Introduction to Ventricular Assist Device (VAD)

action
ADVANCED CARDIAC THERAPIES
IMPROVING OUTCOMES NETWORK

Overview Objectives

1. Defining Pediatric Heart Failure
2. Patient Selection for a VAD
3. Device Types: Pulsatile vs. Continuous Flow
4. Patient Management Highlights

1

Defining Pediatric Heart Failure

Diagnosis of Heart Failure

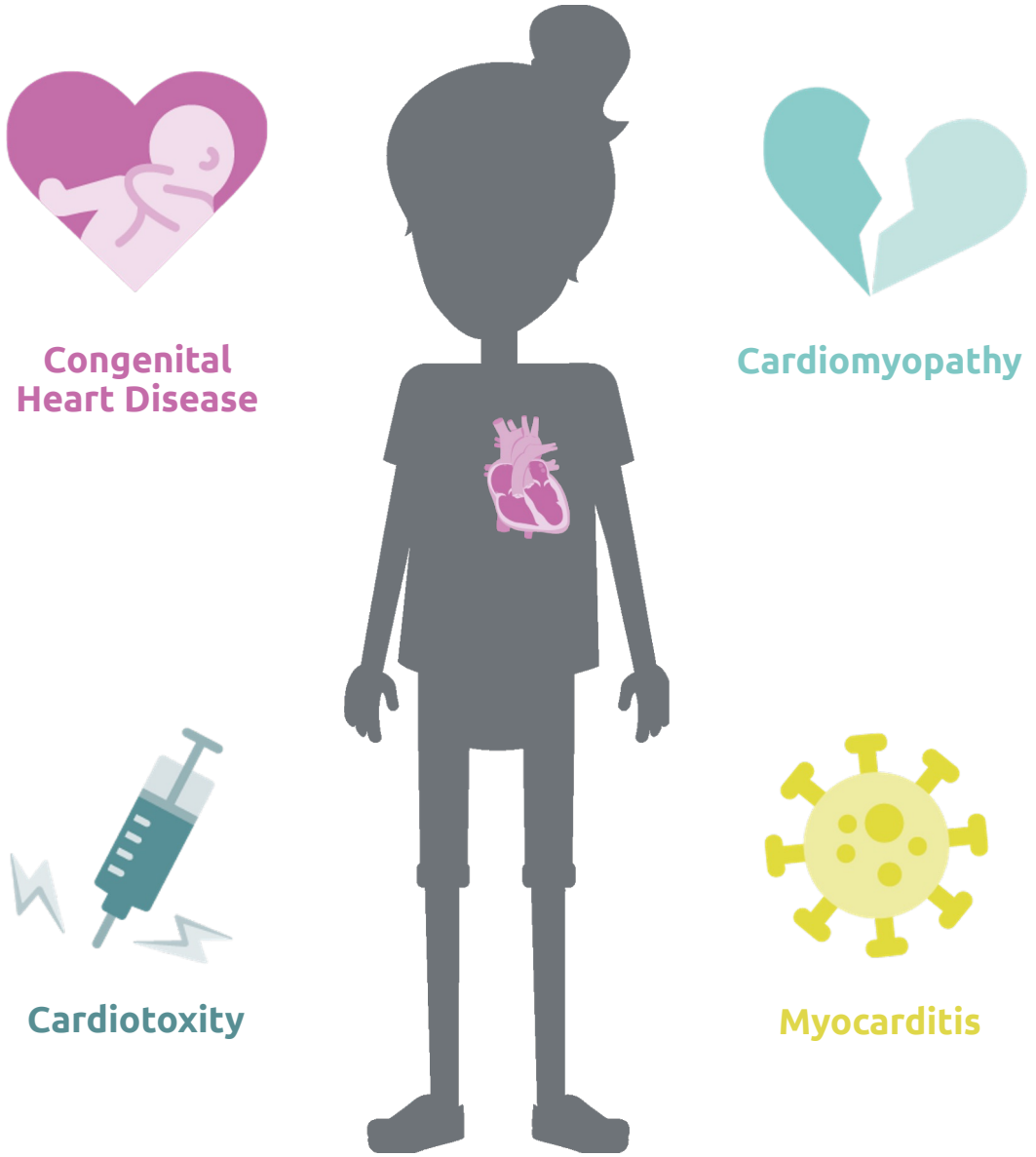
Definition:

A clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection. Cardinal symptoms include breathing difficulty, feeding intolerance, and decreased activity.

–ACTION Heart Failure Committee

Different Etiologies of Pediatric Heart Failure

1. **Congenital Heart Disease (CHD)**
2. **Cardiomyopathy**
   - Dilated
   - Restrictive
   - Hypertrophic
3. **Myocarditis & Cardiotoxicity**

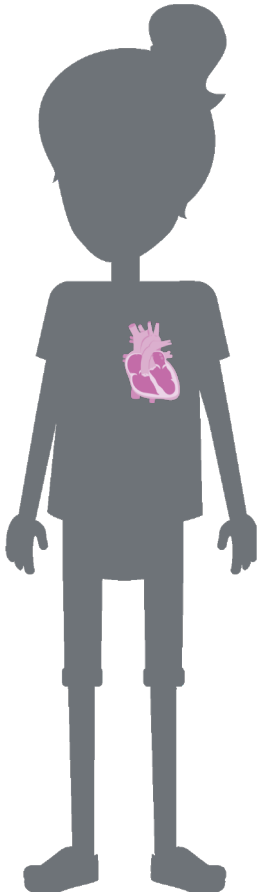


1 Congenital Heart Disease

Overview:

