INTERNATIONAL STANDARD

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Implants for surgery — Partial and total hip joint prostheses —

Part 4: Determination of endurance properties of stemmed femoral components

Implants chirurgicaux — Prothèses partielles et totales de l'articulation de la , tion des j. hanche —

Partie 4: Détermination des propriétés d'endurance des tiges fémorales

Reference number ISO 7206-4:2002(E)

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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 3.

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 part of ISO 7206 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 7206-4:1989), which has been technically revised.

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 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

Implants for surgery — Partial and total hip joint prostheses —

Part 4:

Determination of endurance properties of stemmed femoral components

1 Scope

This part of ISO 7206 specifies a test method for determining the endurance properties, under specified laboratory conditions, of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joints. 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.

This part of ISO 7206 is applicable to prostheses that have a plane of symmetry, or have preformed anteversion or double curvature of the stem, and to prostheses designed for use in revision surgery.

This part of ISO 7206 does not specify methods of examining the test specimen.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 7206. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 7206 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 4965:1979, Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique

ISO 7206-1:1995, 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 part of ISO 7206, the terms and definitions given in ISO 7206-1 apply.

4 Principle of the test method

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

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