



# Edwards

NEWS RELEASE

## EDWARDS' AORTIC VALVE WITH RESILIA TISSUE SHOWS FAVORABLE DURABILITY, SAFETY AND EFFICACY OUTCOMES IN SEVEN YEAR DATA

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LOS ANGELES, May 7, 2023 /PRNewswire/ -- Edwards Lifesciences (NYSE: EW) today announced new data from the COMMENCE aortic trial, demonstrating low rates of structural valve deterioration (SVD) in bioprosthetic aortic valves with the company's innovative RESILIA tissue. The data, which represent the longest clinical follow-up for Edwards' bioprosthetic surgical aortic valve with RESILIA tissue with a mean follow-up of 7.7 years, were presented today at the 103rd annual meeting of the American Association for Thoracic Surgery.

SVD can be caused by a buildup of calcium that may impact long-term durability of bioprosthetic valves. Heart valves with RESILIA tissue are designed to address calcification challenges of conventional tissue valves, potentially allowing valves with RESILIA to last longer. The RESILIA tissue data from the COMMENCE aortic trial reported encouraging results with low rates of SVD (99.3% freedom from SVD), clinically stable gradients and freedom from reoperation (97.2%) through seven years.

"As bioprosthetic aortic valve replacement extends to younger and more active patients, valve durability is becoming increasingly important," said Thomas Beaver, M.D., Grant and Shirle Herron Chair, Professor and Chief of Cardiovascular Surgery, University of Florida College of Medicine. "The seven-year data from the COMMENCE aortic trial demonstrates strong clinical outcomes and excellent durability in a study of younger patients with a mean age of 65.1 years."

Current technologies utilizing this novel tissue include the INSPIRIS RESILIA aortic valve, the KONECT RESILIA aortic valved conduit, the MITRIS RESILIA mitral valve and the SAPIEN 3 Ultra RESILIA transcatheter aortic heart valve. In addition to its anti-calcification properties, RESILIA tissue also allows the valve to be stored under dry packaging conditions, facilitating ease of use in the operating room.

"Edwards Lifesciences is committed to addressing the needs of patients with structural heart disease and our RESILIA tissue technology is designed for enhanced durability, supporting patients' improved quality of life," said Larry Wood, Edwards' corporate vice president and group president, transcatheter aortic valve replacement and surgical structural heart. "The latest COMMENCE aortic trial data emphasizes the value of RESILIA tissue-based offerings in helping patients and their physicians with lifetime management of valve disease."

The latest data from the COMMENCE aortic trial join a growing library of clinical studies in support of RESILIA tissue.

The COMMENCE aortic trial is a prospective, non-randomized, multicenter, single-arm investigational device exemption (IDE) trial comprised of 689 patients at 27 clinical sites across the United States and Europe. The trial is evaluating the safety and effectiveness of Edwards' bioprosthetic aortic valve with RESILIA tissue in patients ages 18 and older with diagnosed aortic valve disease and scheduled to undergo aortic valve replacement surgery. Long-term follow-up data were collected in a subset of these patients and will continue to be evaluated through 10 years.

For more information about RESILIA tissue, please visit the RESILIA tissue newsroom at [edwards.com/about-us/resilia-newsroom](https://www.edwards.com/about-us/resilia-newsroom).

Dr. Beaver is a consultant to Edwards Lifesciences.

## About Edwards Lifesciences

Edwards Lifesciences is the global leader of patient-focused innovations for structural heart disease and critical care monitoring. We are driven by a passion for patients, dedicated to improving and enhancing lives through partnerships with clinicians and stakeholders across the global healthcare landscape. For more information, visit [Edwards.com](https://www.edwards.com) and follow us on Facebook, Instagram, LinkedIn, Twitter and YouTube.

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, but are not limited to, statements made by Mr. Wood and statements regarding expected product benefits, patient outcomes, post-treatment reduction of invasive procedures, objectives and expectations and other statements that are not historical facts. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain and difficult to predict. Our forward-looking statements speak only as of the date on which they are made, and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause results to differ materially from those expressed or implied by the forward-looking statements based on a number of factors as detailed in the company's filings with the Securities and Exchange Commission. These filings, along with important safety information about our products, may be found at [Edwards.com](https://www.edwards.com).

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