SLOVENSKI STANDARD
oSIST prEN ISO 25539-3:2010

01-september-2010

Vsadki (implantati) za srce in ožilje - Znotrajžilni pripomočki - 3. del: Filtri "vena cava" (ISO/DIS 25539-3:2010)

Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO/DIS 25539-3:2010)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 3: Hohlvenenfilter (ISO/DIS 25539-3:2010)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 3: Filtres pour veine cave (ISO/DIS 25539-3:2010)

Ta slovenski standard je istoveten z: **prEN ISO 25539-3**

ICS:

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

oSIST prEN ISO 25539-3:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 25539-3

April 2010

ICS 11.040.40

English Version

Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO/DIS 25539-3:2010)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 3: Filtres pour veine cave (ISO/DIS 25539-3:2010)

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This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 285.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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Foreword

This document (prEN ISO 25539-3:2010) 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 document is currently submitted to the parallel Enquiry.

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(s).

Endorsement notice

The text of ISO/DIS 25539-3:2010 has been approved by CEN as a prEN ISO 25539-3:2010 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 25539-3

ISO/TC **150**/SC **2** Secretariat: **ANSI**

Voting begins on: **2010-04-01**

Voting terminates on: **2010-09-01**

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Cardiovascular implants — Endovascular devices —

Part 3:
Vena cava filters

Implants cardiovasculaires — Dispositifs endovasculaires —

Partie 3: Filtres pour veine cave

ICS 11.040.40

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

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 25539-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

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 International Standard 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 third and final Part of a proposed three-Part standard, addressing vena cava filters; Part 1 addresses endovascular prostheses, Part 2 addresses vascular stents. ISO/TS 15539, from which this Part is derived, serves as a rationale for the requirements of this International Standard. The Technical Specification was developed by first identifying the design requirements for these devices and listing the potential failure modes and potential device and detrimental clinical effects. Tests were then identified to address each of the failure modes. The requirements provided in this International Standard are based on that assessment.

Cardiovascular implants — Endovascular devices —

Part 3:
Vena cava filters

1 Scope

1.1 This International Standard specifies requirements for vena cava filters, 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 includes vena cava filters used to prevent pulmonary embolism by mechanical filtration in the inferior vena cava. While this standard might be useful with respect to filters implanted in other venous locations (e.g., superior vena cava, iliac veins), this standard does not specifically address use of filters in other implantation sites.

1.3 Sheath/dilator kits are included in the standard if they comprise an integral component of the access, delivery or retrieval/conversion of the vena cava filter.

1.4 Delivery systems are included in the standard if they comprise an integral component of the deployment of the vena cava filter.

1.5 Optional filters that can be retrieved or converted and permanent filters as well as their associated endovascular systems are included in the standard. While this standard might be useful with respect to evaluation of repositioning filters after chronic implantation, this standard does not specifically address filter repositioning..

1.6 Temporary filters (e.g., tethered) that have to be removed after a defined period of time are excluded from the scope of this standard.

1.7 Coatings, surface modifications, and/or drugs are excluded from the scope of this standard.

1.8 Procedures and devices (e.g., venous entry needle) used prior to the vena cava filter procedure are excluded from the scope of this standard.

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 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*

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 10555-1, *Sterile, single-use intravascular catheters — Part 1: General requirements*

ISO 10993, *Biological evaluation of medical devices (series)*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices (series)*

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*

3 Definitions

For the purposes of this International Standard, the definitions in ISO 14630 and the following apply:

NOTE Potential device effects of failure and failure modes and detrimental clinical effects are defined in Annex B. Bench and analytical tests are described in Annex C.

3.1
access site
vein that is used for accessing the vena cava

NOTE Examples of access sites include jugular, femoral, subclavian, antecubital veins.

3.2
adverse events
clinical events
complications, failures or device related observations with preclinical *in vivo* and clinical use of the endovascular system or endovascular retrieval/conversion system

NOTE 1 This term relates to the definition of a hazardous situation that might lead to harm as found in ISO 14971 when the consequences are to the patient.

NOTE 2 A clinical event might lead to a detrimental clinical effect.

3.3
conversion system
component of the endovascular conversion system that is intended to structurally alter an optional filter after implantation so that it no longer functions as a filter

3.4
delivery system
component of the filter system, excluding the sheath/dilator, used to deliver the filter to the targeted position and to deploy the filter

NOTE The delivery system is removed after filter placement.

3.5
determine
requirement to quantitatively appraise or analyse

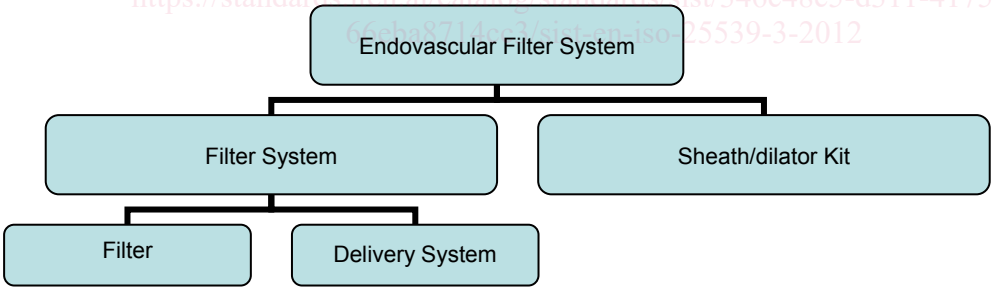
NOTE Also see **evaluate**.

3.6
detrimental clinical effect
discernable negative effect due to an adverse event or device failure

NOTE A list of detrimental clinical effects is contained in Annex B.

3.7
endovascular filter system
filter system and sheath/dilator kit

EXAMPLE



3.8
endovascular retrieval/conversion system
retrieval/conversion system and sheath/dilator kit