AS ISO 25539.1—2003
ISO 25539-1:2003

AS ISO 25539.1

Australian Standard™

Cardiovascular implants—Endovascular devices

Part 1: Endovascular prostheses

Standards Australia

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 21 May 2003 and published on 30 June 2003.

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Part 1: Endovascular prostheses

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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'.

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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

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

CONTENTS

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.

NOTES

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*