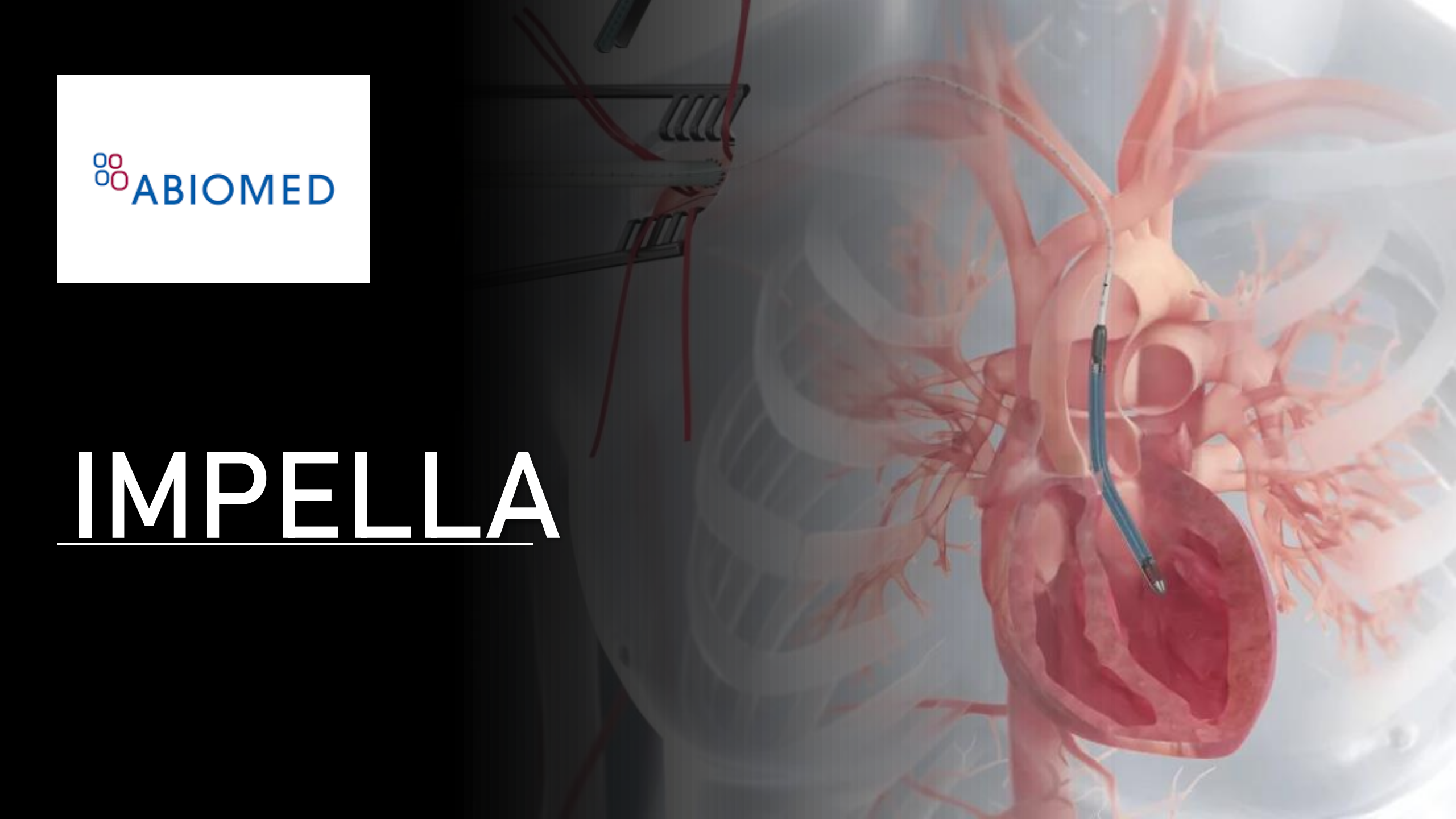
ABIOMED

IMPELLA



Learning Objectives

Access

- Implant locations
- Assess Insertion site
- Catheter locked/secured

Basic Vitals and Biomarkers

Console

- Automatic Impella Controller
- Waveforms
- Alarm Troubleshooting

Dextrose

- Purge Management

Emergencies, Escalation and EcPella, Explant and Weaning

IMPELLA® DEVICE INDICATION & SAFETY INFORMATION

INDICATIONS FOR USE

High-Risk PCI

The Impella 2.5®, Impella CP® and Impella CP® with SmartAssist® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, Impella CP, and Impella CP with SmartAssist Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Cardiogenic Shock

The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, Impella 5.5® with SmartAssist® and Impella LD® Catheters, in conjunction with the Automated Impella Controller™ (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

EMERGENCY USE AUTHORIZATION: Impella Left Ventricular (LV) Support Systems (Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella 5.5 with SmartAssist) are authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients (i.e. patients in the intensive care unit) with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella LV Support Systems have been authorized for the above emergency use by the FDA under an EUA. The Impella LV Support Systems have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IMPORTANT RISK INFORMATION FOR IMPELLA DEVICES

CONTRAINDICATIONS: The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm^2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade*

**This condition is a contraindication for the cardiogenic shock indication only.*

POTENTIAL ADVERSE EVENTS: Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.
Visit ***http://www.abiomed.com/important-safety-information*** to learn more.

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IMPELLA CONNECT®– INDICATION & SAFETY INFO.

INTENDED USE

Impella Connect® transfers a video image of the screen on the Automated Impella Controller™ to an authorized remote user. The transmitted image can be viewed by authorized remote users. The users can include the hospital's clinicians, Abiomed local support staff, and Clinical Support Center (CSC) team members.

PRECAUTIONS

- Impella Connect is not intended to provide real-time information for monitoring patient status on the Automated Impella Controller.
- During use of the Impella Connect, there will be a delay between when an image appears on the controller screen and when it is displayed at a remote viewing location.
- The Impella Connect is not a source of patient alarms, nor is its use intended as a replacement for monitoring the controller's alarms.
- During use of the Impella Connect, receipt of the displayed controller information is not confirmed by the Automated Impella Controller, nor is the delivery of the displayed controller information to the authorized remote users guaranteed.
- The Impella Connect is not designed for use during transport.
- Radiated and conducted electromagnetic interference can affect the performance of the Impella Connect, causing a temporary loss of connectivity. To clear interference, either increase the distance between system components and the EMI source or turn off the EMI source. Any electromagnetic interference related to the Impella Connect will have no impact on any of the controller functional specifications.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

In addition to the information above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.
Visit ***http://www.abiomed.com/important-safety-information*** to learn more.

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The Impella Family of Devices

Impella 2.5®
Impella® makes a Protected PCI procedure possible

Impella CP® / SmartAssist®
Percutaneous insertion, increased flow and repositioning without imaging

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

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

Impella 5.5® with SmartAssist®
Delivers full forward flow from the left ventricle

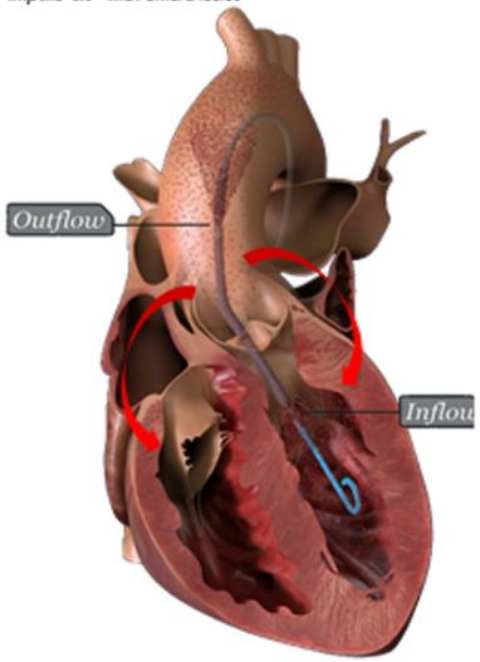
Automated Impella Controller
The primary user control interface for the Impella platform

Hemodynamic Stabilization With Impella Devices

Unloads Left Ventricle & Coronary Perfusion

Left Side

Impella 2.5®
Impella CP®
Impella CP® with SmartAssist®
Impella 5.0®
Impella LD®
Impella 5.5® with SmartAssist®



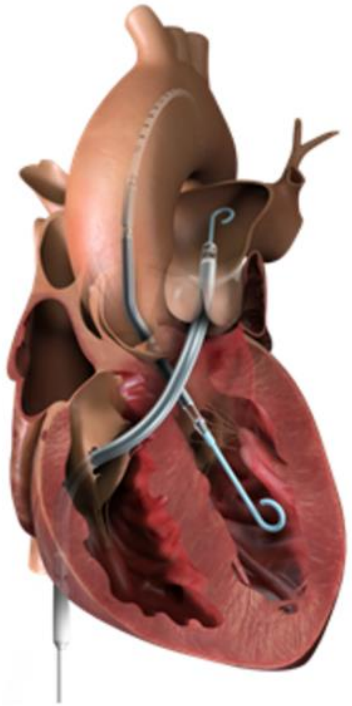
Seyfarth M et al., JACC, 2008
Remmelink M et al., Catheter Cardiovasc Interv, 2007

End Organ Perfusion

Lam K et al., Clin Res Cardiol, 2009
Casassus F et al., JOIC, 2015

Right Side Support

Right Side
Impella RP®



Anderson MB et al., J Heart Lung Transplant, 2015

Escalation & Ambulation

Lima B et al., Am J Cardiol, 2016

IMP-1381 v2

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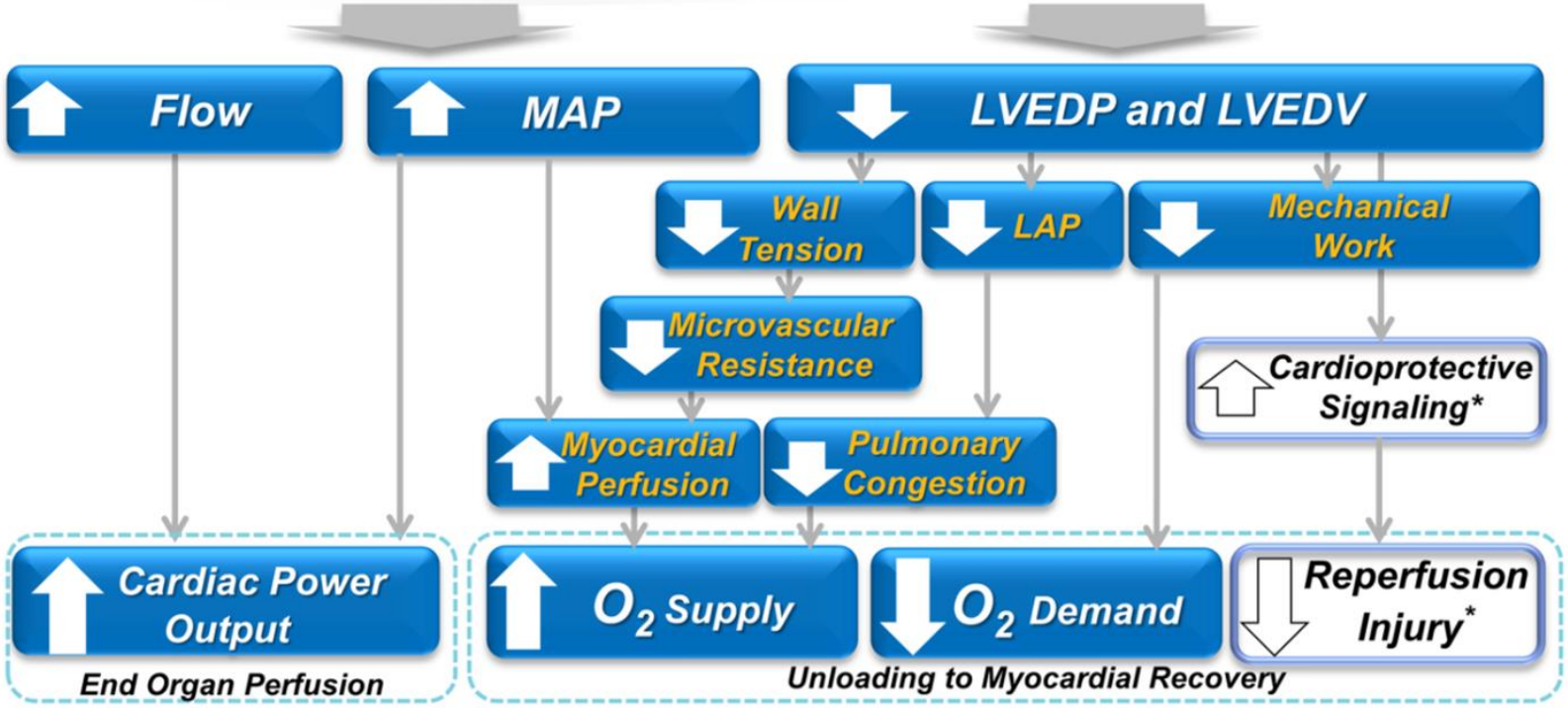
Hemodynamic Effects of Impella Devices



* Under study

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Weber DM, et al. Cardiac Interventions Today Supplement Aug/Sep 2009

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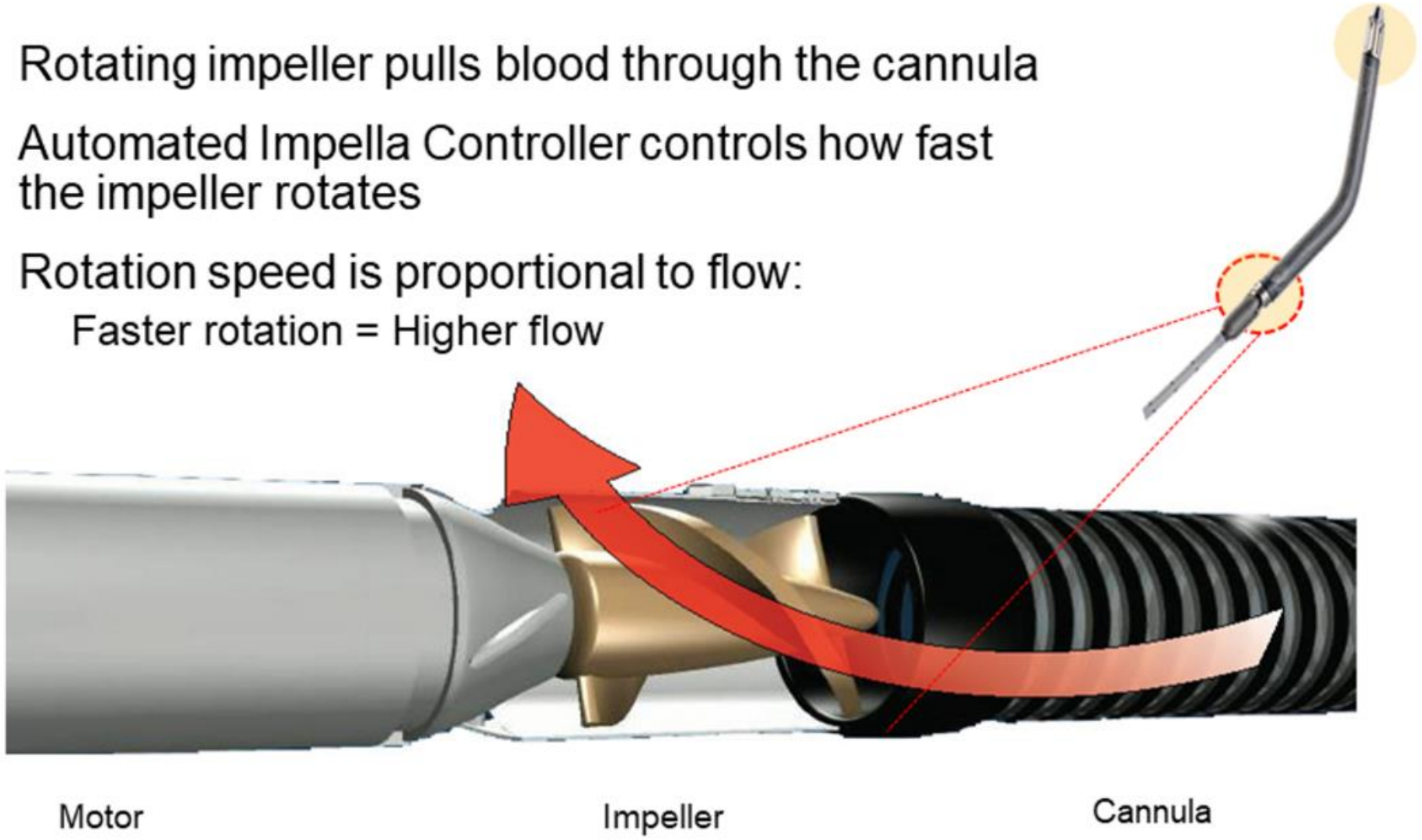
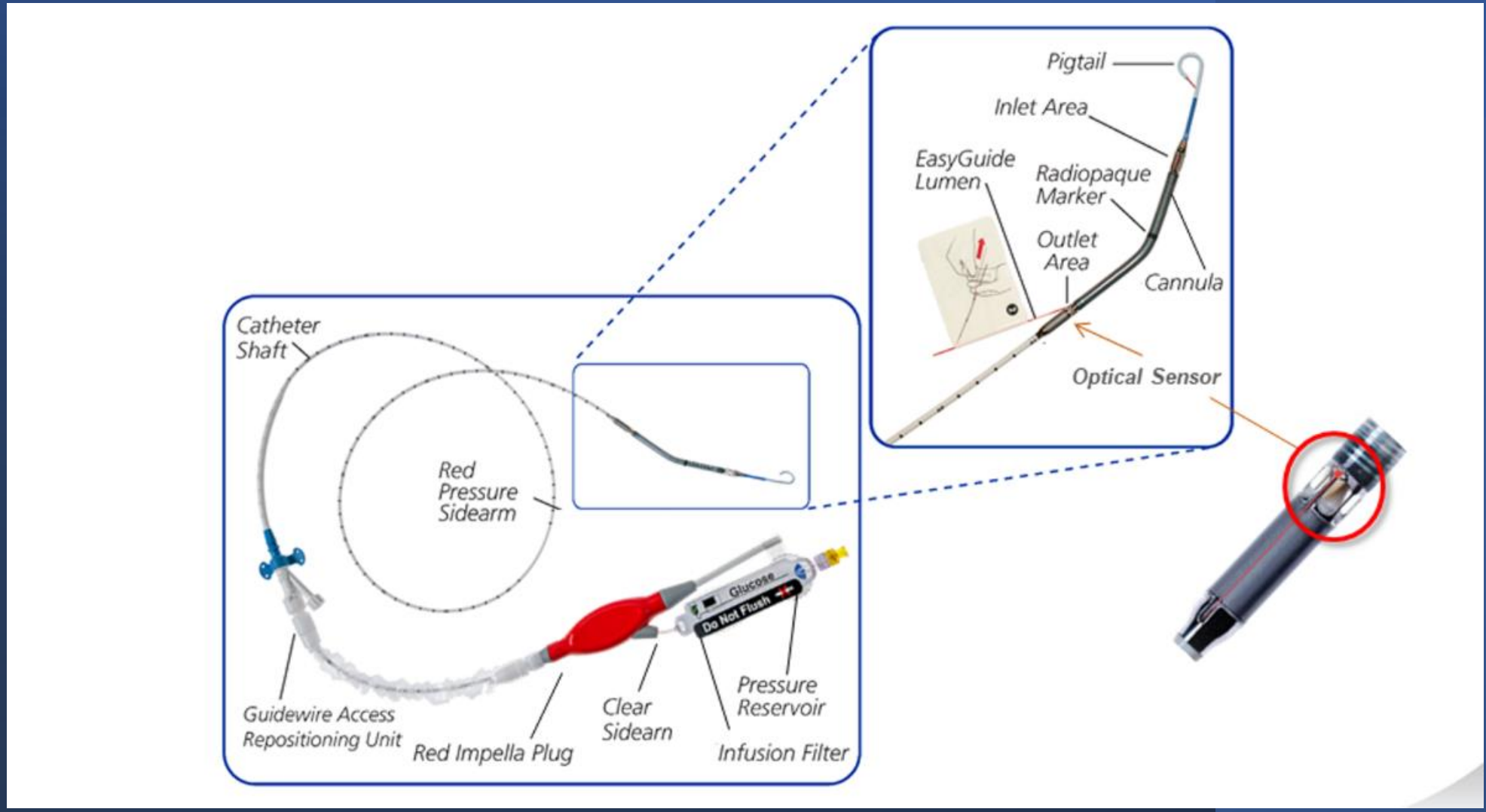
Moving The Blood

