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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

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.

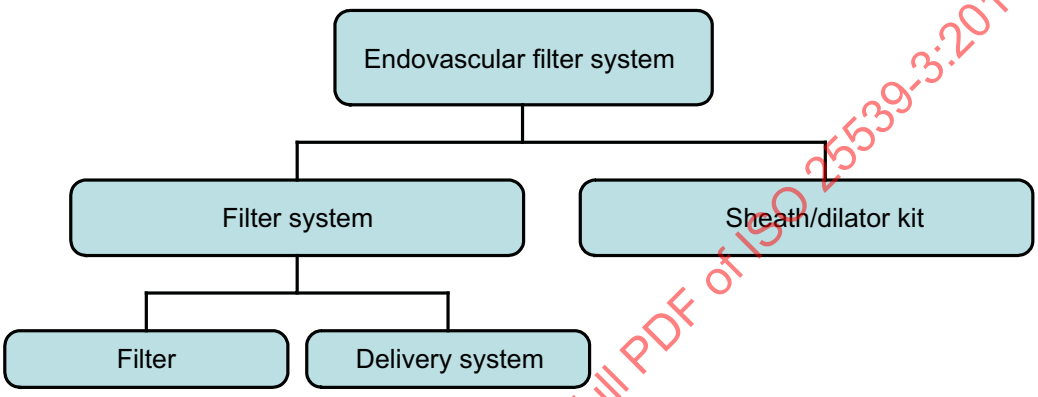

Figure 1 — Example of endovascular filter system

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

See Figure 2.

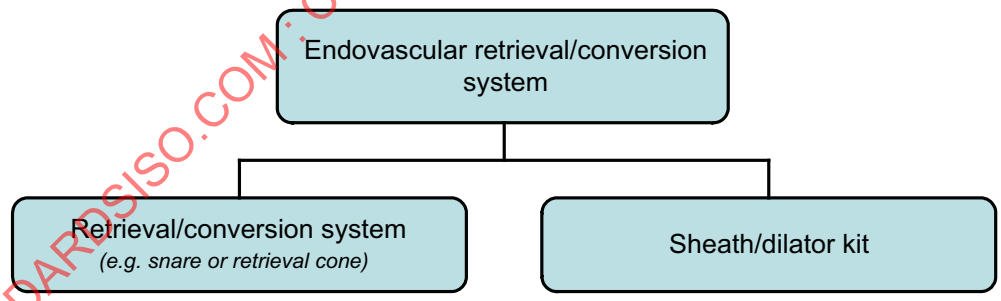

Figure 2 — Example of endovascular retrieval/conversion system

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

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.

Table 2 — Sheath/dilator kit for endovascular filter system

Function(s)	Potential failure mode(s)	Potential effect(s) of failure (device)	Potential effect(s) of failure (clinical)
Ability to access with sheath/dilator kit	— Difficult/unable to push sheath/dilator to target site — Dilator difficult/unable to track over guidewire — Sheath/dilator is incompatible with accessory devices — Sheath is incompatible with dilator	— Access failure — Accessory device failure — Dilator damage — Sheath damage	— ACE1 — Air embolism
Ability to withdraw dilator	— Bond joint separation	— Dilator damage — Foreign body embolization — Withdrawal failure	— ACE2
Ability to perform cavagram	— Hub separation — Catheter burst — Inadequate contrast flow	— Sheath damage — Dilator damage — Leakage of contrast media — Foreign body embolization — Withdrawal failure	— Inadequate cavagram — ACE2

Testing shall include the items listed in 8.5.1.2 to 8.5.1.7, as appropriate to the design of the sheath/dilator kit.

8.5.1.2 Catheter burst

Determine the burst pressure for catheters used for cavagrams.

8.5.1.3 Dimensional verification and component dimensional compatibility

Evaluate the dimensions of the sheath/dilator kit for compatibility with the dimensions of recommended accessories and/or conformance with design specifications.

8.5.1.4 Power injection

Determine the amount and location of contrast leakage from a system during power injection.

8.5.1.5 Simulated use

8.5.1.5.1 General

Evaluate the performance of the sheath/dilator kit using a model or models that simulate(s) the intended use conditions.

8.5.1.5.2 Ability to access

Evaluate the ability of the sheath/dilator kit to access the deployment location in the anatomical model(s).

8.5.1.5.2.1 Flex/kink

Evaluate the ability of the sheath/dilator kit to bend in order to accommodate the minimum radius or angle it will be required to negotiate during access and delivery.

8.5.1.5.2.2 Pushability

Evaluate the ability of the sheath/dilator kit to be pushed or positioned by an operator without bending or buckling.

8.5.1.5.2.3 Trackability

Evaluate the ability of the sheath/dilator kit to advance through the vessel to the target site using the recommended accessories.

8.5.1.5.3 Ability to withdraw

Evaluate the ability of the dilator to be withdrawn from the deployment location in the anatomical model(s).

8.5.1.6 Tensile strength

Determine the tensile strength of relevant components including bond joints and/or fixed connections of the system.

8.5.1.7 Torsional bond strength

Determine the torque/rotation required to break joints and/or materials in the appropriate sheath/dilator kit components, if appropriate for the intended clinical use.

8.5.2 Filter system

8.5.2.1 General

The ability of the filter system to permit safe and consistent delivery, deployment and withdrawal 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 3.

Table 3 — Filter system

Function(s)	Potential failure mode(s)	Potential effect(s) of failure (device)	Potential effect(s) of failure (clinical)
Ability to deliver filter to implant site prior to deployment	— Inability to load filter (if applicable) — Filter system is incompatible with sheath — Inability to advance filter to target site — Generation of particles from system — Premature release of filter — Damage to sheath and/or filter system — Damage of filter	— Delivery failure — Delivery system damage — Sheath damage — Foreign body embolization — Deployment failure — Filter fracture — Filter migration — Inadequate filter formation — Unacceptable filter tilting — Misplacement — Filter system damage — Filter damage	— ACE2 — ACE3
Ability to deploy filter	— Damage to sheath and/or filter system — Damage of filter — Inability to activate deployment mechanism — Difficult to deploy — Inaccurate deployment in relationship to target site — Inability to completely separate filter from delivery system — Partial deployment of filter — Inadequate filter formation — Unacceptable filter tilting	— Delivery failure — Filter system damage — Foreign body embolization — Sheath damage — Filter damage — Filter fracture — Filter migration — Inadequate filter formation — Unacceptable filter tilting — Withdrawal failure — Deployment failure — Misplacement — Delivery system damage — Inadequate filtration — Excessive filtration	— ACE1 — ACE2 — ACE3
Ability to withdraw delivery system and introducer sheath	— Inability to withdraw filter delivery system — Damage to filter — Damage to delivery system — Inability to completely separate filter from delivery system — Change in formation	— Withdrawal failure — Delivery system damage — Foreign body embolization — Filter damage — Filter fracture — Filter migration — Inadequate filter formation — Unacceptable filter tilting — Inadequate filtration — Excessive filtration	— ACE2 — ACE3

Testing shall include the items listed in 8.5.2.2 to 8.5.2.6, as appropriate to the design of the filter system.

8.5.2.2 Dimensional verification and component dimensional compatibility

Determine the dimensions of the filter system and evaluate the dimensional compatibility of the filter system with the recommended accessories. The need for contrast to be able to pass through the lumen of the introducer sheath with the filter system in place shall be considered, as applicable.

8.5.2.3 Force to deploy

Determine the force to deploy the filter from the filter system.

8.5.2.4 Simulated use

8.5.2.4.1 General

Evaluate the performance of the filter system using a model or models that simulate(s) the intended use conditions.

8.5.2.4.2 Ability to deliver

Evaluate the ability of the filter system to be advanced through the introducer sheath. Torquability shall be assessed for designs that require significant rotational control of the filter during delivery to the deployment location.

8.5.2.4.3 Ability to deploy

Evaluate the ability of the filter system to deploy the filter.

8.5.2.4.3.1 Deployment accuracy

Evaluate the accuracy of the filter deployment in relation to the intended target site.

8.5.2.4.3.2 Deployed configuration

Evaluate the ability of the filter to take the proper configuration following deployment from the filter system.

8.5.2.4.4 Ability to withdraw

Evaluate the ability of the filter system and the introducer sheath to be withdrawn from the anatomical model(s), post filter deployment.

8.5.2.5 Tensile strength

Determine the tensile strength of relevant components including bond joints and/or fixed connections of the system.

8.5.2.6 Torsional bond strength

Determine the torque/rotation required to break joints and/or materials in the appropriate filter system components, if appropriate for the intended clinical use.

8.5.3 Filter

8.5.3.1 General

The ability of the implant to filter blood for clots without causing caval occlusion 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 4.

Table 4 — Filter

Function(s)	Potential failure mode(s)	Potential effect(s) of failure (device)	Potential effect(s) of failure (clinical)
Fixation effectiveness	— Excessive radial force — Inadequate fixation	— Filter migration — Unacceptable filter tilting — Inadequate filtration — Excessive filtration — Inadequate filter formation — Filter fracture	— ACE2
Structural integrity	— Corrosion — Fracture	— Filter fracture — Inadequate filtration — Excessive filtration — Filter migration — Foreign body embolization — Inadequate filter formation — Unacceptable filter tilting — Change in filter formation	— ACE2
Filtration	— Ineffective clot capture — Obstruction of blood flow	— Inadequate filtration — Excessive filtration — Migration	— ACE2 — Caval occlusion — Caval stenosis
Sizing	— Excessive oversizing — Undersizing	— Excessive filtration — Filter damage — Filter fracture — Inadequate filter formation — Unacceptable filter tilting — Filter migration — Foreign body embolization — Inadequate filtration	— ACE2 — Caval occlusion
Magnetic resonance imaging (MRI) compatibility	— Heating of filter — Lack of quality MRI — Movement of filter	— Filter migration — Unacceptable filter tilting — Inadequate filtration — Excessive filtration — Filter fracture — Inadequate filter formation	— ACE2 — Inadequate MRI

Testing shall include the items listed in 8.5.3.2 to 8.5.3.10, as appropriate to the design of the filter.

8.5.3.2 Clot trapping

Determine the ability of the filter to capture clots, demonstrating that the device can capture clinically significant emboli, yet still permit sufficient blood flow around trapped emboli without caval occlusion. Clinically significant emboli, usually described as a number of clots with various diameters and lengths, shall be determined and justified by the manufacturer. The clot-trapping ability of the filter shall also be challenged in non-optimal positions (e.g. tilted) to determine the sensitivity of the design. References to literature regarding clot trapping are provided in the Bibliography.

8.5.3.3 Corrosion

Evaluate the susceptibility of the filter to corrosion in an actual or simulated environment. These corrosion mechanisms might include pitting, fretting, and crevice and galvanic corrosion. The potential detrimental clinical effect of by-products produced by corrosion should also be considered. In cases where different metals might be in contact by virtue of the device design or IFU, galvanic corrosion shall be assessed (e.g. radiopaque markers). Corrosion assessment includes, but is not limited to, evaluation of test results, review of literature and consideration of the historical clinical performance of the material(s) under assessment. Guidance on corrosion assessment is given in a variety of sources (e.g. literature, text books, standards, regulatory guidance documents).

NOTE Additional guidance is given in ISO 17475, ASTM B117, ASTM F746, ASTM F2129, ASTM G5, ASTM G15, ASTM G61, ASTM G71 and ASTM G102.

8.5.3.4 Durability

8.5.3.4.1 General

The following items shall be considered in evaluating durability:

— potential failure modes such as wear, fracture, and component separation;

— relevant *in vivo* loads (e.g. compression resulting from respiration).

These items shall be considered in the context of anatomic variability and morphological changes.

8.5.3.4.2 Stress/strain analyses

Determine the critical stresses and/or strains in the filter due to manufacturing, catheter loading, delivery, deployment, *in vivo* loading, and, if appropriate, retrieval/conversion using appropriate tools, such as finite element analysis (FEA). The material properties shall be selected as those appropriate to the specific stage of manufacturing and deployment being analysed (i.e. reflecting any effects of prior thermal or mechanical processing). The results of this stress/strain analysis can be used to determine appropriate design safety margins and can be used to establish the appropriate test conditions and to select the appropriate test articles (e.g. filter sizes) for fatigue testing.

8.5.3.4.3 Fatigue

Conduct an appropriate fatigue analysis. Evaluation of the filter fatigue safety factor requires an engineering approach such as stress-life and/or strain-life. In general, all sizes and configurations should be analysed, unless it can be reasonably demonstrated that a worst case exists. Consideration shall be given specifically to convertible filters in both filtering and converted states. Stress-life or strain-life analysis requires that the mean and cyclic stresses or strains be determined by stress/strain analysis and compared to the appropriate material properties (e.g. ultimate and endurance strength or strain). The safety factor may be expressed based on stress, strain, or fatigue life.

8.5.3.5 Filter dimensional verification

Evaluate the appropriate dimensions of the filter for conformance with design specifications.

8.5.3.6 Filter tensile strength

Determine the tensile strength of relevant components, including bond joints and/or fixed connections of the filter.

8.5.3.7 Migration resistance

Determine the pressure gradient caused by a clot load necessary to cause the filter to migrate in the cephalad direction. Determining migration resistance in the caudal direction shall be considered depending upon the device design.

8.5.3.8 Magnetic resonance imaging (MRI) compatibility

Evaluate the safety and compatibility of the filter with MRI. Evaluations shall include, but are not limited to, the following:

a) magnetically induced displacement force and torque;

b) RF-induced heating of the filter;

c) lack of quality MRI (artefact).

NOTE 1 Additional guidance for evaluating magnetically induced displacement, torque, RF heating, and imaging artefact is given in ASTM F2052, ASTM F2119, ASTM F2182 and ASTM F2213.

NOTE 2 The MRI artefact caused by some filters might compromise the effectiveness and limit the use of MRI in patients with these implants.

8.5.3.9 Radial force

Determine the force exerted on the surrounding tissue by a filter as a function of the filter diameter.

8.5.3.10 Visual inspection

The filter shall conform to the manufacturer's specifications with respect to surface defects.

