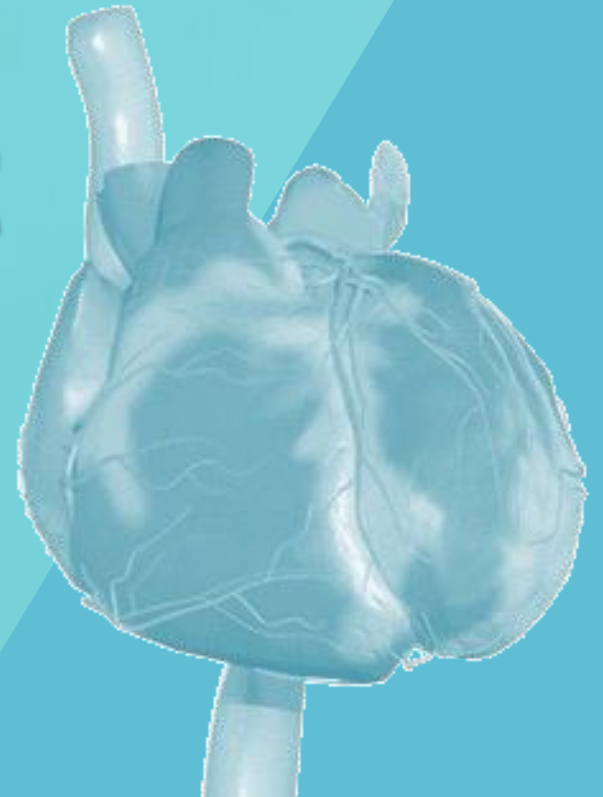




Nursing Management on Impella

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Certified Cardiac Device Specialist (CCDS)





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01 Introduction

What is Impella?

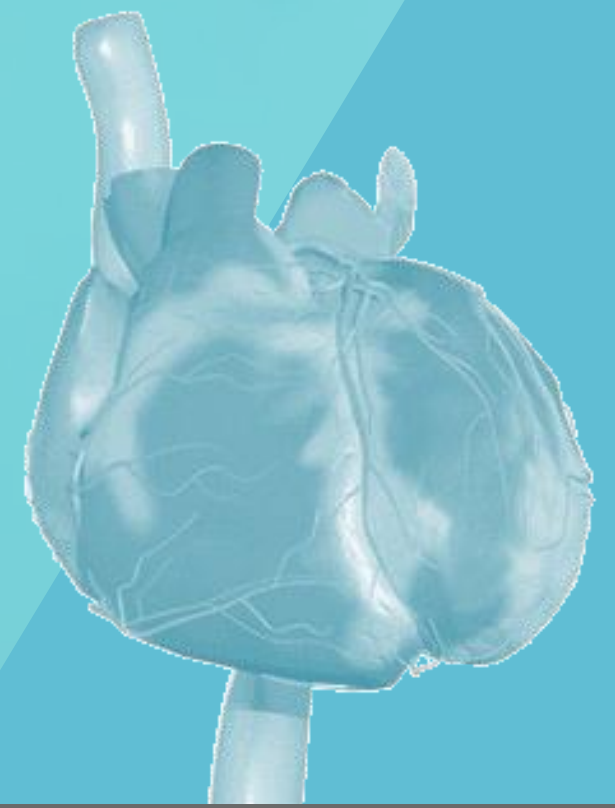
02 Implantation

Set up and insertion

03 Nursing Management

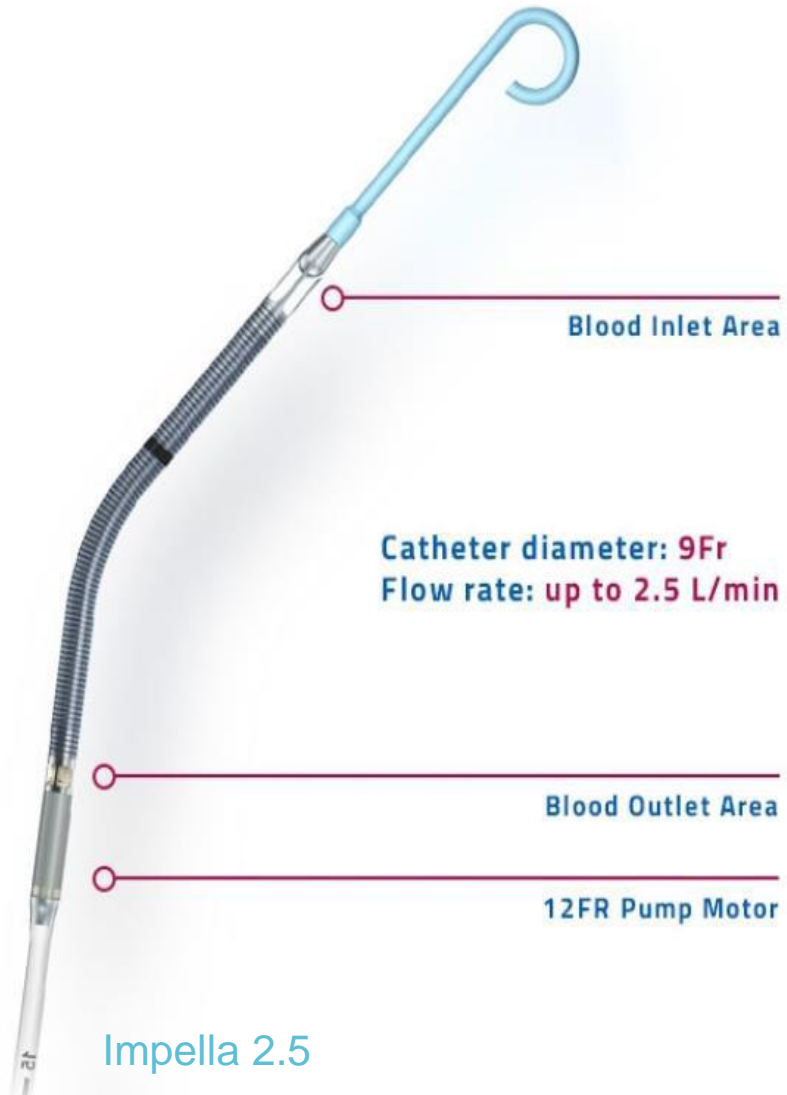
Device and patient monitoring

04 Weaning and explant



01 Introduction

What is Impella?



Automated Impella® Controller

The primary user control interface for the Impella platform

Family of Mechanical Support Device

Continuous Flow Pumps

Pulsatile



IABP

Axia-Flow



Impella CP



PHP*

Centrifugal Flow



TandemHeart



VA-ECMO

Intracorporeal

Extracorporeal

*IABP = intra-aortic balloon pump; PHP = percutaneous heart pump;
VA-ECMO = veno-arterial extracorporeal membrane oxygenation*

Series of Impella

Left side devices

- Impella 2.5
- Impella CP/ SmartAssist
- Impella 5.0/ LD
- Impella 5.5 with SmartAssist



Impella 2.5™

Impella® makes a Protected PCI procedure possible



Impella CP®

Percutaneous insertion and increased flow



Impella 5.0™ /LD™

Delivers up to 5.0 L/min of forward blood flow from the left ventricle

Right side devices

- Impella RP



Impella RP®

The first percutaneous, single vascular access pump designed for right heart support



