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Urgent Medical Device Correction

HeartWare™ Ventricular Assist Device (HVAD™)

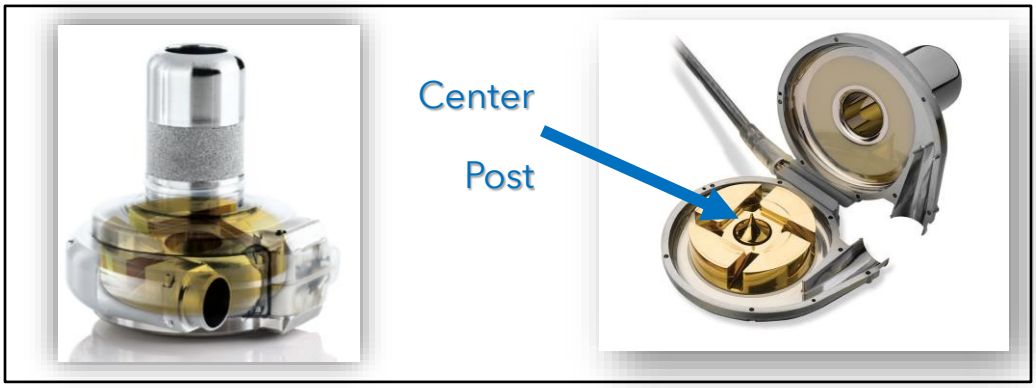
Model	Product Description
1103	HVAD™ Pump Implant Kit
MCS1705PU	HVAD™ Pump Implant Kit

April 2022

Dear Physician and Healthcare Professional:

Medtronic is writing to inform you that we are investigating a new issue with the HeartWare™ Ventricular Assist Device (HVAD™) System. Medtronic has received three (3) complaints of patients with suspicion of pump thrombosis; however, a device malfunction was identified upon inspection of the three (3) returned pumps. Wear marks indicated that the impeller was rotating non-concentrically and contacting the center post of the pump (see Figure 1 Pump Assembly). The ongoing investigation suggests this was caused by a weld defect that allowed moisture into the center post and corroded the magnets that keep the impeller rotating concentrically.

Figure 1: Pump Assembly



These three pumps were manufactured between December 2017 and May 2018. A pump exchange was performed for all three patients. The time between initial presentation and pump exchange was five days for two (2) patients and five months for one (1) patient. One (1) patient was subsequently transplanted two months after the pump exchange and died one month later; one (1) additional patient died three weeks after the VAD exchange.

An active investigation is in progress to identify which HVAD pumps may be affected. At this time Medtronic is communicating the potential of this failure mode to all healthcare providers who implant and manage HVADs, and will issue additional, detailed communication as soon as further information is available.

With this letter, we want to alert you that patients with affected devices may present with signs and symptoms that resemble pump thrombosis.

The three patients presented with one or more of the following signs and symptoms:

- Abnormal pump sounds such as: grinding or excess vibration
- Transient power spikes on the log files and High Watt alarms
- Elevated lactate dehydrogenase (LDH)
- Low motor speed resulting in low perfusion
- Dizziness / lightheadedness

When patients present with these signs and symptoms, please upload and submit all .csv logfiles to https://autologs.medtronic.com. Once on the website, please ensure to select the HVADlogs radio button and select "Urgent". Your Medtronic representative can assist with further logfile submission and analysis questions. Medtronic will analyze these logfiles as part of the ongoing investigation.

Patient Management Recommendations

Routine prophylactic explant of the HVAD device is not recommended, as risks associated with explantation may outweigh the potential benefits. Physicians should make the decision regarding explant and exchange of the HVAD pump on a case-by-case basis (is the patient a candidate for pump exchange, heart transplant, or pump explant for recovery), considering the patient's clinical condition and surgical risks.

For patients presenting with any of the above signs and symptoms consider whether the clinical presentation could be due to a pump thrombus and treat accordingly. Please ensure the .csv logfiles are submitted to Medtronic for review.

Customer Instructions:

Medtronic records indicate that your site has patients that may still be on support; we request that you do the following:

- This notice must be shared with all those who need to be aware within your organization or any organization where potentially affected patients have been transferred.
- Please complete the enclosed Customer Confirmation Form and email to RS.CFQFCA@medtronic.com.

Adverse reactions or quality problems experienced with 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 from 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 will notify all applicable regulatory agencies of this matter. Medtronic remains dedicated to further investigation of this issue and will continue to monitor device performance to ensure we meet your needs and those of your patients. Further communication will follow once more information becomes available. Medtronic Patient Services is available to assist patients at 800-635-3930 (Monday-Friday, 8 a.m.-5 p.m. Central Time). If you have any questions, please contact your local Medtronic Representative. For any additional questions you can reach out to the Medtronic Office of Medical Affairs at rs.mcsmedicalaffairs@medtronic.com.

Sincerely,

Gail Schroeder

Vice President, Quality and Regulatory Affairs

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