8.5.4 Optional filter

8.5.4.1 General

In addition to the attributes listed in 8.5.3.1, the ability of the optional filter to be safely, consistently and accurately retrieved or converted 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 5.

Table 5 — Optional filter

Function(s)	Potential failure mode(s)	Potential effect(s) of failure (device)	Potential effect(s) of failure (clinical)
Ability to engage filter	Inability to engage filter	— Retrieval/conversion failure — Retrieval/conversion system damage — Filter damage — Unacceptable filter tilting — Inadequate filtration — Excessive filtration — Filter fracture — Filter migration — Foreign body embolization	— ACE2
Ability to retrieve filter	Inability to detach filter from vena cava Inability to collapse filter	— Excessive filtration — Filter damage — Filter fracture — Filter migration — Foreign body embolization — Inadequate filtration — Inadequate filter formation — Retrieval failure — Retrieval system damage — Unacceptable filter tilting	— ACE2
Ability to convert filter	Inability to convert filter	— Filter damage — Unacceptable filter tilting — Filter fracture — Unintentional filter movement — Conversion system damage — Foreign body embolization — Inadequate filter formation — Filter migration — Inadequate filtration — Conversion failure	— ACE2
Structural integrity	Bond joint or material failure	— Filter damage — Filter fracture — Unacceptable filter tilting — Foreign body embolization — Inadequate filtration — Excessive filtration — Filter migration — Inadequate filter formation — Retrieval/conversion failure — Retrieval/conversion system damage	— ACE2
	Engagement mechanism deformation/fracture	— Engagement mechanism damage — Engagement mechanism fracture — Foreign body embolization — Retrieval/conversion failure	— ACE2

Testing shall include the items listed in 8.5.4.2 to 8.5.4.4, as appropriate to the design of the optional filter.

8.5.4.2 Filter tensile strength

Determine the tensile strength of relevant components including bond joints and/or fixed connections of the filter.

8.5.4.3 Force to retrieve/convert

Determine the force to retrieve or convert the vena cava filter in an anatomical model, using the retrieval/conversion system as specified in the IFU.

8.5.4.4 Simulated use

8.5.4.4.1 General

Evaluate the performance of the optional filter using a model or models that simulate(s) the intended use conditions.

8.5.4.4.2 Ability to engage

Evaluate the ability of the optional filter to be engaged during retrieval or conversion.

8.5.4.4.3 Ability to retrieve

Evaluate the ability of the filter to be retrieved from the anatomical model.

8.5.4.4.4 Ability to convert

Evaluate the ability of the filter to be converted in the anatomical model.

8.5.5 Sheath/dilator kit for endovascular retrieval/conversion system

8.5.5.1 General

The ability of the sheath/dilator kit to permit safe, consistent and accurate access to the intended location shall be assessed with respect to filter retrieval or conversion.

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 6.

Table 6 — Sheath/dilator kit for retrieval/conversion system

Function(s)	Potential failure mode(s)	Potential effect(s) of failure (device)	Potential effect(s) of failure (clinical)
Ability to access with sheath/dilator kit	— Difficult/unable to push sheath/dilator to retrieval site — Dilator difficult/unable to track over guidewire — Sheath/dilator is incompatible with accessory devices — Sheath is incompatible with dilator	— Access failure — Dilator damage — Sheath damage — Accessory device failure	— ACE1 — Air embolism
Ability to withdraw dilator	— Bond joint separation	— Dilator damage — Foreign body embolization — Withdrawal failure	— ACE2
Ability to perform cavagram	— Hub separation — Inadequate contrast flow	— Delivery system damage — Leakage of contrast media	— Inadequate cavagram

Testing shall include the items listed in 8.5.5.2 to 8.5.5.7, as appropriate to the design of the sheath/dilator kit used for retrieval or conversion.

8.5.5.2 Catheter burst

Determine the burst pressure for catheters used for cavagrams.

8.5.5.3 Dimensional verification and component dimensional compatibility

Determine the dimensions of the sheath/dilator kit and evaluate the dimensional compatibility of the sheath/dilator kit with the recommended accessories and/or conformance with design specifications.

8.5.5.4 Power injection

Determine the amount and location of leakage from the system during contrast power injection (if applicable).

8.5.5.5 Simulated use

8.5.5.5.1 General

Evaluate the performance of the sheath/dilator kit using a model or models that simulate(s) the intended use conditions.

8.5.5.5.2 Ability to access

Evaluate the ability of the sheath/dilator kit to access the retrieval/conversion location in the anatomical model(s).

8.5.5.5.2.1 Flex/kink

Evaluate the ability of the sheath/dilator kit to bend in order to accommodate the minimum radius or angle it will be required to negotiate during access and delivery.

8.5.5.5.2.2 Pushability

Evaluate the ability of the sheath/dilator kit to be pushed or positioned by an operator without bending or buckling.

8.5.5.5.2.3 Trackability

Evaluate the ability of the sheath/dilator kit to advance through the vessel to the target site using the recommended accessories.

8.5.5.5.3 Ability to withdraw

Evaluate the ability of the dilator to be withdrawn from the retrieval/conversion location in the anatomical model(s).

8.5.5.6 Tensile strength

Determine the tensile strength of relevant components including bond joints and/or fixed connections of the system.

8.5.5.7 Torsional bond strength

Determine the torque/rotation required to break joints and/or materials in the appropriate sheath/dilator kit components, if appropriate for the intended clinical use.

8.5.6 Retrieval/conversion system

8.5.6.1 General

The ability of the retrieval/conversion system to permit safe and consistent retrieval/conversion of the filter 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 7.

Table 7 — Retrieval/conversion system

Function(s)	Potential failure mode(s)	Potential effect(s) of failure (device)	Potential effect(s) of failure (clinical)
Ability to deliver retrieval/conversion system to filter location (i.e. only to tip of sheath)	— Retrieval/conversion system is incompatible with introducer sheath — Inability to advance retrieval/conversion system to target site — Damage to retrieval/conversion system	— Retrieval system delivery failure — Conversion system delivery failure — Retrieval system damage — Conversion system damage — Sheath damage — Foreign body embolization	— ACE2 — ACE3
Ability to engage filter	— Inability to engage filter	— Retrieval failure — Conversion failure	— ACE2
Ability to retrieve	— Inability to detach filter from vena cava — Inability to retrieve filter	— Filter damage — Filter fracture — Unacceptable filter tilting — Foreign body embolization — Retrieval failure — Excessive filtration — Filter migration — Inadequate filter formation — Retrieval system damage	— ACE2
Ability to convert	— Inability to initiate filter conversion — Inability to convert	— Conversion system damage — Filter damage — Filter fracture — Foreign body embolization — Conversion failure — Unacceptable filter tilting — Excessive filtration — Filter migration — Inadequate filter formation — Unintentional filter movement	— ACE2
Ability to withdraw retrieval/conversion system and introducer sheath	— Inability to withdraw retrieval/conversion system — Damage to sheath and/or retrieval/conversion system	— Withdrawal failure — Retrieval system damage — Conversion system damage — Sheath damage — Foreign body embolization	— ACE2

Testing shall include the items listed in 8.5.6.2 to 8.5.6.6, as appropriate to the design of the retrieval/conversion system.

8.5.6.2 Dimensional verification and component dimensional compatibility

Determine the dimensions of the retrieval/conversion system and evaluate the dimensional compatibility of the retrieval/conversion system with the recommended accessories and/or conformance with design specifications. The need for contrast to be able to pass through the lumen of the introducer sheath with the retrieval/conversion system in place shall be considered.

8.5.6.3 Force to retrieve/convert

Determine the force to retrieve/convert the filter in an anatomical model using the retrieval/conversion system as specified in the IFU.

8.5.6.4 Simulated use

8.5.6.4.1 General

Evaluate the performance of the retrieval/conversion system using a model or models that simulate(s) the intended use conditions.

8.5.6.4.2 Ability to deliver

Evaluate the ability of the retrieval/conversion system to be advanced through the introducer sheath to the intended location.

8.5.6.4.3 Ability to engage

Evaluate the ability of the retrieval/conversion system to engage the filter.

8.5.6.4.4 Ability to retrieve

Evaluate the ability of the retrieval system to retrieve the filter.

8.5.6.4.5 Ability to convert

Evaluate the ability of the conversion system to convert the filter.

8.5.6.4.6 Ability to withdraw

Evaluate the ability of the retrieval/conversion system (including filter, if applicable) and introducer sheath to be withdrawn from the anatomical model(s).

8.5.6.5 Torsional bond strength

Determine the torque/rotation required to break joints and/or materials in the appropriate retrieval/conversion system components, if appropriate for the intended clinical use.

8.5.6.6 Tensile strength

Determine the tensile strength of relevant components including bond joints and/or fixed connections of the system.

8.5.7 Endovascular systems

8.5.7.1 General

Biocompatibility and visibility of the endovascular filter systems and endovascular retrieval/conversion systems 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 8.

Table 8 — Endovascular systems

Function(s)	Potential failure mode(s)	Potential effect(s) of failure (device)	Potential effect(s) of failure (clinical)
Biocompatibility	— Non-biocompatible	— None	— Adverse biological response
Haemostasis	— Inadequate haemostasis	— None	— Excessive procedural bleeding
Visibility	— Inadequate visibility	— Access failure — Delivery failure — Deployment failure — Withdrawal failure — Retrieval/conversion system delivery failure — Retrieval/conversion failure — Retrieval/conversion system damage — Filter damage — Unacceptable filter tilting — Inadequate filtration — Excessive filtration — Filter fracture — Filter migration — Inadequate filter formation — Foreign body embolization	— ACE1 — ACE2 — ACE3 — Embolization

Testing shall include the items listed in 8.5.7.2 and 8.5.7.3, as appropriate to the design of all device components.

8.5.7.2 Biocompatibility

Biocompatibility shall be evaluated in accordance with the ISO 10993 series.

8.5.7.3 Visibility

Evaluate the ability to visualize any filter and/or system radiopaque components (e.g. markers) as specified in the IFU.

8.6 Preclinical *in vivo* evaluation

8.6.1 Purpose

The purpose of preclinical *in vivo* testing is to evaluate the performance of the endovascular filter system and/or endovascular retrieval/conversion systems in an *in vivo* model in accordance with the IFU. In particular, preclinical testing shall provide data pertaining to safety. If a preclinical *in vivo* study is not required for risk assessment, justification shall be provided.

8.6.2 Specific aims

Specific aims of the study shall be stated and can include the following, as appropriate:

a) evaluate the ability to access the target site with the endovascular filter system;

b) evaluate the handling and visualization of the endovascular filter system and visualization of the filter;

c) evaluate deliverability of the filter to the intended deployment location;

d) verify the accuracy and efficacy of deployment including adequate fixation;

e) characterize the ability to withdraw the delivery system and introducer sheath;

f) evaluate the functional haemostasis of the sheath/dilator kit;

g) assess the position, integrity and functionality of the filter;

h) evaluate the ability to access the intended retrieval/conversion location with the endovascular retrieval/conversion system (if applicable);

i) evaluate the handling and visualization of the retrieval/conversion system (if applicable);

j) evaluate the ability to retrieve/convert the filter (if applicable);

k) evaluate the ability to withdraw the retrieval/conversion system, with any removed previously implanted components, and introducer sheath following retrieval/conversion (if applicable);

l) evaluate histology and pathology of explants and pertinent tissues/organs (e.g. inflammation, injury, and downstream findings);

m) record failure modes and device effects (see Annex B for potential failure modes and effects).

NOTE More than one study can be used to address the specific aims.

8.6.3 Protocol

Each endovascular filter system and/or endovascular retrieval/conversion system shall be tested by implantation of the filter at the intended, or at an analogous, vena cava site in a justified number of animals for a justified period of time (e.g. 12 weeks) in each animal. For retrievability/conversion studies, an appropriate duration prior to removal shall be justified. Type and intervals of interim assessments shall be specified and justified. As far as permitted by the limitations of the animal model, all devices used shall be of clinical quality and size, and of the design intended for clinical use.

Interpretation of preclinical *in vivo* study results can be enhanced by the use of at least a small number of control devices for comparison purposes.

All animals in the study shall be regularly examined. All animals shall undergo post-mortem examination, including any that expire prior to scheduled termination. The cause of death or illness, and the extent to which

the implant was implicated shall be documented. Histological and pathological assessment of explants and appropriate tissues/organs shall be provided.

The design of the preclinical *in vivo* testing including the experimental protocol, measurement methods and data analysis shall be specified. In addition, the choice of animal model (such as species, gender, age, weight) shall be justified and shall be consistent with the study objectives. Implantation shall be consistent with the recommended instructions for clinical use, as far as permitted by the limitations of the animal model, if applicable. In particular, the IVC filter sizing should be as close to the human sizing relationship as possible in order to realistically simulate implantation conditions.

Protocol should be executed using appropriate good laboratory practices, such as the OECD Principles of Good Laboratory Practice[103] and/or Japanese GLP Ministerial Ordinance[105].

