
**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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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).

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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 $\pm 0,1$ 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 $48\text{ h} \pm 4\text{ h}$.

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 $5\text{ min} \pm 15\text{ s}$.

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

readings in rotation until at least two readings per specimen agree within 0,1 mg. Store the test specimen and control specimen in a sealed dust-free container between weighings.

4.5.7 Repeat 4.5.2 to 4.5.6 at intervals until the incremental mass change of the specimen over 24 h is less than 10 % of the previous cumulative mass change.

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

4.5.9 Take photographic records of all the articulation and fixation surfaces of the specimen. Mark the test sample with reference points so that after the wear test the location of the worn surfaces can be identified relative to the axes of the test sample.

4.6 Procedure for gravimetric measurement

4.6.1 Mount the test specimens in the testing machine and conduct the wear test in accordance with ISO 14243-1 or ISO 14243-3 as appropriate.

4.6.2 Record the mass of the specimens.

4.6.3 On each occasion when the test specimen and control specimen are removed from the wear-testing machine, repeat the procedures in 4.5.2 to 4.5.6, 4.6.1 and 4.6.2.

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

$$W_n = W_{an} + S_n \quad (1)$$

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.

4.6.5 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 :

$$W_n = a_G n + b \quad (2)$$

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.

4.6.6 Take photographic records of the articulating and fixation surfaces.

5 Test report

The test report shall include the following information:

- a reference to this part of ISO 14243, i.e. ISO 14243-2,
- the identity of the test specimens, as stated by the party submitting the specimen for test;
- the method of wear measurement (i.e. gravimetric);

- d) the value W_n for each measurement using the gravimetric method;
- e) the wear rate, a_G ;
- f) a reference to the wear test method used from ISO 14243-1 or ISO 14243-3 as appropriate;
- g) photographic records.

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