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

### Part 2 :

Bearing surfaces made of metallic and plastics materials

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

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

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 7206-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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

## Part 2 : Bearing surfaces made of metallic and plastics materials

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### 0 Introduction

This International Standard covering partial and total hip joint prostheses comprises the following four parts :

Part 1 : Classification, designation of dimensions and requirements.

Part 2 : Bearing surfaces made of metallic and plastics materials (this part of ISO 7206).

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.

### 1 Scope and field of application

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

- a) roundness and surface finish requirements and dimensional tolerances for metal femoral components of total hip joint prostheses that are in accordance with classification c) of ISO 7206-1;
- b) surface finish requirements and dimensional tolerances for plastics acetabular components that are in accordance with classification b) of ISO 7206-1;
- c) roundness and surface finish requirements for metal femoral prostheses for partial hip joint replacement that are in accordance with classification a) of ISO 7206-1.

### 2 References

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

ISO 4291, *Methods for the assessment of departure from roundness — Measurement of variations in radius.*

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

### 3 Requirements

#### 3.1 Total hip joint prostheses

3.1.1 Femoral component [in accordance with classification c) of ISO 7206-1]

##### 3.1.1.1 Roundness

When measured in accordance with the minimum zone centre (MZC) method given in ISO 4291, the departure from roundness in more than one plane of the spherical bearing surface of a femoral component made of stainless steel or cobalt-based alloy shall have a radial separation value not greater than 5  $\mu\text{m}$ , and that of a femoral component made of titanium alloy shall have a value not greater than 8  $\mu\text{m}$ .

##### 3.1.1.2 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical bearing surface of a femoral component made of stainless steel or cobalt-based alloy shall have an  $R_a$  value not greater than 0,05  $\mu\text{m}$ , and that of a femoral compo-

ment made of titanium alloy shall have an  $R_a$  value not greater than  $0,1 \mu\text{m}$ .

NOTE — The following details should be reported :

- a) stylus tip radius;
- b) cut-off length of measuring instrument;
- c) position of measurement on specimen.

When inspected visually under X2 magnification, the head of the component shall be free from embedded particles, defects with raised edges, and from scratches and score marks.

### 3.1.1.3 Dimensional tolerances

The spherical bearing surface shall have a diameter equal to the nominal diameter within a tolerance of  $\begin{matrix} 0 \\ -0,2 \end{matrix}$  mm.

## 3.1.2 Plastics acetabular component [in accordance with classification b) of ISO 7206-1]

### 3.1.2.1 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical bearing surface of the acetabular component shall have an  $R_a$  value not greater than  $2 \mu\text{m}$ .

NOTE — The following details should be reported :

- a) stylus tip radius;
- b) cut-off length of measuring instrument;
- c) position of measurement on specimen.

When inspected with normal or corrected vision, the bearing surface shall be free from scale, embedded particles and from

scratches and score marks other than those arising from the finishing process.

### 3.1.2.2 Dimensional tolerances

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

## 3.2 Metal femoral prostheses for partial joint replacement [in accordance with classification a) of ISO 7206-1]

### 3.2.1 Roundness

When measured in accordance with the MZC method given in ISO 4291, the departure from roundness in more than one plane of the spherical bearing surface of femoral prostheses made of stainless steel, cobalt-based alloy or titanium alloy shall have a radial separation value not greater than  $70 \mu\text{m}$ .

### 3.2.2 Surface finish

When measured in accordance with the principles given in ISO 468, the spherical bearing surface of femoral components made of stainless steel, cobalt-based alloy or titanium alloy shall have an  $R_a$  value not greater than  $0,5 \mu\text{m}$ .

NOTE — The following details should be reported :

- a) stylus tip radius;
- b) cut-off length of measuring instrument;
- c) position of measurement on specimen.