



Novel Size-Adjustable Pulmonary Valve U.S. Early Feasibility Study: 1-year Outcomes

Objective: This size-Adjustable Valve (AV) is a novel surgically implanted expandable synthetic pulmonary valve. Mimicking the geometric profile of the human femoral venous valve, the bileaflet AV features a size-adjustable frame with expanded polytetrafluorethylene (ePTFE) leaflets that maintain competency over a functional diameter range of 12.7mm to 22mm (internal diameter, ID), Figure 1. The AV is designed to be size-adjusted at implant to match the patient's body surface area (BSA). The AV may be size-adjusted post-implant via transcatheter balloon dilation to accommodate somatic growth. We report 1-year results of the first-in-human size-Adjustable Valve Early Feasibility IDE study.

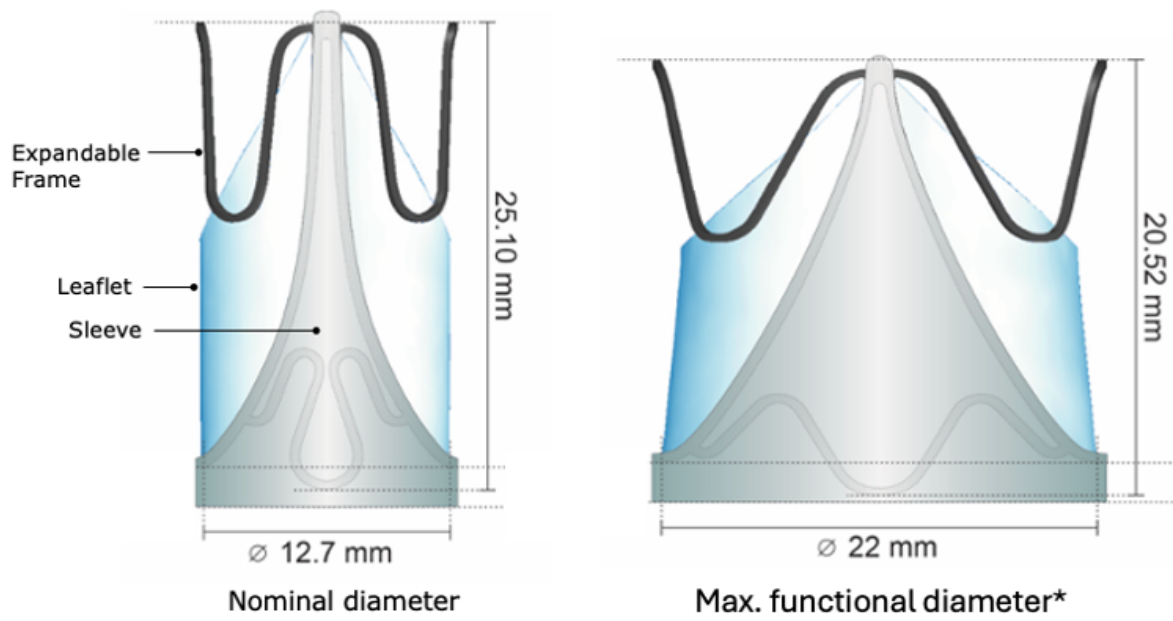
Methods: This was a prospective, single-arm, multi-center study to evaluate safety and preliminary effectiveness of the AV in pediatric patients aged 18 months to 16 years requiring pulmonary valve replacement. Primary endpoints were freedom from a device-related complication (death, valve thrombosis, thromboembolism) as adjudicated by an independent Clinical Events Committee; and clinically acceptable hemodynamic performance (defined as < moderate pulmonary regurgitation (PR) on transthoracic echocardiogram) as assessed by an independent Echo Core Lab, at 1-year post-valve implant.

Results: Eleven patients (nine male) were enrolled at 3 centers. Median age at implant was 8.2 (range, 2.7-13.6) years and BSA ranged from 0.6-1.3m². Primary diagnoses included tetralogy of Fallot (N=8), double outlet right ventricle (N=2) and pulmonary atresia/intact ventricular septum (N=1). All had prior right ventricular outflow tract surgery. The AV was size-adjusted at implant in all patients, ranging from 14mm to 20mm ID (z-score -1 to +1). Acute procedural success (defined as RV to PA peak gradient <40 mmHg, none/trivial PR, no paravalvular leak) was achieved in all patients. Median hospital length of stay was 4 days (range, 3-5). At 1-year follow-up, 100% of patients were alive and free from device-related complications. Ten (91%) had ?mild pulmonary stenosis and all had ?trivial PR. One developed moderate AV stenosis due to marked somatic growth and underwent subsequent transcatheter balloon dilation without complications.

Conclusions: One-year results from this novel size-Adjustable Pulmonary Valve EFS demonstrated no significant valve insufficiency, no device-related adverse events and no thrombotic or infectious complications. The AV is now under evaluation in a Pivotal IDE study.

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*Frame may be further expanded up to 26 mm ID