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The IRIS™ Valve: A Growth Accommodating Transcatheter Pulmonary Valve For Pediatric Patients

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Abstract:

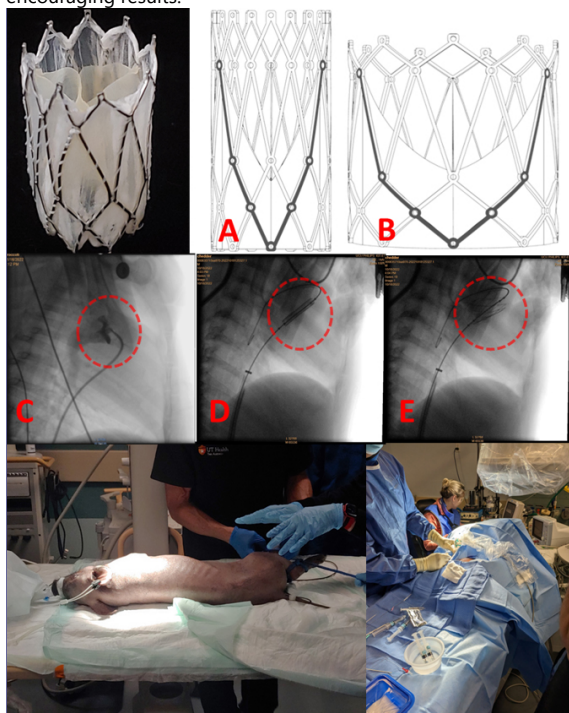
Introduction: It is estimated that at least 1 million children are living with a congenital heart defect (CHD) in the U.S. Most of these patients are born with some degree of right ventricular outflow tract (RVOT) abnormalities that at some point require pulmonary valve replacement to mitigate the detrimental effects of pulmonary valve regurgitation (PVR) on the right ventricle (RV). Due to their size, available solutions, e.g., the Melody™ valve (Medtronic Inc., Minneapolis, MN) cannot be implanted in small children under 20 Kg. Those must wait until they grow to a suitable weight to receive the valve, which may lead to RV dysfunction.

Hypothesis: To mitigate the detrimental effects to the RV, the IRIS™ valve is implantable at 12 mm with a 12-Fr delivery catheter. As the valve annulus grows, the valve would be balloon expanded up to 20 mm.

Methods: The IRIS™ valve has been designed according to origami concepts such that its three leaflets would retain a fully-coapted form as it is expanded to a larger size. Here we report our methods and results of implantation in 9-17Kg Yucatan pigs.

Results: The IRIS™ valve is made of thin porcine pericardial leaflets sewn into a laser-cut stainless-steel stent. The stented valve is covered with an ePTFE skirt to mitigate paravalvular leak. The IRIS™ valve is fully crimped over a 12-Fr delivery catheter for transfemoral implantation. We have successfully implanted the valve at the native pulmonary valve position with minimal regurgitation in three pigs ranging from 9 to 17kg with varying pulmonary annulus sizes.

Conclusions: The IRIS™ transcatheter pulmonary valve has been successfully developed according to proprietary origami concepts. Using the 12Fr delivery catheter, the smallest delivery profile reported, we successfully implanted the IRIS™ valve within the pulmonary annulus of mini pigs with encouraging results.



Abstract Graphic/Image Description (Complete):

If you did not upload a graphic/image for your abstract, please type "No image" in the field. **(Required)** : Top. IRIS™ growth-accommodating transcatheter pulmonary. Coaptation achieves at A) 12mm and B) 20mm sizes. Middle. Fluoroscopic images of valve implantation (C, D and E). Bottom. Transcatheter implantation in the CathLab.

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Category (Complete): 23.95 Pediatric Congenital Heart Defects

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Has this research received full or partial funding support from the American Heart Association? (Required): Yes

Disclosure (Required): There are unlabeled/unapproved uses of drugs or products.

Product One: : IRIS TPVR system

Abstract Copyright Transfer Agreement (Required): Yes

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