SLOVENSKI STANDARD
SIST EN ISO 25539-3:2012

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Nadomešča:
SIST EN 12006-3:2000+A1:2009

Vsadki (implantati) za srce in ožilje - Znotrajžilni pripomočki - 3. del: Filtri "vena cava" (ISO 25539-3:2011)

Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO 25539-3:2011)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 3: Hohlvenenfilter (ISO 25539-3:2011)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 3: Filtres pour veine cave (ISO 25539-3:2011)

Ta slovenski standard je istoveten z: **EN ISO 25539-3:2011**

ICS:

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

SIST EN ISO 25539-3:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 25539-3

December 2011

ICS 11.040.40

Supersedes EN 12006-3:1998+A1:2009

English Version

Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO 25539-3:2011)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 3: Filtres caves (ISO 25539-3:2011)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 3: Hohlvenenfilter (ISO 25539-3:2011)

This European Standard was approved by CEN on 30 November 2011.

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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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 25539-3:2011) 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of an identical text or by endorsement, at the latest by June 2012, and conflicting national standards shall be withdrawn at the latest by June 2012.

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 12006-3:1998+A1:2009.

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 organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, 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 25539-3:2011 has been approved by CEN as a EN ISO 25539-3:2011 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 to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices as amended by Directive 2007/47/EC.

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	
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 product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 25539-3

First edition
2011-12-01

Cardiovascular implants — Endovascular devices —

Part 3: Vena cava filters

Implants cardiovasculaires — Dispositifs endovasculaires —

Partie 3: Filtres caves

Reference number
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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 part of ISO 25539 provides minimum requirements for endovascular devices and the methods of test that will enable their evaluation. It is derived from ISO/TS 15539, which serves as a rationale for its requirements. ISO/TS 15539 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 specified in this part of ISO 25539 are based on that assessment.

Cardiovascular implants — Endovascular devices —

Part 3: Vena cava filters

1 Scope

This part of ISO 25539 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. This part of ISO 25539 supplements ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

The following are within the scope of this part of ISO 25539:

— vena cava filters used to prevent pulmonary embolism by mechanical filtration in the inferior vena cava (IVC). While this part of ISO 25539 might be useful with respect to filters implanted in other venous locations (e.g. superior vena cava, iliac veins), it does not specifically address use of filters in other implantation sites;

— sheath/dilator kits, providing that they comprise an integral component of the access, delivery or retrieval/conversion of the vena cava filter;

— delivery systems, providing that they comprise an integral component of the deployment of the vena cava filter;

— optional filters that can be retrieved or converted, and permanent filters together with their associated endovascular systems. While this part of ISO 25539 might be useful with respect to the evaluation of repositioning filters after chronic implantation, it does not specifically address filter repositioning.

The following are outside the scope of this part of ISO 25539:

— temporary filters (e.g. tethered) that need to be removed after a defined period of time;

— coatings, surface modifications, and/or drugs;

— issues associated with viable tissues and non-viable biological materials;

— degradation and other time-dependent aspects of absorbable materials;

— procedures and devices (e.g. venous entry needle) used prior to the vena cava filter procedure.

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*

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 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*

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 given in ISO 14630 and the following apply.

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

EXAMPLE Jugular vein; femoral vein; subclavian vein; antecubital vein.

3.2
adverse event
clinical event
complication, failure or device-related observation 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** (3.9).

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

NOTE Descriptions of potential device effects of failure and failure modes and of detrimental clinical effects are given in Annex B.

3.7
endovascular filter system
filter system and sheath/dilator kit

See Figure 1.

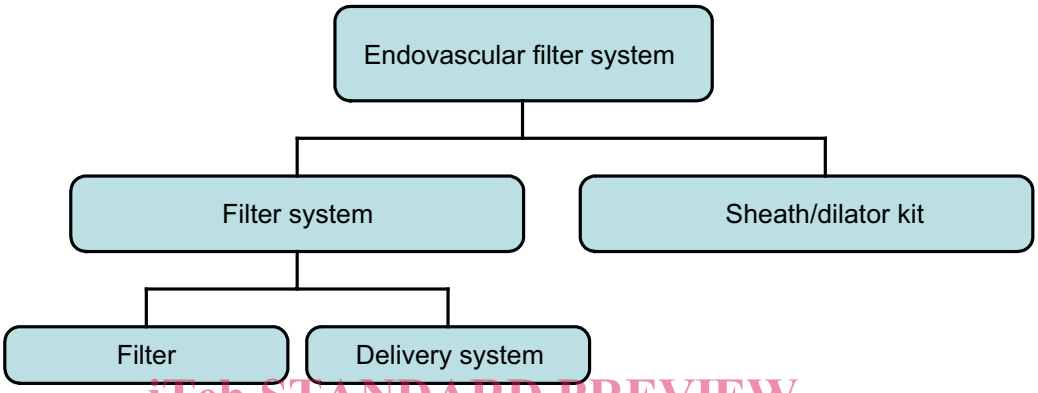

Figure 1 — Example of endovascular filter system

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

See Figure 2.

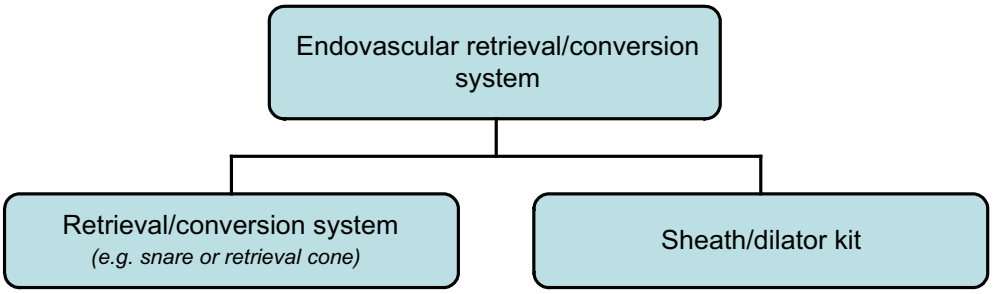

Figure 2 — Example of endovascular retrieval/conversion system

NOTE The term retrieval/conversion is used to describe either the retrieval or the conversion system and does not imply that one system can be used for both purposes.

3.9
evaluate
requirement to qualitatively appraise or analyse

NOTE Also see **determine** (3.5).

3.10
filter formation
manufacturer's specified final expanded geometric configuration of the filter in the vena cava