SECTION: **PATIENT CARE**

SUBSECTION: **SPECIALTY PROCEDURES**

SUBJECT: **IMPELLA DEVICE**

APPROVED BY: _____
Hospital Director

POLICY

This policy provides guidelines to facilitate care of the patient on the Impella device.

PROCEDURES

I. Indications for use include but is not limited to:
   - A. High Risk Primary Coronary Intervention (PCI)
   - B. Emergent ST- elevation Myocardial Infarction (STEMI) with Cardiogenic Shock
   - C. Myocarditis and Cardiogenic Shock

II. Contraindications for use includes but is not limited to:
   - A. Mechanical Aortic Valve or Heart Constrictive Device
   - B. Moderate to Severe Aortic Insufficiency
   - C. Severe Aortic Stenosis
   - D. Left Ventricular and/or Left Atrial Thrombus on Echo
   - E. Severe Peripheral Vascular Disease
   - F. Uncontrolled Sepsis
   - G. Bleeding Diathesis
   - H. Aortic Aneurysm and /or Aortic Dissection

III. Insertion
   - A. Personnel Qualified to Perform Procedure include Cardiologist or Cardio-Thoracic Surgeon trained on the Impella device
   - B. Required supplies for insertion
     1. Automated impella controller
     2. Standard 0.035” j-tipped guide wire
     3. 5-8 french initial introducer
     4. Impella set-up and insertion kit
     5. IV 5% Dextrose with 25 units of heparin per ml and Impella purger tubing/cassette
   - C. Set-up procedure/patient connection and initiation of therapy
     1. Refer to Impella Systems Operation manual and quick reference guide

IV. Patient Care
   - A. Initial care and ongoing assessments
     1. Assess vital signs, circulation checks, hemodynamics, access site, and device assessment every 15 min x 4, every 30 min x 2, then hourly as ordered
     2. Assess volume status hourly

3. Chart hourly urine outputs
4. Monitor distal perfusion of leg, especially if 14 French Introducer is in place
5. Maintain Performance (P) Levels between P2-P9 to achieve target hemodynamics as ordered.
6. Do not decrease below P2 unless the pump is being removed from ventricle into the aorta. Retrograde flow will occur across the Aortic Valve if the pump is set at P0
7. Decrease the Pump to P1 when being pulled back into aorta then P0 for removal

B. The distal tip of the Impella catheter is designed to be in the left ventricle. Monitor pump placement using dual signal waveforms and aortic pressure monitoring. In the event the distal tip of the Impella becomes displaced, call the cardiologist stat. decrease to P2 and obtain order for STAT Echocardiogram for repositioning. Only Cardiologists can reposition device.

C. The patient is on complete bedrest. The HOB can be elevated up to a maximum of 30 degrees, reverse Trendelenburg positioning is acceptable. Patient may be turned carefully (log roll recommended) side to side. Immobilize the affected leg if indicated.

D. Anticoagulation is required for the duration of Impella support. While in the cardiac lab the Activated Clotting Time (ACT) goal is 250. The ACT post procedure goal will be 160-180 or Partial Thromboplastin Time (PTT) of 45-65. Monitor ACT's or PTT per practitioner order.

E. Maintain Purge Pressures between 300-1100mmHg. Purge infusion rates 2-30 ml/hr. are auto-regulated by the Impella Console.

F. Change Purge fluid every 24 hours, change purge cassette / tubing every 96 hours. Changing Purge fluid set up needs to occur within two minutes to prevent damage to catheter pump.

G. Side Port of the Repositioning introducer sheath is not used after first flush during insertion.

V. Device repositioning

A. Only Practitioners trained on the use of Impella may reposition the device. Practitioner, Cardiac Lab Personnel or the physician affiliates may discontinue the sheath & device once the device is removed from the ventricle.

VI. Emergent Situations

A. Chest compressions and defibrillation, if needed, can be administered during Impella support. During chest compressions, decrease performance level to P2. The Impella system does not have to be stopped or unplugged to defibrillate. After successful defibrillation and resuscitation, obtain a post Echocardiogram or Trans esophageal echocardiogram (TEE) to verify pump position in the left ventricle.

VII. Nursing Documentation

A. Initiate and document hourly on the Impella flow sheet, parameters include but is not limited to:
1. P (performance) level (P0-P8)
2. Flow l/min (0.0-4.0)
3. Placement Signal (mmHg, Sys. / Dia.)
4. Purge Pressure – mmHg (300-1100)

5. Motor Current (mA) (Sys. / Dia)
6. Pump Position
7. Purge flow (2-30 ml.hr)

REFERENCES: Impella CP® Circulatory Support System Instructions for Use & Clinical Reference Manual, Abiomed 2021 Abiomed®, Inc. U.S.A.
Impella Circulatory Support System Quick Reference Guide, Abiomed
Impella 2.5 Circulatory Support System Instructions for Use & Clinical Reference Manual, Abiomed 2021 Abiomed®, Inc. U.S.A

DEFINITIONS: N/A

ATTACHMENTS: N/A

APPROVAL DATE:	**N/A**	**Policy, Procedure and Standards Committee**
	8/25/2023	**Critical Care Committee** Applicable Administrator, Hospital or Medical Committee
	10/03/2023	**Nursing Standards Committee** Applicable Administrator, Hospital or Medical Committee
	10/19/2023	**Pharmacy & Therapeutics Committee** Applicable Administrator, Hospital or Medical Committee
	1/10/2024	**Department of Internal Medicine** Applicable Administrator, Hospital or Medical Committee
	1/24/2024	**Patient Safety and Quality Committee** Applicable Administrator, Hospital or Medical Committee
	11/02/2023	**Quality Management Committee** Applicable Administrator, Hospital or Medical Committee
	1/25/2024	**Medical Executive Committee** Applicable Administrator, Hospital or Medical Committee
		Board of Supervisors Approved by the Governing Body

REPLACES: **N/A**

EFFECTIVE:

REVISED: **N/A**

REVIEWED: **N/A**