

# PATIENT INFORMATION LEAFLET

PLEASE PROVIDE TO THE PATIENT



## VASCULAR ACCESS DEVICE FOR HEMODIALYSIS



### RECIPROCAL INTERFERENCE/MAGNETIC RESONANCE IMAGING (MRI)

Non-clinical testing has demonstrated that the HeRO Graft is MR conditional. A patient with this device can be safely scanned in a 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 (40T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode)

### EXPECTED DEVICE LIFETIME

The clinical-use lifetime of the HeRO Graft varies by system component. The VOC and Adapter are designed to function for a 10-year lifetime in-situ. Given that the ePTFE graft portion of the AGC as well as other third party vascular grafts are punctured with needles multiple times each week for dialysis access, the expected AGC/graft lifetime is 2 years. Once the ePTFE dialysis access graft has been adequately incorporated into the surrounding tissue, it is the physiological environment and patient condition that govern long-term graft viability rather than the mechanical properties of the graft.

### NECESSARY FOLLOW-UP

- Your doctor will discuss with you how often you will need follow-up appointments
- Your doctor will instruct you on proper postoperative care and measures to be taken in the event of malfunction of the device.
- Always follow your doctor's or nurse's instructions and promptly tell your care team about any unusual symptoms or pain.

## Qualitative/Quantitative Information On Patient Exposure To Materials And Substances

Material	Duration of Exposure	Level of Patient Exposure (grams)
<b>Arterial Graft Component</b>		
ePTFE (graft)	≥30 days	≈4.57
FEP (beading)	≥30 days	≈0.66
Silicone	≥30 days	≈0.50
Silicone and Barium Sulfate mixture	≥30 days	≈0.02
Ink	≥30 days	≈0.0015
Titanium Alloy (TiAl6V4)	≥30 days	≈0.89
<b>Venous Outflow Component</b>		
Outer Surface Silicone	≥30 days	≈45.23
Inner Surface Silicone with 10% Barium Sulfate	≥30 days	≈3.19
Nitinol	≥30 days	≈3.13
Platinum / Iridium	≥30 days	≈0.01
<b>Adapter</b>		
Titanium Alloy (TiAl6V4)	≥30 days	≈1.99
Mixture of Silicone and Barium Sulfate	≥30 days	≈0.02
Nitinol	≥30 days	≈0.01
<b>Support Seal</b>		
Nitinol	≥30 days	≈2.42
Silicone	≥30 days	≈2.67
Silicone Adhesive	≥30 days	≈0.01

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

### ADDITIONAL INFORMATION

- **DO NOT** attempt intervention without device information
- **DO NOT** place central lines or other medical devices on the same side as the HeRO Graft.



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.