
**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**

*Implants chirurgicaux — Usure des prothèses totales de
remplacement des disques intervertébraux lombaires —*

*Partie 3: Essai d'incidence d'usure et conditions environnementales
correspondantes pour l'essai de prothèses lombaires sous conditions
cinématiques défavorables*



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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).

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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 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.

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 $20 \text{ g} \pm 2 \text{ g}$ 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

of the implant system. If the component forming the articulating surface is fixed to the backing by a rim/snap-fit system, the machined replica shall provide the same fixation conditions.

If it is not practical to use the normal backing or cement fixation due to physical features of the implant system, the support system for the inferior and/or superior component should represent normal design features and conditions of use but should allow removal of the component for measurement of wear without destruction.

It is recommended that six specimens be tested for the impingement-wear test. If less than six specimens are tested, appropriate justification shall be given.

NOTE The number of specimens tested can be the subject of national legislation.

If polymers are the object of investigation, a load soak control specimen is to be subjected to the same axial load to determine the creep of the test specimen and/or the amount of mass change due to fluid transfer. The test should take place in a controlled environment of test medium to simulate physiological conditions (see 5.1).

In the test cases where surrounding fluid is not absorbed by the specimens, test specimens shall be weighed prior to testing with an instrument having a precision of 0,1 mg.

The tested implant size should be selected by an engineering analysis including theoretical, computational, or experimental methods. If computational methods are used, experimental verification that considers the point of impingement, the materials in contact and the range of motion of the specimens is recommended. The point of impingement and the centre of rotation of the bearing are detected in all testing directions. The combination of implant components with the highest contact stress in the tested direction is selected for the test. If the materials in contact during impingement change with size, then tests with different implant sizes should be considered. The number of test specimens of each size should not be less than three with no less than six test specimens in total.

6 Apparatus

For the kinematical analysis the following testing configuration shall be applied. Deviation from this testing configuration shall be justified.

6.1 Test machine, in accordance with ISO 4965-1 and ISO 23788, as specified in ISO 18192-1 for lumbar prosthesis, and capable of associating and replacing the required corresponding angular displacements and forces (see Clause 7) for each specific protocol of movement.

6.2 Means of mounting and enclosing the test specimen, as specified in ISO 18192-1 for lumbar prosthesis.

6.3 Means of aligning and positioning, as specified in ISO 18192-1 for lumbar prosthesis.

6.4 Motion control system, capable of generating the required angular movements of the inferior component with an accuracy of $\pm 1^\circ$ at the maxima and minima of the motion and $\pm 5\%$ of cycle time phasing. For multi-station test systems, capabilities shall be assessed with all stations active.

6.5 Force control system, capable of generating a force in the z-direction (see Figure 1), which varies for each specific protocol of movement, and capable of maintaining the magnitude of the maxima and minima of this force cycle to a tolerance of $\pm 5\%$ of the maximum force value for the cycle and $\pm 5\%$ of the full cycle time for phasing. For multi-station test systems, capabilities shall be assessed with all stations active.

6.6 Lubrication system, as specified in ISO 18192-1 for lumbar prosthesis.

6.7 Temperature control system, as specified in ISO 18192-1.