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You are being considered for Ventricular Assist Device (VAD) Therapy. The VAD is an electric powered pump implanted alongside your own heart that increases blood flow back to the rest of your body. VAD therapy is considered for patients with advanced heart failure. Advanced heart failure is a terminal illness when a person's own heart is unable to pump enough blood to support the needs of their body. The decrease in blood flow throughout the body causes severe physical limitations such as fatigue, difficulty breathing even at rest, and fluid retention. In addition, decreased blood flow to the other organs of our body can lead to irreversible damage and/or failure of those organs. Advanced heart failure patients have a greater than 50% chance of dying in the next year with medical therapy alone.

There is a lengthy evaluation and testing process to help determine who will benefit from a VAD. Most importantly, successful living with a VAD depends on the patient, their care giver(s) and the VAD Team working together. The purpose of receiving a VAD is to help relieve heart failure symptoms so that you feel better and have a healthier life.

The information that is given to you in this document and by the VAD team is to help teach you about Ventricular Assist Device (VAD) Therapy. Specifically, the evaluation process, surgery, potential risks and benefits, after surgery plans, what to expect, and changes you might face after VAD surgery. The team will talk with you about these things during the testing. You have the right to review with your VAD team any part of this paper that you do not understand.

After reviewing each section, please write your initials at the bottom of each page. This shows the team that the information has been explained to you and that you understand and agree with the information. Once you have read this paper and all your questions have been answered, you will be asked to sign the end of this paper showing you fully understand the information in this document. You will be given a signed copy of this paper for your records.

Treatment Options for Advanced Heart Failure

Medical Treatment:

You may choose to only take medicines for your heart sickness and not have VAD surgery.

Heart Transplant:

A heart transplant is a surgery where a doctor removes a sick heart and replaces it with a donor heart. If transplant is an option for you, the Heart Transplant Team will talk about it in more detail with you.

Ventricular Assist Device (VAD):

Ventricular assist devices are surgically placed heart pumps that sit alongside your own heart to restore normal blood flow to the rest of your body. Your own heart continues to pump as well.

VAD Evaluation and Testing

A VAD is used either as Bridge-to-Transplantation Therapy for heart failure patients waiting for a heart transplant or as Destination Therapy for patients who are not able to receive a heart transplant.

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Bridge-to-Transplant (BTT): Bridge-to-transplant Therapy (BTT) is a VAD therapy option for people in the worst stages of heart failure who qualify and are waiting a heart transplant. The implant of the VAD device is used to improve the heart failure symptoms and extend someone's life while awaiting a heart transplant. This document only pertains to VAD therapy. The transplant team will provide you with information regarding the transplant. It is possible that after you receive a VAD that you are no longer eligible for transplant due to a worsening medical condition or you no longer meet qualifications.

<u>Destination Therapy (DT)</u>:

Destination Therapy (DT) is a permanent VAD therapy for people who do not qualify for heart transplant. It is possible for some people to experience changes in their health while on the VAD that could lead to them qualifying for heart transplant. Your doctor will talk about this possibility with you.

Heart Pumps:

There are many different types of VADs including FDA approved devices for Bridge-to-Transplant (BTT) and/or Destination Therapy (DT) and study only pumps. The VAD Coordinator will review the information about the type of heart pump that you are being considered for. They will also show you the pump and review with you the equipment for the device. If a device is currently in a study, this information will be presented to you with any additional study information.

You are being considered for one of these heart pumps:

- HeartMate II LVAD
- HeartMate 3 LVAD
- HeartWare HVAD

VAD Evaluation Testing:

The testing is made up of many medical exams and tests to help the team determine if a VAD could help improve your heart failure symptoms. You will also meet with various members of the VAD Team as part of your evaluation. They evaluate if you would be able to manage the VAD equipment on a daily basis, if you are committed to participate in the strict ongoing follow-up care that is associated with successful VAD therapy outcomes, if you have adequate caregiver support and if you have financial needs or concerns.

Other medical problems that are found during the testing will be followed up on as needed. The purpose is to fully check all medical issues and possible problems to make sure VAD surgery can help you. The testing may also show other medical problems which make the VAD surgery a poor choice.

