
**Implants for surgery — Partial and total
hip joint prostheses —**

Part 4:

**Determination of endurance properties
and performance of stemmed femoral
components**

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*Implants chirurgicaux — Prothèses partielles et totales de l'articulation
de la hanche —*

*Partie 4: Détermination des propriétés d'endurance et des
performances des tiges fémorales*

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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 7206-4 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This third edition cancels and replaces the second edition (ISO 7206-4:2002), which has been technically revised (see **Introduction**).

ISO 7206 consists of the following parts, under the general title *Implants for surgery — Partial and total hip joint prostheses*:

- *Part 1: Classification and designation of dimensions*
- *Part 2: Articulating surfaces made of metallic, ceramic and plastics materials*
- *Part 4: Determination of endurance properties and performance of stemmed femoral components*
- *Part 6: Determination of endurance properties of head and neck region of stemmed femoral components*
- *Part 8: Endurance performance of stemmed femoral components with application of torsion*
- *Part 10: Determination of resistance to static load of modular femoral heads*

A future part 12 will cover deformation testing for acetabular cups.

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Introduction

Some aspects of the prior editions of ISO 7206-4 were not sufficiently described and some parts of the test method did not reflect the current test practice as shown below.

- a) Test conditions for anteverted stems will result in a significant decrease of the medial-lateral bending forces. This reflects the “best case” test condition in comparison to “worst case” conditions for non-anteverted stems and will lead to test results not reflecting the high forces in the human body, because the rotated position is not considered.
- b) Specific test conditions for stemmed femoral components with CT distance ≤ 120 mm are not considered.

NOTE The dimension CT is the distance between the centre of the femoral head, C, and the most distal point of the stem, T.

- c) Changes in the potting level in comparison to ISO 7206-4:2002 without changes in the corresponding performance standard ISO 7206-8.

In order to overcome these disadvantages it was proposed to define the test conditions for three types of stem length, to describe the test procedure and stem axis definition particularly for anteverted stems more precisely and to harmonize the test conditions with the endurance performance of ISO 7206-8.

This edition in some respects allows more accurate and easier handling by the test laboratories and defines a clear separation of stemmed femoral components into three categories:

- stems with CT distance ≤ 120 mm; [ISO 7206-4:2010](https://standards.iteh.ai/catalog/standards/sist/2e1b165a-27fd-4e40-9fcd-f9b057a5e18/iso-7206-4-2010)
- stems with CT distance $120 \text{ mm} < \text{CT} \leq 250 \text{ mm}$;
- stems with CT distance > 250 mm.

It includes performance criteria for these components. This will lead to a higher acceptance of the test method and more reproducible test results.

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Implants for surgery — Partial and total hip joint prostheses —

Part 4:

Determination of endurance properties and performance of stemmed femoral components

1 Scope

This part of ISO 7206 specifies a test method for determining the endurance properties of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joints under specified laboratory conditions. It also defines the conditions of testing so that the important parameters that affect the components are taken into account, and describes how the specimen is set up for testing.

Furthermore, this part of ISO 7206 specifies the test parameters and the requirements for the endurance limit of stemmed femoral components tested in accordance with this document. The value of the endurance limit test forces and the corresponding number of load cycles are specified.

This test method has been developed for prostheses that have a plane of symmetry, that have preformed anteversion and/or antetorsion and/or double curvature of the stem.

This part of ISO 7206 does not cover methods of examining the test specimen after testing; these should be agreed between the test laboratory and the party submitting the specimen for test.

For tests on modular stemmed femoral components a fluid to surround the component during the test is specified.

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 4965, *Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique*

ISO 7206-1 *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7206-1 and the following apply.

3.1

modular neck stem

stem designed to be used with a separate femoral neck that has a self-locking taper that connects with a mating taper on the most proximal aspect of the stem

3.2
endurance limit
 F_D
maximum value of the cyclic test force applied for N_D cycles after which the specimen is unbroken and undeformed (see Table 2)

3.3
endurance cycles
 N_D
prescribed number of cycles of the test force

4 Principle

The lower portion of the test specimen is embedded in a solid medium and a cyclic load is applied to the head of the test specimen to produce axial compression, two-plane bending and torsion until the specimen exhibits failure or until the prescribed number of cycles has been attained. The specimen is subsequently examined for defects caused by the loading regime.

NOTE Methods of examining the test specimen should be agreed between the test laboratory and the party submitting the specimen for test.

5 Materials

5.1 Embedding material

Embedding medium, i.e. a casting medium, which shall:

- a) not break under the load applied during testing;
- b) not exhibit excessive deformation or creep;
- c) be reproducible in strength and other characteristics.

NOTE The media that appear satisfactory are acrylic bone cement (see ISO 5833), filled epoxy casting resin and liquid metal alloy. The media should have a modulus of elasticity between 2 000 N/mm² and 6 000 N/mm².

