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ISO 7198:1998

Australian Standard™

Cardiovascular implants—Tubular vascular 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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Cardiovascular implants—Tubular vascular 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 7198:1998, *Cardiovascular implants—Tubular vascular prostheses*.

The objective of this Standard is to specify requirements relating to testing, packaging, labelling and terminology for sterile tubular vascular prostheses intended to replace, bypass or to form shunts between segments of the vascular system in humans.

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	
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
14155	Clinical investigation of medical devices	14155	Clinical investigation of medical devices

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INTRODUCTION

ISO 7198 has been prepared in order to provide basic requirements for sterile vascular prostheses and the methods of test which will enable evaluation of vascular prostheses.

AUSTRALIAN STANDARD

Cardiovascular implants—Tubular vascular prostheses

1 Scope

1.1 This International Standard specifies requirements relating to testing, packaging, labelling and terminology for sterile tubular vascular prostheses intended to replace, bypass or to form shunts between segments of the vascular system in humans.

This International Standard addresses vascular prostheses that are made wholly or partly of: materials of biological origin; synthetic textile materials; and synthetic nontextile materials. In addition, guidance for characterization of compound and composite prostheses is provided. It specifies the designation of materials of manufacture and the construction, and specifies the designation of sizes and dimensions of vascular prostheses. It refers to biological requirements of the materials of construction and of the finished product, taking into account the appropriate part of the horizontal International Standard ISO 10993.

This International Standard also specifies the designation of mechanical properties. It describes methods for the measurement and verification of the dimensions and mechanical properties declared by the manufacturer. It refers to sterilization of prostheses and specifies requirements for labelling and packaging. It also provides definitions of terms in common use.

1.2 This International Standard does not specify all the performance or dimensional characteristics, but it does include methods for verifying that the nominal values disclosed by the manufacturer are within the permitted tolerances. These recommendations do not purport to comprise a complete test program.

1.3 For the purposes of this International Standard, the disclosure of test methods, results and other information on request shall relate solely to requests from a National Regulatory Authority with responsibility for surgical implants.

This International Standard does not apply to human donor tissue devices such as cryopreserved vessels. Also excluded are all patches, pledgets and stents.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 472:1988, *Plastics — Vocabulary*.

ISO 2076:1989, *Textiles — Man-made fibres — Generic names*.

ISO 2859-1:1989, *Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*.

ISO 2859-2:1985, *Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*.

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