

URGENT MEDICAL DEVICE NOTICE**Medtronic HeartWare™ Ventricular Assist Device (HVAD™) System**

CFN/Model #	Product Description
1101	HVAD Pump Implant Kit
1103	
MCS1705PU	

August 2021

Dear Physician,

Medtronic is writing to alert you <and your patients> to important safety information related to HVAD™ Systems that have undergone a driveline strain relief repair performed by a Medtronic field service representative.

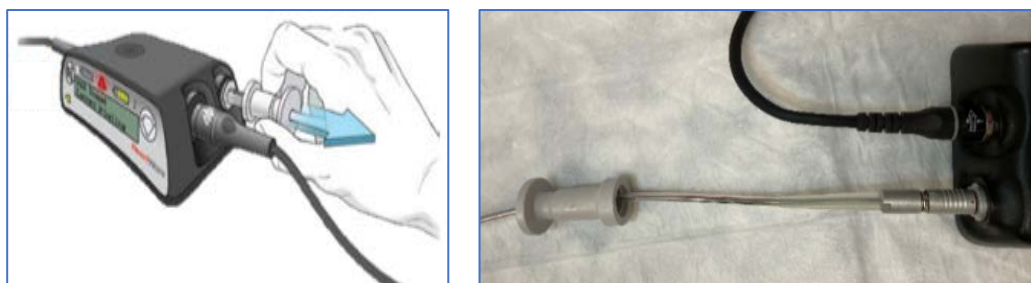
Medtronic is taking this opportunity to inform you and your patients of this issue, including those patients whose HVAD Systems have not received a strain relief repair.

While our records indicate that none of your patients' HVAD equipment has received a strain relief repair, Medtronic is communicating to inform you and your patients of the potential for this issue. Medtronic internal testing has shown that it may be difficult to pull back the driveline cover over a strain relief repair when attempting to access the driveline connector. On the next page, we have provided the Medtronic patient management recommendations associated with pulling back the driveline cover.

Difficulty in pulling back the driveline cover over a strain relief repair may cause a delay in accessing the driveline connector. This delay may lead to a prolonged pump stop if access to the driveline connector is required to address a marginal driveline connection or change controllers. In addition, pulling back the driveline cover over a driveline strain relief repair may compromise the integrity of the repair. In lab testing, the most common issue observed was the tape that overlaps the end of the driveline connector rolled back when pulling the driveline cover away from the controller.

A strain relief repair is intended to repair damage to the strain relief without requiring pump-off time for a driveline splice repair or a pump exchange. The potential difficulty in pulling back the driveline cover over the repair is not currently included in the labeling; therefore, we are communicating to clinicians so they can make informed risk/benefit decisions and appropriately manage their patients. Pulling back the driveline cover is required to access the driveline connector (see figure 1 below), for example, during a controller exchange to disconnect the driveline from the controller.

Figure 1



Between 2009 and 29-June-2021, 75 HVAD Pump driveline connectors received a Medtronic performed driveline strain relief repair service (39 of those HVAD Pumps potentially still in use worldwide). Medtronic received three (3) complaints (two (2) in 2012 and one (1) in 2016) related to the inability or difficulty in pulling back the driveline cover over the repair, all of which reported no or negligible patient harm. In addition, Medtronic received one complaint in 2013 where a patient taped over the strain relief, without Medtronic involvement. This self-repair later interfered with reconnecting the driveline, resulting in hospitalization and patient death due to related complications.

As indicated in the Precautions sections of the Information For Use (IFU) and Patient Manual (PM), patients and clinicians are cautioned **not** to repair or service any components of the HeartWare HVAD Systems. Only authorized Medtronic representatives should perform driveline servicing. In the event of any driveline damage, contact Medtronic for assessment and/or repair.

PATIENT MANAGEMENT RECOMMENDATIONS

The risk of this issue presents when the driveline cover needs to be pulled back to expose the driveline connection to the controller (e.g., during a controller exchange to disconnect the driveline from the controller or while inspecting the driveline connection). As such, Medtronic is providing the following patient management recommendations for the affected HVAD Pumps that have received a driveline strain relief repair service (39 active HVAD Pumps according to Medtronic records):

- Leave the driveline cover in place. Medtronic does not recommend to tamper with or cut off the Driveline cover or otherwise remove it.
- Advise patients that, whenever possible, controller exchanges should be performed under clinical supervision, as it will likely be difficult to pull back the driveline cover to access the driveline connector. When a prospective controller exchange is planned (e.g., when exchanging a controller that has exceeded its 2-year useful life), schedule a Medtronic Field Service Engineer to be present to assess the strain relief repair and evaluate the need for a splice repair, a more extensive repair requiring brief pump off time which replaces the distal end of the driveline including the connector and strain relief.
- Consider a splice repair to replace the portion of the driveline outside the patient's body. A splice repair requires pump-off time to replace the damaged area. The decision to perform a splice repair should be made on a case-by-case basis, considering the unique risks for each patient's ability to withstand pump-off time and risk acceptance.

YOUR ACTIONS

- Consider the patient management recommendations above in managing care for your HVAD patients.

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

Please maintain a copy of this notice in your records. Medtronic will notify all applicable regulatory agencies about this matter. Please share this notification with others in your organization as appropriate. 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.

Sincerely,



Gail Schroeder
Senior Quality Director
Medtronic Mechanical Circulatory Support (MCS)