Impella CP®
with SmartAssist®

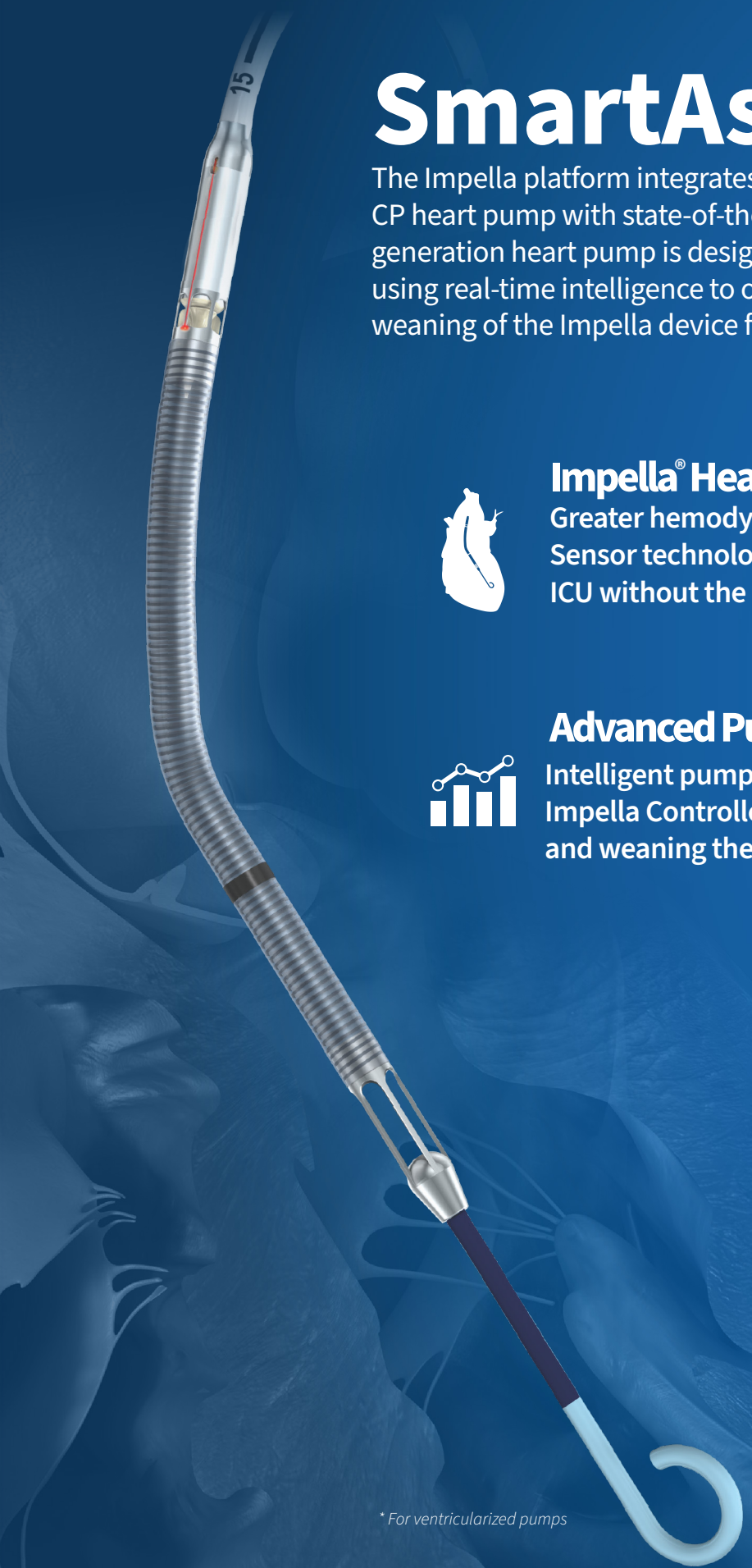
Next Generation Heart Recovery Technology

ABIOMED®

Recovering hearts. Saving lives.

SmartAssist® Platform

The Impella platform integrates the trusted performance of the Impella CP heart pump with state-of-the-art SmartAssist technology. This next generation heart pump is designed to improve patient outcomes by using real-time intelligence to optimize positioning, managing and weaning of the Impella device for better patient care.



Impella® Heart Pump

Greater hemodynamic support and ease of use. Sensor technology allows for repositioning in the ICU without the need for imaging.*

Advanced Pump Metrics

Intelligent pump metrics on the Automated Impella Controller assist in positioning, managing and weaning the Impella device.

