ADVANCED CARDIAC THERAPIES IMPROVING OUTCOMES NETWORK

Berlin Heart EXCOR®

Patient & Family Education Handbook

action

action

ADVANCED CARDIAC THERAPIES
IMPROVING OUTCOMES NETWORK

Working together to improve critical outcomes for all pediatric and congenital heart failure patients.

The Advanced Cardiac Therapies Improving Outcomes Network (ACTION) was established to improve the care of patients with heart failure. ACTION unites all stakeholders (providers, patients/families and researchers) to share experiences, improve education and search for best practices to drive improvement in areas that are often untouched by clinical trials alone.

The learning network approach allows for critical improvements to be made faster across a collaborative system.

Visit our online education site ***myactioneducation.org*** to learn more about:

- understanding your heart failure diagnosis
- medicine treatment options
- knowing your device and surgery options
- maintaining your health and wellness

For more information about the learning network approach or the work ACTION is doing, visit ***actionlearningnetwork.org.***

This is MY* VAD Journey

Hi, my name is:

☎ (___) ___-____

✉ ____________________

My caregiver is:

____

*Most patients needing a Berlin Heart EXCOR® are young, so this handbook is for the patient, family, and caregivers as a whole.

Quick References

It's important to keep some basic information about your ***diagnosis*** and surgeries available for quick reference. This handbook will also serve as a great resource to record all the memories and milestones experienced throughout your VAD journey.

My VAD Care Team Contact Info

My Hospital

Name

Street Address

City, State, Zip

My ACTION Site ID

– My Heart Disease –

I am Allergic to:

♥

♥

♥

♥

♥

information above completed on ____/____/_____

My Past Surgeries

____

____

____

____

____

____

My VAD Surgery | Date:

Notes: ______________________________

____

____

My Berlin Heart EXCOR® is on the:

☐ Left ☐ Right ☐ Both

I am listed for transplant:

☐ No ☐ Yes ______________________
Listing Date

My blood pressure goal: ______________________

Blood thinner medicine(s) I take: ______________________

____

____

____

information above completed on ____/____/____

Using this Handbook

This is a quick educational reference guide and scrapbook to keep track of topics that may come up during your child's journey. There are times when your care team may ask you to follow different instructions, make sure to write down these important pieces of information.

Additional education will be provided by your care team. Please ask your care team if you need more information or clarification.

For complete instructions regarding the Berlin Heart EXCOR®, please refer to the ***EXCOR® Pediatric VAD instructions for use manual*** online at: ***berlinheart.com/medicalprofessionals.***

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Introduction to the Berlin Heart EXCOR®

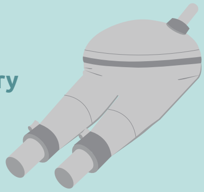
- Berlin Heart EXCOR® Patient Journey
- What is a VAD?
- How will a VAD help?
- Why do I want a VAD?
- Who will be the care team?

Berlin Heart EXCOR® Patient Journey

Note: The Berlin Heart EXCOR® device has been approved by the Food and Drug Administration (FDA) with a Pre-Market Approval (PMA). All patients are unique and may not follow the path exactly as shown. Some steps will need to be determined by your care team and/or some may not apply.

VAD consult

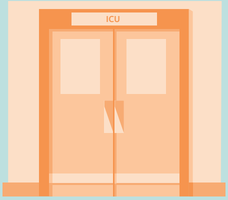
Learn about the VAD and meet the care team



VAD surgery

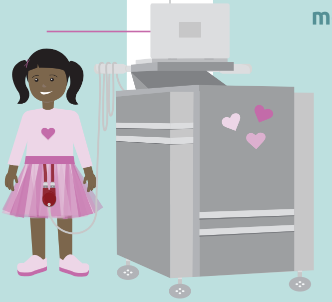
Start blood thinning medicines and work toward goal level

Remove breathing tube



Transfer ready: VAD settings and medicine levels stable*

Transition out of ICU to step down care, focusing on heathy nutrition and getting stronger*



What is a VAD?

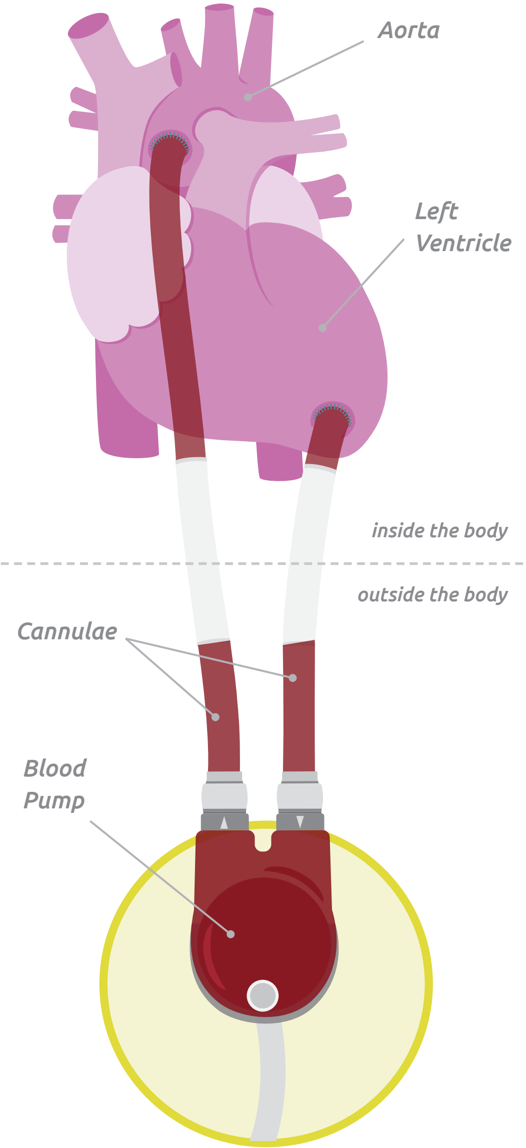
VAD stands for "Ventricular Assist Device". It helps a weak or really sick heart to pump blood to the body. The type of VAD that we are talking with you about is called the **Berlin Heart EXCOR®** (or Berlin Heart).

Cannula (or cannulae):

The cannulae are ***implanted*** securely inside the heart during surgery. They come out through the stomach wall and connect to the blood pump. They are soft silicone tubes that move blood from the body to the pump and back to the body.

Blood Pump:

The blood pump is located outside of the body. The pump works by pumping blood in and out of a chamber. Air moves a membrane to fill and eject blood from the chamber to the cannula and out of the ***aorta*** to the body. A large machine, called an IKUS, is connected to the pump to provide it power.

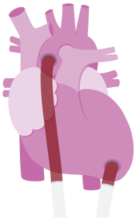


The most common device placement is the LVAD (pictured above). See next page for additional device placement options.

How does the VAD work?

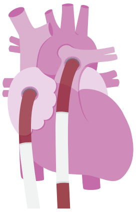
The Berlin Heart can support any part of a weak heart. The cannulae are placed in different positions depending on which part of the heart needs support. The cannulae are then attached to the blood pump. With your care team, check the box next to the kind of support that is right for you.