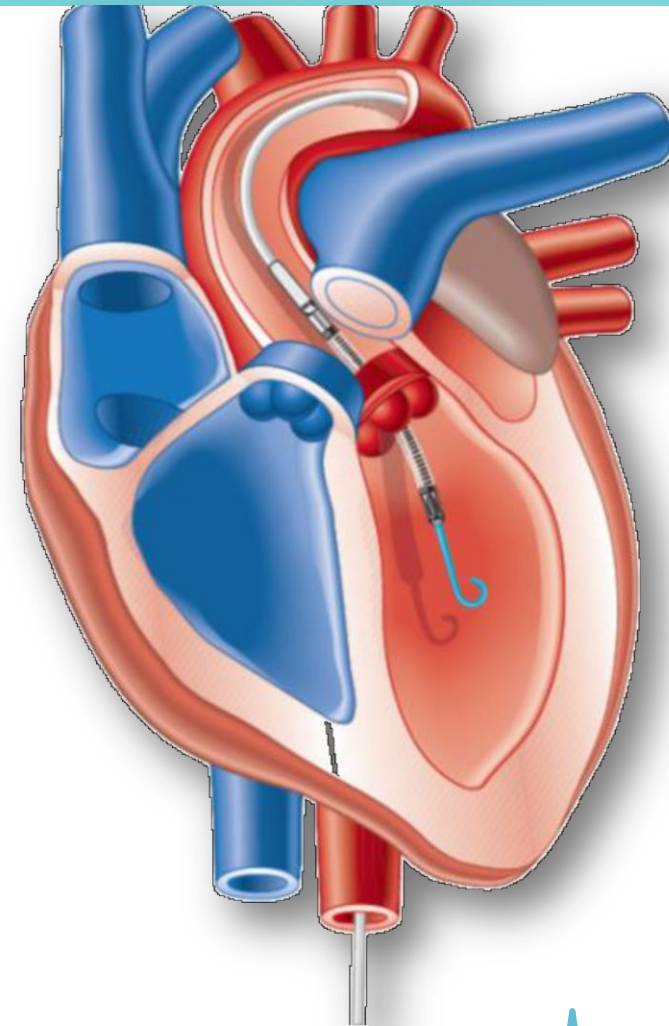
Indications

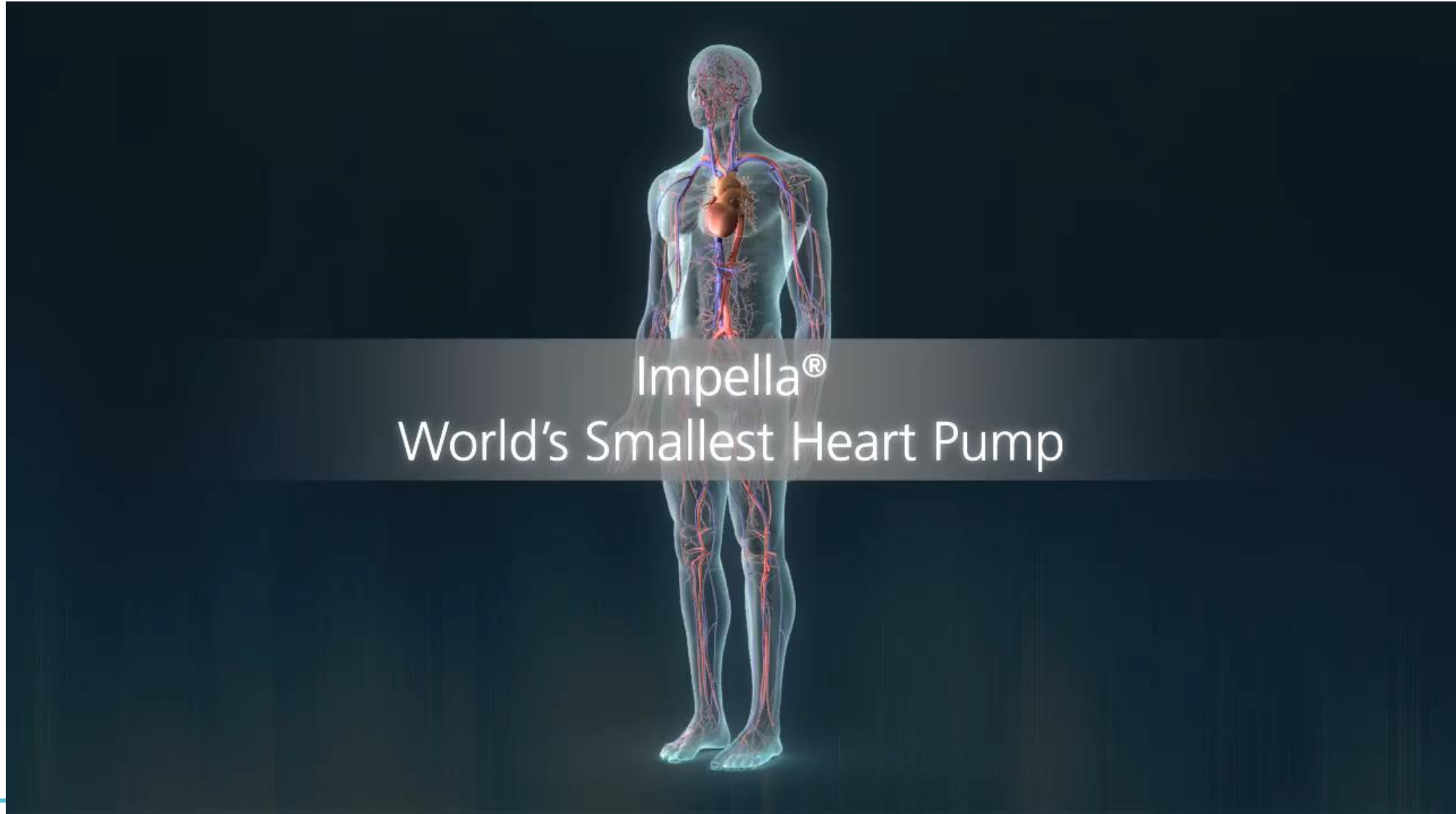
High-risk PCI (≤ 6 hours)

- Single surviving vessel, severe LM Dx, TVD
- surgical turndown

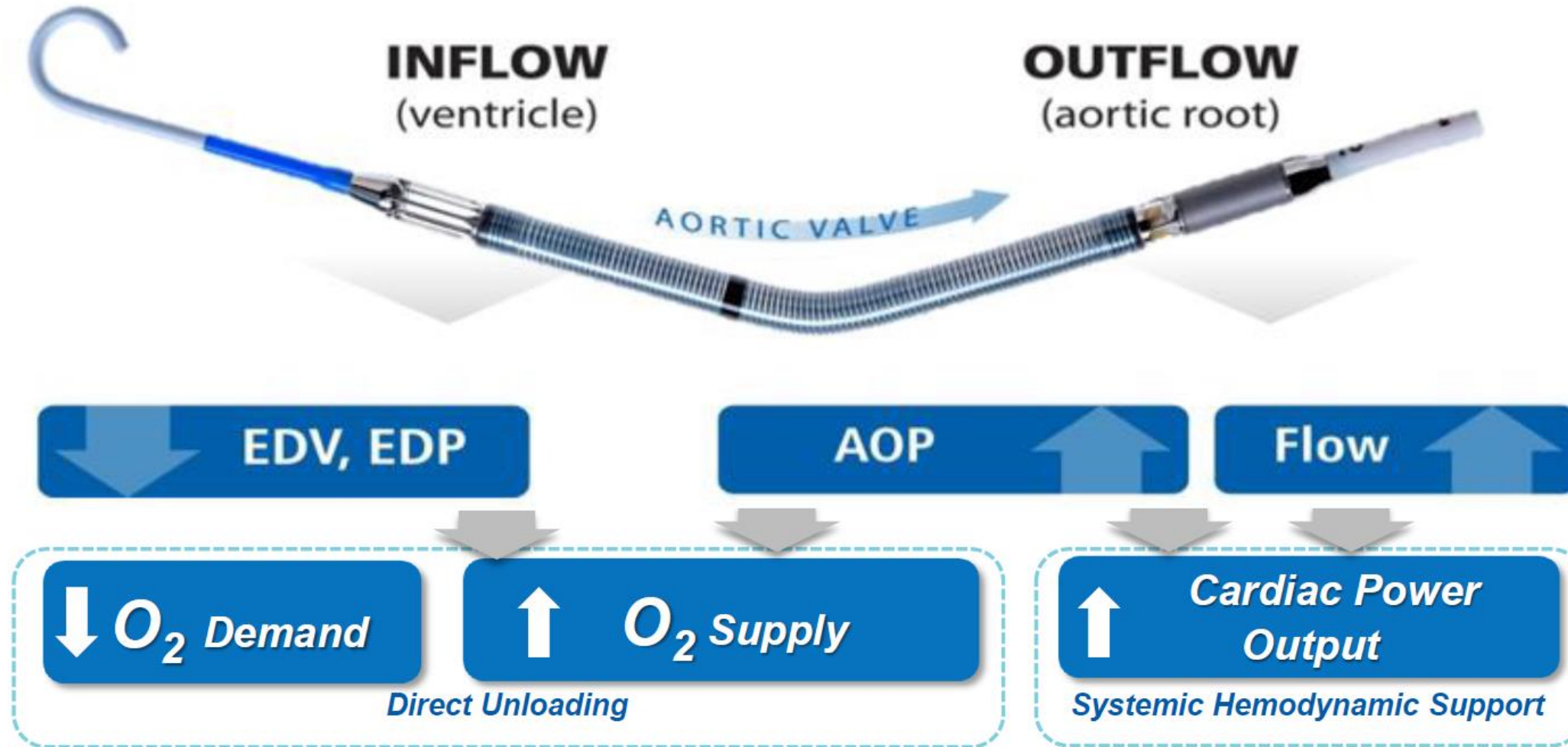
Cardiogenic Shock (≤ 4 days)

- ongoing cardiogenic shock that occurs immediately (< 48 hours)



