INTERNATIONAL STANDARD

ISO 14243-2

Third edition
2016-09-01

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

Reference number
ISO 14243-2:2016(E)

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

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 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.