☐



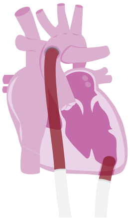
LVAD: A left ventricular assist device, or LVAD, supports the left side of the heart. The blood moves from the weak left side through the blood pump to the aorta, and then it travels to the body.

☐



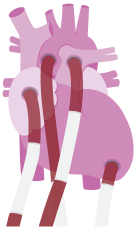
RVAD: A right ventricular assist device, or RVAD, supports the right side of the heart. The blood moves from the weak right side through the blood pump to the pulmonary artery, and then it travels to the lungs.

☐



SVAD: A systemic ventricular assist device, or SVAD, supports the entire heart in patients born with a single ventricle. The blood moves from the weak heart through the blood pump to the aorta, and then it travels to the body.

☐



BiVAD: A biventricular assist device, or BiVAD, supports both sides of the weak heart.

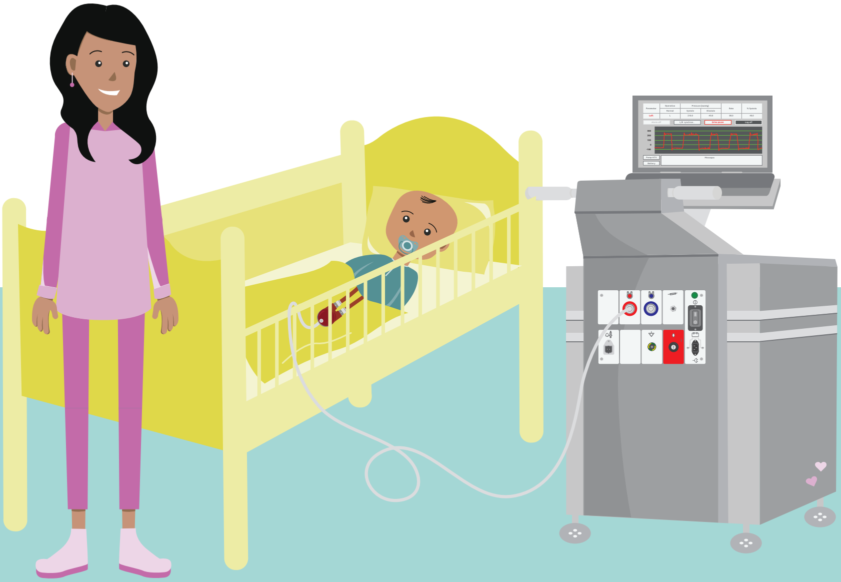
How will a VAD help?

VADs are placed for different reasons. Check the boxes below that apply for why a VAD is needed.

☐ The VAD will help my body prepare for transplant while I wait for the best heart to be available.

☐ The VAD will give more blood flow to my body and make me feel better.

☐ The VAD may help my heart get stronger.



Why do I want a VAD?

As a caregiver, what are your biggest worries about the VAD? Use the space below to note reasons you think a VAD will be right for your loved one or any concerns you may have.

Who will be the care team?

There are many people that will care for you during your journey. You and your family are a very important part of the team and will always help to make decisions about your child's care.

Fill in your care team members' names under their titles.

Cardiac Surgeon ______________________

Heart Failure/ Transplant Doctor ______________________

VAD Coordinator ______________________

Nurse Practitioner/ APRN ______________________

ICU Doctor ____________________

Nurse(s) ____________________

____

____

Physical Therapist(PT)/
Occupational Therapist(OT) ____________________

____

Psychologist ____________________

Cardiac Rehabilitation
Specialist ____________________

Nutrition Specialist ____________________

Pharmacist ____________________

Child Life Specialist ____________________

Social Worker ____________________

Who will be the care team?

Other people from your journey to remember are:

Name	Why are they special?

Send Thanks!

Send a thank you note to anyone who has made an impact on your journey. Let them know how they are doing or why they are special.

2

What to Expect

- Introduction
- Surgery
- Intensive Care
- Transfer Ready

Introduction

Many VAD patients notice an improvement in symptoms, but it can take months to get stronger and recover. During recovery, emotions will change frequently. Feelings of sadness or anxiety are normal. Make sure to share your honest feelings with your care team. Here are some other things to keep in mind:

- The recovery time varies; it can take a while to get stronger.
- Medicines and time will help lessen the pain.
- The ***Intensive Care Unit (ICU)*** can be loud and it may be hard to sleep at times. If sleeping is difficult, talk with your care team.
- Nutrition is really important to recovery.
- The care team will frequently look at the pump with a flashlight and mirror to make sure it's working properly.
- Sometimes, things may not go as planned, and there may be bumps in the road. Ask questions if you feel like things are not going as planned.

Changes in Your Journey

There are times when a plan may not go as expected, causing your journey to take a different path. Sometimes patients receiving a VAD as a bridge to transplant experience ***complications.*** Those complications could remove you from being a candidate for transplant. If this happens, your care team will talk to you and your family about the options.

Surgery

Questions about the surgery...

How is the VAD placed?

The surgery can take an entire day. Your surgeon performs a ***sternotomy*** (an incision in the chest bone), and implants the cannulae into the heart. The cannulae are secured tight and are attached to the blood pump outside of the body. There will be a scar on the chest. The surgery may require a heart and lung bypass machine to circulate blood to the body during the operation. After surgery, the heart and VAD work together to send blood to the body.

The surgery took ____________ hours.

Things to know after surgery...

Intensive Care

After surgery, recovery happens in the ICU. There will likely be a breathing tube connected to a ventilator (breathing machine) and many lines, tubes, and medical equipment *(see illustration below)*.

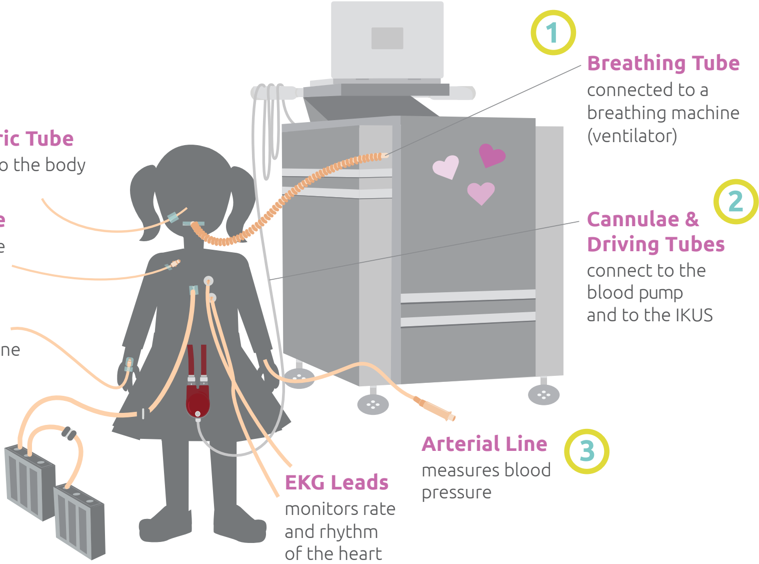
This equipment is necessary to monitor the body and give medicine needed for recovery. The equipment and lines can be scary, but they are completely normal. Day by day, the care team will work towards removing lines and tubes. The breathing tube is one of the first to be removed. It is also important to get out of bed as soon as possible to help with the recovery process.

