

19. Detach the Y-adapter from the delivery stylet. Open the stopcock and attach the Y-adapter to the silicone Luer on the **Venous Outflow Component**.
20. Attach a syringe to the stopcock and unclamp the **Venous Outflow Component**. Aspirate and close the stopcock. Reclamp the **Venous Outflow Component** and remove the syringe.
21. Attach a syringe with heparinized saline. Open the stopcock, remove the clamp and flush the **Venous Outflow Component.** Reclamp the **Venous Outflow Component** at the incision site and close the stopcock.
22. Return the patient to standard supine position.
23. Refer to the instructions for use for the Venous Outflow Component for the remainder of the HeRO® Graft implant procedure.

NOTE: The HeRO® Graft Accessory Component Kit has been in contact with bodily fluids and is a potential biohazard. Handle the device using acceptable medical practice and applicable local, state and federal laws and regulations.

MERITMEDICAL®

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www.merit.com/hero

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