UHS Impella® Pump Overview

General Information:
The Abiomed Impella® is a percutaneous mechanical circulatory support (MCS) device indicated in key patient populations to support left ventricular function (hemodynamics) and minimize myocardial ischemia or infarct size. Impella is a catheter based system that contains a nonpulsatile microaxial continuous flow pump, inserted via the femoral artery and advanced to position across the aortic valve, which propels blood forward from the left ventricle into the aorta. This action leads to an increase in mean arterial pressure (MAP) and cardiac output (CO), thus optimizing organ perfusion, while unloading the left ventricle, leading to a favorable improvement in the balance of myocardial oxygen supply and demand.

Indications for use:
- High-risk PCI*
- Cardiogenic shock*
- Acute decompensated heart failure

Intra-Device Purge Solution:
To prevent blood from entering the Impella® motor, a pressure barrier is created by running a purge solution through the Impella® Catheter in the opposite direction of blood being drawn into the catheter. A recommended 300 mmHg of purge pressure is maintained by running a dextrose solution through the system. A range of solutions from 5 to 40% have been studied by the device manufacturer, with the current recommendation being the use of Dextrose 5% (D5W) solution. To maintain an appropriate purge pressure, flow rates may range from 2-30 mL/hr, though the average is 7-20 mL/hr. The D5W purge solution allows clinicians to replace the purge cassette less frequently than the previously recommended D20W solution and simplifies availability of purge fluid since D5W is commercial available, eliminating the need for inpatient pharmacy compounding. If the Impella® device will be used outside of the cath lab, Abiomed recommends the addition of unfractionated heparin to the purge solution, at a concentration ranging from 0 to 100 IU/mL, with the default recommendation being 50 IU/mL.

Concomitant Systemic Anticoagulation:
Most patients will require concomitant systemic anticoagulation with intravenous (IV) unfractionated heparin (UFH). UHS has a heparin clinical pathway/guideline specifically for use with Impella®, accounting for systemic UFH exposure via the Impella® purge solution.

Developed by: Bethany A. Kalich, PharmD, BCPS-AQ Cardiology
Approved by: Cardiovascular Subcommittee: 2/2018
Anticoagulation Safety Committee: 2/2018
P&T Committee: 3/2018

Adult *Impella® Catheter* Unfractionated Heparin Infusion Protocol
University Health System

Objective

To standardize heparin anticoagulation therapy at University Hospital in patients receiving percutaneous mechanical circulatory support via Abiomed Impella® catheter system. Per device manufacturer recommendations, the device purge solution contains unfractionated heparin (UFH) at a concentration of 0 to 50 units/mL. Purge flow rates fluctuate continually with average purge speeds of 7 to 20 mL/hr.

This protocol was updated in February 2018 to provide IV UFH dosing guidelines which account for the additional heparin being provided in the purge solution.

Population

Adult patients with an Impella® catheter system in place and systemic IV UFH anticoagulation therapy.

Dosing and Monitoring Guidelines

I. Baseline Labs (upon arrival to the CCU)

a. CBC (Hgb, Hct, platelet count)
b. Serum creatinine and BUN
c. Heparin assay

II. Systemic Heparin Infusion Dosing (100 units/mL)

Initial Bolus: None
Initial Infusion Rate: 6 units/kg/hr
(Max initial rate: 1,000 units/hr)
Monitor: Heparin Assay at least 6 hours after initiation and 6 hours after each dosage change

Heparin Assay AntiXa (unit/mL)	Action*
< 0.15	Increase by 4 units/kg/hr
0.15 – 0.29	Increase by 2 units/kg/hr
0.3 - 0.5	**No Change**
0.51 - 0.7	Decrease by 2 units/kg/hr
> 0.7	Stop infusion 1 hr, then decrease by 3 units/kg/hr

III. Routine Labs and Monitoring

a. **Heparin assay** 6 hours after initiating purge fluid containing heparin. If <0.3 units/mL, start system IV UFH.
b. **Heparin assay** 6 hours after initiating systemic IV UFH
c. **Heparin assay 6 hours** after each dosage change, **until 2 consecutive therapeutic levels** are reached at a constant rate of infusion, then can begin monitoring **once daily**
d. **Target therapeutic heparin level by Anti Xa assay is 0.3-0.5 unit/mL**
e. Order CBC at least every other day and more frequently if deemed medically necessary
f. Monitor for signs of HIT (Platelet drop by > 50% OR decrease to < 150 K/µL)
   i. Treatment of HIT
      a) Stop **all** sources of heparin, including the purge fluid
      b) Change purge fluid to dextrose only solution

Impella 2.5 Catheter System Treatment* (Target AntiXa 0.3 - 0.5 unit/mL)[6]

References:

1. 5% Dextrose with Heparin as Default Impella Purge Solution. *Protected PCI Community*. http://www.protectedpci.com/custom_resources/5-dextrose-with-heparin-as-default-impella-purge-solution/. Accessed December 6, 2016.
2. Rihal CS, Naidu SS, Givertz MM, et al. 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care. *Journal of the American College of Cardiology*. 2015;65(19):e7-e26.
3. Myat A, Patel N, Tehrani S, Banning AP, Redwood SR, Bhatt DL. Percutaneous Circulatory Assist Devices for High-Risk Coronary Intervention. *JACC: Cardiovascular Interventions*. 2015;8(2):229-244.
4. Impella Program Protocols & Tools. Protected PCI Community. Abiomed®. Available at: http://www.protectedpci.com/. Accessed. December 2016.
5. McCulloch B. Use of the Impella 2.5 in High-Risk Percutaneous Coronary Intervention. *Critical Care Nurse*. 2011;31(1):e1-e16.
6. Impella Program Protocols & Tools. Protected PCI Community. Abiomed®. Available at: http://www.protectedpci.com/. Accessed. December 2016.

*FDA approved indication

Developed by: Bethany A. Kalich, PharmD, BCPS-AQ Cardiology
Approved by: Cardiovascular Subcommittee: 2/2018
Anticoagulation Safety Committee: 2/2018
P&T Committee: 3/2018