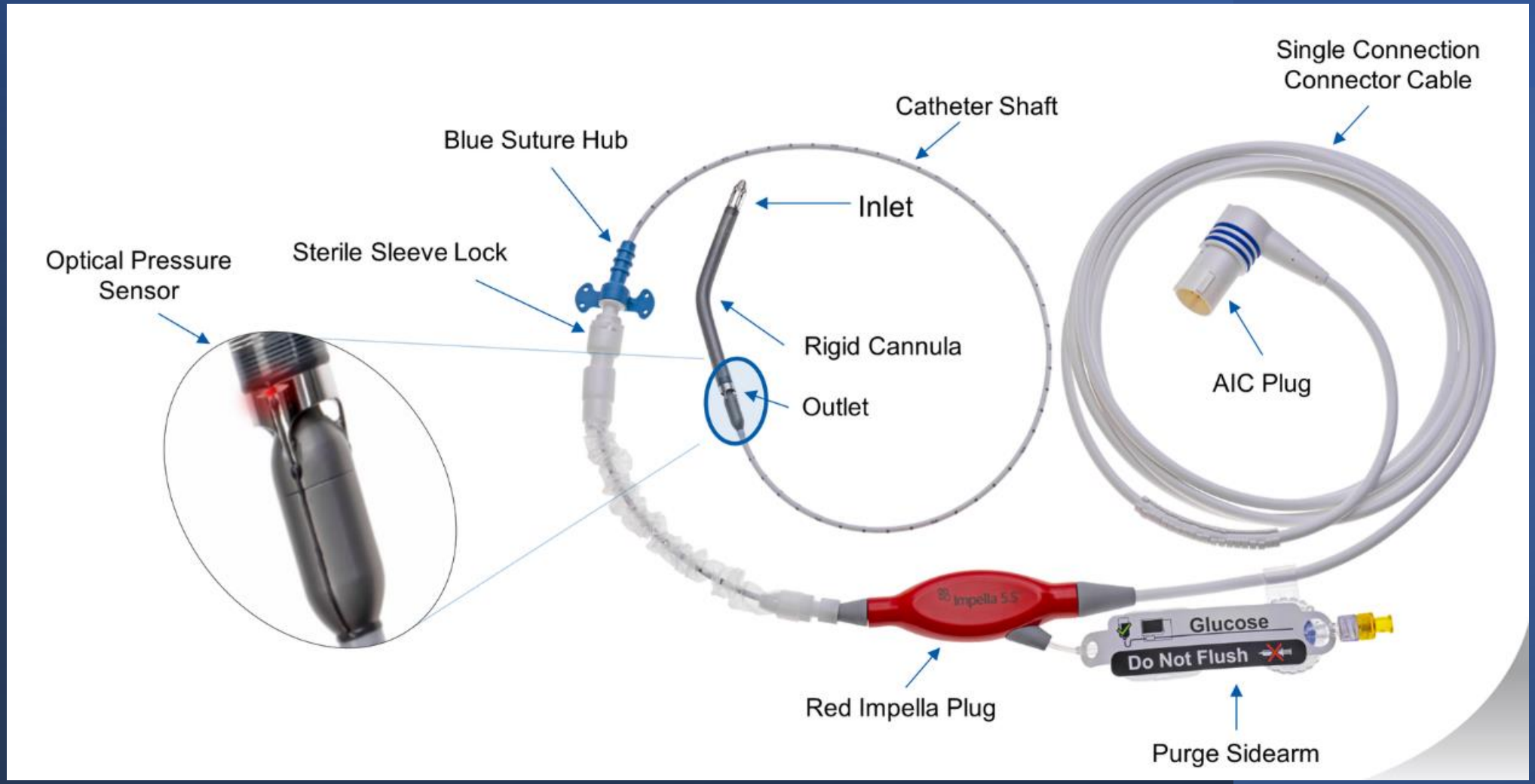
- Rotating impeller pulls blood through the cannula
- Automated Impella Controller controls how fast the impeller rotates
- Rotation speed is proportional to flow:
  Faster rotation = Higher flow



Impella CP


Pigtail
Inlet Area
EasyGuide Lumen
Radiopaque Marker
Outlet Area
Cannula
Optical Sensor
Catheter Shaft
Red Pressure Sidearm
Glucose
Do Not Flush
Guidewire Access Repositioning Unit
Red Impella Plug
Clear Sidearn
Pressure Reservoir
Infusion Filter

Impella 5.5


Single Connection
Connector Cable
Catheter Shaft
Blue Suture Hub
Inlet
Optical Pressure
Sensor
Sterile Sleeve Lock
Rigid Cannula
Outlet
AIC Plug
Glucose
Do Not Flush
Red Impella Plug
Purge Sidearm

Access

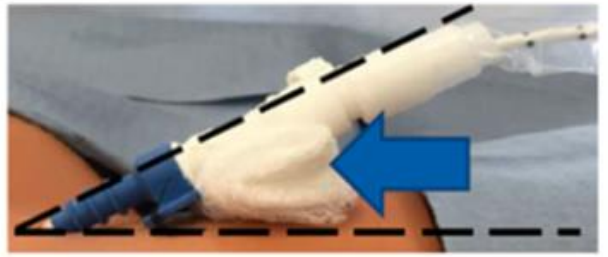
- Implant locations
- Assessment | Best Practices
- No Alcohol

IMPELLA CP PATIENT CHECK-IN | ASSESSMENT

ICU PATIENT CHECK-IN: ASSESSMENT

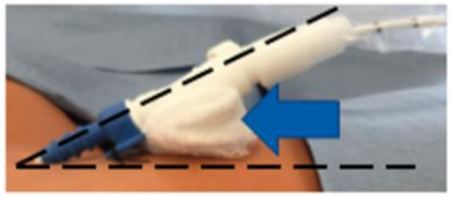
Patient Check-In:

- Call the Clinical Support Center or local Abiomed Representative to Check-In patient
- Ensure access angle of entry is maintained
- Record CM marking on the Impella catheter closest to the sheath
- Ensure Tuohy-Borst valve is locked

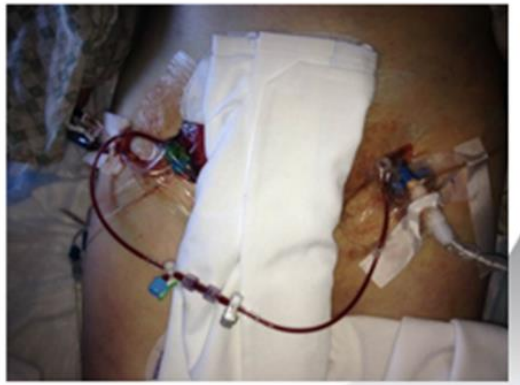


ICU Groin Management

- Bleeding troubleshooting
  - ACT should be between 160 – 180 seconds
  - Peel-away sheaths should be removed in Cath Lab
  - Recommend minimizing unnecessary movement/rolling of patient. Consider physician orders for no rolling.
  - Use of leg immobilizer can 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



- Ischemia troubleshooting
  - Increased likelihood if introducer sheath is left in place
  - Physician may use fem-fem bypass for life vs. limb considerations – contact Medical Affairs for more information
  - Be aware of clotting in sidearm connection (the smaller the tubing, the greater the chance for clotting)



ICU GROIN MANAGEMENT

What to do if there is bleeding around the sheath?

- Notify MD
- Assess sheath position and type
- Apply folded gauze under repositioning sheath hub to prevent tenting of the arteriotomy
- Apply pressure as needed

- Ensure ability to visualize and assess site
- Monitor marked edges for bleeding progression

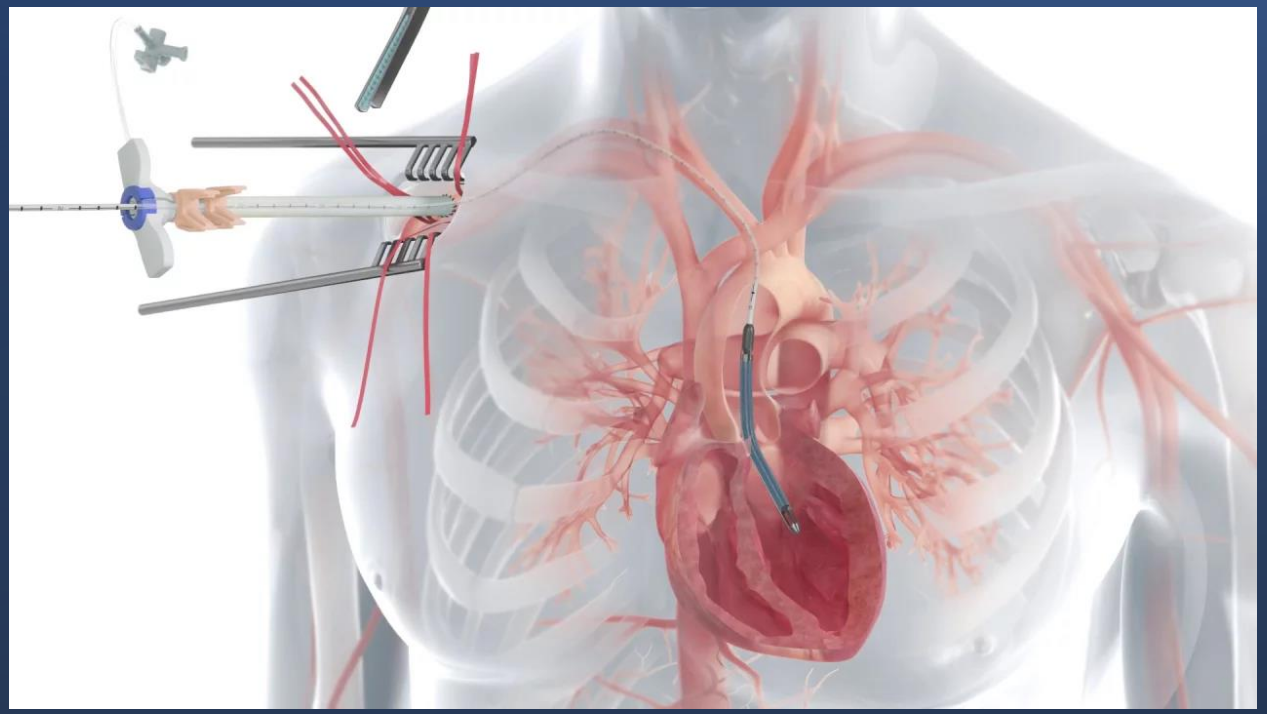
What to do if there is blood in the sterile sleeve of the Impella device?

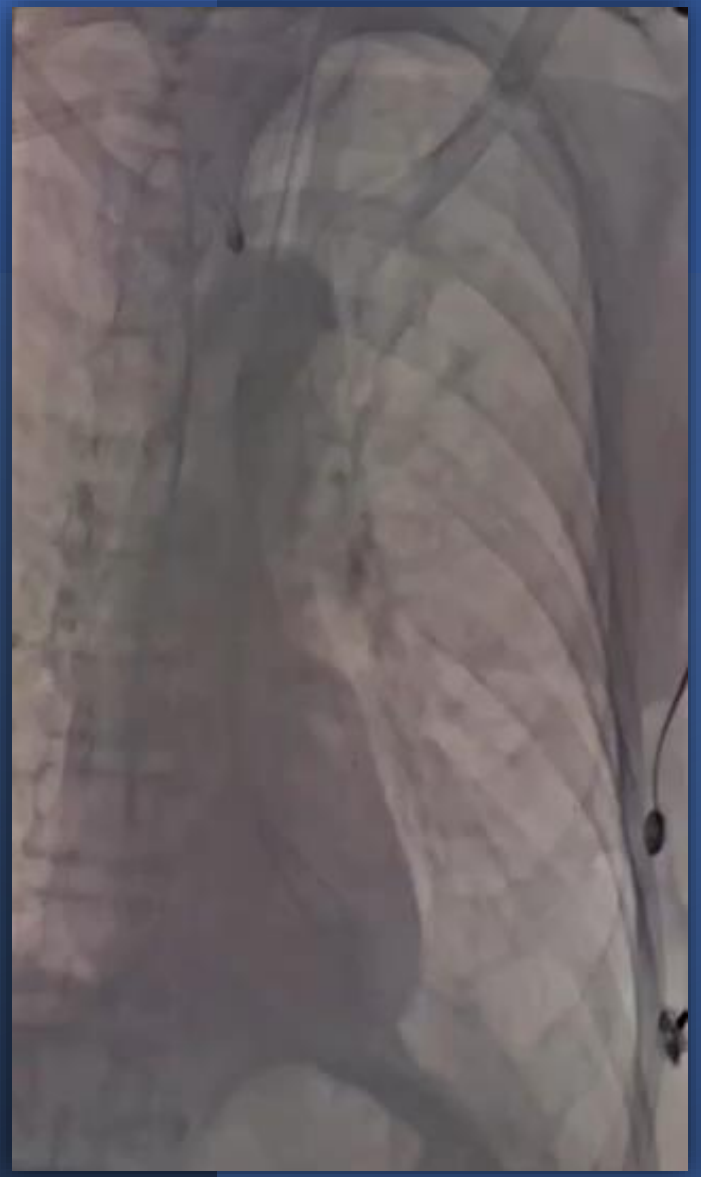
- Ensure the sidearm has a dead-end cap
- Loosen distal sleeve and milk the blood out through the sleeve

GENERAL PATIENT CONSIDERATIONS

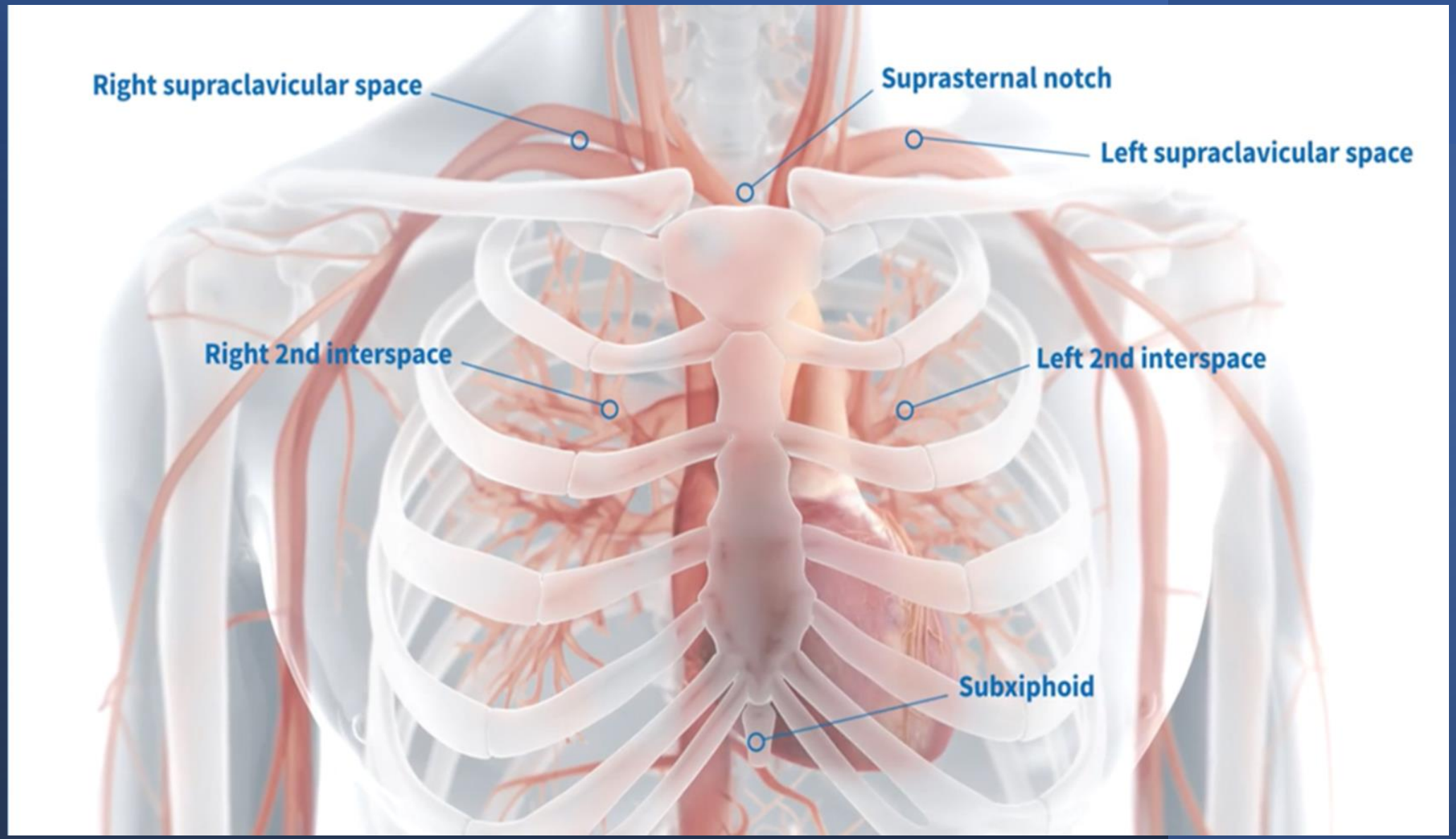
- With femoral access site, do not raise the head of the bed to higher than a 30-degree angle.
- Use knee immobilizer as needed to maintain access site straight.
- Perform dressing changes per hospital protocol, using aseptic technique.
- Assess access site for bleeding and hematoma.
- Be careful not to pull on the Impella Catheter when transferring a patient from one bed to another.
- Monitor distal pulses.
- Maintain an ACT of 160 – 180 or an equivalent pTT.

IMPELLA 5.5
AXILLARY INSERTION





Impella 5.5 Direct Approach Externalization Options



IMPELLA 5.5 PATIENT CHECK-IN | ASSESSMENT

ICU PATIENT CHECK-IN: ASSESSMENT

Check-In your patient:

- ✓ Call the Clinical Support Center or your local Abiomed Representative to check in your patient
- ✓ Tuohy-Borst valve is locked
- ✓ Impella Sidearm Retainer is equipped on purge sidearm
- ✓ External fixations secured near Tuohy-Borst and red plug
- ✓ CM marking on the Impella catheter closest to the Tuohy-Borst is recorded
- ✓ Volume status is assessed and is adequate (target CVP ≥ 10 mmHg if frequent suction alarms)
- ✓ Urinary output for color and amount is recorded

IMP-1434 .v4

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IMPORTANT ICU HANDLING REMARKS

4 Key Points

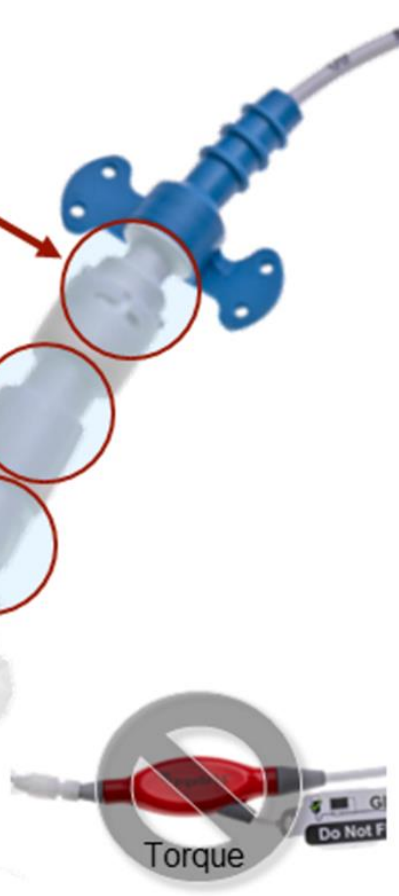
1. Attach Sidearm Retainer
2. Clip Purge Sidearm
3. Tighten Tuohy-Borst
4. Three-Point Fixations

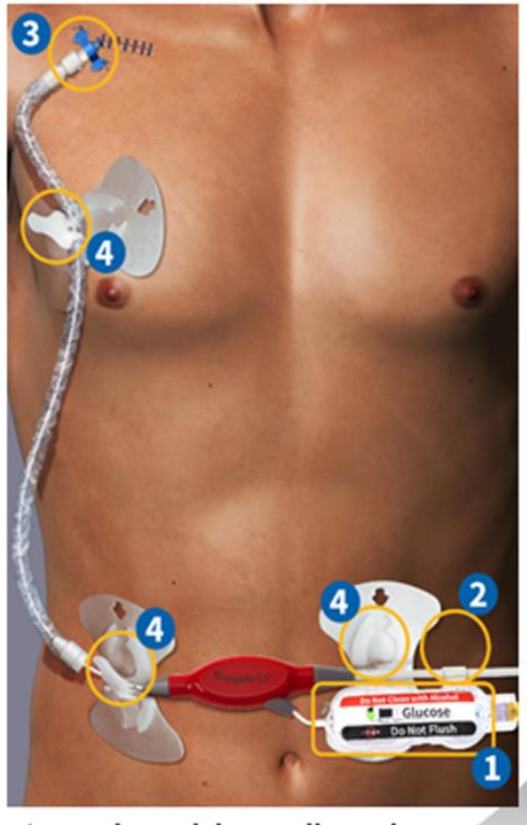
Ensure to lock sterile sleeve clockwise

Check Tuohy-Borst adapter is locked and tightened clockwise

Check centimeter marking and document for future reference

Torque the catheter near the Tuohy-Borst when repositioning the Impella 5.5, ***not*** the red pump plug





*Make sure fixation devices are properly secured near Tuohy-Borst and red Impella plug

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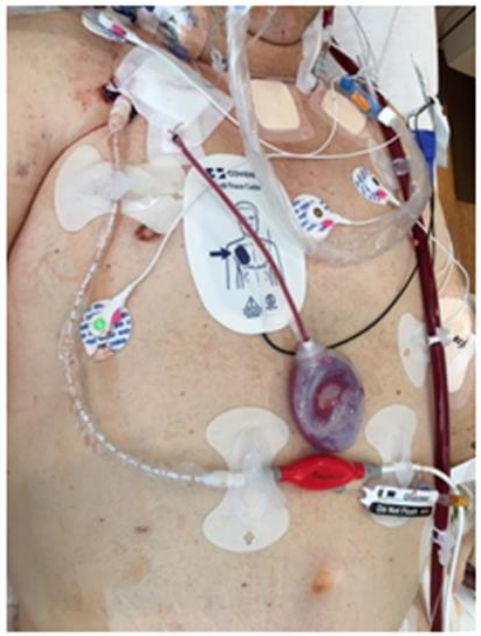
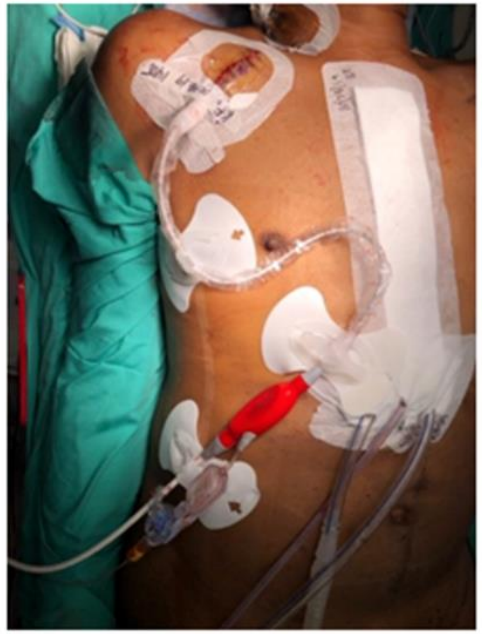
EXTERNAL FIXATIONS FOR IMPELLA 5.5



Good Position - Purge Sidearm positioned above waist away from patient's side



Poor Position - Purge Sidearm on side (rolling concern)

Poor Position - Purge Sidearm below waist on hip (rolling, sitting, and ambulating concerns)

Position the Red Impella Handle and Purge Sidearm more midline above the waist and away from the patient's side

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B

- Basic Vitals
- Biomarkers
- Balancing Preload/Afterload

Patient Management – Vitals & Biomarkers

Impella Hemodynamic Target Values

MAP		≥ 60 mmHg
CVP		≥ 10 mmHg
CPO		≥ 0.6 Watts
CI		≥ 2.2 L/min/m²
UOP		≥ 30 ml/hr
PAPi		> 1.0
PaS		
PaD		

Additional Values to Consider

Lactate		2 mmol/L
Creatinine		
pTT		
ACT		160-180 sec
Hemoglobin		
Hematocrit		
SPO_2		
SVR		
PVR		

WHAT IS P-A-P?

