VENTRICULAR SUPPORT DEVICE - IMPELLA® - ICU, Cath Lab

PURPOSE: To outline the management of patients receiving cardiac ventricular support using the Impella® device.

SUPPORTIVE DATA:

Impella® is a percutaneous circulatory assist device that is used in high-risk coronary interventional procedures to provide hemodynamic support for patients with acute myocardial infarction or with cardiogenic shock.

The Impella® catheter is placed percutaneously through the common femoral artery and advanced retrograde to the left ventricle over a guidewire. Fluoroscopic guidance in the catheterization laboratory or operating room is required.

After the device is properly positioned, it is activated and blood is rapidly withdrawn by the blood pump from the inlet valve in the left ventricle and moved to the aorta via the outlet area, which sits above the aortic valve in the aorta. The device supports the patient's circulatory system and is designed to directly unload the left ventricle, reduce myocardial workload and oxygen consumption, and increase cardiac output, coronary and end-organ perfusion.

A Cardiologist or Cardio-Thoracic Surgeon trained on the Impella® system inserts the catheter and manages the device. An ICU RN or Cardiac Cath Lab RN trained on the Impella® system cares for the patient with the Impella® Device.

Indications for Impella®:

- Protected Percutaneous Coronary Intervention (PCI):
  Less than 6 hours temporary ventricular support is indicated for use during high -risk elective or urgent PCI performed for hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction.

- Cardiogenic Shock:
  As needed for temporary ventricular support device is indicated for the treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction or open-heart surgery as a result of isolated left ventricular failure.

Contraindications:

- Mechanical Aortic Valve or Heart Constrictive Device
- Moderate to Severe Aortic Insufficiency (echocardiographic assessment graded as $\geq +2$)
- Severe Aortic Stenosis/calcification (equivalent to an orifice area of 0.6 cm^2 or less)
- Left ventricular thrombus on echocardiogram
- Severe peripheral vascular disease (PVD)/ peripheral artery disease (PAD)

- Significant right heart failure
- Known ventricular septal/atrial defect
- Left Ventricular rupture
- Cardiac tamponade

If patient is receiving both intra-aortic balloon pump (IABP) and Impella® support, set IABP ratio as ordered; 1:3 is generally recommended to prevent hemolysis.

Only providers may reposition or remove the catheter.

IMPELLA® NURSE ASSESSMENT:

1. Assess the following every 15 minutes x 4 after initiation, then every 30 minutes x 4, then hourly for the duration of Impella® support:
   - Vital signs
     Note: Document arterial line or non-invasive cuff for blood pressure; do not document blood pressure from console.
   - Neurovascular checks of cannulated limb including color, temperature, capillary refill, and distal pulses
   - Hemodynamic values [Pulmonary artery pressure (PAP) and central venous pressure (CVP)]
     Note: Low CVP may cause suction alarms
   - Access site condition (e.g., bleeding, hematoma formation, kinking)
2. Assess the following a upon initiation and a minimum of every hour:
   - Catheter centimeter marking at insertion site
   - Urine amount and color (assess for hemolysis)
   - Verify the Tuoy -Borst connection is secure to prevent catheter migration
   - Purge pressure
   - Purge flow
   - Pressure bag is inflated to 300 mmHg
3. Monitor pump placement using the Placement screen a minimum of every hour and prn:
   - The Placement screen displays both placement signal waveform and motor current waveform
     - The **placement signal** is used to verify whether the Impella® catheter is in the aorta or in the ventricle by evaluating the current pressure waveform as an aortic or ventricular waveform.
     - The **motor current** provides information about the catheter position relative to the aortic valve. When catheter is positioned correctly, with inlet in ventricle and outlet area in aorta, the motor current is **pulsatile** because of the pressure difference between the inlet and outlet areas changes with the cardiac cycle.
     - Motor current is dampened or flat when there is no pressure difference between the inlet and outlet area indicating malpositioning.
4. Assess knee immobilizer (if present) and skin underneath every 4 hours for pressure injury.

