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

**Part 13:
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 13: Détermination de la résistance au couple de la fixation des
têtes des tiges fémorales*

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is 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: Endurance properties testing and performance requirements of neck region of stemmed femoral components*
- *Part 10: Determination of resistance to static load of modular femoral heads*
- *Part 12: Deformation test method for acetabular shells*
- *Part 13: Determination of resistance to torque of head fixation of stemmed femoral components*

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 using metal or 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 a metal or a ceramic femoral head component on a metal stem/neck component will cause the metal components to wear, while metal-on-metal movement may lead to severe fretting corrosion (see Reference [1]).

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. The maximum torque applied to the interface connection depends on several design, material, and manufacturing specific parameters, e.g. pairing of bearing materials, bearing diameter, and clearance, surface finish, etc. (see Reference [2]).

The locking strength of the interface connection depends on several design, material, and manufacturing specific parameters for the taper geometry of the mating components, as taper angle and tolerances, taper clearance, surface finish, etc. In consequence, the torsional locking strength of nominal identical taper fixations might vary significantly (see Reference [3]) and needs to be determined prior to clinical use.

Clinical failure of taper connections is related to particle generation by interface micromotion, fretting, and fatigue failure (see Reference [4]). Torsional interface stability is essential for stable fixation of taper connections in order to limit the above listed adverse effects.

Implants for surgery — Partial and total hip joint prostheses —

Part 13:

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 neck/stem (in the following referred to as cone) are secured together by a locking conical taper or any other means and in which the head and cone are separate components, and which are made of metallic or 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 7206-10, *Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7206-1 and ISO 7206-10 apply.

4 Principle

A static torque is applied to the head/cone assembly of the hip-joint prosthesis and increased until the connection between the head and the cone fails or until the chosen maximum torque has been applied without occurrence of failure.

5 Apparatus

5.1 Testing machine, according to ISO 7500-1 requirements, shall have the following characteristics:

- ability to apply an axial compressive force through the axis of the head/cone for assembly, with an accuracy of 1 % of full scale reading;