



IS 17843 Cardiovascular Implants and Extracorporeal Systems Cardiovascular Absorbable Implants

This Standards describes the design evaluation requirements for *absorbable cardiovascular implants* used in the circulatory system. It focuses on implants intended to be absorbed by the body and act directly on the cardiovascular system. It does not cover implants involving living tissues, biological materials, or related devices that don't affect absorption.

This document outlines the key considerations for the design, fabrication, packaging, and use of medical devices, in accordance with the general requirements of IS 18076 and IS/ISO 12417-1 for drug-eluting absorbable implants. Packaging and labelling should comply with IS/ISO 11607-1, IS 18076 (Clauses 10 and 11). Sterilization must follow IS 18076 requirements, using validated methods such as radiation, ethylene oxide, steam and alternative sterilization. Additionally, product shelf life should be established through both real-time and accelerated aging studies to ensure the device safety and performance.

This document also establishes a risk management framework in accordance with IS/ISO 25539 series, IS/ISO 10993-1, and IS/ISO 14971, addressing potential failure modes throughout the device lifecycle. It outlines key aspects of design and performance evaluation, including in vitro procedural and degradation assessments, physical and chemical degradation studies, material and degradation product testing, imaging compatibility, biological evaluation, and in vitro - in vivo correlation (IVIVC).

In vivo preclinical evaluation must include the collection of minimum data as specified in relevant parts of the IS/ISO 25539 series. Additional guidance specific to absorbable implants is also provided in IS/ISO 10993-6 and IS/ISO 10993-11. For clinical evaluation, IS/ISO 12417-1 offers guidelines covering cardiovascular device-drug combination implants, including patient selection, study duration, control groups, clinical endpoints, data reporting, and analysis requirements.