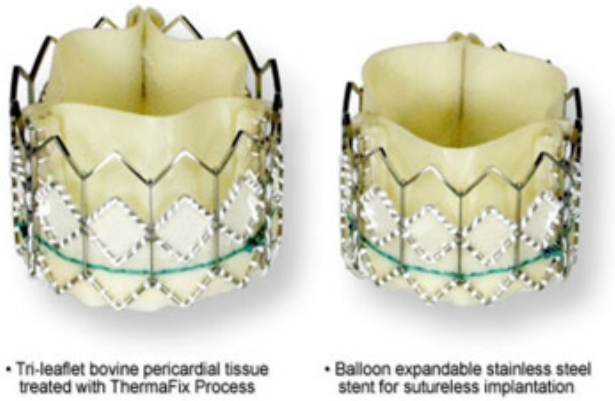
Edwards SAPIEN Transcatheter Heart Valve (THV) - P100041



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Edwards SAPIEN Transcatheter Heart Valve Model 9000TFX and accessories
PMA Applicant: Edwards Lifesciences
Address: Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 9261
Approval Date: November 2, 2011
Approval Letter: **http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100041a.pdf (https://wayback.archive-it.org/7993/20161023015438/http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100041a.pdf)**

What is it? The Edwards SAPIEN Transcatheter Heart Valve (THV) is a heart valve that is made of cow tissue attached to a stainless steel mesh frame with a polyester wrap.

How does it work? The device is inserted into the body by cutting a small opening in the artery carrying blood to the leg. The valve is placed on the end of a tube-like device called a balloon catheter, and is inserted into the opening in the leg. The catheter is pushed through the blood vessels until it reaches the damaged and/or diseased valve. The balloon on the end of the catheter is then blown up

to expand the valve so it stays in place. Once the new valve is in place, it helps the blood flow properly by opening and closing like a door at the correct time to force the blood to flow in the correct direction.

When is it used? The SAPIEN THV is used in patients whose aortic heart valve is damaged and/or diseased due to calcium build up and causes the valve to narrow (senile aortic valve stenosis) so blood is not able to flow efficiently. As the heart works harder to pump enough blood through the smaller opening, the heart eventually becomes weak. This can lead to symptoms and life-threatening heart problems such as fainting, chest pain, heart failure, irregular heart rhythms (**arrhythmias (https://wayback.archive-it.org/7993/20161023015438/http://www.nlm.nih.gov/medlineplus/arrhythmia.html)**), or **cardiac arrest (https://wayback.archive-it.org/7993/20161023015438/http://www.nlm.nih.gov/medlineplus/cardiacarrest.html)**. Once symptoms of senile aortic valve stenosis occur, over half of the patients die within two years. The SAPIEN THV should only be used in patients who cannot undergo open heart surgery to have their valve replaced, as determined by a surgeon.

What will it accomplish? Implantation of the SAPIEN THV can help restore normal blood flow in the heart in patients with senile aortic valve stenosis who need open-heart surgery to replace the damaged and/or diseased valve, but for whom such a procedure is too risky. Patients who received this device had 3 times more strokes than those who did not get the device. They also had many more complications with the arteries leading to their legs.

When should it not be used? The device and delivery system should not be used in patients who cannot tolerate blood-thinning medicines, or who have active infections near the valve or in the body.

Additional information: Summary of Safety and Effectiveness and labeling (https://wayback.archive-it.org/7993/20161023015438/http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p100041) are available online.

Other Resources:

- **FDA News Release (/7993/20161023015438/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm278348.htm)**
- **Society of Thoracic Surgeons - Aortic Valve (https://wayback.archive-it.org/7993/20161023015438/http://www.sts.org/patient-information/valve-repair/replacement-surgery/aortic-valve) (https://wayback.archive-it.org/7993/20161023015438/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

More in Recently-Approved Devices (/7993/20161023015438/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/default.htm)

2015 Device Approvals (/7993/20161023015438/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm430692.htm)

2016 Device Approvals (/7993/20161023015438/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm494389.htm)