Medtronic

Medtronic HeartWare™ Ventricular Assist Device (HVAD™) Battery Performance Update (FA1265) SUPPLEMENTAL LIMITED WARRANTY

Effective December 16, 2023, until December 15, 2024

(December 2023 U.S. ONLY)

Instructions on how to request exchange of power sources under these Supplemental Limited Warranty terms and conditions:

- Complete the Medtronic HVAD™ System Battery Performance Update FCA Supplemental Limited Warranty Claim Form for patient-issued and hospital owned loaner batteries.
- These warranty claim forms will be provided by your Medtronic Field Representative and must be completed electronically to be accepted and processed. Customers should e-mail the completed warranty claim forms to your local MCS Field Representative. Once received, the MCS Field Representative will review and submit the claim to the Medtronic MCS Warranty Team.
- For this exchange program only, please dispose of your patient's used and hospital owned loaner batteries per your local hazardous waste guidelines.

This Supplemental Limited Warranty relates to the May 31, 2023, Medtronic HeartWare™ Ventricular Assist Device (HVAD™) System Battery Performance Update communication. Medtronic is communicating a manufacturing change to the HeartWare HVAD System batteries. Specifically, the manufacturing change is intended to lessen the occurrence of potential battery electrical fault issues. This Supplemental Limited Warranty applies to the replacement of all patient's used batteries and hospital owned loaner batteries.

Under this Supplemental Limited Warranty, Medtronic is offering the following:

- Replacement of a patient's active batteries at a 1:1 exchange ratio.
- Replacement of hospital owned loaner batteries at a 1:1 exchange ratio.

Patient Support: Patients are eligible to apply for up to \$2000 in Unreimbursed Medical (URM) expenses related to travel, outside of a normal clinic visit, to their VAD center for the exchange of product outlined in the FCA (inclusive of any co-pays, coinsurance or deductibles paid or owed by patients and/or travel expenses). Receipts for all potentially reimbursable expenses are required.

Warranty eligibility requirements for product replacement under this Supplemental Limited Warranty are as follows:

- The patient has an HVAD™ pump implanted and is currently on pump support.
- Products should be within their useful life per the product's Instructions for Use (IFU).
- 1 Pursuant to the HIPAA Privacy Rule (45 C.F.R. § 164.512(b)), covered entities may disclose protected health information without an authorization to a person or entity subject to FDA jurisdiction for public health purposes related to the quality, safety, or effectiveness of an FDA-regulated product

This Supplemental Limited Warranty is limited to its express terms and does not constitute a representation, judgment, or admission or assumption of liability by Medtronic with respect to the replaced HVAD power sources.

By filling out and signing the Medtronic HVAD™ System Bent Pins FCA Supplemental Limited Warranty Claim Forms, the hospital confirms that:

- Any credit or exchange extended because of this Supplemental Limited Warranty is for the sole benefit of the patient and will be credited in full to the patient's account; and
- Claims for reimbursement to third party payors will be submitted in accordance with all applicable payor requirements, including any such requirements relating to reporting either free or reduced-price products or warranty credits.

For warranty related questions, contact Medtronic at: (877) 359-6407 or rs.mcswarranty@medtronic.com