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

Reference number
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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.

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.

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*.

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;