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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

Foreword ... **iv**
Introduction ... **vi**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **3**
4 Intended performance ... **7**
5 Design attributes ... **7**
5.1 General ... 7
5.2 Tolerances and dimensions ... 8
5.2.1 Tolerances and dimensions of taper connections ... 8
5.2.2 Tolerances on diameters of articulating surfaces, sphericity of articulating surfaces and surface finish of articulating surfaces ... 8
5.3 Thickness of acetabular components, bipolar heads and dual mobility heads ... 9
5.3.1 General ... 9
5.3.2 Thickness of UHMWPE in acetabular components, bipolar heads and dual mobility heads ... 9
5.3.3 Thickness of metal and ceramic acetabular shell and acetabular liner components, bipolar heads, and dual mobility heads ... 10
6 Materials ... **11**
7 Design evaluation ... **11**
7.1 General ... 11
7.2 Pre-clinical evaluation ... 12
7.2.1 General ... 12
7.2.2 Test methods and performance requirements ... 14
7.3 Clinical investigation ... 20
7.4 Post market surveillance ... 20
8 Manufacture ... **20**
9 Sterilization ... **20**
10 Packaging ... **21**
11 Information to be supplied by the manufacturer ... **21**
11.1 General ... 21
11.2 Product type and dimensions ... 21
11.3 Structural and functional compatibility of components ... 21
11.4 Marking ... 21
11.5 Information for the patient ... 22
11.6 Information for the surgeon ... 22
11.7 Electronic instructions for use ... 22
Annex A (normative) **Evaluation of the range of relative angular motion of the femoral and acetabular components of a total hip replacement** ... **23**
Bibliography ... **26**

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 document 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.

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 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,

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.

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.

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.

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 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 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*

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 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 given in ISO 7206-1, ISO 7206-2, ISO 7206-10, ISO 14630, ISO 21534 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

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).

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)

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.

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.

Note 3 to entry: Some regulatory authorities can 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) according to 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)

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 can 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 according to 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

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

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

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

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

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

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 to

a) 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) 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.

Note 2 to entry: For any modification to the implant design or change in compatibility with other components, the design shall be assessed to determine if a new worst case(s) is created for a given test.

4 Intended performance

The requirements of this clause 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.

The requirements of ISO 21534:2007, Clause 4, shall apply together with the following.

The range of angular movement between the femoral and acetabular components of a total hip replacement shall have the following minimum values:

— 100° in flexion/extension,

— 60° in abduction/adduction, and

— 90° in internal/external rotation.

Annex A shows the method by which the range of motion between the femoral and acetabular components of a total hip replacement shall be measured.

5 Design attributes

5.1 General

The requirements of Clause 5 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.

The design attributes, to meet the intended performance, shall conform to the requirements of ISO 21534:2007, Clause 5, and those specified in 5.2 and 5.3 to meet the intended use.

In addition, the following points shall at least be taken into account, if applicable:

NOTE 1 A suitable way to take account of the listed points is to include them in the product development process.

a) the femoral head diameter, offset(s) and other head features (e.g. skirts),

b) the stem length; stem medial/lateral and anterior/posterior dimensions; stem shape (straight, curved, tapered, collared, collarless), and the amount of ante-version or retro-version,

c) the neck length and the stem/neck angle(s),

d) head offset length,

e) all modular components and connections (e.g. femoral taper adapters, modular hip stem sleeves),

f) the means of fixation (cemented or uncemented) and features for fixation (e.g. screws, fins, spikes, pegs, grooves) for all components which appose bone or bone cement,

g) the type, size and location of any porous coated surface or intentionally roughened surface,

NOTE 2 Additional information can be found in ISO 13179-1, ISO 13779-2, ASTM F1609[11], ASTM F1854[13], Reference [21] and Reference [22].

h) the inner and outer diameter of acetabular components,

i) the recommended positioning (e.g. as stated in the surgical technique manual) of the femoral stem and the acetabular component (e.g. cup inclination angle, cup and stem version angles),

j) for revision cups or for acetabular reconstruction specific design features (e.g. flanges, augments, patient matched external shell geometries),

k) for components to be cemented, the intended thickness of the cement mantle,

l) for acetabular shells, the design and location of features intended for fixation such as the screws and the screw holes,

m) for modular acetabular systems, the features intended to attach the acetabular liner to the acetabular shell,

n) the diametral clearance for hard-on-hard or hard-on-soft bearings of total hip joint replacements,

NOTE 3 Diametral clearance is defined in ASTM F3018.

o) the Cup Articular Arc Angle (CAAA) and Contact Patch Edge to Rim (CPER) distance both as described in ASTM F3018,

p) type of total hip joint replacement constraint: constrained or semi-constrained, and

q) the accessories to be used with the hip system [e.g. screw(s), distal stem centralizer, acetabular shell plug(s)].

