

Fixing Broken Hearts

Heart -- Selection Criteria for Ventricular Assist Device for Bridge to Transplant

Things to consider when creating your organization's policy:

SCOPE: Transplant Surgeons and Physicians, Transplant Coordinators, and other members of the Heart Transplant Patient Selection Committee

PURPOSE: To establish guidelines for the appropriate criteria for Ventricular Assist Device (VAD) placement for bridge to transplant candidates. All patients referred to the heart transplant/VAD program will be considered for bridge to transplant VAD placement against the following criteria. Patients must be approved by both the Medical and Surgical Directors as well as by a majority vote of the Selection Committee at the time of the patient care conference. All patients approved for bridge to transplant must also be considered against the heart transplant selection criteria and must be listed on the United Network for Organ Sharing (UNOS) transplant wait list prior to implantation.

GUIDELINES:

- Indications for VAD Support, include:
1. Chronic Cardiomyopathy with acute decompensation
 - a. Ischemic
 - b. Hypertensive
 - c. Dilated
 2. Postpartum Cardiomyopathy
 3. Acute viral Myocarditis
 4. Intractable Ventricular Arrhythmias
 5. Myocardial Infarction complicated by:
 - a. Cardiogenic shock
 - b. Ventricular Septal Rupture
 - c. Mitral Valve Papillary Muscle Rupture with severe Mitral Regurgitation
 6. Postcardiotomy Shock
 7. Cardiac Contusion

Refractory Criteria:

1. Heart failure (NYHA) Class IV symptoms despite maximally tolerated medical therapy within last 30 days OR acute Cardiogenic shock refractory to inotropic / Intra-Aortic Balloon Pump (IABP) / percutaneous VAD support
2. Left ventricular ejection fraction (LVEF) \leq 25%; CI \leq 2.2 l/min; Pulmonary capillary wedge pressure (PCWP) \geq 18 mmHg
3. Peak VO2 \leq 14 ml/kg/min or IV inotropic dependent
4. Body Surface Area (BSA) $>$ 1.5m Heartware BSA $>$ 1.3m2 (Heartmate II)
5. Eligible for or awaiting cardiac transplantation
6. Appropriate nutritional status after consultation with the transplant dietician
7. Psychological clearance either by transplant psychologist and/or transplant social worker
8. Financial clearance, including documented financial counseling from the transplant financial coordinator.

Exclusion Criteria:

1. Correctable cause of heart failure
2. Pulmonary hypertension, fixed (pulmonary vascular resistance [PVR] $>$ 4 wood units, transpulmonary gradient [TPG] $>$ 15 mmHg) (relative)
3. Creatinine \geq 3.5 mg/dl or urine output $<$ 30cc/hr
4. Total bilirubin $>$ 5.0
5. Prothrombin time $>$ 16 seconds (uncorrectable)
6. Respiratory failure due to primary pulmonary disease / Adult respiratory distress syndrome (ARDS)
7. Mechanical aortic valve (must be oversewn or changed to a bioprosthesis)
8. Significant Aortic valve insufficiency or mitral stenosis (unless corrected)
9. Active systemic infection
10. Severe peripheral vascular disease
11. Stroke $<$ 90 days; internal carotid artery (ICA) stenosis; Impaired cognitive function
12. Active malignancy or history of malignancy without low likelihood of recurrence, exceptions must be approved by the Selection Committee
13. Uncorrectable bleeding disorder

Risk Factors for Death with VAD

1. Respiratory failure / Mechanical Ventilation (RR 3.0)
2. Sepsis
3. Age $>$ 65
4. Central venous pressure (CVP) $>$ 16 mmHg (RR 3.1)
5. Acute Postcardiotomy
6. Acute Myocardial Infarction
7. Reoperation (respiratory rate [RR] 1.8)
8. Leukocyte count $>$ 15,000/ mm3 (RR 1.1)
9. Elevated serum creatinine, urine output $<$ 30 cc/hr (RR 3.9)
10. Elevated bilirubin or transaminases $>$ 5 times normal
11. Elevated prothrombin time $>$ 16 seconds (RR 2.4)
12. Extracorporeal membrane oxygenation (ECMO)/Cycles per second (CPS)
13. Platelets $<$ 148
14. Albumin $<$ 3.3

Strategy for Left Ventricular Assist device (LVAD) vs. Bi-Ventricular Assist Device (BiVAD) Support

