TECHNICAL SPECIFICATION

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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

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

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 deploy: Self-expanding	-Inability to activate deployment mechanism -Disproportionate dimensions of "modelling" balloon relative to device/vessel -Balloon failure -Damage of device components by other components -Inadequate visualization -Emboli generation -Device (e.g. stent) dislodgement	-Deployment system failure -Neurological deficit -Vascular trauma -Ischaemia -Spinal neurological deficit -Embolization -Damage to implant	-Component dimension compatibility -Torsional bond strength -Bond strength -Simulated use -Dimensional verification -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
Ability to withdraw: Balloon expandable	-Improper balloon deflation -Balloon winging -Lack of structural integrity -Emboli generation -Diameter mismatch -Device dislodgement -Damage of device components by other components -Delivery system snagging on the implant -Inadequate visualization	-Deployment system failure -Neurological deficit -Vascular trauma -Ischaemia -Spinal neurological deficit -Embolization -Damage to implant	-Tubing tensile strength -Component dimension compatibility -Torsional bond strength -Bond strength -Simulated use -Dimensional verification -Flex/kink -Radiopacity	-Verify efficacy of withdrawal -Assess handling and visualization -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of withdrawal -Assess handling and visualization -Evaluate reportable clinical events	-Information should include recommendations or specifications for accessory devices

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

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 withdraw: Self-expanding	-Diameter mismatch -Lack of structural integrity -Emboli generation -Device dislodgement -Damage of device components by other components -Delivery system snagging on the implant -Inadequate visualization	-Deployment system failure -Neurological deficit -Vascular trauma -Ischaemia -Spinal neurological deficit -Embolization -Damage to implant	-Tubing tensile strength -Component dimension compatibility -Torsional bond strength -Bond strength -Simulated use -Dimensional verification -Flex/kink -Radiopacity	-Verify efficacy of withdrawal -Assess handling and visualization -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of withdrawal -Assess handling and visualization -Evaluate reportable clinical events	-Information should include recommendations or specifications for accessory devices
Biocompatibility	-Lack of appropriate biocompatibility	-Complications attributable to a lack of appropriate biocompatibility	-ISO 10993	-ISO 10993 -Appropriate histological and pathological investigation of explants -Evaluate adverse events with particular attention to events listed in column 3	-Evaluate reportable clinical events	N/A
Sterility	-Non-sterile product	-Infection	-Sterilization assurance	N/A	-Evaluate reportable clinical events	-Appropriate handling instructions -Whether single or multiple use
Haemostasis	-Size mismatch -Haemostasis valve incompetency -Leaking	-Procedural bleeding -Haematoma	-Haemostatic seal leak assessment -Catheter leak -Simulated use -Dimensional verification	-Evaluate appropriateness of sizing -Assess blood loss -Evaluate adverse events with particular attention to events listed in column 3	-Evaluate appropriateness of sizing -Assess blood loss -Evaluate reportable clinical events	-Sizing recommendations -Specifications for accessory devices

Table A.3 — Attributes of endovascular devices — Technical and clinical considerations for implants

Implant						
Device/ procedure – related attributes (1)	**Problem(s)** (2)	**Reportable clinical events** (3)	**Bench and analytical tests** (4)	**Preclinical *in vivo* studies** (5)	**Clinical studies** (6)	**Information supplied by the manufacturer** (7)
Ability to accurately deploy	-Inaccurate positioning or orientation -Improper deployment configuration -Incomplete deployment -Inadequate visualization	-Branch vessel occlusion -Deployment system failure -Attachment site leak -Prosthesis migration -Lumen obstruction -Aneurysm enlargement -Aneurysm rupture -Vascular trauma	-Simulated use -Device length to diameter relationship -Radiopacity	-Assess visualization -Verify accuracy and efficacy of deployment -Evaluate adverse events with particular attention to events listed in column 3	-Assess visualization -Verify accuracy and efficacy of deployment -Evaluate reportable clinical events	-Location and description of radio-opaque landmarks whenever present
Fixation effectiveness	-Incomplete apposition to vessel wall -Excessive or inadequate radial force	-Attachment site leak -Prosthesis migration -Lumen obstruction -Vascular trauma -Trauma to adjacent structures -Branch vessel occlusion -Aneurysm enlargement -Aneurysm rupture	-Radial force -Crush resistance -Recoil -Local compression -Conformability to vessel wall -Migration resistance -Simulated use	-Assess position, integrity and functionality -Appropriate histological and pathological investigation of explants -Evaluate adverse events with particular attention to events listed in column 3	-Assess position, integrity and functionality -Monitor lesion morphology -Appropriate histological and pathological investigation of explants if occurring -Evaluate reportable clinical events	-Directions regarding restrictions and requirements to assure proper fixation