5.2 Tolerances and dimensions

5.2.1 Tolerances and dimensions of taper connections

For taper connections, particular attention shall be paid to the dimensions and tolerance of the following:

a) the surface roughness, straightness, circularity (where specified), angle and diameter of the bore,

b) the surface roughness, straightness, circularity (where specified), angle and diameter of the cone, and

c) the bore and cone nominal engagement length.

NOTE 1 Examples for the use of the terms surface roughness, bore, cone, bore angle, cone angle, straightness, circularity, diameter, concentricity and engagement length can be found in ISO 7206-10.

NOTE 2 Instead of straightness and circularity, it is also possible to use the profile of the surface as an alternative parameter for the bore and cone.

NOTE 3 The initial location of the contact area between the bore and cone (e.g. distal or proximal contact) is an important consideration in evaluating taper connection failure modes (e.g. taper locking failure, taper corrosion, ceramic component failure).

NOTE 4 There can be other types of connections in addition to taper connections. In 7.2.2.14, requirements for tapered and non-tapered connections are provided.

In the design of modular components, the risk of generation of wear particles and occurrence of fretting and crevice corrosion at modular component interfaces shall be taken into account.

5.2.2 Tolerances on diameters of articulating surfaces, sphericity of articulating surfaces and surface finish of articulating surfaces

The tolerances on the diameters of the articulating surfaces, the sphericity of the articulating surfaces and the surface finish of the articulating surfaces of:

a) femoral components intended for total or partial hip joint replacement,

b) acetabular components,

c) bipolar heads intended for bipolar femoral hips,

d) constrained hip components,

e) dual mobility hip components, and

f) resurfacing hip joint replacements

shall be in accordance with ISO 7206-2 or ASTM F2033 or, where not specified in ISO 7206-2 or ASTM F2033, shall be the same or better than the tolerances on the diameters of the articulating surfaces, the sphericity of the articulating surfaces and the surface finish of the articulating surfaces in at least one reference implant as defined in 3.13.

NOTE For articulating surfaces that are not intended to be spherical (e.g. some surfaces intended to articulate with the natural acetabulum), the sphericity requirement is not applicable.

5.3 Thickness of acetabular components, bipolar heads and dual mobility heads

5.3.1 General

When evaluating thickness of acetabular components, bipolar heads, and dual mobility heads, the nominal thickness and associated tolerance(s) shall be taken into account.

5.3.2 Thickness of UHMWPE in acetabular components, bipolar heads and dual mobility heads

5.3.2.1 Acetabular components

The UHMWPE component shall have the following minimum thickness (in the least material condition) in loaded areas including the spherical pole, 45-degree angle to the polar axis, rim and locking mechanism:

a) 5 mm for components with a metal or other backing;

NOTE 1 The 5 mm value is the minimum thickness of the UHMWPE component only and not the minimum thickness of the UHMWPE component plus the thickness of the metal or other backing.

b) 6 mm for components without metal or other backing.

If the UHMWPE acetabular component does not meet the requirements for thickness stated above, the minimum thickness in the loaded areas shall be the same or greater than the minimum thickness in all corresponding loaded areas of at least one reference implant as defined in 3.13.

NOTE 2 For the purpose of comparing the minimum thickness of the implant under evaluation to the minimum thickness of a reference implant as defined in 3.13, it is sufficient to make use of a single reference implant. Alternatively, if the minimum thickness of the implant under evaluation in all of the loaded areas including those stated above is not the same or greater than the minimum thickness of this reference implant in all of the corresponding loaded areas, then it is acceptable to use more than one reference implant, but only if the use of more than one reference implant is justified. In this case, the first reference implant can be used to demonstrate the acceptability of the minimum thickness in one or more loaded areas and one or more other reference implants can be used to demonstrate the acceptability of the minimum thickness in other loaded areas.

If the above requirements are not met, the manufacturer may conduct a clinical investigation to verify the acceptability of the component (7.3).

5.3.2.2 Bipolar heads

For bipolar heads the minimum thickness of the UHMWPE component shall be 5 mm in loaded areas including the spherical pole, 45-degree angle to the polar axis, rim and locking mechanism.

If the UHMWPE bipolar head does not meet the requirements for thickness stated above, the minimum thickness in the loaded areas shall be the same or greater than the minimum thickness in all corresponding loaded areas of at least one reference implant as defined in 3.13.