5. Monitor activated clotting time (ACT) in Cath Lab and partial thromboplastic time (PTT) or anti-Xa in CCU as ordered:
   - Cardiac Cath Lab/Operating Room:
     - ACT goal prior to device insertion is greater than 250
     - ACT post procedure goal is 160-180
   - ICU:
     - Maintain anti-Xa level per pharmacy protocol
     - Initiate purge heparin per provider
     - Systemic low-dose heparin infusion per pharmacy protocol. DO NOT administer heparin boluses.
     - For patients on systemic Argatroban drip due to heparin induced thrombocytopenia (HITT), also include activated partial thromboplastin clotting time (aPTT) and international normalized ratio (INR).

PRIMARY NURSE LABORATORY & DIAGNOSTIC PROCEDURES:

6. Obtain labs as ordered:
7. Obtain and assess value of anti-Xa as follows (as ordered):
   - Heparinized purge solution**:** Per provider order
   - Systemic low-dose heparin infusion**:** Per pharmacy protocol

8. Obtain the following as ordered:
   - Daily chest Xray
   - Echocardiogram
     - STAT upon arrival and PRN for suspected catheter migration

IMPELLA® NURSE MANAGEMENT:

9. Maintain Performance (P) Levels between P-2 and P-8 to achieve target hemodynamics as ordered
   - P-8 is the maximum recommended level
   - Do not decrease below P-2 unless the pump is being removed from the ventricle into the aorta. Retrograde flow will occur across the aortic valve if the pump is set at P-0 to P-1
   - Boost mode maximized Impella® flow for 5 minutes if blood pressure drops suddenly. At the end of 5 minutes, the controller returns to the AUTO setting (or P-8 if previously running in P-level mode).
10. Maintain saline pressurized flush bag to red pressure side arm.
    Note: The red Impella® plug contains the pressure transducer. Do Not Add a Transducer.
    - Change tubing every 96 hours.
    - Change the normal saline bag every 24 hours.
11. Maintain Purge Pressures between 300-1100 mmHg. Normal purge infusion rates 2-30ml/hr. If glucose concentrations are changed (i.e. D_5 changed to D_{20} or D_{40}) purge rate and pressure will be affected. See Impella® Quick Reference Guide.
    Heparinize **purge** solution as ordered by provider. Available concentrations: 25 units/ml and 50 units/mL
12. Do the following if HITT is suspected or diagnosed, as ordered:
    - Discontinue heparin in purge solution. Use dextrose (D_5W or D_{10}) or Sodium Bicarbonate(25mEq NaHCO3/1L D5W) in purge solution as ordered.
    - Discontinue systemic heparin, as ordered.
    - Administer Argatroban drip (requires hematology approval)

13. Change Purge fluid every 24 hours and tubing every 96 hours.
    - Press purge system soft keys and select "Change Purge Fluid". See Impella® Quick Reference Guide for more detail.
14. Change tubing/cassette every 4 days.

SAFETY:

15. Logroll patient when turning patient every 2 hours and prn.
16. Ensure Automated Impella® Controller (AIC) is always plugged into red power outlet:
    - 5 hours of charging time is required for 1 hour of battery life
    - The machine will operate for about 60 minutes after batteries have been fully charged if unplugged
17. Ensure the patient is on complete bedrest.
18. Do not raise head of bed higher than 30 degrees.
19. Immobilize the affected leg. May use knee immobilizer if needed.

EMERGENCY MANAGEMENT:

20. Do the following in case of emergency:
    - Do chest compressions and defibrillation during pump operation.
    - Decrease current P-Level to P-2 during CPR; Pump position will be verified by the provider using imaging methods after successful resuscitation
    - Defibrillate/ cardiovert at current performance level
    - Note during defibrillation do not touch AIC
21. Do the following if suction alarm occurs:
    - Reduce P-Levels by 1-2 P-Levels to break suction
    - Ensure that the patient has adequate volume (CVP greater than 10)
    - Notify provider; catheter will be checked for correct positioning by the provider using imaging.
    - Return flow rate to pre-alarm setting when suction resolved
22. Do the following if catheter becomes displaced:
    - Decrease current P level to P-2
    - Call Cardiologist or Cardiothoracic surgeon STAT
    - Order stat echocardiogram to prepare for repositioning by the provider

