
**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**

*Implants chirurgicaux — Usure des prothèses totales de l'articulation
du genou —*

*Partie 3: Paramètres de charge et de déplacement pour machines
d'essai d'usure avec contrôle de déplacement et conditions
environnementales correspondantes d'essai*



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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 (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 (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 replacement*.

This second edition cancels and replaces the first edition (ISO 14243-3:2004) which has been technically revised. It incorporates also the Technical corrigendum ISO 14243-3:2004/Cor 1: 2006.

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 3:

Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test

1 Scope

This part of ISO 14243 describes a test method that specifies flexion/extension relative angular movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the wear testing of total knee-joint prostheses in wear-testing machines having axial load control, flexion/extension angular motion control, AP displacement control and tibial rotation control.

The kinematics of this part of ISO 14243 may not be applicable to knee designs with a high degree of constraint, which could result in damage to the articulating components in the early stages of the test that would not be representative of clinical service.

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 7207-1, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*

ISO 14243-2:2009, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14243-1 and the following apply.

3.1

Anterior/Posterior (AP) displacement

offset between the femoral component and the tibial component, measured in a direction which is perpendicular to both the force and flexion/extension axes

Note 1 to entry: The AP displacement is considered to be zero when the total knee-joint prosthesis is in the *reference position* (3.7) and is considered to be positive when the tibial component is anterior to its position with the total knee-joint prosthesis in the reference position.

3.2

AP force

shear force applied by the tibial on the femoral component along a line of action which is perpendicular to both the tibial axis and the flexion/extension axis and which passes through the axial force axis.

Note 1 to entry: The AP force is considered to be positive when it acts in a posterior-to-anterior direction.