English

HeRO® GRAFT

INSTRUCTIONS FOR USE

Federal (USA) law restricts this device to sale by or on the order of a physician.
Only qualified healthcare providers should place, manipulate, de-clot, revise or explant the device.
Carefully read all instructions prior to use.
Adhere to universal precautions when inserting, maintaining or explanting the device.
Not made with natural rubber latex.

STERILE (EO) – FOR SINGLE USE ONLY

Each component of the HeRO Graft is provided in double sterile barrier packaging and is EO sterilized in accordance with ISO 11135-1. DO NOT resterilize.

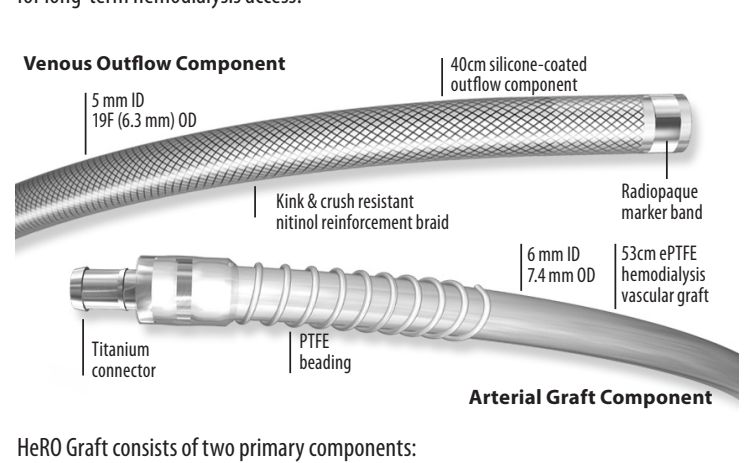
STORAGE

To provide maximum protection, store the HeRO Graft components in their original, unopened packages at room temperature. Keep dry and out of direct sunlight. Each component must be used before the use by date printed on the individual labels.

[i]	Consult Instructions for Use	MR	MR Conditional
RxONLY	Prescription Device		Non-Pyrogenic
	Use-By Date		Do Not Resterilize
②	Do Not Re-Use		Manufacturer
STERILE EO	Sterilized Using Ethylene Oxide		Keep Dry
REF	Catalogue Number		Keep Away from Sunlight
LOT	Batch Code		Do Not Use if Package is Damaged
EC REP	Authorized Representative in the European Community		

DEVICE DESCRIPTION

The HeRO (Hemodialysis Reliable Outflow) Graft is a longterm access solution for access-challenged and catheter-dependent patients. HeRO Graft is a fully subcutaneous surgical implant. It provides arterial venous (AV) access with continuous outflow into the central venous system. The HeRO Graft traverses central venous stenosis allowing for long-term hemodialysis access.



HeRO Graft consists of two primary components:

- A proprietary Venous Outflow Component
- A proprietary ePTFE Arterial Graft Component

The HeRO Graft Venous Outflow Component has a 5 mm inner diameter (ID), 19F outer diameter (OD), and is 40cm long. It consists of radiopaque silicone with braided nitinol reinforcement (for kink and crush resistance) and a radiopaque marker band at the tip.

The HeRO Graft Arterial Graft Component has a 6 mm ID, 7.4 mm OD, and is 53cm long, inclusive of the connector. It consists of an ePTFE hemodialysis graft with PTFE beading to provide kink resistance near the titanium connector. The titanium connector has a tapered ID (6 mm to 5 mm) and attaches the Arterial Graft Component to the Venous Outflow Component. The HeRO Graft Arterial Graft Component is cannulated using standard technique according to KDOQI guidelines.

The Accessory Component Kit provides instruments and accessories that may aid in the placement of the HeRO Graft.

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

INTENDED USE

The HeRO Graft is intended for use in maintaining long-term vascular access for chronic hemodialysis patients who have exhausted peripheral venous access sites suitable for fistulas or grafts.

INDICATIONS FOR USE

The HeRO Graft is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the KDOQI guidelines[1] as patients who:

- Have become catheter-dependent or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts).
- Are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or venography.
- Are failing fistulas or grafts due to poor venous outflow as determined by access failure or venography (e.g., fistula/graft salvage).
- Have poor remaining venous access sites for creation of a fistula or graft as determined by ultrasound or venography.
- Have a compromised central venous system or central venous stenosis (CVS) as determined by a history of previous access failures, symptomatic CVS (i.e., via arm, neck, or face swelling), or venography.
- Are receiving inadequate dialysis clearance (i.e., low Kt/V) via catheters. KDOQI guidelines recommend a minimum Kt/V of 1.4.[2]

CONTRAINDICATIONS

Implantation of the HeRO Graft is contraindicated if:

- The brachial or target artery inner diameter (ID) is less than 3 mm.
- The internal jugular vein (IJV) or target vasculature cannot be dilated to accommodate the 19F HeRO Graft Venous Outflow Component.
- There is significant arterial occlusive disease that would preclude safe placement of an upper extremity hemodialysis access.
- There is known or suspected allergy to device materials (i.e., ePTFE, silicone, titanium, nitinol).
- The patient has a topical or subcutaneous infection associated with the implantation site.
- The patient has known or suspected systemic infection, bacteremia or septicemia.

GENERAL WARNINGS

- Use of the HeRO Graft was clinically studied in the IJV. Implantation of the device in other vasculature has NOT been studied and may increase the risk of adverse events not encountered in the clinical trial.
- **DO NOT** use product if package has been damaged, opened, or the use by date has passed, as sterility may be compromised.
- The HeRO Graft is a single use only product. DO NOT resterilize or reuse any component.

