IS 17840 Cardiac Valve Prostheses

Part 2 Surgically Implanted Heart Valve Substitute

This Standards defines the requirements for ***surgical heart valve substitutes*** used in human hearts, covering both new and modified devices, along with their accessories, packaging, and labelling. It also outlines pre-clinical and clinical evaluation requirements.

Design, packaging, labelling, sterilization, risk management, structural property, mterial performance assessment and verification of surgical heart valve substitutes with the general requirements outlined in IS 17840 (Part 1). Additional requirements for detailed valve labelling and risk-based in-vitro assessments to ensure safety and performance throughout manufacturing and implantation.

Preclinical in-vivo testing of surgical heart valves ensures safety and performance, focusing on function, handling, and biological response. Testing is risk-based and follows IS/ISO 10993 (Part 2) guidelines. It utilizes animal models, includes comparisons with control groups, replicates clinical conditions, and upholds animal welfare standards. It includes chemical treatments, surface modifications, or coatings used, including primary fixation of tissue and any anti-calcification, anti-infection, or anti-thrombotic treatments. For device-drug combination products, elements of IS/ISO 12417 (Part 1) may be applicable.

The standard requires rigorous assessment of material and structural properties, includes haemodynamic test should be performed, at a range of cardiac indices (2,5 l/min/m2 to 6,0 l/min/m2) and hydrodynamic behaviour is assessed through pulsatile flow testing, and the flow meter should have an upper frequency limit (−3 dB cut-off) of at least 30 Hz.

For clinical investigations the general requirements of IS 18076 and IS/ISO 14155 shall apply. It also includes pre-procedure, peri-procedure, and follow-up data from a specified number of subjects, each with a follow-up appropriate for the device and its intended use. The clinical investigation programme shall be designed to provide substantial evidence of acceptable safety and effectiveness to support the intended labelling for the device.