During this testing, if you have questions about any exams or tests, please talk to the VAD Team. It is important that you ask questions and understand your health care plans.

If during the testing process you decide that you do not want a VAD, you may tell any member of the VAD Team and VAD evaluation portion of testing will stop. In the future, if your health changes or you change your mind, you may restart testing. You may need to repeat some tests to decide if VAD surgery can help you.

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VAD Team:

VAD Coordinators are a team of advanced practice providers and RNs who are experts with heart pumps. During evaluation they will meet with you and discuss the evaluation process and educate you about the VAD devices. If you are approved for getting a VAD, the coordinator will teach you and your care giver(s) before and after your surgery about the ongoing care and maintenance of your VAD device. The VAD Coordinator provider is part of the Advanced Heart Failure Team. They will continue to see you on an ongoing basis both inpatient during hospital admissions and outpatient in the advanced heart failure clinic. They will be involved in your ongoing VAD health care for as long as you have the VAD.

VAD Cardiologists are part of the Advanced Heart Failure Team at the University of Rochester Medical Center and specialize in heart failure, transplant and VAD patient management. They will continue to see you on an ongoing basis both inpatient during hospital admissions and outpatient in the advanced heart failure clinic.

VAD Surgeon is the doctor who will perform the VAD surgery. The VAD Surgeon also takes care of any follow up heart surgery after the heart pump is placed if needed. You will meet your VAD Surgeon during your testing. They continue to see all VAD patients on an as needed basis post VAD surgery discharge.

VAD Social Worker will help you with social, emotional, and financial concerns you have related to living with a VAD. The VAD Social Worker can help you prepare for some of the life changes that are part of living with a VAD. Talking with the VAD Social Worker can ease worries for you, your loved ones, and/or care giver(s). The social worker will talk with you and your care giver(s) about needs you may have. If not already done so, they can also assist in completing an Advanced Medical Directive* or Living Will*. You will meet with the VAD Social Worker during the testing as part of your evaluation.

VAD Financial Counselors work with your insurance company, the hospital and you about financial concerns. Prior to being tested for a VAD, they will review your insurance coverage. The Financial Coordinators are available to help answer questions regarding insurance and copayments.

VAD Nutritionist will meet with you and discuss your nutritional status and determine an appropriate nutritional plan based on your medical history and needs.

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Exams and Tests:

- Insurance approval/review
- Height/weight, body mass index (BMI), body surface area (BSA)
- Complete physical check up
- Full medical history including reports of all previous surgeries, allergy history, history of receiving blood products, pregnancy history, vaccination/shot history, smoking and alcohol history, and drug/alcohol abuse history.
- Discussion with a social worker about your family, current living situation, and support
- Registered dietitian evaluation
- Cardiopulmonary exercise test (VO2)
- Measurement of right and left heart function by echocardiogram (ECHO) and /or a heart magnetic resonance imaging (MRI)
- Right heart catheterization
- Left heart catheterization
- Chest X-ray and/or Chest computed tomography (CT)
- Lung function test, includes an arterial blood gas as needed
- Labs blood tests: Serological testing for HIV, Hepatitis panel, Comprehensive metabolic panel, Complete blood count, Coagulation studies, Iron Studies, Lactase Dehydrogenase, Blood Type and Screen, Thyroid panel, Pre-albumin, B-type natriuretic peptide, Prostate specific antigen, Pregnancy test in women, HgbA1C.
- Stool occult blood screen and as needed Colonoscopy or Cologuard© screen
- Carotid ultrasound
- Abdominal Ultrasound
- Ankle-Brachial Index (ABI's)
- Possible tests include: Dental Consult, Toxicology Screen, Gastrointestinal Consult, Infections Disease Consult, Occupational Therapy Consult, Gynecology Consult, Psychiatric Consult, Pulmonary Consult, Palliative Care Consult, Vascular Surgery Consult, Hematology Consult, and Ophthalmology Consult
- Additional tests may be required by your insurance or the VAD Team.

Who Can Receive a VAD?

