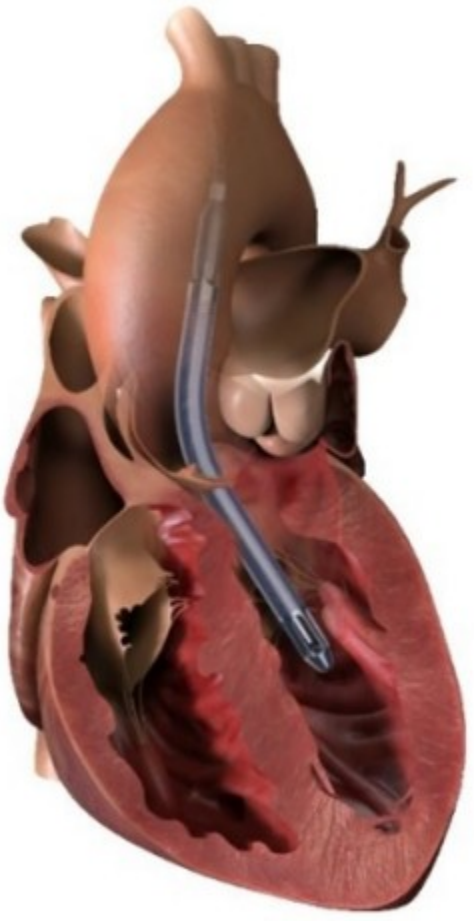
Large Clinical Study Presented at STS 2021 Finds 79% Survival Rate with Impella 5.5 with SmartAssist

January 29, 2021

DANVERS, Mass.--(BUSINESS WIRE)--Jan. 29, 2021-- Abiomed (NASDAQ: ABMD) announces a large study of 356 patients treated with Impella 5.5 with SmartAssist at 16 U.S. and German centers found a 79% survival rate at explant. A majority of surviving patients recovered their native heart function without needing further mechanical support or a heart transplant.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210129005016/en/



Impella 5.5 with SmartAssist pulls blood from the left ventricle through an inlet area near the tip of the pump and expels blood through the catheter into the ascending aorta. (Graphic: Business Wire)

The study is the first large, multicenter experience examining survival rates with Impella 5.5 with SmartAssist support. It was presented at The Society of Thoracic Surgeons (STS) 2021 Annual Meeting by lead author Edward Soltesz, MD, MPH, a cardiovascular and heart transplant surgeon at Cleveland Clinic's Miller Family Heart, Vascular & Thoracic Institute. The data was obtained from the Impella Quality (IQ) database and examined centers with ten or more patients treated with Impella 5.5 with SmartAssist.

The authors conclude Impella 5.5 with SmartAssist demonstrates successful clinical and device outcomes, including:

- 79% overall patient survival rate (n=301)
- 86% survival for cardiomyopathy cardiogenic shock patients (n=141)
- 67% survival for AMI cardiogenic shock patients (n=88)
- 68% survival for postcardiotomy cardiogenic shock patients (n=34)

"We were able to achieve a 79% overall survival rate by taking a novel approach in supporting these critically ill patients," said Dr. Soltesz. "I am looking forward to seeing more prospective studies around this minimally invasive, high-flow temporary device."

"This report demonstrates the benefit of the significant unloading with Impella 5.5 use in cardiogenic shock patients. We are impressed with the improved survival rates seen with Impella 5.5 use compared to traditional therapies," said Scott Silvestry, MD, co-author of the study and surgical director of thoracic transplant, thoracic and cardiovascular surgery at AdventHealth in Orlando. "The use of best practices, techniques and this innovative new technology allows us to provide a better outlook to our patients."

The STS study presentation provides additional evidence of improved outcomes with use of Impella 5.5 with SmartAssist. A study published in July in the *American Society for Artificial Internal Organs (ASAIO) Journal* found 84% survival to explant for Impella 5.5 with SmartAssist patients in cardiogenic shock and other challenging cardiac conditions. 76% of those patients achieved native heart recovery. The study examined the outcomes of the first 55 patients treated with Impella 5.5 with SmartAssist at Cleveland Clinic, Hackensack University Medical Center/Hackensack Meridian Health and Cedars-Sinai Medical Center.

In 2019, Impella 5.5 with SmartAssist received the U.S. Food and Drug Administration's (FDA) highest level of approval for safety and efficacy in the therapy of cardiogenic shock for up to 14 days. Impella 5.5 with SmartAssist delivers peak flows of greater than 6 liters per minute. Benefits of the Impella 5.5 with SmartAssist include:

- **Impella Connect**, providing cloud-based remote monitoring
- **Ease of insertion**, via the axillary artery or ascending aorta
- **Designed for long-duration support**, with patient ambulation, ceramic bearings and no pigtail
- **Forward flow with maximum unloading**, to provide end organ and coronary perfusion and allow the heart to rest

- **Enables heart recovery**, as a minimally invasive, weanable VAD
- **Ease of patient management**, can be intelligently positioned, weaned and managed with SmartAssist

In August, 2020, the FDA granted all left-sided Impella heart pumps, including Impella 5.5 with SmartAssist, an emergency use authorization (EUA) to treat certain patients with COVID-19-related complications who are undergoing extracorporeal membrane oxygenation (ECMO) treatment in the United States.

Attendees of STS 2021 are invited to attend two symposia related to Impella 5.5 with SmartAssist:

- *Role of Surgeon: Managing the Shock Patient and Escalation*, presented by Zain Khalpey, MD, PhD, from Northwest Medical Center in Tucson. This symposium will take place on Friday, January 29, from 3:30 – 4:00pm EST.
- *Post Cardiotomy Cardiogenic Shock (PCCS): Is it Time for a New Strategy?*, moderated by Scott Silvestry, MD, from AdventHealth Orlando and featuring a panel discussion with Zain Khalpey, MD, PhD, from Northwest Medical Center in Tucson, Masahiro Ono, MD, PhD, from Methodist Hospital in San Antonio, Danny Ramzy, MD, from Cedars-Sinai Medical Center in Los Angeles, and Deane Smith, MD, from NYU Langone Health in New York City. This symposium will take place on Sunday, January 31, from 7:30 – 8:30am EST.

ABOUT IMPELLA HEART PUMPS

The Impella 2.5, Impella CP, Impella CP with SmartAssist®, Impella 5.0®, Impella LD®, and Impella 5.5® with SmartAssist® are U.S. FDA approved 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.

Impella Left Ventricular (LV) Support Systems are also authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The authorized Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella RP and Impella LV Support Systems have been authorized for the above emergency use by FDA under an EUA and have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

ABOUT ABIOMED

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

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements. Forward-looking statements are subject to risks and uncertainties such as those described in Abiomed's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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