

---

---

**Cardiovascular implants — Endovascular  
devices —**

Part 3:  
**Vena cava filters**

*Implants cardiovasculaires — Dispositifs endovasculaires —  
Partie 3: Filtres caves*



This document is a preview generated by EVIS



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2011

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

Foreword .....	v
Introduction.....	vi
<b>1 Scope .....</b>	<b>1</b>
<b>2 Normative references .....</b>	<b>1</b>
<b>3 Terms and definitions .....</b>	<b>2</b>
<b>4 General requirements .....</b>	<b>5</b>
4.1 Classification .....	5
4.2 Size.....	5
<b>5 Intended performance.....</b>	<b>5</b>
<b>6 Design attributes .....</b>	<b>5</b>
6.1 General .....	5
6.2 Sheath/dilator kit for endovascular filter system.....	5
6.3 Filter system .....	5
6.4 Filter .....	5
6.5 Optional filter .....	6
6.6 Sheath/dilator kit for endovascular retrieval/conversion system .....	6
6.7 Retrieval/conversion system.....	6
6.8 Endovascular systems.....	6
<b>7 Materials .....</b>	<b>7</b>
<b>8 Design evaluation.....</b>	<b>7</b>
8.1 General .....	7
8.2 Sampling .....	7
8.3 Conditioning of test samples .....	8
8.4 Reporting.....	8
8.5 Bench and analytical tests .....	9
8.6 Preclinical <i>in vivo</i> evaluation .....	24
8.7 Clinical evaluation .....	28
<b>9 Post-market surveillance.....</b>	<b>32</b>
<b>10 Manufacturing.....</b>	<b>32</b>
<b>11 Sterilization .....</b>	<b>32</b>
11.1 Products supplied sterile.....	32
11.2 Products supplied non-sterile.....	33
11.3 Sterilization residuals .....	33
<b>12 Packaging.....</b>	<b>33</b>
12.1 Protection from damage in storage and transport .....	33
12.2 Marking.....	34
12.3 Information supplied by the manufacturer .....	35
<b>Annex A (informative) Attributes of endovascular devices — Vena cava filters — Technical and clinical considerations.....</b>	<b>37</b>
<b>Annex B (informative) Descriptions of potential device effects of failure and failure modes and descriptions of detrimental clinical effects .....</b>	<b>51</b>
<b>Annex C (informative) Bench and analytical tests .....</b>	<b>55</b>
<b>Annex D (informative) Test methods .....</b>	<b>59</b>

**Annex E (informative) Examples of terms for clinical use of vena cava filters .....86**  
**Bibliography.....88**

This document is a preview generated by EVS

## 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).