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Size designation of surgical valve prostheses: ~~Guidance on~~Requirements regarding the application of ISO 5840~~-~~-2~~)~~

~~DPAS/stage~~

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Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*~~, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, Non-active surgical implants, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).~~.

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Introduction

0.1 General

In the past, inconsistencies have been reported with the labelling and instructions for use associated with size designations 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~~:2021 Cardiovascular implants — Cardiac valve prostheses — Surgically implanted heart valve substitutes identify~~ identifies a number of sizing parameters that are required in the labelling (including on the unit box, see ~~Clause~~ISO 5840-1:2021, 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 ~~the Standard for~~ISO 5840-2 on how these measurements should be obtained.

~~This document (PAS 7020) describes in vitro methods of measurement of these 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 inter-laboratory round-robin studies.~~

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 ~~may~~can result in prosthesis-patient mismatch. For aortic valve replacements, severe mismatch has been reported in 5 % to 15 % of patients~~[.[1].]~~. Severe prosthesis-patient mismatch leads to increased early, mid-term and late mortality, especially if the left ventricular ejection fraction (LVEF) is reduced~~[.[2]-[5].]~~. In the mid-term, it causes a higher incidence of heart failure[5] and limits left ventricular mass regression~~[.[5].]~~. In the long -term, it ~~may~~can also contribute to accelerated structural valve degeneration (SVD)~~[].[6].~~ Patients with severe prosthesis-patient mismatch ~~may~~can require replacement of the valve substitute with another having a larger 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 size 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[1] and studies of ~~hemodynamic~~haemodynamic function commonly compare valve substitutes by labelled size, but there ~~may~~can be major differences between the patient native valve annulus diameter and the labelled size of the valve substitute~~[.[8]-[11].]~~. 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 ~~may~~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 ~~may~~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 ~~criticised~~criticized because

of variability in the measurements obtained in vivo~~[.][12].~~ 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 ~~revisions~~editions of ISO 5840-2.

This document provides further specifications to explain these new measures and to guide the manufacturer in selecting reproducible methods to obtain these parameters and the degree of accuracy required.

~~**ISO/PAS 7020** (Sizing~~

Size designation of surgical valve prostheses: ~~Guidance on~~Requirements regarding the application of ISO 5840-2~~)~~

1 Scope

This document describes in vitro methods of measurement of these 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 ~~shall~~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.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5840-1:2021, *Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements*~~.~~

ISO 5840-2:2021, *Cardiovascular implants ~~–~~— Cardiac valve prostheses ~~–~~— Part 2: Surgically implanted heart valve substitutes*~~.~~

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain ~~terminological~~terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
effective orifice area
~~,~~EOA
orifice area that has been derived from flow and pressure or velocity data

Note 1 to entry: For in vitro testing, EOA is defined as: