TECHNICAL SPECIFICATION

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Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants

Implants cardiovasculaires et systèmes extracorporels — Implants cardiovasculaires absorbables

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Contents

Page

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 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.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This third edition cancels and replaces the second edition (ISO/TS 17137:2019), which has been technically revised.

The main changes compared to the previous edition are as follows:

— considerations have been added to multiple clauses regarding degradation-induced device fracture and the generation of absorbable particulate matter after mechanical attributes are lost;

— clauses about labelling and instructions for use (IFU) have been modified;

— Figure 2 has been modified to facilitate translation into multiple languages;

— standards with guidance for characterization of absorbable polymers and metals have been elaborated.

— additional guidance regarding animal and clinical study design, limitations, and assessment has been added.

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

Absorbable cardiovascular implants are medical devices with various clinical indications for use in the human cardiovascular blood system. An absorbable cardiovascular implant, or at least a portion thereof, is designed to intentionally degrade over time into degradation products that are absorbed by the body through either metabolism, assimilation, or excretion (elimination), or all. Such implants can be either surgically introduced or introduced through intervention to the site of treatment.

This document outlines requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer. This document is intended to be a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants. This document is intended to also be a supplement to relevant device-specific standards such as the ISO 25539 series specifying requirements for endovascular devices, which do not address degradation and other time dependent aspects of absorbable implants and coatings. Additionally, this document should be considered in conjunction with ISO 14155, which specifies proper practices in clinical investigations.

This document is not comprehensive with respect to the pharmacological evaluation of cardiovascular absorbable implants. More detailed safety and performance requirements for pharmacological agents included in the absorbable cardiovascular implant are described in ISO 12417-1.

Only issues related to degradation and absorption combined with the cardiovascular implant are covered by this document. Due to the variations in the design of implants covered by this document and in some cases due to the relatively recent development of some of these implants (e.g. absorbable stents), acceptable standardized in vitro tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this document will be necessary.

NOTE For issues related to the common mechanical function of the cardiovascular implant, it can be useful to consider a number of other international standards that are given in the Bibliography.

Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants

1 Scope

This document establishes design evaluation requirements and recommendations for absorbable cardiovascular implants used to treat vessels and/or the vascular space within the circulatory system, including the heart and all vasculature. This document is intended to supplement device-specific standards by providing guidelines specific for either absorbable implants or components, or both.

This document is applicable to implants in direct contact with the cardiovascular system, where the intended action is upon the circulatory system. This document does not address the specific evaluation of issues associated with viable tissues, viable cells, and/or implants with non-viable biological materials and their derivatives. Additionally, procedures and devices used prior to and following the introduction of the absorbable cardiovascular implant (e.g. balloon angioplasty devices) are excluded from the scope of this document if they do not affect the absorption aspects of the implant. A cardiovascular absorbable implant can incorporate substance(s) which, if used separately, can be considered to be a medicinal product (drug product) but the action of the medicinal substance is ancillary to that of the implant and supports the primary mode of action of the implant.

NOTE 1 Some aspects of absorbable components of cardiovascular device-drug combination products (e.g. coatings) in their connection with drug-related aspects of the device are addressed in ISO 12417-1.

NOTE 2 An explanation of the nomenclature of absorb, degrade and related terms can be found in Annex A.

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 undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5840 (all parts), *Cardiovascular implants — Cardiac valve prostheses*

ISO 10993 (all parts), *— Biological evaluation of medical devices*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 12417-1, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements*

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

ISO 14630:2012, *Non-active surgical implants — General requirements*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 25539 (all parts), *Cardiovascular implants — Endovascular devices*

ISO/TS 37137-1, *Biological evaluation of absorbable medical devices — Part 1: General requirements*

3 Terms and definitions

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

ISO and IEC maintain terminological 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
absorb
absorption
<biomaterial> action of a non-endogenous (foreign) material or substance or its degradation products passing through or being assimilated by either cells or tissue, or both over time

3.2
degradation product
intermediate or final result from the physical, metabolic, and/or chemical decomposition, of a material or substance

3.3
degrade
physically, metabolically, and/or chemically decompose a material or substance

3.4
leachable
substance that can be released from a medical device or material during clinical use

Note 1 to entry: In absorbable devices, leachables can be substances released from the as-manufactured product or substances generated and released as a consequence of its degradation (i.e. degradation products).

3.5
particulate
particle
particulate matter
mobile material (other than gas bubbles) that are either present on or arise from the presence or use of the device

4 Device design, fabrication, packaging, and use considerations

4.1 Classification

A cardiovascular absorbable implant is a product that accomplishes its intended clinical use and performance through primarily either physical or mechanical, or both, means over a defined time period. An absorbable cardiovascular implant may also incorporate a medicinal substance. A cardiovascular absorbable implant accomplishes its intended clinical use and is then fully or partially absorbed by the body over a finite period of time. The implant's temporary nature is provided by its