INTERNATIONAL STANDARD

ISO 7206-8

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Implants for surgery — Partial and total hip joint prostheses —

Part 8:
Endurance performance of stemmed femoral components with application of torsion

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

Partie 8: Performances en matière d'endurance des tiges fémorales avec application de torsion

Reference number
ISO 7206-8:1995(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 7206-8 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee 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 and designation of dimensions*

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

— *Part 10: Requirements, classification and designation of dimensions of bores and cones for prostheses with a modular head*

Introduction

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

Part 4 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 correlation of the results from this test method in relation to specific designs and materials, and to reflect developing clinical experience.

Implants for surgery — Partial and total hip joint prostheses —

Part 8:
Endurance performance of stemmed femoral components with 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 includes the application of torsion.

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

a) prostheses for special clinical cases;

b) prostheses for which the centreline of the stem is three-dimensionally curved and does not lie in any plane in which the axis of the neck lies.

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 7206-4:1989, *Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties of stemmed femoral components with application of torsion.*

3 Test conditions

The femoral component shall be tested in its ready-for-use condition.

4 Endurance performance

When tested as described in ISO 7206-4, the femoral component shall not fracture during 5×10^6 cycles of application of a cyclic load of 2 kN with a minimum load of 300 N and a maximum load of 2,3 kN. Neither shall the tests have been terminated before completion of the loading regime (see ISO 7206-4:1989, subclause 7.8) for reasons other than loosening of the specimen in the embedding medium.

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Descriptors: medical equipment, surgical implants, orthopaedic implants, hips, joints (articulation), prosthetic devices, specifications, durability.

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