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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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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14243-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 14243-2:2000), which has been technically revised.

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*

# 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.

### 2 Normative references

The following referenced documents are indispensable for the application of this document. 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 tests*

### 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.

**4.2.2 Control specimen**, in accordance with ISO 14243-1.

**4.2.3 Propan-2-ol.**