Stable Patient

- CVP $<$ 20 and PCWP $>$ 25: LVAD
CVP $>$ 20: LVAD and temporary right ventricular assist device (RVAD)

Unstable Patient

- Fever, ARDS, hepatic or renal dysfunction, ventricular arrhythmias, ascites.
Right ventricular (RV) infarct or right coronary artery (RCA) disease: BiVAD

DAVID TAYLOR, MSN, RN, CNOR

Abstract: The purpose of this poster is to educate not only tenured, but new CVOR staff on the basic requirements necessary to care for cardiovascular compromised patients requiring a ventricular assist device (VAD), either as destination therapy or as a bridge to transplant. Cardiovascular operating rooms (CVOR) who experience a large turnover rate among its surgical technologists, first assistants and RN circulators require a mechanism to rapidly train new staff members. Because new hires will have various levels of experience, many have little to no VAD background knowledge. Because of this it is necessary to not only train, but quickly educate staff so they are competent and able to assist surgeons during these complex procedures, have the knowledge necessary to identify what ventricular assist device's and can demonstrate they are VAD aware.

This poster is one of the tools that can be used to familiarize and educate the staff about the various aspects of a VAD program.

Ware

HeartWare HVAD Outflow Graft, Battery Charger, Patient Pack, Controller, Batteries, Driveline Cables, HVAD Pump Implant Kit & HVAD Pump Surgical Tools



HVAD® Pump Pre-Implant

1. On the sterile field, fill a basin with 2 liters of 5% dextrose.
2. Attach the sterile driveline extension cable to the HVAD Pump and pass the distal portion (labeled "Controller") of the cable to the non-sterile assistant.
3. Clamp the sterile portion of the extension cable to the sterile field to prevent cable movement.
4. The Non Sterile Assistant should have the BACK-UP controller and a charged battery ready for use.
5. Completely submerge the HVAD Pump in the dextrose solution. Fill the HVAD Pump with dextrose and gently rotate the pump in the dextrose to allow any trapped air to escape.
6. When HVAD Pump is completely submerged in the sterile basin connect the driveline extension cable to BACK-UP controller.
7. Connect a battery to the controller. The pump will start at 1800 RPMs.
8. After 30-60 seconds, stop the pump by disconnecting the battery and then disconnect the driveline extension.
 - To silence the no power alarm, prior to removing power, either attach the red alarm adapter, or press and hold the alarm mute and scroll buttons until a beep is heard, or for at least 5 seconds.

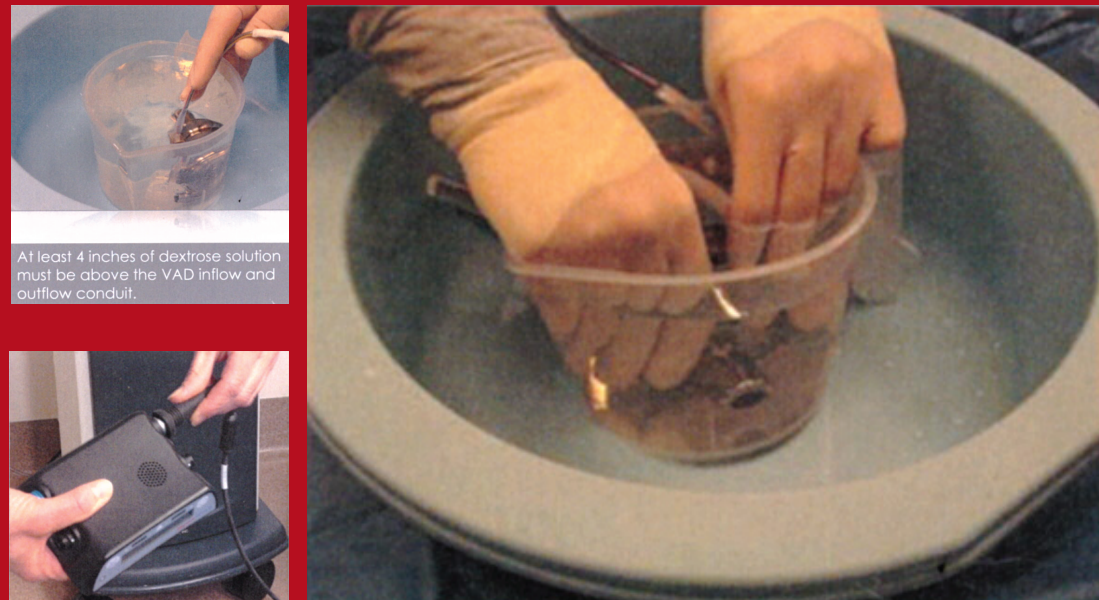
Pre-Implant Test

WARNING!

