IMPELLA PERCUTANEOUS TEMPORARY VAD

Management in Pediatric Patient

**BACKGROUND**

Use of mechanical circulatory support in children is restricted to few devices translated from adult population. Impella temporary VAD offers opportunities for mechanical circulatory support in older children. Due to limited pediatric experience with this device, a structured approach to patient selection, assessment and device deployment is essential followed by careful monitoring and guided therapy de-escalation.

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**OBJECTIVES**

This document will provide an overview of the Impella® 2.5®, Impella CP®, Impella CP with SmartAssist®, Impella 5.0®, Impella 5.5 with SmartAssist®, and Impella RP® devices, patient selection, implantation techniques and management strategies.

**PROTOCOL**

# **IMPLANTATION INDICATIONS**

As with many temporary and durable mechanical support devices the success of support is dependent on careful patient selection. Current pediatric experience highlights 3 primary disease spectrums for left sided support.

1. Support and recovery from acute cardiogenic shock (left sided or biventricular support) 1
	1. Acute myocarditis
	2. Acute decompensated heart failure
	3. Acute transplant rejection with graft dysfunction
	4. Malignant arrhythmias
2. Bridge to decision for durable support or transplantation 2
	1. Circulatory support to allow for short term cardiac recovery
	2. LV support to assess response to pulmonary vasodilators when concern for elevated PVR
	3. Potential support for patients who are poor candidates for durable VAD due to anatomical or surgical factors
	4. If concern for RV failure post LVAD implant and consideration of need for BiVAD support, can trial Impella first to see how the RV responds to increased preload
3. Left heart unloading on VA-ECMO support 3–5
	1. Decompress and unload the left heart and potentially maximize myocardial recovery
	2. Eliminates the need for LA vent or balloon atrial septostomy that would subsequently require surgical closure
	3. Facilitate weaning off ECMO

Right ventricular support can be provided with Impella RP. The following are potential indications for use of Impella RP 6:

1. Acute right ventricular failure secondary to:
	1. RV failure post LVAD placement
	2. Acute myocarditis
	3. Ventricular arrhythmias

# **CONTRAINDICATIONS**

The following conditions **may not be appropriate for implantation of the Impella system for LV support**.

* Inadequately sized vessels for insertion – will vary based on device type
* Presence of ventricular thrombus
* Presence of severe aortic regurgitation or stenosis
* Artificial aortic valve
* Presence of significant right to left shunts (ie. VSD, ASD)
* Abnormal arch anatomy precluding catheter advancement
* Known coagulopathy - should warrant discussion with hematology
* Anticipated need for durable VAD support (but may use as transition to durable support)
* Manufacturer contraindications: Ventricular long axis length <7cm and aortic valve diameter <1.5cm

The following conditions **may not be appropriate for implantation of the Impella system for RV support.**

* Inadequately sized vessels for insertion
* Presence of RA, RV or PA thrombus
* Presence of moderate to severe pulmonary regurgitation or stenosis or presence of PA conduit
* Mechanical valves in the right heart
* Severe pulmonary hypertension
* Presence of DVT or IVC filter

# **PRE-IMPLANTATION EVALUATION AND ASSESSMENT**

## **IMAGING**

**Echocardiography Assessment and Measurements**

Optimal candidacy and device selection will depend on a comprehensive assessment which includes detailed cardiac and vascular imaging.

The following echocardiographic measurements should be performed:

* Advanced assessment of LV or systemic ventricular systolic function
* Measurements of the following cardiac structures are necessary for determining candidacy for Impella insertion:
	+ Measure of the systemic ventricular length from the apex to the aortic valve annulus in both an apical 4 chamber view and parasternal long axis view. This is particularly important for smaller patients (<40 kg) as the systemic ventricular length can limit options for device placement. The Impella 2.5 pump has a length of 7.5 cm from the pigtail to the aortic valve annulus marker on the motor housing. Implants can be performed in patients with a systemic ventricular length of <7.5 cm but may require angulation of the pigtail in the ventricular apex.
	+ Measure length of the ascending aorta from the aortic valve annulus to the origin of the innominate artery (typically from a high parasternal long axis view). This measurement is not as critical for device selection as the ventricular length.
* Presence of aortic valve insufficiency
	+ More than mild insufficiency at baseline could result in worsening AI with Impella placement.
	+ Moderate to severe AI is a contraindication to Impella placement.
* Evaluate for any LV or aortic root thrombus.
* Evaluate RV function and TR. Biventricular failure may require support of both the LV and RV with a left sided Impella in combination with an RP or with another mode of MCS. Frequently, the RV function can be managed medically and only left sided support is necessary, even in the setting of RV dysfunction.
* For additional diagnostic imaging please refer to publication by Morray et al. 2019 7

**Advanced cardiac imaging**

* If any anatomical structures are in question, the assessment should extend to advanced cardiac imaging such as CT chest with contrast.
* Advanced imaging might also be required for planning of surgical implantation to ensure appropriate size of branch vessels as well as determine path of device insertion.

**Vascular Imaging**

* Vascular ultrasound should be used for assessment of potential access sites to exclude presence of any obstruction such as arterial thrombus or arterial collaterals especially in children with chronic illness. For the Impella 2.5 and CP the vessel diameter should be >4 mm. 7
* Larger devices (Impella 5.0 or 5.5) generally require larger vessel sizes but have been implanted in patients in which the arterial vessels measure smaller than the motor given vessel wall elasticity.
* If any suspicion of compromise in distal extremity perfusion (i.e. arterial thrombosis) full assessment for arterial thrombosis in that extremity should be performed prior to device implantation. This might require US doppler at bedside or arterial angiography in interventional suite.

