Edwards Lifesciences

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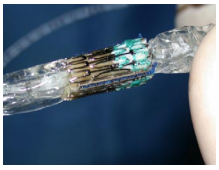
FACT SHEET: Cribier-Edwards Percutaneous Aortic Heart Valve

What?

- Experimental therapy designed for use in patients who are not good candidates for surgical heart-valve replacement (e.g., too sick to withstand open-heart surgery)
- Aortic (equine pericardial) tissue heart valve
- Mounted on a balloon-expandable stent
- Size of a human valve (approx 23 mm), compressible to about the diameter of a pencil (approx 8 mm) for delivery through percutaneous catheter
- Makes non-surgical aortic valve replacement possible



Compressed

Expanded

How?

1. Procedure performed on a beating heart in a cardiac catheterization laboratory
2. Patient receives local anesthesia at site of catheter insertion
3. Catheter introduced into the patient's femoral artery (just above thigh), then the percutaneous heart valve is threaded through the circulatory system until it reaches the patient's malfunctioning aortic valve
4. Using fluoroscopic imaging, the physician guides the compressed Cribier-Edwards percutaneous heart valve through the catheter delivery system to the aortic valve
5. The Cribier-Edwards percutaneous heart valve is expanded by a balloon catheter where it pushes the patient's existing valve leaflets aside and anchors inside the valve opening

Who?

- Named for co-inventor Prof. Alain Cribier, MD, chief of cardiology of the Rouen University Hospital in Rouen, France
- Developed by Edwards Lifesciences in Irvine, Calif.

Where?

- Currently in clinical trials in select European sites
- U.S. clinical feasibility trial initiated at William Beaumont Hospital in Royal Oak, Mich.

When?

- First implant in April 2002 by Prof. Cribier
- U.S. feasibility trials began with first U.S. implant on March 10, 2005
- U.S. commercialization approval expected in three to four years

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DOCKET ALARM

Edwards Lifesciences v. Boston Scientific Scimed
IPR2017-00060, U.S. Patent 8,992,608
Exhibit 2047

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