

Second edition
2007-10-01

AMENDMENT 1
2016-11-15

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

AMENDMENT 1

iTeh STANDARD PREVIEW
*Implants chirurgicaux non-actifs — Implants de remplacement
d'articulation — Exigences spécifiques relatives aux implants de
remplacement de l'articulation de la hanche*
(standards.iteh.ai)

AMENDEMENT 1

ISO 21535:2007/Amd 1:2016

<https://standards.iteh.ai/catalog/standards/sist/1256cc80-e9e0-43bd-b0f7-5047962a9aa9/iso-21535-2007-amd-1-2016>



Reference number
ISO 21535:2007/Amd.1:2016(E)

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The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

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

AMENDMENT 1

Page 1, Clause 2

Update the normative references with the following:

ISO 7206-1, *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 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 14630, 2012, *Non-active surgical implants — General requirements*

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

Page 3, 5.2.2

Delete the year and cited subclauses in the text to read:

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.

Delete the NOTE then add the following subclauses after 5.2.2:

5.2.3 Sphericity of femoral heads and plastic acetabular components

For femoral heads of total hip replacements and for plastic acetabular components the sphericity shall be in accordance with the requirements given in ISO 7206-2.

5.2.4 Surface finish of femoral heads and plastic acetabular components

For femoral heads of total hip replacements and for plastic acetabular components the surface finish shall be in accordance with the requirements given in ISO 7206-2.

Page 4, 7.2.1

Replace the text with the following sentence:

Stemmed femoral components of total hip replacement implants shall be tested in accordance with ISO 7206-4 and shall satisfy the performance requirements given in ISO 7206-4.

Delete the NOTE.

Page 4, 7.2.2

Delete “head and” in the subheading title to read:

7.2.2 Endurance properties of neck region of stemmed femoral components

Replace text with the following sentence:

The neck region of stemmed femoral components shall be tested in accordance with ISO 7206-6 and shall satisfy the performance requirements given in ISO 7206-6.

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Page 4, 7.2.3

Add the word “femoral” before “heads” in the subheading title, to read:

7.2.3 Pull-off characteristics of femoral heads

Page 4, 7.2.4

Replace the text with the following sentence:

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 either ISO 14242-1 or ISO 14242-3, and the amount of wear shall be measured in accordance with ISO 14242-2.

Add the following sentence as a NOTE:

NOTE Additional wear tests may be necessary to simulate adverse or other clinically relevant conditions. Possible test methods are included in the Bibliography.

Page 5, Clauses 9 and 10, and 11.1

Replace the “—” in ISO 14630:— with the actual year “2012”.

Page 9, Bibliography

Delete bibliography entries [1] to [5]. Add a new reference [1] so the Bibliography reads as follows:

[1] ASTM F3047M-15, *Standard Guide for High Demand Hip Simulator Wear Testing of Hard-on-hard Articulations*

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