Table A.3 — Attributes of endovascular devices — Technical and clinical considerations for implants
(continued)

Implant						
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)**
Implant integrity	-Structural failure of implant -Loss of complete apposition to vessel wall -Leaking	-Stent/attachment system fracture -Graft dilatation/rupture -Device thrombosis -Prosthesis migration -Attachment site leak -Aneurysm enlargement -Aneurysm rupture -Transgraft leak -Vascular trauma -Lumen obstruction -Venous thrombosis -Trauma to adjacent structures	-Fatigue and durability -Stress / strain analysis -Corrosion -Longitudinal tensile strength -Burst/ circumferential strength -Factory anastomotic strength -Strength of stent/ attachment system to graft bond (e.g. adhesive, sutures) -Strength after repeated puncture for vascular access	-Assess position, integrity and functionality -Appropriate histological and pathological investigation of explants -Evaluate adverse events with particular attention to events listed in column 3	-Assess position, integrity and functionality -Appropriate histological and pathological investigation of explants if occurring -Evaluate reportable clinical events	N/A
Filtration for vena cava filters	-Thrombus generation -Failure to filter emboli	-Venous thrombosis -Pulmonary embolism	-Filtration flow loop	-Evaluate filtration efficiency -Evaluate adverse events with particular attention to events listed in column 3	-Evaluate reportable clinical events	N/A
Impermeable to blood flow through device wall	-Inadequate healing -Leaking	-Transgraft leak -Aneurysm enlargement -Aneurysm rupture	-Porosity, water permeability, integral water permeability/ leakage and water entry pressure	-Evaluate adverse events with particular attention to events listed in column 3	-Monitor lesion morphology -Evaluate reportable clinical events	N/A

Table A.3 — Attributes of endovascular devices — Technical and clinical considerations for implants
(continued)

Implant						
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)**
Modularity	-Dimensional mismatch -Inaccurate positioning or orientation -Separation between modules -Damage to or obstruction of modules by other modules -Angulation or kink between modules	-Prosthesis migration -Attachment site leak -Vascular trauma -Branch vessel occlusion -Aneurysm enlargement -Aneurysm rupture -Lumen obstruction	-Pull test for modular components	-Assess position, integrity and functionality -Appropriate histological and pathological investigation of explants -Evaluate adverse events with particular attention to events listed in column 3	-Assess position, integrity and functionality -Monitor lesion morphology -Appropriate histological and pathological investigation of explants if occurring -Evaluate reportable clinical events	-Location and description of radio-opaque landmarks whenever present -Directions regarding restrictions and requirements to assure proper fixation
Appropriate sizing	-Inappropriate sizing	-Stent/attachment system failure -Prosthesis migration -Device thrombosis -Attachment site leak -Aneurysm enlargement -Aneurysm rupture -Branch vessel occlusion -Vessel trauma -Trauma to adjacent structures -Lumen obstruction	-Simulated use -Device length to diameter relationship -Recoil -Dimensional verification	-Verify sizing scheme -Evaluate adverse events with particular attention to events listed in column 3	-Evaluate reportable clinical events	-Sizing recommendations

Table A.3 — Attributes of endovascular devices — Technical and clinical considerations for implants
(continued)

