INTERNATIONAL STANDARD

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Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

Implants cardiovasculaires — Prothèses valvulaires —
Partie 2: Prothèse valvulaires implantées chirurgicalement

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems.*

This first edition of ISO 5840-2, together with ISO 5840-1 and ISO 5840-3, cancels and replaces ISO 5840:2005, which has been technically revised.

ISO 5840 consists of the following parts, under the general title *Cardiovascular implants — Cardiac valve prostheses:*

— *Part 1: General requirements*

— *Part 2: Surgically implanted heart valve substitutes*

— *Part 3: Heart valve substitutes implanted by transcatheter techniques*

Introduction

This part of ISO 5840 has been prepared for surgical heart valve substitutes with emphasis on specifying types of *in vitro* testing, preclinical *in vivo* and clinical evaluations, reporting of all *in vitro*, preclinical *in vivo*, and clinical evaluations and labelling and packaging of the device. This process is intended to clarify the required procedures prior to market release and to enable prompt identification and management of any subsequent issues.

This part of ISO 5840 is to be used in conjunction with ISO 5840-1.

Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

1 Scope

This part of ISO 5840 is applicable to heart valve substitutes intended for implantation in human hearts, generally requiring cardiopulmonary bypass and generally with direct visualization.

This part of ISO 5840 is applicable to both newly developed and modified surgical heart valve substitutes and to the accessories, packaging, and labelling required for their implantation and for determining the appropriate size of the surgical heart valve substitute to be implanted.

This part of ISO 5840 outlines an approach for qualifying the design and manufacture of a surgical heart valve substitute through risk management. The selection of appropriate qualification tests and methods are derived from the risk assessment. The tests may include those to assess the physical, chemical, biological, and mechanical properties of surgical heart valve substitutes and of their materials and components. The tests may also include those for pre-clinical *in vivo* evaluation and clinical evaluation of the finished surgical heart valve substitute.

This part of ISO 5840 defines performance requirements for surgical heart valve substitutes where adequate scientific and/or clinical evidence exists for their justification.

For novel surgical heart valve substitutes, e.g. sutureless, the requirements of both this International Standard and ISO 5840-3 might be relevant and shall be considered as applicable to the specific device design and shall be based on the results of the risk analysis.

This part of ISO 5840 excludes heart valve substitutes designed for implantation in artificial hearts or heart assist devices.

This part of ISO 5840 excludes homografts.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5840-1:2015, *Cardiovascular implants and extracorporeal systems — Cardiac valve prostheses — Part 1: General requirements*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 16061, *Instrumentation for use in association with non-active surgical implants – General requirements*

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO 22442 (all parts), *Medical devices utilizing animal tissues and their derivatives*

ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM F2119, *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*

ASTM F2182, *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*

ASTM F2213, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*

ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions given in ISO 5840-1 and the following apply.

3.1
cycle rate
number of complete cycles per unit of time, usually expressed as cycles per minute (cycles/min)

3.2
internal orifice diameter
numerical indication of the minimum diameter within a surgical heart valve substitute through which blood flows

Note 1 to entry: See Figure 1.

3.3
intra-annular sewing ring
sewing ring designed to secure the surgical heart valve wholly or mostly within the patient's tissue annulus

Note 1 to entry: See Figure 1.

Note 2 to entry: See also 3.2, 3.10, and 3.12.