SLOVENSKI STANDARD
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Vsadki (implantati) za srce in ožilje - Znotrajžilni pripomočki - 2. del: Žilne opornice (stent) (ISO/DIS 25539-2:2019)

Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO/DIS 25539-2:2019)

KardiovaskulÃ¤re Implantate - EndovaskulÃ¤re Implantate - Teil 2: GefÃ¤Ãstents (ISO 25539-2:2012)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 2: Endoprothèses vasculaires (ISO/DIS 25539-2:2019)

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Cardiovascular implants — Endovascular devices —

Part 2: Vascular stents

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Partie 2: Endoprothèses vasculaires

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 25539-2 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 25539-2:2012)

ISO 25539 consists of the following parts, under the general title *Cardiovascular implants — Endovascular devices*:

— *Part 1: Endovascular prostheses*

— *Part 2: Vascular stents*

— *Part 3: Vena cava filters*

Introduction

This part of ISO 25539 was prepared to provide minimum requirements for vascular stents. 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 is provided in additional informative annexes.

The standard 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 the standard.

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 requirements in these standards are relevant to vascular stents. Information regarding applicability of these standards to specific types of stents (e.g. coated) are clarified by the definitions in Clause 3 of this standard. For example, the definition of a coated stent excludes stents with an oxide layer and therefore the requirements of ISO 17327-1 *Non-active surgical implants — Implant coating —Part 1:General requirements* are not applicable to stents with only an oxide layer. In addition, not all tests listed in the respective standards are applicable to vascular stents. Only tests that address the design attributes specified in section 6 are required for compliance to this part of ISO 25539.

The revised standard 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.

NOTE The revision of Part 1: Endovascular prostheses includes tables that may be used to justify the testing needed for device design modifications and changes in intended use in Annex A. In Part 2, this concept is called a focused device evaluation strategy table and may 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.

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.

The revisions to the titles of the annexes to this standard are as follows:

Annex	2012 Standard	Revision
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.
B	Bench and analytical tests	The list of tests is included in the Table of Contents for Annex D. Annex B now includes a description of potential clinical effects of failure. Effects of failure for stents used with endovascular prostheses are included.
C	Definitions of reportable clinical events	The term reportable clinical events is no longer used in this standard. Annex C now includes a description of potential device effects of failure. Effects of failure for stents used with endovascular prostheses are included.
D	Test methods	Incorporates sample equations as a supplement to the radial fatigue and durability test from Annex E.
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 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 standard 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 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.

Cardiovascular implants — Endovascular devices —

Part 2: Vascular stents

1 Scope

Part 2 of ISO 25539 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 an informative annex to this standard. This standard should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

NOTE Due to the variations in the design of implants covered by this part of ISO 25539 and in some cases due to the relatively recent development of some of these implants (e.g. absorbable stents, polymeric 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 part of ISO 25539 will be necessary.

The scope of this part of ISO 25539 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 standard, 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 standard, but test methods are not described for the combination. The preclinical *in vivo* and clinical evaluations of these stents may be addressed with the evaluations of the associated endovascular prosthesis in accordance with ISO 25539-1.

Vascular stents that have surface modifications, such as drug and/or other coatings, are within the scope of this standard. 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 part of ISO 25539 (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 standard. This part of ISO 25539 provides requirements beyond the requirements of ISO 10555-4 *Intravascular catheters — Sterile and single-use catheters*, specific to the use of balloons with vascular stents.

This part of ISO 25539 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-angioplasy dissections, coil supporting devices, and flow diverters are within the scope of this standard, but comprehensive requirements and testing are not described for these devices.

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

NOTE Vascular device-drug combination products are within the scope of ISO 12417-1 *Cardiovascular implants and extracorporeal systems – Vascular device-drug combination products*.

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

NOTE Absorbable implants are within the scope of ISO/TS 17137 *Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants.*

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

NOTE Some coating properties are within the scope of ISO 17327-1 *Non-active surgical implants — Implant coating — Part 1: General requirements.*

This standard 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 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 14971:2007, *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 in ISO 14630 and the following apply.

Note 1 to entry Additional descriptions of clinical and device effects of failure are included in Annex B and Annex C, respectively.

3.1
adverse event
an 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: for the purpose of this standard, clinical effects of failure are a subset of adverse events and are described separately

Note 1 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

3.3
bridging stent
vascular stent (see 3.15) used in combination with an endovascular prosthesis to complete the treatment of a lesion

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.

3.5
coating
an 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.

Note 2 to entry: For the purposes of this document, the term coating does not include metal oxide layers.

3.5.1
absorbable coating
coating that is intended to be absorbed. 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
to quantitatively appraise or analyse

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

3.8
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 C.

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

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

3.11
device evaluation strategy table – focused
an 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

3.14
evaluate
to qualitatively appraise or analyse

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

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

3.16
rated burst pressure
RBP
calculated pressure at which a balloon would not be expected to burst based on an appropriate confidence and reliability from measured burst pressures

3.17
stent configuration
stent shape (e.g. cylindrical, tapered, flared, coiled, segmented, bifurcated)

3.18
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.

3.19
stent-free surface area
percentage of surface area of cylinder formed by the implant frame, which is not covered by implant material

3.20
stent system
vascular stent and its delivery system

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 standard, 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.

3.21
vascular stent
vascular scaffold
stent
implant
transluminally placed balloon-expandable or self-expanding implant intended to maintain or restore vessel patency or function

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

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

Note 3 to entry: The following stent types are within the scope of this part of ISO 25539.

3.21.1
absorbable stent
stent that is designed to be a temporary structure without requiring explantation

3.21.2
articulated stent
stent constructed of segments with distinct connections

3.21.3
balloon-expandable stent
stent where the diameter is increased from its pre-deployed size to its deployed size with the aid of a balloon

3.21.4
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.

3.21.5
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)

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

3.21.6
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).

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 part of ISO 25539.