TECHNICAL SPECIFICATION

ISO/TS 15539

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Cardiovascular implants — Endovascular prostheses

Implants cardiovasculaires — Prothèses endovasculaires

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed every three years with a view to deciding whether it can be transformed into an International Standard.

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

ISO/TS 15339 was developed by Technical Subcommittee ISO/TC 150, *Implants for surgery,* Subcommittee SC 2, *Cardiovascular implants*.

Annexes A to D of this Technical Specification are for information only.

Introduction

This Technical Specification, in addition to ISO 14630, provides a method to demonstrate compliance with the relevant recommendations as outlined concerning medical devices, as they apply to a family of cardiovascular devices.

Cardiovascular implants — Endovascular prostheses

1 Scope

1.1 This Technical Specification gives recommendations, based on current medical knowledge, for evaluating the ability of an endovascular device to meet specified medical situations. Additional recommendations on packaging and sterilization are also provided.

This Technical Specification should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

1.2 This Technical Specification is applicable to endovascular devices, such as endovascular prostheses, vascular stents and filters used in the following locations:

a) aorta;

b) coronary arteries;

c) supra-aortic trunks (e.g. carotid arteries, vertebral arteries);

d) pulmonary artery;

e) visceral arteries (e.g. renal, mesenteric);

f) peripheral arteries;

g) arterio-venous access shunts;

h) veins;

i) vena cava;

j) transjugular intrahepatic porto-systemic shunts (TIPS or TIPSS).

1.3 This Technical Specification is not applicable to vascular occluders, with the exception of contra-lateral iliac occluders when used as an integral part of an aorto-uni-iliac device. The requirements as stated in ISO 14630 apply for excluded products.

1.4 This Technical Specification is not applicable to procedures and devices used prior to the introduction of the endovascular devices (defined in 3.1 through 3.4), such as balloon angioplasty devices.

NOTE Annexes A and B give structured guidelines to the appropriate tests/studies and information on requirements to check against specific device-related problems during the design of medical devices and accessories. Annex C gives guidelines to appropriate tests. Annex D gives medical definitions for reportable clinical events.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Technical Specification. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Technical Specification are encouraged to

investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 11134, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization.*

ISO 11135, *Medical devices — Validation and routine control of ethylene oxide sterilization.*

ISO 11137, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization.*

ISO 11607, *Packaging for terminally sterilized medical devices.*

ISO 13485, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001.*

ISO 13488, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002.*

ISO 14160, *Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants.*

ISO 14630:1997, *Non-active surgical implants — General requirements.*

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

ISO 14971-1, *Medical devices — Risk management — Part 1: Application of risk analysis.*

EN 556, *Sterilization of medical devices — Requirements for terminally sterilized devices to be labelled "Sterile".*

3 Terms and definitions

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

3.1
endovascular device
implant and its delivery system in which the implant is introduced transluminally and resides partially or completely within a vascular conduit

NOTE 1 The following types of implant are included within this definition of endovascular device: vascular stents (3.2), vena cava filters (3.3), endovascular prostheses (3.4).

NOTE 2 For the purposes of this Technical Specification, the accessory devices addressed within this document, as well as the implant, are considered within this definition.

3.2
vascular stent
bare structure, coated or uncoated, transluminally placed, residing in and stabilizing a vascular conduit

NOTE For the purposes of this Technical Specification, the term "bare" is used to define the absence of a manufactured covering on a vascular stent.

3.3
vena cava filter
filter, transluminally placed, residing in the vena cava

3.4
endovascular prosthesis
transluminally placed vascular prosthesis, residing partially or completely within a vascular conduit to form an internal bypass or shunt between sections of the vascular system

4 Intended performance

The requirements of clause 4 of ISO 14630:1997 shall apply.

5 Design attributes

The requirements of clause 5 of ISO 14630:1997 shall apply. Further information is contained in tabular form in annexes A and B.

6 Materials

The requirements of clause 6 of ISO 14630:1997 shall apply.

7 Design evaluation

The requirements of clause 7 of ISO 14630:1997 shall apply. A risk analysis carried out in accordance with ISO 14971-1 shall apply. Recommendations for the hazards to be evaluated are contained in tabular form in annexes A and B.

8 Manufacturing

The requirements of ISO 13485 and ISO 13488 or clause 8 of ISO 14630:1997 shall apply.

9 Sterilization

9.1 Products supplied sterile

9.1.1 Implants which are labelled ‘Sterile’ shall comply with EN 556 or other national or regional standards specifying a sterility assurance level of 10^{-6} for implants.

9.1.2 Sterilization processes shall be validated and routinely controlled.

9.1.3 If endovascular devices are to be sterilized by ethylene oxide, ISO 11135 shall apply.

9.1.4 If endovascular devices are to be sterilized by moist heat, ISO 11134 shall apply.

9.1.5 If endovascular devices are to be sterilized by radiation, ISO 11137 shall apply.

9.1.6 If single-use endovascular devices incorporating animal tissue are to be sterilized using liquid chemical sterilants, ISO 14160 shall apply.

