FDA News Release

FDA approves expanded indication for two transcatheter heart valves for patients at intermediate risk for death or complications associated with open-heart surgery

For Immediate Release

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Release

The U.S. Food and Drug Administration today approved an expanded indication for the Sapien XT and Sapien 3 transcatheter heart valves for patients with aortic valve stenosis who are at intermediate risk for death or complications associated with open-heart surgery. These devices were previously approved only in patients at high or greater risk for death or complications during surgery.

“This is the first time in the U.S. that a transcatheter aortic valve has been approved for use in intermediate risk patients,” said Bram Zuckerman, M.D., director of the division of cardiovascular devices at the FDA’s Center for Devices and Radiological Health. “This new approval significantly expands the number of patients indicated for this less invasive procedure for aortic valve replacement.”

Aortic valve stenosis increases with age as the aortic valve becomes narrow, causing the heart to work harder to pump enough blood through a smaller opening. It occurs in about three percent of Americans over age 75 and can cause fainting, chest pain, heart failure, irregular heart rhythms (arrhythmias), cardiac arrest or death. Patients with severe aortic valve stenosis generally need to have a heart valve replacement to improve blood flow through their aortic valve.

Traditionally, open-heart surgery has been the gold standard for aortic valve replacement in intermediate risk patients, but it involves a larger incision and longer recovery time than the minimally invasive procedure used to insert the transcatheter heart valve. About one-third of patients referred for open-heart surgery for aortic valve replacement fall into the “intermediate risk” category, which is defined as having a greater than three percent risk of dying within 30 days following surgery.

In a clinical study to evaluate safety and effectiveness, 1,011 aortic stenosis patients at intermediate risk for surgical complications were randomly selected to have a transcatheter aortic valve replacement procedure using the Sapien XT valve and 1,021 were randomly selected to have a traditional aortic valve replacement during open-heart surgery

using a surgical tissue valve. In a second study, 1,078 intermediate risk patients were implanted with the Sapien 3 valve; and outcomes in these patients were compared to the same group of 1,021 surgical control patients in the first study. The two studies demonstrated a reasonable assurance of safety and effectiveness of the Sapien XT and Sapien 3 devices in intermediate risk patients.

Patients who receive either the Sapien XT or the Sapien 3 valve face a potential risk of serious complications from the device or implantation procedure, such as death, stroke, acute kidney injury, heart attack, bleeding, and the need for a permanent pacemaker.

The devices are contraindicated for patients who cannot tolerate blood thinning medication. They are also contraindicated for those who are currently being treated for a bacterial or other infection.

As part of the approval of these devices, the FDA is requiring the manufacturer to conduct a post-approval study to follow the patients treated with either device in the first and second clinical studies for 10 years to further monitor safety and effectiveness.

Sapien XT and Sapien 3 are manufactured by Edwards Lifesciences, LLC, based in Irvine, California.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **FDA: Medical Devices (/MedicalDevices/default.htm)**
- **National Heart Lung and Blood Institute: What is heart valve disease? (https://www.nhlbi.nih.gov/health/health-topics/topics/hvd/)**
- **Edwards SAPIEN XT Transcatheter Heart Valve - P130009/S057 (/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-**

ApprovedDevices/ucm517194.htm)

- **Edwards SAPIEN 3 Transcatheter Heart Valve - P140031/S010 (/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm517195.htm)**

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