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

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

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

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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.

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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).

3.3

cone angle

included angle of the conical surface of the cone

See Figure 1 b).

3.4

head

spherical, modular femoral component which includes a conical bore and is engaged by a cone

See Figure 1 a).

3.5

installation load

load used to connect the head and neck components prior to testing

3.6

load axis

line of action of the compressive load applied to the head

See Figures 2, 3 a), 3 b), 4 and 5.

3.7

neck

region of the femoral stem component between the cone and the stem

See Figures 1 b), 2, 3 a), 3 b), 4 and 5.

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3.8

neck axis

centreline of the femoral cone

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See Figures 2, 3 a), 3 b), 4 and 5.

3.9

stroke rate

nominal rate of movement of the moving component of the test machine

4 Principle

A static compressive or tensile load is applied to the head/neck assembly of the hip-joint prosthesis and increased until either the head or the neck, or the connection between them, fails, or until the chosen maximum force has been applied without the occurrence of failure.

The nomenclature and designation of dimensions given in ISO 7206-1 shall apply.

5 Apparatus

5.1 Static compression test

5.1.1 Testing machine, capable of applying and recording an axial compressive force to the head/neck assembly, with an accuracy of $\pm 1\%$ at between 20 % and 100 % of the machine range used (see ISO 7500-1).

5.1.2 Loading fixtures, capable of sustaining loads up to the anticipated fracture or deformation level of the femoral head (up to 200 kN); constructed so that the line of load application passes through the centre of the femoral head and is aligned with the neck axis as indicated in Figure 2.

5.1.3 Conical loading bore, of dimensions shown in Figure 3 a), and made of metal having a hardness of 150 HB to 200 HB (see ISO 6506-1).

5.1.4 Copper ring load distributing device, as shown in Figure 3 b).

5.1.5 Neck unit, comprising a neck/cone of the type to which the head is to be mounted in service, or a dummy having the same dimensions and being made of the same material, by the same manufacturing process and to the same specification [see Figure 1 b)]. In cases of dispute, the test should be performed using the complete stemmed femoral component.

5.2 Static tension test

5.2.1 Testing machine, capable of applying and recording an axial tensile force to the head/neck assembly, with an accuracy of $\pm 1\%$ at between 20 % and 100 % of the machine range used (see ISO 7500-1).

5.2.2 Loading fixtures, capable of sustaining expected loads and constructed so that the line of force application passes through the centre of the femoral head and is aligned with the neck axis as indicated in Figure 2 and Figure 4.

5.2.3 Neck unit, comprising a neck and cone of the type to which the head is to be mounted in service, or a dummy having the same dimensions and being made of the same material, by the same manufacturing process and to the same specification [see Figure 1 b)]. In cases of dispute, the test should be performed using the complete stemmed femoral component.

6 Procedure

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6.1 Assembly of test specimens (installation)

6.1.1 Use new femoral heads and neck units for each test. Remove any debris or other surface contaminants. If requested by the person or organization submitting the specimens for test, measure the circularity, linearity and surface roughness.

NOTE The procedure in Annex A has been found to be suitable.

6.1.2 Mount the head onto the cone using a method such as that illustrated in Figure 3 a), Figure 3 b) or Figure 4, or any other method provided the following requirements are met:

- a) the alignment tolerances shown in Figure 2 shall be maintained;
- b) apply an installation force of $(2,0 \pm 0,2)$ kN at a loading rate of $(0,5 \pm 0,1)$ kN/s or, if this not possible, at a stroke rate of $(0,04 \pm 0,01)$ mm/s;
- c) inspect the specimen; if it is damaged terminate the test;
- d) if the fixtures used for installation are to be used for the test, inspect them and replace them if they are damaged.

CAUTION — Protect the test operator from injury by fragments in case the specimen should shatter when under load or when disassembling or when storing the specimen after removal of the load from unfractured specimens.