AS ISO 14602:2015
ISO 14602:2010

AS ISO 14602:2015

Non-active surgical implants—Implants for osteosynthesis—Particular requirements

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- Australian Dental Association
- Australian Society for Biomaterials
- Medical Technology Association of Australia
- Neurosurgical Society of Australasia
- Royal Australasian College of Surgeons
- Royal Perth Hospital
- Therapeutic Goods Administration
- University of Sydney

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Australian Standard®

Non-active surgical implants—Implants for osteosynthesis—Particular requirements

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-012, Surgical Implants, to supersede AS ISO 14602—2003.

The objective of this Standard is to specify particular requirements for non-active surgical implants for osteosynthesis, hereafter referred to as 'implants'. It also gives particular requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer. The objective of the revision is to adopt the current edition of ISO 14602.

The particular requirements of this Standard supplement the general requirements specified in AS ISO 14630. This Standard is intended to be read in conjunction with AS ISO 14630:2015.

This Standard is identical with, and has been reproduced from ISO 14602:2010, *Non-active surgical implants—Implants for osteosynthesis—Particular requirements*.

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian Standard'.

(b) 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

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

CONTENTS

INTRODUCTION

In general, non-active surgical implants for osteosynthesis are used in trauma treatment or corrective surgery. They maintain the reduction of fractured bones and stabilize 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*.

This International Standard, in addition to the requirements in ISO 14630, provides a method for addressing the fundamental principles in ISO/TR 14283 as they apply to non-active surgical implants for osteosynthesis. Annex A shows the correspondence between the clauses of this International Standard and those of ISO/TR 14283:2004.

This International Standard also provides a method of demonstrating compliance with the relevant essential requirements (ERs) as outlined in general terms in Annex 1 of European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive 2007/47/EC of 5 September 2007, as they apply to non-active surgical implants for osteosynthesis. It might also assist manufacturers to comply with the requirements of other regulatory bodies.

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

There are three levels of standard concerned with non-active surgical implants and related instrumentation. For the implants themselves, there are the following levels, with level 1 being the highest:

— level 1: general requirements for non-active surgical implants;

— level 2: particular requirements for families of non-active surgical implants;

— level 3: specific requirements for types of non-active surgical implants.

Level 1 standards contain requirements that apply to all non-active surgical implants. They also indicate that additional requirements are given in the level 2 and level 3 standards.

Level 2 standards, such as this International Standard, contain requirements that apply to a more restricted set or family of non-active surgical implants. This International Standard is a Level 2 standard that lays down particular requirements for non-active surgical implants for osteosynthesis that are in addition to those general requirements stated in ISO 14630 for non-active surgical implants. It is to be applied in conjunction with ISO 14630.

Level 3 standards, such as those listed in the annexes, apply to specific types of implant within a family of non-active surgical implants, in this case particular types of non-active surgical implant for osteosynthesis.

To address all requirements for a specific implant, it is advisable that the standard of the lowest available level be consulted first.

NOTE The requirements in this International Standard correspond to international consensus. Individual or national standards or regulatory bodies can prescribe other requirements.

AUSTRALIAN STANDARD

Non-active surgical implants—Implants for osteosynthesis—Particular requirements

1 Scope

This International Standard specifies particular requirements for non-active surgical implants for osteosynthesis, hereafter referred to as implants.

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14630:2008, *Non-active surgical implants — General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630 and the following apply.

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

4.1 General

The intended performance of implants shall conform to ISO 14630:2008, Clause 4, taking account of the additional aspects listed in 4.2, 4.3 and 4.4 as applicable.

NOTE Because of variations in anatomy, fracture sites and applications, it is necessary that implants for osteosynthesis be 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.