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URGENT MEDICAL DEVICE COMMUNICATION
HeartWare™ Ventricular Assist Device (HVAD™) System
Patient Management Recommendations

| Model | Geography |
|-------|-----------|
| 1103 | US |

December 2020

Dear Physician or Healthcare Professional:

This letter is to inform you of a potential issue for the Medtronic HeartWare™ Ventricular Assist Device (HVAD™) System. Medtronic has identified an issue with implanted HVADs where the pump may experience a delay to restart or failure to restart. An internal pump component from three (3) specific lots puts a subset of the finished pumps at higher risk of delay to restart or failure to restart. The risk exists only when the pump is stopped, for example in a controller exchange when an attempt is made to restart the pump. A delay to restart or failure to restart could occur at any time after a pump stop, even if the pump initially started at the time of implant. If a pump has successfully restarted after a pump stop event, a delay to restart or failure to restart could be experienced in the future.

This issue does not impact the performance of a pump while it is running.

Medtronic records indicate you are following one or more patients implanted with an HVAD System from the identified subset, as noted in the enclosed report.

Worldwide, 506 HVAD Systems (268 in the U.S.) were manufactured and distributed with the impacted components. This subset of pumps was manufactured between 2017-2019. Medtronic has received 26 complaints between March 1, 2017- November 16, 2020, associated with pumps in this identified subset failing to initially start, restart or experiencing a delay to restart.

Pumps in this subset have experienced a 5.2% rate of failing to initially start, restart or experiencing a delay to restart. As of November 16, 2020, Medtronic has identified two (2) deaths, nine (9) cases of critical harm (such as cardiac arrest or reoperation for pump exchange), seven (7) cases of major harm (such as hospitalization or prolonged implant procedure due to interoperative pump exchange), and eight (8) cases of negligible harm (such as a potentially life threatening event in which the patient recovered without long term effects, or a patient experienced a delay in implant). See table below.

| Category | # of Complaints | Subset Rate of Occurrence |
|---|-----------------|---------------------------|
| Failures at implant | 6 | 1.2% |
| Delay in restart (did restart) post-implant | 7 | 1.4% |
| Failure to restart post-implant | 13 | 2.6% |

In the general pump population, the observed rate of pumps failing to initially start, restart or experiencing a delay to restart is 0.087% for pumps operating in dual stator (normal operation with both stators driving the pump) and 0.4% for pumps operating in single stator (when continuity in the pump to controller electrical connection is interrupted) for example, due to accidental damage to the driveline cable during use.

Patient Management Recommendations

In consultation with our Independent Practitioner Quality Panel, Medtronic recommends the following actions for the subset of devices that exhibit the higher rate of failure (the 3 lots):

- Reinforce to patients and staff the following points from the current Instructions for Use (IFU) to avoid unnecessary pump stops:
 - Do NOT disconnect the driveline from the controller.
 - NEVER disconnect both power sources (batteries and AC or DC adapter) from the controller at the same time; one external power source should remain connected to the controller at all times.
 - Do NOT exchange the controller unless explicitly directed by a High Priority alarm condition or by a VAD team member.
 - Reinforce the proper response to a [Controller Fault] alarm and [Electrical Fault] alarm. These are Medium Priority alarms unrelated to an immediate pump stop. These alarms will result in the word [Call] in the Controller Display, notifying the patient to call their clinician.
 - Reinforce making good connections of power sources and the data cable in the controller ports.

- Inform patients implanted with one of these identified pumps to contact their VAD coordinator prior to any controller exchange, and to coordinate performing an exchange of controllers in a clinical setting.

- If a controller exchange is deemed necessary for patients implanted with one of these identified pumps, consider the following:
 - Controller exchanges should be performed under clinician supervision in a controlled environment with immediate ability to put the patient on hemodynamic support. **Failure to restart can be fatal.**
 - Upon a pump stop, a High Priority [VAD Stopped] alarm will result in the words [Change Controller] or [Connect Driveline] in the Controller Display. Once power and driveline connections are reestablished, if the pump does not restart:
 - Consider power cycling of the current controller or consider a controller exchange. This will allow the restart algorithm to reset and start over. The controller automatically attempts to restart the pump a maximum of 30 times; the [VAD Stopped] alarm begins after five (5) attempts.
 - **If the pump still does not restart, proceed with temporary hemodynamic support and pump exchange.**

- If a patient's controller is beyond two (2) years of service, consider proactively scheduling a controller exchange prior to the internal controller battery reaching end of life and triggering a [Controller Fault] alarm. Although a [Controller Fault] alarm is a Medium Priority alarm that is not related to a pump stop, proactively scheduling a controller exchange could help avoid a patient reacting to the alarm by exchanging a controller outside of a clinical setting. Per the IFU, patients should call their clinician upon receiving a Medium Priority alarm.

Root cause investigation of the issue in the three (3) lots is ongoing and Medtronic will notify you if there are changes in our recommendations.

Medtronic will notify all applicable regulatory agencies about this matter.

Your Actions

- Please review the attached serial numbers and confirm that your patient(s) is still on support
- This notice must be shared with all those who need to be aware within your organization or to any organization where potentially affected patients have been transferred
- Please complete the enclosed Physician Confirmation Form and return via email to RS.CFQFCA@medtronic.com

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

We sincerely regret any difficulties this may cause you and your patients. 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,

A handwritten signature in blue ink, appearing to read "Kirk Hauge". The signature is stylized with a large initial "K" and a long horizontal stroke at the end.

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