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Cardiovascular implants — Transcatheter cardiac occluders

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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).

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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.

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.

ISO and IEC maintain 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
access system
system consisting of a variety of components (e.g. sheath, haemostasis control valve, side ports for administration of physiological fluids and medications) to provide vascular access for the *cardiac occluder* (3.3) *delivery system* (3.8)

3.2
adverse event
AE
untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings), in subjects, users or other persons, whether or not related to the investigational medical device

Note 1 to entry: This definition includes events related to the investigational medical device or the comparator.

Note 2 to entry: This definition includes events related to the procedures involved.

Note 3 to entry: For users or other persons, this definition is restricted to events related to investigational medical devices.

3.3
cardiac occluder
non-active (3.20) implant to occlude a specific cardiac anatomic structure (e.g. atrial septal defects, ventricular septal defects, patent foramen ovale, left atrial appendage) or seal an abnormal site of blood flow (e.g. heart valve substitute paravalvular leak)

3.3.1
atrial septal occluder
cardiac occluder (3.3) used to treat an atrial septal defect

3.3.2
left atrial appendage occluder
cardiac occluder (3.3) used to close the opening of the left atrial appendage

3.3.3
paravalvular leak occluder
cardiac occluder (3.3) used to close a paravalvular leak

3.3.4
patent ductus arteriosus occluder
occluder used to close a patent ductus arteriosus

3.3.5
patent foramen ovale occluder
cardiac occluder (3.3) used to close a patent foramen ovale

3.3.6
ventricular septal occluder
cardiac occluder (3.3) used to treat a ventricular septal defect

3.4
cardiac occluder system
supplied components, such as the *cardiac occluder* (3.3), *access system* (3.1), *delivery system* (3.8), accessories, packaging and labelling

3.5
delivery approach
anatomical access used to deliver the *cardiac occluder* (3.3) to the intended *implant site* (3.17) (e.g. transfemoral, transseptal)

3.6
delivery catheter
component of the *delivery system* (3.8), used to advance and deploy a *cardiac occluder* (3.3) to the intended implantation site

3.7
delivery sheath
hollow tube that traverses the skin and subcutaneous tissue and enters the endovascular space to facilitate entry of wires and catheters

3.8
delivery system
system [e.g. *delivery catheter* (3.6)] used to deliver, deploy, attach or adjust [i.e. *recapture* (3.22) or retrieve] a *cardiac occluder* (3.3) in the intended implantation site

3.9
design validation
establishment by objective evidence that device specifications conform with user needs and *intended use(s)* (3.18)

3.10
design verification
establishment by objective evidence that the design output meets the design input requirements

3.11
device embolization
post-deployment or peri-procedural dislodgement of the *cardiac occluder* (3.3), from the implantation site or catheter, respectively, to an unintended and non-therapeutic location via the bloodstream

3.12
device failure
inability of a *cardiac occluder* (3.3) to perform its intended function sufficient to cause a hazard

3.13
device migration
detectable movement or displacement of the *cardiac occluder* (3.3) from its original position within close proximity of the intended *implant site* (3.17), without embolization

3.14
failure mode
mechanism of *device failure* (3.12) [e.g. catastrophic support structure *fracture* (3.15)]

3.15
fracture
unintentional disruption, under the action of applied load (e.g. force, torque, or deformation), of a *structural element* (3.32) of the *cardiac occluder system* (3.4) that were previously intact

3.16
imaging modality
imaging method used to facilitate diagnosis, delivery and/or *retrieval* (3.24)/*recapture* (3.22) of the implant within the target *implant site* (3.17), as well as to assess *cardiac occluder* (3.3) performance after implantation

3.17
implant site
intended anatomic site of a *cardiac occluder* (3.3) deployment

3.18
intended use
use of a *cardiac occluder* (3.3) in accordance with the specifications, instructions and information provided by the manufacturer

3.19
membrane
flexible synthetic material covering or integrated within a portion or all of the cardiac occlude

