

## **USDA Approves Low-Risk Patients for Transcatheter Aortic Valve Replacement**

*Greater number of patients now have a less invasive option for treatment*

*Friday, August 16, 2019* -- The U.S Food and Drug Administration has approved Transcatheter Aortic Valve Replacement procedure for low-risk patients, greatly expanding the availability of the less-invasive procedure that takes the place of open-heart surgery.

The announcement came Friday, August 16<sup>th</sup>, after years of studies\* indicating that the procedure, known as TAVR, was as safe and effective as open-heart surgery to treat severe aortic stenosis. Introduced in France in 2002, TAVR was approved by the FDA in 2011 for high-risk patients unlikely to endure open-heart surgery, and in 2016 for intermediate-risk patients.

“This new approval significantly expands the number of patients that can be treated with this less invasive procedure for aortic valve replacement and follows a thorough review of data demonstrating these devices are safe and effective for this larger population,” said Dr. Bram Zuckerman, director of the Office of Cardiovascular Devices in the FDA’s Center for Devices and Radiological Health in the FDA official news release.

Baylor Scott & White Heart and Vascular Hospital - Dallas has been in the forefront of TAVR innovation, participating in research and clinical trials, and performing more than 1,000 successful TAVR procedures since 2011. The Dallas campus is one of the highest volume programs in the nation.

“The team at Baylor Scott & White Heart and Vascular Hospital – Dallas has been pioneers in TAVR through all of the clinical trials,” said Robert Stoler, MD, FACC, FSCAI, medical director of the Cardiac Catheterization Lab and co-director for the division of cardiology at the Dallas hospital. “We’re ready to treat all patients of all risk levels who need an aortic valve replacement.”

Baylor Scott & White Heart and Vascular Hospital – Fort Worth launched its TAVR program almost two years ago with the opening of the Valve Disorders Center. Within the first year, nearly 100 patients received TAVR. The Center is a part of the comprehensive Structural Heart Disease Program.

Aortic stenosis is a life-threatening condition that occurs when the aortic valve is narrowed, usually by calcium deposits that occur over time, although the condition can also develop from birth defects, rheumatic fever or radiation therapy. That makes the heart work harder to pump blood, and the consequences progress from thickening the heart muscle to causing blood to back up in the lungs to heart failure.

Once the condition is diagnosed, doctors can treat moderate cases with lifestyle changes and medication and by valvuloplasty, which involves threading a thin tube holding an expandable balloon through an artery to the heart, then inflating the balloon to open the valve.

But severe cases require replacing the valve, either with a mechanical device or animal tissue. Doing that with open-heart surgery means cutting through the breastbone, putting the patient on a heart-lung bypass machine and opening the chest, requiring a long recovery period.

With TAVR, a catheter is inserted with the new valve attached, into an artery through the leg or groin and guided through the body to the heart. The benefits were obvious: less trauma to the body, less time in the hospital and a much quicker recovery.

As the procedure gained wider acceptance, studies focused on whether TAVR's outcomes were good enough to warrant its use even in patients who could endure open-heart surgery. On Friday, the FDA decided that the answer is yes.

"This means that the majority of patients who need an aortic valve replaced can have it done with a less invasive procedure," Dr. Stoler said.

The approval covered four artificial valves - Sapien 3 and Sapien 3 Ultra, made by Edwards Lifesciences LLC, and CoreValve Evolut R and CoreValve Evolut PRO, made by Medtronic CoreValve LLC. It requires both manufacturers to follow patients in randomized studies for 10 years to monitor the valves' safety, effectiveness and long-term durability.

For more information about the Center for Valve Disorders at Baylor Scott & White Heart and Vascular Hospital – Dallas, please call 214.820.3604. The Valve Disorders Center at Baylor Scott & White Heart and Vascular Hospital – Fort Worth can be reached at 817.825.1374. Additional information may be found at the hospital's website, BaylorHeartHospital.com or on the app, Baylor Heart Center, downloaded from the Apple store.

### **About Baylor Scott & White Heart and Vascular Hospital - Dallas**

Founded in a tradition of research and innovation, Baylor Scott & White Heart and Vascular Hospital – Dallas† opened in 2002 as the region's first and only dedicated hospital to heart and vascular care. The Dallas hospital is located on the main campus of Baylor University Medical Center - Dallas, a part of Baylor Scott & White Health. Baylor Scott & White Heart and Vascular Hospital – Dallas has cardiology services available at Baylor Scott & White All Saints Medical Center – Fort Worth. With more than 44,000 patient registrations annually, a broad array of advanced cardiac interventional procedures and vascular surgeries are available, as well as diagnostic imaging and cardiac rehabilitative services. Programs on wellness and prevention are offered for the community. Additional information may be found at the hospital's website, BaylorHeartHospital.com or on the app, Baylor Heart Center, downloaded from the Apple store. To find a specialist who performs TAVR, call 1.844.BSW.DOCS.

\* <https://www.fda.gov/news-events/press-announcements/fda-expands-indication-several-transcatheter-heart-valves-patients-low-risk-death-or-major>

† Joint ownership with physicians.

*Notice Regarding Physician Ownership: Baylor Scott & White Heart and Vascular Hospital is a hospital in which physicians have an ownership or investment interest. The list of the physician owners or investors is available to you upon request. Physicians provide clinical services as members of the medical staff at one of Baylor Scott & White Health's subsidiary, community or affiliated medical centers and are neither employees nor agents of those medical centers, Baylor Health Care System, Scott & White Healthcare or Baylor Scott & White Health.*

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