Implant						
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)**
Patency	-Kinking -Twisting -Inaccurate deployment -Deformation -Thrombus generation	-Device thrombosis -Lumen obstruction -Restenosis -Abrupt reclosure -Angina -Recurrence of portal hypertension -Myocardial infarction -Ischaemia -Pulmonary embolism	-Radial force -Crush resistance -Simulated use -Stent free surface area	-Assess position, integrity and functionality -Appropriate histological and pathological investigation of explants -Evaluate adverse events with particular attention to events listed in column 3	-Assess position, integrity and functionality -Monitor lesion morphology -Appropriate histological and pathological investigation of explants if occurring -Evaluate reportable clinical events	N/A
Magnetic resonance imaging (MRI) compatibility	-Lack of quality imaging -Movement of the device or heating of wire	-Vascular trauma -Device migration	-MRI compatibility	N/A	-Evaluate reportable clinical events	-Describe MRI safety and compatibility of the device
Biocompatibility	-Lack of appropriate biocompatibility	-Complications attributable to a lack of appropriate biocompatibility	-ISO 10993	-ISO 10993 -Appropriate histological and pathological investigation of explants	-Evaluate reportable clinical events	-List of materials utilized
Sterility	-Non-sterile product	-Infection	-Sterilization assurance	N/A	-Evaluate reportable clinical events	-Appropriate handling instructions -Whether single or multiple use

Annex B
(informative)

Accessory devices for endovascular procedures — Technical and clinical considerations

Tables B.1 to B.4 provide a logical method for identifying a set of biocompatibility, bench, preclinical *in vivo* and clinical tests to assess device performance. 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 tables.

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

Table B.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 B.2 — Accessory devices for endovascular procedures — Technical and clinical considerations for balloon catheters

Balloon catheters						
Device/ procedure-related attributes (1)	**Problem(s)** (2)	**Reportable clinical events** (3)	**Bench and analytical tests** (4)	**Preclinical *in vivo* studies** (5)	**Clinical studies** (6)	**Information supplied by the manufacturer** (7)
Ability to insert catheter	-Inability to insert over guidewire -Inability to insert through sheath introducer	-Vascular trauma -Accessory device failure	-Simulated use -Dimensional verification -Trackability	-Evaluate ability to access -Evaluate adverse events with particular attention to events listed in column 3	-Evaluate ability to access -Evaluate reportable clinical events	-Guidewire size and sheath-introducer dimensional requirements
Ability to withdraw catheter	-Balloon winging -Incomplete balloon deflation -Damage of implant by balloon	-Vascular trauma -Accessory device failure -Damage to implant	-Simulated use -Balloon deflation -Tubing tensile strength -Bond strength -Kink/flex tests	-Verify efficacy of withdrawal -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of withdrawal -Evaluate reportable clinical events	-Withdrawal technique
Ability to inflate balloon	-Vessel to balloon size mismatch -Balloon rupture -Balloon leak -Catheter leak -Damage of implant by balloon	-Vascular trauma -Damage to implant -Accessory device failure	-Simulated use -Balloon inflation time -Balloon rated burst -Catheter leak	-Evaluate adverse events with particular attention to events listed in column 3	-Evaluate reportable clinical events	-Balloon inflation technique
Radiodetectibility of balloon	-Balloon marker(s) can not be visualized	-Accessory device failure	-Marker visibility	-Evaluate adverse events with particular attention to events listed in column 3	-Evaluate reportable clinical events	-Identify balloon marker(s) location(s)
Sterility	-Non-sterile product	-Infection	-Sterilization assurance	N/A	-Evaluate reportable clinical events	-Appropriate handling instructions
Biocompatibility	-Lack of appropriate biocompatibility	-Complications attributable to a lack of appropriate biocompatibility	-ISO 10993	-ISO 10993	-Evaluate reportable clinical events	N/A

Table B.3 — Accessory devices for endovascular procedures — Technical and clinical considerations for sheath introducers

