

HeartWare™ Urgent Medical Device Notice

Instructions for Use and Patient Manual Updates – Power Source Connector Cleaning

February 2022

Dear Patient,

Medtronic HeartWare™ recently notified our office about important information related to upcoming updates to the Patient Manual (PM) for the HeartWare Ventricular Assist Device (HVAD™) System. While performing a review of the PM it was identified that additional clarity was required around cleaning the Power Source Connectors (Controller AC Adapter, DC Adapter, and Battery). The pins (see figures 1 and 2) on the interior of the power source connectors are coated with a lubricant, that should not be removed as it is intended to help prevent unexpected power switching. Power switching can occur when there are transient interruptions to the electrical connection with the HVAD System power sources.

- 1 Pins (6)
- 2 Power Source Connector

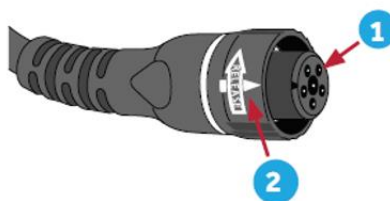


Figure 1 – Side view of Power Source Connectors



Figure 2 – Front view of Power Source Connectors

Below is a summary of the changes to the cleaning instructions for the Controller AC Adapter, DC Adapter, and Battery:

- DO NOT clean the Controller AC Adapter, DC adapter, or Battery connector pins.
- Attempting to clean the interior of the connectors may damage HeartWare™ HVAD™ System components. If the connector pins contain any dirt or debris, do not use the device, and report the condition to your VAD team.
- You may clean the external surfaces per the PM, but do not clean the interior of the connectors.

Attempting to clean the interior of a power source connector can lead to damage of the HeartWare HVAD system components which may impact controller and pump performance. Potential performance issues from damaging the power source connectors range from negligible harm to an unanticipated VAD Stop.

Please contact our office at [\(585\) 273-4964](tel:585-273-4964) to speak with your VAD team about this issue or if you have any questions.