



BSI Standards Publication

Implants for surgery — Wear of total knee prostheses

Part 5: Durability performance of the patellofemoral joint

National foreword

This British Standard is the UK implementation of ISO 14243-5:2019.

The UK participation in its preparation was entrusted to Technical Committee CH/150/4, Surgical Implants - Bone and Joint Replacements.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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).

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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.

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