Temporary Devices

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Disclosures

Abbott, Berlin, Syncardia, Medtronic, Abiomed, Bayer -
Research Grants

All Patients have signed media releases.

Can we get to a point that

“every patient that needs a device receives one”.

The Problem

Despite the prevalence of pediatric heart failure…. it is **underfunded** and **understudied.**

Cardiac devices and medicines are **not developed** for children.

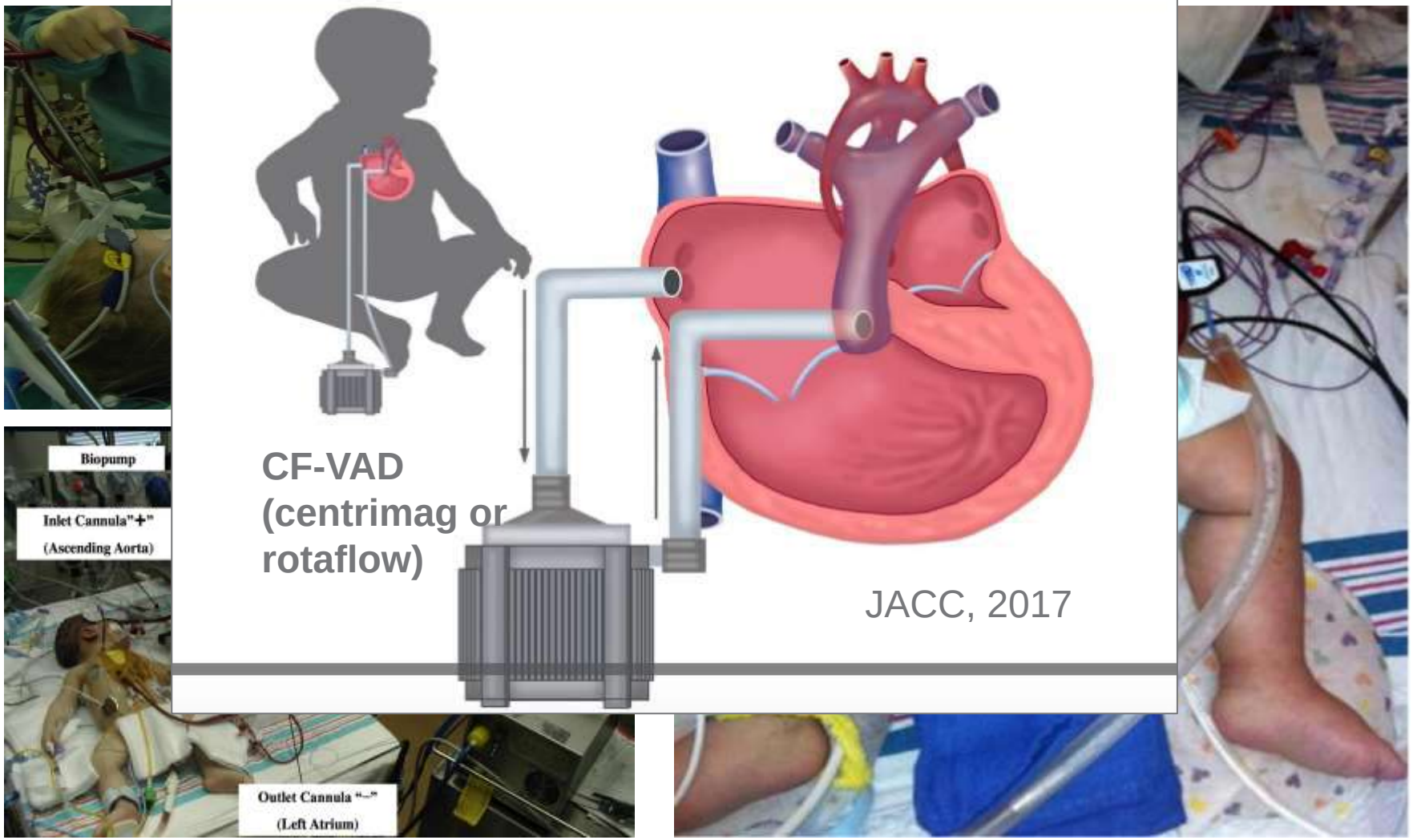
The Barriers

We don’t have ALL the right temporary treatments...

Our temporary devices currently do not have their own cannulas.

Different etiologies of HF including CHD. I.e. Is there a VAD for Fontan Failure?

NOW, >50% of children needing a temporary VAD
are too small for the Impella.



