INTERNATIONAL STANDARD

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Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences spécifiques relatives aux implants de remplacement de l'articulation de la hanche

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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 21535 was prepared by The European Committee for Standardization (CEN) (as EN 12563:1998) and was adopted, under a special “fast-track procedure”, by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*, in parallel with its approval by the ISO member bodies.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 285 "Non-active surgical implants", the secretariat of which is held by NNI.

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of an identical text or by endorsement, at the latest by June 1999, and conflicting national standards shall be withdrawn at the latest by June 1999.

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

There are three levels of European Standards dealing with non-active surgical implants. These are as follows, with level 1 being the highest:

- level 1: General requirements for non-active surgical implants; EN ISO 14630:1997
- level 2: Particular requirements for families of non-active surgical implants (for example for joint replacement implants - EN 12010)
- level 3: Specific requirements for types of non-active surgical implants.

This standard is a level 3 standard and contains requirements applying specifically to hip joint replacements.

The level 1 standard EN ISO 14630:1997 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 2 standards apply to more restricted sets or families of implants such as those designed for use in osteosynthesis, cardiovascular surgery or joint replacement.

To address all requirements, it is necessary to start with a standard of the lowest available level.

References to other European or international standards can also be found in Annex B.

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 EN ISO 14630:1997 and EN 12010:1997, provides a method to demonstrate compliance with the relevant essential requirements, 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 hip joint replacement implants.

1 Scope

This European Standard provides specific requirements for hip joint replacement implants.

With regard to safety, the standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and methods of test.

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.

ISO 7206-1:1995	Implants for surgery - Partial and total hip joint prostheses - Part 1: Classification, designation of dimensions and requirements.
ISO 7206-2:1996	Implants for surgery - Partial and total hip joint prostheses - Part 2: Bearing surfaces made of metallic and plastics materials
ISO 7206-4	Implants for surgery - Partial and total hip joint prostheses - Part 4: Determination of endurance properties of stemmed femoral components with application of torsion
ISO 7206-6:1992	Implants for surgery - Partial and total hip joint prostheses - Part 6: Determination of endurance properties of head and neck region of stemmed femoral components.
ISO 7206-8	Implants for surgery - Partial and total hip joint prostheses - Part 8: Endurance performance of stemmed femoral components with the application of torsion.
ISO 7206-9	Implants for surgery - Partial and total hip joint prostheses - Part 9: Determination of resistance to torque of head fixation of modular stemmed femoral components.
EN 12010:1998	Non-active surgical implants - Joint replacement implants - Particular requirements.