TRANSCATHETER AORTIC VALVE REPLACEMENT
WITH THE EDWARDS SAPIEN 3 VALVE

Moderate-Risk Patients n=1,077*

Average Age* 81.9 YEARS OLD
Average Hospital Length of Stay* 5.6 DAYS

Freedom from All Stroke† 99.0% AT 30 DAYS
Survival† 98.9% AT 30 DAYS

The most serious RISKS of the TAVR procedure are:
death from any cause, major stroke, major vascular complications, and disabling bleeding event.**

It is important to talk with your doctor about the exact procedure you will have, the product you will receive, and the literature on clinical studies using that product.

*The PARTNER II S3i trial
†The PARTNER II trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, as treated population (n=1077).
**See the Edwards SAPIEN 3 patient brochure for more detailed information on these and other risks.
**IMPORTANT RISK INFORMATION**

**Indications:**
The Edwards SAPIEN 3 transcatheter heart valve (THV), model 9600TFX, and accessories are indicated for patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team to be at intermediate or greater risk for open surgical therapy (i.e., the patient has comorbidities such that the Heart Team agrees the predicted risk of operative mortality is ≥ 3% at 30 days).

**Contraindications (Who should not use):**
The Edwards SAPIEN 3 transcatheter heart valve and delivery system should not be used in patients who:
- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.

**Warnings:**
- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are allergic to chromium, nickel, molybdenum, manganese, copper, silicon, and/or polymeric materials.
- The SAPIEN 3 valve may not last as long in patients whose bodies do not process calcium normally.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage. X-ray guidance used during the procedure may cause injury to the skin, which may be painful, damaging, and long-lasting.
- Transcatheter aortic heart valve patients should take medications that thin the blood or prevent blood clots from forming, except when likely to have an adverse reaction, as determined by their physician. The Edwards SAPIEN 3 transcatheter heart valve has not been tested for use without medications that thin the blood or prevent blood clots from forming.

**Precautions:**
The long-term durability of the Edwards SAPIEN 3 transcatheter heart valve is not known, at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. For patients who have previously had aortic valve replacement, the safety, effectiveness, and durability of putting a transcatheter valve in an already implanted artificial valve are not known at this time.

The safety and effectiveness of the transcatheter heart valve is also not known for patients who have:
- An aortic heart valve that is not calcified, contains only one or two leaflets, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks
- Previous heart valve replacement or repair
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities such as a blood clot, a diseased mitral valve that is calcified or leaking, or Gorlin syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors
- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly
- Diseased or irregularly shaped vessels leading to the heart. Vessels in the legs which are heavily diseased or too small for associated delivery devices, or a large amount of calcification at the point of entry to the heart
- Allergies to blood-thinning medications or dye injected during the procedure

**Potential risks associated with the procedure include:**
- Death, stroke, paralysis (loss of muscle function), permanent disability, or severe bleeding
- Risks to the heart, including heart attack or heart failure, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pacemaker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis(narrowing), too much fluid around the heart
- Risks to your lungs or breathing, including difficulty breathing, fainting, buildup of fluid in or around the lungs, weakness or inability to exercise
- Risks involving bleeding or your blood supply, including formation of a blood clot, high or low blood pressure, limited blood supply, a decrease in red blood cells, or abnormal lab values, bleeding in the abdominal cavity, collection of blood under the skin
- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection or bleeding at incision sites, or swelling

**Additional potential risks specifically associated with the use of the heart valve include:**
- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery and possible removal of the SAPIEN 3 valve, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), nonstructural valve dysfunction (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage, etc.) or mechanical failure of the delivery system and/or accessories

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician

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