GENERAL CAUTIONS

- Only qualified healthcare practitioners should place, manipulate, cannulate, declot, revise or explant the device.
- The HeRO Graft is intended for use by physicians trained and experienced in endovascular and surgical interventions and techniques.
- Adhere to universal precautions when implanting, cannulating, maintaining or explanting the device.
- **DO NOT** place the HeRO Graft in the same vessel as a catheter, defibrillator or pacemaker lead.
- To avoid vessel damage, fluoroscopy must be used when inserting the HeRO Graft into the central venous system.
- 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.
- Caution should be used when placing or removing the Venous Outflow Component where stent contact may occur due to the potential for Venous Outflow Component or vessel damage.
- **DO NOT** use mechanical/rotational thrombectomy devices (e.g., Arrow-Trerotola PTD®) in the Venous Outflow Component and/or connector as internal damage may occur to these components.

POTENTIAL COMPLICATIONS

The HeRO Graft provides an important means of treating patients requiring hemodialysis; however, the potential exists for serious complications including, but not limited to, the following:

Potential Vascular Graft & Catheter Complications	Potential Intraoperative & Post-Operative Complications
• Seroma	• Reactions to anesthesia
• Infection	• Respiratory / cardiac arrest
• Foreign body reaction or rejection	• Myocardial infarction
• Vascular graft revision / replacement	• Hypotension / hypertension
• Vascular insufficiency due to steal syndrome	• Death
• Partial stenosis or full occlusion of prosthesis or vasculature	• Bleeding
• Superior Vena Cava Syndrome	• Hematoma
• Prosthesis failure	• Heart failure
• Device kinking or compression	• Cardiac arrhythmia
• Site pain	• Cardiac tamponade
• Device migration	• Sepsis
• Anastomosis or wound dehiscence	• Trauma to major vasculature or nerves
• Pseudoaneurysm	• Embolism
• Edema	• Pneumothorax / hemothorax / hydrothorax
• Ectasia	• Aneurysm
• Abnormal healing / skin erosion	• Allergic reaction
• Graft extravasation	

SUMMARY OF HeRO GRAFT CLINICAL EXPERIENCE

The HeRO Graft was evaluated in a prospective clinical study to demonstrate that the device raises no new concerns of safety and effectiveness when used as indicated in patients requiring long-term hemodialysis.

The HeRO Graft was studied in two different patient populations. One was a prospective literature controlled study of HeRO Graft / implant procedure-related bacteremia rates in catheter-dependent subjects (the "bacteremia study"),[3] and; the other was a randomized study of HeRO Graft patency in upper arm graft-eligible subjects compared to subjects receiving an ePTFE control graft (the "patency study").[3] Fourteen (14) institutions treated 86 subjects with the HeRO Graft. Subjects were required to return for post-operative evaluation at three-month intervals for a minimum of 12 months. Endpoint and performance results are summarized in Table 1.

The study results show that the rate of device / procedure-related bacteremia associated with the HeRO Graft is statistically lower than reported in the literature for tunneled catheters and comparable to that reported in the literature for conventional ePTFE grafts. HeRO Graft patency and adequacy of dialysis are significantly improved compared to catheter literature and comparable to graft literature.

The HeRO Graft has an associated safety profile that is comparable to existing graft and catheters used for hemodialysis. In this study, no new concerns of safety and effectiveness for a long-term vascular access device were observed. There were no unanticipated events. Serious HeRO Graft and / or procedure-related adverse events by type are summarized in Table 2.

Device-related adverse events occurred at a frequency comparable to both the catheter and graft literature with the exception of bleeding.[4,5] Of the six (6) bleeding events in the patency study, two (2) were indirectly related to the HeRO Graft implant procedure; in the first patient, coagulopathy was caused by other conditions and bleeding was not unexpected, and in the second patient, a heparin administrative error occurred. Three (3) bleeding events were directly attributed to an earlier generation 22F HeRO Graft Venous Outflow Component, which required an internal jugular venous cut-down. The sixth bleeding event was related to a HeRO Graft explant procedure. There was one (1) device-related death in the patency study due to device-related sepsis complications, a known vascular access complication reported in the literature.[4,5]

TABLE 1: Final HeRO Graft Endpoint & Performance Data from U.S. Multi-Center Pivotal Clinical Trials

		HeRO Graft Bacteremia Study (N=36)[3]	HeRO Graft Patency Study (N=50)[3]	Catheter Literature	ePTFE Graft Literature	KDOQI Adequacy of Hemo-dialysis Guidelines
Device/Procedure-Related Bacteremia Rate/1,000 Days I		0.70/1,000 days (1.45 Upper Confidence Bound (UCB))	0.13/1,000 days (0.39 Upper Confidence Bound (UCB))	2.3/1,000[7]	0.11/1,000[6]	Not Applicable
Primary Patency at 6 Months % (n/N)		47.2 (17/36)	48.0 (24/50)	50%[7]	58%[7]	Not Applicable
Assisted Primary Patency at 6 Months % (n/N)		94.4 (34/36)	88.0 (44/50)	92%[7]	68%[7]	Not Applicable
Secondary Patency at 6 Months % (n/N)		77.8 (28/36)	78.0 (39/50)	55%[7]	76%[7]	Not Applicable
Primary Patency at 12 Months % (n/N)		33.3 (12/36)	36.0 (18/50)	36%[7]	42%[7]	Not Applicable
Assisted Primary Patency at 12 Months % (n/N)		88.9 (32/36)	84.0 (42/50)	Not Reported	52%[7]	Not Applicable
Secondary Patency at 12 Months % (n/N)		77.8 (28/36)	70.0 (35/50)	37%[7]	65%[7]	Not Applicable
Adequacy of Dialysis ±SD [Min,Max]	Kt/V	1.7 ± 0.3 (N=25) [1.2,2.4]	1.6 ± 0.3 (N=33) [0.9,2.3]	1.29 -1.46[3]	1.37-1.62[3]	1.4 target[2]
	URR	74.3 ± 3.8 (N=24) [65.3,83.0]	72.8 ± 6.0 (N=21) [61.0,83.8]	65-70[3]	70-73[3]	70 target[2]

I. Procedure-related bacteremia was defined as any bacteremia seeded by the subject's previous tunneled dialysis catheter (cultured at the time of HeRO Graft implant), any bacteremia that may have been seeded by a pre-existing infection elsewhere in the subject's body possibly making the subject more susceptible to bacteremia in the peri-operative period, or where there is no other source for the bacteremia identified other than the implant procedure. Bacteremia was categorized as device-related when no other source for the infection could be identified.

TABLE 2: Final HeRO Graft Serious Device and/or Implant Procedure-Related Adverse Events by Type from U.S. Multi-Center Clinical Trials

	HeRO Graft Bacteremia Study # Events I / # Subject II (%) III (N = 38)[3]	HeRO Graft Patency Study # Events/ # Subject (%) (N = 52)[3]	Catheter Literature[3]	ePTFE Graft Literature[3]
Bleeding, hemorrhage or hematoma	2/2 (5.3%)	6/6 (11.5%)	79/4209 (1.9%) per Catheter	76/1587 (4.8%)
Cardiac arrhythmia	1/1 (2.6%)	0/0 (0.0%)	30/432 (6.9%) of ESRD subjects	30/432 (6.9%) of ESRD subjects
Death	0/0 (0.0%)	1/1 (1.9%)	21%IV (249/1200)	18.6%IV (327/1754)
Edema (includes swelling)	1/1 (2.6%)	0/0 (0.0%)	5/86 (5.8%) per Catheter	32/222 (14.4%)
Pulmonary embolism	1/1 (2.6%)	1/1 (1.9%)	28/686 (4.1%) of ESRD subjects	28/686 (4.1%) of ESRD subjects
Infection (non-bacteremia)	1/1 (2.6%)	2/2 (3.8%)	1.6/1,000 days	9.8%V (260/2663)
Stroke	0/0 (0.0%)	1/1 (1.9%)	0.08-0.088/per year in ESRD subjects	0.08-0.088/per year in ESRD subjects
Vascular insufficiency due to steal syndrome (includes ischemia)	1/1 (2.6%)	2/2 (3.8%)	Not Applicable	47/1229 (3.8%)
Site pain	0/0 (0.0%)	1/1 (1.9%)	Not Reported	Not Reported
Trauma to major veins, arteries, nerves	0/0 (0.0%)	1/1 (1.9%)	101/2823 (3.6%) per Catheter	7/93 (7.5%)
Wound problems (includes wound dehiscence)	1/1 (2.6%)	0/0 (0.0%)	Not Reported	3/129 (2.3%)
Breakage or mechanical failure (prosthesis technical failure)	0/0 (0.0%)	2/1 (1.9%)	278/2214 (12.6%) per subjects	Not Reported
Other VI	1/1 (2.6%)	8/5 (9.6%)	Not Reported	Not Reported

This table includes all enrolled HeRO Graft subjects including the 4 that did not receive the device.

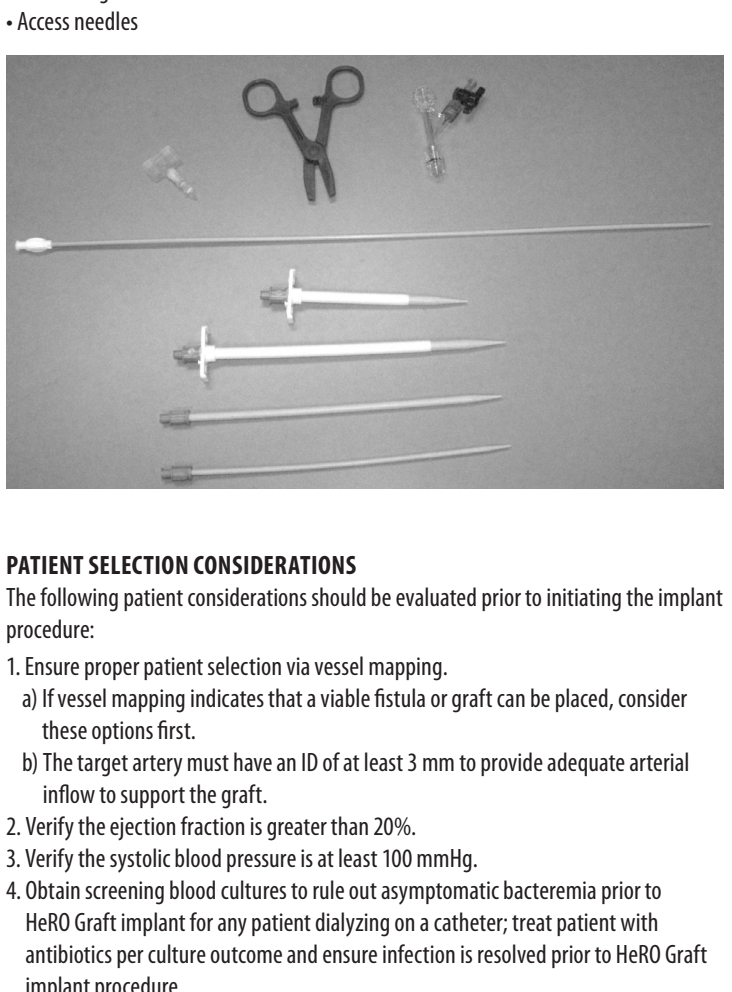
I. Total number of events; II. Subjects with at least one event; III. Percent of subjects with at least one event; IV. Literature reports all deaths and not just device or procedure-related deaths; V. Graft literature reports all infections including bacteremia or sepsis; VI 'Other' serious device and/or procedure related events included right atrial clot, hypotension with fever, non-sustained mild and ventricular tachycardia, pneumonia, cardiogenic shock, hypoxia, hyperkalemia, hypoxemia, elevated white blood cell count.