3.20
non-active
implant which does not depend on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.21
protective packaging
configuration of materials designed to prevent damage to the *sterile barrier system* (3.31) and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11607-1:2019, 3.14]

3.22
recapture
process of returning the *cardiac occluder* (3.3) back into the *delivery system* (3.8), following partial or full deployment, but prior to its release

3.23
repositioning
change in implant position and/or orientation of a partially or fully deployed *cardiac occluder* (3.3) via a transcatheter technique, possibly requiring full or partial recapturing of the device

3.24
retrieval
removal of a partially or fully deployed *cardiac occluder* (3.3) via a transcatheter or surgical technique

3.25
risk
combination of the probability of occurrence of harm and the *severity* (3.30) of that harm

[SOURCE: ISO 14971:2019, 3.18]

3.26
risk analysis
systematic use of available information to identify hazards and to estimate the associated *risk(s)* (3.25)

[SOURCE: ISO 14971:2019, 3.19, modified — "associated" has been added and "(s)" has been added to "risk".]

3.27
risk assessment
overall process comprising a *risk analysis* (3.26) and a *risk* (3.25) evaluation

[SOURCE: ISO 14971:2019, 3.20]

3.28
sample size
quantity of individual specimens of a device tested

[SOURCE: ASTM F3172-15:2015, 3.1.13]

3.29
safety
freedom from unacceptable *risk* (3.25)

[SOURCE: ISO 14971:2019, 3.26]

3.30
severity
measure of the possible consequences of a hazard

[SOURCE: ISO 14971:2019, 3.27]

3.31
sterile barrier system
minimum package that minimizes the *risk* (3.25) of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

[SOURCE: ISO 11607-1:2019, 3.23]

3.32
structural element
stent or frame component of a *cardiac occluder* (3.3)

3.33
withdrawal
removal of the occluder *delivery system* (3.8) with or without the *cardiac occluder* (3.3)

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

ADE	adverse device effect
AE	adverse event
AFib	atrial fibrillation
ASD	atrial septic defect
CEC	Clinical Events Committee
CIP	clinical investigation plan
CMR	cardiac magnetic resonance
CRF	case report form
CT	computed tomography
DIC	disseminated intravascular coagulation
DSMB	Data Safety Monitoring Board
EC	Ethics Committee
GCP	Good Clinical Practice
HIT	heparin-induced thrombocytopenia
ICE	intracardiac echocardiography

IFU	instructions for use
IRB	Institutional Review Board
LAA	left atrial appendage
MRI	magnetic resonance imaging
NYHA	New York Heart Association
PCI	percutaneous coronary intervention
PMCF	post-market clinical follow-up
PDA	patent ductus arteriosus
PET	position emission tomography
PFO	patent foramen ovale
PVL	paravalvular leak
SADE	serious adverse device effect
SAE	serious adverse event
TEE	transesophageal echocardiography
TTE	transthoracic echocardiography
VSD	ventricular septal defect

5 Fundamental requirements

5.1 General

The activities described within this document shall be carried out within a formal quality system.

NOTE ISO 13485 contains requirements for a suitable quality system for a medical manufacturer. Additional requirements can be specified by a country or region.

5.2 Risk management

The manufacturer shall define, implement and document risk management activities in accordance with ISO 14971. A risk-based methodology challenges the manufacturer to continually analyse and evaluate known and theoretical risks of the device, to develop the most appropriate methods for mitigating the risks of the device, and to implement the appropriate test, analysis methods, or rationale to demonstrate the residual risks are acceptable (see Annex A).

Annex B provides an example of a hazard analysis to serve as a starting point for a risk analysis specific to some cardiac occluder devices.

Annex I provides definitions and examples of adverse events that can be useful in the risk management process.

As part of the risk management process, the manufacturer shall establish, document, implement and maintain a usability engineering process, linked but distinct from the device design process, as detailed in IEC 62366-1.

6 Device description

6.1 General

The requirements of ISO 14630 shall apply.

