

# DRAFT AMENDMENT ISO 7207-2:2011/DAM 1

ISO/TC 150/SC 4

Secretariat: BSI

Voting begins on:  
2016-02-03

Voting terminates on:  
2016-05-03

---

---

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

Part 2:

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

#### AMENDMENT 1

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

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

AMENDEMENT 1

ICS: 11.040.40

**ITeH STANDARD PREVIEW**  
(standards.iteh.ai)  
Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/bcca17-fce4-415d-aa3c-92a731990f4a/iso-7207-2-2011-dam-1-2016>

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.



Reference number  
ISO 7207-2:2011/DAM 1:2015(E)

© ISO 2015

**iTeh STANDARD PREVIEW**  
(standards.iteh.ai)  
Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/a3cca17-fce4-415d-aa3c-92a731990f4a/iso-7207-2-2011-amd-1-2016>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
copyright@iso.org  
www.iso.org

## 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.

Amendment 1 to ISO 7207-2:2011 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

**ITeH STANDARD PREVIEW**  
(standards.iteh.ai)  
Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/a3cc017-fce4-415d-aa3c-92a731990f4a/iso-7207-2-2011-amd-1>  
2016

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/a3cca17-fce4-415d-aa3c-92a731990f4a/iso-7207-2-2011-amd-1-2016>

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

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

### AMENDMENT 1

#### Changes to clause 2: Normative references

Add the following standard (see text in green)

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 7207-1:2007 Implants for surgery -- Components for partial and total knee joint prostheses -- Part 1: Classification, definitions and designation of dimensions

#### Changes to clause 3.1: General

→ amend to read:

The principles for the surface finish measurements of knee joint prostheses components are given in ISO 4287. The measurements shall be performed according to the rules and procedures described in ISO 4288:1996.

#### Changes to clause 3.2.1: Metallic or ceramic femoral components

→ amend to read:

When measured in accordance with ISO 4288, 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 **0,25 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.

**Changes to clause 3.2.2: Metallic or ceramic tibial articulating components of a mobile bearing knee**

→ *amend to read:*

When measured in accordance with ISO 4288, 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 **0,25** 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.

**Changes to clause 3.2.3: Plastics tibial and patella components**

→ *amend to read:*

When measured in accordance with ISO 4288, 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 **0,8** 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.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/a3cca17-fce4-415d-aa3c-92a731990f4a/iso-7207-2-2011-amd-1-2016>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

Full standard:  
<https://standards.iteh.ai/catalog/standards/sist/a3cca17-fce4-415d-aa3c-92a731990f4a/iso-7207-2-2011-amd-1-2016>