In some instances, a direct comparison between the HeRO Graft data and the literature cannot be made because the only literature data available is reported per the overall ESRD population vs specific catheter or graft populations. Additionally, some catheter literature data is only appropriate to report per catheter rather than per subject such as procedure related adverse events.

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:

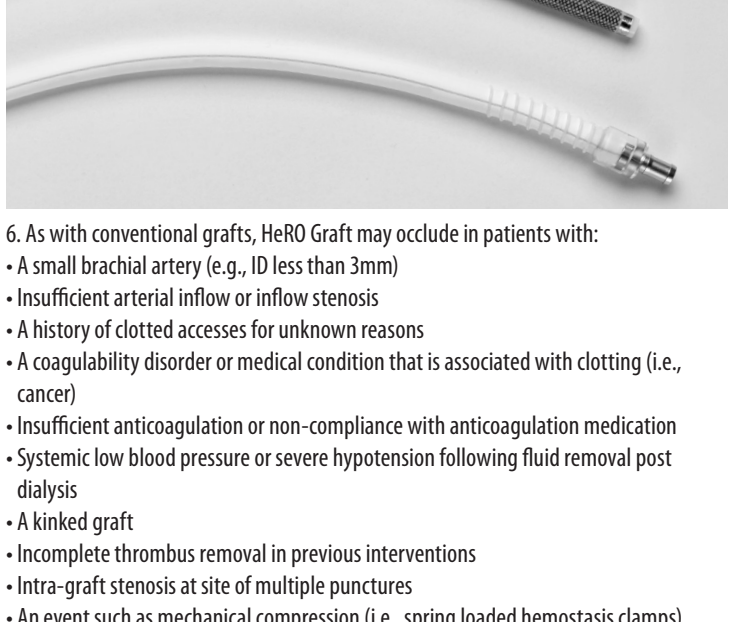
- 5F micro-puncture set
- Various 0.035" guidewires at least 150cm in length
- Heavy duty scissors
- Heparinized saline
- 4 x 4 sterile gauze pads
- Various subcutaneous tissue & skin sutures
- Radiographic contrast fluid
- Tissue tunneler set with 6 mm & 7 mm bullet tips
- Various atraumatic vascular clamps (for the Arterial Graft Component)
- Standard vessel loops
- Syringe & syringe adapter
- Sterile surgical lubricant
- Access needles



PATIENT SELECTION CONSIDERATIONS

The following patient considerations should be evaluated prior to initiating the implant procedure:

1. Ensure proper patient selection via vessel mapping.
   a) If vessel mapping indicates that a viable fistula or graft can be placed, consider these options first.
   b) The target artery must have an ID of at least 3 mm to provide adequate arterial inflow to support the graft.
2. Verify the ejection fraction is greater than 20%.
3. Verify the systolic blood pressure is at least 100 mmHg.
4. Obtain screening blood cultures to rule out asymptomatic bacteremia prior to HeRO Graft implant for any patient dialyzing on a catheter; treat patient with antibiotics per culture outcome and ensure infection is resolved prior to HeRO Graft implant procedure.
5. Swab the patient's nose prior to HeRO Graft implant for potential methicillin resistant staphylococcus aureus; treat accordingly.



6. As with conventional grafts, HeRO Graft may occlude in patients with:

- A small brachial artery (e.g., ID less than 3mm)
- Insufficient arterial inflow or inflow stenosis
- A history of clotted accesses for unknown reasons
- A coagulability disorder or medical condition that is associated with clotting (i.e., cancer)
- Insufficient anticoagulation or non-compliance with anticoagulation medication
- Systemic low blood pressure or severe hypotension following fluid removal post dialysis
- A kinked graft
- Incomplete thrombus removal in previous interventions
- Intra-graft stenosis at site of multiple punctures
- An event such as mechanical compression (i.e., spring loaded hemostasis clamps)

Thrombosis is the most common cause of vascular access dysfunction. Missed hemodialysis sessions significantly increase the number of thrombosis episodes in AVFs and AVGs.[8]

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. Pre-plan the surgical implant utilizing a surgical marker to indicate appropriate incisions and tunneling paths. Draw the HeRO Graft routing path in a soft C configuration on the upper arm.
3. If choosing to utilize an existing tunneled catheter tract, use standard over-the-wire exchange techniques to remove catheter.
4. Open the Accessory Component Kit using aseptic technique and prep the contents for use.

Caution: Use a separate tray for removal of the existing tunneled catheter to aid in sterile preservation. Culture any catheters removed at time of implant.

Caution: Suture the tract closed from the existing catheter to HeRO Graft tract.

Caution: Cover any catheter extensions with antimicrobial incise drape covering to protect the sterile area.

Caution: Plan for increased bacteremia risk after an ipsilateral HeRO Graft placement or with femoral bridging catheters and treat prophylactically with antibiotics knowing patients are at higher infection risk.

Caution: Apply antibiotic ointment to the bridging catheter exit site.

5. Prophylactically treat the patient in the peri-operative period with antibiotics based upon the patient's bacteremia history:

- Ancef or combination Vancomycin and Gentamycin for native stick Venous Outflow Component placement
- Vancomycin and Gentamycin for over-the-wire exchange of a tunneled cuffed dialysis catheter
- Vancomycin and Gentamycin for femoral catheter placement and atypical HeRO Graft placement

6. Using ultrasound guidance, gain percutaneous access to the venous system utilizing a 5F micropuncture set and standard Seldinger technique.

