



BSI Standards Publication

Implants for surgery — Wear of total intervertebral spinal disc prostheses

Part 3: Impingement-wear testing and corresponding environmental conditions for test of lumbar and cervical prostheses

National foreword

This British Standard is the UK implementation of ISO 18192-3:2025. It supersedes BS ISO 18192-3:2017, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/5, Surgical Implants - Osteosynthesis and spinal devices.

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

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Standard**

ISO 18192-3

**Implants for surgery — Wear of
total intervertebral spinal disc
protheses —**

**Part 3:
Impingement-wear testing and
corresponding environmental
conditions for test of lumbar and
cervical protheses**

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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 document 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 5, *Osteosynthesis and spinal devices*.

This second edition cancels and replaces the first edition (ISO 18192-3:2017), which has been technically revised.

The main changes are as follows:

- the scope of this document has been extended to cervical prosthesis;
- values for the impingement testing of cervical prosthesis have been integrated.

A list of all parts in the ISO 18192 series can be found on the ISO website.

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.

Implants for surgery — Wear of total intervertebral spinal disc prostheses —

Part 3:

Impingement-wear testing and corresponding environmental conditions for test of lumbar and cervical prostheses

1 Scope

This document specifies a test procedure to simulate and to evaluate lumbar and cervical spinal disc prostheses wear under adverse impingement conditions.

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 7500-1, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification of the force-measuring system*

ISO 18192-1, *Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test*

ISO 23788, *Metallic materials — Verification of the alignment of fatigue testing machines*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18192-1 and the following apply.

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

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

3.1

impingement

point at which two opposing components collide or restrict motion usually indicated by a sharp change in force or moment

3.2

range of motion

ROM

amount of angular displacement that a total disk replacement prosthesis can undergo from the device neutral position to the point at which *impingement* (3.1) occurs around a defined global axis

Note 1 to entry: If an implant impinges at 15° from the implant neutral position in flexion and 20° from the implant neutral position in extension, the implant range of motion can be defined as +15°/-20° in flexion and extension.