- Patients who are expected to live and enjoy normal life activities after VAD surgery.
- Patients with a prognosis of 2 years or more from any other disease.
- Patients whose heart failure symptoms have not improved even when taking the best heart failure medications
- Patients whose left ventricular ejection fraction (EF) is less than 25%.
- Patients whose maximum lung function test (VO2) is less than 14ml/kg/min, when test available
- Patients who need intravenous heart failure medications and/or balloon pump therapy

Absolute Contraindications to VAD Therapy:

- Inadequate social support
- Coexisting terminal condition such as cancer or widespread disease

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Relative Contraindications to VAD Therapy are:

If you have any of the below items it may affect if you receive a VAD or your quality of life after the VAD.

- History of mental or social problems which stop you from following doctors' directions
- History of not following doctors' medical orders
- Currently serving a prison or jail sentence
- Scoring Frail on frailty test
- Moderate to severe malnutrition
- Currently using illegal drugs or drinking too much alcohol. The VAD Team may require an agreement, counseling, or completion of a rehab program
- Blood clotting disorders
- High bleeding risk
- Current infection that is not being treated
- Poor function of the right side of the heart
- Lung Disease that cannot be fixed
- Vascular Disease this is unable to be medical or surgically corrected
- Liver Disease that cannot be fixed
- History of Strokes or Cerebrovascular disease in your brain
- Neuromuscular disease that will prevent the ability to manage the VAD equipment
- Kidney Disease that cannot be fixed
- Inadequate Social support
- Body Mass Index (BMI) greater then 45
- Ongoing dialysis
- Inability to tolerate or contraindication to anticoagulation
- Lack of insurance coverage and not being able to pay for medical care
- Homelessness

Other medical problems that are found during the testing will be followed up on as needed. The purpose is to fully check all medical issues and possible problems to make sure VAD surgery can help you.

Risks of Testing Phase:

The possible risks include, but are not only: slight pain when drawing blood, bleeding or bruising at the site where the needle is inserted into the arm, and risk of infection or clot in your blood. There is a risk of infection from being in the hospital, having blood draws, heart catheterizations, or other tests. The testing time may also be emotionally difficult.

Pregnancy Risks:

Not enough information is available about the effect of VADs on unborn babies or newborn breastfed infants. Women of childbearing age must have a negative pregnancy test at the time of VAD surgery. Also, you must agree to use a dependable form of birth control to prevent pregnancy the entire time you have a VAD.

Even if you use an allowed birth control, you could still become pregnant. It is important to the safety of your unborn baby that if you get pregnant or think you are pregnant you tell the VAD Team immediately.

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Medical Studies:

The VAD Coordinators will review your records to see if it is possible for you to participate in any VAD related studies. If it is possible, the VAD Coordinator will give you more information about the specific study so you can decide if you wish to participate. Medical studies will have a separate agreement to sign if you want to participate. The VAD Coordinator will provide the agreements, answer questions, and review specific information. Being in a medical study is your choice. You will not be put into a study without agreeing to it.

Surgery Phase:

To implant the device alongside the heart, the cardiac surgeon will perform open heart surgery. After being put to sleep with medications, you will have a breathing tube placed in your mouth and lungs to breathe for you. You will stay asleep during the entire surgery. VAD surgery involves making a cut down the middle of your chest (or the side of your chest) that goes down to your stomach area. You will then be placed on a heart/lung machine. Surgery usually takes about 4-6 hours. The VAD will be placed alongside of your heart and will connect your heart to a large blood vessel which carries blood from your heart to the rest of your body. A driveline/power cable will be placed through the skin of your lower stomach area. This driveline/power cable is connected to a controller/computer on the outside of your body. The small controller/computer is also connected to batteries or wall power at all times.

Once the surgery is complete, you will be taken on a breathing machine to the Intensive Care Unit (ICU) to recover. As you wake up and when your doctor feels it is safe, the breathing tube will be removed. As you recover, you will participate in exercises to get stronger and learn about your VAD.

The long term survival of heart pump patients is 75% at two years. Improvements in symptoms show that 85% of heart pump patients are heart failure class I or II at 6 months.

Risks of VAD Surgery Phase:

The possible risks during surgery and immediately after include, but are not limited to: bleeding, infection, multi-system organ failure, stroke, thrombosis (blood clots) or embolisms, damage to blood cells, need for blood transfusion and possibility of a transfusion reaction or disease, complications of anesthesia, need for prolonged ventilation, chronic shortness of breath, need for dialysis, delayed healing, excessive scarring, loss of limb(s), chronic pain or nerve damage, need for an RVAD, device failure, death.

