AS ISO 25539.1—2003
ISO 25539-1:2003

Australian Standard™

Cardiovascular implants—Endovascular devices

Part 1: Endovascular prostheses

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Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

Australian Dental Association

Australian Industry Group

Australian Orthopaedic Association

Australian Society for Biomaterials

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This Standard was issued in draft form for comment as DR 03181.

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First published as AS ISO 25539.1—2003.

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Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5341 8

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-012, Surgical Implants. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 25539-1:2003, *Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses.*

The objective of this Standard is to specify requirements for endovascular prostheses, based upon current medical knowledge. With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization packaging and information supplied by the manufacturer. It should be considered as a supplement to AS ISO 14630, which specifies general requirements for the performance of non-active surgical implants. It is applicable to endovascular prostheses used to treat arterial aneurysms, arterial stenoses, or other appropriate vascular abnormalities.

The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

As this Standard is reproduced from an international Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
7198	Cardiovascular implants—Tubular vascular prostheses	7198	Cardiovascular implants—Tubular vascular prostheses
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-1	Part 1: Evaluation and testing	10993.1	Part 1: Evaluation and testing
10993-3	Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	10993.3	Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
10993-4	Part 4: Selection of tests for interactions with blood	10993.4	Part 4: Selection of tests for interactions with blood
10993-5	Part 5: Tests for in vitro cytotoxicity	10993.5	Part 5: Tests for in vitro cytotoxicity
10993-6	Part 6: Tests for local effects after implantation	10993.6	Part 6: Tests for local effects after implantation
10993-7	Part 7: Ethylene oxide sterilization residuals	10993.7	Part 7: Ethylene oxide sterilization residuals
10993-8	Part 8: Selection and qualification of reference materials for	10993.8	Part 8: Selection and qualification of reference materials for

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Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
	biological tests		biological tests
10993-9	Part 9: Framework for identification and quantification of potential degradation products	10993.9	Part 9: Framework for identification and quantification of potential degradation products
10993-10	Part 10: Tests for irritation and delayed-type hypersensitivity	10993.10	Part 10: Tests for irritation and delayed-type hypersensitivity
10993-11	Part 11: Tests for systematic toxicity	10993.11	Part 11: Tests for systematic toxicity
10993-12	Part 12: Sample preparation and reference materials	10993.12	Part 12: Sample preparation and reference materials
10993-13	Part 13: Identification and quantification of degradation products from polymeric medical devices	10993.13	Part 13: Identification and quantification of degradation products from polymeric medical devices
10993-14	Part 14: Identification and quantification of degradation products from ceramics	10993.14	Part 14: Identification and quantification of degradation products from ceramics
10993-15	Part 15: Identification and quantification of degradation products from metals and alloys	10993.15	Part 15: Identification and quantification of degradation products from metals and alloys
10993-16	Part 16: Toxicokinetic study design for degradation products and leachables	10993.16	Part 16: Toxicokinetic study design for degradation products and leachables
11134	Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization	11134	Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization
11135	Medical devices—Validation and routine control of ethylene oxide sterilization	11135	Medical devices—Validation and routine control of ethylene oxide sterilization
11137	Sterilization of health care products—Requirements for validation and routine control —Radiation sterilization	11137	Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization
13485	Quality systems—Medical devices—Particular requirements for the application of ISO 9001	13485	Quality systems—Medical devices—Particular requirements for the application of ISO 9001
13488	Quality systems—Medical devices—Particular requirements for the application of ISO 9002	13488	Quality systems—Medical devices—Particular requirements for the application of ISO 9002
14155	Clinical investigation of medical devices	14155	Clinical investigation of medical devices
14160	Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid sterilants	14160	Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid sterilants
14630	Non-active surgical implants—General requirements	14630	Non-active surgical implants—General requirements

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INTRODUCTION

This part of ISO 25539 has been prepared in order to provide minimum requirements for endovascular prostheses and the methods of test that will enable their evaluation. It is the first part of a proposed three-part International Standard. ISO/TS 15539, from which this part of ISO 25539 is derived, serves as a rationale for the requirements. The Technical Specification was developed by first identifying the design requirements for endovascular implants and listing the potential implant and clinical failure modes. Tests were then identified to address each of the failure modes. The requirements provided in this part of ISO 25539 are based on that assessment.

