

Südame-veresoonkonna implantaadid. Soonesised seadmed. Osa 3: Õõnesveeni filter (ISO 25539-3:2011)

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 25539-3:2011 sisaldab Euroopa standardi EN ISO 25539-3:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 25539-3:2011 consists of the English text of the European standard EN ISO 25539-3:2011.
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Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO 25539-3:2011)

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Partie 3: Filtres caves (ISO 25539-3:2011)

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

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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of an identical text or by endorsement, at the latest by June 2012, and conflicting national standards shall be withdrawn at the latest by June 2012.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 1 st 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, 2 nd 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.

Contents

Page

Foreword	v
Introduction.....	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	5
4.1 Classification	5
4.2 Size.....	5
5 Intended performance.....	5
6 Design attributes	5
6.1 General	5
6.2 Sheath/dilator kit for endovascular filter system.....	5
6.3 Filter system	5
6.4 Filter	5
6.5 Optional filter	6
6.6 Sheath/dilator kit for endovascular retrieval/conversion system	6
6.7 Retrieval/conversion system.....	6
6.8 Endovascular systems.....	6
7 Materials	7
8 Design evaluation.....	7
8.1 General	7
8.2 Sampling	7
8.3 Conditioning of test samples	8
8.4 Reporting.....	8
8.5 Bench and analytical tests	9
8.6 Preclinical <i>in vivo</i> evaluation	24
8.7 Clinical evaluation	28
9 Post-market surveillance.....	32
10 Manufacturing.....	32
11 Sterilization	32
11.1 Products supplied sterile.....	32
11.2 Products supplied non-sterile.....	33
11.3 Sterilization residuals	33
12 Packaging.....	33
12.1 Protection from damage in storage and transport	33
12.2 Marking.....	34
12.3 Information supplied by the manufacturer	35
Annex A (informative) Attributes of endovascular devices — Vena cava filters — Technical and clinical considerations.....	37
Annex B (informative) Descriptions of potential device effects of failure and failure modes and descriptions of detrimental clinical effects	51
Annex C (informative) Bench and analytical tests	55
Annex D (informative) Test methods	59

Annex E (informative) Examples of terms for clinical use of vena cava filters	86
Bibliography.....	88

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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).