Preload	The pressure and volume in the ventricle at end diastole
Afterload	The pressure the ventricle must overcome to eject blood
Positioning	Correct positioning is critical for optimal Impella function and patient outcomes

The Impella device is Preload dependent and Afterload sensitive

PRELOAD DEPENDENT

Impella® is preload dependent.

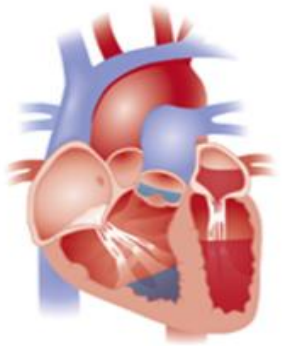
What if there is inadequate preload?

- Increased likelihood of suction alarms
- RBC shearing may become a concern

Why is there inadequate preload?

Patient may be:

- Receiving diuretics
- On continuous dialysis
- Bleeding
- Right heart dysfunction
- Concurrently on ECMO



Recommendations for Preload

- ☑ CVP >10 mmHg
- ☑ PCWP ≥ 10 mmHg
- ☑ Monitor volume status through PA catheter

This is important for proper preload maintenance as well as overall hemodynamic monitoring.

Reminder:

- If there are signs of hemolysis and/or suction alarms, CVP and/or PCWP should be >10 mmHg
- If CVP and/or PCWP is < 10 mmHg and there are no issues, there is no reason to recommend additional volume.

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AFTERLOAD SENSITIVE

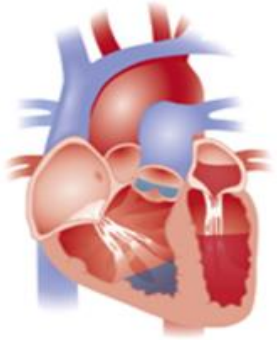
Impella® is afterload sensitive.

What if there is high afterload?

- Impella flow is sensitive to the pressure gradient between the aorta and the left ventricle.
- Impella device flows may be lower than expected when afterload is high

Why is there high afterload?

- Physiologic effects
- Use of vasopressors
- Concurrently on V-A ECMO



Recommendations for Afterload

- ☑ Monitor MAP (Mean Arterial Pressure) and Systemic Vascular Resistance (SVR)
- ☑ MAP goal, while on Impella device: 60 - 80 mmHg

Medical therapy, such as inotropes and/or vasopressors may be reduced with appropriate Impella support which can also lead to decreased mortality rates.

MAINTAINING PROPER AFTERLOAD

If patient is hemodynamically stable, reduce the use of vasopressors when possible.

In situations of high arterial pressures, due to chronic conditions, vasodilators may assist in reducing afterload.

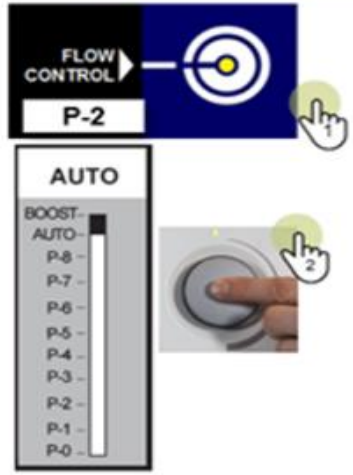
If a patient remains on V-A ECMO while on Impella support, it will be necessary to reduce P-level to account for the lower flows from the device.

Vasopressors

Constrict blood vessels, increasing blood pressure

Vasodilators

Dilate blood vessels, decreasing blood pressure



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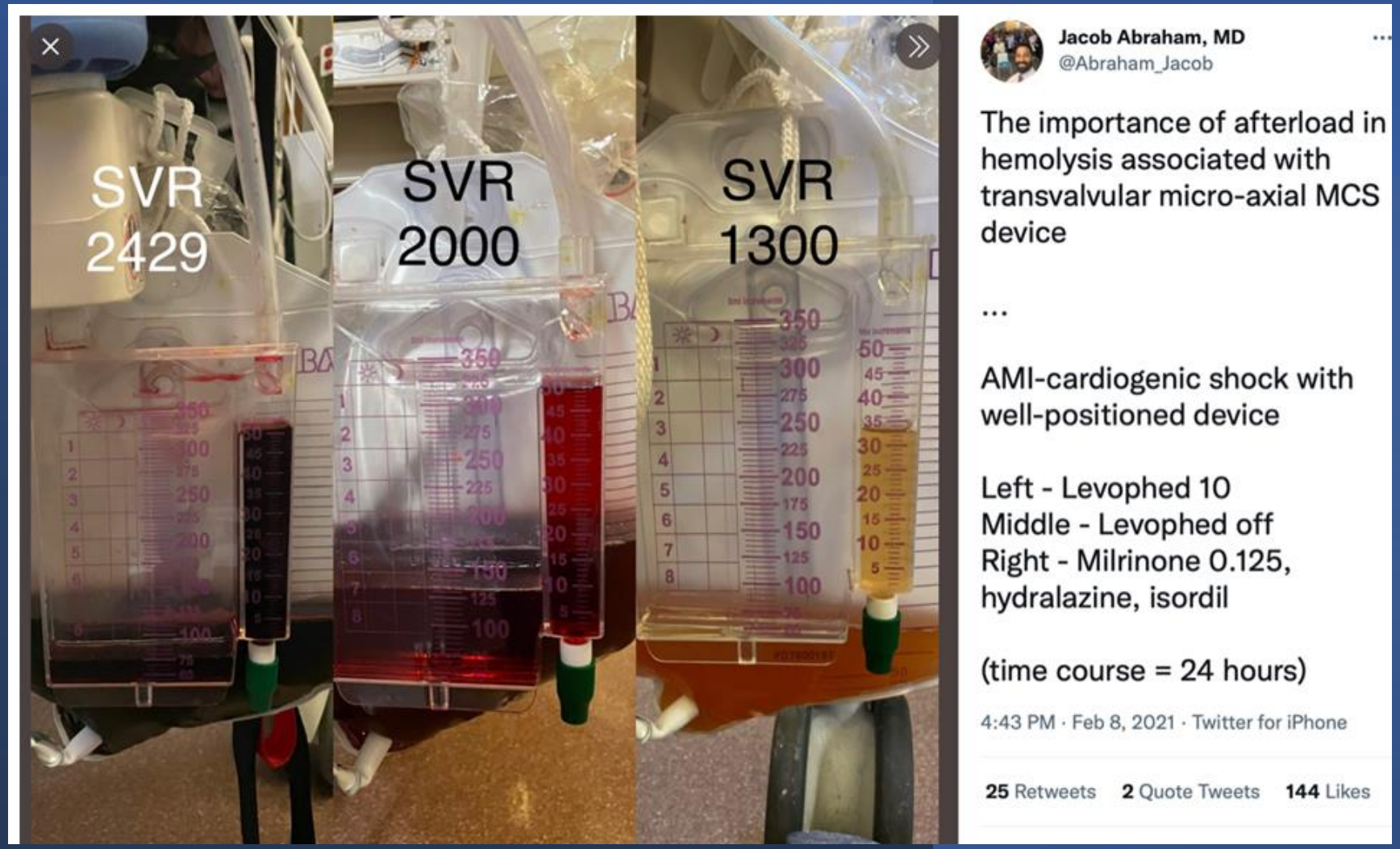
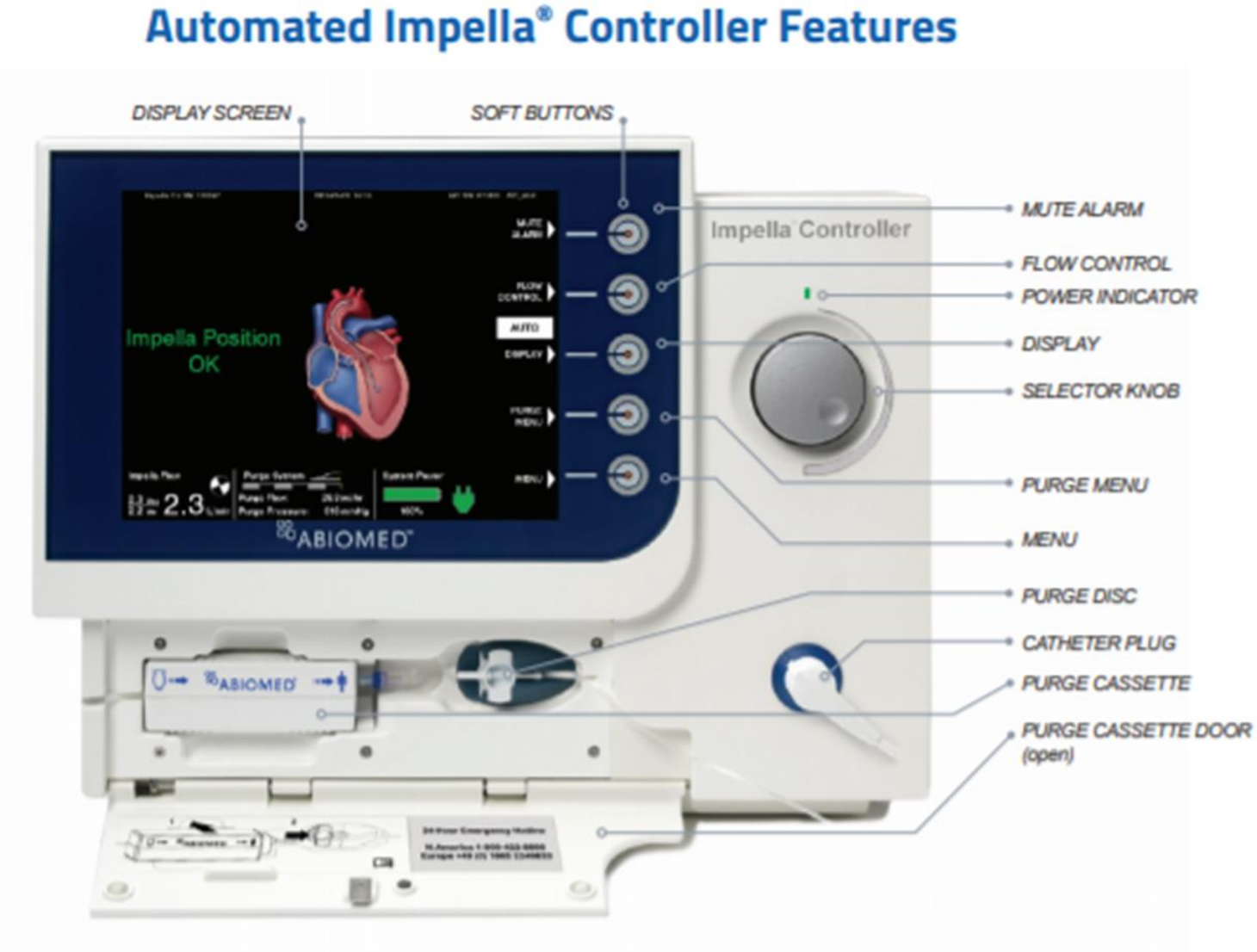
Afterload Sensitive



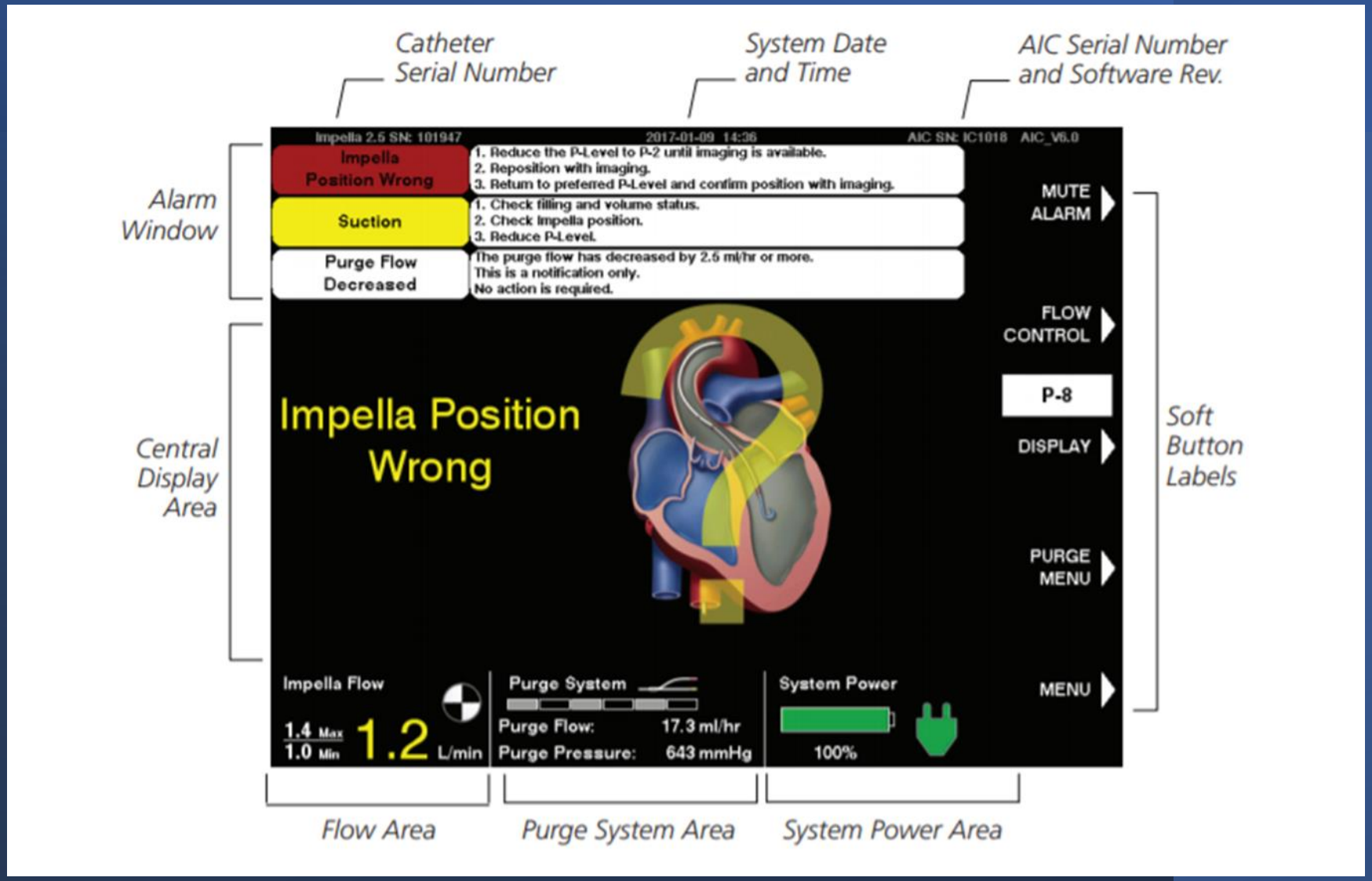
CONSOLE

- Automated Impella Controller
- Waveforms
- Position Monitoring
- Suction Alarms

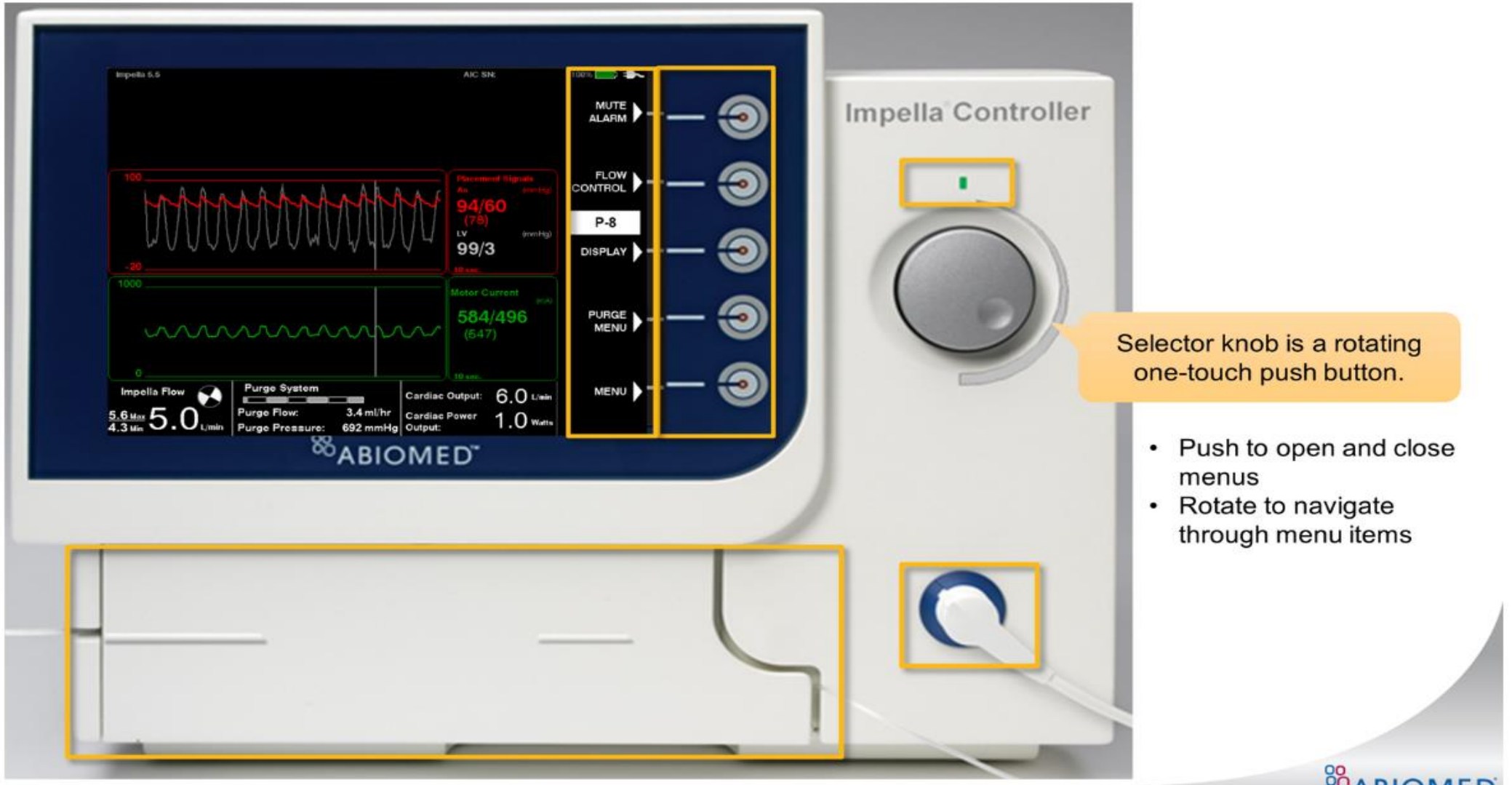
Automated Impella Controller



IMPELLA AIC SCREEN FEATURES



AIC INTERFACE



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SOFT BUTTONS

MUTE ALARM silences or clears an alarm;
bell icon with red X displayed when alarm is muted for two minutes or until a new alarm is detected

