Medtronic
Medtronic International, Ltd. (Singapore Branch)
(Co. Reg. No. S98FC5604C)
50 Pasir Panjang Road
#04-51
Mapletree Business City
Singapore 117384
www.medtronic.com

tel 65.6870.5300
fax 65.6482.0300

HeartWare
14400 NW 60th Avenue
Miami Lakes, FL 33014
USA
www.heartware.com

Urgent Medical Device Correction

HeartWare™ Ventricular Assist Device (HVAD™)

Model	Product Description
1103	HVAD™ Pump Implant Kit
1104	HVAD™ Pump Implant Kit
1104JP	HVAD™ Pump Implant Kit
MCS1705PU	HVAD™ Pump Implant Kit

27 April 2022

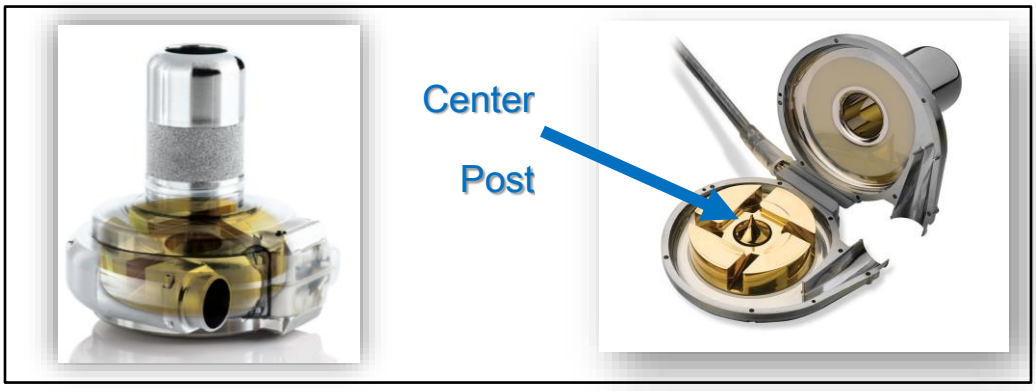
Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

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 local Medtronic field 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 hand or email back to your local Medtronic field representative.

Adverse reactions or quality problems experienced with this product may be reported to you local Medtronic field representative.

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. If you have any questions, please contact your local Medtronic field representative. For any additional questions you can reach out to the Medtronic Office of Medical Affairs at rs.mcsmedicalaffairs@medtronic.com.

Sincerely,

DocuSigned by:

Signer Name: Diana Teo
Signing Reason: I approve this document
Signing Time: 26 April 2022 | 19:10 CDT
05FB18D83D7745D787A6E905DEAE1FD1

Medtronic QRA Lead

Singapore & Malaysia

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 27 April 2022 | 09:36 SGT
90D0724C9B1C402A99B286449A1644B8

Medtronic QRA Lead

Indochina & Frontier Markets Plus

DocuSigned by:

Signer Name: Parichart Bunjobchokchai
Signing Reason: I approve this document
Signing Time: 27 April 2022 | 00:27 CDT
1EE8203B3B0D401EAAC8FA853EBB987A

Medtronic QRA Lead

Thailand

Medtronic
Medtronic International, Ltd. (Singapore Branch)
(Co. Reg. No. S98FC5604C)
50 Pasir Panjang Road
#04-51
Mapletree Business City
Singapore 117384
www.medtronic.com

tel 65.6870.5300
fax 65.6482.0300

Customer Confirmation Form

Urgent Medical Device Correction

Medtronic HeartWare™ Ventricular Assist Device (HVAD) system

For completion by Medtronic Customers Only – Please complete all fields below and return immediately

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

Medtronic is asking that you sign and date this form to acknowledge receipt of the enclosed letter.

Note: The addressee may continue to receive reminders of this notice until a response is received.

By signing this form, I confirm that I have read the Urgent Medical Device Correction Notification Letter, dated 27 April 2022, from Medtronic regarding the HeartWare™ Ventricular Assist Device (HVAD) system listed above and will take appropriate action.

Name (print): _____ Signature: _____ Stamp: _____
Date:_____

For questions, contact your local Medtronic Field Representative.