Pictures courtesy of Morales, Heinle, Gossett

1,499

Patients Enrolled

in VAD Registry as of 1/17/24

46

Sites Reporting Data

46/64

		LVAD	RVAD	SVAD
1771	Total Devices	1299	286	507
1499	Total Patients	1077	227	347

Number of patients being supported on

Berlin Heart EXCOR®

742

HeartMate 3™

283

HVAD™ System

202

Impella®

145

CentriMag™

219

PediMag™

234

Rotaflow

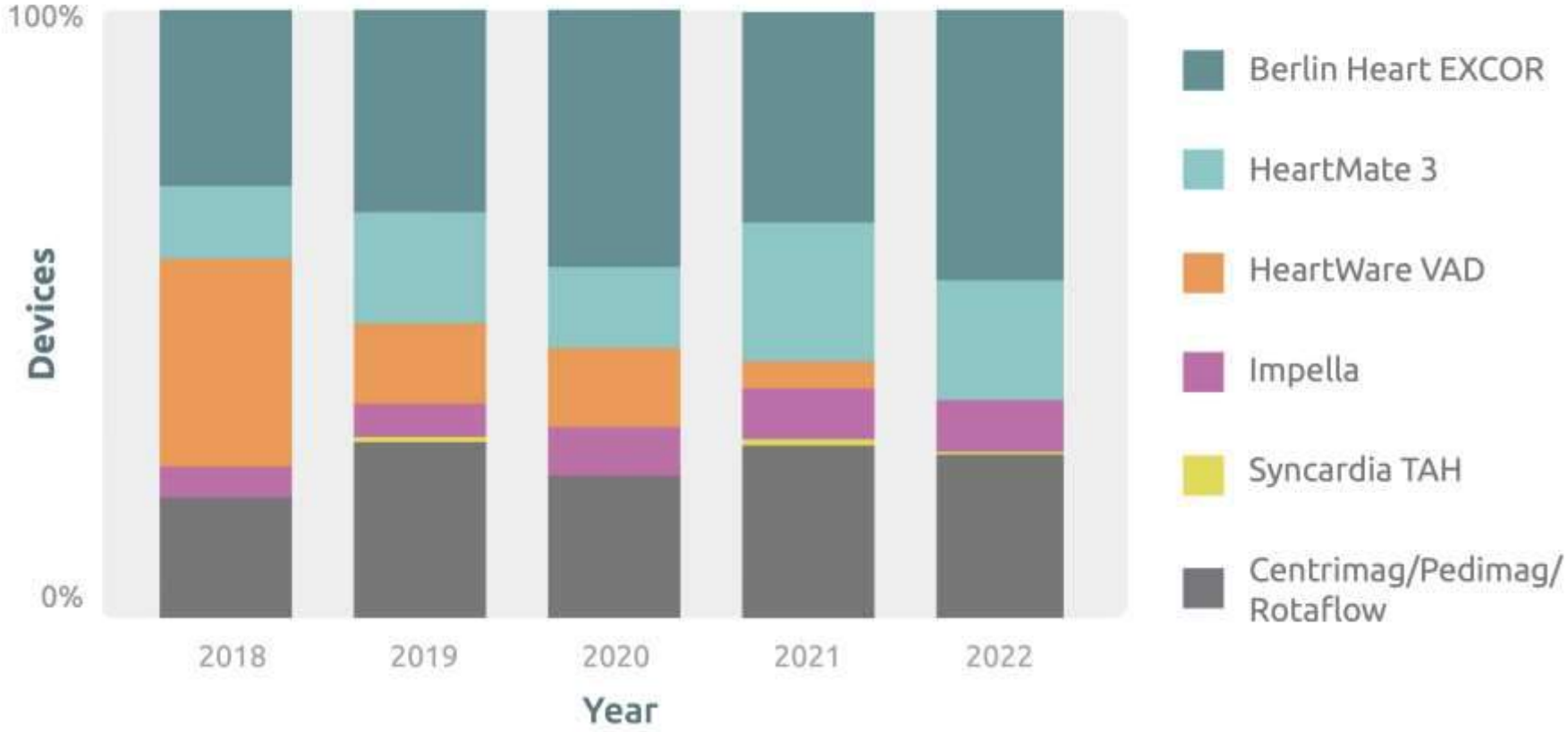
67

SynCardia TAH

11

Types of Devices Implanted by Year

Devices Implanted Each Year Between April 2018 and December 2022



When to use a temporary VAD?

- Shock
- Resuscitate end organs prior to a durable device
- Complex anatomy??
- Adolescent that could possibly go to transplant
- Anytime you think there may be recovery

Temporary CF-VAD

Recovery Expected or High Risk Durable VAD

Yes

Acute Process
- Myocarditis
- Acute graft rejection
- Unknown Pt status

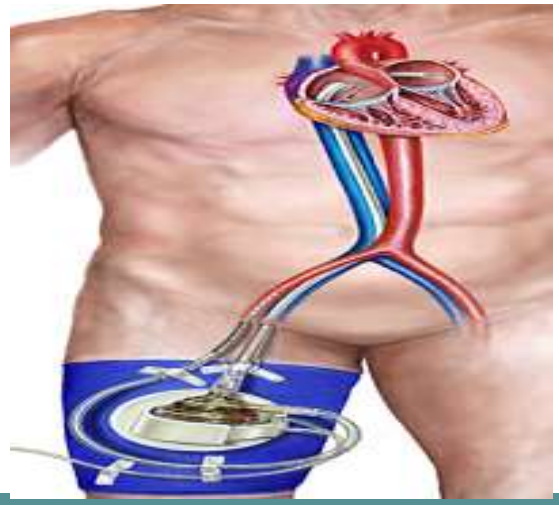
High Risk VAD
- Small infant
- Single ventricle

Short-Term VAD

Recovery

Durable VAD

Transplant



Shock

6 year old with myocarditis on high dose inotropes

Goal: Recovery; ability to give therapy

Device: Centrimag with Temporary Cannulas

Advantages: No septostomy, Full unloading, low anticoagulation needs

Disadvantage: Sternotomy

Duration: <2 weeks

Resuscitate End-Organs Prior to Durable Device

22-year-old with Fontan with AKI necessitating dialysis, Hepatic dysfunction, intubated on ventilator

