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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

FDIS stage

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: + 41 22 749 01 11
E-mail: copyright@iso.org
Website: www.iso.org

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 21536:2007), which has been technically revised. It also incorporates the Amendment ISO 21536:2007/Amd 1:2014.

~~This third edition is a major revision with many added requirements.~~ The main changes are as follows:

~~— 1 Scope~~

— The scope ~~is~~has been expanded to specify more precisely the knee joint replacement types which are the subject of this document. Also, the scope now clarifies the requirements for implants which have been legally marketed and for which there is a history of sufficient and safe clinical use.

~~— 2 Normative references~~

— The number of normative references has been expanded, including the addition of several ASTM standards.

~~— 3 Terms and definitions~~

— Several new definitions ~~are~~have been added, including: ~~a)~~ maximum claimed flexion, ~~b)~~ mobile-bearing component, ~~c)~~ mobile-bearing knee joint prosthesis, ~~d)~~ partial knee joint prosthesis and partial knee joint replacement, ~~e)~~ posterior stabilized tibial insert, ~~f)~~ reference implant, ~~g)~~ sufficient and safe clinical use, ~~h)~~ tibial insert, ~~i)~~ total knee joint prosthesis and total knee joint replacement,

~~j)~~ultra-high molecular weight polyethylene and UHMWPE, uni-compartmental knee joint replacement and UKR, ~~k) UHMWPE~~ and ~~l)~~ worst case.

~~5 Design attributes~~

The design attributes to be taken into account ~~are~~have been specified in Clause 5~~.~~

— ~~.~~The requirements for the thickness of various knee joint components made from plastic, metal and ceramic have been expanded.

~~7.2.1 General~~

— Several new general requirements ~~are~~have been added in 7.2.1~~. These new requirements a)~~, which specify

a) the circumstances when a test can be omitted, ~~b) specify that~~

b) the testing of the worst case ~~shall be tested and c) specify~~ ~~.~~

~~a)~~c) the processes to be followed when no performance requirement has been specified, and

~~b)~~d) ~~d) specify~~ the processes to be followed when a performance requirement has been specified but has not been met.

~~7.2.2 Pre-clinical evaluation~~

— The number of pre-clinical evaluations (bench tests) to be performed ~~is~~has been greatly increased in 7.2.2~~.~~ For some of the tests, a performance requirement ~~is~~has been specified. For some of the tests no performance requirement ~~is~~has been specified and, in these cases, a new requirement has been added, namely the requirement to demonstrate that the performance of the implant under evaluation is the same or better than that of a reference implant. If no reference implant exists, a sequence of alternative options ~~is~~has been specified. These alternative options are also available in the case where there is a performance requirement, which is not met by the implant being tested.

~~7.3 Clinical investigation~~

— A new clinical investigation subclause ~~is~~has been added in 7.3, with several requirements which specify the circumstances in which a clinical investigation can be required.

~~7.4 Post-market surveillance~~

A new post-market surveillance subclause ~~is~~has been added in 7.4~~.~~, which references the requirements in ISO 21534:2007, 7~~.4.~~

— ~~11~~.4 ~~Marking.~~

— Several new marking requirements ~~are~~have been specified in 11.4~~.~~

~~11.6 Electronic instructions for use~~

— A note ~~is~~has been added in 11.6 which states that in some jurisdictions there is the option to provide the instructions for use in electronic instead of paper format.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Field Code Changed

Introduction

There are three levels of 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 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 document is a level 3 standard and contains requirements applying specifically to knee joint replacements.

The level 1 standard, ISO 14630, 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. For joint replacement implants, the level 2 standard is ISO 21534.

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 — Specific requirements for knee-joint replacement implants

1 Scope

This document specifies requirements for knee-joint replacement implants. Regarding safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer and methods of test.

This document applies to both total and partial knee joint replacement implants. It applies to these replacements both with and without the replacement of the patella-femoral joint. It applies to components made of metallic and non-metallic materials.

This document applies to a wide variety of knee replacement implants, but for some specific knee replacement implant types, some considerations, not specifically covered in this document, can be applicable. Further details are given in 7.2.1.2~~7.2.1.2.~~.

