Update to Urgent Field Safety Notice

Medtronic HeartWare™ HVAD™ System

Power Source Lubricant Servicing

Product	Model Numbers (may include various suffixes)	Devices with lubricant applied during manufacturing
Controller Kits	1400, 1401, 1407	Device label number: DL01928-02
DC Adapter	1435, 1440	Serial numbers CDC300000 and higher
AC Adapter	1425, 1430	Serial numbers CAC300000 and higher
Battery Pack	1650	Serial numbers BAT850000 and higher

July 2020

Medtronic reference: FA817 Phase III

Dear Physician, Healthcare Professional, or Risk Manager,

HeartWare, now a part of Medtronic, is providing this letter as a follow-up to our June 2018 customer notification titled "Update to An Urgent Medical Device Correction" (attached). At that time, we recommended that Medtronic HeartWare Field Representatives apply a lubricant solution to HeartWare™ HVAD™ system power source connectors as a method for mitigating unexpected transient power switching due to the effects of oxidation.

We are writing to inform you that Medtronic has obtained the necessary regulatory approval for lubricant to be applied to the connectors of all HeartWare™ HVAD™ System power sources (Battery, AC Adapter, and DC Adapter) during manufacturing. Power sources identified and listed in the table above will be lubricated during manufacturing, prior to distribution; as a result, field application of lubricant will NOT be needed going forward.

Medtronic continues to recommend lubricant be applied to all HVAD power source devices with serial numbers outside of the range noted at the top of this letter, regardless of whether they have exhibited symptoms of unexpected transient power switching.

Next Step:
Your local Medtronic representative will work with you to determine whether any power sources outside of this range (that are with your patients or in your inventory) still need servicing and will schedule such service, as necessary. Lubricant servicing of power sources by Medtronic HeartWare Field Reps will be available through October 31, 2020.

Controller Kits (Models 1400, 1401, 1407) containing an AC Adapter (Model 1425 or 1430) that are lubricated during manufacturing are identified by device label number, DL01928-02 as shown by location of the red box on the packaging label below.

Medtronic will notify all applicable regulatory agencies about this matter.

Share this notice with all those who need to be aware within your organization or to any organization where potentially affected devices have been transferred.

Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have any questions, please contact your Medtronic Representative.

Sincerely,

Local / BU Manager