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Cardiovascular implants — Endovascular devices —

Part 2: Vascular stents

Implants cardiovasculaires — Dispositifs endovasculaires — Partie 2: Endoprothèses vasculaires

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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).

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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.

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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 third edition cancels and replaces the second edition (ISO 25539-2:2012), which has been technically revised.

The main changes compared to the previous edition are updates to the testing and clinical use of vascular stents as well as improved consistency in nomenclature and reporting requirements.

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

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.

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Introduction

This document was prepared to provide minimum requirements for vascular stents. 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 is provided in additional informative annexes.

This document has been updated to reflect current knowledge regarding the testing and clinical use of vascular stents, 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.

Requirements particular to the evaluation of specific characteristics of stents (e.g. coatings, drug-elution, absorption) are incorporated by reference to appropriate standards. However, not all tests listed in the referenced standards are applicable to vascular stents. Only tests that address the design attributes specified in Clause 6 are required for compliance to this document.

This revised document introduces methodology to identify appropriate testing and analyses for a specific vascular stent, designated as the device evaluation strategy. The requirement regarding the device evaluation strategy is in the main body. Annex A provides guidance for developing a focused device evaluation strategy table that is specific to the unique characteristics of a device, device design modifications, or changes in intended use. Annex A also provides guidance for the development of a comprehensive device evaluation strategy table that may be used when it is not sufficient to focus only on the unique characteristics or changes.

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NOTE ISO 25539-1:2017 includes tables that can be used to justify the testing needed for device design modifications and changes in intended use in Annex A. In this document, this concept is called a focused device evaluation strategy table and can be applied to a new device as well as device design modifications or changes in the 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.

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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.

The specific requirements to evaluate pushability, flexibility, torquability, trackability, and deployment accuracy of a stent 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.

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 only included in Annex D.

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The revisions to the annexes to this document are as follows:

Annex of ISO 25539-2:2012	Revision
Annex A — Attributes of endovascular devices — Vascular stents — Technical and clinical considerations	Annex A now includes the relationship between testing requirements, device attributes, and potential failure modes and guidance for the creation of a device evaluation strategy.
Annex B — Bench and analytical tests	The list of tests is included in Table D.1. Annex B now includes a description of potential clinical effects of failure. Effects of failure for stents used with endovascular prostheses are included.
Annex C — Definitions of reportable clinical events	The term "reportable" clinical events is no longer used in this document. Annex C now includes a description of potential device effects of failure. Effects of failure for stents used with endovascular prostheses are included.
Annex D — Test methods	This edition incorporates the sample equations as a supplement to the radial fatigue durability test from ISO 25539-2:2012, Annex E in Annex D.
Annex E — Supplement to the radial fatigue and durability test analytical approach	There is no longer an Annex E as the sample equations as a supplement to the fatigue durability test have been incorporated in Annex D.

It is recognized by this ISO committee that many stent 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 edition of ISO 25539-2. 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.

NOTE The relationship between testing requirements, device attributes, and potential failure modes is provided in Clause A.1. Clause A.1 also provides general information regarding device evaluation strategies. Tables A.2 and A.3 provide the rationale for the requirements specified in this document for bench tests and analyses to assess device performance. An explanation of the table headings for A.2 and A.3 are described in Table A.1.

Guidance for the creation of a device-specific evaluation strategy is provided in Clause A.2. Two approaches to create a device-specific evaluation strategy are provided: 1) focused device evaluation strategy in A.2.1; and 2) comprehensive device evaluation strategy in A.2.2.

Annex B provides a description of the potential clinical effects of failure identified in Annex A.

Annex C provides a description of the potential device effects of failure identified in Annex A.

Additional descriptions of clinical and device effects of failure are included in Annexes B and C, respectively.

Annex D provides information to consider in developing appropriate bench test and analytical methods.

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Cardiovascular implants — Endovascular devices —

Part 2: Vascular stents

1 Scope

This document specifies requirements for the evaluation of stent systems (vascular stents 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 Annex D. This document is supplemental to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

NOTE 1 Due to the variations in the design of implants covered by this document, and in some cases due to the emergence of novel types of such implants, 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.