## **LABORATORY ASSESSMENT**

**Table 1:** Diagnostics blood tests recommended prior to device deployment

|  |
| --- |
| **Chemistry and Microbiology** |
|  |  | Comprehensive Metabolic Panel |  | Brain Natriuretic Peptide or NT pro-BNP |
|  | Cystatin C |  | Urinalysis |
|  | CRP |  | +/- MRSA screen (institutional preference) |
| **Hematology** |
|  |  | Type and Screen |  | Plasma-free Hemoglobin |
|  | CBC w/ Differential |  | LDH |
|  | PT/INR, PTT |  | Anti-Xa if on heparin |
|  | Fibrinogen, D-dimer |  | TEG or ROTEM Thromboelastography |
| * Consider additional thrombophilia or bleeding work up if concerning family history or clinical course (see Action Pre-Implant Protocol for details)
 |
| **Ancillary Studies** |
|  |  | EKG |  | Ultrasound Doppler (arterial & venous) to establish vessel size, information on access and line placement |
|  | Echocardiogram |  |  |
| * Consider Head CT if patient at high risk (i.e., ECMO) or unable to get reliable neurologic exam
* Consider if MRI study (heart or brain) is warranted as cannot be performed after Impella is placed
* Consider Chest CT if needed for fit testing/size of heart if anticipate converting to durable VAD later
 |

## **MONITORING**

* Ensure accurate weight and height is measured on the day of procedure.
* The following hemodynamic monitoring should be in place prior to or at the time of Impella implantation:
	+ Arterial line
	+ Central venous access
	+ Swan Ganz catheter in biventricular anatomy and if no contraindications (may not be utilized in all institutions)
	+ Foley catheter

# **IMPLANTATION TECHNIQUES**

## **ANTICOAGULATION AT TIME OF IMPLANT**

* A bolus dose of heparin should be administered to achieve an ACT >250 seconds prior to introduction of the Impella catheter.
* Depending on the device type, the initial purge fluid containing D5W may be run without heparin during initiation of support but should then be transitioned to purge fluid containing standard concentration of heparin of 25 U/mL depending on the anticoagulation needs of the patient. Discussion with an Abiomed representative is recommended.

## **CATHETERIZATION-BASED IMPLANTATION**

**Femoral Access Approach**

* Impella implantation should be performed with fluoroscopic and echocardiographic (TTE or TEE) guidance. This is typically done in the catheterization laboratory although implantation in an operating room can be performed with the use of a portable fluoroscopic C-arm. Bedside implantation in an intensive care unit is discouraged.
* The arterial access site will vary depending on the intended duration of support, the size of the patient and size of the pump that will be inserted.
* After ensuring adequate size (> 4mm). Access should also be obtained with ultrasound guidance whenever possible. Other imaging techniques, including the use of bony landmarks and angiography may be performed as well. Percutaneous insertion is performed using the Impella 2.5, CP and RP devices. Surgical implantation (see below) should be used for Impella 5.0 and 5.5 devices.
* Once access is obtained the arteriotomy can be “pre-closed” with 1 or 2 pre-closure sutures. This will assist with hemostasis once the device is removed.
* For implant in smaller patients or for axillary artery implantation of the larger Impella devices (5.0 and 5.5) in adult-sized patients an axillary artery cutdown is performed and a chimney graft is sewn to the vessel (refer to section on surgical implantation). Typically, a Hemashield Platinum or Vascutek Gelweave graft is used. For the Impella 2.5 a 6 mm graft is adequate and for the larger pumps an 8 mm or 10 mm graft is necessary. The graft can then be cut to the appropriate size and tunneled under the skin for enhanced stability
* After vascular access is obtained (either percutaneously or via cutdown) appropriately sized peel away sheath is placed in the vessel or chimney graft. This will be peeled away after the Impella is in the appropriate position and the repositioning sheath is advanced through the arteriotomy and sutured into position.
* A pigtail catheter is advanced to the systemic ventricle and a guidewire (included with the pump, 0.018 Platinum Plus) is inserted anterior and away from the mitral valve, in the systemic ventricular apex.
* The Impella device is advanced over the guidewire using fluoroscopic guidance and the guidewire removed once the tip of the pigtail is in the systemic ventricular apex.
* The position of the Impella device is verified by echocardiography (see corresponding imaging section). The device may be adjusted if needed using echocardiographic guidance.
* Impella can be used in combination with ECMO for left heart decompression. In these circumstances, retrograde insertion of a small caliber sheath in the superficial femoral artery can be performed to augment distal arterial perfusion to the limb and prevent ischemia complications.
* The Impella repositioning sheath/catheter may be adjusted (end of catheter is tapered) to optimize distal limb perfusion (based on signal from a distal pulse oximeter and clinical exam).
* In some older patients, percutaneous axillary artery access may be performed as well. The axillary artery is not an end artery and the arm is generally protected from ischemia due to the subscapular arterial anastomosis. Percutaneous axillary artery access should also be performed using landmarks and ultrasound. For larger patients or those with challenging vascular anatomy, the axillary artery can be visualized angiographically with a catheter advanced from the femoral artery or contralateral radial artery. A wire can then be placed in the axillary artery to provide a fluoroscopic landmark for precise vascular access. A review of this technique is available in publication by Dawson K et al. 2020 8

## **SURGICAL IMPLANTATION**

**Right axillary artery approach**

* Follow institutional practices for pre-op cleansing, anesthesia, time-outs, and ensure appropriate equipment is available.
* Sizes available for this technique: Impella CP, 5.0 and 5.5.
* Preop evaluation with CT scan (CTA ideal) to determine the anatomy and largest size Impella device that the vascular access will allow.
* Graft selection: (Hemashield, Gel-weave) Gel-weave graft has better hemostatic properties than the non-Gel-weave standard Hemashield graft (institutional preference).
* Pump standby (CPB), fluoroscopy, and transesophageal echocardiogram are necessary for this approach.
* Place standard monitoring lines.
* Position patient supine with arms tucked at the side.
* Make an incision 1 fingerbreadth below the clavicle and perform dissection down to the right axillary artery adjacent to the deltopectoral groove.
* The incision is taken to the level of the right axillary artery, and the artery is exposed and encircled with vessel loops in standard fashion. Great care should be taken not to injure or avulse any of the delicate side branches.
* Meticulous hemostasis is critical.
* Care is taken to avoid injury to the surrounding axillary vein and brachial plexus located superiorly.
* Administer heparin dose as per institutional protocol for goal ACT.
* Isolate and control the right axillary artery using a C-clamp and make an anterior arteriotomy.
* Trim an 8 or 10 mm graft to match the arteriotomy and create an end-to-side anastomosis using a running 5-0 Prolene suture to the right axillary artery. The graft should be beveled (based on surgeon preference and vessel size) to create a very gentle curve so as to ease pump head entrance later.
* Great care should be taken to ensure precise suturing and place additional hemostatic sutures as needed as the inferior aspect of the anastomosis is very difficult to see once the graft is tunneled.
* Consider topical hemostatic agents (institutional preference).
* Remove the c-clamp and inspect for hemostasis, while clamping the distal graft.
* Once hemostasis is satisfactory, clamp the proximal graft and tunnel the graft to a remote site (usually anterior to mid-axillary line), bring it out through the skin and temporarily secure it with a clamp.
* Place introducer system in distal graft and de-air.
* Under fluoroscopic guidance (may require cardiac interventionalist or interventional radiology), deliver guide wire into the left ventricle, followed by long sheath for wire exchange and then exchange for a stiff wire.
* Advance the flushed Impella device over the guidewire through the sheath and the graft. It is often helpful to use manual guidance from outside the anastomosis as the device pump reaches the artery, particularly in smaller patients, in order to help the device advance across the anastomosis and into the artery itself.
* Confirm Impella device is across the aortic valve and inflow and outflow ports are properly positioned with fluoroscopy and transesophageal echocardiography.
* Start the Impella LVAD device and slowly increase P-level to desired output/decompression based on position on TEE.
* Reconfirm positioning after final device placement with TEE, as the device has a tendency to advance into the ventricle as flows are increased. Make sure to check positioning again prior to break down of the sterile field at the end of the case.
* Secure the Impella catheter in place to the skin.
* Ensure hemostasis of the right axillary artery cutdown site.
* Close the right axillary artery cutdown sight in multiple layers and skin.
* Note the final pump P-level and flow, aortic to mid- inlet measurement by TEE, and pump placement at the Tuohy-Borst valve cm marker number for changes and repositioning postoperatively.