NOTE For the purpose of comparing the minimum thickness of the implant under evaluation to the minimum thickness of a reference implant as defined in 3.13, it is sufficient to make use of a single reference implant. Alternatively, if the minimum thickness of the implant under evaluation in all of the loaded areas including those stated above is not the same or greater than the minimum thickness of this reference implant in all of the corresponding loaded areas, then it is acceptable to use more than one reference implant, but only if the use of more than one reference implant is justified. In this case, the first reference implant can be used to demonstrate the acceptability of the minimum thickness in one or more loaded areas and one or more other reference implants can be used to demonstrate the acceptability of the minimum thickness in other loaded areas.

If the above requirements are not met, the manufacturer may conduct a clinical investigation to verify the acceptability of the component (7.3).

5.3.2.3 Dual mobility heads

The minimum thickness of an UHMWPE dual mobility head shall be the same as the minimum thickness of a bipolar head, as specified in 5.3.2.2.

5.3.3 Thickness of metal and ceramic acetabular shell and acetabular liner components, bipolar heads, and dual mobility heads

5.3.3.1 For an acetabular shell made of a typical titanium alloy (i.e. ISO 5832-3, ASTM F136[7] or ASTM F1472[9]) or a typical cobalt-chrome alloy (i.e. ISO 5832-12 or ASTM F1537[10]) and not made by additive manufacturing, the minimum thickness shall be 3 mm in loaded areas including the spherical pole, 45-degree angle to the polar axis, rim and locking mechanism. Where screw or spherical pole holes, including features such as chamfers, counter-sinks and surrounding radii, prevent measurements to be made, the measurement shall be made at the closest adjacent location.

If a surface coating is applied to the shell, the thickness of the shell shall be determined by deducting the coating thickness from the total thickness.

When selecting a reference implant for thickness comparison for metal acetabular components, the means of fixation (cemented or uncemented) shall be taken into consideration.

If the minimum thickness in the loaded areas is less than 3 mm, then the minimum thickness in the loaded areas shall be the same or greater than the minimum thickness in all corresponding loaded areas of at least one reference implant as defined in 3.13.

NOTE For the purpose of comparing the minimum thickness of the implant under evaluation to the minimum thickness of a reference implant as defined in 3.13, it is sufficient to make use of a single reference implant. Alternatively, if the minimum thickness of the implant under evaluation in all of the loaded areas including those stated above is not the same or greater than the minimum thickness of this reference implant in all of the corresponding loaded areas, then it is acceptable to use more than one reference implant, but only if the use of more than one reference implant is justified. In this case, the first reference implant can be used to demonstrate the acceptability of the minimum thickness in one or more loaded areas and one or more other reference implants can be used to demonstrate the acceptability of the minimum thickness in other loaded areas.

If the above requirements are not met, the manufacturer may conduct a clinical investigation to verify the acceptability of the component (7.3).

5.3.3.2 For metal and ceramic components, such as:

a) bipolar heads, dual mobility heads and acetabular liner components;

b) acetabular shell components not made of a typical titanium or cobalt-chrome alloy (see above lists), including variations of the above alloys which do not fulfil the above-mentioned standards (e.g. increased porosity);

c) acetabular shells, acetabular liner components, bipolar heads and dual mobility heads that are additively manufactured;

the minimum thickness in the loaded areas including the spherical pole, 45-degree angle to the polar axis, rim and locking mechanism shall be the same or greater than the minimum thickness in the corresponding loaded areas of at least one reference implant as defined in 3.13. Where screw or spherical pole holes, including features such as chamfers, counter-sinks and surrounding radii, prevent measurements to be made, the measurement shall be made at the closest adjacent location.

NOTE For the purpose of comparing the minimum thickness of the implant under evaluation to the minimum thickness of a reference implant as defined in 3.13, it is sufficient to make use of a single reference implant. Alternatively, if the minimum thickness of the implant under evaluation in all of the loaded areas including those stated above is not the same or greater than the minimum thickness of this reference implant in all of the corresponding loaded areas, then it is acceptable to use more than one reference implant, but only if the use of more than one reference implant is justified. In this case, the first reference implant can be used to demonstrate the acceptability of the minimum thickness in one or more loaded areas and one or more other reference implants can be used to demonstrate the acceptability of the minimum thickness in other loaded areas.

If the above requirements are not met, the manufacturer may conduct a clinical investigation to verify the acceptability of the component (7.3).

When selecting a reference implant, as defined in 3.13, for thickness comparison for a fully porous component under evaluation, the reference implant shall also be fully porous.

If a surface coating is applied to the shell, the thickness of the shell shall be considered to be only the thickness of the substrate.

For acetabular shells that are additively manufactured, there can be a dense structure (similar to a substrate) and a less dense structure (similar to a coating). In such cases, the thickness of the component shall be considered to be only the thickness of the dense structure.

