Teleflex Receives FDA 510(k) Clearance for the Arrow® AC3 OptimusTM Intra-Aortic Balloon Pump (IABP)

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Advanced IABP performance with the ability to provide optimized therapy to the most challenging patient conditions, even patients with the most severe arrhythmias and heart rates as high as 200 bpm.[1]

WAYNE, Pa.--(BUSINESS WIRE)--May 2, 2017-- Teleflex Incorporated (NYSE: TFX), a leading global provider of medical technologies for critical care and surgery, has announced 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its AC3 Optimus™ Intra-Aortic Balloon Pump (IABP).

This device helps a weakened heart pump blood and can deliver IABP therapy to a broad range of patients, even those not previously considered candidates for IABP therapy. Clinicians may use the pump on patients with the most severe arrhythmias or with heart rates as high as 200 beats per minute.[1, 2]

In IABP therapy, a physician inserts an intra-aortic balloon catheter into an artery, and using x-ray or imaging, advances the catheter into the aorta. An IABP console, connected to the catheter, controls the inflation and deflation of the balloon.

“When a patient has an elevated heart rate or severe arrhythmia, his or her survival can suddenly depend on the ability of the IABP to keep pace and provide accurate therapy,” said Kyle Spear*, CCP, Chief Perfusionist at a major U.S. medical center. “The AC3 Optimus IABP does this with precision across a wide range of patient conditions.”

The AC3 Optimus IABP has a third-generation AutoPilot® Mode, which uses proprietary algorithms to address key clinical challenges and to simplify the delivery of IABP therapy.[3] In AutoPilot Mode, the AC3 Optimus IABP automatically adjusts timing and triggering parameters, freeing clinicians to focus on the patient rather than the pump. In addition, the AC3 Optimus IABP includes several exclusive algorithms, such as WAVE® Inflation Timing, Deflation Timing Management, and Best Signal Analysis, which optimize key functions of the IABP to deliver therapy to the most challenging patients.

“The AC3 Optimus IABP global launch marks a major milestone for Teleflex. This highly anticipated launch will enable the Company to become a more significant player with a product that can enhance patient outcomes and make it easier for clinicians to deliver IABP therapy,” said Liam Kelly, President and Chief Operating Officer at Teleflex.

The AC3 Optimus IABP will be launched at two key scientific meetings in May. In North America, the AC3 Optimus IABP will be on display at the American Association for Thoracic Surgery and American Society of ExtraCorporeal Technology (AATS/AmSECT) Annual Meeting being held April 29th-May 3rd, 2017 in Boston, MA. Additionally, the AC3 Optimus IABP will be on display at the EuroPCR 2017 Conference being held May 16th-19th in Paris, France. The device has received its CE Mark and has launched in India and parts of Europe.

“As innovators in intra-aortic balloon pumping technology, we continue to advance the performance and reliability of automated therapy to the benefit of patients, clinicians, and health systems everywhere,” said Stewart Strong, President and General Manager of the Interventional Division at Teleflex. “We’ve put everything in to provide a total solution.”

About Teleflex Incorporated

Teleflex is a global provider of medical technologies designed to improve the health and quality of people’s lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rusch® and Weck® – trusted brands united by a common sense of purpose.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

*Paid consultant of Teleflex

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