# **POST-OPERATIVE PATIENT AND DEVICE MANAGEMENT**

## **ANTICOAGULATION**

Anticoagulation is required to prevent clot formation around the catheter as well as to preserve device motor and pressure monitoring. Optimal anticoagulation is achieved through a combination of purge fluid heparin and systemic heparin administration.

**Role of Purge Fluid**

* All Impella pump motors are protected from biomaterial build-up by running fluid through a purge system. The purge fluid is required to lubricate and maintain function of the device motor and is infused through the internal channel of the catheter, bearings and across the motor. This creates a protective interface or barrier that prevents blood from entering the motor housing.
* Purge system uses a dextrose water solution between D5W and D40W. The solution flows through the internal channel of the Impella catheter in the opposite direction of the blood flow. Through a built-in pressure sensor, the device automatically sets and adjusts the purge flow anywhere between 2 and 30 mL/h to maintain an adequate purge pressure of 300–1100 mm Hg. The dextrose concentration of purge fluid determines the viscosity and flow rate. Since the rate of purge fluid is automatically regulated by the controller, the purge infusion rate must be monitored for large changes in dose as this might affect dose of delivered heparin.
* Lower dextrose concentrations, such as 5%, are less viscous and flow more quickly through the purge system, thereby systemically delivering more heparin. Higher (more viscous) concentrations result in a slower purge flow rate and less overall systemic heparin exposure for the patient. Higher dextrose concentrations can also result in more pressure on the pump and should be avoided when possible. The manufacturer recommends a **starting heparin concentration of 25 IU/mL in a 5% DW as the initial purge solution**.
* Since the purge fluid is infused under pressure, care must be taken to document and monitor purge lines and maintain proper fluid and purge cassette change according to manufacturer recommendations.
* In cases of heparin-induced thrombocytopenia other agents can be considered for anticoagulation and device protection. Please see section below.

**Anticoagulating in Specific Scenarios:**

**Anticoagulation for Impella only support**

* After implantation of Impella 2.5, CP, or 5.0, purge fluid is started without any Heparin and should be changed to D5W with 25 units/ml heparin immediately upon arrival to ICU.
* After implantation of Impella 5.5 or RP, the purge fluid should contain Heparin 25units/ml upon initiation of support in cardiac cath lab or operating room unless there is concern for significant bleeding.
* In clinical settings where D5W with 25 units/ml heparin causes excessive anticoagulation the heparin concentration can be reduced to 12.5 units/ml or dextrose concentration can be increased to reduce the purge infusion rate.
* In situations where D5W with 25 units/mL in the purge solution does not allow one to achieve therapeutic goals it is advised to add systemic Heparin drip and titrate that drip to achieve therapeutic goals.
* Antiplatelet agents are typically not indicated for management of anticoagulation on Impella support.

**Anticoagulation on ECMO**

* In the setting of Impella with ECMO support, patients should continue to have purge fluid driven anticoagulation with D5W with 25 units/ml heparin and systemic heparin added to achieve desired level of anticoagulation per institutional and patient specific ECMO goals.
* Purge heparin contribution to anticoagulation must be taken into consideration, thus systemic heparin requirements might be lower than prior to Impella insertion.
* Frequent monitoring is recommended especially if the patient is inflamed, infected, coagulopathic or displaying signs of insertion site oozing.

**Anticoagulation for Impella RP**

* Impella RP anticoagulation is also achieved through purge fluid
* Recommended starting purge concentration is D5W with 50 units/mL of heparin and systemic heparin should be added to achieve goal anticoagulation if purge delivered heparin is not achieving therapeutic goals

**Initiation and Monitoring of Anticoagulation**

* Timing of initiation of heparin purge fluid and systemic heparin (if need additional anticoagulation) may vary based on institutional practice. It is recommended to start Heparin in purge as soon as possible in the cath lab or immediately in the ICU assuming life threatening bleeding is not present.
* Manufacturer recommends maintaining an ACT of 160-180
	+ If bleeding is noted one may lower the ACT goal or even briefly hold systemic heparin
	+ Subtherapeutic ACT <130 for several consecutive hours might increase risk of pump thrombosis
* Institutional practice can include use of PTT or Anti Xa UF Heparin levels for goal anticoagulation (see table below)
* **If the Impella purge system delivers too much heparin**, a purge solution with a lower heparin concentration (12.5 units/mL) should be used first followed by increased dextrose concentration to reduce purge infusion rate.

**TOTAL HEPARIN DELIVERED TO PATIENT = IMPELLA PURGE HEPARIN + SYSTEMIC IV HEPARIN**

**Table 2 (data taken from Sieg et al. 2015)** 9

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Anti Xa UF Heparin Level** | **PTT** | **ACT** |
| **ECMO + Impella** | ECMO goals | ECMO goals | ECMO Goals |
| **Impella Support Alone**Low risk of thrombosis, short-term use or surgical site bleeding | 0.15-0.25 | 50-60 | 160-180 |
| **Impella Support Alone**High risk of thrombosis or long-term use | 0.2-0.3 | 60-70 | 180-200 |
| **Impella RP** | 0.15-0.25 | 50-60 | 160-180 |

**Other agents:**

The decision to use agents other than Heparin in the purge system should be based on institutional experience with monitoring of the listed agents and careful analysis of risk benefit ratio based on clinical condition. Information presented in this section is based on institutional experience and adult experience from published case reports.