When selecting a reference implant for thickness comparison for metal and ceramic acetabular components, the means of fixation (cemented or uncemented) shall be taken into consideration.

6 Materials

The requirements of this clause 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.

The requirements of ISO 21534:2007, Clause 6, shall apply together with the following. Unalloyed titanium and titanium alloys shall not be used as the articulating surfaces of total hip joint replacements, unless an appropriate surface treatment is undertaken and demonstrated to be suitable in clinical use compared to at least one reference implant as defined in 3.13.

7 Design evaluation

7.1 General

The requirements of ISO 21534:2007, Clause 7, shall apply together with the requirements specified in 7.2, 7.3 and 7.4.

7.2 Pre-clinical evaluation

7.2.1 General

7.2.1.1 Information

The requirements of 7.2.2 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 each test specified in 7.2.2, sterilized components shall be tested unless a justification is provided for the use of non-sterilized components.

7.2.1.2 Tests

Subclause 7.2.2 lists the tests to be performed.

The test methods listed in 7.2.2 were developed to mitigate the effect of known failure modes. These tests cannot evaluate failure modes for which they were not designed. Therefore, the intended use, materials and design of the implant under evaluation shall be analysed to determine whether additional failure modes exist. If additional failure modes are identified, these shall be stated and appropriate testing shall be performed.

NOTE 1 The test methods specified in 7.2.2 can require modification for specific types of hip replacement implants. For example, for dual mobility hip components and for constrained hip replacement implants the wear testing, range of motion testing and disassembly force (locking mechanism) testing can require modification.

NOTE 2 Additively manufactured materials can require additional evaluation, particularly related to the fatigue strength.

7.2.1.3 Circumstances when a test can be omitted

Each test in 7.2.2 shall be performed unless at least one of the following apply:

a) the test is not applicable;

b) performing the test is considered unnecessary based on the risk analysis for the implant.

In these cases, a justification for omitting the test shall be documented for each test omitted.

For stemmed femoral components tests 7.2.2.1 and 7.2.2.2 are always applicable.

Examples of situations in which one or more tests may not be applicable include:

— the hip stem is a monobloc component, unipolar head, partial hip joint replacement that is not for use with a bipolar head; so, the tests specified in 7.2.2.3, and 7.2.2.5 to 7.2.2.18 do not apply as these tests address features or components which this type of implant does not have;

— the total hip joint replacement does not include a modular metal or ceramic head so, tests specified in 7.2.2.3, 7.2.2.6, 7.2.2.8, 7.2.2.9 and 7.2.2.11 (for the head and stem taper interface) do not apply as these tests have to do with modular metal or ceramic heads.

7.2.1.4 Worst case testing

For each test specified in 7.2.2 the worst case or worst cases shall be tested. A justification for selecting the chosen component(s) and conditions for testing shall be documented.

Physical testing can be used to determine the worst case(s).

Theoretical analysis and modelling, including finite element analysis, can also be used to select the most appropriate size(s) of component(s) for testing the worst case(s) (e.g. see ASTM F2996[17]). If used, the credibility of such modelling for its context of use shall be demonstrated (see ASME V&V 40-2018[24]).

NOTE Information and guidance with regard to formatting, organization and content of reports on computational modelling and simulation are given in Reference [23].

7.2.1.5 Process to be followed when no pass-fail performance requirement has been specified or when a pass-fail performance requirement has been specified, but has not been met

7.2.1.5.1 In the cases where:

a) no pass-fail performance requirement has been specified in a subclause of 7.2.2, or

b) a pass-fail performance requirement has been specified in a subclause of 7.2.2, but the implant under evaluation did not meet the pass-fail performance requirement,

the performance of the implant under evaluation shall be the same as or better than the performance of at least one reference implant as defined in 3.13.

The comparison of the performance of the implant under evaluation with the performance of one or more reference implants shall be made using at least one of the following methods:

— side-by-side testing (a test program in which the implants are tested in parallel under identical test conditions);

— comparison of the results of tests performed on the implant under evaluation with the results of tests performed previously on a reference implant where it can be demonstrated that the test conditions are identical;

— comparison of the results of tests performed on the implant under evaluation with the results of tests reported on a reference implant in peer-reviewed literature where it can be demonstrated that the test conditions are identical.

The comparison methods listed above are listed in order of most preferred to least preferred in terms of reliability, repeatability and demonstrating comparability with reference implants.

When following this process, the method chosen shall be stated and justified.

7.2.1.5.2 If the comparison of performance of the implant under evaluation to a reference implant, as stated above, does not show the same or better performance, the implant under evaluation shall not satisfy the requirements of 7.2.2, which means it is possible that the implant is not adequate for its intended use and shall not be marketed or will need to be redesigned.