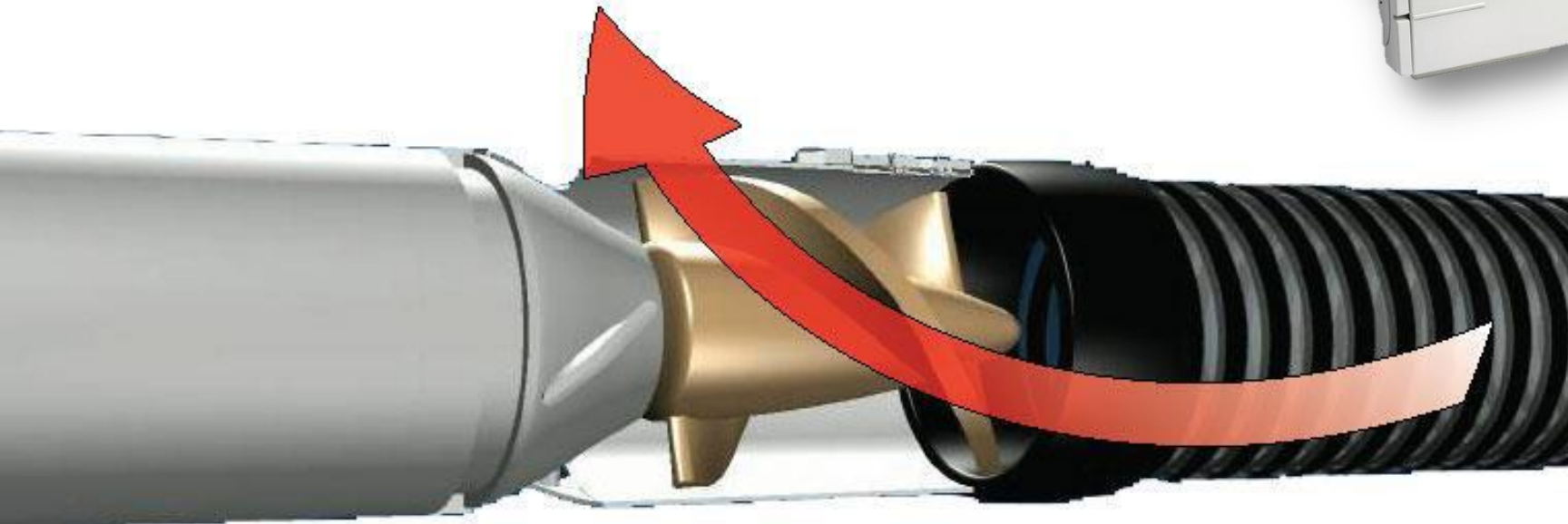
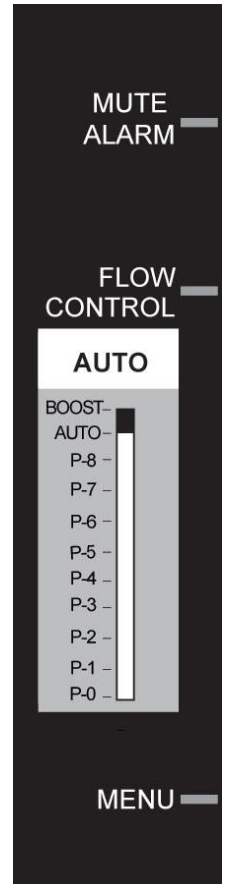


Physiological Results of Impella Support



Mechanism of Impella

- Automated Impella[®] Controller controls how fast the impeller rotates
- Rotation speed is proportional to flow:
Faster rotation = Higher flow



Components of the Purge System

Purge Fluid

D5 with 25-50U/mL of heparin
5 – 40% dextrose in water
(5% dextrose recommended)
Concentration proportional to viscosity



250 mL SINGLE-DOSE CONTAINER NDC 0409-77-114-62
RX ONLY

HEPARIN

12,500 USP Heparin Units/250 mL
(50 USP Heparin Units/mL)

HEPARIN SODIUM IN 5% DEXTROSE INJECTION

CONTAINS A SULFITE.

EACH 100 mL CONTAINS

HEPARIN SODIUM 5000 USP

UNITS (PORCINE INTESTINAL

MUCOSA); DEXTROSE, HYDROUS

5 g; CITRIC ACID, ANHYDROUS

51 mg; SODIUM CITRATE,

DIHYDRATE 334 mg; SODIUM

METABISULFITE 20 mg;

ELECTROLYTES: SODIUM

38 mEq/L; CITRATE 42 mEq/L

304 mOsm/L (CALC.); pH 5.0 TO

6.0. STERILE, FOR IV USE. USUAL

DOSAGE: SEE INSERT. ADDITIVES

SHOULD NOT BE MADE TO THIS

SOLUTION. LATEX-FREE.

50

100

150

200



OTHER

IM-2236
HOSPIRA, INC., LAKE FOREST, IL 60045 USA



Purge Cassette

Delivers purge fluid to
Impella[®] device



Purge System Animation



PURPOSE

Prevents blood from entering the motor

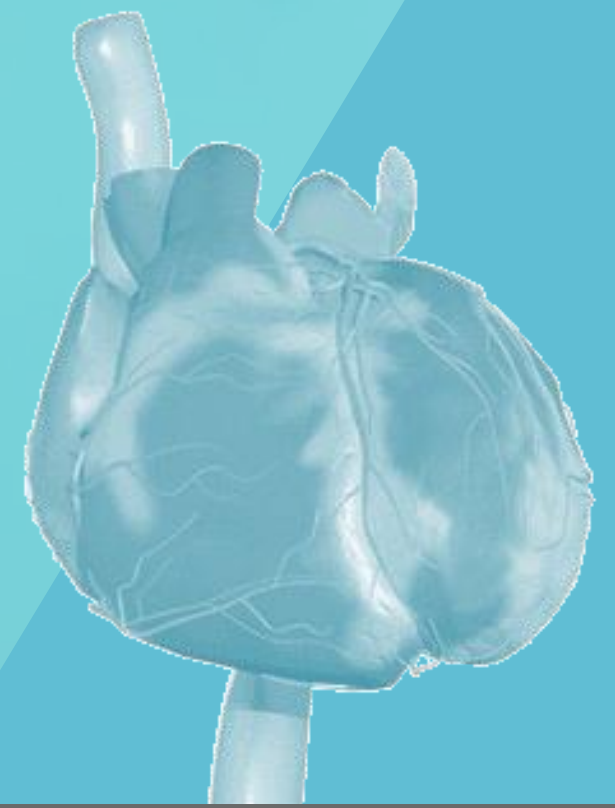
MECHANISM

Creates pressure barrier from purge fluid



Purge Pressure must always be $> 300\text{mHg}$





02 Implantation

Patient assessment prior to implantation

LV thrombus

→ may cause the Impella motor to stop

Mechanical aortic valve

→ contraindicated to impella use

Aortic stenosis/ calcification

→ may inhibit motor to pass the AV

Tortuous iliac artery

→ cause difficulty in insertion



1 Access the femoral artery



Support the shaft of the introducer while advancing into the artery.

- A. Access the femoral artery
- B. Pre-dilate and place peel away introducer
- C. Achieve ACT of 250 seconds or higher
- D. Remove the dilator



2 Insert 4-5 Fr pigtail into left ventricle



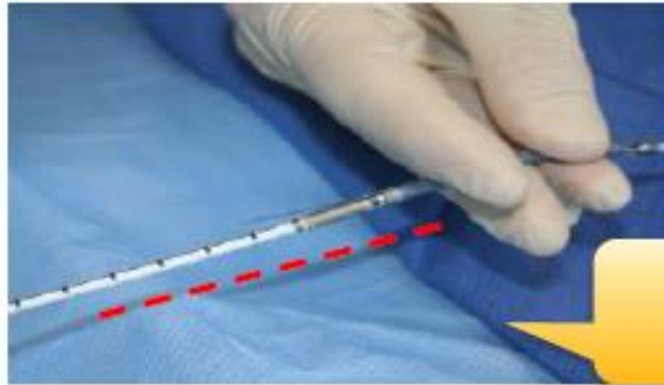
Alternative guidewires are listed in the IFU.

- A. Insert a 4-5 Fr pigtail with or without side holes or a 6 Fr AL1 or MP without side holes into the left ventricle over a 0.035" diagnostic guidewire
- B. Exchange the 0.035" guidewire for the 0.018" placement guidewire
- C. Remove the diagnostic catheter

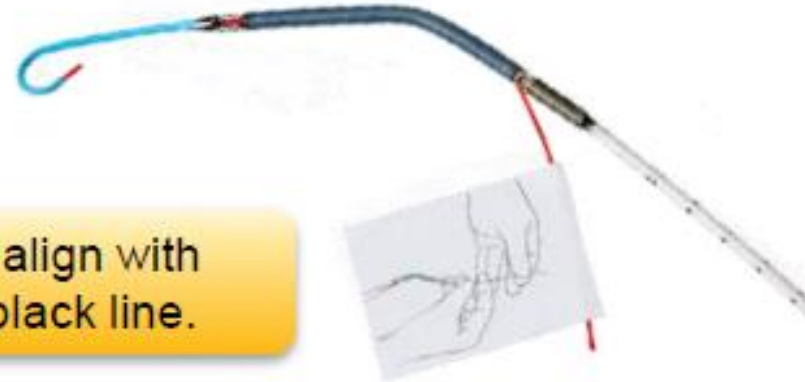


3

Backload using EasyGuide lumen



Wire will align with straight black line.



