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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

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Foreword

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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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 7206-10:2003), which has been technically revised.

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 forces 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 document 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 document specifies methods of determining the compressive (fracture) or the tension (disassembly) loads required, under specific laboratory conditions, to cause failure of a modular head system.

This document applies to components made of metallic and non-metallic materials, such as femoral heads of partial or total hip-joint replacements of modular construction (i.e. a head/neck conical taper connection).

This document excludes methods of examining and reporting the test specimens.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

ISO 6506-1, *Metallic materials — Brinell hardness test — Part 1: Test method*

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

ISO 7500-1, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification 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 the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
bore
conical blind hole in the surface of the modular femoral head

3.2
bore angle
included angle of the conical surface of the bore

Note 1 to entry: See Figure 1 a).

3.3
cone
metal truncated right-circular cone (male component) used to engage with a mating conical bore (female component) of the modular femoral head

Note 1 to entry: See Figure 1 b).

3.4
cone angle
included angle of the conical surface of the cone

Note 1 to entry: See Figure 1 b).

3.5
basic design control
<Morse taper system> parameter that governs the self-locking potential of a Morse taper system

EXAMPLE Engagement length between the bore and the cone, bore surface roughness, cone surface roughness, and, the three-dimensional (3D) control elements

3.6
3D control elements

<Morse taper system> set of three-dimensional (3D) elements that, along with the other basic design controls, are required to govern the self-locking potential of a Morse taper system

EXAMPLE Bore and cone circularity, bore and cone straightness, cone angle, bore angle, bore and cone concentricity and bore and cone diameter at a reference point

Note 1 to entry: All the 3D control elements can affect the other 3D control elements. For maintaining the viability of the system, is important that the tolerance ranges for all 3D control elements are well defined.

3.7
head
spherical, modular femoral component which includes a conical bore and is engaged by a cone

Note 1 to entry: See Figure 1 a).

3.8
installation force
force used to connect the head and neck components prior to testing

3.9
load axis
line of action of the compressive force applied to the head

Note 1 to entry: See Figures 2, 3, 4 and 5.

3.10
head/neck conical taper connection
<Morse taper system> precision machined truncated conical tapers and bores intended to self-lock together with application of compressive force along the axes of the tapers

3.11
neck
region of the femoral stem component between the cone and the stem

Note 1 to entry: See Figures 1 b), 2, 4 and 5.

3.12
neck axis
centreline of the femoral cone

Note 1 to entry: See Figures 2, 3, 4 and 5.

3.13
stroke rate
nominal rate of movement of the moving component of the test machine

4 Principle of the test method

A static compressive or tensile force 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.

5 Apparatus

5.1 Static compression test

5.1.1 Testing machine, according to ISO 7500-1, capable of applying and recording an axial compressive force to the head/neck assembly, with an accuracy of ± 2 %.

5.1.2 Loading fixtures, capable of sustaining forces up to the anticipated fracture or deformation level of the femoral head 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 and made of metal having a hardness of at least 150 HB, when determined according to ISO 6506-1.

5.1.4 Copper ring load distributing device, as shown in Figure 3 shall be made from soft annealed copper. The copper ring inner diameter (a) as shown in Figure 3. a = 0,643 × nominal head diameter − 3 mm.

NOTE The copper ring load distributing device has a complementary function of protecting the contact surface of the head and the conical loading bore.

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, according to ISO 7500-1 capable of applying and recording an axial tensile force to the head/neck assembly, with an accuracy of ± 1 %.

5.2.2 Loading fixtures, capable of sustaining expected forces 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 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 shall be sufficiently rigid to prevent deformation which might apply a bending moment or torque to the neck.