

## **New 10-Year Study Demonstrates Freedom Solo Stentless Aortic Valve Excellent Hemodynamic Performance and Long-term Durability**

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**In clinical use since 2004 and approved in Canada, Japan and the US since 2014, Freedom Solo is designed to overcome the obstructive limitation associated with stented bioprostheses and provides enhanced, native-like valve performance**

Orlando, Florida, November 17, 2015. Data from a 10-year, European multi-center study of patients implanted with the Freedom Solo stentless valve shows the valve's excellent hemodynamic performance and long-term durability. The results were presented by Dr. Alberto Repossini, M.D., Cardiac Surgery University of Brescia, Spedali Civili, Brescia, Italy, during the American Heart Association 2015 Scientific Sessions in Orlando, Florida, November 7-11, 2015.

Between 2004 and 2009, 478 patients underwent isolated (n=321) or combined (n=157) aortic valve replacement (AVR) with the Freedom Solo valve at three European centers. The trial population included 41.6% female patients with a mean age of  $73\pm 8.6$  years. The primary endpoint of the study was independence from structural valve deterioration, and secondary endpoints were freedom from reoperation and overall survival. The Freedom Solo 10-year study follow-up demonstrated excellent hemodynamics in terms of pressure gradients and effective orifice area. Preoperative peak gradients were  $76.1\pm 30.6$  mmHg ( $47.1\pm 18.7$  mmHg), decreased to  $17.7\pm 9.1$  mmHg ( $9.9\pm 5.4$  mmHg), and remained stable through the follow-up. Post-operative effective orifice area for valve sizes 21, 23, 25 and 27 were  $1.8\pm 0.6$  cm<sup>2</sup>,  $1.98\pm 0.5$  cm<sup>2</sup>,  $2.13\pm 0.43$  cm<sup>2</sup> and  $2.21\pm 0.56$  cm<sup>2</sup>, respectively. The overall operative mortality rate was 2.9% — 1.5% for isolated and 5.7% for combined AVR — and none was valve-related.

"Stentless aortic valves were developed to achieve a more physiological flow pattern and superior hemodynamics in comparison to stented valves. These advantages were borne out in this study that underscored the sustained durability and excellent hemodynamic performance of Freedom Solo even after 10 years," said Alberto Repossini, MD, University of Brescia, Clinical Department of Cardiac Surgery, Brescia, Italy, and lead author of the study. "These long-term data coupled with Freedom Solo's ease of implantability, suggest that it is a reliable aortic valve choice for cardiac surgeons and brings a clinically beneficial solution for a broad range of patients."

Follow-up was completed on 97.4% of patients in the study and included clinical and strict echocardiographic evaluation, with an average duration of  $6.5\pm 3.2$  years; cumulative follow-up was 2,612 patient/years. Over the 10-year follow-up, 24 patients underwent reoperation, and freedom from structural valve deterioration and reoperation was 90.6% [88.2-93%] and 88.3% [85.8-90.8%], respectively, at 10-year follow-up. The overall actuarial survival was 55.8% at 10 year follow-up [52.5-59.1%].

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