



**The Society of Thoracic Surgeons**  
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# News

## For Immediate Release

### **FDA Approval of Device Labeling Highlights Growing Use of Clinical Registry Data for Post-Market Device Surveillance** *STS/ACC TVT Registry™ data cited as part of FDA decision process*

CHICAGO—Signifying an increasing confidence in clinical outcomes registries, the U.S. Food and Drug Administration has approved expanded labeling for the Edwards SAPIEN Transcatheter Heart Valve, making the device available to a larger group of patients with aortic stenosis, a heart valve disease that causes narrowing of the aortic valve, restricting blood flow from the heart.

In announcing its decision on Monday to approve the expanded device labeling, the agency cited data from The Society for Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry, as well as FDA-approved clinical studies and peer-reviewed medical journals.

“Less than 2 years after transcatheter heart valve therapy became available for a very select patient population, the STS/ACC TVT Registry supplied the needed data to support label expansion,” said STS President Douglas E. Wood, MD. “We are thrilled that more patients will now have access to this life-saving therapy.”

ACC President John G. Harold, MD, MACC concurred. “The FDA’s decision to make this device available to an expanded group of patients highlights the value of the TVT Registry,” Dr. Harold said. “This decision demonstrates the efficiency of rigorous clinical registries, which allowed the FDA to make a prompt decision that will impact thousands of patients who previously would not have had access to this procedure.”

#### **Importance of Clinical Registries**

The TVT Registry, launched in 2011, is a benchmarking tool developed to track patient safety and real-world outcomes involving transcatheter aortic valve replacement (TAVR). When TAVR was first approved, it was for device insertion using only the transfemoral approach (via an artery from the leg) in inoperable patients. The labeled indication was subsequently extended to high-risk, operable patients using either a transfemoral or transapical (between the ribs through the tip of the heart) approach; however, that still left a significant number of patients who were unable to be treated—patients who were inoperable and not able to be treated by a transfemoral approach and high-risk or inoperable patients who would be best treated by another “alternative” approach.

#### **STS Press Release**

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The TVT Registry supplied the FDA with data collected from several th procedures showing no evidence that the device performed differently or had a different benefit-risk profile when alternative access approaches were used.

First-year outcomes from the TVT Registry are expected to be published later this year, and Edwards and the FDA will continue to monitor all short- and long-term patient outcomes with the SAPIEN device.

“More patients are anticipated to benefit based on the ability of physicians and hospitals participating in the TVT Registry to collect timely and accurate data and the ACC’s and STS’s ability to promptly provide outcomes information to regulatory agencies and device manufacturers,” said Michael J. Mack, MD, STS Past President and Chair of the STS/ACC TVT Registry Steering Committee.

“The collaborative relationship between the professional societies, the FDA, and CMS in developing the TVT Registry for monitoring continued safety and efficacy of the transformational technology of TAVR will allow optimal management of care for an increasing number of patients suffering from aortic stenosis,” said David Holmes, MD, ACC Past President and Vice Chair of the STS/ACC TVT Registry Steering Committee. “This development provides opportunity for care of high-risk patients who were previously not treated.”

#### **Future of the STS/ACC TVT Registry**

The STS/ACC TVT Registry will continue to provide robust, real-time information for better post-market device surveillance and will serve as a platform for future potential investigational device exemption studies, such as one involving valve-in-valve procedures.

“Data from the TVT Registry provide a unique opportunity to evaluate current clinical practice and patient outcomes” said STS Research Center Director Fred Edwards, MD. “We are hopeful that this level of collaboration and use of registries will continue to fuel innovations for the medical device approval process in the United States.”

Currently, 248 US institutions are enrolled in the TVT Registry. The institutions are located across 45 states and the District of Columbia.

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#### **About The Society of Thoracic Surgeons**

Founded in 1964, STS is a not-for-profit organization representing more than 6,700 cardiothoracic surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society’s mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research and advocacy.

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#### **About the American College of Cardiology**

The mission of the American College of Cardiology is to transform cardiovascular care and improve heart health. The College is a 43,000-member medical society comprised of physicians, surgeons, nurses, physician assistants, pharmacists and practice managers. The College is a leader in the formulation of health policy, standards and guidelines. The ACC provides professional education, operates national registries to measure and improve quality of care, disseminates cardiovascular research, and bestows credentials upon cardiovascular specialists who meet stringent qualifications. For more information, visit [cardiosource.org/ACC](http://cardiosource.org/ACC).

**About the STS/ACC TVT Registry™**

The TVT Registry is a benchmarking tool developed to track patient safety and real-world outcomes related to the TAVR procedure. Created by STS and the ACC, the TVT Registry is designed to monitor the safety and efficacy of TAVR for the treatment of aortic stenosis. [www.tvtregistry.org](http://www.tvtregistry.org)