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Cardiovascular implants — Endovascular devices —

Part 3: Vena cava filters

Implants cardiovasculaires — Dispositifs endovasculaires —

Partie 3: Filtres caves

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Foreword

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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.

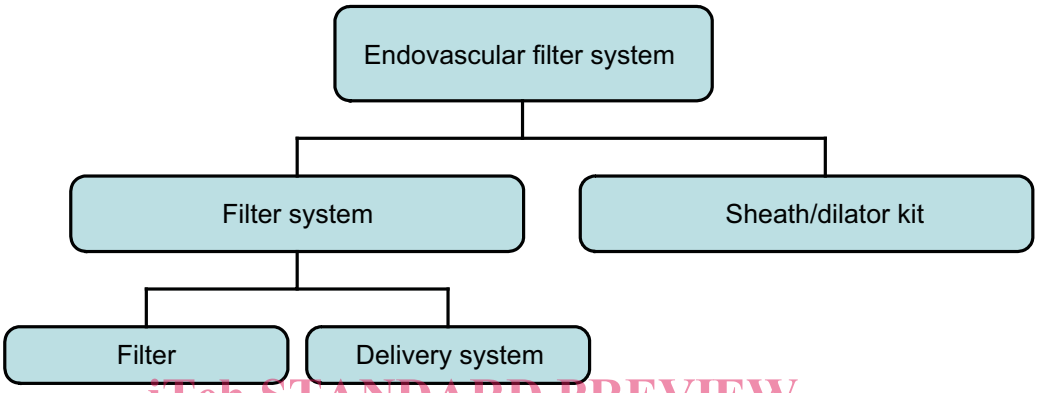

Figure 1 — Example of endovascular filter system

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

See Figure 2.

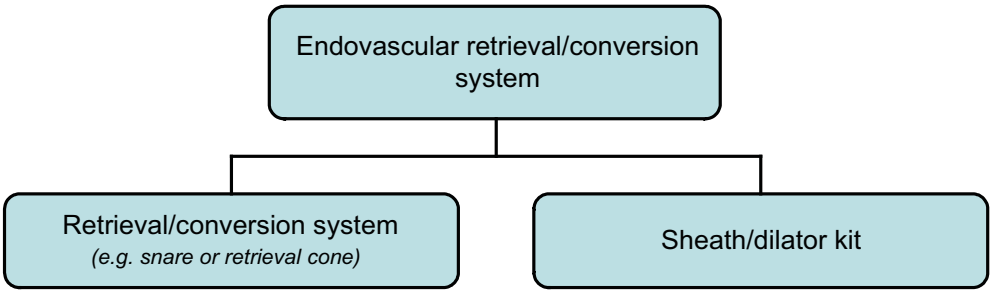

Figure 2 — Example of endovascular retrieval/conversion system

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

3.11
filter system
component of the endovascular filter system that consists of the filter and delivery system

3.12
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)

3.13
implantation site
location of placement within the body

3.14
potential effect of failure
possible consequence of the failure mode on the device or patient

NOTE See introduction to Annex A for further clarification. This term relates to the definition of hazard as found in ISO 14971:2007, 2.3.

3.15
potential failure mode
difficulty or failure that might be encountered and that could result in consequences (potential effects of failure) for the patient or device

NOTE This term relates to the definition of hazard as found in ISO 14971:2007, 2.3.

3.16
retrieval system
component of the endovascular retrieval system that is intended to remove a specific filter in accordance with the instructions for use (IFU)

3.17
sheath/dilator
kit that includes an introducer sheath and dilator and that is used to access the target deployment, retrieval, or conversion location

3.18
vena cava filter
filter
implant
transluminally placed implant, which is used to prevent pulmonary embolism by mechanical filtration

3.18.1
optional filter
permanent filter that can be optionally removed (retrievable filter), or permanent filter that can be optionally altered structurally after implantation, so that it no longer functions as a filter (convertible filter)

3.18.2
permanent filter
filter that is designed to permanently function as a filter

NOTE 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.

4 General requirements

4.1 Classification

A vena cava filter system shall be designated by its access site (see 3.1), orientation (see 3.12), implantation site (see 3.13), type (see 3.18), materials of construction, and any surface modifications, coatings, and/or drugs.

4.2 Size

The size of a filter shall be designated by the sizes of vena cava intended to be treated, if applicable.

5 Intended performance

The requirements of ISO 14630 apply.

