
**Implants for surgery — Wear of total
knee prostheses —**

Part 5:
**Durability performance of the
patellofemoral joint**

Implants chirurgicaux — Usure des prothèses totales du genou —

*Partie 5: Performance de durabilité de l'articulation fémoro-
patellaire*



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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

A list of all parts in the ISO 14243 series can be found on the ISO website.

The main changes compared to the previous edition are as follows:

- In Clause 4, Principle: Total number of cycles has been changed from 220 000 to 50 000;
- [3.14](#), [3.15](#) and [3.16](#) have been changed;
- Figures have been renumbered;
- Failure and damage pattern ([8.14](#)) has been updated;
- a Typo in [Formula \(2\)](#) has been corrected.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is applied for the qualitative visual assessment of durability of an ultra-high molecular weight polyethylene patella when articulating against a femoral component by observing the occurrence of delamination, cracking, or other damage characteristics that occur as a result of the specified displacement and loading inputs.

This standard test method is comprehensive, but it needs to be noted that it is complex to implement - maybe the most complex in its particular field. The reader/user needs to note that:

- 1) The main compressive force waveforms are to be calculated to suit the individual implant (size).
- 2) The waveforms for the kinematics on two testing actuators are calculated to suit the particular geometry of the implant tested involving sophisticated CAD measurements, and in each case thorough care is needed when using degrees or radians for the angle computations in setting up the test.
- 3) Intricate friction sensitive medial-lateral force imposing fixtures are involved, with measurement needed of such force to be provided on the testing machines.

Implants for surgery — Wear of total knee prostheses —

Part 5:

Durability performance of the patellofemoral joint

1 Scope

This document specifies the relative angular movement between articulating patellofemoral joint components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the durability testing of total knee-joint prostheses in wear-testing machines with load control and displacement.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5833, *Implants for surgery — Acrylic resin cements*

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

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

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*

ASTM F2003, *Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7207-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

Applied nomenclature is illustrated in [Figure 1](#).