**Bivalirudin:**

* Bivalirudin can be used in a split-dose protocol which allows for constant infusion of medication in purge solution and additional titration of the systemic bivalirudin. As the purge solution range of flow rates varies, a variation in the dose of anticoagulant delivered to the patient through the purge solution is possible. Three variables should be considered. Total dose of bivalirudin delivered to the patient, the purge fluid flow rate and the concentration of the bivalirudin-based purge solution.
* Appropriate concentration for the purge solution can be made to supply up to a 50% of the required bivalirudin. Different described concentrations used for the purge fluid include 100mg of bivalirudin in 250ml of D5W, 50 mg/500 ml and 20 mg/500 mL. The bivalirudin dose from the purge solution alone can range between 0.015-0.07 mg/kg/h.
* Starting dose of systemic Bivalirudin in pediatrics is 0.3 mg/kg/hr, with the dose adjusted down with renal insufficiency. ACTs or aPTTs are initially monitored every 4 hours. Please refer to the ACTION bivalirudin protocol for more information. 10,11

**Argatroban:**

* Argatroban at concentration of 25 mg/25 mL can be added to 475 mL of D5W to produce an argatroban purge solution with a concentration of 50 mcg/mL. Split-dose protocol can be used to deliver constant infusion of medication in purge solution at 50% anticoagulation goal and additional titration of the systemic argatroban. The total argatroban dose is calculated by adding the rate of argatroban purge solution and the systemic argatroban infusion.
* Purge dose is typically 0.05-0.1 mcg/kg/min. Usual systemic dose in pediatrics is 0.5-12 mcg/kg/min (usually <6) with doses titrated by 10-25% to goal activated partial thromboplastin time. While a patient is receiving argatroban purge solution, ACTs or aPTTs should be monitored every 6 hours.
* In hepatic impairment, dose should be adjusted down by 20-50%. 12

**Tissue plasminogen activator (tPA) alteplase:**

* ​Tissue plasminogen activator (tPA) alteplase has been reported to be used for suspected Impella thrombosis (increasing purge pressure, elevated LDH levels)
* Sterile water is used as the diluent used in the tPA purge solution instead of D5W or normal saline. The solution is prepared by diluting tPA (2 mg) in 50 or 25 ml sterile water for injection in an intravenous piggyback (IVPB) to produce a 0.04 or 0.08 mg/ml solution. The tPA solution replaces the Impella purge anticoagulation solution and runs at the device determined rate while systemic anticoagulation is used to maintain a therapeutic ACT or aPTT. The lower tPA (0.04 mg/hr) purge solution can run over up to 12 hours, or longer if there is improvement but not normalization of the purge pressure. If there is no improvement in purge pressure at 12 hours, the higher tPA (0.08 mg/ml) purge solution can be used for up to 12 hours. Once tPA finishes infusing, the purge solution is switched back to the prior anticoagulation solution. 13

## **LABORATORY MONITORING**

Post Implantation labs obtained should reflect baseline assessment of patient oxygen delivery, coagulation profile, hemolysis, hemoglobin and end organ function, as well as frequency which allows monitoring of the Impella device and patient response to the device and anticoagulation.

**Baseline labs post Impella placement:** CBC; Chemistry with liver function; Hemolysis labs: plasma Hb, LDH; Coagulation profile: PTT, PT/INR, Fibrinogen, D-dimer, anti-Xa, ACT (POCT), TEG or ROTEM; blood gas with lactate and mixed venous oxygen saturation if available.

**Table 3:** Recommended laboratory testing following device deployment

|  |  |  |
| --- | --- | --- |
| **Laboratory Markers** | **24-48h post implantation** | **Chronic Monitoring** |
| **Hematology and Coagulation** |
| CBC | Q12H | Daily |
| Plasma free hemoglobin and LDH | Q12H | Daily until stable |
| DIC Panel | Q24H | Daily until stable |
| Coagulation panel | Q12H or with every titration | Daily |
| TEG or ROTEM | Q12H | Daily until stable |
| **Chemistry and Microbiology** |
| Comprehensive Metabolic Panel | Q24 | As indicated |
| Brain Natriuretic Peptide or NT pro-BNP | Q24 | Weekly |
| Cystatin C | Once | Weekly |
| **Ancillary Studies** |
| CXR | Daily | Daily |
| Echocardiogram | Daily | Weekly |

**These are recommendations only and each center is encouraged to use center-based practice.**

**Additional Labs**:

* Renal panel to assess end organ function
* Hepatic panel to assess end organ function and monitor for hemolysis
* Due to high risk of pancreatitis in patients recovering after cardiogenic shock a pancreatic enzyme panel should be performed and monitored accordingly.

## **IMAGING TO MONITOR DEVICE POSITION**

An echocardiogram provides useful information on Impella positioning for surveillance, if there is an increase in ventricular ectopy, or when evaluating ventricular decompression.

**Echo Imaging Protocol:**

* Positioning of the Impella is best seen by echocardiogram in the parasternal long-axis view. To appropriately measure the distance of the Impella in the left ventricle, measure from the aortic valve to the inlet (lucent area prior to teardrop). This will allow for consistent measurements over the patients’ course.

**Figure 1**: Long axis parasternal view delineating intracardiac structures used for measurement of Impella position



## **DEVICE POSITION**

Appropriate device position is crucial for optimal device function. Each device has specific position recommendations which can be found in the imaging section.

* Initial device position should be confirmed in the cath lab using fluoroscopy as well as TTE or TEE for correlation.
* It is recommended to re-evaluate the device position upon arrival to ICU and monitor every 48 hours.
* Positioning or suction alarms should prompt a bedside TTE to evaluate device position. The device can be repositioned at the bedside using TTE guidance.
* In smaller patients it may not be possible to place the inlet in the optimal location based on the manufacturer recommendation on distance from AV to pump inlet. ECHO should be used to ensure the inlet of the device is placed in the mid ventricular cavity, away from cardiac structure, the mitral valve apparatus, and LVOT to avoid suction. The outlet of the device should be a few centimeters above the AV to ensure uninterrupted flow from the device.