Caution: Use of the HeRO Graft was clinically studied utilizing the Internal Jugular vein. Central venous access through any other veins, for example, the subclavian vein, has NOT been studied and may increase the risk of adverse events not encountered in the clinical trial. When using the subclavian vein for venous access, a more lateral percutaneous approach might mitigate the risk of clavicle crush or occlusion of the Venous Outflow Component. Consideration should be made to follow these patients with clavicle imaging to monitor the potential of interaction of the clavicle and first rib with the Venous Outflow Component.[9]

7. Using fluoroscopic guidance, advance a 0.035" guidewire, at least 150cm in length, to the inferior vena cava (IVC).

Caution: Maintain wire placement throughout the implantation of the Venous Outflow Component.

8. If performing venography to diagnose venous anatomy, select a appropriately sized introducer sheath.
9. 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, utilize the Valsalva maneuver to reduce air embolus potential.

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

NOTE: Balloon angioplasty may also be required for severely stenosed anatomy.

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

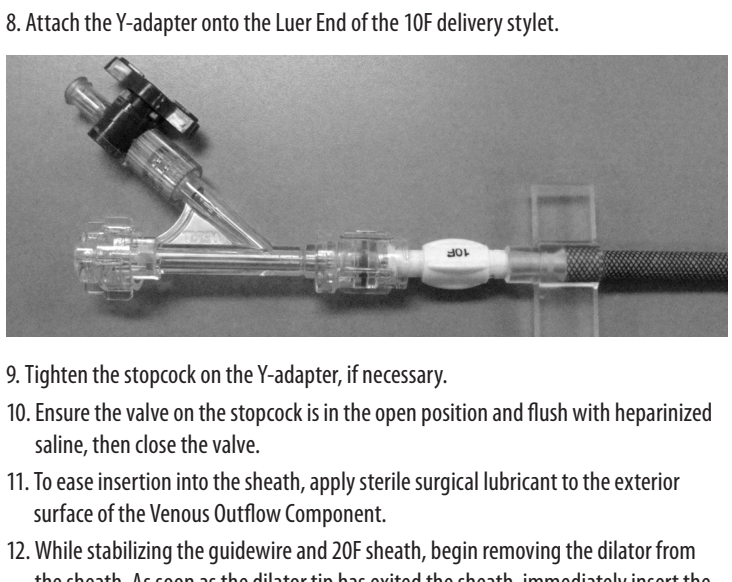
3. Insert the short 20F introducer from the Accessory Component Kit over the guidewire. The long 20F introducer may be used if needed for atypical accesses.

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

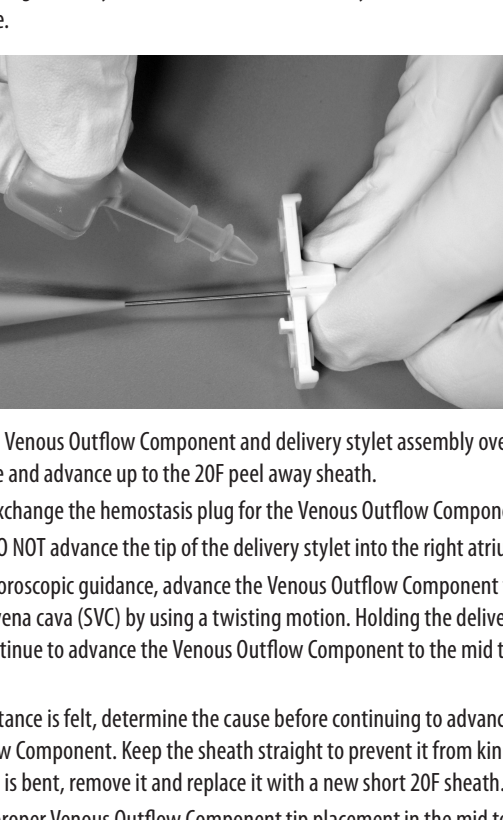
4. Advance the dilator and sheath together over the guidewire into the vessel using a twisting motion.

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

5. Open the Venous Outflow Component using aseptic technique.
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.



9. Tighten the stopcock on the Y-adapter, if necessary.
10. Ensure the valve on the stopcock is in the open position and flush with heparinized saline, then close the valve.
11. To ease insertion into the sheath, apply sterile surgical lubricant to the exterior surface of the Venous Outflow Component.
12. 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.



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

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

15. 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.

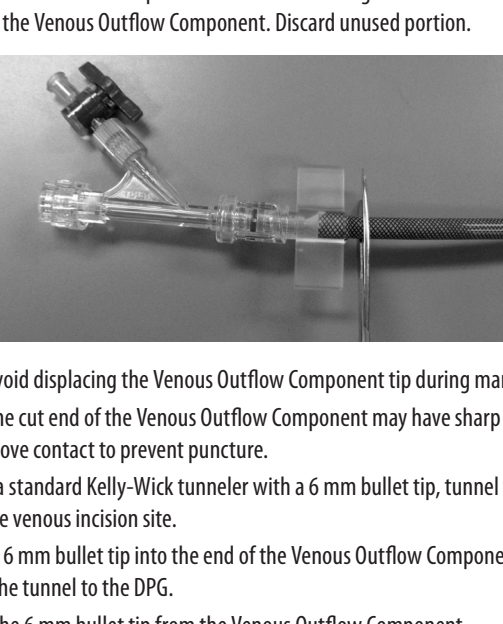
NOTE: If resistance is felt, determine the cause before continuing to advance the Venous Outflow Component. Keep the sheath straight to prevent it from kinking. If the sheath is bent, remove it and replace it with a new short 20F sheath.

