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

Part 2:

**Articulating surfaces made of metallic,
ceramic and plastics materials**

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

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

ISO 7206-2:2011

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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 7206-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This third edition cancels and replaces the second edition (ISO 7206-2:1996), 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 4: Determination of endurance properties and performance of stemmed femoral components*
- *Part 6: Determination of endurance properties of head and neck region of stemmed femoral components*
- *Part 8: Endurance performance of stemmed femoral components with application of torsion*
- *Part 10: Determination of resistance to static load of modular femoral heads*

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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 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 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 4288:1996, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

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

3 Terms and definitions

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

3.1 spherical pole
point created by the intersection of the axis of symmetry of the partial sphere of the head or cup with the spherical surface of the head or cup

4 Requirements

4.1 Femoral components of total hip joint prostheses

4.1.1 General

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

4.1.2 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 .

4.1.3 Surface finish

When measured in accordance with the principles given in ISO 4287 and performed according to the max.-rule in ISO 4288:1996, 5.3, the spherical articulating surfaces of metallic and ceramic components shall have R_{max} values not greater than 0,05 μm and 0,02 μm respectively and an R_{tmax} value not greater than 1,0 μm , using a cut-off value of 0,08 mm. The measurements shall be taken at five locations on the spherical surface. One measurement shall be taken in each of four quadrants approximately 30° from the spherical pole and one at the spherical pole. The following details shall be reported along with the R_{max} value:

- a) stylus tip radius;
- b) position of measurement on specimen;
- c) average R_a .

When examined by normal or corrected vision, the articulating surface shall be free from embedded particles and from scratches and score marks other than those arising from the finishing process.

4.1.4 Dimensional tolerances

The spherical head shall have a diameter equal to the nominal diameter within a tolerance of $-0,2$ mm to 0 mm, i.e. it shall be undersized within the given tolerance.

4.2 Plastics acetabular components

4.2.1 General

This subclause refers to plastics acetabular components for total hip joint replacements in accordance with classification b) of ISO 7206-1.

4.2.2 Sphericity

When measured in accordance with the method given in A.2, the departure from sphericity shall have a radial separation value no greater than 100 μm .

4.2.3 Surface finish

When measured in accordance with the principles given in ISO 4288, the spherical articulating surface of the implant shall have an R_a value not greater than 2 μm , using a cut-off value of 0,08 mm. The measurements shall be taken at five locations evenly distributed around the equator of the acetabular component on the spherical surface. The locations shall be at least 5 mm from the edge of the acetabular component and the measurement direction shall be oriented approximately perpendicular to any machining marks that are present.

NOTE Although ISO 4288 requires a cut-off of 0,8 mm if the surface finish approaches 2 μm , a cut-off value as long as that is not practical due to the curvature of the spherical surface.

The following details shall be reported along with the measured values:

- a) stylus tip radius;
- b) position of measurement on specimen;
- c) average R_a .

When examined by normal or corrected vision, the articulating surface shall be free from embedded particles and from scratches and score marks other than those arising from the finishing process.

4.2.4 Dimensional tolerances (standards.iteh.ai)

The spherical socket shall have a diameter equal to the nominal diameter within a tolerance of +0,1 mm to +0,3 mm at a temperature of $20\text{ }^\circ\text{C} \pm 2\text{ }^\circ\text{C}$, i.e. it shall be oversized within the given tolerance.

4.3 Femoral prostheses for partial joint replacements

4.3.1 General

This subclause refers to spherical articulating surfaces of femoral prostheses for partial joint replacements in accordance with classification a) of ISO 7206-1.

4.3.2 Sphericity

When measured in accordance with the method given in A.1, the departure from sphericity of the spherical articulating surface shall have a radial separation value no greater than 100 μm .

4.3.3 Surface finish

When measured in accordance with the principles given in ISO 4287, the spherical articulating surface of the implant shall have an R_a value not greater than 0,5 μm and an R_t value not greater than 1,0 μm , using a cut-off value of 0,08 mm.

The following details shall be reported along with the measured values:

- a) stylus tip radius;
- b) position of measurement on specimen.

When examined by normal or corrected vision, the articulating surface shall be free from embedded particles and from scratches and score marks other than those arising from the finishing process.

4.3.4 Dimensional tolerances

The tolerance for the spherical head shall be $\pm 0,5$ mm on the nominal diameter.

4.4 Bipolar heads

4.4.1 General

This subclause refers to bipolar heads for femoral prostheses consisting of a concave (inner) spherical surface in a plastics component intended to articulate with a femoral component of a partial or total hip joint. The bipolar head also has a convex (outer) spherical surface which is intended to articulate with the biological acetabulum.

4.4.2 Inner articulating surface

The inner articulating surface of the plastics part of a bipolar head shall conform to 4.2.

4.4.3 Outer articulating surface

The outer articulating surface of a bipolar head shall conform to 4.3.

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Annex A (normative)

Determination of radial separation value

A.1 Femoral ball

Measurements shall be made using a three-dimensional measuring machine with a measuring stylus which will allow contact with any point on the articulating surface to be tested. For the measurement, the sphere is divided into 90° quadrants projected down from the spherical pole. Each of these 90° quadrants is divided again at the equator of the sphere to form sectors. This means that there are eight sectors on any sphere. A minimum of 15 measurement points shall be made in each sector. These measurement points shall be evenly distributed in the sector, covering a major portion of the sector. They can be in a line or near linear as long as the path covers at least 50 % of the longest line that can be made in the sector. At least five points shall be collected within 3° of the spherical pole. See Figure A.1.

Another method for measurement consists of using a scanning technique with a three-dimensional measuring machine and dividing the sphere into two 90° segments from the spherical pole. For each segment, an angle of 200° (2 × 100° from the spherical pole) is measured. The actual sphericity is determined using Gaussian distribution.

NOTE With state-of-the-art three-dimensional measuring machines, it is common to register individual points used in the calculation a distance of at least 100 µm apart for a proper determination of the radial separation value. See Figure A.1.

Determine, using the least-squares method, the average diameter, D , and the coordinates of the centre O of the sphere of average diameter.

Calculate, for each of the measurement points, P, the radial separation value, r_s , using the equation:

$$r_s = \text{distance OP} - 0,5 D$$

The radial separation value referred to in 4.1.2 shall be the greatest of these calculated values.

A.2 Acetabular cup

Measurements shall be made using a three-dimensional measuring machine with a measuring stylus which will allow contact with any point on the articulating surface to be tested. For the measurement, the concave spherical surface is divided into 90° quadrants projected down from the spherical pole. This means that there are four quadrants on the concave spherical surface. A minimum of 25 measurement points shall be made in each quadrant. These measurement points shall be evenly distributed in the quadrant, covering a major portion of the quadrant. They can be in a line or near linear as long as the path covers at least 50 % of the longest line that can be made in the quadrant. At least five points shall be collected within 3° of the spherical pole. See Figure A.2.

Another method for measurement consists of using a scanning technique with a three-dimensional measuring machine and dividing the sphere into four 45° quadrants from the spherical pole (deepest point of the concave sphere). For each quadrant, an angle of 140° (2 × 70° from the spherical pole) is measured. The actual sphericity is determined using Gaussian distribution.

Plane A-A shall be a diametral plane or, if the articulating surface extends to less than half of a circumference, it shall intersect the articulating surface within 1 mm of its border. The spherical pole shall lie on the perpendicular line drawn from the centre of the plane A-A.