DAILY DIARY: HEARTWARE™ HVAD™ SYSTEM

Medtronic

IT IS IMPORTANT TO MANAGE AND MONITOR YOUR PHYSICAL AND LVAD PARAMETERS CAREFULLY WHILE YOU HAVE THE HEARTWARE™ HVAD™ SYSTEM IMPLANTED.

Patient Information

Name: _____

Phone: _____

Date of implant: _____

Hospital Information

Name: _____

Physician: _____

Phone number: _____

VAD team / contact person: _____

Phone number: _____

Next Appointments

Date & time: _____

Date & time: _____

Date & time: _____

Reminder: Please bring your diary with you to each regular clinic visit.

The VAD team recommendations are (e.g. INR, blood pressure, dressing changes):

Call your VAD team when:

The HVAD System is a continuous flow device. This means there may be a narrow pulse pressure, which can make it difficult to obtain a blood pressure. The VAD Team will discuss with you the best way to obtain your blood pressure.

1. If you have a palpable radial pulse, a blood pressure cuff will be used to obtain the measurements that you should write down in the diary as SBP and DBP.

2. If you do not have a palpable radial pulse, a doppler and blood pressure cuff will be used to obtain the measurements that you should write down in the diary as doppler pressure.

	Physical Parameters							LVAD Parameters				Additional Remarks
	Blood Pressure				INR	Weight	Exit Site	Flow	Speed	Power	Alarms	
Date	Time (AM/PM)	SBP	DBP	Doppler Pressure		Lbs/kg	Status 1 to 3	L/min	RPM	Watts	Y/N	Please record any abnormalities you are realizing e.g. body temperature, exit site, change in health, pain, system components, alarm details, etc.

	Physical Parameters							LVAD Parameters				Additional Remarks
	Blood Pressure				INR	Weight	Exit Site	Flow	Speed	Power	Alarms	Please record any abnormalities you are realizing e.g. body temperature, exit site, change in health, pain, system components, alarm details, etc.
Date	Time (AM/PM)	SBP	DBP	Doppler Pressure		Lbs/kg	Status 1 to 3	L/min	RPM	Watts	Y/N	

	Physical Parameters							LVAD Parameters				Additional Remarks
	Blood Pressure				INR	Weight	Exit Site	Flow	Speed	Power	Alarms	Please record any abnormalities you are realizing e.g. body temperature, exit site, change in health, pain, system components, alarm details, etc.
Date	Time (AM/PM)	SBP	DBP	Doppler Pressure		Lbs/kg	Status 1 to 3	L/min	RPM	Watts	Y/N	

	Physical Parameters							LVAD Parameters				Additional Remarks
	Blood Pressure				INR	Weight	Exit Site	Flow	Speed	Power	Alarms	Please record any abnormalities you are realizing e.g. body temperature, exit site, change in health, pain, system components, alarm details, etc.
Date	Time (AM/PM)	SBP	DBP	Doppler Pressure		Lbs/kg	Status 1 to 3	L/min	RPM	Watts	Y/N	

	Physical Parameters							LVAD Parameters				Additional Remarks
	Blood Pressure				INR	Weight	Exit Site	Flow	Speed	Power	Alarms	Please record any abnormalities you are realizing e.g. body temperature, exit site, change in health, pain, system components, alarm details, etc.
Date	Time (AM/PM)	SBP	DBP	Doppler Pressure		Lbs/kg	Status 1 to 3	L/min	RPM	Watts	Y/N	

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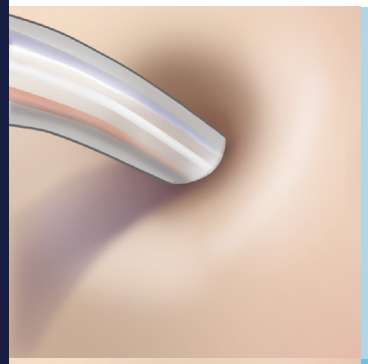
DRIVELINE EXIT SITE EXAM

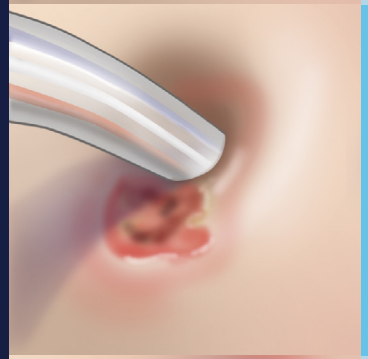
Check the exit site for signs of infection as part of every dressing change.

Record the site score (1-3) in the diary.

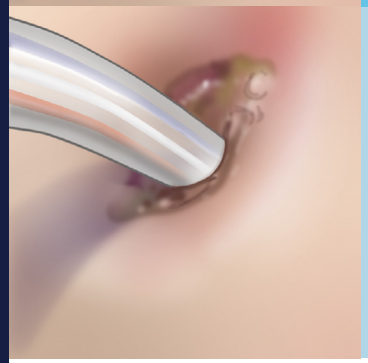
1. Normal driveline exit site
2. Superficial infection
3. Deep infection



✓ **Normal driveline exit site:**
No redness, tenderness or drainage.
Skin well incorporated (tight) to the driveline.



X **Superficial infection:**
Purulent (pus) drainage, tenderness and redness spreading around the exit site.
Skin may be pulling away from the driveline.



X **Deep infection:**
Increased drainage and redness, odor and painful.
Abscess deep to the incision around the driveline. Skin pulled away from the driveline.

Brief Statement: HVAD™ System

Indications
The HeartWare Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

Contraindications
The HeartWare 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. 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 expose batteries to excessive shock or vibration since this may affect battery operation. Do not grasp the driveline cable as this may damage the driveline. Do not pull, kink or twist the driveline or the power cables, as these actions may damage the driveline. Special care should be taken not to twist the driveline including while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag. Do not disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

Potential Complications
Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. There are numerous risks associated with this surgical procedure and the therapy including but not limited to, death, stroke, device malfunction, peripheral and device-related thromboembolic events, bleeding, 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. The IFU can be found at www.heartware.com/clinicians/instructions-use.

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

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