Intended Use

- The Impella Sidearm Retainer and its intended use is to provide optional support to the Impella purge line assembly during procedures and patient transport.
- The Impella Sidearm Retainer surrounds the Purge Sidearm to aid in preventing potential mishandling of the assembly.

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Data Sheet

Impella® Sidearm Retainer

The Impella Sidearm Retainer is an optional cover designed to help with patient management for longer duration cases.

- Transparent cover to see all sidearm components while in use
- Flat surface to help with device fixation for longer duration cases and ambulation
- Easy click-together attachment
- Access to luer connection for purge cassette change out
- Compatible with all optical Impella heart pumps
- Redesigned to fully encapsulate the sidearm

Installation Procedure

Note: The Impella Sidearm Retainer is not removable. Do not attempt to put together before installing on the purge sidearm.

1. Hold clear purge sidearm flat with label facing upwards with the clip attached to the white catheter.

2. Place the purge sidearm into the bottom half of the Impella Sidearm Retainer. **Note:** Tuck the label into the Impella Sidearm Retainer on the side closest to the red handle, to avoid the label sticking out of the Impella Sidearm Retainer.

3. Keeping the bottom half of the Impella Sidearm Retainer in place, place the top half of the Impella Sidearm Retainer over the purge sidearm and label.

4. Uniformly push the two Impella Sidearm Retainer halves together until they click. **Note:** When cleaning the purge sidearm or the Impella Sidearm Retainer, only use water. Do not use alcohol or alcohol-based products to clean the retainer.

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Recovering hearts. Saving lives.

INDICATIONS

High-Risk PCI
The Impella 2.5®, Impella CP® and Impella CP® with SmartAssist® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, Impella CP, and Impella CP with SmartAssist Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

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) in adult patients, and in pediatric patients weighing ≥ 52 kg for Impella CP with SmartAssist and ≥ 30 kg for Impella 5.5 with SmartAssist. 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 0.6 cm^2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe 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 Cardiac or Vascular injury (including ventricular perforation).

Right-Side Support
The Impella RP® System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation for less than 48 hours following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery, without the presence of profound shock, end organ failure, or acute neurologic injury.

Important Risk Information for Impella devices

CONTRAINDICATIONS
The Impella RP System is contraindicated for patients with the following conditions: Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP device. Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid or pulmonary valve. Mural thrombus of the right atrium or vena cava. Anatomic conditions precluding insertion of the pump. Presence of a vena cava filter or caval interruption device, unless there is clear access from the internal jugular or femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter.

POTENTIAL ADVERSE EVENTS
The potential adverse effects (eg, complications) associated with the use of the Impella RP System: Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device malfunction, Hemolysis, Hepatic failure, Insertion site infection, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system) complication, Tricuspid valve injury, Cardiac or Vascular injury (including ventricular perforation)" as per IFU., Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.

Visit ***www.abiomed.com/important-safety-information*** to learn more

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