

## Medtronic HeartWare™ Ventricular Assist Device (HVAD™) Pump

### SUPPLEMENTAL LIMITED WARRANTY (U.S. ONLY)

Effective December 16, 2023 until December 15, 2024

(December 16, 2023 U.S. ONLY)

#### **Instructions on how to request reimbursement of costs under these Supplemental Limited Warranty terms and conditions:**

- Complete the Medtronic MCS Standard and Supplemental Warranty Claim Form which can found at [www.medtronic.com/mcswarranty](http://www.medtronic.com/mcswarranty).
- Ensure the correct Warranty Type has been selected, "Non-Prophylactic" or "Prophylactic."
- E-mail the completed Warranty Claim Form to [rs.mcswarranty@medtronic.com](mailto:rs.mcswarranty@medtronic.com).
- Utilizing a Pump Explant Kit, return explanted Medtronic HeartWare™ Pump within thirty (30) days of explant.

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This Supplemental Limited Warranty relates to the April 26, 2022 Medtronic HeartWare™ Ventricular Assist Device (HVAD™) Pump Weld communication. This Supplemental Limited Warranty applies to a Non-Prophylactic removal or a Prophylactic removal where the physician has made the medical judgment that explant of an HVAD Pump, although not recommended by Medtronic, is in the individual patient's best interest.

Under this Supplemental Limited Warranty Medtronic is offering the following:

- A. For Non-Prophylactic exchanges, logfiles must be uploaded and submitted to Medtronic Technical Services for analysis. Upon completion of such logfile analysis, the report must contain a statement that Medtronic believes the pump to exhibit findings/observations related to the FCA FA1243 based on the information available to Medtronic at that time:
- Replacement System. Warranty holders are eligible for a warranty credit in the amount of the cost of an HVAD System. If an insurance claim is denied, warranty holders are also eligible for 150% of the hospital specific DRG payment.
  - Patient Support. Patients are eligible to apply for up to \$10,000 in Unreimbursed Medical (URM) expenses associated with the patient's portion of costs of the HVAD System exchange procedure to a competitive device (inclusive of any co-pays, coinsurance or deductibles paid or owed by patients, travel expenses).
- B. For Non-Prophylactic pump removal which results in a transplant, logfiles must be uploaded and submitted to Medtronic Technical Services for analysis. Upon completion of such logfile analysis, the report must contain a statement that Medtronic believes the pump to exhibit findings/observations related to the FCA FA1243 based on the information available to Medtronic at that time:
- Patient Support. Patients are eligible to apply for up to \$10,000 in Unreimbursed Medical (URM) expenses associated with the patient's portion of costs of the HVAD System removal (inclusive of any co-pays, coinsurance or deductibles paid or owed by patients, travel expenses).

C. For Prophylactic exchanges of any HVAD Pump where the physician has made the medical judgment that the prophylactic exchange, although not recommended by Medtronic, is in the individual patient's best interests:

- Patient Support. Patients are eligible to apply for up to \$10,000 in URM expenses associated with the patient's portion of costs of the HVAD System exchange procedure to a competitive device (inclusive of any co-pays, coinsurance or deductibles paid or owed by patients, travel expenses).
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As part of this Supplemental Limited Warranty, pursuant to all terms and conditions, hospitals should bill all related medical care and costs relating to the explant procedure of the HVAD Pump through ordinary course of action.

Warranty eligibility requirements for a Non-Prophylactic or Prophylactic exchange or explant under this Supplemental Limited Warranty are as follows:

- The patient is implanted with a Medtronic HVAD Pump.
- The exchange or explant procedure (either Prophylactic or Non-Prophylactic) must have occurred between the effective date and the expiration date of this Supplemental Limited Warranty.
- Logfiles must be uploaded and submitted to Medtronic Technical Services for technical analysis via the autologs.medtronic.com website utilizing the HVAD logs analysis option.
- The physician and institution must complete, sign, and submit to Medtronic the MCS Standard and Supplemental Warranty Claim Form.
- The hospital must return the explanted HVAD Pump to the Medtronic address below within thirty (30) days of explant.
- Written proof of claim denial if warranty holder is requesting the 150% of the hospital specific DRG payment, as detailed above.

This Supplemental Warranty will be reassessed for renewal and republished for use on December 16, 2023. Medtronic HeartWare™ products must be used in accordance with product labeling and not altered or subjected to misuse, reuse, abuse, neglect, improper storage, attempts to repair, improper handling or the like, or damaged by accident, fire, or another hazard.

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

**By filling out and signing the Medtronic Standard and Supplemental Warranty Claim Form, the physician confirms that:**

- The physician has made the medical judgment based on the patient's individual circumstances that explant of the HVAD Pump covered under the Supplemental Limited Warranty is in the best interests of the individual patient.

**By filling out and signing the Medtronic Standard and Supplemental Warranty Claim Form, the hospital confirms that:**

- Any credit 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](mailto:rs.mcswarranty@medtronic.com)

Return HVAD Pump within 30 days of product explant to:  
Medtronic, Inc., 14400 NW 60th Ave., Miami Lakes, FL 33014