- A. Insert the guidewire into the red EasyGuide lumen at the tip of the pigtail
- B. Advance the guidewire until it exits the red lumen near the label
- C. Remove the EasyGuide lumen by gently pulling the label while holding the Impella pump



4

Advance the Impella pump



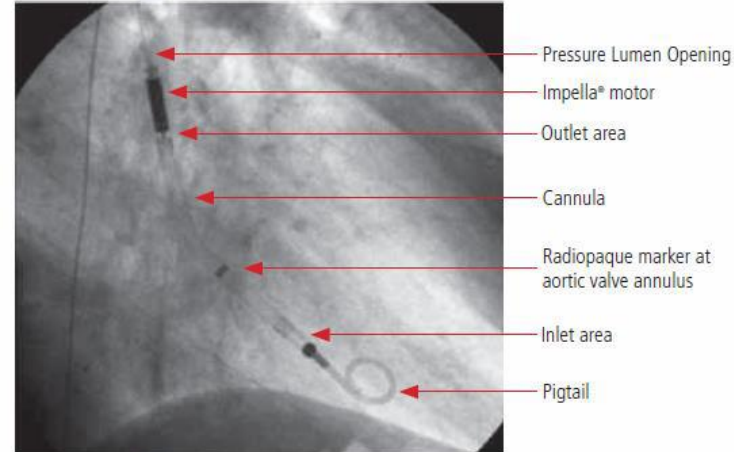
If you feel any resistance as the Impella Catheter passes the tip of the introducer, pull back about 1 cm, advance the Impella, and reposition the introducer.

- A. Advance Impella through peel away sheath
- B. Follow and confirm position with fluoroscopy



Verifying placement

1 Verify proper placement with fluoroscopy



2 Monitor AIC Placement Screen

Aortic placement signal →

Pulsatile motor current →



3 Reposition if needed and remove excess slack

Start a New Impella Case

1. Press the **START IMPELLA** soft button to turn on the Impella® device
2. Press **BACK** to edit Purge Fluid Information
3. Confirm that the guidewire has been removed and pump should be started by pressing the **YES** soft button

The image displays two screenshots of the Impella control interface. The left screenshot shows the main control panel with a 'START IMPELLA' button highlighted by a hand cursor. The right screenshot shows a confirmation dialog box titled 'Start the Impella Catheter?' with a 'YES' button highlighted.

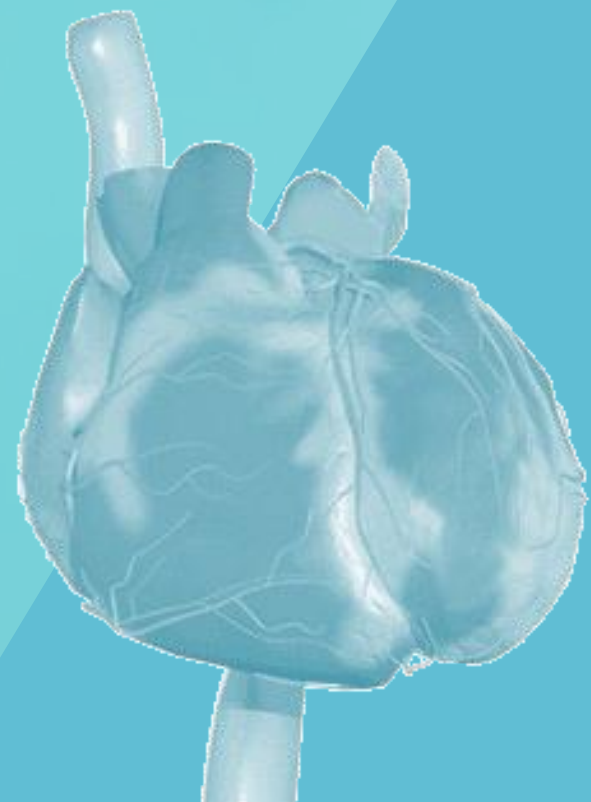
Left Screenshot (Main Control Panel):

- Top left: Impella 2.5 S/N: 42357, 08-12-2014 13:41
- Top right: MUTE ALARM button
- Center: Placement Signal (mmHg) graph showing a red waveform. Values: 109/80 (93), 10 sec.
- Bottom right: START IMPELLA button (highlighted by a hand cursor)
- Bottom left: BACK button
- Bottom center: CANCEL button
- Bottom right: Progress indicator (7 dots, 7th dot highlighted)
- Bottom left: Three CONFIRM messages:
 - CONFIRM - Anticoagulate before removing dilator. (Recommend ACT above 250 seconds)
 - CONFIRM - Purge fluid exits Impella Catheter.
 - CONFIRM - Remove Guidewire before starting Impella.

Right Screenshot (Confirmation Dialog):

- Top right: MUTE ALARM button
- Center: Start the Impella Catheter?
- Bottom right: YES button (highlighted)
- Bottom center: NO button
- Bottom left: Confirm icon (red exclamation mark in a circle)
- Bottom center: Confirm text
- Bottom right: List of confirmation items:
 - Impella inserted in patient
 - Guidewire is removed
 - Red lumen is removed

03 Management



Management



A. Device Monitoring

- Normal Function
- Purge system monitoring
- Normal Position



B. Patient Monitoring

- Hemodynamic
- Wound management

C. Complications/ Trouble shooting

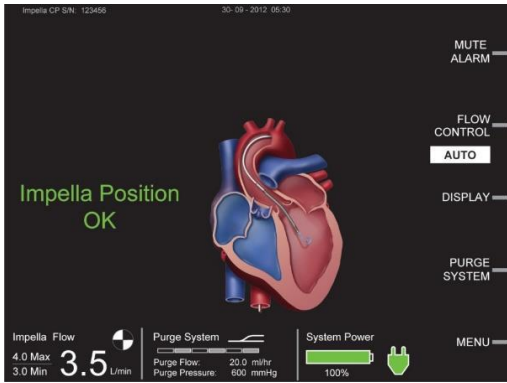
- Suction
- Obstruction
- HIT
- CPR/ Defibrillation