16. Confirm proper Venous Outflow Component tip placement in the mid to upper right atrium.
17. 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.
18. Remove the guidewire and close the cap on the Y-adapter.
19. Prior to completing removal of the 10F delivery stylet from the Venous Outflow Component, clamp the Venous Outflow Component at the incision site to avoid loss of hemostasis. Complete the removal of the delivery stylet from the guidewire.

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.

20. 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.
21. Attach a syringe to the stopcock and unclamp the Venous Outflow Component. Aspirate the Venous Outflow Component. Close the stopcock, reclamp the Venous Outflow Component and remove the syringe.
22. 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.
23. Return the patient to standard supine position.
24. Make the connector site incision at the deltopectoral groove (DPG).
25. Holding the Venous Outflow Component away from the incision sites, use heavy duty scissors to cut the silicone Luer off of the Venous Outflow Component. The end of the Venous Outflow Component should be cut straight across ensuring the cut is square to the Venous Outflow Component. Discard unused portion.



Caution: Avoid displacing the Venous Outflow Component tip during manipulation.

Caution: The cut end of the Venous Outflow Component may have sharp edges. Avoid glove contact to prevent puncture.

26. Utilizing a standard Kelly-Wick tunneler with a 6 mm bullet tip, tunnel from the DPG to the venous incision site.
27. Insert the 6 mm bullet tip into the end of the Venous Outflow Component and pull through the tunnel to the DPG.
28. Remove the 6 mm bullet tip from the Venous Outflow Component.

Caution: DO NOT bend the Venous Outflow Component beyond a 2.5cm diameter anywhere along its length to prevent kinking.

NOTE: Alternatively, a GORE Tunneler or Bard Bi-Directional Tunneler may be used. Consult manufacturer IFUs for proper utilization.

IMPLANTING THE ARTERIAL GRAFT COMPONENT

1. Open the Arterial Graft Component using aseptic technique.
2. Make an incision at the selected arterial anastomosis site. Utilizing a standard vessel loop, expose the artery and verify the ID is greater than 3 mm in size. Verify patency via Doppler or tactile feel.

Caution: Use of the HeRO Graft was clinically studied utilizing the brachial artery. Arterial implantation of the device to other arteries has NOT been studied and may increase the risk of adverse events not encountered in the clinical trial. However, identification of an alternative artery with an ID of 3 mm or greater may result in improved blood flow compared to a brachial artery with an ID of less than 3 mm.

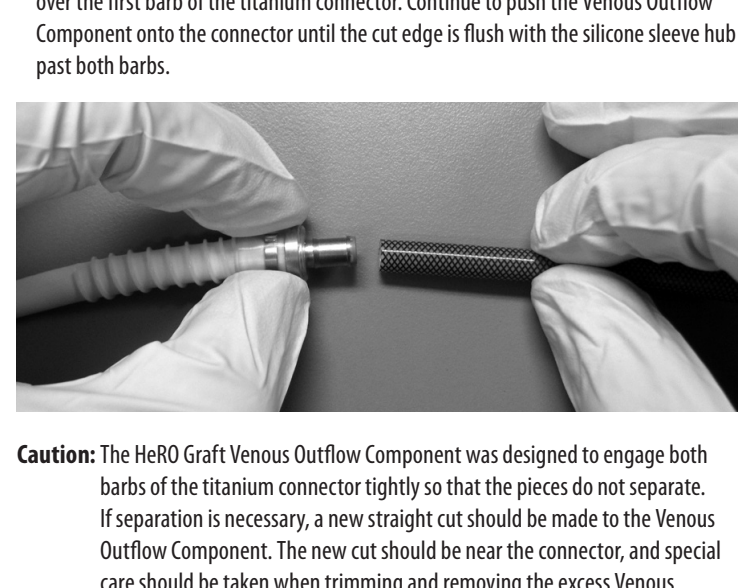
3. Utilizing a standard Kelly-Wick tunneler with a 7 mm bullet tip, follow the previously drawn soft C graft routing path to create a subcutaneous tunnel from the arterial incision site to the connector incision site at the DPG. Graft routing will vary depending on patient-specific anatomy.
4. Remove the 7 mm bullet tip from the Kelly-Wick tunneler and reattach the 6 mm bullet tip.
5. Attach the non-connector end of the Arterial Graft Component onto the 6 mm bullet tip and secure a tight connection with a suture(s).
6. Gently pull the Arterial Graft Component through the tunnel to the arterial incision site. Utilize the markings on the Arterial Graft Component to verify it has not twisted.
7. Leave approximately 8cm of the Arterial Graft Component exposed at the DPG incision site to facilitate the connection from the Arterial Graft Component to the Venous Outflow Component.
8. Cut the Arterial Graft Component from the tunneler and use a standard vascular clamp to occlude the Arterial Graft Component at the anastomosis site.

CONNECTING THE HeRO GRAFT

1. Place a sterile 4x4 gauze pad between the Venous Outflow Component and the DPG incision site to prevent debris from contaminating the incision.
2. Determine the Venous Outflow Component length required to make the connection to the Arterial Graft Component at the final DPG location. Utilizing a pair of heavy duty scissors, straight cut the Venous Outflow Component to the desired length ensuring that the cut is square to the Venous Outflow Component.

Caution: DO NOT test fit the Venous Outflow Component onto the titanium connector as it was designed not to separate once connected.

3. Press the cut end of the Venous Outflow Component onto the titanium connector. Connecting the two components is done by grasping the Venous Outflow Component approximately 2cm back from the cut edge and pushing so it slides more easily over the first barb of the titanium connector. Continue to push the Venous Outflow Component onto the connector until the cut edge is flush with the silicone sleeve hub past both barbs.

