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Implants for surgery — Partial and total hip joint prostheses —

Part 6:
Endurance properties testing and performance requirements of neck region of stemmed femoral components

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

Partie 6: Exigences de performance et essais des propriétés d'endurance de la région du col des tiges fémorales

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 7206-6:1992), of which it constitutes a minor revision.

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: Endurance properties testing and performance requirements of neck region of stemmed femoral components*

— *Part 10: Determination of resistance to static load of modular femoral heads*

Introduction

The test method described in this part of ISO 7206 is intended for the verification of the endurance properties of the neck region of stemmed femoral components of hip joint prostheses. This method is based extensively on that given in ISO 7206-4, which verifies the endurance properties of the complete femoral component under loading conditions that include a torsional component. The test conditions in ISO 7206-4, especially the height of the specimen embedding, are intended to represent the clinical situation where the prosthesis has become loosened in the femur, whereas the test conditions in this part of ISO 7206 are intended to represent a correctly and firmly fixed prosthesis. Therefore, it should be noted that the tests in this part of ISO 7206 may not be representative of the most unfavourable clinical conditions.

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Implants for surgery — Partial and total hip joint prostheses —

Part 6:
Endurance properties testing and performance requirements of neck region of stemmed femoral components

1 Scope

This part of ISO 7206 specifies test methods and the fatigue performance for the endurance properties, under specified laboratory conditions, of neck region of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joint replacement. This part of ISO 7206 does not cover the investigation of the performance of the head or the neck-head junction. It is applicable to modular and non-modular designs made of metallic or non-metallic materials.

It also specifies the test conditions so that the important parameters that affect the hip femoral components are taken into account and describes how the specimen is set up for testing.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 4965-1:2012, *Metallic materials — Dynamic force calibration for uniaxial fatigue testing — Part 1: Testing systems*

ISO 4965-2:2012, *Metallic materials — Dynamic force calibration for uniaxial fatigue testing — Part 2: Dynamic calibration device (DCD) instrumentation*

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
implantable
condition of a test sample which has received all the machining processes, cleaning, degreasing, and sterilization procedures required prior to implantation

3.2
resection line/level
level prescribed by the manufacturer which, in clinical use of the femoral hip stem, corresponds to the proximal cut of the bone shaft

4   Principle of the test method

The test specimen is embedded in a solid medium. For modular stems, the protruding part of the test specimen is immersed in a fluid test medium. A cyclic load is applied to the head of the test specimen until one of the conditions mentioned in 8.10 occurs.

5   Materials

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

a)   not crack or break under the load applied during testing;

b)   not exhibit excessive deformation or creep;

c)   be reproducible in strength and other characteristics.

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

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, has the following characteristics:

a)   ability to apply a cyclic load in accordance with Clause 8, at the chosen frequency;

b)   tolerance in applied load is not greater than ± 2 % at maximum load applied, as specified in ISO 4965;

c)   dynamic loading waveform is sinusoidal at the primary frequency;

d)   instrumentation to monitor the values of the maximum and minimum loads and the vertical deflection of the head of the test specimen with an uncertainty lower than ± 0,4 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, has a construction and dimensions to suit the testing machine and test specimens.

An example of a suitable holder is shown in Figure A.1.

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

6.3   Fluid container, for tests on modular stemmed femoral components where the container surrounding the test specimen is used to contain the test fluid together with a means of heating it.

6.4   Gripping device, used to grip the test specimen by the head or neck, which retains the specimen in the orientation specified in 8.4. An example of a suitable device is shown in Figure A.2.

6.5   A means of loading the test specimen, shall be employed which maintains loading through the centre of the head of the specimen, along the axis of the testing machine.

It shall also incorporate a low-friction mechanism that in the horizontal plane minimizes loads not coincident with the axis of the testing machine.

7   Selection of test specimens

Six specimens shall be selected and shall be technically equivalent to the implantable product. The combination of hip stem, head, and other components to be tested should be the "worst case" expected to produce the highest levels of stress in the neck region of the stem. The technical equivalence of the tested components with the implantable products shall be documented.

8   Procedure

8.1   Measurement of the distance (CT)

Measure the distance (CT) between the centre of the head (C) and the most distal point of the stem (T) in accordance with Figures A.3a, A.3b, A.4a, and A.4b.

