BS ISO 18192-3:2017

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 prostheses under adverse kinematic conditions

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National foreword

This British Standard is the UK implementation of ISO 18192-3:2017.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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

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Foreword

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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 5, *Osteosynthesis and spinal devices*.

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

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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 prostheses under adverse kinematic conditions

1 Scope

This document defines a test procedure to simulate and evaluate lumbar 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 4965-1, *Metallic materials — Dynamic force calibration for uniaxial fatigue testing — Part 1: Testing systems*

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 terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://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.

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3.3
distance between centre of rotation and point of impingement
DCI
distance between the point of impingement 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
point of impingement
point of contact between two opposing components that results in impingement

4 Principle

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

Adverse impingement testing conditions are determined based on available clinical data, engineering analysis and other relevant information in the literature.

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 a clinically relevant impingement wear scar and/or worst case impingement scenario.

A load soak control specimen, if polymers are the object of investigation, is subjected to the same time-varying force to determine the creep of the test specimen and/or the amount of mass change due to fluid transfer. 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 protein/l shall be prepared according to 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) 6)] as an increase in pH could indicate an increase in microbial activity[1].

5.2 Test and control specimen.

Between the inferior and superior components shall be the articulating surface of the inferior and superior components, attached by its normal immediate backing (for example, bone cement or a machined replica of the inner surface of the backing), unless this is impractical due to physical features

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