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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**

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

Reference number
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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.

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).

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.

3.8
neck axis
centreline of the femoral cone

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 ± 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 ± 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

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 ± 0,2) kN at a loading rate of (0,5 ± 0,1) kN/s or, if this not possible, at a stroke rate of (0,04 ± 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.

6.2 Static compression

6.2.1 Load the femoral head through a conical loading bore [5.1.3 and Figure 3 a)]. Maintain the alignment tolerances shown in Figure 2. A copper ring (5.1.4) may be inserted between the femoral head and loading bore [Figure 3 b)] to protect the contact surface of the head.

6.2.2 Apply a compressive force at a loading rate of (0,5 ± 0,1) kN/s; or if this is not possible, at a stroke rate of (0,04 ± 0,01) mm/s taking a record of the force/time or displacement/time behaviour.

6.2.3 Increase the load until one of the following occurs:

a) discontinuity or peak in the recorded load profile;

b) the occurrence of cracks or fracture of the head;

c) fracture or permanent deformation of the neck;

d) the chosen maximum force has been applied.

NOTE A discontinuity may occur in the initial state of the static compression test, due to stick-slip effects, while the neck unit subsides.

6.2.4 Examine the conical loading bore after each test, and discard it if damaged. If a copper ring is used for the contact, replace it for each test.

6.2.5 Conduct tests on a minimum of five samples of each type.

If it is intended to test more than one sample group, the minimum number should be determined according to the desired confidence level.

6.3 Static tension

6.3.1 Place the head/neck assembly in a fixture, such as that shown in Figure 5, capable of holding the neck component securely, achieving uniform flat contact around the base of the head, and maintaining the alignment tolerances shown in Figure 5.

The design of the fixture used to pull against the head requires either an opening on one side or a modular design. This fixture should be sufficiently rigid to prevent deformation which might apply a bending moment or torque to the neck.

6.3.2 Remove the head by applying to the assembly a tensile force at a stroke rate of (0,008 ± 0,000 8) mm/s, maintaining the alignment tolerances shown in Figure 5.

6.3.3 Terminate the test when the loading force registered is less than 100 N.

7 Test report

The test report shall include the following information:

a) a reference to this part of ISO 7206;

b) the identity of the femoral head test specimen, including the manufacturer's name, femoral head diameter, neck length (standard, long, etc.), and material and if requested by the submitter the bore angle, bore diameter, and bore surface roughness (Ra and Rz in accordance with ISO 4288) [see Figure 1 a)];

c) the identity of the cone specimen, including the manufacturer's name, the cone material, cone angle, cone diameter, and cone surface roughness (Ra and Rz in accordance with ISO 4288) [see Figure 1 b)];

d) for compressive tests, the load rate at which the test was conducted, the load at which the test was terminated, the maximum value of the test force applied and the reason for termination. If the machine was set at a stroke rate, the reason for this and the value of this stroke rate shall be stated;

e) for tensile tests, the stroke rate at which the test was conducted, the load at which the test was terminated, and the reason for termination;

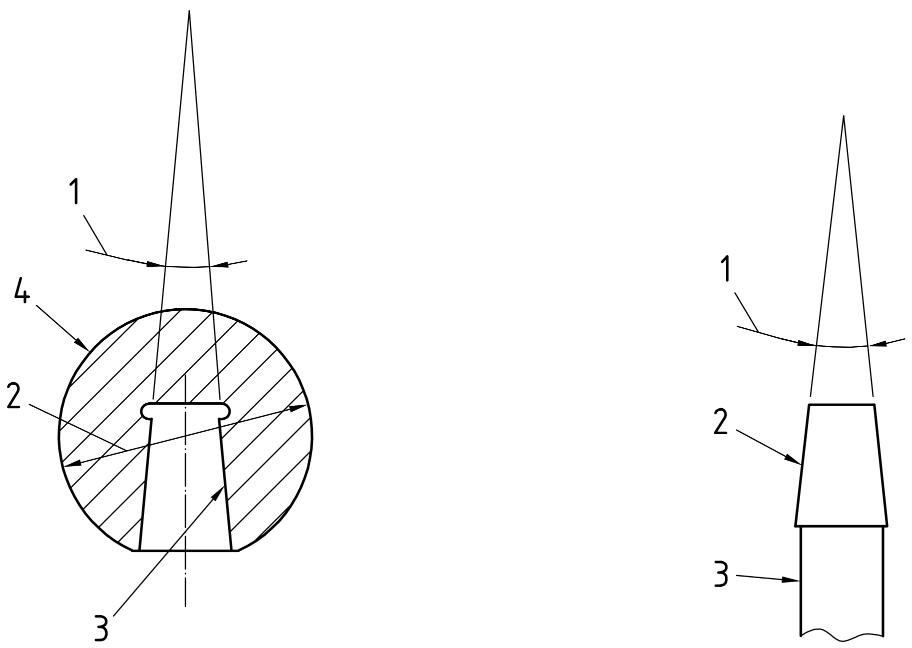
f) the results of the examination requested by the party submitting the specimen for test, if appropriate.

