
**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**

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

*Partie 1: Paramètres de charge et de déplacement pour essais d'usure
et conditions environnementales correspondantes*

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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 18192-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

This second edition cancels and replaces the first edition (ISO 18192-1:2008), of which it constitutes a minor revision. The main modifications are the introduction of the term “cycle limit” (an explicit statement that a different cycle limit can be used with appropriate justification) and the change of the required concentration of calf serum in the fluid test medium to 20 g protein/l.

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 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test

1 Scope

This part of ISO 18192 defines a test procedure for the relative angular movement between articulating components, and specifies the pattern of the applied force, speed and duration of testing, sample configuration and test environment for use for the wear testing of total intervertebral spinal disc prostheses.

Both lumbar and cervical prostheses are addressed. This part of ISO 18192 is not applicable to partial disc replacements, such as nucleus replacements or facet joint replacements. The test method focuses on wear testing. Additional mechanical tests, such as fatigue testing, can be required.

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

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

axial rotation

angular movement in the transverse plane around the Z-axis

See Figure 1 c).

3.2

flexion/extension

angular movement in the sagittal plane around the Y-axis

See Figure 1 a).

3.3 functional failure
failure that renders the implant unable to resist the load and/or move as initially intended by the design of the implant

3.4 lateral bending
angular movement in the frontal plane around the X-axis

See Figure 1 b).

3.5 mechanical failure
onset of a defect in the material

EXAMPLE Initiation of fatigue crack.

3.6 origin
centre of the coordinate system located at the instantaneous centre of rotation at the neutral position of the total disc replacement

NOTE The nominal centre is specified by the design.

3.7 user-defined failure
any failure criterion that is established and controlled by the user considering the specific design of the implant to be tested

3.8 X-axis
positive X-axis directed anteriorly

See Figure 1.

3.9 Y-axis
positive Y-axis directed laterally to the left

See Figure 1.

3.10 Z-axis
positive Z-axis directed superiorly

See Figure 1.

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

4 Principle

The inferior and superior components of a test specimen are placed in position in the configuration intended for clinical use. The test apparatus transmits a specified time-varying force between the components, together with specified relative angular displacements. 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.

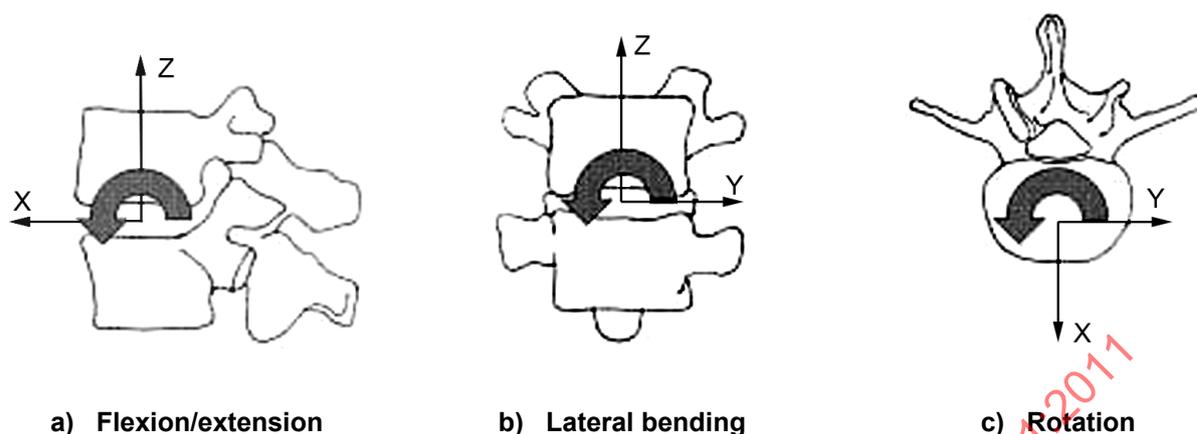


Figure 1 — Definition of the angular movements and coordinate axes

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 should be stored frozen until required for test. An antimicrobial reagent (such as sodium azide) may be added. Such reagents can be potentially hazardous.

The addition of 20 mmol/l EDTA solution may be used to bind calcium in solution and to minimize precipitation of calcium phosphate on to the bearing surfaces. The effect of EDTA depends on the material combination tested. The addition of EDTA shall be justified by the user.

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 8 k) 6)].

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.

A recommended minimum sample number of six should be used for wear testing. 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.

At least one additional sample shall be used to correct weight gain by fluid uptake (load soak control). The load soak control shall 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).

6 Apparatus

6.1 Testing machine, capable of producing the angular displacements specified in Table 1 and Figures 2 and 3 in association with the corresponding forces specified in Table 2 and operating at a frequency of $(1 \pm 0,1)$ Hz based on one cycle being the shortest repetitive interval for all motions and loads combined.

Table 1 — Angular displacements of the testing machine

Implant	Angle	Flexion/extension	Axial rotation	Lateral bending
Cervical	min.	-7,5°	-4°	-6°
	max.	7,5	4°	6°
Lumbar	min.	-3°	2°	2°
	max.	6°	-2°	-2°

The angular displacements indicated may be varied according to data given by the test requester.

Table 2 — Load parameters of the testing machine

Implant	Load N	
Cervical	max.	150
	min.	50
Lumbar	max.	2 000
	min.	600

The load parameters indicated may be varied according to data given by the test requester.

A defined level of shear loading shall be implemented for lumbar implants being restrained in the transverse plane. Shear loading is achieved by inclining the implant with respect to the axial load axis in the sagittal plane at the reference position (see Figure 4). Certain designs can be sensitive to shear loads. The user may intensify the test conditions by increasing the shear load and/or adding alternating load directions.

NOTE 1 It is the responsibility of the user of this part of ISO 18192 to be aware that a certain amount of shear load is generated by the motion of the device with respect to the axial load. With regard to the implant design, it is intended that the user give a justification for intended physiological conditions, especially for motion of any articulating surfaces during the load and motion cycle.

NOTE 2 See Annex A for load and motion rationale.

