Date 2007-09-11
Reference
ISO/TC 150/SC 5/WG 2 **N 114**

ISO/TC 150/SC 5/WG 2
Spinal Devices

ISO/WD 18192-2.1, Implants for surgery – Wear of total intervertebral spinal disc prostheses – Part 2: Nucleus replacements

Secretary Note: The working draft document circulated with the New Work Item Proposal for this project (doc. ISO/TC 150/SC 5 N 414) was reviewed at the meeting of WG 2 in Tianjin, China on 11 September 2007. The Working Group reviewed in detail the Scope, Normative references, Terms and definitions, Principle, Reagents and materials, and Apparatus clauses of the working draft. The Working Group noted a number of potential refinements to the draft as well as a several key questions for the project team to consider. These are marked in this document and are noted as comments, which appear in balloons and at the end of the document.

Secretariat address:
Charles Sidebottom PE.
Medtronic, Inc.
710 Medtronic Parkway, MS LC270
Minneapolis, MN 55432-5604 USA
charles.sidebottom@medtronic.com

ISO/TC 150/SC 5/WG 2 **N 114**

Date: 2007-09-11

ISO/WD 18192-2.1

ISO/TC 150/SC 5

Secretariat: ANSI

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: ((French translation))

Copyright notice

Contents

Page

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 tests*

— *Part 2: Nucleus replacements*

Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 2: Nucleus replacements

1 Scope

This International Standard defines a test procedure for spinal nucleus prostheses under the load and relative angular movement conditions specified by ISO 18192-1.

Both lumbar and cervical prostheses are addressed. This standard does not address total disc replacements and facet joint replacements. The test method focuses on wear and fatigue testing, additional mechanical tests such as creep tests may be required.

This standard 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 implants but may differ from the clinical wear performance. The user of this standard should consider running additional tests addressing specific safety issues of the individual implant design to be tested.

Comment [WG2-1]: The WG is concerned that handling both wear and fatigue in a single test brings excessive complexity to the test. The Project Team should consider if two test procedures are appropriate and if they should be in two part of a single standard or should be constructed as two standards.

Deleted: may

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 14243-2, Implants for Surgery – Wear of Total Knee – 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 tests

Comment [WG2-2]: The WG considered that this standard may also contain useful information that could be used.

Comment [WG2-3]: This document is normatively referenced in this standard.

3 Terms and definitions

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

3.1
Origin
centre of the coordinate system is located at the geometrical centre of the simulated annulus.

NOTE See Figure 1.

Comment [WG2-4]: The leading article is unnecessary in a definition.

Deleted: the

Deleted:

Comment [WG2-5]: The reference to Figure 1A is ambiguous as a sub-figure is not defined. The WG thought that the reference would be better resolved by labelling the origin in Figure 1.

Deleted: figure 1A

4 Principle

A simulated annulus is placed in a test station according to ISO 18192-1. The nucleus replacement is placed into the simulated annulus. The apparatus applies a specified time-varying force on the simulated annulus,

together with specified relative angular displacements. A 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

Bovine serum diluted with de-ionized water (balance) to a concentration of 30 g ± 2 g protein/l.

The fluid test medium may be filtered through a 2 µm filter if desired.

To minimize microbial contamination, the fluid test medium should 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 hazardous.

The addition of 20 mmol/l EDTA should be used to bind calcium in solution and to minimize precipitation of calcium phosphate onto the bearing surfaces. The effect of EDTA will depend on the material combination tested. The absence of ETDA in the fluid test medium of EDTA shall be justified by the user.

NOTE Alternative test fluids such as Hanks solution might 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 8 item k) 6)].

5.2 Test and control specimen

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 has to be loaded according to the load profile given for the type of implant. 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 specimens are tested appropriate justification shall be given.

NOTE 1 The number of specimens tested can be the subject of national legislation.

6 Apparatus

6.1 Simulated annulus

The geometry of the simulated annulus is given by Figure 1.

Comment [WG2-6]: The WG was of the opinion that bovine serim, as opposed to calf serum in particaulr, would be adequate and asks the project team to consider this change or to include rational as to why calf serum is needed.

Deleted: Calf

Comment [WG2-7]: After considerable discussion of the advisable of requiring an anti-microbial agent. The WG request the project team to consider requiring an agent that is both anti-bacterial and anti-fungal. It is noted the "possibility" (can) that such agents are hazardous.

Deleted: microbial

Deleted: may

Deleted: may

Deleted: potentially

Comment [WG2-8]: This paragraph contains a requirement (a shall statement) and cannot be a note.

