 Potential for Incorrect HVAD Driveline Cover Installation

Medtronic has received a low incidence of complaints associated with HeartWare™ HVAD™ Systems (Ventricular Assist Devices) in which the driveline cover has been incorrectly oriented 180 degrees onto the driveline cable during the implant procedure or a controller exchange. Incorrect orientation of the driveline cover may result in intermittent driveline disconnects or unintentional disconnects to the controller where the locking mechanism was inadvertently released due to the tighter fit of the cover in the backwards position. The rate of occurrence falls within predicted estimates.

The potential harms associated with these complaints are directly related to the patient’s ability to tolerate pump off time during intermittent driveline disconnects, unintentional disconnects, or the intentional disconnect while correcting the orientation of the driveline cover. Some users reported experiencing driveline disconnect alarms, electrical fault alarms, high watt alarms, and VAD stop alarms, all of which may indicate intermittent or unintentional driveline disconnections. Some users reported experiencing a pump stop. Reported harms included presyncope or loss of consciousness due to disconnection of the driveline from the controller and some patients required hemodynamic support during the procedure to reorient the driveline cover to the proper position. However, of the complaints submitted, the majority of patients did not experience harm and reported events included anxiety, light-headedness, or no patient complications. For events in which incorrect orientation of the HVAD Driveline Cover was confirmed, correcting the orientation occurred in the clinic/hospital under supervised medical care. There have been no reports of permanent harm to patients as a result of this issue.

Background Information

The Medtronic HeartWare™ HVAD™ System is designed to provide Ventricular Assist Support via an implantable pump controlled and powered by an external, non-implantable controller and power sources. A percutaneous driveline (refer to Figure 1a) connects the external controller and provides power to the implanted HVAD pump. A driveline cover (small, white cover; refer to Figure 1b) slides over the controller-driveline connection to keep the connection clean and free from potential contamination and prevent inadvertent disconnection of the HVAD driveline once the pump is connected to the HVAD controller.

Figure 24: HVAD® Pump and Left Ventricular (LV) Cannulation
The driveline cover overlays the driveline cable and is first installed during the HVAD surgical implant procedure. The driveline cover (sometimes referred to as the boot cover or driveline connection cover) should always cover the silver driveline connector unless a controller exchange is being performed. During a controller exchange, the Instructions for Use (IFU) provides guidance on how to slide the driveline cover away from the connector (up the driveline) to disconnect/reconnect the driveline. The driveline cover is slid back into place after reconnection of the driveline and completion of the controller exchange. The driveline connector has a locking mechanism (refer to Figure 2) that is designed to prevent inadvertent detachment of the driveline cable from the controller.
Continue to Follow Driveline Connection Instructions for Use – Pay Attention to Cover Orientation

At HVAD system implant, follow the steps below to ensure proper driveline connection, paying close attention to the orientation of the driveline cover to ensure proper coverage of the driveline connector has occurred (refer to Figure 3).

To Connect the Driveline:

1. Line up the red dots on the driveline connector and on the controller driveline port.

2. Push the driveline connector straight into the port.
   Note: Verify the pump is running to ensure proper connection.

3. Slide the driveline cover over the driveline connector.

When a Controller exchange is warranted, carefully follow the Instructions for Use for disconnecting and re-connecting the driveline cable and cover (Figure 4); refer to Step 3 below for depiction of proper orientation of the Driveline Cover.
Steps to Change the Controller:

1. Have patient sit or lie down and place the new controller within easy reach.

2. Connect one POWER source to the new controller.
   NOTE: The new controller may alarm after 10 seconds with a [VAD Stopped, Connect Driveline] high alarm. This is expected behavior.

3. Disconnect the driveline from the original controller and connect the driveline to the new controller. This should restart your PUMP.
   • Verify that the pump is working. The RPM, L/min and Watts numbers should show on Controller Display. If your pump does not restart, re-check driveline and power source connections. If it still doesn’t start call for medical assistance immediately.
   • If you have only connected 1 power source to the new controller, you will also have a [Power Disconnect. Reconnect Power] alarm.

Additional Details
Contact your Medtronic HVAD Representative if you have questions or concerns.