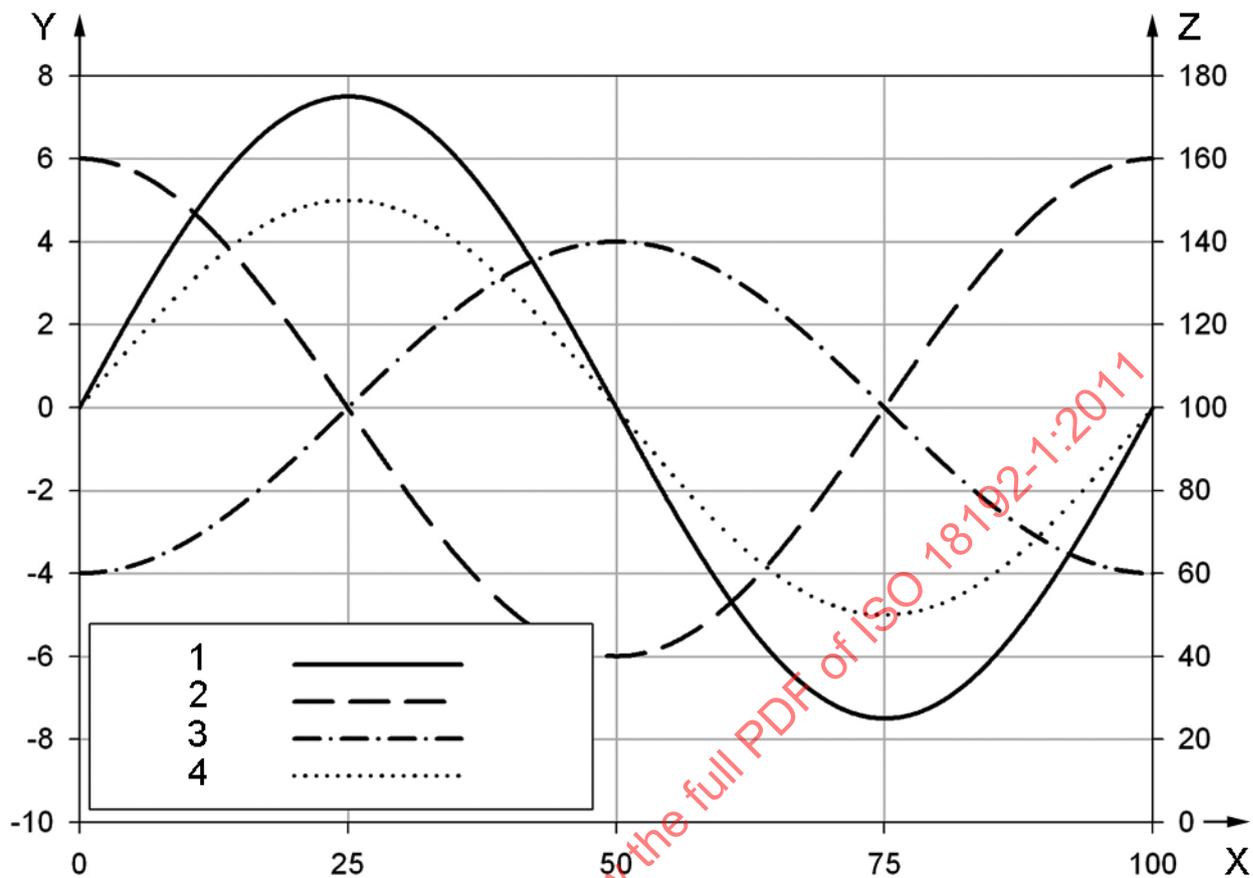
All angular displacement curves and load curves are smooth. The curves shall reach the given values at 0 %, 25 %, 50 % and 75 % of the motion cycle within the tolerances given in 6.4. Sample data sets are provided in Annexes B and C.

The angles refer to a moving coordinate system.

The intended sequence of the angular transformation is: lateral bending — flexion/extension — axial rotation.

NOTE 3 The sequence of the axial rotations slightly impacts the motion and the final position after each motion step (Euler angles). Due to the small angles applied, Euler sequences differing from the above result in almost identical relative motions. The Euler sequence chosen can be selected according to the mechanical set-up of the wear testing machine.

NOTE 4 The load curve is sinusoidal.



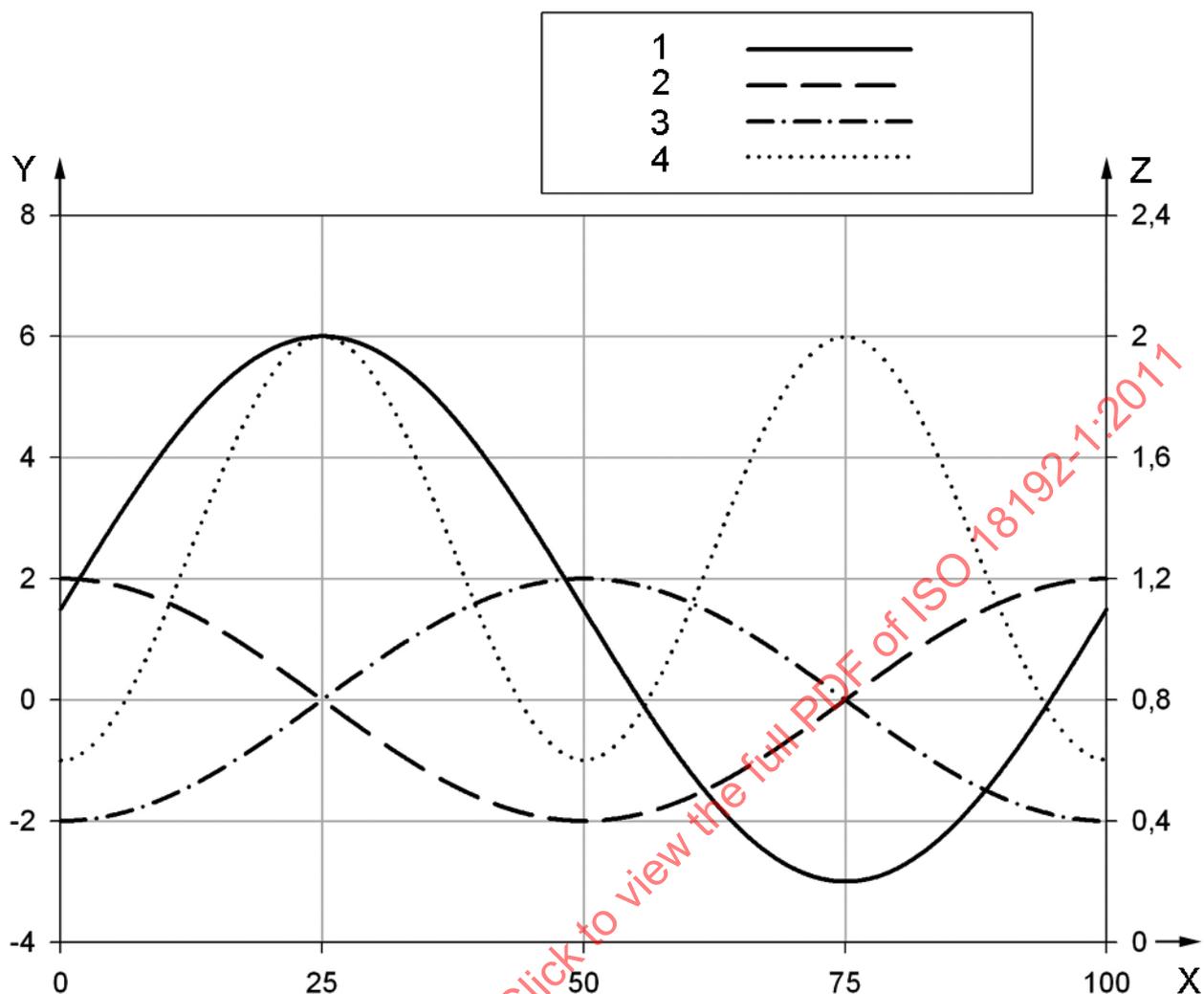
Key

- X cycle (%)
- Y angle (°)
- Z load (N)

- 1 flexion/extension
- 2 lateral bending
- 3 rotation
- 4 load

The lateral bending is shifted 90° relative to the flexion/extension axis; the axial rotation and the lateral bending are 180° out of phase.

