150

INTERNATIONAL STANDARD

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Implants for surgery — Partial and total hip joint prostheses —

Part 5:

Determination of resistance to static load of head and neck region of stemmed femoral components

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

Partie 5: Détermination de la résistance à la charge statique des têtes et cols des tiges fémorales

Reference number
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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.

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 7206-5 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Sub-Committee 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, designation of dimensions and requirements*

— *Part 2: Bearing surfaces made of metallic 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*

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. It is important, therefore, that the head and neck are of sufficient strength to withstand the static axial loads likely to be exerted on the prosthesis during 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 5:
Determination of resistance to static load of head and neck region of stemmed femoral components

1 Scope

This part of ISO 7206 describes a method of determining the static load required, under specified laboratory conditions, to cause failure of either the head or neck of hip joint prostheses in which the head and neck are separate components. It applies to components made of metallic and non-metallic materials.

This part of ISO 7206 does not cover methods of examining and reporting 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 6506:1981, *Metallic materials — Hardness test — Brinell test.*

ISO 7206-1:1985, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification, designation of dimensions and requirements.*

ISO 7500-1:1986, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tensile testing machines.*

3 Nomenclature and designation of dimensions

For the purposes of this part of ISO 7206, the nomenclature and designation of dimensions given in ISO 7206-1 apply.

4 Principle

Application of a static load to the head/neck assembly. Increase of the load until either the head or the neck, or the connection between them, fails, or until chosen maximum load has been applied without component failure.

5 Apparatus

5.1 Testing machine, capable of applying and recording an axial compressive load to the head/neck assembly, with an accuracy of ± 1 % at between 20 % and 100 % of the machine range used (see ISO 7500-1).

5.2 Neck unit, comprising a neck/stem 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 item 1 in figure 1.)

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

5.3 Means of supporting the neck unit, which maintains loading through the centre of the test specimen, parallel to the axis of the testing machine. (See item 2 in figure 1.)

5.4 Loading cone, of dimensions shown in figure 1, and made of metal having a hardness of 150 HB to 200 HB in accordance with ISO 6506 (e.g. mild steel). (See item 3 in figure 1.)

6 Procedure

6.1 Use a new neck unit and loading cone for each test.

6.2 If the components of the test specimen are not already assembled, ensure the mating surfaces are clean and dry. Assemble the head to the neck unit in accordance with the manufacturer's instructions or if none, by hand with a twisting movement.

6.3 Support the head/neck assembly on the neck support (5.3), place the loading cone (5.4) in position and mount the assembly in the testing machine (5.1). Align the assembly so that the line of action of the force coincides with the axis of the neck unit.

6.4 Apply a force to the head/neck assembly, increasing the load at a rate of not more than 60 kN/min until one of the following events occurs:

a) fracture of, or the occurrence of cracks in, the head;

b) fracture or permanent deformation of the neck unit;

c) relative movement of the head on the neck exceeds 2 mm;

d) the chosen maximum force has been applied.

In each case, record the maximum force applied.

WARNING — It is necessary for the test operator to observe the specimen being tested. Precautions should be taken to protect the test operator from injury by fragments should the specimen shatter when under load or when disassembling the specimen after removal of the load.

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

7 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 force at which the test was terminated and, if appropriate, the form of failure;

d) the results of the examination requested by the party submitting the specimen for test, if appropriate.

8 Disposal of test specimens

It is imperative that components which survive the test should not be used for clinical purposes after testing.

Care should be exercised in the use of the components for further mechanical tests because the loading regime may have altered the mechanical properties. In particular, it is recommended that neither component is used for further tests by the method described in this part of ISO 7206.

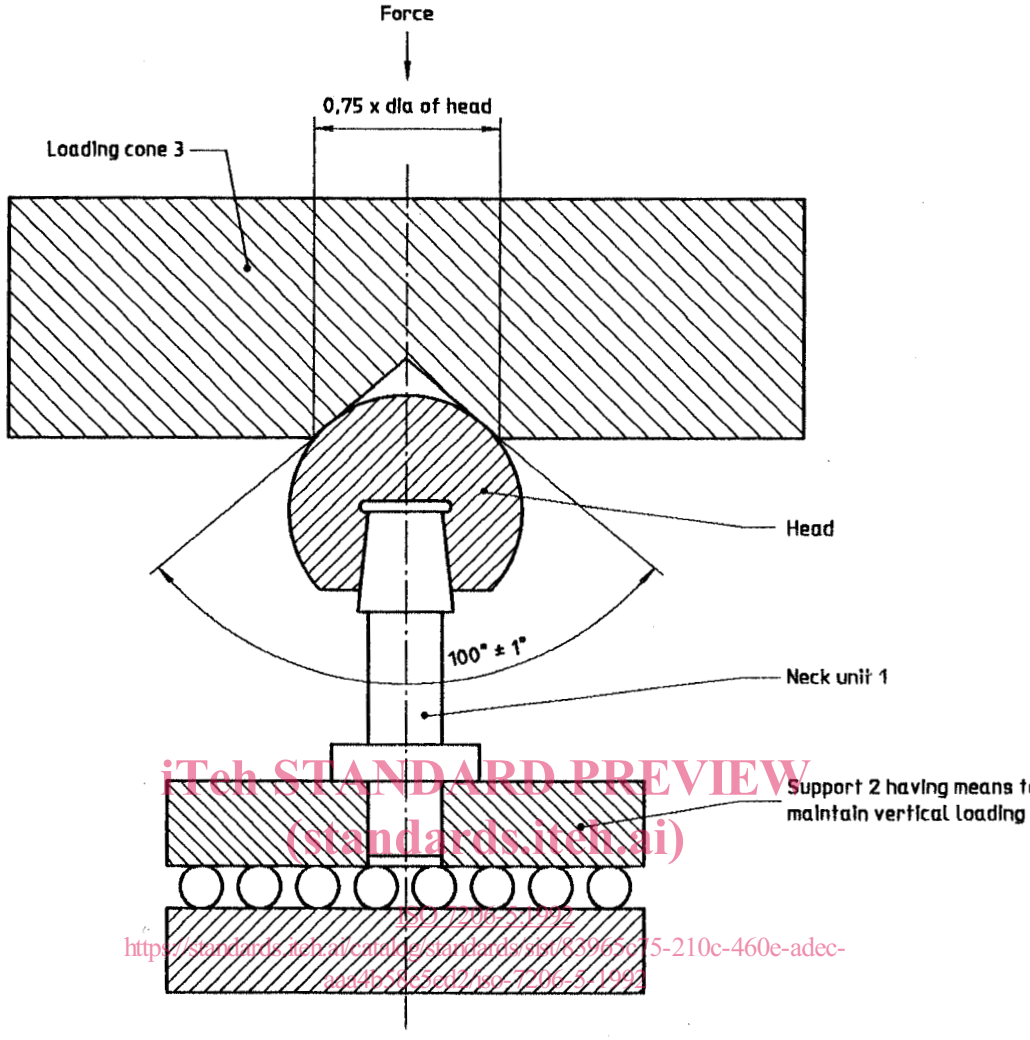

Figure 1 — Example of apparatus for static load test

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Descriptors: medical equipment, surgical implants, prosthetic devices, hips, joints (articulation), tests, determination, mechanical strength, static loads.

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