
**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	v
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	1
4 Intended performance	2
5 Design attributes.....	3
5.1 General.....	3
5.2 Tolerances and dimensions	3
5.3 Thickness of UHMWPE in acetabular components and bipolar heads.....	3
6 Materials	3
7 Design evaluation	4
7.1 General.....	4
7.2 Preclinical evaluation	4
8 Manufacture.....	4
9 Sterilization.....	5
10 Packaging	5
11 Information to be supplied by the manufacturer.....	5
11.1 General.....	5
11.2 Dimensions.....	5
11.3 Structural and functional compatibility of components	5
11.4 Marking	5
11.5 Information for the patient	6
Annex A (informative) Evaluation of relative angular motion of components.....	7
Bibliography	9

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21535 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 21535:2002), which has been technically revised.

Introduction

There are three levels of International Standard 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 International Standard is a level 3 standard and contains requirements applying specifically to hip joint replacements.

The level 1 International 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.

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 International Standard provides specific requirements for hip joint replacement implants. With regard to safety, this International Standard specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer, and methods of test.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 7206-2:1996, *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 of stemmed femoral components*

ISO 7206-6:1992, *Implants for surgery — Partial and total hip joint prostheses — Part 6: Determination of endurance properties of head and 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 14630:—¹⁾, *Non-active surgical implants — General requirements*

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

3 Terms and definitions

For the purposes of this document the terms and definitions in ISO 21534 and ISO 7206-1 together with the following apply.

3.1

acetabular component

implant intended to be fixed to the prepared biological acetabulum

NOTE The component can be of monobloc or modular construction.

1) To be published. (Revision of ISO 14630:2005)

3.2

bipolar head

component of a hip joint replacement with a concave (inner) surface intended to articulate with the spherical head of the femoral component and a convex (outer) spherical surface intended to articulate with the biological acetabulum

3.3

femoral component

part of a total or partial hip joint replacement which is intended to be attached to the femur

3.4

hip joint replacement

hip arthroplasty

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

3.5

modular component

femoral or acetabular component that is assembled by the user from a number of sub-components

3.6

monobloc component

femoral or acetabular component that is supplied as a single unit

3.7

partial hip joint replacement

hip hemiarthroplasty

implant comprising a femoral component intended to replace the femoral articulating surface of the hip joint

NOTE 1 Partial hip joint replacement implants incorporate either a bipolar or a unipolar head.

NOTE 2 The component can be of monobloc or modular construction.

3.8

total hip joint replacement

total hip arthroplasty

implant comprising a femoral component and an acetabular component intended to replace both of the articulating surfaces of the hip joints

NOTE The component can be of monobloc or modular construction.

3.9

unipolar head

head of a femoral component intended to articulate with the biological acetabulum

4 Intended performance

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

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

- 100° in flexion/extension;
- 60° in abduction/adduction;
- 90° in internal/external rotation.

NOTE Annex A shows a method by which this can be measured.

5 Design attributes

5.1 General

The requirements of Clause 5 of ISO 21534:2007 shall apply together with the following requirements specified in 5.2 and 5.3.

5.2 Tolerances and dimensions

NOTE Concerning requirements for metal-on-metal and ceramic-on-ceramic articulating surfaces, there is not yet sufficient information on the surface roughness, tolerance on diameters and clearances to allow specification of these parameters in this edition of this International Standard.

5.2.1 Tolerances and dimensions of taper connections

Particular attention should be paid to at least the following: diameter, taper angle, straightness, roundness, micro and macro surface texture.

In the design of modular femoral components the risk of generation of wear particles and occurrence of corrosion at modular component interfaces should be taken into account.

5.2.2 Tolerances on diameters of articulating surfaces

The tolerances on the diameters of the articulating surfaces of metallic or ceramic femoral components intended to be used with ultra-high molecular weight polyethylene (UHMWPE) acetabular components and the tolerance on the diameters of the articulating surface of UHMWPE acetabular components shall be in accordance with ISO 7206-2:1996, 4.1.3 and 4.2.3 respectively.

NOTE The requirements for sphericity and surface finish for UHMWPE on metal and on ceramic are prescribed in ISO 7206-2.

5.3 Thickness of UHMWPE in acetabular components and bipolar heads

5.3.1 Acetabular components

For acetabular components of outside diameter 42 mm or more, the UHMWPE component shall have the following minimum thickness in the loaded sector:

- a) 5 mm for components with a metal or other backing;
- b) 6 mm for components without backing.