Figure 2 — Phasing of the displacement and load curves for cervical prostheses



Key

- X cycle (%)
- Y angle (°)
- Z load (kN)

- 1 flexion/extension
- 2 lateral bending
- 3 rotation
- 4 load

The lateral bending is shifted 90° relative to the flexion/extension axis; the axial rotation and the lateral bending are 180° out of phase.

Figure 3 — Phasing of the displacement and load curves for lumbar prostheses

6.2 Means of mounting and enclosing the test specimen, of corrosion-resistant material, capable of holding inferior and superior components using attachment methods comparable to the intended anatomical fixation.

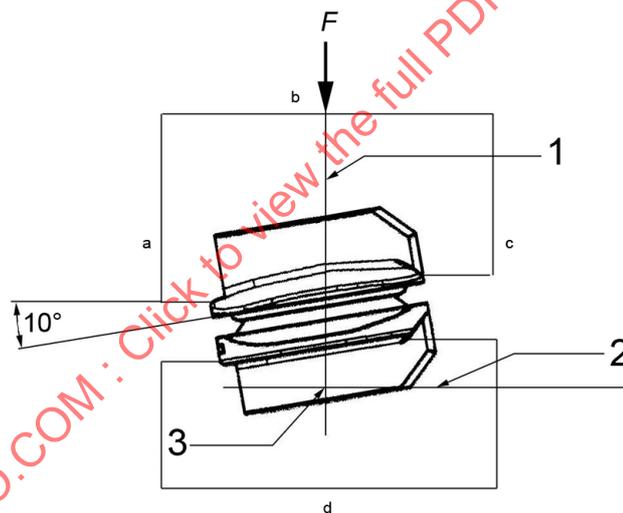
6.3 Means of aligning and positioning, to align the superior component of the test specimen in the superior position, so that its instantaneous axis of rotation at the neutral position is situated at the centre of the axes of rotation of the test machine and the same position and orientation can be reproduced following removal for measurement or cleaning, if required.

Align the inferior component of the test specimen, 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. This alignment is intended to prevent preloads in the initial test position.

Incline the Z-axis of lumbar implants 10° with respect to the load axis to generate enhanced shear (see Figure 4). The shear load is intended to act from posterior to anterior. Cervical implants are not inclined with respect to the axial load.

NOTE 1 Some designs using mobile bearings can generate less wear if the mobile bearing is forced by the shear load to remain in one position. In this case, it is intended that the user use no inclination to generate worst case conditions.

NOTE 2 Shear forces act on the device due to the cyclic inclination with respect to the axial load.



Key

- 1 rotation axis
- 2 lateral bending axis
- 3 centre of rotation

F axial force

- a Anterior.
- b Superior.
- c Posterior.
- d Inferior.

Figure 4 — Inclination of the lumbar implant in the sagittal plane to simulate shear loading

6.4 Motion control system, capable of generating the angular movements of the superior component as given in Figures 2 and 3 with an accuracy of $\pm 0,5^\circ$ at the maxima and minima of the motion and $\pm 2\%$ of the full cycle time for 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 as shown in Figures 2 and 3, 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 $\pm 3\%$ of the full cycle time for phasing. For multi-station test systems, capabilities shall be assessed with all stations active.

6.6 Lubrication system, capable of maintaining the contact surfaces immersed in the fluid test medium.

NOTE The use of sealed enclosures can prevent evaporation and contamination.

6.7 Temperature control system, capable of maintaining the temperature of the fluid test medium (see 5.1) at $(37 \pm 2)^\circ\text{C}$.

6.8 Control station(s), capable of applying the loading regime shown in Figures 2 and 3 and incorporating the requirements given in 6.2, 6.3, 6.6 and 6.7.

7 Procedure

7.1 Clean the test specimen.

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

7.2 Make any initial measurements required to determine the subsequent amount of wear and/or creep. Calibrate all test stations with a time-varying load to ensure the system load meets the requirements in 6.5. For multi-station test systems, perform calibration with all stations active.

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

7.3 Mount the specimen in the testing machine.

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

7.5 Introduce fresh fluid test medium (see 5.1) to completely immerse the contact surfaces of the test specimen and the control specimen. Maintain the temperature of the fluid test medium at $(37 \pm 2)^\circ\text{C}$, taking the measurement at a location representative of the bulk temperature of the fluid. Determine the pH value (optional).

7.6 Wait until the specimen has reached a steady-state temperature.

7.7 Start the testing machine and adjust it so that the loads and displacements specified in Figures 1 to 3 are applied to the test specimen (see 6.4 and 6.5). The curves between the defined maxima and minima in Figures 2 and 3 shall be smooth with no overshoots. Record the displacement and load waveforms at start-up, and after each change of fluid test medium, for every single test station, if independent test stations are used, and for one test station, if mechanically connected test stations are used.

7.8 Operate the testing machine at a frequency of 1 Hz with an accuracy of $\pm 0,1$ Hz. 1 Hz refers to one cycle per second, where one cycle is defined as the shortest repetitive interval for all motions and loads combined. Test frequencies up to 2 Hz may be used. The impact 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 lost by evaporation during the test at least daily, by adding de-ionized water. Replace the fluid test medium completely at least every 5×10^5 cycles, or every seven days, whichever is the shorter.

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

7.11 Remove the test specimen and load soak control from the testing machine and clean the test specimens.

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

7.12 Take wear measurements in accordance with ISO 14242-2.

Reinstall the test specimen and load soak control in the testing machine.

7.13 Repeat the steps given in 7.5 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 the 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 (see A.5);

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

- b) Functional or user-defined failure of the implant;

NOTE 2 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).

8 Test report

The test report shall include the following information:

- a) a dated reference to this part of ISO 18192, i.e. ISO 18192-1:2011;
- 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 frequency higher 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 antimicrobial 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) 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 the surfaces of all 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 (as specified in 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 used 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.

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

A.1 At the time of publication of this part of ISO 18192, very little knowledge about the *in vivo*, daily living loading situation of spinal disc implants is available. The aim of this test method is to give a single set of motions and loading conditions until more data becomes available.

A.2 The choice of the test fluid has been based on International Standards on wear, such as ISO 14242-1 and ISO 14243-1. At the time of publication of this part of ISO 18192, there is no information available indicating the composition of the fluid surrounding an artificial disc implant. The user can consider worst-case scenarios for the specific implant material when selecting the appropriate test fluid.

A.3 The magnitude of the load and motion profiles is based on the range of motion data published in the literature (see for example References [4] to [13]). Daily living activities are assumed to cover a certain percentage of the maximum range of motion with single events of higher loads and motions. The aim of the wear test method is to simulate average loading conditions rather than the extremes. Nevertheless, the user should consider running tests at maximum loads and deflections, such as migration tests, impingement tests and fatigue tests.

A.4 The definition of shear loads has been limited to the anterior-posterior direction neglecting changes in load direction (see ISO 14630 and ISO 14242-1). Generating the shear load by inclining the implant with respect to the axial load is accepted to be a simple method. The justification for doing so is to simplify the test set-up by avoiding additional force actuators. The user of this part of ISO 18192 may decide to set up a more complex load regime for implants that involve a safety risk under enhanced shear loading.