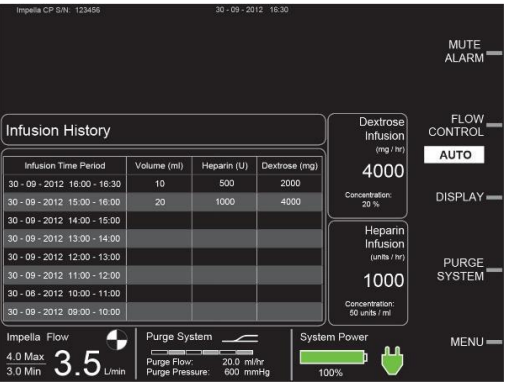
Device monitoring



Placement Screen



Home Screen



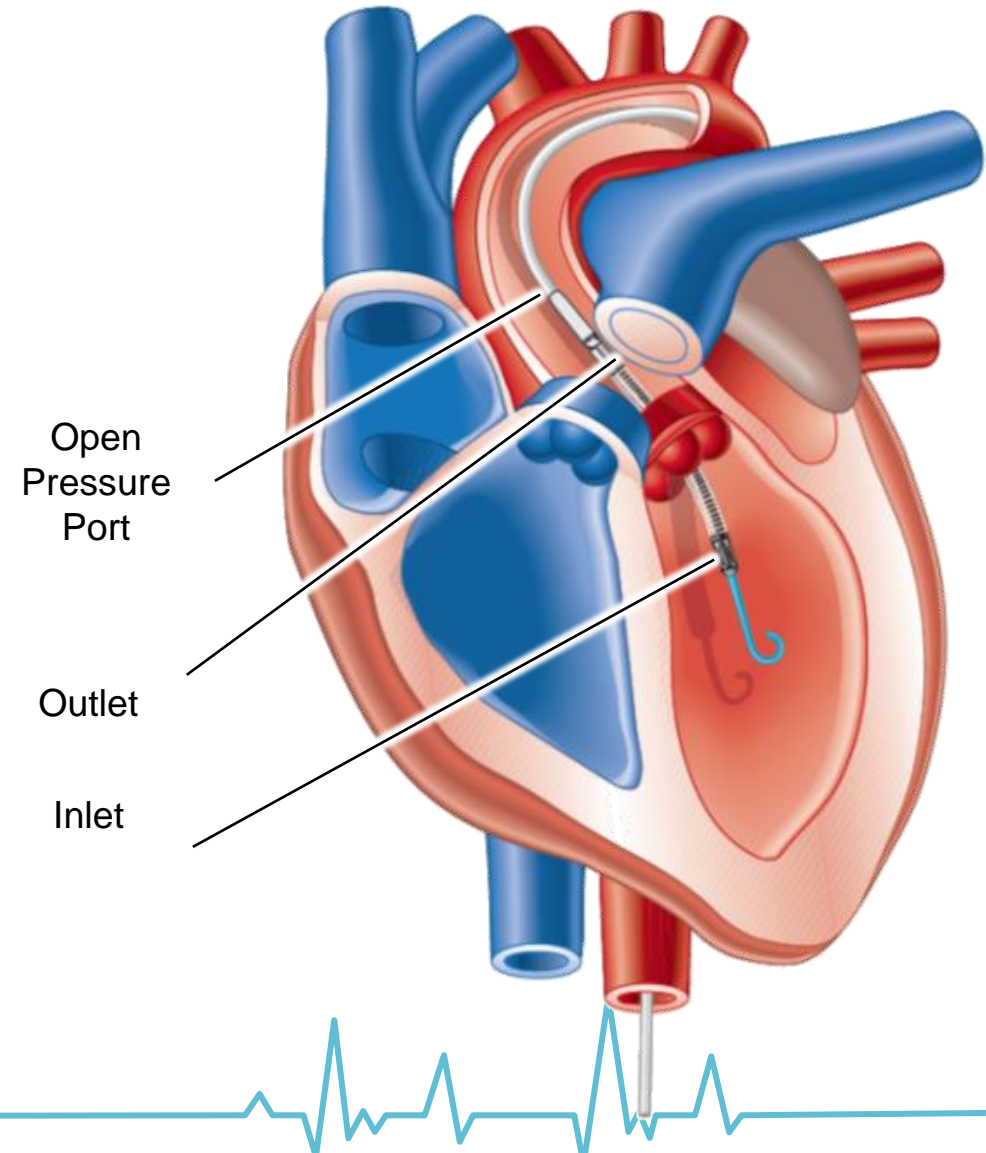
Infusion history Screen



Purge Screen



Normal Function



Purge system monitoring



- Current flow rate
- Max / Min display
- Catheter operation icon

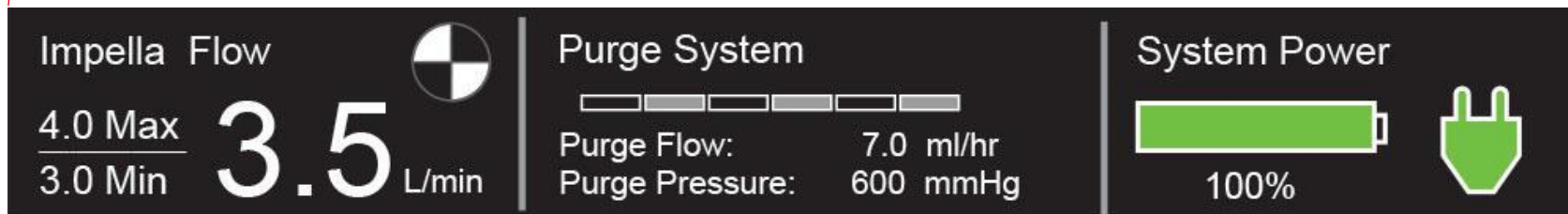
- Purge system marquee
- Purge flow
- Purge Pressure

Battery status

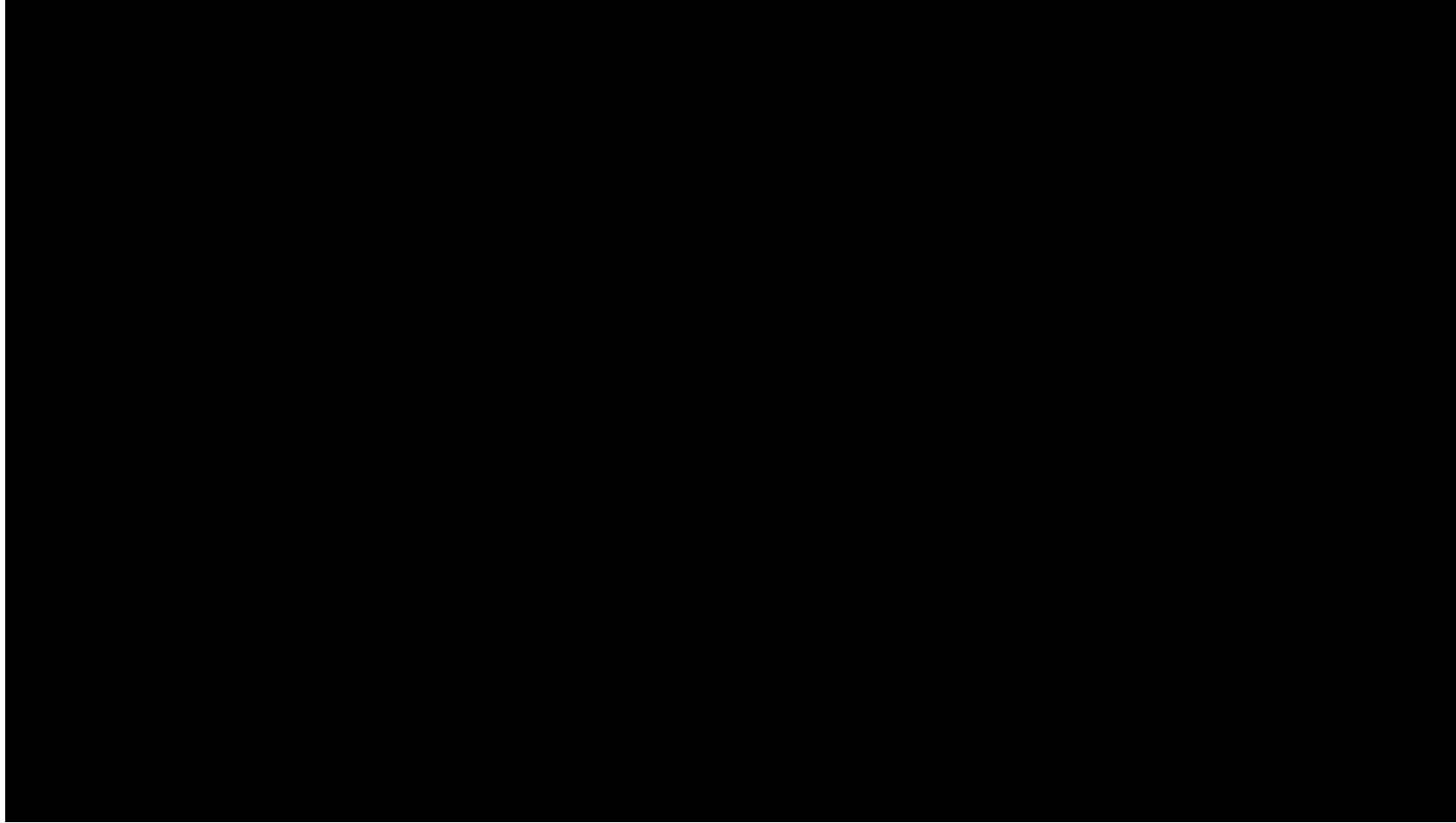
- Full-partial green: >50% charged
- Partial yellow: 16% to <50% charged
- Partial red: <15% charged
- Moving gray: charging

AC plug indicator

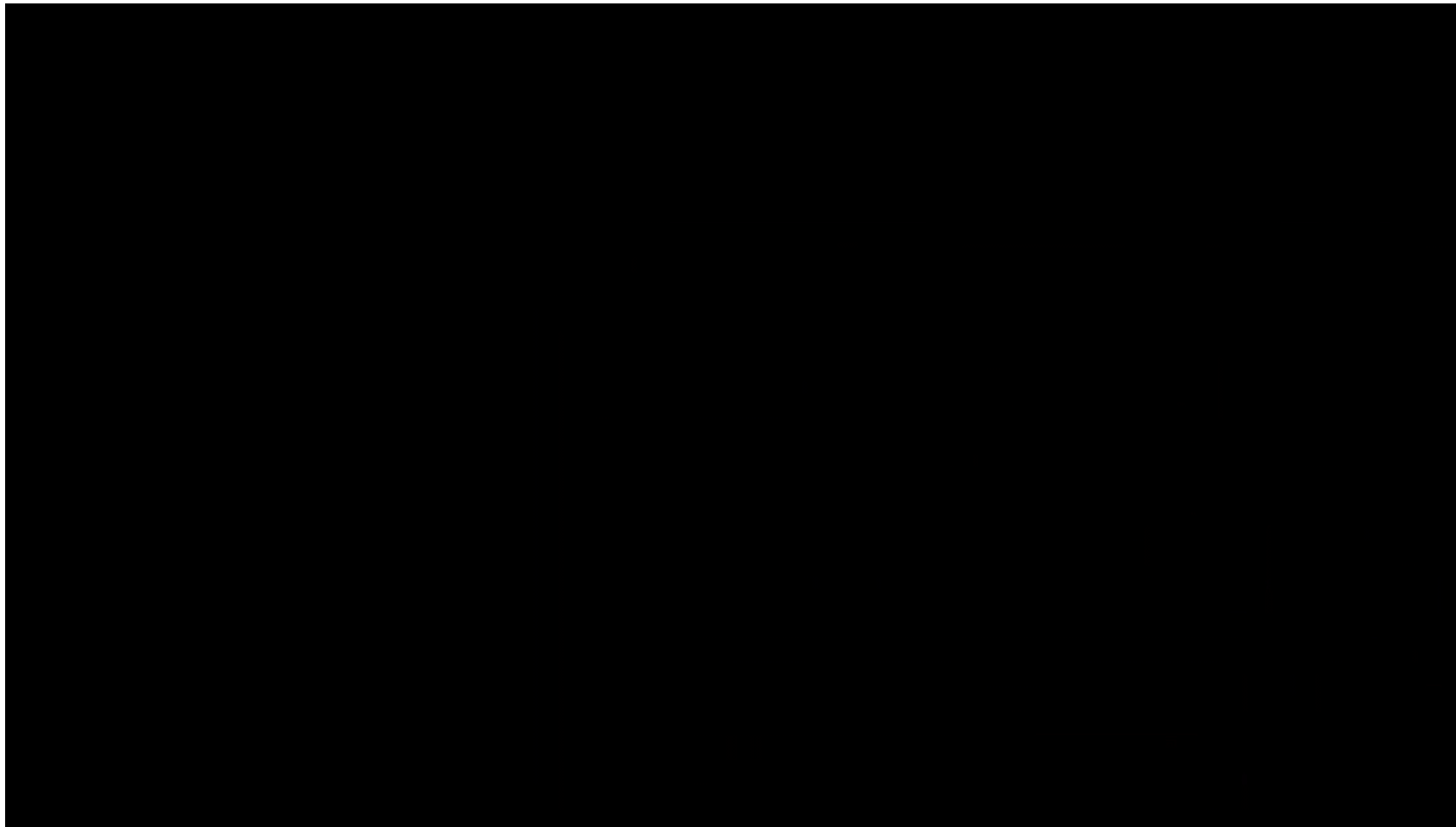
- Green: running on AC power
- Gray with red X: on Battery



