
**Implants for surgery — Partial and total hip
joint prostheses —**

Part 2:

Articulating surfaces made of metallic, ceramic
and plastics materials

*Implants chirurgicaux — Prothèses partielles et totales de l'articulation de la
hanche —*

*Partie 2: Surfaces articulaires constituées de matériaux métalliques,
céramiques et plastiques*



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.

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.

International Standard ISO 7206-2 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 7206-2:1987), which has been technically revised.

ISO 7206 consists of the following parts, under the general title *Implants for surgery — Partial and total hip joint prostheses*:

- *Part 1: Classification and designation of dimensions*
- *Part 2: Articulating surfaces made of metallic, ceramic and plastics materials*
- *Part 3: Determination of endurance properties of stemmed femoral components without application of torsion*
- *Part 4: Determination of endurance properties of stemmed femoral components with application of torsion*
- *Part 5: Determination of resistance to static load of head and neck region of stemmed femoral components*
- *Part 6: Determination of endurance properties of head and neck region of stemmed femoral components*

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- *Part 7: Endurance performance of stemmed femoral components without application of torsion*
- *Part 8: Endurance performance of stemmed femoral components with application of torsion*
- *Part 9: Determination of resistance to torque of head fixation of stemmed femoral components*

Annex A forms an integral part of this part of ISO 7206.

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Implants for surgery — Partial and total hip joint prostheses —

Part 2:

Articulating surfaces made of metallic, ceramic and plastics materials

1 Scope

This part of ISO 7206 specifies requirements for the articulating surfaces of those types of total and partial hip joint prostheses that provide a joint replacement of ball and socket configuration, as follows:

- a) sphericity and surface finish requirements for metallic and ceramic femoral prostheses for partial hip joint replacement that are in accordance with classification a) of ISO 7206-1;
- b) sphericity and surface finish requirements for bipolar heads with plastics inner surfaces which articulate on femoral components that are in accordance with classification a) of ISO 7206-1 and with metallic or ceramic outer surfaces which articulate on the biological acetabulum;
- c) sphericity and surface finish requirements and dimensional tolerances for plastics acetabular components that are in accordance with classification b) of ISO 7206-1;
- d) sphericity and surface finish requirements and dimensional tolerances for metallic or ceramic femoral components of total hip joint prostheses that are in accordance with classification c) of ISO 7206-1, designed to articulate on plastics acetabular components.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7206. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this

part of ISO 7206 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 468:1982, *Surface roughness — Parameters, their values and general rules for specifying requirements*.

ISO 7206-1:1995, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*.

3 Definitions

For the purposes of this part of ISO 7206, the definitions given in ISO 7206-1 apply.

4 Requirements

4.1 Femoral components of total hip joint prostheses

NOTE 1 This subclause refers to spherical articulating surfaces of femoral components of total joint hip prostheses in accordance with classification c) of ISO 7206-1.

4.1.1 Sphericity

When measured in accordance with the method given in A.1, the departure from sphericity of the spherical articulating surface of a femoral component shall have a radial separation value not greater than 10 µm.