5.3.2 Bipolar heads

For bipolar heads of outside diameter ≥ 44 mm, the minimum thickness of UHMWPE liners shall be 5 mm.

NOTE Where the skeletal size of the population for which these implants are intended requires an acetabular component of less than 42 mm diameter or a bipolar component of less than 44 mm diameter it might be necessary to use thickness values less than those specified.

6 Materials

The requirements of Clause 6 of ISO 21534:2007 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.

7 Design evaluation

7.1 General

The requirements of Clause 7 of ISO 21534:2007 shall apply together with the following.

One or more of the tests in 7.2 of ISO 21534:2007 might not be required:

- a) for every component within a range of components (product family);
- b) where the required test results already exist for the same or a similar component.

In these cases a justification for omitting any given test on any given component shall be documented.

7.2 Preclinical evaluation

7.2.1 Endurance testing of femoral components

Femoral components of total hip joint replacement implants shall be tested in accordance with ISO 7206-4. The results of the test shall be recorded.

NOTE Work is in progress to produce a revised version of ISO 7206-4 incorporating test configurations from the test specified in ISO 7206-8 and prescribing the test parameters for cyclic tests to determine the endurance of femoral components with stem lengths in three different ranges.

7.2.2 Endurance properties of head and neck region of stemmed femoral components

The head and neck region of stemmed femoral components shall be tested in accordance with 7.2 of ISO 7206-6:1992.

7.2.3 Pull-off characteristics of heads

The relevant clauses of ISO 7206-10 shall apply.

7.2.4 Wear testing of total 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 a metal, ceramic or UHMWPE acetabular component, shall be tested in accordance with a controlled, validated and documented procedure.

7.2.5 Minimum and maximum angles

The intended minimum and maximum angles between the skeletal parts referred to in 4 a) of ISO 21534:2007 shall be determined as described in Annex A.

8 Manufacture

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

- Implants manufactured from cast cobalt chromium alloys shall be solution treated if appropriate.
- Any heat treatment undertaken shall be recorded and documented.

NOTE One example of solution heat treatment found to be satisfactory is holding the castings for 4 h at a temperature of 1 200 °C.

9 Sterilization

The requirements of Clause 9 of ISO 14630:— shall apply.

10 Packaging

The requirements of Clause 10 of ISO 14630:— shall apply.

11 Information to be supplied by the manufacturer

11.1 General

The requirements of Clause 11 of ISO 14630:—, and Clause 11 of ISO 21534:2007, shall apply together with the following.

11.2 Dimensions

The following shall be recorded on the label, instruction leaflet or manual as indicated:

- a) product type;
- b) nominal head diameter (see ISO 7206-1) for a hip joint monobloc femoral component or for a modular femoral head (label, instruction leaflet and/or manual);
- c) nominal diameter (see ISO 7206-1) of the articulating surface of an acetabular component (label, instruction leaflet and/or manual);
- d) symbols defining the connection between head and neck for a modular implant (instruction leaflet and/or manual).

11.3 Structural and functional compatibility of components

11.3.1 For a femoral component or a modular femoral head which is intended to be structurally and functionally compatible only with specific acetabular cups, the label, instruction leaflet or manual shall state the acetabular cups with which it is compatible.

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

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

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

11.4 Marking

11.4.1 The nominal diameter of the femoral head shall be marked on a monobloc femoral component.

11.4.2 A mark or marks shall be placed on a modular femoral head to identify its nominal outer diameter and the characteristics of the cone and bore connection. This marking shall be legible using normal or corrected vision.

11.4.3 The stemmed part of a modular femoral component of a hip joint replacement implant having a male/female cone connection for a modular head shall carry a mark indicating the category of the connection provided that this does not impair the intended function of the component. Marking shall be placed on the neck of the femoral component of a hip replacement implant for identification or other reasons, only if it is demonstrated that it does not impair the endurance strength. For implants with modular heads, the marking should be placed on the plane area at the proximal end of the conical region to which the head is fitted. This marking shall be legible using normal or corrected vision.

11.4.4 The acetabular component which bears the articulating surface of a total hip joint replacement shall carry a mark indicating the nominal diameter of the articulating surface. This marking shall be legible using normal or corrected vision.

11.5 Information for the patient

The manufacturer shall include in the instructional leaflet or manual at least the following statement or equivalent.

“Patients receiving hip joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity.”

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