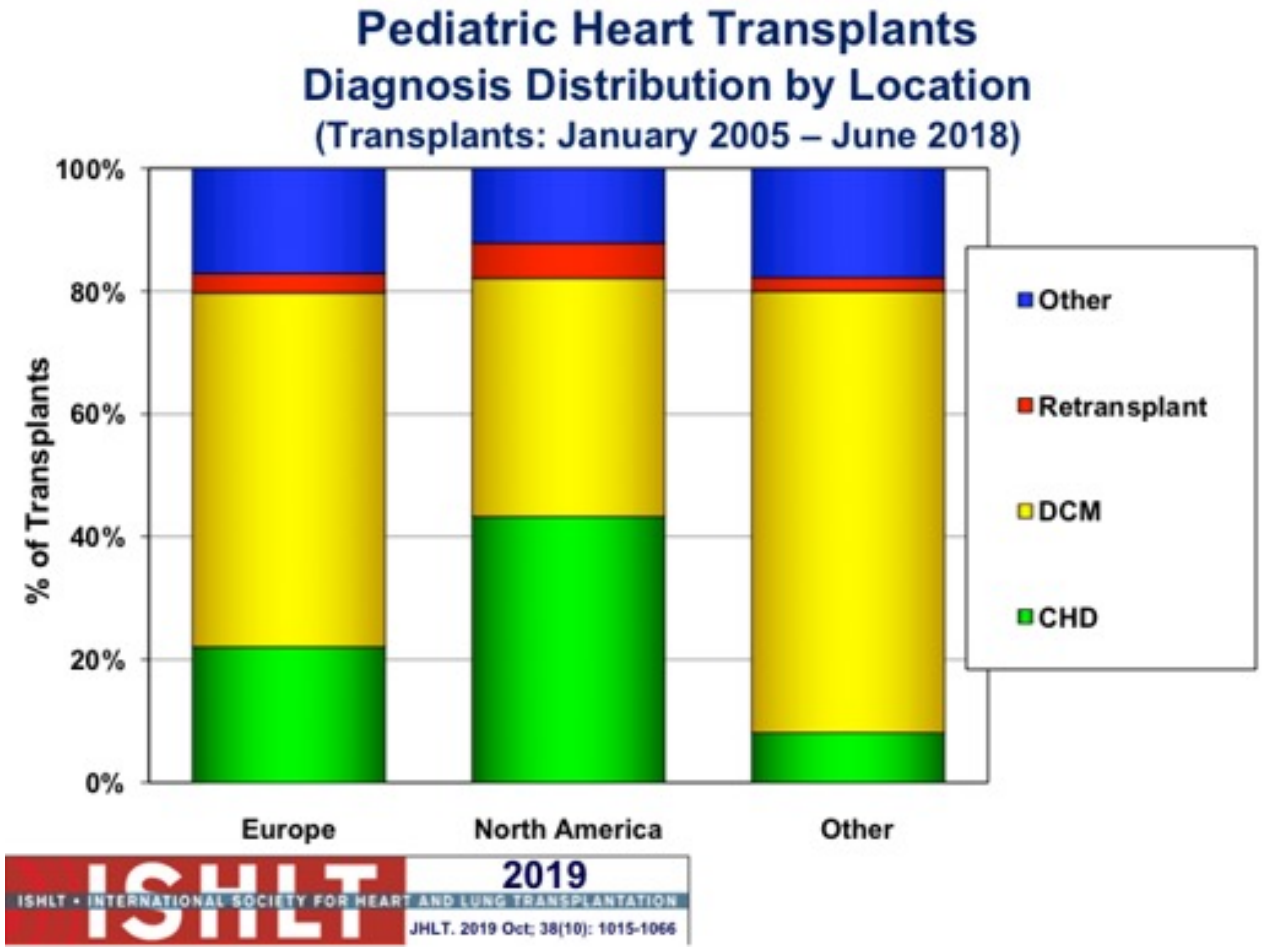
- When heart chambers and connections are not formed properly during fetal development, surgeries to correct the anatomical defects may cause stress and damage to the heart.
- Majority of patients with heart failure associated with CHD have single ventricle physiology.

Congenital Heart Disease



Many pediatric heart failure patients that need advanced therapies have congenital heart disease.

- The indication for >40% of all North American pediatric transplants is congenital heart disease and many of these children need a VAD to support them while they are awaiting a suitable donor.
- For more information, visit: *https://ishltregistries.org/registries/slides.asp?yearToDisplay=2019*

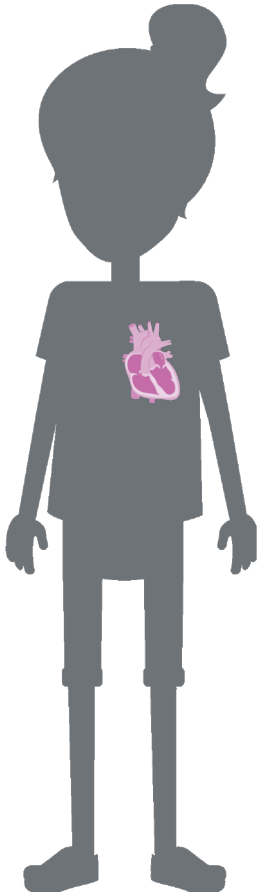


2 Cardiomyopathy

Overview:

- An abnormality of the heart muscle that may be present from birth or can be caused by other diseases
- **Types include:**
  - Dilated Cardiomyopathy
  - Restrictive Cardiomyopathy
  - Hypertrophic Cardiomyopathy

Cardiomyopathy



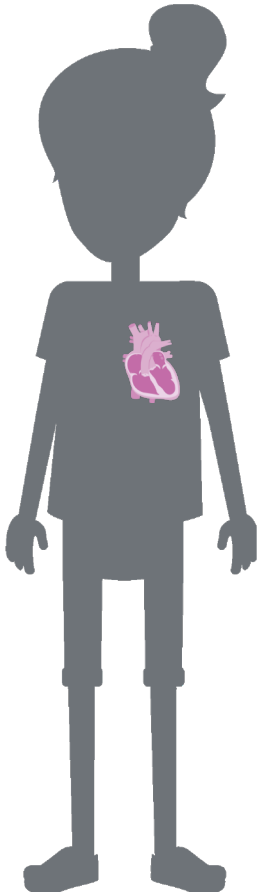
3 Cardiotoxicity & Myocarditis

Overview:

- **Cardiotoxicity:** Heart muscle injury often caused by certain medications and treatments, such as chemotherapy or radiation
- **Myocarditis:** A heart muscle injury often caused by certain infections

Cardiotoxicity

Myocarditis



2

Patient Selection for a VAD

VAD Therapy in Pediatric Advanced Heart Failure

What is a VAD?

- A device used to support patients (who do not respond to medical management) with advanced heart failure.

How does a VAD work?

- A VAD is implanted to bypass or augment the function of one or both ventricles of the heart. It circulates blood to vital organs.

