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Interested committees:

Title: Draft BS ISO 18192-3 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.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 18192-3

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

ICS: ISO ics

ISO/TC 150/SC 5

Secretariat: **ANSI**

Voting begins on:
2024-07-25

Voting terminates on:
2024-10-17

This document is circulated as received from the committee secretariat.

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

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

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 defines a test procedure to simulate and 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*

ASTM F 3292, *Standard Practice for Inspection of Spinal Implants Undergoing Testing*

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 terminological databases for use in standardization at the following addresses:

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

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 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/extension.