**Table 4**: Manufacturer recommended device position based on distance of device from the aortic valve to the inlet.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Impella Device** | **2.5** | **CP** | **5.0** | **5.5** | **RP** |
| Position below aortic valve per manufacturer IFU | 3.5 cm | 3.5 cm | 3.5 cm | 5.0 cm | Via CXR outlet 2-4 cm above pulmonary valve |

# **DEVICE MONITORING AND MANAGEMENT**

## **DEVICE TERMINOLOGY**

* **P-level:** Represents various rotational speed levels at which the device can be programmed to operate. P levels represent range of RPMs that the device will maintain to achieve optimal output (see device manual for specific P-level RPMs and flow rates)
* **Impella Flow (L/min):** Flow is calculated from the current and pressure gradient across the device based on the measured pressure flow curves. Each device is tested in the lab for its performance and accuracy. The flow accuracy is within 10% of max flow error.
* **Motor Current (mA - Green Waveform):** Motor current is the measured amount of energy required to achieve a set range of RPMs.
	+ The current value changes based on the amount of blood flowing through the device and other potential resistors (i.e. motor thrombus, afterload and preload).
	+ Waveform pulsatility displays the difference in energy requirement to drive the blood across the catheter between the inlet (in the LV) and outlet (in the aorta). Since the amount of flow differs in systole and diastole the current requirement changes reflecting a pulsatile motor current waveform.
	+ Motor current provides information regarding catheter placement. When the inlet and outlet of the device are in different compartments (i.e. ventricle and aorta) the change in pressure across these two compartments results in higher or lower amount of blood flowing through the device. This creates a pulsatile current waveform. When a device is malpositioned and migrates into the same compartment (ie aorta or ventricle), the current waveform will disappear. A dampened or flat motor current waveform can be also diagnostic of device malposition (see troubleshooting section)**.**
	+ A dampened or flat motor current waveform in the setting of confirmed accurate position of the device might reflect very poor ventricular function.
	+ Each Impella device has a different motor current level at specific P settings**.** Ensure motor current upper threshold parameters for each Impella device and P setting are available to the team. Monitor individual patient/device trends over time as a rise in motor current may be an early sign of device wear or thrombus formation, potentially requiring device exchange.
	+ **A rapid rise in motor current may precede or indicate a pending device failure.**
* **Pressure Signal (mmHg - Red Waveform):** Pressure signal differs between various Impella types. Pressure is either measured through direct water column (Impella 2.5 and CP) or using an optical sensor at the motor head thus measuring aortic pressures. In most clinical cases the waveform should be pulsatile.
	+ **Direct aortic pressure monitoring (available on Impella 2.5 and CP):** Aortic pressure in these devices is measured by direct pressure measurement using a pressure transducer and pressure bag system. It reflects the true aortic pressure. Care must be taken to maintain constant pressure in the system to prevent lumen obstruction or clotting.
	+ Impella CP with SmartAssist and Impella 5.5 with SmartAssist contain optical sensors for pressure monitoring
	+ Impella 5.0 and Impella RP use Differential Pressure Sensor
	+ The pressure signal can be used together with motor current waveform to diagnose Impella malposition.
* The pressure signal can be used together with power waveform to diagnose Impella malposition (see troubleshooting section).
* **LV pressure Signal (mmHg -White Waveform on Impella 5.5):** This signal is only available on Impella CP and 5.5 with Smart Assist and represents calculated LV pressure. The measurement is deducted from the optical sensor derived by motor current indirectly measuring LVEDP and LVESP. This feature is available when the P level is a P4 of above.
* **Purge Flow (mL/hr):** The purge flow rate is delivered by purge cassette inside the Automated Impella Control (AIC) and is measured in mL/hr. The purge flow is automatically adjusted by the AIC based on the device needs. Higher dextrose concentration of the purge fluid will slow down the purge rate and lower dextrose content will increase purge rate.
* **Purge Pressure (mmHg):** The Impella console automatically adjusts the purge flow rate to maintain purge pressures between 300-1100mmHg.
	+ High/low purge pressure alarms should be evaluated by following on-screen instructions.
	+ If a ‘purge pressure low’ alarm remains unresolved for more than 20 minutes, the purge cassette will likely need to be changed.

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**Figure 2: Example of Impella placement screen**

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**Figure 3: Example of the Impella Purge Screen**

## **DEVICE SPEED**

* Device speed is regulated by P-levels on the controller (P0-P8) Impella 2.5 and Impella CP. Boost speed (P9) should only be used in the cath lab during high risk procedures. Initial speed after implantation can be at boost level however the device should not be left on boost speed for an extended period of time.
* It is recommended that the device is operated at the lowest speed possible. Optimal lowest speed level should be determined to minimize hemolysis, suction events and other complications.

**Determining optimal device support**:

* Optimal speed can change with changes in clinical status (ie. recovery of ventricular function, afterload reduction, intravascular volume status). Advanced hemodynamic monitoring including invasive arterial and venous pressures must be monitored to determine optimal support. PCWP can be directly measured in the cath lab to determine lowest LV filling pressure at the lowest P level.
* Outside of the cath lab environment, a Swan Ganz (SG) catheter can be used to determine level of LV unloading and optimal speed, as well as the function of the RV. While escalating the P level, the level of unloading should be measured by monitoring PCWP.
* In addition to the SG catheter, echocardiographic findings can further guide titration of support and monitoring of myocardial response to support.
* Finding the optimal speed will help minimize hemolysis and optimize device function. The support level should not exceed the required CO for the patient.

## **MALPOSITION**

* The device position should be assessed with any device alarms, >20% change in flows, acute onset of hematuria or evidence of hemolysis, or suspected device movement.
* If repositioning is required, it should be done under direct TTE or TEE guidance.
* **If the device is found to be outside of the LV it should only be repositioned under fluoroscopy guidance.**
* If the device is found to be deep in the LV, it can be repositioned at bedside with TTE/TEE guidance.

# **PATIENT MANAGEMENT**

## **ICU ADMISSION**

Upon arrival to the ICU, the following should be completed:

* Ensure the AIC is plugged into AC power on arrival to ICU. The controller battery life is only 1 hour.
* The AIC should be positioned at the base of the bed for easy access and screen visibility.
* Device performance and setting should be evaluated and documented.
* For Impella 2.5 and CP, pressure bag systems should be set up as soon as possible.
	+ If not started in the cath lab, ICU nursing should transition to heparinized purge fluid.
* Verify that the Tuohy connection is tightened to the right and locked in order to prevent catheter displacement or migration.
* Document insertion length of Impella catheter where the sterile sleeve connects to the sheath.
* Inspect dressing at the insertion site for bleeding and integrity.
* If femoral access, secure the extremity with the knee brace to prevent flexion and injury to the arterial insertion site (see limb care section).