NOTE Measurements of linearity (or straightness) and circularity (or roundness, conicity, or concentricity) of the head bore and the cone [see Figures 1 a) and 1 b)] can be useful in explaining test results.

8 Disposal of test specimens

Components that survive the test shall not be used for clinical purposes after testing.

Care should be exercised in the use of the components for further mechanical tests, because the loading regime may have altered the mechanical properties. In particular, it is recommended that neither component be used for further tests by the methods described in this part of ISO 7206.



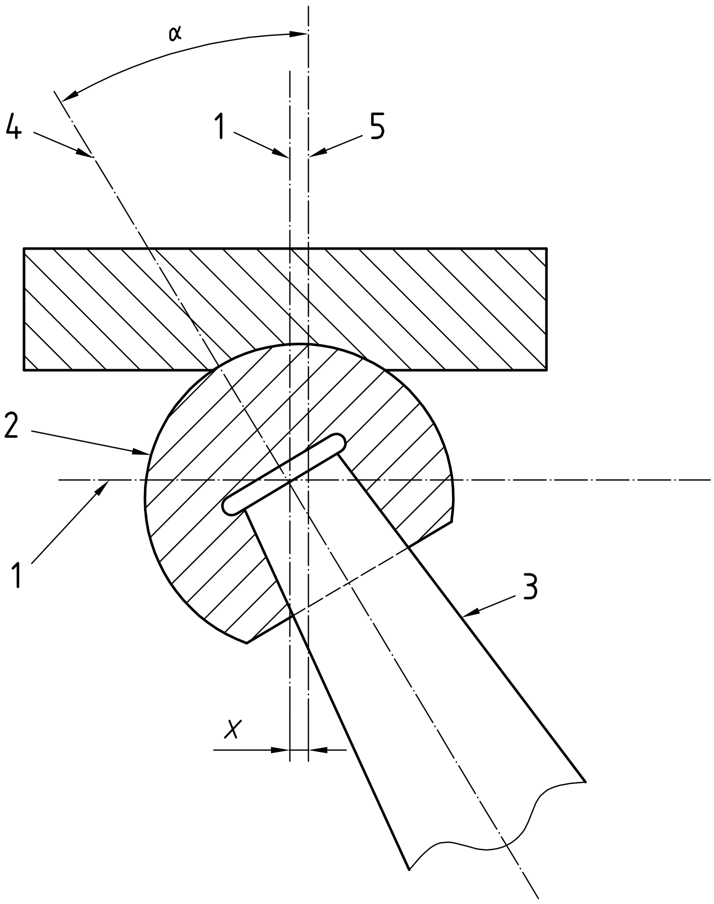
Key
1 bore angle
2 head diameter
3 bore diameter
4 head

a) Geometrical features on femoral head

Key
1 cone angle
2 cone diameter
3 neck

b) Geometrical features on neck specimen

Figure 1 — Geometrical features on mating head and neck specimens

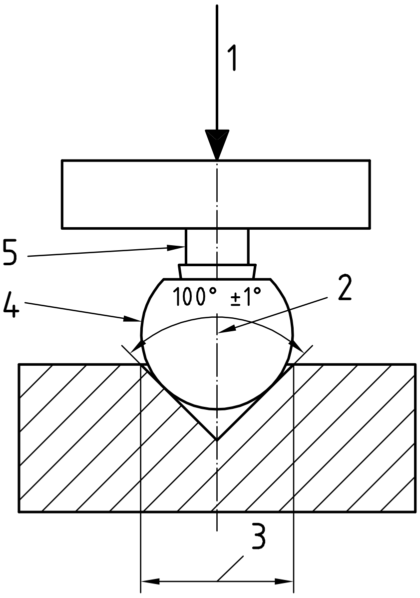


Key

1 centrelines of head
2 head
3 neck
4 neck axis
5 load axis
α inclination of neck axis to load axis of testing machine, = (0 ± 1)°
X offset of load axis from centre of head = (0 ± 0,1) mm

