

CoreValve Evolut R System

Medtronic, Inc.
(763) 514-4000
www.medtronicendovascular.com

KEY FEATURES

- 23-, 26-, or 29-mm self-expanding valve
- 14-F–equivalent delivery system
- Enables recapture and repositioning during deployment
- Low-profile InLine sheath



Medtronic, Inc. has received United States Food and Drug Administration approval for the CoreValve Evolut R transcatheter aortic valve replacement system. The self-expanding valve and 14-F–equivalent EnVeo R delivery system offer new capabilities for valve performance and deliverability during the procedure while providing the option to recapture and reposition the valve during deployment. The valve is anatomically designed to increase conformability at the annulus for optimal annular fit and sealing while maintaining supra-annular valve position for improved hemodynamic performance.

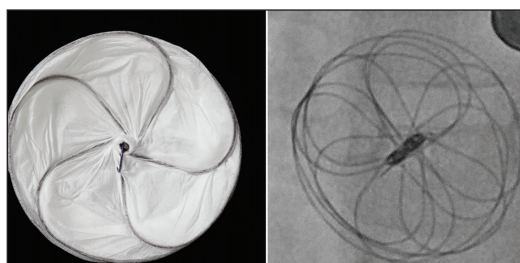
“Clinical data have shown the best patient outcomes are achieved when the valve is properly positioned,” commented Mathew Williams, MD, Chief of Adult Cardiac Surgery and Director of Interventional Cardiology and Structural Heart at the NYU Langone Medical Center in New York, New York. “The advancement of recapturability with Evolut R gives physicians more confidence during the procedure and provides advantages that are nonexistent in other TAVR systems.”

Gore Cardioform Septal Occluder

W. L. Gore & Associates, Inc.
(800) 528-8763
www.goremedical.com

KEY FEATURES

- Soft, conformable, and minimal wire frame
- Thromboresistant ePTFE material
- Preloaded occluder
- Improved delivery system



The Gore Cardioform septal occluder (formally known as Gore septal occluder) first received CE Mark in Europe for atrial septal defect and patent foramen ovale in 2011. In the United States, the Gore Cardioform septal occluder (studied as Gore septal occluder) received approval in 2015.

The Gore Cardioform septal occluder is designed with two independent conformable discs that span and cover the anatomy, enabling treatment of ASDs, including challenging defects. Proprietary, thromboresistant ePTFE material allows tissue ingrowth for short- and long-term performance. The soft and conformable construction of the minimal wire frame is designed to provide superior apposition to the surrounding anatomy.

The results from the United States investigational device exemption pivotal study will be presented at PICS-AICS 2015 in September in Las Vegas, Nevada.

Edwards SAPIEN 3 Transcatheter Heart Valve

Edwards Lifesciences Corporation
1-800-424-3278
www.sapien3.com

KEY FEATURES

- Balloon-expandable
- Bovine pericardial tissue
- Cobalt-chromium frame
- Outer sealing skirt

The SAPIEN 3 transcatheter heart valve builds on Edwards' decades of experience in the development of tissue heart valves, and the proven benefits of the Edwards SAPIEN valves. The Edwards SAPIEN 3 valve is composed of a balloon-expandable, cobalt-chromium frame, trileaflet bovine pericardial tissue

valve, and polyethylene terephthalate (PET) fabric inner and outer skirt. The SAPIEN 3 valve is available in four sizes: 20 mm, 23 mm, 26 mm, and 29 mm.

The Edwards SAPIEN 3 transcatheter heart valve received FDA approval June 17, 2015 and received CE Mark approval in January 2014. ■

