Study Finds 84% Survival Rate in Patients in Cardiogenic Shock and Other Challenging Cardiac Conditions with the New Impella 5.5 with SmartAssist

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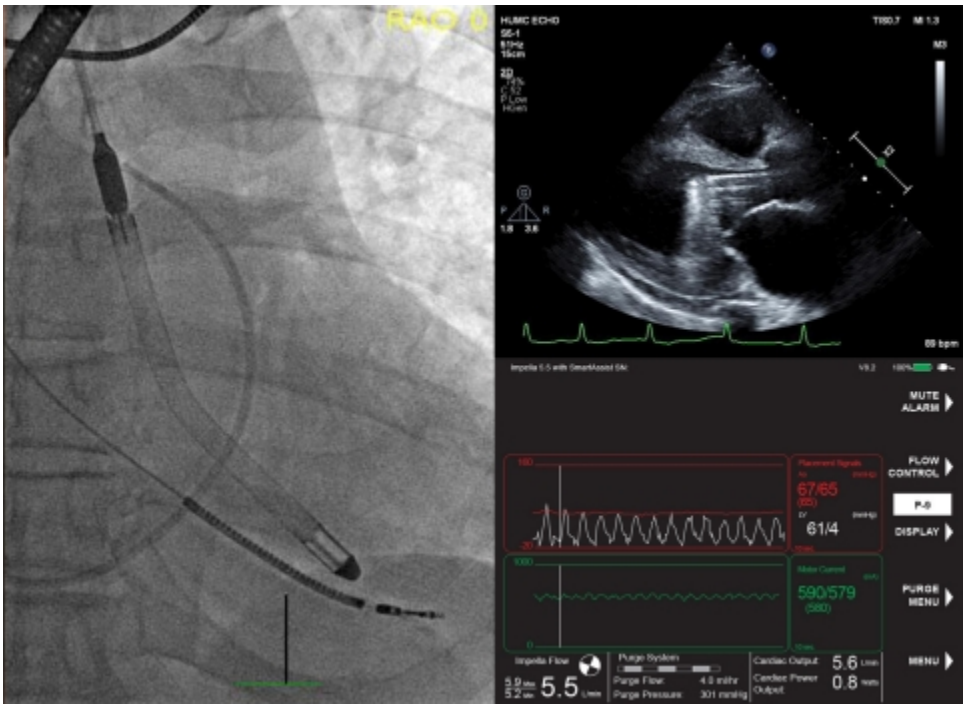
DANVERS, Mass.--(BUSINESS WIRE)--Jul. 1, 2020-- The first published United States experience of patients who received Abiomed's newest heart pump, Impella 5.5 with SmartAssist, finds 84% of the patients survived to explant with 76% native heart recovery. The study was published in the July edition of the American Society for Artificial Internal Organs (ASAIO) Journal.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200701005293/en/



The Impella 5.5 with SmartAssist is featured on the front cover of the July 2020 edition of the ASAIO Journal. (Photo: Business Wire)

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. Study authors and cardiac surgeons Ed Soltesz, MD, Mark Anderson, MD, and Danny Ramzy, MD, conclude Impella 5.5 with SmartAssist is safe and effective for a number of challenging clinical scenarios, including AMI cardiogenic shock.

"This report demonstrates the benefit of unloading cardiogenic shock patients and it is encouraging to see real-world data demonstrate improved survival rates with use of Impella 5.5 with SmartAssist," said Danny Ramzy, MD, assistant professor, surgical director of the lung transplant program, and director, robotic and minimally invasive cardiac surgery at Cedars-Sinai Medical Center. "The continued use of best practices, techniques and innovative technology like Impella allows us to provide better patient care that improves outcomes and quality of life."

In September 2019, Impella 5.5 with SmartAssist received FDA pre-market approval (PMA) for safety and efficacy in the therapy of cardiogenic shock for up to 14 days. It is a micro-axial, surgically implanted, temporary heart pump that unloads the left ventricle, reduces ventricular work, and provides the circulatory support necessary to allow native heart recovery and early assessment of residual myocardial function. Its benefits include:

- **Ease of insertion** through the axillary artery or the anterior aorta
- **Designed for long-duration support** with durable ceramic bearings, no pigtail to minimize adhesions, and ability for patient ambulation
- **Forward flow with maximum unloading**, to provide end organ and coronary perfusion, while allowing the heart to rest
- **Better patient management** with intelligent device positioning, management, and weaning with SmartAssist technology
- **Equipped with Impella Connect**, a cloud-based monitoring and collaborative patient management platform that allows for remote monitoring of the Impella console. During the COVID-19 crisis, this online, HIPAA-compliant monitoring service is being provided at no cost to help medical providers manage patients 24/7.

The 55 patients in the study were implanted with Impella 5.5 with SmartAssist between October 16, 2019 and March 4, 2020. Specifically, the study authors determined:

- 35 patients (63.6%) were successfully weaned off the technology.
- 11 patients (20.0%) went on to receive another therapy, two patients (3.6%) expired while on support, and seven patients (12.7%) had care withdrawn.
- 76.1% of survivors recovered native heart function.
- There were no device-related strokes, hemolysis, or limb ischemia observed.
- The results demonstrate Impella provides dependable acute mechanical circulatory support for patients who need it by stabilizing their hemodynamics during treatment.

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 SmartAssist® 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. The Impella RP is also authorized for emergency use by healthcare providers (HCPs) in the hospital setting for providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m2, for the treatment of acute right heart failure or decompensation caused by complications related to coronavirus disease 2019 (COVID-19), including pulmonary embolism (PE). The Impella RP has not been cleared or approved for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19. The Impella RP has been authorized for the above emergency use by FDA under an EUA and has 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.

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 with SmartAssist 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.

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 the scope, scale and duration of the impact of the COVID-19 pandemic, 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 the filings subsequently filed with or furnished to the SEC. 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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