A.5 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 [18] and [19]). The cycle limit of 1×10^7 approximates 10 years of *in vivo* function.

Annex B (informative)

Load and displacement data for cervical implants

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
0	0,000	6,000	-4,000	100,0
1	0,471	5,988	-3,992	103,1
2	0,940	5,953	-3,968	106,3
3	1,405	5,894	-3,929	109,4
4	1,865	5,811	-3,874	112,4
5	2,318	5,706	-3,804	115,5
6	2,761	5,579	-3,719	118,4
7	3,193	5,429	-3,619	121,3
8	3,613	5,258	-3,505	124,1
9	4,019	5,066	-3,377	126,8
10	4,408	4,854	-3,236	129,4
11	4,781	4,623	-3,082	131,9
12	5,134	4,374	-2,916	134,2
13	5,467	4,107	-2,738	136,4
14	5,779	3,825	-2,550	138,5
15	6,068	3,527	-2,351	140,5
16	6,332	3,215	-2,143	142,2
17	6,572	2,891	-1,927	143,8
18	6,786	2,555	-1,703	145,2
19	6,973	2,209	-1,472	146,5
20	7,133	1,854	-1,236	147,6
21	7,264	1,492	-0,995	148,4
22	7,367	1,124	-0,750	149,1
23	7,441	0,752	-0,501	149,6
24	7,485	0,377	-0,251	149,9
25	7,500	0,000	0,000	150,0
26	7,485	-0,377	0,251	149,9
27	7,441	-0,752	0,501	149,6
28	7,367	-1,124	0,750	149,1
29	7,264	-1,492	0,995	148,4
30	7,133	-1,854	1,236	147,6
31	6,973	-2,209	1,472	146,5
32	6,786	-2,555	1,703	145,2
33	6,572	-2,891	1,927	143,8
34	6,332	-3,215	2,143	142,2
35	6,068	-3,527	2,351	140,5
36	5,779	-3,825	2,550	138,5
37	5,467	-4,107	2,738	136,4
38	5,134	-4,374	2,916	134,2
39	4,781	-4,623	3,082	131,9
40	4,408	-4,854	3,236	129,4
41	4,019	-5,066	3,377	126,8
42	3,613	-5,258	3,505	124,1
43	3,193	-5,429	3,619	121,3
44	2,761	-5,579	3,719	118,4
45	2,318	-5,706	3,804	115,5
46	1,865	-5,811	3,874	112,4
47	1,405	-5,894	3,929	109,4
48	0,940	-5,953	3,968	106,3
49	0,471	-5,988	3,992	103,1

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
50	0,000	-6,000	4,000	100,0
51	-0,471	-5,988	3,992	96,9
52	-0,940	-5,953	3,968	93,7
53	-1,405	-5,894	3,929	90,6
54	-1,865	-5,811	3,874	87,6
55	-2,318	-5,706	3,804	84,5
56	-2,761	-5,579	3,719	81,6
57	-3,193	-5,429	3,619	78,7
58	-3,613	-5,258	3,505	75,9
59	-4,019	-5,066	3,377	73,2
60	-4,408	-4,854	3,236	70,6
61	-4,781	-4,623	3,082	68,1
62	-5,134	-4,374	2,916	65,8
63	-5,467	-4,107	2,738	63,6
64	-5,779	-3,825	2,550	61,5
65	-6,068	-3,527	2,351	59,5
66	-6,332	-3,215	2,143	57,8
67	-6,572	-2,891	1,927	56,2
68	-6,786	-2,555	1,703	54,8
69	-6,973	-2,209	1,472	53,5
70	-7,133	-1,854	1,236	52,4
71	-7,264	-1,492	0,995	51,6
72	-7,367	-1,124	0,750	50,9
73	-7,441	-0,752	0,501	50,4
74	-7,485	-0,377	0,251	50,1
75	-7,500	0,000	0,000	50,0
76	-7,485	0,377	-0,251	50,1
77	-7,441	0,752	-0,501	50,4
78	-7,367	1,124	-0,750	50,9
79	-7,264	1,492	-0,995	51,6
80	-7,133	1,854	-1,236	52,4
81	-6,973	2,209	-1,472	53,5
82	-6,786	2,555	-1,703	54,8
83	-6,572	2,891	-1,927	56,2
84	-6,332	3,215	-2,143	57,8
85	-6,068	3,527	-2,351	59,5
86	-5,779	3,825	-2,550	61,5
87	-5,467	4,107	-2,738	63,6
88	-5,134	4,374	-2,916	65,8
89	-4,781	4,623	-3,082	68,1
90	-4,408	4,854	-3,236	70,6
91	-4,019	5,066	-3,377	73,2
92	-3,613	5,258	-3,505	75,9
93	-3,193	5,429	-3,619	78,7
94	-2,761	5,579	-3,719	81,6
95	-2,318	5,706	-3,804	84,5
96	-1,865	5,811	-3,874	87,6
97	-1,405	5,894	-3,929	90,6
98	-0,940	5,953	-3,968	93,7
99	-0,471	5,988	-3,992	96,9

NOTE 100 % loading cycle corresponds to 1s.

Annex C (informative)