Immediately After VAD Surgery:

- You will be up and walking almost immediately after VAD surgery and be expected to walk at least 3 times/day while in hospital.
- Teaching will be provided to you and your caregiver at the bedside and in classes using literature, videos, and practice equipment. Education is provided M-F during normal business hours and reinforced by nursing staff on the weekends. Your caregiver will need to be spend considerable time at the hospital to learn with you care of the VAD equipment and how to perform a sterile dressing.
- Discharge to home is typically 1-3 weeks after surgery. Before leaving the hospital, you will be given a 24-hour number to call in case of emergencies.

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Patient and Care Partner Expectations:

To help you decide whether this is the best option for you, there needs to be an agreement about what is required of all parties before and after your device placement. Successful outcomes depend on the commitment to following a medical program that includes frequent clinic visits, out-patient hospital procedures, exercise, dietary guidelines and taking prescribed medications every day. Following ALL guidelines is mandatory for success.

Both the <u>patient</u> and the <u>care giver(s)</u> should review the following expectations carefully:

I will follow the treatment plan as prescribed by the physicians, VAD Coordinators, and nurses. I will keep my clinic appointments, get my labs checked and take my medications as directed.

I am financially responsible for all cost associated with housing, living, travel and medical care.

I will receive detailed education about the VAD. I will watch LVAD video, Coumadin video, read and learn the information in the VAD instruction booklets. I will attend all required classes as described above. I will take and pass a written test, participate in education, and explain how I will deal with an emergency.

I will have sterile dressing changes of VAD site as long as I have a VAD. I understand that the care of my driveline site will require the assistance of my care giver and that I will be advised to refrain from showering due to infection risk. The sterile dressing frequency is based on drainage and exit site healing.

I will follow all of the instructions I receive from the VAD team regarding the prevention of infections and understand that infection is the leading cause of death with these devices.

I understand that I am financially responsible for the costs of the VAD which include; hospitalization, physician charges, outpatient testing, laboratory charges, medication expenses and *dressing supplies*.

I understand that I will require dressing supplies lifelong and charges for supplies are dependent upon insurance coverage. I will be responsible for contacting my individual dressing supply provider and ordering my sterile dressing supplies before I run out.

I understand that it is my responsibility to stay updated on my insurance coverage.

I will care for the VAD and its equipment which includes preventing pulls, kinks, bends, and damage to the driveline. I understand that damage to the driveline cable may cause the VAD to stop and result in death. I agree to return to the VAD clinic for equipment problems as instructed by the VAD team.

I understand after VAD surgery I am required to have a dedicated VAD trained caregiver to assist with my recovery from surgery and care of the VAD for at least the first 4 weeks after discharge. This may include assistance with hands on person care such as bathing, dressing and toileting. My dedicated care giver(s) must come to doctors' appointments with me as much as possible, agree to participate in education training and assist me with getting to and from my appointments.

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I understand that the URMC LVAD team recommends that patients never live alone with an LVAD. In some instances, this need for supervision can be indefinite. While rare, care teams need to consider how they would want to handle this outcome. Referrals to other levels of care, such as, skilled nursing facilities, rehab programs, and assisted living, are rarely possible or are severely limited for LVAD patients

I understand if I do not have a care giver(s) there is an increased risk living alone. I may not be able to respond to alarms or be able to call emergency care teams which could affect my health negatively or lead to death.

I will know all my medicines and the reason I am taking them.

I will keep daily records including temperature, weight, and VAD readings and bring the information to all clinic visits.

I will participate in Cardiac Rehab before and after my VAD surgery.

I will always maintain a working phone and electricity.

I will not participate in activities that may hit/shake the VAD site. Activities that are <u>not allowed</u> with a VAD are:

- Putting my body/driveline under water (for example: going swimming or taking a bath).
- Playing contact sports where I can get hit.
- Sleeping with electric blankets.

I will absolutely not be able to drive any vehicle for the first 4 weeks after surgery. After the 4 week time period I can discuss if I am able to resume driving with my VAD coordinators or Heart Failure Cardiologist. I cannot drive if I am taking pain medication or any substance that makes be sleepy. I cannot drive if I am not feeling well, got shocked by my implanted defibrillator (AICD) or passed out within the last 6 months. I also need to comply with my local and/or national driving laws.

