



IS 17840 Cardiac Valve Prostheses

Part 3 Heart Valve Substitutes Implanted by Transcatheter Techniques

This Standard provides guidance for testing, evaluating, and labelling of *transcatheter heart valve substitutes*. It outlines in-vitro, preclinical in-vivo, and clinical evaluation methods, emphasizing a risk-based approach to select appropriate verification and validation tests. These tests assess the physical, chemical, biological, and mechanical properties of the valves and their components.

This document provides design, testing, and safety requirements for transcatheter heart valve systems, including valve-in-valve (ViV) and valve-in-ring (ViR) procedures. It also explained the method of neo-LVOT and neo-sinus in transcatheter heart valve procedures.

Implemented alongside IS 17840 (Part 1), and IS 17840 (Part 2), the standard defines the operational framework, terminology, and evaluation procedures applicable to heart valve substitutes. It also includes reliable blood flow, minimal leakage, resistance to migration, and prevention of complications like haemolysis or thrombosis. In vitro testing must simulate real-life use, including valve loading, delivery, and repositioning, with full size-range coverage. All design and testing activities must be guided by risk analysis. Preclinical in-vivo evaluation must include clear guidance for imaging, sizing, implant preparation, MRI compatibility and usability under IS/IEC/TR 62366-2.

The standard recommends that the clinical investigations should be risk-based, covering pre, peri and post-procedure data to demonstrate safety and effectiveness. All investigations must comply with IS 18076:2023 and IS/ISO 14155:2020.

This standard provides also guidance for verifying hydrodynamic performance through pulsatile flow testing, specifically for the TAVI hydrodynamic test fixture. Additionally, it offers general guidance on using multimodality imaging techniques such as CT, transthoracic echocardiography (TTE), transesophageal echocardiography (TEE), and fluoroscopy to assess aortic valve and mitral apparatus and the implantation of transcatheter aortic valve implantation (TAVI) and transcatheter mitral valve implantation (TMVI) devices.