



FINAL DRAFT International Standard

ISO/FDIS 25539-3

Cardiovascular implants — Endovascular devices —

Part 3: Vena cava filters

Implants cardiovasculaires — Dispositifs endovasculaires —

Partie 3: Filtres caves

ISO/TC 150/SC 2

Secretariat: **ANSI**

Voting begins on:
2024-05-27

Voting terminates on:
2024-07-22

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO/FDIS 25539-3](#)

<https://standards.iteh.ai/catalog/standards/iso/4b3c3314-692e-4e00-a2e9-6c02cb554d9a/iso-fdis-25539-3>

ISO/CEN PARALLEL PROCESSING

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO/FDIS 25539-3](https://standards.iteh.ai/catalog/standards/iso/4b3c3314-692e-4e00-a2e9-6c02cb554d9a/iso-fdis-25539-3)

<https://standards.iteh.ai/catalog/standards/iso/4b3c3314-692e-4e00-a2e9-6c02cb554d9a/iso-fdis-25539-3>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword.....	v
Introduction.....	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	5
4.1 Classification.....	5
4.2 Materials of construction for filter system.....	5
4.3 Configuration and size designation for filters.....	5
4.4 Intended clinical use designation.....	5
5 Intended performance	6
6 Design attributes	6
6.1 General.....	6
6.2 Filter system.....	6
6.3 Vena cava filter.....	6
6.4 Optional filter.....	6
6.5 Convertible filter.....	7
6.6 Retrieval system.....	7
6.7 Conversion system.....	7
6.8 Filter system, retrieval system and conversion system.....	7
6.9 Coating on delivery system or filter.....	7
6.10 Absorbable filter or coating.....	8
7 Materials	8
8 Design evaluation	8
8.1 General.....	8
8.2 Sampling.....	9
8.3 Conditioning of test samples.....	10
8.4 Reporting.....	10
8.5 Bench and analytical tests.....	11
8.5.1 General.....	11
8.5.2 Filter system.....	11
8.5.3 Vena cava filter.....	12
8.5.4 Optional filter.....	15
8.5.5 Convertible filter.....	15
8.5.6 Retrieval system.....	16
8.5.7 Conversion system.....	17
8.5.8 Filter system, retrieval system and conversion system.....	18
8.5.9 Coating on the delivery system, the retrieval system, the conversion system or the filter.....	19
8.5.10 Absorbable filter or coating.....	19
8.6 Preclinical in vivo evaluation.....	19
8.6.1 Purpose.....	19
8.6.2 Specific aims.....	20
8.6.3 Protocol considerations.....	20
8.6.4 Data acquisition.....	21
8.6.5 Test report and additional information.....	23
8.7 Clinical evaluation.....	24
8.7.1 Purpose.....	24
8.7.2 Specific aims.....	24
8.7.3 Protocol considerations.....	25
8.7.4 Data acquisition.....	26
8.7.5 Final report.....	28

9	Post-market experience	29
10	Manufacturing	30
11	Sterilization	30
	11.1 Products supplied sterile	30
	11.2 Sterilization residuals	30
12	Packaging	30
	12.1 General	30
	12.1.1 General	30
	12.1.2 Unit container	30
	12.1.3 Outer container	30
	12.1.4 Shipping container	30
	12.1.5 Maintenance of sterility in transit	31
	12.2 Labelling	31
	12.2.1 Container label	31
	12.2.2 Filter systems	31
	12.2.3 Retrieval systems	32
	12.2.4 Conversion systems	32
	12.2.5 Record label	32
	12.3 Information supplied by the manufacturer	32
	12.3.1 General	32
	12.3.2 Information and instructions for use	32
	Annex A (informative) Relationship between testing requirements, device attributes and potential failure modes, and guidance for the creation of a device evaluation strategy	34
	Annex B (informative) Description of clinical effects of failure	51
	Annex C (informative) Description of device effects of failure	53
	Annex D (informative) Test methods	54
	Annex E (informative) Examples of general issues related to the clinical use of vena cava filters	90
	Bibliography	92

[ISO/FDIS 25539-3](https://standards.iteh.ai/standards/iso/4b3c3314-692e-4e00-a2e9-6c02cb554d9a/iso-fdis-25539-3)

<https://standards.iteh.ai/catalog/standards/iso/4b3c3314-692e-4e00-a2e9-6c02cb554d9a/iso-fdis-25539-3>

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

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

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

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

<https://standards.iteh.ai/catalog/standards/iso/4b3c3314-692e-4c00-a2e9-6c02cb554d9a/iso-fdis-25539-3>

The main changes are as follows:

- the testing and clinical use related to vena cava filters has been updated;
- the consistency in nomenclature and reporting requirements has been improved.

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

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

Introduction

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

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

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

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

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

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

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

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

Many filter systems have been shown to be safe and effective in clinical use – this update is not intended to require additional evaluations of these devices to remain in compliance with this document as the testing would not provide useful information regarding the expected clinical performance of the device. Manufacturers may rely on historical data gathered under the guidance of the previous edition of this document (i.e. ISO 25539-3:2011). Similarly, for device modifications or changes in intended clinical use,

this update is not intended to require additional evaluation of aspects of the device that are not expected to change clinical performance.

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

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

- a) focused device evaluation strategy in [A.2.1](#); and
- b) comprehensive device evaluation strategy in [A.2.2](#).

