MINIMALLY INVASIVE HEMODYNAMIC SUPPORT

Stabilize. Unload. Recover.

Impella 5.0®

Heart Pump

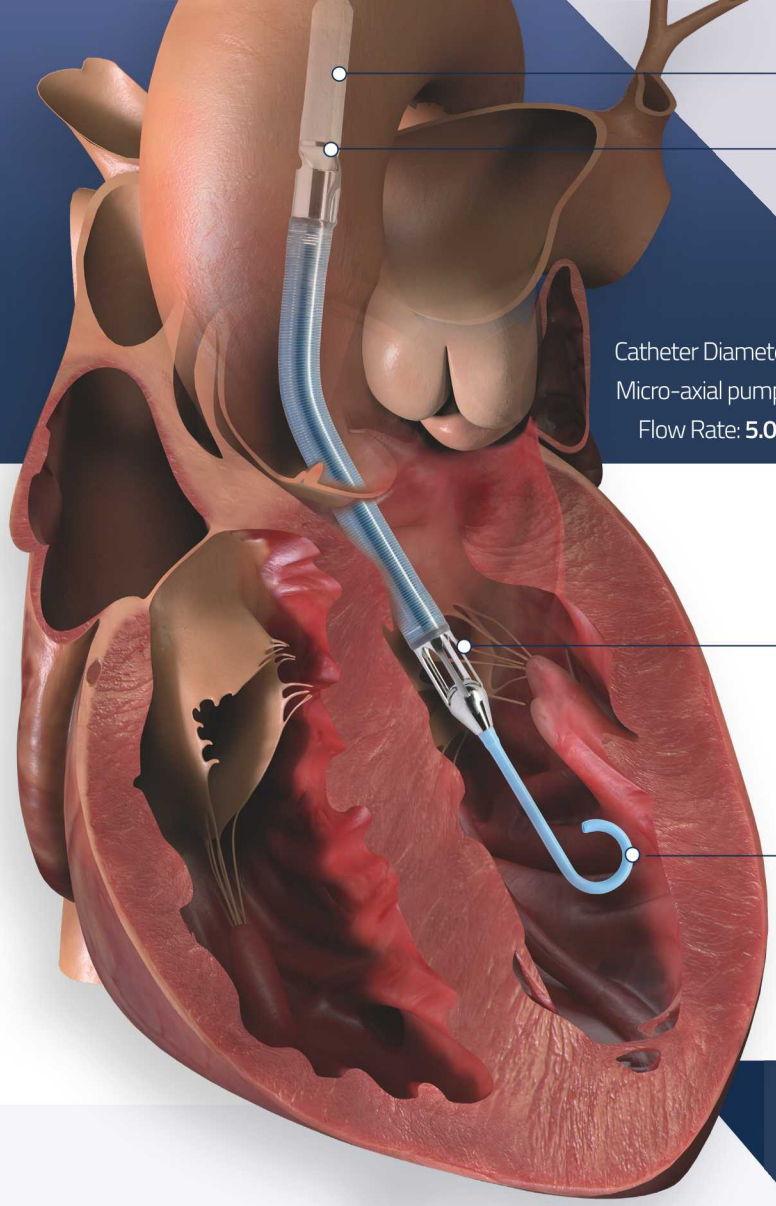
ABIOMED®

Recovering hearts. Saving lives.

Impella 5.0® Heart Pump

For Patients with Cardiogenic Shock

An intravascular microaxial blood pump offering full hemodynamic support.



Catheter Diameter: **9 Fr**
Micro-axial pump **21 Fr**
Flow Rate: **5.0 L/min**

- Safe and effective in patients presenting with post-cardiotomy and AMI cardiogenic shock[1]
- 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 myocardial oxygen supply/demand ratio[2,3]
- Impella 5.0 provides circulatory support to enable heart recovery

More than 140,000 patients worldwide have been treated with the Impella platform of heart pumps.[4]

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.[5]

