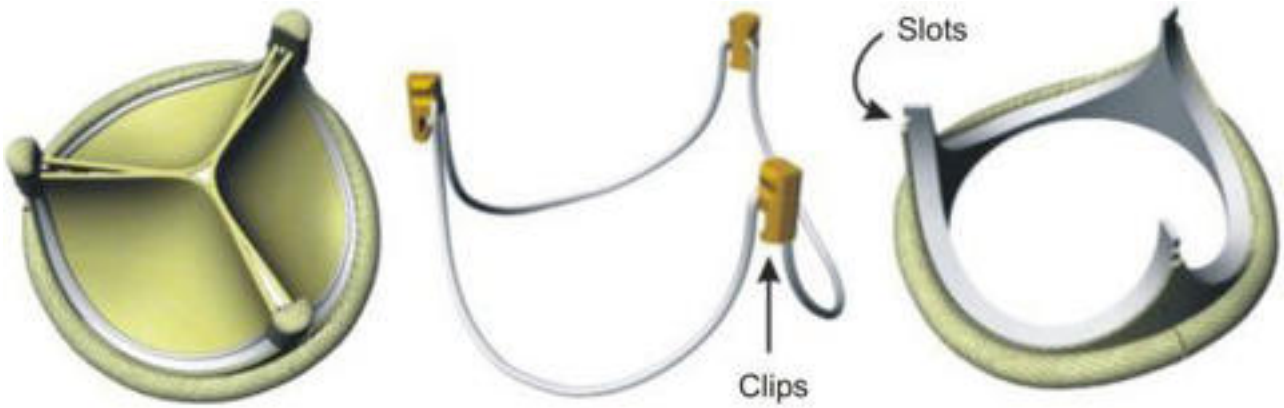
Clinical Trial Completed on New Two-Part Heart Valve

ValveXchange

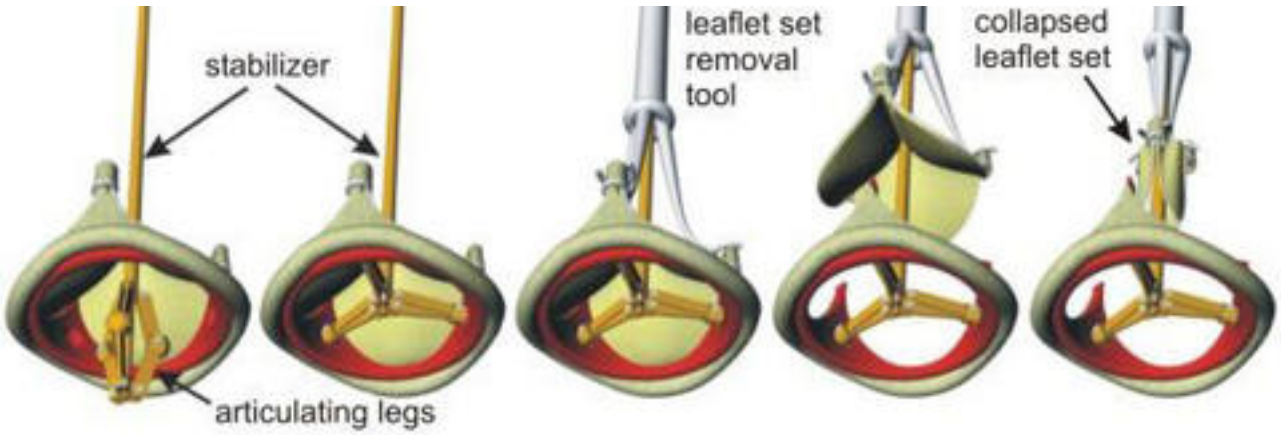


Surgeons in Europe have completed clinical trials on the world's first serviceable bioprosthetic heart valve, paving the way for the CE mark and commercial sale of an advanced heart valve that eliminates many common problems for cardiac valve patients.

Cardiac surgeons in Germany, Austria and Poland have successfully completed implants and patient enrollment in the VITAL-2 clinical trial for the Vitality Heart Valve System™ from ValveXchange, Inc. The system incorporates a two-piece heart valve [1] and allows a simple two-step implant procedure that provides excellent visibility into the aortic chamber, according to John Parrish, chairman and CEO of ValveXchange. The valve enables the smaller incisions that patients are now demanding. The design of the valve also allows a surgeon to replace just the leaflet set later in life, without having to completely explant and remove the entire valve.

By resolving conflicts between conventional mechanical and tissue-based prosthetic values, the Vitality system eliminates patients' need for complex future open-heart surgeries and high doses of anti-coagulation drugs. Currently, adult patients require repeated open-heart surgeries, as they typically receive tissue valves that wear out every 10-15 years. Younger and physically active patients often receive mechanical heart valves that do not wear out, but require lifelong high doses of anti-coagulation drugs that force a sedentary lifestyle with serious side effects.

The completion of the implants, and patient enrollment places ValveXchange on track to obtain a CE mark for the system later this year. At that point, ValveXchange will release the product for commercial sale in the European Union and in other regions of the world recognizing the CE mark. The CE mark indicates a product's compliance with European Union requirements, and enables the free movement of products within the European Economic Area. ValveXchange will also implement the process for FDA clearance in the United States.



“This milestone represents a major achievement for ValveXchange,” says Parrish. “The completion of enrollment in the VITAL-2 trial, and the best-in-class valve performance results, substantiate the ValveXchange philosophy that better science equals better valves.”

For more information visit www.valvexchange.com. [2]

Source URL (retrieved on *12/20/2013 - 8:08am*):
http://www.mdtmag.com/news/2013/07/clinical-trial-completed-new-two-part-heart-valve

Links:
[1] http://valvexchange.com/company/index.html
[2] http://www.valvexchange.com