8.6.4 Data acquisition

The following minimum data shall be recorded for each animal receiving a filter:

a) identification data:

   1) species;

   2) source of animals;

   3) animal identification;

   4) sex;

   5) age;

   6) weight;

b) pre-operative data:

   1) verification of health status;

   2) medications (e.g. prophylactic antibiotics);

c) operative data:

   1) date of procedure;

   2) name of person performing procedure;

   3) description of the implant procedure including:

      i) identification of endovascular filter system and/or endovascular retrieval/conversion systems;

      ii) identification of accessory devices;

      iii) filter identification number;

      iv) diameter(s) of recipient vessel(s), including major and minor axes before and after implant;

      v) use of any medications;

      vi) implant location;

      vii) access site;

4) assessment of parameters specified in the protocol, such as:

   i) ability to access the target site with the endovascular filter system;

   ii) handling and visualization of the endovascular filter system and visualization of the filter;

   iii) deliverability of the filter to the intended deployment location;

   iv) accuracy and efficacy of deployment, including adequate fixation;

   v) ability to withdraw the delivery system and introducer sheath;

   vi) functional haemostasis of the sheath/dilator kit;

   vii) position, integrity and functionality of the filter, at pre-specified intervals;

   viii) ability to access the intended retrieval/conversion location with the endovascular retrieval/conversion system (if applicable);

   ix) handling and visualization of the retrieval/conversion system (if applicable);

   x) ability to retrieve/convert filter (if applicable);

   xi) ability to withdraw the retrieval/conversion system, with any removed previously implanted components, and introducer sheath following retrieval/conversion (if applicable);

   xii) histology and pathology of explants and pertinent tissues/organs (e.g. inflammation, injury, and downstream findings);

   xiii) detrimental *in vivo* effects, failure modes and device effects (see Annex B for potential failure modes and effects);

      I) event, date of occurrence, severity, management, outcome;

      II) documentation of filter involvement;

      III) documentation of probable causative factors (i.e. is the complication caused by filter, animal factors, technical factors, or other);

5) description of the explant procedure including:

   i) identification of filter retrieval/conversion system and accessory devices (if applicable);

   ii) filter identification number;

   iii) diameter(s) of recipient vessel(s);

   iv) description of filter formation;

   v) location of filter prior to explant;

   vi) access site for retrieval/conversion (if applicable);

d) post-operative and follow-up data:

1) post-operative duration at the time of follow-up;

2) medications, including those that affect coagulation;

3) verification of health status;

4) methods used and results of the assessments specified in the protocol, such as:

   i) observation of integrity, functionality and position of implant;

   ii) detrimental *in vivo* effects, failure modes and device effects;

      I) event, date of occurrence, severity, management, outcome;

      II) documentation of filter involvement;

      III) documentation of probable causative factors (i.e. is the complication caused by filter, animal factors, technical factors, or other);

5) any major deviation from protocol;

e) termination data:

1) date of death;

2) reason for early termination or death, if applicable;

3) assessments specified in the protocol (e.g. observation of integrity, functionality, patency and position of implant);

4) gross observation of the explanted filter and surrounding tissue;

5) pathological assessment of appropriate tissues and/or organs, particularly downstream organs such as lungs, if required in accordance with the protocol.

8.6.5 Test report and additional information

Results of all animals enrolled in the protocol shall be recorded and reported even if excluded from the final analysis.

The test report shall include the following:

a) study protocol;

b) rationale for selection of the following:

1) animal species, gender, age and weight;

2) implantation site;

3) implantation durations;

4) methods of assessment;

5) type and intervals of interim assessments;

6) sample size (i.e. number of animals and implants);

7) control, if applicable;

c) results:

1) animal accountability, including rationale for exclusion of data;

2) summary of adverse events, failure modes and device effects;

3) summary of early deaths or animals having to be killed;

4) significant and/or relevant deviations from protocol;

5) summary of results, discussion and conclusions for each specific aim of the study;

6) summary of pathological assessment of appropriate tissues and/or organs, including representative gross photographs and micrographs, if required in accordance with the protocol;

7) summary of quality assurance and data auditing procedures, including a statement relative to their compliance to standards, if applicable.

8.7 Clinical evaluation

8.7.1 Purpose

The purpose of clinical evaluation is to assess the safety and effectiveness of endovascular filter systems and/or endovascular retrieval/conversion systems. A clinical investigation might be necessary for novel designs and for any filter system incorporating design characteristics for which the safety and effectiveness has not been previously demonstrated. The investigation shall be carried out using the principles given in ISO 14155 or an equivalent standard. Specific aims listed in 8.7.2 shall also apply, as appropriate. The filter shall have satisfied all appropriate preclinical testing requirements of this part of ISO 25539 before starting the clinical investigation.

8.7.2 Specific aims

Specific aims of the study shall be stated and can include the following, as appropriate:

a) evaluate the ability to access the target site with the endovascular filter system;

b) evaluate the handling and visualization of the endovascular filter system and visualization of the filter;

c) evaluate deliverability of the filter to the intended deployment location;

d) verify the accuracy and efficacy of deployment, including adequate fixation;

e) characterize the ability to withdraw the system and introducer sheath;

f) evaluate the functional haemostasis of the sheath/dilator kit;

g) evaluate the appropriateness of filter sizing;

h) evaluate the structural integrity and functionality of the filter;

i) monitor filter positioning (over time), including filter tilting, migration and formation;

j) evaluate the ability to access the intended retrieval/conversion location with the endovascular retrieval/conversion system (if applicable);

k) evaluate the handling and visualization of the retrieval/conversion system (if applicable);

l) evaluate the ability to retrieve/convert the filter (if applicable);

m) evaluate the ability to withdraw the retrieval/conversion system, with any removed previously implanted components, and introducer sheath following retrieval/conversion (if applicable);

n) evaluate any explants;

o) record adverse events, failure modes and device effects (see Annex B for potential failure modes and effects).

8.7.3 Clinical investigation plan

A justification for the number of investigational sites shall be provided. A justification for the number of patients studied shall also be provided based upon the clinical hypotheses. The calculation of the number of patients to be enrolled shall take account of the effect of comorbidities on the life expectancy of the patient population.

The duration of patient follow-up shall be determined in relation to the objectives of the clinical investigation. All patients implanted, including those excluded from the final analysis, shall be recorded and reported. The final report shall include current follow-up data on all patients, with follow-up as specified by the clinical investigation plan for the last patient enrolled. Patient follow-up intervals shall include a minimum of a baseline assessment at discharge and at the end of the trial. A justification will be required for follow-up intervals.

A method for evaluating the clinical outcomes shall be prospectively defined and justified. A specific question or set of questions shall be defined prospectively. These questions shall delineate the appropriate endpoints to be measured and include definitions of success and failure for each endpoint. The definitions of success and failure shall incorporate quantitative values specifically applicable for the imaging modalities or other evaluation techniques to be used in the study.

Patient selection and exclusion criteria shall be clearly established. The criteria shall specify the target population (i.e. those for whom the filter is intended) and the accessible population (i.e. those who agree to participate fully in the study). An appropriate epidemiological approach shall be utilized for recruiting subjects to minimize bias.

8.7.4 Data acquisition

At a minimum, the following data shall be recorded for each patient in the study:

a) identification data:

   1) patient identification;

   2) sex;

   3) date of birth;

   4) name of investigator;

   5) name of institution;

b) pre-operative data:

   1) risk factors, such as deep vein thrombosis (DVT), trauma, malignancy, anticoagulation therapy, pelvic and orthopaedic procedures, female contraceptive pill and female hormone replacement therapy, hypercoaguable states including post-splenectomy, post-operative cessation of anticoagulant therapy, severe cardiopulmonary disease, varicose veins, history of pulmonary embolism (PE), obesity, smoking, anaesthesia risk, prolonged immobility, and any other cardiovascular risk factors, with some measure of severity and current treatment;

      NOTE Additional definitions and risk factors are given in Quality Improvement Guidelines, *JVIR* 2003[33].

   2) summary of previous cardiovascular interventions, including non-surgical interventions, and cardiovascular implants;

   3) urgency of intervention (i.e. emergent, urgent, or elective);

   4) diagnostic criteria:

      i) clinical assessment;

      ii) objective assessment of access vessel characteristics and other relevant factors (such as size of vena cava and presence and site of thrombus);

c) operative data:

1) name of implanting physician;

2) date of procedure;

3) identification data for the filter system(s), including product name, model number, filter traceability, size and orientation;

4) details of procedure, including any adjunctive vascular procedures performed;

5) relevant medications;

6) assessment of access, handling, visualization, deliverability, and withdrawal of endovascular filter system;

7) assessment of haemostasis of the sheath/dilator kit;

8) assessment of accuracy and efficacy of filter deployment;

9) assessment of filter sizing;

10) assessment of patency, positioning and integrity of the filter;

11) detrimental clinical effects, failure modes and device effects (see Annex B for potential failure modes and effects);

i) severity, management, outcome;

ii) documentation of filter system involvement (i.e. determine if the complication involves the filter system);

iii) documentation of probable causative factors (i.e. determine if the complication is caused by the filter system, patient factors, technical factors, or other);

12) comparison of intended and actual filter location;

13) confirmation of proper filter formation;

14) date of hospital discharge;

d) post-operative data:

1) date of each follow-up visit;

2) summary of cardiovascular interventions since last follow-up;

3) clinical evaluation (assessment protocol might differ between the control group and the treatment group);

4) relevant medications, such as antithrombotic or antibiotics;

5) detrimental clinical effects, failure modes and device effects;

i) event, date of occurrence, severity, management, outcome;

ii) documentation of filter involvement;

iii) documentation of probable causative factors (i.e. determine if the complication is caused by the filter, patient factors, technical factors, or other);

e) filter retrieval/conversion data (if applicable):

1) date of procedure;

2) access site;

3) retrieval device(s) used, including product name, model number, size and traceability;

4) details of procedure, including any adjunctive vascular procedures performed;

5) relevant medications;

6) assessment of access, handling, visualization, deliverability and withdrawal of retrieval/conversion system;

7) assessment of patency, positioning and integrity of the filter;

8) documentation of clinical decision not to retrieve/convert filter (e.g. thrombus formation), if applicable;

9) assessment of ability to retrieve/convert filter;

10) integrity inspection of retrieved filter(s);

11) configuration and/or status of converted filter detrimental clinical effects, failure modes and device effects (see Annex B for potential failure modes and effects);

i) severity, management, outcome;

ii) documentation of filter system involvement (i.e. determine if the complication involves the filter system);

iii) documentation of probable causative factors (i.e. determine if the complication is caused by the filter system, patient factors, technical factors, or other);

f) patient withdrawal:

1) date;

2) months of study completed;

3) reason for withdrawal (lost to follow-up, death).

8.7.5 Final report

The final report shall include the following:

a) study protocol;

b) descriptions of detrimental clinical effects, failure modes and device effects;

c) rationale for selection of the following:

1) study size;

2) measurement methods;

3) analyses employed;

4) patient follow-up intervals;

d) procedural data and periprocedural (less than or equal to 30 days following procedure) and late (more than 30 days following procedure) follow-up data:

   1) patient accountability, including rationale for exclusion of data;

   2) significant and/or relevant deviations from protocol;

   3) summary of patients not completing study (e.g. lost to follow-up or death);

   4) summary of detrimental clinical effects, failure modes and device effects, including documentation of filter involvement and probable causative factors;

      i) by type of event, including timing of event relative to procedure (i.e. procedural, periprocedural and for each follow-up time interval);

      ii) by patient, including timing of events;

   5) summary of delivery system performance;

   6) summary of filter performance over time (e.g. migration, patency, filter integrity, formation);

   7) summary of intraprocedural, adjunctive and subsequent secondary endovascular interventions (e.g. placement of additional filter) or filter-related surgical interventions needed post-filtering, if any, to optimize results;

   8) summary of periprocedural and late deaths;

   9) summary of pathology, if appropriate, including representative gross photographs and micrographs;

   10) comparison of results for test and control groups;

   11) conclusions for each specific objective of the study.

9 Post-market surveillance

A systematic procedure to review post-market experience gained from implants shall be in place using the principles given in ISO 14630, ISO 14971 or an equivalent standard.

10 Manufacturing

Endovascular filter systems and endovascular retrieval/conversion systems shall be manufactured in such a way that the specified design attributes are achieved. Requirements are specified in other related International Standards.

NOTE Additional guidance is given in ISO 13485.

11 Sterilization

11.1 Products supplied sterile

Endovascular filter systems and endovascular retrieval/conversion systems that are labelled “sterile” shall comply with international, national or regional standards. Systems which are labelled “sterile” shall have a sterility assurance level (SAL) of 10^{-6}.

Sterilization processes shall be validated and routinely controlled.

a) If systems are to be sterilized by ethylene oxide, ISO 11135-1 shall apply.

b) If systems are to be sterilized by moist heat, ISO 17665-1 shall apply.

c) If systems are to be sterilized by radiation, ISO 11137-1 shall apply.

d) If systems are to be sterilized by other sterilization processes, ISO 14937 shall apply.

11.2 Products supplied non-sterile

The requirements of ISO 14630 apply.

11.3 Sterilization residuals

The requirements of ISO 14630 apply.

12 Packaging

12.1 Protection from damage in storage and transport

12.1.1 General

The requirements of ISO 14630 apply.

12.1.2 Unit container

Each endovascular filter system and endovascular retrieval/conversion system shall be packaged in a unit container providing a sterile barrier, if applicable. It shall be readily apparent if the unit container has been opened.

12.1.3 Outer container

Each unit container shall be packaged in an outer container. This outer container shall be designed so as to protect the unit container from damage caused by storage.

12.1.4 Shipping container

Each outer container, or a number of outer containers not necessarily of the same type, can be packaged in a shipping container designed to protect the contents under normal conditions of handling, transit and storage.

12.1.5 Maintenance of sterility in transit

For endovascular filter systems and endovascular retrieval/conversion systems supplied sterile, the unit container shall be designed to maintain the sterility of the system under normal conditions of handling, transit and storage, and to allow the contents to be presented for use in an aseptic manner.

The packaging shall conform to ISO 11607-1.

12.2 Marking

12.2.1 Container label

Each endovascular filter system and endovascular retrieval/conversion system shall be accompanied by one or more labels on an appropriate container.

12.2.2 Filters without deployment systems

At least the following information shall be provided in words, phrases, symbols or drawings on the label(s):

— description of the contents;

— name and/or trademark and contact information of the manufacturer and/or the representative;

— name of the device;

— model/reference number;

— lot/serial number;

— sterilization method and the notification “STERILE”, if applicable;

— single use;

— expiry/expiration date;

— warnings or reference to read the IFU (symbol);

— size and configuration of filter, if applicable;

— recommended caval diameters;

— manufacturer's recommendation for storage, if applicable;

— the chemical nature of any storage medium in the unit container, with appropriate hazard warning, if applicable.

12.2.3 Endovascular filter systems

At least the following information shall be provided in words, phrases, symbols or drawings on the label(s):

a) information as described in 12.2.2;

b) endovascular filter system information, including at least:

   — dimensions: size of introducer (internal diameter), required size of guidewire and effective length of catheter;

   — filter system orientation.