The requirements which are specified in this document are not intended to require the re-design or re-testing of implants which have been legally marketed and for which there is a history of sufficient and safe clinical use. For such implants, compliance with this document can be demonstrated by providing evidence of the implant's sufficient and safe clinical use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5834-1, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form*

ISO 7207-1:2007, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*

ISO 7207-2, *Implants for surgery — Components for partial and total knee joint prostheses — Part 2: Articulating surfaces made of metal, ceramic and plastics materials*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14243-1, *Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test*

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

ISO 14243-3, *Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test*

ISO 14243-5, *Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint*

ISO 14630, *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*

ISO 21534:2007, *Non-active surgical implants — Joint replacement implants — Particular requirements*

ASTM F648, *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*

ASTM F1223, *Standard Test Method for Determination of Total Knee Replacement Constraint*

ASTM F2722, *Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops*

ASTM F2723, *Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation*

ASTM F2724, *Standard Test Method for Evaluating Mobile Bearing Knee Dislocation*

ASTM F2777, *Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion*

ASTM F3210, *Standard Test Method for Fatigue Testing of Total Knee Femoral Components under Closing Conditions*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630, ISO 21534 and ISO 7207-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available ~~from~~at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
femoral component
component of a *total knee joint prosthesis* [3.14~~(3.14),~~], patella-femoral knee joint prosthesis, or *uni-compartmental knee joint prosthesis* [3.16~~(3.16)~~] intended to be secured to the femur to replace its articulating surface(s)

~~[SOURCE: ISO 7207-1:2007, 3.2.3, modified – text has been added and NOTE has been deleted]~~

3.2
maximum claimed flexion
highest amount of flexion the *total knee joint prosthesis* [3.14~~(3.14)~~] or *uni-compartmental knee joint prosthesis* [3.16~~(3.16)~~] can achieve as claimed by the manufacturer based on the requirements defined in 7.2.2.11~~7.2.2.11~~

Note 1 to entry: A higher amount of flexion than the maximum claimed flexion can exist based on computer aided design (CAD) or implant shape considerations.

3.3
mobile-bearing component
component of a total or uni-compartmental *mobile-bearing knee joint prosthesis* [3.4~~(3.4)~~] which articulates with both the *femoral component* [3.1~~(3.1)~~] and the *tibial tray* [3.13~~(3.13)~~]

~~[SOURCE: ISO 7207-1:2007, 3.2.10, modified – NOTE has been deleted]~~

Note 1 to entry: The mobile-bearing component can be manufactured as one component or a set of components, in both cases intended to be assembled in the *mobile-bearing knee joint prosthesis* [3.4~~(3.4)~~] by the user.

Note 2 to entry: The mobile-bearing component is usually a sub-component of the *tibial component* [3.11~~(3.11),~~], supported by the *tibial tray* [3.13~~(3.13),~~].

Note 3 to entry: The mobile-bearing component can also be referred to as the meniscal component.

[SOURCE: ISO 7207-1:2007, 3.2.10, modified — Note 1 to entry has been replaced and Notes 2 and 3 to entry have been added.]

3.4
mobile-bearing knee joint prosthesis
total knee joint prosthesis (3.14) or *uni-compartmental knee joint prosthesis* (3.16) which allows relative motion between the *mobile-bearing component* (3.3) and both the *femoral component* (3.1) and the *tibial tray* (3.13)

[SOURCE: ISO 7207-1:2007, 3.1.6, modified —text— "knee joint prosthesis" has been added after "total" in the definition and NOTENote 1 to entry has been deleted.]

3.5
partial knee joint prosthesis
partial knee joint replacement

either a *uni-compartmental knee joint prosthesis* (3.16) or a set of components used to replace the femoral and tibial articulating surfaces in the medial compartment of a knee joint and also the patellar and femoral articulating surfaces in the patella-femoral compartment

Note 1 to entry: Implants which are intended to repair a cartilage focal defect(s) or to be used for a surgical procedure like mosaicplasty are not partial knee joint prostheses for the purposes of this document.

3.6
patellar component
component of a *total knee joint prosthesis* (3.14) or *partial knee joint prosthesis* (3.5) or patella-femoral knee joint prosthesis which is used to replace the articulating surface of the patella

Note 1 to entry: Patellar components can be monobloc or modular.

