Medtronic HeartWare

UPDATE TO URGENT FIELD SAFETY NOTICE

New Product Design Available
Medtronic HeartWare™ HVAD™ System

CFN/Model #	Product Description
1125	HVAD PUMP OUTFLOW GRAFT
1104	HVAD PUMP IMPLANT KIT
1153	HVAD PUMP IMPLANT ACCESSORIES
1318	HVAD PUMP SURGICAL TOOLS
1328	HVAD PUMP SURGICAL TOOLS – EXTENDED LENGTH>

January 2021

Medtronic Reference: FA908 Phase II

Dear VAD Coordinator, Healthcare Professional, or Risk Manager,

This letter is a follow-up to Medtronic's April 2020 customer notification titled "Urgent Field Safety Notice" letter regarding the HVAD Outflow Graft and Strain Relief **<which is available at https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance.html>.**

Medtronic has obtained the necessary regulatory approvals for a newly designed product, and we are now informing you that the new product is available. We will begin exchanging your unused product (listed above) for the newly approved product. Medtronic representatives will train Clinicians at your facility prior to the availability and use of this new product.

Until you receive the new product, you may continue to use the current product (listed above), along with the previously provided additional steps for assembly and attachment, to reduce the risk of damage to the Outflow Graft and Strain Relief screws during the pre-implant pump assembly procedure. The additional steps can be found in the April 2020 communication. As indicated in the April 2020 communication, no action is needed for patients already implanted with an HVAD Pump.

Next Steps

- Contact your Medtronic Field Representative for assistance in exchanging unused product listed above in your inventory.
- Newly approved product should not be used with current products (listed above) for new implants. Therefore, after you've been trained on and receive the newly approved replacement product, immediately quarantine current product for exchange.
- Please share this notice with all those who need to be aware within your organization or to any organization where the existing product has been transferred.

Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

Sincerely,

Taha Saricimen,
Business Manager, MCS, CEMA