## **HEMODYNAMIC MONITORING**

* Patients in the critical phase of the illness will require more aggressive hemodynamic monitoring than those on long term support.
* Invasive hemodynamic monitoring of arterial blood pressure and central venous pressures is recommended until organ recovery and satisfactory organ function is achieved.
* Hemodynamic parameters and device performance should be documented every hour and as per unit policies.
* Use of a pulmonary artery catheter should be considered strongly, however it must be balanced with experience and training. Parameters (ie. PCWP, PAP, CI) obtained from Swan Ganz catheters can help determine response to device support, need for additional therapies and need for RV support.
* Balance between risk and benefit must be evaluated daily to minimize adverse events associated with invasive monitoring.

**The following Impella assessment should be performed at the beginning and end of the shift as well as PRN:**

* Device monitoring should include assessment and documentation of the following Q1H:
	+ P-level
	+ Impella flow (L/min)
	+ Motor current (mA -green waveform)
	+ Placement signal (mmHg -red waveform)
	+ Purge pressure (mmHg)
	+ Purge flow (ml/h)
	+ Assessment of connections and device alarms
* Verify that the Tuohy connection is tightened to the right and locked in order to prevent catheter displacement and migration.
* Inspect dressing at the insertion site and confirm securement of Impella catheter.
	+ Change dressing as per institutional guidelines.
* Document insertion length of Impella catheter where the sterile sleeve connects to the sheath.
	+ Recommended position documentation with any positional changes and patient movement.
* Back-up Impella AIC console should be easily accessible and plugged into AC power.
* Check purge solution: Abiomed recommends using a concentration D5W with 25 U/mL Heparin in the purge system.
	+ Purge solution bag must be changed Q24H
	+ Purge cassette tubing must be changed Q72H (with fluid bag change)
	+ Ensure one extra Impella tubing cassette is easily accessible
* Reposition patient as per unit protocols.

## **LIMB CARE, INSERTION SITE AND PERFUSION MONITORING:**

The extremity with the Impella insertion site is at a high risk for compromise if there is limited perfusion or nerve compression. Close monitoring and assessment is crucial to minimize these complications.

* If the device is implanted percutaneously in the femoral position, extremity immobilization is recommended.
	+ A knee immobilizer can be used to prevent the patient from bending the extremity and causing arterial rupture.
	+ Attention must be placed on any pressure points and extremity hyperextension which can result in temporary or permanent foot drop if not recognized early.
	+ A physical therapy consult should always be considered for appropriate assessment of knee immobilization.
* **Extremity with Impella must be closely monitored for acute arterial thrombosis or occlusion**. Pulse oximeter provides continuous pulse assessment and local NIRS may be used to monitor deterioration of perfusion. Palpate (or obtain by Doppler) peripheral pulses Q1H. Some institutions use a myometer to monitor loss of neurologic function.
* **Any compromise in perfusion must be immediately addressed**. Potential interventions include arterial jump graft. If unable to improve extremity perfusion, the device must be removed and another MCS strategy considered.
* Observe and document Q1H: Color, capillary refill, warmth, movement, and sensation
* Notify MD if noted signs of diminished peripheral circulation or limb ischemia (i.e. quality of pulses diminished, cool peripheries, change in skin color/mottling or sensory changes including numbness and/or tingling)
* Consider early involvement of physical and occupational therapy to minimize the above complications and address any motor deficiency early
* Observe puncture sites, sheath insertion site or surgical access site for active bleeding, swelling, bruising or hematoma especially when anticoagulation is escalated. Additional bleeding control may be needed by placing mattress sutures at the insertion site.
* With femoral insertion, avoid flexion of leg and keep the head of bed greater than 30 degrees.

**Skin integrity**

Due to limitations in patient mobility especially when femoral insertion site is used, close attention must be paid to skin integrity and pressure areas.

* Assess skin integrity Q2H & PRN
* Assess risk of skin breakdown using appropriate pressure ulcer risk assessment tool
* Reposition patient as per hospital protocols

**Urine output**

Change in urine color can be one of the first indicators of excessive hemolysis indicating device malposition or suction. Foley catheters can be used to diagnose these complications early.

* Observe and document characteristics of urinary output Q1H
* Observe for signs of hemolysis: discoloration of urine, decreasing hemoglobin/hematocrit, increased LDH, plasma free Hgb, AST and bilirubin
* Once stable device position and appropriate hemodynamic status is achieved, and end organ recovery is established, Foley catheter should be removed to minimize risk of infection.

## **PATIENT TRANSPORT**

* Safe transport checklist and expectations should be generated based on intuitional practices with following in mind:
	+ Prior to transport, document the insertion length (cm) of the Impella catheter where the sterile sleeve connects to the sheath.
	+ A transfer board should be utilized to ensure that the catheter remains in situ and does not kink. The limb with the Impella catheter in situ must remain straight at all times during transport.
	+ In preparation for transport the team should check purge fluid, check battery life and that Impella was charging prior to transport, check the catheter connections so as not to dislodge with movement and transfer of patient, monitor urine quality prior and during transport.
	+ The Impella controller battery life is 1-hour.

# **MANAGING COMPLICATIONS AND ADVERSE EVENTS**

Potential adverse events include, but are not limited to: aortic valve injury, bleeding, cerebral vascular accident/stroke, hemolysis, limb ischemia, thrombocytopenia, vascular injury and death.

## **BLEEDING**

* + Depending on method of Impella insertion, bleeding may occur at the access site and/or surgical sites (subclavian cut down and graft anastomosis). This should always be assessed by the cath or surgical teams and intervened on if needed.
	+ Compression devices such as safeguard or dressing may be used briefly (<6 hours) and extremity perfusion must be closely monitored during this period and while on support.
	+ Assess the patient and evaluate the cause of bleeding (over anticoagulation, coagulopathy vs surgical site bleeding).
		- Send labs evaluating for coagulopathy (CBC, PT, PTT, Fibrinogen, Rotem, Anti-Xa) and assess the need for blood transfusions during prolonged periods of bleeding and correct any deficiencies.
	+ Anticoagulation goals may need to be adjusted if there is ongoing bleeding or oozing and the pump itself is otherwise functioning well. Heparin may even need to be held for short periods of time (<6-12 hours) for clinically concerning bleeding.
		- If clinically indicated for clinically significant bleeding, per manufacturer recommendations, maximum duration of running the Impella pump without heparin is no longer than 24 hours.
	+ If bleeding continues, consider platelet dysfunction, low fibrinogen, HIT.
	+ Surgical intervention for bleeding should be considered if bleeding is difficult to control with medical therapies.

