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

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences spécifiques relatives aux implants de remplacement de l'articulation de la hanche

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Contents

Page

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Foreword

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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).

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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.

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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).

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This third edition cancels and replaces the second edition (ISO 21535:2007), which has been technically revised. It also incorporates the Amendment ISO 21535:2007/Amd 1:2016.

The main changes are as follows:

— The scope has been expanded to specify more precisely the hip 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.

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

— Several new definitions have been added, including: bipolar femoral hip and bipolar femoral hip joint replacement, bipolar femoral component, constrained hip and constrained hip joint replacement, dual mobility head and dual mobility femoral component, dual mobility hip and dual mobility hip joint replacement, femoral head, reference implant, resurfacing hip joint replacement, sufficient and safe clinical use, ultra-high molecular weight polyethylene and UHMWPE, and worst case.

— The design attributes to be taken into account have been specified in Clause 5. The requirements for tolerances, dimensions and thickness of various hip components made from plastic, metal and ceramic have been expanded.

— Several new general requirements have been added in 7.2.1, which specify

  a) the circumstances when a test can be omitted,

  b) the testing of the worst case,

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

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

— The number of pre-clinical evaluations (bench tests) to be performed has been greatly increased in 7.2.2. For some of the tests, a performance requirement has been specified. For some of the tests, no performance requirement 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 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.

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

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

— A warning for the surgeon about the consequences of component malposition or the use of specific components which can decrease joint range of motion has been added in 11.6.

— A note has been added in 11.7 which states that in some jurisdictions there is the option to provide the instructions for use in electronic instead of paper format.

— All the figures have been revised.

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.

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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 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.

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

1 Scope

This document specifies 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, can be applicable. Further details are given in 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.

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2 Normative references

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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 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*

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

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

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

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

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

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

ISO/FDIS 21535

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

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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*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630, ISO 21534, ISO 7206-1, ISO 7206-2, ISO 7206-10 and the following apply.

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

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

— IEC Electropedia: available at 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 also referred to as the shell or cup.

3.2
bipolar femoral hip
bipolar femoral hip joint replacement
type of *partial hip joint replacement* (3.12) consisting of a *bipolar head* (3.3) and a *femoral component* (3.7)

3.3
bipolar head
bipolar femoral component
component of a *bipolar femoral hip* (3.2) with a concave (inner) surface intended to articulate with the spherical head of the *femoral component* (3.7) and a convex (outer) spherical surface intended to articulate with the biological acetabulum

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ISO/FDIS 21535
https://standards.iteh.ai/catalog/standards/sist/e2216fd6-905f-4b34-95de-7798c0e712e6/iso-fdis-21535

Note 1 to entry: The bipolar head can be a *monobloc component* (3.11) or a *modular component* (3.10).

Note 2 to entry: The above definition for bipolar femoral component above is compatible with the definition included in ISO 7206-1:2008, 3.1, but it includes additional information for clarity.

3.4
constrained hip
constrained hip joint replacement
type of *total hip joint replacement* (3.16) intended to prevent hip dislocation in more than one anatomic plane, which consists of a *femoral component* (3.7) and an *acetabular component* (3.1), 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* (3.16) with a concave (inner) surface intended to articulate with the spherical head of the *femoral component* (3.7) and a convex (outer) spherical surface intended to articulate with an *acetabular component* (3.1)

Note 1 to entry: The dual mobility head can be a *monobloc component* (3.11) or a *modular component* (3.10).

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3.6
dual mobility hip
dual mobility hip joint replacement
type of *total hip joint replacement* (3.16) 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 hip joint replacement* (3.16) or a *partial hip joint replacement* (3.12) which is intended to be fixed to the proximal femur

Note 1 to entry: The femoral component fulfils 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 two sub-components, each fulfilling a different function: one is the modular *femoral head* (3.8) and the other is the modular femoral stem. A modular femoral stem 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 3 to entry: The femoral component of a *resurfacing hip joint replacement* (3.14) can also be referred to as the femoral cap.

3.8
femoral head
part of a *total hip joint replacement* (3.16) or a *partial hip joint replacement* (3.12) which articulates with:

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

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

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ISO/FDIS 21535
https://standards.iteh.ai/catalog/standards/sist/e2216fd6-905f-4b34-95de-

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* (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* (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 component (3.7) or *acetabular component* (3.1) 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

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

Note 1 to entry: A modular partial hip joint replacement incorporates 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.

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

3.13
reference implant
legally-marketed implant which, when compared to the implant under evaluation, satisfies both of the following conditions:

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) 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.

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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.

ISO/FDIS 21535
https://standards.iteh.ai/catalog/standards/sist/
7798c0c712e6/iso-fdis-21535

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.

3.14
resurfacing hip joint replacement
type of *total hip joint replacement* (3.16) or *partial hip joint replacement* (3.12) intended to replace:

a) only the femoral articulating surface of the joint in a *partial hip joint replacement* (3.12), which usually consists of a monobloc femoral cap component, with a central stem, that is placed over the head of a prepared biological femoral head and intended to articulate with the biological acetabulum, or

b) both the femoral and acetabular articulating surfaces of the joint in a *total hip joint replacement* (3.16), which consists of a monobloc femoral cap component, and a matching monobloc or modular *acetabular component* (3.1)

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3.15
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 hip 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.

3.16
total hip joint replacement
implant comprising a *femoral component* (3.7) and an *acetabular component* (3.1) intended to replace both of the articulating surfaces of the hip joints

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Note 1 to entry: The term total hip arthroplasty refers to the act of implanting a total hip joint replacement.

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3.17
ultra-high molecular weight polyethylene
UHMWPE
type of polymer material including the following types:

ISO/FDIS 21535
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a) "conventional" [not intentionally cross-linked and sterilized with a radiation dose of ≤ 40 kGy or by other accepted sterilization methods (e.g. ethylene oxide)],

b) "crosslinked" [achieved by radiation treatment (with a radiation dose of > 40 kGy) or by other means], and

c) "anti-oxidant" ["crosslinked" or not "crosslinked" with the addition of vitamin E or another anti-oxidant]

Note 1 to entry: The types of UHMWPE materials listed above shall be manufactured from UHMWPE powders which meet the requirements given in either ISO 5834-1 or ASTM F648, or both.

3.18
unipolar head
head of a *femoral component* (3.7) intended to articulate with the biological acetabulum

3.19
worst case
designation given

a) to an implant component or combination of components in an implant family which is most susceptible to failure in a given test (e.g. based on size, geometry, design features, materials, means of fixation, surface treatments or coatings, modularity), and

b) to testing condition(s) which produce the most severe anticipated physiological condition(s) or failure mode(s) for the requirements to which the implant is under evaluation

Note 1 to entry: For any given implant component or combination of components or set of testing conditions, there can be more than one worst case.

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