INTERNATIONAL STANDARD

ISO 14602

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

Implants chirurgicaux non actifs — Implants pour ostéosynthèse — Exigences particulières

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.

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.

International Standard ISO 14602 was prepared by the European Committee for Standardization (CEN) in collaboration with ISO Technical Committee TC 150, *Implants for surgery*, SC 5, *Osteosynthesis*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this standard, read ".. this European Standard ..." to mean "... this International Standard ...".

Annexes A, B and C of this International Standard are for information only.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

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Foreword

The text of EN ISO 14602:1998 has been prepared by Technical Committee CEN/TC 285 "Non- active surgical implants", the secretariat of which is held by NNI, in collaboration with ISO/TC 150 "Implants for surgery".

This European Standard has been prepared under a mandate given to CEN by the Commission of the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

There are three levels of European Standards concerned with non-active surgical implants. These are as follows, 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.

This standard is a level 2 standard and contains requirements that apply to all non-active surgical implants in the family of osteosynthesis implants.

The level 1 standard contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards.
The level 1 standard has been published as EN ISO 14630:1997.

Level 3 Standards apply to specific types of implants within a family such as knee and hip joints. To address all requirements, it is necessary to start with a standard of lowest available level.

References can also be found in the Annexes of this standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 1998 and conflicting national standards shall be withdrawn at the latest by September 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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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;

f) action on bone and adjacent structures, for example:
- stabilization;
- restriction or control of movement;
- 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.

4.2 Typical clinical applications

In describing and documenting the intended performance of the implants, 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 Conditions of use

Physiological or anatomical variables that may 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 devices;
j) activity level of the patient.

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

5 Design attributes

The requirements of clause 5 of EN ISO 14630:1997 apply, together with the following particular requirements.

5.1 Where osteosynthesis 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.

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

NOTE 1: Where an implant comprises two or more components, the design should be such that potential wear, electrolytic and corrosive effects are taken into account [compare with clause 5a), c), e), i) and j) of EN ISO 14630:1997].

NOTE 2: The design of the implants should take into account anatomical structures, types of tissue defects, operative techniques, bone healing, fusion rates, and methods of post operative treatment. The final design may be a compromise to satisfy such diverse requirements.

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

6 Materials

The requirements of clause 6 of EN ISO 14630:1997 apply.

NOTE: In Annex B an informative list of standards is provided for materials found acceptable for osteosynthesis through proven clinical use.

7 Design evaluation

7.1 General

Implants shall be evaluated in accordance with clause 7 of EN ISO 14630:1997, together with the following particular requirements for preclinical evaluation.

NOTE: In Annex C (informative) standards are listed that can be used for assessment of compliance with requirements stated above for different types of implants.

7.2 Preclinical evaluation

7.2.1 *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.

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

7.2.2 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,