Comment [WG2-9]: This forumlation aligns with a comment on Part 1.

Comment [WG2-10]: The WG suggest the use of "should" to indicate a strong recommendation.

Deleted: Note:

Deleted: at 20 mM

Deleted: may

Deleted: recommended

Comment [WG2-11]: The WG suggest that as the use of EDTA is a strong recommendation, it is the absence (non-use) EDTA not its presence that should be justified.

Deleted: addition

Comment [WG2-12]: A restructuring of ... [1]

Deleted: recommended

Deleted: sample number

Deleted: should be used

Deleted: must be used

Comment [WG2-13]: This is also seen ... [2]

Comment [WG2-14]: "Impractical" is s ... [3]

Deleted: impossible

Comment [WG2-15]: This statement c ... [4]

Comment [WG2-16]: Better English.

Comment [WG2-17]: A better construc ... [5]

Deleted: NOTE 2

Deleted: less

Deleted: has to

Comment [WG2-18]: This is the staten ... [6]

Deleted: may

Comment [WG2-19]: The WG discuss ... [7]

Deleted: Fig. 1

Dimensions in millimetres

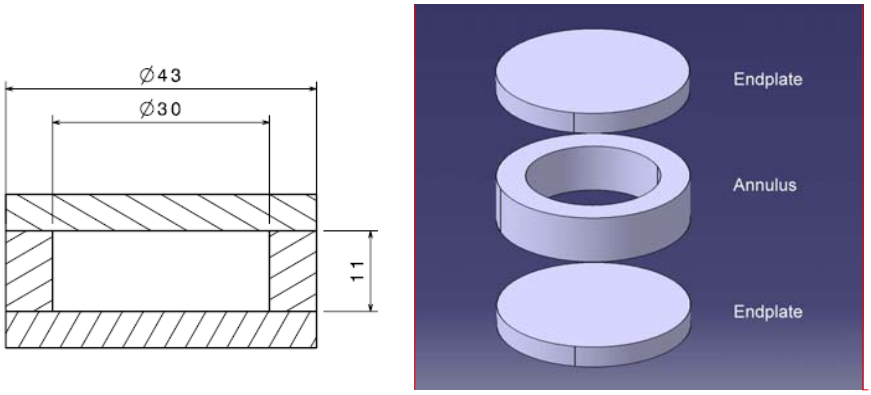

Figure 1 — Geometry of the artificial annulus

The endplates are made of a corrosion resistant material with a roughness value of Ra=0,1 (±0,02).

The axial stiffness of the simulated annulus filled completely with water should have a nonlinear stiffness. At 0,5 kN, a deflection of 1 mm ± 0,2mm should be achieved, at 1,5 kN a deflection of 2 mm ± 0,2mm should be achieved.

The shear stiffness of the simulated annulus filled completely with water should have a value of 115 N/mm ± 10 N/mm).

6.2 Means of aligning and positioning

Align the simulated annulus of 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 test machine and the same position and orientation can be reproduced following removal for measurement or cleaning, if required.

6.3 Lubrication system

The internal cavity of the annulus should be completely sealed versus the test chamber of the test frame.

6.4 Temperature control system

The temperature control system shall be capable of maintaining the temperature of a fluid surrounding the simulated annulus at (37 ± 2) °C.

NOTE The surrounding fluid can be distilled water.

7 Procedure

7.1 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.

7.2 Make any initial measurements which 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.

Comment [WG2-20]: When all units for a quantity are the same, a suitable statement (for example, “Dimensions in millimetres”) shall be placed above the right-hand corner of the figure. The project team needs to verify the units and include the approprate ones.

Comment [WG2-21]: Per the comment on 3.1, the origin needs to be indicated in this figure.

Comment [WG2-22]: The WG is concered that only specifying a roughness value is not an adequate description of the endplate condition and asks the Project Team to consider what additioanl inforamtion is appropriate to fully descrbe the endplates for this test. Also units are needed for this specificaton.

Comment [WG2-23]: The decimal sign shall be a comma on the line in all language versions. Values and dimensions shall be indicated as being minimum or maximum, and specified with their tolerances in an unambiguous manner. EXAMPLE 2 80 µF ± 2 µF or (80 ± 2) µF

Comment [WG2-24]: The WG request the project team to cosider if tis is clinically relevant and to provide a rationale for the requirement.

Deleted: C

Deleted: might

Deleted: as given

Deleted: cleaning

Deleted: s

NOTE Methods of measurement of wear are given in ISO 14242-2.