5.2 Fluid test medium

A 9,0 g/l solution of analytical grade sodium chloride (NaCl) in distilled or deionized water of grade 3 as specified in ISO 3696.

6 Apparatus

6.1 Testing machine, having the following characteristics:

- a) ability to apply a cyclic load according to Clause 9 at a frequency of between 1 Hz and 30 Hz;
- b) error in applied load: no greater than ± 2 % of maximum load as specified in ISO 4965;
- c) dynamic loading waveform: sinusoidal at the primary frequency;
- d) instrumentation to monitor the values of the maximum and minimum loads and the vertical deflection of the test specimen to a tolerance of $\pm 0,2$ mm, to stop the machine if deflection exceeds a prescribed value and to record the corresponding number of cycles or the elapsed time of operation.

6.2 Specimen holders, that have a construction and dimensions to suit the testing machine and test specimens. An example of a suitable holder is shown in Figure A.1.

6.3 Fluid container, for tests on modular stemmed femoral components where the container surrounds the test specimen and contains the test fluid together with means of heating and aerating it.

6.4 Device to grip the test specimen by the head or neck, which retains the specimen in the orientation specified in 8.3 during embedding. An example of a suitable device to grip the head of the specimen is shown in Figure A.2.

6.5 Means of loading the test specimen, which maintains loading through the centre of the head of the specimen, along the axis of the testing machine, and which incorporates a low-friction mechanism that minimizes loads not coincident with the axis of the testing machine (see Figure A.1). The frictional moment of the articulation between head and loading mechanism can significantly influence the test results. Two different loading mechanisms found suitable are shown in Figure A.1.

NOTE 1 Attention is drawn to the importance of lubricating the loading mechanism correctly during testing. The use of ceramic heads in combination with the metal plate loading might cause sudden head fractures and is not recommended.

NOTE 2 Thrust bearings used as a low-friction mechanism should be carefully designed. Thrust bearings will tend to migrate under the fatigue load. If the bearing ends up against a significant retaining mechanism such as a lip or post, it no longer functions as a low friction mechanism. It can, in this condition, actually apply a back force perpendicular to the main load that can significantly decrease the bending forces in the stem.

7 Selection of test specimens

Test specimens shall be selected as a batch of six and shall be technically equivalent to the implantable product. The combination of hip stem and head to be tested should be the “worst case” expected to produce the highest levels of stress in the stem.

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8 Procedure

8.1 Measure the distance between the centre of the head and the most distal point of the stem, length CT, as shown in Figures A.3 to A.6.

For all stems (i.e. monobloc and modular), a head with a neck length considering the worst case scenario shall be used for the measurement of the length CT, measurements associated with defining the axis of the distal stem, orientation of the stem in the potting medium, determination of the location of the potting level and testing.

8.2 Define the axis of the distal stem as the stem axis joining the centres of cross-sections as described in Figures A.3 to A.6.

For femoral stem components with a CT distance < 120 mm it is possible that the line KL coincides with the intended alignment of the stem relative to the femoral bone axis. In such a case, position the distal region of the stem of the implant along a virtual axis defined by the shape of the proximal region of an implant as shown in Figure A.5.

8.3 Hold the head or neck of the test specimen by means of the gripping device (6.4) and position the specimen so that the axis KL of the stem or the virtual stem axis of the short stem hip joint component is oriented at angles α and β as given in Table 1 for all stem lengths as shown in:

- Figures A.3 and A.4 for a stemmed femoral component with a CT distance $120 \text{ mm} < CT \leq 250 \text{ mm}$;
- Figure A.5 for a stemmed femoral component with a CT distance $\leq 120 \text{ mm}$;
- Figure A.6 for a stemmed femoral component with a CT distance $> 250 \text{ mm}$.

For an anteverted/curved stem (Figure A.4) the stem shall be rotated about the stem axis KL by an angle equal to the angle of anteversion with a tolerance of $\pm 1^\circ$.

8.4 Mount the holder and specimen in the gripping device (6.4) so that the load line of the testing machine intersects point C of the specimen, as designated in ISO 7206-1. Clamp the holder firmly in position and ensure that the correct orientation of the specimen is maintained.

NOTE 1 The angles α and β should be measured relative to the load line of the test machine.

NOTE 2 It is essential that the neck of the prosthesis is not marked or damaged during this installation process because damage can affect the endurance properties. Damage to the head of the prosthesis should also be avoided as this can increase the friction between the head and the loading system during testing.

8.5 Embed the specimen in the embedding medium (5.1) in the holder (6.2) so that the upper surface of the potting medium is at a distance D below the centre of the head. The dimension D is shown in Table 1.

