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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

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 21534 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 21534:2002), which has been technically revised.

Introduction

There are three levels of International Standard 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 and instrumentation used in association with implants;

— level 2: particular requirements for families of non-active surgical implants;

— level 3: specific requirements for types of non-active surgical implant.

This International 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 ISO 14630.

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 that a standard of the lowest available level be consulted first.

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

1 Scope

This International 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 International Standard, artificial ligaments and their associated fixing devices are included in the term "implant".

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 conformance to this International Standard are contained in or referenced in level 3 standards.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 7206-4, *Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties of stemmed femoral components*

ISO 7206-8, *Implants for surgery — Partial and total hip joint prostheses — Part 8: Methods of determining endurance performance of stemmed femoral components*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14242-1, *Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for tests*

ISO 14242-2, *Implants for surgery — Wear of total hip joint prostheses — Part 2: Methods of measurement*

ISO 14243-2, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

ISO 14630:—[1)], *Non-active surgical implants — General requirements*

ISO 14879-1, *Implants for surgery — Total knee-joint prostheses — Part 1: Determination of endurance properties of knee tibial trays*

1) To be published. (Revision of ISO 14630:2005)

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 14630 together with the following apply.

3.1
artificial ligament
device, including its necessary fixing devices, intended to augment or replace the natural ligament

3.2
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

3.3
mean centre
position within the spherical head for which the average of the distances to a set of points uniformly distributed over the surface of the sphere is minimum

3.4
radial separation value
difference between the mean radius of the spherical surface and the radius to the point on the spherical surface furthest from the mean centre

NOTE The units of the radial separation value are in micrometres.

4 Intended performance

For the purpose of this International Standard, the intended performance of implants shall conform to Clause 4 of ISO 14630:—, and the design input shall additionally address 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;

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 ISO 14630:—, 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 are prescribed in, e.g. ISO 14242-2 and ISO 14243-1, -2 and -3.

NOTE 2 More specific requirements, such as that for hip joint replacements, might appear in other standards.

5.2 Surface finish of metallic or ceramic implants articulating on ultra-high-molecular-weight polyethylene (UHMWPE)

The articulating surfaces of metallic or ceramic components of total joint replacements intended to articulate on UHMWPE shall have a surface roughness value Ra no greater than 0,1 µm (when measured in accordance with 7.2.2).

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 Ra no greater than 0,5 µm (when measured in accordance with 7.2.2).

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 Ra no greater than 0,05 µm and a radial separation value for sphericity no greater than 10 µm (when measured in accordance with 7.2.2 and 7.2.3).

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 Ra no greater than 0,5 µm and a radial separation value for sphericity no greater than 100 µm (when measured in accordance with 7.2.2 and 7.2.3).

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 Ra no greater than 2 µm and a radial separation value for sphericity no greater than 200 µm (when measured in accordance with 7.2.2 and 7.2.3).

6 Materials

6.1 General

The requirements of Clause 6 of ISO 14630:— apply together with the particular requirement of 6.2 of the present document.

NOTE 1 Annex A gives a list of International Standards for materials found acceptable through proven use for the manufacture of implants or for use in association with implants.

NOTE 2 Annex B gives lists of International Standards for pairs of materials found acceptable or not acceptable through proven use for articulating surfaces of implants.

NOTE 3 Where 6.1 of ISO 14630:— 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 International 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 the same metals or alloys 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 International Standards for 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 in order to demonstrate that the intended performance is achieved. This evaluation shall be in accordance with Clause 7 of ISO 14630:— together with the particular requirements of 7.2 to 7.4. This evaluation shall be undertaken using components fully representative of the final condition ready for implantation.

7.2 Preclinical evaluation

7.2.1 General

Preclinical evaluation shall consider:

a) biocompatibility of any materials not previously used;

b) mechanical loads and the related movements to which the implants can be subjected when functioning as prescribed by ISO 14630;

c) fatigue testing of highly stressed parts in accordance with ISO 7206-4, ISO 7206-8 and ISO 14879-1;

d) wear testing of articulating bearing surfaces in accordance with e.g. ISO 14242-1, ISO 14242-2 and ISO 14243-1;

e) the suitability of the dimensions and shape of the implant for the intended population;

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

f) adhesion and durability of coatings if present.

7.2.2 Surface roughness measurement

Surface roughness shall be measured according to one of the methods given in ISO 4287.

7.2.3 Sphericity measurement

Radial separation values for sphericity shall be measured according to a method demonstrated to be accurate and repeatable.

NOTE A suitable method is described in the National Physical Laboratory (NPL) [30].

7.3 Clinical investigation

The clinical investigation shall be conducted according to the general requirements of ISO 14155-1.

7.4 Post market surveillance

The post-market performance of joint replacement implants shall be determined.

NOTE Suitable methodologies include survival analysis (with revision as the endpoint) and clinical assessment. Where it is available, relevant information from joint replacement registries are taken into account.

8 Manufacture and inspection

8.1 General

The requirements of Clause 8 of ISO 14630:— apply together with the particular requirements of 8.2 to 8.4.

8.2 Metal surfaces

All polishing operations on metallic components shall be performed using an iron-free material. Clean, degrease, rinse and dry all components and examine the articulating surfaces using normal or corrected vision. The surfaces shall be free of any imperfections that would impair their function and also be free from deposited finishing materials or other contaminants.

NOTE Examples of imperfections which might impair function include scale, tool marks, nicks, scratches, cracks, cavities, burrs and other defects.

8.3 Plastic surfaces

Articulating surfaces of plastic components shall not be prepared using non-removable abrasive or polishing compounds. Clean, degrease (if necessary), rinse and dry the components and examine them using normal or corrected vision. The surfaces shall be free from particulate contamination.

8.4 Ceramic surfaces

Ceramic components shall be cleaned, degreased, rinsed, dried and examined using normal or corrected vision. The articulating surfaces shall be free of any imperfections that would impair their function.

NOTE Examples of imperfections which might impair function include particulate contamination, chemical discolouration (spots or larger areas), tool marks, nicks, chips, cavities and cracks.