Load and displacement data for lumbar implants

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
0	1,500	2,000	-2,000	0,600
1	1,783	1,996	-1,996	0,606
2	2,064	1,984	-1,984	0,622
3	2,343	1,965	-1,965	0,649
4	2,619	1,937	-1,937	0,687
5	2,891	1,902	-1,902	0,734
6	3,157	1,860	-1,860	0,790
7	3,416	1,810	-1,810	0,854
8	3,668	1,753	-1,753	0,925
9	3,911	1,689	-1,689	1,002
10	4,145	1,618	-1,618	1,084
11	4,368	1,541	-1,541	1,169
12	4,580	1,458	-1,458	1,256
13	4,780	1,369	-1,369	1,344
14	4,967	1,275	-1,275	1,431
15	5,141	1,176	-1,176	1,516
16	5,299	1,072	-1,072	1,598
17	5,443	0,964	-0,964	1,675
18	5,572	0,852	-0,852	1,746
19	5,684	0,736	-0,736	1,810
20	5,780	0,618	-0,618	1,866
21	5,859	0,497	-0,497	1,913
22	5,920	0,375	-0,375	1,951
23	5,965	0,251	-0,251	1,978
24	5,991	0,126	-0,126	1,994
25	6,000	0,000	0,000	2,000
26	5,991	-0,126	0,126	1,994
27	5,965	-0,251	0,251	1,978
28	5,920	-0,375	0,375	1,951
29	5,859	-0,497	0,497	1,913
30	5,780	-0,618	0,618	1,866
31	5,684	-0,736	0,736	1,810
32	5,572	-0,852	0,852	1,746
33	5,443	-0,964	0,964	1,675
34	5,299	-1,072	1,072	1,598
35	5,141	-1,176	1,176	1,516
36	4,967	-1,275	1,275	1,431
37	4,780	-1,369	1,369	1,344
38	4,580	-1,458	1,458	1,256
39	4,368	-1,541	1,541	1,169
40	4,145	-1,618	1,618	1,084
41	3,911	-1,689	1,689	1,002
42	3,668	-1,753	1,753	0,925
43	3,416	-1,810	1,810	0,854
44	3,157	-1,860	1,860	0,790
45	2,891	-1,902	1,902	0,734
46	2,619	-1,937	1,937	0,687
47	2,343	-1,965	1,965	0,649
48	2,064	-1,984	1,984	0,622
49	1,783	-1,996	1,996	0,606
50	1,500	-2,000	2,000	0,600
51	1,217	-1,996	1,996	0,606
52	0,936	-1,984	1,984	0,622
53	0,657	-1,965	1,965	0,649
54	0,381	-1,937	1,937	0,687
55	0,109	-1,902	1,902	0,734
56	-0,157	-1,860	1,860	0,790
57	-0,416	-1,810	1,810	0,854
58	-0,668	-1,753	1,753	0,925
59	-0,911	-1,689	1,689	1,002
60	-1,145	-1,618	1,618	1,084
61	-1,368	-1,541	1,541	1,169
62	-1,580	-1,458	1,458	1,256
63	-1,780	-1,369	1,369	1,344
64	-1,967	-1,275	1,275	1,431
65	-2,141	-1,176	1,176	1,516
66	-2,299	-1,072	1,072	1,598
67	-2,443	-0,964	0,964	1,675
68	-2,572	-0,852	0,852	1,746
69	-2,684	-0,736	0,736	1,810
70	-2,780	-0,618	0,618	1,866
71	-2,859	-0,497	0,497	1,913
72	-2,920	-0,375	0,375	1,951
73	-2,965	-0,251	0,251	1,978
74	-2,991	-0,126	0,126	1,994
75	-3,000	0,000	0,000	2,000
76	-2,991	0,126	-0,126	1,994
77	-2,965	0,251	-0,251	1,978
78	-2,920	0,375	-0,375	1,951
79	-2,859	0,497	-0,497	1,913
80	-2,780	0,618	-0,618	1,866
81	-2,684	0,736	-0,736	1,810
82	-2,572	0,852	-0,852	1,746
83	-2,443	0,964	-0,964	1,675
84	-2,299	1,072	-1,072	1,598
85	-2,141	1,176	-1,176	1,516
86	-1,967	1,275	-1,275	1,431
87	-1,780	1,369	-1,369	1,344
88	-1,580	1,458	-1,458	1,256
89	-1,368	1,541	-1,541	1,169
90	-1,145	1,618	-1,618	1,084
91	-0,911	1,689	-1,689	1,002
92	-0,668	1,753	-1,753	0,925
93	-0,416	1,810	-1,810	0,854
94	-0,157	1,860	-1,860	0,790
95	0,109	1,902	-1,902	0,734
96	0,381	1,937	-1,937	0,687
97	0,657	1,965	-1,965	0,649
98	0,936	1,984	-1,984	0,622
99	1,217	1,996	-1,996	0,606

NOTE 100 % loading cycle corresponds to 1s.

Annex D
(informative)

Alternative loading conditions

D.1 General

The test in this annex is not intended to replace the standard wear test as described in this part of ISO 18192.

The user of this part of ISO 18192 may consider running an additional wear test using alternative loading conditions. A set of data is provided for this purpose. Using these data results in the following three major differences compared to the regular loading conditions:

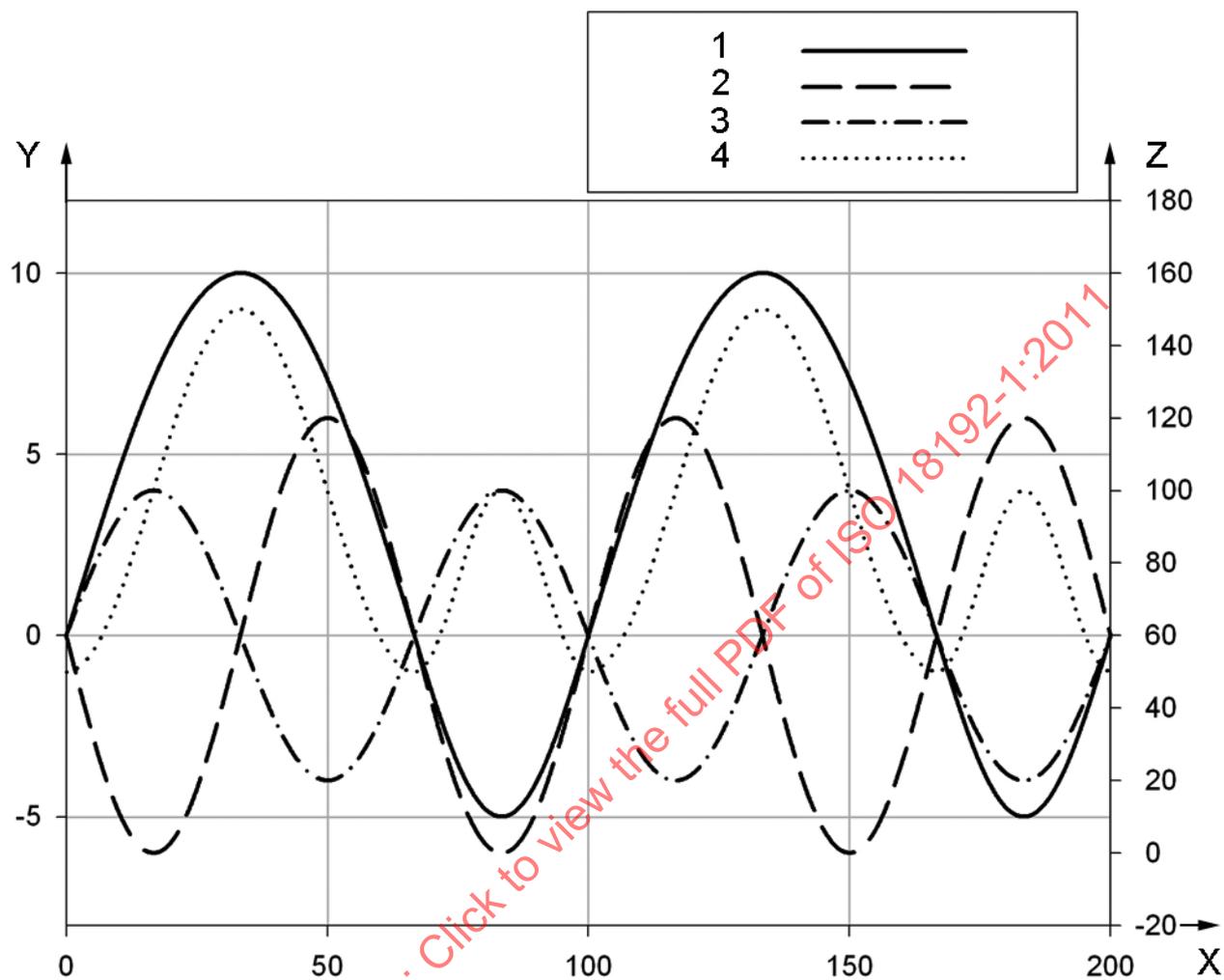
- the implant passes the reference position (no deflection in either direction);
- there are two stopping points within one cycle with no relative motion between the components;

NOTE The stopping points can affect the wear characteristics of certain material combinations due to breakdown of the lubrication film.