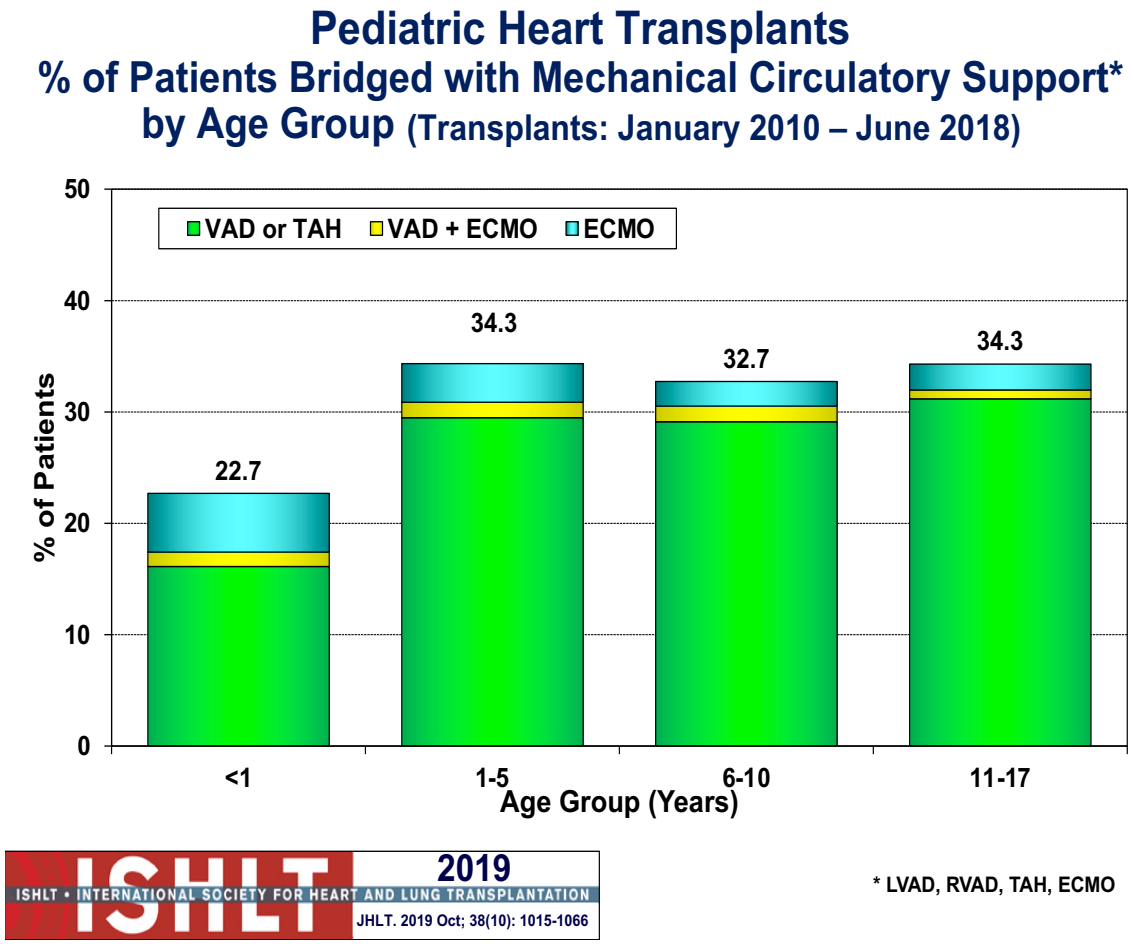
VAD Therapy in Pediatric Advanced Heart Failure *continued…*

What are the challenges of pediatric VAD therapy?

- The varied age and size range of the pediatric population.
- The various etiologies of pediatric heart failure.
- The complex anatomical structures of congenital heart disease patients.
- Difficult to predict when a child needs a VAD. Often decompensates quickly.

VAD therapy is becoming increasingly more common.

- The percent of patients that need a VAD as a bridge to transplant varies with the age of the child.
- 1/3 of patients are supported to transplant with a VAD.
- For more information, visit: *https://ishltregistries.org/registries/slides.asp?yearToDisplay=2019*



VAD Implantation Indications

- Decompensated heart failure unresponsive to medical management
- Escalating inotropic support
- End-organ dysfunction
  - Liver Failure
  - Renal Failure
  - Respiratory Failure
  - Poor nutritional status
  - Decreased activity

VAD Implantation Contraindications

- Bleeding or clotting disorders
- Severe neurological deficits
- Irreversible end organ dysfunction
- Social support or nonadherence concerns (rarely)

Patient Selection: When does a child need a VAD?

INTERMACS Profiles

Profile	Description
1.	Critical cardiogenic shock (33% of pediatric patients)*
2.	Progressive decline on inotropic support (55% of pediatric patients)
3.	Stable but inotrope dependent
4.	Resting symptoms home on oral therapy
5.	Exertion intolerant
6.	Exertion limited
7.	Advanced NYHA Class lll symptoms

