

THE HEARTWARE™ HVAD™ SYSTEM

MANAGING THE DRIVELINE

The driveline is the cable that passes through the skin connecting the implanted pump to the external HVAD System Controller.

- Do not pull, twist or kink the driveline; this could result in damage
- Do not let any portion of the driveline hang freely where it could get caught on external items such as doorknobs or corners of furniture

It is important if you notice driveline tears, punctures or wear to notify your clinician.

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Do not attempt to repair the driveline yourself

- ALWAYS notify your clinician if you notice blood or fluid in the driveline. Your clinician should examine the driveline to fully evaluate the situation



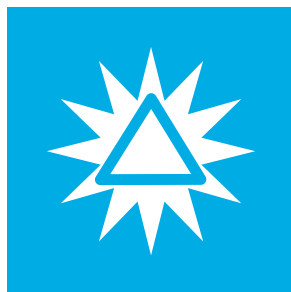
Do not use prophylactic topical antibiotic ointments

- Avoid products containing silver sulfadiazine, povidine-iodine (betadine), or polymyxin-neomycin-bacitracin ointment; these ointments can injure the tissue adjacent to the exit site



Electrical Fault Alarm

- Indicates there is a problem within the electrical system: pump, driveline or controller
- Follow instructions on the controller and call your clinician
- DO NOT change your controller during an active electrical fault alarm



Refer to the Patient Manual for a full list of precautions, warnings and potential complications.

Brief Statement: HeartWare™ HVAD™ System

Additional Device Information

The HeartWare™ HVAD™ System assists a failing heart and relieves the symptoms of advanced heart failure. It may be used in advanced heart failure patients whether or not a subsequent heart transplant is planned. You should not receive an HVAD System if you are pregnant or cannot tolerate blood thinning medications.

Implantation of the HVAD System requires major surgery. Risks associated with the implant surgery and with HVAD System use include, but are not limited to, death, stroke, device malfunction, blood clots, bleeding, other types of heart failure, infection, red blood cell destruction, and total body infection. Managing your blood pressure may reduce the risk of stroke.

The HVAD System includes external components that connect to and provide power to the heart pump inside your body. After receiving an HVAD System, you will have some limitations. You will not be able to swim, or otherwise submerge external components in water. You will not be able to shower until your clinician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare shower bag. You may need to modify or perhaps avoid interactions with some sources of electromagnetic interference, electric or gas-powered appliances, and tools. Magnetic resonance imaging (MRI) should not be used, as it could cause severe harm to you

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and the pump. You must keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.

Proper use and upkeep of the HeartWare HVAD System is required to keep the system working well. Never remove both power sources (batteries or power adapters) from the controller at the same time since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected to the controller 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 kinking or twisting your driveline.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk with your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary.

See the HeartWare HVAD System Patient Manual for detailed information regarding instructions on operating the HeartWare HVAD System and on necessary medical care. If you have any questions after reading the manual, please ask your clinician.

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

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