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Urgent Medical Device Correction

Pump Weld Update for HeartWare™ Ventricular Assist Device (HVAD™)

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

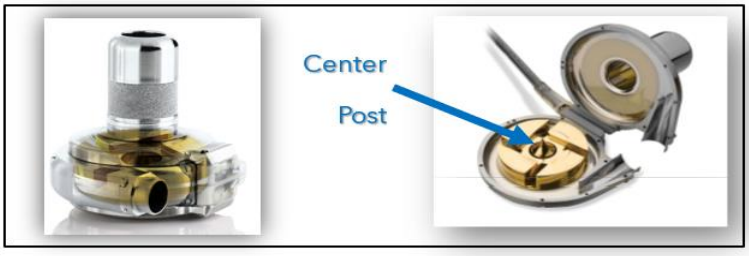
26 July 2022

Dear Physician and Healthcare Professional:

Medtronic is providing this letter as a follow-up to our April 2022 communication titled "Urgent Medical Device Correction" (attached), which communicated a pump weld non-conformance with the HeartWare™ Ventricular Assist Device (HVAD™) System where (3) pumps were identified to have an impeller rotating non-concentrically and contacting the center post of the pump (see Figure 1: Pump Assembly). Medtronic's investigation was not able to conclusively isolate this issue to a specific subset of pumps. This communication provides updated information on the number of events, additional event details, and root cause.

There are no new patient management recommendations since the April 2022 communication. Consistent with the April communication, **routine prophylactic explant of the HVAD device is not recommended**, as risks associated with explantation may outweigh the potential benefits of continued HVAD therapy.

Figure 1: Pump Assembly



Summary of Confirmed Complaints

Since the April communication, Medtronic has received one (1) additional confirmed complaint related to this non-conformance, for a total of four (4) complaints. In all four complaints, each patient underwent a pump exchange due to suspicion of pump thrombus; however, no evidence of thrombus was found. Inspection of the explanted pumps revealed evidence of the impeller contacting the center post due to non-concentric rotation, consistent with corrosion of the center post magnet. Two (2) deaths were reported in association with these four complaints: in one case the patient underwent a cardiac transplant two months after the pump exchange and died one month after the transplant; in the other case the patient died three weeks after the VAD exchange.

Investigation of the four (4) complaints and bench testing of simulated corroded magnets indicates that an abnormal noise or vibration, commonly described as a "grinding" sound, was heard by either the patients or their clinicians. The grinding sound did not resolve after treatment for thrombus and is a likely initial indication that the impeller is contacting the center-post due to nonconcentric rotation. Over time, transient power spikes occurred on the logfiles causing [High Watt] alarms. This is unlike the gradual steady increase in power consumption typically seen with pump thrombus.

Although the root cause of the four complaints referenced above has been confirmed by analysis of the returned pumps, Medtronic continues to investigate complaints of suspected pump weld non-conformances.

Patients with affected devices may present with signs and symptoms that resemble pump thrombus. It is not known if a patient's pump with this issue will present with the same signs/symptoms. In all four (4) instances the following were consistently encountered:

- Suspected Thrombus
- High Watt Alarms
- Grinding sound

The table below provides a summary of the four (4) confirmed complaints provided to Medtronic.

	Manufacturing Date	**Implant Duration**	**Reported Signs and Symptoms**
Complaint 1	Dec 2017	25 months	• Suspected thrombus • High watt alarms • Grinding sounds • Vibration • Reported Patient Symptoms: fatigue, light-headedness and dizziness, shortness of breath
Complaint 2	Jan 2018	28 months	• Suspected thrombus • Grinding sounds • High watt alarms • Elevated LDH level

			• Reported Patient Symptoms: dark urine
Complaint 3	May 2018	35 months	• Suspected thrombus • Grinding sounds • High watt alarms • Elevated LDH level • Reported Patient Symptoms: unknown
Complaint 4	April 2019	30 months	• Suspected thrombus • Grinding sounds • High watt alarms • Low flow alarms • Elevated LDH level • Reported Patient Symptoms: unknown

Summary of Root Cause Investigation

As a part of the investigation, Medtronic conducted a broad search of historical complaints and product returns to determine if there were additional pumps with suspected thrombus that may have a previously undetected corroded center-post magnet. As of JUL 2022, Medtronic completed an analysis of over 747 complaints from our returned product archives. Of those 747 complaints, Medtronic conducted a further analysis on 54 explanted pumps that had been returned to our analysis lab from 2012 to 2022. The returned pumps had allegations of thrombus, or a report of grinding sound or vibration. No additional occurrences of center-post magnet corrosion were found.

The investigation has determined that the occurrence of a weld crack is the result of a combination of factors that may include the initial presence of contamination in the weld area from previously applied substances as part of the manufacturing process, the misalignment of the cap and housing prior to welding, or the depth/thickness of the weld. Medtronic's investigation employed multiple methods to isolate the issue to a specific subset of pumps including quantifying weld thickness, alignment indicators, and visual indications of contamination using over 8000 digital photos. Medtronic has found that there is not enough data available to conclusively isolate this issue to a specific subset of pumps.

Patient Management Recommendations

Consistent with the April 2022 communication, 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. If a pump is explanted or exchanged for any reason, please return it to Medtronic for further analysis.

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 contact your Medtronic representative to provide details regarding the sequence of events and patient outcomes.

If patients present with these signs and symptoms listed above, 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. An immediate answer to the etiology of the issue may not always be possible. Medtronic will analyze these logfiles and any other signs/symptoms as part of the ongoing investigation.

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 patients have been transferred.
- Please share the attached Patient Template letter with your patients to ensure they are informed of the latest information on the internal pump weld defect.
- 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. 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

Medtronic Mechanical Circulatory Support