**3rd annual Pedimacs Report*

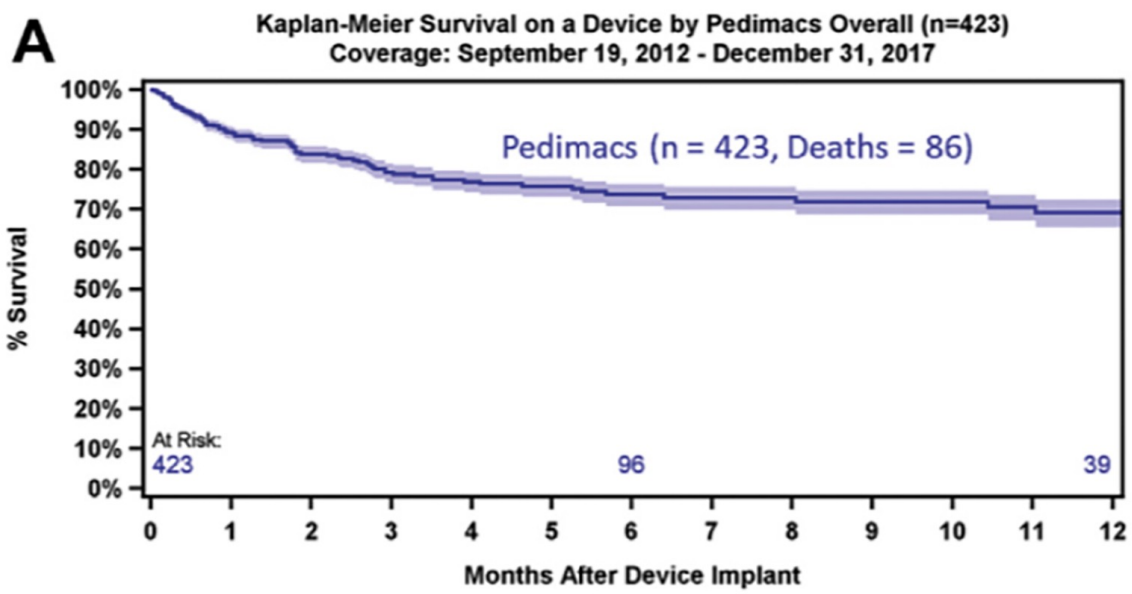
NYHA, New York Heart Association

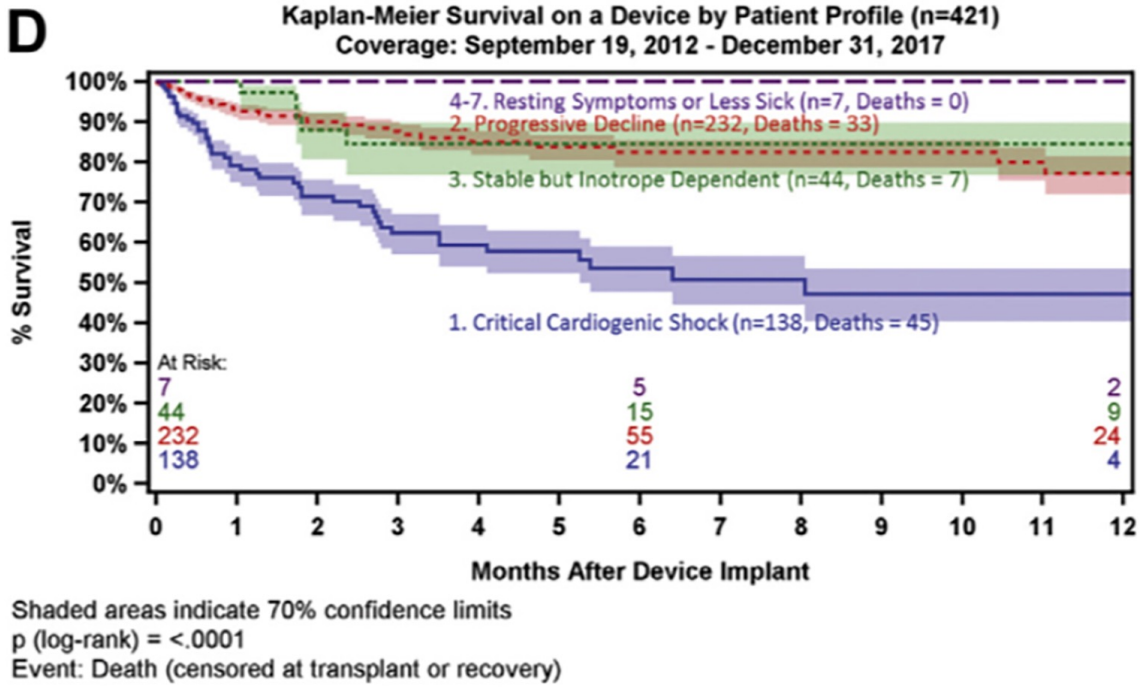
NOTE:

Outcomes are better if implanted before the patient becomes a profile 1. Timing is difficult to predict in children.

The sicker the patient is at implant, the less likely they are to survive.

- INTERMACS 1 patients have a 50% survival at 6 months
- INTERMACS 2 and 3 patients have an 80–90% survival





Morales DLS. Third Annual Pediatric Interagency Registry for Mechanical Circulatory Support (Pedimacs) Report: Preimplant Characteristics and Outcomes. Ann Thorac Surg. 2019 Apr;107(4):993-1004.

Patient Selection: Pediatric VAD Support Options by Age

Pediatric Subpopulation	Approximate Age Range	VAD Support Options
Newborn / Infant	Birth to 1 month of age. 1 months to 2 years of age	Berlin Heart EXCOR ®, CentriMag™/PediMag™/RotaFlow™
Child	2 to 12 years of age	Berlin EXCOR®, HVAD™ System, HeartMate 3™ LVAD, CentriMag™/PediMag™/RotaFlow™
Adolescent	13 to 21 years of age	HVAD™ System, HeartMate 3™ LVAD, SynCardia Total Artificial Heart (TAH-t), CentriMag™/PediMag™/RotaFlow™
Young Adult	22 + years of age	HVAD™ System, HeartMate 3™ LVAD, SynCardia Total Artificial Heart (TAH-t), CentriMag™/PediMag™/RotaFlow™

The FDA, for the purposes of medical devices, classifies anyone through the age of 21 as pediatric due to biological factors (under 22 years old).

Therapeutic Goals (Bridges) for VAD Implantation

Bridge to Transplant (49%)*
- Support the heart until the patient can receive a new heart

Bridge to Recovery (7.6%)
- Temporarily support the heart while the function stabilizes
- Explant the device

Bridge to Eligibility/Decision (38%)
- Unsure of long term: recovery vs transplant/destination

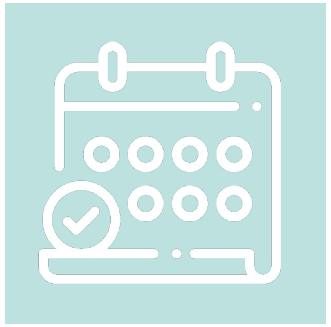
Destination Therapy (1.3%)
- Not a transplant candidate but desire to improve quality and quantity of life
- Patient will have VAD indefinitely

**3rd annual Pedimacs Report*

Support Duration

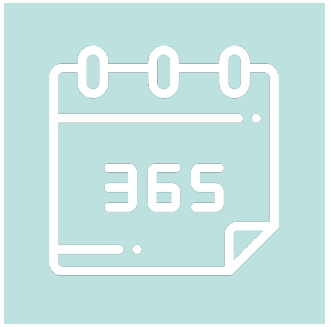
Short Term

- Use for weeks/months
- Potential of recovery or unsure of long-term plan for patient
- Patient must stay in the hospital



Long Term

- Use for months/years
- Usually for bridge to transplant or destination therapy
- Patient may be able to be discharged



Flow Delivery

Pulsatile Flow VADs

- Operate by using a pneumatic air compressor that delivers air to a two-sided pump.
- Device is set by systolic/diastolic pressures, rate, and percent systole. It mimics the movement of the heart with ejection and fill phases.
- The patient is pulsatile due to the device ejecting the blood to the body.

Device examples:

- Berlin Heart EXCOR®*
- SynCardia Total Artificial Heart (TAH-t)*

Continuous Flow VADs (CF VADs)

- Operate by using an impeller or rotor, a round disc with blades, that spins and propels blood forward.
- Device is set by revolutions per minute (RPM).
- The patient may not have palpable pulse.

Device examples:

