
**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



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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*

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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.

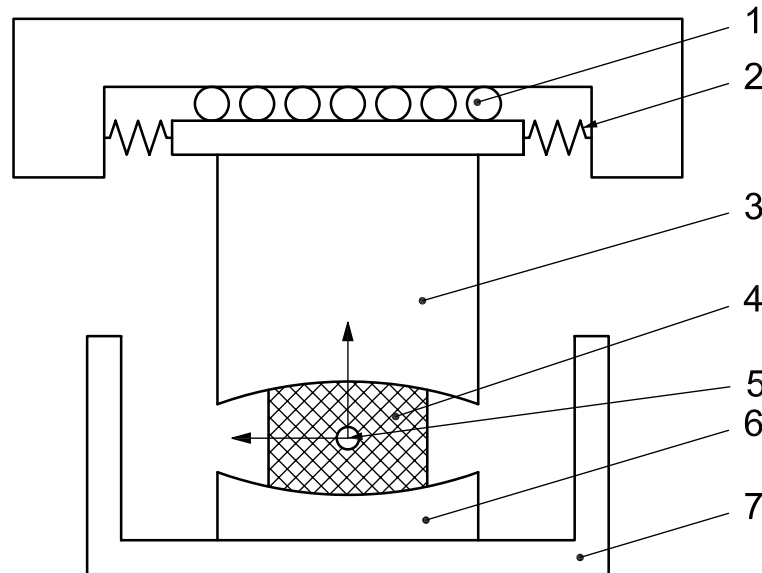
3.2

cycle limit

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

4 Principle

The nucleus replacement is placed in a test station in accordance with ISO 18192-1 (see Figure 1). The shear stiffness of the annulus is simulated by a motion restraint system. The apparatus applies a specified time-varying force on the nucleus replacement, together with specified relative angular displacements. If polymers are the object of investigation, a control specimen 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.



Key

- | | |
|---------------------------|------------------|
| 1 ball bearing | 5 origin |
| 2 motion restraint system | 6 lower endplate |
| 3 upper endplate | 7 test chamber |
| 4 nucleus device | |

Figure 1 — Principle of the test set-up

5 Reagents and materials

5.1 Fluid test medium

Calf serum diluted with de-ionized water (balance) to a concentration of $20 \text{ g} \pm 2 \text{ g protein/l}$.

The fluid test medium may be filtered through a $2 \text{ }\mu\text{m}$ filter, if desired.

To minimize microbial contamination, the fluid test medium shall be stored frozen until required for test. An anti-bacterial and anti-fungal reagent (such as sodium azide) shall be added. Such reagents can be potentially hazardous.

The addition of $20 \text{ mmol/l EDTA}^{1)}$ may be used to bind calcium in solution and to minimize precipitation of calcium phosphate on the bearing surfaces. The effect of EDTA will depend on the material combination tested. The absence of EDTA from the fluid test medium shall be justified by the user.

NOTE Alternative test fluids such as Hanks solution can be used.

Routine monitoring of the pH of the fluid test medium should be undertaken. If it is, the values shall be included in the test report [see Clause 9 item l) 6)].

1) Ethylenediaminetetraacetic acid.

5.2 Test and control specimens

A minimum of six samples is recommended for wear/fatigue testing. At least one additional sample is recommended to correct weight gain by fluid uptake (soak control). The soak control(s) shall be loaded according to the load profile given for the type of implant (see Table 1). The user may decide not to use a soak control when testing materials that do not absorb surrounding fluid (for example metal materials) or if weight readings are impractical due to high fluid absorption of the material to be tested (for example, hydrogels).

If fewer than six samples are tested, appropriate justification shall be given.

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

6 Apparatus

6.1 Testing machine

The testing machine shall conform to ISO 18192-1.

6.2 Motion restraint system

A motion restraint system capable of applying a restraining force in the horizontal plane is used in order to simulate the shear stiffness of the annulus. The magnitude of the restraining force is proportional to the horizontal displacement of the superior side of the implant. The stiffness of the motion restraint system shall be $115 \text{ N/mm} \pm 10 \text{ N/mm}$ (see Reference [7]). An example of a motion restraint system is shown in Figure 2.