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

8.2   Definition of the distal stem axis

Define the distal stem axis as the line (KL) joining the centres of cross sections at distances $0,1 \times CT$ and $0,4 \times CT$ from the most distal end of the stem (point T) when CT is shorter than 200 mm and $0,1 \times CT$ and $0,8 \times CT$ when CT is longer than 200 mm, as shown in Table 1.

NOTE   Femoral stems > 200 mm may be shortened to a minimum of 200 mm stem length for embedding after appropriate orientation (as given in Table 1 and Figure A.4: K 0,1 x CT; L 0,8 CT) by using a template.

Table 1 — K and L distance from the stem tip depending on CT length

	CT length	
	≤ 200 mm	> 200 mm
K	$0,1 \times CT$	$0,1 \times CT$
L	$0,4 \times CT$	$0,8 \times CT$

8.3   Definition of the proximal stem axis

Define the proximal stem axis as the neck or taper axis when this axis is obvious or the line joining the head centre (C) and the centre (M) of the cross sections located 10 mm above the resection line when no taper or neck axis is easily defined. For curved neck stems, the second definition should be preferred.

8.4   Specimen positioning

Hold the head or neck of the test specimen by means of the gripping device (6.4) and position the specimen so that the distal axis is oriented at angle α and the proximal axis is oriented at angle β, where α = 10° ± 1° and β = 9° ± 1° for all stem lengths, as shown in Figures A.3a, A.3b, A.4a, and A.4b.

Mount the holder and specimen in the gripping device 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. Measure and record the angles α and β, as designated in Figures A.3a, A.3b, A.4a, and A.4b.

The angles α and β should be measured between projection of KL axis in two vertical planes and the load line of the test machine. The angle α should be measured before angle β.

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.

For a neck with anteversion or retroversion, the stem shall be rotated around KL axis with an angle corresponding to anteversion or retroversion angle with a tolerance of ± 1°.

8.5 Specimen embedding

Embed the specimen in the embedding medium (5.1) in the holder (6.2) so that the embedding medium extends up to the resection level ± 2 mm (see Figure A.1).

Areas of high stress (for example, impaction holes and extraction holes) should not be covered by the embedding medium.

8.6 Embedding medium hardening

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.

8.7 Test conditions

Implants having non-modular stems (except for the neck-head junction), 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°C ± 2°C.

8.8 Loading

Start the testing machine and adjust it to apply sinusoidal loading of the desired range 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 500 N and 600 N.

8.9 Frequency

For implants having non-modular stems (except for the neck-head junction), 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 ± 2 % of the load range, as verified in 6.1.

For implants that have modular femoral stems, these tests shall be conducted at a frequency of 5 Hz or less.

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

8.10 Test end

Continue the test until one of the following events occurs:

a) the vertical deflection exceeds a value of 3 mm greater than the deflection occurring in the first minute of running at test load;

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.

8.11 Complementary analysis

At the conclusion of the test, if the prescribed number of cycles has not been reached and a fracture is not visible in the neck, remove the embedding medium to establish if the stem is fractured.

8.12 Test repetition

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

9 Endurance performance

The six specimens shall satisfy the requirements of this standard if, after performing the complementary analysis, all femoral components are undamaged after 10 000 000 cycles with a load of 5 340 N. This load may be lowered only when endurance equivalence can be demonstrated with regularly marketed stems of the same design, material, and indications which can demonstrate over 10 years of clinical use with no statistically significant mechanical failure rates.

For stems which do not meet this criterion, the manufacturer shall indicate that they are designed for limited indications.

10 Test report

The test report shall include the following information, where necessary:

a) a reference to this part of ISO 7206 (i.e. ISO 7206-6);

b) the identity and a description of the test specimens (at least the part number, size, offset, and batch), as stated by the party submitting the specimens for the test and the manufacturer's name and list reference;

c) the femoral head used for testing;

d) the embedding medium used;

e) an illustration of the embedding level;

f) the minimum and maximum loads applied;

g) the loading frequency;

h) the duration of the test, in cycles;

i) for each specimen in the batch, the reason why the test was terminated and whether the batch satisfied the requirements of this part of ISO 7206;

j) a statement of results including location of fracture (if fracture occurred), description of each test specimen at the end of the test, and the results of the examination, if any, requested by the party submitting the specimen for test;

k) a statement from manufacturer justifying that the size tested was "worst case";

l) the values of the offset angles (α and β) in degrees;

m) if applicable, a rationale demonstrating the relevance of the chosen test procedure when the test procedure has been modified for particular stems made for particular indications (i.e. dysplasia, revision).