I understand that if I stop taking care of my VAD and stop following doctors' instructions I may have problems with my VAD such as: the VAD clotting off, VAD stopping, VAD or driveline infections or worsening heart failure symptoms. All of these things may lead to health problems including death.

I will go to VAD/transplant education and support groups meetings as available. I understand that it is important for me and my caregiver to attend group meetings to receive ongoing education and support.

If alcohol, tobacco or illegal drugs are being abused or dependence has been identified as an issue for me, I commit to STOP any or all of these activities. I understand that use of illegal drugs, cigarettes and alcohol will negatively impact my health.

I will complete all drug testing and/or Narcotics Anonymous or Alcoholic Anonymous meetings as required by the Advanced Heart Failure Team.

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If alcohol is not identified as an issue, I commit to limiting alcohol intake as it can affect decision making and could lead to death if I cannot respond to an alarm.

I understand women of childbearing potential must have a negative pregnancy test at time of implant and agree to use reliable contraception while being supported by a mechanical pump. The contraceptive options will be discussed with me and decided upon prior to discharge.

If there are any emergencies I will page 911 FIRST and then I will inform the team (by paging the VAD team, someone is available 24/7)

I understand if my heart pump should stop working, death may occur. If the heart pump stops working, I may or may not get another surgery for another heart pump.

Care Giver Burden:

Being a care giver can be a difficult job. Depression, stress, anxiety, feeling trapped and burned out are all possible. We have a support groups on a regular basis that you are able to talk about your concerns or frustrations. Please ask for help when needed, take some time for yourself and communicate with friends and family to help you destress.

Risks of Living with a VAD:

The possible risks after VAD surgery include, but are not limited to: stroke, significant bleeding, pump thrombosis (blood clot inside pump), driveline infection, abnormal heart beats, heart failure, kidney failure, need for another operation, and death.

It is common for you to feel sad or depressed after VAD surgery and being in the hospital. These feelings can be from not knowing what to expect, not being able to do simple things without becoming very tired, or from having to get help from others which may cause feelings of guilt. Short term feelings of sadness are normal, and should go away within a few weeks as you get back to your normal activities. Sometimes a sad mood can stop you from leading your normal life. If your sad mood gets worse or lasts every day for two or more weeks, help is sometimes needed for you to recover.

End of Life with a VAD:

You will be asked to talk about and decide what treatments you would want if you don't get better. This is also called an Advanced Medical Directive or Living Will. We have these forms available if you need them. While we don't expect any problems after your VAD surgery, planning in advance allows you to stay in control of your medical treatment.

Our goal is to support VAD patients from the time you are evaluated and for as long as you have a VAD. Our goal is for you return to good health and return home. However, sometimes bad things happen and you may not have a good quality of life or good chance of surviving. You may be faced with deciding whether to continue living with the VAD. The VAD Team and/or Palliative Care Team can help you with these decisions.

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Increased blood flow that you will lik daily life with few limits on activity.	VAD include helping you feel better and living a healthier life. ely get after the VAD surgery, should allow you to return to your You should be able to walk or exercise with limited heart failure ergy and be able to enjoy social & family activities, return to work,
	ds including all medical care follow up, and ongoing equipment with financial concerns may be available to you. You may meet ded.
Certification Information: The University of Rochester Medical Certification Information:	nter Advanced Heart Failure Program meets all The Joint
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Appendix

Abdominal ultrasound: A test which uses sound waves to create a picture of the inside of your stomach area. It is used to check for any problems with your internal organs*.

Advanced Medical Directive or Living Will: A legal paper written and signed by someone telling what treatments and medical help they want if they become too sick to make their own decisions.

Ankle-Brachial Index (ABI): A test to check your legs or arms for narrowed or blocked blood vessels. People with narrowed vessels are at a high risk of heart attack, stroke, poor circulation and leg pain.

Anti-coagulation: Medicines given to stop the body from making blood clots.

Arterial blood gas: A blood test from your artery which measures how much oxygen and carbon dioxide is in your blood.