** For ventricularized pumps*

Impella CP® with SmartAssist®

Features to Improve Hemodynamic Support and Ease of Use

Greater Hemodynamic Support

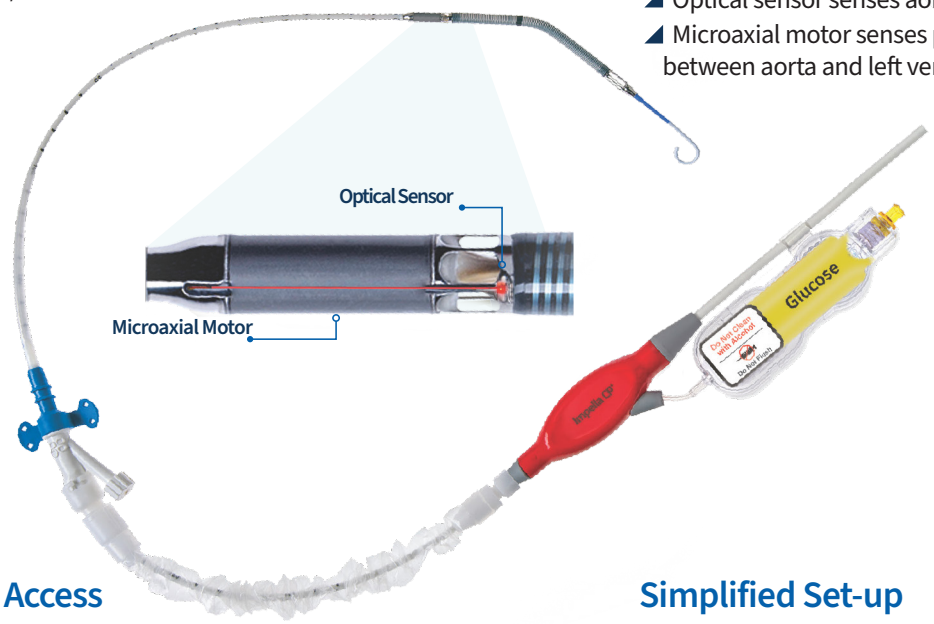
Confident positioning allows for sustained higher flows.

- Peak flows up to 4.3 L/min

Confident Positioning

Hemodynamic sensors assist in managing and positioning Impella CP.

- Optical sensor senses aortic pressure
- Microaxial motor senses pressure difference between aorta and left ventricle



Maintain Arterial Access

Reaccess sheath allows for escalation of care and is designed to improve hemostasis.

- Allows access to the artery with up to a 0.035” guidewire
- 4 cm additional length

Simplified Set-up

Improve ease of use and faster set-up time.

- Reduction in set-up steps with fewer connections
- Single fluid line management in ICU

Advanced Pump Metrics

Designed to optimize pump management and assist in weaning

- Left-ventricular placement signal
- Displays Cardiac Power Output
- Displays trends of LVEDP and MAP to assist weaning
- 50% reduction in timing to resolve suction event[2]

Cardiac Power Output: #1 Correlation to Mortality in AMI Cardiogenic Shock[1]

- CPO (in watts) = (MAP x Cardiac Output) / 451

®

Metrics only available with Impella Catheters with SmartAssist Technology.

1.Fincke, et. al. JACC, 2004 SHOCK TRIAL 2. Abiomed Data on File ES 2019 -129

Impella CP® with SmartAssist® Heart Pump Specifications

PART NUMBER	DESCRIPTION
0048-0003	Impella heart pump, 9 Fr catheter, 6 Fr pigtail, 14 Fr microaxial pump, Percutaneous insertion through the femoral artery
0043-0003	Impella Controller Purge Cassettes, Box of 5
0052-3046	14Fr Combo Introducer Kit containing 13cm and 25cm length sheaths
0052-3005	0.018" x 260 cm PTFE Guidewire for Impella 2.5 and Impella CP

Maximum Flow: 4.3 L/min | **Maximum Mean:** 3.7 L/min | **Speed Range:** 0 to 46,000 rpm | **Interventional Length:** 92-98cm

To learn more, visit www.HeartRecovery.com

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 cm2 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 containdication for the cardiogenic shock indication only. **** 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 (including ventricular perforation).

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices. Visit ***http://www.abiomed.com/important-safety-information*** to learn more.

Impella® CLINICAL SUPPORT CENTER 24/7

24/7 Impella Clinical Support and Technical Expertise 1-800-422-8666(US)

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