6 Design attributes

6.1 General

The requirements of ISO 14630 apply. The design attributes for vena cava filters are listed in Tables A.3 to A.9, with reference to the preclinical testing necessary for evaluation of the design. It is recognized that not all tests identified in a category will be 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 recorded.

6.2 Sheath/dilator kit for endovascular filter system

The design attributes needed to meet consistently the intended performance of the sheath/dilator shall also take into account at least the following:

a) the ability to permit safe access to the intended deployment location;

b) the ability to permit safe withdrawal of the dilator;

c) the ability to perform cavagrams.

6.3 Filter system

The design attributes needed to meet consistently the intended performance of the filter system shall also take into account at least the following:

a) the ability to permit safe 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 permit safe withdrawal of the delivery system and introducer sheath following deployment.

6.4 Filter

The design attributes needed to meet consistently the intended performance of the filter shall also take into account at least the following:

a) the ability to ensure effective fixation in the intended location within the 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 compatibility of the filter dimensions for use with specified caval diameters;

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

6.5 Optional filter

In addition to the attributes listed in 6.4, the design attributes needed to meet consistently the intended performance of optional filters shall take into account at least the following:

a) the ability to be engaged;

b) the ability to be retrieved/converted;

c) the ability to maintain structural integrity associated with retrieval, if applicable;

d) the ability for converted filters to maintain structural integrity after conversion, if applicable.

6.6 Sheath/dilator kit for endovascular retrieval/conversion system

The design attributes needed to meet consistently the intended performance of the sheath/dilator kit for retrieval or conversion shall also take into account at least the following:

a) the ability to permit safe access to the intended retrieval/conversion location;

b) the ability to permit safe withdrawal of the dilator;

c) the ability to perform cavagrams.

6.7 Retrieval/conversion system

The design attributes needed to meet consistently the intended performance of the retrieval/conversion system shall also take into account at least the following:

a) the ability to permit safe deliverability to the filter location;

b) the ability to permit safe engagement with the filter;

c) the ability to permit safe retrieval/conversion of the filter;

d) the ability to permit safe withdrawal of the retrieval/conversion system, with any previously removed implanted components and introducer sheath, following retrieval/conversion.

6.8 Endovascular systems

The design attributes needed to meet consistently the intended performance of all endovascular systems shall also take into account at least the following:

a) the requirements of ISO 10993-1 and other appropriate parts of the ISO 10993 series (biocompatibility);

b) the sterility assurance;

c) the ability to control blood loss (haemostasis);

d) the visibility under fluoroscopy or other technologies.

7 Materials

The requirements of ISO 14630 apply. Additional testing specific to certain materials (e.g. nitinol, titanium, and stainless steel) should be performed to determine the appropriateness of the material for use in the design. For example, nitinol materials dependent on shape memory properties should be subjected to testing in order to assess transformation properties.

8 Design evaluation

8.1 General

The requirements of ISO 14630 apply. A risk assessment shall be carried out and the requirements of ISO 14971 shall apply.

Because optional filters can be used as permanent filters, testing appropriate for a permanent filter shall be conducted for optional filters. Additional testing is appropriate for optional filters.

Justification shall be provided for the design attributes not evaluated.

NOTE All tests might not be appropriate for all filter system designs.

At the time of publishing this edition of this part of ISO 25539, it is impossible to account for all future and emerging technologies. New filter systems will need to be evaluated following the basic requirements of this part of ISO 25539. Testing beyond the scope of this part of ISO 25539 might also be necessary to characterize new filter systems. Consideration shall be given to the failure modes of the filter systems and their effects on the performance of the implant in identifying the appropriate testing.

Whenever changes are made in filter type, materials, construction, configuration, implantation site, or processing methods, an appropriate analysis of the potential impact of the change on the failure modes and performance of the filter system shall be performed. Appropriate testing shall be conducted as deemed necessary.

The use of a control device for comparison should be considered in the evaluation of certain design attributes.

Testing to establish the labelled shelf-life shall be conducted by repeating appropriate tests. Justification for the selection of tests shall be provided.

8.2 Sampling

A sampling plan shall be used which will ensure that adequate representation of the data has been obtained for each characteristic measured. It shall be verified that the design attributes of the sheath/dilator kit for the endovascular filter system, filter system, filter, optional filter, sheath/dilator kit for the endovascular retrieval/conversion system, and filter retrieval/conversion system are representative of the devices to be released for distribution, including all sizes and orientations.

The samples selected for each test shall at a minimum represent the worst case(s). Consideration shall be given to filter size, delivery system sizes (diameter and length) and orientation, and implant conditions (e.g. intended vena cava size and shape). Analysis might be necessary to identify the samples with the greatest potential for failure under specified implant conditions.

