INTERNATIONAL STANDARD

ISO 14602

Second edition
2010-04-15

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

Implants chirurgicaux non actifs — Implants pour ostéosynthèse — Exigences particulières

Reference number
ISO 14602:2010(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14602 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

This second edition cancels and replaces the first edition (ISO 14602:1998), which has been technically revised.

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.

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.

4.2 Intended purpose

The intended purpose is osteosynthesis, which can include the areas of application listed below. In describing and documenting the implant's intended performance for osteosynthesis, the area(s) of intended typical application(s) shall be specified, for example:

a) fracture treatment;

b) tumour treatment;

c) stabilization of osteotomy;

d) stabilization of arthrodesis;

e) bone lengthening, shortening or transport;

f) support of bone replacement (bone graft sites);

g) adjunct to joint replacement;

h) scoliosis treatment;

i) spinal stabilization;

j) treatment of degenerative diseases;

k) tendon reconstruction;

l) ligament reconstruction.

NOTE Where appropriate, the anatomical site(s) should be indicated.

4.3 Functional characteristics

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

a) type of fixation to bony, 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;

f) action on bone and adjacent structures, for example:

- stabilization;
- support of the reduction of fractures and dislocations of bone and other structures;
- correction or control of alignment;
- transport of fragments;
- control of compression or distraction;
- safe placement in relation to adjacent structures.

4.4 Intended conditions of use

Variables that can influence the intended performance of the implant, including the following, shall be taken into account:

a) body build (size, weight);

b) age of patient;

c) pathological conditions;

d) bone quality;

e) tissue vitality;

f) surrounding tissue conditions;

g) loading conditions;

h) method of implantation;

i) interaction and combination with other fixation device;

j) activity level of the patient;

NOTE Certain conditions might restrict the application of the implants or call for caution in clinical usage. The performance of the implant might be affected by patient-related conditions.

k) operative techniques;

l) methods of post-operative treatment.

5 Design attributes

The requirements of Clause 5 of ISO 14630:2008 apply, together with the following particular requirements.

a) Where implants are designed as part of an interconnecting system, shape, dimensions and tolerances shall be such that the intended use and performance of the implant is not impaired.

NOTE 1 Where an implant comprises two or more components, the design should be such that potential wear as well as electrolytic and corrosive effects are taken into account [compare with items 5 a), c), h), k) and l) of ISO 14630:2008].

b) Where appropriate, the dimensions of the implants shall be consistent with the anatomical features of the population for whom they are intended.

NOTE 2 The design of the implants should take into account anatomical structures, types of tissue defect and bone healing/fusion rates. The final design can be a compromise that satisfies such diverse requirements.

c) The designer of the implant shall consider the required operative techniques and the appropriate care and handling of the implant to reduce the risk of use error while not impairing the intended use and performance of the implant.

NOTE 3 Annex B contains an informative list of standard implant designs found acceptable through proven use for given applications.

6 Materials

The requirements of Clause 6 of ISO 14630:2008 apply.

NOTE In Annex C, an informative list of standards is provided for materials found acceptable for different types of implant through proven clinical use.

7 Design evaluation

7.1 General

Implants shall be evaluated in accordance with ISO 14630:2008, Clause 7, together with the following particular requirements for preclinical evaluation.

NOTE Annex D provides a list of standards that can be used to assess compliance with requirements stated above for different types of implant.

7.2 Pre-clinical evaluation

The requirements of 7.2 of ISO 14630:2008 apply, together with the following particular requirements.

a) *In vitro* handling tests shall be carried out to verify the intended interaction between the implant and the instrumentation and, if appropriate, between interconnecting implants.

In instances when implantation and, where appropriate, removal cannot be evaluated by direct comparison with existing devices, cadaveric evaluation should be performed where possible.

b) If static and/or dynamic loading tests are relevant for the evaluation of the implant, either accepted test standards, when available, or customized test models taking into account the characteristics of the implant shall be applied. Because of the wide variance of implants and their features, testing standards might not exist or may be modified as needed.

c) When properly validated, biophysical or modelling research may be used to demonstrate that the intended performance of the implant is achieved.

NOTE 1 The extent of preclinical evaluation takes account of existing data in relation to similar implants or design features.

NOTE 2 Test methods can be related to different levels of testing: a) basic technical testing of implants or implant sections for characterization of the device (e.g. tensile, bending, torsion); b) testing of mounted components in relation to anticipated loading conditions; c) testing of assemblies of parts under biomechanical conditions (bone can be replaced by suitable artificial material); d) testing under static conditions or dynamic conditions (cyclic fatigue).

NOTE 3 Tests can be set up to evaluate features of specific implants or assemblies in relation to specific loading conditions and/or environmental conditions.

7.3 Clinical evaluation

The requirements of 7.3 of ISO 14630:2008 apply.

7.4 Post-market surveillance

The requirements of 7.4 of ISO 14630:2008 apply.

8 Manufacturing

The requirements of Clause 8 of ISO 14630:2008 apply.

9 Sterilization

The requirements of Clause 9 of ISO 14630:2008 apply.

10 Packaging

The requirements of Clause 10 of ISO 14630:2008 apply.

11 Information supplied by manufacturer

11.1 General

The requirements of 11.1 of ISO 14630:2008 apply.

11.2 Labelling

The requirements of 11.2 of ISO 14630:2008 apply.

11.3 Instructions for use

The requirements of 11.3 of ISO 14630:2008 apply, together with the following particular requirements. The information supplied by the manufacturer shall include the following details when relevant:

a) any constraints concerning modifications to the implant after supply, e.g. size, shape, surface condition;

b) the date of issue or the latest revision of the instructions for use.

11.4 Restrictions on combinations

The requirements of 11.4 of ISO 14630:2008 apply.

11.5 Marking on implant

The requirements of 11.5 of ISO 14630:2008, apply together with the following particular requirement.

The marking on an implant shall be made and placed in such a way that it does not affect its intended performance.

11.6 Marking for special purposes

The requirements of 11.6 of ISO 14630:2008 apply.