- HeartMate 3™ LVAD*
- HVAD™ System
- CentriMag™/PediMag™
- Rotaflow™

*approved pediatric use

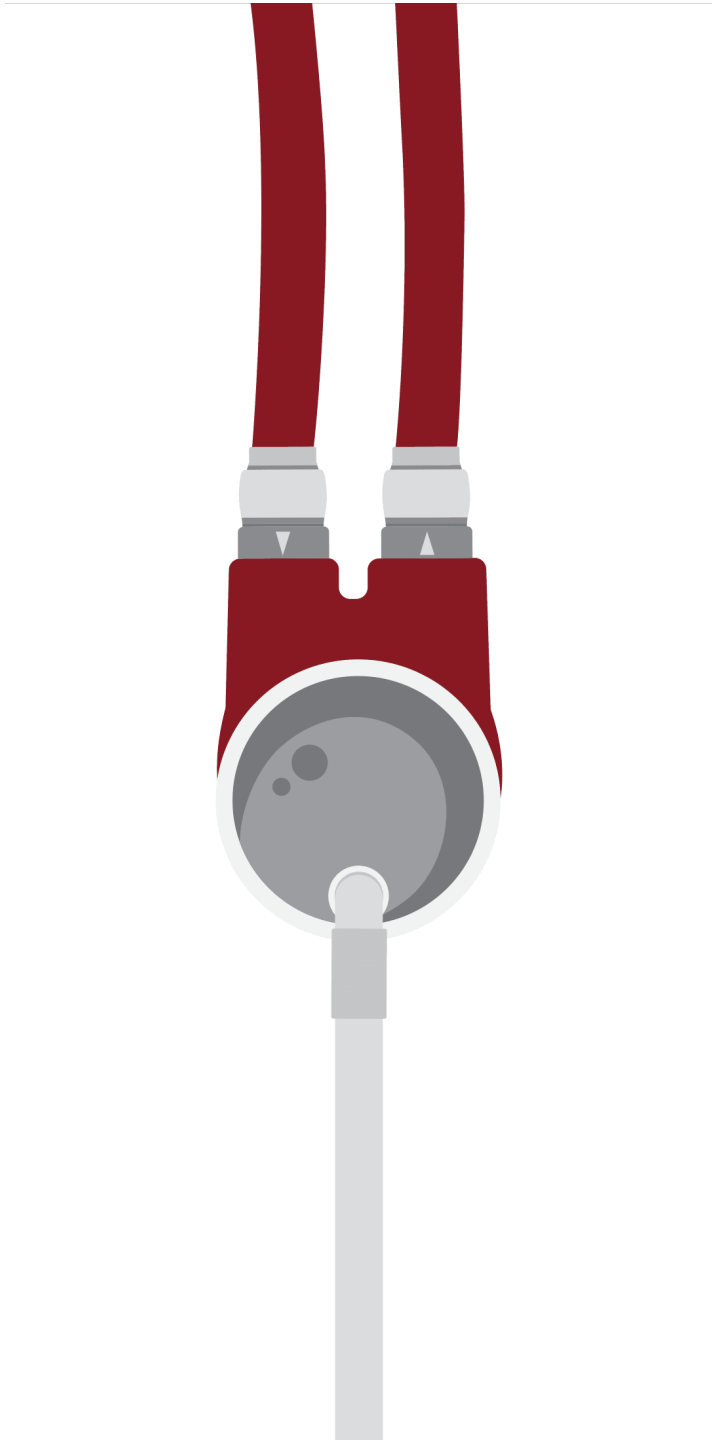
3

Device Types: Pulsatile vs. Continuous Flow

Pulsatile Flow Principles

Pulsatile devices have a two-sided chamber (air on one side and blood on the other) separated by a strong flexible membrane:

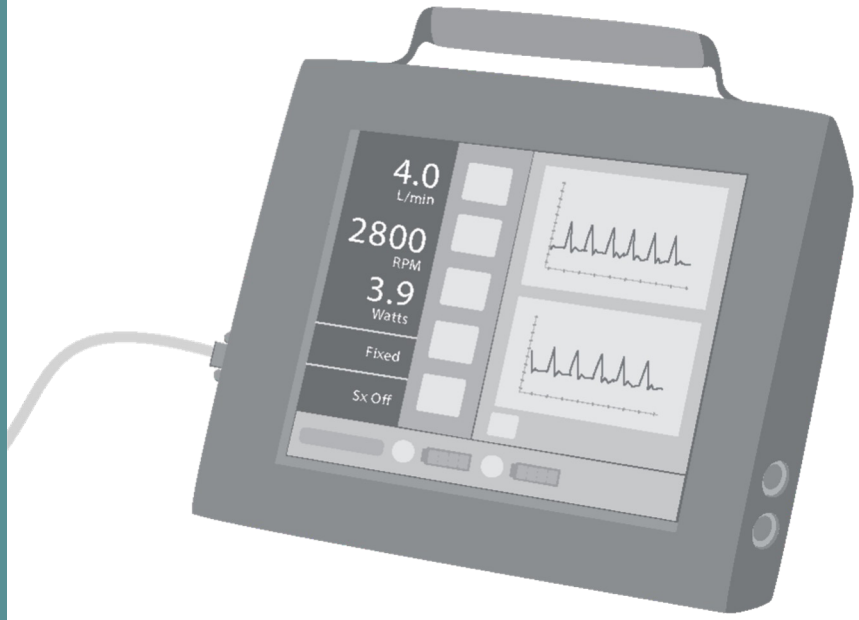
- The blood chamber is connected directly to the heart, which fills with blood during every beat.
- The air chamber is connected to the pneumatic driver that pushes and pulls air against the membrane. As the membrane moves, the blood fills and ejects through the blood side.
- The care team will alter the air pressure and the beats per minute to give the patient the right amount of blood flow for them.



Continuous Flow Principles

Continuous flow devices have an impeller or rotor that spins and sends blood out to the body:

- Revolutions per minute (RPM) is the number of times the impeller/rotor spins per minute and is the only thing the care team can change.
- Power is measured in Watts and is the energy it takes to move the impeller/rotor.
- Flow is the cardiac output that the device generates. It is calculated based on an algorithm of blood viscosity (HCT) and power.