WEANING & DICONTINUATION

23. Initiate weaning as ordered and per Impella® Weaning Protocol (attached).

PATIENT/CAREGIVER EDUCATION::

24. Instruct on the following
    - Purpose and function of Impella® management and monitoring
    - To notify the nurse immediately for the following:
      - Cannula dislocation
      - Bleeding
      - Leg pain

REPORTABLE CONDITIONS:

25. Notify provider immediately for the following:
    - Loss of distal pulses or change in neurovascular assessment
    - Displacement of catheter
    - Dark urine (sign of hemolysis)
    - Bleeding from insertion site
    - Suction alarms
    - Abnormal lab values including:
        - Plasma Free Hemoglobin hours greater than 40 mg/dL twice in 24 hours is indicative of significant hemolysis.
        - Thrombocytopenia

ADDITIONAL STANDARDS:

26. Implement the following as indicated:
    - Central Venous Catheter
    - Central Venous Pressure Monitoring - ICU
    - Pulmonary Artery Catheter – ICU
    - Femoral Compression Device (Femostop™)/Internal Closure Device-ICU, Cath lab & recovery, PCU.

DOCUMENTATION:

27. Document in accordance with "documentation standards".
29. Document in iView on the:
    - Impella® Settings/Measures in Adult ICU Lines-Devices Navigator band
    - Neurovascular section in ICU Systems Assessment Navigator band

Initial date approved:	Reviewed and approved by:	Revision Date:
07/19	Professional Practice Committee Pharmacy & Therapeutics Committee Nurse Executive Council Attending Staff Association Executive Committee	04/23

REFERENCES:

AACN Procedure Manual for High Acuity, Progressive, and Critical Care. 7th Edition. Debra L. Wiegand. Elsevier. (2017)

Impella Weaning Protocol	
Rapid Weaning as ordered by provider managing Impella® *(Cath Lab/OR)*	Slow Weaning as ordered by provider managing Impella ®*(ICU)*
1. Decrease performance level by 2 level increments over time as cardiac function allows (i.e., P-6 to P-4 to P-2) 2. Keep Impella® Catheter P-level at P-2 or above until catheter is ready to be explanted by provider from the ventricle. If patient becomes unstable, notify the provider. 3. When the patient's hemodynamics are stable, reduce the P-Level to P-1 as provider pulls the Impella® Catheter back across the aortic valve into the aorta. 4. Once provider is ready to remove catheter, decrease to P-0. If introducer is still in place, provider will remove catheter through the introducer. 5. Disconnect the connector cable from the Automated Impella® Controller (connector cable is for one-time use- discard after disconnected). Turn the controller off by pressing the power switch on the side of the controller for 3 seconds. 6. When ACT is below 150 seconds, the provider can remove the introducer. Hold manual compression for 40 minutes. May apply Femostop ™ or Internal Closure Device after manual hold per protocol.	1. Decrease performance level by 2 levels every 2-3 hours (i.e., P-6 to P-4 to P-2). 2. Maintain at P-2 for 2-3 hours. If patient becomes unstable, notify provider. 3. When the patient's hemodynamics are stable, reduce the P-Level to P-1, as provider pulls the Impella® Catheter back across the aortic valve into the aorta 4. When ACT is below 150 seconds, press FLOW CONTROL and reduce the P-Level to P-0 5. Provider will remove the Impella® Catheter and reposition sheath together (the catheter will not come through repositioning sheath) 6. Disconnect the connector cable from the Automated Impella® Controller (connector cable is for one-time use- discard after disconnected). Turn the controller off by pressing the power switch on the side of the controller for 3 seconds. 7. Provider will apply manual compression for 40 minutes, may apply Femostop™ or Internal Closure Device after manual hold per protocol.