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STN	**Srdcovo-cievne implantáty Vnútrocievne pomôcky Časť 3: Vnútrožilové filtre (ISO 25539-3: 2024)**	**STN EN ISO 25539-3 85 2925**

Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO 25539-3:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/24

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English Version

Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO 25539-3:2024)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 3 : Filtres de veine cave (ISO 25539-3:2024)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 3: Hohlvenenfilter (ISO 25539-3:2024)

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European foreword

This document (EN ISO 25539-3:2024) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2025, and conflicting national standards shall be withdrawn at the latest by April 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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The text of ISO 25539-3:2024 has been approved by CEN as EN ISO 25539-3:2024 without any modification.

International Standard

ISO 25539-3

Cardiovascular implants — Endovascular devices —

Part 3: Vena cava filters

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

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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.

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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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.

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 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

edition of this document 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 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.

International Standard **ISO 25539-3:2024(en)**

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, a 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*