This document is applicable to vascular stents and vascular scaffolds (e.g. absorbable vascular scaffolds) used to treat vascular stenoses or other vascular abnormalities or pathologies. Some of the requirements are specific to endovascular treatment of arterial stenoses. Although uses of stent systems other than treatment of arterial stenoses (e.g. venous stenting) are within the scope of this document, comprehensive requirements and testing are not described for these uses. Similarly, specific stent configurations (e.g. bifurcation stents) are within the scope, but comprehensive requirements and testing are not described for these devices.

Stents used in combination with an endovascular prosthesis to complete the treatment of a lesion, including bridging stents (e.g. stents placed in the renal arteries after deployment of a fenestrated endovascular prosthesis), are within the scope of this document, but test methods are not described for the combination. ISO 25539-1 also provides information relevant to the preclinical *in vivo* and clinical evaluations of such stents.

Vascular stents that have surface modifications, such as drug and/or other coatings, are within the scope of this document. Stents covered with materials that significantly modify the permeability of the uncovered stent (e.g. by covering the stent-free-surface area) are within the scope of ISO 25539-1. The stent design or intended use might dictate the need to address functional requirements identified in both ISO 25539-1 and this document (e.g. stents used in combination with endovascular prostheses, stents used to treat aortic aneurysms).

Balloons integral to the stent system are within the scope of this document. This document provides requirements beyond the requirements of ISO 10555-4, which are specific to the use of balloons with vascular stents.

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

Tacking devices intended to spot treat post-angioplasty dissections, coil supporting devices, and flow diverters are within the scope of this document, but comprehensive requirements and testing are not described for these devices.

Although drug-eluting stents are within the scope of this document, this document is not comprehensive with respect to the drug-eluting properties of these devices.

NOTE 2 Vascular device-drug combination products are within the scope of ISO 12417-1.

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Although absorbable stents and stents with absorbable coatings are within the scope of this document, this document is not comprehensive with respect to the absorbable properties of these devices.

NOTE 3 Absorbable implants are within the scope of ISO/TS 17137.

Although coated stents and coated stent systems are within the scope of this document, this document is not comprehensive with respect to coatings.

NOTE 4 Some coating properties are within the scope of ISO 17327-1.

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

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 10993 (all parts), *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, *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*

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 14630 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 http://www.electropedia.org/

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3.1
adverse event
unfavorable 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
post-dilation
use of a balloon to facilitate the complete deployment (or expansion) of a *self-expanding stent* (3.22.9)

3.3
bridging stent
vascular stent used in combination with an endovascular prosthesis to complete the treatment of a lesion

Note 1 to entry: See 3.22 for vascular stent.

3.4
clinical effect of failure
specific clinical observations potentially associated with device failures

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

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3.5
coating
additional layer of organic or inorganic material, other than living cells, on the surface of a substrate that modifies its surface properties

Note 1 to entry: This coating can be intended to be permanent or temporary and can be applied to the external and/or internal surface.

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3.5.1
absorbable coating
coating (3.5) that is intended to be absorbed

Note 1 to entry: Drugs are excluded from this definition of absorbable coatings.

3.6
delivery system
system or mechanism used to deliver the stent to the targeted position and to deploy the stent

Note 1 to entry: The delivery system is removed after stent placement. Examples of delivery systems include balloon catheters or mechanically activated systems.

3.7
determine
appraise or analyse quantitatively

Note 1 to entry: Also see *evaluate* (3.14).

3.8
device effects of failure
consequence to the device potentially associated with device failures

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

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3.9
device evaluation strategy
rationale for the testing selected for a specific stent system, based on the requirements of the device design and potential failure modes

3.10
comprehensive device evaluation strategy table
optional communication tool to present the device evaluation strategy for a specific stent system that addresses all attributes and *failure modes* (3.15)

3.11
focused device evaluation strategy table
optional communication tool to present the device evaluation strategy for a specific stent system that focuses on the unique characteristics of the device design or procedure and unique aspects of the intended use

3.12
dogboning
dumbbell-shaped balloon observed when the unconstrained ends of the balloon expand beyond the dilated stent outer diameter

3.13
drug
active pharmaceutical ingredient [pharmacologically active (drug or medicinal) substance used as a raw material, which is coated on, bound to, or incorporated into the device to achieve an ancillary device function (e.g. minimizing vascular restenosis)] in its final form for administration to the patient (e.g. tablet, solution, spray), that is intended to prevent, diagnose, or treat disease and that achieves its principal intended action in or on the body by pharmacological, immunological, or metabolic means

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3.14
evaluate
qualitatively appraise or analyse

Note 1 to entry: Also see *determine* (3.7).