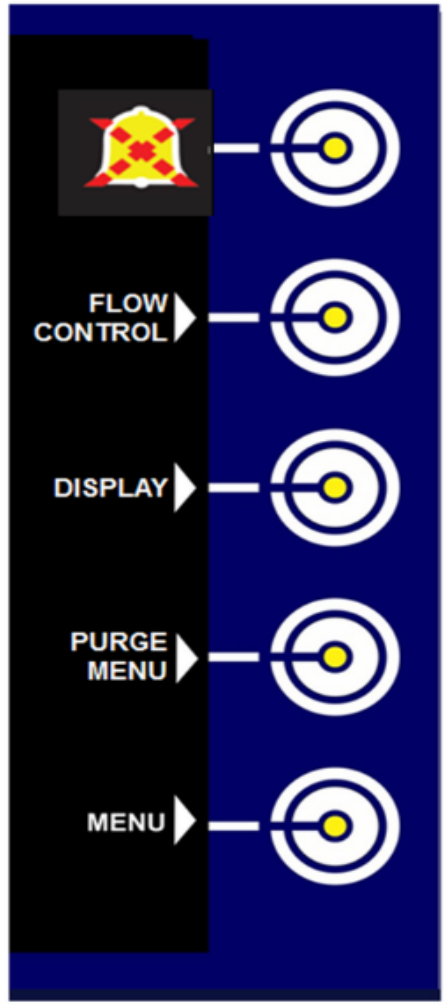
FLOW CONTROL sets the flow rate to one of ten P-level settings: P-0 through P-9

DISPLAY opens a menu from which you can select different display screens and change time and display scale

PURGE MENU opens the Purge System menu for selecting various purge procedures

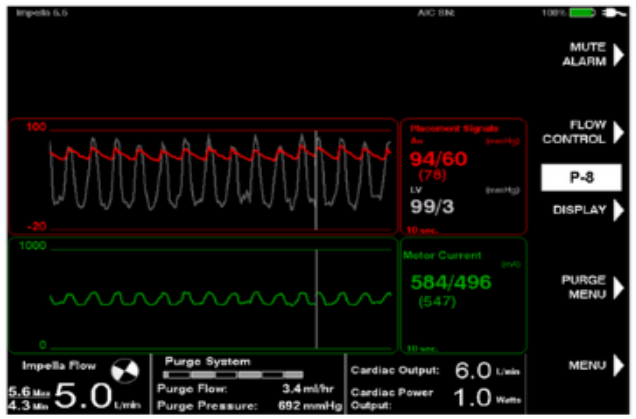
MENU

- Settings/Service
- Start Manual Zero
- Alarm History
- Start Data Snapshot
- Case Start

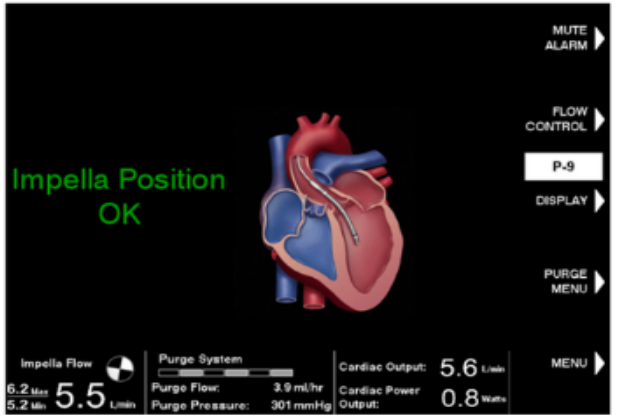


DISPLAY SCREENS

Changes the central display of the console.

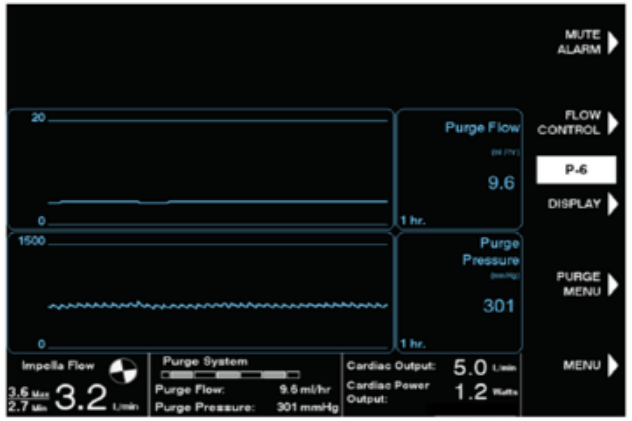


Placement Screen

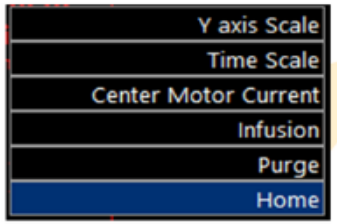


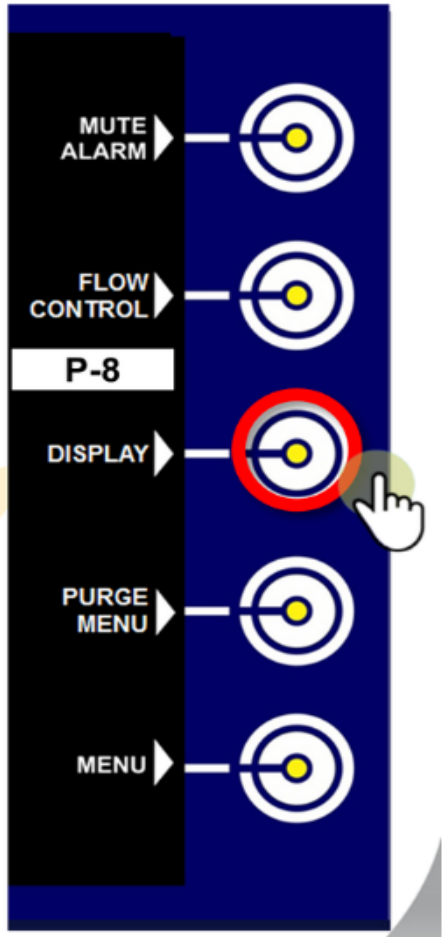
Home Screen

Infusion History Screen



Purge Screen





ABIOMED
Recovering hearts. Saving lives.

SmartAssist Common Screen Elements

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

- Purge system marquee
- Purge flow
- Purge Pressure

- Cardiac Output*
- Cardiac Power Output

*Shown after entering a reference Cardiac Output measurement.

ABIOMED
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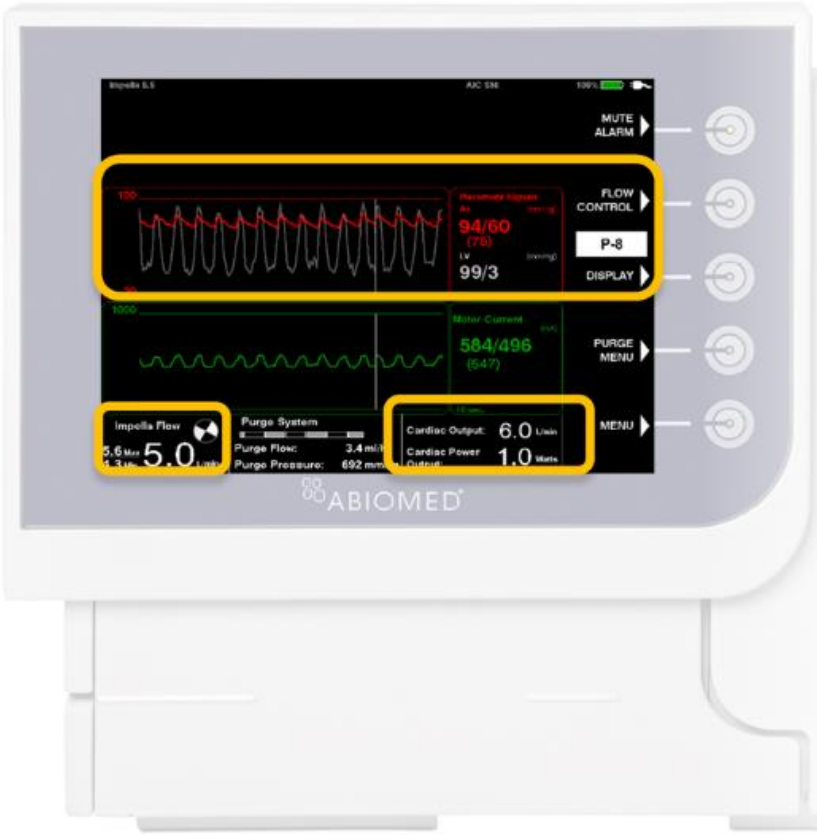
SMARTASSIST OVERVIEW



Impella Heart Pump

- Repositioning in the ICU without the need for imaging*
- New sensor technology for confident positioning
- Greater hemodynamic support and ease of use

Advanced Metrics

- Better and faster resolution of suction alarms
- Earlier identification of right heart failure
- Assist in hemodynamic assessment and successful weaning

Impella Connect®

- Cloud-based, remote viewing for better patient outcomes
- Collaborative patient management
- Streamlined continuity of care

*For ventricularized pumps

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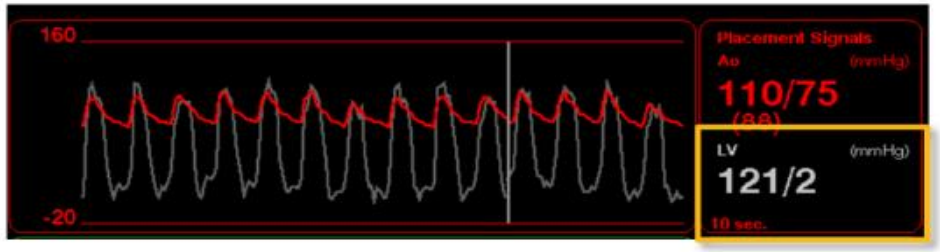
HOW ARE THE NUMBERS DERIVED?

Intelligent pump metrics[1] on console to position, manage, wean

Optical Sensor

Senses Aortic pressure (Ao)

$$AoP - \Delta P_{(A0\text{-}LV)} = LV\ Waveform$$



Micro-axial motor

Senses pressure difference between aorta and left ventricle

- Real-time in-vivo pump flow

1- FDA Approved, PMA Supplement, 2019

Metrics are for information purposes only and are not intended for diagnostic use. Values must be verified independently using an approved diagnostic device, and must not be used for patient monitoring.

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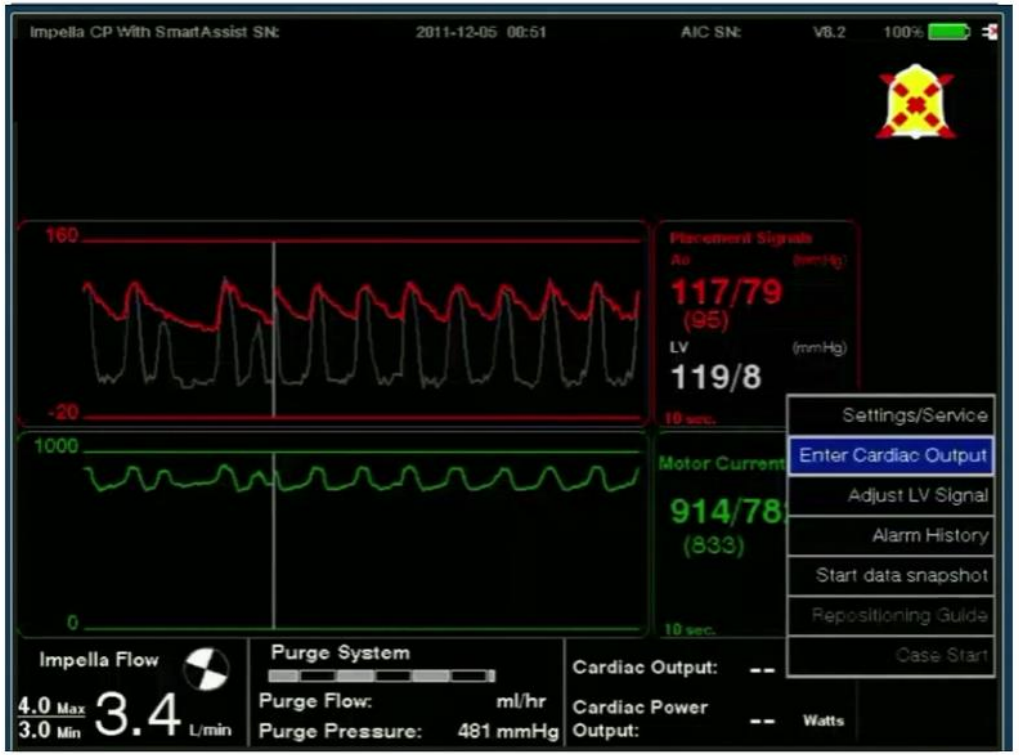
CARDIAC OUTPUT ENTRY | CPO

AIC now continuously calculates Cardiac Output & Cardiac Power Output

- Enter patient's total cardiac output to match reference measurement
  - Enter Cardiac Output immediately following reference measurement
- AIC will detect if there is a significant change in the vascular state and will display a white notification
- AIC will automatically calculate CPO following entry
- If CPO ≤ 0.6, it will appear yellow
- AIC will continuously update CO & CPO for up to 8 hours
- Cardiac Output should be entered every 8 hours OR if there is a change in the patient's vascular state
  - Reminder notification is triggered after 7 hours of last Cardiac Output



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Metrics are for informational purposes and are not intended for diagnostic use. Values must be verified independently using an approved diagnostic device and must not be used for patient monitoring

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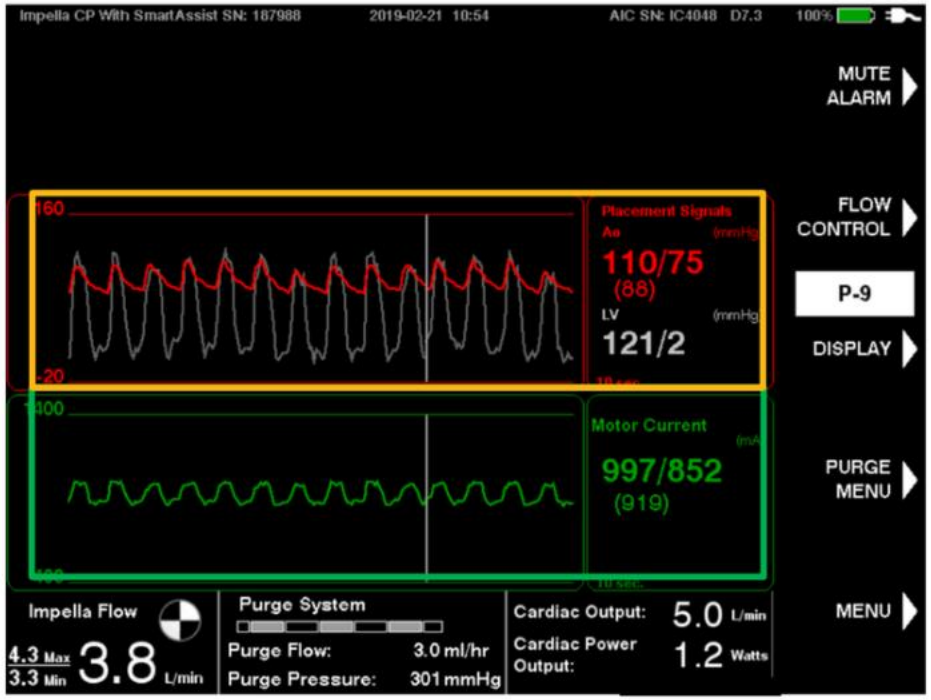
HOW IMPELLA POSITION IS DETERMINTED

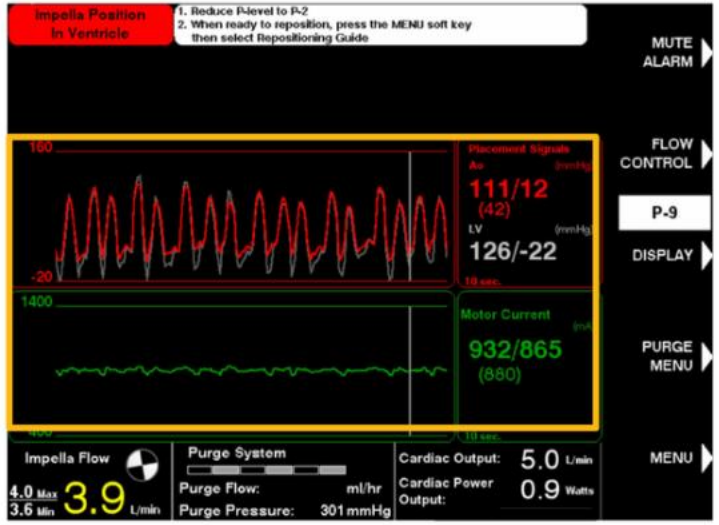
Placement signal waveform

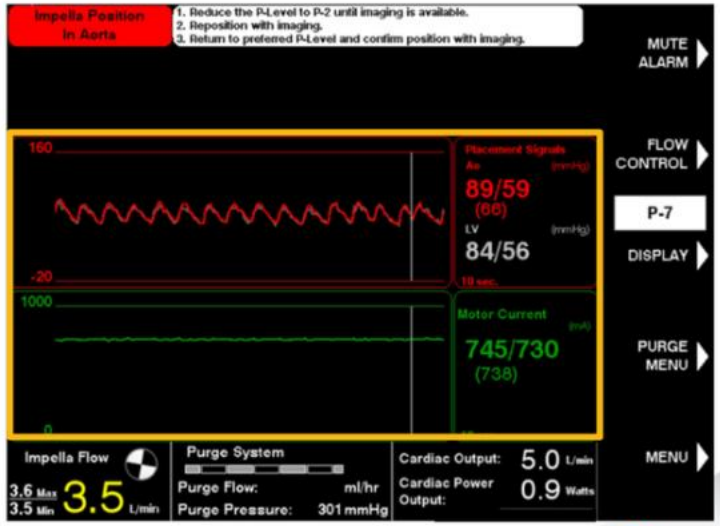
Motor current waveform



Impella CP with SmartAssist
Correct Waveforms

When the Impella device is properly placed, a pulsatile motor current is displayed.





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IMPELLA POSITION IN AORTA ALARM

Where to look?

DISPLAY soft button > Placement Screen

What to look for?

Alarm: "Impella Position in Aorta"

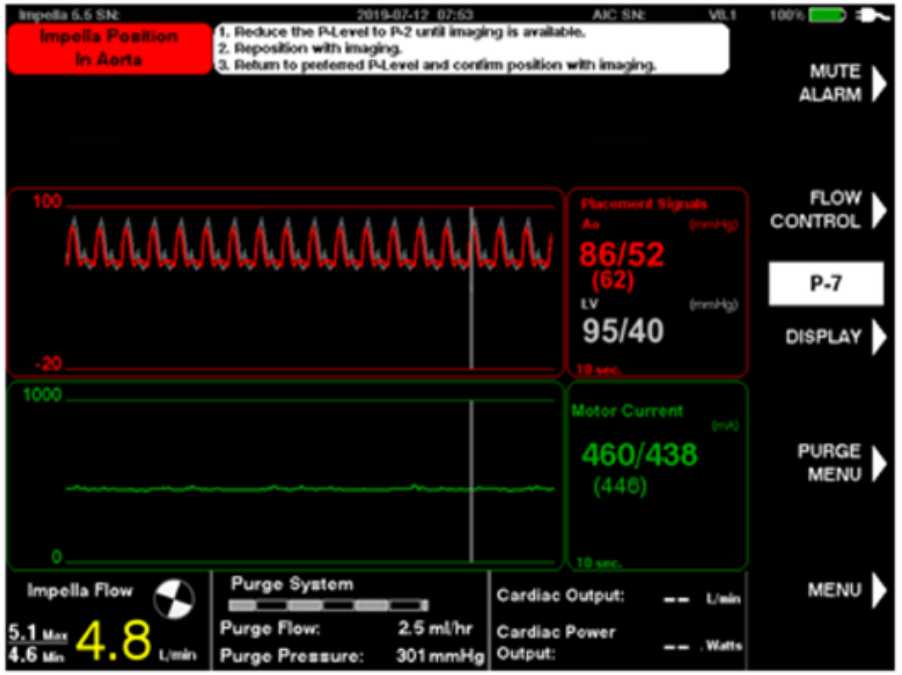
Impella sensor is in the aorta and there is an Aortic Placement Signal

Both Inlet and Outlet are in the aorta and there is a flat Motor Current

Torque the catheter near the Tuohy-Borst when repositioning the Impella 5.5, ***not*** the red pump plug

What to do?

1. Reduce P-level to P-2
2. Reposition with imaging guidance
3. Return to preferred P-level and confirm position with imaging



Placement signal waveform will overlap the LV pressure waveform.

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IMPELLA POSITION PLACEMENT SIGNAL LOW

Where to look?

DISPLAY soft button > Placement Screen

What to look for?

