Impella 5.5®
with SmartAssist®

Minimally Invasive Heart Pump Providing
Full Support with Maximum Unloading

ABIOMED®
Recovering hearts. Saving lives.

SmartAssist® Platform

The latest innovation on the Impella platform integrates the trusted performance of the Impella 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 5.5® Heart Pump

Greater hemodynamic support and ease of use. New 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.

Impella Connect®

Cloud-based mobile view of the Impella device status for remote patient monitoring and collaborative patient management to optimize patient outcomes.

** For ventricularized pumps*

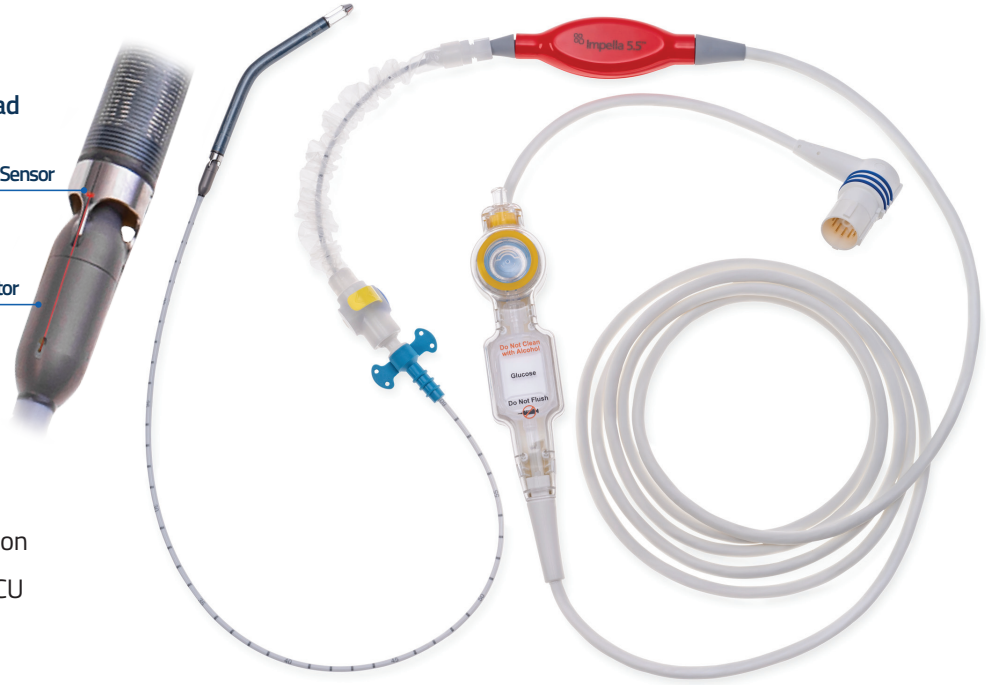
Impella 5.5 with SmartAssist

New Features to Improve Hemodynamic Support for Your Sickest Patients

Full Support with Maximum Unloading

Reduces the heart's oxygen demand and workload

- Forward flow provides coronary and end organ perfusion
- Peak flows up to 6 L/min



Confident Positioning

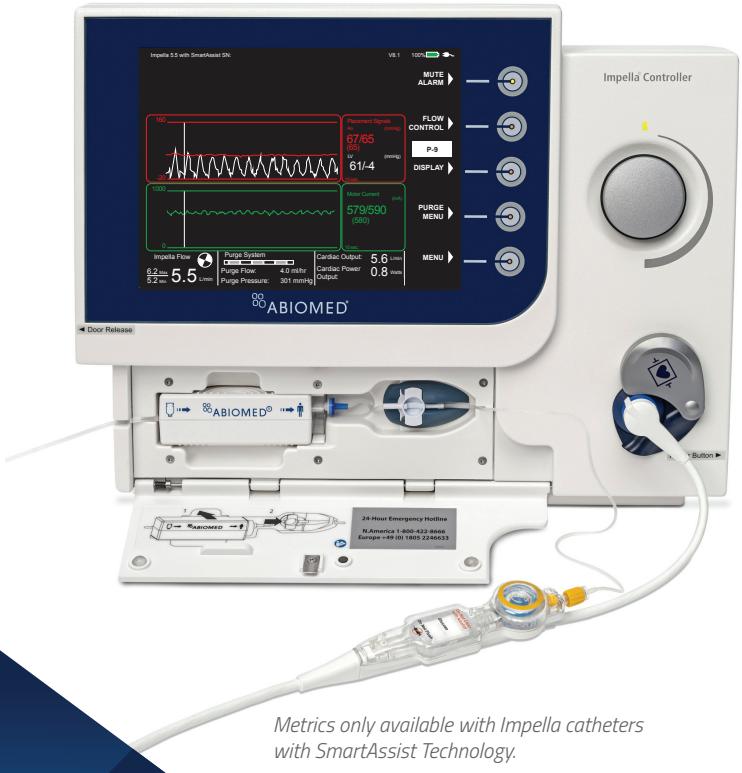
New hemodynamic sensors to intelligently position, manage, and wean

