SLOVENSKI STANDARD
oSIST prEN ISO 21536:2021

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Neaktivni kirurški vsadki (implantati) - Sklepne proteze - Posebne zahteve za kolenske proteze (ISO/DIS 21536:2021)

Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO/DIS 21536:2021)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen an Implantate für den Kniegelenkersatz (ISO/DIS 21536:2021)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation du genou (ISO/DIS 21536:2021)

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

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

This third edition cancels and replaces the second edition (ISO 21536:2007), which has been technically revised.

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 standard 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 provides specific requirements for knee joint replacement implants. With regard to 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, may be applicable. Further details are given in Clause 7.2.1.1.

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

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 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 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 17853, *Wear of implant materials — Polymer and metal wear particles — Isolation and characterization*

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

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

ASTM F1672-14(2019), *Standard Specification for Resurfacing Patellar Prosthesis*

ASTM F1877, *Standard Practice for Characterization of Particles*

ASTM F2083-21, *Standard Specification for Knee Replacement Prosthesis*

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*

3 Terms and definitions

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

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

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

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

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

Note 1 to entry: From ISO 7207-1: 2007. 3.2.3

3.2
mobile-bearing component
component of a total or uni-compartmental mobile-bearing knee joint prosthesis which articulates with both the femoral component and the tibial tray

Note 1 to entry: From ISO 7207-1:2007, 3.2.10

Note 2 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 by the user.

Note 3 to entry: The mobile-bearing component is usually a sub-component of the tibial component, supported by the tibial tray.

Note 4 to entry: The mobile-bearing component can also be referred to as the meniscal component.

3.3
mobile-bearing knee joint prosthesis
total or uni-compartmental knee joint prosthesis which allows relative motion between the mobile-bearing component and both the femoral component and the tibial tray

Note 1 to entry: From ISO 7207-1:2007, 3.1.6

3.4
patellar component
component of a total or patella-femoral knee joint prosthesis which is used to replace the articulating surface of the patella

Note 1 to entry: From ISO 7207-1:2007, 3.2.13

Note 2 to entry: Patellar components can be monobloc or modular

3.5
patellar tray
sub-component of a modular patellar component used to support and secure the patellar insert

Note 1 to entry: Derived from ISO 7207-1:2007, 3.2.14

3.6
posterior stabilized tibial insert
A tibial insert with a centre post protruding superiorly or some other mechanism which interfaces with the femoral component to restrict anterior translation of the femoral component when the knee is in flexion.

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

3.7
reference device
a legally-marketed device which, when compared to the device under investigation, satisfies both of the following conditions:

1) 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

2) there is evidence of clinical use in sufficient numbers; for a sufficient period of time; and, without known or reasonably known evidence of device-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 device under investigation and the reference device are "equivalent" or that the reference device is a "predicate" device. This is because in some regulatory regimes 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: For the purposes of this document, a reference device is the comparison device for the performance parameter under consideration. For each performance parameter there can be a different reference device. The reference device can be different from the device under investigation with respect to other parameters.

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

Note 4 to entry: There is no agreed interpretation for what constitutes "sufficient numbers" or a "sufficient period of time" in the above definition. ISO 21534:2007, Clause 6.1, Note 3 gives an example of what may be a sufficient number of implants and a sufficient number of years of evidence. The example in ISO 21534: 2007, Clause 6.1 is not included here as a requirement, only as an example which may be useful when interpreting what may be "sufficient clinical evidence". 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 device performance.

Note 5 to entry: A justification for a "similar material" might include information that although the materials are not the same, the material(s) used for the device under investigation 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 may be taken into consideration when evaluating whether a device has 'similar design' to the device under investigation include means of fixation, modularity, constraint, key dimensions, processing, surface treatment, etc. A justification for a "similar design" therefore might include information that although the designs are not the same, the design of the device under investigation can be shown to perform similarly with regard to the test or its underlying clinical concern.

Note 7 to entry: Identification of a reference device is at the discretion of the manufacturer and regulatory body in accordance with the regulatory requirements in the jurisdictions where the device is marketed.

3.8
sufficient and safe clinical use
Clinical use of a legally-marketed device a) in sufficient numbers, b) for a sufficient period of time and c) at a minimum, without known or reasonably-known evidence of device-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 device performance.

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

Note 3 to entry: For a legally-marketed system of hip replacement implants there may 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.

Note 4 to entry: This document does apply to those parts of a legally-marketed hip replacement implant system for which there is not sufficient evidence to demonstrate sufficient and safe clinical use.

Note 5 to entry: Identification of a device with sufficient and safe clinical use is at the discretion of the manufacturer and regulatory body in accordance with the regulatory requirements in the jurisdictions where the device is marketed.

3.9
tibial component
component of a total or uni-compartmental knee joint prosthesis intended to be secured to the tibia to replace its articulating surface(s)

Note 1 to entry: From ISO 7207-1:2007, 3.2.5

Note 2 to entry: Tibial components can be monobloc or modular. When modular the tibial component usually consists either of a tibial insert (3.10) or a mobile-bearing component (3.2); and a tibial tray (3.11)

3.10
tibial insert
sub-component of a modular tibial component of a total or uni-compartmental knee joint prosthesis which is attached to the tibial tray and which articulates with the femoral component

Note 1 to entry: From ISO 7207-1:2007, 3.2.9

3.11
tibial tray
sub-component of a modular tibial component of a total or uni-compartmental knee joint prosthesis used to support the tibial insert or mobile-bearing component

Note 1 to entry: From ISO 7207-1:2007, 3.2.8

Note 2 to entry: The tibial tray is also referred to as the tibial baseplate

Note 3 to entry: The central stem or other prominence on the inferior surface of the tibial tray is also referred to as the keel.