Only after performing at least one of the comparisons in 7.2.1.5.1, the safety and performance of the implant can still be demonstrated by means of either:

a) a biomechanical rationale, which includes an in-depth analysis of relevant in vivo loads and physiological conditions and justifies the test conditions and results obtained, with a justified safety factor, or

b) a pre-market clinical investigation (see 7.3), or both.

7.2.1.5.3 If a reference implant does not exist, the safety and performance of the implant can still be demonstrated by means of either 7.2.1.5.2 a) or b), or both, above.

7.2.2 Test methods and performance requirements

7.2.2.1 Endurance testing of stemmed femoral components

Stemmed femoral components of total and partial hip replacement implants shall be tested in accordance with ISO 7206-4.

The components shall satisfy the performance requirements given in ISO 7206-4.

Otherwise, if the performance requirement is not met, the performance shall be the same or greater than the performance of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

For resurfacing hip femoral components, the static and fatigue strengths of the stem shall be evaluated. The strengths shall be the same or greater than the strengths of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

NOTE For stemmed femoral components that satisfy the performance requirements given in ISO 7206-4, one or more specimens can be tested to failure in order to determine the performance limit. To determine the performance limit, either the number of cycles or the applied load, or both, can be increased until failure occurs. Depending on the performance limit and the limitations of the test equipment, it can be impossible to test to failure.

7.2.2.2 Endurance properties of the neck region of stemmed femoral components

The neck region of stemmed femoral components shall be tested in accordance with ISO 7206-6.

The components shall satisfy the performance requirements given in ISO 7206-6.

Otherwise, if the performance requirement is not met, the performance shall be the same or greater than the performance of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

NOTE For stemmed femoral components that satisfy the performance requirements given in ISO 7206-6, one or more specimens can be tested to failure in order to determine the performance limit. To determine the performance limit, either the number of cycles or the applied load, or both, can be increased until failure occurs. Depending on the performance limit and the limitations of the test equipment, it can be impossible to test to failure.

7.2.2.3 Pull-off characteristics of femoral heads and pull-off/lever-off characteristics of bipolar heads, dual mobility heads and constrained hips

Femoral heads shall be tested in static tension (pull-off test) using the test method in ISO 7206-10 or ASTM F2009.

The femoral head pull-off force shall be the same or greater than the femoral head pull-off force of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

For bipolar heads and dual mobility heads the pull-off and lever-off strengths (force required to dissociate the bipolar head or dual mobility head from the femoral head) shall be evaluated. The strengths shall be the same or greater than the strengths of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

For constrained hips, the pull-off and lever-off strengths [force required to dissociate the constrained acetabular component (e.g. the liner) from the femoral head] shall be evaluated. The strengths shall be the same or greater than the strengths of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

In addition, for constrained hips, bipolar heads and dual mobility heads the lever-off strength post-impingement (see 7.2.2.12) shall be evaluated. The strength shall be the same or greater than the post-

impingement lever-off strength of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.4 Wear testing of hip joint replacements

The wear characteristics of total hip joint replacement implants comprising a femoral component with an integral head or a modular head articulating on an acetabular component, shall be tested in accordance with either ISO 14242-1 or ISO 14242-3 and the wear shall be measured in accordance with ISO 14242-2.

The wear shall be the same or less than the wear of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

The above wear test shall be performed regardless of whether or not any of the following additional wear tests outlined below are performed.

Following the above wear testing, the fluid from the joint simulator shall be analysed. Applicable standards for the isolation and characterization of wear particles include ISO 17853, ASTM F561[8] and ASTM F1877[14]. Wear particle analysis for dual mobility hips shall be performed for the "overall wear" test as described below.

A biological evaluation of wear particles (e.g. metal, ceramic, polyethylene particles) shall be performed in accordance with ISO 10993-1.

NOTE 1 Metal and ceramic wear particles can be produced when articulating against polyethylene.

Additional wear tests shall be performed to simulate adverse or other clinically relevant conditions.

For hard-on-hard articulations, the additional adverse/high-demand wear tests included in 7.2.2.17 shall be performed.

For hard-on-UHMWPE components, the following additional tests shall be performed:

— wear testing of aged components;

— wear testing of components with the addition of third-body particles;

— wear testing of components with a roughened femoral head;

— wear testing of components with steep acetabular cup inclination angle per ISO 14242-4.

As part of the above wear tests, the loaded area of the articulating surfaces shall be examined pre- and post-wear testing using optical or electro-optical techniques (e.g. microscopy, interferometry, scanning electron microscopy) with sufficient magnifications to evaluate damage (e.g. fracture, cracks, deformation) to the implant.

