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Implants for surgery — Partial and total hip joint prostheses —

Part 8:
Endurance performance of stemmed femoral components

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

Partie 8: Performances en matière d'endurance des tiges fémorales

[Revision of first edition (ISO 7206-8:1995)]

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Foreword

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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.

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ISO 7206-8 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

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This second edition cancels and replaces the first edition (ISO 7206-8:1995), which has been technically revised.

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

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— *Part 1: Classification and designation of dimensions*

— *Part 2: Articulating surfaces made of metallic, ceramic and plastics materials*

— *Part 4: Determination of endurance properties 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*

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

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Introduction

Endurance properties are important attributes of *in vivo* performance of orthopaedic implants.

This Part of ISO 7206-8 provides performance requirements for stemmed femoral components of hip replacement implants when tested in accordance with Part 4 of this International Standard.

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Implants for surgery — Partial and total hip joint prostheses — Part 8: Endurance performance of stemmed femoral components

1 Scope

This Part of ISO 7206 specifies the test parameters and the requirements for the endurance limit of stemmed femoral components of total hip joint replacements and of stemmed components of partial hip joint replacement tested in accordance with ISO 7206-4.

The allowed test methods, maxima and minima of the cyclic load, the minimum number of load cycles for each method and the needed number of specimens are determined.

2 Normative references

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The following referenced document is 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.

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ISO 7206-4, *Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties of stemmed femoral components*

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3 Terms, definitions, and abbreviations

3.1 Terms and definitions

For the purposes of this Part of ISO 7206, the following terms and definitions apply:

3.1.1
Locati test
multiple step test

3.1.2
endurance limit
F_D
maximum load where the hip stem survives 5 000 000 cycles

3.1.3
determined number of cycles
N_D
number of cycles for the demanded endurance limit F_D ($N_D = 5\ 000\ 000$)

3.1.4
run-out
specimen which survives 5 million cycles without failure

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3.2 Abbreviations

For the purposes of this Part of ISO 7206, the following abbreviations apply.

3.2.1
F_o
maximum load

3.2.2
F_u
minimum load

3.2.3
$F_{D,\,min}$
demanded endurance limit for hip stems

3.2.4
F_{DW}
endurance calculated from the regression line (method A)

3.2.5
F_{DL}
endurance limit estimated from the Locati-test (method B)

3.2.6
L
index of load level where the specimen fails in the Locati – test

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3.2.7
$F_{o,L}$
maximum load at the level were the specimen fails in the Locati – test

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3.2.8
n_L
number of cycles to failure at load level $F_{o,L}$

3.2.9
Δn
number of cycles at one load level in the Locati-test ($\Delta n = 1\ 000\ 000$)

4 Selection of test specimens

The hip stems shall be tested in implantable condition. The combination of hip stem and hip ball selected shall have the dimensions expected to produce the highest levels of stress (i.e. worst case).

NOTE The test equipment and method of mounting the specimen are stated in ISO 7206-4.

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5 Test conditions

5.1 General

The required endurance limit $F_{D,min}$ is the load level where the specimens survive a determined number of cycles N_D without failure. For hip stems, N_D is determined to 5 000 000 cycles and $F_{D,min}$ to at least 2 300 N.

NOTE For modular stemmed femoral components N_D should be determined to 10 000 000 cycles.

The evidence that the specimens fulfil these requirements shall be given by one of the three following methods.

5.2 Method A

Determination and confirmation of an endurance limit F_{DW}.

With four specimens tested in single step tests the endurance limit is determined by using a regression line. If F_{DW} is higher than 3 300 N, two run-out tests shall be performed for its confirmation. If it is lower than 3 300 N, six run-out tests shall be performed on load levels equal or higher than 2 300 N to confirm the required endurance limit $F_{D,min}$ (see figure A.1)

5.3 Method B

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Determination and confirmation of an endurance limit F_{DL}.

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One multiple step test (so-called Locati-test) is performed to determine F_{DL}. If F_{DL} is higher than 3 300 N, two run-out tests shall be performed for its confirmation. If it is lower than 3 300 N, six run-out tests shall be performed on load levels equal or higher than 2 300 N to confirm the required endurance limit $F_{D,min}$ (see figure A.2).

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5.4 Method C

Test of six specimens with a maximum load of 2 300 N or higher and a minimum load of 230 N, which are able to withstand cyclic loading with 5 000 000 cycles without failure (see figure A.3).

6 Testing according to Method A

6.1 Test performance and parameters

The test consists of two parts. The first part contains the determination of the endurance limit F_{DW} of the tested hip stems on a basis of four single step tests. The second part is the confirmation of this endurance limit F_{DW} with two or six run-outs (see Clause 5).

At first, four single step tests have to be performed on different load levels. These load levels shall be approximately uniformly distributed above the estimated value F_{DW} with the aim of producing failures. For all tests $F_u = 0{,}1 \times F_o$ is recommended. The numbers of cycles to failure should be situated between 50 000 and 5 000 000 cycles for all these specimens. The results of the tests shall be transferred into a double-logarithmic-coordinate system. Subsequently, the regression line (in a double-logarithmic-coordinate system) is calculated. F_{DW} is the load that corresponds to 5 million cycles on the regression line (see figure A.1).

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