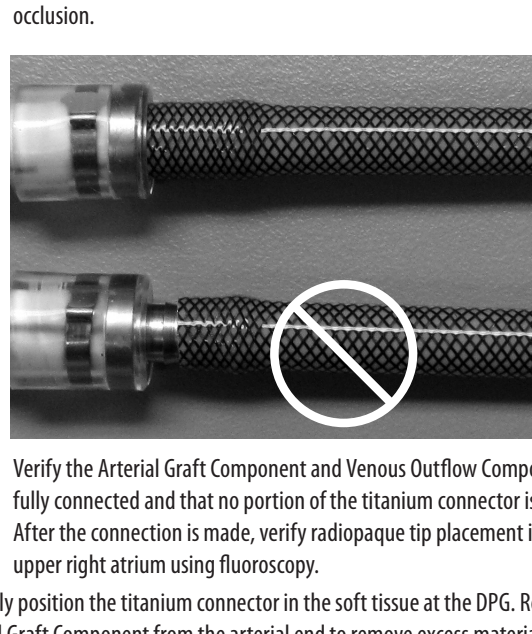


Caution: The HeRO Graft Venous Outflow Component was designed to engage both barbs of the titanium connector tightly so that the pieces do not separate. If separation is necessary, a new straight cut should be made to the Venous Outflow Component. The new cut should be near the connector, and special care should be taken when trimming and removing the excess Venous Outflow Component piece from the connector. Clean the connector of any material or residue. If damage occurs to the connector during separation, a new Arterial Graft Component should be used. Use fluoroscopy to recheck radiopaque tip placement after any adjustment is made.

Caution: DO NOT grasp, peel, or otherwise damage the Arterial Graft Component beads as this may adversely impact the integrity of the graft. It is important during device connection to grasp the silicone sleeve of the Arterial Graft Component and avoid contact with the beading. Ensure the beading is not crushed or damaged.

Caution: If damage to the beading is noted during implant, a new Arterial Graft Component should be used.

Caution: Damaged or crushed beading may lead to flow disruption within the HeRO Graft, and may contribute to early device occlusion and/or repeated occlusion.



Caution: Verify the Arterial Graft Component and Venous Outflow Component are fully connected and that no portion of the titanium connector is exposed. After the connection is made, verify radiopaque tip placement in the mid to upper right atrium using fluoroscopy.

4. Carefully position the titanium connector in the soft tissue at the DPG. Reposition the Arterial Graft Component from the arterial end to remove excess material.
5. Remove the clamps at the Venous Outflow Component and arterial anastomosis sites to backbleed the entire HeRO Graft.
6. Reclamp the Arterial Graft Component.

NOTE: Avoid beaded region of Arterial Graft Component.

7. Attach a syringe with heparinized saline to the Arterial Graft Component using a syringe adapter. Remove the clamp and flush the entire HeRO Graft. Observe the DPG connection site for leakage. Reclamp the Arterial Graft Component.

Caution: If leakage is observed, check for proper connection of the Arterial Graft Component to the Venous Outflow Component.

ARTERIAL GRAFT COMPONENT AND ARTERY CONNECTION

1. Cut the Arterial Graft Component to length, avoiding excessive tension or excess material. Verify there are no kinks, twists, or bends in the Arterial Graft Component.
2. Perform the arterial anastomosis utilizing standard surgical techniques.

Caution: Use a small diameter tapered needle with a non-cutting edge to reduce the incidence of suture hole bleeding.

3. Remove the clamp and check the device patency utilizing standard Doppler technique.
4. Verify thrill and bruit.
5. Evaluate for steal syndrome during the implant procedure with Doppler of the radial and ulnar arteries. If steal syndrome symptoms occur, consider surgical interventions such as:

- DRIL (distal revascularization-interval ligation) procedure
- Banding, though this may reduce the flow in the HeRO Graft
- Proximalization of the inflow

6. Close all three incision sites.

POST IMPLANT INFORMATION

1. Complete the Implant Notification Fax Form in the Patient Information Pouch and fax the completed form to the patient's dialysis center.
2. Provide the patient with the remaining items in the Patient Information Pouch.

VASCULAR ACCESS CANNULATION

Follow KDOQI guidelines for graft assessment, preparation and cannulation.

- The Arterial Graft Component requires 2-4 weeks to incorporate prior to cannulation.
- Swelling must subside enough to allow palpation of the entire Arterial Graft Component.
- Rotation of cannulation sites is needed to avoid pseudoaneurysm formation.
- A light tourniquet may be used for cannulation as the thrill and bruit may be softer than a conventional ePTFE graft due to the elimination of the venous anastomosis.

Post-dialysis, and following needle removal, apply moderate digital pressure at the puncture site until hemostasis is achieved. To decrease the risk of an occlusion, do not use mechanical clamps or straps.

Caution: DO NOT cannulate the HeRO Graft within 8cm (3") of the DPG incision to avoid damage to the beaded section of the Arterial Graft Component.

Caution: DO NOT cannulate the Venous Outflow Component.

Caution: Remove the bridging catheter as soon as possible once the HeRO Graft is ready to be cannulated to decrease the risk of an infection related to the bridging catheter.

Caution: All bridging catheters should be cultured upon explant. In the event catheter tip cultures are positive, treat the patient with appropriate antibiotics to decrease the risk of the HeRO Graft becoming infected.

For additional information refer to the HeRO Graft Care & Cannulation Guide in the patient information or review online at www.merit.com/hero.

PERCUTANEOUS THROMBECTOMY

The HeRO Graft will require maintenance equivalent to conventional ePTFE grafts. The HeRO Graft can be up to 90cm long; thus requiring a longer thrombectomy device to traverse the entire length of the device.