Balloon pump therapy: A pump connected to a balloon that is put in through a groin vessel. It gives short term help to a weak heart.

Birth control: Methods, medicines or devices used to stop a woman from getting pregnant. Such as birth control pills, or shot, intrauterine device (IUD), condom, diaphragm, or tubal ligation.

BMI: A measure of someone's weight related to height. Overweight is a BMI greater than 25; Obese is a BMI greater than 30.

BSA: The total surface area of the human body.

Blood transfusion: Giving one person's blood to someone else who needs it.

Cardiac Rehab: A program designed to improve heart health by supervised exercise and counseling.

Cardiopulmonary Exercise Testing (VO2): A test that measures the maximum amount of oxygen that your body can use during exercise.

Carotid ultrasound: This is a test that looks at the blood flow in the carotid arteries which bring blood from your heart to your head. The test is performed to check for any increased risk of stroke.

Cerebrovascular disease: Disease of the blood vessels that take blood to the brain. Cerebrovascular disease is usually caused by hardening of the vessels.

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Chest computed tomography (CT scan): CT scans are a kind of \underline{X} -ray that give a very detailed picture of what is going on inside the body.

Colonoscopy: A test where a long, flexible, tube is used to look at the inside of a person's colon (large intestine) and the rectum.

Driveline: A wire that exits your abdomen and connects the pump to the external controller and power.

Donor: Someone who will give an organ (heart, lungs, kidney) or blood to another person after they die.

Echocardiogram (ECHO): A test which uses sound waves to create a picture of the inside of the heart. It is used to check how well the heart is working.

Electrocardiogram (EKG): A test which records the electrical activity of the heart.

FDA approved: Federal Drug Administration is a government agency that is responsible to approve and monitor safety standards for food and drugs in the United States.

General anesthesia: Medicine that will make you fall asleep for a short time so you don't feel any pain while the doctors are fixing something.

Heart attack: When a blood clot or other blockage stops blood flow to a part of the heart.

HIV/AIDS: A virus that destroys part of the immune system that helps the body fight off germs and diseases.

Intensive Care Unit (ICU): Hospital units where patients requiring very close monitoring are treated. An ICU has special monitoring equipment and has specially trained staff to care for very sick people.

Intravenous (IV): A tiny straw-like tube that goes into a vein. Often it is a way to give medicines or fluid directly to a person.

Left heart catheterization: A tube (catheter) is put into a blood vessel, usually into the aorta, and then goes into the blood vessels of the heart to see how well they are delivering blood to the heart muscle.

Narcotics Anonymous or Alcoholic Anonymous: A group that offers support and a program to help people stop using drugs or alcohol.

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PATIENT & CAREGIVER AGREEMENT FOR VENTRICULAR ASSIST DEVICE (VAD) THERAPY	☐ Outpatient
SMH 2253 MR	
419	

Open heart surgery: Surgery in which the chest is opened and surgery is performed on the heart. The term "open" refers to the chest, not to the heart itself.

Palliative Care Team: A group made up of nurses and doctors who specialize in pain management, emotional and spiritual support, and provide guidance in clarifying patient goals of care.

Pulmonary Function Test/Lung Function Test (PFT): This is a test that shows how much air your <u>lungs</u> can hold and how quickly you can move air in and out of your lungs.

Quality of life: The person's ability to enjoy normal life activities.

Rehabilitation (rehab) program: This is a program that helps people return to a healthy life. Treatment can be for people using alcohol and/or drugs.

Right Heart Catheterization: A tube (catheter) is put into a blood vessel, usually in the groin. A dye is then put into the vessel through the tube to measure how well the right ventricle works and to check for high blood pressure in the lungs that cannot be treated with medication.

Right heart failure: The right side of the heart is not able to pump blood normally to the left side of the heart.

Stroke: When the blood supply to part of your brain is severely decreased or stops. Brain cells start to die within minutes of the decrease of blood.

Thought and Personality Disorders: Disorders within the brain that cause confusion.

VAD Team: A group made up of VAD coordinators, doctors, surgeons and social workers who specialize in care of patients implanted with a heart pump.

Ventricular Assist Device (VAD) Therapy: Surgically placed electric powered heart pumps that increase blood flow from your heart to the rest of your body.