

## LivaNova Announces New Data Reaffirming Value of Perceval for Aortic Valve Replacement in Aortic Stenosis Patients

*Among the Data Presentations at AATS, LivaNova Unveiled New Data Reinforcing the Memo 3D ReChord as a Safe and Effective Device for Mitral Valve Repair Procedures*

**LONDON, May 4, 2017** – LivaNova, PLC (NASDAQ:LIVN) (“LivaNova” or the “Company”), a market-leading medical technology and innovation company, announced the presentation of data from multiple studies demonstrating the safety and the effectiveness of the Perceval™ sutureless valve for Aortic Valve Replacement (AVR) patients and the Memo 3D ReChord™ for mitral valve repair. The three data presentations on Perceval, which included a late-breaking clinical trial and a poster presentation on the Memo 3D ReChord, were unveiled at the American Association for Thoracic Surgery (AATS) Centennial meeting in Boston on April 29 – May 3, 2017.

“For more than 30 years, LivaNova has been dedicated to creating and delivering safe, superior and innovative technology, like the Perceval sutureless valve and Memo 3D ReChord. We are proud to unveil these new clinical results which underscore our legacy and commitment to develop best-in-class cardiac solutions in the aortic and mitral field,” said Brian Duncan, M.D., Vice President, Medical Affairs, Cardiac Surgery at LivaNova. “Also, as we celebrate the 10<sup>th</sup> anniversary of Perceval introduction into the AVR treatment process, we are encouraged to continue supporting cardiac surgeons to advance the standard of care and enhance the lives of patients worldwide.”

Key data presented included the late-breaking clinical trial presentation, “Prospective US IDE Trial of a New Sutureless Aortic Bioprosthesis in Standard Risk Surgical Patients: One Year Hemodynamic, Clinical and Functional Outcomes,” which found that Perceval was a safe and effective AVR valve in surgical patients. The prospective, single-arm clinical trial consisting of 300 patients demonstrated that following sutureless valve therapy support, patients experienced hemodynamic relief from aortic stenosis and improvement in quality of life. At one-year follow up, health-related quality of life score increased from  $63.2 \pm 22$  before surgery to  $85.4 \pm 18.1$  at follow up.



Perceval™

“The results of this prospective clinical trial approved under a Food and Drug Administration Investigational Device Exemption (IDE) confirmed the safety and efficacy outcomes previously reported in three European clinical trials and several independent publications both in isolated and combined procedure and in any surgical approach,” said Rakesh Suri, M.D., D.Phil., Cleveland Clinic and Cleveland Clinic Abu Dhabi. “From this prospective trial, the demonstrated hemodynamics and enhancements in patient quality of life support the practice and use of sutureless valves in patients with severe aortic valve stenosis.”

“The study’s validating data provides further evidence that the use of the Perceval valve can lead to a significant reduction in cross-clamp time compared to the STS average,” said David Heimansohn, M.D., St. Vincent Heart Center, Indiana. “Since I began using the valve over 3 years ago, I have found that the use of Perceval is associated with a shorter procedure and recovery time, which allows patients to return back to their day-to-day life more quickly.”

The second presentation, *“Sutureless Aortic Valves Versus Transcatheter Aortic Valve in Patients with Severe Aortic Stenosis and Intermediate Risk Profile: A Propensity Match Comparison in the Real World,”* analyzed and compared the outcome of intermediate-risk aortic stenosis patients undergoing isolated sutureless and transcatheter aortic valve replacement (TAVR) implants. The study found that at 30-day follow up, patients treated with the sutureless valve had a significantly lower mortality rate. At mean follow up of 36 months, the overall survival and freedom from adverse events were significantly better among patients who underwent sutureless valve procedures. When compared to TAVR, the use of Perceval significantly improved patient outcomes for intermediate-risk patients with isolated aortic stenosis.

“With Perceval’s technology, cardiac surgeons have a viable solution to standard bioprostheses that can decrease procedure time and reduce post-operative complications. These encouraging results demonstrated that the Perceval valve, when compared to TAVR, significantly improved patient outcomes for intermediate-risk patients with isolated aortic stenosis,” said Prof. Claudio Muneretto, M.D., University of Brescia Medical School, Italy.

Adding to the growing Perceval evidence base, the data presentation, *“Sutureless Aortic Valve Replacement in High Risk Patients Neutralizes Expected Worse Hospital Outcome: a Clinical Economic Analysis,”* highlighted the clinical and economic impact of using the Perceval valve in high-risk patients compared to those who underwent sutured valve AVR with lower preoperative risk. The analysis found that, despite the higher patient risk profile in Perceval group, the use of the sutureless valve resulted in no change to hospital mortality and hospital resources consumption compared to sutured valves.

Finally, in addition to the Perceval sutureless valve data unveiled at AATS Week, Dr. Antonio Lio from Istituto Clinico S. Ambrogio, Milan, Italy presented a poster on a multicenter study from European and Asian centers demonstrating the benefits of the Memo 3D ReChord annuloplasty ring. As a prosthetic ring featuring an innovative chordal guiding system, the Memo 3D ReChord is used to treat patients with degenerative mitral valve disease.



**Memo 3D ReChord™**

The study, *“Early Outcomes of Mitral Valve Repair Using a New Prosthetic Ring with a Chordal Guiding System: A Multicenter Study,”* showed that the use of Memo 3D ReChord during mitral valve repair procedures allowed surgeons to implant more accurately. With a short learning curve, use of the device could potentially improve surgical safety and shorten operation times for patients.

To learn more about LivaNova and its portfolio of innovative cardiac solutions, please visit [www.livanova.com](http://www.livanova.com).

## **About LivaNova**

LivaNova PLC is a global medical technology company built on nearly five decades of experience and a relentless commitment to improve the lives of patients around the world. LivaNova's advanced technologies and breakthrough treatments provide meaningful solutions for the benefit of patients, healthcare professionals and healthcare systems. Headquartered in London and with a presence in more than 100 countries worldwide, the company employs more than 4,500 employees. LivaNova operates as three business franchises: Cardiac Surgery, Neuromodulation and Cardiac Rhythm Management, with operating headquarters in Mirandola (Italy), Houston (U.S.A.) and Clamart (France), respectively.

For more information, please visit [www.livanova.com](http://www.livanova.com).

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