INTERNATIONAL STANDARD

ISO 7206-4

Third edition
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Implants for surgery — Partial and total hip joint prostheses —

Part 4:

Determination of endurance properties and performance of stemmed femoral components

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

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

Reference number
ISO 7206-4:2010(E)

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This third edition cancels and replaces the second edition (ISO 7206-4:2002), which has been technically revised (see **Introduction**).

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: 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*

A future part 12 will cover deformation testing for acetabular cups.

Introduction

Some aspects of the prior editions of ISO 7206-4 were not sufficiently described and some parts of the test method did not reflect the current test practice as shown below.

a) Test conditions for anteverted stems will result in a significant decrease of the medial-lateral bending forces. This reflects the “best case” test condition in comparison to “worst case” conditions for non-anteverted stems and will lead to test results not reflecting the high forces in the human body, because the rotated position is not considered.

b) Specific test conditions for stemmed femoral components with CT distance $\leqslant$ 120 mm are not considered.

NOTE The dimension CT is the distance between the centre of the femoral head, C, and the most distal point of the stem, T.

c) Changes in the potting level in comparison to ISO 7206-4:2002 without changes in the corresponding performance standard ISO 7206-8.

In order to overcome these disadvantages it was proposed to define the test conditions for three types of stem length, to describe the test procedure and stem axis definition particularly for anteverted stems more precisely and to harmonize the test conditions with the endurance performance of ISO 7206-8.

This edition in some respects allows more accurate and easier handling by the test laboratories and defines a clear separation of stemmed femoral components into three categories:

— stems with CT distance $\leqslant$ 120 mm;

— stems with CT distance 120 mm $<$ CT $\leqslant$ 250 mm;

— stems with CT distance $>$ 250 mm.

It includes performance criteria for these components. This will lead to a higher acceptance of the test method and more reproducible test results.

Implants for surgery — Partial and total hip joint prostheses —

Part 4:
Determination of endurance properties and performance of stemmed femoral components

1 Scope

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

Furthermore, this part of ISO 7206 specifies the test parameters and the requirements for the endurance limit of stemmed femoral components tested in accordance with this document. The value of the endurance limit test forces and the corresponding number of load cycles are specified.

This test method has been developed for prostheses that have a plane of symmetry, that have preformed anteversion and/or antetorsion and/or double curvature of the stem.

This part of ISO 7206 does not cover methods of examining the test specimen after testing; these should be agreed between the test laboratory and the party submitting the specimen for test.

For tests on modular stemmed femoral components a fluid to surround the component during the test is specified.

2 Normative references

The following referenced documents are 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.

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

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

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
modular neck stem
stem designed to be used with a separate femoral neck that has a self-locking taper that connects with a mating taper on the most proximal aspect of the stem