12.2.4 Endovascular retrieval/conversion system

At least the following information shall be provided in words, phrases, symbols or drawings on the label(s):

a) applicable information as described in 12.2.2;

b) endovascular retrieval/conversion system information, including at least:

- dimensions: size of introducer (internal diameter), required size of guidewire and effective length of catheter;
- recommended accessory devices;
- retrieval/conversion system orientation.

12.2.5 Record label

Each filter and/or filter system should be supplied with transferable record labels suitable for attachment to the records of the patient receiving the filter. The record label should include the following information:

- manufacturer's identification;
- product name;
- manufacturer's batch and/or sterile lot number;
- part or model number (manufacturer's catalogue number).

12.3 Information supplied by the manufacturer

12.3.1 General

The requirements of ISO 14630 apply. Further information is contained in tabular form in Annex A, which can be included in the information supplied by the manufacturer. Specific information for endovascular systems follows.

12.3.2 Information and instructions for use (IFU)

Each unit container or outer container whose contents are identical shall be supplied with IFU of the device. The instructions shall include the information needed to use the device safely and properly, taking into account the training and knowledge of the potential users.

The instructions shall include the following:

- indications for use;
- any applicable contraindications, cautions, and warnings;
- recommendations for filter sizing, including vena cava diameters, as applicable;
- potential adverse events;
- data from clinical studies, if applicable;
- recommended methods for the aseptic presentation and the preparation of the filter and delivery system;
- recommended methods for vessel preparations, such as pre-dilatation, and methods for access, delivery of the filter, retrieval/conversion of the filter, and withdrawal of the system;

— the statement “STERILE—DO NOT RESTERILIZE—SINGLE USE ONLY” in prominent form, if applicable;

— if required by local regulations, a list of characteristics and technical factors known to the manufacturer to pose a risk if the device were to be re-used;

— resterilization information, if applicable;

— notification of additives and/or leachable components, if applicable;

— recommendations for storage, if applicable;

— date of issue of the latest revision;

— recommendations for visualization;

— MRI compatibility information;

— material of construction of the filter;

— recommended method, when applicable, for retrieval or conversion of the filter, including time frame (e.g. time to retrieval/conversion).

Annex A
(informative)

Attributes of endovascular devices — Vena cava filters — Technical and clinical considerations

A.1 General

Tables A.1 to A.9 provide a logical method for identifying a set of bench, analytical, and preclinical *in vivo* studies to assess device performance.

Annex B provides an alphabetical listing and description of potential device effects of failure and failure modes (see Table B.1) and detrimental clinical effects (see Table B.2), both identified in Annex A.

Annex C provides a list of bench and analytical tests, with a description of the purpose of each test and relevant design evaluation clauses.

Annex D provides a list of bench test methods for information purposes.

Identification of the appropriate testing is achieved by first listing the necessary functions for the components of the system, including the sheath/dilator kit, filter system, filter, optional filter, sheath/dilator kit for retrieval/conversion system, retrieval system, and conversion system, as applicable. Next, the types of problems or failures that might result if the component does not function properly are identified. The specific effects of the failure modes can be clinical or device-related, and are listed separately. Further categorization is included for potential effects of failure on devices to acknowledge that one effect might lead to another. For example, filter migration might lead to filter fracture. For this example, filter migration would be listed under "device" and filter fracture would be listed under "secondary device". Many device effects of failure can be found in the "device" or "secondary device" categories, depending on the potential failure mode associated with a specific function. Regarding the clinical effects of failure, "observations that might lead to a non-specific clinical event or use of additional devices or procedures", designated as ACE3 in Table A.2, only appears in Tables A.3 to A.10 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, even though it is a known potential detrimental clinical effect, because this event is correlated to the severity of the failure and not helpful in identifying tests to evaluate device function.

Although preclinical *in vivo* assessment is not specifically listed in all sections of the tables of this annex, it can be associated with most device functions and should therefore be considered when assessing test requirements. Preclinical *in vivo* assessment is specifically listed in the table for haemostasis since bench testing is not needed to evaluate this function.

The table headings and explanations are listed in Table A.1. In addition, a form is given to help provide the proper context for the information contained within the matrix.

Table A.1 — Table headings and explanations

Column number	Title	Explanation	Context
1	Device-related/ procedure-related function(s)	The intended or defined performance of the product	The device should have an adequate _____(column 1).
2	Potential failure mode(s)	Difficulties or failures that might be encountered that could result in consequences (effects) for the patient or device	If the device does not have an adequate _____(column 1), there could be a problem with _____(column 2).
3a	Potential effect(s) of failure (device)	The initial effect(s) of the failure mode on the device	If there is a problem with _____ (column 2), _____ (column 3a/b/c) could occur and should be documented.
3b	Potential effect(s) of failure (secondary device)	The secondary effect(s) of the failure mode on the device	
3c	Potential effect(s) of failure (clinical)	The effect(s) of the failure mode on the patient	
4	Preclinical test(s)	A list of preclinical tests (e.g. bench, analytical, and animal) that should be conducted to verify/validate the individual device function	To evaluate the adequacy of the _____(column 1), the following tests should be conducted: _____ (column 4).

Table A.2 — Legend for grouped associated detrimental clinical effects

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	An observation that might lead to a non-specific clinical event or use of additional devices or procedures

Table A.3 — Attributes of sheath/dilator kit (endovascular deployment system)

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.3.1 Ability to access with sheath/dilator kit	Difficult/unable to push sheath/dilator to target site	— Access failure — Dilator damage — Sheath damage	None	— ACE1	— Tensile strength — Dimensional verification and component dimensional compatibility — Simulated use — Ability to access — Torsional bond strength
	Dilator difficult/unable to track over guidewire	— Access failure — Dilator damage			
	Sheath/dilator is incompatible with accessory devices	— Access failure			
	Sheath is incompatible with dilator	— Access failure — Accessory device failure — Dilator damage — Sheath damage	None	— ACE1 — Air embolism	
A.3.2 Ability to withdraw dilator	Bond joint separation	— Dilator damage — Foreign body embolization — Withdrawal failure	None	— ACE2	— Tensile strength — Torsional bond strength — Simulated use — Ability to withdraw
A.3.3 Ability to perform cavagram	Hub separation	— Sheath damage — Dilator damage — Leakage of contrast media	— Foreign body embolization — Withdrawal failure	— Inadequate cavagram — ACE2	— Catheter burst — Power injection
	Catheter burst				
	Inadequate contrast flow	None	None	— Inadequate cavagram	

Table A.4 — Attributes of filter systems

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.4.1 Ability to deliver filter to implant site prior to deployment	Inability to load filter (if applicable)	— Delivery failure	None	ACE3	— Simulated use — Ability to deliver
	Filter system is incompatible with introducer sheath	— Delivery failure — Delivery system damage — Sheath damage	— Foreign body embolization	ACE2	— Simulated use — Ability to deliver — Dimensional verification and component dimensional compatibility
	Inability to advance filter system to target site				— Simulated use — Ability to deliver
	Generation of particles from system	— Foreign body embolization	None	ACE2	— Simulated use — Ability to deliver
	Premature release of filter	— Delivery failure — Deployment failure	— Excessive filtration — Inadequate filtration — Filter fracture — Filter migration — Inadequate filter formation — Unacceptable filter tilting — Misplacement	ACE2	— Simulated use — Ability to deliver
	Damage to sheath and/or filter system	— Delivery failure — Filter system damage — Foreign body embolization — Sheath damage	None	ACE2	— Simulated use — Ability to deliver — Dimensional verification and component dimensional compatibility — Tensile strength
	Damage of filter	— Filter damage — Filter fracture	— Excessive filtration — Inadequate filtration — Filter migration — Foreign body embolization — Inadequate filter formation — Unacceptable filter tilting	ACE2	

Table A.4 (*continued*)

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.4.2 Ability to deploy filter	Damage to sheath and/or filter system	— Delivery failure — Filter system damage — Foreign body embolization Sheath damage	None	ACE2	— Simulated use — Ability to deploy — Dimensional verification and component dimensional compatibility — Tensile strength
	Damage to filter	— Filter damage — Filter fracture	— Excessive filtration — Inadequate filtration — Filter migration — Foreign body embolization — Inadequate filter formation — Unacceptable filter tilting Withdrawal failure	ACE2	— Dimensional verification and component dimensional compatibility — Force to deploy — Simulated use — Ability to deploy
	Inability to activate deployment mechanism	— Deployment failure	None	ACE3	— Simulated use — Ability to deploy
	Difficult to deploy	— Deployment difficulty	— Excessive filtration — Inadequate filtration — Filter fracture — Filter migration — Inadequate filter formation — Unacceptable filter tilting — Misplacement	ACE2	— Force to deploy — Simulated use — Ability to deploy
	Inaccurate deployment in relation to target site	— Deployment difficulty	— Excessive filtration — Inadequate filtration — Filter fracture — Filter migration — Inadequate filter formation — Unacceptable filter tilting — Misplacement	ACE2	— Simulated use — Ability to deploy

Table A.4 (*continued*)

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
	Inability to completely separate filter from delivery system	— Deployment failure	None	ACE3	— Simulated use — Ability to deploy
	Partial deployment of filter	— Deployment failure	None	ACE1 Caval perforation	— Simulated use — Ability to deploy
	Inadequate filter formation	— Inadequate filtration — Excessive filtration — Filter fracture — Filter migration — Unacceptable filter tilting	None	ACE2	— Simulated use — Ability to deploy
	Unacceptable filter tilting	— Inadequate filtration — Excessive filtration — Filter fracture — Filter migration — Inadequate filter formation	— Foreign body embolization	ACE2	— Simulated use — Ability to deploy

Table A.4 (*continued*)

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.4.3 Ability to withdraw delivery system and introducer sheath	Inability to withdraw filter delivery system	— Withdrawal failure — Delivery system damage	— Foreign body embolization	ACE2	— Tensile strength — Simulated use — Ability to withdraw — Torsional bond strength
	Damage to filter	— Filter damage — Filter fracture	— Excessive filtration — Inadequate filtration — Filter migration — Foreign body embolization — Inadequate filter formation — Unacceptable filter tilting — Withdrawal failure	ACE2	— Simulated use — Ability to withdraw
	Damage to delivery system	— Delivery system damage	— Foreign body embolization	ACE2	— Tensile strength — Simulated use — Ability to withdraw — Torsional bond strength
	Inability to completely separate filter from delivery system	— Withdrawal failure	None	ACE3	— Simulated use — Ability to withdraw
	Change in filter formation	— Inadequate filtration — Excessive filtration — Filter damage — Filter fracture — Filter migration — Foreign body embolization — Inadequate filter formation — Unacceptable filter tilting	None	ACE2	— Simulated use — Ability to withdraw

Table A.5 — Attributes of filters

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.5.1 Fixation effectiveness	Excessive radial force	None	None	— Caval perforation — Caval injury or damage — Trauma to adjacent structures	— Radial force
	Inadequate fixation	— Filter migration — Unacceptable filter tilting	— Inadequate filtration — Excessive filtration — Inadequate filter formation — Filter fracture	ACE2	— Migration resistance — Radial force
A.5.2 Structural integrity	Corrosion	— Filter fracture	— Inadequate filtration — Filter migration — Foreign body embolization — Change in filter formation — Unacceptable filter tilting	ACE2	— Corrosion
	Fracture	— Inadequate filtration — Excessive filtration — Filter migration — Foreign body embolization — Inadequate filter formation — Unacceptable filter tilting	None	ACE2	— Fatigue/durability — Stress/strain analyses — Visual inspection
	Bond joint or material failure	— Filter damage — Filter fracture — Unacceptable filter tilting — Foreign body embolization	— Inadequate filtration — Excessive filtration — Filter migration — Inadequate filter formation	ACE2	— Filter tensile strength

Table A.5 (*continued*)

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Device	Device	
A.5.3 Filtration	Ineffective clot capture	— Inadequate filtration	None	— Pulmonary embolism	— Clot trapping
	Obstruction of blood flow	— Excessive filtration	— Migration	ACE2 — Caval occlusion — Caval stenosis	— Clot trapping
A.5.4 Sizing	Excessive oversizing	— Excessive filtration — Filter damage — Filter fracture — Inadequate filter formation — Unacceptable filter tilting	— Filter migration — Foreign body embolization	ACE2 — Caval occlusion	— Filter dimensional verification
	Undersizing	— Filter migration — Unacceptable filter tilting	— Inadequate filtration — Excessive filtration — Inadequate filter formation — Filter fracture	ACE2	— Filter dimensional verification
A.5.5 Magnetic resonance imaging (MRI) compatibility	Heating of filter	None	None	— Caval injury or damage	— MRI compatibility
	Lack of quality MRI	None	None	— Inadequate MRI	— MRI compatibility
	Movement of filter	— Filter migration — Unacceptable filter tilting	— Inadequate filtration — Excessive filtration — Filter fracture — Inadequate filter formation	ACE2	— MRI compatibility

Table A.6 — Attributes of optional filters

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.6.1 Ability to engage filter	Inability to engage filter	— Retrieval failure — Conversion failure — Retrieval system damage — Conversion system damage — Filter damage — Unacceptable filter tilting	— Inadequate filtration — Excessive filtration — Filter fracture — Filter migration — Foreign body embolization	ACE2	— Simulated use — Ability to engage filter
A.6.2 Ability to retrieve filter	Inability to detach filter from vena cava	— Retrieval system damage — Filter damage — Filter fracture — Unacceptable filter tilting — Foreign body embolization	— Inadequate filtration — Excessive filtration — Filter migration — Inadequate filter formation — Retrieval failure — Retrieval system damage	ACE2	— Simulated use — Ability to retrieve — Force to retrieve/convert
	Inability to collapse filter				— Simulated use — Ability to retrieve
A.6.3 Ability to convert filter	Inability to convert filter	— Filter damage — Unacceptable filter tilting — Filter fracture — Unintentional filter movement — Conversion system damage	— Foreign body embolization — Inadequate filter formation — Filter migration — Inadequate filtration — Conversion failure	ACE2	— Simulated use — Ability to convert — Force to retrieve/convert
A.6.4 Structural integrity	Bond joint or material failure	— Filter damage — Filter fracture — Unacceptable filter tilting — Foreign body embolization	— Inadequate filtration — Excessive filtration — Filter migration — Inadequate filter formation — Retrieval failure — Conversion failure — Retrieval system damage — Conversion system damage	ACE2	— Filter tensile strength
	Engagement mechanism deformation/fracture	— Engagement mechanism damage — Engagement mechanism fracture — Foreign body embolization	— Retrieval failure — Conversion failure	ACE2	— Force to retrieve/convert

