INTERNATIONAL STANDARD

ISO 14242-2

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

Part 2: Methods of measurement

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

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Contents

Page

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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 second edition cancels and replaces the first edition (ISO 14242-2:2000), of which it constitutes a minor revision.

ISO 14242 consists of the following parts, under the general title *Implants for surgery — Wear of total hip-joint prostheses*:

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

— *Part 2: Methods of measurement*

— *Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test*

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

Part 2: Methods of measurement

1 Scope

This part of ISO 14242 specifies methods of assessment of wear of the acetabular component of total hip-joint prostheses using gravimetric techniques and changes in dimensional form of components tested in accordance with ISO 14242-1 or ISO 14242-3 as appropriate.

NOTE Some investigators have experienced problems with organic deposits affecting the results of measurements, especially with hard/hard combinations. No specific precautions are included in this part of ISO 14242, but cleaning techniques adopted is intended to be suitable for the soils produced.

2 Normative reference

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 14242-1, *Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*

ISO 14242-3, *Implants for surgery — Wear of total hip-joint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines 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-hip simulator. A loaded, non-articulating control specimen 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 14242-1 or ISO 14242-3 as appropriate.

4.2.2 **Control specimen**, in accordance with ISO 14242-1 or ISO 14242-3 as appropriate.

4.2.3 **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.

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

4.4 Preparation of test specimen for gravimetric measurements

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

4.4.2 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 in deionized water 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 change in mass.

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

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

4.4.5 Dry the test specimen and control specimen with a jet of filtered inert gas (4.3.4), then dry further in a vacuum of better than 13,3 Pa ± 0,13 Pa for at least 30 min.

4.4.6 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 are not identical within 0,1 mg, continue taking readings in rotation until at least two readings per specimen are identical within 0,1 mg. Store the test specimen and control specimen in a sealed dust-free container between weighings.