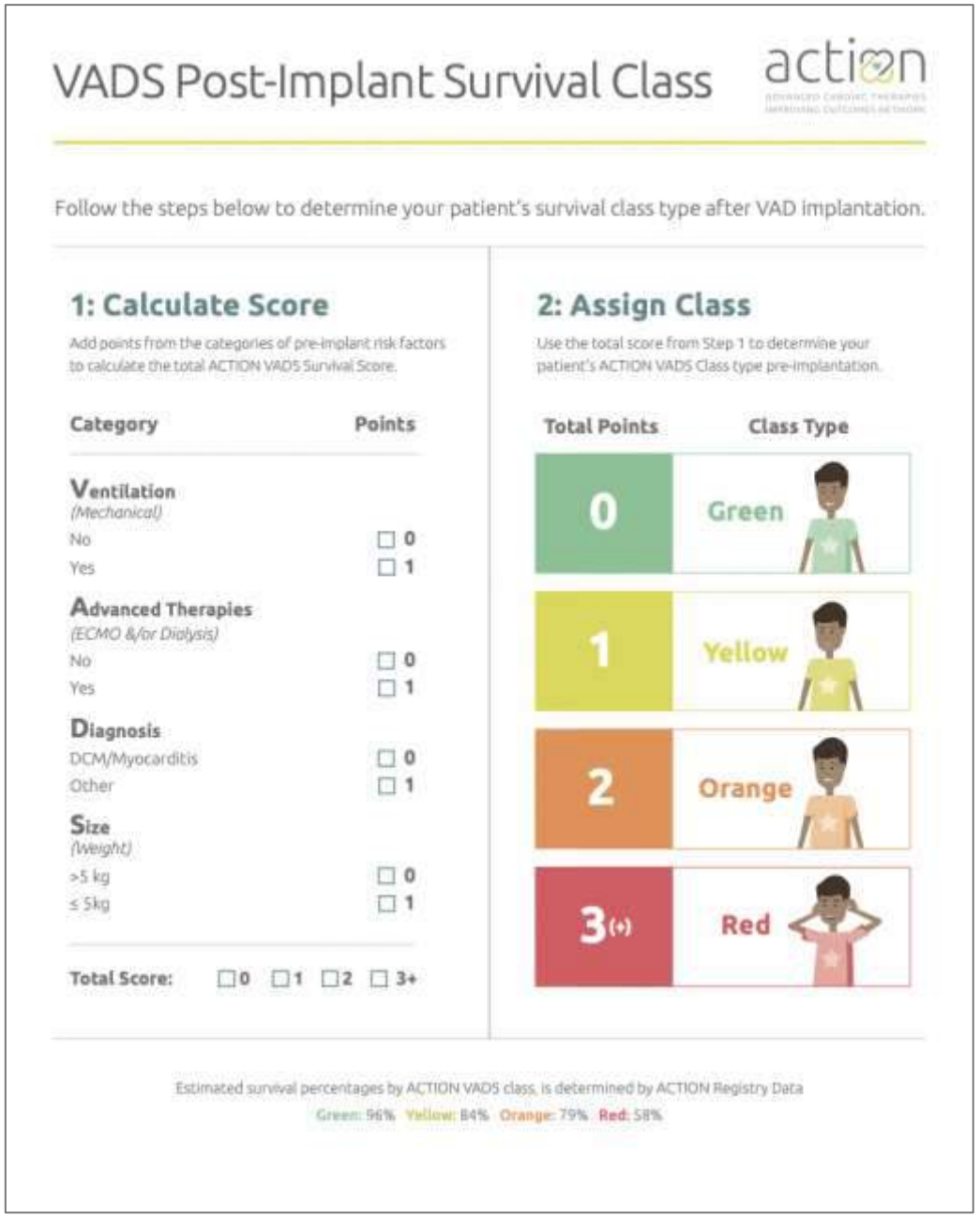
Goal: Planning for durable device (HM3) and resuscitation to improve long term outcomes.

Device: Centrimag with Temporary Cannulas or Impella.

Advantages: Full flow, end organ recovery. If needing dialysis use CMAG

Disadvantage: Sternotomy

Duration: <2 weeks (cmag), Impella (approx. 5 weeks)



VADS Post-Implant Survival Class

action

Follow the steps below to determine your patient's survival class type after VAD implantation.

1: Calculate Score

Add points from the categories of pre-implant risk factors to calculate the total ACTION VADS Survival Score.

Category	Points
Ventilation *(Mechanical)*	
No	☐ 0
Yes	☐ 1
Advanced Therapies *(ECMO &/or Dialysis)*	
No	☐ 0
Yes	☐ 1
Diagnosis	
DCM/Myocarditis	☐ 0
Other	☐ 1
Size *(Weight)*	
>5 kg	☐ 0
≤ 5kg	☐ 1

Total Score: ☐0 ☐1 ☐2 ☐3+

2: Assign Class

Use the total score from Step 1 to determine your patient's ACTION VADS Class type pre-implantation.