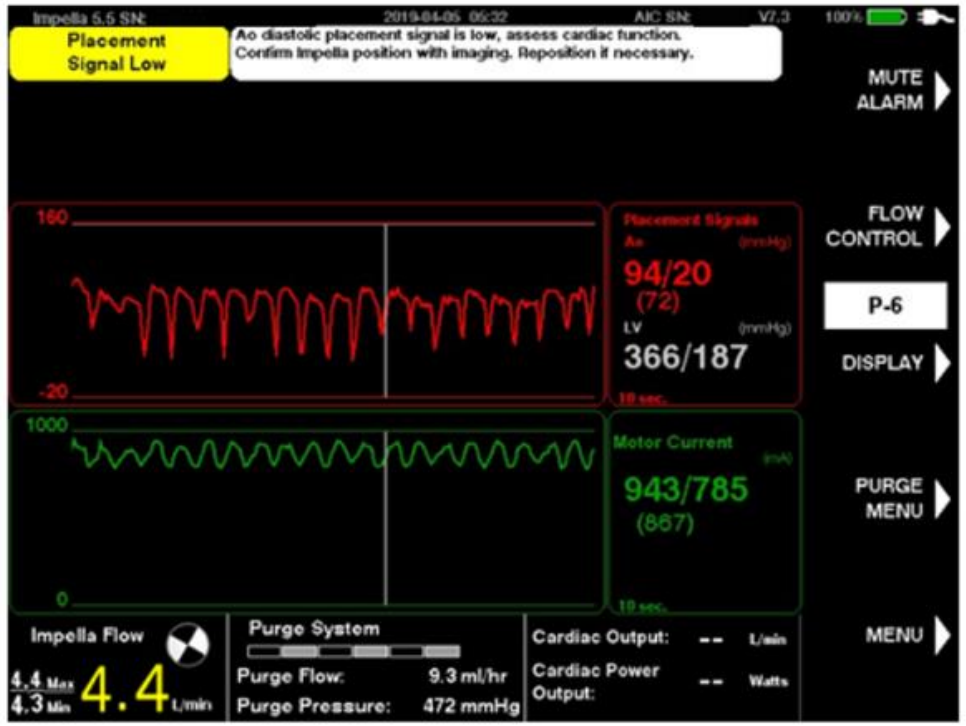
Alarm: "Placement Signal Low "

Will trigger in events of low diastolic pressures, < 30mmHg

Motor current remains pulsatile

What to do?

1. Assess cardiac function
2. Confirm Impella position with imaging. Reposition if necessary.



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IMPELLA POSITION IN VENTRICLE ALARM

Where to look?

DISPLAY soft button > Placement Screen

What to look for?

Alarm: "Impella Position in Ventricle"

Impella sensor is in the ventricle and there is a Ventricular Placement Signal →

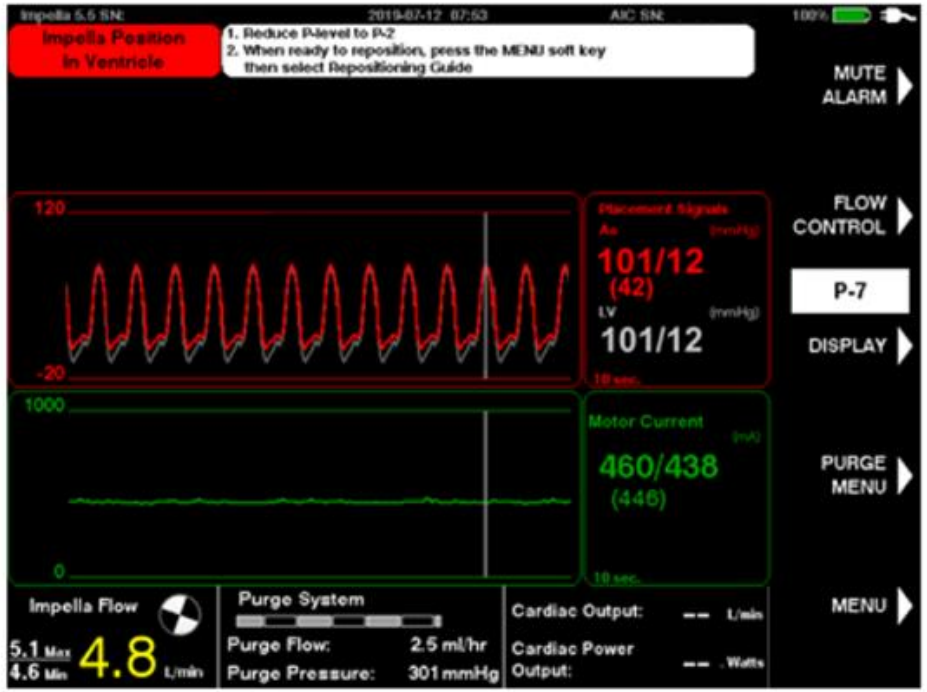
Both Inlet and Outlet are in the ventricle and there is a Flat Motor Current →

⚠ Once repositioning is complete, an Echo is recommended to assess position of the Impella catheter

Torque the catheter near the Tuohy-Borst when repositioning the Impella 5.5, ***not*** the red pump plug

What to do?

1. Reduce P-level to P-2
2. When ready to reposition, press the MENU soft key then select Repositioning Guide



Repositioning Guide is only accessible in the setting of an Impella Position in the Ventricle alarm and allows the pump to be repositioned without Echo

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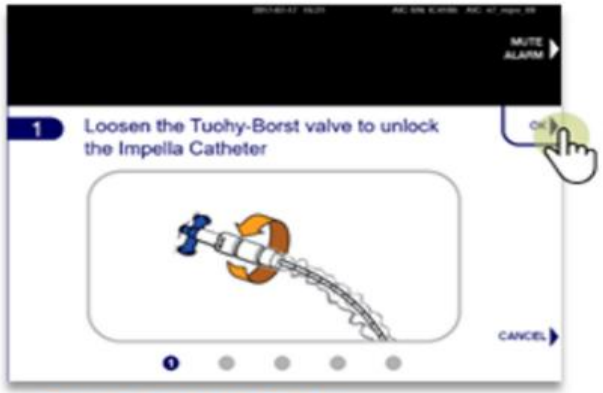
IMPELLA POSITION IN VENTRICLE ALARM | REPOSITIONING GUIDE

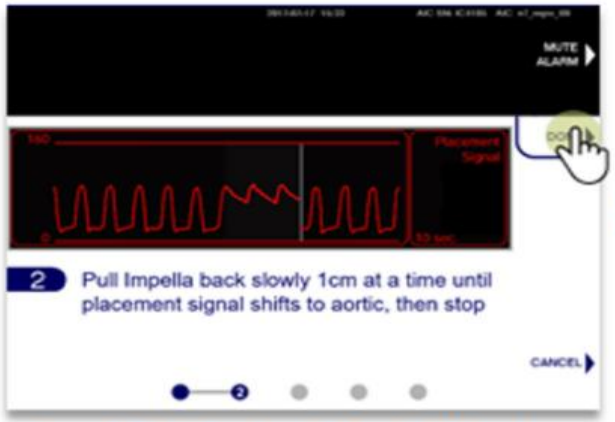
Impella Position In Ventricle

1. Reduce P-level to P-2
2. When ready to reposition, press the MENU soft key then select Repositioning Guide

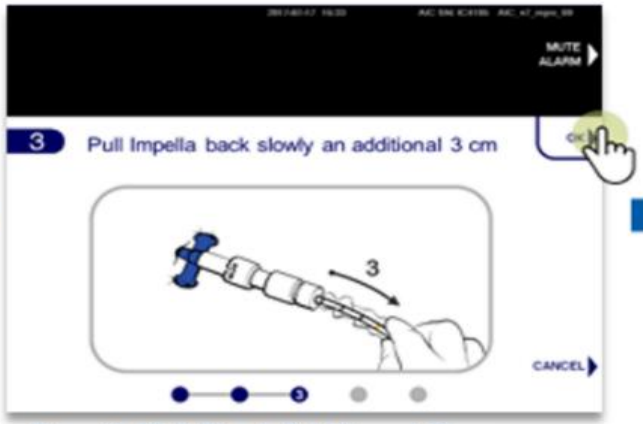
Start Repositioning Guide
Press MENU > Repositioning Guide > START



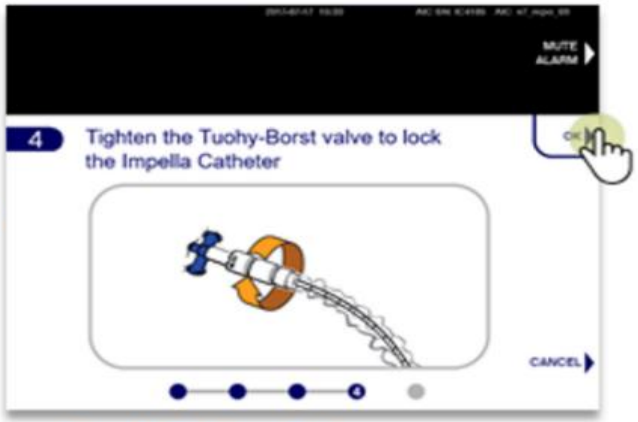
Step 1: Loosen Tuohy



Step 2: Pull Back until Aortic Waveform is Displayed, Then Stop



Step 3: Pull Back Additional 3 cm



Step 4: Tighten Tuohy

Once repositioning is complete, press DONE.
Increase the P-level to preferred level of support.

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Position Monitoring | Low Native Pulsatility

Patients with low native heart function may not generate sufficient pressure difference across the aortic valve. The controller may not be able to determine if the Impella device is correctly positioned.

What to look for?

Alarm: “Impella Position Unknown”

Placement signal Pulsatile with dampened amplitude or flattened

Dampened or Flat Motor Current

Yellow question mark

What to do?

Monitor Impella device position using:

- Patient hemodynamics
- Periodic echo assessment

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SUCTION | WHAT TO LOOK FOR & WHAT TO DO

What causes suction?

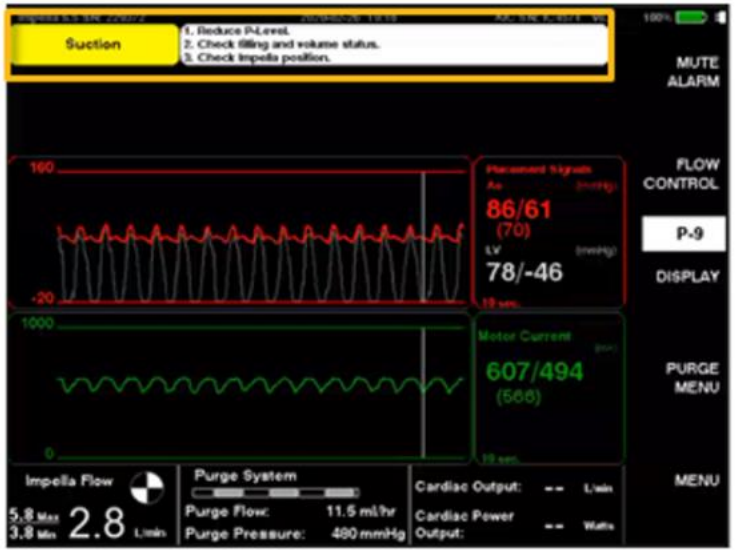
- Inadequate LV filling
- Incorrect position in LV
- RV failure

What are the effects of suction?

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

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 to do?

- Reduce P-level by 1 or 2 levels; continue to reduce if suction alarms continue
- Assess volume status; consider adding volume if CVP or PCWP (PAD) < 10 mmHg
- Evaluate catheter position using placement signal, motor current and imaging; reposition if necessary
- Confirm RV function
- Return flow rate to pre-alarm setting when suction resolved

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SUCTION | POTENTIAL CAUSES

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

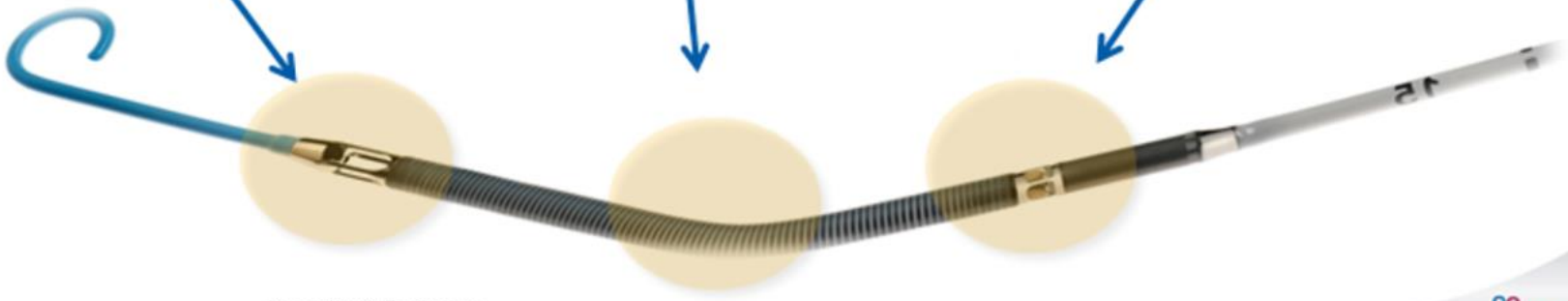
- Obstruction within pump (clot, fiber, etc) creates narrowing of cannula and small passages for blood to pass through, creating high shear and hemolysis

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



Impella 2.5 shown

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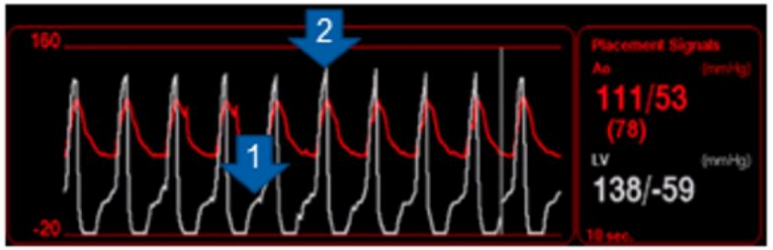
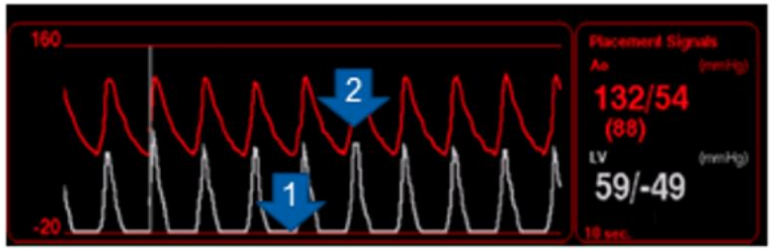
SUCTION | SUSPECTED HEMOLYSIS

When urine is red:

- Rule out blood in urine as a reason for red urine
  - Simple urinalysis showing multiple red cells is diagnostic
  - Check pfHgb (Plasma free Hgb), a simple colorimetric test
  - Check spun plasma color if pfHg is not available
- Consider adding volume if hemolysis is accompanied by CVP or PCWP (PAD) < 10mmHg
- Assess the position of the Impella heart pump with echo

Suction Management

Type	How to Recognize	How to Resolve
Diastolic Suction	1. Negative diastolic pressure; recovers by end of diastole 2. Normal systolic pressure 3. Low diastolic flows	 	1. Check filling and volume status 2. Check Impella Position
Continuous Suction	1. Negative diastolic pressure; Does not recover 2. Low systolic pressure 3. Low systolic & diastolic flows	 	1. Check Impella Position 2. Check filling and volume status

Check RHF if you are experiencing persistent suction alarms with OK volume & position

A Approved, PMA Supplement, 2018

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IP-865 .v4

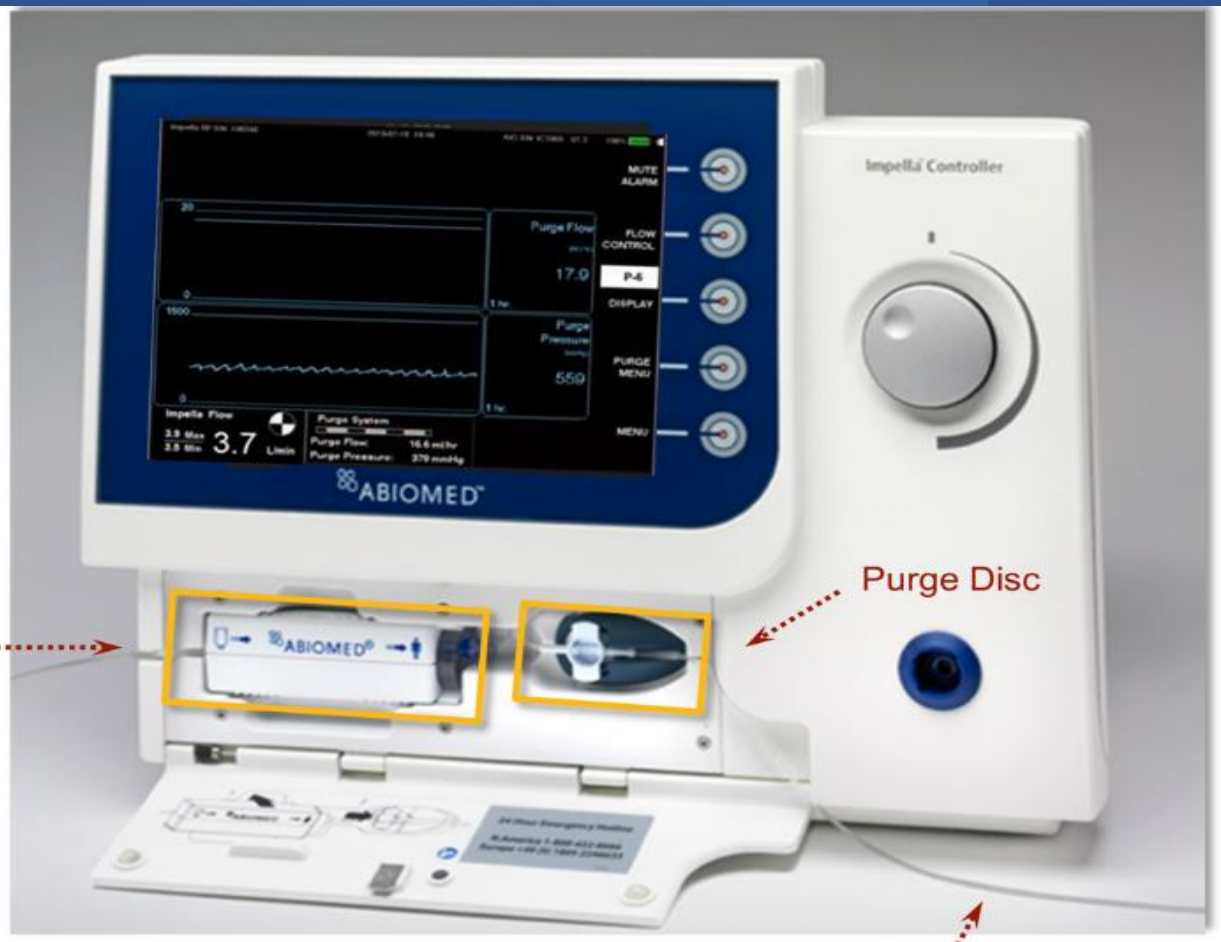
ABIOMED

Dextrose

- What is the purge system?
- What makes up the purge system?
- Infusion History Screen
- Purge Alarms

PURGE SYSTEM

The Impella purge system delivers rinsing fluid (purge fluid) to prevent blood from entering the Impella device motor.



