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BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

शल्य चिकित्सा द्वारा कपाटिका प्रत्यारोपण के लिए परिमाण मापदण्ड : आईएसओ 5840-2 के आवेदन सन्दर्भ में अपेक्षाएं (ISO/PAS 7020:2023)

Draft Indian Standard
Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2 (ISO/PAS 7020:2023)

[ICS: 11.040.40]

Medical and Surgical Cardiology Equipment Sectional Committee (MHD 06)	Last Date for Comments: 29 April 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Standard*	*Degree of Equivalence*
ISO 5840-1:2021, Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements	IS 17840 (Part 1) : 2022 5840-1:2021 Cardiovascular Implants Cardiac Valve Prostheses Part 1 General Requirements	Identical under dual numbering
ISO 5840-2:2021, Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes	IS 17840 (Part 2) : 2022 5840-2:2021 Cardiovascular Implants Cardiac Valve Prostheses Part 2 Surgically Implanted Heart Valve Substitute First Revision	Identical under dual numbering

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

Introduction

0.1 General

In the past, inconsistencies have been reported with the labelling and instructions for use associated with sizing parameters and sizing procedures for surgical replacement heart valves, specifically, mechanical and stented bioprosthetic valves. These inconsistencies have led to confusion among some users about which size valve to implant in a particular patient and have also led to challenges in comparing results (published or otherwise) from one valve model to another. A solution to the problem can be achieved by providing more complete and accurate sizing information to the clinicians, which will ultimately benefit the patients.

ISO 5840-2 identifies a number of sizing parameters that are required in the labelling (including on the unit box, see ISO 5840-2:2021, 6.3.3, and instructions for use) to inform the selection of a surgical heart valve prosthesis to be implanted in a specific patient. However, no guidance is offered in ISO 5840-2 on how these parameters should be obtained.

0.2 Clinical rationale for additional sizing information

Successful valve replacement therapy requires that an adequate size surgical heart valve substitute is used, based on patient body size and the native valve annulus size. An understanding of valve sizing parameters and appropriate choice of size is critical to post-procedure success since a valve substitute that is too small for the patient can result in prosthesis-patient mismatch. For aortic valve replacements, severe mismatch has been reported in 5 % to 15 % of patients. Severe prosthesis-patient mismatch leads to increased early, mid-term and late mortality, especially if the left ventricular ejection fraction (LVEF) is reduced. In the mid-term, it causes a higher incidence of heart failure and limits left ventricular mass regression. In the long term, it can also contribute to accelerated structural valve degeneration (SVD). Patients with severe prosthesis-patient mismatch can require replacement of the valve substitute with another having a larger effective orifice area (EOA). However, re-intervention has significant risk of mortality and morbidity.

The best approach to prosthesis-patient mismatch is prevention. This requires the surgeon to have clear and accurate information about the sizing parameters and EOA of each valve substitute. A surgical heart valve substitute is described by a labelled size given by the manufacturer, which is assumed to be broadly consistent with the size of the patient native valve annulus for which the valve is intended. Literature reviews and studies of haemodynamic function commonly compare valve substitutes by labelled size, but there can be major differences between the patient native valve annulus diameter and the labelled size of the valve substitute. Intraoperative sizing is further complicated by the need for aortic supra-annular valves to fit within the aortic sinus. The disparity between labelled size and actual size means that echocardiographic or clinical comparisons based on labelled size can be misleading.

The issue of valve sizing is a complex problem and is being addressed in a stepwise fashion. The working group revising ISO 5840-2 proposed a first step toward greater transparency by requiring additional information be added to the unit box, namely, internal orifice diameter and effective orifice diameter. Although this information does not necessarily inform the surgeon on whether the valve would fit in the patient's annulus, it helps to estimate the internal orifice available for blood flow and thus

indirectly the EOA. It is not feasible to use clinically measured EOA's since sizing information must be available before a surgical heart valve substitute is released for use in patients. Indeed, it can take a number of years to gather sufficient echocardiographic data to confirm the clinical EOAs. Furthermore, the use of echocardiographic data to help avoid prosthesis-patient mismatch has been criticized because of variability in the measurements obtained in vivo. In vitro steady flow data have less variability and allow meaningful comparison of every design and size of surgical heart valve substitute under the same flow conditions. This information can be used by the surgeon to choose a specific valve substitute type and size based on more standardized parameters than labelled valve size. It is anticipated that further steps toward a standardised approach to sizing will be addressed in subsequent editions of ISO 5840-2.

Scope

This document describes in vitro methods of measurement of the sizing parameters for surgical valves (referring to mechanical and stented bioprosthetic valves only here and hereafter). It represents a consensus reached among manufacturers, independent bioengineers and clinicians, and is underpinned by interlaboratory studies.

This document relates to surgical heart valve prostheses and is intended to be used in conjunction with ISO 5840-1:2021 and ISO 5840-2:2021. Where noted, the requirements of this document clarify certain requirements of ISO 5840-1 and/or ISO 5840-2. Specific methodologies are included for flexible leaflet (bioprosthetic) and rigid (mechanical) valves. Sutureless valves, stentless valves and valved conduits are not included.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO/PAS 7020:2023 or kindly contact:

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