Cleveland Clinic Innovations

PRODUCT
Stented Pulmonary Autograft Prosthesis for Pediatric mitral valve insufficiency

INDICATION
Cardiovascular, Cardiac surgery, Mitral valve repair, Pulmonary autograft. Mitral regurgitation.

VALUE PROPOSITION
- Live valve tissue which will repair itself.
- The device does not need anticoagulation.
- Easy anchoring of prosthesis to the annulus of the mitral valve via sutures or self-anchoring.
- Good hemodynamics: the device will not have stenosis or dilate.
- No inflow turbulence or significant left ventricular outflow tract obstruction.

DEVELOPMENT STAGE
Prototype available
Ex-vivo Study

INTELLECTUAL PROPERTY
US Patent: 11,076,954

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Stented Pulmonary Autograft in the Mitral Position

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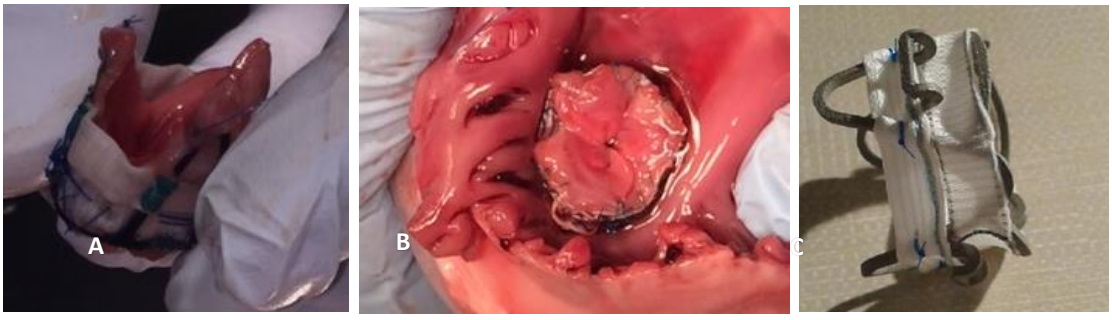
UNMET NEED

Pediatric mitral valve insufficiency causes severe regurgitation and there are limited options for treatment in this population. The surgical management of mitral valve disease in pediatric population as well as women of childbearing age is made difficult by the prospect of lifelong anticoagulation. There are currently no available bio-prostheses that have an expected life beyond 5 years and free of degeneration for young patients, and some of these patients are contraindicated for warfarin or anticoagulation. The Ross II procedure, a possible option, involves surgically harvesting the patient's pulmonary valve, implanting it inside a Dacron tube and inserting it into the mitral position in an inverted position. This implantation technique has not been standardized and the results therefore has been variable with less-than-optimal outcome because of the complication rate. There is a clear need for a viable mitral valve substitute that will last for lifetime and will not require anticoagulation.

SOLUTION

A scaffold or prosthesis that is either partially absorbable or expandable and can grow with the patient will provide a longer lasting solution than current option. The Stented Pulmonary Autograft prosthesis is intended for use in the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic aortic or mitral valves in adults and pediatric population. In this procedure, the harvested pulmonary valve is mounted on a frame or stented prosthesis which supports the allograft. The technology is to use the pulmonary autograft in the mitral position but after attaching it on the bench to a stented that is placed expeditiously in the mitral position. Anchoring this prosthesis to the annulus of the mitral valve can be done either self-anchoring or with sutures. This is performed in a fast and safe way to make this operation smooth and simple.



(A) Device is a nitinol stent conduit used to mount the harvested autograft (B) The prototype implanted into an ex vivo porcine heart. (C) The prototype without autograft attached.