Due to the variations in the design of implants covered by this part of ISO 25539 and in some cases due to the relatively recent development of some of these implants, acceptable standardized *in vitro* tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this part of ISO 25539 will be undertaken.

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AUSTRALIAN STANDARD

Cardiovascular implants—Endovascular devices

Part 1: Endovascular prostheses

1 Scope

1.1 This part of ISO 25539 specifies requirements for endovascular prostheses, based upon current medical knowledge. With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization packaging and information supplied by the manufacturer. It should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

1.2 This part of ISO 25539 is applicable to endovascular prostheses used to treat arterial aneurysms, arterial stenoses, or other appropriate vascular abnormalities.

1.3 This part of ISO 25539 is applicable to delivery systems if they comprise an integral component of the deployment of the endovascular prostheses.

1.4 This part of ISO 25539 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. See ISO 14630 for excluded products.

1.5 This part of ISO 25539 is not applicable to procedures and devices used prior to the introduction of the endovascular system (defined in 3.6), such as balloon angioplasty devices.

2 Normative references

The following referenced documents are indispensable for the application 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 7198:1998, *Cardiovascular implants — Tubular vascular prostheses*

ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11607:1997, *Packaging for terminally sterilized medical devices*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 13488:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002*

ISO 14155 (all parts), *Clinical investigation of medical devices for human subjects*

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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 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 14971:2000, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7198 and ISO 14630 and the following apply.

3.1
attachment system
system integral to the endovascular prosthesis that is designed to interface directly with vessel wall in order to prevent migration

NOTE The system may also prevent blood flow on the outside of the prostheses at the attachment sites.

3.2
delivery system
system or mechanism used to deliver the endovascular prosthesis to the targeted position

NOTE The delivery system is removed after implant placement.

3.3
determine
quantitatively appraise or analyse

3.4
endoleak
persistence of blood flow outside the lumen of an endovascular prosthesis but within an aneurysm sac or adjacent vascular segment being treated by the graft

NOTE Endoleaks are catagorized as follows:

— a Type I endoleak is periprosthetic and occurs at the proximal or distal attachment zone;

— a Type II endoleak is caused by retrograde flow from patent branch arteries, for example lumbar and intercostal;

— a Type III endoleak arises from a defect in the graft material or from an inadequate seal between modular graft components;

— a Type IV endoleak is due to graft permeability, often identified by a generalized blush of contrast within the aneurysm sac.

3.5
endovascular prosthesis
endovascular graft
endovascular implant
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

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3.6
endovascular system
system used to treat a vascular lesion from within the vessel, typically comprised of an endovascular prosthesis and its delivery system

NOTE 1 An abdominal aortic aneurysm is an example of a vascular lesion which can be treated with an endovascular system.

NOTE 2 For the purposes of this part of ISO 25539, the delivery system as well as the implant are included within this definition.

3.7
evaluate
qualitatively appraise or analyse

3.8
graft material
non-metallic component of the endovascular prosthesis

3.9
reportable clinical events
complications or failures that may be observed with clinical use of the endovascular system

4 Intended performance

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

5 Design attributes

5.1 General

The requirements of Clause 5 of ISO 14630:1997 shall apply. In addition, the following shall be taken into account:

a) with regard to oxidation potential: the possibility of crevice corrosion passivation level over the relevant parts;

b) with regard to wear: fretting corrosion;

c) with regard to interface between implant and body:

   1) fixation hooks if present;

   2) relative movement between implant and tissue;

   3) forces exerted by the device on the surrounding tissue;

   4) forces required to deform the implant if the deformation is permanent;

d) expected ingrowth, penetration, perforation, tilting and migration;

e) introduction and delivery systems.

NOTE These additional items are adapted from Clause 5 of EN 12006-3:1998.

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5.2 Delivery system

The design attributes to meet the intended performance of the delivery system shall additionally take into account at least the following:

a) the ability of the system to permit consistent, accurate and safe access to the intended location;

b) the ability of the system to permit consistent, accurate and safe deployment of the implant;

c) the ability of the system to permit consistent and safe withdrawal of the delivery system;

d) the compliance of the system with the requirements of ISO 10993-1 and appropriate other parts of the ISO 10993 series;

e) the ability of the system to minimize blood loss (haemostasis);

f) the visibility of the system under fluoroscopy or other technologies.