Table A.7 — Attributes of sheath/dilator kit (endovascular retrieval/conversion system)

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.7.1 Ability to access with sheath/dilator kit	Difficult/unable to push sheath/dilator to target site	— Access failure — Dilator damage — Sheath damage	None	ACE1	— Tensile strength — Dimensional verification and component dimensional compatibility — Simulated use — Ability to access — Torsional bond strength
	Dilator difficult/unable to track over guidewire	— Access failure — Dilator damage			
	Sheath/dilator is incompatible with accessory devices	— Access failure			
	Sheath is incompatible with dilator	— Access failure — Accessory device failure — Dilator damage — Sheath damage	None	ACE1 — Air embolism	
A.7.2 Ability to withdraw dilator	Bond joint separation	— Dilator damage — Foreign body embolization — Withdrawal failure	None	ACE2	— Tensile strength — Torsional bond strength — Simulated use — Ability to withdraw
A.7.3 Ability to perform cavagram	Hub separation	— Delivery system damage — Leakage of contrast media	None	— Inadequate cavagram	— Power injection — Catheter burst
	Inadequate contrast flow	None	None	— Inadequate cavagram	

Table A.8 — Attributes of filter retrieval/conversion systems

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.8.1 Ability to deliver retrieval/conversion system to filter location (i.e. only to tip of sheath)	Retrieval/conversion system is incompatible with introducer sheath	— Retrieval system delivery failure — Conversion system delivery failure — Retrieval system damage — Conversion system damage Sheath damage	— Foreign body embolization	ACE3	— Simulated use — Ability to deliver — Dimensional verification and component dimensional compatibility
	Inability to advance retrieval/conversion system to target site	None	None	None	— Simulated use — Ability to deliver
	Damage to retrieval/conversion system	— Retrieval system delivery failure — Conversion system delivery failure — Retrieval system damage — Conversion system damage — Foreign body embolization	None	ACE2	— Simulated use — Ability to deliver — Dimensional verification and component dimensional compatibility — Tensile strength
A.8.2 Ability to engage filter	Inability to engage filter	— Retrieval failure — Conversion failure	None	None	— Simulated use — Ability to engage
A.8.3 Ability to retrieve filter	Inability to detach filter from vena cava	— Retrieval system damage — Filter damage — Filter fracture — Unacceptable filter tilting — Foreign body embolization — Retrieval failure	— Excessive filtration — Filter migration — Inadequate filter formation — Retrieval system damage	None	— Simulated use — Ability to retrieve — Force to retrieve/convert
	Inability to retrieve filter	— Filter damage — Filter fracture — Filter migration — Unacceptable filter tilting — Foreign body embolization — Retrieval failure	— Excessive filtration — Inadequate filter formation	None	— Simulated use — Ability to retrieve

Table A.8 (*continued*)

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.8.4 Ability to convert filter	Inability to initiate filter conversion	— Conversion system damage — Filter damage — Filter fracture Foreign body embolization — Conversion failure — Unacceptable filter tilting	— Excessive filtration — Filter migration — Inadequate filter formation	None	— Simulated use — Ability to convert — Force to retrieve/convert
	Inability to convert filter	— Filter damage — Filter fracture — Unintentional filter movement — Foreign body embolization — Conversion failure — Unacceptable filter tilting	— Excessive filtration — Inadequate filter formation	ACE2	— Simulated use — Ability to convert
A.8.5 Ability to withdraw retrieval/conversion system and introducer sheath	Inability to withdraw retrieval/conversion system and sheath	— Withdrawal failure — Retrieval system damage — Conversion system damage — Sheath damage	— Foreign body embolization	ACE2	— Tensile strength — Simulated use — Ability to withdraw — Torsional bond strength
	Damage to sheath and/or retrieval/conversion system	— Sheath damage — Retrieval system damage — Conversion system damage	— Foreign body embolization	ACE2	— Simulated use — Ability to withdraw

Table A.9 — Attributes of endovascular systems

Device-related/ procedure-related function(s)	Potential failure mode(s)	Potential effect(s) of failure			Preclinical tests
		Device	Secondary device	Clinical	
A.9.1 Sterility	Improper procedures leading to contamination	None	None	— Filter infection — Insertion site infection	— Sterilization assurance
	Non-sterile product	None	None	None	None
	Unclean environment	None	None	None	None
A.9.2 Biocompatibility	Non-biocompatible	None	None	— Adverse biological response	— Biocompatibility
A.9.3 Haemostasis	Inadequate haemostasis	None	None	— Excessive procedural bleeding	— Preclinical *in vivo* assessment
A.9.4 Visualization	Inadequate visibility	— Access failure	None	ACE1	— Visibility
		— Delivery failure	None	— Embolization	
		— Deployment failure	— Excessive filtration — Inadequate filtration — Filter fracture — Filter migration — Inadequate filter formation — Unacceptable filter tilting	ACE2	
		— Withdrawal failure	None	ACE3	
		— Retrieval system delivery failure — Conversion system delivery failure	None	ACE2	
		— Retrieval failure — Conversion failure — Retrieval system damage — Conversion system damage — Filter damage — Unacceptable filter tilting	— Excessive filtration — Inadequate filtration — Filter fracture — Filter migration — Foreign body embolization	ACE2	

Annex B
(informative)

Descriptions of potential device effects of failure and failure modes and descriptions of detrimental clinical effects

B.1 General

This annex provides an alphabetical listing and description of potential device effects of failure and failure modes (see Table B.1) and detrimental clinical effects (see Table B.2), both identified in Annex A.

Table B.1 — Description of potential device effects of failure and failure modes

Potential failure mode or effect of failure	Description
Access failure	Failure to reach the intended site with the filter due to mechanical failure or patient anatomy.
Accessory device failure	Inability to use an accessory device as intended due to mechanical failure or patient anatomy. Whether or not the failure contributed to an unsuccessful filter deployment should be documented.
Bond joint failure	Complete or partial separation of discrete structural or material elements of the filter at bond joints. NOTE This is a failure of the bond joint and not the base material.
Bond joint separation	Complete or partial separation of discrete structural or material elements of the endovascular deployment system or the endovascular retrieval/conversion system at bond joints. NOTE This is a failure of the bond joint and not the base material.
Catheter burst	Loss of catheter integrity due to internal pressurization.
Change in filter formation	A change in the manufacturers specified final expanded geometric configuration of the filter.
Conversion failure	Inability to fully convert the filter as intended due to filter position, mechanical failure or patient anatomy.
Conversion system delivery failure	Inability to advance the conversion system to the intended conversion location due to mechanical failure, patient anatomy or user error.
Corrosion	Deterioration of implant surface, reduction of its strength and/or structural integrity due to electrochemical reactions with surrounding body fluids.
Delivery failure	Inability to load and/or deliver the filter to the intended deployment location due to mechanical failure, patient anatomy or user error.
Deployment difficulty	Issues with deployment due to mechanical failure or patient anatomy, which could result in inaccurate deployment.
Deployment failure	Inability to fully deploy the filter at the intended site due to mechanical failure or patient anatomy. Whether or not successful filter deployment was achieved should be documented.
Engagement mechanism deformation/fracture	Damage to a component of the filter that is designed for retrieval/conversion.
Excessive filtration	Clinically significant occluding clot formation which might be due to filter design or patient factors (e.g. anatomy, excessively large clots).
Excessive oversizing	The filter is too large for the vena cava.

Table B.1 (*continued*)

Potential failure mode or effect of failure	Description
Excessive radial force	Excessive radial force exerted by filter element(s) on the vessel wall resulting in caval injury or trauma to adjacent structures.
Filter damage	Damage to the filter by any cause, such as by an accessory device or the delivery system.
Filter fracture	Breakage, separation or embolization of any portion of the filter that might or might not result in a medical or surgical intervention as documented by imaging or autopsy.
Filter migration	A change in filter position compared to its deployed position (either cephalad or caudal) of more than 2 cm as documented by plain film imaging, CT, or venography.
Foreign body embolization	Movement of any portion of the endovascular system to an unintended location, excluding filter migration. See separate definition for filter migration.
Generation of particles from system	Generation of particles through abrasion, whereby particles detach from their source and might migrate into the blood stream.
Heating of filter	Radio-frequency-induced temperature rise of a filter during MRI.
Hub separation	Complete or partial separation of hub from accessory device (e.g. power injector) during cavagram.
Inability to convert filter	Unable to structurally alter an implanted vena cava filter to an implanted non-filtering device. See “Inability to initiate filter conversion”.
Inability to engage filter	Unable to connect optional filter with retrieval/conversion system.
Inability to initiate filter conversion	Unable to structurally alter an implanted vena cava filter to an implanted non-filtering device as a result of a conversion system malfunction.
Inability to load filter (if applicable)	Unable to collapse and constrain a filter into a storage tube or retention device when the filter is packaged in a partially or fully formed state.
Inability to retrieve filter	Unable to separate filter from vessel, collapse (constrain) filter and capture (isolate from vasculature) a deployed filter from the vessel into the retrieval system.
Inaccurate deployment in relation to target site	See “Misplacement”.
Inadequate contrast flow	Inability to inject sufficient volumes of contrast media through the sheath/dilator at the necessary rate to properly visualize the implantation site and/or patient anatomy.
Inadequate filter formation	A filter which does not deploy in the intended specified configuration due to mechanical failure, patient anatomy or user error (e.g. twisting, kinking or failure of the filter to fully open).
Inadequate filtration	Inability of filter to capture clinically significant clots as intended.
Inadequate fixation	Inability of the filter to maintain its intended position relative to the vena cava after deployment.
Inadequate haemostasis	Inability to avoid excessive flow of blood from the insertion site or the access lumen of the endovascular system.
Inadequate visibility	Inability to image the filter or a necessary portion of the filter according to the requirements of the IFU.
Ineffective clot capture	See “Inadequate filtration”.
Leakage of contrast media	Leakage of contrast media in an unintended location within the vena cava due to lack of delivery system integrity.
Misplacement	Deployment of filter in an unintended location.
Movement of filter	Magnetically (MRI) induced clinically significant displacement of filter relative to vena cava.
Non-sterile product	Ineffective sterilization of the device.
Premature release of filter	Unintentional release of the filter that results in the filter being misplaced.

Table B.1 (*continued*)

Potential failure mode or effect of failure	Description
Retrieval failure	Inability to fully retrieve the filter as intended due to filter position, mechanical failure, patient anatomy or other patient factors (e.g. tissue ingrowth).
Retrieval system delivery failure	Inability to advance the retrieval system to the intended retrieval location due to mechanical failure, patient anatomy or user error.
Retrieval system withdrawal failure	Inability to remove retrieval system as intended due to mechanical failure or patient anatomy.
Unacceptable filter tilting	Clinically significant rotation of the filter relative to the longitudinal IVC axis resulting in loss of filter efficiency.
Undersizing	The filter is too small for the vena cava resulting in inadequate fixation.
Unintentional filter movement	Movement of filter due to physical interaction with another device (e.g. retrieval/conversion system, central line, or snare).
Withdrawal failure	Inability to remove endovascular deployment system or endovascular retrieval/conversion system as intended due to mechanical failure or patient anatomy or other patient factors.

Table B.2 — Descriptions of detrimental clinical effects

Potential detrimental clinical effect	Description
Adverse biological response (toxicity) to filter system	Local, regional and/or systemic toxic reaction to filter system. The type of reaction should be documented.
Air embolism	Inadvertent introduction of air or gas which requires medical intervention.
Arrhythmia	Development of a new atrial or ventricular arrhythmia or exacerbation of a prior arrhythmia requiring treatment (i.e. medical therapy, cardioversion, pacemaker) within 30 days of the procedure.
Branch vessel occlusion	Clinically significant, unplanned occlusion or obstruction of a major branch vessel.
Cardiac damage	Injury to any section of the heart related to filter embolization or filter system component embolization.
Cardiac tamponade	Mechanical compression of the heart by large amounts of fluid or blood within the pericardial space that limits the normal range of motion and function of the heart.
Caval injury or damage	Vessel injury or damage observed on imaging study or by direct visualization that requires intervention or surgical repair to address condition.
Caval occlusion	Presence of an occluding thrombus in the IVC, occurring after filter insertion and documented by ultrasound, CT, MRI, venography or autopsy.
Caval perforation	Filter strut or anchor devices extending more than 3 mm outside the wall of the IVC, as demonstrated by CT or autopsy. Acute perforation occurring during placement of the filter is considered an insertion problem.
Caval penetration	Filter strut or anchor devices which become incorporated in the wall of the cava but do not extend more than 3 mm outside of the wall. Does not cause extravasation of dye.
Caval stenosis	A narrowing of more than 50 % of the lumen of the vena cava at the filter implant site, with or without haemodynamic significance confirmed by imaging.
Coagulopathy	Development of a bleeding disorder, which can lead to an increased propensity for thrombosis, documented by appropriate laboratory studies within 30 days of the procedure. The specific syndrome or factor deficiencies should also be noted.
Deep vein thrombosis	A thrombus which forms in a deep vein of the body, usually occurring in the deep veins of the lower limb(s), iliac or other pelvic veins or the vena cava.