① The breathing tube was removed on ____________________.

② The 1st cannulae dressing change was on ______________.

③ The arterial line was removed on ________________________.

Got out of bed post-surgery day # ____________________.



Breathing Tube
connected to a breathing machine (ventilator)

Nasogastric Tube
takes food to the body

Central Line
takes medicine to the body

Cannulae & Driving Tubes
connect to the blood pump and to the IKUS

Peripheral IV
takes fluids/medicine to the body

Chest Tube
drains fluid from surgery

Arterial Line
measures blood pressure

EKG Leads
monitors rate and rhythm of the heart

Transfer Ready

If available at your care center, the Cardiac Floor or Step Down Unit is where you would be transferred after the ICU. These areas of care centers are for patients who are not as critically ill but are still recovering after surgery.

After surgery, I was in the ICU for
________________ days. I transferred out of
the ICU on ____________________________ .

Your focus will be on healthy nutrition and getting stronger in order to move on to the next step in your journey.

3

Device Education

- Online Resources
- Berlin Heart EXCOR® Components
- Routine Device Care

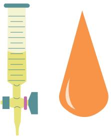
Online Resources

Learning about your VAD is an important part of keeping you safe. Your care team and our online learning site: ***myactioneducation.org*** will provide more in depth training with electronic modules and videos.

The life-saving equipment is complex, and learning how each piece works together will help you feel more comfortable.

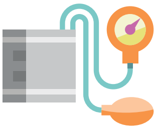
Below are some examples of topics covered:

A



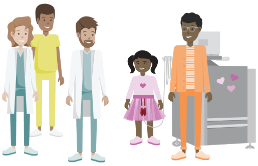
ANTICOAGULATION
management perfection

B



BLOOD PRESSURE
management perfection

C



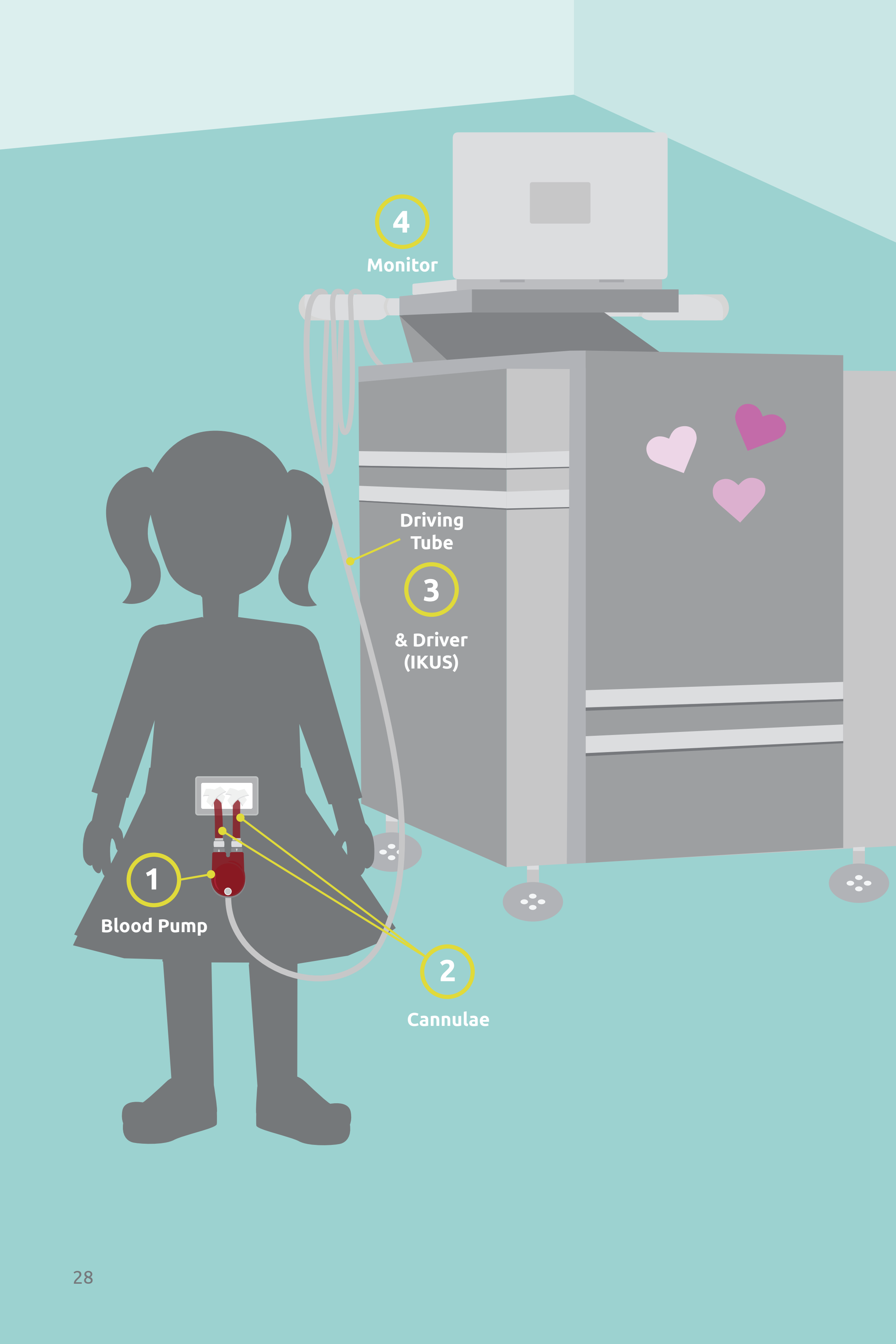
COMMUNICATION
amongst hospital staff and
with patients/families

myactioneducation.org

My Login Information

Username: ____________________

Password: ____________________


4
Monitor
Driving
Tube
3
& Driver
(IKUS)
1
Blood Pump
2
Cannulae

Berlin Heart EXCOR® Components

Below are the many components that make up the Berlin Heart.

1 Blood Pump

The blood pump is specially chosen for each heart it supports. The size of the pump depends on both the body size and the kind of heart disease that has caused the heart to fail. The blood pump is hand-crafted by scientists and engineers to provide proper blood flow to the entire body. It looks like a little heart that is outside of the body. You will be able to see the blood going in and out of the pump. The care team will be watching the membrane as the pump “fills” and “ejects.” They will also be looking for any visible ***clots*** in the device.