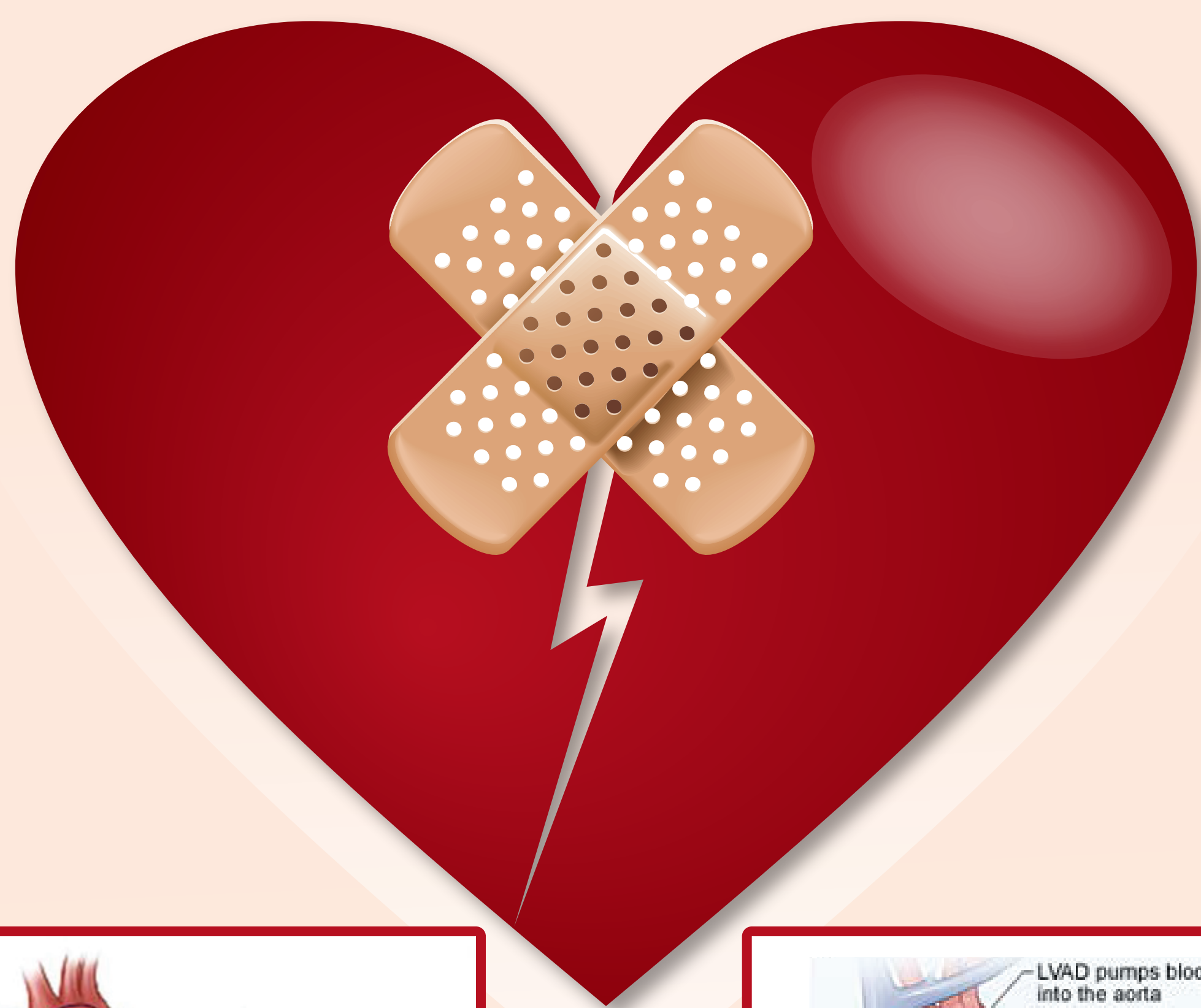
During the Pre-Implant Test and prior to implantation, the HVAD® Pump must be completely submerged in fluid when turned on

Never turn on the HVAD Pump in air

DO NOT use an HVAD Pump that was turned on without total submersion in fluid.



NOTE: During HVAD Pump wet test, the power should remain $<$ 3 watts.