5.3 Implant

The design attributes to meet the intended performance of the implant shall additionally take into account at least the following:

a) the ability of the implant to be consistently, accurately and safely deployed;

b) the ability of the implant to ensure effective fixation within the vasculature;

c) the ability of the implant to maintain adequate integrity;

d) the ability of the implant to prevent blood from flowing through the implant wall as appropriate to its intended use;

   Changes in wall permeability after implantation shall be taken into account.

e) the appropriate interaction between and among the modules of endovascular systems designed with modular components (modularity);

f) the consistency of the implant dimensions and its design for compatibility for use in specified vessel diameters;

g) the ability of the implant to maintain adequate blood flow through the lumen (patency);

h) the compatibility of the implant with exposure to magnetic resonance imaging (MRI) fields;

i) the compliance of the implant with the requirements of ISO 10993-1 and appropriate other parts of the ISO 10993 series;

j) the visibility of the implant under fluoroscopy or other technologies.

6 Materials

The requirements of Clause 6 of ISO 14630:1997 shall apply. Additional testing specific to certain materials should be performed to determine the appropriateness of the material for use in the design. For example, Nitinol materials dependent on shape-memory properties should be subjected to testing in order to assess transformation properties.

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7 Design evaluation

7.1 General

The requirements of Clause 7 of ISO 14630:1997 shall apply. A risk analysis shall be carried out in accordance with the requirements of ISO 14971.

NOTE All testing may not be appropriate for all prosthesis designs.

Justification shall be provided for the properties not measured for characterization.

It is impossible to take into consideration all future and emerging technologies. These emerging-technology prostheses will need to follow the basic test protocols of this part of ISO 25539 to characterize the endovascular system. Testing beyond the scope of this part of ISO 25539 may also be necessary to characterize new emerging-technology prostheses. Consideration shall be given to the failure modes of the prostheses and their effects on the performance of the implant in identifying the appropriate testing. For compound prostheses, as defined in ISO 7198:1998, 3.9, although it may be appropriate to conduct some of the testing described in this part of ISO 25539 on components of the prosthesis, testing of the endovascular system as a whole is also required. In addition, if the compound prosthesis is partially constructed of a resorbable component, the non-resorbable portion of the implant shall be characterized as well as the implant as a whole.

Each segment of a composite prosthesis, as defined in ISO 7198:1998, 3.8, shall be tested. In addition, any manufactured anastomosis shall satisfy the requirements of this part of ISO 25539 relating to leakage and factory anastomotic strength.

Retesting shall be performed whenever significant changes are made in materials, construction, configuration, application, or processing methods.

A complete description of the validated test methods and sample preparation procedures used to address the requirements of this part of ISO 25539 shall be documented by the manufacturer. The method and sample size chosen shall be justified. Where acceptance criteria are not specified, the manufacturer shall evaluate the acceptability of the results against predetermined criteria.

For certain design attributes, the use of a reference device should be considered.

If it can be justified that sterilization has no effect on the characteristics of the device that are under evaluation, the required tests may be carried out on non-sterilized devices.

7.2 Delivery (and/or endovascular) system

7.2.1 Ability to access

7.2.1.1 General

The ability of the system to permit safe, consistent and accurate access to the intended location shall be evaluated.

Hazards to be evaluated include, but are not limited to, the following:

a) guidewire not crossing the lesion;

b) introducer and delivery systems not matching the access site (i.e. size mismatch);

c) delivery system not advancing to target site;

d) emboli generation;

e) implant dislodgement.

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These hazards can result in the following reportable clinical events, including but not limited to the following:

— access failure;

— vascular trauma;

— neurological deficit;

— ischaemia;

— spinal neurological deficit;

— embolization.

Testing shall include the following items listed in 7.2.1.2 through 7.2.1.12, as appropriate to the design of the endovascular system.

