

INTERNATIONAL STANDARD

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Implants for surgery — Partial and total hip joint prostheses —

Part 9:

Determination of resistance to torque of head
fixation of stemmed femoral components

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

*Partie 9: Détermination de la résistance au couple de la fixation des têtes
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.

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 7206-9 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

Some designs of stemmed femoral components of total hip joint prostheses comprise a stem/neck component and a bearing head component, which is commonly in the form of a partial sphere incorporating a female fixation feature for attachment to the neck of the stem. Such heads are generally produced in metal or in ceramic material. It is important that after assembly, whether by the manufacturer or by the surgeon in the operating theatre, the head subsequently remains immobile on the neck, because movement of the ceramic component on the metal component will cause the metal component to wear, whilst metal-on-metal movement may lead to severe fretting corrosion. It is essential, therefore, that the strength of the fixation between the head and the neck is sufficient to withstand the torque likely to be transmitted through the prosthesis in use. It should be noted that the test conditions described in this part of ISO 7206 do not exactly reproduce all the factors in the clinical situation.