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Südame-veresoonkonna implantaadid. Soonesisesed vahendid. Osa 2: Arteriaalpingutid

Cardiovascular implants - Endovascular devices - Part 2: Vascular stents

EESTI STANDARDI EESSÕNA

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Käesolev Eesti standard EVS-EN ISO 25539-2:2009 sisaldab Euroopa standardi EN ISO 25539-2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 25539-2:2009 consists of the English text of the European standard EN ISO 25539-2:2009.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 25539-2

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Supersedes EN ISO 25539-2:2008

English Version

Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2008)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 2: Stents vasculaires (ISO 25539-2:2008)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 2: Gefäßstents (ISO 25539-2:2008)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

The text of ISO 25539-2:2008 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 25539-2:2009 by Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 25539-2:2008.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 25539-2:2008 has been approved by CEN as a EN ISO 25539-2:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 4, 7.1	
5	1, 2, 3, 4, 5, 7.1, 7.2, 7.3, 7.5, 8, 9.2	
6	1, 2, 7.1, 7.2, 7.3, 7.5, 8.2, 9.2	
7	1, 2, 3, 4, 6, 6a., 7.1, 7.2, 8, 9.2,	
8	1, 2, 3, 5, 7.1, 7.2	
9	1, 2, 3, 7.2, 8.1, 8.3, 8.4	
10	1, 2, 3, 5, 7.2, 8.3, 8.4	
11	1, 2, 8.7, 13.1, 13.3, 13.4, 13.6	Part of 13.3 a relating to the authorised representative is not covered. Part of ER 13.3 f concerning single use is not addressed in this European Standard. 13.6 h) concerning single use is not addressed in this European Standard.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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Introduction

This part of ISO 25539 has been prepared in order to provide minimum requirements for endovascular devices and the methods of test that will enable their evaluation. It is the second part of a proposed three-part standard. ISO 25539-1 addresses endovascular prostheses and ISO 25539-3 will address vena cava filters. ISO/TS 15539, from which this part of ISO 25539 is derived, serves as a rationale for the requirements of this document. The Technical Specification ISO/TS 15539 was developed by first identifying the design requirements for these devices and listing the potential device and clinical failure modes. Tests were then identified to address each of the failure modes. The requirements provided in this part of ISO 25539 are based on that assessment.

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Cardiovascular implants — Endovascular devices —

Part 2:
Vascular stents

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1 Scope

1.1 This part of ISO 25539 specifies requirements for vascular stents, based upon current medical knowledge. With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer. It 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. bioabsorbable 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 document will be necessary.

1.2 The scope of this part of ISO 25539 includes vascular stents used to treat vascular lesions or stenoses, or other vascular abnormalities. These devices might or might not incorporate surface modifications of the stent such as drug and/or other coatings. Stents covered with materials that significantly modify the permeability of the uncovered stent 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.

1.3 Delivery systems are included in this part of ISO 25539 if they comprise an integral component of the deployment of the vascular stent.

1.4 Procedures and devices used prior to the introduction of the vascular stent, such as balloon angioplasty devices, are excluded from the scope of this part of ISO 25539.

1.5 Some pharmacological aspects of drug eluting stents are addressed in this part of ISO 25539, but this document is not comprehensive with respect to the pharmacological evaluation of drug eluting stents.

1.6 Degradation and other time-dependent aspects of bioabsorbable and polymeric stents and coatings are not addressed by this part of ISO 25539.

1.7 With the exception of sterilization, this part of ISO 25539 does not address requirements for the evaluation of animal tissue products.

2 Normative references

The following referenced documents are indispensable for the application 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*

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

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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 11607 (both parts), *Packaging for terminally sterilized medical devices*

ISO 14155 (both parts), *Clinical investigation of medical devices for human subjects*

ISO 14160, *Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants*

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*

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 14630 and the following apply.

NOTE Bench and analytical tests are described in Annex B. Reportable clinical events are defined in Annex C.

3.1
balloon-assisted deployment
use of a balloon to facilitate the complete deployment (or expansion) of a self-expanding stent

3.2
balloon winging
cross-sectional shape of the balloon when deflated which can cause problems during withdrawal

NOTE Examples include stent migration, damage to host vessel or balloon, and inability to remove the balloon.

3.3
delivery system
system or mechanism used to deliver the stent to the targeted position and to deploy the stent

NOTE The delivery system is removed after stent placement. Examples of delivery systems include balloon catheters or mechanically activated systems.

3.4
determine
to quantitatively appraise or analyse

NOTE Also see **evaluate (3.8)**.

3.5
dogboning
dumbbell-shaped balloon observed during stent deployment when the unconstrained ends of the balloon expand beyond the dilated stent outer diameter

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