

Australian Standard™

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

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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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
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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 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.
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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:

<i>Reference to International Standard</i>		<i>Australian Standard</i>	
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
<i>Reference to European Standard</i>		<i>Australian Standard</i>	
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	Part 1: Requirements for terminally sterilized medical devices

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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*.

EN 556:1994 + A1:1998, *Sterilization of medical devices — Requirements for terminally-sterilized medical devices to be labelled “Sterile”*.

EN 1041:1998, *Information supplied by the manufacturer with medical devices*.

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1

associated instrument **instrument**

non-active medical device intended for use during surgical procedures related to a specific non-active surgical implant

3.2

resupplied instrument

instrument or set of instruments that has been returned to the manufacturer and has been reissued

4 Intended performance

The intended performance of an instrument shall be described and documented by addressing the following:

- a) functional characteristics;
- b) intended conditions of use.

NOTE Account should be taken of:

- published standards;
- published clinical and scientific literature;
- validated test results.

The extent to which the intended performance of an instrument has been achieved shall be determined (see clause 7).

5 Design attributes

The development of the design attributes of an instrument to meet the performance intended by the manufacturer shall take into account at least the following:

- a) physical, mechanical and chemical properties of the instrument materials (see clauses 6 and 7);
- b) microbiological and particulate contamination levels (see clauses 7, 9 and 10);
- c) ease of use, cleaning and maintenance (see clause 7);
- d) potential deterioration of the material characteristics due to sterilization and storage (see clauses 6, 7 and 8);
- e) effects of contact between the instrument and body, the implant and other instruments (see clause 7);
- f) shape and dimensions of the instrument, including their possible effects on the body (see clause 7);

- g) wear characteristics of materials and the effect of wear and wear products on the instrument and the body (see clauses 6 and 7);
- h) insertion, removal and interconnecting parts (see clause 7);
- i) extent of fluid leakage and/or diffusion of substances into or out of instruments (see clauses 6 and 7);
- j) accuracy and stability of instruments with a measuring function (see clauses 7 and 8);
- k) ability of the instrument or fragment of instrument to be located by means of an external imaging device (see 11.5).

6 Selection of materials

Materials for the manufacture of instruments shall be selected with regard to the properties required for the intended purpose, taking into account the effects of manufacture, handling, sterilization and storage (see clause 7).

The suitability of a given material for a particular application shall be demonstrated by either:

- a) evaluating in accordance with clause 7; or
- b) by selection from the materials found suitable by proven clinical use in similar applications.

NOTE Annex A lists some of the materials that have been found acceptable in certain applications.

7 Design evaluation

7.1 General

Instruments shall be evaluated in association with the implant they are designed for, in order to demonstrate that the intended performance (see clause 4) is achieved. Safety shall be demonstrated by pre-clinical evaluation and by carrying out a risk analysis in accordance with ISO 14971-1.

NOTE In certain circumstances a clinical evaluation can also be required.

7.2 Pre-clinical evaluation

If pre-clinical testing of instruments is required, the testing shall simulate conditions of intended use.

7.3 Clinical evaluation

If a clinical evaluation is required, it shall be conducted using the associated implant under the intended conditions of use. Where a clinical investigation is carried out, it shall be managed in accordance with ISO 14155.

8 Manufacture

Instruments shall be manufactured to specifications in accordance with the required design attributes (see clause 5).

NOTE 1 The application of quality systems as described in EN 46001 and EN 46002 may be appropriate.

NOTE 2 The design specification for re-supplied instruments need not necessarily be the same as the original, provided that the requirements of this International Standard are met.