INTERNATIONAL STANDARD

ISO 5840-3

Redline version compares Second edition to First edition

Cardiovascular implants — Cardiac valve prostheses —

Part 3: Heart valve substitutes implanted by transcatheter techniques

Implants cardiovasculaires — Prothèses valvulaires —

Partie 3: Valves cardiaques de substitution implantées par des techniques transcathéter

Reference number
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IMPORTANT

This marked-up version uses the following colour-coding:

Text example 1 — Text has been added (in green)

~~Text example 2~~ — Text has been deleted (in red)

 — Graphic figure has been added

 — Graphic figure has been deleted

1.x ... — If there are changes in a clause/subclause, the corresponding clause/subclause number is highlighted in yellow in the Table of contents

DISCLAIMER

This marked-up version highlights the main changes in this edition of the document compared with the previous edition. It does not focus on details (e.g. changes in punctuation).

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Foreword

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~~International Standards are~~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 ~~rules given in~~editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.~~

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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

~~ISO 5840-3~~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).

This second edition cancels and replaces the first edition (ISO 5840-3:2013), which has been technically revised.

The main changes compared to the previous edition are as follows: the engineering and clinical requirements in the ISO 5840 series have been updated to current specifications and integrated and harmonized across all parts.

A list of all parts in the ISO 5840 series ~~consists of the following parts, under the general title~~can be found on the ~~*Cardiovascular implants — Cardiac valve prostheses*~~ISO website.

~~— *Part 3: Heart valve substitutes implanted by minimally invasive techniques*~~

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

~~No heart valve substitute is ideal. Therefore, a group of engineers, scientists and clinicians well aware of the problems associated with~~This document has been prepared for transcatheter heart valve substitutes ~~and their development has prepared this part of ISO 5840. In several areas, the provisions of this part of ISO 5840 have been deliberately left partially defined so as not to inhibit development and innovation. This part of ISO 5840 specifies types of tests, test methods and requirements for test apparatus. It requires documentation of test methods and results. This part of ISO 5840 deals with those areas that will ensure adequate mitigation of device-associated risks for patients and other users of the device, facilitate quality assurance, aid the cardiac surgeon and cardiologist in choosing a heart valve substitute, and ensure that the device will be presented in a convenient form. This part of~~with emphasis on providing guidance for ~~ISO 5840 emphasizes the need to specify types of~~ *in vitro* testing, preclinical *in vivo* and clinical evaluations ~~as well as to report~~, reporting of all *~~in vitro~~ vitro*, preclinical *in vivo*, and clinical evaluations. ~~It describes the labels~~ and labelling and packaging of the device. ~~Such a process involving~~This process ~~*in vitro*, preclinical *in vivo* and clinical evaluations~~ is intended to clarify the required procedures prior to market release and to enable prompt identification and management of any subsequent ~~problems~~issues.

~~With regard to *in vitro* testing and reporting, apart from basic material testing for mechanical, physical, chemical and biocompatibility characteristics, this part of ISO 5840 also covers important hydrodynamic and durability characteristics of transcatheter heart valve substitutes and their delivery systems. This part of ISO 5840 does not specify exact test methods for hydrodynamic and durability testing but it offers guidelines for the test apparatus.~~

~~This part of ISO 5840 should be revised, updated and amended as knowledge and techniques in heart valve substitute technology improve.~~

This ~~part of ISO 5840~~document is ~~to be~~ used in conjunction with ISO 5840~~:2005~~-1, ~~which will be replaced by~~ and ISO 5840-~~1~~2 ~~in future~~.

Cardiovascular implants — Cardiac valve prostheses —

Part 3: Heart valve substitutes implanted by transcatheter techniques

1 Scope

This document is applicable to all devices intended for implantation as a transcatheter heart valve substitute.

This document is applicable to transcatheter heart valve substitutes and to the accessory devices, packaging and labelling required for their implantation and for determining the appropriate size of heart valve substitute to be implanted.

This ~~part of ISO 5840 outlines~~document establishes an approach for verifying/validating the design and manufacture of a transcatheter heart valve substitute through risk management. The selection of appropriate verification/validation tests and methods are to be derived from the risk assessment. The tests can include those to assess the physical, chemical, biological and mechanical properties of heart valve substitutes and of their materials and components. The tests can also include those for preclinical *in vivo* evaluation and clinical evaluation of the finished heart valve substitute.

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

This ~~part of ISO 5840 is applicable to all devices intended for implantation in human hearts as~~document includes considerations for implantation of a transcatheter heart valve substitute: inside a pre-existing prosthetic device (e.g. valve-in-valve and valve-in-ring configurations).

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

~~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 valve-in-valve configurations and homografts.~~

~~This part of ISO 5840 does not specifically address non-traditional surgically implanted heart valve substitutes (e.g. sutureless). For these devices, the requirements of both this part of ISO 5840 and ISO 5840:2005 might be relevant and can be considered.~~

~~NOTE A rationale for the provisions of this part of ISO 5840 is given in Annex A.~~

2 Normative references

The following ~~referenced~~ documents are ~~indispensable for the application of~~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 ~~10993~~5840-1:2021, ~~*Biological evaluation of medical devices*~~*Cardiovascular implants — Cardiac valve prostheses — Part 1: ~~Evaluation and testing within a risk management process~~General requirements*