

## Important Medical Device Information

### For HeartWare™ Ventricular Assist Device (HVAD™) System

August 2021

Dear Patient,

At Medtronic, patient safety is our first priority. Medtronic is writing to inform you about important information related to your Medtronic HVAD™ System, the device that is helping your heart pump blood to your body. This information has recently been provided to your VAD Clinical team (surgeon, physician or VAD coordinator).

1. The first topic relates to a situation if your HVAD Driveline is damaged during use and requires a repair.
2. The second topic relates to a message that was previously communicated to your VAD Clinical team on June 3, 2021, that Medtronic decided to stop selling and distributing the Medtronic HVAD System.

Please review the information below and reach out to your VAD Clinical team with any questions.

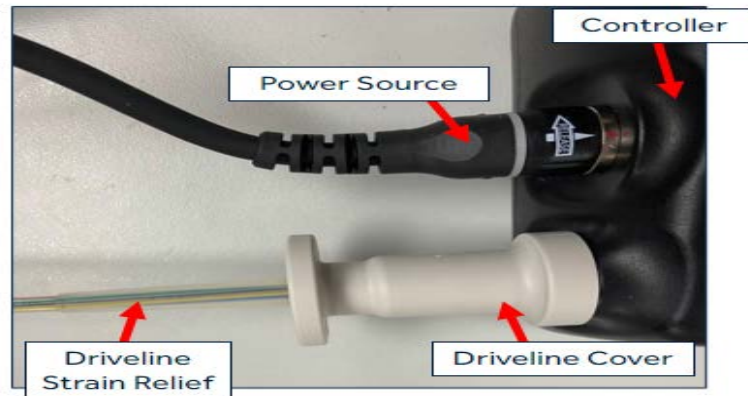
#### **HVAD Driveline Repair**

First, Medtronic reminds you to continue to follow the Patient Manual relating to potential repair of your HVAD Driveline – **DO NOT attempt to repair or service the HVAD Driveline yourself**. As indicated in the Warnings and Precautions section of the Patient Manual, patients are cautioned **NOT** to “attempt to repair or service” any components of the HeartWare™ HVAD System, **including the driveline**, which includes adding tape and glue. If service is required, contact your clinician. If needed, your VAD Clinical team will contact a Medtronic representative to repair your HVAD Driveline. **Repairs are only to be performed by a Medtronic representative.**

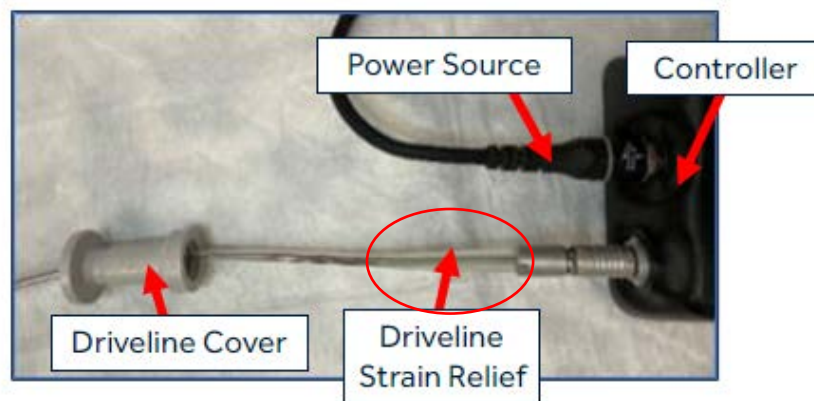
We are contacting you directly to remind you of these important instructions because Medtronic received a complaint involving a patient who self-repaired the HVAD Driveline by taping over the Driveline. This self-repair later interfered with the patient’s ability to pull back the Driveline Cover to access the Driveline Connector to perform a Controller exchange. This resulted in hospitalization, and the patient died due to related complications.

Separately, we also want to provide information that is only applicable if your HVAD Driveline has undergone a Driveline strain relief repair performed by a Medtronic representative. If you are not sure whether your HVAD Driveline has undergone this repair, contact your VAD Clinical team. The Driveline strain relief is the portion of the Driveline cable at the connection point between the Driveline and metal connector (see **Figure 2** below). If you received this repair, it may be difficult to pull back the Driveline cover when attempting to access your Driveline connector during a controller exchange. Difficulty in pulling back the Driveline cover could lead to a prolonged pump stop and may compromise the previous Driveline repair.

**Figure 1.** Picture of the Driveline Strain Relief with Driveline cover in place.



**Figure 2.** Picture of the Driveline Strain Relief with Driveline cover pulled back.



To minimize any risks to your health, Medtronic provided recommendations to your VAD Clinical team (see bullet points below). We want to ensure you have these recommendations directly from Medtronic as well, if they are applicable to you. Please contact your VAD Clinical team directly if you are unsure whether you have undergone a Driveline strain relief repair.

- Leave the Driveline cover in place. Do not tamper with or cut off the Driveline cover or otherwise remove it.
- For patients who have undergone a Driveline strain relief repair, whenever possible, have your controller exchanges performed under clinical supervision.

### **Stopping of Sales and Distribution of the Medtronic HVAD System**

Medtronic also wants to ensure that you have received information that we previously communicated to your VAD Clinical team on June 3, 2021. You may have received this information from your VAD Clinical team directly. As of June 3, 2021, Medtronic decided to stop selling and distributing the HVAD System. Please contact your VAD Clinical team to discuss what this decision means for you and to discuss any questions you may have. Additional details about the decision to stop selling and distributing the HVAD System can be found at [medtronic.com/hvadsafety](https://www.medtronic.com/hvadsafety).

Medtronic is doing everything possible to minimize any risks to your health. We previously provided the recommendations below to your VAD Clinical team, and want to make sure you also have this information about our commitment to supporting you:

- Medtronic will provide ongoing product support for the HVAD System and will ensure continued availability of equipment for your device, including items such as batteries, chargers, and replacement controllers needed to support your HVAD Pump.
- Continue to follow-up regularly with your VAD Clinical team and follow your healthcare providers' advice and directions.
- **NEVER disconnect your HVAD pump from two power sources at the same time. Always have a back-up controller and fully charged spare batteries available.**
- Continue to maintain your blood pressure and anti-coagulation (blood thinners) within the range set by your VAD Clinical team to minimize the risk of a stroke.
- Immediately notify your VAD Clinical team if you experience any issues including but not limited to any damage to the equipment, high and medium priority alarms, or any alarms that may resolve too quickly to identify, with your HVAD pump and equipment.
- **A patient and provider support program has been developed. Information on the support program can be found on our website at [medtronic.com/hvadsafety](http://medtronic.com/hvadsafety).**

**Please connect with your VAD Clinical team** to confirm that you have received this letter and discuss any questions about the information provided in this letter. If you need a new copy of the HVAD System Patient Manual, contact your VAD Clinical team. If you have questions after speaking with your VAD Clinical team or do not have contact information for your VAD Clinical team, contact Medtronic at 1-800-635-3930. We sincerely regret any difficulties this may cause you and your caregivers. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs.

Sincerely,



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