Total Points	Class Type
0	Green
1	Yellow
2	Orange
3(+)	Red

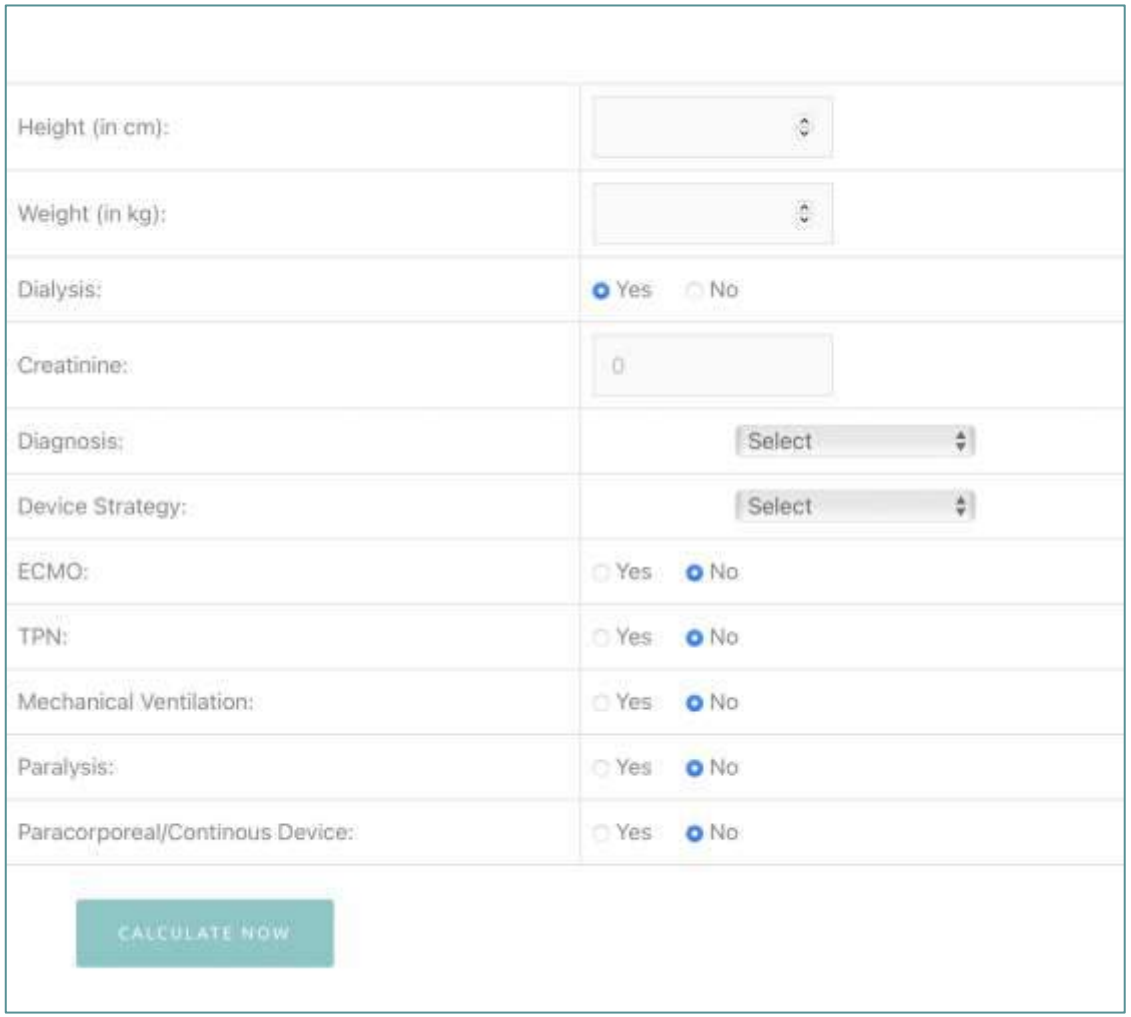
Estimated survival percentages by ACTION VADS class, is determined by ACTION Registry Data

Green: 96% Yellow: 84% Orange: 79% Red: 58%

ACTION Calculator

Used to estimate mortality

Use to make the patient a better candidate, possibly by using temporary MCS before durable



Boucek K, Alzubi A, Zafar F, O'Connor MJ, Mehegan M, Mokshagundam D, Davies RR, Adachi I, Lorts A, Rosenthal DN. Taking ACTION: A Prognostic Tool for Pediatric Ventricular Assist Device Mortality. ASAIO J. 2023 Jun 1;69(6):602-609. doi: 10.1097/MAT.0000000000001899. Epub 2023 May 27. PMID: 37261722.

Complex Anatomy

1 year old with Glenn, Severe AV valve regurg and massive collaterals.

Goal: Transition to Berlin Heart

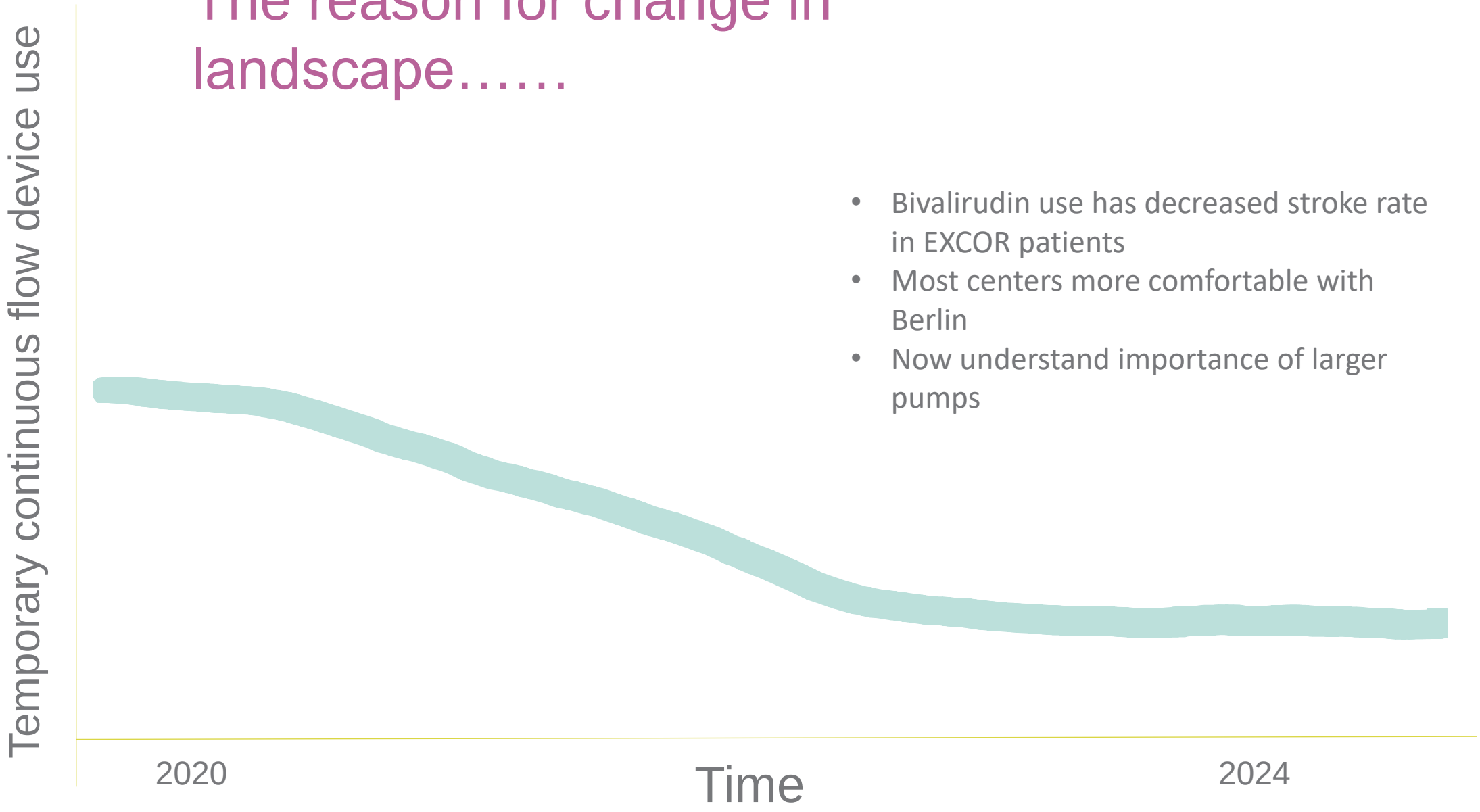
Device: Centrimag with Berlin Cannulas (inflow -atria or ventricle)