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

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

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

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

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

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO/FDIS 25539-3](#)

<https://standards.iteh.ai/catalog/standards/iso/4b3c3314-692e-4e00-a2e9-6c02cb554d9a/iso-fdis-25539-3>

Cardiovascular implants — Endovascular devices —

Part 3: Vena cava filters

1 Scope

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

NOTE 1 Due to the variations in the design of implants covered by this document, and in some cases due to the emergence of novel types of such implants, acceptable standardized in vitro tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this document will be necessary.

This document is applicable to vena cava filters intended to prevent symptomatic pulmonary embolism by capturing blood clots in the inferior vena cava (IVC). While this document can be useful with respect to filters implanted in other venous locations (e.g. superior vena cava, iliac veins), it does not specifically address the use of filters in other implantation sites.

This document is also applicable to permanent filters together with their associated delivery systems, optional filters that can be retrieved and their associated retrieval systems, and convertible filters and their associated conversion systems. While this document can be useful with respect to the evaluation of repositioning filters after chronic implantation, it does not specifically address filter repositioning.

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

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

NOTE 2 Absorbable implants are covered in ISO/TS 17137.

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

NOTE 3 Vascular device-drug combination products are covered in ISO 12417-1 and some coating properties are covered in ISO 25539-4.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993 (all parts), *Biological evaluation of medical devices*

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

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

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

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

ISO 14630:2012, *Non-active surgical implants — General requirements*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

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

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

absorption

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

3.2

absorbable coating

implant coating (3.20) that is intended to be absorbed

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

3.3

access site

vein that is used for accessing the vena cava

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

3.4

adverse event

unfavourable change in health that occurs in a subject who participates in a study while receiving the treatment or within a specified time after receiving treatment

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

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

3.5

caval perforation/penetration

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

3.6

clinical effect of failure

specific detrimental clinical observations potentially associated with device failures

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

3.7

clinical perforation/penetration

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

3.8

conversion system

components that are intended to structurally alter a *convertible filter* ([3.23.2](#)) after implantation so that it no longer functions as a filter

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

3.9

delivery system

components of the *filter system* ([3.18](#)) used to deliver the filter to the target position and to deploy the filter

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

3.10

determine

appraise or analyse quantitatively

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

3.11

device effect of failure

consequence to the device potentially associated with device failure

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

3.12

device evaluation strategy

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

3.13

comprehensive device evaluation strategy table

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

3.14

focused device evaluation strategy table

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

3.15

evaluate

qualitatively appraise or analyse

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

3.16

failure mode

type of difficulty or failure of the *filter system* (3.18) that can be encountered (hazards) in preclinical in vivo or clinical use and can result in consequences (harm) to the subject

3.17

filter formation

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

3.18

filter system

components consisting of the *vena cava filter* (3.23) and the *delivery system* (3.9)

3.19

filter system orientation

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

3.20

implant coating

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

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

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

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

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

3.21

implantation site

location of *vena cava filter* (3.23) placement within the body

3.22

retrieval system

components that are intended to remove a specific filter

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

3.23

vena cava filter

filter implant

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

3.23.1

absorbable filter

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

Note 1 to entry: A filter with a component designed to be absorbed can function as a *convertible filter* (3.23.2) without intervention.

3.23.2

convertible filter

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

3.23.3

optional filter

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

3.23.4

permanent filter

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

Note 1 to entry: All *optional filters* (3.23.3) are also permanent filters. Permanent filters can incorporate design characteristics that allow for retrieval or conversion and can be labelled for use of these optional features, if applicable.

3.24

surface coating

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

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

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

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

3.25

surface modification

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

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

3.26

unacceptable filter tilting

clinically significant rotation of the filter relative to the longitudinal axis of the vena cava and resulting in performance failure (e.g. inadequate filtration, excessive filtration, filter migration, filter embolization, *caval perforation/penetration* (3.5), clinical perforation/penetration, inability to retrieve the filter as applicable, inability to convert the filter as applicable)

[ISO/FDIS 25539-3](https://standards.iteh.ai/catalog/standards/iso/4b3c3314-692e-4c00-a2e9-6c02cb554d9a/iso-fdis-25539-3)

<https://standards.iteh.ai/catalog/standards/iso/4b3c3314-692e-4c00-a2e9-6c02cb554d9a/iso-fdis-25539-3>

4 General requirements

4.1 Classification

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

4.2 Materials of construction for filter system

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

4.3 Configuration and size designation for filters

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

4.4 Intended clinical use designation

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

5 Intended performance

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

6 Design attributes

6.1 General

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

6.2 Filter system

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

- a) the ability to permit safe and consistent deliverability of the filter to the intended deployment location;
- b) the ability to permit accurate and safe deployment of the filter;
- c) the ability to inject contrast via the delivery system if indicated in the IFU;
- d) the ability to permit safe withdrawal of the delivery system following deployment;
- e) the ability to maintain adequate structural integrity.

6.3 Vena cava filter

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

- a) the ability to ensure effective fixation in the intended location within the inferior vena cava;
- b) the ability to maintain adequate integrity;
- c) the ability to capture clots in the blood, while allowing acceptable blood flow;
- d) the ability to prevent clinical perforation/penetration;
- e) the compatibility of the filter dimensions for use with the specified caval diameters;
- f) the compatibility with exposure to magnetic resonance imaging (MRI) fields.

6.4 Optional filter

In addition to the attributes listed in 6.3, the design attributes of the optional filter shall at least take into account the following:

- a) the ability to be engaged;
- b) the ability to be retrieved;
- c) the ability to maintain adequate structural integrity through retrieval.