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AMENDMENT 1
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Implants for surgery — Partial and total hip joint prostheses —

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

AMENDMENT 1

Implants chirurgicaux — Prothèses partielles et totales de l'articulation de la hanche —

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*.

Implants for surgery — Partial and total hip joint prostheses —

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

AMENDMENT 1

Page iii, Foreword

Remove the following part, as it was withdrawn:

— *Part 8: Endurance performance of stemmed femoral components with application of torsion*

Page 2, subclause 4.1.1

This subclause refers to spherical articulating surfaces of femoral components of total hip joint prostheses in accordance with classification c) of ISO 7206-1.

Add to the existing text the following sentence:

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

Page 2, subclause 4.1.3

Amend to read:

"The spherical articulating surfaces of metallic and ceramic components shall have *Ramax* values not greater than 0,05 µm and 0,02 µm respectively. ISO 4288:1996, Table 1, requires using a cut-off value of 0,25 mm for the 0,05 µm requirement and requires using a cut-off value of 0,08 mm for the 0,02 µm requirement. The *Rtmax* value shall not be greater than 1,0 µm. The cut-off value used to determine the *Rt* value shall be in accordance with ISO 4288:1996, Table 2.

The measurements shall be taken at five locations on the spherical surface. One measurement shall be taken in each of four quadrants approximately 30° from the spherical pole and one at the spherical pole. The following details shall be reported along with the *Ramax* value:

a) stylus tip radius;

b) position of measurement on specimen;

c) average *Ra* of the five locations measured.

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

Page 2, subclause 4.2.1

This subclause refers to plastics acetabular components for total hip joint prostheses in accordance with classification c) of ISO 7206-1.

Add the following sentence to the existing text:

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

Page 3, subclause 4.2.3

Remove the following note:

"NOTE Although ISO 4288 requires a cut-off of 0,8 mm if the surface finish approaches 2 µm, a cut-off value as long as that is not practical due to the curvature of the spherical surface."

Amend to read:

"Following the requirements of ISO 4288:1996, Table 1, the spherical articulating surface of the implant shall have a *Ramax* value not greater than 2 µm, using a cut-off value of 0,8 mm.

The measurements shall be taken at five locations evenly distributed around the equator of the acetabular component on the spherical surface. The locations shall be at least 5 mm from the edge of the acetabular component and the measurement direction shall be oriented approximately perpendicular to any machining marks that are present.

The following details shall be reported along with the measured values:

a) stylus tip radius;

b) position of measurement on specimen;

c) average *Ra* of the five locations measured.

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

Page 3, subclause 4.3.1

This subclause refers to spherical articulating surfaces of femoral prosthesis for partial joint replacements in accordance with classification c) of ISO 7206-1.

Add the following sentence to the existing text:

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

Page 3, subclause 4.3.3

Amend to read:

"The spherical articulating surface of the implant shall have an *Ramax* value not greater than 0,5 µm using a cut-off value of 0,8 mm. The *Rtmax* value shall not be greater than 1,0 µm. The cut-off value

used to determine the *Rt* value shall be in accordance with ISO 4288:1996, Table 2. The measurements shall be taken at five locations on the spherical surface. One measurement shall be taken in each of four quadrants approximately 30° from the spherical pole and one at the spherical pole.

The following details shall be reported along with the measured values:

a) stylus tip radius;

b) position of measurement on specimen.

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

Page 4, new subclause 4.5

Add a new subclause 4.5 as follows:

"4.5 Metallic and ceramic acetabular components of total hip joint prostheses

4.5.1 General

This subclause refers to spherical articulating surfaces of acetabular components of total hip joint prosthesis with classification c) of ISO 7206-1.

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

4.5.2 Surface finish

The spherical articulating surfaces of metallic and ceramic components shall have *Ramax* values not greater than 0,05 µm (acknowledging to ASTM F2033). ISO 4288:1996, Table 1, requires using a cut-off value of 0,25 mm for the 0,05 µm requirement."

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