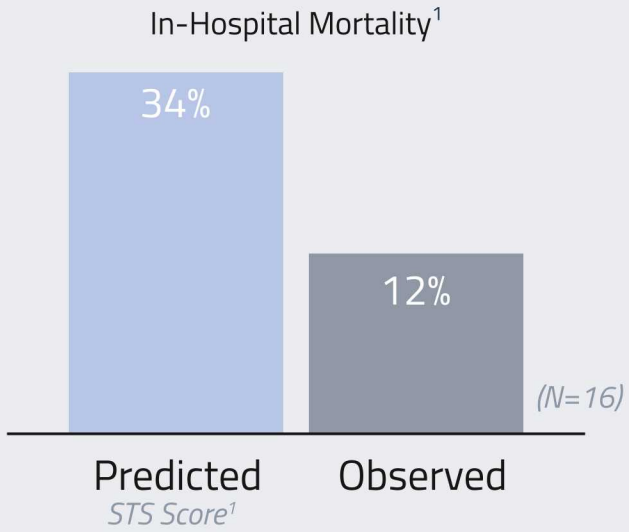
- Without hemodynamic support, patients with post-cardiotomy cardiogenic shock (PCCS) continue to have poor outcomes[6]
- PCCS occurs in patients with normal preoperative myocardial function as well as those with pre-existing impaired function[6]
- Refractory PCCS leads rapidly to multi-organ dysfunction and is often fatal[6]

RECOVER I[1]: FDA Pivotal Safety Study

A prospective, single-arm study. 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 Methods[1]

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

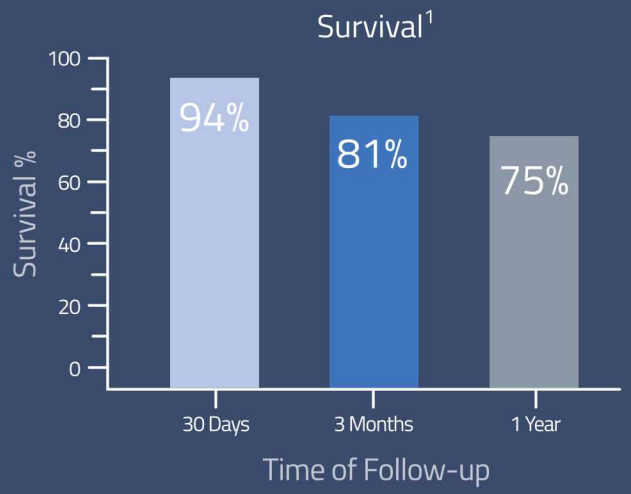


93%

of patients recovered their native heart function[1]

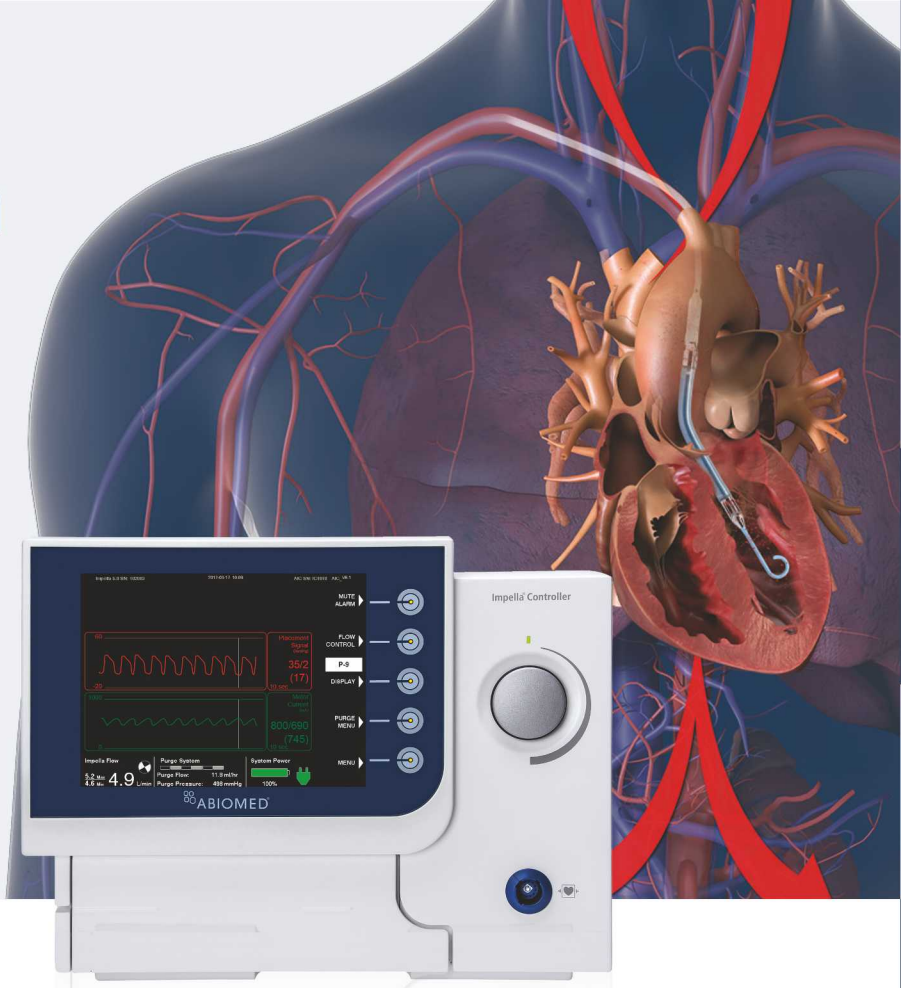
Clinical Results[1]

