INTERNATIONAL STANDARD

ISO 7207-2

Second edition
2011-07-01

AMENDMENT 2
2020-06

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

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

AMENDMENT 2

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 2

Reference number
ISO 7207-2:2011/Amd.2:2020(E)

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Published in Switzerland

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This document was prepared by Technical Committee 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 2

3.2.1, first paragraph

Replace the 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 articulating surface at characteristic locations. The component shall have a Ra_{max} value of ≤0,1 µm, using a cut-off value of 0,25 mm.

When analysing a bi- or tri- compartmental knee joint prosthesis, the roughness of the lateral and medial condyle of the femoral component each shall be measured

a) at a location on the articulating surface in contact at 0° flexion,

b) at a location on the articulating surface in contact at 30° flexion, and

c) at a location on the articulating surface in contact at 60° flexion or higher angulation.

When analysing a tri-compartmental knee joint prosthesis, the patellar flange of the femoral component shall be measured at three evenly distributed locations at the articulating surface.

When analysing a uni-compartmental knee joint prosthesis, the roughness of the femoral component condyle shall be measured

a) at a location on the articulating surface in contact at 0° flexion,

b) at a location on the articulating surface in contact at 30° flexion, and

c) at a location on the articulating surface in contact at 60° flexion.

When analysing a patello-femoral knee joint prosthesis, the patellar flange of the femoral component shall be measured at three evenly distributed locations at the articulating surface.

3.2.1, NOTE

Delete the NOTE.

3.2.2, first paragraph

Replace the 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 articulating surface at characteristic locations. The component shall have a Ra_{max} value of ≤0,1 µm, using a cut-off value of 0,25 mm.

When analysing a bi- or tri compartmental knee joint prosthesis, the roughness at six evenly distributed locations at the articulating surface of the tibial component (three locations at the medial side and three locations at the lateral side) shall be measured.

When analysing a uni-compartmental knee joint prosthesis, the roughness at three evenly distributed locations at the articulating surface of the tibial component shall be measured.

3.2.3, first paragraph

Replace the 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 articulating surface at characteristic locations. The component shall have a Ra_{max} value ≤2 µm, using a cut-off value of 0,8 mm.

When analysing a bi- or tri compartmental knee joint prosthesis, the roughness at six evenly distributed locations at the articulating surface of the plastic tibial component (three locations at the medial side and three locations at the lateral side) shall be measured. The measurement direction shall be oriented approximately perpendicular to any machining marks that are present. If the tibial component allows for articulation at the tibial side (e.g. mobile bearing), measurements at the femoral side as well as at the tibial side shall be performed (six locations at the femoral side and six locations at the tibial side of the tibial component). If the tibial component provides a post, measurements at the post shall be performed as well. The measurements shall be taken at three evenly distributed locations at the intended articulating surface.

When analysing a uni-compartmental knee joint prosthesis, the roughness at three evenly distributed locations at the articulating surface of the plastic tibial component) shall be measured. The measurement direction shall be oriented approximately perpendicular to any machining marks that are present. If the tibial component allows for articulation at the tibial side (e.g. mobile bearing), measurements at the femoral side as well as at the tibial side shall be performed (three locations at the femoral side and three locations at the tibial side of the tibial component).

When analysing a patello-femoral knee joint prosthesis, the roughness at three evenly distributed locations at the articulating surface of the plastic patella component shall be measured. The measurement direction shall be oriented approximately perpendicular to any machining marks that are present.

The following details should be reported along with the measured surface roughness, *Ra*, values: