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Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

Implants cardiovasculaires — Dispositifs endovasculaires —

Partie 1: Prothèses endovasculaires

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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso. org/iso/foreword. html.

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

This second edition cancels and replaces the first edition (ISO 25539-1:2003), which has been technically revised.

It also incorporates the Amendment ISO 25539-1:2003/Amd1:2005.

A list of all the parts of ISO 25539 can be found on the ISO website.

Introduction

This document was prepared to provide minimum requirements for endovascular prostheses. The normative requirements are provided in the main body. The rationale for the requirements for bench tests and analyses to assess device performance, guidance on the identification of appropriate testing to evaluate a specific device design and guidance for developing test methods are provided in informative annexes. Further clarification of terminology and a cross reference between the main body and these annexes are provided in additional informative annexes.

This document has been updated to reflect current knowledge regarding the testing and clinical use of endovascular prostheses, reflected in modifications to the requirements in the main body and in the guidance for developing test methods in Annex D. In addition, revisions have been made to improve consistency in nomenclature and reporting and to enhance the utility of this document.

This document introduces methodology to identify appropriate testing and analyses for specific endovascular prosthesis, designated as the device evaluation strategy (DES). The requirement regarding the DES is in the main body, with informative guidance for the preparation of a DES table included in Annex A. Annex A also provides guidance for developing a DES for device design modifications and changes in intended use.

The other significant modifications in the requirements include the addition of non-radial durability testing, with guidance on the selection of appropriate testing, and specific requirements for testing to evaluate patency-related characteristics. Guidance for the development of appropriate tests to meet these requirements is included in Annex D.

The guidance on the development of methods to address the requirement for evaluating fatigue and durability through computational analyses has been modified significantly to include recommendations regarding verification of the solution and validation of the computational model, as well as reporting. The guidance on the model development for simulated use has also been significantly revised to improve the clinical relevance of this testing.

New requirements also include the evaluation of leakage at a seal zone and dislodgement force of endovascular prosthesis from a balloon. Guidance for the development of appropriate tests to meet these requirements is included in Annex D.

The requirement for evaluating the strength of the connection(s) between the graft material and a discrete fixation system(s) has been clarified with respect to the applicability of this requirement, that is, this requirement is only applicable for prostheses with a fixation system that is discrete from any stent(s) intended to provide structural support within the prosthesis [e.g. suprarenal stent that is not continuous with the stent(s) in the prosthesis body].

The specific requirements to evaluate pushability, flexibility, torquability, trackability and deployment accuracy of an endovascular system have been removed and incorporated within the simulated use evaluation requirement to better reflect how these attributes are evaluated. Similarly, the requirement to evaluate tubing tensile strength has been removed and incorporated within the evaluation of tensile bond strength.

The requirement to evaluate stent-free surface area has been removed as this attribute is not relevant for endovascular prostheses, which includes covered stents.

In addition to modifications to specific design evaluation requirements, guidance has been provided regarding the assessment of the acceptability of test results. When the requirement is to quantitatively appraise or analyse a parameter, test results generally may be compared to a quantitative value (i.e. acceptance criteria). For characterization tests, it is appropriate to provide an explanation of the relevance of the results. Additionally, some testing may include comparison to test data or existing data from a previously evaluated device.

For design evaluation, requirements regarding sampling, conditioning of test samples and reporting have been incorporated in the main body. Guidance on these elements of testing and documentation were previously included in Annex D.

The revisions to the titles of the annexes to this document are as follows.

Annex	ISO 25539-1:2003+A1:2005	ISO 25539-1:2017
A	Attributes of endovascular devices — Technical and clinical considerations	Relationship between testing requirements and device attributes and potential failure modes
B	Bench and analytical tests	Description of device and clinical effects of failure
C	Definitions of reportable clinical events	Bench and analytical tests
D	Test methods	Test methods
E	Sample equations as a supplement to the radial fatigue and durability test	There is no Annex E as this information was incorporated in Annex D

It is recognised by this ISO committee that many endovascular systems have been shown to be safe and effective in clinical use. This update is not intended to require additional evaluation of these devices to remain in compliance with this document as the testing would not provide useful information regarding the expected clinical performance of the device. Manufacturers may rely on historical data gathered under the guidance of the previous version of this document. Similarly, for device modifications or changes in intended clinical use, this update is not intended to require additional evaluation of any aspects of the device that are not expected to change clinical performance.

Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

1 Scope

This document specifies requirements for the evaluation of endovascular systems (prostheses and delivery systems) and requirements with respect to nomenclature, design attributes and information supplied by the manufacturer based upon current medical knowledge. Guidance for the development of *in vitro* test methods is included in an informative annex to this document. This document can be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

This document is applicable to endovascular systems used to treat aneurysms, stenoses or other vascular anomalies or pathologies (e.g. dissections, transections) or to create shunts between vessels [e.g. creation of transjugular intrahepatic portosystemic shunting (TIPS)]. Some of the requirements are specific to endovascular treatment of arterial aneurysms or stenoses. Although uses of endovascular systems other than treatment of arterial aneurysms or stenoses (e.g. dissections, transections, shunts) are within the scope of this document, the specific requirements and testing are not described. Similarly, specific prosthesis configurations (e.g. fenestrated, branched) are within the scope, but specific requirements and testing are not described for these devices.

This document is not applicable to vascular occluders, with the exception of contra-lateral iliac artery occluders when used as an integral part of aorto-uni-iliac endovascular prosthesis. Although contra-lateral iliac artery occluders when used as an integral part of aorto-uni-iliac endovascular prosthesis are within the scope of this document, specific requirements and testing are not described for these devices.

Balloons used to achieve adequate apposition of the prosthesis with the vessel wall or overlapping components are within the scope of this document, even if they are not integral to the endovascular system. This document provides requirements beyond the requirements of ISO 10555-4, specific to the use of balloons with endovascular prostheses.

This document is not applicable to procedures and devices used prior to the introduction of the endovascular system, such as balloon angioplasty devices.

The valve component of valved conduits constructed with an endovascular prosthesis component and the combination of the valved component and the endovascular prosthesis component are excluded from the scope of this document. This document can be helpful in identifying the appropriate evaluation of the endovascular prosthesis component of a valved conduit, but specific requirements and testing are not described for these devices.

NOTE 1 Cardiac valved conduits are within the scope of ISO 5840-1.

Pharmacological aspects of drug eluting or drug coated endovascular prostheses are not addressed in this document.

NOTE 2 Vascular device-drug combination products are within the scope of ISO 12417.

This document does not address the requirements for, and the evaluation of, viable tissues and non-viable biologic materials used in the construction of endovascular prostheses.

The requirements for, and the evaluation of, degradation and other time-dependant aspects of absorbable materials used in the construction of endovascular prostheses are not addressed in this document.

NOTE 3 Absorbable materials are within the scope of ISO/TS 17137 and ISO/TR 37137.

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 7198:2016, *Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches*

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

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 (all parts), *Sterilization of health care products — Radiation*

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

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

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

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*

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 terms and definitions given in ISO 7198 and ISO 14630 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp/

NOTE Additional descriptions of device and clinical effects of failure are included in Annex B.

3.1
adverse event
adverse change in health that occurs in a subject who participates in a study while receiving the treatment or within a specified time after receiving treatment

Note 1 to entry: For the purpose of this document, clinical effects of failure are a subset of adverse events and are described separately.

Note 2 to entry: Adverse events are categorized by the system affected (e.g. cardiac, vascular, respiratory, neurological, renal, gastro-intestinal) and the severity of the event.

3.2
clinical effect of failure
specific clinical observations potentially associated with device failures

Note 1 to entry: The term device failure relates to the definition of a hazard as found in ISO 14971.

Note 2 to entry: Clinical effects of failure are described in Annex B.

3.3
delivery system
system or mechanism used to deliver the *endovascular prosthesis* (3.9) to the targeted position and then to deploy the prosthesis

Note 1 to entry: The delivery system is removed after implant deployment.

3.4
determine
quantitatively appraise or analyse

3.5
device effect of failure
consequence to the device potentially associated with device failures

Note 1 to entry: Device effects of failure are described in Annex B.

