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ISO 25539-3

Cardiovascular implants —
Endovascular devices —

Part 3:
Vena cava filters

*Implants cardiovasculaires — Dispositifs endovasculaires —
Partie 3: Filtres de veine cave*

Second edition
2024-10

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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).

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

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

The main changes are as follows:

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

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

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

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

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

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

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

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

The revisions to the annexes to this document are given in [Table 1](#).

Table 1 — Revisions to the annexes in this document

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

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

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

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

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

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

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

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

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