AS ISO 16061—2003
ISO 16061:2000

Australian Standard™

Instrumentation for use in association with non-active surgical implants—General requirements

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.

The following are represented on Committee HE-012:

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

Commonwealth Department of Health and Ageing

Department of Defence (Australia)

Medical Industry Association of Australia Inc

Neurological Society of Australasia

Royal Australasian College of Surgeons

Royal Perth Hospital

University of New South Wales

University of Sydney

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Australia web site at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Global Standard*, has a full listing of revisions and amendments published each month.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

This Standard was issued in draft form for comment as DR 03122.

Australian Standard™

Instrumentation for use in association with non-active surgical implants—General requirements

First published as AS ISO 16061—2003.

COPYRIGHT

© Standards Australia International

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher.

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

ISBN 0 7337 5350 7

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 16061:2000, *Instrumentation for use in association with non-active surgical implants—General requirements.*

The objective of this Standard is to specify general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are resupplied after refurbishment.

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 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
14155	Clinical investigation of medical devices	14155	Clinical investigation of medical devices
Reference to European Standard		*Australian Standard*	
EN		AS EN	
556	Sterilization of medical devices—Requirements for terminally sterilized medical devices to be labelled 'STERILE'	556 556.1	Sterilization of medical devices—Requirements for medical devices to be designated [STERILE] Part 1: Requirements for terminally sterilized medical devices

CONTENTS

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **2**

4 Intended performance **2**

5 Design attributes **2**

6 Selection of materials **3**

7 Design evaluation **3**
7.1 General **3**
7.2 Pre-clinical evaluation **3**
7.3 Clinical evaluation **3**

8 Manufacture **3**

9 Sterilization **4**
9.1 Products supplied sterile **4**
9.2 Products provided non-sterile **4**

10 Packaging **4**
10.1 Protection from damage in storage and transport **4**
10.2 Maintenance of sterility in transit **4**

11 Information to be supplied by the manufacturer **4**
11.1 General **4**
11.2 Instruments with measuring function **4**
11.3 Restrictions in combinations **5**
11.4 Marking on instruments **5**
11.5 Instructions for use **5**
11.6 Instruments intended for single use **5**

Annex A (informative) **Examples of typical instrument applications, together with materials found acceptable for instrument manufacture** **6**

Bibliography **18**

NOTES

AUSTRALIAN STANDARD

Instrumentation for use in association with non–active surgical implants—General requirements

1 Scope

This International Standard specifies general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are resupplied after refurbishment.

This International Standard applies to instruments which may be connected to power-driven systems, but does not apply to the power-driven systems themselves.

With regard to safety, this International Standard gives requirements for intended performance, design attributes, selection of materials, design evaluation, manufacture, sterilization, packaging and information to be supplied by the manufacturer.

This International Standard is not applicable to instruments associated with dental implants, transendodontic and transradicular implants and ophthalmic implants.

NOTE References to standards for non-active surgical implants are listed in the Bibliography.

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 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 14155, *Clinical investigation of medical devices.*

ISO 14971-1, *Medical devices — Risk management — Part 1: Application of risk analysis.*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.*

© Standards Australia