NOTE 2 Information and guidance with regard to wear testing of components with the addition of third body particles are given in ASTM F3047M.

NOTE 3 ISO 5834-3 or ASTM F2003[15] provide established methods for accelerated ageing.

An adequate justification for the methods used for ageing of the polyethylene component and for the materials and methods used for third-body particle and roughened femoral head wear testing shall be provided. For each of the above additional tests, the wear shall be the same or less than the wear of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

For dual mobility hips, the wear characteristics shall be evaluated, as follows:

— Outer bearing only wear: To evaluate the worst case outer bearing wear between the dual mobility head and acetabular components of a dual mobility hip, the inner articulation between the dual mobility head and femoral head shall be locked to prevent motion at this interface. Then, wear testing shall be performed in accordance with either ISO 14242-1 or ISO 14242-3.

— Overall wear: In addition, to evaluate the total wear of a dual mobility hip, both articulations shall be unlocked and wear testing shall be performed in accordance with either ISO 14242-1 or ISO 14242-3.

NOTE 4 The "overall wear" is typically less than the "outer bearing only wear" because when testing the "overall wear" the motion is predominantly at the inner articulation.

The outer bearing only wear and the overall wear for a dual mobility hip shall be the same or less than the outer bearing only wear and the overall wear, respectively, of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

For bipolar heads (inner bearing) the wear characteristics shall be evaluated. The wear shall be the same or less than the wear of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

The wear characteristics of partial hip joint replacement implants including bipolar heads (outer bearing) shall be evaluated. A method shall be chosen to evaluate the wear of the articulating surfaces (i.e. femoral component and native acetabular cartilage surfaces) and shall be justified. The wear shall be the same or less than the wear of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.5 Minimum and maximum angles — Range of motion

For total hip joint replacements, the range of motion between the femoral and acetabular components shall be evaluated in accordance with the method described in Annex A. The range of motion shall satisfy the performance requirements given in Clause 4.

For partial hip replacements, it is not necessary to evaluate the range of motion between the unipolar or bipolar head and the natural acetabulum (outer bearing).

For bipolar heads, the range of motion between the bipolar and femoral head components shall be evaluated. The range of motion can be less than given in Clause 4. The range of motion shall either satisfy the performance requirements given in Clause 4 or shall be the same or greater than the range of motion of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

For constrained hips, the range of motion shall be evaluated. The range of motion shall either satisfy the performance requirements given in Clause 4 or shall be the same or greater than the range of motion of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

For dual mobility hips, the range of motion shall be evaluated for the femoral head/dual mobility head articulation, and for the total articulation of the dual mobility system. The range of motion for the femoral head/dual mobility head articulation can be less than given in Clause 4. The range of motion for the femoral head/dual mobility head articulation shall either satisfy the performance requirements given in Clause 4 or shall be the same or greater than the range of motion of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5. The range of motion for the total articulation of the dual mobility system shall satisfy the performance requirements given in Clause 4.

For constrained hips or total hips with a modular skirted head or tapered sleeve, the range of motion can be less than that given in Clause 4. In such cases, an appropriate warning shall be added to the labelling; see 11.6.

7.2.2.6 Resistance to torque of femoral head/taper combinations

Femoral head/taper combinations shall be tested in accordance with ISO 7206-13.

The resistance to torque (i.e. the torque required to rotate the femoral head on the taper) shall be the same or greater than the resistance to torque of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.7 Deformation of press-fit acetabular components

Press-fit acetabular components shall be tested in accordance with ISO 7206-12.

The deformation of the press-fit acetabular component shall be the same or less than the deformation of the press-fit acetabular component of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.8 Femoral head compression (static and fatigue) for ceramic femoral heads

Ceramic femoral heads shall be tested in static compression (burst test) using the test method in ISO 7206-10.

At least 5 femoral heads shall be tested and the average fracture strength shall exceed 46 kN. No head shall fail at less than 20 kN.

NOTE The above fracture strength requirements are taken from Reference [20].

Otherwise, if the performance requirement is not met, the average static compression strength shall be the same or greater than the average static compression strength of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

Ceramic femoral heads shall be tested in fatigue compression using the test method in ASTM F2345. The ceramic heads shall be axially loaded for 10 million cycles with a load amplitude of 14 kN. All heads shall pass the test without fracture.

Otherwise, if the performance requirement is not met, the average fatigue compression strength shall be the same or greater than the average fatigue compression strength of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

Ceramic heads which have undergone fatigue testing using the test method in ASTM F2345 shall undergo a post-fatigue burst test using the test method in ISO 7206-10. No head shall fail at less than 20 kN.