## **HEMOLYSIS**

* + Some degree of hemolysis may occur at higher P settings. It is typical to see some mild hemolysis in the first 24-48 hours of support. This should improve.
	+ The etiology of hemolysis can be due to the expected mild sheering from the device, from higher P-level settings, suction events, or malpositioning of the Impella device.
	+ To evaluate the etiology, consider ECHO to assess positioning of cannula, check fluid status, suction events, and P-level setting.
		- P-level setting may need to be adjusted if the setting is too high, as well as fluid administration if patient appears hypovolemic
	+ If P-level setting and fluid status are unchanged but hemolysis is noted, consider ECHO to assess positioning of cannula. If the Impella has moved further towards the LV apex, the outflow may be close to the aortic valve and cells may be lysed as they exit the outflow of the Impella and hit the aortic valve leaflets.
	+ Hemolysis is clinically seen as a constellation of findings depending on the degree.
	Mild hemolysis may be seen only with lab findings of elevated LDH or plasma Hb with a stable or slowly decreasing hemoglobin value. Moderate to severe hemolysis manifests with elevated LDH, plasma Hb, elevated bilirubin, AST, and red/tea colored urine with an acute drop in hemoglobin.
	+ Significant hemolysis can induce AKI, continue to monitor renal function.

## **DEVICE CLOT**

* + In the setting of subtherapeutic anticoagulation or periods of profound inflammation, the device is at risk of developing fibrin deposition or thrombus formation, resulting in device failure.
	+ There may be a rise in purge pressure and drop in purge flow, rise in motor current either acutely or gradually, or drop in device flow overall.
	+ Consider TPA administration to the device in consultation with Abiomed, or your institution’s protocol.
	+ If the device stops, support the patient clinically as indicated, and consult interventional cardiology and CT surgery as soon as possible.

## **DEVICE FAILURE**

* + This is not a common occurrence with the Impella device, however, when used for prolonged periods, there may be a risk of device failure/stoppage.
	+ Close monitoring of motor current trends will help to assess the function of the motor.
	+ If the motor current is increasing and is nearing its upper threshold, the ICU team, and proceduralist should be notified, as this may be an early sign of the motor reaching end of life. Each type of Impella device, at each P setting, will have a different motor current upper limit. Discussion may be had with your Abiomed representative regarding recommended thresholds and potential device exchange.

## **INFECTION**

* As with any foreign indwelling device, there is a risk of infection. Prophylactic antibiotics are not generally recommended for the duration of the device. However, for surgical prophylaxis, cefazolin or other antibiotic covering skin flora may be administered for 24 hours postoperatively.
* Monitor site and continue site care, as described above, continuously evaluating for infection.
* If an infection occurs related to the device, antibiotic regimen to be individualized based on your institution.

## **SUCTION**

* + Several factors may cause a Suction alarm, including inadequate left ventricular filling or preload, incorrect Impella position against the papillary muscle or the mitral valve, or right ventricular failure.
	+ Suction may occur if the blood volume available for the Impella catheter is inadequate or restricted.
	+ Suction limits the amount of support that the Impella can provide to the patient and results in a decrease in expected Impella flow, arterial pressure and cardiac output. It can damage blood cells, leading to hemolysis.
	+ If the Impella detects suction, it automatically reduces motor speed to lower the flow rate to resolve the suction and displays the “Impella Flow Reduced” advisory alarm. If the suction is cleared, the controller returns the flow rate to the desired setting. If suction is still detected at the lowest motor speed, the controller displays the “Suction” alarm.
	+ If a suction alarm occurs, reduce the Impella P-level by 1 or 2 levels, or more, if suction continues. Assess the patient’s volume status, assess hemodynamics and RV function, evaluate catheter position using the placement signal, motor current, and imaging. Reposition Impella if necessary. When the suction alarm is resolved, resume pre-alarm flow rate.

## **OTHER CLINICAL CHALLENGES**

**Ectopy and arrhythmias**

* + Periods of ectopy or arrhythmia might be experienced with the Impella device in place. As long as there is preload to the left ventricle, the patient should be adequately supported with the Impella providing continuous flow and perfusion pressure.
	+ Recurrent refractory ventricular arrhythmias warrant assessment of device parameters and alarms for suction events as well as device position, LV filling and RV function by echo.
	+ During periods of arrhythmia, the patient may lose synchronous intrinsic contractility and therefore pulsatility, however will have a non-pulsatile blood pressure instead, a mean arterial pressure (MAP). If the MAP range is appropriate during the periods of arrhythmia, the patient is well supported.
	+ If the patient doesn’t have adequate MAPs during periods of arrhythmia, assess RV function, volume status, antiarrhythmic agent and consider adjusting P-level if appropriate to better support the patient clinically while the arrhythmia is being medically managed.

## **EMERGENCY PROCEDURES**

**CARDIOPULMONARY ARREST**
If your patient arrests and loses blood pressure and perfusion pressure, and CPR is required:

* Decrease Impella to P-2 and continue chest compression as usual
* Notify interventional cardiologist and/or surgeon ASAP

During CPR P-2 is utilized to minimize potential damage due to dislodgement of the device during resuscitation. Once hemodynamics have been restored, an echo should be done to re-confirm placement. Increase P-level by two levels at a time until desired P-level is achieved.

**DEFIBRILLATION/CARDIOVERSION**

If defibrillation and/or cardioversion is required:

* P-level does not need to be adjusted
* Defibrillate/cardiovert as usual
* Image after to confirm accurate device position

# **DEVICE ALARMS AND MAINTENANCE**

## **ALARMS**

The Impella controller will sound an alarm tone, and display both an alarm message and a resolution message on the display screen. Alarm severity is color coded and please refer to device manual for alarm indications:

* Advisory (White)
* Serious (Yellow)
* Critical (Red)

**Mispositioning:**

* Assess positioning of the Impella device. Consider obtaining x-ray for gross patient movement. Evaluate with echo at bedside for exact positioning.
* If repositioning is required, it should be done under direct TTE/TEE guidance.
* If the device is found to be outside of the LV, it should only be repositioned under fluoroscopic guidance.
* If the device is found to be deep in LV, it can be repositioned at bedside with cath and close TTE/TEE guidance.

**Low flow on Impella:**

* Flow is lower than expected for set performance level. Either due to suction, inadequate preload or due to high afterload. Assess positioning with echo, volume status and blood pressure.