3.6
device evaluation strategy
DES
rationale for the testing selected to evaluate a specific *endovascular system* (3.10), based on the requirements of the device design and potential *failure modes* (3.13)

3.7
device evaluation strategy table
DES table
optional communication tool to present the *DES* (3.6) for a specific *endovascular system* (3.10)

3.8
endoleak
persistence of blood flow outside the lumen of an *endovascular prosthesis* (3.9), but within an aneurysm sac or vascular segment being treated by the graft

Note 1 to entry: Endoleaks in the presence of aneurysm are categorized as follows.

— Type I endoleak arising at or from a sealing zone, occurring at the proximal (Type Ia) or distal (Type Ib) attachment zone.

— Type II endoleak is caused by retrograde flow from patent branch arteries, for example, lumbar and intercostal arteries.

— Type III endoleak arises from an inadequate seal between modular graft components (Type IIIa) or from a defect in the *graft material* (3.15) (Type IIIb).

— Type IV endoleak is due to graft permeability, often identified by a generalized blush of contrast within the aneurysm sac.

3.9
endovascular prosthesis
endovascular graft
endovascular implant
vascular prosthesis (including modular components) which resides partially or completely within a blood vessel, or vascular conduit to form an internal bypass or shunt between sections of the vascular system, delivered and deployed using a *delivery system* (3.3)

3.10
endovascular system
system comprised of an *endovascular prosthesis* (3.9) and its *delivery system* (3.3)

3.11
evaluate
qualitatively appraise or analyse

3.12
factory anastomosis
factory manufactured seam-line in which two or more edges of *graft material* (3.15) are joined (e.g. sewn) together

Note 1 to entry: Bonds between stents or between the graft material and a stent or an attachment system are not covered under this definition.

3.13
failure mode
difficulty or failure of the *endovascular system* (3.10) that may be encountered (hazards) in pre-clinical *in vivo* or clinical use of an *endovascular system* (3.10) and could result in consequences (harm) to the subject

3.14
fixation system
system or feature of the *endovascular prosthesis* (3.9) that is designed to interface directly with the vessel wall in order to prevent migration

3.15
graft material
textile or non-textile, non-metallic material [e.g. polyethylene terephthalate (PET), polytetrafluoroethylene (PTFE), polyurethane] used to line or cover the mechanical support structures of the *endovascular prosthesis* (3.9) or to provide a vascular conduit for blood flow

4 General requirements for endovascular system

The following requirements shall apply to all endovascular systems.

4.1 Type of endovascular prosthesis

The type of endovascular prosthesis shall be designated by balloon-expandable, self-expanding or other.

4.2 Materials and construction for endovascular system

Materials of the endovascular system (e.g. graft material, wire, stent, mechanical support, imaging markers, coatings, drugs) shall be described by their generic or chemical names.

4.3 Configuration and size designation for endovascular prosthesis

The configuration of endovascular prosthesis shall be designated by its geometry (e.g. straight, bifurcated, branched, fenestrated, tapered, flared).

The size of an endovascular system shall be designated by the outer diameter of the delivery system and the appropriate nominal relaxed diameters of each component of the endovascular prosthesis (e.g. main body, branches, extenders, cuffs) and the appropriate lengths.

4.4 Intended clinical use for endovascular system

The intended clinical use shall be designated by the disease state or lesion type to be treated (e.g. occlusive disease, stenosis, restenosis, aneurysm, dissection, transection) and one or more of the following implant locations:

a) ascending thoracic aortic;

b) aortic arch;

c) great vessels;

   — left subclavian;

   — left carotid;

   — innominate (brachiocephalic);

d) descending thoracic aortic;

e) thoraco-abdominal aortic;

f) abdominal aortic and/or aorto-iliac;

   — infrarenal;

   — juxtarenal;

   — pararenal and paravisceral;

g) visceral;

   — renal;

   — superior mesenteric;

   — celiac;

h) peripheral;

   — iliac;

   — internal iliac;

   — femoral;

   — popliteal;

   — tibial;

   — carotid;

i) coronary;

j) arterio-venous shunt for vascular access;

k) transjugular intrahepatic shunt;

l) other vessels to be specified.