Sampling should ensure adequate representation (e.g. multiple lots) of the expected variability in device characteristics.

A rationale should be provided for sample selection. For all tests, the number of samples shall be justified.

8.3 Conditioning of test samples

All samples shall be subjected to sterilization, including multiple sterilizations, if appropriate, unless justification is provided for use of nonsterilized products.

Samples should be subjected to conditions normally encountered that might affect the test results. Conditioning should include preparation of the sheath/dilator kit, loading of the filter inside the delivery catheter, preconditioning of the filter and retrieval/conversion system, and deployment of the filter, as stated in the IFU.

A simulated physiological environment (e.g. a temperature-controlled water bath) should be used when appropriate.

8.4 Reporting

For the purposes of this part of ISO 25539, reporting is carried out at the request of a national regulatory authority.

The test report for the preclinical *in vitro* testing should include an executive summary of all testing. This summary should include identification of tests, with the rationale for the omission of any tests identified in Annex C or the selection of alternative tests. The information provided in each test report should be based upon a prospectively defined test protocol.

A summary of results, with acceptance criteria and any potential clinical significance of the results, should be included and may be in tabular form. Consideration shall be given to the anatomical, physiological and morphological conditions of the intended use when establishing the acceptance criteria. Justification and clinical applicability of acceptance criteria for each test shall be provided. A table of contents should be provided and pages should be numbered sequentially.

Individual test reports should include the following information:

a) Purpose: state the purpose of the test as it corresponds to this part of ISO 25539.

b) Materials: list all materials (e.g. test articles with lot/serial numbers or other appropriate means of traceability, equipment) used in performing the test, using figures and diagrams as appropriate.

c) Sampling: state the sampling plan, including the basis for and the number of samples tested; the selection of test article shall be justified (e.g. sizes, conditioning).

d) Acceptance criteria: state the acceptance criteria for the test results.

e) Test method: describe in detail the method used to perform the test, including any prospectively defined inspection procedures, and provide a justification for critical test parameters.

f) Protocol deviations: describe any deviations and their potential significance on the interpretation of the results.

g) Expression of results: describe testing results using the units indicated in the test method.

h) Conclusion: state conclusions, based on comparing results to acceptance criteria, including any potential clinical significance of these results.

8.5 Bench and analytical tests

Testing of the sheath/dilator kit for the endovascular filter system, filter system, filter, optional filter, sheath/dilator kit for endovascular retrieval/conversion system, and filter retrieval/conversion systems shall be conducted for evaluating the design attributes described in Clause 6, as applicable. The appropriate tests for evaluating each design attribute are based on the potential associated failure modes, device effects and detrimental clinical effects of failure. This information is outlined in Tables 2 to 8, and fully described in Annex A.

NOTE Annex C provides a list of bench and analytical tests.

In Tables 2 to 8, potential effects of failure are identified. The specific effects of the failure modes can be clinical or device-related, and are listed separately. Regarding the clinical effects of failure, the comment "observation that might lead to a non-specific clinical event or use of additional devices or procedures" (designated as ACE3 in Table 1) only appears in Tables 2 to 8 when it is the only identified potential detrimental clinical effect of failure. This effect is applicable for all potential failure modes, but is not repeated to decrease redundancy. "Death" is not listed in the tables, though it is a known potential effect, because this event is correlated to the severity of the failure and is not helpful in identifying tests to evaluate device function.

To minimize redundancy, commonly listed groups of clinical effects have been assigned abbreviations as described in Table 1. These abbreviations are used throughout this part of ISO 25539.

Table 1 — Associated detrimental clinical effects key

ACE1	ACE2		ACE3
— Caval injury or damage — Embolization — Haematoma — Vascular trauma	— Arrhythmia — Branch vessel occlusion — Cardiac damage — Cardiac tamponade — Caval injury or damage — Caval perforation — Oedema — Embolization	— Filter thrombosis — Lung damage — Intimal tear — Pulmonary embolism — Trauma to adjacent structures — Vascular trauma — Vessel occlusion	Observation that might lead to a non-specific clinical event or use of additional devices or procedures

8.5.1 Sheath/dilator kit for endovascular filter system

8.5.1.1 General

The ability of the sheath/dilator kit to permit safe and consistent access to the intended location shall be assessed.

The associated device-related/procedure-related functions, potential failure modes and potential device and detrimental clinical effects of failure to be considered are listed in Table 2.