
**Implants for surgery — Partial and total
hip-joint prostheses —**

**Part 10:
Determination of resistance to static load
of modular femoral heads**

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

*Partie 10: Détermination de la résistance à la charge statique de têtes
fémorales modulaires*



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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 7206-10 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 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*

Introduction

Some designs of stemmed femoral components of total hip-joint prostheses comprise a stem/neck component and a component that forms the articulating surface, which is commonly in the form of a partial sphere incorporating a female conical taper connection for attachment to the neck of the stem. It is important, therefore, that the head and neck are of sufficient strength to withstand the static axial loads likely to be exerted on the prosthesis during use. This method addresses the static strength and attachment of the head. 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.

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Implants for surgery — Partial and total hip-joint prostheses —

Part 10:

Determination of resistance to static load of modular femoral heads

1 Scope

This part of ISO 7206 applies to femoral heads of partial or total hip-joint replacements of modular construction (i.e. a head/neck conical taper connection) and describes methods of determining the load required, under specified laboratory conditions, to cause failure of the head (disassembly or fracture). It applies to components made of metallic and non-metallic materials.

This part of ISO 7206 does not cover methods of examining and reporting the test specimens.

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 4288:1996, *Geometrical Product Specification (GPS) — Surface texture : Profile method — Rules and procedures for the assessment of surface texture*

ISO 7206-1:1995, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*

ISO 7500-1:1999, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration of the force-measuring system*

ISO 6506-1:1999, *Metallic materials — Brinell hardness test — Part 1: Test method*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

bore angle

included angle of the conical surface of the bore

See Figure 1 a).

3.2

cone

metal truncated right-circular cone (male component) used to engage with a mating conical bore (female component) of the modular femoral head

See Figure 1 b).