Anatomical indications (e.g. vessel diameter ranges for treatment of occlusive disease, range of landing zone diameters and lengths for the treatment of aneurysms, maximum angulation) shall be specified.

For branched or fenestrated devices, the additional vessels to be treated shall be specified.

For endovascular prostheses intended to be used in conjunction with adjunctive procedures (e.g. percutaneous transluminal angioplasty), the adjunctive procedure shall be specified.

If an endovascular prostheses may be used in a secondary procedure (e.g. treatment of in-stent restenosis, secondary repair of previously placed endovascular prosthesis with inadequate seal or fixation), the conditions of use shall be specified.

4.5 Balloon designation

Balloons integral to the endovascular system and balloons intended to achieve adequate apposition of the prosthesis shall be designated by the nominal diameter(s) as a function of the inflation pressure(s) or volume(s), the maximum recommended inflation pressure or volume and the rated burst pressure (RBP).

If a commercially available balloon is recommended for use in the instructions for use (IFU), the balloon shall be designated by the balloon type [e.g. percutaneous transluminal angioplasty (PTA), moulding, low-pressure aortic, compliant].

5 Intended performance

The requirements of ISO 14630:2012, Clause 4 shall apply.

6 Design attributes

6.1 General

The requirements of ISO 14630:2012, Clause 5 shall apply. General design attributes for endovascular systems are listed in Tables A.3 and A.4 with reference to the nonclinical testing necessary for the evaluation of the design. It is recognised that not all tests identified in a category will be necessary or practical for any given endovascular prosthesis and/or system. The rationale for the selection of tests shall be documented.

6.2 Endovascular system

In addition to the general requirements, the design attributes of the endovascular system shall at least take into account the following:

a) ability to consistently, accurately and safely access the intended location;

b) ability to consistently, accurately and safely deploy the endovascular prosthesis;

c) ability to safely withdraw the delivery system;

d) ability to minimize blood loss (haemostasis).

6.3 Endovascular prosthesis

In addition to the general requirements, the design attributes of the endovascular prosthesis shall at least take into account the following:

a) ability of the endovascular prosthesis to ensure effective fixation within the vasculature;

b) ability of the endovascular prosthesis to maintain adequate integrity;

c) ability of the endovascular prosthesis to isolate the lesion as appropriate to its intended use (e.g. provide seal between the endovascular prosthesis and aneurysm, prevent blood from flowing through the implant wall);

Changes in wall permeability after implantation shall be considered when establishing an appropriate *in vitro* specification for permeability.

d) appropriate interaction between endovascular prosthesis modular components;

e) compatibility of the endovascular prosthesis dimensions for use in specified vessel diameters;

f) ability of the endovascular prosthesis to maintain adequate blood flow through the lumen (patency);

g) ability to safely use magnetic resonance imaging (MRI) on a patient with an implanted endovascular prosthesis.

6.4 Endovascular system and endovascular prosthesis

In addition to the general requirements, the design attributes of the endovascular system and endovascular prosthesis shall at least take into account the following:

a) visibility of the endovascular system, delivery system and endovascular prosthesis under fluoroscopy or other technologies;

b) compliance of the delivery system and endovascular prosthesis with the requirements of ISO 10993-1 and other appropriate parts of the ISO 10993- series;

c) sterility of the endovascular system and endovascular prosthesis.

7 Materials

The requirements of ISO 14630:2012, Clause 6 shall apply. Additional testing specific to certain materials should be performed to determine the appropriateness of the material for use in the design. For example, nitinol materials dependent on shape-memory properties should be subjected to testing in order to assess transformation properties.

8 Design evaluation

8.1 General

The requirements of ISO 14630:2012, Clause 7 shall apply. A risk analysis shall be carried out in accordance with the requirements of ISO 14971.

The requirements and testing described in ISO 10555-1 may apply to the design evaluation of an endovascular system.

The device design concept shall be considered in the selection of appropriate tests and associated test methods. The device design concept includes the following:

— device description (e.g. physical description, figures, materials of construction), what the device key design features are intended to do, how the key design features accomplish the intended objective;

— intended clinical use (see 4.4);

— conditions of use/intended *in vivo* environment;

— minimum design life of the device.