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AMENDMENT 1
2016-08-15

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

Part 2:

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

AMENDMENT 1

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

<https://standards.iteh.ai/catalog/standards/sist/a15cca17-fce4-415d-aa3c-92a731>

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

AMENDEMENT 1



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The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

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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

AMENDMENT 1

Page 1, Clause 2

Add the following normative reference and delete it in the Bibliography:

“ISO 7207-1, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*”

Page 1, 3.1

Replace the subclause with the following:

“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.”

Page 1, 3.2.1

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<https://standards.iteh.ai/catalog/standards/sist/af3cca17-fce4-415d-aa3c-92a731990f4a/iso-7207-2-2011-amd-1-2016>

Replace the first paragraph with the following:

“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.”

Page 2, 3.2.2

Replace the first paragraph with the following:

“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.”

Page 2, 3.2.3

Replace the first paragraph with the following:

“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:”

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