
**Implants for surgery — Components for
partial and total knee-joint prostheses —**

Part 2:

Articulating surfaces made of metal, ceramic
and plastics materials

iTeh STANDARD PREVIEW

*Implants chirurgicaux — Éléments de prothèses partielle et totale de
l'articulation du genou*

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

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Foreword

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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 7207-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

ISO 7207 consists of the following parts, under the general title *Implants for surgery — Components for partial and total knee-joint prostheses*:

- *Part 1: Classification, definitions and designation of dimensions.*
- *Part 2: Articulating surfaces made of metal, ceramic and plastics materials.*

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Printed in Switzerland

Implants for surgery — Components for partial and total knee-joint prostheses —

Part 2:

Articulating surfaces made of metal, ceramic and plastics materials

1 Scope

This part of ISO 7207 specifies surface finish requirements for the articulating surfaces of total and partial knee-joint prostheses that are classified in accordance with ISO 7207-1.

2 Normative reference

ISO 7207-2:1998

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The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 7207. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7207 are encouraged to investigate the possibility of applying the most recent edition of the standard listed 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.*

3 Surface finish requirements

3.1 Total knee-joint prostheses

3.1.1 Metallic or ceramic femoral components

When measured in accordance with ISO 468, the articulating surface of a metallic or ceramic femoral component shall have an R_a value not greater than 0,1 μm , using a cut-off value of 0,08 mm.

The following details should be reported:

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

When examined with normal or corrected vision, the articulating surface shall be free from embedded particles, defects, raised edges and from scratches and score marks.

3.1.2 Plastics tibial and patella components

When measured in accordance with ISO 468, the articulating surface of a tibial and patella component shall have an R_a value not greater than 2 μm , using a cut-off value of 0,08 mm.

The following details should be reported:

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

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

3.2 Metallic or ceramic femoral prostheses for partial knee-joint replacement

When measured in accordance with ISO 468, the articulating surface of a metallic or ceramic femoral component shall have an R_a value not greater than 0,5 μm , using a cut-off value of 0,08 mm.

The following details should be reported:

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

When examined with normal or corrected vision, the articulating surface shall be free from embedded particles, defects, raised edges and from scratches and score marks.

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ICS 11.040.40

Descriptors: medical equipment, surgical implants, joints (articulation), knees, prosthetic devices, specifications.

Price based on 2 pages
