Impella Advances to Higher Level of Recommendation in Newest ESC Guidelines

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DANVERS, Mass.--(BUSINESS WIRE)--Nov. 3, 2021-- The 2021 guidelines of the European Society of Cardiology (ESC) for treatment of acute heart failure patients, including patients in cardiogenic shock, raise the recommendation level for short-term mechanical circulatory support systems such as Impella heart pumps from Class IIb ("may be considered") to Class IIa ("should be considered"). In addition, the authors expand the type of patient who may benefit from technology such as Impella to include patients with mildly reduced left ventricular ejection fraction.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20211103005409/en/

Impella heart pumps include Impella CP with SmartAssist. (Photo: Business Wire)

This is the first update of the ESC guidelines in five years and reflects the growing body of robust clinical evidence supporting the use of Impella for high-risk PCI, cardiogenic shock and right heart failure patients. It also reinforces the recent European Association of Percutaneous Cardiovascular Interventions (EAPCI) consensus, which states the value of Impella therapy in cardiogenic shock and high-risk PCI.

In the new ESC guidelines, the expert authors:

- Clearly position themselves in favor of using mechanical circulatory support, which includes Impella, in the treatment of cardiogenic shock.
- Recommend Impella be used to unload VA-ECMO patients who are experiencing increased left ventricular (LV) afterload with an increase in LV end-diastolic pressure and pulmonary congestion.
- State that the intra-aortic balloon pump (IABP) should only be considered in special cases of acute heart failure and not as a routine treatment option. IABP is Class III (not recommended) in post-MI cardiogenic shock. Randomized clinical trial evidence demonstrates IABP therapy is not effective and, in some cases, may be harmful.

"The elevated ESC recommendation for Impella technology reflects growing expert consensus that Impella improves patient outcomes by stabilizing hemodynamics, unloading the heart and perfusing the end organs," said Chuck Simonton, MD, chief medical officer at Abiomed.

In addition to the 2021 ESC guidelines for heart failure patients, ten society guidelines support the use of Impella heart pumps. They are:

Protected PCI Guidelines:

- 2020 SCAI Position Statement on Optimal PCI Therapy for Complex Coronary Artery Disease
- 2014 AHA/ACC Guideline for the Management of Patients with Non–ST-Elevation Acute Coronary Syndromes
- 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Cardiogenic Shock and Other Guidelines:

- 2020 EACTS/ELSO/STS/AATS Expert Consensus on Post-Cardiotomy Extracorporeal Life Support in Adult Patients
- 2019 HRS/EHRA/APHRS/LAHRS Expert Consensus Statement on Catheter Ablation of Ventricular Arrhythmias
- 2013 ACCF/AHA Guideline for the Management of STEMI
- 2013 ACCF/AHA Guideline for the Management of Heart Failure
- 2013 International Society for Heart and Lung Transplantation Guidelines for MCS
- 2012 Use of MCS: American Heart Association
- 2011 ACCF/AHA/SCAI Guideline for PCI

Additional information about the guidelines that support the use of Impella is available for download from this page of www.heartrecovery.com. Impella heart pumps are manufactured by Abiomed (NASDAQ: ABMD).

ABOUT IMPELLA HEART PUMPS

The Impella 2.5® and Impella CP® devices are U.S. FDA approved to treat certain advanced heart failure patients undergoing elective and urgent percutaneous coronary interventions (PCI), such as stenting or balloon angioplasty, to reopen 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 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.

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

Any 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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