Table 1 — Parameters for test set-up

Parameter	Tolerance	Stem length		
		≤ 120	$120 < CT \leq 250$	> 250
CT (mm)	± 2	≤ 120	$120 < CT \leq 250$	> 250
D (mm)	± 2	$0,66 \times CT$	80	$CT-100$
α ($^\circ$)	$\pm 1,0$	10	10	0
β ($^\circ$)	$\pm 1,0$	9	9	4

NOTE 1 For stems that are intended for revision cases where there has been significant proximal loss of support at the time of implantation, an additional test is recommended using a potting level at a distance below the centre of the head of the prosthesis, which corresponds to the maximum proximal bone loss for which the revision stem is intended to treat, as recommended by the manufacturer.

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NOTE 2 It might be necessary to adjust the potting level so that stress risers (e.g. stems with design features such as slots, ribs, changes in material/material coatings, or surface characteristics) that are near the potting level are above the potting level.

8.6 Support the test specimen in position until the embedding medium has hardened sufficiently to support the specimen unaided. Do not start testing until the embedding medium has fully hardened.

NOTE In a few cases (circular or slightly elliptical cross-sections of stem) an additional rotational stabilization may be used. This stabilization should fix only the tip of the stem.

8.7 Implants having non-modular stems shall be tested at room temperature under dry conditions. For testing implants that have modular femoral stems, add fluid test medium (5.2) to the fluid container so as to cover all of the modular femoral stems' or modular neck stems' modular components above the cement level for the duration of the entire test. Maintain the temperature of the fluid test medium at $37^\circ\text{C} \pm 1^\circ\text{C}$ and continuously aerate it. These tests shall be conducted at a frequency of 5 Hz or less.

8.8 Start the testing machine and adjust it so that the desired load range is applied to the test specimen through the loading mechanism (6.5).

NOTE The value of the minimum load in the load cycle necessary for satisfactory operation of the testing machine has been found to be a force between 200 N and 300 N.

8.9 Operate the testing machine at a frequency of between 1 Hz and 30 Hz which allows the application of the prescribed load to an accuracy of $\pm 2\%$ of the load range.

NOTE The testing frequency might influence the test results for non-metallic specimens.

8.10 Measure the initial vertical load. Measure the initial vertical load axis deflection of the test sample, f . After approximately 300 test cycles, stop the test and set the cut-off switch to stop the test if the deflection exceeds $1,25 \times f$ or 5 mm, whichever is greater.

If this indication is given by the testing machine or the instrument, terminate the test. Examine the embedding medium and the specimen to determine whether the specimen has loosened in the embedding medium or permanent yield of the specimen has occurred.

8.11 Continue the test until one of the following events occurs:

- a) excess deflection as described in 8.10;
- b) fracture of the specimen;
- c) completion of the prescribed number of load cycles;
- d) inability of the testing machine to maintain the required load values.

In each case, record the number of cycles and the reason for termination of the test.

8.12 Remove the specimen from the embedding medium.

8.13 Examine the test specimen, using the methods, if any, requested by the party who submitted the specimen for testing.

8.14 Repeat the procedures stated until all of the test samples in the batch have been tested.

9 Endurance performance

The required endurance limit F_D is the load level where the specimens survive 5 000 000 cycles without failure, as shown in Table 2. The batch of specimens shall satisfy the requirements of this part of ISO 7206 if all are unbroken.

Table 2 — Parameters for testing

Kind of stem	Short, monobloc, modular neck, modular femoral		
CT (mm)	≤ 120	$120 < CT \leq 250$	> 250
F_D (N)	1 200 ^a	2 300 ^b	1 200 ^c
Number of cycles	5×10^6		
Number of unbroken specimens	6		
NOTE 1 Alternative methods might be deemed to be acceptable if minimum run-out loads calculated by statistical means meet the requirements given by this part of ISO 7206 at 95 % confidence.			
NOTE 2 For modular femoral stems additional tests might be necessary.			
<p>^a This value is not based on extensive clinical experience but given as a lower limit and may need to be adjusted upwards based on design and material considerations, and clinical experience with stems of similar design and material that have been implanted in significant numbers with a long-term (> 5 years) history with no significant numbers of fractures in the highly stressed regions evaluated by this test method.</p> <p>^b This value is based on the previous requirement in ISO 7206-8 for a stem for the average patient (in Europe). Some smaller stems in the size range (120 mm to 250 mm) and not intended for use in the average patient (in Europe) have been used clinically long-term without fracture and have not met the 2 300 N requirement. Smaller stems in this size range could have a performance requirement lower than 2 300 N when they can be shown to be as strong as stems of similar design and material, which have been implanted in significant numbers with a long-term (> 5 years) history with no significant numbers of fractures in the highly stressed regions evaluated by this test method.</p> <p>^c This value is based on limited clinical experience but given as a lower limit and may need to be adjusted upwards based on design and material considerations, and clinical experience of similar devices.</p>			