SLOVENSKI STANDARD
SIST EN ISO 25539-1:2009

01-januar-2009

Nadomeģļ a:
SIST EN 14299:2004

Vsadki (implantati) za srce in oģilje - Znotrajģilni pripomoļ ki - 1. del: Znotrajģilne proteze (ISO 25539-1:2003, vkljuļ no z Amd 1:2005)

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 1: Endovaskuläre Prothesen (ISO 25539-1:2003, einschließlich A1:2005)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 1: Prothèses endovasculaires (ISO 25539-1:2003, Amd 1:2005 inclus)

Ta slovenski standard je istoveten z: EN ISO 25539-1:2008

ICS:

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

SIST EN ISO 25539-1:2009 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 25539-1

October 2008

ICS 11.040.40

Supersedes EN 14299:2004

English Version

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 1: Prothèses endovasculaires (ISO 25539-1:2003, Amd 1:2005 inclus)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 1: Endovaskuläre Prothesen (ISO 25539-1:2003, einschließlich A1:2005)

This European Standard was approved by CEN on 9 September 2008.

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

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Foreword

The text of ISO 25539-1:2003 including Amd 1:2005 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 25539-1:2008 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of an identical text or by endorsement, at the latest by April 2009, and conflicting national standards shall be withdrawn at the latest by April 2009.

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 together with EN ISO 25539-2 supersedes EN 14299:2004.

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 EC Directive.

For relationship with EC 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 25539-1:2003 including Amd 1:2005 has been approved by CEN as a EN ISO 25539-1:2008 without any modification.

Annex ZA
(informative)

Relationship between this International 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 of 14 June 1993 concerning 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.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 this International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1 - 2 -3 - 4 - 7.1	
5	1 - 2 - 3 - 4 - 5 - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2	
6	1 - 2 - 7.1 - 7.2 - 7.3 - 7.4 - 7.5 - 7.6 - 8.2 - 9.2	
7	1 - 2 - 3 - 4 - 6 - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2 - 14	
8	1 - 2 - 3 - 5 - 7.1 - 7.2	
9	1 - 2 - 7.2 - 8.1 - 8.2 - 8.3 - 8.4	
10.1	1 - 2 - 3 - 5 - 7.2 - 7.3 - 7.4 - 7.6 - 8.3 - 8.4	
10.2 - 10.3	1 - 2 - 8.7 - 9.1 - 13	

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

INTERNATIONAL STANDARD

ISO 25539-1

First edition
2003-03-01

Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

Implants cardiovasculaires — Dispositifs endovasculaires —
Partie 1: Prothèses endovasculaires

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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.

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ISO 25539-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

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 prostheses and the methods of test that will enable their evaluation. It is the first part of a proposed three-part International Standard. ISO/TS 15539, from which this part of ISO 25539 is derived, serves as a rationale for the requirements. The Technical Specification was developed by first identifying the design requirements for endovascular implants and listing the potential implant 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.

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, 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 undertaken.

Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

1 Scope

1.1 This part of ISO 25539 specifies requirements for endovascular prostheses, 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.

1.2 This part of ISO 25539 is applicable to endovascular prostheses used to treat arterial aneurysms, arterial stenoses, or other appropriate vascular abnormalities.

1.3 This part of ISO 25539 is applicable to delivery systems if they comprise an integral component of the deployment of the endovascular prostheses.

1.4 This part of ISO 25539 is not applicable to vascular occluders, with the exception of contra-lateral iliac occluders when used as an integral part of an aorto-uni-iliac device. See ISO 14630 for excluded products.

1.5 This part of ISO 25539 is not applicable to procedures and devices used prior to the introduction of the endovascular system (defined in 3.6), such as balloon angioplasty devices.

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 7198:1998, *Cardiovascular implants — Tubular vascular prostheses*

ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11607:1997, *Packaging for terminally sterilized medical devices*

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

ISO 13488:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002*

ISO 14155 (all 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 14630:1997, *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 14971:2000, *Medical devices — Application of risk management to medical devices*

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.

3.1
attachment system
system integral to the endovascular prosthesis that is designed to interface directly with vessel wall in order to prevent migration

NOTE The system may also prevent blood flow on the outside of the prostheses at the attachment sites.

3.2
delivery system
system or mechanism used to deliver the endovascular prosthesis to the targeted position

NOTE The delivery system is removed after implant placement.

3.3
determine
quantitatively appraise or analyse

3.4
endoleak
persistence of blood flow outside the lumen of an endovascular prosthesis but within an aneurysm sac or adjacent vascular segment being treated by the graft

NOTE Endoleaks are catagorized as follows:

— a Type I endoleak is periprosthetic and occurs at the proximal or distal attachment zone;

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

— a Type III endoleak arises from a defect in the graft material or from an inadequate seal between modular graft components;

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

3.5
endovascular prosthesis
endovascular graft
endovascular implant
transluminally placed vascular prosthesis, residing partially or completely within a vascular conduit to form an internal bypass or shunt between sections of the vascular system

3.6
endovascular system
system used to treat a vascular lesion from within the vessel, typically comprised of an endovascular prosthesis and its delivery system

NOTE 1 An abdominal aortic aneurysm is an example of a vascular lesion which can be treated with an endovascular system.

NOTE 2 For the purposes of this part of ISO 25539, the delivery system as well as the implant are included within this definition.

3.7
evaluate
qualitatively appraise or analyse

3.8
graft material
non-metallic component of the endovascular prosthesis

3.9
reportable clinical events
complications or failures that may be observed with clinical use of the endovascular system

4 Intended performance

The requirements of Clause 4 of ISO 14630:1997 shall apply.

5 Design attributes

5.1 General

The requirements of Clause 5 of ISO 14630:1997 shall apply. In addition, the following shall be taken into account:

a) with regard to oxidation potential: the possibility of crevice corrosion passivation level over the relevant parts;

b) with regard to wear: fretting corrosion;

c) with regard to interface between implant and body:

  1) fixation hooks if present;

  2) relative movement between implant and tissue;

  3) forces exerted by the device on the surrounding tissue;

  4) forces required to deform the implant if the deformation is permanent;

d) expected ingrowth, penetration, perforation, tilting and migration;

e) introduction and delivery systems.

NOTE These additional items are adapted from Clause 5 of EN 12006-3:1998.