Advantages: Understand what size Berlin Pump you will need. Easy to cut in oxygenator. Get AC right

Disadvantage: Centrimag has slightly higher stroke risk. Less likely to rehabilitate.

Duration: <2 weeks (cmag), Impella (approx. 5 weeks)

The reason for change in landscape……



- Bivalirudin use has decreased stroke rate in EXCOR patients
- Most centers more comfortable with Berlin
- Now understand importance of larger pumps

Explore this journal >

Main Text Article

Use of Ventricular Assist Device in Univentricular Physiology: The Role of Lumped Parameter Models

Arianna Di Molfetta ✉, Gianfranco Ferrari, Sergio Filippelli, Libera Fresiello, Roberta Iacobelli, Maria G. Gagliardi, Antonio Amodeo

First published: 23 October 2015 Full publication history

View issue TOC
Volume 40, Issue 5
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Int J Artif Organs. 2017 Mar 16;40(2):74-81. doi: 10.5301/ijao.5000562. Epub 2017 Feb 11.

Concomitant pulsatile and continuous flow VAD in biventricular and univentricular physiology: a comparison study with a numerical model.

Di Molfetta A[1], Ferrari G[2], Iacobelli R[1], Filippelli S[1], Guccione P[1], Fresiello L[3], Perri G[1], Amodeo A[1].

Some Glenn patients will be supported easier with continuous flow (CF) devices

- CF may decrease atrial pressure consistently
- If collaterals, there is a need for large CO that is easily titrated with CF
- Allows for team to determine cardiac output needs prior to committing to Berlin pump size

- *ASAIO J 2014;60:119-21*
- *J Thorac Cardiovasc Surg. 2013 Jun;145(6):e62-3*.

Adolescent that could be transplanted quickly

16-year- old comes in with acute HF. Not Frail. Gene positive. Good transplant candidate. Can wait extubated.

