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Cardiovascular implants — Transcatheter cardiac occluders

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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*.

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

The field of transcatheter cardiac occluders has advanced and expanded significantly in recent years. Therefore, a group of engineers, scientists, and clinicians, experts well aware of the problems associated with transcatheter cardiac occluder devices and their development, has prepared this document. This document deals with those areas that will help ensure adequate mitigation of device-associated risks for patients and other users of the device, facilitate quality assurance, and help ensure that the device will be provided in a convenient and usable form. This document emphasizes the need to specify and report types of in vitro testing, preclinical in vivo, and clinical evaluations. It describes the requirements for labels and packaging of the device. The in vitro, preclinical in vivo, and clinical evaluations described in this document are intended to help establish safety and performance of a transcatheter cardiac occluder.

This document outlines an approach for minimizing adverse events from the implantation of a transcatheter cardiac occluder through risk management. The selection of appropriate verification or validation tests and methods are derived from the risk assessment and design input requirements. The tests include those to assess the physical, mechanical, chemical, and biological properties of transcatheter cardiac occluders and of their materials and components. The tests also include those for preclinical in vivo evaluation and clinical evaluation of the transcatheter cardiac occluders.

Cardiovascular implants — Transcatheter cardiac occluders

1 Scope

This document specifies important in vitro tests including functional and durability characteristics of transcatheter cardiac occluders, and their delivery systems and accessories. This document does not specify exact test methods for functional and durability testing, but it offers requirements and recommendations for performance tests of the cardiac occluder system.

Surgical occluders have been omitted from the scope of this document given their significant differences in device geometry, materials, implantation methods, and test methods as compared to transcatheter cardiac occluders.

This document is applicable to all intracardiac occluders intended for transcatheter implantation in humans (e.g. atrial septal occluder, ventricular septal occluder, patent foramen ovale occluder, left atrial appendage occluder, and paravalvular leak occluders). This document does not cover non-cardiac occluders, but elements of this document can be applicable to patent ductus arteriosus occluders.

The following devices and components are outside the scope of this document: surgical devices, cardiac shunt devices, atrial flow regulators, active components (such as sensors), or degradable or animal tissue components.

This document is applicable to both newly developed and modified cardiac occluders, their accessory devices, packaging, and labelling.

This document defines operational conditions and performance requirements for cardiac occluders where either adequate scientific or clinical evidence, or both, exists for their justification.

NOTE At the time of this document, it is impossible to take all future and emerging technologies into consideration. The cardiac occluder systems based on these new technologies can benefit from evaluation based on the basic requirements of this document. Testing beyond the scope of this document can also be necessary in order to verify and validate these cardiac occluder systems.

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 10555-1, *Intravascular catheters — Sterile and single-use catheters — 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 11070, *Sterile single-use intravascular introducers, dilators and guidewires*

ISO 11135-1, *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 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

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

ISO 14630, *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 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical 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/TS 17665-2, *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1*

ISO/TS 17665-3, *Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

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 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 apply.