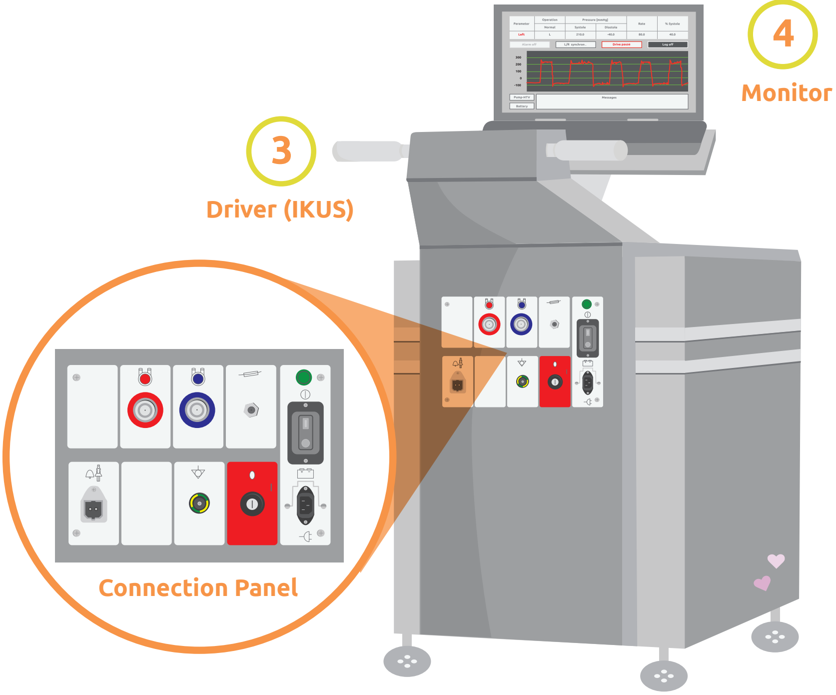
2 Cannula (Cannulae)

The cannulae are special tubes made of a very soft silicone material. These soft tubes will be placed in the heart and come out of the lower chest area just below the chest bone. The cannulae are connected to the blood pump. Blood goes from your heart to the Berlin Heart and out to the body (or lungs) through these soft silicone cannulae.

3 Driving Tube & Driver (IKUS)

The IKUS is an air compressor. It’s connected to a small driving tube which moves air in and out of the blood pump. As the IKUS moves air in and out of the Berlin Heart, the membrane will move, allowing blood to fill and eject. A computer sits on top of the IKUS and allows the care team to adjust the settings of the Berlin Heart. There are several settings that may be adjusted, including the air pressure strength and how many times the pump beats.

Berlin Heart EXCOR® Components

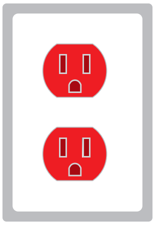


4 Monitor

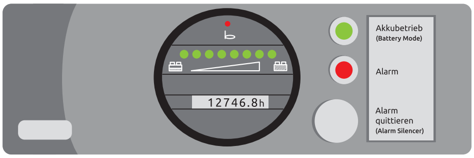
The monitor sits on top of the IKUS and allows the care team to make changes to the device settings. The settings calculated are based on the amount of blood flowing through the device and can be quickly changed to provide more or less flow. The monitor also informs the care team if any alarms have occurred and provides a way to download information in order to troubleshoot issues.

5 Power

The IKUS **must be plugged into an electrical power outlet**. While plugged in, the IKUS batteries are charging. The care team will switch the IKUS from the main electrical power to battery power if leaving the hospital room.



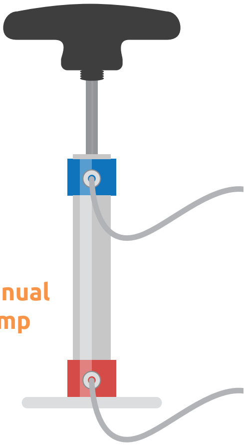
Main Electrical Power



Battery Power (Display Screen)

The batteries can only power the IKUS for **30 minutes.** There is a battery indicator that helps the care team know when the IKUS needs to be plugged back into a power outlet. An alarm will sound when the IKUS is not plugged into a power outlet. The care team will need to plug the IKUS back into the power outlet and it will take **at least 6 hours** before it is able to operate using battery power again.

The IKUS has a manual pump, like a bicycle tire pump, in case it were to malfunction. The care team will disconnect the driving tube from the IKUS and plug it into the manual pump if needed.



Manual Pump

Routine Device Care

The care team will work daily to provide routine device care in order to keep your child safe.

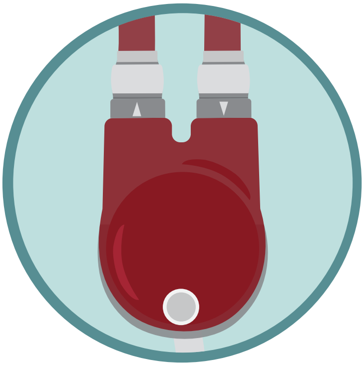
Monitoring the Blood Pump

The blood pump will be watched closely for the following:

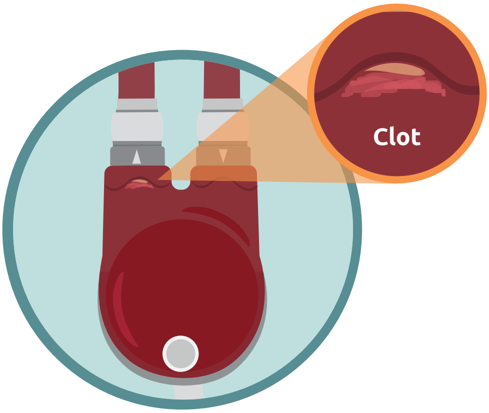
Clot (thrombus): Clots can form in the blood pump and travel from the pump out to the body. The care team looks closely for clots to try to prevent this from happening. The care team will follow the location, the color, the size, and whether the clot is moving in the pump. If a clot is seen, the care team may recommend to change the blood thinning medicine or to change the blood pump. If needed, the blood pump would be changed quickly and without surgery.

Fill and Eject: Watching the fill and eject of the blood pump allows the care team to determine optimal settings and fluid balance.

Membrane Function: The care team will watch the membrane movement to make sure it is working well.



Blood Pump WITHOUT a Clot



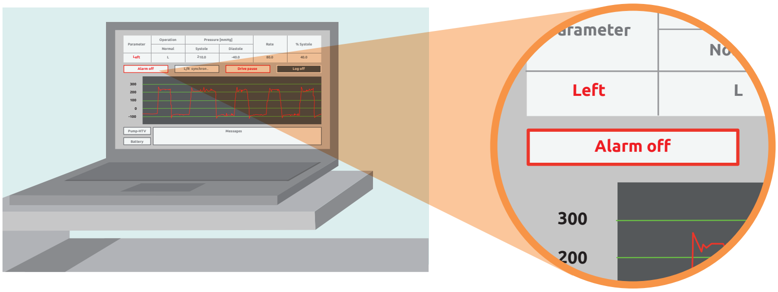
Blood Pump WITH a Clot

Alarms

Alarms can be loud and scary, but they are designed to let the care team know when your VAD needs attention.

When an error message occurs, the following happens:

- An acoustic signal sounds (two different beep sounds).
- The indicator light on the control panel of the handle and the monitor light up.



NOTE:
When you hear an alarm contact your care team immediately!