- the cervical waveform has an increased compressive load in extension.

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D.2 Alternative loading conditions for cervical implants



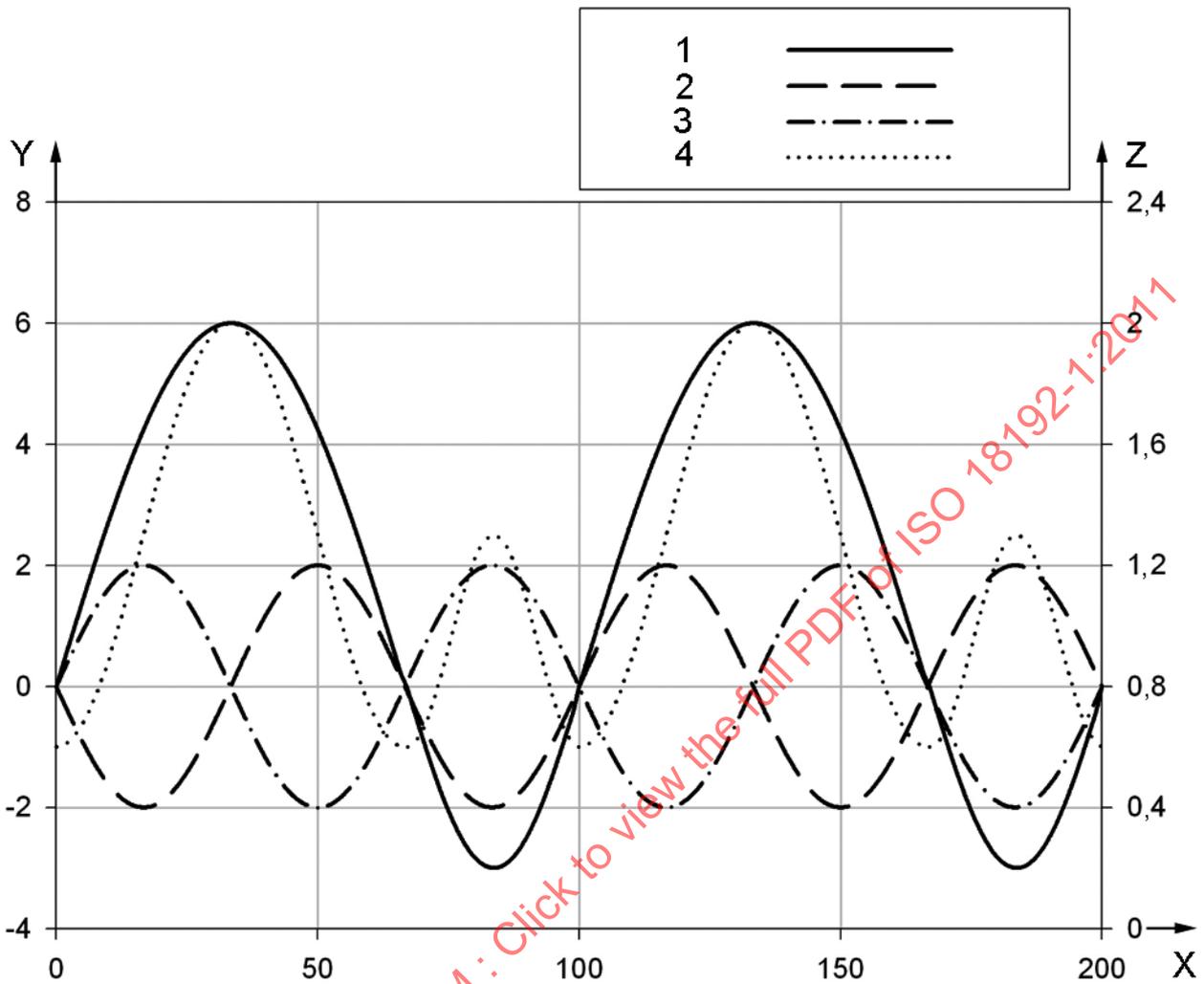
Key

- X cycle (%)
- Y angle (°)
- Z load (N)
- 1 flexion/extension
- 2 lateral bending
- 3 rotation
- 4 load

NOTE A 100 % cycle corresponds to one cycle. The description of cycle given in 6.1 does not apply to this figure.

Figure D.1 — Phasing of the displacement and load curves (alternative) for cervical prostheses

D.3 Alternative loading conditions for lumbar implants



Key

- X cycle (%)
- Y angle (°)
- Z load (N)

- 1 flexion/extension
- 2 lateral bending
- 3 rotation
- 4 load

NOTE A 100 % cycle corresponds to one cycle. The description of cycle given in 6.1 does not apply to this figure.

Figure D.2 — Phasing of the displacement and load curves (alternative) for lumbar prostheses

D.4 Alternative load and displacement data for cervical implants

Table D.1 — Alternative load and displacement data for cervical implants

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
0	0,000	0,000	0,000	50,0
1	0,471	-0,565	0,376	50,2
2	0,941	-1,124	0,750	50,9
3	1,409	-1,674	1,116	52,0
4	1,874	-2,209	1,472	53,5
5	2,334	-2,724	1,816	55,4
6	2,790	-3,215	2,143	57,8
7	3,239	-3,677	2,452	60,5
8	3,681	-4,107	2,738	63,6
9	4,115	-4,501	3,000	66,9
10	4,540	-4,854	3,236	70,6
11	4,955	-5,164	3,443	74,5
12	5,358	-5,429	3,619	78,7
13	5,750	-5,645	3,764	83,1
14	6,129	-5,811	3,874	87,6
15	6,494	-5,926	3,951	92,2
16	6,845	-5,988	3,992	96,9
17	7,181	-5,997	3,998	101,6
18	7,501	-5,953	3,968	106,3
19	7,804	-5,856	3,904	110,9
20	8,090	-5,706	3,804	115,5
21	8,358	-5,507	3,671	119,9
22	8,607	-5,258	3,505	124,1
23	8,838	-4,962	3,308	128,1
24	9,048	-4,623	3,082	131,9
25	9,239	-4,243	2,828	135,4
26	9,409	-3,825	2,550	138,5
27	9,558	-3,373	2,248	141,4
28	9,686	-2,891	1,927	143,8
29	9,792	-2,383	1,589	145,9
30	9,877	-1,854	1,236	147,6
31	9,940	-1,309	0,873	148,8
32	9,980	-0,752	0,501	149,6
50	7,071	6,000	-4,000	100,0
51	6,730	5,973	-3,982	95,3
52	6,374	5,894	-3,929	90,6
53	6,004	5,762	-3,841	86,1
54	5,621	5,579	-3,719	81,6
55	5,225	5,346	-3,564	77,3
56	4,818	5,066	-3,377	73,2
57	4,399	4,741	-3,161	69,4
58	3,971	4,374	-2,916	65,8
59	3,535	3,968	-2,645	62,5
60	3,090	3,527	-2,351	59,5
61	2,639	3,054	-2,036	57,0
62	2,181	2,555	-1,703	54,8
63	1,719	2,032	-1,355	53,0
64	1,253	1,492	-0,995	51,6
65	0,785	0,939	-0,626	50,6
66	0,314	0,377	-0,251	50,1
67	-0,157	-0,188	0,126	50,0
68	-0,627	-0,752	0,501	50,8
69	-1,091	-1,309	0,873	52,4
70	-1,545	-1,854	1,236	54,8
71	-1,986	-2,383	1,589	57,9
72	-2,409	-2,891	1,927	61,6
73	-2,810	-3,373	2,248	65,8
74	-3,187	-3,825	2,550	70,3
75	-3,536	-4,243	2,828	75,0
76	-3,853	-4,623	3,082	79,7
77	-4,135	-4,962	3,308	84,2
78	-4,382	-5,258	3,505	88,4
79	-4,589	-5,507	3,671	92,1
80	-4,755	-5,706	3,804	95,2
81	-4,880	-5,856	3,904	97,6
82	-4,961	-5,953	3,968	99,2

