



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 25539-3:2023**  
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**Vsadki (implantati) za srce in ožilje - Znotrajžilni pripomočki - 3. del: Filtri "vena cava" (ISO/DIS 25539-3:2023)**

Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO/DIS 25539-3:2023)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 3: Hohlvenenfilter (ISO/DIS 25539-3:2023)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 3 : Filtres caves (ISO/DIS 25539-3:2023)

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**ICS:**

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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## Cardiovascular implants — Endovascular devices —

### Part 3: Vena cava filters

*Implants cardiovasculaires — Dispositifs endovasculaires —*

*Partie 3: Filtres caves*

ICS: 11.040.40

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CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 150, Implants for surgery, Subcommittee SC2, Cardiovascular implants and extracorporeal systems, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, Non-active surgical implants, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

The second edition cancels and replaces the first edition (ISO 25539-3:2011), which has been technically revised.

The main changes compared to the previous edition are updates to the testing and clinical use related to vena cava filters as well as improved consistency in nomenclature and reporting requirements.

A list of all parts in the ISO 25539 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document was prepared to provide guidance on the minimum requirements for vena cava filter systems. The rationale for the requirements for bench tests and analyses to assess device performance and safety, guidance on the identification of appropriate testing to evaluate a specific device design, and guidance for developing test methods are provided in informative annexes. Further clarification of terminology is provided in additional informative annexes.

This document has been updated to reflect current knowledge regarding the testing and clinical use related to vena cava filters, reflected in modifications to the requirements in the main body and in the guidance for developing test methods in [Annex D](#). In addition, revisions have been made to improve consistency in nomenclature and reporting and to enhance the utility of this document.

This revised document introduces methodology to identify appropriate testing and analyses applicable to intended clinical use, design, and potential failure modes for a specific vena cava filter system, designated as the device evaluation strategy. The requirement regarding the device evaluation strategy is in the main body. [Annex A](#) provides guidance for developing a focused device evaluation strategy table that is specific to the unique characteristics of a device, device design modifications, or changes in intended use. [Annex A](#) also provides guidance for the development of a comprehensive device evaluation strategy table that may be used when it is not sufficient to focus only on the unique characteristics or changes.

The guidance on the development of methods to address the requirement for evaluating fatigue and durability through computational analyses has been modified to include recommendations regarding verification of the solution and validation of the computational model, as well as reporting. The guidance on the model development for simulated use has also been significantly revised to improve the clinical relevance of this testing.

In addition to modifications to specific design evaluation requirements, guidance has been provided regarding the assessment of the acceptability of test results. When the requirement is to quantitatively appraise or analyse a parameter, test results generally may be compared to a quantitative value (i.e., acceptance criteria). For characterization tests it is appropriate to provide an explanation of the relevance of the results. Additionally, some testing may include comparison to test data or existing data from a previously evaluated device.

For design evaluation, requirements regarding sampling, conditioning of test samples, and reporting have been incorporated in the main body. Guidance on these elements of testing and documentation were previously only included in [Annex D](#).



The revisions to the annexes to this document are as follows:

Annex of ISO 25539-3:2011	Revision
<a href="#">Annex A</a> – Attributes of endovascular devices – Vena cava filters – Technical and clinical considerations	<a href="#">Annex A</a> now includes the relationship between testing requirements, device attributes, and potential failure modes and guidance for the creation of a device evaluation strategy.
<a href="#">Annex B</a> – Descriptions of potential device effects of failure and failure modes and descriptions of detrimental clinical effects	<a href="#">Annex B</a> now includes a description of potential clinical effects of failure.
<a href="#">Annex C</a> – Bench and analytical tests	The list of tests is included in <a href="#">Table D.1</a> . <a href="#">Annex C</a> now includes a description of potential device effects of failure.
<a href="#">Annex D</a> – Test methods	<a href="#">Annex D</a> – Test methods
<a href="#">Annex E</a> – Examples of terms for clinical use of vena cava filters	<a href="#">Annex E</a> – Examples of terms for clinical use related to vena cava filters

It is recognized by this ISO committee that many filter systems have been shown to be safe and effective in clinical use. This update is not intended to require additional evaluation of these devices to remain in compliance with this document as the testing would not provide useful information regarding the expected clinical performance of the device. Manufacturers may rely on historical data gathered under the guidance of the previous edition of ISO 25539-3. Similarly, for device modifications or changes in intended clinical use, this update is not intended to require additional evaluation of aspects of the device that are not expected to change clinical performance.