Otherwise, if the performance requirement is not met, the post-fatigue burst strength shall be the same or greater than the post-fatigue burst strength of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.9 Femoral head impact for ceramic femoral heads

Ceramic femoral heads shall be tested using one of the test methods in ISO 11491.

The impact resistance of ceramic femoral heads shall be the same or greater than the impact resistance of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.10 Disassembly force for modular acetabular implants

The attachment strength between the modular acetabular shell and liner (i.e. push-out, lever-out or offset pull-out and torque-out) shall be evaluated in accordance to the procedures given by ASTM F1820.

NOTE The terms axial disassembly and push-out are synonymous.

In the push-out test the force to separate the liner from the shell shall be the same or greater than the push-out force of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

In the lever-out or offset pull-out test the force to lever out the liner from the shell shall be the same or greater than the lever-out or offset pull-out force of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

In the torque-out test the torque to rotate the liner within the shell shall be the same or greater than the torque to rotate the liner within the shell of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.11 Fretting corrosion of modular interfaces

The bore and cone interface of the head and stem junction of modular hip implants shall be subjected to cyclic loading to measure fretting corrosion in accordance with the test methods given in ASTM F1875 or to an alternative validated test method.

NOTE 1 ASTM F3129[18] can be used to measure the material loss from the taper.

All other modular interfaces shall be subjected to cyclic loading to measure fretting corrosion using an appropriate test method.

NOTE 2 A revision of ASTM F1875 (ASTM WK60713[19]) is currently under development and will include a test method for accelerated fretting corrosion testing of modular connections.

The fretting corrosion properties (e.g. the material loss) shall be the same or less than the fretting corrosion properties of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

NOTE 3 Where modular interfaces exist having the same design, but a different diameter, then in this case it can be unnecessary to test each combination, provided the worst case has been tested.

7.2.2.12 Impingement testing of the acetabular cups and stems

Acetabular and femoral component dislocation; separation or loosening of a modular acetabular liner from the shell; fracture or gross deformation of any component; modular component locking mechanism fracture or failure; or, wear under dynamic impingement conditions shall be evaluated in accordance with ASTM F2582. If failure occurs prior to reaching 1 million impingement cycles, the number of cycles to failure shall be recorded.

The impingement properties shall be the same or better than the impingement properties of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.13 Fatigue of modular connections of proximally fixed femoral hip prostheses

Modular femoral hip stems intended for proximal fixation shall be tested in accordance with ASTM F2580. At least five specimens shall be tested.

The fatigue properties shall be the same or better than the fatigue properties of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.14 Other modular connection static and fatigue properties

In addition to the modular component connection tests outlined in 7.2.2.3, 7.2.2.6, 7.2.2.8, 7.2.2.9, 7.2.2.10 and 7.2.2.11, the assembly and disassembly strength of modular connections under static and fatigue loading and associated effects including fracture, corrosion and fretting shall be evaluated. If testing is conducted, at least five specimens shall be tested in each test.

If testing is performed, the resistance of modular connections to disassembly under static and fatigue loading conditions shall be the same or greater than the corresponding results for at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

The modular components to be tested shall be assembled as described in the applicable surgical technique manual and, where possible, using the applicable instrumentation.

NOTE ASTM F1814[12] provides guidance for evaluating modular femoral components.

7.2.2.15 Frictional torque of total hip joint replacements

The frictional torque of the bearing of total hip joint replacements shall be evaluated using either ASTM F3446 or ASTM F3143.

The frictional torque shall be the same or less than the frictional torque of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.16 Fatigue strength of metallic acetabular shells

The acetabular shell fatigue strength shall be evaluated using the test method given in ASTM F3090.

The fatigue properties shall be the same or better than the fatigue properties of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.2.2.17 Assessment of hard-on-hard articulation for total hip joint replacements and resurfacing hip joint replacements

The following additional tests shall be performed for hard-on-hard articulations as included in ASTM F3018:

- adverse/high-demand hip simulator testing, as specified in ASTM F3047M, including:
  - wear testing of components with a steep acetabular cup inclination angle per ISO 14242-4;
  - wear testing of components with edge loading combined with steep cup inclination angle per ISO 14242-4;
  - wear testing of components with the addition of third-body particles;
  - high demand gait cycles such as 'fast jogging' with higher peak loads and faster test frequencies than used in ISO 14242-1 and ISO 14242-3;
  - stop-dwell-start tests with dwell times and stop-dwell-start cyclic rates representative of typical patient activities;
  - as part of the above wear tests, the loaded area of the articulating surfaces shall be examined pre- and post-wear testing using optical or electro-optical techniques (e.g. microscopy, interferometry, scanning electron microscopy) with sufficient magnifications to evaluate damage (e.g. fracture, cracks, deformation) to the implant;
- static, fatigue, and post-fatigue static strength of modular and monobloc acetabular ceramic components;
- intra-operative chipping resistance of modular and monobloc acetabular ceramic components.