**No flow or Impella stops/acute device stoppage:**

* Clinically support the patient. If CPR is needed, drop Impella P-level to 2 and perform CPR.
* To troubleshoot the device, check the electric outlet and ensure that the Impella is plugged in. If off, attempt to restart.
* Obtain STAT echo and Xray. Decrease P-level by 1-3 lower than what was set, not going below 2, and monitor for improvement of flow and function along with patient hemodynamics. If flow resumes at a lower P-level, evaluate the patient's intravascular volume status as well as RV function and positioning. Under these circumstances, catheter function is not reliable and the Impella may stop again.
* If flow does not resume at lower P-level or P2, assess the patient and make sure the patient is stable, call Abiomed, Interventional cardiology and CT surgery STAT for potentially removing and/or replacing malfunctioning Impella.

**Suction alarms (see above in complications):**

* Suction waveforms will differ based on which Impella catheter is being used. Note the ‘suction alarm’ alert.
	+ Intermittent suction alarm: will alert ‘suction alarm’ and the Impella controller will reduce the motor speed to resolve the suction, then resume flow and will resolve itself. If this occurs, assess positioning with echo, assess preload as suction events may be due to low intravascular volume state and underfilled ventricle and evaluate RV function.
	+ Continuous suction alarm is an event that does not resolve and continues to alarm and you will see lower flows delivered on the Impella console as well as lower systolic pressures. If you see a continuous suction alarm, lower your P-level and assess positioning of the catheter with echo, assess RV function and preload. Once troubleshooting is complete and flows resume, resume P-level to prior settings.

## **MAINTENANCE**

**Impella Connect System Setup**

* Please see figure in appendix

**Transfer from AIC to AIC:**

* Please see device manual or manufacturer App for detailed instructions

**Changing Impella Purge Solution:**

* + Please refer to Impella App and AIC directions

**Changing the Impella Purge Cassette and Fluid Bag:**

* Please refer to Impella App and AIC directions

**De-airing the Purge System:**

* Please refer to Impella App and AIC directions

# **DEVICE WEANING AND REMOVAL**

* Length of use of the devices: please refer to FDA PMA indications on page 1.
* The length of Impella support is dependent on underlying myocardial disease and indications for its use. In setting of acute cardiogenic shock, the length of therapy tends to be short (<7days). In the setting of bridge to decision the length of therapy might be longer depending on the designated destination or recovery.
* In the setting of good hemodynamics and evidence of improved ventricular function, the Impella can be weaned gradually.
* If a patient shows clinical improvement and the care team feels Impella support may no longer be needed, a gradual decrease in P settings may be performed first with close monitoring of hemodynamic parameters.
* Impella 5.5 with Smart Assist allows for monitoring of LVEDP trends as long as the P level is 4 or greater.

**Rapid weaning:**
If the Impella has been used for temporary circulatory support (< 7 days or clinically showing early signs of hemodynamic improvement with ability to wean P-level), the device can be weaned rapidly over the course of 24-48 hours while closely watching hemodynamics and patient tolerance to weaning. While weaning, assess hemodynamics and echocardiograms to assess native heart recovery with decreasing pump flows. If the patient has been weaned successfully to P2, do not wean further until ready to remove the device. If the patient’s hemodynamics remain stable, decrease the P-level to P-1, pull the catheter into the aorta, and stop the motor by decreasing the P-level to P-0.

**Weaning on ECMO:**

For patients supported with Impella on ECMO the sequence of transition includes weaning Impella to lowest level possible before deciding to wean off ECMO (not lower than P2). Typically, Impella support is maintained until the patient is liberalized from ECMO and then weaned off.

**Slow weaning:**

* If the patient has been supported by the Impella over a long period of time (> 7 days or clinically needing full Impella support and showing slow signs of clinical improvement on Impella support), the Impella should be weaned gradually. Wean the P level on the Impella 1 or 2 times a day, while closely watching hemodynamics and clinical tolerance. While weaning, assess hemodynamics and echocardiograms to assess native heart recovery with decreasing pump flows. Wean Impella P-level until you’ve reached P2 and wean no further unless ready to remove the catheter.
	+ On the Impella 5.5, the LVEDP and native cardiac output can be monitored while weaning.
* Monitoring the hemodynamics (blood pressure, perfusion, CVP) are very important at this time.
* Echo guidance during Impella support wean may also be beneficial to evaluate ventricular size and function.
* In the event the patient doesn’t tolerate Impella support wean, the team must consider continuation of current therapy versus transition to a durable VAD.
* While weaning and once at P2, if the patient’s hemodynamics remain stable and the team is ready to remove the device, decrease the P-level to P-1, pull the catheter into the aorta, and stop the motor by decreasing the P-level to P-0.

**Specific instruction for removal of the device:**

* Femoral access:
	+ With the device in the descending aorta turn the device to P-0 and unplug the power cable from the AIC.
	+ The catheter shaft is pulled until the motor housing reaches the repositioning sheath at which point the repositioning sheath and the catheter are removed. Apply pressure to the puncture site.
	+ If pre-closure sutures have been previously placed, tie down the sutures and observe hemostasis.
	+ This can be done in the cath lab or at the bedside for uncomplicated femoral arterial access.
* Axillary access:
	+ If the Impella was placed via a chimney graft, device removal should be performed in the cath lab or operating room. The surgeons will assist with removal and control bleeding at the graft before tying off the graft and closing the incision.
	+ If the Impella was placed percutaneously, it is advised to remove it in the cath lab. Access can be obtained in the femoral artery and a wire advanced into the axillary artery. This will allow for balloon tamponade of the subclavian to create a dry field for obtaining hemostasis.
	+ The Impella pump is removed as described in the femoral access section. Hemostasis can be achieved by pressing the vessel against the second rib. If pre-closure sutures have been previously placed those can be tied down. Again, having another point of access and a compliant balloon in the subclavian artery can allow for tamponade to temporarily control bleeding if necessary.

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***Disclaimer:*** *The ACTION network is focused on quality improvement efforts such as harmonizing best practice protocols, disseminating them among institutions, and helping centers to improve care practices at the local level. This protocol was developed as a consensus tool for pediatric VAD programs. The information in the protocols are based on center practices, individual opinions, experiences, and, where available, published literature. Centers may choose to adapt this protocol to include in their center-specific protocols with reference to ACTION with the understanding that these are meant as guidelines and not standard of care. (Revised: 01/22/2021)*

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