

Update to Urgent Field Safety Notice

Medtronic HeartWare™ HVAD™ System

Models: 1400, 1401, 1403, 1407, 1420, 1435, 1440, 1425, 1430, 1650

Important device information

June 2018

Medtronic reference: FA817

Dear Physician or Healthcare Professional,

We are writing to inform you that a lubricant solution that can be applied to HeartWare™ HVAD™ System power source connectors, as a method for mitigating unexpected transient power switching due to the effects of oxidation, is now available.

In May 2018, HeartWare, now a part of Medtronic, alerted clinicians to the potential for a transient interruption of the electrical connection between an HVAD System power source (Battery, AC Adapter, or DC Adapter) and the HVAD Controller (see attachment). As part of that communication, we indicated specific mitigations for current patients would be implemented once available.

The lubricant is being distributed to Medtronic HeartWare Field Representatives who will apply the lubricant to power source (Battery, AC Adapter, and DC Adapter) connectors. Medtronic HeartWare Field Representatives will work with you to coordinate bringing patients to the clinic for servicing of their HVAD power source components.

Next Steps

- For patients previously implanted with the HVAD System, Medtronic recommends the lubricant be applied to all HVAD System power sources (Battery, AC Adapter, and DC Adapter), regardless of whether they have exhibited symptoms of this issue.
- For newly implanted patients it is recommended the lubricant be applied prior to discharge following the implant procedure, or at the patients first follow-up appointment.
- The application of the lubricant is anticipated to be a one-time field service; however, it will continue to be available for any patients who experience this situation in the future.
- Continue to monitor your patients' HVAD Systems for unexpected power source switch behaviors as described under the Patient Management Recommendations in the original notification.

We apologize for the inconvenience this may cause you. Please share this notification with others in your organization as appropriate. 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,

Mohamad Elkhatib

Business Manager, CRHF, APS