

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*



Reference number
ISO 7206-9:1994(E)

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*

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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.

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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

1 Scope

This part of ISO 7206 describes a method of determining the torque required, under specified laboratory conditions, to loosen the fixation of the head of hip joint prostheses in which the head is not intended to rotate relative to the neck. It applies to the femoral component of total or partial hip joint replacements in which the head and arm are secured together by a locking conical taper or any other means and in which the head and neck are separate components, and which are made of metallic and non-metallic materials.

This part of ISO 7206 does not cover methods of examining the test specimens; these should be agreed between the test laboratory and the party submitting the specimen for test.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7206. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7206 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

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

3 Definitions

For the purposes of this part of ISO 7206, the definitions given in ISO 7206-1 apply.

4 Principle

Mounting of the head on a firmly fixed neck unit. Immersion of the assembly in liquid at a controlled temperature. Application of an axial load to the assembly. Application of a torque to the head and the measurement of the torque required to initiate rotation of the head on the neck.

5 Reagent

Fluid test medium, comprising either:

- distilled or deionized water of Grade 3 in accordance with ISO 3696; or
- liquid of a composition stated by the party submitting the specimen for test.

1) To be published. (Revision of ISO 7206-1:1985)

6 Apparatus

See figure 1 for an example of test apparatus.

6.1 Specimen holder, of a corrosion-resistant material, and having a construction and dimensions to suit the testing machine and test specimen.

6.2 Testing machine, capable of applying an axial load through the axis of the head/neck assembly, with accuracy of 1 % of full scale reading, and of applying a torque to the head in a plane at right angles to the axial load, with an accuracy of 1 % of full scale reading.

6.3 Means of transmitting the axial load, e.g. an acetabular cup of ultra-high-molecular-weight polyethylene.

6.4 Means of maintaining the temperature of the fluid test medium at $37\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

6.5 Means of continuously aerating the fluid test medium, e.g. a small air pump of the type used for aquaria.

6.6 Means of measuring the torque applied to the head of the assembly, with an accuracy of 1 %.

6.7 Neck unit, comprising a neck/stem of the type to which the head is to be fitted in service, or a dummy neck having the same dimensions and being made of the same material, by the same manufacturing process and to the same specification.

NOTE 1 The use of a dummy neck is convenient and economical compared with fully finished femoral components: however in cases of dispute the test should be performed using the complete stemmed femoral component.