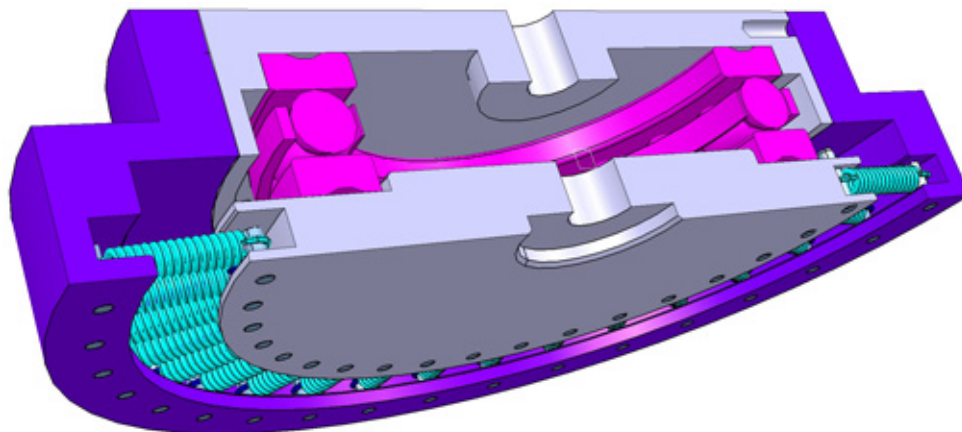


Figure 2 — Example (half model) of a motion restraint system using an array of springs

The endplates are made of a corrosion resistant material with a roughness value of $Ra = 0,05 \mu\text{m} \pm 0,01 \mu\text{m}$.

NOTE The shape of the endplates will depend on the specimen to be tested. A concave shape of the endplates might be required to prevent luxation of the nucleus device. An elliptical shape might be helpful to prevent rotation of the nucleus device.

6.3 Means of aligning and positioning

Align the test specimen in the superior position, so that its instantaneous axis of rotation at the neutral position is situated at the centre of the axes of rotation of the testing machine and ensure that the same position and orientation can be reproduced following removal for measurement or cleaning, if required.

6.4 Test chamber

The test chamber should be completely sealed from the external environment. The test chamber encloses the specimen and the endplates.

NOTE Generation of wear particles at the fixation of the endplates within the test chamber should be avoided although it will not always be possible to completely avoid the generation of wear particles.

6.5 Temperature control system

The temperature control system shall be capable of maintaining the temperature of the fluid test medium surrounding the test specimen at (37 ± 2) °C.

7 Cycle limit

The cycle limit shall be 1×10^7 cycles unless the submitter of the specimen requests a different cycle limit, which may be used with appropriate justification.

NOTE The cycle limit can be the subject of national legislation.

8 Procedure

8.1 Clean the test specimen.

NOTE Cleaning of the test specimen can be carried out as described in ISO 14242-2 or by an alternative method.

8.2 Make any initial measurements that are required to determine the subsequent amount of wear and/or creep, and to calibrate each test station using a load cell. Undertake this calibration while the load is being developed at other stations, if any, in the test rig. Measure the wear of the test specimen by one of the methods described in ISO 14242-2.

8.3 Mount the specimen in the testing machine.

8.4 Take the control specimen and repeat steps in 8.1, 8.2 and 8.3.

8.5 Introduce the fluid test medium (see 5.1) to completely fill the test chamber. Maintain the temperature of the surrounding fluid at (37 ± 2) °C, taking the measurement at a location representative of the bulk temperature of the fluid.

8.6 Wait until the specimen has reached steady state temperature.

8.7 Start the testing machine and adjust it so that the loads given in Table 1 and displacements specified by ISO 18192-1 are applied to the test specimen.

Table 1 — Load parameters of the testing machine

Region	Load (N)	
	Cervical	max.
min.		25
Lumbar	max.	1 000
	min.	300

NOTE The loads given in this table have been reduced by 50 % compared to those specified in ISO 18192-1 (see References [2] and [3]).

8.8 Operate the testing machine at a frequency of 1 Hz with an accuracy of $\pm 0,1$ Hz. Test frequencies up to 2 Hz may be used. The implications of test frequencies higher than 1 Hz on the implant material behaviour as well as on the accuracy of the testing machine shall be investigated by the user. Adequate justification shall be given by the user.