Table B.2 (*continued*)

Potential detrimental clinical effect	Description
Oedema	An abnormal excess accumulation of serous fluid in connective tissue, typically seen in the periphery, due to venous occlusion.
Embolization	Movement of intraluminal debris or thrombus with clinical sequelae.
Excessive procedural bleeding	Any blood loss requiring intervention (i.e. blood transfusion, medical therapy). The volume of blood lost during the procedure should be determined from the procedure report. The need for blood transfusion and the volume and source (banked, autologous, autotransfused) of transfused blood should also be reported.
Extravasation of contrast	Extravascular leaking of contrast material noted during a vena cavagram.
Filter infection	Development of a confirmed filter infection occurring at any time following filter placement. The etiology (i.e. device sterility, endocarditis, etc.) should be reported if known.
Filter thrombosis	Haemodynamically significant clot formation within the lumen of the filter occurring at any time following filter placement. The degree of narrowing, the timing of the thrombosis in relation to the procedure, and the imaging modality should be specified.
Haematoma	Development of a haematoma related to the endovascular procedure requiring medical intervention.
Inadequate cavagram	Inability to adequately image the vena cava using contrast media and fluoroscopy.
Inadequate MRI	Inability to adequately visualize the anatomy as a result of MRI artefact caused by the filter *in situ*.
Insertion site infection	Documented wound infection at insertion site.
Intimal tear	Disruption or tear of the inner lining of the caval wall that results in a clinically significant compromise of the lumen or thrombosis confirmed on imaging studies.
Lack of quality MRI	See “Inadequate MRI”.
Lung damage	Injury to any section of the lung related to filter embolization or filter system component embolization.
Obstruction of blood flow	Restriction of blood flow through the vena cava.
Post-procedure bleeding	Procedure-related bleeding which occurs after the patient leaves the procedure room, resulting in the need for blood transfusion. The volume of replaced blood, the source of the bleeding and whether or not surgical intervention was required to stop the bleeding should also be reported.
Pulmonary embolism	Clinical evidence of a blood clot in the pulmonary vasculature, confirmed by high probability VQ scan, CT scan, pulmonary angiography or autopsy.
Trauma to adjacent structures	Damage to adjacent organs due to unintentional perforation of the vena cava by the filter or endovascular system.
Vascular trauma	Injuries to vessels as a result of an endovascular procedure, including dissections or perforations.
Vessel occlusion	Occlusion of flow within the target or other vessel which was previously documented to be patent. Might be due to twisting or kinking of the filter, failure of the filter to fully open, filter fragment, dissection, or any other cause.

Annex C
(informative)

Bench and analytical tests

C.1 General

This annex provides a list of bench and analytical tests, with a description of the purpose of each test and relevant device-related/procedure-related function(s) as listed in Annex A. Not all test methods listed in Table C.1 are included in Annex D, e.g. biocompatibility, corrosion, MRI compatibility.

Table C.1 — Bench and analytical tests grouped by system

— Endovascular filter system — Dimensional verification and component dimension compatibility — Simulated use (endovascular filter system) — Force to deploy — Visibility — Biocompatibility
— Filter — Clot trapping — Fatigue/durability — Filter dimensional verification — Filter tensile strength — Migration resistance — Radial force — Stress/strain analyses — Visual inspection — Corrosion — MRI
— Delivery system — Tensile strength — Torsional bond strength
— Sheath/dilator kit for endovascular filter system — Catheter burst — Power injection — Tensile strength — Torsional bond strength
— Endovascular retrieval/conversion system — Dimensional verification and component dimensional compatibility — Simulated use (endovascular retrieval/conversion system) — Force to retrieve/convert — Visibility — Biocompatibility
— Retrieval/conversion system — Tensile strength — Torsional bond strength
— Sheath/dilator kit for endovascular retrieval/conversion system — Catheter burst — Power injection — Tensile strength — Torsional bond strength

Table C.2 — Bench and analytical tests in alphabetical order

Tests	Purpose of test	Device-related/ procedure-related function(s)	Test method guidance
Biocompatibility	The purpose of this evaluation is to assess the biocompatibility in accordance with ISO 10993-1 and other appropriate parts of the ISO 10993 series.	Biocompatibility [A.9.2]	ISO 10993
Catheter burst	The purpose of this test is to determine the burst pressure for catheters.	Ability to perform cavagram [A.3.3, A.7.3]	D.5.4.1, D.5.7.1
Clot trapping	The purpose of this test is to determine the *in vitro* clot-trapping ability of the vena cava filter in an anatomical model.	Filtration [A.5.3]	D.5.2.1
Corrosion	The purpose of this assessment is to evaluate the susceptibility of the metallic components of the filter to corrosion in simulated physiological environment.	Structural integrity [A.5.2]	8.5.3.3, NOTE
Dimensional verification and component dimensional compatibility	The purpose of this test is to determine the system dimensions, including, but not limited to, the outer diameter, guidewire lumen diameter and useable length, to verify compliance with design specifications, and to evaluate the dimensional compatibility between the system and the recommended accessory devices listed in the product IFU.	Ability to access with sheath/dilator kit [A.3.1, A.7.1] Ability to deliver filter to implant site prior to deployment [A.4.1] Ability to deploy filter [A.4.2] Ability to deliver retrieval/conversion system to filter location [A.8.1]	D.5.1.1, D.5.5.1
Fatigue/durability	The purpose of this test is to evaluate aspects of the long-term integrity of the filter under simulated physiological loading conditions.	Structural integrity [A.5.2]	D.5.2.2
Filter dimensional verification	The purpose of this test is to determine the appropriate dimensions of the filter [e.g. outer diameter(s), length(s)] to verify compliance with design specifications.	Sizing [A.5.4]	D.5.2.3
Filter tensile strength	The purpose of this test is to determine the tensile strength of bonds or components of the filter.	Structural integrity [A.5.2]	D.5.2.4
Force to deploy	The purpose of this test is to determine the force needed to deploy the filter in an anatomical model.	Ability to deploy filter [A.4.2]	D.5.1.3
Force to retrieve/convert	The purpose of this test is to determine the force needed to retrieve or convert the vena cava filter in an anatomical model using recommended endovascular retrieval/conversion systems as specified in the IFU.	Ability to convert filter [A.6.3, A.8.4] Ability to retrieve filter [A.6.2, A.8.3] Structural integrity [A.6.4]	D.5.5.3
Migration resistance	The purpose of this test is to determine the acute migration resistance of the vena cava filter in an anatomical model.	Fixation effectiveness [A.5.1]	D.5.2.5
MRI compatibility	The purpose of this test is to evaluate MRI safety and compatibility.	Magnetic Resonance Imaging (MRI) compatibility [A.5.5]	8.5.3.8, NOTE 1
Power injection	The purpose of this test is to determine the amount and location of leakage from the system during contrast power injection (if applicable).	Ability to perform cavagram [A.3.3, A.7.3]	D.5.4.2, D.5.7.2

Table C.2 (*continued*)

Tests	Purpose of test	Device-related/ procedure-related function(s)	Test method guidance
Radial force	The purpose of this test is to determine the force exerted by a filter as a function of filter formation and anatomical dimensions, under the conditions of expansion and compression.	Fixation effectiveness [A.5.1]	D.5.2.6
Simulated use (endovascular filter system)	The purpose of this test is to evaluate the performance of the endovascular filter system using one or more anatomical models that simulate the intended use conditions. This test addresses the requirements for qualitative evaluation of simulated use as follows: the ability to access the deployment location with sheath/dilator kit, including flex/kink, pushability, trackability, and torquability; the ability to withdraw the dilator; the ability to load the filter into a delivery catheter; the ability to deliver the filter to the implant location; the ability to deploy the filter accurately in the intended configuration; and the ability to withdraw the delivery system.	Ability to access with sheath/dilator kit [A.3.1] Ability to withdraw dilator [A.3.2] Ability to deploy filter [A.4.2] Ability to deliver filter to implant site prior to deployment [A.4.1] Ability to withdraw delivery system and introducer sheath [A.4.3]	D.5.1.2
Simulated use (endovascular retrieval/conversion system)	The purpose of this test is to evaluate the performance of the endovascular retrieval/conversion system and the optional filter using one or more anatomical models that simulate the intended use conditions. This test addresses the requirements for qualitative evaluation of simulated use as follows: the ability to access the retrieval/conversion location with sheath/dilator kit, including flex/kink, pushability, trackability, and torquability; the ability to withdraw the dilator; the ability to deliver the retrieval/conversion system to the filter location; the ability to engage the filter with the system; the ability to retrieve or convert (if applicable) the filter; the ability to withdraw the system.	Ability to access with sheath/dilator kit [A.7.1] Ability to withdraw dilator [A.7.2] Ability to engage filter [A.6.1, A.8.2] Ability to retrieve filter [A.6.2, A.8.3] Ability to convert filter [A.6.3, A.8.4] Ability to deliver retrieval/conversion system to filter location [A.8.1] Ability to withdraw retrieval/conversion system and introducer sheath [A.8.5]	D.5.5.2
Stress/strain analyses	The purpose of these analyses is to locate and determine the critical stresses and/or strains within the filter due to manufacture, deployment, *in vivo* loading, and if appropriate retrieval/conversion. This information should be used to determine appropriate design safety margins and can be used to establish appropriate test conditions for fatigue testing.	Structural integrity [A.5.2]	D.5.2.7

Table C.2 (*continued*)

Tests	Purpose of test	Device-related/ procedure-related function(s)	Test method guidance
Torsional bond strength	The purpose of this test is to determine the torsional bond strength of the joints and or fixed connections of the system.	Ability to access with sheath/dilator kit [A.3.1, A.7.1] Ability to withdraw dilator [A.3.2, A.7.2] Ability to withdraw delivery system and introducer sheath [A.4.3] Ability to withdraw retrieval/conversion system and introducer sheath [A.8.5]	D.5.3.2, D.5.4.4, D.5.6.2, D.5.7.4
Tensile strength	Determine the tensile strength of relevant components including bond joints and/or fixed connections of the system.	Ability to access with sheath/dilator kit [A.3.1, A.7.1] Ability to withdraw dilator [A.3.2, A.7.2] Ability to deliver filter to implant site prior to deployment [A.4.1] Ability to deploy filter [A.4.2] Ability to withdraw delivery system and introducer sheath [A.4.3] Ability to deliver retrieval/conversion system to filter location [A.8.1] Ability to withdraw retrieval/conversion system and introducer sheath [A.8.5]	D.5.3.1, D.5.4.3, D.5.6.1, D.5.7.3
Visibility	The purpose of this test is to evaluate the ability to visualize any filter and/or system radiopaque components (e.g. markers) as specified in the IFU.	Visualization [A.9.4]	D.5.1.4, D.5.5.4
Visual inspection	The purpose of this test is to evaluate whether the filter conforms to the appropriate specifications with respect to surface defects that would render the filter unsuitable for its intended use.	Structural integrity [A.5.2]	D.5.2.8

Annex D
(informative)

Test methods

D.1 General

The information included in this annex is intended to provide guidance for preclinical *in vitro* testing performed in order to verify the design of the endovascular filter system and/or endovascular retrieval/conversion system. Guidance for reporting the test results is also provided. It is recognized that not all the tests described in this annex are applicable to all system designs. It is also recognized that testing intended to ensure that the device meets specifications during manufacture may be conducted in a manner other than those outlined in this annex.

To ensure consistency in the testing of devices, use of the methods in this annex is recommended. If alternative methods are employed, these methods should be justified.

In some cases, in this annex, one or more of the methods for the tests identified in the body of this part of ISO 25539 were combined into a single method to reflect the manner in which this testing is often conducted. It is also recognized that additional methods can be combined when testing is conducted for a specific device. For those tests performed simultaneously, the report should provide the individual test results for each of the tests listed in the body of this part of ISO 25539.

Some requirements in the body of this part of ISO 25539 do not have associated test method guidance in this annex, as either the methodologies have not been standardized or are better addressed by other standards (e.g. MRI compatibility).

To ensure valid results, equipment used during testing should have appropriate precision and accuracy and be calibrated or verified against traceable measurement standards, as appropriate.

Modifications to existing test methods or inclusion of additional test methods might be required for various filter formations (e.g. crossed legs). In addition, when identifying testing conditions, attention should be paid to physiological conditions in the IVC.

D.2 Sampling

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

The samples selected for each test should at a minimum represent worst cases. Consideration should 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 should be justified.

Additional recommendations regarding sampling are included with each test method as appropriate.

D.3 Conditioning of test samples

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

Samples should be subjected to conditions that are normally encountered that can 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.

D.4 Reporting

For the purposes of this part of ISO 25539, reporting is carried out of 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 prospectively defined acceptance criteria and any potential clinical significance of the results should be included and may be in tabular form. Consideration should 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 should 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(s) 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.

D.5 Test methods

This clause lists guidelines for tests where appropriate. An index of test methods is given in Table D.1.

Table D.1 — Index of test methods

Tests	Relevant subclause
Catheter burst	D.5.4.1 and D.5.7.1
Clot trapping	D.5.2.1
Dimensional verification and component dimensional compatibility	D.5.1.1 and D.5.5.1
Fatigue/durability	D.5.2.2
Filter dimensional verification	D.5.2.3
Filter tensile strength	D.5.2.4
Force to deploy	D.5.1.3
Force to retrieve/convert	D.5.5.3
Migration resistance	D.5.2.5
Power injection	D.5.4.2 and D.5.7.2
Radial force	D.5.2.6
Simulated use (endovascular filter system)	D.5.1.2
Simulated use (endovascular retrieval/conversion system)	D.5.5.2
Stress/strain analysis	D.5.2.7
Torsional bond strength	D.5.3.2, D.5.4.4, D.5.6.2 and D.5.7.4
Tensile strength	D.5.3.1, D.5.4.3, D.5.6.1 and D.5.7.3
Visibility	D.5.1.4 and D.5.5.4
Visual inspection	D.5.2.8

D.5.1 Endovascular filter system

D.5.1.1 Dimensional verification and component dimension compatibility

D.5.1.1.1 Purpose

The purpose of this test is to determine the system dimensions, including, but not limited to, the outer diameter, guidewire lumen diameter and useable length, to verify comnpliance with design specifications, and to evaluate the dimensional compatibility between the system and the recommended accessory devices listed in the product IFU.

D.5.1.1.2 Materials

D.5.1.1.2.1 **Endovascular filter system** (except for filter).

