

UPDATE TO AN IMPORTANT MEDICAL DEVICE SAFETY ALERT**New Product Design Approved
Medtronic HeartWare™ HVAD™ System**

CFN/Model #	Product Description
1125	HVAD PUMP OUTFLOW GRAFT
1103	HVAD PUMP IMPLANT KIT
1153	HVAD PUMP IMPLANT ACCESSORIES
1318	HVAD PUMP SURGICAL TOOLS
1328	HVAD PUMP SURGICAL TOOLS - EXTEND

September 2020

Dear Healthcare Professional or Risk Manager,

Medtronic is communicating a follow-up to our April 2020 customer notification titled "Important Medical Device Safety Alert" letter regarding the HVAD Outflow Graft which is available at <https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance.html>. At that time, we provided additional steps for assembly and attachment to reduce the risk of damage and tearing during the assembly procedure.

We are writing to inform you that Medtronic has recently obtained the necessary regulatory approvals for newly designed product. When available, your Medtronic Field Representative will be in contact to coordinate new product training at your facility and to assist with exchanging unused product (listed above) for newly approved product.

Pending the exchange for this newly approved 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. As indicated in the April 2020 communication, no action is needed for patients already implanted with an HVAD Pump.

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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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,



Kirk Hauge
Vice President, Quality
Medtronic Cardiac Rhythm and Heart Failure