INTERNATIONAL STANDARD

ISO 7206-9

First edition
1994-12-15

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*

International Organization for Standardization
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Printed in Switzerland

— *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.

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:

a) distilled or deionized water of Grade 3 in accordance with ISO 3696; or

b) liquid of a composition stated by the party submitting the specimen for test.

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