6.2 Intended use

The manufacturer shall identify the pathological condition(s) to be treated, the intended patient population and intended claims. The manufacturer shall also consider the intended user(s) of the medical device and the environments in which it is used.

6.3 Design inputs

6.3.1 Operational principles and specifications

The manufacturer shall define the operational specifications for the device including the principles of operation, intended device delivery approach or process, durability, shelf life, shipping or storage limits, and the physiological environment in which it is intended to function. The manufacturer shall define relevant anatomical characteristics and device dimensional parameters that will be required to select either the device model or size, or both. Additionally, if designed for periprocedural modification, define how the device configuration will be determined (see Annex O and Annex G).

6.3.2 Functional, performance and safety requirements

6.3.2.1 General

The manufacturer shall establish (i.e. define, document and implement) the functional, performance and safety requirements of the cardiac occluder system for the intended use and device claims.

6.3.2.2 Implantable device

The intended performance of the cardiac occluder device shall take into consideration at least the following:

a) the ability to occlude undesired blood flow;

b) the ability to resist migration and embolization;

c) the ability to minimize haemolysis;

d) the ability to minimize undesired thrombus formation;

e) biocompatibility;

f) the ability to resist corrosion;

g) the ability to minimize particulate shedding;

h) compatibility with adjacent anatomical structures or other implanted devices, if applicable;

i) compatibility with diagnostic imaging techniques (e.g. MRI);

j) visibility under diagnostic imaging techniques (e.g. MRI, echocardiography, fluoroscopy, CT);

k) deliverability and implantability in the target population;

l) the ability to maintain structural and functional integrity during the expected lifetime of the device;

m) the ability to maintain structural integrity, functionality and sterility for the labelled shelf life prior to implantation;

n) the ability to be consistently and safely prepared for implantation;

o) the ability to be consistently and safely implanted in the intended implantation site and achieve the aforementioned performance objectives;

p) the ability to be either safely retrieved, adjusted or repositioned, or all, if applicable.

NOTE See ISO 14630.

6.3.2.3 Access and delivery system

The functional, performance and safety requirements of the access and delivery system shall be established (see Annex M). All supplied sterile single-use intravascular catheters shall follow ISO 10555-1. If sterile single-use intravascular introducers, dilators or guidewires are supplied by the manufacturer, then they shall follow ISO 11070, as applicable. For cardiac occluder systems which either require or allow the user to select a non-supplied access system, the attributes of the non-supplied access system shall be established for it to be compatible with the cardiac occluder delivery system. These attributes include minimum inner diameter and length.

The design attributes shall take into consideration at least the following to meet the intended performance of the delivery and access system:

a) compatibility of the access system, delivery system, and the cardiac occluder;

b) the ability to permit consistent, accurate and safe loading, access, delivery, deployment and release of the cardiac occluder to the intended implantation site;

c) the ability to permit consistent and safe withdrawal of the delivery system prior to and after deployment of the cardiac occluder device;

d) the ability to minimize thrombus formation;

e) the ability to minimize blood loss;

f) the ability to either retrieve, reposition, or remove the cardiac occluder device, or all, if applicable;

g) biocompatibility;

h) the ability to resist corrosion;

i) the ability to maintain integrity of the coating, if applicable;

j) the ability to minimize particulate generation;

k) the ability to maintain its functionality and sterility for the labelled shelf life;

l) compatibility and visibility with diagnostic imaging techniques (e.g. MRI, echo, fluoroscopy, CT), if applicable;

m) compatibility with tools and accessories required to complete the procedure.

n) the ability to avoid air thrombus during the procedure;

o) the ability to inject contrast agent through the applicable changes of the procedure, if applicable.

6.3.3 Implant procedure: Device and usability requirements

The cardiac occluder system shall provide intended users the ability to safely and effectively perform pre-operative, intra-operative, and post-operative procedural tasks to achieve desired outcome. This shall include procedure-specific tools and accessories that intended users will need to complete the