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URGENT MEDICAL DEVICE COMMUNICATION
HeartWare™ Ventricular Assist Device (HVAD™) System Retrieval Instructions

July 2021

Dear VAD Coordinator/Healthcare Professional:

Medtronic is providing this letter as a follow-up to our June 2021 customer communication titled "Urgent Medical Device Communication: Notification Letter Medtronic HVAD™ System" (attached). The June 2021 communication announced our decision to stop the distribution and sale of the HeartWare Ventricular Assist Device (HVAD)™ System and advised physicians to immediately stop new implants of the Medtronic HVAD System. This communication serves as the retrieval instructions for the Medtronic HVAD System and other components. There is no change to the Patient Management Recommendations outlined in the June 2021 communication.

Please return the following product:

Model Number	Product Description
1103	HVAD™ Pump Implant Kit
MCS1705PU	HVAD™ Pump Implant Kit
1125	HVAD™ Pump Outflow Graft
MCS1725OG	HVAD™ Pump Outflow Graft
1153	HVAD™ Pump Implant Accessories
MCS1753AK	HVAD™ Pump Implant Accessories
100US	Driveline Extension Cable

Medtronic is recommending that you **do not** return peripherals or HVAD Surgical Tools needed to manage patients currently on support. Medtronic will continue to support these products and you may order them as needed. If your Center has no active patients on HVAD support, Medtronic requests you return all HVAD products to Medtronic.

Medtronic will notify all applicable regulatory agencies about this matter.

Your Actions

- Return all unused affected product (listed in the table above) in your inventory to Medtronic. Contact Medtronic Customer Service at 1-877-367-4823 or rs.mcscustomerservice@medtronic.com to initiate a product return. Your local Medtronic Representative can assist you in the return of affected product.
- For any other questions or concerns, including if you are having trouble locating an alternative device for your patient during this transitional period, please contact the Medtronic Office of Medical Affairs at rs.mcsmedicalaffairs@medtronic.com.
- Please complete the enclosed Customer Confirmation Form and email to RS.CFQFCA@medtronic.com.
- Please forward this notice to all those who need to be aware within your organization.

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.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have any questions, please contact your local Medtronic Representative.

Sincerely,

Nnamdi Njoku
President
Medtronic Mechanical Circulatory Support