Most Common Error Message:

Please Check Left / Right Pump and Driving Tube: The IKUS has detected an improper flow. This is most commonly caused by a kink in one of the cannulae.

Routine Device Care

Safety Tips

Blood Pump, Cannulae & Driving Tube

- **It is important to protect the blood pump, cannulae and the driving tube.** Do not stretch, pull, kink or do any activity, such as belly flops, that could put stress on any of them. These actions may cause the cannulae and blood pump to not work properly which will cause harm to your child.
- **Do not use pointed or sharp-edged objects near any of the Berlin Heart components.** The blood pump and cannulae could be damaged causing a leak. A leak could cause your child to not get enough blood flow.

IKUS Driver

- **Protect the IKUS from exposure to moisture and wetness.** Do not use water or fluids near the IKUS. There is a risk of a short circuit or a malfunction of the device if it gets wet. Never store or use the IKUS in a damp environment (e.g. bathroom, etc.).
- **Never unplug the IKUS.** Your care team is trained to safely disconnect the IKUS if necessary. If the IKUS doesn't have enough power, it could stop pumping, causing your child to not get enough blood flow.
- **Do not cover the IKUS air vents.** The IKUS could overheat if the vents are blocked and may have a malfunction in device operation that would cause your child to not get enough blood flow. Protect the IKUS against extreme temperature changes (e.g. direct sunlight or heaters).
- **Place the IKUS driving unit on a firm and even surface.** Never place objects on top of the IKUS driving unit. If the objects fall, they could cause damage to the IKUS.
- **Avoid exposure to strong electromagnetic radiation.** When using a cell phone make sure to keep a distance of at least 3 feet away.

4

A Lot to Learn

- Labs
- Tests
- Medicines
- Nutrition & Hydration
- Routine Baby Care
- Cannula Care
- Emotional Wellbeing

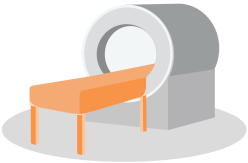
Labs

Laboratory testing (labs), including blood draws, will occur both at scheduled times and whenever the care team thinks it's necessary. Requested labs may include the following:

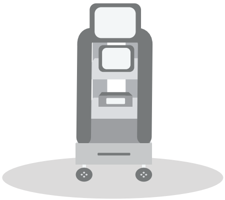
ANTICOAGULATION	
Heparin Level or Anti-Xa	♥ measures how thick the blood is when on Heparin or Lovenox
PT/INR	♥ measures how thick the blood is when on Warfarin
PTT	♥ test performed as frequently as every 6 hours when on IV medications ♥ measures how thick the blood is when on Heparin or Bivalirudin
DTT	♥ measures how thick the blood is when on Bivalirudin
LDH	♥ shows if red blood cells are breaking, signaling there may be a clot in the device or settings may need to be adjusted
CARDIAC	
BNP	♥ helps monitor fluid status and how well the heart and VAD are working together
HEMATOLOGY	
CBC	♥ measures red blood cells, white blood cells and platelets in the blood
KIDNEY	
Renal (BUN/ Creatinine)	♥ monitors ***kidney*** function and measures fluid status and electrolytes
LIVER FUNCTION	
Hepatic Profile	♥ measures how well the ***liver*** is functioning
INFECTION & INFLAMATION	
CRP	♥ measures if there is any infection or inflammation within the body

Tests

Tests will be performed at scheduled times and additional ones can be requested whenever the care team thinks it's necessary. Tests include:



CT Scan: If the care team is concerned about the cannulae, they may order a CT scan of the heart. A CT scan of the head may be performed if there is a concern for ***stroke.***



Echocardiogram: An "Echo" is an ultrasound that uses nonradioactive, high-frequency sound waves to view the heart. An Echo is a non-invasive test to help the care team diagnose any heart or device problems.

IMPORTANT **Once you have a VAD, DO NOT have an MRI test**. A MRI uses strong magnets that attract metal objects and would damage your VAD.

Medicines

Below is a list of medicines that may be taken. Check off the medicines you are taking and write in any additional ones that are not listed below.

- ☐ Aspirin
- ☐ Warfarin (Coumadin)
- ☐ Bilvalirudin (Angiomax)
- ☐ Heparin
- ☐ Enoxaparin sodium (Lovenox)
- ☐ Clopidogrel (Plavix)
- ☐ Dipyridamole (Persantine)
- ☐ Enalapril/Lisinopril
- ☐ Hydralazine
- ☐ Clonidine
- ☐ Amlodipine
- ☐ Antibiotics
- ☐ Acid Reflux Reducers
- ☐ Furosemide (Lasix)
- ☐ Chlorothiazide (Diuril)
- ☐ Spironolactone (Aldactone)
- ☐ Sildenafil (Revatio)
- ☐ ____________________
- ☐ ____________________

information above completed on ____/____/_____

Medicines

Blood Thinners

When you are on a VAD, you will usually be taking blood thinner medicines.

Aspirin, Clopidogrel (Plavix), Dipyridamole (Persantine): You will usually take one or more of these medicines to prevent platelets from sticking together and forming a clot in your VAD.

Bivalirudin (Angiomax), Heparin, Enoxaparin sodium (Lovenox): Once you are ready, you will start blood thinning medicine to help treat and prevent blood clots. While on bivalirudin, heparin, or enoxaparin sodium you will need frequent labs performed to monitor the thickness of your blood. The dose of medicine will be adjusted based on the lab results.

Warfarin (Coumadin): Once your care team determines the time is right, you may take warfarin pills by mouth. The dose needed will go up and down frequently depending on your INR and it can take a number of days to get it right. Once your dose is correct, your IV blood thinner medicine will be turned off. Warfarin is what makes your INR (blood levels for ***anticoagulation*** or how thick or thin your blood is) increase. Below are causes for:

High INR *(thin blood)*

- New medicines
- Prolonged vomiting/diarrhea*
- Prolonged inability to eat*
- **Decrease** in food/drink containing vitamin K

**Discuss with your care team*

Low INR *(thick blood)*

- Missed doses of warfarin
- **Increase** in food/drink containing vitamin K
- increase in activity

Blood Pressure

On a VAD, you may have high blood pressure, which will prevent the VAD from pumping blood to the rest of your body well. Your care team will determine a target blood pressure goal. Blood pressure medicine examples include:

- Enalapril
- Clonidine
- Amlodipine
- and other medicines

Preventing Infection

Antibiotics are given in the operating room and ICU to prevent infection. They are also given if your cannula gets infected. You may need antibiotics indefinitely to prevent infection.

Acid Reflux

Medicines to prevent “heartburn” are used to decrease the acid in the stomach. This may help with decreasing your stomach discomfort.

