

**Medtronic HeartWare™ HVAD™ System  
SUPPLEMENTAL LIMITED WARRANTY  
(U.S. ONLY – O.U.S. COVERAGE TO BE ASSESSED AND DETERMINED LOCALLY)  
Effective December 16, 2022 until December 15, 2024**

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

1. Complete the Medtronic MCS Standard and Supplemental Warranty Claim Form which can be found at [www.medtronic.com/mcswarranty](http://www.medtronic.com/mcswarranty).
2. Ensure the correct Warranty Type has been selected, “Non-Prophylactic” or “Prophylactic.”
3. E-mail the completed Warranty Claim Form to [rs.mcswarranty@medtronic.com](mailto:rs.mcswarranty@medtronic.com).
4. Return explanted Medtronic HeartWare™ Systems, within thirty (30) days of explant, to Medtronic, Inc, 14400 NW 60<sup>th</sup> Ave., Miami Lakes, FL 33014.

This Supplemental Limited Warranty relates to the June 3, 2021 Medtronic communication announcing Medtronic’s decision to stop the distribution and sale of the HVAD System and alerting physicians to immediately stop new implants of the HVAD System. In light of this, Medtronic is offering this Supplemental Limited Warranty for the HVAD Systems (i) to apply to all HVAD Systems that experience a failure to restart at any time (ii) to apply to the subset of “Affected Devices” from the December 2020 and August 2023 Product Advisory where the physician has made the medical judgment that prophylactic explant of an HVAD System, although not recommended by Medtronic, is in the individual patient’s best interests, and (iii) to offer financial assistance to all patients with an HVAD System for out-of-pocket expenses relating to any exchange procedure.

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

- A. For **Non-Prophylactic** exchange due to any device failure to restart at any 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 **Prophylactic** exchanges of an HVAD Pump serial number that is in the subset of “Affected Devices” from the December 2020 and August 2023 Product Advisory 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:
  - **Replacement Device 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 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).
- C. For **Prophylactic** exchanges of an HVAD Pump serial number that is outside of the subset of “Affected Devices” from the December 2020 and August 2023 Product Advisory 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).

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 System through ordinary course of action.

Warranty eligibility requirements for a non-prophylactic or prophylactic explant under this Supplemental Limited Warranty are as follows

- The patient is implanted with a Medtronic HVAD System.
- The exchange procedure (either due to a device failure to restart or a physician’s decision to exchange prophylactically) must have occurred between the effective date and the expiration date of this Supplemental Limited Warranty.
- 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 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, 2024. 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 explanted device or the explant or exchange procedures.

**By filling out and signing the Medtronic MCS 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 Medtronic device covered under the Supplemental Limited Warranty is in the best interests of the individual patient.

**By filling out and signing the Medtronic MCS 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)**