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Non-active surgical implants — Joint replacement implants — Particular requirements

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences particulières

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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 21534 was prepared by The European Committee for Standardization (CEN) (as EN 12010:1998) 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 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;
- 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 joint replacement 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 recommended to start with a standard of the 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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 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 EN ISO 14630:1997 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 joint replacement implants, ligaments and components for implants such as bone cement, screws, wire, meshes, wedges, augmentation blocks etc, and implants used in repair of articular surfaces.

NOTE: For certain products, specific requirements may apply. These requirements are specified in the level 3 standards.

1 Scope

This European Standard specifies particular requirements for total and partial joint replacement implants, artificial ligaments and bone cement, hereafter referred to as implants. For the purposes of this standard, artificial ligaments and their associated fixing devices are included in the term implant, hereinafter referred to as implants.

It specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information to be supplied by the manufacturer.

Some tests required to demonstrate compliance with this standard are contained in or referenced in level 3 standards.

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 (ISO 14630:1997)
ISO 7206-2	Implants for surgery - Partial and total hip joint prostheses - Part 2: Articulating surfaces made of metallic, ceramic and plastics materials.

3 Definitions

For the purposes of this European Standard the definitions in EN ISO 14630:1997 apply together with the following.

3.1 joint replacement implant: Implantable device, including ancillary implanted components and materials, intended to provide function similar to a natural joint and which is connected to the corresponding bones.

3.2 artificial ligament: Device, including its necessary fixing devices, intended to augment or replace the natural ligament.

NOTE: The artificial ligament provides short-term or long-term augmentation.

4 Intended performance

For the purpose of this European Standard, the intended performance of implants shall conform to clause 4 of EN ISO 14630:1997, and shall address additionally the following matters:

a) intended minimum and maximum relative angular movement between the skeletal parts to which the joint replacement implant is attached;
b) expected maximum load actions (forces and moments) to be transmitted to the bony parts to which the joint replacement implant is attached;
c) dynamic response of the body to the shape/stiffness of the implants;
d) expected wear of articulating surfaces or ligaments;
e) suitability of the dimensions and shape of the implant for the population for which it is intended;
f) strength of the adhesion and durability of surface coatings or surface treatments.

NOTE 1: The clinical indications and contra-indications for the use of a particular implant are complex and should be reviewed by the surgeons when they are selecting implants to be used for particular patients, relying upon their own personal judgment and experience.

NOTE 2: The lifetime of an implant depends on the interaction of various factors:
some are the responsibility of the manufacturer, some, such as the implantation technique, are the responsibility of the surgeon in conducting the operation, and some relate to the patient, for example, the biological and physiological response to the implant,the medical condition of the patient, the conduct of the patient in respect of increasing body weight, carriage of heavy loads and adopting a high level of physical activity.

5 Design Attributes

5.1 General

The development of the design attributes to meet the performance intended by the manufacturer shall conform to the requirements of clause 5 of EN ISO 14630:1997, and in addition, account shall be taken of the following points:

a) the strength of adhesion and durability of surface coatings and surface treatments;
b) the wear of the articulating and other surfaces;
c) stability of the implant while allowing prescribed minimum and maximum relative movements between the skeletal parts;
d) avoidance of cutting or abrading tissue during function other than insertion or removal;
e) the creep resistance and rupture characteristics, particularly as they relate to ligaments.

NOTE 1: Methods of assessment of the wear of articulating and other surfaces and allowable values will be prescribed in level 3 standards at present in preparation.

NOTE 2: More specific requirements may appear in level 3 standards, such as for hip joints.

5.2 Surface finish of metallic or ceramic implants articulating on UHMWPE

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

The articulating surfaces of metallic or ceramic components of total joint replacements intended to articulate on UHMWPE shall have a surface roughness value R_a no greater that 0,1 µm (when measured according to 7.2.1).

5.3 Surface finish of metallic or ceramic partial implants

The articulating surface of metallic or ceramic components of partial joint replacements shall have a surface roughness value R_a no greater than 0,5 µm (when measured according to 7.2.1).

5.4 Surfaces of convex spherically conforming metallic or ceramic implants articulating on UHMWPE

The articulating surface of convex spherically conforming metallic or ceramic components of total joint replacements intended to articulate on UHMWPE shall have a surface roughness R_a no greater than 0,05 µm and a radial separation value for sphericity no greater than 10 µm (when measured according to 7.2.1 and 7.2.2).

5.5 Surfaces of spherically conforming metallic or ceramic partial implants

The articulating surface of spherically conforming metallic or ceramic components of partial joint replacements shall have a surface roughness value R_a no greater than 0,5 µm and a radial separation value for sphericity no greater than 100 µm (when measured according to 7.2.1 and 7.2.2).

5.6 Surfaces of concave spherically conforming UHMWPE components

The articulating surface of concave spherically conforming UHMWPE components of total joint replacements shall have a surface roughness R_a no greater than 2 µm and a radial separation value for sphericity no greater than
200 µm (when measured according to 7.2.1 and 7.2.2).

6 Materials

6.1 General

The requirements of clause 6 of EN ISO 14630:1997 apply together with the particular requirement of 6.2 of this standard.