Extra Body Water (Diuretics)

Diuretics were important when you were in heart failure. When you are on a VAD you should require less, but you still may need a small amount to get the fluids in your body just right. Examples include:

- Furosemide (Lasix)
- Chlorothiazide (Diuril)
- Spironolactone (Aldactone)

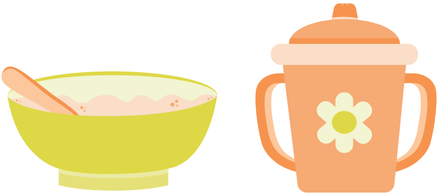
Steroids

Sometimes the VAD can trigger an inflammatory response. This can cause fevers and an increase in your CRP lab value. It can also increase the risk of forming a clot. Your care team may use a steroid to decrease the inflammation.

information above completed on ____/____/_____

Nutrition & Hydration

Once you have your VAD, you must be on a healthy and ***consistent diet.*** This will help you heal and get stronger.



Fluids

To function properly, the VAD needs a certain amount of fluid flowing through it. ***Preload*** is the amount of fluid in the body or how "full" the heart is. Being ***dehydrated*** from not drinking enough or increased fluid losses (vomiting, diarrhea, sweating) will lead to low preload. High preload is usually caused by drinking too much or not peeing enough.

With **low preload** (dehydrated) you may experience:

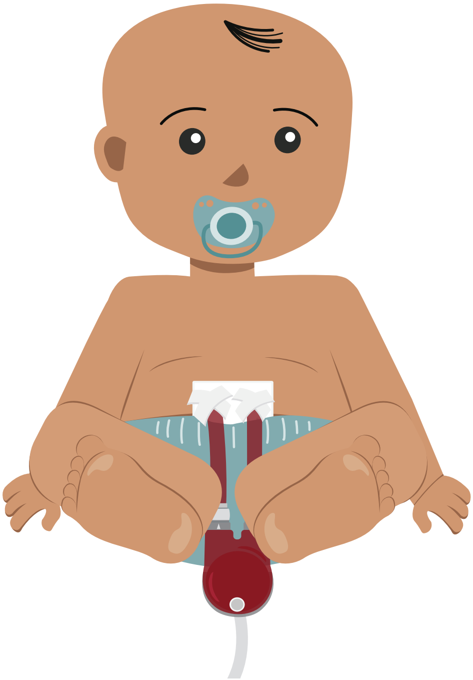
- lightheadedness, tiredness, falls
- poor filling of the VAD

With **high preload** (fluid-overload) you may experience:

- swollen face, hands, or legs
- poor appetite
- shortness of breath

Your care team will track your weight and fluid intake to know if your fluid balance is off. To make sure there is a perfect fluid balance, medicines (diuretics) are given to help get rid of extra fluid. In some cases, your care team may need to put restrictions on how much fluid you are able to drink as well.

Routine Baby Care



When your child is in the ICU, changing a diaper, clothing, holding, and feeding your child will seem challenging at first. As lines and tubes are removed, the simple tasks that help you bond with your child will become easier. Ask your care team to teach you the safest way to perform routine baby care activities. If available at your care center and your care team says you are ready, here is a list of activities your child may be able to do:

- be held and visit with family members
- play under an activity mat, in an exersaucer, or sit in a bouncy chair
- sit at a table or in a high chair (eat in the cafeteria)
- visit the physical therapy gym
- walk around on the unit (do scavenger hunts)
- walk around outside (visit a garden)
- ride in a stroller or on a tricycle

Routine Baby Care

Changing Diapers/Using the Bathroom

The blood pump will rest directly in between your child's legs making it difficult to change a diaper or assist your child when using the bathroom. With guidance from your care team, you may gently lift the blood pump upward to remove a soiled diaper, clean the soiled area, and secure a new diaper. If the IKUS sounds an alarm, it may be indicating the blood pump was lifted too high. Gently lower the blood pump to stop the alarm.

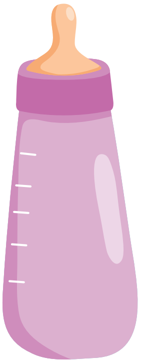
Bathing and Clothing

Due to the risk of infection your child will not be able to be fully submerged in a bath tub. You may, however, be able to use a wet wash cloth and basin of warm water to wipe your child down each day. Clothing options are limited because of the blood pump, but there are some options that work better including: wrap style garments, two piece clothing options, and shirts or sleepers with snaps.

Holding and Feeding

It is natural to want to hold and comfort your child especially when they are upset. When the care team determines it is safe, you will be able to hold your child and/or assist with feeding. The care team may ask you to practice sternal precautions which are guidelines that prevent injury to the sternum (chest bone) before it has healed from surgery. These guidelines include not lifting your child directly from under the arms, no tummy time, and no pulling or pushing against the arms for several weeks after surgery.

Good nutrition is essential for healing and growth. Younger children may require a feeding tube to help supplement calorie needs or prevent complications with swallowing. Talk to your care team about any possible food, fluid or feeding restrictions.



Cannula Care

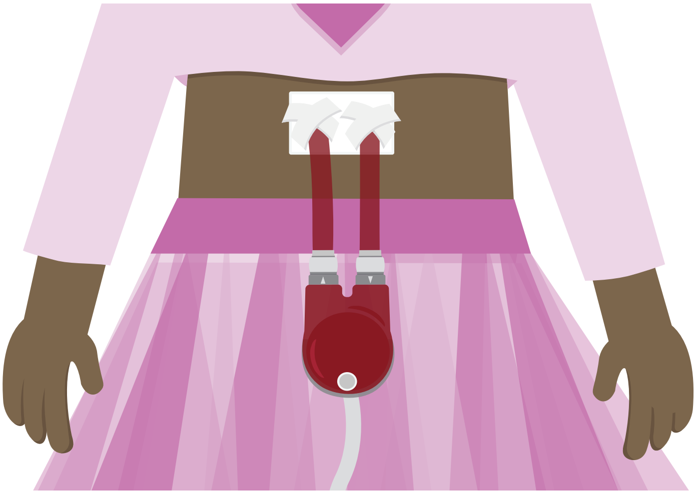
If an infection develops on or around a cannula site, it can be very serious. Depending on how bad, the infection may be treated with IV or long-term antibiotics taken by mouth.

It's important to properly care for the cannula site to prevent infection. Germs that collect at the cannula site could travel to the heart if left untreated.

Frequent movement of the cannula can cause damage above and underneath the skin and increase the risk of infection.

Dressing Changes: Your cannula site will need to have ***dressing*** changes using ***sterile*** technique. Everyone should use sterile gloves and wear masks during dressing changes. How often your dressing is changed will be determined by your care team.