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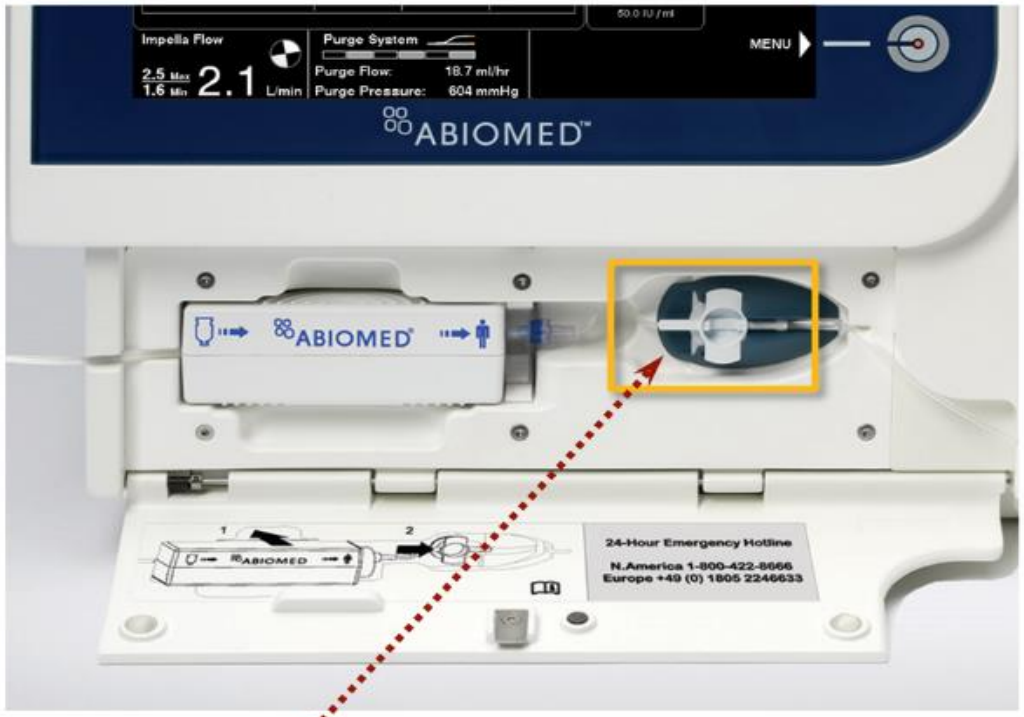
AUTOMATIC PURGE PRESSURE MANAGEMENT

- Pressure sensor reads purge pressure from the purge disc
- Controller automatically adjusts purge flow between 2 – 30 mL/hr to maintain the purge pressure between 300 – 1100 mmHg
- Warnings or alarms are displayed if purge pressure is too high or too low



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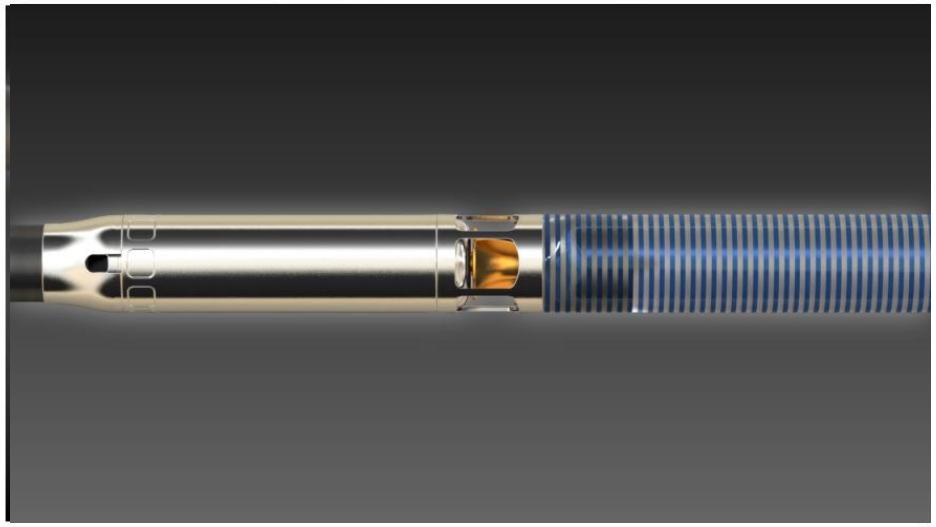
PURGE MANAGEMENT SYSTEM

PURPOSE

Prevents blood from entering the motor

MECHANISM

Creates pressure barrier from purge fluid



Purge Pressure must always be > 300mmHg

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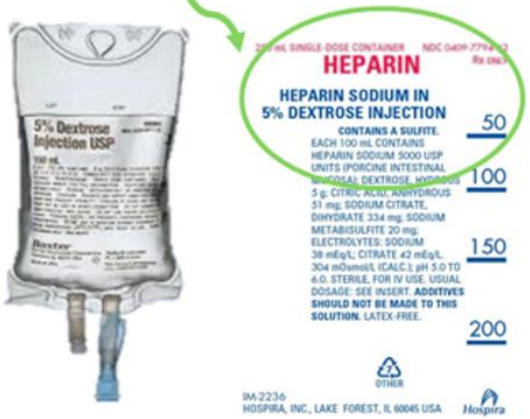
COMPONENTS OF THE PURGE SYSTEM

COMPONENTS OF THE PURGE SYSTEM

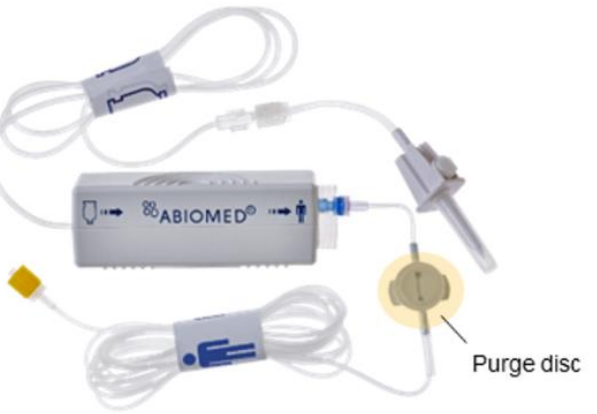
Purge Fluid

D5W with heparin 25U/mL
(D5W preferred; D5W – D20W acceptable)
D5W with Sodium Bicarbonate 25 mEq/1L is the preferred replacement for heparin in the purge solution within the indicated duration of use for patients who are intolerant to heparin or in whom heparin is contraindicated*
Concentration of dextrose proportional to viscosity



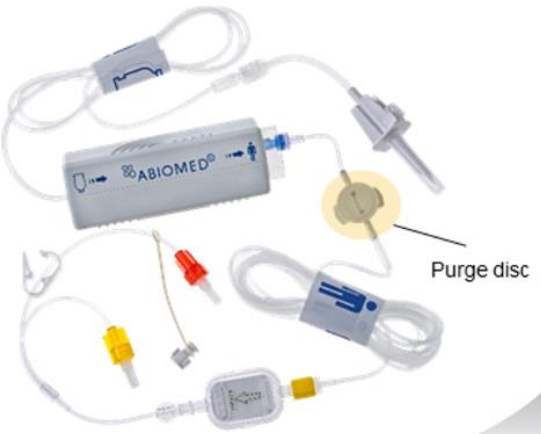
Purge Cassette

Delivers purge fluid to Impella device



Purge Cassette

Delivers purge fluid to Impella® device



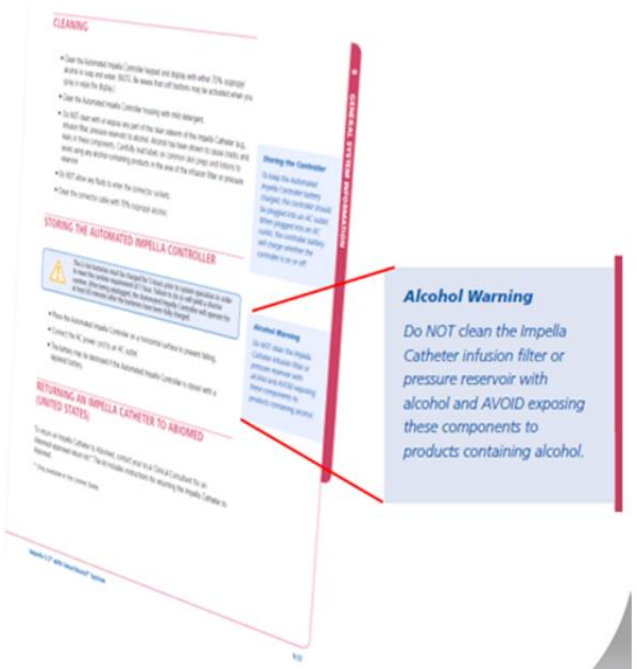
D5W with heparin 25U/mL or 50U/mL is acceptable
*Abiomed recommends the use of Sodium Bicarbonate in the purge solution for femorally-inserted pumps such as Impella and Impella RP® with SmartAssist®. The use Sodium Bicarbonate is not recommended for Impella 5.5®.

ALCOHOL REMINDER

DO NOT Clean the Purge Sidearm with Alcohol or Alcohol-based products

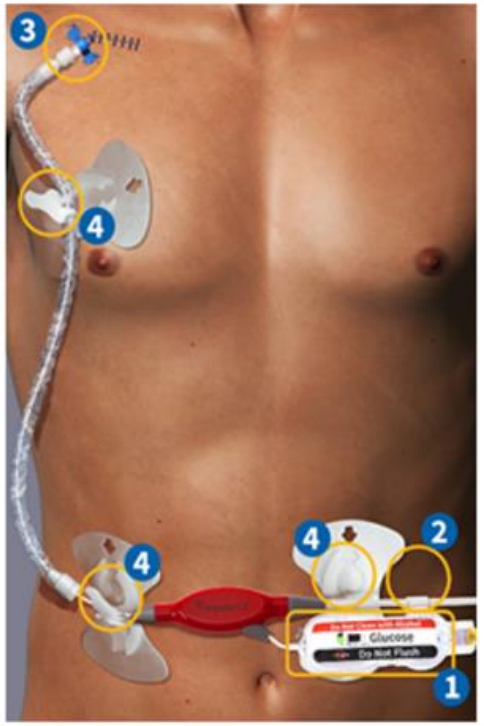
- Alcohol may cause cracks and leaks in the infusion filter and pressure reservoir
- All cleaning labels should be reviewed (skin preps and lotions)
- If needed only use water to clean the purge sidearm

Note: Recommended cleaning solution would be water, however, there are other solutions that are alcohol-free but contain bleach or hydrogen peroxide. Concerns with these products could be the concentration and exposure time



4 Key Points

1. Attach Sidearm Retainer
2. Clip Purge Sidearm
3. Tighten Tuohy-Borst
4. Three-Point Fixations



*D5W with heparin 25U/mL or 50U/mL is acceptable

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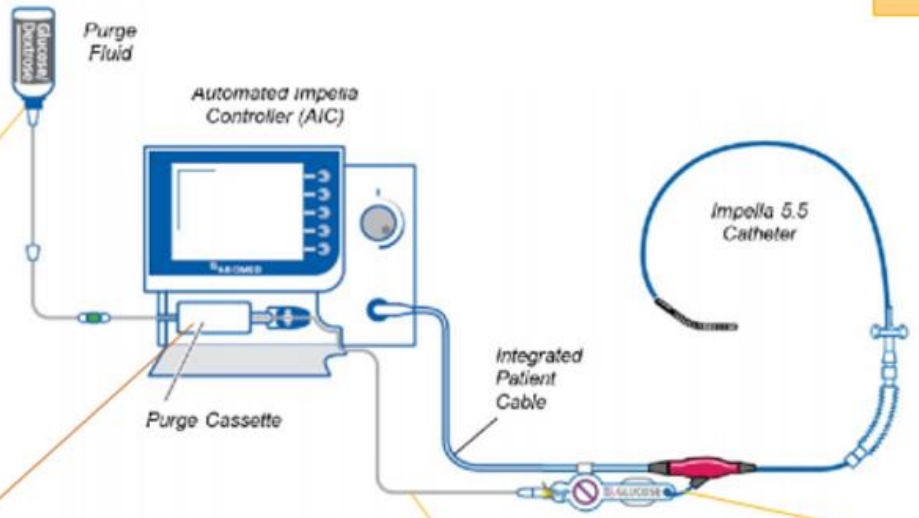
IMP-1379 .v3

PURGE ALARM | LOW PURGE PRESSURE

- Purge Pressure ≤ 300mmHg
- Purge Flow 30mL/hr

If unable to resolve the alarm, contact CSC for advanced protocols such as sidearm bypass. Observe for increases in motor current.

Consider increasing the dextrose concentration.



Do not replace the purge cassette as part of initial troubleshooting for Impella 5.5 with SmartAssist.

Check for leaks in the purge tubing, from the purge fluid bag all the way to the Impella Catheter.

Check for leaks or cracks in the purge sidearm. Tighten any loose connections.

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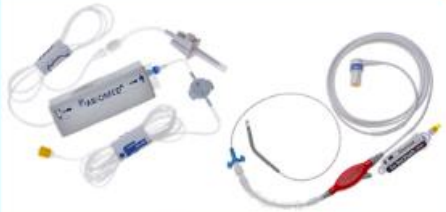
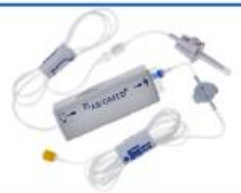
LOW PURGE PRESSURE CHECKLIST

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

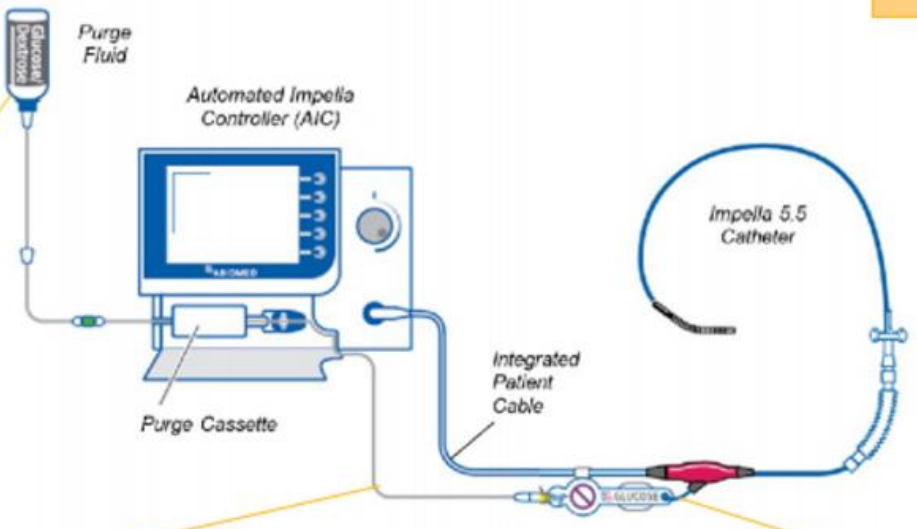
	Where to look	What to look for	What to do
1		Are there any leaks in the purge cassette or luer connections to the catheter?	Tighten any loose connections
2		Is the dextrose (purge fluid) concentration too low?	Increase the dextrose (purge fluid) concentration
3		Is the leak coming from the purge cassette?	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	Contact the Clinical Support Center; may need to replace pump

PURGE ALARM | HIGH PURGE PRESSURE

- Purge Pressure ≥ 1100mmHg
- Purge Flow ≤ 2mL/hr

If unable to resolve the alarm, contact CSC for advanced protocols. Observe for increases in motor current.

Consider decreasing the dextrose concentration if not already running D5W.



Check for kinks in the purge tubing, from the purge fluid bag all the way to the Impella Catheter.

Check for kinks in the purge sidearm. Ensure the sidearm is secured to the white connector cable with the retainer.

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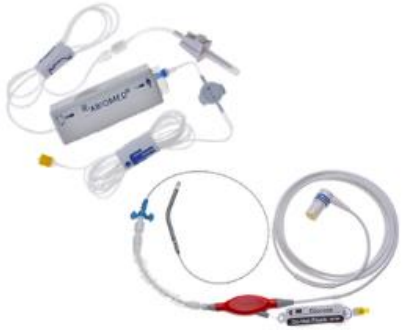
High Purge Pressure Checklist

Measurement: Purge Flow ≤ 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 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	Contact the Clinical Support Center; may need to replace pump

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INFUSION HISTORY SCREEN

Impella Delivered Heparin Rate

+

Systemic IV Heparin Rate

=

Total Heparin Delivered to Patient (Rate)

The AIC will automatically calculate the Impella Delivered Heparin provided each hour, based on the heparin concentration in the purge, entered by the user and purge flow rate

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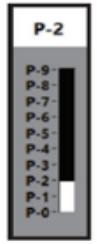
E

- Emergencies
- Escalation & EcPella
- Echo
- Explant & Weaning

WHAT TO DO IN AN EMERGENCY

CPR – *What to do?*

1. Initiate CPR per hospital protocol
2. Reduce Impella device 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 an echo when possible

Defibrillation – *What to do?*

→ Initiate defibrillation per hospital protocol

NOTE: It is not necessary to reduce P-level

During resuscitation, placement monitoring and flow calculations will not be accurate.

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HELP IDENTIFY ESCALATION NEED

REASSESS PRIOR TO DISCHARGE FROM CATH LAB

Wean inotropes/pressors & reassess hemodynamics prior to leaving the cath lab

1. Cardiac Power Output (CPO) = (CO × MAP) / 451
2. Pulmonary Artery Pulsatility Index (PAPi) = (sPAP-dPAP) / RA

CPO ≤ 0.6
(≤ 0.8 with inotropes/pressors)

PAPi

≤ 0.9

RV Dysfunction
Consider right-side support with Impella RP® if no persistent hypoxemia

>0.9

RV Preserved
Consider left-side support escalation to Impella 5.0®/Impella 5.5® or transfer to LVAD/Transplant Center

CPO > 0.6 without inotropes/pressors
(> 0.8 with inotropes/pressors)

Persistent Hypoxemia?
PaO_2 < 55 on 100% FiO_2

Yes

V-A or V-V ECMO
Recommend maintaining Impella at low speed for LV unloading

No

Admit to ICU to maximize supportive care and to actively **assess for myocardial recovery**

** Optimize survival by aiming for the green area below prior to leaving the cath lab*

Survival to Discharge based on CPO/Inotropes in Cath Lab (N=185)

CPO (Watts)	# Inotropes: 0	1	≥2
≤0.6	63% (N=19)	43% (N=30)	35% (N=17)
0.6 to <0.8	89% (N=18)	63% (N=24)	64% (N=11)
≥0.8	89% (N=35)	71% (N=42)	64% (N=14)

O'Neill. Insights from National Cardiogenic Shock Initiative. TCT Connect 2020

Monitoring for Right Heart Failure

What to look for	What to do
• Reduced flow from the Impella Catheter • Suction alarms • Elevated filling pressures (CVP) • Signs of liver failure • Reduced PAPi score	✓ Consider treatment for patients exhibiting signs of right heart failure

EVALUATING RHF – PAPI

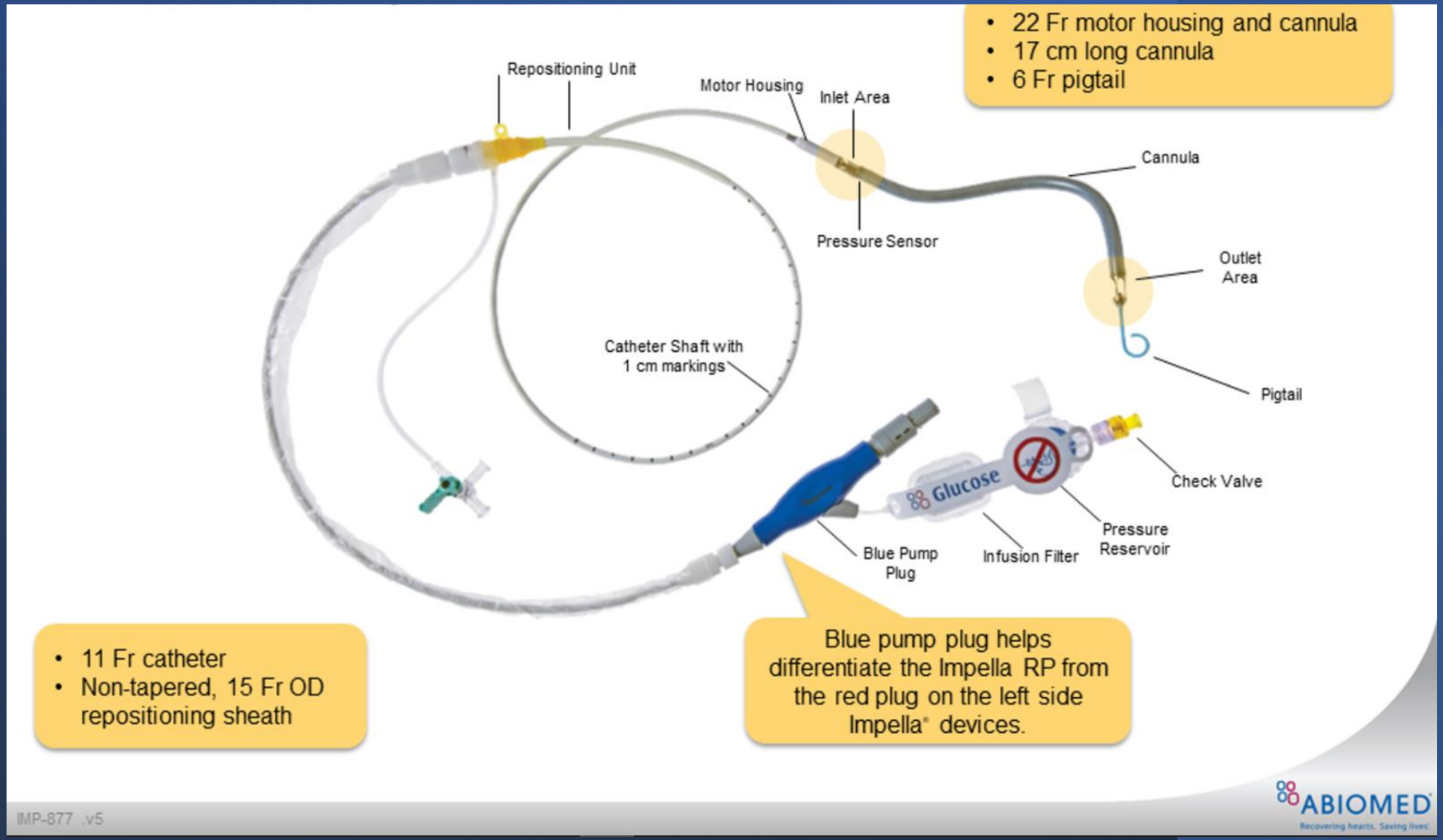
↓ PA Pulse Pressure and ↑ CVP = ↓ PAPi Score → Worsening RV Fx

$$\frac{(PAS - PAD)}{RA} = \textbf{PAPi}$$

<1.0 considered indicator of RV Failure in RVMI

<1.85 considered indicator in LVAD recipients post-implantation

IMPELLA RP


• 22 Fr motor housing and cannula
• 17 cm long cannula
• 6 Fr pigtail
Repositioning Unit
Motor Housing
Inlet Area
Cannula
Pressure Sensor
Outlet Area
Catheter Shaft with 1 cm markings
Pigtail
Glucose
Check Valve
Pressure Reservoir
Infusion Filter
Blue Pump Plug
• 11 Fr catheter
• Non-tapered, 15 Fr OD repositioning sheath
Blue pump plug helps differentiate the Impella RP from the red plug on the left side Impella® devices.
IMP-877 .v5
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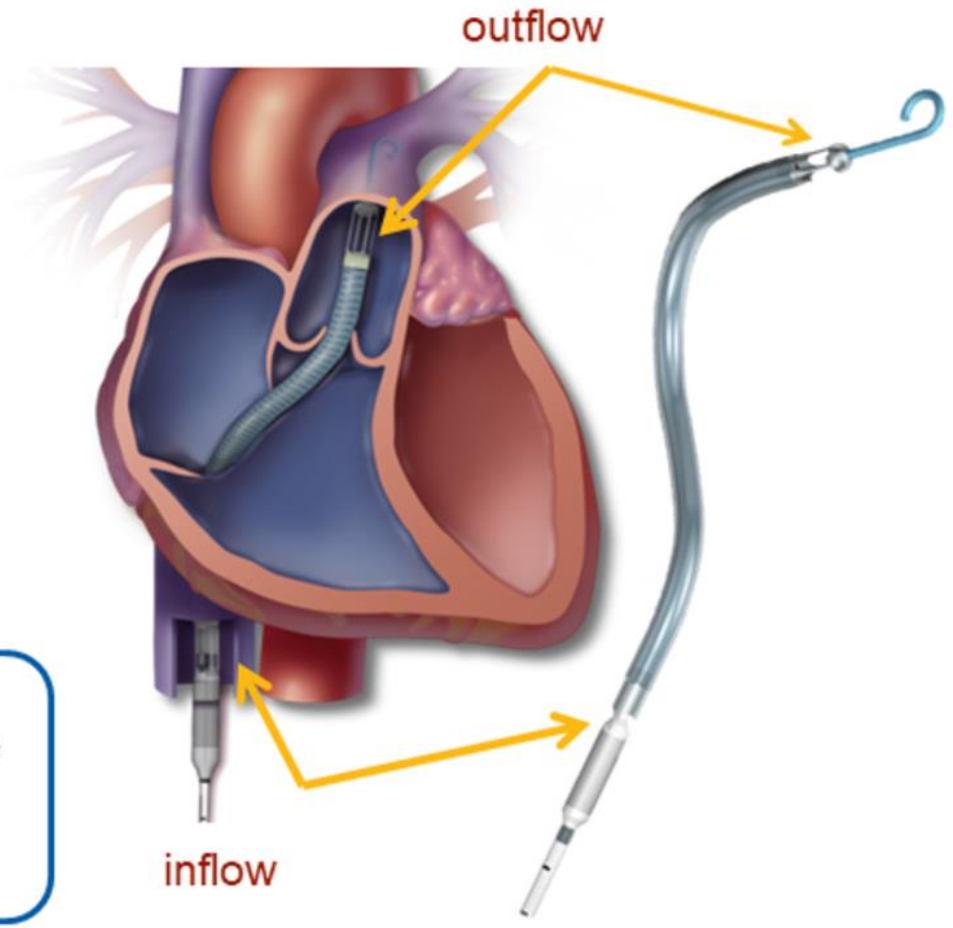
IMPELLA RP

- Single vascular access (femoral vein)
- Placed under fluoroscopic guidance
- No sternotomy required
- No extracorporeal circulation
- Size: 22 Fr pump on an 11 Fr catheter
- Maximum flows > 4 L/min

The Impella RP is indicated for providing circulatory assistance for up to 14 days in patients who develop acute right heart failure or decompensation following left ventricular assist device (LVAD) implantation, myocardial infarction (MI), heart transplant, or open-heart surgery.