4

Patient Management Highlights

Optimizing the Pump

Optimize Preload

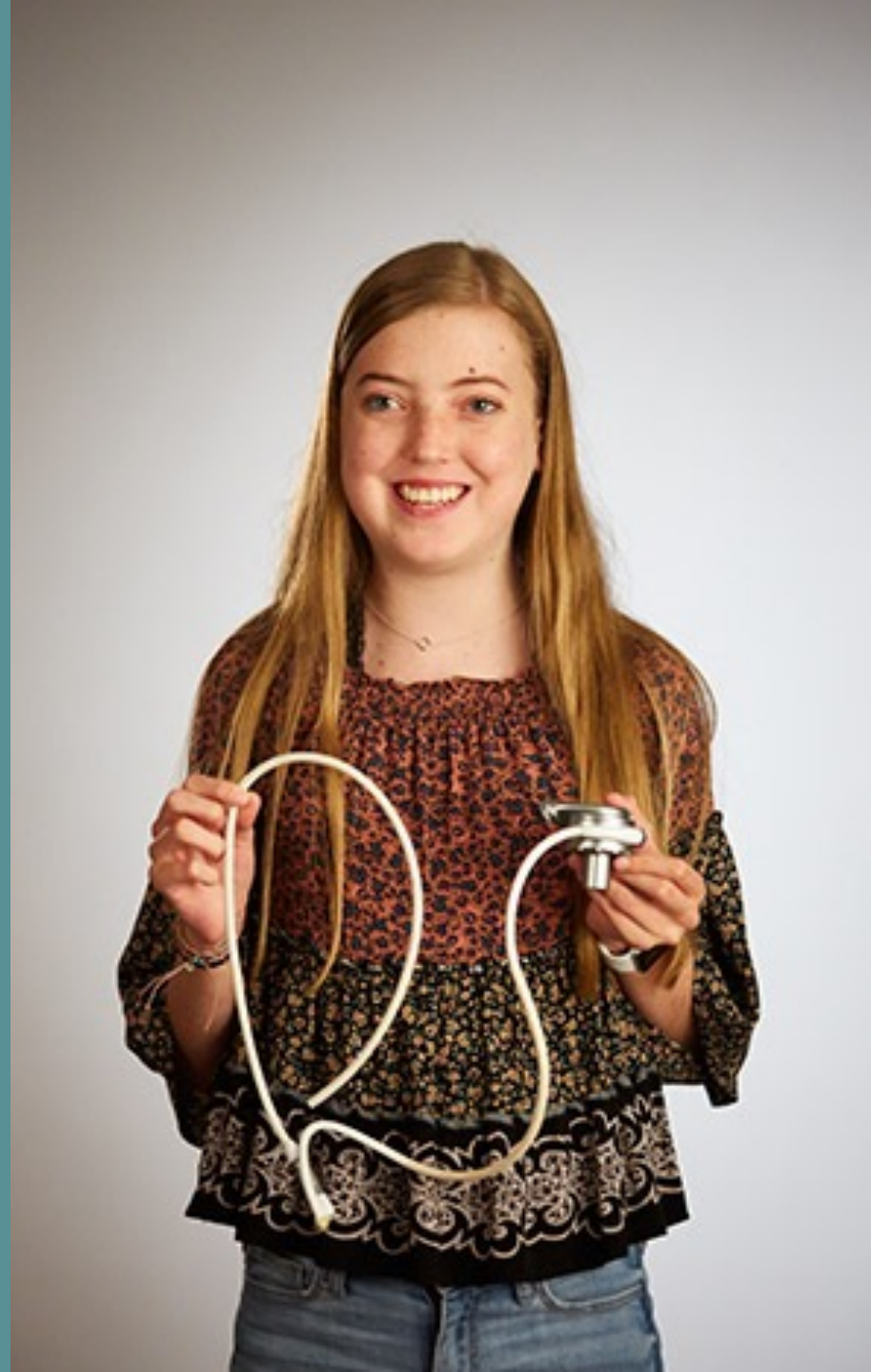
- Keep patient euvolemic- each patient has their own target
- Prevent dehydration

Control Afterload

- Avoid hypertension – each patient has their own target

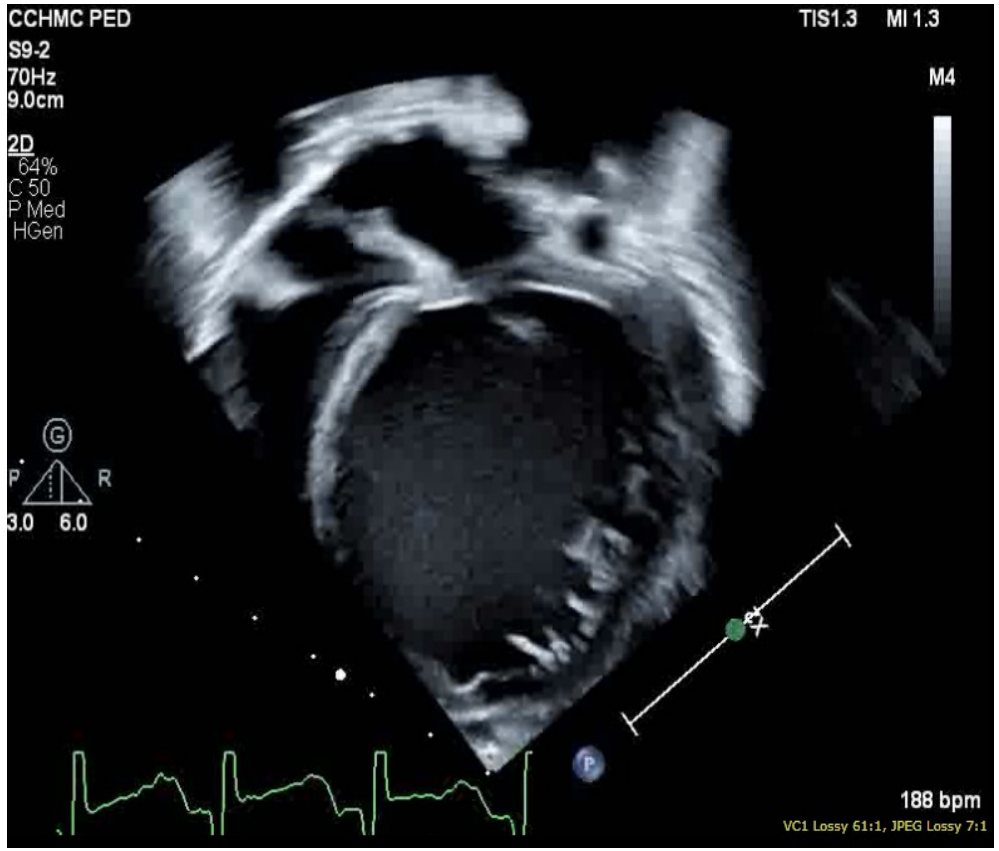
Control Bleeding & Prevent Thrombosis

- Titrate anticoagulation carefully
- Watch closely for signs of bleeding and thrombosis