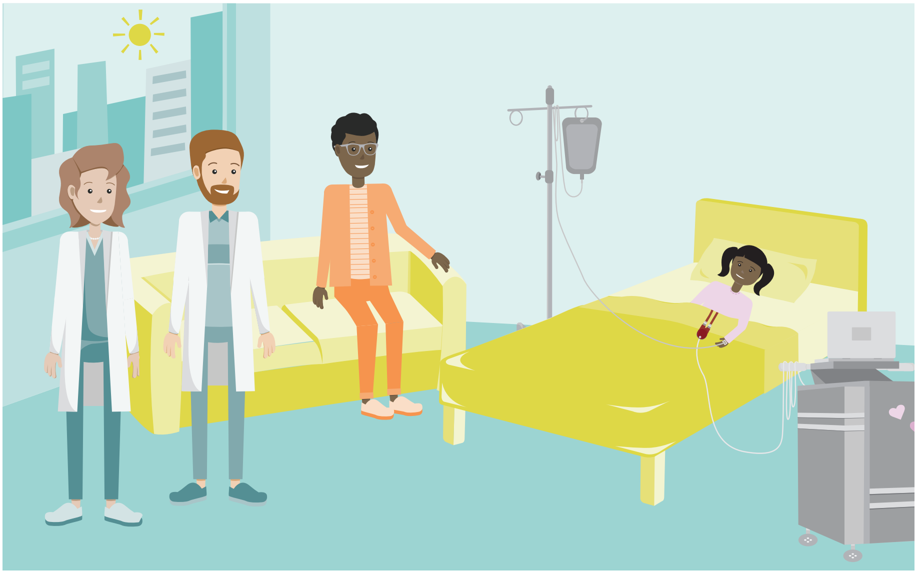
My dressing will be changed every ________ day(s).



information above completed on ____/____/_____

Emotional Wellbeing

For some patients, having a VAD and needing lots of medical care can be hard. You or your caregiver may feel sad, worried, or even angry at times. Taking care of your emotional and mental health is a very important part of your care. Be sure to talk with your care team if you have these feelings or any changes in behavior. Your care team will be able to connect you with the right support services.



5

Potential Challenges

- Infections
- Strokes
- Bleeding
- Right Heart Failure
- Pump Clots or Malfunction

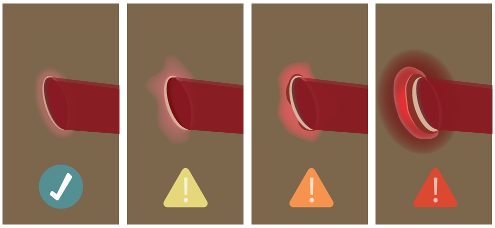
Infections

When you come out of the operating room you will be on antibiotics to help prevent infection. Everything will be kept as clean as possible to ensure good ***hygiene.*** Your care team will perform frequent dressing changes to prevent germs from causing an infection at your surgical and cannula sites.

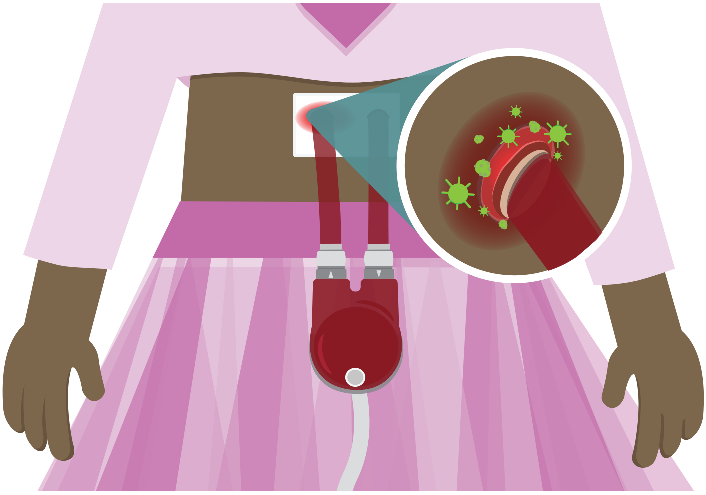
If an infection develops in or around your cannula, it can be very serious. Most infections can be treated with antibiotics and changes to your dressing care. If the infection becomes more severe and spreads to your blood, it is called ***sepsis*** or bacteremia. This will need to be treated with antibiotics through an IV.

Signs and symptoms of a cannula infection include:

- Redness
- Pain or tenderness
- Drainage
  (new or increased)
- Swelling and warmth
- Fever



None **Mild** **Moderate** **Severe**

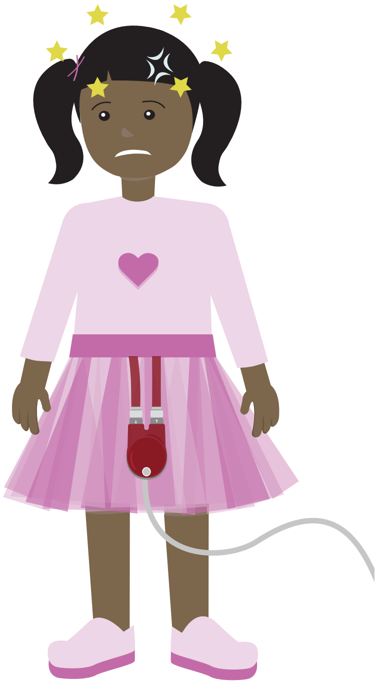


Strokes

With all VADs there is a risk of stroke, which is caused by bleeding or a blood clot in your brain. Both may cause injury to your brain. Your care team manages your medicines carefully to prevent strokes; however sometimes strokes may occur.

Symptoms or signs that may occur with a stroke:

- Headaches that are different than usual
- Numbness and/or tingling on one side of the body
- Weakness on one side of the body
- Losing feeling and/or movement in the legs or arms
- Slurring words or trouble when talking
- Facial expressions and movements don't match (or mirror) on each side of the face
- Pupil (the dark circle in the middle of the eye) sizes don't match



Bleeding

When taking blood thinner medicines, you are always at risk of bleeding.

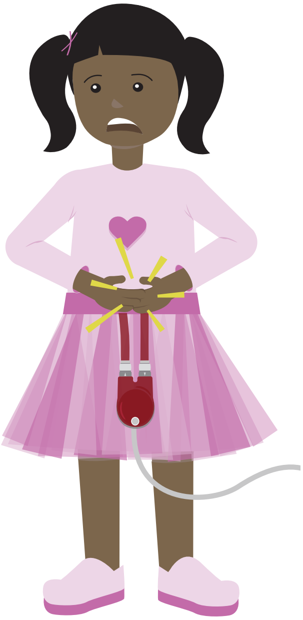
When you are in the ICU, you may have bleeding in your chest from the surgery. Later, you might have bleeding from other places such as your nose, belly, or at your cannula sites.

Chest Bleeds: After surgery, there will be some bleeding in your chest that is captured and removed by the chest tube. In most cases, a blood transfusion will be given to replace lost blood. When the bleeding has slowed, ***anticoagulation*** medicines (blood thinners) will be started to prevent the pump from getting a clot inside of it. In rare cases, you may need to go back into surgery in order for your surgeon to stop the bleeding.

Gastrointestinal (GI) Bleeds: In rare cases, a more serious bleed in your belly may occur. Signs and symptoms of a GI bleed include:

- Belly pain and no appetite
- Vomit with blood in it
- Black, tarry, or sticky stools

Nose Bleeds: Blood thinners often can lead to nose bleeds. Talk to your care team on ways to prevent nose bleeds.