- New always-locked catheter
- Replacement of differential sensor with aortic placement signal for improved position detection
- Enables repositioning without imaging in the ICU

Even More Simplified Set-up

Improved ease of use and faster set-up time

- New integrated purge filter unit improves patient management and mobility
- New user-friendly three-point fixation
- New integrated tubing for optimal purge line setup and management
- Streamlined single fluid line management in ICU



Metrics only available with Impella catheters with SmartAssist Technology.

The Surgeon's Heart Pump

Insert via axillary artery or anterior aorta using familiar surgical skills

- Directly unloads the left ventricle reducing ventricular work for up to 14 days for indications including support during cardiogenic shock
- Enhanced deliverability and torque response
- New sodium bicarbonate compatible luer for heparin-free purge alternative

Advanced Pump Metrics

Designed to optimize pump management and assist in weaning

- Left ventricular placement signal
- Less invasive heart pump with the ability to display Cardiac Power Output[1]
- Designed to optimize survival and native heart recovery
- Clear, concise alarms for improved troubleshooting

Cardiac Power Output: #1 Correlation to Mortality in AMI Cardiogenic Shock[2]

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

1. These trends are informational, do not use for diagnostic purposes. Refer to section 9 of IFU for information on accuracies.

2. Fincke, et. al. JACC, 2004 SHOCK TRIAL

Impella 5.5 Heart Pump Specifications

PART NUMBER	DESCRIPTION
1000100	Impella 5.5 with SmartAssist Set, U.S.
1000200	Impella Controller Modular Purge Cassettes, Box of 5
0052-3009	Vascular access kit used for axillary insertion sheath of the Impella catheter, 2 graft locks, 23 Fr x 6 cm peel-away introducer with hemostatic valve, and 8 Fr silicone-coated dilator
0052-3005	0.018" x 260 cm PTFE guidewire with a radiopaque, shapable tip used for placement of Impella catheter into left ventricle

Learn more visit www.HeartRecovery.com

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 0.6 cm^2 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** to learn more.

Impella Connect
Impella Connect® transfers a video image of the screen on the Automated Impella Controller to an authorized remote user. The transmitted image can be viewed by authorized remote users. The users can include the hospital's clinicians, Abiomed local support staff, and Clinical Support Center (CSC) team members.

PRECAUTIONS
- Impella Connect is not intended to provide real-time information for monitoring patient status on the Automated Impella Controller.
- During use of the Impella Connect, there will be a delay between when an image appears on the controller screen and when it is displayed at a remote viewing location.
- The Impella Connect is not a source of patient alarms, nor is its use intended as a replacement for monitoring the controller's alarms.
- During use of the Impella Connect, receipt of the displayed controller information is not confirmed by the Automated Impella Controller, nor is the delivery of the displayed controller information to the authorized remote users guaranteed.
- The Impella Connect is not designed for use during transport.
- Radiated and conducted electromagnetic interference can affect the performance of the Impella Connect, causing a temporary loss of connectivity. To clear interference, either increase the distance between system components and the EMI source or turn off the EMI source. Any electromagnetic interference related to the Impella Connect will have no impact on any of the controller functional specifications.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

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.

Impella® CLINICAL SUPPORT CENTER 24/7

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