INTERNATIONAL STANDARD

ISO 18192-2

First edition
2010-06-15

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

Part 2: Nucleus replacements

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

Partie 2: Remplacements nucléaires

Reference number
ISO 18192-2:2010(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 18192-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

ISO 18192 consists of the following parts, under the general title *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*

— *Part 2: Nucleus replacements*

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

Part 2: Nucleus replacements

1 Scope

This part of ISO 18192 defines a test procedure for spinal nucleus prostheses under the relative angular movement conditions specified by ISO 18192-1.

This part of ISO 18192 is applicable to both lumbar and cervical prostheses. It is not applicable to total disc replacements and facet joint replacements. The method includes wear and fatigue testing. Additional mechanical tests such as creep tests can be required.

This part of ISO 18192 does not reproduce the complex *in vivo* loads and motions. The wear and fatigue data obtained with this test method will enable comparison between different types of implant but can differ from the clinical wear performance. The user of this part of ISO 18192 should consider running additional tests addressing specific safety issues of the individual implant design to be tested.

2 Normative references

The following referenced documents are indispensable for the application 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 14242-2, *Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement*

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*

3 Terms and definitions

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

3.1
origin
centre of the coordinate system located at the geometrical centre of the simulated annulus

NOTE See Figure 1.

3.2
cycle limit
number of cycles at which the test is terminated if no functional failure has occurred