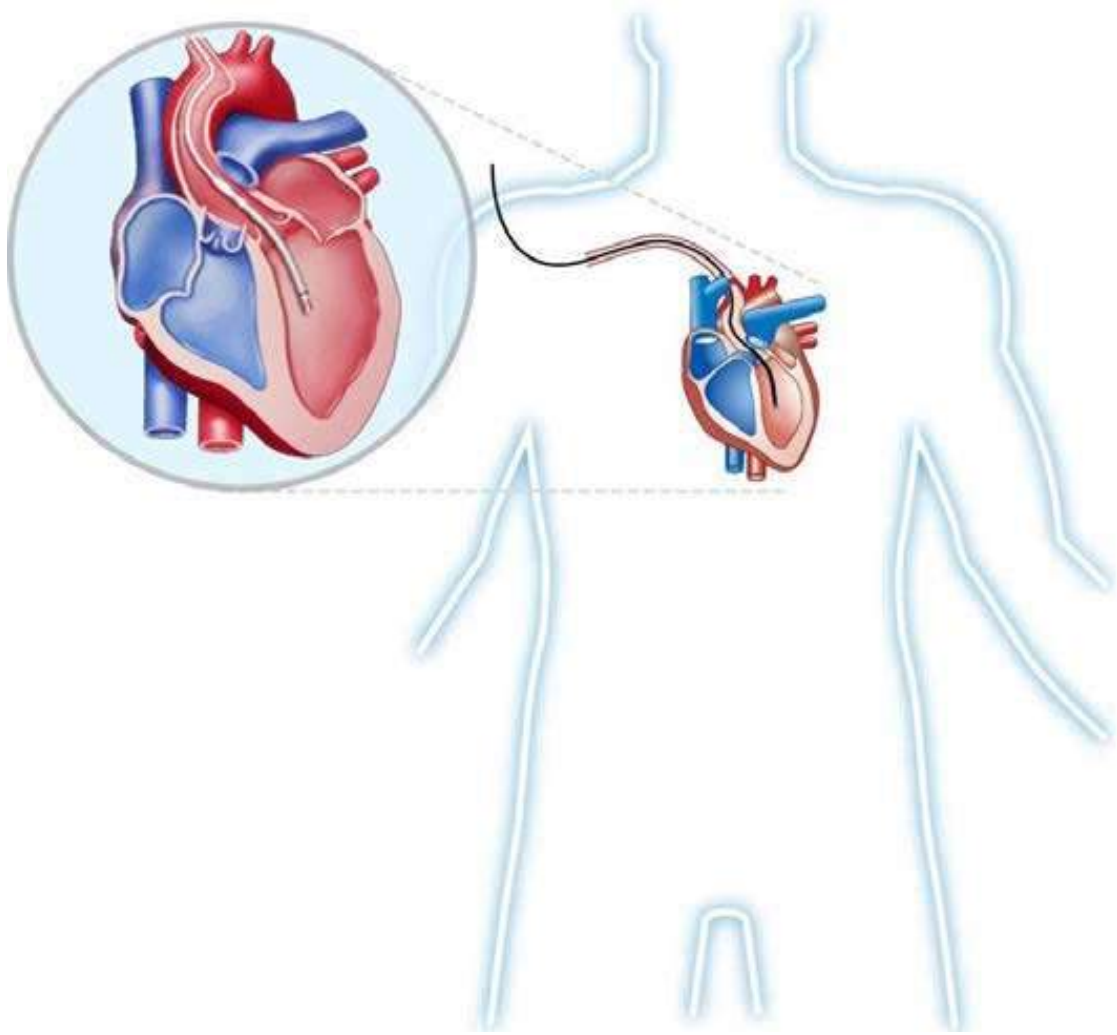
Goal: Transplant

Device: Impella

Advantages: Axillary – can do some inpatient rehab and not have a sternotomy

Disadvantage: In house till transplant, AE profile

Duration: Impella (approx. 5 weeks)



Pump Support & Size Options

LVAD

RVAD

	Impella 2.5	Impella CP	Impella 5.0	Impella 5.5 with SmartAssist	Impella RP
					
Average Peak Flow	2.5 L/min	4.3L/min	5.0 L/min	6.0 L/min	4.0 L/min

Choosing a VAD: Is an **Impella®** right for your patient?

What is the intent of support / planned duration?

- ✓ Acute cardiogenic shock / Bridge to recovery (BTR)
- ✓ Bridge to durable device
- ✓ Bridge to transplant (BTT)
- ✓ Bridge to decision (BTD)
- ✓ ECMO left heart decompression

Is the size of the patient adequate?

- ✓ What are the vessel measurements? Are they patent?
- ✓ Is the LV length appropriate?

Which ventricle needs to be supported?

- ✓ Left ventricle (LVAD)
- ✓ Right ventricle (RVAD)
- ✓ Biventricular support (BiVAD)
- ✓ Single ventricle (SVAD)

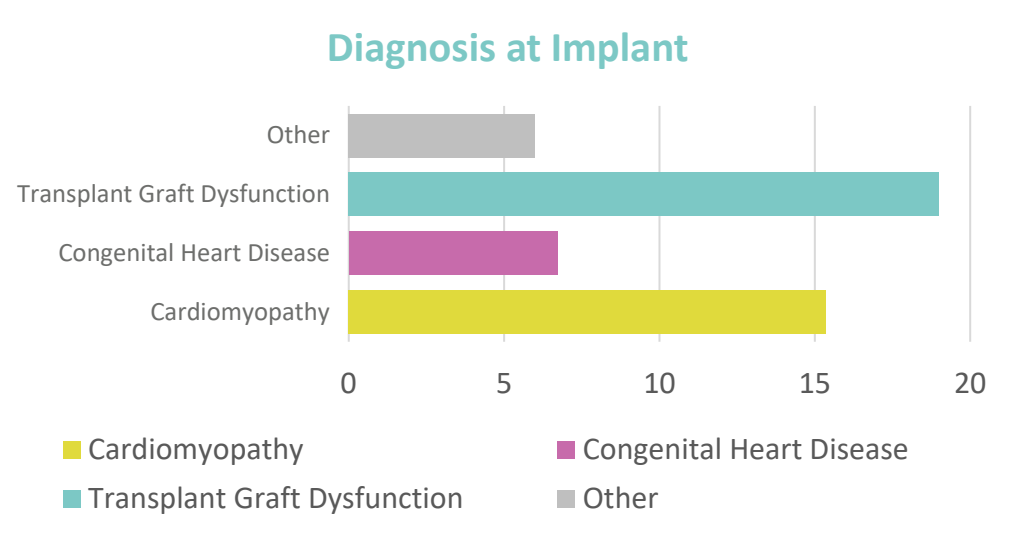
Are there contraindications to Impella® placement?

- ✓ Presence of ventricular thrombus
- ✓ Severe aortic regurgitation or stenosis (LVAD) or pulmonary regurgitation or stenosis (RVAD) or mechanical valves
- ✓ Is there a known clotting disorder?
- ✓ Significant right to left shunts (LVAD)

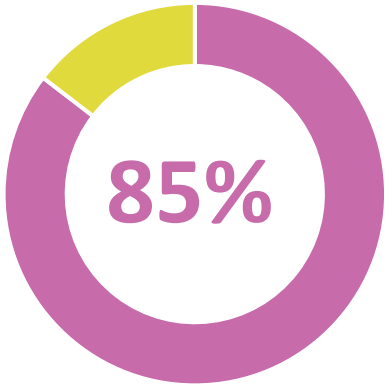
The Outcomes*

Demographics

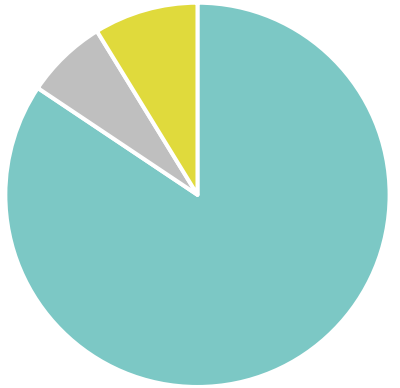
- 48 patients
  - Median age 15.9 yrs (range 6.8, 34.4)
  - Mean BSA 1.75m^2 (range 1.05-2.02)