NOTE The relationship between testing requirements, device attributes, and potential failure modes is provided in [Clause A.1](#). [Clause A.1](#) also provides general information regarding device evaluation strategies. [Tables A.3](#) to [A.9](#) provide the rationale for the requirements specified in this document for bench tests and analyses to assess device performance and safety. An explanation of the table headings for [A.3](#) to [A.9](#) are described in [Table A.1](#).

Guidance for the creation of a device-specific evaluation strategy is provided in [Clause A.2](#). Two approaches to create a device-specific evaluation strategy are provided: 1) focused device evaluation strategy in [A.2.1](#); and 2) comprehensive device evaluation strategy in [A.2.2](#).

[Annex B](#) provides a description of the potential clinical effects of failure identified in [Annex A](#).

[Annex C](#) provides a description of the potential device effects of failure identified in [Annex A](#).

Additional descriptions of clinical and device effects of failure are included in [Annexes B](#) and [C](#), respectively.

[Annex D](#) provides information to consider in developing appropriate bench test and analytical methods.

[Annex E](#) provides examples of terms for clinical use related to vena cava filters.



# Cardiovascular implants — Endovascular devices —

## Part 3: Vena cava filters

### 1 Scope

This document specifies requirements for the evaluation of vena cava filter systems (filters and delivery systems) and requirements with respect to nomenclature, design attributes and information supplied by the manufacturer, based upon current medical knowledge. Guidance for development of in vitro test methods is included in [Annex D](#). This document is supplemental to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

NOTE 1 Due to the variations in the design of implants covered by this document, and in some cases due to the emergence of novel types of such 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 document will be necessary.

This document is applicable to vena cava filters intended to prevent symptomatic pulmonary embolism by capturing blood clots 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.

This document is also applicable to permanent filters together with their associated delivery systems, optional filters that can be retrieved and their associated retrieval systems, and convertible filters and their associated conversion 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.

This document is not applicable to temporary filters (e.g., tethered) that need to be removed after a defined period of time; issues associated with viable tissues and non-viable biological materials; and procedures and devices (e.g., venous entry needle) used prior to the vena cava filter procedure.

Although absorbable filters and filters with absorbable coatings are within the scope of this document, this document is not comprehensive with respect to the absorbable properties of these devices.

NOTE 2 Absorbable implants are within the scope of ISO/TR 17137.

Although coated filters and coated filter systems are within the scope of this document, this document is not comprehensive with respect to coatings.

NOTE 3 Vascular device-drug combination products are within the scope of ISO 12417-1, and some coating properties are within the scope of ISO 25539-4.

### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 – Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices*

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ISO 11137 (all parts), *Sterilization of health care products – Radiation*

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

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

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*

ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

**3 Terms and definitions**

For the purposes of this document, the terms and definitions given in ISO 14630 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <https://www.electropedia.org/>

**3.1**  
**absorb**  
absorption  
<biomaterials> action of a non-endogenous (foreign) material or substance or its degradation products passing through or being assimilated by cells and/or tissue over time

**3.2**  
**absorbable coating**  
implant coating (3.18) that is intended to be absorbed

Note 1 to entry: Drugs are excluded from this definition of absorbable coatings.

**3.3**  
**access site**  
vein that is used for accessing the vena cava

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

**3.4**  
**adverse event**  
unfavorable change in health that occurs in a subject who participates in a study while receiving the treatment or within a specified time after receiving treatment

Note 1 to entry: For the purpose of this document, clinical effects of failure are a subset of adverse events and are described separately.

Note 2 to entry: Adverse events are categorized by the system affected (e.g., cardiac, vascular, respiratory, neurological, renal, gastro-intestinal) and the severity of the event.

### 3.5

#### **caval perforation/penetration**

imaging (e.g., venography, CT) showing filter components (e.g., struts, anchors) extending more than 5 mm outside the wall of the vena cava.

### 3.6

#### **clinical effect of failure**

specific detrimental clinical observations potentially associated with device failures

Note 1 to entry: Clinical effects of failure are described in [Annex B](#).

### 3.7

#### **clinical perforation/penetration**

protrusion of filter components (e.g., struts, anchors) through the vena cava wall causing hemorrhage or hematoma, or interacting with another organ (e.g., liver, bowel, aorta, psoas muscle, vertebral body, lymph nodes), and resulting in adverse clinical symptoms (e.g., abdominal or back pain) or autopsy findings

### 3.8

#### **conversion system**

components that are intended to structurally alter an convertible filter after implantation so that it no longer functions as a filter

Note 1 to entry: May also be used to inject contrast media (e.g., to obtain a cavagram) if indicated in the IFU.

### 3.9

#### **delivery system**

components of the filter system used to deliver the filter to the target position and to deploy the filter

Note 1 to entry: May also be used to inject contrast media (e.g., to obtain a cavagram) if indicated in the IFU.