[SOURCE: ISO 7207-1:2007, 3.2.13, modified – text has been added and NOTE has been modified to delete reference to Figure]

3.7
patellar tray
sub-component of a modular *patellar component* (3.6) of a *total knee joint prosthesis* (3.14) used to support and secure the patellar insert

[SOURCE: ISO 7207-1:2007, 3.2.14]

3.8
posterior stabilized tibial insert
tibial insert (3.12) with a centre post protruding superiorly or some other mechanism which interfaces with the *femoral component* (3.1) to restrict anterior translation of the *femoral component* (3.1) when the knee is in flexion

Note 1 to entry: The portion of the *femoral component* (3.1) interfacing with the tibial insert (3.12) centre post is sometimes referred to as the "cam".

3.9
reference implant
legally-marketed implant which, when compared to the implant under evaluation, satisfies both of the following conditions:

a) a) it has the same intended use, similar materials and a similar design with regard to the specific dimensional or performance criteria under evaluation to address the same clinical and technical requirements, and

b) ~~b)~~ there is evidence of successful clinical use in sufficient numbers; for a sufficient period of time; and, at a minimum, without known or reasonably-known evidence of design or performance-related recalls with regard to the specific dimensional or performance criteria under evaluation

Note 1 to entry: The term “reference” is not intended to imply that the implant under evaluation and the reference implant are “equivalent” or that the reference implant is a “predicate” implant. This is because for some regulatory authorities, the terms “equivalent” and “predicate” have a meaning~~,~~ which is beyond that intended by the term “reference” as used in this document.

Note 2 to entry: A reference implant is the comparison implant for dimensional or performance parameter(s) under evaluation. Other characteristics of the reference implant shall be considered in order for the comparison to be suitable, as in some situations there can be cross-effects. Ideally, for the majority of dimensional and performance parameters, a single reference implant should be used for comparison to the implant under evaluation. However, more than one reference implant may be used for comparison purposes, with adequate scientific and clinical justification.

Note 3 to entry: Some regulatory authorities require that a reference implant is one that is legally marketed in their own country or jurisdiction. This fact can be taken into account when selecting a reference implant for the purposes of this document.

Note 4 to entry: There is no agreed upon interpretation for what constitutes “sufficient numbers” or a “sufficient period of time” in the above definition. Typically, a determination of what constitutes “sufficient numbers” and a “sufficient period of time” is demonstrated by using statistical methods and clinical judgement in the evaluation of implant performance.

Note 5 to entry: A justification for a “similar material” may include information that although the materials are not the same, the material(s) used for the implant under evaluation can be shown to perform similarly with regard to the test or its underlying clinical concern.

Note 6 to entry: Examples of design features that can be taken into consideration when evaluating whether an implant has a ‘similar design’ to the implant under evaluation include means of fixation, modularity, constraint, key dimensions and shape, processing, surface topography, surface treatment, etc. A justification for a “similar design” therefore may include information that although the designs are not the same, the design of the implant under evaluation can be shown to perform similarly with regard to the test or its underlying clinical concern.

Note 7 to entry: The manufacturer is responsible for identifying the reference implant(s) in accordance with the regulatory requirements in the jurisdictions where the implant under evaluation is to be marketed.

3.10
sufficient and safe clinical use
clinical use of a legally-marketed implant in sufficient numbers, for a sufficient period of time and, at a minimum, without known or reasonably-known evidence of design or performance-related recalls

Note 1 to entry: There is no agreed interpretation for what constitutes “sufficient numbers” or “sufficient period of time” in the above definition. Typically, these are demonstrated by using statistical methods and clinical judgement in the evaluation of implant performance.

Note 2 to entry: Some regulatory authorities require that a legally-marketed implant is one which is legally marketed in their country or jurisdiction.

Note 3 to entry: For a legally-marketed system of knee replacement implants, there can be evidence to demonstrate sufficient and safe clinical use for some parts of the system (e.g. some components and some sizes) but not for others. For those parts of the system for which there is sufficient evidence, the requirements of this document relating to design and testing shall not apply. For those parts of the system for which there is not sufficient evidence to demonstrate sufficient and safe clinical use the requirements of this document relating to design and testing shall apply.

Note 4 to entry: The manufacturer is responsible for identifying the implant with sufficient and safe clinical use in accordance with the regulatory requirements in the jurisdictions where the implant is to be marketed.