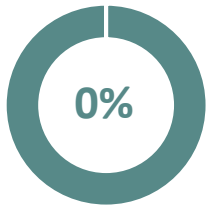


Tume, ISHLT 2022

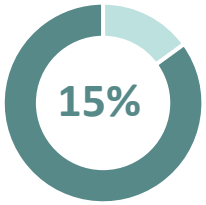


of patients had a positive outcome

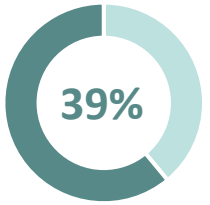




of all patients had a **stroke.**



of all patients had a major **bleeding event.**

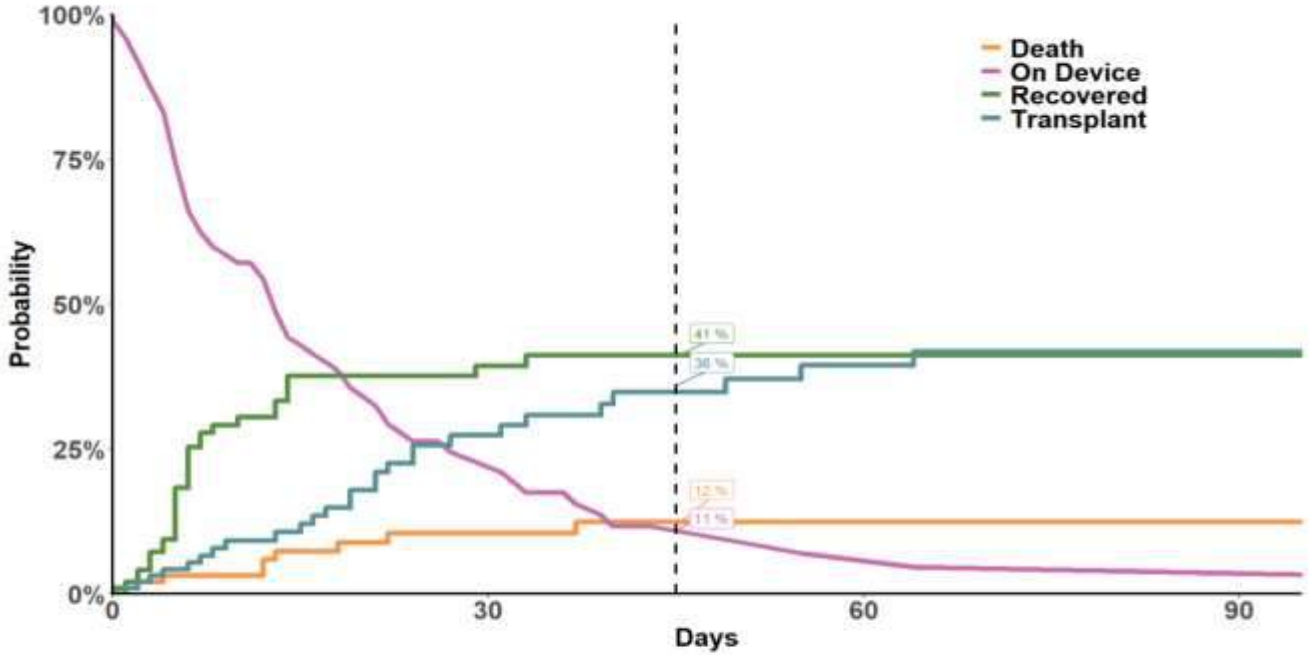


of all patients had **hemolysis.**

5.5 days Median duration of support

Advanced Cardiac Therapies Improving Outcomes Network

Figure 5. Competing risk curves depicting alive on device, death, recovery, and transplant for the group of 99 patients receiving Impella devices between April 2018 and July 2023.



Impella patients (n=99)				
	30 days	**45 days**	**60 days**	**90 days**
Alive on Device	23%	11%	7%	6%
Death	11%	12%	12%	12%
Recovered	39%	41%	41%	41%
Transplant	27%	36%	40%	41%

- Ventricular recovery, wean - Any device explanted for ventricular recovery or support no longer needed, no other device type implanted

	Impella patients N=99
Alive on device	5 (5%)
Deceased	12 (12%)
Transplanted	46 (47%)
Ventricular recovery, wean	36 (36%)

Anytime you think there may be recovery

3-year-old transplant patient with acute rejection needing ATG

Goal: Recovery

Device: Centrimag with Temporary Cannulas

Advantages: Full flow, end organ recovery. If needing dialysis use CMAG.

Disadvantage: Sternotomy

Duration: <2 weeks (cmag)

PediMag™ & CentriMag™

OPS

Pump Settings

Speed: Revolutions per minute (RPM)
Only parameter that can be changed
- 0–5500 RPM

Flow: Liters Per Minute (LPM)
- Pedimag: 0–1.5 LPM
- Centrimag: 0–9.9 LPM

High/Low Flow Alarms: Set within 20% of target flow

Device Assessment

- Look closely at all connection points for thrombus
- Listen to and examine the pump to make sure it's situated correctly on motor
- Document any thrombus formation and follow progression

Types of Defects

Fibrin: white, usually small

Thrombus: dark in color, concerning if:
- Increasing in size > 3 mm
- Quick increase in amount of clot
- Becoming darker
- Mobile
- Located near the outflow

Blood Pressure

- This is a continuous flow device, so the patient will have little pulsatility
- Pump is afterload sensitive, must keep blood pressure within parameters

Emergency Care

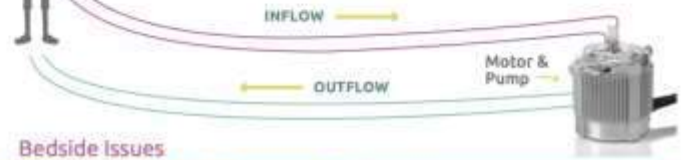
Motor Failure: Switch to backup console and motor

CPR: Compressions and defibrillation or cardioversion as needed without stopping the pump