### 3.10

#### **determine**

appraise or analyse quantitatively

Note 1 to entry: Also see *evaluate* ([3.13](#))

### 3.11

#### **device effects of failure**

consequence to the device potentially associated with device failures

Note 1 to entry: Device effects of failure are described in [Annex C](#).

### 3.12

#### **device evaluation strategy**

rationale for the testing selected for a specific vena cava filter system, based on requirements of the device design and potential failure modes

### 3.13

#### **comprehensive device evaluation strategy table**

optional communication tool to present the device evaluation strategy for a specific vena cava filter system that addresses attributes of failure modes ([3.14](#))

### 3.14

#### **focused device evaluation strategy table**

optional communication tool to present the device evaluation strategy for a specific vena cava filter system that focuses on the unique characteristics of the device design or procedure and unique aspects of the intended use

**ISO/DIS 25539-3:2023(E)****3.15****evaluate**

qualitatively appraise or analyse

Note 1 to entry: Also see *determine* (3.8).

**3.16****failure mode**

a type of difficulty or failure of the filter system that can be encountered (hazards) in preclinical in vivo or clinical use and could result in consequences (harm) to the subject

**3.17****filter formation**

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

**3.18****filter system**

components consisting of the vena cava filter (3.22) and the delivery system (3.7)

**3.19****filter system orientation**

orientation (e.g., jugular, femoral) of the loaded filter within the delivery system, based on the designated access site (e.g., jugular, femoral, subclavian, antecubital)

**3.20****implant coating**

*surface coating* (3.23) or *surface modification* (3.24)

Note 1 to entry: Implant coating is considered a constituent of an implant.

Note 2 to entry: A laminate, i.e., a composite material made of multiple layers of the same or different materials with the same or different internal structures assembled sandwich-like and bonded by heat, pressure, welding, soldering or adhesives, is not in itself considered an implant coating. But the exposed surface of the laminate can be an implant coating.

Note 3 to entry: A covering, for example additional material (e.g., a graft) added to a structure (e.g., a stent) specifically to bridge elements of the structure for the sole purpose of reducing the permeability of the structure, is not considered an implant coating.

[SOURCE: ISO 17327-1:2018, 3.1]

**3.21****implantation site**

location of vena cava filter placement within the body

**3.22****retrieval system**

components that are intended to remove a specific filter

Note 1 to entry: May also be used to inject contrast media (e.g., to obtain a cavagram) if indicated in the IFU.

**3.23****vena cava filter**

filter implant

transluminally placed implant, which is used to prevent pulmonary embolism by capturing blood clots traveling in the inferior vena cava (IVC)

### 3.23.1

#### **absorbable filter**

a filter, or a filter with a component, that is designed to be *absorbed* (3.1)

Note 1 to entry: A filter with a component designed to be absorbed could function as a convertible filter without intervention.

### 3.23.2

#### **convertible filter**

filter that can be altered structurally after implantation such that some permanent implant remains that no longer functions as a filter (e.g., functions as a stent)

### 3.23.3

#### **optional filter**

filter that can be removed (retrievable filter) or can be left as an implant that permanently functions as a filter

### 3.23.4

#### **permanent filter**

filter that is designed as an implant which permanently functions as a filter

Note 1 to entry: All optional filters are also permanent filters. Permanent filters might or might not incorporate design characteristics that allow for retrieval or conversion and might or might not be labelled for use of these optional features.

### 3.24

#### **surface coating**

layer of material with any different property than the natural surface of the substrate that is intentionally added to the substrate

Note 1 to entry: The coating can partially or fully cover the substrate surface.

Note 2 to entry: The term includes surface coatings created as a result of additive manufacturing.

[SOURCE: ISO 17327-1:2018, 3.2]

### 3.25

#### **surface modification**

intentional conversion or reconstruction of the surface of the original substrate to form a new surface material consisting of components of the substrate's own material and possibly foreign material and forming a surface layer with different properties

[SOURCE: ISO 17327-1:2018, 3.3]

### 3.26

#### **unacceptable filter tilting**

clinically significant rotation of the filter relative to the longitudinal axis of the vena cava and resulting in performance failure (e.g., inadequate filtration, excessive filtration, filter migration, filter embolization, caval perforation/penetration, clinical perforation/penetration, inability to retrieve the filter as applicable, inability to convert the filter as applicable)

## 4 General requirements

### 4.1 Classification

A filter system shall be designated by its access site (see 3.3), orientation (see 3.17), implantation site (see 3.19), type (see 3.22), materials of construction, as well as surface modifications, coatings, and/or drugs.