Creating a Repository for Ongoing Training, Education & Annual Competency Validation

How to find Transplant, VAD and Heartmate Information

1. Go to (insert name of your institution's intranet)
2. Click on Department
3. Click on box, click on

Transplant Services

4. Find choices on the right side of the screen and click on the one you wish to open

Heartmat II LVAD-Thoratec Corporation
Heartmat II LVAS: Patient Management Guidelines
HeartWare
Helpful Links
IFU & Manuals (USA) - Thoratec Corporation
Kidney and Pancreas Clinic Schedule.doc
LIVING DONOR TRANSPLANT SURGERY SCHEDULE
mapquest.doc
My LVAD
Nursing
Transplant Department
Transplant Members
TTI vignette medium.jpg
VAD MANUAL
VAD SCHEDULE CALENDAR

How to find VAD Manuals and Information

1. Go to (insert name of your institution's intranet)
2. Click on Department
3. Click on box, click on

Transplant Services

4. Find choices on the right side of the screen and click on the one you wish to open

Transplant Department
Transplant Members
TTI vignette medium.jpg
Vad Manual
Vad Schedule Calendar

VAD SCHEDULED?

THINGS TO CONSIDER
CALL THE NURSE ADMINISTRATOR
ON CALL FOR THE CVOR

THEY WILL CALL:

