INTERNATIONAL STANDARD

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

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

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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 21536 was prepared by The European Committee for Standardization (CEN) (as EN 12564:1998) 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of an identical text or by endorsement, at the latest by June 1999, and conflicting national standards shall be withdrawn at the latest by June 1999.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;

- level 2: Particular requirements for families of non-active surgical implants (for example 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 knee joint replacements.

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 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 and EN 12010, 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 knee joint replacement implants.

1 Scope

This European Standard provides specific requirements for knee 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 7207-1	Implants for surgery - Components for partial and total knee joint prostheses - Part 1: Classification, definitions and designation of dimensions
EN 12010:1998	Non-active surgical implants - Joint replacement implants - Particular requirements

3 Definitions

For the purposes of this standard the definitions of EN 12010 and ISO 7207-1 apply, together with the following:

3.1 femoral component: Component of a total knee joint replacement intended to be secured to the femur to replace its articulating surfaces. These implants may be manufactured as one component or a set of components to be assembled by the user.

3.2 tibial component: Component of a total knee joint replacement intended to be secured to the tibia to replace its articulating surfaces. These implants may be manufactured as one component or a set of components to be assembled by the user.

3.3 tibial tray: Sub-component used to support and secure the articulating sub-component of a tibial component of a unicompartmental or total knee joint prosthesis.

3.4 patella component: Component of a total or partial knee joint replacement which is used to replace the articulating surface of the patella.

3.5 patella tray: Sub-component used to support and secure the articulating sub-component of a patella component.

3.6 unicompartmental knee joint prosthesis[1]: Knee joint prosthesis designed to replace the femoral and tibial bearing surfaces in one compartment of the knee.

3.7 meniscal component: Component of certain total knee joint prostheses which is intended to transmit tibio-femoral load and which moves relative to both the tibial and femoral components.

4 Intended performance

The requirements of clause 4 of EN 12010:1998 shall apply together with the following:

Range of angular movment
The intended range of movement between the skeletal parts referred to in 4.1(a) of EN 12010:1998 shall be determined. Annex A indicates a suitable method. This measurement shall be limited to fully constrained knee joints.

5 Design attributes

The requirements of clause 5 of EN 12010:1998 shall apply together with the following:

5.1 Thickness of UHMWPE in tibial components and meniscal components

NOTE: In this standard ultra high molecular weight polyethylene is referred to as UHMWPE.

For tibial components and meniscal components made of UHMWPE the UHMWPE component or sub-component shall have the following minimum thickness in the load bearing area:

[1] This definition supersedes the one presented in ISO 7207-1

a) 6mm for components having a tibial tray of metal or other material
b) 8mm for components without tibial tray

5.2 Finish of non-articulating regions of metallic knee joint components
The surface of the non-articulating regions of metallic knee joint components intended to be exposed to soft tissue shall be smooth and non abrasive.

NOTE: A roughness value Ra of 1,5µm has been found to be satisfactory.

6 Materials

The requirements of clause 6 of EN 12010:1998 shall apply together with the following:

Titanium and titanium alloys
Unalloyed titanium and titanium alloys shall not be used as the articulating surfaces of knee joint replacement components unless an appropriate surface treatment is undertaken and demonstrated to be suitable in clinical use.

7 Design evaluation

7.1 General
The requirements of clause 7 of EN 12010:1998 shall apply together with the following:

7.1.1 Number of tests
One or more of the tests in clause 7.2 may not be required:

a) for every component within a range of components (product family)
b) where the required test results already exist for the same or a similar component.

In these cases a justification for omitting any given test on any given component shall be documented.

7.2 Preclinical evaluation

7.2.1 Endurance of tibial trays of knee joint components - cemented and non-cemented
The tibial trays of knee joint components intended for use with or without bone cement shall be tested to determine their endurance under cyclic load.

NOTE: ISO have been approached to prepare a standard which will enable the specification of performance requirements based on the test method given in ISO/CD14879-1

7.2.2 Wear testing of total knee joint replacements.
The wear characteristics of total knee joint replacements comprising a metallic or ceramic femoral component articulating on a tibial component shall be tested in accordance with a controlled, validated and documented procedure.

NOTE: ISO has been approached to prepare a standard which will enable the specification of performance requirements based on the test method given in ISO/CD14243 parts 1 and 2.