NOTE 1: Annex A of this standard gives lists of materials found acceptable through proven use for the manufacture of implants or for use in association with implants.

NOTE 2: Annex B gives a list of pairs of materials found acceptable or not acceptable through proven use for articulating surfaces of implants.

NOTE 3: Where 6.1 of EN ISO 14630:1997 states that the acceptability of materials may be demonstrated by selection from the materials found suitable by proven clinical use in similar applications, for the purposes of this standard, proven use should be demonstrated by records of implantation of at least 500 of the implants and recorded satisfactory clinical use over a period of not less than five years.

6.2 Dissimilar metals or alloys

For applications in which two dissimilar metals or alloys or two metals in different metallurgical states are in contact where articulation is not intended, combinations used shall not produce unacceptable galvanic effects.

NOTE: Annex C gives lists of acceptable and unacceptable metallic combinations for use in non articulating bearing surfaces of implants.

7 Design evaluation

7.1 General

Joint replacement implants shall be evaluated to demonstrate that the intended performance is achieved. This evaluation shall be in accordance with clause 7 of EN ISO 14630:1997 together with the particular requirements of 7.2 and with the guidance of the note in 7.3 of this standard.

7.2 Preclinical evaluation

Preclinical evaluation shall consider:

a) mechanical loads and the related movements to which the implants may be subjected when functioning as prescribed by EN ISO 14630:1997;
b) fatigue testing of highly stressed parts (see level 3 standards, in preparation);
c) wear testing of articulating bearing surfaces and ligaments (see level 3 standards, in preparation);
d) the suitability of the dimensions and shape of the implant for the intended population (see Note);

NOTE: The suitability of the dimensions and shape of the implant for the intended population may be demonstrated by cadaver implantation, the use of imaging systems such as x-rays, CAT scan or magnetic resonance imaging, or by reference to corresponding implants of proven clinical use (see Note 3 of 6.1).

e) adhesion and durability of coatings if present.

7.2.1 Surface roughness measurement

Surface roughness shall be measured according to the method given in ISO 7206-2.

7.2.2 Sphericity measurement

Radial separation values for sphericity shall be measured according to the methods given in ISO 7206-2:1996.

7.3 Clinical evaluation

NOTE: The extent and nature of any clinical investigation should be governed by the novelty of the design and the novelty of the materials used in the implant.

8 Manufacture and inspection

The requirements of clause 8 of EN ISO 14630:1997 apply together with the particular requirements of 8.1, 8.2, 8.3 of this standard.

8.1 Metal surfaces

The surfaces of metallic components when examined with normal or corrected vision shall be free of imperfections which would impair the function of the implant and shall additionally be free from embedded or deposited finishing materials or other contaminants. To achieve this, components shall be cleaned, degreased, rinsed and dried. All polishing operations shall be performed using an iron free medium.

NOTE: Imperfections which would impair function include scale, tool marks, nicks, scratches, cracks, cavities, burrs and other defects.

8.2 Plastics surfaces

The articulating surfaces of implants made of plastics materials shall be free from particulate contamination when examined with normal or corrected vision.

Bearing surfaces shall not be prepared using a non removable abrasive or polishing compound.

Components shall be cleaned, rinsed and dried.

8.3 Ceramic surfaces

The articulating surfaces of ceramic components when examined with normal or corrected vision shall be free of imperfections which would impair the function of the implant.

NOTE: Such imperfections include particulate contamination, chemical discolouration spots or larger areas, tool marks, nicks, chips, cavities and cracks.

9 Sterilization

The requirements of clause 9 of EN ISO 14630:1997 apply together with the following.

9.1 Implants containing UHMWPE

Implants containing UHMWPE and sterilised by ionizing radiation, shall not be supplied for clinical use if an accumulated dose of radiation higher than 40 kGy has been received.

If other methods of sterilization are used, the effects of the sterilization process shall not impair the intended performance of the implant (see clause 4 and 7.2 b), c) and e)).

10 Packaging

The requirements of clause 10 of EN ISO 14630:1997 apply.

11 Information supplied by the manufacturer

The requirements of clause 11 of EN ISO 14630:1997 apply together with the following.

11.1 Labelling of implants for use on one side of the body only

Labelling for implants designed for use on one side of the body only shall bear the symbol 'LEFT' for implants to be used on the left side or 'RIGHT' for implants to be used on the right side.

11.2 Instructions for orientation of implants

The instruction leaflet and/or manual shall where necessary indicate the required orientation of the implant relative to the body part. It shall also refer to the relevant marking(s) on the implant or the label (see 11.1 and 11.3).

11.3 Markings for orientation of the implants

The implant shall be marked "ANT" on the front and/or "POST" on the back where this is necessary for interpretation of the instructions relating to the required orientation of the implant to the body given in the instruction leaflet and/or manual (see 11.2).

11.4 Placing of markings on implants

Markings shall be placed on the implant where they will not impair the intended function (see 7.2 b), c) and e)).

11.5 Restrictions on use

If an implant is intended for a restricted population this shall be stated in the instructions for use or in the manual.