ICU INVOLVED
Notify PRODUCT REP
VAD COORDINATOR

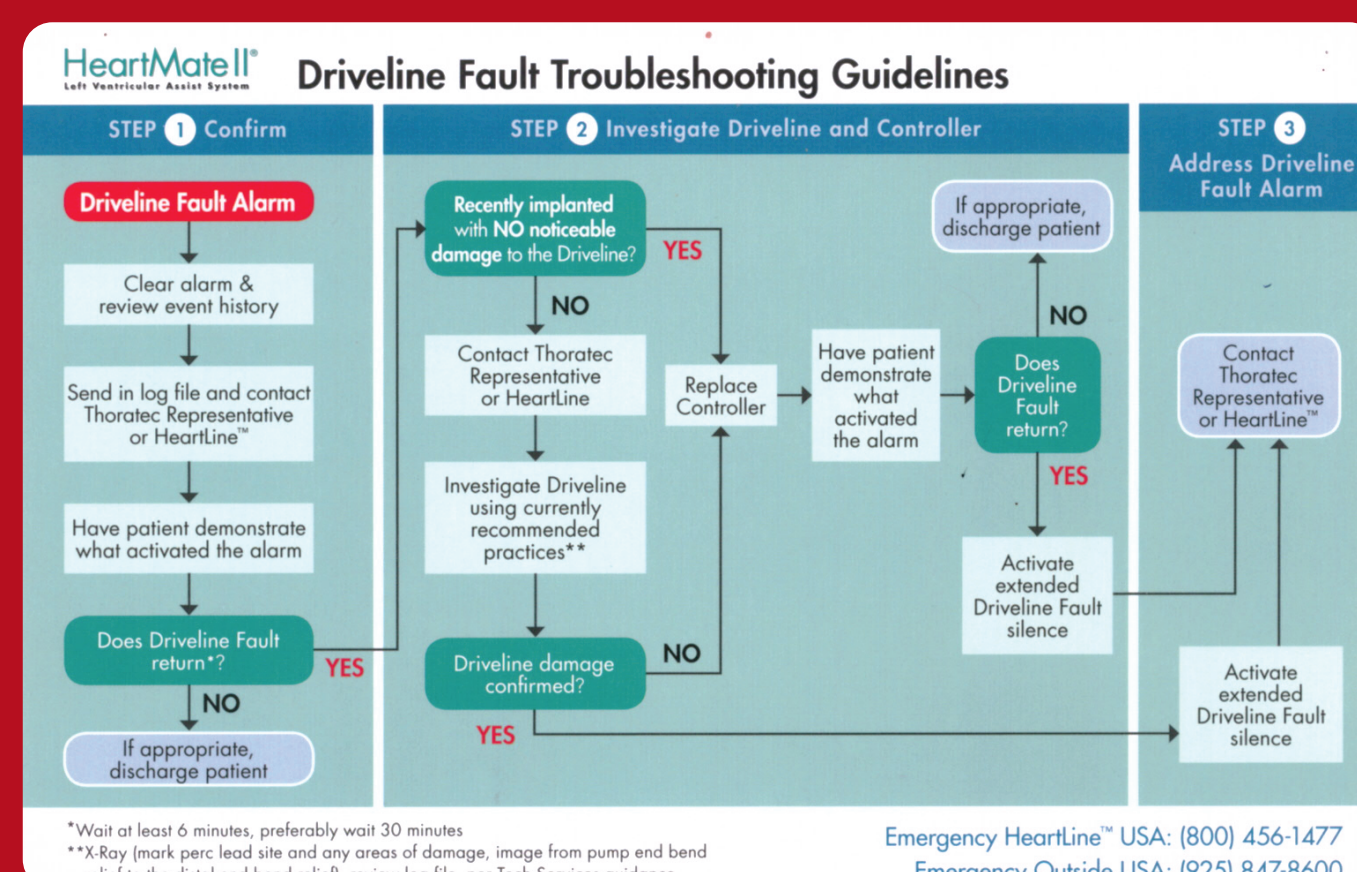
Mate

Thoratec Heartmate II Sealed Outflow Bend Relief Collar



Thoratec Heartmate II LVAS Implant Kit (with sealed graft)

What you need for a heartmate



5 SURGICAL PROCEDURES

Preparing the Pump

For this task you need:

- 1 HeartMate II Left Ventricular Assist Device with driveline
- 1 HeartMate II System Controller
- 1 System Monitor, connected to the Power Module
- 1 Power Module, connected to the System Monitor and plugged into an AC electrical outlet
- 1 sterile basin with at least 3 liters of Sterile Saline for Injection

CAUTION!

Never operate the pump in the air, as this will immediately damage the device. Make sure that the pump is fully submerged.

To PREPARE THE PUMP:

1. Examine the outflow elbow of the pump to verify the presence of a white washer. If the white washer is missing or damaged, do not use the pump. Obtain another pump device before continuing.
2. Fully submerge the pump in a sterile basin with at least 3 liters of Sterile Saline for Injection.
3. Follow the procedure below to run the pump for a minimum of 5 minutes at 6,000 rpm:
 - a. Attach the pump's driveline to the System Controller; confirm that the connection is secure (see Connecting the Driveline to the System Controller on page 2-22).
 - b. Initiate pump speed at 6,000 rpm by pressing the Pump Start button on the Settings screen of the System Monitor. The PUMP OFF message should disappear.

Heart -- Selection Criteria for Ventricular Assist Device as Destination Therapy

Things to consider when creating your organization's policy:

SCOPE: Heart Transplant Surgeons and physicians, Transplant Coordinators, other member of the heart transplant/VAD patient selection committee.

PURPOSE: To establish selection criteria for Ventricular Assist Device (VAD) placement in destination therapy candidates.

POLICY: All patients referred to the heart transplant/VAD program will be considered for destination therapy VAD placement against the following guidelines. Physicians medical judgement will be used when selecting patients for advanced therapies. Patients that are selected as candidates from the following criteria must be approved by both the Medical and Surgical Directors at the time of the patient care conference, or telephonically if implant is semi-emergent, and cannot wait until the next scheduled patient care conference, in order to be offered destination therapy VAD placement.

Eligibility Criteria:

1. Patients with New York Heart Association Functional Classification Class IV heart failure symptoms who have failed to respond to optimal medical management
2. Patients who have anticipated survival benefit
3. LVEF \leq 25%; CI \leq 2.2 l/min; PCWP \geq 18 mmHg
4. Patients with a continued need for inotropic therapy
5. Peak VO2 \leq 14 ml/kg/min unless balloon pump or inotrope dependent or physically unable toperform the test
6. Patients who have been evaluated for heart transplant and were not selected as candidates
7. BSA \geq 1.3m2 (Heartmate II)
8. Appropriate nutritional status after consultation with the transplant dietician
9. Psychological clearance either by transplant psychologist and/or transplant social worker
10. Financial clearance, including long-term financial planning in place regarding device maintenance.
11. Palliative Care consult

