Qualitative/Quantitative Information On Patient Exposure To Materials And Substances

Material	Duration of Exposure	Level of Patient Exposure (cm^2)
Arterial Graft Component (HER01002)		
PTFE and ePTFE	≥30 days	≈225.03
Med-4850 Silicone	≥30 days	≈0.40
Med-1137 Silicone and Barium Sulfate mixture	≥30 days	≈3.87
Note: While the Arterial Graft Component has a titanium alloy connector, there is no patient contact as the connector is encapsulated within the silicone coating and silicone sleeve.		
Venous Outflow Component (HER01001VOC and HER01000)		
Mixture of Med-6233 Silicone and Med-6219 Silicone	≥30 days	≈100.00
NuSil MED-4750 Silicone with 10% Barium Sulfate	≥30 days	≈67.74
Note: The Venous Outflow Component contains a nitinol braid and a nitinol band with underlying platinum-iridium flat wire, there is not patient exposure as they are encapsulated within the silicone		
Adapter (HER01000 and HER01006)		
Titanium Alloy (TiAl6V4)	≥30 days	≈5.03
Mixture of Med-1137 Silicone and Barium Sulfate	≥30 days	≈0.52
Nitinol	≥30 days	≈0.06
Support Seal if used (HER01000 and HER01006)		
Nitinol	≥30 days	≈30.00
Med-4850 Silicone	≥30 days	≈7.16

*Material present below the Generally Recognized as Safe (GRAS) level for this exposure per https://echa.europa.eu/information-on-chemicals/registered-substances.

Any serious incident that occurs in relation to the HeRO Graft should be reported to the manufacturer and to the Therapeutic Goods Administration at www.tga.gov.au

MERIT MEDICAL®

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

The information presented here should not be construed as specific medical advice, diagnosis, treatment or recommendation. This material is not a substitute for a consultation or physical examination by a physician. Always seek the advice of a qualified physician regarding any medical questions or conditions. Merit Medical assumes no responsibility for a patient's success as results may vary.

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PATIENT INFORMATION LEAFLET

PLEASE PROVIDE TO THE PATIENT

HERO ALLY HER01006
SUPER HERO HER01000
VENOUS OUTFLOW COMPONENT HER01001VOC
ARTERIAL GRAFT COMPONENT HER01002

HERO® GRAFT

The HeRO® (Hemodialysis Reliable Outflow) Graft is a long-term vascular access device for access-challenged and catheter-dependent patients or patients approaching catheter dependency, due to the blockage of the veins leading to the heart. The device is a fully subcutaneous surgical implant which provides the ability to traverse central venous stenoses. It provides arterial venous (AV) access through the graft portion of the system with continuous outflow into the central venous system through the Venous Outflow Component.

THE HeRO® GRAFT CONSISTS OF THREE PRIMARY COMPONENTS:

1. The Venous Outflow Component (VOC) is a reinforced tube that bypasses blockage in veins.
2. The Arterial Graft Component has a connector for attachment to the VOC. The graft is sewn to an artery (graft/artery anastomosis) and accessed for hemodialysis.
3. The Adapter (with or without support seal) is an alternative option to the AGC (original HeRO Graft) that allows the physician to select from a specific list of marketed 6mm ID vascular access grafts that have been qualified for use with the HeRO Graft System.

The Venous Outflow Component (VOC) and graft are connected to form the HeRO Graft.

INTENDED PURPOSE:

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.

USING THE HeRO GRAFT:

- Once the HeRO Graft has been implanted, it requires 2–4 weeks to incorporate prior to cannulation.
- The device can be accessed for hemodialysis using standard hemodialysis access needles. The access is performed in the graft portion of the HeRO Graft.
- The cannulation must be a minimum of 8 cm distal to the connection area between the graft and the Venous Outflow Component in the deltopectoral groove.
- The access must also be a minimum of the length of the access needle away from the graft/artery anastomosis site.
- Rotation of cannulation sites is needed to avoid pseudoaneurysm formation.
- 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.

ALWAYS FOLLOW YOUR DOCTOR'S OR NURSE'S INSTRUCTIONS AND PROMPTLY TELL YOUR CARE TEAM ABOUT ANY UNUSUAL SYMPTOMS OR PAIN.

For the first few weeks after surgery, follow these tips:

- Keep your access arm clean and dry
- Watch for signs of infection (e.g., redness, tenderness, swelling, or fever)
- Be gentle with your access arm, and avoid lifting heavy objects
- Use your arm as normally as possible, avoiding movements that cause pain or discomfort
- When sitting or lying down, rest your arm on pillows higher than your heart to reduce swelling
- Don't overwork your upper arm muscles during the healing period

Other tips to care for your new access:

- Wear loose clothes over your access arm
- Avoid carrying a backpack/purse on your dialysis shoulder
- Try not to lie down on your access arm or shoulder while you sleep
- You should feel for the "thrill" or vibration in your HeRO® Graft several times a day, noting if it stops or feels different. If the vibration stops or changes, report this to your dialysis provider or doctor as soon as possible.

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

- Abnormal healing / skin erosion
- Anastomosis or wound dehiscence
- Device kinking or compression
- Device migration
- Ectasia
- Edema
- Foreign body reaction or rejection
- Graft extravasation
- Infection
- Partial stenosis or full occlusion of prosthesis or vasculature
- Prosthesis failure
- Pseudoaneurysm
- Seroma
- Site pain
- Superior Vena Cava Syndrome
- Vascular graft revision / replacement
- Vascular insufficiency due to steal syndrome

Potential Intraoperative & Post-Operative Complications

- Allergic reaction
- Aneurysm
- Bleeding
- Cardiac arrhythmia
- Cardiac tamponade
- Death
- Embolism
- Heart failure
- Hematoma
- Hemorrhage
- Hypotension / hypertension
- Myocardial infarction
- Pneumothorax / hemothorax / hydro-thorax
- Reactions to anesthesia
- Respiratory / cardiac arrest
- Sepsis
- Trauma to major vasculature or nerves

RESIDUAL RISKS FOR THE HeRO GRAFT

- Bleeding, Hemorrhage
- Cardiac Arrhythmia
- Death
- Edema, swelling
- Inflammatory Reaction
- Pulmonary Embolism
- Infection
- Stroke
- Embolism
- Vascular Insufficiency Steal Syndrome, Ischemia
- Site Pain
- Trauma to major vessels
- Neointimal Hyperplasia
- Nerve Injury
- Wound Problems
- Implant Failure
- MRI Interaction, Displacement
- Seroma
- Stricture

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.
- When connecting the Venous Outflow Component to the Arterial Graft Component, verify the Venous Outflow Component is flush with the shoulder of the connector.
- **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.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the HeRO® Graft System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the HeRO Graft System is expected to produce a maximum temperature rise of 4.8°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 10mm from the HeRO Graft System when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

EXPECTED DEVICE LIFETIME

The device is intended to function through the patient's expected lifespan provided adequate medical surveillance to prevent/treat thrombosis or other access related complications.