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IMPELLA RP w/ SmartAssist

SmartAssist Hemodynamic Sensors

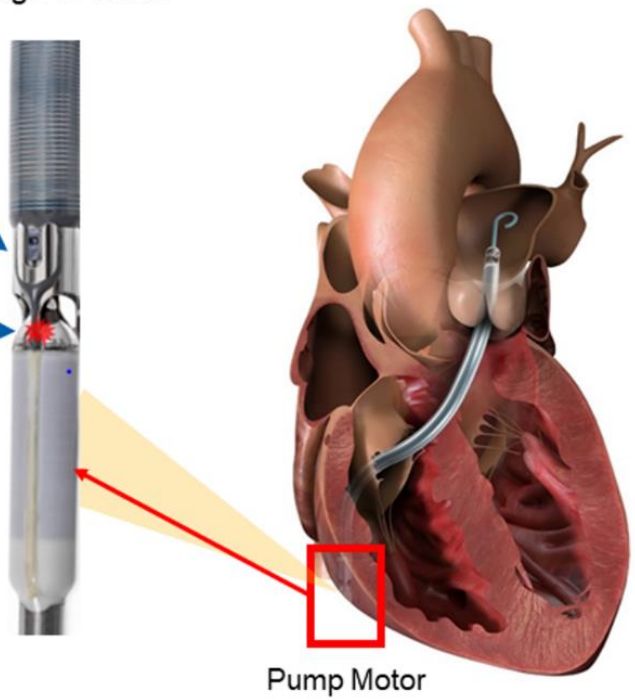
Intelligent pump metrics[1] on console to manage & wean

Differential Pressure Sensor

- Senses pressure difference between CVP and PA

Optical Pressure Sensor

- Same sensor used across SmartAssist platform
- Senses CVP



1. FDA Approved, PMA Supplement, 2021

ABIOMED
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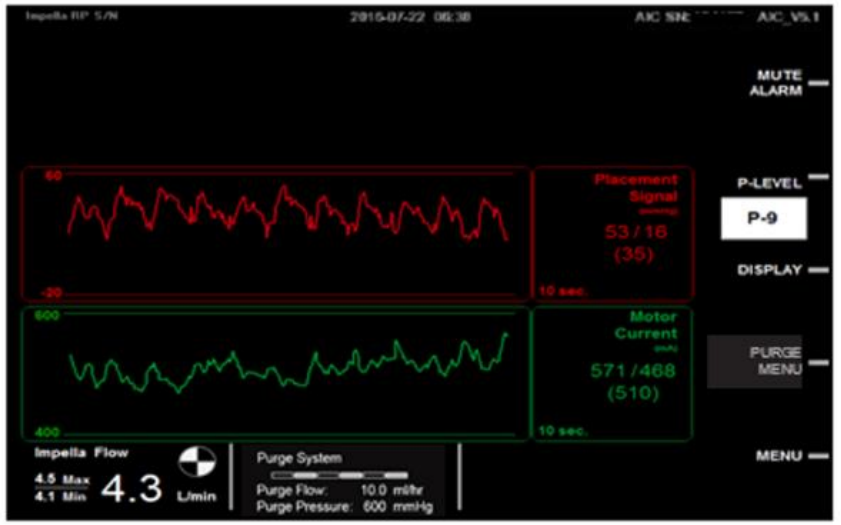
IMPELLA RP: NORMAL WAVEFORMS

Motor current scale: 0 to 1000 mA



Motor current scale: 400 to 600 mA

Lowering the motor current scale allows for better visualization of the pulsatile motor current.

- Select DISPLAY soft button > Y-axis > Motor Current
- Rotate the selector knob to lower the y-axis and press in to make selection

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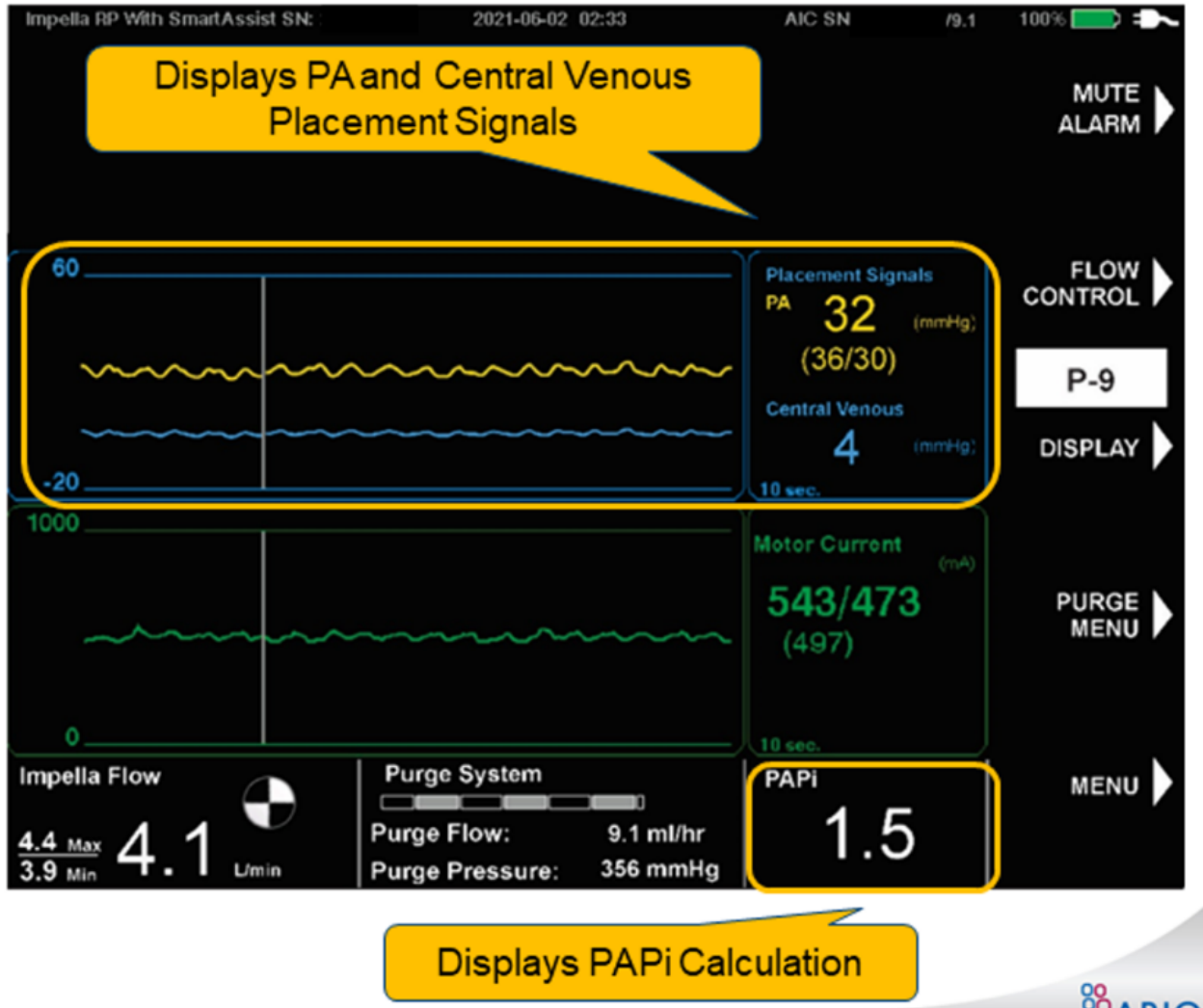
Pump Metrics Overview

Placement Screen Shows:

- PA Placement Signal
- Central Venous Placement Signal
- PAPi Calculation



These new metrics are for informational purposes only and must be validated by an approved clinical diagnostic device. The use of Invasive Hemodynamic Monitoring (PA Catheter) is still recommended as a best practice for managing Impella pumps.

1. FDA Approved, PMA Supplement, 2021

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IMPELLA RP: GENERAL PATIENT CONSIDERATIONS

- Maintain ACT at 160-180 sec for duration of Impella RP device support (≥ 250 sec at time of insertion)
- pTT should correspond to an ACT of 160-180 sec during support
- ★ Chest x-ray completed upon arrival to the ICU to verify position
- ★ Ensure outlet is at or above the bifurcation of the right and left PA branch
- ★ Ensure inlet is positioned in the IVC at the level of the diaphragm or apex of heart and away from RA and TV
- ★ **When the Impella RP pump is in use . . .**

  Thermodilution cardiac output and continuous cardiac output monitoring are not accurate; must calculate FICK cardiac output for accurate reading.

★ = different than left-sided devices

IMPELLA RP: PATIENT MANAGEMENT, CONTINUED

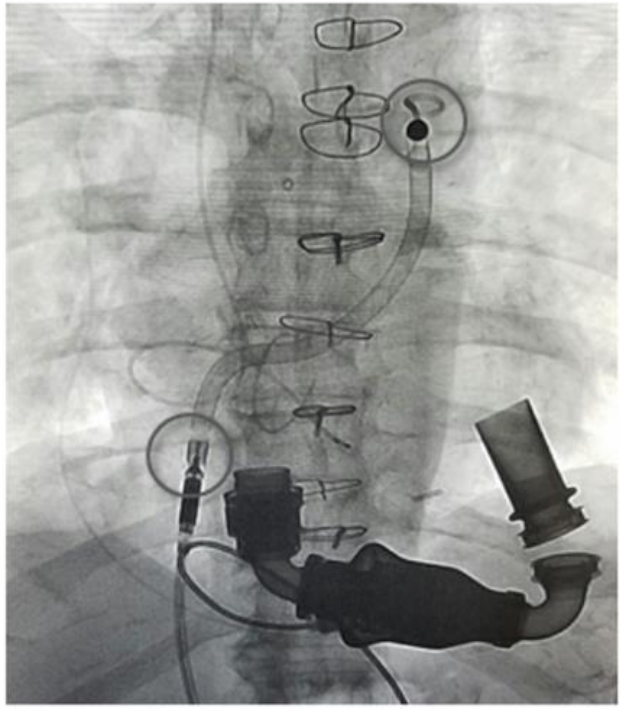
- Monitor placement signal and motor current to detect inlet/outlet obstruction and suction events; pay attention to alarms
- Manage patient fluid status/preload to obtain acceptable target flows; maintain a positive CVP
- ★ Reduce air entrainment risks via venous access sites by maintaining occlusive dressings on all applicable sites and caps on all IV lines
- Chart routine Impella device operational parameters every hour as per protocol
- Head of bed should remain < 30 degrees; reverse Trendelenburg is acceptable
- ★ Device should be maintained at P-6 or higher unless actively weaning

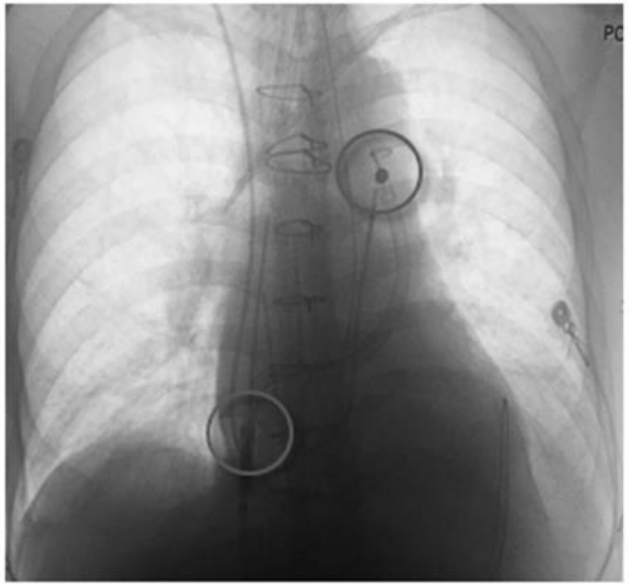
★ = different than left-sided devices

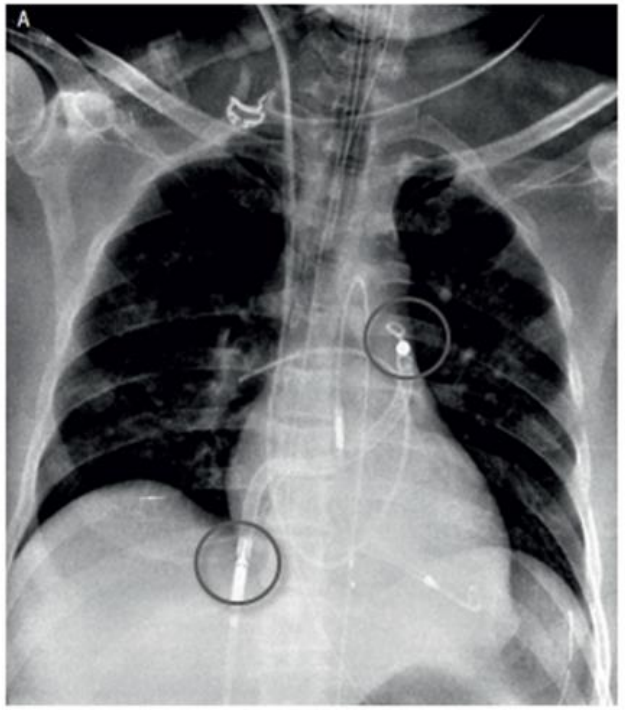
CHEST X-RAY: GOOD POSITION

Acceptable Position

Why is this a good Impella RP position?







- Inlet in the inferior vena cava (IVC) at or slightly below the level of the diaphragm
- Cannula is not running along the apex of the RV
- Outlet is above the pulmonic valve (PV) with the pigtail prolapsed into the pulmonary artery (PA)

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IMPELLA RP WITH SMARTASSIST : SUCTION ALARMS

Suction is most often caused by inadequate preload or malposition.

The procedure to treat a suction alarm is the same for all Impella® devices.

If a suction alarm occurs:

- Decrease P-level to break suction
- Evaluate patient volume status. Maintain a positive CVP
- Check device position and adjust as needed (use chest X-ray, fluoroscopy, or echo)
- When suction is resolved, return to previous P-level

If position and preload are acceptable and suction cannot be resolved at P-2 or P-3, momentarily stop the device to break the suction event and restart immediately.

= different than left-sided devices

IMPELLA RP: WEANING RECOMMENDATIONS

Perform a trial wean of Impella RP and view echo to confirm RV contractility

To Perform a Trial Wean

1. Decrease to P-2 temporarily
2. Record the VAD flow, P-level, CVP, echo parameters and hemodynamics
3. After 15-20 minutes and no adverse effect, the process can be continued, and further weaning can be undertaken
4. Once RV contractility is confirmed, resume previous P-level and initiate slow wean

To Perform a Slow Wean

- Decrease by 2 P-levels every 2-3 hours and monitor patient hemodynamics

While weaning always maintain flow > 1.5 L/min until removal of Impella RP device

– If flows are ≤ 1.5 L/min, ≥ 20 min, consider increasing ACT to ≥ 250 sec

The Impella RP device is ready to be removed when the weaning steps are complete and the ACT is ≤ 150 sec.

SmartAssist – Intelligently Manage

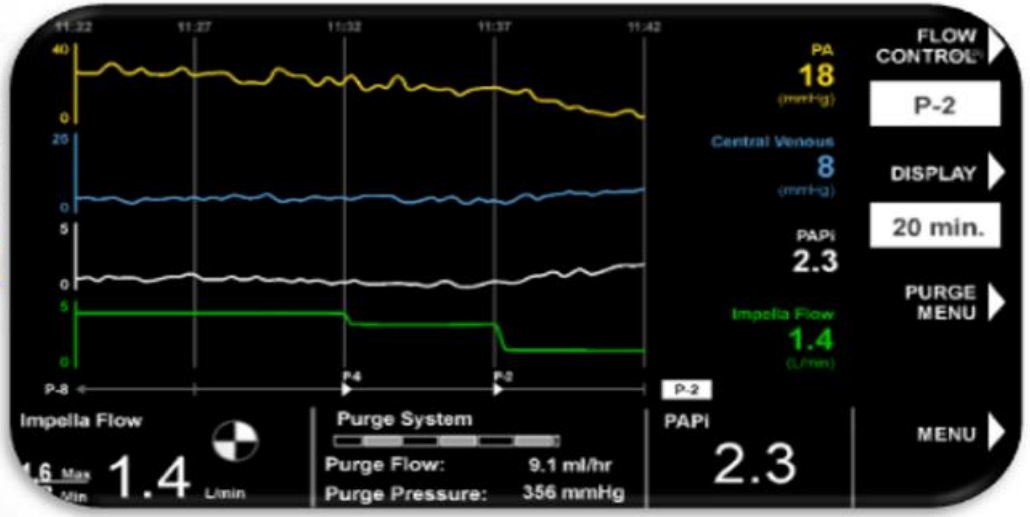
Guidance for Successful Weaning

DISPLAY > Trend Screen

To return to Placement screen, select

DISPLAY > Placement

Trend screen



FDA Approved, PMA Supplement, 2021

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USE OF IMPELLA WITH ECMO

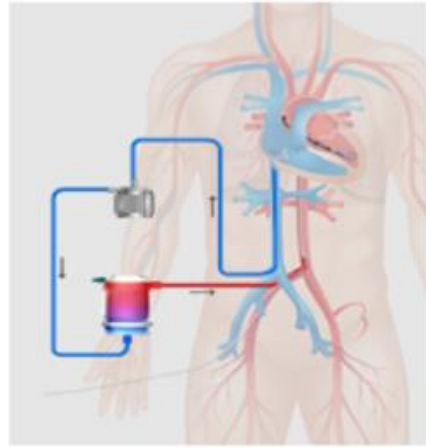
For cardiogenic shock patients Impella may be placed with ECMO to ***unload*** the left ventricle

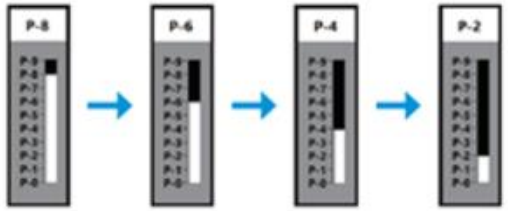
After initial period of unloading/decompression of the ventricle, the Impella usually should be turned down to prevent suction