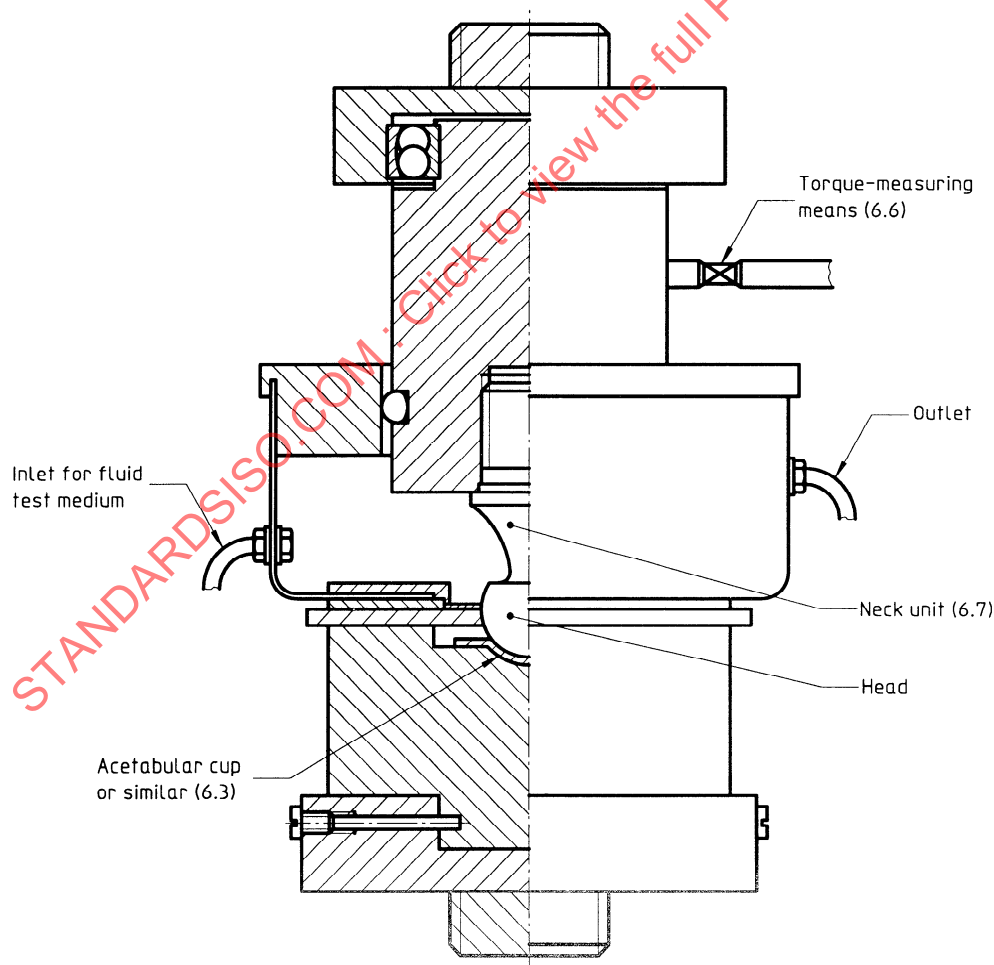


Figure 1 — Example of equipment for determination of resistance to torque of head/neck assembly

7 Procedure

7.1 If the head is not in place on the stem, mount the head to be tested on the neck unit (6.7) in the manner recommended by the manufacturer, and mount the assembly in the specimen holder (6.1). If the head is in place on the stem, mount the assembly in the specimen holder.

7.2 Mount the specimen holder and assembly in the testing machine (6.2).

7.3 Apply and maintain a load of 1 000 N axially to the head through the loading device (6.3).

7.4 Circulate heated fluid test medium through the specimen holder until the temperature of the holder and contents stabilizes at $37\text{ °C} \pm 1\text{ °C}$. Maintain this temperature and maintain aeration of the fluid test medium (6.4 and 6.5). Allow all electronic amplifiers, recorders, etc. that form part of the test equipment to reach a stable operating temperature.

7.5 Apply (6.2) an incrementally increasing torque to the head until the head begins to rotate on the neck, continuously recording the torque applied. Note the maximum torque applied before rotation commences. Record or calculate from the recording the rate of application of torque.

If fixation is achieved by the use of a screw thread the torque should be applied in the loosening direction.

NOTE 2 Depending on the means used for gripping the head, it may be necessary to grind small flats on the surface of the head, especially in the case of hard materials such as ceramics.

7.6 Remove the head/neck assembly from the testing machine and specimen holder.

7.7 Examine the test specimens, using the methods requested by the party that submitted the specimen for testing.

8 Test report

The test report shall include the following information:

- a) a reference to this part of ISO 7206;
- b) the identity of the test specimen, as stated by the party submitting the specimen for test;
- c) the maximum torque applied before the head commenced to rotate on the neck;
- d) the torque application rate;
- e) the results of the examination requested by the party submitting the specimen for test.

9 Disposal of test specimens

No part of the prosthesis shall be used for clinical purposes after testing.

This test normally results in the transfer of material from one component to the other and changes the nature of both mating surfaces. Care should be exercised in the use of the specimen for further mechanical tests because the loading regime may have altered the mechanical properties. In particular, it is recommended that neither the neck/stem components nor the head are used for further testing by the method given in this part of ISO 7206.

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