## Freestyle® Aortic Root BioProsthesis

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Heart disease has numerous causes from poor diet to congenital defects causing a range of damage to the heart. However, when one of the cardiac valves becomes diseased, one of two things happens. Either the valve hardens, stenosis, where there is an obstruction of flow, or there is incomplete closing, regurgitation, where blood tends to leak back.

Causes for valve disease include advanced age, congenital heart disorders (up to 32,000 infants a year), infection, and untreated strep throat (which leads to rheumatic fever). A diagnosis may be achieved through medical imaging such as electrocardiograms, echocardiograms, chest x-rays, and cardiac cathederization.

In some minor instances valve repair may be introduced, otherwise the valve is surgically replaced by one of two types of artificial valves, mechanical or tissue. Approximately 95% of replaced valves are either the mitral or aortic valve.

Mechanical valves consist of three categories: ball/cage, tilting disk, or the bileaflet, which is most commonly used today. Advantages to these valves are there durability and longevity. Disadvantages include infection surrounding the implant, calcification and the need for long-term use of anticoagulants by the patient.

Tissue (bioprosthetic) valves are made from donor tissue from porcine, bovine or human donors. These valves may be stented or not. Their longevity is shorter than that of their counterparts, and they have the risk of calcification, but they tend to have better hemodynamics and lack the need for long term use of anticoagulants.

The Freestyle® Aortic Root BioProsthesis is an innovative natural valve implant that gives a variety of options to prospective patients. The main feature is its "root" design. This gives surgeons a greater versatility with surgery, thus reducing complications, and increasing customization. Its polyester coating protects and strengthens the porcine valve, while a physiological fixation application to the sheath helps keep the shape of the valve, optimizing blood flow. Lastly AOA® is applied to help the slowing of any calcification.

Clinical and case studies have shown there to be better hemodynamics comparable to native valves. Surgeons report the ease of trimming and rotation of the valves to better tailor to their patients.

Since 1996, approximately 896 patients in 21 medical centers, across the U.S., Canada, Europe and New Zealand have received these valves with great success.

References:

- <u>www.health.allrefer.com</u>
- <u>www.medtronic.com</u>
- <u>www.che.iit.edu</u>
- <u>www.me.utexas.edu</u>
- www.nlm.nih.gov/medlineplus
- <u>www.sjm.com</u>