8.9 Replace the fluid test medium completely at least every 5×10^5 cycles, or every seven days, whichever is shorter.

8.10 Stop the test for measurements at least at 5×10^5 cycles, 1×10^6 cycles and at least every 5×10^5 cycles thereafter until the test is terminated (see 8.14).

8.11 Remove the test specimen from the testing machine and clean the test specimens.

NOTE Cleaning of the test specimen can be carried out as described in ISO 14242-2 or by an alternative method.

8.12 Take wear measurements.

Reinstall the test specimen in the testing machine (8.3 and 8.4).

8.13 Repeat the steps given in 8.6 to 8.12 until the test is terminated (see 8.14).

8.14 Continue the test until one of the following occurs:

- a) completion of the cycle limit;
- b) functional or user defined failure of the implant.

NOTE A mechanical failure might not necessitate termination of the test since this test method attempts to characterize the time dependent wear properties of the device.

9 Test report

The test report shall include the following information:

- a) a dated reference to this part of ISO 18192, i.e. ISO 18192-2:2010;
- b) the identity of the test specimens, as stated by the submitter of the specimens for test, including size, material, type and manufacturer;
- c) a description of the testing machine, including number of stations, type of systems used for generating motions and forces, range of motions and forces, type of systems used for measuring motions and forces, arrangement for mounting specimen (see 5.2), arrangement for lubrication of articulating surfaces, arrangement for temperature control and arrangement for the exclusion of contaminant particles;
- d) the test frequency including a justification if a higher frequency than 1 Hz has been used;
- e) the inclination angle of the device and a justification of the selection with regard to the motion of the articulating surfaces;
- f) the number of specimens and a justification if less than six specimens (excluding the soak specimen) have been tested;
- g) the addition or avoidance of EDTA and a justification for doing so;
- h) the addition or avoidance of an anti-microbial reagent and a justification for doing so;
- i) the selection of the nominal centre of rotation based on the implant design;

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- j) whether control specimens were used and, if not, the reference to the tests from which the control data were taken;
- k) the cycle limit including a justification if a cycle limit of other than 1×10^7 cycles was used;
- l) a statement of results, including:
 - 1) total number of cycles applied;
 - 2) reason for terminating the test if fewer cycles than the designated cycle limit were applied;
 - 3) description of all the surfaces of both components at which relative movement has occurred;
 - 4) description of the condition of the interfaces between subcomponents, if the components are of modular construction;
 - 5) description of the failure mode if failure occurred;
 - 6) pH values, if routine monitoring was undertaken (see 5.1);
- m) details of the method of measurement of wear and the results obtained (see ISO 14242-2), namely:
 - 1) method of wear measurement (i.e. gravimetric or dimensional);
 - 2) change in mass for each measurement using the gravimetric method, or change in volume for each measurement using the dimensional method;
 - 3) both the mean wear rate (gravimetric or dimensional method) and a description of the method to determine the mean wear rate (non-linear approximation, least squares fit, etc.);
 - 4) descriptive statistics including standard deviation;
 - 5) graphic presentation of wear as a function of cycle count;
- n) any deviations made from the original test protocol including the corresponding rationale.

10 Disposal of test specimen

No part of the test specimen shall be used for clinical purposes after testing.

Annex A (informative)

Statement of rationale for test methods

A.1 This part of ISO 18192 is not limited to specific types of implant materials or geometries. However, *in situ* formed implants will need to be cast into a user defined mold representing the intended clinical use. Testing of tissue engineered material is currently under investigation and is not covered by this part of ISO 18192.

A.2 At the time of publication of this part of ISO 18192, very little information about the material, surface and geometry surrounding a nucleus replacement is available. The surface roughness of the articulating tissue might vary between smooth (fibrous tissue) and rough (cancellous bone). The endplate roughness chosen for this part of ISO 18192 is assumed to represent mild wear characteristics.

A.3 Given the relative concordance of *in vitro* and *in vivo* wear testing in lumbar total disc arthroplasty, one year of wear has been shown to correspond to 1×10^6 cycles (see References [5] and [6]). The cycle limit of 1×10^7 approximates 10 years of *in vivo* function.

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