The above properties of the hard-on-hard articulations shall be the same or better than the properties of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

NOTE The literature referenced in ASTM F3018 and ASTM F3047M is for information only and the various techniques described therein are not intended as required tests for this document.

7.2.2.18 Testing of acetabular cup flanges and screws

The acetabular shell flange static and fatigue strength shall be evaluated under cantilever bending loading conditions.

The static and fatigue properties shall be the same or better than the static and fatigue properties of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

The acetabular shell screws shall be evaluated for torsional strength, breaking angle, axial pull-out strength, insertion and removal torque using the test methods given in ASTM F543.

The screws shall satisfy the torsional strength and breaking angle requirements given in ISO 6475 or ASTM F543.

Otherwise, if the torsional strength or breaking angle requirements are not met, the performance of the screws shall be the same or greater than the performance of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

The axial pull-out strength, insertion and removal torque of the screws shall be the same or better than the corresponding properties of at least one reference implant as defined in 3.13 using the process outlined in 7.2.1.5.

7.3 Clinical investigation

A pre-market clinical investigation can be necessary in cases where:

a) no pass-fail performance requirement has been specified in a subclause of 7.2.2 (or a pass-fail performance requirement has been specified but has not been met by the implant under evaluation), and

EITHER:

b) a reference implant as defined in 3.13 exists but a comparison of the performance of the implant under evaluation to a reference implant(s) does not show similar or better results (see 7.2.1.5.2), and

c) no adequate biomechanical rationale can be provided (see 7.2.1.5.2),

OR

d) no reference implant as defined in 3.13 exists, and

e) no adequate biomechanical rationale can be provided (see 7.2.1.5.3).

In these cases, the implant under evaluation shall not satisfy the requirements of this document. In these cases, a pre-market clinical investigation can be required to demonstrate adequate performance and safety.

NOTE A pre-market clinical investigation can be required by certain regulatory authorities. It can still be required even if compliance with this document has been achieved for the implant under evaluation.

7.4 Post market surveillance

The requirements of ISO 21534:2007, 7.4, shall apply.

8 Manufacture

The requirements of ISO 21534:2007, Clause 8, shall apply together with the following:

— implants or implant components manufactured from cast cobalt chromium alloys shall be solution treated if appropriate;

— any heat treatment undertaken shall be recorded and documented; this requirement applies both to implants manufactured by conventional means and by additive manufacturing.

9 Sterilization

The requirements of ISO 21534:2007, Clause 9, shall apply.

10 Packaging

The requirements of ISO 21534:2007, Clause 10, shall apply.

11 Information to be supplied by the manufacturer

11.1 General

The requirements of ISO 21534:2007, Clause 11, shall apply together with the requirements specified in 11.2 to 11.6.

NOTE Further guidance can be found in ASTM F2943[16].

11.2 Product type and dimensions

The following shall be stated on the label:

a) product type,

b) nominal head diameter (see ISO 7206-1) for a hip joint monobloc femoral component or for a modular femoral head, and

c) nominal diameter (see ISO 7206-1) of the articulating surface of an acetabular component.

11.3 Structural and functional compatibility of components

For a femoral component or a modular femoral head which is intended to be either structurally or functionally compatible, or both, only with specific acetabular cups, the label, instruction for use or surgical technique manual shall state the acetabular cups with which it is compatible.

For an acetabular component which is intended to be structurally and functionally compatible only with specific femoral components, the label, instruction for use or surgical technique manual shall state the femoral components with which it is compatible.

For a femoral component and head of modular construction, the label, instruction for use or surgical technique manual shall state for each, the corresponding components with which they are structurally and functionally compatible.

NOTE In general, components manufactured by one company are not compatible with components manufactured by another company. This applies in particular to modular components which incorporate a male or female taper connection.

11.4 Marking

A monobloc femoral component shall be marked to identify the nominal diameter of the femoral head.

A modular femoral head shall be marked to identify its nominal outer diameter and the characteristics of the cone and bore connection.

The stemmed part of a modular femoral component of a hip joint replacement implant having a male/female cone connection for a modular femoral head shall be marked to identify the category of the connection. Markings should be placed on the planar area at the proximal end of the conical region to which the head is fitted.

An acetabular component which bears the articulating surface of a total hip joint replacement shall be marked to identify the nominal diameter of the articulating surface.

All of these markings shall be legible using normal or corrected vision.