D.5.1.1.2.2 **Accessory devices** as specified in the IFU.

D.5.1.1.2.3 **Measuring equipment for diameters** (e.g. micrometer, optical profile projector, laser-micrometer, appropriate profile hole gauges, wire mandrels, pin gauges) capable of measuring to 10 % of the specified tolerance or 1 % of the measured value. If a tolerance is specified, the lesser value of the respective percentage should be used.

D.5.1.1.2.4 Measuring equipment for length capable of measuring to 10 % of the specified tolerance or 1 % of the measured value. If a tolerance is specified, the lesser value of the respective percentage should be used.

D.5.1.1.3 Sampling

Sampling should be carried out as described in Clause D.2.

D.5.1.1.4 Conditioning

Conditioning should be carried out as described in Clause D.3.

D.5.1.1.5 Test method

Develop a test method based on the following.

a) Insert an appropriately sized pin gauge or mandrel into the system components to verify lumen dimensions.

b) Measure the maximum outer diameter of the system components or verify that the outer diameter fits through the appropriately sized profile hole gauge. It is only necessary to measure the region of the system intended to be passed through the specified accessory. Consideration should be given to the potential for asymmetry.

c) Measure the length of the system components. It is only necessary to measure the length of the system intended to be passed through other components, accessory devices or anatomy.

d) Measure all other appropriate dimensions.

e) Verify dimensional compatibility between system components and recommended accessory devices.

D.5.1.1.6 Expression of results

Length should be expressed in centimetres. Other dimensions should be expressed in millimetres. Results regarding the compatibility of the recommended accessory devices and the verification of the lumen and outer diameters, if applicable, should be documented.

D.5.1.1.7 Test report

The test report should be completed as described in Clause D.4. It should include the maximum, minimum, mean and standard deviation of all measured dimensions, the results of any verified dimensions, and the results of the observations of the accessory compatibility.

D.5.1.2 Simulated use (endovascular filter system)

D.5.1.2.1 Purpose

The purpose of this test is to evaluate the performance of the endovascular filter system using one or more anatomical models that simulate the intended use conditions. This test addresses the requirements for qualitative evaluation of simulated use as follows: the ability to access the deployment location with sheath/dilator kit, including flex/kink, pushability, trackability, and torquability; the ability to withdraw the dilator; the ability to load the filter into a delivery catheter; the ability to deliver the filter to the intended location; the ability to deploy the filter accurately in the intended configuration; and the ability to withdraw the delivery system and the introducer sheath.

NOTE Quantitative assessment of the attributes listed above might need to be considered dependent on the design of the device.

D.5.1.2.2 Materials

D.5.1.2.2.1 Endovascular filter system.

D.5.1.2.2.2 Accessory devices as specified in the IFU.

D.5.1.2.2.3 Anatomical model that includes a delivery pathway and a deployment location. The angulation and tortuosity of the delivery pathway and the intended filter location should be considered in the design of the model. Use of a physiologically relevant compliant model should be considered. Additionally, clinically relevant flow conditions through the model should be considered.

D.5.1.2.2.4 Test fluid (e.g. simulated blood, saline, water).

D.5.1.2.2.5 Temperature-controlled environment capable of producing (37 ± 2) °C.

D.5.1.2.3 Sampling

Sampling should be carried out as described in Clause D.2.

D.5.1.2.4 Conditioning

Conditioning should be carried out as described in Clause D.3.

D.5.1.2.5 Test method

Develop a test method based on the following.

a) Deploy the filter in the model in accordance with the IFU while evaluating the following applicable attributes:

   — the ability to access the deployment location in the anatomical model with the sheath/dilator kit (e.g. flex/kink, pushability, trackability, torquability);

   — the ability to withdraw the dilator;

   — the ability to load the filter into a delivery system;

   — the ability to deliver the filter to the deployment location;

   — the ability to deploy the filter accurately in the intended configuration;

   — the ability to withdraw the delivery system and the introducer sheath.

b) Note any damage, such as kinking or buckling of the system, the inability to fully and accurately deploy the filter, filter displacement while withdrawing the delivery system and any other appropriate observations.

c) Visually inspect the deployed filter in the anatomical model. Note the centering of the filter to the model vessel, the placement accuracy, uniformity of filter formation (e.g. unintended crossed filter components), component separation, any damage and any other critical observations.

NOTE A quantitative model might be needed if a specific amount of torque is necessary for appropriate placement of the device.

D.5.1.2.6 Expression of results

For each test, all critical observations and aspects of the attributes listed above should be documented.

D.5.1.2.7 Test report

The test report should be completed as described in Clause D.4 and should include all critical observations and aspects of the applicable attributes. The results for the applicable attributes listed in the test method section should be individually reported. The report should include a description of the anatomical model used, including the geometry and material of construction. The test fluid should also be reported.

D.5.1.3 Force to deploy

D.5.1.3.1 Purpose

The purpose of this test is to determine the force needed to deploy the filter in an anatomical model. All applicable steps of the deployment process will be evaluated.

D.5.1.3.2 Materials

D.5.1.3.2.1 **Endovascular filter system**.

D.5.1.3.2.2 **Accessory devices** as specified in the IFU.

D.5.1.3.2.3 **Anatomical model** that includes a delivery pathway and a deployment location. The angulation and tortuosity of the delivery pathway and the intended filter location should be considered in the design of the model.

D.5.1.3.2.4 **Force-measuring mechanism** (e.g. force gauge, universal mechanical testing system), capable of measuring force to an accuracy of ±5 % of the reported value.

D.5.1.3.2.5 **Attachment fixture** capable of connecting the force-measuring mechanism to the delivery system.

D.5.1.3.2.6 **Test fluid** (e.g. simulated blood, saline, water).

D.5.1.3.2.7 **Temperature-controlled environment** capable of producing (37 ± 2) °C.

D.5.1.3.3 Sampling

Sampling should be carried out as described in Clause D.2. Devices to be tested should represent worst-case deployment force conditions.

D.5.1.3.4 Conditioning

Conditioning should be carried out as described in Clause D.3.

D.5.1.3.5 Test method

Develop a test method based on the following:

a) prepare the filter system in accordance with the IFU;

   1) insert the filter system into the anatomical model;

   2) attach the deployment mechanism to the load-measuring equipment;

   3) initiate and complete the deployment in accordance with the IFU at a rate that simulates clinical use while measuring the maximum force of each step to deploy (e.g. unsheath and disengage) the filter;

b) record any anomalous observations (e.g. buckling) for each test sample.

D.5.1.3.6 Expression of results

The maximum force of each step required to deploy (e.g. unsheath) the filter is recorded in newtons.

D.5.1.3.7 Test report

The test report should be completed as described in Clause D.4 and should include the maximum, minimum, mean and standard deviation of the deployment forces and any anomalous observations.

D.5.1.4 Visibility

D.5.1.4.1 Purpose

The purpose of this test is to evaluate the ability to visualize the system and/or filter using the imaging techniques specified in the IFU.

D.5.1.4.2 Materials

D.5.1.4.2.1 **Endovascular filter system**.

D.5.1.4.2.2 **Phantom tissue model** or **equivalent**, with appropriate accessories, such as two radiopaque markers and a ruler.

D.5.1.4.2.3 **Imaging system** capable of operating at clinically relevant power levels.

NOTE Visibility is significantly affected by variations in equipment and parameter settings. In the selection of the equipment used for this evaluation, it is advisable to consider this variability.

D.5.1.4.2.4 **Accessory devices** as specified in the IFU.

D.5.1.4.3 Sampling

Sampling should be carried out as described in Clause D.2.

D.5.1.4.4 Conditioning

Conditioning should be carried out as described in Clause D.3.

D.5.1.4.5 Test method

Develop a test method based on the following.

a) Position the filter system and the phantom tissue model to simulate clinical conditions.

b) Use the imaging system to visualize the filter system and any radiopaque markers.

c) Qualitatively examine the images for ease of visibility. For example, the degree of visibility can be assessed by locating the exact ends, orientation of critical points and/or parts of the endovascular filter system. Alternatively, the degree of visibility can be qualitatively or quantitatively compared to a specified control device.

d) Repeat a) to c) above for the filter.

NOTE Additional guidance is given in ASTM F640.

D.5.1.4.6 Expression of results

This is a qualitative assessment. Record the degree of visibility for all applicable components and any comparison to a specified control.

D.5.1.4.7 Test report

The test report should be completed as described in Clause D.4 and should include the assessment of visibility and visual results (e.g. representative fluoroscopic images). The test report should also include the make and model of the imaging equipment, the parameter settings and details of the phantom tissue model. Use of specific phantom tissue characteristics (e.g. thickness) should be justified.

D.5.2 Filter

D.5.2.1 Clot trapping

D.5.2.1.1 Purpose

The purpose of this test is to determine the *in vitro* clot trapping ability of the vena cava filter in an anatomical model.

D.5.2.1.2 Materials

D.5.2.1.2.1 Filter.

NOTE This test is not designed to evaluate the entire endovascular filter system; however, this system or its components might be required to deploy the filter that is under test.

D.5.2.1.2.2 Anatomical model such as a mock vena cava of the appropriate diameter and length. The worst-case filter condition should be tested in the model (e.g. maximum indicated diameter).

D.5.2.1.2.3 Clots of multiple sizes should be coagulated animal blood; however, equivalent natural and synthetic materials may be used if justified.

NOTE It is important to ensure that the clots do not deteriorate over time or through multiple uses.

D.5.2.1.2.4 Test fluid simulating the viscosity of blood should be used unless testing in a different environment (e.g. distilled water) can be justified.

NOTE The test fluid is not supposed to have an adverse affect on the clots used for evaluation of the device (e.g. by causing the clots to break up prematurely).

D.5.2.1.2.5 Circulating pump capable of producing clinically relevant flow rates (e.g. 1 l/min to 6 l/min).

D.5.2.1.2.6 Temperature-controlled environment capable of producing (37 ± 2) °C.

D.5.2.1.2.7 Pressure gauge(s) capable of measuring clinically relevant pressures.

D.5.2.1.3 Sampling

Sampling should be carried out as described in Clause D.2.

D.5.2.1.4 Conditioning

Conditioning should be carried out as described in Clause D.3.

D.5.2.1.5 Test method

Develop a test method based on the following.

a) Establish the clinically relevant conditions under which samples will be tested. References to literature regarding clot trapping are provided in the Bibliography (specifically, References [13][14][15][16][26][37][43][44][46][47][48][49]). Conditions should include flow, device configuration (e.g. centered, tilted), model configuration (e.g. horizontal, vertical), worst-case mock vessel dimensions and multiple clot sizes. Additional conditions can include multiple fluid flow rates.

b) Assemble the test fixture including the filter in the anatomical model, the pressure gauge, the circulating pump and the temperature-controlled fluid reservoir.

c) Establish the maximum number of clots per test run, the time(s) between clot releases and the time(s) of observation of captured clots.

d) Inject clots serially into the system at the predetermined intervals until the total number of clots is reached. Record any anomalous observations for each test sample.

e) Record maximum pressure gradient across the filter and the flow rate after all clots were injected. Also record number of clots in the filter during the pressure measurements.

f) Repeat procedure per sampling plan (e.g. multiple clot introductions, device configurations).

D.5.2.1.6 Expression of results

Clot-trapping ability is reported as the percentage of injected clots retained by the filter versus the number released. Pressure gradient across the filter should be recorded in millimetres of mercury.

D.5.2.1.7 Test report

The test report should be completed as described in Clause D.4 and should include the minimum, maximum, average and standard deviation of the clot-trapping ability and the pressure gradient for each condition tested. The number of associated clots, device configuration, model configuration and clot size should also be reported. The anatomical model, including diameter(s) and length(s), clot material, test fluid and flow rate(s) used during testing should also be reported. Any anomalous observations should be reported as well.

D.5.2.2 Fatigue/durability

D.5.2.2.1 Purpose

The purpose of this test is to evaluate aspects of the long-term integrity of the filter under simulated physiologic loading conditions.

The method outlined in this subclause provides guidance for flat-plate fatigue testing. The committee recognizes that other methods might be more appropriate in testing specific vena cava filter designs. Other methods may be used when appropriately justified.

The basis for any durability testing consists of the following:

a) determine the physiologic loads imparted to the filter and how frequently the loads repeat over ten years;

b) determine the response of the filter to the application of the physiologic loads;

c) determine a method to mimic the implant response to the applied physiologic loads, ensuring repeated application of the appropriate stresses and/or strains on the filter.

Potential failure modes that can be identified by this test include, but are not limited to, filter fracture due to fatigue, and wear or abrasion between filter elements.

This test is not intended to fully evaluate the potential for failures related to corrosion, or filter migration. It is acknowledged that these types of potential failure modes might be observed during testing and consideration should be given as to whether such observations indicate an increased potential for these failure modes to appear clinically.

This test may be modified to include evaluation of failure modes induced by flexion, extension, tension, compression or deployment in a tilted position. Other types of testing or evaluation of devices or components might be necessary to fully evaluate all potential failure modes.

Convertible filters should be evaluated in both filtering and converted (unfiltering) states.

Results of component and preliminary testing should be considered in development of this test method.

D.5.2.2.2 Materials

D.5.2.2.2.1 **Endovascular filter system**.

NOTE This test is not designed to evaluate the entire system; however, the system or representative system is required to deploy the filter that is under test.

D.5.2.2.2.2 Accessory devices as specified in the IFU.

D.5.2.2.2.3 Mock vena cava in the form of a compressible tube having an inner diameter consistent with clinical use and worst-case fatigue conditions. It is not required that the mock vena cava have physiologically relevant compliance. In place of using a mock vena cava, the filter may be fixtured between the two flat plates as long as the desired filter displacements are obtained such that there is no reduction in the stress/strain imposed on the filter. The potential for the filter to extend the vena cava beyond its nominal dimensions should be considered for the establishment of the mock vessel dimensions.

