MINIMALLY INVASIVE HEMODYNAMIC SUPPORT


Impella 5.0®
Heart Pump
Impella 5.0® Heart Pump
For Patients with AMI Cardiogenic Shock

An intravascular microaxial blood pump offering full hemodynamic support.

- Safe and effective in patients presenting with post-cardiotomy and AMI cardiogenic shock
- Full hemodynamic support promotes myocardial recovery by stabilizing hemodynamics, unloading the left ventricle, and perfusing the coronaries and end organs
- Actively unloads the LV and increases coronary perfusion, thereby improving the myocardium oxygen supply/demand ratio
- Impella 5.0 provides circulatory support to enable heart recovery

More than 100,000 patients have been treated with the Impella platform of heart pumps in the United States, Germany and Japan.

Micro-axial Blood Pump
Delivers forward flow from the left ventricle to the aorta.

Single Access Point
Minimally invasive placement through a single artery and into the left ventricle.

Direct Ventricular Unloading
Actively unloads up to 5.0 L/min from the left ventricle.
Post-Cardiotomy and AMI Cardiogenic Shock

Approximately 0.2% to 6% of patients undergoing coronary or valvular cardiac procedures will develop PCCS.²

- Without hemodynamic support, patients with post-cardiotomy cardiogenic shock (PCCS) continue to have poor outcomes²
- PCCS occurs in patients with normal preoperative myocardial function as well as those with pre-existing impaired function²
- Refractory PCCS leads rapidly to multi-organ dysfunction and is often fatal²

RECOVER I: FDA Pivotal Safety Study

A prospective, single-arm study, involving 16 enrolled patients. The primary efficacy endpoint was survival of the patient to implementation of the next therapy, which included recovery at 30 days after device removal.

Patients and Methods¹

- Post-cardiotomy and AMI Cardiogenic Shock patients
- Baseline EF 23% (±7%)
- 93% Multi-vessel disease
- 70% either emergent or urgent

Clinical Results¹

- Hemodynamic indexes improved immediately once support was initiated.
- Less inotropes required post implant
- Low adverse events

93% of surviving patients recovered their native heart function¹

In-Hospital Mortality¹

Predicted
STS Score¹  Observed

Survival¹

Time of Follow-up

30 Days  3 Months  1 Year

Survival %

94%  81%  75%

Survival %

34%  12%

(N=16)
The Impella 5.0® Heart Pump Allows for Patient Ambulation

The Axillary insertion kit

- 2 Graft locks
- 23 Fr x 6 cm Peel-away introducer with hemostatic valve
- 8 Fr Silicone-coated dilator

Learn how the Impella device provides hemodynamic support. Download the Impella® App Avaliable on iTunes® or Google play.

INDICATIONS FOR USE
Cardiogenic Shock
The Impella 2.5®, Impella CP®, Impella SmartAssist®, Impella 5.0® 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 ≤ 6 days for the Impella 5.0, 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 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 cm² 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 www.abiomed.com/Important-safety-information