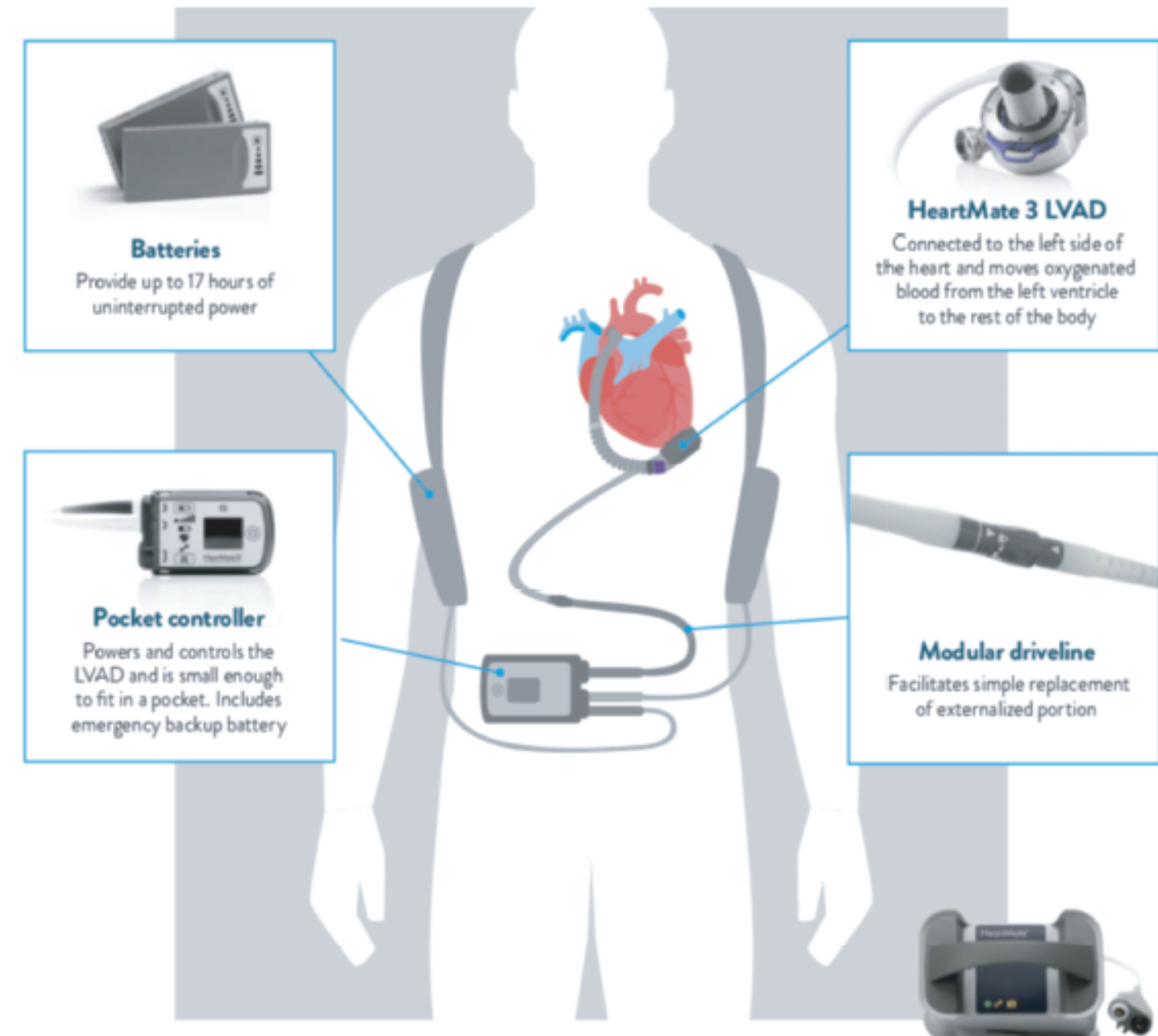
Exclusion Criteria:

1. Correctable cause of heart failure
2. Age $>$ 75 years- consider on a case by case basis
3. Untreated refractory right heart Failure
4. Irreversible renal failure (Creatinine \geq 2.5 mg/dl or urine output $<$ 30 cc/hr)
5. Total bilirubin $>$ 5.0
6. Prothrombin time $>$ 16 seconds (uncorrectable)
7. Mechanical ventilation / ARDS
8. Mechanical aortic valve (unless changed to a bioprosthesis)
9. Significant aortic valve insufficiency or mitral stenosis (unless corrected)
10. Active systemic infection
11. Severe peripheral vascular disease
12. Stroke $<$ 90 days; ICA stenosis; with significant impaired cognitive function
13. Life expectancy $<$ 2 years from non-cardiac causes
14. Metastatic cancer- consider on a case by case basis

REFERENCES: Centers for Medicare/Medicaid CMS, Conditions of Participation Disease Specific Thoratec Advanced Practice Guidelines

Who uses these?

Perfusion



"I am VAD Aware!!"
means
**"I know what products to pull
and I know who to call for the
help I may need!"**