Table D.1 (continued)

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
33	9,999	- 0,188	0,126	150,0
34	9,995	0,377	- 0,251	149,9
35	9,969	0,939	- 0,626	149,4
36	9,921	1,492	- 0,995	148,4
37	9,851	2,032	- 1,355	147,0
38	9,759	2,555	- 1,703	145,2
39	9,646	3,054	- 2,036	143,0
40	9,511	3,527	- 2,351	140,5
41	9,354	3,968	- 2,645	137,5
42	9,178	4,374	- 2,916	134,2
43	8,980	4,741	- 3,161	130,6
44	8,763	5,066	- 3,377	126,8
45	8,526	5,346	- 3,564	122,7
46	8,271	5,579	- 3,719	118,4
47	7,997	5,762	- 3,841	113,9
48	7,705	5,894	- 3,929	109,4
49	7,396	5,973	- 3,982	104,7
100	0,000	0,000	0,000	50,0
101	0,471	0,565	- 0,376	50,2
102	0,941	1,124	- 0,750	50,9
103	1,409	1,674	- 1,116	52,0
104	1,874	2,209	- 1,472	53,5
105	2,334	2,724	- 1,816	55,4
106	2,790	3,215	- 2,143	57,8
107	3,239	3,677	- 2,452	60,5
108	3,681	4,107	- 2,738	63,6
109	4,115	4,501	- 3,000	66,9
110	4,540	4,854	- 3,236	70,6
111	4,955	5,164	- 3,443	74,5
112	5,358	5,429	- 3,619	78,7
113	5,750	5,645	- 3,764	83,1
114	6,129	5,811	- 3,874	87,6
115	6,494	5,926	- 3,951	92,2
116	6,845	5,988	- 3,992	96,9
117	7,181	5,997	- 3,998	101,6

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
83	- 4,998	- 5,997	3,998	100,0
84	- 4,990	- 5,988	3,992	99,8
85	- 4,938	- 5,926	3,951	98,8
86	- 4,843	- 5,811	3,874	96,9
87	- 4,704	- 5,645	3,764	94,3
88	- 4,524	- 5,429	3,619	90,9
89	- 4,304	- 5,164	3,443	87,0
90	- 4,045	- 4,854	3,236	82,7
91	- 3,751	- 4,501	3,000	78,1
92	- 3,423	- 4,107	2,738	73,4
93	- 3,065	- 3,677	2,452	68,8
94	- 2,679	- 3,215	2,143	64,4
95	- 2,270	- 2,724	1,816	60,3
96	- 1,841	- 2,209	1,472	56,8
97	- 1,395	- 1,674	1,116	53,9
98	- 0,937	- 1,124	0,750	51,8
99	- 0,471	- 0,565	0,376	0,000
50,0	7,071	- 6,000	4,000	100,0
151	6,730	- 5,973	3,982	95,3
152	6,374	- 5,894	3,929	90,6
153	6,004	- 5,762	3,841	86,1
154	5,621	- 5,579	3,719	81,6
155	5,225	- 5,346	3,564	77,3
156	4,818	- 5,066	3,377	73,2
157	4,399	- 4,741	3,161	69,4
158	3,971	- 4,374	2,916	65,8
159	3,535	- 3,968	2,645	62,5
160	3,090	- 3,527	2,351	59,5
161	2,639	- 3,054	2,036	57,0
162	2,181	- 2,555	1,703	54,8
163	1,719	- 2,032	1,355	53,0
164	1,253	- 1,492	0,995	51,6
165	0,785	- 0,939	0,626	50,6
166	0,314	- 0,377	0,251	50,1
167	- 0,157	0,188	- 0,126	50,0

Table D.1 (continued)

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)	Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
118	7,501	5,953	-3,968	106,3	168	-0,627	0,752	-0,501	50,8
119	7,804	5,856	-3,904	110,9	169	-1,091	1,309	-0,873	52,4
120	8,090	5,706	-3,804	115,5	170	-1,545	1,854	-1,236	54,8
121	8,358	5,507	-3,671	119,9	171	-1,986	2,383	-1,589	57,9
122	8,607	5,258	-3,505	124,1	172	-2,409	2,891	-1,927	61,6
123	8,838	4,962	-3,308	128,1	173	-2,810	3,373	-2,248	65,8
124	9,048	4,623	-3,082	131,9	174	-3,187	3,825	-2,550	70,3
125	9,239	4,243	-2,828	135,4	175	-3,536	4,243	-2,828	75,0
126	9,409	3,825	-2,550	138,5	176	-3,853	4,623	-3,082	79,7
127	9,558	3,373	-2,248	141,4	177	-4,135	4,962	-3,308	84,2
128	9,686	2,891	-1,927	143,8	178	-4,382	5,258	-3,505	88,4
129	9,792	2,383	-1,589	145,9	179	-4,589	5,507	-3,671	92,1
130	9,877	1,854	-1,236	147,6	180	-4,755	5,706	-3,804	95,2
131	9,940	1,309	-0,873	148,8	181	-4,880	5,856	-3,904	97,6
132	9,980	0,752	-0,501	149,6	182	-4,961	5,953	-3,968	99,2
133	9,999	0,188	-0,126	150,0	183	-4,998	5,997	-3,998	100,0
134	9,995	-0,377	0,251	149,9	184	-4,990	5,988	-3,992	99,8
135	9,969	-0,939	0,626	149,4	185	-4,938	5,926	-3,951	98,8
136	9,921	-1,492	0,995	148,4	186	-4,843	5,811	-3,874	96,9
137	9,851	-2,032	1,355	147,0	187	-4,704	5,645	-3,764	94,3
138	9,759	-2,555	1,703	145,2	188	-4,524	5,429	-3,619	90,9
139	9,646	-3,054	2,036	143,0	189	-4,304	5,164	-3,443	87,0
140	9,511	-3,527	2,351	140,5	190	-4,045	4,854	-3,236	82,7
141	9,354	-3,968	2,645	137,5	191	-3,751	4,501	-3,000	78,1
142	9,178	-4,374	2,916	134,2	192	-3,423	4,107	-2,738	73,4
143	8,980	-4,741	3,161	130,6	193	-3,065	3,677	-2,452	68,8
144	8,763	-5,066	3,377	126,8	194	-2,679	3,215	-2,143	64,4
145	8,526	-5,346	3,564	122,7	195	-2,270	2,724	-1,816	60,3
146	8,271	-5,579	3,719	118,4	196	-1,841	2,209	-1,472	56,8
147	7,997	-5,762	3,841	113,9	197	-1,395	1,674	-1,116	53,9
148	7,705	-5,894	3,929	109,4	198	-0,937	1,124	-0,750	51,8
149	7,396	-5,973	3,982	104,7	199	-0,471	0,565	-0,376	50,4

NOTE 100 % loading cycle corresponds to 1 s.

