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

Part 2:

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

*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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Published in Switzerland

Foreword

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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 7207-2 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 7207-2:1998), which has been technically revised.

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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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 classified in ISO 7207-1. This part of ISO 7207 is intended to provide guidance for periodic validation of production processes.

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*

3 Surface finish requirements

3.1 General

All surface finish measurements shall be performed according to the max.-rule in ISO 4288:1996, 5.3. The max.-rule states that no measurement values shall exceed the specified *R_{max}*.

3.2 Knee joint prostheses

3.2.1 Metallic or ceramic femoral components

When measured in accordance with ISO 4287, all articulating surfaces of a metallic or ceramic femoral component shall be measured across the full articulating surface at locations in an approximately square grid of locations no more than 10 mm apart. The component shall have an *R_{max}* value $\leq 0,1 \mu\text{m}$, using a cut-off value of 0,08 mm.

NOTE The patellar flange is considered an articulating surface in bicompartamental, tricompartmental and patellar femoral replacement systems.

The following details should be reported along with the surface roughness, R_a , values:

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

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

3.2.2 Metallic or ceramic tibial articulating components of a mobile bearing knee

When measured in accordance with ISO 4287, all articulating surfaces of a metallic or ceramic tibial component shall be measured across the full articulating surface at locations in an approximately square grid of locations no more than 10 mm apart. The component shall have an R_{max} value $\leq 0,1 \mu\text{m}$, using a cut-off value of 0,08 mm.

The following details should be reported along with the surface roughness, R_a , values:

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

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

3.2.3 Plastics tibial and patella components

When measured in accordance with ISO 4287, all articulating surfaces of a tibial and patella component shall be measured across the full articulating surface at locations in an approximately square grid of locations no more than 10 mm apart. The component shall have an R_{max} value $\leq 2 \mu\text{m}$, using a cut-off value of 0,08 mm. The following details should be reported along with the measured surface roughness, R_a , values:

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

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