

# ISO 25539-3:2024-10 (E)

## Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters

---

<b>Contents</b>		<b>Page</b>
	<b>Foreword</b> .....	<b>v</b>
	<b>Introduction</b> .....	<b>vi</b>
<b>1</b>	<b>Scope</b> .....	<b>1</b>
<b>2</b>	<b>Normative references</b> .....	<b>1</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>2</b>
<b>4</b>	<b>General requirements</b> .....	<b>5</b>
	4.1 Classification.....	5
	4.2 Materials of construction for filter system.....	5
	4.3 Configuration and size designation for filters.....	6
	4.4 Intended clinical use designation.....	6
<b>5</b>	<b>Intended performance</b> .....	<b>6</b>
<b>6</b>	<b>Design attributes</b> .....	<b>6</b>
	6.1 General.....	6
	6.2 Filter system.....	6
	6.3 Vena cava filter.....	6
	6.4 Optional filter.....	7
	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.....	8
	6.10 Absorbable filter or coating.....	8
<b>7</b>	<b>Materials</b> .....	<b>8</b>
<b>8</b>	<b>Design evaluation</b> .....	<b>8</b>
	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.....	13
	8.5.4 Optional filter.....	15
	8.5.5 Convertible filter.....	16
	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.....	20
	8.6.1 Purpose.....	20
	8.6.2 Specific aims.....	20
	8.6.3 Protocol considerations.....	21
	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.....	25
8.7.3	Protocol considerations.....	25
8.7.4	Data acquisition.....	26
8.7.5	Final report.....	29
<b>9</b>	<b>Post-market experience.....</b>	<b>30</b>
<b>10</b>	<b>Manufacturing.....</b>	<b>30</b>
<b>11</b>	<b>Sterilization.....</b>	<b>30</b>
11.1	Products supplied sterile.....	30
11.2	Sterilization residuals.....	30
<b>12</b>	<b>Packaging.....</b>	<b>31</b>
12.1	General.....	31
12.1.1	General.....	31
12.1.2	Unit container.....	31
12.1.3	Outer container.....	31
12.1.4	Shipping container.....	31
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.....	33
12.3.1	General.....	33
12.3.2	Information and instructions for use.....	33
<b>Annex A (informative) Relationship between testing requirements, device attributes and potential failure modes, and guidance for the creation of a device evaluation strategy.....</b>		<b>35</b>
<b>Annex B (informative) Description of clinical effects of failure.....</b>		<b>53</b>
<b>Annex C (informative) Description of device effects of failure.....</b>		<b>55</b>
<b>Annex D (informative) Test methods.....</b>		<b>56</b>
<b>Annex E (informative) Examples of general issues related to the clinical use of vena cava filters.....</b>		<b>92</b>
<b>Bibliography.....</b>		<b>94</b>