D.5 Alternative load and displacement data for lumbar implants

Table D.2 — Alternative load and displacement data for lumbar implants

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
0	0,000	0,000	0,000	0,600
1	0,283	-0,188	0,188	0,603
2	0,565	-0,375	0,375	0,612
3	0,845	-0,558	0,558	0,628
4	1,124	-0,736	0,736	0,649
5	1,401	-0,908	0,908	0,676
6	1,674	-1,072	1,072	0,709
7	1,944	-1,226	1,226	0,747
8	2,209	-1,369	1,369	0,790
9	2,469	-1,500	1,500	0,837
10	2,724	-1,618	1,618	0,889
11	2,973	-1,721	1,721	0,944
12	3,215	-1,810	1,810	1,002
13	3,450	-1,882	1,882	1,063
14	3,677	-1,937	1,937	1,126
15	3,897	-1,975	1,975	1,190
16	4,107	-1,996	1,996	1,256
17	4,309	-1,999	1,999	1,322
18	4,501	-1,984	1,984	1,388
19	4,683	-1,952	1,952	1,453
20	4,854	-1,902	1,902	1,516
21	5,015	-1,836	1,836	1,578
22	5,164	-1,753	1,753	1,637
23	5,303	-1,654	1,654	1,693
24	5,429	-1,541	1,541	1,746
25	5,543	-1,414	1,414	1,795
26	5,645	-1,275	1,275	1,839
27	5,735	-1,124	1,124	1,879
28	5,811	-0,964	0,964	1,913
29	5,875	-0,794	0,794	1,942
30	5,926	-0,618	0,618	1,966
31	5,964	-0,436	0,436	1,983
32	5,988	-0,251	0,251	1,994

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
50	4,243	2,000	-2,000	1,300
51	4,038	1,991	-1,991	1,234
52	3,825	1,965	-1,965	1,169
53	3,603	1,921	-1,921	1,105
54	3,373	1,860	-1,860	1,042
55	3,135	1,782	-1,782	0,982
56	2,891	1,689	-1,689	0,925
57	2,640	1,580	-1,580	0,871
58	2,383	1,458	-1,458	0,821
59	2,121	1,323	-1,323	0,775
60	1,854	1,176	-1,176	0,734
61	1,583	1,018	-1,018	0,697
62	1,309	0,852	-0,852	0,667
63	1,032	0,677	-0,677	0,641
64	0,752	0,497	-0,497	0,622
65	0,471	0,313	-0,313	0,609
66	0,188	0,126	-0,126	0,601
67	0,000	-0,063	0,063	0,600
68	-0,282	-0,251	0,251	0,606
69	-0,562	-0,436	0,436	0,625
70	-0,837	-0,618	0,618	0,654
71	-1,104	-0,794	0,794	0,695
72	-1,362	-0,964	0,964	0,744
73	-1,607	-1,124	1,124	0,801
74	-1,839	-1,275	1,275	0,863
75	-2,054	-1,414	1,414	0,928
76	-2,250	-1,541	1,541	0,994
77	-2,427	-1,654	1,654	1,058
78	-2,582	-1,753	1,753	1,119
79	-2,714	-1,836	1,836	1,173
80	-2,823	-1,902	1,902	1,220
81	-2,906	-1,952	1,952	1,257
82	-2,963	-1,984	1,984	1,283

Table D.2 (continued)

Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)	Loading cycle (%)	Flexion/extension (°)	Lateral bending (°)	Rotation (°)	Load (N)
33	5,999	-0,063	0,063	2,000	83	-2,994	-1,999	1,999	1,297
34	5,997	0,126	-0,126	1,999	84	-2,999	-1,996	1,996	1,299
35	5,982	0,313	-0,313	1,991	85	-2,976	-1,975	1,975	1,289
36	5,953	0,497	-0,497	1,978	86	-2,928	-1,937	1,937	1,267
37	5,911	0,677	-0,677	1,959	87	-2,853	-1,882	1,882	1,233
38	5,856	0,852	-0,852	1,933	88	-2,753	-1,810	1,810	1,190
39	5,787	1,018	-1,018	1,903	89	-2,629	-1,721	1,721	1,138
40	5,706	1,176	-1,176	1,866	90	-2,481	-1,618	1,618	1,079
41	5,613	1,323	-1,323	1,825	91	-2,312	-1,500	1,500	1,016
42	5,507	1,458	-1,458	1,779	92	-2,121	-1,369	1,369	0,950
43	5,388	1,580	-1,580	1,729	93	-1,912	-1,226	1,226	0,884
44	5,258	1,689	-1,689	1,675	94	-1,686	-1,072	1,072	0,821
45	5,116	1,782	-1,782	1,618	95	-1,445	-0,908	0,908	0,762
46	4,962	1,860	-1,860	1,558	96	-1,191	-0,736	0,736	0,710
47	4,798	1,921	-1,921	1,495	97	-0,927	-0,558	0,558	0,667
48	4,623	1,965	-1,965	1,431	98	-0,654	-0,375	0,375	0,633
49	4,438	1,991	-1,991	1,366	99	-0,376	-0,188	0,188	0,611
100	0,000	0,000	0,000	0,600	150	4,243	-2,000	2,000	1,300
101	0,283	0,188	-0,188	0,603	151	4,038	-1,991	1,991	1,234
102	0,565	0,375	-0,375	0,612	152	3,825	-1,965	1,965	1,169
103	0,845	0,558	-0,558	0,628	153	3,603	-1,921	1,921	1,105
104	1,124	0,736	-0,736	0,649	154	3,373	-1,860	1,860	1,042
105	1,401	0,908	-0,908	0,676	155	3,135	-1,782	1,782	0,982
106	1,674	1,072	-1,072	0,709	156	2,891	-1,689	1,689	0,925
107	1,944	1,226	-1,226	0,747	157	2,640	-1,580	1,580	0,871
108	2,209	1,369	-1,369	0,790	158	2,383	-1,458	1,458	0,821
109	2,469	1,500	-1,500	0,837	159	2,121	-1,323	1,323	0,775
110	2,724	1,618	-1,618	0,889	160	1,854	-1,176	1,176	0,734
111	2,973	1,721	-1,721	0,944	161	1,583	-1,018	1,018	0,697
112	3,215	1,810	-1,810	1,002	162	1,309	-0,852	0,852	0,667
113	3,450	1,882	-1,882	1,063	163	1,032	-0,677	0,677	0,641
114	3,677	1,937	-1,937	1,126	164	0,752	-0,497	0,497	0,622
115	3,897	1,975	-1,975	1,190	165	0,471	-0,313	0,313	0,609
116	4,107	1,996	-1,996	1,256	166	0,188	-0,126	0,126	0,601
117	4,309	1,999	-1,999	1,322	167	0,000	0,063	-0,063	0,600