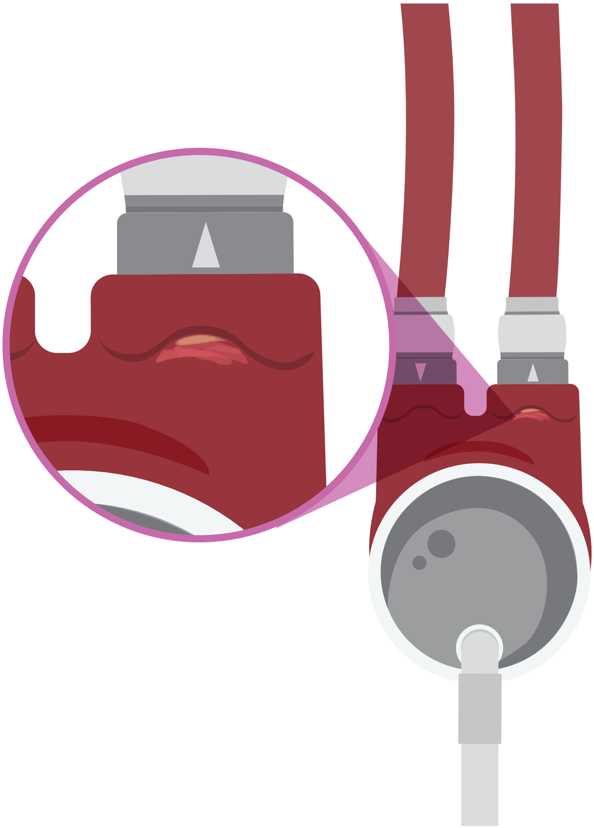
Right Heart Failure

It's difficult to predict how the right side of the heart will handle LVAD surgery. If your child has an LVAD, the right side of the heart has to be able to move blood to the left side of the heart. When it doesn't, this is called "right heart failure." In some instances, you may need to remain on IV medicines or even need a second VAD to help the right side of the heart move blood to the left side of the heart.

Pump Clots or Malfunction

The care team will watch for clots in the Berlin Heart. They will easily use a flash light and a mirror to examine the pump everyday. It is not unusual to see light spots in the pump. If the spots become dark in color, start to move around, or grow in size quickly, the care team may decide to change out the blood pump. This can happen at the bedside, but in rare cases you may need to go back into surgery. To change the blood pump, the cannulae are clamped and the blood pump is switched out for a brand new one. This is a very quick and painless procedure.

It's also possible for the blood pump to have membrane or valve issues. Your care team will be watching closely for signs of these issues and may change the blood pump if they feel it's necessary.



6

Your Journey Continues

- The Waitlist
- Recovery

The Waitlist

With heart failure, patients often feel uncomfortable, sad, frustrated, or even angry. Our goal is to help you feel better and get back to doing the things you enjoy. A VAD should help to relieve the symptoms of heart failure, although it may take a while to see the benefit. Always discuss how you feel with your care team so they can help you achieve the best quality of life possible.

Waitlist Video: If you are on the waitlist for transplant and want more information about how ACTION can help with your journey, visit ***actionlearningnetwork.org*** or the ***ACTION YouTube channel*** to watch our waitlist video.

Recovery

In rare occasions, some patients will recover their own heart function while on the VAD. The care team will be watching closely for signs of recovery.

If the care team thinks the heart is recovering, they may suggest the pump settings be turned down to see what the heart can do on its own. They may also start medicines to help the heart heal. If positive signs of recovery are seen, the care team will follow an established protocol to determine if there is enough recovery progress made and it's possible to take out the Berlin Heart.

7

Glossary

- Glossary
- Word Search

Glossary

Antibiotics: Medicines to treat bacteria and germs.

Anticoagulation: Medicines to make your blood thinner so your VAD pump does not clot.

Aorta: The large artery that brings blood from the heart to the rest of the body.

Clot: When red blood cells stick together to form a 'glob' in one of your blood vessels. Similar to a scab.

Complications: A disease or problem that happens in addition to the first disease.

Consistent Diet: Always eating the same kind of foods.

Dehydrated: When you do not drink enough water, or you have diarrhea, the volume of fluid in your body goes down. This can make your pump not work as well.

Diagnosis: Determining the cause of the disease or problem.

Diuretics: Medicine to make you pee more.

Dressing: A bandage around the driveline that is coming out of your belly.

Hygiene: Keeping yourself clean to prevent infection.

Implant/Implanted: During surgery your VAD is placed in your heart.

Intensive Care Unit (ICU): A place in the hospital where patients recover after surgery when they leave the operating room.

Kidney: The organs in your body that remove waste and make pee.

Liver: The organ in your body that cleans the blood.

Preload: The amount of fluid that travels through your blood vessels to your heart.

Sepsis: An infection in your blood which can make you very sick.

Sterile: Keeping a wound clean. Using a procedure that includes clean gloves and masks to make sure germs do not get near the driveline.

Sternotomy: An incision in the chest bone that is made by the surgeon to get to your heart.

Stroke: When a blood clot travels to your brain through a blood vessel.

Word Search

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          W Z X A             N A C V
        N L W N N L         V M L O V D
      G L O T W S G U     H N M F M T A T
    Q W B J I D R M N E B C Y Y T P V O O V
  D E T E I D T N E T S I S N O C L R L L Q E
C E R Y F F V G A D V D V H J I P I C E C M J Z
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☐ Antibiotics
☐ Anticoagulation
☐ Aorta
☐ Clot
☐ Complications
☐ Consistent Diet
☐ Dehydrated
☐ Diagnosis
☐ Diuretics
☐ Dressing
☐ Hygiene
☐ Implant
☐ ICU
☐ Kidney
☐ Liver
☐ Preload
☐ Sepsis
☐ Sterile
☐ Sternotomy
☐ Stroke

Berlin Heart®

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Rx Only

Brief Summary: Prior to using the Berlin Heart EXCOR® Pediatric VAD, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Berlin Heart EXCOR® Pediatric Indications: The Berlin Heart EXCOR® Pediatric VAD is intended to provide mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients. Pediatric patients with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support may be treated using the EXCOR Pediatric.

Berlin Heart EXCOR® Pediatric Contraindications: Patients unable to tolerate systemic anticoagulation therapy should not be implanted with The Berlin Heart EXCOR® Pediatric VAD. Magnetic Resonance Imaging (MRI) is contraindicated in patients after being implanted with the EXCOR® Pediatric VAD. Patients with aortic valve regurgitation that is more than moderate that cannot be repaired at the time of implantation should not be implanted with the EXCOR® Pediatric VAD. If repair of the aortic valve regurgitation requires surgical closure of the aortic valve, the EXCOR® Pediatric VAD should not be implanted. The EXCOR® Pediatric VAD is not intended to be used as a total artificial heart and should not be used in this configuration.

EXCOR® Pediatric Adverse Events: Potential Adverse Events may include but are not limited to the following: major bleeding, cardiac arrhythmia, pericardia fluid collection, hemolysis, hepatic dysfunction, hypertension, infection, psychiatric episode, neurological dysfunction, renal dysfunction, respiratory failure, right heart failure, arterial non-CNS thromboembolism, venous thromboembolism, wound dehiscence, device malfunction.

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09.2021