Urgent Field Safety Notice

HeartWare™ Ventricular Assist Device (HVAD™) System

Retrieval Instructions

July 2021

Medtronic reference: FA981 Phase II

Dear VAD Coordinator/Healthcare Professional,

Medtronic is providing this letter as a follow-up to our June 2021 customer communication titled "Urgent Field Safety Notice: 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
1104	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
100	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.

Your Actions

- Return all unused affected product (listed in the table above) in your inventory to Medtronic. 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 forward this notice to all those who need to be aware within your organization.

The Competent Authority of your country has been notified of this action.
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,

Medtronic Mechanical Circulatory Support

Enclosure: June 2021 Urgent Field Safety Notice