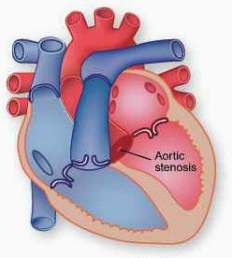


# FACT SHEET: Medtronic CoreValve® Transcatheter Aortic Valve System

**\*\*NOT APPROVED FOR COMMERCIAL USE IN THE UNITED STATES\*\***

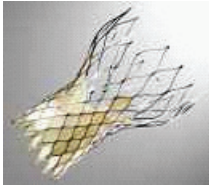
## Severe Aortic Stenosis Overview:



Approximately 300,000 people worldwide suffer from severe aortic stenosis, which occurs when the heart's aortic valve is narrowed, restricting blood flow from the heart to the body. The condition primarily affects older people and typically develops in individuals between the ages of 50 and 70.

The standard treatment for severe aortic stenosis is open-heart valve replacement surgery. Research shows that, left untreated, as many as 50 percent of aortic stenosis patients with severe symptoms may die within two years. A significant number of severe aortic stenosis patients are at high risk for open-heart surgery, and one-third are altogether ineligible for open-heart surgery. The Medtronic CoreValve U.S. Clinical Trial will evaluate the safety and effectiveness of the CoreValve Transcatheter Aortic Valve System in these groups of patients.

## Technology Description:



The Medtronic CoreValve U.S. Clinical Trial will evaluate safety and effectiveness of the CoreValve Delivery System (above) with Accutrak™ Stability Layer (below).



In the U.S. the Medtronic CoreValve System is currently under clinical investigation and is not approved by the U.S. Food & Drug Administration (FDA) for commercial use.

The Medtronic CoreValve System is a new technology designed to replace a diseased aortic heart valve percutaneously – meaning through the skin – without open heart surgery and without surgical removal of the diseased valve.

In the Medtronic CoreValve U.S. Clinical Trial, the replacement valve will be delivered primarily through a small opening in the femoral artery, threaded through arteries and across the aorta, and deployed in the native aortic valve. Once in place, the CoreValve is designed to take over the native valve's function and ensure that oxygen-rich blood flows into the aorta and circulates throughout the body.

The CoreValve System is sized at 18-French (less than 1/4 of an inch). It is made from porcine (pig) cardiac tissue fixed to a self-expanding, Nitinol frame and is delivered through the femoral artery by a catheter (long thin tube). The self-expanding frame is designed to help physicians control and accurately deploy the valve.

## Regulatory Status and Other Milestones:

The CoreValve System is not currently available for commercial use in the United States. In 2010, the FDA approved its Investigational Device Exemption (IDE) application and pivotal clinical trial protocol to begin evaluating the Medtronic CoreValve System for transcatheter aortic valve implantation.

The CoreValve System received Conformité Européenne (CE) Mark in 2007, and it has been implanted in patients in more than 35 countries outside the U.S. since then.

**For more information about the Medtronic CoreValve U.S. Clinical Trial at DMC Cardiovascular Institute, visit [www.dmccvi.org/aortic](http://www.dmccvi.org/aortic).**