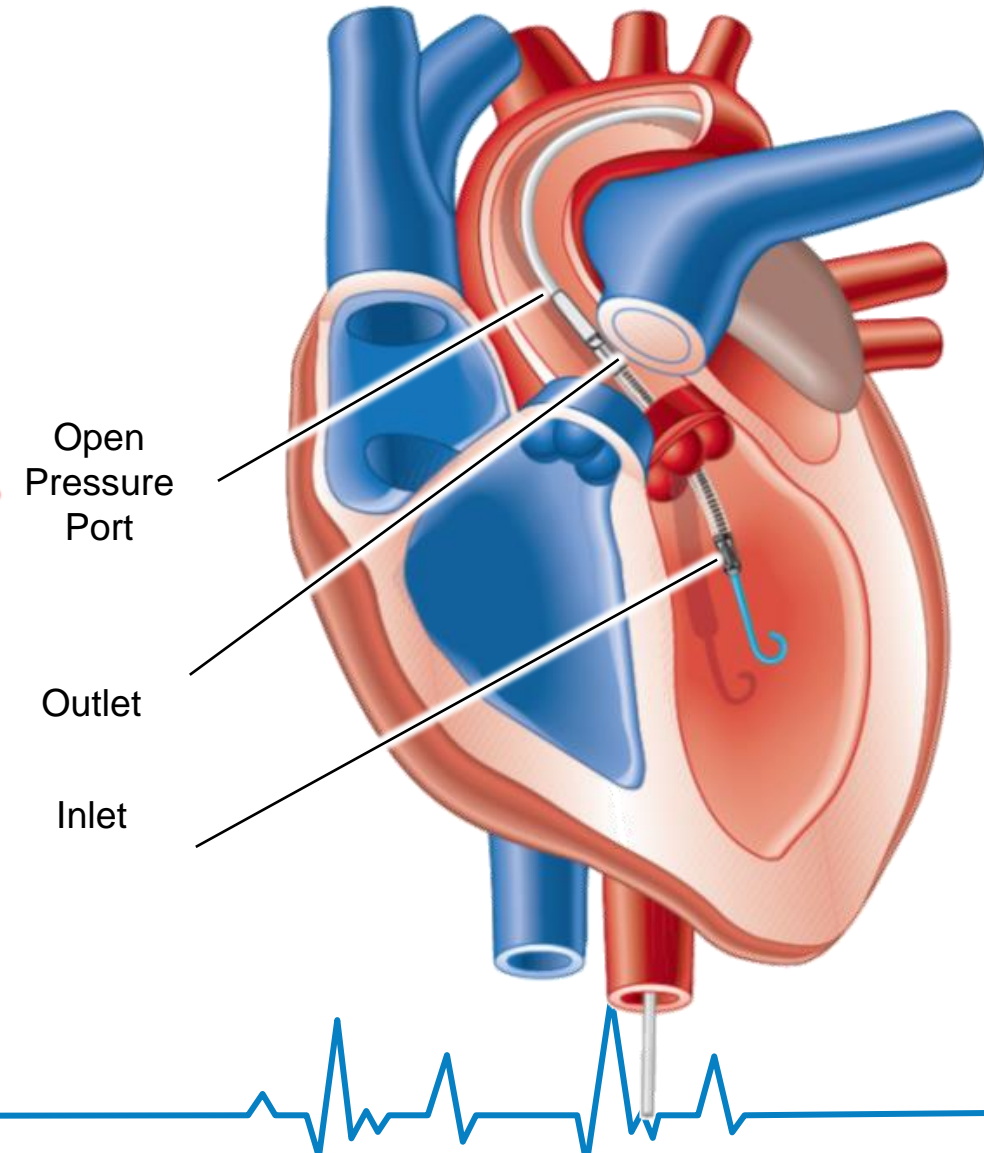
Incorrect position: Impella Position in Ventricle



Incorrect position: Impella Position in Aorta

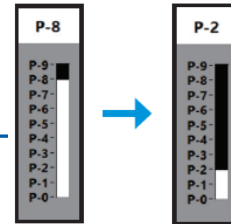


Normal Function



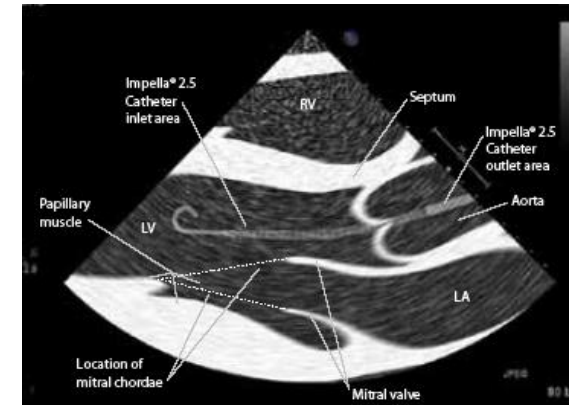
Repositioning

1 Reduce P-level to P-2

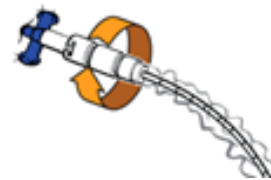


2 Reposition via Echo

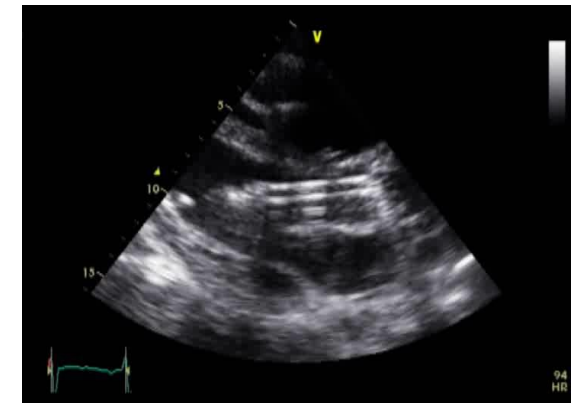
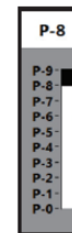
- The inlet should be 3.5 cm below the aortic valve annulus
- Use a parasternal long axis view (TTE) or long axis view (TEE) to make the measurement
- Ensure the device is free from the anterior leaflet of the MV and the subannular structures
- Remove all slack by pulling back on the Impella catheter until you see it just start to move backwards



3 Lock Down the Tuohy



4 Resume Previous P-level Setting



Patient Hemodynamic

Parameter	Goal (with Impella®)	Relation to Patient Management
CVP	≥ 10 mmHg	<ul style="list-style-type: none">• Goal of ≥ 10 mmHg indicate that volume is adequate• Lower suggests that additional volume may be required• Consider adding volume with CVP or PCWP < 10 mmHg and symptoms of suction or hemolysis
PCWP	≥ 10-12 mmHg	
MAP	≥ 60-90 mmHg	<ul style="list-style-type: none">• Goal indicates adequate support• Lower suggests that support may be inadequate• Escalation of therapy may be considered if measures are beneath the goal
CI	≥ 2.2 L/min/m ²	
UOP Urine Output	≥ 30 mL/h	
SvO₂	≥ 60%	