Sheath introducers						
Device/ procedure-related attributes (1)	**Problem(s)** (2)	**Reportable clinical events** (3)	**Bench and analytical tests** (4)	**Preclinical *in vivo* studies** (5)	**Clinical studies** (6)	**Information supplied by the manufacturer** (7)
Ability to maintain haemostasis	-Valve failure -Deployment catheter to sheath size mismatch	-Procedural bleeding -Haematoma	-Simulated use -Haemostatic seal leak assessment -Dimensional verification	-Evaluate appropriateness of sizing -Assess blood loss -Evaluate adverse events with particular attention to events listed in column 3	-Evaluate appropriateness of sizing -Assess blood loss -Evaluate reportable clinical events	-Sheath introducer dimensional requirements
Ability to insert sheath introducer	-Vessel to sheath size mismatch -Incomplete sheath insertion	-Vascular trauma	N/A	-Verify efficacy of insertion -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of insertion -Evaluate reportable clinical events	-Introducer insertion technique
Ability to dilate vessel	-Unable to dilate vessel	-Vascular trauma	N/A	-Verify efficacy of vessel dilation -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of vessel dilation -Evaluate reportable clinical events	-Vessel dilation technique
Ability to withdraw sheath introducer	-Vessel impedes sheath retraction	-Vascular trauma	N/A	-Verify efficacy of sheath withdrawal -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of sheath withdrawal -Evaluate reportable clinical events	-Sheath withdrawal technique
Radiodetectibility of sheath/ components	-Sheath components can not be visualized	-Accessory device failure	-Marker visibility	-Evaluate adverse events with particular attention to events listed in column 3	-Evaluate reportable clinical events	-Identify marker location
Sterility	-Non-sterile product	-Infection	-Sterilization assurance	N/A	-Evaluate reportable clinical events	-Appropriate handling instructions -Whether single or multiple use
Biocompatibility	-Lack of appropriate biocompatibility	-Complications attributable to a lack of appropriate biocompatibility	-ISO 10993	-ISO 10993 -Appropriate histological and pathological investigation of explants	-Evaluate reportable clinical events	N/A

Table B.4 — Accessory devices for endovascular procedures — Technical and clinical considerations for guide wires

Guide wires						
Device/ procedure-related attributes (1)	**Problem(s)** (2)	**Reportable clinical events** (3)	**Bench and analytical tests** (4)	**Preclinical *in vivo* studies** (5)	**Clinical studies** (6)	**Information supplied by the manufacturer** (7)
Ability of delivery catheter to track over the guide wire	-Guide wire is not stiff enough -Guide wire to catheter deployment size mismatch	-Vascular trauma	-Simulated use -Trackability -Flex/kink -Torqueability -Dimensional verification -Profile -Guide wire compatibility	-Verify efficacy of tracking/ability to access -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of tracking/ability to access -Evaluate reportable clinical events	-Guide wire stiffness and size
Implant deployment accuracy	-Inaccurate positioning or orientation	-Branch vessel occlusion -Attachment site leak -Prosthesis migration -Aneurysm enlargement -Aneurysm rupture	-Simulated use -Radiopacity	-Verify deployment accuracy -Evaluate adverse events with particular attention to events listed in column 3	-Verify deployment accuracy -Evaluate reportable clinical events	-Guide wire stiffness
Guide wire insertion	-Guide wire tip penetrates vessel	-Vascular trauma	-Simulated use	-Verify efficacy of insertion -Evaluate adverse events with particular attention to events listed in column 3	-Verify efficacy of insertion -Evaluate reportable clinical events	-Insertion technique
Sterility	-Non-sterile product	-Infection	-Sterilization assurance	N/A	-Evaluate reportable clinical events	-Appropriate handling instructions -Whether single or multiple use
Biocompatibility	-Lack of appropriate biocompatibility	-Complications attributable to a lack of appropriate biocompatibility	-ISO 10993	-ISO 10993	-Evaluate reportable clinical events	N/A

Annex C
(informative)

