INTERNATIONAL STANDARD

Implants for surgery — Partial and total hip joint prostheses —

Part 2:
Articulating surfaces made of metallic, ceramic and plastics materials

iTeh STANDARD PREVIEW

(standards.iteh.ai)

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

ISO 7206-2:1996

https://standards.iteh.ai/catalog/standards/sist/b05ab20c-8d74-4446-b515-

Partie 2: Surfaces articulaires constituées de matériaux métalliques,
6f2435175d15/iso-7206-2-1996
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*

— *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.

This page intentionally left blank

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.

1

4.1.2 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical articulating surfaces of metallic and ceramic components shall have R_a values not greater than 0,05 µm and 0,02 µm respectively, using a cutoff value of 0,08 mm.

The following details should be reported:

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.

4.1.3 Dimensional tolerances

The spherical head shall have a diameter equal to the nominal diameter within a tolerance of −0,2 mm to 0 mm.

4.2 Plastics acetabular components

NOTE 2 This subclause refers to plastics acetabular components for total hip joint replacements in accordance with classification b) of ISO 7206-1.

4.2.1 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.

4.2.2 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical articulating surface of the implant shall have an R_a value not greater than 2 µm, using a cutoff value of 0,08 mm.

The following details should be reported:

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.

4.2.3 Dimensional tolerances

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 °C ± 2 °C (i.e. it shall be oversized within the given tolerance).

4.3 Femoral prostheses for partial joint replacements

NOTE 3 This subclause refers to spherical articulating surfaces of femoral prostheses for partial joint replacements in accordance with classification a) of ISO 7206-1.

4.3.1 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.

4.3.2 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical articulating surface of the implant shall have an R_a value not greater than 0,5 µm, using a cutoff value of 0,08 mm.

The following details should be reported:

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.

4.3.3 Dimensional tolerances

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

4.4 Bipolar heads

NOTE 4 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 has also a convex (outer) spherical surface which is intended to articulate with the biological acetabulum.

4.4.1 Inner articulating surface

The inner articulating surface of the plastics part of a bipolar head shall comply with 4.2.

4.4.2 Outer articulating surface

The outer articulating surface of a bipolar head shall comply with 4.3.

Annex A

(normative)

Determination of radial separation value

A.1 Femoral ball

Using a three-dimensional measuring machine with a measuring stylus which will allow contact with any point on the articulating surface to be tested, measure the coordinates of 25 points P′ on the articulating surface, 8 spaced equally round the circumference in each of the planes AA, BB and CC, and 1 point at the pole (P) (see figure A.1).

The pole is the intersection of the axis of the neck with the articulating surface. Planes AA, BB and CC shall be perpendicular to the axis of the neck. If the articulating surface extends to half of the circumference or to more than half, AA shall be a diametral plane, otherwise it shall intersect the articulating surface within 1 mm of its border.

Angles a, b and c define the positions of the planes AA, BB and CC relative to the neck axis and shall meet the following requirements:

$$c = a/3$$

$$b = 2a/3$$

NOTE 5   If AA is a diametral plane, $a = 90°$, $b = 60°$ and $c = 30°$.

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 25 measurement points P′, the radial separation value R_s, using the equation:

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

The radial separation value referred to in 4.1.1 shall be the greatest of these calculated values.

A.2 Acetabular cup

Using a three-dimensional measuring machine with a measuring stylus which will allow contact with any point on the articulating surface to be tested, measure the coordinates of 25 points P′ of the articulating surface, 8 spaced equally round the circumference in each of the planes AA, BB and CC, and 1 point at the pole (P) (see figure A.2).

Plane AA 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 pole shall lie on the perpendicular drawn from the centre of the plane AA.

Angles a, b and c define the positions of the planes AA, BB and CC relative to the axis through the pole and shall meet the following requirements:

$$c = a/3$$

$$b = 2a/3$$

NOTE 6   If AA is a diametral plane, $a = 90°$, $b = 60°$ and $c = 30°$.

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 25 measurement points P′, the radial separation value R_s, using the equation:

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

The radial separation value referred to in 4.2.1 shall be the greatest of these calculated values.

Dimensions in millimetres
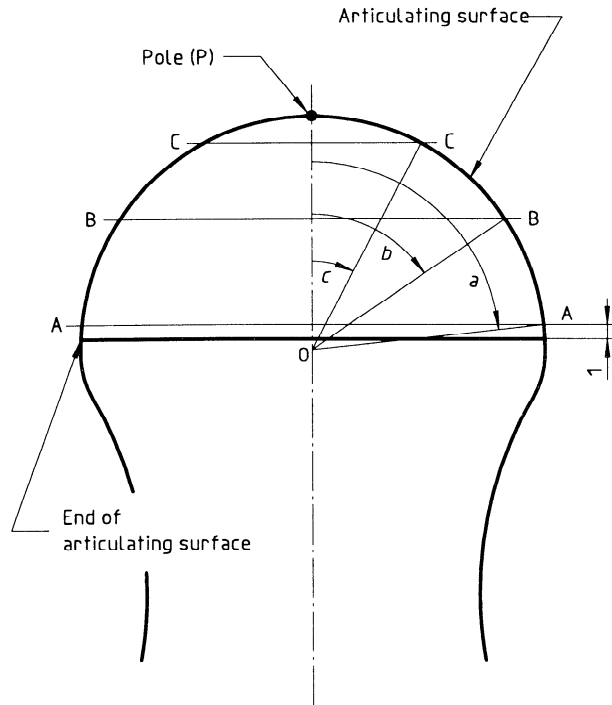
Figure A.1 — Location of points to be measured on the spherical head

Dimensions in millimetres
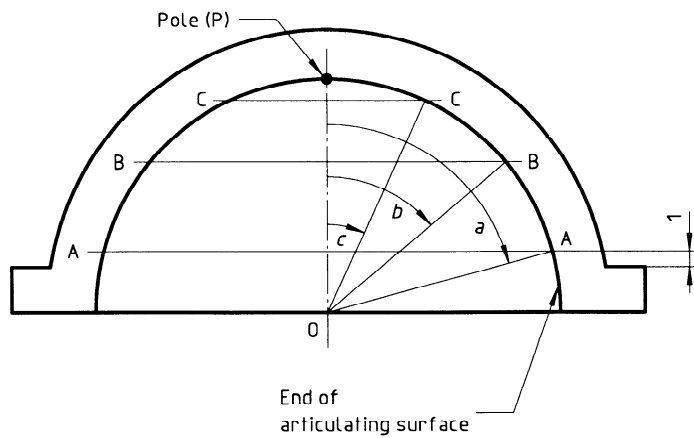
Figure A.2 — Location of points to be measured on the acetabulum

This page intentionally left blank