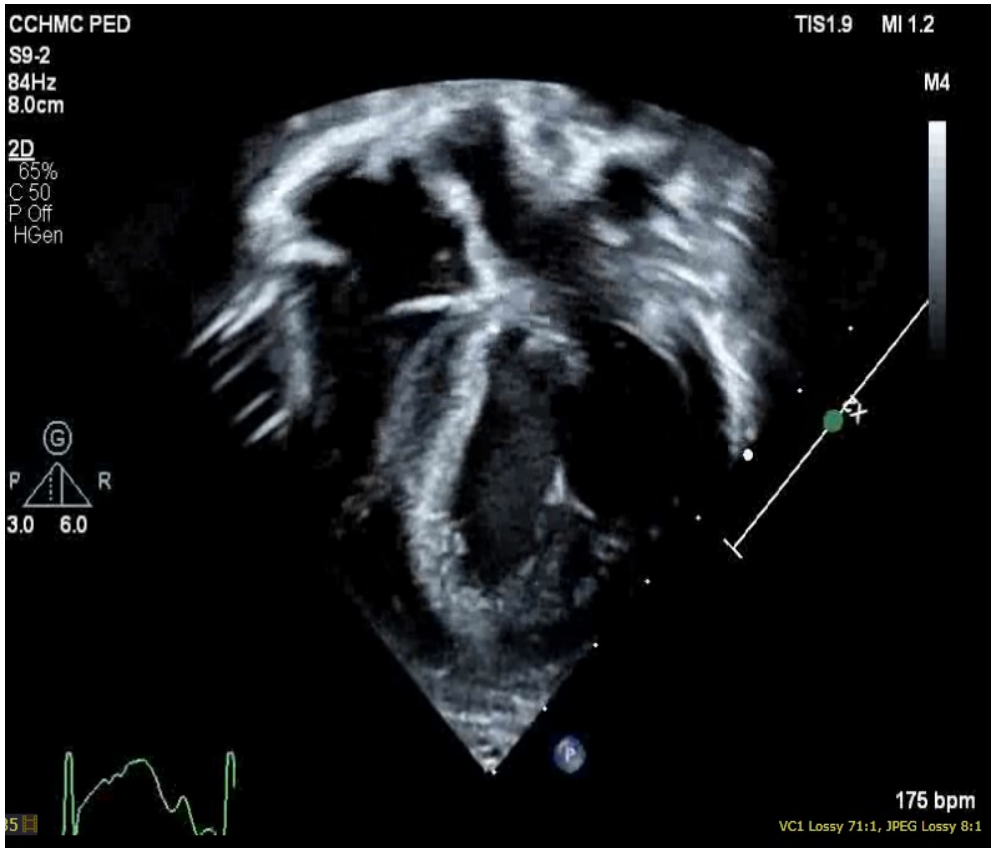


Device Optimization

Before VAD



After VAD



Major VAD Complications

Bleeding
- Patient requires anticoagulation to prevent thrombus

Stroke
- Risk of developing a thrombus in pump that can go to brain

Infection
- Bacteria can track along driveline and lead to severe infection

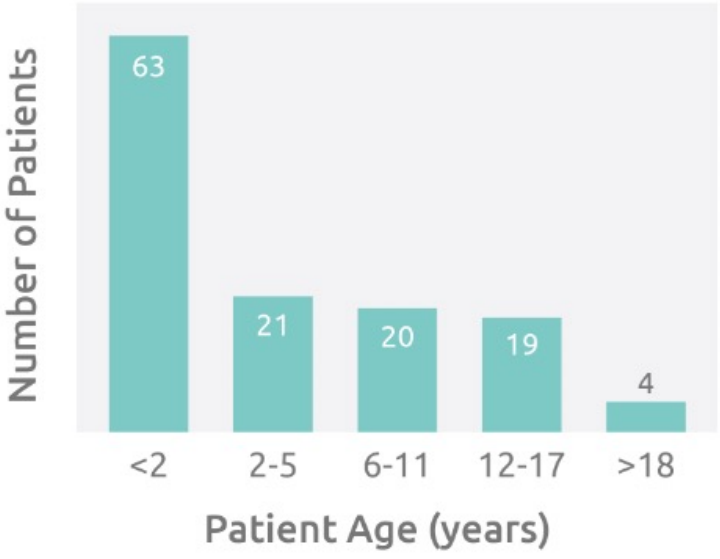
Right Heart Failure
- If only the left side receives a VAD the right side may fail

Device Malfunction
- Rare complication – if pump stops it will need to be replaced

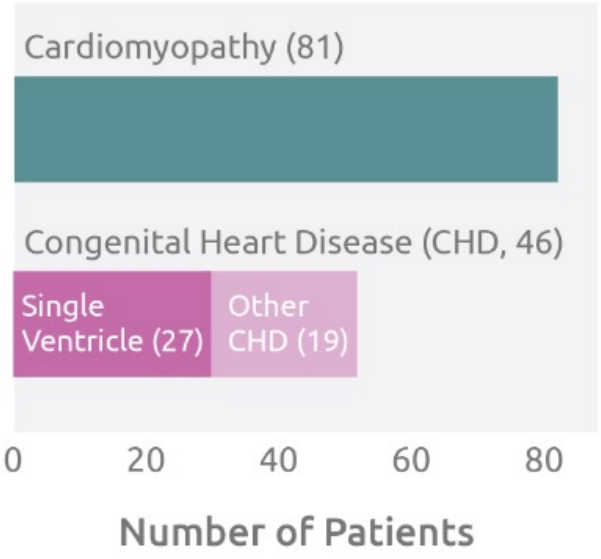
2020 ACTION Outcomes

In 2020:

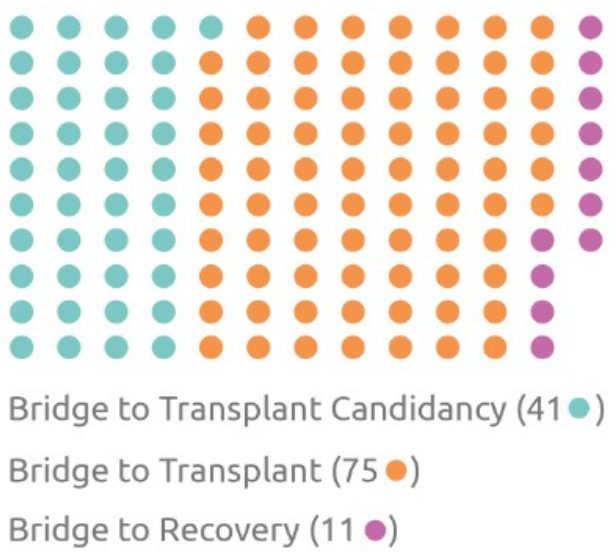
We served 127 new patients…



with these conditions…



for these goals.

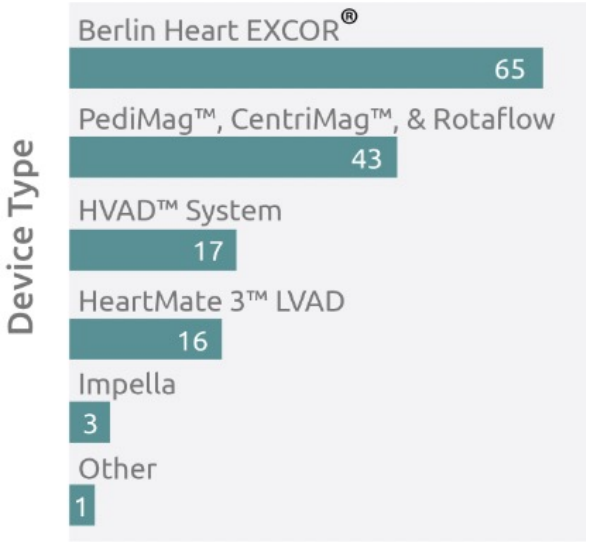


2020 ACTION Outcomes *continued...*

We're making an impact.

We're improving safety and efficiency of VADs in children and end-stage heart failure.

145 New Devices Implanted[3]



[3] *Unique device implants across ACTION centers.*

Outcomes

of patients had **positive outcomes.**

of patients had **a stroke.**

of patients had **a bleeding event.**

of patients had **an infection event.**

VAD Patient Journey

VAD Consultation & Evaluation

The care team gathers info to make informed decisions regarding device type, strategy, duration, and plan for implant procedure.