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3.15
failure mode
difficulty or failure of the stent system that can be encountered (hazards) in preclinical *in vivo* or clinical use of a vascular stent and could result in consequences (harm) to the subject

3.16
nominal diameter
primary labelled diameter of the stent

3.17
rated burst pressure
RBP
pressure at which a balloon would not be expected to burst based on appropriate confidence and reliability

3.18
stent configuration
stent shape and geometry

Note 1 to entry: Examples include cylindrical, tapered, flared, coiled, segmented, bifurcated, articulated, closed cell, open cell.

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3.19
stent outer surface area
maximum contact area between the stent and the vessel

Note 1 to entry: Although the entire stent may not contact the vessel wall depending on the conformance to the vessel wall and the intended clinical use (e.g. for treatment of aneurysms), the stent outer surface area would include the maximum potential area along the entire length of the stent.

3.20
stent-free surface area
percentage of surface area of cylinder formed by the implant frame, which is not covered by implant material

3.21
stent system
vascular stent and its *delivery system* (3.6)

Note 1 to entry: If a stent is to be mounted on a delivery balloon, as specified in the instructions for use (IFU), the balloon catheter is not considered part of the stent system with respect to the design requirements and evaluation specified in this document, with the exception of the simulated use, *in vivo* animal, and clinical study requirements. The balloon catheter would be part of the stent system for testing that evaluates the stent only where the stent system is needed to conduct the testing.

3.22
vascular stent
vascular scaffold
stent
implant
transluminally placed balloon-expandable or self-expanding implant intended to maintain or restore vessel patency or function

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Note 1 to entry: Stents can have surface modifications, such as drug and/or other coatings.

Note 2 to entry: The requirements of this document include vascular stents and vascular scaffolds (e.g. absorbable vascular scaffolds) and both are covered by the term stent for simplicity.

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Note 3 to entry: The following stent types are within the scope of this document.

3.22.1
absorbable stent
stent that is designed to be a temporary structure without requiring explantation

3.22.2
articulated stent
stent constructed of segments with distinct connections

3.22.3
balloon-expandable stent
stent where the diameter is increased from its pre-deployed size to its deployed size with the aid of a balloon

3.22.4
bare stent
stent without a coating or covering

Note 1 to entry: Bare stents can be constructed of a single or multiple materials.

Note 2 to entry: Bare stents can contain a metal oxide layer.

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3.22.5
coated stent
stent with a surface layer of an additional material(s) that does not provide significant (e.g. more than 5 %) structural support or appreciably reduce the permeability of the bare stent [e.g. by covering the *stent-free surface area* (3.20)]

Note 1 to entry: Stents containing only a metal oxide layer are not considered a coated stent for the purposes of this document.

3.22.6
covered stent
stent covered with an additional material(s) that appreciably reduces permeability of the bare stent [e.g. by covering the *stent-free surface area* (3.20)]

Note 1 to entry: Covered stents are within the scope of ISO 25539-1. The stent design might dictate the need to address functional requirements identified in both ISO 25539-1 and this document.

3.22.7
drug-containing stent
stent that has a drug coating that is not intended to release the drug

Note 1 to entry: For the purposes of this document, drug-eluting refers to both drug-eluting and drug-containing stents, unless otherwise noted.

3.22.8
drug-eluting stent
DES
stent that releases a drug

3.22.9
self-expanding stent
stent where the diameter increases from its pre-deployed size to its deployed size when released from the delivery mechanism in absence of balloon inflation or other mechanical assistance

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4 General requirements for stent systems

4.1 General

The following requirements shall apply to all stent systems.

4.2 Type of stent

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

4.3 Materials of construction for stent system

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

4.4 Configuration and size designation for stents and stent systems

The configuration of a stent shall be designated by its shape and geometry (e.g. cylindrical, tapered, flared, coiled, segmented, bifurcated, articulated, closed cell, open cell).

The size of the stent system shall be designated by the outer diameter of the stent system and the appropriate lengths.

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