MyVal - 1 Study

A study to evaluate safety and effectiveness of Myval Transcatheter Aortic Valve Replacement System in intermediate and high risk, symptomatic patients with severe aortic valve stenosis

Study Design

- A First-in-Man, prospective, multicentre, single arm, open label study
- 30 patients enrolled at 14 sites across India

CTRI No.	CTRI/2017/07/009008
Study Objective	The objective of the study is to assess the safety and effectiveness of the Myval Transcatheter Aortic Valve Replacement System in intermediate and high risk, symptomatic patients with severe aortic valve stenosis.
Safety Endpoints	• Kaplan-Meier survivorship at 30-day, 6-month, 12-month and annually thereafter till 5 years • Freedom from major adverse cardiac cerebrovascular and renal events • Evidence of prosthetic valve dysfunction (haemolysis, infection, thrombosis, severe paravalvular leak, or migration) • Length of index hospital stay • Improved Quality of Life (QoL)
Performance Endpoints	Functional improvement from baseline is measured as per • NYHA functional classification • Effective Orifice Area (EOA) • Six-minute walk test at 30-day, 6-month and 12-month
Clinical Sites	14 sites across India
Sample Size	30 patients
Follow-Up	1, 6-month, and 12-month and annually thereafter till 5 years
Study Duration	Study start date: November 2016 Estimated Study completion date: February 2022

❖ Reference:

1. Clinical Trial Registry- India (CTRI): CTRI/2017/07/009008 http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=15317&EncHid=&userName=