How hemodynamics effect the Impella® device

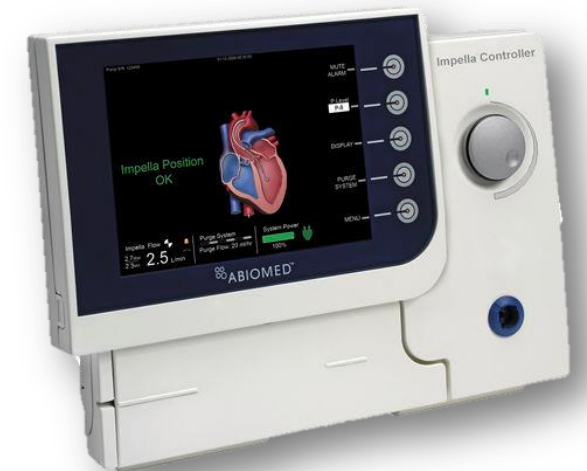
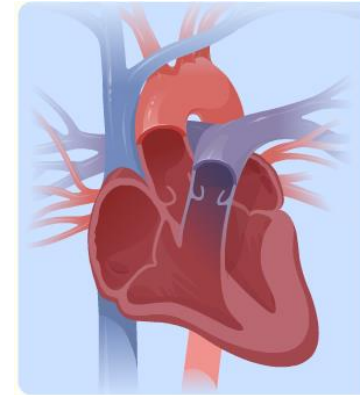
The Impella device is preload dependent; low CVP could precipitate a suction alarm

Rapid infusion of IV fluids may help resolve a suction alarm if low CVP is the cause

Swan Ganz Cardiac Output = Impella device flow + native heart ejection

Native heart will compete with Impella device for volume

The Impella device is afterload sensitive; high SVR can decrease flows from the device



Wound Management and mobility

Bleeding Troubleshooting

ACT should be maintained between 160-180

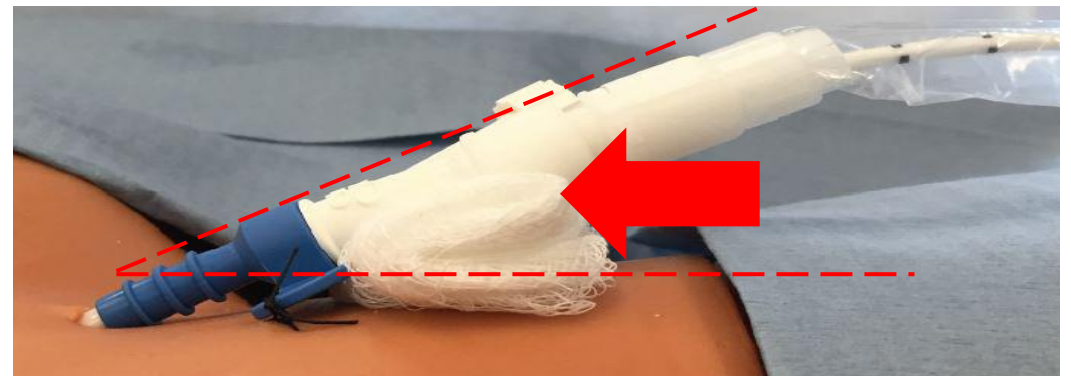
Peel-away sheaths should be removed in Cath Lab

Minimize unnecessary movement

Use leg immobilizer to reduce trauma to access site

Check for forward suturing of repositioning unit butterfly

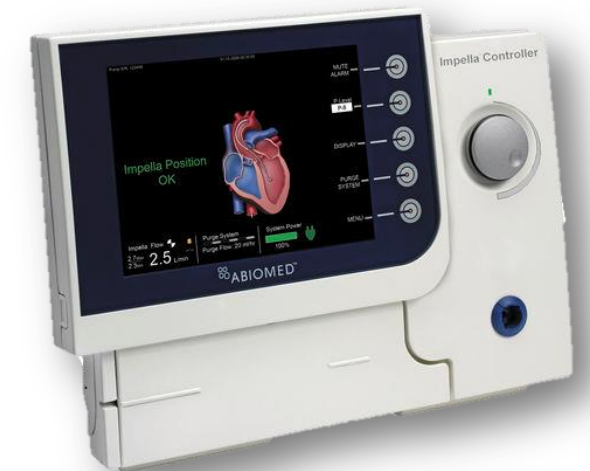
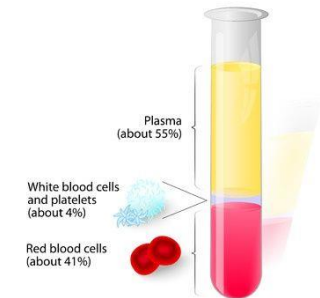
If butterfly is flat against skin, use 4x4s to angle match and reduce lift on vessel



- Impella is designed to be operated with heparin in the purge solution to protect the Impella motor
- HIT should be verified by:
 - 50% drop in platelets since the administration of Heparin
 - positive ELISA test
 - positive serotonin release test (SRA)
 - presence of megakaryocytes on a peripheral smear
- If Heparin must be removed:
 - Any *systemic* DTI may be used to keep the ACT between 160-180 seconds
 - Clinicians can request DTI protocol for use in purge solution by contacting medical affairs ()

*for use of Angiomax or Argatroban in purge solution by visiting

COMPOSITION OF WHOLE BLOOD



Suction Alarm

What causes suction?

- Inadequate LV filling
- Incorrect position in LV
- RV failure

What to look for?

- Alarm: "Suction"
- Lower than expected flows before a suction alarm
- Lower patient blood pressure
- Reduced mean motor current (5-minute display)

What are the effects of suction?

- Lower than expected Impella flow
- Patient may not fully benefit from Impella
- Risk of hemolysis



POSSIBILITIES FOR INTERFERENCE WITH DEVICE OPERATION

Inflow Obstruction

Suction

**Suction
Alarm**

- If ventricular structures obstruct inflow windows, blood will travel faster to enter through unobstructed windows
- Higher speed against cannula wall and other structures causes higher shear and hemolysis

Cannula Obstruction

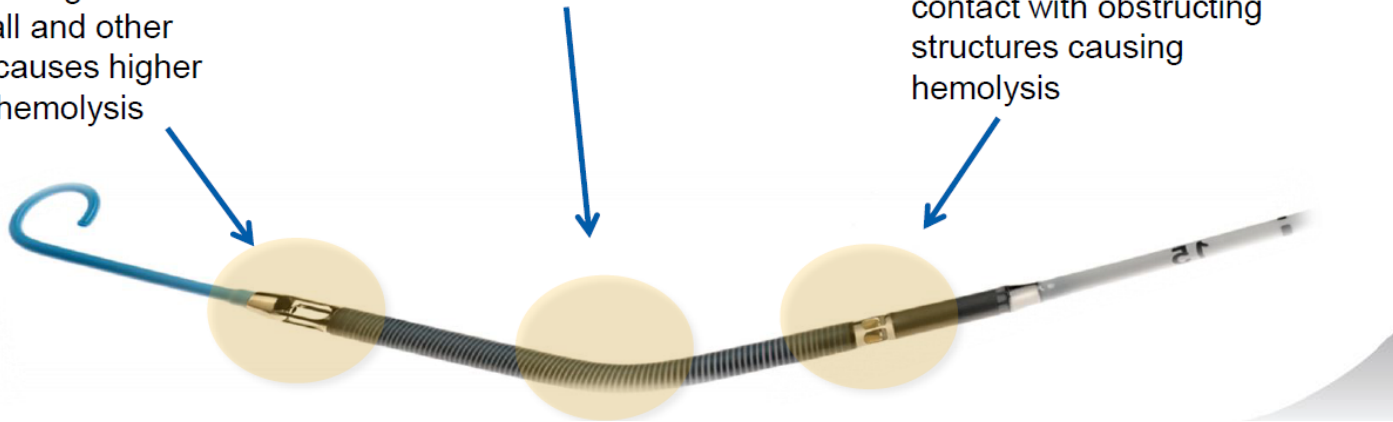
- Obstruction within pump (clot, fiber, etc) creates narrowing of cannula and small passages for blood to pass through, creating high shear and hemolysis

Outflow Obstruction

Impella
Position Wrong

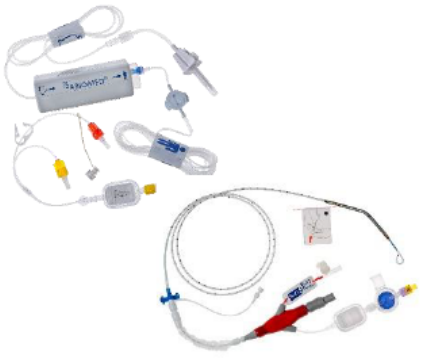
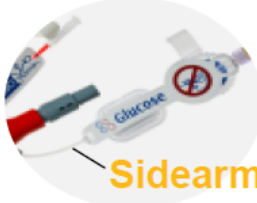