7.3 Mount the specimen in the test machine.

7.4 Take the control specimen and repeat steps in 7.1, 7.2, and 7.3.

7.5 Introduce the fluid test medium according to 5.1 to completely fill the simulated annulus of the test specimen and the control specimen. 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.

7.6 Wait until the specimen has reached steady state temperature.

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

7.8 Operate the testing machine at a frequency of 1 Hz with an accuracy of ± 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 test machine shall be investigated by the user. Adequate justification shall be given by the user.

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

7.10 Stop the test for measurements at least 5 x 10^5 cycles, 1 x 10^6 cycles and at least every 5 x 10^5 cycles thereafter until the test is terminated (see 7.14).

7.11 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.

7.12 Take wear measurements.

Reinstall the test specimen in the testing machine (7.3 and 7.4).

7.13 Repeat the steps given in 7.6 to 7.12 until the test is terminated (see 7.14).

7.14 Continue the test until one of the following occurs:

a) completion of 10^7 cycles (see A.5);

NOTE 1 At the request of the submitter of the specimen, the test can be continued beyond this limit.

NOTE 2 The number of cycles tested can be subject of national legislation.

b) functional or user defined failure of the implant;

NOTE 3 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.

c) failure of the testing machine to maintain the force and displacement parameters within the given tolerances (see 6.5 and 6.6).

Comment [WG2-25]: The WG thought that "implications" or a similar work would be a better choice here.

Deleted: impact

Comment [WG2-26]: The remainder of the changes were introduced by the secretary to align with ISO/FDIS 18192-1.

Deleted: has to

Deleted: has to

Deleted: 12

Deleted: as given

Deleted: cleaning

Deleted: s

Deleted: may

Deleted: may

Deleted: may

Deleted: ,

8 Test report

The test report shall include the following information:

a) a reference to this Standard;

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 in 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.

j) whether control specimens were used and, if not, the reference to the tests from which the control data were taken;

k) a statement of results, including:

   1) total number of cycles applied;

   2) reason for terminating the test if less than 10^7 cycles 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).

l) details of the method of measurement of wear and the results obtained (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 (nonlinear approximation, least squares fit, etc.);

   4) descriptive statistics including standard deviation;

   5) graphic presentation of wear as a function of cycle count;

m) any deviations made from the original test protocol including the corresponding rational.

Deleted: . Describe

9 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

Page 2: [1] Comment [WG2-12] **ISO/TC 150/SC 5/WG 2** **9/14/2007 3:11:00 AM**

A restructuring of this sentence is suggested for clarity.

Page 2: [2] Comment [WG2-13] **ISO/TC 150/SC 5/WG 2** **9/14/2007 3:11:00 AM**

This is also seen as a recommendation since the minimum number of samples is a recommendation. "Must" is reserved for regulatory requirments.

Page 2: [3] Comment [WG2-14] **ISO/TC 150/SC 5/WG 2** **9/13/2007 3:45:00 PM**

"Impractical" is seen as a better term here than "impossible" since a measure might be possible but not feasible.

Page 2: [4] Comment [WG2-15] **ISO/TC 150/SC 5/WG 2** **9/14/2007 3:11:00 AM**

This statement contains a requirement so it cannot be a note.

Page 2: [5] Comment [WG2-17] **ISO/TC 150/SC 5/WG 2** **9/13/2007 3:49:00 PM**

A better construction of a requirement (shall be vs. has to be).

Page 2: [6] Comment [WG2-18] **ISO/TC 150/SC 5/WG 2** **9/13/2007 3:51:00 PM**

This is the statement of a possibiliy ("can") not a permissive requirement ("may").

Page 2: [7] Comment [WG2-19] **ISO/TC 150/SC 5/WG 2** **9/14/2007 3:12:00 AM**

The WG discussed the requirement for a simulated annulus at some length and has several questions/comments for the Project Team to consider in preparing their next draft. They are:

1. There is a concern that the test method is testing the annulus not the product, Can a test method be developed without an annulus? Do we need to limit the scope of the test to non-fluid devices? See also the general concern about handling both wear and fatigue in a single test.

2. The annulus material and dimensions should be fully specified by the standard.

3. The region of the spine coverd (cervical and lumbar) needs to be included in the standard.

4. The mechanism for connecting the annulus to the test mechanism needs to be specified.

5. The WG requestes the Project Team consider a Taber test for wear simulation (separate from a fatigue test) The Taber test is specified in both ISO and ASTM standards.