9.1.7 If endovascular devices are to be sterilized by other sterilization processes, ISO 14937 shall apply.

NOTE European medical device sterilization standards are listed in the Bibliography.

9.2 Products supplied non-sterile

The requirements of 9.2 of ISO 14630:1997 shall apply.

9.3 Sterilization residuals

The requirements of 9.3 of ISO 14630:1997 shall apply.

10 Packaging

10.1 Protection from damage in storage and transport

The requirements of 10.1 of ISO 14630:1997 shall apply.

10.2 Maintenance of sterility in transit

10.2.1 Endovascular devices labelled “Sterile” shall be packaged in such a way that they remain sterile under normal storage, transport and handling conditions unless the protective package is damaged or opened.

10.2.2 The packaging shall conform to ISO 11607.

NOTE A European standard for sterilization packaging for medical devices is listed in the Bibliography.

11 Information supplied by the manufacturer

The requirements of clause 11 of ISO 14630:1997 shall apply. Further information is contained in tabular form in annexes A and B.

Annex A
(informative)

Attributes of endovascular devices — Technical and clinical considerations

Tables A.1 through A.3 provide a logical method for identifying a set of biocompatibility, bench, preclinical *in vivo* and clinical tests to assess device performance. Annex B includes a list of the bench tests identified in the table, with a description of the purpose of each test. Annex C includes a list of the bench tests identified in the table, with a description of the purpose of each test, and annex D includes definitions for the reportable clinical events listed in the table.

The table headings and explanations are listed in Table A.1. In addition, a form is given to help provide the proper context for the information contained within the matrix.

Table A.1 — Table headings and explanations

Column number	Title	Explanation	Context
1	Device/procedure – related attributes	Individual design goals	The device should have an adequate _____(column 1).
2	Problem(s)	Difficulties that may be encountered that could result in not meeting the individual design goal	If the device does not have an adequate _____(column 1), there could be a problem with _____(column 2).
3	Reportable clinical events	Complications or failures that may be observed with clinical use if the problems occur	If there is a problem with _____ (column 2), _____ (column 3) could occur and should be documented.
4	Bench and analytical tests	A list of tests, exclusive of preclinical *in vivo* and clinical studies, that may be conducted to validate the individual design goal	The following tests may be conducted to evaluate the adequacy of the _____ (column 1): _____ (column 4).
5	Preclinical *in vivo* studies	Specific aims of preclinical *in vivo* studies to validate and verify the individual design goal	In order to evaluate the adequacy of the _____ (column 1) in an *in vivo* environment, the preclinical *in vivo* study should _____ (column 5).
6	Clinical studies	Specific aims of clinical studies to verify the individual design goal	In order to evaluate the adequacy of the _____ (column 1) in a clinical environment, the clinical study should _____ (column 6).
7	Information supplied by the manufacturer	Information to be supplied by the manufacturer to minimize the potential for failures to occur	To minimize the risk of _____ (column 2) or _____ (column 3), _____ (column 7) should be provided by the manufacturer.

Table A.2 — Attributes of endovascular devices — Technical and clinical considerations for delivery systems

Delivery system						
Device/ procedure – related attributes	**Problem(s)**	**Reportable clinical events**	**Bench and analytical tests**	**Preclinical *in vivo* studies**	**Clinical studies**	**Information supplied by the manufacturer**
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**
Ability to access	-Wire not crossing the lesion -Introducer and delivery system not matching the access site (i.e. size mismatch) -Delivery system not advancing to target site -Emboli generation -Device (e.g. stent) dislodgement	-Access failure -Vascular trauma -Neurological deficit -Ischaemia -Spinal neurological deficit -Embolization	-Component dimension compatibility -Flex/kink -Torsional bond strength -Bond strength -Torquability -Pushability -Trackability -Simulated use -Dimensional verification -Profile -Radiopacity	-Evaluate ability to access -Assess handling and visualization -Evaluate adverse events with particular attention to events listed in column 3	-Evaluate ability to access -Assess handling and visualization -Evaluate reportable clinical events	-Device profile, wire dimensions compatible with delivery system -Sizing recommendations -For user-mounted devices, information supplied by manufacturer should include recommendations or specifications for delivery components -Information should include recommendations or specifications for accessory devices
Ability to deploy: Balloon expandable	-Inability to activate deployment mechanism -Disproportionate dimensions of balloon relative to vessel -Device (e.g. stent) dislodgement -Balloon failure -Damage of device components by other components -Inadequate visualization -Emboli generation	-Deployment system failure -Spinal neurological deficit -Neurological deficit -Vascular trauma -Ischaemia -Embolization -Damage to implant	-Component dimension compatibility -Torsional bond strength -Bond strength -Simulated use -Dimensional verification -Balloon deflation -Balloon mean burst -Balloon rated burst -Balloon rated fatigue -Balloon inflation time -Radiopacity	-Verify efficacy of deployment -Assess handling and visualization -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of deployment -Assess handling and visualization -Evaluate reportable clinical events	-For user-mounted devices, information supplied by manufacturer should include recommendations or specifications for delivery components -Information should include recommendations or specifications for accessory devices