Bench and analytical tests

Table C.1 — Bench and analytical tests, with descriptions

Test	Description
Balloon deflation	Quantify time required to deflate balloon and quantify ability to remove deflated balloon.
Balloon inflation time	Quantify time required to expand balloon.
Balloon mean burst	Observe mean burst strength (loss of pressure). See ISO 10555-1 and ISO 10555-4.
Balloon rated burst	Quantify mean burst strength with an appropriate safety margin.
Balloon rated fatigue	Determine the maximum number of cycles of inflation to the recommended inflation pressure.
Biocompatibility	Assess biological safety (e.g. ISO 10993-1).
Bond strength	Evaluate the strength of junction bonds between parts of the device delivery system. All bonds must remain intact under recommended conditions of use.
Burst/circumferential strength	Measure the burst strength and/or the circumferential strength of the appropriate components of the implant in accordance with ISO 7198.
Component dimension compatibility	Evaluate the compatibility of the device dimensions with the dimensions of recommended accessory devices. All components shall be functionally compatible.
Conformability to vessel wall	Evaluate device conformability to vessel wall.
Corrosion	Determine the susceptibility of the material to corrosion in an actual or simulated environment.
Crush resistance	Record the minimum force at which permanent deformation occurs.
Device length to diameter relationship	For balloon-delivered devices, quantify the relationship of device diameter/length to balloon diameter. For self-expanding devices, quantify the relationship between the deployed diameter and length. This information should be made available by the manufacturer.
Dimensional verification	Measure the appropriate dimensions for conformance with design specifications.
Factory anastomotic strength	Quantify the factory anastomotic strength of the device in accordance with ISO 7198:1998, 8.3.2.4.
Fatigue and durability	Testing to evaluate the long-term dimensional and structural integrity of the device.
Flex/kink	Evaluate the ability of the device/delivery system to bend in order to accommodate the minimum radius or angle it will be required to negotiate during access and delivery. Also, evaluate minimum radius of curvature that the device can accommodate without kinking.
Graft to stent/attachment system strength	Evaluate the strength of the connection of the graft to the stent/attachment system.

Table C.1 — Bench and analytical tests,with descriptions *(continued)*

Test	Description
Haemostatic seal leak assessment	Evaluate the ability of valve to maintain an adequate seal.
Local Compression	Evaluate the elastic deformation of the device in response to localized pressure.
Longitudinal tensile strength	Quantify the longitudinal tensile strength of the device in accordance with ISO 7198:1998, 8.3.2.
Material characterization	Characterize the chemical composition of the device.
Marker visibility	Evaluate the ability to visualize the device under simulated use.
Migration resistance	Evaluate the ability of device to remain stationary under simulated use.
MRI compatibility	Assess MRI safety and compatibility.
Permeability	Quantify the amount of fluid flow through the appropriate components of the implant.
Porosity	Estimate or index of the ratio of the void within a material to the total volume occupied by the material including the voids.
Profile	Maximum diameter along defined sections of device/delivery system.
Pull test for modular components	Quantify the force required to disengage modular components.
Pushability	Evaluate the ability of the system to transmit sufficient force/movement from the catheter proximal end to the catheter distal end of the delivery system.
Radial force (hoop strength)	Evaluate the change in diameter of a self-expanding device as a function of radially applied pressure.
Radiopacity	Evaluate the ability to visualize the device.
Recoil	Quantify the amount of elastic recoil and correlate this to recommended sizing. This information should be made available by the manufacturer.
Simulated use	Evaluate the applicable performance parameters using a model that simulates the intended use conditions.
Stent free surface area	Determine the percentage change in free or open area and decrease in length as a function of stent diameter.
Sterilization assurance	Demonstrate a specified Sterility Assurance Level (SAL) in accordance with appropriate International Standards.
Strength after repeated puncture	Assess structural integrity after repeated puncture.
Stress/strain analysis	Evaluate the stress/strain characteristics of the device when subjected to a worst-case physiological load using appropriate tools such as Finite Element Analysis (FEA).
Torqueability	Evaluate the ability of the delivery system to provide sufficient rotation to the distal end to deliver the device within the anatomy in accordance with the design constraints of the system.
Torsional bond strength	Quantify the torque/rotation required to break joints and/or materials in the non-implantable device components. All bonds shall remain intact under recommended conditions of use.
Trackability	Evaluate the ability of the system to advance over a guidewire, following the guidewire tip, along the path of the vessel, including in narrow, tortuous vessels.
Tubing tensile strength	Evaluate the strength of the tubing.
Visual inspection	See ISO 7198.