**Position
Alarm**

- If the aortic valve or wall of the aorta obstruct outflow windows, blood will exit pump at higher speeds from unobstructed windows and will make violent contact with obstructing structures causing hemolysis



High Purge Pressure

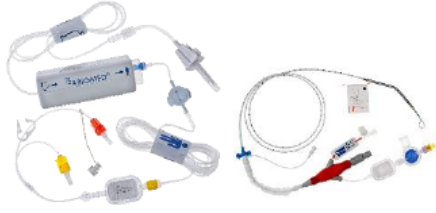


Measurement: Purge Flow \leq 2 mL/hr and Purge Pressure $>$ 1100 mmHg

	Where to look	What to look for	What to do
1		Are there any kinks in the purge tubing, the clear sidearm, or anywhere along the catheter? 	Straighten the tubing, clear the sidearm, or catheter
2		Is the purge fluid concentration too high?	Reduce the purge fluid (dextrose) concentration
3	Motor Current	If unable to resolve high purge pressure, monitor for increases in motor current which can indicate impending pump failure	May need to replace pump



Low Purge Pressure

Measurement: Purge Pressure < 300 mmHg and Purge Flow 30 mL/hr

	Where to look	What to look for	What to do
1		Are there any leaks in the purge cassette, Y connector, or luer connections to the catheter?	Tighten any loose connections
2		Is the dextrose (purge fluid) concentration too low?	Increase the dextrose (purge fluid) concentration
3		Is the leak coming from the purge cassette?	Replace the purge cassette
4	Motor Current	If unable to resolve low purge pressure, monitor for increases in motor current which can indicate impending pump failure	May need to replace pump



Low Pulsatility

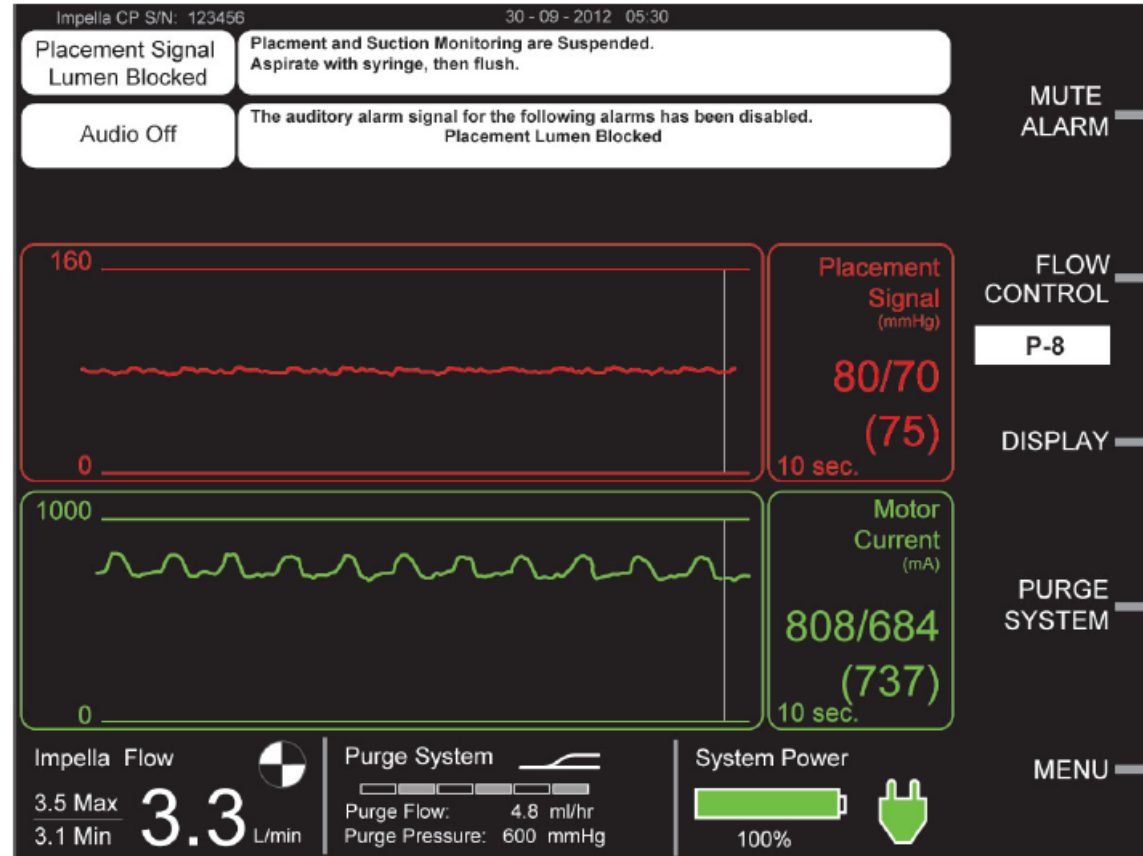
Condition	Alarm	Placement Signal	Motor Current
Low native heart pulsatility	White advisory alarm: "Impella® position unknown due to low pulsatility, assess cardiac function"	Placement signal pulse pressure narrowed to < 20mmHg	Pulsatile but dampened



Placement Signal Lumen Blocked

Placement signal lumen clotted off due to:

1. Closed or partially closed roller clamp on saline bag
2. Pressure bag not inflated > 300 mmHg

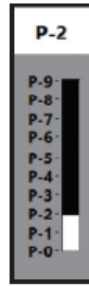


Emergency situations

CPR – *What to do?*



1. Initiate CPR per hospital protocol
2. Reduce Impella flow rate to P-2
3. When cardiac function has been restored:
 - Assess motor current
 - If pulsatile, return to previous setting
4. Check positioning using echo when possible

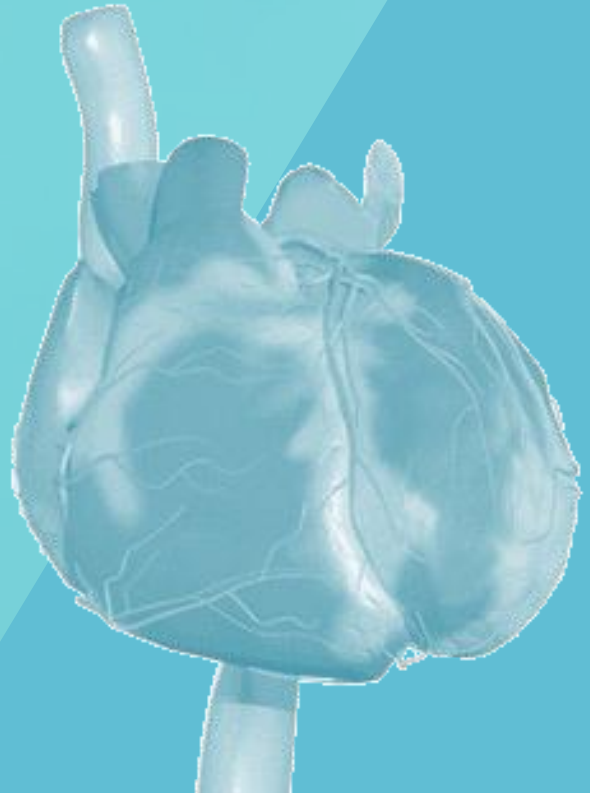


Defibrillation – *What to do?*

- Initiate defibrillation per hospital protocol

NOTE: It is not necessary to reduce P-level



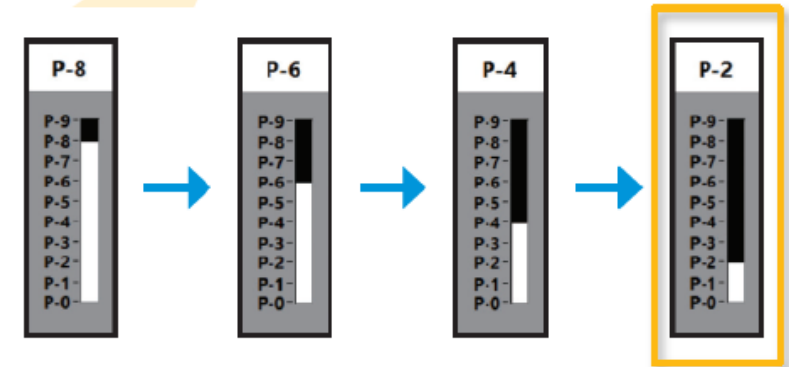


04 Weaning & Explant

Weaning and explant

To initiate weaning a patient from Impella[®] support . . .

1. Press **FLOW CONTROL** and decrease flow rate by 2 level increments as cardiac function allows
2. Maintain support at P-2 until hemodynamics are stable
3. Reduce to P-1 and pull catheter into the aorta
4. Reduce flow to P-0 (0.0 L/min) and remove the Impella device
5. When ACT < 150 seconds, apply manual compression per hospital protocol



Do not reduce flow below P-2 until just before removing the catheter from the ventricle.





Thank you