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HeartWare
14400 NW 60th Avenue
Miami Lakes, FL 33014
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May 2018

Re: Update to Urgent Medical Device Correction; Medtronic HeartWare™ HVAD™ System

Dear Study Principal Investigator:

Medtronic HeartWare is issuing a notification letter to physicians, titled Update to an Urgent Medical Device Correction, related to the Medtronic HeartWare™ HVAD™ System 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. (see attached)

You are receiving this communication because patients enrolled in an HVAD clinical trial with Controller 1.0 or 2.0 at your site have the potential to be impacted by this issue.

No revisions need to be made to the Patient Informed Consent or Clinical Investigation Plan.

Next Steps:

1. Review this letter and the attachments, and forward to those individuals within your organization who need to be aware of its contents.
2. Submit a copy of this letter and the attachments to your Institutional Review Board (IRB)/Ethics Board, in accordance with their policies, for all applicable HVAD clinical trials.
3. Provide Medtronic with a copy of the IRB submission/acknowledgement of this information. Please also file this communication in your investigator site file.
4. Upon receipt of IRB approval, please contact your local Medtronic/HeartWare Field Representative to schedule servicing of the power source connectors for clinical research subjects.

Should you have any questions or comments, please contact your local Medtronic/HeartWare Field Representative.

Sincerely,

Thomas A. Vassiliades, MD, MBA, FACS
Chief Medical Officer
VP, Clinical and Medical Affairs
Mechanical Circulatory Support (HeartWare)

Enclosure: Update to Urgent Medical Device Correction letter