Medtronic HVAD™ System

Indications for Use
The Medtronic HVAD System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

Contraindications
The HVAD System is contraindicated in patients who cannot tolerate anticoagulation therapy.

Warnings/Precautions
Proper usage and maintenance of the HVAD System is critical for the functioning of the device. Serious and life-threatening adverse events, including stroke, have been associated with use of this device. Blood pressure management may reduce the risk of stroke. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not disconnect the driveline from the controller or the pump will stop. Avoid devices and conditions that may induce strong static discharges as this may cause the VAD to perform improperly or stop. Magnetic resonance imaging (MRI) could cause harm to the patient or could cause the pump to stop. The HVAD Pump may cause interference with automatic implantable cardioverter-defibrillators (AICDs), which may lead to inappropriate shocks, arrhythmia and death. Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta - use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD Pump post CPR.

Potential Complications
Implantation of a VAD is an invasive procedure requiring general anesthesia and entry into the thoracic cavity. There are numerous known risks associated with this surgical procedure and the therapy including, but not limited to, death, stroke, neurological dysfunction, device malfunction, peripheral and device-related thromboembolic events, bleeding, right ventricular failure, infection, hemolysis, and sepsis.

Refer to the “Instructions for Use” for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device.

Caution:
Federal law (USA) restricts these devices to sale by or on the order of a physician.

REASONS TO CHANGE TO THE BACKUP CONTROLLER
There are four main reasons why you would need to change the controller:
1. Controller displays a high priority alarm instructing the user to Change Controller.
2. Blank controller display and/or no audible alarms.
3. Blank controller display with continuous audible tone that isn’t resolved by connecting power.
4. Instructed by VAD team.

CHANGING TO THE BACKUP CONTROLLER
PATIENT AND CLINICIAN GUIDE

Medtronic HVAD™ System

Patent Information
Practice Your Skills
Surgical Skills Lab
Surgical Skills Lab

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Printed in USA. 11/2021
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FOLD LINE
FOLD LINE
FOLD LINE
FOLD LINE
SEVEN STEPS FOR CHANGING TO THE BACKUP CONTROLLER

1. Locate the backup controller.
   - The backup controller will become the new controller.
   - Have the patient sit or lie down before continuing the steps.

2. Connect one power source to the backup controller.
   - Move the power source from the original controller’s power connector to the backup controller.

3. Disconnect the driveline from the original controller.
   - Slide the driveline cover away from the controller to reveal the silver connector.
   - Place your fingers on the silver connector, over the ringed area.
   - Pull straight back on the ringed area to release the locking mechanism.

4. Reconnect the driveline to the backup controller.
   - Line up the red dot on the controller’s driveline connector with the red dot or black line on the driveline connector.
   - Push the driveline connector straight into the port.

5. Prevent the No Power alarm from sounding.
   - Option 1: Insert the red alarm adapter into the original controller’s data port. You can now remove power from the original controller.
   - Option 2: Press and hold the Alarm Mute and Scroll buttons simultaneously on the original controller until a beep is heard, or for at least five seconds. Then, release both buttons and remove power from the original controller.

6. Connect a second power source to the backup controller.
   - Move the power source from the original controller’s power connector to the backup controller. The original controller should now stop sounding.

7. Check controller data port.
   - If the red alarm adapter is connected to the controller that is now running the pump, remove it and secure the dust cap.

Note: The new controller may alarm after 10 seconds with a [VAD Stopped, Connect Driveline] high-priority alarm. This is expected behavior.

Warning: Do NOT remove the driveline cover from the driveline. Maintaining proper driveline cover attachment prevents accidental disconnection which will lead to a pump stop.

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