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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

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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).

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).

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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 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.

4.4.7 Repeat 4.4.2 to 4.4.6 at intervals until the incremental mass change of the specimen over 24 h is less than 10 % of the previous cumulative mass change.

4.4.8 Record the average increase in mass S of the control specimen.

4.5 Procedure for gravimetric measurement

4.5.1 Mount the test pieces in the testing machine and conduct the wear test in accordance with ISO 14242-1 or ISO 14242-3 as appropriate.

4.5.2 Record the mass of the specimens.

4.5.3 On each occasion when the test specimen and control specimen are removed from the wear-testing machine, repeat the procedures 4.4.2 to 4.4.6, 4.5.1 and 4.5.2.

4.5.4 Calculate the gravimetric wear as shown in Formula (1):

$$W_n = W_{an} + S_n \tag{1}$$

where

W_n is the net mass loss after n cycles of loading;

W_{an} is the average uncorrected mass loss;

S_n is the average increase in mass of the control specimen over the same period.

4.5.5 Calculate the average wear rate a_G using Formula (2) for the least squares linear fit relationship between W_n and the number of loading cycles n:

$$W_n = a_G \times n + b \tag{2}$$

where W_n is the net loss in mass after n cycles and b is a constant.

The zero time point shall not be used in this calculation.

5 Dimensional change method

5.1 Principle

A coordinate measuring machine is used to map the articulating surface of a total hip prosthesis relative to a reference position, direction and plane prior to the start of the wear test and at suitable intervals during the test. From these data, the volumetric change between measurements is determined. Loaded non-articulating controls are intended to allow the effects of plastic flow, mainly occurring in the first 5×10^5 cycles, to be separated from material loss.

5.2 Apparatus

5.2.1 Three-dimensional coordinate measuring machine, with maximum axial-position error of measurement D, in micrometres, of:

$$D = 4 + 4l \times 10^{-6} \tag{3}$$

where l is the numerical value of the dimension, expressed in metres.

5.2.2 Ultrasonic cleaner.

5.3 Procedure for dimensional change measurement

5.3.1 Select a point of reference, an origin and a plane on the test specimen. Maintain this reference system throughout the procedure.

5.3.2 Clean the specimens.

5.3.3 To ensure dimensional stability, retain the test specimen at the measurement temperature ±2 °C (measured at the normal points of the metrology laboratory) for at least 48 h.

5.3.4 At the beginning of a series of tests, check that relocation of the test specimen does not affect the measured volume by more than 0,05 %.

This may be achieved by the use of fixturing or the recognition of features in software, for example.

5.3.5 Start the measurement machine and produce a full three-dimensional contour mesh of the articulating surface of the test specimen. Ensure the mesh spacing is no greater than 1 mm in the horizontal plane or along any arc.

5.3.6 Calculate the volume V_n of the acetabular cavity, where n is the number of wear cycles which have been applied.

5.3.7 Express the wear as the volume change after n loading cycles, ΔV_n, as shown in Formula (4):

$$\Delta V_n = V_n - V_o \tag{4}$$

where V_o is the original volume.

5.3.8 Insert the test specimen and any control specimen in the testing machine and conduct the tests in accordance with ISO 14242-1 or ISO 14242-3 as appropriate.

5.3.9 On each occasion when the test specimen and the control specimen are removed from the testing machine, repeat procedures 5.3.2 to 5.3.7.

5.3.10 Calculate the wear rate, a_V, using Formula (5) for the least squares linear relationship between ΔV_n and n as:

$$\Delta V_n = a_V \times n + b \tag{5}$$

where b is a constant, using a least squares fit.

When controls are provided, the slope of the line, representing the rate of creep, should be calculated including the zero time point. The zero time point shall not be used in the slope calculation for the wear rate a_V.

6 Test report

The test report shall include the following information:

a) a reference to this part of ISO 14242, i.e. ISO 14242-2;

b) the identity of the test specimens, as stated by the party submitting the specimen for test;

