SLOVENSKI STANDARD
SIST EN ISO 25539-2:2013

01-marec-2013

Nadomešča:
SIST EN ISO 25539-2:2009
SIST EN ISO 25539-2:2009/AC:2011

Vsadki (implantati) za srce in ožilje - Znotrajžilni pripomočki - 2. del: Žilne opornice (stent) (ISO 25539-2:2012)

Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2012)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 2: Gefäßstents (ISO 25539 -2:2012)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 2: Endoprothèses vasculaires (ISO 25539-2:2012)

Ta slovenski standard je istoveten z: **EN ISO 25539-2:2012**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN ISO 25539-2:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 25539-2

December 2012

ICS 11.040.40

Supersedes EN ISO 25539-2:2009

English Version

Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2012)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 2: Endoprothèses vasculaires (ISO 25539-2:2012)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 2: Gefäßstents (ISO 25539-2:2012)

This European Standard was approved by CEN on 30 November 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN ISO 25539-2:2012) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with 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 June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

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 25539-2:2009.

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 organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 25539-2:2012 has been approved by CEN as a EN ISO 25539-2:2012 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 one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Medical devices.

Once this standard is cited in the Official Journal of the European Union 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.1 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.1 — Correspondence between Directive 93/42/EEC and this European Standard

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
6,8,10 and 12	7.2	
6.3 and 7	7.3	
6	7.5 1st sentence	
6 and 7	7.6	
7	8.2	
12.1.5	8.3	
11.1	8.4	
11.2	8.5	
6 and 7	9.2, 2nd indent	
12.2.2	13.3 a)	
12.2.2	13.3 b)	
12.2.2	13.3 c)	
12.2.2	13.3 d)	
12.2.2	13.3 e)	
12.2.2	13.3 f)	
12.2.2	13.3 i)	
12.2.2	13.3 k)	
12.2.2	13.3 m)	
5	13.5	
12.3.2	13.6 g)	
12.3.2	13.6 k)	
12.3.2	13.6 q)	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 25539-2

Second edition
2012-12-01

Cardiovascular implants — Endovascular devices — Part 2: Vascular stents

Part 2:
Vascular stent

Implants cardiovasculaires — Dispositifs endovasculaires — Partie 2: Endoprothèses vasculaires

Reference number
ISO 25539-2:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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 second edition cancels and replaces the first edition (ISO 25539-2:2008), of which it constitutes a minor revision. This minor revision updates the normative references and provides minor editorial changes to Clause 8 and Annex D for clarification.

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 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 three-part standard. ISO 25539-1 addresses endovascular prostheses and ISO 25539-3 addresses vena cava filters. ISO/TS 15539, from which this part of ISO 25539 is derived, serves as a rationale for the requirements of this part of ISO 25539. 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.

Cardiovascular implants — Endovascular devices —

Part 2: Vascular stents

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 part of ISO 25539 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 part of ISO 25539 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 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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*

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 11607-1, *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 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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 m<edical 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 14971:2007, *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*

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

3.6
coating
organic or inorganic material, other than living cells, intentionally applied by a manufacturer to a substrate

NOTE This coating can be intended to be permanent or temporary, and can be applied to the external and/or internal surface.

3.7
drug content
amount of drug present on the surface(s) of a coating, as part of a coating or within the stent

3.8
evaluate
to qualitatively appraise or analyse

NOTE Also see **determine (3.4)**.

3.9
lumen reduction
reduction of diameter or cross sectional area as observed by imaging

3.10
reportable clinical events
complications, failures or device-related observations, including all adverse events and adverse device effects, that might be observed with clinical use of the stent system

NOTE Examples are listed in Annex C. These events might not have clinical significance and might not be attributable to the device.

3.11
stent configuration
stent shape (e.g. cylindrical, tapered, flared, coiled, segmented, bifurcated)

3.12
stent outer surface area
contact area between the stent and the vessel

3.13
stent-free surface area
percentage of surface area of cylinder formed by the implant frame, which is not covered by implant material

3.14
stent system
vascular stent and its delivery system or a vascular stent mounted on the delivery balloon as specified in the instructions for use (IFU)

3.15
vascular stent
stent
implant
transluminally placed balloon-expandable or self-expanding implant, which is used to treat vascular lesions by providing a mechanical support after deployment to maintain or restore vessel integrity

NOTE 1 Stents can or cannot incorporate surface modifications of the stent such as drug and/or other coatings.

NOTE 2 The following stent types are within the scope of this part of ISO 25539.

3.15.1
articulated stent
stent constructed of segments with distinct connections

3.15.2
bare stent
stent without a coating or covering

NOTE Bare stents can be constructed of single or multiple materials.

3.15.3
bioabsorbable stent
stent that is designed to be a temporary structure without requiring explantation