



Abiomed Receives FDA PMA Approval for Impella 5.5 with SmartAssist, a Minimally Invasive, Forward Flow Heart Pump

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DANVERS, Mass.--(BUSINESS WIRE)--Sep. 25, 2019-- [Abiomed's](#) (NASDAQ: ABMD) newest heart pump, the Impella 5.5 with SmartAssist, has received U.S. Food and Drug Administration (FDA) pre-market approval (PMA) for safety and efficacy in the therapy of cardiogenic shock for up to 14 days.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20190925005454/en/>



Impella 5.5 with SmartAssist delivers peak flows of greater than 6 liters per minute. A motor housing that is thinner and 45% shorter than the Impella 5.0 improves ease of pump insertion through the vasculature. (Photo: Business Wire)

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.

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The inclusion of SmartAssist enables intelligent decision making with weaning algorithms designed to increase survival with heart recovery. SmartAssist also integrates data informatics including left ventricular pressure (LVP), end-diastolic pressure (EDP) and cardiac power output (CPO). The SmartAssist fiberoptic pressure sensor allows for precise pump positioning, management and repositioning in the ICU. Impella Connect enables clinicians to view the Impella control screen through a secure, HIPAA compliant website to track and review cases at any time from any internet-connected device.

Impella 5.5 with SmartAssist is:

- **Minimally invasive**, eliminating the need for a sternotomy or coring of the left ventricle
- **Designed for heart surgeons**, implanted via the axillary artery or the anterior aorta
- **Forward flow**, to provide the patient with coronary flow and renal perfusion
- **Fully unloading**, to reduce the heart's oxygen demand and work
- **Equipped with SmartAssist**, designed to provide weaning algorithms to optimize survival and native heart recovery

"A minimally invasive, forward flow, fully unloading heart pump that is designed for surgery is game changing," said Mark Anderson, M.D., chief of the Division of Cardiac Surgery and cardiothoracic surgeon at the Heart and Vascular Hospital at Hackensack University Medical Center and Hackensack Meridian Health. "This gives cardiac surgeons a new and potentially better option that can provide the benefits of heart recovery to some of our sickest patients."

"The Impella 5.5 is designed to give severely ill patients the best chance for recovery of the heart," said Hermann Reichenspurner, MD, PhD, professor and chief, Department of Cardiovascular Surgery, University Heart Center Hamburg. "A forward flow, minimally invasive heart pump that unloads the left ventricle and perfuses the end organs adequately is an ideal tool to help stabilize a patient after cardiac decompensation and give the heart time to rest and recover."

The FDA indication for use of Impella 5.5 with SmartAssist is as follows:

The Impella 5.5 with SmartAssist System is a temporary ventricular support device intended for short term (14 days) use and indicated for the treatment

The Impella 5.5 with SmartAssist will be introduced in the United States through a controlled rollout at hospitals with established heart recovery protocols. Impella 5.5 with SmartAssist received CE marking approval in Europe in April 2018 and was introduced in Germany through a similar controlled rollout.

The supplement approval for the Impella 5.5 with SmartAssist stems from the FDA's Impella PMA approvals indicating Impella devices as safe and effective for the treatment of cardiogenic shock. The approvals were based on analyses of Impella clinical results in 508 patients, which includes the FDA study RECOVER I, and the U.S. Impella registry, and of Impella literature reviews of 801 patients in 33 clinical studies. Additionally, more than 49,000 patients supported by Impella technology were reviewed in a safety analysis.

ABOUT IMPELLA HEART PUMPS

The Impella 2.5[®] and Impella CP[®] devices are U.S. FDA PMA approved to treat certain advanced heart failure patients undergoing elective and urgent percutaneous coronary interventions (PCI) such as stenting or balloon angioplasty, to re-open blocked coronary arteries. The Impella 2.5, Impella CP, Impella CP with SmartAssist[®], Impella 5.0[®], Impella LD[®], and Impella 5.5[™] with Smart Assist[®] are U.S. FDA approved heart pumps used to treat heart attack or cardiomyopathy patients in cardiogenic shock, and have the unique ability to enable native heart recovery, allowing patients to return home with their own heart. The Impella RP[®] is U.S. FDA approved to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. Impella is the most studied mechanical circulatory support device in the history of the FDA with real world clinical data on more than 100,000 patients and more than 550 peer-reviewed publications.

In Europe, the Impella 2.5, Impella CP and Impella CP with SmartAssist are CE marked for treatment of high-risk PCI and AMI cardiogenic shock patients for up to 5 days. Impella 5.0 and Impella LD are CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 10 days. The Impella 5.5[™] heart pump is CE marked to treat heart attack or cardiomyopathy patients in cardiogenic shock for up to 30 days. The Impella RP is CE marked to treat right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, open-heart surgery, or refractory ventricular arrhythmia.

To learn more about the Impella platform of heart pumps, including their approved indications and important safety and risk information associated with the use of the devices, please visit www.impella.com.

ABOUT ABIOMED

Based in Danvers, Massachusetts, USA, Abiomed, Inc. is a leading provider of medical devices that provide circulatory support. Our products are designed to enable the heart to rest by improving blood flow and/or performing the pumping of the heart. For additional information, please visit www.abiomed.com.

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FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including statements regarding development of Abiomed's existing and new products, the company's progress toward commercial growth, and future opportunities and expected regulatory approvals. The company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, including the potential for future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, litigation matters, future capital needs and uncertainty of additional financing, and other risks and challenges detailed in the company's filings with the Securities and Exchange Commission, including the most recently filed Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. The company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

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Source: Abiomed

Tom Langford
Director, Communications and Public Relations
978-882-8408
tlangford@abiomed.com

Ingrid Goldberg Ward
Director, Investor Relations
978-646-1590
igoldberg@abiomed.com