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Implants for surgery — Wear of total knee-joint prostheses —

Part 2: Methods of measurement

Implants chirurgicaux — Usure des prothèses totales de l'articulation du genou —
Partie 2: Méthodes de mesure

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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

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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

This third edition cancels and replaces the second edition (ISO 14243-2:2009), of which it constitutes a minor revision.

ISO 14243 consists of the following parts, under the general title *Implants for surgery — Wear of total knee-joint prostheses*:

— *Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test*

— *Part 2: Methods of measurement*

— *Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test*

The following parts are under preparation

— *Part 5: Loading and displacement parameters for testing machines and corresponding environmental conditions when testing durability performance of the patellofemoral joint*

Implants for surgery — Wear of total knee-joint prostheses —

Part 2: Methods of measurement

1 Scope

This part of ISO 14243 specifies a method of assessment of wear of the tibial component of total knee-joint prostheses using the gravimetric technique for components tested in accordance with ISO 14243-1 or ISO 14243-3 as appropriate.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14243-1, *Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test*

ISO 14243-3, *Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
wear
material loss from components of the prosthetic joint due to combined movement and loading

4 Gravimetric method

4.1 Principle

The test specimen is soaked in a lubricant. It is repeatedly removed from the lubricant, cleaned, dried and weighed until a steady rate of fluid sorption is established. The test specimen is assessed subsequently for wear by testing for loss in mass in a knee-joint simulator. A loaded or unloaded, non-articulating control specimen submerged in the same lubricating fluid medium is intended to allow for fluid sorption and undergoes the same procedure for reference purposes.

4.2 Reagents and materials

4.2.1 Fluid test medium, in accordance with ISO 14243-1 or ISO 14243-3 as appropriate.

4.2.2 Propan-2-ol.

4.3 Apparatus

4.3.1 **Balance**, with an accuracy of ±0,1 mg, of sufficient capacity for the mass of the test specimen.

4.3.2 **Ultrasonic cleaner**.

4.3.3 **Vacuum drying system**, capable of achieving a vacuum of at least 13,33 Pa (100 milliTorr).

4.3.4 **Filtered inert-gas jet**, e.g. nitrogen.

4.4 Test and control specimens

4.4.1 **Test specimen**, conforming to ISO 14243-1 or ISO 14243-3 as appropriate.

4.4.2 **Control specimen**, conforming to ISO 14243-1 or ISO 14243-3 as appropriate.

4.5 Preparation of test and control specimens for gravimetric measurements (pre-soak conditioning)

4.5.1 Soak the test specimen and control specimen in the fluid test medium (4.2.1) for 48 h ± 4 h.

4.5.2 Remove the test specimen and control specimen from the fluid test medium (4.2.1) and clean in the ultrasonic cleaner (4.3.2).

A typical cleaning regime in the ultrasonic cleaner is as follows:

a) vibrate for 10 min in deionized water;

b) rinse in deionized water;

c) vibrate for 10 min in a mixture of ultrasonic cleaning detergent at the concentration recommended by the detergent manufacturer;

d) rinse in deionized water;

e) vibrate for 10 min in deionized water;

f) rinse in deionized water;

g) vibrate for 3 min in deionized water;

h) rinse in deionized water;

i) dry in a vacuum drying chamber (4.3.3).

Care should be taken to avoid abrasion in the ultrasonic cleaner which could lead to a change in mass.

4.5.3 Dry the test specimen and control specimen with a jet of filtered inert gas (4.3.4).

4.5.4 Soak the test specimen and control specimen in propan-2-ol (4.2.3) for 5 min ± 15 s.

4.5.5 Dry the test specimen and control specimen with a jet of filtered inert gas (4.3.4), then dry further in a vacuum of at least 13,3 Pa for at least 30 min.

4.5.6 Weigh the test specimen and control specimen on the balance twice in rotation within 90 min of removal from the vacuum. If the two readings per specimen do not agree within 0,1 mg, continue taking