Figure 2 — Illustration of the alignment tolerances in the compressive loading test

Dimensions in millimetres



Key

1 load axis

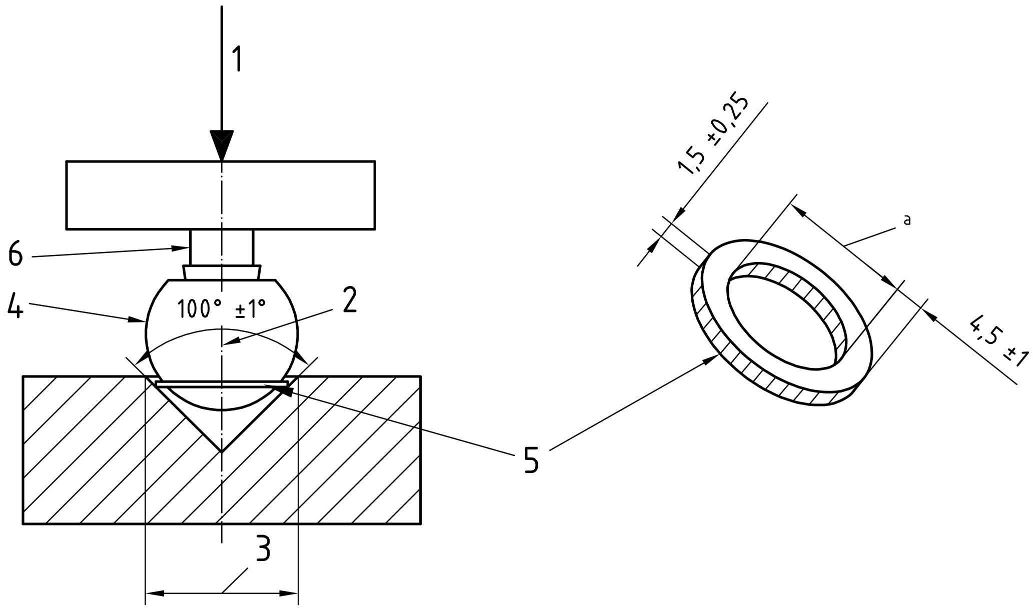
2 neck axis

3 0,75 × diameter of head (min.)

4 head

5 neck

a) Example of compressive loading method in conical metal bore assemblies



Key

1 load axis

2 neck axis

3 0,75 × diameter of head (min.)

4 head

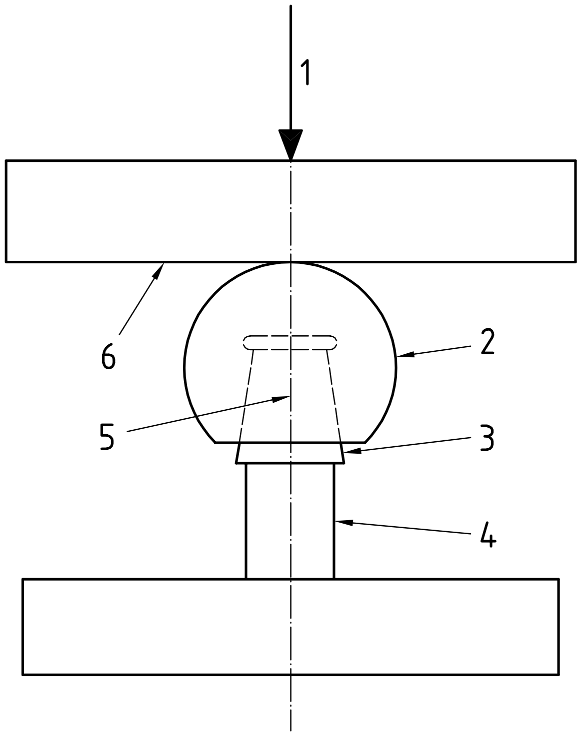
5 copper ring

6 neck

a 0,643 × diameter of the head ± 0,5 mm

b) Example of compressive loading method in conical metal bore assemblies using a copper ring

Figure 3 — Example of loading method in conical metal bore assemblies

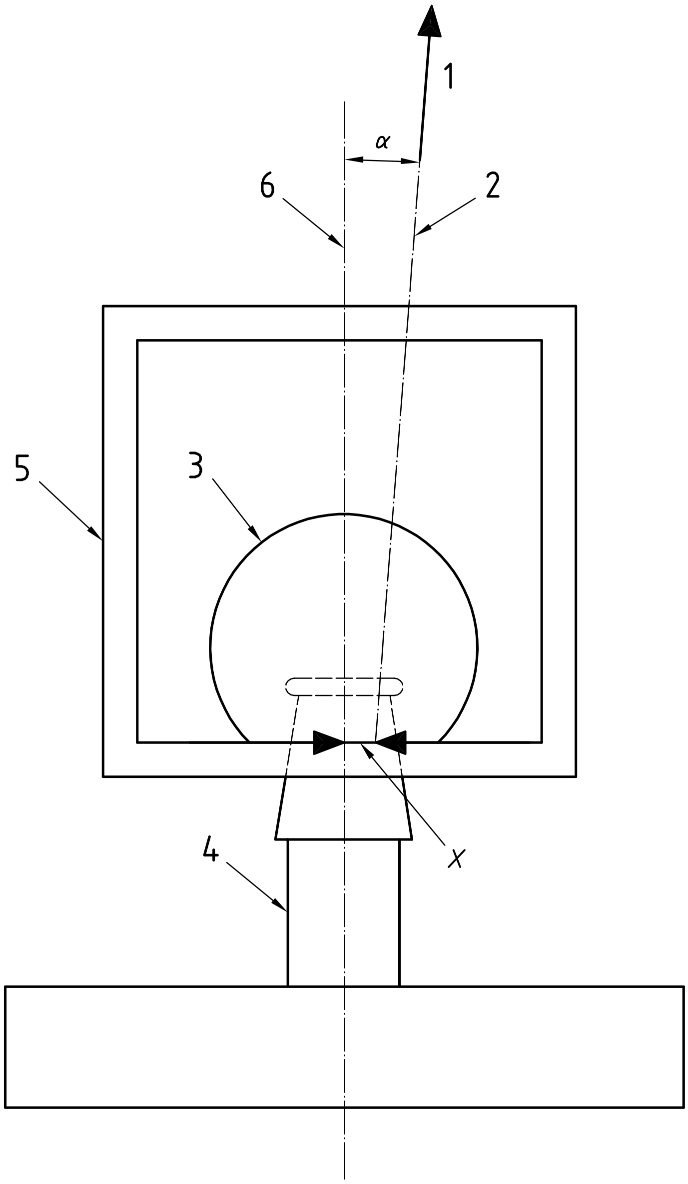


The methods shown in Figure 3 a) or 3 b) may also be used.

Key

1	load axis	4	neck
2	head	5	neck axis
3	cone	6	flat plate

Figure 4 — Loading method for installing modular head assemblies



Key

1	load	5	disassembly cage
2	load axis	6	neck axis
3	head	α	(0 ± 1)° loading tolerance
4	neck	X	(0 ± 0,1) mm loading tolerance

Figure 5 — Illustration of tensile loading method for modular head disassembly and the required alignment tolerances

Annex A
(informative)

Method for cleaning specimens

A.1 General

Normal laboratory cleaning procedures should be used to remove any debris or surface contaminants prior to assembling modular components. A suggested procedure is provided. Other methods may be used but should be consistent with manufacturing practices.

A.2 Procedure

The following steps are recommended:

a) rinse with tap water to remove bulk contaminants;

b) wash using an ultrasonic cleaner in a solution of 1 % detergent for 15 min;

c) rinse in a stream of distilled water;

d) rinse in an ultrasonic cleaner in distilled water for 5 min;

e) rinse in a stream of distilled water;

f) dry in air at ambient temperature.

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