SLOVENSKI STANDARD
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Neaktivni kirurški vsadki (implantati) - Sklepne proteze - Posebne zahteve za umetni kolk (ISO/DIS 21535:2021)

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants (ISO/DIS 21535:2021)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen an Implantate für den Hüftgelenkersatz (ISO/DIS 21535:2021)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation de la hanche (ISO/DIS 21535:2021)

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Non-active surgical implants — Joint replacement implants — Specific requirements for hip-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 21535 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 21535:2007), 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 hip 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 hip-joint replacement implants

1 Scope

This document provides specific requirements for hip 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 hip joint replacement implants. It applies to components made of metallic and non-metallic materials.

This document applies to a wide variety of hip replacement implants, but for some specific hip 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 6475, *Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods*

ISO 7206-1:2008, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*

ISO 7206-2, *Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials*

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

ISO 7206-6, *Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components*

ISO 7206-10, *Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads*

ISO 7206-12, *Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells*

ISO 7206-13, *Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components*

ISO 11491, *Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses*

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 test*

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

ISO 14242-3, *Implants for surgery — Wear of total hip-joint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test*

ISO 14242-4, *Implants for surgery — Wear of total hip-joint prostheses — Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading*

ISO 14630, *Non-active surgical implants — General requirements*

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 F543, *Standard Specification and Test Methods for Metallic Medical Bone Screws*

ASTM F1820, *Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices*

ASTM F1875, *Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface*

ASTM F1877, *Standard Practice for Characterization of Particles*

ASTM F2009, *Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses*

ASTM F2033, *Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials*

ASTM F2345, *Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads*

ASTM F2580, *Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis*

ASTM F2582, *Standard Test Method for Impingement of Acetabular Prostheses*

ASTM F3018, *Standard Guide for Assessment of Hard-on-Hard Articulation Total Hip Replacement and Hip Resurfacing Arthroplasty Devices*

ASTM F3047M, *Standard Guide for High Demand Hip Simulator Wear Testing of Hard-on-hard Articulations*

ASTM F3090, *Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement*

ASTM F3143, *Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Replacement Bearings Under Standard Conditions Using a Reciprocal Friction Simulator*

ASTM F3446, *Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator*

3 Terms and definitions

For the purposes of this document the terms and definitions in ISO 21534, ISO 7206-1, ISO 7206-2 and ISO 7206-10 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
acetabular component
implant intended to be fixed to the prepared biological acetabulum

Note 1 to entry: The acetabular component can be of monobloc or modular construction. If modular, typically there can be two sub-components, each fulfilling a different function: one is the bearing surface and the other provides the means of fixation to the prepared biological acetabulum. The bearing surface is also referred to as the liner (or the insert) and the other sub-component is sometimes referred to as the shell.

3.2
bipolar femoral hip
type of partial hip joint replacement consisting of a bipolar femoral component and a femoral component

3.3
bipolar head
bipolar femoral component
component of a partial 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

Note 1 to entry: The bipolar head can be a monobloc component or a modular component.

3.4
constrained hip
type of total hip joint replacement intended to prevent hip dislocation in more than one anatomic plane, which consists of femoral and acetabular components, which are connected across the joint

Note 1 to entry: A dual mobility constrained hip is a type of constrained hip which consists of a femoral component (3.7), a dual mobility head (3.5), and a modular constrained acetabular component, which are connected across the joint. This type of constrained hip is also called a "tripolar hip". Although the term "tripolar" is used to describe the construct, there are only two bearings.

3.5
dual mobility head
dual mobility femoral component
component of a total 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 an acetabular component

Note 1 to entry: The dual mobility head can be a monobloc component or a modular component.

3.6
dual mobility hip
type of total hip joint replacement consisting of a femoral component (3.7), dual mobility head (3.5) and an acetabular component (3.1)

3.7
femoral component
part of a total or partial hip joint replacement which is intended to be fixed to the proximal femur

Note 1 to entry: The femoral component fulfills two different functions: one is to provide the bearing surface and the other is to provide the means of fixation to the proximal femur.

Note 2 to entry: The femoral component can be monobloc or modular. If modular, typically there are 2 sub-components, each fulfilling a different function: one is the modular femoral head (3.8) and the other is the modular femoral stem.

Note 3 to entry: A modular femoral stem (see Note 2 to entry) can itself be modular, consisting of a single or multi-component modular femoral stem and a single or multi-component modular femoral neck and taper connection(s).

Note 4 to entry: The femoral component of a resurfacing hip joint replacement can also be referred to as the femoral cap.

3.8
femoral head
the part of a total or partial hip joint replacement which articulates with:

a) the natural acetabulum or a bipolar head (3.3), in the case of a partial hip joint replacement (3.12);

b) the acetabular component (3.1) or a dual mobility head (3.5), in the case of a total hip joint replacement (3.16)

3.9
hip joint replacement
implant used to replace one or both of the articulating surfaces of the hip joint

Note 1 to entry: An implant intended to replace only the femoral articulating surface of the hip joint is referred to as partial hip joint replacement (see 3.12).

Note 2 to entry: An implant intended to replace the femoral and acetabular surfaces of the hip joint is referred to as total hip joint replacement (see 3.16).

Note 3 to entry: The term hip arthroplasty refers to the act of implanting a hip joint replacement.

3.10
modular component
femoral or acetabular component that consists of two or more sub-components

Note 1 to entry: A modular component can be supplied preassembled or as separate components to be assembled by the user.

3.11
monobloc component
component that consists of a single part with no modularity

Note 1 to entry: Derived from ISO 7206-1:2008, 3.6

3.12
partial hip joint replacement
implant comprising a femoral component (3.7) intended to replace the femoral articulating surface of the hip joint

Note 1 to entry: Modular partial hip joint replacement implants incorporate either a bipolar or a unipolar head.

Note 2 to entry: The term hip hemiarthroplasty refers to the act of implanting a partial hip joint replacement.

Note 3 to entry: A partial hip joint replacement is sometimes referred to as a “hemi”.

3.13
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, at a minimum, without known or reasonably-known evidence of device-related recalls with regard to the specific dimensional or performance criteria under evaluation.

