AS ISO 15539—2003
ISO TS 15539:2000

Australian Standard™

Cardiovascular implants—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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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 TS 15539:2000, *Cardiovascular implants—Endovascular prostheses.*

The objective of this Standard is to specify, based on current medical knowledge, the evaluation of the ability of an endovascular device to meet specified medical situations. Additional recommendations on packaging and sterilization are also provided. This Standard is a supplement to AS ISO 14630, which specifies general requirements for the performance of non-active surgical implants. It is applicable to endovascular devices, such as endovascular prostheses, vascular stents and filters.

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 and European Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
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

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
14630	Non-active surgical implants—General requirements	14630	Non-active surgical implants—General requirements
Reference to European Standard		*Australian Standard*	
EN		AS EN	
556	Sterilization of medical devices—Requirements for terminally sterilized medical devices to be labelled ‘STERILE’	556	Sterilization of medical devices—Requirements for medical devices to be designated [STERILE]
		556.1	Requirements for terminally sterilized medical devices

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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.

NOTES

AUSTRALIAN STANDARD

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

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