Caution: Do not use mechanical/rotational thrombectomy devices (e.g., Arrow-Trerotola PTD®) in the Venous Outflow Component and/or connector as internal damage may occur to these components.

For specific thrombectomy instructions or guidance, please contact Customer Service for a copy of the Thrombectomy Guidelines or it may also be found on www.merit.com/hero.

DEVICE EXPLANT, EXCHANGE, REVISION OR ABANDONMENT

The HeRO Graft Venous Outflow Component and connection portion should be removed if the device will not be used for hemodialysis access. In situations where the HeRO Graft requires exchange, explant or revision, please contact Customer Service for an instruction procedure and an Explant Return Kit. Instructions may also be found in the Frequently Asked Questions section of www.merit.com/hero.

MRI INFORMATION

The HeRO Graft was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing has demonstrated that the HeRO Graft is MR-conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial gradient magnetic field of 720-Gauss / cm or less

MRI-Related Heating

In non-clinical testing, the device produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla / 128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.6°C.

Therefore, the MRI-related heating experiments for the device at 3-Tesla using a transmit / receive radiofrequency (RF) body coil at an MR system reported whole body averaged SAR of 3.0-W / kg (i.e., associated with a calorimetry measured value of 2.8-W / kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size:	7,849 mm^2	295 mm^2	9,519 mm^2	1,273 mm^2
Plane Orientation:	Parallel	Perpendicular	Parallel	Perpendicular

WARRANTY DISCLAIMER

THIS PRODUCT HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS WITH ALL REASONABLE CARE, MERIT MEDICAL SYSTEMS, INC. HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MERIT MEDICAL SYSTEMS, INC. THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. DESCRIPTIONS OR SPECIFICATIONS IN MERIT MEDICAL SYSTEMS, INC. PRINTED MATERIAL, INCLUDING THIS PUBLICATION, ARE MEANT SOLELY TO GENERALLY DESCRIBE THE PRODUCT AT THE TIME OF MANUFACTURE AND DO NOT CONSTITUTE ANY EXPRESS WARRANTIES. MERIT MEDICAL SYSTEMS, INC. SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MERIT MEDICAL SYSTEMS, INC. TO ANY REPRESENTATION, CONDITION, WARRANTY OR LIABILITY WITH RESPECT TO THE PRODUCT.

THE EXCLUSIONS AND LIMITATIONS SET OUT ABOVE ARE NOT INTENDED TO, AND SHOULD NOT BE CONSTRUED SO AS TO CONTRAVENE MANDATORY PROVISIONS OF APPLICABLE LAW. IF ANY PART OR TERM OF THIS WARRANTY DISCLAIMER IS HELD TO BE ILLEGAL, UNENFORCEABLE OR IN CONFLICT WITH APPLICABLE LAW BY A COURT OF COMPETENT JURISDICTION, THE VALIDITY OF THE REMAINING PORTIONS OF THIS WARRANTY DISCLAIMER SHALL NOT BE AFFECTED, AND ALL RIGHTS AND OBLIGATIONS SHALL BE CONSTRUED AND ENFORCED AS IF THIS WARRANTY DISCLAIMER DID NOT CONTAIN THE PARTICULAR PART OR TERM HELD TO BE INVALID AND THE INVALID PART OR TERM SHALL BE SUBSTITUTED BY A VALID PART OR TERM WHICH BEST REFLECTS MERIT MEDICAL SYSTEMS, INC.'S LEGITIMATE INTEREST IN LIMITING ITS LIABILITY OR WARRANTY.

In the event that such a disclaimer is found invalid or unenforceable for any reason: (i) any action for breach of warranty must be commenced within one year after any such claim or cause of action accrued and (ii) the remedy for such breach is limited to the replacement of the product. Prices, specifications and availability are subject to change without notice.

TECHNICAL SUPPORT

To obtain additional information on the HeRO Graft, including questions on infection control procedures, contact the customer service department at:

REFERENCES

1. Vascular Access Work Group. National Kidney Foundation KDOQI clinical practice guidelines for vascular access. Guideline 1: patient preparation for permanent hemodialysis access. Am J Kidney Dis 2006;48(1Suppl1):S188-91.
2. Hemodialysis Adequacy 2006 Work Group. National Kidney Foundation KDOQI clinical practice guidelines for hemodialysis adequacy, update 2006. Am J Kidney Dis 2006;48(Suppl 1):S2-S90.
3. Data on file.
4. Lucas, George F. 2007. Scientific Review of Adverse Events related to the use of Chronic Hemodialysis Catheters (not including infections). Data on file.
5. Lucas, George F. 2007. Scientific Review of Adverse Events in Hemodialysis Grafts. Data on file.
6. Hajjar J, Girard R, Marc JM, et al. [Surveillance of infections in chronic hemodialysis patients (Article in French)]. Nephrologie 2004;25:133-40.
7. Katzman H. (2009). Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients. Journal Vascular Surgery, 600-607.
8. Shah, Ravish. 2010. Impact of Missing Hemodialysis sessions on Arteriovenous Access Thrombosis. Data on file.
9. Illig KA. Management of Central Vein Stenosis and Occlusions: The Critical Importance of the Costoclavicular Junction. Semin Vasc Surg 24:113-118, 2011.

A bibliography of HeRO Graft publications and presentations is available at www.merit.com/hero.

GENERAL WARNING

- 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.

MERIT MEDICAL®

www.merit.com

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095, U.S.A.
1-801-253-1600 U.S.A
Customer Service 1-800-356-3748
www.merit.com/hero

EC REP **Authorized Representative:**
Merit Medical Ireland Ltd
Parkmore Business Park West
Galway, Ireland
EC Customer Service +31 43 358822
www.merit.com/hero

403225001EN_001 2016-03-16