D.5.2.2.2.4 Flat-plate fatigue tester capable of applying cyclic displacement to the mock vena cava with the filter deployed. The test equipment should include provisions for either direct or indirect measurement of the pertinent dimensions (i.e. plate-to-plate maximum and minimum distance), maintaining physiological temperature (37 ± 2) °C of the test assembly, and counting the cycles.

D.5.2.2.2.5 Appropriate inspection equipment (e.g. light microscope, lighted magnifying glass, SEM).

D.5.2.2.3 Sampling

Sampling should be carried out as described in Clause D.2. The device size(s) should be selected to represent the greatest potential for each failure mode being evaluated based upon appropriate engineering analyses such as stress/strain analyses.

D.5.2.2.4 Conditioning

Conditioning should be carried out as described in Clause D.3. The filter should be maintained at physiological temperature (37 ± 2) °C, unless testing at ambient temperatures can be justified. Testing should be conducted in an appropriate test solution such as phosphate buffered saline or equivalent.

D.5.2.2.5 Test method

Develop a test method based on the following.

a) Establish the conditions under which samples will be tested. These conditions include establishing the mock vena cava system for testing, the method for determining the device displacement, the establishment of the filter orientation and the test frequency.

   1) Establish the mock vena cava. Testing is performed using a mock vena cava that allows for expected physiological displacement of the device during testing. The mock vena cava should have a diameter consistent with clinical use and worst-case fatigue conditions.

   2) Establish the method for determining filter displacement during testing. The maximum and minimum distance between the flat plates of the testing machine should be measured and maintained throughout the test. The mock vena cava dimensions should be accounted for to determine the actual filter displacement, if applicable. The location and method for measuring the maximum and minimum displacement should be specified and justified. Plate-to-plate front-to-back and side-to-side parallelism should be verified.

   3) Establish the filter orientation during testing. The worst-case filter orientation should be considered based on stress/strain analysis. Effects of tilting should also be considered.

   4) Establish the test duration. The worst-case test duration should be considered based on applicable physiological loading conditions.

   5) Establish the test frequency. The test frequency should be such that the cyclic displacements of the filter remain within the required limits for the duration of the test. The maximum testing frequency might be limited by the effects of the strain rate on the mechanical properties of the materials. For example, at high frequency the device might not follow the flat-plate displacement or remain in contact with the mock vena cava. Additionally, the test frequency might be limited by the test equipment. The maximum and minimum distance between flat plates may be measured/monitored statically; however, the dynamic (i.e. at test frequency) effects to the effective displacements should be considered. Harmonics might be introduced when testing at some frequencies. Similarly, heating might be induced when testing in some medias (e.g. air). The potential effects of these harmonics and heating on the test conditions should be carefully evaluated.

b) Set up the equipment and prepare the samples for testing.

   1) Deploy the filter into the mock vena cava in accordance with the IFU. The filter should be positioned in the worst-case orientation. Care should be taken to ensure the filter does not migrate and the desired filter orientation is maintained (e.g. silicone attachment) in the mock vena cava during the test as long as the desired displacements are still obtained and there are no significant artifactual stresses/strains imposed on the filter.

   2) Visually inspect the deployed device, using appropriate visual aids, and record the location and severity of any anomalies (e.g. non-uniform device expansion).

c) Start testing.

   1) Set the frequency to the established rate and adjust the test system to achieve the intended cyclic displacement of the filter. Once final equipment adjustments are made, begin counting the applied fatigue cycles.

   2) Verify the maximum and minimum displacement, and the position of the filter within the mock vena cava at regular time intervals (e.g. daily) to ensure that the defined values are maintained. Adjust the system as necessary to maintain the desired operational range. The potential effects of these adjustments on the test results should be discussed in the test report.

3) If appropriate, stop the test at periodic intervals for device inspection.

NOTE If the device is removed from the mock vena cava, it is important to remove and reinstall in a manner that minimizes effects on the test results.

4) Continue the test until 10 years' equivalent cycles (e.g. 80 million cycles) have been applied to each device. If the intended filter life is less than 10 years, a shorter duration of fatigue testing may be justified.

NOTE It is also important to consider testing to fracture. While test methods have not yet been standardized, durability testing to fracture has several potential advantages; including identification of failure modes, verification of device fatigue analysis and appropriateness of factor of safety.

5) Inspect all device components as defined in the test protocol. In general, the entire device should be visually inspected for evidence of macroscopic damage. Further inspection of the device can include light microscopy, SEM, or X-ray with special attention paid to the regions of high stress as predicted by stress/strain or other analysis. Any anomalous findings should be documented, such as cracks, fractures, or abrasion of the filter.

D.5.2.2.6 Expression of results

The test frequency should be expressed in cycles per second (Hz). All pressures should be expressed in kilopascals and millimetres of mercury. All diameters and displacements should be expressed in millimetres.

Observations such as cracks, fractures, abrasion or permanent deformation of the filter should be recorded. All results of inspections, including the cycle count at which the inspections take place and the number and precise location of any observed anomalies, should be recorded.

D.5.2.2.7 Test report

The test report should be completed as described in Clause D.4. The intended and measured maximum and minimum filter displacements should be reported. Observations such as cracks, fractures, abrasion or permanent deformation should be reported. All results of inspections, including the cycle count at which the inspections take place and the number and precise location of any observed anomalies, should be reported. The test report should include a justification for considering negative findings as test artefacts and/or discounting their clinical significance, where applicable. Results should be considered and interpreted in relation to any applicable *in vivo* data.

D.5.2.3 Filter dimensional verification

D.5.2.3.1 Purpose

The purpose of this test is to determine the appropriate dimensions of the filter [e.g. outer diameter(s), length(s)] in the fully deployed, unconstrained state to verify compliance with design specifications.

NOTE Other measurements might be needed to completely verify the dimensions of a particular implant.

D.5.2.3.2 Materials

D.5.2.3.2.1 Endovascular filter system.

NOTE This test is not designed to evaluate the entire system; however, the system is required to deploy the filter that is under test.

D.5.2.3.2.2 Measuring equipment for diameters (e.g. micrometer, optical profile projector, laser-micrometer, calibrated calipers) capable of measuring with an accuracy of ±0,1 mm.

D.5.2.3.2.3 Measuring equipment for lengths capable of measuring with an accuracy of ±1 mm.

D.5.2.3.2.4 **Temperature-controlled environment** capable of producing (37 ± 2) °C for filters with dimensions that are sensitive to changes between ambient and physiological temperatures.

D.5.2.3.3 Sampling

Sampling should be carried out as described in Clause D.2.

D.5.2.3.4 Conditioning

Conditioning should be carried out as described in Clause D.3 and should include loading, preconditioning and deployment.

D.5.2.3.5 Test method

Diameters, lengths and other measurements appropriate to the filter design should be measured at appropriate locations after deployment in accordance with the IFU.

NOTE For non-circular cross-sections, it might be appropriate to measure and report the maximum and minimum values.

D.5.2.3.6 Expression of results

Diameters should be expressed in millimetres. Lengths should be expressed in millimetres or centimetres.

D.5.2.3.7 Test report

The test report should be completed as described in Clause D.4 and should include the maximum, minimum, mean and standard deviation of all measured and calculated dimensions.

D.5.2.4 Filter tensile strength

D.5.2.4.1 Purpose

The purpose of this test is to determine the tensile strength of bonds or components of the filter.

D.5.2.4.2 Materials

D.5.2.4.2.1 **Filter or appropriate components**.

D.5.2.4.2.2 **Universal mechanical testing system**, equipped with a suitable load cell capable of measuring force to an accuracy of ±5 % of the reported value, a constant rate of traverse and appropriate gripping fixtures.

D.5.2.4.2.3 **Temperature-controlled environment** capable of producing (37 ± 2) °C, as appropriate.

D.5.2.4.3 Sampling

Sampling should be carried out as described in Clause D.2.

D.5.2.4.4 Conditioning

Conditioning should be carried out as described in Clause D.3.

D.5.2.4.5 Test method

Develop a test method based on the following:

a) using a mechanical testing system with an appropriate crosshead speed, apply tension to each filter component until failure is achieved;

b) record the force at which failure occurs and describe the type and location of the failure.

D.5.2.4.6 Expression of results

Tensile strength should be expressed in newtons.

D.5.2.4.7 Test report

The test report should be completed as described in Clause D.4 and should include the type and location of the failure, and the maximum, minimum, mean and standard deviation of tensile strength.

D.5.2.5 Migration resistance

D.5.2.5.1 Purpose

The purpose of this test is to determine the acute cephalad migration resistance of the vena cava filter in a simulated anatomical model. Consideration should be given to the need to test caudal migration resistance as well.

NOTE This method is not appropriate for testing migration resistance in the caudal direction.

D.5.2.5.2 Materials

D.5.2.5.2.1 Endovascular filter system.

NOTE This test is not designed to evaluate the entire system; however, the system might be required to deploy the filter that is under test.

D.5.2.5.2.2 Suitable reference sample (e.g. filter with an adequate clinical history of use).

D.5.2.5.2.3 Accessory devices as specified in the IFU.

D.5.2.5.2.4 Anatomical model (e.g. mock vena cava, animal vena cava) of the appropriate diameter and length. The worst-case filter condition should be tested in the model (e.g. maximum indicated diameter, minimum fixation condition). Test conditions can include alternative device configurations (e.g. centered, tilted) or alternative mock vessel dimensions (e.g. oval vessels, smaller diameters). Also, the validity of the mock vena cava (e.g. synthetic material) for the assessment of the acute migration should be justified.

D.5.2.5.2.5 Clots should be coagulated animal blood or equivalent natural and synthetic materials.

D.5.2.5.2.6 Test fluid simulating the viscosity of blood should be used unless testing in a different environment (e.g. distilled water) can be justified.

D.5.2.5.2.7 Circulating pump capable of producing clinically relevant flow conditions (e.g. flow rates of 1 l/min to 6 l/min).

D.5.2.5.2.8 Pressure gauge(s) capable of measuring clinically relevant pressures.

D.5.2.5.2.9 Temperature-controlled environment capable of producing (37 ± 2) °C.

D.5.2.5.2.10 Measuring equipment for lengths (e.g. ruler, caliper).

D.5.2.5.3 Sampling

Sampling should be carried out as described in Clause D.2.

D.5.2.5.4 Conditioning

Conditioning should be carried out as described in Clause D.3.

D.5.2.5.5 Test method

Develop a test method based on the following.

a) Establish the conditions under which samples will be tested. These conditions include establishing clot size, fluid flow rates, pressures and the mock vessel dimensions.

b) Assemble the test fixture including the filter in the anatomical model, the circulating pump and the temperature-controlled fluid reservoir.

c) Visually inspect the filter in the anatomical model. Note any critical observations (e.g. tilting, crossed struts, inadequate formation).

d) Mark initial filter position.

e) Inject clots into the system until filter migrates or peak pressure differential across the filter is reached. Record the peak pressure differential across the filter at the point where migration occurs. It should be noted that it is considered normal for the filter to settle and move slightly as clot builds up during this simulated test.

f) Record any anomalous observations for each test sample.

D.5.2.5.6 Expression of results

Migration resistance is recorded as the peak pressure differential, expressed in kilopascals, that the filter is able to withstand without migration. Any anomalous observations should be recorded.

D.5.2.5.7 Test report

The test report should be completed as described in Clause D.4 and include the maximum, minimum, mean and standard deviation of the peak pressure differential across the filter for each condition tested. The anatomical model, including diameter(s) and length(s), clot material, clot size(s), test fluid, the flow rate(s) and pressure used during testing should also be reported.

D.5.2.6 Radial force

D.5.2.6.1 Purpose

The purpose of this test is to determine the force exerted on the surrounding tissue by a filter as a function of filter formation and anatomical dimensions, under the conditions of expansion and compression.

NOTE This test is not intended to mimic forces generated during *in vivo* cycling of the device after initial deployment.

D.5.2.6.2 Materials

D.5.2.6.2.1 Endovascular filter system.

NOTE This test is not designed to evaluate the entire system; however, the system is required to deploy the filter that is under test.

D.5.2.6.2.2 Mechanical testing system equipped with a suitable load cell capable of measuring force to an accuracy of ±5 % of the reported value and a constant rate of compression or expansion. Static force can alternately be measured at discrete compression or expansion conditions.

D.5.2.6.2.3 Expansion and compression clamps/fixtures such as “Clamshell”, “V” Block, “Iris” or a circumferential tension device such as a loop or snare. The fixture diameter/dimensions should be appropriate for the filter being tested.

D.5.2.6.2.4 Temperature-controlled environment capable of producing (37 ± 2) °C for filters with material properties that are sensitive to changes between ambient and physiological temperatures.

NOTE When selecting the test fixture, it is important to consider the width or area under study, the effects of friction and the influence of the fixture geometry on the measured loads.

D.5.2.6.3 Sampling

Sampling should be carried out as described in Clause D.2.

D.5.2.6.4 Conditioning

Conditioning should be carried out as described in Clause D.3 and should include loading and preconditioning.

D.5.2.6.5 Test method

Develop a test method based on the following.

a) Deploy the filter within the fixture such that the initial diameter is less than or equal to the minimum vessel diameter indicated in the IFU.

b) Measure the radial force as a function of diameter as the filter is expanded to the maximum indicated vessel diameter. The speed of testing should be such that the results represent static conditions.

c) Measure the radial force as a function of diameter as the filter is compressed to the minimum indicated vessel diameter. The speed of testing should be such that the results represent static conditions.

D.5.2.6.6 Expression of results

Radial force should be expressed in newtons.

D.5.2.6.7 Test report

The test report should be completed as described in Clause D.4 and should include a description of the filter feature(s) tested (e.g. fixation legs), the minimum, maximum, mean and standard deviation of the radial force at the minimum and maximum diameters for each device size tested. Results from both expansion and compression should be reported, with the respective speeds used during testing.

D.5.2.7 Stress/strain analyses

D.5.2.7.1 Purpose

The purpose of these analyses is to locate and determine the critical stresses and/or strains within the filter due to manufacture, deployment, *in vivo* loading and retrieval/conversion. This information should be used to determine appropriate design safety margins and can be used to establish appropriate test conditions for fatigue durability testing.