P-level after unloading usually should be P-2 or P-3

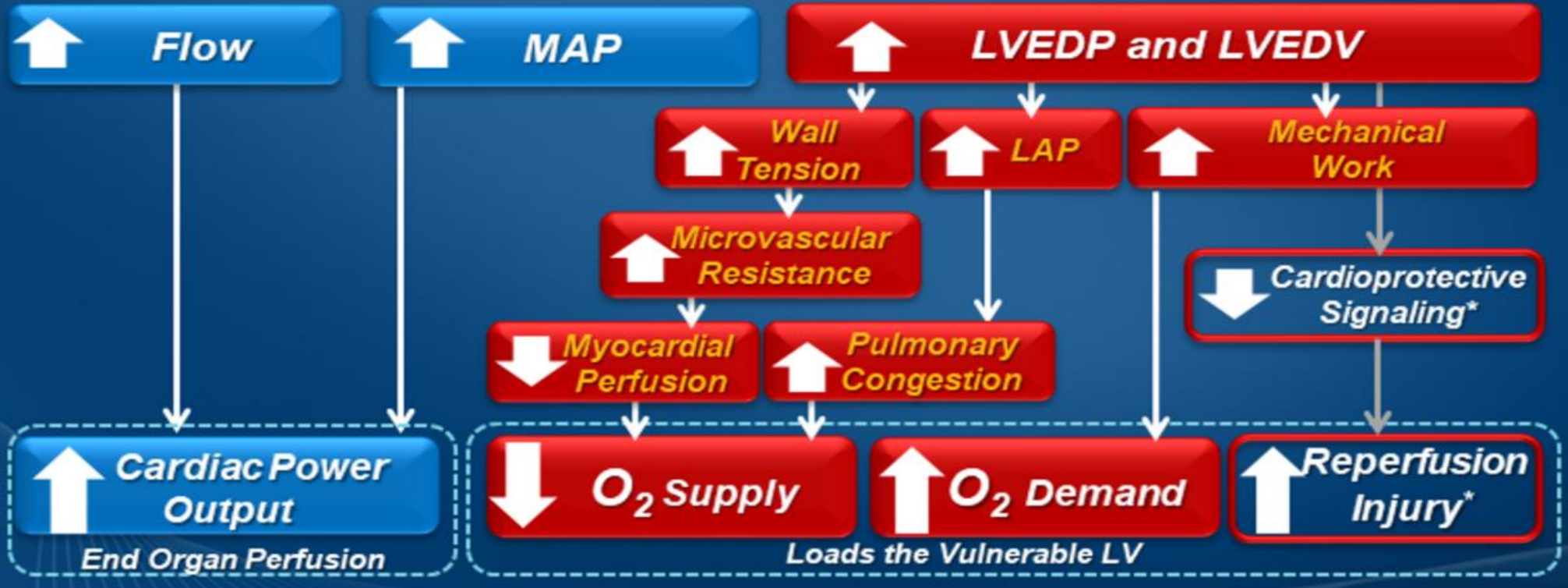
Raising the P-level too high may set up competition between ECMO and Impella resulting in suction and reduced flows for both

Central hypoxia can result from inability to oxygenate blood returning to the left ventricle, so upper extremity oxygenation needs to be carefully monitored





V-A ECMO Loads the Left Ventricle



* Under study

Fincke R, et al. J Am Coll Cardiol 2004
den Uil CA, et al. Eur Heart J 2010
Mendoza DD, et al. Am Heart J 2007
Torgersen C, et al. Crit Care 2009
Torre-Amione G, et al. J Card Fail 2009

Suga H. Am J Physiol 1979
Suga H, et al. Am J Physiol 1981
Burkhoff D, et al. Am J Physiol Heart Circ Physiol 2005
Burkhoff D. Mechanical Properties Of The Heart And Its Interaction With The Vascular System. (White Paper) 2011

Sauren LDC, et al. Artif Organs 2007
Meyns B, et al. J Am Coll Cardiol 2003
Remmelink M, et al. Catheter Cardiovasc Interv 2007
Aqel RA, et al. J Nucl Cardiol 2009
Lam K, et al. Clin Res Cardiol 2009

Reesink KD, et al. Chest 2004
Esposito M, et al. J Am Coll Cardiol 2015
Remmelink M, et al. Catheter Cardiovasc Interv 2010
Naidu SS. Circulation 2011
Weber DM, et al. Cardiac Interventions Today Supplement Aug/Sep 2009

IMPELLA UNLOADS THE LEFT VENTRICLE

Venoarterial ECMO

Impella Unloading

Outflow

Inflow

- ↑ *Flow*
- ↑ *MAP*
- ↓ *LVEDP and LVEDV*
  - ↓ *Wall Tension*
    - ↓ *Microvascular Resistance*
      - ↑ *Myocardial Perfusion*
      - ↓ *Pulmonary Congestion*
  - ↓ *LAP*
  - ↓ *Mechanical Work*
    - ↑ *Cardioprotective Signaling**

↑ *Cardiac Power Output*

End Organ Perfusion

↑ O_2 *Supply*

↓ O_2 *Demand*

↓ *Reperfusion Injury**

Unloading to Myocardial Recovery

** Under study*

Fincke R, et al. J Am Coll Cardiol 2004
den Uil CA, et al. Eur Heart J 2010
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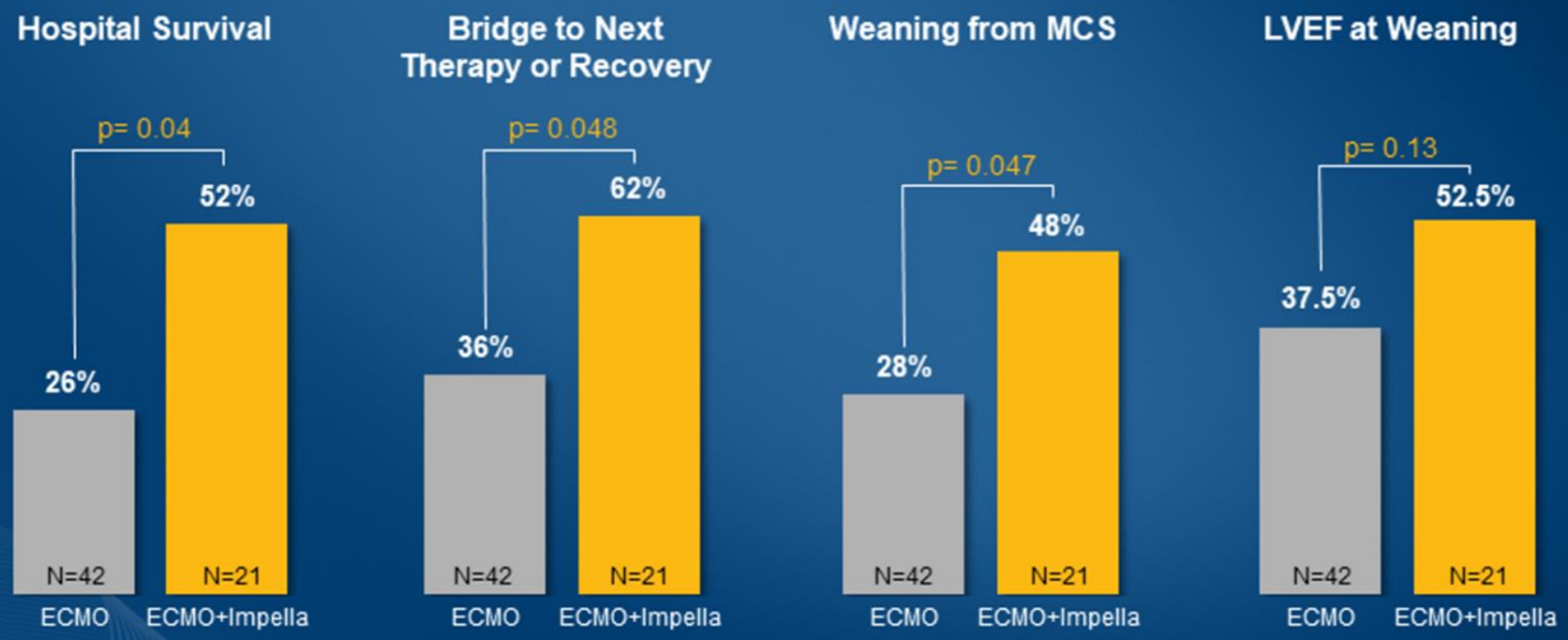
Weber DM, et al. Cardiac Interventions Today Supplement Aug/Sep 2009

IMPELLA+ECMO VS ECMO ALONE IS ASSOCIATED WITH SURVIVAL BENEFIT IN LIFE-THREATENING CS



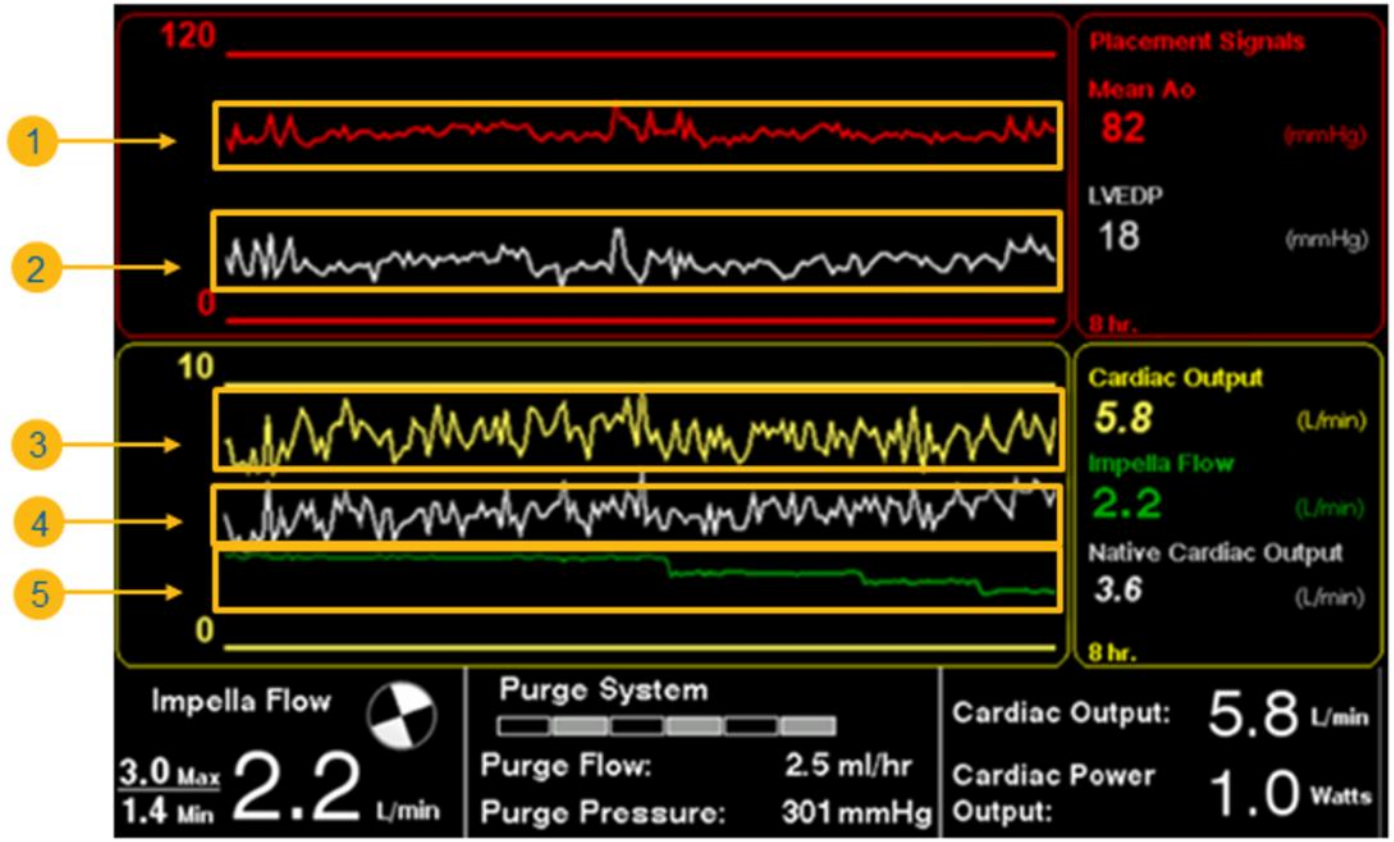
Improved survival, higher rate of successful bridge to next therapy/recovery, and higher LVEF at weaning with Impella unloading

Pappalardo, F, et al.,(2016).European Journal of Heart Failure, 19(3), 404–412.

LVEDP/CO TREND SCREEN

Hemodynamic trends over selectable time-scales assist clinical decision-making

1. Mean Ao Trend
2. LVEDP Trend
3. Total Cardiac Output
4. Native Cardiac Output
5. Impella Flow



FDA Approved, PMA Supplement, 2018

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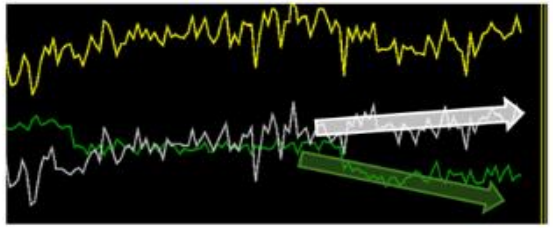
WEANING GUIDANCE : SUCCESSFUL WEAN

Observe trends in pump metrics during weaning.

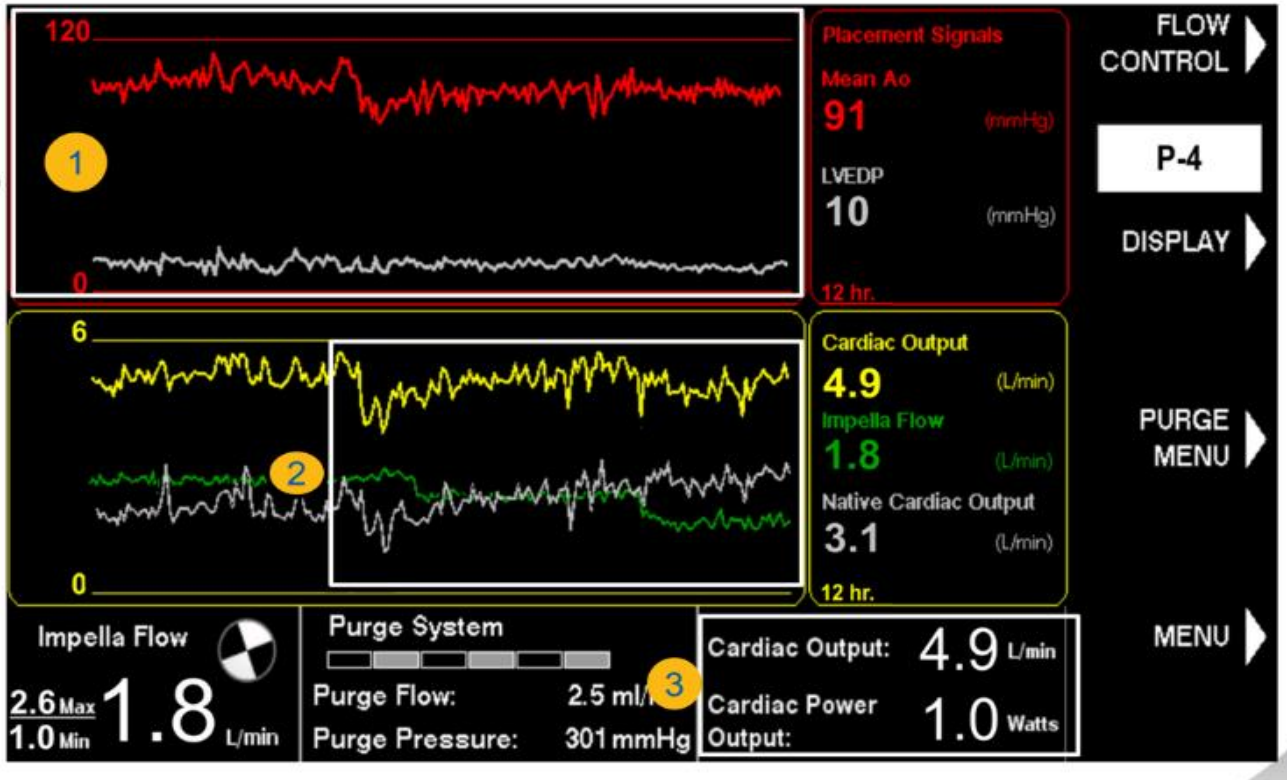
As the Impella flow decreases, confirm preservation of total cardiac output

3 Steps to Guide Weaning:

1. Look for stable MAP and LVEDP
2. Assess native heart recovery



3. Maintain Stable Total Cardiac Output/Cardiac Power Output



FDA Approved, PMA Supplement, 2019

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WEANING GUIDANCE : UNSUCCESSFUL WEAN

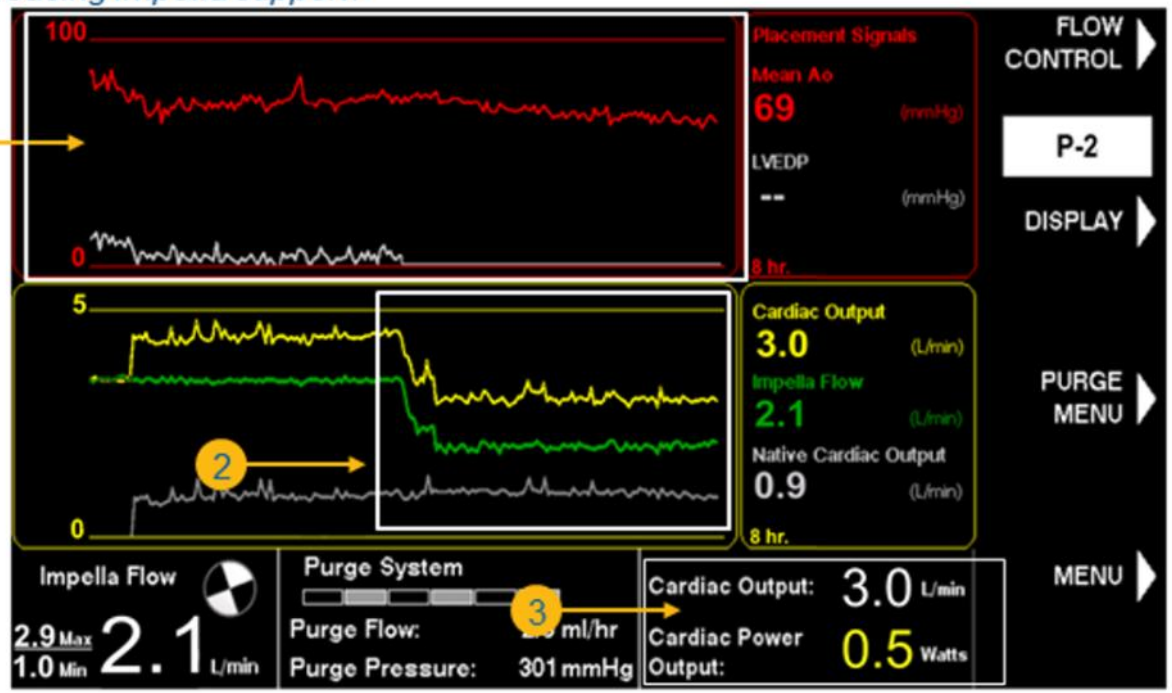
Case information:

First weaning attempt; shows no NCO response with decrease in Impella flows

Trends indicate that the patient is dependent on Impella for hemodynamic support

Are the patient's hemodynamics stable while decreasing Impella support?

1. Look for stable MAP and LVEDP ✓
2. Assess native heart recovery ✗
3. Maintain stable Cardiac Output/Cardiac Power Output ✗



Representative trend screen recreated from console logs. Weaning guidance as per Impella CP with SmartAssist IFU 0048-0007 rJ
Weaning should be conducted in increments as cardiac function allows. Explant Impella only if patient's hemodynamics remain stable.

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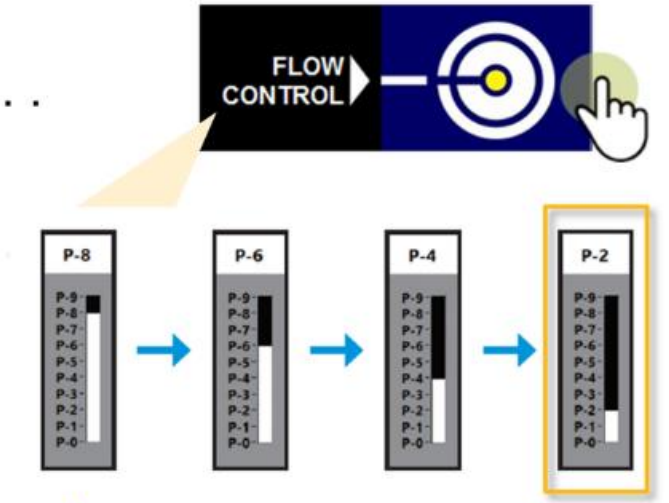
WEANING AND EXPLANT

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. The Impella 5.5 catheter must be surgically explanted; once in the Operating Room, 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. Ligate the graft and close the site surgically



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

Monitor hemodynamics closely; if inotropic or vasopressor support is needed it indicates the patient may not be ready for weaning.

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Resources

Download the Impella App!

ABIOMED

www.abiomedtraining.com
www.heartrecovery.com/resources

Your Local Abiomed Team!

Nashville 24/7 Call Number

(833) 486.5623