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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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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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of an identical text or by endorsement, at the latest by June 1999, and conflicting national standards shall be withdrawn at the latest by June 1999.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

3 Definitions

For the purposes of this standard the definitions in EN 12010 and ISO 7206-1 apply, together with the following.

3.1 hip joint replacement (hip arthroplasty): Implant used to replace one or both of the articulating surfaces of the hip joint.

3.2 total hip joint replacement (total hip arthroplasty): Implant comprising a femoral component and an acetabular component whether monobloc or modular intended to replace both of the articulating surfaces of the hip joints.

3.3 partial hip joint replacement (hip hemiarthroplasty): Implant comprising a femoral component whether monobloc or modular intended to replace the femoral articulating surface of the hip joint.

NOTE: partial hip joint replacement implants incorporate either a bipolar or a unipolar head.

3.4 bipolar head: Component of a hip joint replacement with a concave (inner) surface intended to articulate with the spherical head of the femoral component and a convex (outer) spherical surface intended to articulate with the biological acetabulum.

3.5 unipolar head: Head of a femoral component intended to articulate with the biological acetabulum.

3.6 femoral component: Part of a total or partial hip joint replacement which is intended to be attached to the femur.

3.7 modular component: Femoral or acetabular component which is assembled by the user from a number of sub-components .

3.8 monobloc component: Femoral or acetabular component which is supplied as a single unit.

3.9 acetabular component: Implant of monobloc or modular construction intended to be fixed to the prepared biological acetabulum.

4 Intended performance

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

Range of angular movement
When measured in accordance with the method given in Annex A the range of movement between the femoral and acetabular components shall be at least 80^{o} in flexion/extension, at least 60^{o} in abduction/adduction and at least 90^{o} in internal/external rotation.

5 Design attributes

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

5.1 Radio-opacity of acetabular components made of radiolucent materials alone
Monobloc acetabular components made of radio translucent material alone shall comply with the requirements of clause 4 of ISO 7206-1:1995.

5.2 Tolerances and dimensions
Tolerances and dimensions shall be in accordance with the following:

5.2.1 Tolerances and dimensions of taper connections.

NOTE 1: Particular attention should be paid to at least the following: diameter, taper angle, straightness, roundness, micro and macro surface texture.

NOTE 2: In the design of modular femoral components the risk of generation of wear particles at modular component interfaces should be taken into account.

5.2.2 Tolerances on diameters of articulating surfaces

NOTE 1: In this standard ultra high molecular weight polyethylene is designated UHMWPE.

The tolerances on the diameters of the articulating surfaces of metallic or ceramic femoral components intended to be used with UHMWPE acetabular components and the tolerance on the diameters of the articulating surface of UHMWPE acetabular components shall be in accordance with ISO 7206-2:1996 clauses 4.1.3 and 4.2.3 respectively.

NOTE 2: The requirements for sphericity and surface finish for UHMWPE on metal and on ceramic are prescribed in ISO 7206-2.

5.2.3 Requirements for metal-on-metal and ceramic-on-ceramic articulating surfaces

NOTE: there is not yet sufficient information on the surface roughness, tolerance on diameters and clearances to allow specification of these parameters.

5.3 Thickness of UHMWPE in acetabular components and bipolar heads

5.3.1 Acetabular components
For acetabular components of outside diameter 42mm or more the UHMWPE component shall have the following minimum thickness.

a) 5mm for components with a metal or other backing
b) 6mm for components without backing

5.3.2 Bipolar heads
For bipolar heads of outside diameter 44 mm or more the minimum thickness of UHMWPE liners shall be 5mm.

NOTE: Where the skeletal size of the population for which these implants are intended requires an acetabular component of less than 42 mm diameter or a bipolar component of less than 44mm diameter it may be necessary to use thickness values less than those specified.