

INTERNATIONAL STANDARD

ISO 7206-7

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Implants for surgery — Partial and total hip joint prostheses —

Part 7:

Endurance performance of stemmed femoral
components without application of torsion

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

*Partie 7: Performances en matière d'endurance des tiges fémorales sans
application de torsion*

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Reference number
ISO 7206-7:1993(E)

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.

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.

International Standard ISO 7206-7 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Sub-Committee SC 4, *Bone and joint replacements*.

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

- *Part 1: Classification, designation of dimensions and requirements*
- *Part 2: Bearing surfaces made of metallic and plastics materials*
- *Part 3: Determination of endurance properties of stemmed femoral components without application of torsion*
- *Part 4: Determination of endurance properties of stemmed femoral components with application of torsion*
- *Part 5: Determination of resistance to static load of head and neck region of stemmed femoral components*
- *Part 6: Determination of endurance properties of head and neck region of stemmed femoral components*
- *Part 7: Endurance performance of stemmed femoral components without application of torsion*

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- Part 8: Endurance performance of stemmed femoral components with application of torsion
- Part 9: Determination of resistance to torque of head fixation of stemmed femoral components

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Introduction

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

Part 3 of this International Standard provides a means of evaluating designs of femoral components of partial or total hip joint replacements but more data on different stem designs for the smallest stem sizes needs to be obtained to establish minimum loading values using this test method for sizes smaller than those intended for the average size patient (in Europe). More data is also required to establish correlations of the results from this test method in relation to specific designs and materials and to reflect developing clinical experience.

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Implants for surgery — Partial and total hip joint prostheses —

Part 7:

Endurance performance of stemmed femoral components without application of torsion

1 Scope

This part of ISO 7206 specifies the endurance performance of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joint replacement as determined under specified laboratory conditions by a method that does not include the application of torsion.

This part of ISO 7206 does not apply to the following:

- a) prostheses for special clinical cases;
- b) prostheses in which the stem is curved out of the plane of the axis of the neck.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 7206. At the time of publication, the

edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7206 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7206-3:1988, *Implants for surgery — Partial and total hip joint prostheses — Part 3: Determination of endurance properties of stemmed femoral components without application of torsion.*

3 Endurance performance

When tested as described in ISO 7206-3, the femoral component shall not fracture during 5×10^6 cycles of application of a cyclic load of 3 kN with a minimum load of 300 N and a maximum load of 3,3 kN. Neither shall the test have been terminated before completion of the loading regime (see subclause 7.8 of ISO 7206-3:1988) for reasons other than loosening of the specimen in the embedding medium.