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



The Impella 5.0® Heart Pump Allows for Patient Ambulation

PART NUMBER	DESCRIPTION
005060	Impella 5.0 heart pump, Purge Cassette, 0.025" placement guidewire, White Silicone Plugs
0052-0011-EU	Vascular access kit: 23 Fr x 6 cm peel-away introducer with hemostatic valve, 2 Graft locks, 8 Fr Silicone-coated dilator
0042-0002	White Connector Cable
0043-0003	Impella Controller Purge Cassettes, Box of 5
0052-3005	Guidewire, 0.018'' x 260 cm, PTFE Coated



References:
1. *Griffith et al. The RECOVER I: A multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support. Journal of Thoracic and Cardiovascular Surgery, 2012* **2.** *Garatti A, Colombo T, Russo C, Lanfranconi M, Milazzo F, Catena E, et al. Different applications for left ventricular mechanical support with the Impella Recover 100 microaxial blood pump. J Heart Lung Transplant. 2005;24:481-5.* **3.** *Siegenthaler MP, Brehm K, Strecker T, Hanke T, Nö tzold A, Olschewski M, et al. The Impella Recover microaxial left ventricular assist device reduces mortality for postcardiotomy failure: a three-center experience. J Thorac Cardiovasc Surg. 2004;127:812-22.* **4.** *Abiomed Data on File. The Impella platform includes Impella 2.5®, Impella CP®, Impella 5.0®, Impella LD® and Impella RP®* **5.** *Sylvin EA, Stern DR, Goldstein DJ. Mechanical support for postcardiotomy cardiogenic shock: has progress been made? J Card Surg. 2010;25:442-54.* **6.** *Khorsandi et al. Advanced mechanical circulatory support for post-cardiotomy cardiogenic shock: a 20-year outcome analysis in a non-transplant unit. Journal of Cardiothoracic Surgery (2016) 11:29.*

The ABIOMED Logo, ABIOMED, Impella, Impella 2.5, Impella 5.0, Impella LD, Impella CP, Impella RP, and Recovering Hearts. Saving Lives. are registered trademarks of ABIOMED, Inc. in the US and in certain foreign countries.

INDICATIONS FOR USE (EU)

The Impella 5.0® (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 10 days for the following indications, as well as others:

- The Impella 5.0® is a cardiovascular support system for patients with reduced left ventricular function, eg, post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction
- The Impella 5.0® may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome

CONTRAINDICATIONS (EU)

- Mechanical aortic valves, severe aortic valvular stenosis or valvular regurgitation
- Hematological disorder causing fragility of the blood cells or hemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrotomy or severe anomaly of the ascending aorta and/or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) after myocardial infarction
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PAOD) is a relative contraindication

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** please see the user manual. 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.protectedpci.eu/en/therapy/product-variations/***

ABIOMED

EC REP **Abiomed Europe GmbH**
Neuenhofer Weg 3
52074 Aachen, Germany
Phone: +49 (0) 241 8860-0
Fax: +49 (0) 241 8860-111
Email: europe@abiomed.com

Abiomed Inc.
22 Cherry Hill Drive
Danvers, MA 01923 USA
Telefon: +1 978-777-5410
Fax: +1 978-777-8411
Email: marketing@abiomed.com

Clinical Support Center
24 hours per day, 7 days a week
+49(0) 1805 2246633 (EU)
+1 800-422-8666 (US)

www.abiomed.com
© 2020 ABIOMED, INC. ALL RIGHTS RESERVED.

CE 0482

IMP-114 EU-EN (v2.0)
Educational material intended for European customers under CE Mark