INTERNATIONAL STANDARD

ISO 7206-6

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Implants for surgery — Partial and total hip joint prostheses —

Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components

Implants chirurgicaux — Prothèses partielles et totales de l'articulation de la hanche —

Partie 6: Exigences de performance et essais des propriétés d'endurance de la région du col 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. www.iso.org/directives

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 7206-6:1992), of which it constitutes a minor revision.

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 and performance 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*

Introduction

The test method described in this part of ISO 7206 is intended for the verification of the endurance properties of the neck region of stemmed femoral components of hip joint prostheses. This method is based extensively on that given in ISO 7206-4, which verifies the endurance properties of the complete femoral component under loading conditions that include a torsional component. The test conditions in ISO 7206-4, especially the height of the specimen embedding, are intended to represent the clinical situation where the prosthesis has become loosened in the femur, whereas the test conditions in this part of ISO 7206 are intended to represent a correctly and firmly fixed prosthesis. Therefore, it should be noted that the tests in this part of ISO 7206 may not be representative of the most unfavourable clinical conditions.

Implants for surgery — Partial and total hip joint prostheses —

Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components

1 Scope

This part of ISO 7206 specifies test methods and the fatigue performance for the endurance properties, under specified laboratory conditions, of neck region of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joint replacement. This part of ISO 7206 does not cover the investigation of the performance of the head or the neck-head junction. It is applicable to modular and non-modular designs made of metallic or non-metallic materials.

It also specifies the test conditions so that the important parameters that affect the hip femoral components are taken into account and describes how the specimen is set up for testing.

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

ISO 4965-1:2012, *Metallic materials — Dynamic force calibration for uniaxial fatigue testing — Part 1: Testing systems*

ISO 4965-2:2012, *Metallic materials — Dynamic force calibration for uniaxial fatigue testing — Part 2: Dynamic calibration device (DCD) instrumentation*

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

3 Terms and definitions

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

3.1
implantable
condition of a test sample which has received all the machining processes, cleaning, degreasing, and sterilization procedures required prior to implantation

3.2
resection line/level
level prescribed by the manufacturer which, in clinical use of the femoral hip stem, corresponds to the proximal cut of the bone shaft