Johnson & Johnson MedTech

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U.S. FDA Expands Indication for Impella Heart Pumps to Treat Pediatric Patients

Impella 5.5 and Impella CP are the first left-sided, minimally invasive temporary mechanical circulatory support options for pediatric patients with symptomatic ADHF and cardiogenic shock

Danvers, Mass. – December 12, 2024 – Physicians have a new treatment option for many of the sickest pediatric patients with heart failure and cardiogenic shock. Johnson & Johnson MedTech, the global leader in heart recovery, announced today that the U.S. Food and Drug Administration (FDA) has expanded the indications for the Impella 5.5 with SmartAssist and Impella CP with SmartAssist heart pumps, granting premarket approval (PMA) for use in specific pediatric patients with symptomatic acute decompensated heart failure (ADHF) and cardiogenic shock. A PMA is the highest level of approval granted by the FDA for the safety and efficacy of medical devices.

Impella 5.5 and Impella CP enable heart recovery as part of the world's smallest heart pump platform. Johnson & Johnson MedTech (Abiomed, Inc.) has partnered with the Advanced Cardiac Therapies Improving Outcomes Network (ACTION)[1] to provide the real-world data necessary to support on-label use of Impella 5.5 and Impella CP, both left-sided heart pumps, for pediatric patients with symptomatic ADHF and cardiogenic shock. ACTION is a global healthcare network comprised of patients, families, clinicians, researchers and industry representatives that collaborate with ACTION leadership to improve outcomes for patients.

"This marks a monumental achievement for children with heart failure as, historically, this area of pediatric care has been underfunded and understudied," said Angela Lorts, MD, MBA[2], and David Rosenthal, MD, Co-Founders of ACTION. "We are proud to have worked with Johnson & Johnson MedTech on this crucial approval and look forward to further collaborations that will enhance care for these vulnerable patients."

Impella CP and Impella 5.5 heart pumps unload the heart's left ventricle, allowing the heart to rest while also ensuring delivery of oxygenated blood throughout the body. The PMA amendment expands the usage of left-sided Impella devices to specific pediatric patients weighing ≥52kg for Impella CP and ≥30kg for Impella 5.5.

"The opportunity to treat the hearts of pediatric patients with our life-supporting technology is incredible and fills us with gratitude," said Sonya Bhavsar, PhD, Senior Director, R&D, ECP & Pediatrics Platform, Heart Recovery, Johnson & Johnson MedTech. "This milestone motivates us to continue innovating solutions to increase the number of life years that these patients have and can spend with their families and loved ones."

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[1]Cincinnati Children's Hospital Medical Center (CHMC) is the coordinating center for the research and health care quality improvement efforts of Advanced Cardiac Therapies Outcome Network (ACTON). Funding for this ACTION research program was provided by Abiomed, Inc. to CHMC.

[2] Angela Lorts, MD, MBA was compensated for her role as principal Investigator on this research program.

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A dedicated team will develop and refine training and education programs designed specifically for pediatric patients alongside these patients' doctors. In collaboration with ACTION and previously identified hospitals, these tools and resources will be optimized to help improve outcomes and the quality of life for these pediatric patients. This strategic approach will equip the best-in-class heart recovery field team and providers with the skills to best support these patients now and in the future.

The FDA indication for use of Impella CP with SmartAssist has been expanded as follows:

The Impella CP with SmartAssist Catheter, in conjunction with the Automated Impella Controller (collectively, "Impella System Therapy"), are temporary ventricular support devices intended for short term use (≤4 days) 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. 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.

The FDA indication for use of Impella 5.5 with SmartAssist has been expanded 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 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 ≥30 kg. 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.

Cardiovascular Solutions from Johnson & Johnson MedTech
Across Johnson & Johnson, we are tackling the world's most complex and pervasive health challenges. Through a cardiovascular portfolio that provides healthcare professionals with advanced mapping and navigation, miniaturized tech, and precise ablation we are addressing conditions with significant unmet needs such as heart failure, coronary artery disease, stroke, and atrial fibrillation. We are the global leaders in heart recovery, circulatory restoration and the treatment of heart rhythm disorders, as well as an emerging leader in neurovascular care, committed to taking on two of the leading causes of death worldwide in heart failure and stroke. For more information about heart recovery technology, visit www.heartrecovery.com.

About Johnson & Johnson
At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation

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empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more about our MedTech sector's global scale and deep expertise in cardiovascular, orthopaedics, surgery and vision solutions at https://thenext.jnjmedtech.com. Follow us at @JNJMedTech and on LinkedIn. Abiomed, Inc. is part of Johnson & Johnson MedTech.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the Impella Platform. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Abiomed, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of healthcare products and services; and trends toward healthcare cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at sec.gov, jnj.com or on request from Johnson & Johnson. Neither Abiomed, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments

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