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Australian Standard™

Non-active surgical implants—Implants for Osteosynthesis—Particular 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.

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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 14602:1998, *Non-active surgical implants—Implants for Osteosynthesis—Particular requirements*, which was prepared by the European Committee for Standardization (CEN) Technical Committee TC 285, Non-active surgical implants, in collaboration with ISO Technical Committee TC 150, Implants for surgery, in accordance with the Vienna Agreement on technical cooperation between ISO and CEN.

The objective of this Standard is to specify particular requirements for non-active surgical implants for osteosynthesis that are in addition to the requirements outlined in the relevant parts of AS ISO 14630. The particular requirements proposed are for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer.

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.

Normative and informative references listed in AS ISO 14630 apply, but are not repeated in this Standard.

As this Standard is reproduced from a European 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 European Standard’ should read ‘this Australian Standard’.

(c) A full point substitutes for a comma when referring to a decimal marker.

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	
14630	Non-active surgical implants—General requirements	14630	Non-active surgical implants—General requirements

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INTRODUCTION

This European standard, in addition to the requirements in EN ISO 14630:1997 provides a method to demonstrate compliance with the relevant Essential Requirements (ERs) as outlined in general terms in Annex 1 of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to non-active surgical implants for osteosynthesis.

Alternative methods of demonstrating compliance may be acceptable, in particular with respect to implants which have demonstrated satisfactory long-term clinical performance.

This Level 2 European Standard lays down particular requirements for osteosynthesis implants, in addition to those general requirements stated in EN ISO 14630:1997 for non-active surgical implants, and shall only be applied in conjunction with EN ISO 14630:1997.

In general, non-active surgical implants for osteosynthesis are used in trauma treatment or corrective surgery. They maintain the reduction of fractured bones and stabilise bony (or adjacent) structures to allow bone healing or fusion and/or to provide support or correction. When they have achieved their objective, the implants are either retrieved or left *in situ*.

AUSTRALIAN STANDARD

Non–active surgical implants—Implants for Osteosynthesis—Particular requirements

1 Scope

This European standard specifies particular requirements for non-active surgical Implants for osteosynthesis, hereafter referred to as implants.

In addition to EN ISO 14630:1997, this standard gives particular requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN ISO 14630:1997 Non-active surgical implants - General requirements.

> NOTE: Normative and informative references listed in EN ISO 14630:1997 apply, but are not repeated in this standard.

3 Definitions

For the purposes of this European Standard, the definitions in EN ISO 14630:1997 apply together with the following:

3.1 non-active surgical implant for osteosynthesis: Non-active implantable device intended to provide support to bony, cartilaginous, tendinous or ligamentous structures.

4 Intended performance

The intended performance of implants shall conform to clause 4 of EN ISO 14630:1997, taking account of the additional aspects as listed in the following 4.1, 4.2 and 4.3 as applicable.

> NOTE: Because of variations in anatomy, fracture sites and applications, it is necessary that implants for osteosynthesis are versatile. For anatomical reasons the size of the implants is necessarily restricted. The condition of the bone and the configuration of bony and other defects can affect the performance of the implants.

4.1 Functional characteristics

In describing and documenting the intended performance of the implants, the following aspects shall be addressed as appropriate:

a) type of fixation to bone, cartilaginous, tendinous or ligamentous structures;
b) means of attachment to or anchorage in bone;
c) linkage between implant components and bone or other structures;
d) use for revision procedures;
e) ability to be removed;