7.2.1.2 Bond strength

Determine the longitudinal bond strength between parts of the delivery system. All bonds shall remain intact under recommended conditions of use. The results shall be evaluated in relation to the force(s) necessary to access, deploy and withdraw the system.

7.2.1.3 Component dimension compatibility

Determine the dimensions of the endovascular system for compatibility with the dimensions of recommended accessories. All components shall be dimensionally compatible.

7.2.1.4 Dimensional verification

Determine the appropriate dimensions for conformance with design specifications.

7.2.1.5 Flex/kink

Evaluate the ability of the endovascular system to bend in order to accommodate the minimum radius or angle to be negotiated during access and delivery.

7.2.1.6 Profile

Determine the maximum diameter along defined sections of the endovascular system.

7.2.1.7 Pushability

Evaluate the ability of the endovascular system to be pushed or positioned by an operator without bending or buckling.

7.2.1.8 Visibility

Evaluate the ability to visualize the delivery system during access using fluoroscopy. The use of other technologies shall be justified.

7.2.1.9 Simulated use

Evaluate the performance of the delivery system using a model that simulates the intended use conditions.

7.2.1.10 Torquability

Evaluate the ability of the endovascular system to provide sufficient rotation to the distal (leading) end to deliver the implant within the anatomy in accordance with the design constraints of the system.

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7.2.1.11 Torsional bond strength

Determine the torque required to break joints and/or materials in the appropriate delivery system components. The results shall be evaluated in relation to the force(s) necessary to access, deploy and withdraw the system.

7.2.1.12 Trackability

Evaluate the ability of the endovascular system to advance over the recommended guidewire and to follow the guidewire tip along the path of the vessel, including in narrow, tortuous vessels.

7.2.2 Ability to deploy

7.2.2.1 General

The ability of the system to permit safe, consistent and accurate deployment of the implant shall be evaluated.

Hazards to be evaluated include, but are not limited to, the following:

a) inability to fully and properly deploy the prosthesis;

b) disproportionate dimensions and properties, such as balloon compliance and burst pressure, of balloon relative to endovascular system and vessel (if applicable);

c) implant dislodgement;

d) balloon failure (if applicable);

e) damage of implant components by other components;

f) inadequate visualization;

g) emboli generation.

These hazards can result in the following reportable clinical events, including but not limited to the following:

— delivery system failure;

— spinal neurological deficit;

— neurological deficit;

— vascular trauma;

— ischaemia;

— embolization;

— damage to implant.

Testing shall include the following items listed in 7.2.2.2 through 7.2.2.14, as appropriate to the design of the endovascular system.

7.2.2.2 Bond strength

Determine the longitudinal bond strength between parts of the delivery system. All bonds shall remain intact under recommended conditions of use.

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7.2.2.3 Balloon inflation time

Determine the time required to expand the balloon to the maximum recommended inflation pressure.

7.2.2.4 Balloon deflation time

Determine the time required to deflate the balloon and characterize the ability to remove the deflated balloon.

7.2.2.5 Balloon mean burst pressure

Determine the mean burst pressure.

7.2.2.6 Balloon rated burst pressure

Determine the burst pressure with an appropriate safety margin including reliability parameters.

Designate the maximum recommended inflation pressure and operating pressure(s).

7.2.2.7 Balloon rated fatigue

Determine the maximum number of recommended inflation cycles to the recommended inflation pressure including reliability parameters.

Designate the maximum recommended number of inflation cycles.

7.2.2.8 Component dimension compatibility

Determine the dimensions of the endovascular system for compatibility with the dimensions of recommended accessories. All components shall be dimensionally compatible.

7.2.2.9 Dimensional verification

Determine the appropriate dimensions for conformance with design specifications.

7.2.2.10 Force to deploy

Determine the force to deploy the implant.

7.2.2.11 Visibility

Evaluate the ability to visualize the implant and delivery system during placement and deployment using fluoroscopy. The use of other technologies shall be justified.

7.2.2.12 Simulated use

Evaluate the performance of the endovascular system using a model that simulates the intended use conditions.

7.2.2.13 Torsional bond strength

Determine the torque required to break joints and/or materials in the appropriate delivery system components.

7.2.2.14 Tubing tensile strength

Determine the strength of the tubing used in the delivery system as appropriate to the material.

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