Thrombus Necessitating Change: Scan QR code for pump change information

Cannulation Strategies

Temporary (ECMO or bypass) or Durable (Berlin) cannulae may be used.
- **LVAD:** Cannulation from LA/LV to Aorta
- **RVAD:** Cannulation from RA to PA
- **BiVAD:** Biventricular support. Cannulation for LVAD and RVAD
- **SVAD:** Cannulation from common Atria or Ventricle to Aorta



Bedside Issues

Issue	Cause	Treatment
CHATTER/ INTERMITTENT SUCTION	Hypovolemia	Give Fluid
	RPM too High	Adjust Settings
	Intermittent Cannula Obstruction	Evaluate positioning
LOW FLOW	Hypertension	Afterload Reduction/Sedation
	Hypovolemia	Give Fluid
	Cannula Obstruction	Evaluate Positioning
	RPM too low	Adjust Settings

Back Up Equipment

- Console and motor
- Sterile pump and circuit
- Priming kit
- 2 large ECMO clamps per VAD

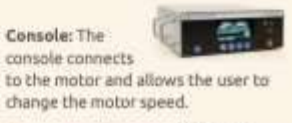
System Components

Circuit: tubing connecting the cannulae and pump
- PediMag: ¼ inch Tubing
- CentriMag: ⅛ inch Tubing

Pump: Polycarbonate device with a magnetically levitated impeller inside. The pump inflow sits at the top of the pump and connects to the cannula draining blood from the heart. The outflow sits on the side of the pump and connects to the cannula returning blood to the heart.

Motor: The pump is seated inside the motor which spins continuously to move the blood forward.

Console: The console connects to the motor and allows the user to change the motor speed.



Monitor: Connects to the console and displays the settings. Shows the waveforms and allows the user to make settings changes.

Flow Probe: Direct measurement of the blood flow within the circuit.

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Impella® Heart Pump Overview

PART TWO

action
ADVANCED CARDIAC THERAPIES IMPROVING OUTCOMES NETWORK

Abiomed Impella® 2.5, CP, 5.0/LD, 5.5

OPS

The Device

The Impella® is inserted into a vessel either surgically or percutaneously (see table for device types).

Left Ventricle Support: Pump inlet sits in the left ventricle and outlet rests above the aortic valve

Right Ventricle Support: Pump inlet sits in the right ventricle and outlet rests above the pulmonary artery valve

	Impella 2.5	Impella CP®	Impella 5.0/LD	Impella 5.5®	Impella RP®
Average Peak Flow	2.5 L/min	4.3 L/min	5.0 L/min	6.2 L/min	4 L/min

Pump Settings *(on Display Screen)*

Speed: The main setting that can be changed to alter CO. P levels go from 0-9.

Flow (L/min): calculated CO through the pump. If number is yellow pump is not in good position. If white it is appropriately placed.

Purge Flow (ml/hour): The rate the Dextrose fluid is going to lubricate the motor.

Purge Pressure (mmHg): The amount of pressure needed to push the purge fluid through the pump.

Power Sources

- Battery life = 1 Hour
- Plug into AC outlet at all times

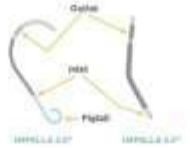
Red: Critical Yellow: Serious White: Advisory notifications
Note: More information and instructions will display on screen

System Components

Heart Pump
The motor spins continuously, with blood entering through the inlet, and being ejected via the outlet.

The 2.5, CP, and 5.0 all have a pigtail at the end of the catheter – the 5.5 has a blunt tip

Pumps with Smart Assist® also have an optical placement sensor that will display data on the Impella® Controller.



Controller
Soft Knobs: Open, display, and close menu options

Selector Knob: Button rotates to navigate through menus, press to make a selection

Purge Cassette Door: Spring-loaded door housing the purge cassette

Catheter Plug: Connects Impella® catheter to the controller

Pump settings on display screen

Purge System
The purge cassette delivers purge fluid, which acts as a rinsing fluid, to the microaxial pump to keep blood from entering the motor.

Purge Fluid: Purge fluid is typically made up of 5% DSW (dextrose in water), with 25 IU/mL of heparin.

Wave Forms

Type	Color	Measurement Description	Range
AO Placement Signal	Red	Monitors Ao Pressure – Used to determine location of the pump's sensor in relation to aortic valve	0-160 mmHg
LV Placement Signal—only displays with Smart Assist® and P level >4	White	Monitors LV Pressure – Used with Ao placement signal to determine pump's location in the LV Waveform peak should couple with Ao waveform to indicate optimal placement	0-160 mmHg Negative values may indicate malposition
Motor Current	Green	Measurement of the pump's energy usage during systole and diastole	0-1000 mA, Goal 200 mA difference b/t numbers

Anticoagulation

- Total Heparin delivered to patient = Impella® purge Heparin + systemic IV Heparin
- Purge fluid Heparin concentration D5W 25 U/ml (50 U/ml may be used)
- Goal: ACT 160–200 depending on clinical situation

Potential Emergencies

Hemolysis
Possible thrombosis or malposition of device

Watch For: Urine color changes and increase in LDH, Plasma free Hgb

Treatment: Check placement of catheter and reposition. Possibly lower P level.

Suction
Inadequate ventricular filling from hypovolemia or device malposition

Watch For: Decrease in flow or change in hemodynamics. There may also be a low flow alarm.

Treatment: Decrease P level and assess volume status. Evaluate catheter position.

No Flow / Low Flow
The catheter may have moved and be malpositioned or a thrombus is obstructing flow.

Watch For: Decreased CO, low flow alarms, and flat motor current waveforms.

Treatment: Decrease the P level below baseline. Troubleshoot device with X-ray and ECHO. May need repositioning or replacement of the pump.

CPR
If there is a cardiac arrest and CPR is needed decrease the P level to 2 and start CPR. When ROSC returns check positioning of catheter.

If only defibrillation or cardioversion is required do not adjust P level.

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Thoughts and Questions?

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