NOTE 1 Tests in italics require specific reliability parameters.

NOTE 2 Test conditions, such as viscosity, temperature, etc., should be those of simulated use.

Annex D
(informative)

Definitions of reportable clinical events

Table D.1 — Definitions of reportable clinical events

Event	Definition
Abrupt reclosure	Obstructed flow in a dilated lesion which was previously documented to be patent with antegrade flow.
Access failure	Failure to reach the intended site with the device due to mechanical failure or patient anatomy. Whether or not successful implant deployment was achieved should be documented.
Accessory device failure	Inability to use the accessory device as intended due to mechanical failure or patient anatomy. Whether or not the failure contributed to an unsuccessful implant deployment should be documented.
Adynamic ileus	Inability to tolerate oral intake without supplemental IV therapy developing more than 48 h after, but within 30 days of the procedure. The duration of the event should also be reported.
Aneurysm enlargement	Any enlargement of the diameter or volume of the aneurysm sac greater than documented measurement error, as determined by contrast-enhanced CT or other appropriate modality.
Aneurysm rupture	Rupture of the native aneurysm sac.
Angina	Chest, neck, arm or other pain related to decreased coronary blood flow.
Arrhythmia	Development of a new atrial or ventricular arrhythmia or exacerbation of a prior arrhythmia requiring treatment (i.e. medical therapy, cardioversion, pacemaker) within 30 days of the procedure.
Atelectasis/pneumonia	Atelectasis or pneumonia documented by chest X-ray within 30 days of the procedure and requiring treatment with antibiotics, inhalation therapy, intubation or suctioning. The type of treatment required should be reported.
Attachment site leak	Blood flow into the aneurysm sac arising at or from the attachment site occurring at any time after endovascular repair as determined by contrast CT scan, ultrasound, angiography or direct observation at surgery or autopsy. Includes leaks between modular components.
Branch flow	Blood flow into the aneurysm sac arising from a patent branch vessel (i.e. lumbar or inferior messenteric branch) of the excluded aorta occurring at any time after endovascular repair as determined by contrast CT scan, ultrasound, angiography or direct observation at surgery or autopsy.
Branch vessel occlusion	Clinically significant, unplanned exclusion of a major branch vessel.
Coagulopathy	Development of a bleeding disorder documented by appropriate laboratory studies within 30 days of the procedure. The specific syndrome should also be noted.
Congestive heart failure	Development of an acute episode or exacerbation of existing low cardiac output accompanied by distal and/or pulmonary edema. The need for treatment and the type of treatment administered, as well as the duration of the episode, should be reported.
Damage to implant	Damage to the implant caused by an accessory device or the delivery system.
Deployment system failure	Inability to deploy the device at the intended site due to mechanical failure or patient anatomy. Whether or not successful implant deployment was achieved should be documented.

