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# Cardiovascular implants — Endovascular devices —

## Part 3: Vena cava filters

*Implants cardiovasculaires — Dispositifs endovasculaires —*

*Partie 3: Filtres de veine cave*



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# Foreword

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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 are as follows:

— the testing and clinical use related to vena cava filters has been updated;

— the consistency in nomenclature and reporting requirements has been improved.

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.

# 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 Annexes B, C and E.

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 can include a 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 given in Table 1.

**Table 1 — Revisions to the annexes in this document**

| Annex of ISO 25539-3:2011 | Changes in ISO 25539-3:2024 |
|---|---|
| Annex A – Attributes of endovascular devices – Vena cava filters – Technical and clinical considerations | Annex A now includes the relationship between testing requirements, device attributes, and potential failure modes and guidance for the creation of a device evaluation strategy. |
| Annex B – Descriptions of potential device effects of failure and failure modes and descriptions of detrimental clinical effects | Annex B now includes a description of potential clinical effects of failure. |
| Annex C – Bench and analytical tests | The list of tests is included in Table D.1.<br>Annex C now includes a description of potential device effects of failure. |
| Annex D – Test methods | Annex D – Test methods |

Many filter systems have been shown to be safe and effective in clinical use – this update is not intended to require additional evaluations 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 this document (i.e. ISO 25539-3:2011). Similarly, for device modifications or changes in intended clinical use, this

edition of this document 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 Tables A.3 to A.9 is given 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:

a) focused device evaluation strategy in A.2.1;

b) 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 the requirements for the evaluation of vena cava filter systems (filters and delivery systems) and the requirements with respect to nomenclature, design attributes and information supplied by the manufacturer. Guidance for the development of in vitro test methods is included in Annex D. This document is intended to be used in conjunction with 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, a 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 document can be useful with respect to filters implanted in other venous locations (e.g. superior vena cava, iliac veins), it does not specifically address the 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 document can 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 covered in ISO/TS 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 covered in ISO 12417-1 and some coating properties are covered in 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*

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

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 14630:2012, *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**
**absorption**
<biomaterial> 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* (3.20) 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**
unfavourable 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, computed tomography (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: The 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 haemorrhage 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 a *convertible filter* (3.23.2) after implantation so that it no longer functions as a filter

Note 1 to entry: A conversion system may also be used to inject contrast media (e.g. to obtain a cavagram) if indicated in the instructions for use (IFU).

**3.9**
**delivery system**
components of the *filter system* (3.18) used to deliver the filter to the target position and to deploy the filter

Note 1 to entry: The delivery system may also be used to inject contrast media (e.g. to obtain a cavagram) if indicated in the instructions for use (IFU).



**3.10**
**determine**
appraise or analyse quantitatively

Note 1 to entry: Also see *evaluate* (3.15).



**3.11**
**device effect of failure**
consequence to the device potentially associated with device failure

Note 1 to entry: The device effects of failure are described in Annex C.

**3.12**
**device evaluation strategy**
rationale for testing selected for a specific vena cava *filter system* (3.18), based on requirements of the device design and potential *failure modes* (3.16)

**3.13**
**comprehensive device evaluation strategy table**
optional communication tool to present the *device evaluation strategy* (3.12) for a specific vena cava *filter system* (3.18) that addresses attributes of *failure modes* (3.16)

**3.14**
**focused device evaluation strategy table**
optional communication tool to present the *device evaluation strategy* (3.12) for a specific vena cava *filter system* (3.18) that focuses on the unique characteristics of the device design or procedure and unique aspects of the intended use

**3.15**
**evaluate**
qualitatively appraise or analyse

Note 1 to entry: Also see *determine* (3.10).

**3.16**
**failure mode**
type of difficulty or failure of the *filter system* (3.18) that can be encountered (hazards) in preclinical in vivo or clinical use and can 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**
component consisting of the *vena cava filter* (3.23) and the *delivery system* (3.9)

**3.19**
**filter system orientation**
orientation (e.g. jugular, femoral) of the loaded filter within the *delivery system* (3.9), based on the designated *access site* (3.3) (e.g. jugular, femoral, subclavian, antecubital)

**3.20**
**implant coating**
*surface coating* (3.24) or *surface modification* (3.25)

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* (3.23) placement within the body

**3.22**
**retrieval system**
components that are intended to remove a specific filter

Note 1 to entry: A retrieval system may also be used to inject contrast media (e.g. to obtain a cavagram) if indicated in the instructions for use (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**
filter, or 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 can function as a *convertible filter* (3.23.2) 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* (3.23.3) are also permanent filters. Permanent filters can incorporate design characteristics that allow for retrieval or conversion and can be labelled for use of these optional features, if applicable.

**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* (3.5), *clinical perforation/penetration* (3.7), 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.

### 4.2 Materials of construction for filter system

Materials of the filter system (e.g. wire, imaging markers, coatings) shall be described by their generic or chemical names.

### 4.3 Configuration and size designation for filters

The configuration of a filter shall be designated by its geometry (e.g. conical) and whether it is permanent, optional or convertible. The size of a filter shall be designated by the minimum and maximum intended caval lumen diameters.

### 4.4 Intended clinical use designation

Vena cava filters are intended to prevent symptomatic pulmonary embolism by capturing blood clots in the IVC.

## 5 Intended performance

The requirements of ISO 14630:2012, Clause 4 shall apply.

## 6 Design attributes

### 6.1 General

The requirements for design attributes in 6.2 to 6.10 and of ISO 14630:2012, Clause 5 apply. General design attributes for the filter system, the filter, the filter retrieval system and the filter conversion system are listed in Tables A.3 and A.9 with reference to the nonclinical testing necessary for the evaluation of the design. It is recognized that not all tests identified in a category are necessary or practical for any given filter and/or system. The tests considered and the rationale for selection and/or waiving of tests shall be documented.



### 6.2 Filter system

In addition to the general requirements, the design attributes of the filter system shall at least take into account the following:

a) the ability to permit safe and consistent deliverability of the filter to the intended deployment location;

b) the ability to permit accurate and safe deployment of the filter;



c) the ability to inject contrast via the delivery system if indicated in the IFU;

d) the ability to permit safe withdrawal of the delivery system following deployment;

e) the ability to maintain adequate structural integrity.

### 6.3 Vena cava filter

The design attributes of the vena cava filter shall at least take into account the following:

a) the ability to ensure effective fixation in the intended location within the inferior vena cava;

b) the ability to maintain adequate integrity;

c) the ability to capture clots in the blood, while allowing acceptable blood flow;

d) the ability to prevent clinical perforation/penetration;

e) the compatibility of the filter dimensions for use with the specified caval diameters;

f) the compatibility with exposure to magnetic resonance imaging (MRI) fields.