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Third edition  
2010-06-15

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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*



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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.

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## 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  $\leq 120$  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  $\leq 120$  mm;
- stems with CT distance  $120 \text{ mm} < \text{CT} \leq 250$  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.