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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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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 prothesis 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.

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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.

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3.3
distance between centre of rotation and point of impingement
DCI
distance between the point of *impingement* (3.1) and the nominal centre of rotation for the flexion, extension or lateral bending motions

3.4
axial load during impingement
ALI
axial load applied to the device in newtons while the device is in an impinged condition

3.5
axial load minimum
ALM
minimum of the time-varying axial load applied to the device in newtons during the repeated test cycle

3.6
point of impingement
point of contact between two opposing components that results in *impingement* (3.1)

4 Principle

Based on current clinical evidence, lumbar and cervical spinal disc prostheses have experienced impingement in extension/flexion, lateral bending, axial rotation and combinations thereof with extension being the most commonly reported mode.

Adverse impingement testing conditions are determined based on available clinical data, engineering analysis and other relevant information in the literature. This information is summarized in Annex B and a justification for the test method is also given in Annex B.

An axial load and a time-varying angular displacement are applied to the test specimens to simulate repeated contact between design features of the specimens.

Four possible individual impingement scenarios have been identified in the literature:

a) flexion;

b) extension;

c) lateral bending;

d) combined flexion and lateral bending.

In addition, combined axial rotation with any of the aforementioned motion modes should be considered, if necessary to achieve either a clinically relevant impingement wear scar or worst case impingement scenario, or both.

A load soak control specimen, if polymers are the object of investigation, is subjected to the same time-varying force to determine either the creep of the test specimen or the amount of mass change, due to fluid transfer or both. The test takes place in a controlled environment simulating physiological conditions.

5 Reagents and materials

5.1 Fluid test medium

The fluid test medium consisting of calf serum diluted with de-ionized water (balance) to a concentration of 20 g ± 2 g of protein per litre shall be prepared in accordance with ISO 18192-1. If routine monitoring of the pH of the fluid test medium is undertaken, the values shall be included in the test report [see Clause 8 m) 7)] as an increase in pH can indicate an increase in microbial activity[1].

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