Patients/caregivers meets care team and gets VAD education.

VAD Surgical Implantation

Typical implantation takes 6–12 hours depending on the device type. The surgeon will implant the device via sternotomy approach while the patient is on cardiopulmonary bypass.

VAD Post Operative Recovery (ICU)

During the immediate post operative period, it is critical to monitor for bleeding, stroke and RV failure (if LVAD only).

VAD Patient Journey *continued...*

VAD De-escalation & Rehabilitation

Focus on de-escalation, pain management, and rehabilitation.

VAD Education & Discharge (if applicable)

If discharge eligible, patients/caregivers are required to complete VAD education prior to being discharged.

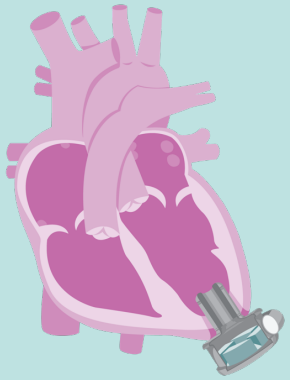
Living with a VAD

Pediatric VAD patients who live at home or require prolonged hospitalization deserve to have fun and have a great quality of life.

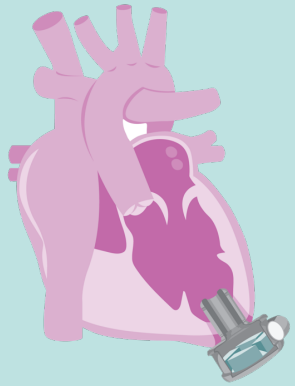
Appendix: **VAD Terminology**

Support type

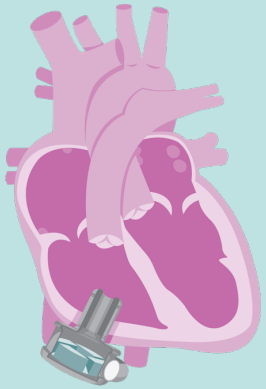
LVAD



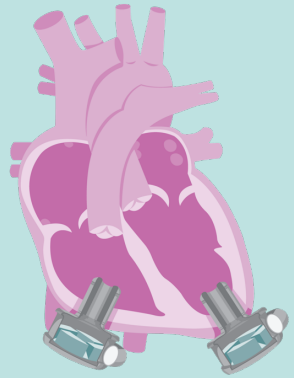
SVAD



RVAD



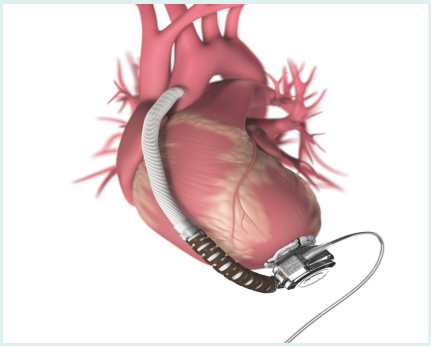
BIVAD



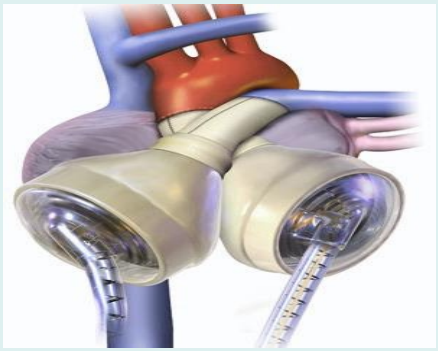
Device Type

Paracorporeal Pulsatile

Paracorporeal Continuous



Intracorporeal Continuous



Corporeal Pulsatile

Appendix: **Short Term VAD Reference**

Device	Manufacture	Pediatric FDA indication	Type	Output	Patient Size Industry Recommendation	Support Time
RotaFlow ™	Getinge		Paracorporeal/ Continuous Flow	Up to 10 LPM	All	6 hrs (US)/ Up to 30 d (Europe)[6]
PediMag™	Abbott	X	Paracorporeal/ Continuous Flow	Up to 1.5 LPM	<20 kg	LVAD: 6 hrs (US), 30 d (Europe)/RVAD: 30 d
CentriMag™	Abbott		Paracorporeal/ Continuous Flow	Up to 10 LPM	Not studied in patients <18 yrs	LVAD: 30 days (US), 30 d (Europe)/RVAD: 30 d
TandemHeart™	LivaNova		Paracorporeal / Continuous Flow	Up to 5 LPM	>1.3m²	6 hrs
Tandem Life Protek Duo™	LivaNova		Paracorporeal/ Continuous Flow	Up to 4.5 LPM	Requires 29F Sheath	6 hrs
Impella 2.5™, CP™, 5.0™, 5.5™	Abiomed		Intracorporeal/ Continuous Flow / Intravascular	2.5: up to 2.5 LPM/CP: up to 4.3 LPM/5.0: up to 5.0 LPM/5.5: >5.5LPM	2.5, CP: advisory board >1.0m² 5.0, 5.5: advisory board >1.5m²	4 days Impella 2.5, CP) to 14 d (Impella 5.0 and 5.5)
Impella RP ™	Abiomed		Intracorporeal/Continuous Flow/Intravascular	Up to 4.0 LPM	>1.5 m²	14 d

Appendix: **Long Term VAD Reference**

Device	Manufacturer	Pediatric FDA indication	Type	Output	Patient Size Industry Recommendation	Support Time
Berlin Heart EXCOR®	Berlin Heart	X	Intracorporeal/ Continuous Flow	0.6 – 8 lpm	>2.2 kg (smallest patient)	BTT (US), BTT, DT (Europe)
HVAD™ System	Medtronic		Intracorporeal/ Continuous Flow	2 - 10 lpm	≥1.2 m^2	BTT, DT
HeartMate 3™ LVAD	Abbott	X	Intracorporeal/ Continuous Flow	Up to 10 lpm	≥1..0 m^2	BTT, DT or short and long term
Jarvik 2015™	Jarvik		Intracorporeal/ Continuous Flow	0.5 – 3 lpm	Study Cohort 8–30kg	No approval, trial ongoing
SynCardia Total Artificial Heart (TAH-t) 50cc™	SynCardia	X	Corporeal/Paracorporeal Continuous	Up to 7.5 lpm	>1.2 –1.85 m^2 Needs room in the chest	BTT
SynCardia Total Artificial Heart (TAH-t) 70cc™	SynCardia		Intracorporeal/Paracorporeal Continuous	Up to 9.5 lpm	≥1.7 m^2 Needs room in the chest[5]	BTT/DT

All set!

Let’s move on to the next step in your training.