



Reminder of Impella 5.5[®] with SmartAssist[®] Best Practices for Purge Management

What's New

Abiomed would like to draw attention to the importance of carefully following the Instructions for Use (IFU) and best practices for the Impella 5.5 with SmartAssist pump, particularly with regard to proper device priming during implantation and management of the purge system in the ICU.

Recommendations

Proper functioning of the purge system is essential for optimal operation of the Impella 5.5. Abiomed suggests the following best practices be scrupulously followed during the initial priming of the Impella 5.5 and during subsequent purge system changes.

1. Ideal priming of the Impella 5.5 should take place concurrently during preparations for implant, while the vascular exposure or graft anastomosis are being performed. Longer duration purge priming, when convenient, ensures optimal delivery of the purge solution to the motor assembly prior to implantation.
2. Ensure that purge fluid droplets are observed at the outlet window of the Impella 5.5 prior to exposing the pump to the blood environment.
3. Heparin in the purge system at the outset is a very important element of the purge system. Physicians should use their clinical judgement to assess the risks versus benefits of operating the Impella 5.5 device with lower concentrations of heparin to no heparin in the purge system. *Note that in comparison to the other Impella devices, Impella 5.5 is designed with a lower purge flow rate which will result in an overall reduction in device delivered heparin to your patient*
4. Upon initial placement, ensure that the guidewire is removed prior to starting the Impella 5.5 device. Ideal start of the Impella 5.5 device is by slowly increasing the pump speed through selection of pump performance levels (P-levels) until the desired maximum performance level is achieved for patient support. It is recommended to start at P2 and increase by one to two P-levels every few minutes. (i.e. P2 and wait for 5 – 10 minutes, increase to P4 and wait 5 – 10 minutes, increase to P6 and wait 5 – 10 minutes, etc.). Physicians should use their clinical judgement to assess patient hemodynamic stability and the rate of increasing pump speed to the target performance level.
5. Abiomed recommends externally fixating the pump catheter and using the Impella Sidearm Retainer immediately upon implant, prior to transferring the patient to the ICU. It is important to remember that Isopropyl Alcohol (IPA) should not be used to wipe down any of the Impella pump components, including the Impella sidearm and purge filter.
6. Finally, carefully review purge cassette and purge fluid bag replacement procedures prior to exchanging. The Abiomed Clinical Support Center (CSC) is available 24/7/365 to answer questions or walk bedside personnel thru the step-by-step purge cassette change wizard on the AIC console.

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Putting it into Action

The points below reinforce information available in the Impella 5.5 Instructions for Use (IFU) document and previously published information about Impella best practices.

Best practice procedures for proper priming of the Impella 5.5 should never be rushed. Since there is a surgical procedure required for Impella 5.5 implantation, Abiomed recommends that the catheter preparation begin at an appropriate time, at least 15-20 min prior to anticipated insertion. Optimal device preparation starts with first laying the catheter out on a back or side table to remove any torque in the system. The Automated Impella Controller™ (AIC) should then be turned on and connected to the pump, walking through the step-by-step case start prompts which include priming the system using D5W with heparin 25 U/mL. We recognize that some patients may require a lower dose of heparin secondary to surgical bleeding concerns. It is recommended to maintain at least 12.5 U/mL in the purge solution for these patients to achieve similar device performance.* *Note that in comparison to the other Impella devices, Impella 5.5 is designed with a lower purge flow rate which will result in an overall reduction in device delivered heparin to your patient.*

The durability of Impella 5.5 using direct thrombin inhibitors in the purge system is unknown. Use of alternative anticoagulants may reduce the longevity or performance of the Impella catheter.

The Impella Sidearm Retainer is now available for use with the Impella 5.5 and will ultimately be included in the Impella 5.5 product package. This fixture could prevent damage to the purge system from inadvertent mishandling. In the remaining Limited Market Release programs, please contact your Abiomed representative for information regarding acquisition of the Impella Sidearm Retainer. It is also worth reminding users that Isopropyl Alcohol (IPA) should never be applied to any of the Impella components, particularly the purge reservoir and purge filter as IPA could weaken or damage these components of the Impella purge system.

We hope attention to these points during the priming of the Impella 5.5 with SmartAssist will help to ensure a successful Impella experience for you and a successful recovery for your patients.

**Data on file*

IMPELLA® INDICATION & SAFETY INFORMATION

IMPELLA® LEFT-SIDE DEVICES

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.

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 0.6cm² 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/impella> to learn more.

Abiomed Clinical Support Center (CSC) can be reached 24/7 at 1-888-422-8666

Clinical Support
24 hours per day, 7 days a week
1-800-422-8666 (US)
IMP-1255_V2

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: www.abiomed.com/important-safety-information

**This bulletin is intended for dissemination of technical information only.*

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Recovering hearts. Saving lives.