Table D.1 — Definitions of reportable clinical events *(continued)*

Complication	Definition
Device infection	Development of a confirmed device infection. The etiology (i.e. device sterility, endocarditis, etc.) should be reported if known.
Device thrombosis	Haemodynamically significant thrombus formation within the lumen of the endovascular device. The degree of narrowing should be specified.
Embolization	Migration of intraluminal debris in the presence of clinical sequelae. This is a reportable category that may encompass events reported under other categories.
Endoleak	Any blood flow outside the endovascular graft within the intact aneurysm sac.
Graft dilatation/rupture	Graft dilatation to more than 50 % of the manufacturer's labelled diameter or any graft rupture.
Haematoma	Development of a haematoma related to the endovascular procedure requiring surgical intervention, evacuation and/or transfusion. If the patient requires transfusion, the volume of replaced blood should be reported. If surgical intervention is required, this should also be reported.
Hepatic encephalopathy	Neurological dysfunction due to inadequate metabolism by the liver.
Hypotension	Low blood pressure.
Impotence	Subjective report of failure to resume the degree of sexual function registered preoperatively within 6 months of the procedure.
Ischaemia	Development of the clinical picture of acute or chronic ischaemia within 30 days of the procedure. The cause of the ischaemia should be diagnosed and reported (i.e. embolism, thrombosis or dissection). Define severity and location.
Lumen obstruction	Unintentional obstruction of flow through the vascular lumen due to twisting or kinking of the prosthesis, oversizing, failure of the device to fully open, or any other cause.
Lymphocele/lymph fistula	Cystic accumulation of lymph or groin wound drainage occurring at the incision site. Any intervention required to resolve the event should also be reported.
Myocardial infarction	Myocardial infarction documented by the presence of raised cardiac enzymes within 30 days of the procedure. Clinical symptoms, EKG changes and/or haemodynamic instability associated with the event should also be reported.
Neurological deficit	Development of a new transient or permanent neurological deficit or exacerbation of a prior deficit as determined by CT/MRI Scan and/or clinical exam that occurs within 30 days of the procedure. Whether the deficit was permanent or transient should also be reported.
Post-procedure bleeding	Procedure-related bleeding which occurs after the patient leaves the OR resulting in the need for transfusion. The volume of replaced blood, the source of the bleeding and whether or not surgical intervention was required to stop the bleeding should also be reported.
Procedural bleeding	Any blood loss requiring intervention (i.e. transfusion, medical therapy). The volume of blood lost during the procedure should be determined from the operative report. The need for transfusion and the volume and source (banked, autologous, autotransfused) of transfused blood should also be reported.
Prosthesis migration	Longitudinal movement of all or part of a stent or attachment system for a distance of greater than 1 cm relative to anatomical landmarks that were determined prior to discharge.
Prosthesis realignment	Clinical symptoms associated with movement of the aorta relative to the implant as a result of post-implantation morphological changes. The clinical symptoms should be specified.
Pulmonary embolism	Clinical evidence of pulmonary embolism confirmed by high-probability VQ scan or pulmonary angiography occurring within 30 days after the procedure.
Recurrence of portal hypertension	Recurrent high blood pressure in the portal venous system.
Renal failure	Rise in creatinine greater than 50 % above the pre-procedure level resulting in a creatinine level above high normal that does not spontaneously resolve. The need for and the duration of dialysis treatment should also be reported.

Table D.1— Definitions of reportable clinical events *(continued)*

Complication	Definition
Respiratory failure	Need for mechanical ventilation beyond the first 24 h after the procedure or the need for reintubation or ventilator support any time between 24 h and 30 days postoperative (unless the patient was ventilator-dependent when he/she entered the study). The duration of ventilator support should be reported.
Restenosis	Reduction in diameter when compared to the reference diameter.
Spinal neurological deficit	Neurological deficit related to spinal chord ischaemia developing within 30 days of the procedure.
Stent/attachment system fracture	Fracture or breakage of any portion of the stent or attachment system, including metallic fracture or breakage of any of the suture material used to construct the stent or secure the stent or attachment system to the graft material.
Transgraft leak	The documented leakage of blood through the graft wall.
Trauma to adjacent structures	Injury to adjacent structures associated with vascular trauma (see definition below).
Vascular trauma	Injuries to vessels as a result of an endovascular procedure, including dissections or perforations, false or true aneurysms. The specific site and source of the injury as well as the clinical sequelae should be reported. All required surgical or interventional procedures required to repair the injury should also be reported.
Vasospasm	Vessel spasm.
Venous thrombosis	Development of a new or recurring episode of venous thrombosis as verified by an appropriate modality.
Wound infection	Wound drainage or erythema of the incision site requiring drainage and/or debridement in addition to antibiotic therapy.
Other complications	Unusual complications not specifically included in the above list which are determined to be associated with either the device or the procedure.

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