INTERNATIONAL STANDARD

ISO 7206-6

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Implants for surgery — Partial and total hip joint prostheses —

Part 6:
Determination of endurance properties of head and neck region of stemmed femoral components

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

Partie 6: Détermination des propriétés d'endurance des têtes et cols des tiges fémorales

Reference number
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Contents

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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 7206-6 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

The two test methods described in this part of ISO 7206 are intended for the measurement of the endurance properties of the head and neck region of stemmed femoral components of hip joint prostheses. The methods are based extensively on those given in parts 3 and 4 of ISO 7206, which measure the endurance properties of the complete femoral component under loading conditions that respectively exclude and include a torsional component of load. Whereas the test conditions in parts 3 and 4, particularly the depth to which the specimen is embedded, are intended to represent the clinical situation where the prosthesis has become loosened in the femur, 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 these tests may not be representative of the most unfavourable clinical conditions.

Implants for surgery — Partial and total hip joint prostheses —

Part 6:
Determination of endurance properties of head and neck region of stemmed femoral components

1 Scope

This part of ISO 7206 describes test methods for determining the endurance properties under specified laboratory conditions, of the head and neck region of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joint replacement. It applies to modular and non-modular designs made of metallic or non-metallic materials.

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

This part of ISO 7206 does not cover methods of examining and reporting of the test specimen; these should be agreed between the test laboratory and the parties 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 7206-1:1985, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification, designation of dimensions and requirements.*

ISO 7206-3:1988, *Implants for surgery — Partial and total hip joint prostheses — Part 3: Determination of endurance properties of stemmed femoral components without application of torsion.*

ISO 7206-4:1989, *Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties of stemmed femoral components with application of torsion.*

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

Embedding of the stem of the test specimen in a solid medium. Partial immersion of the protruding part of the test specimen in a fluid test medium. Application of a cyclic load to the head of the test specimen until the head or neck exhibits failure or until the chosen number of cycles has been attained. Subsequent examination of the specimen for defects caused by the loading regime.

5 Reagents and materials

Use the reagents and the materials specified in ISO 7206-3 and ISO 7206-4.

6 Apparatus

Use the apparatus specified in ISO 7206-3 and ISO 7206-4.

7 Procedure

7.1 Test with load applied parallel (with no torsion effect) to plane of neck

Perform the test as described in ISO 7206-3, except as follows:

a) Embed the specimen so that the embedding medium extends up the stem to the level which, in clinical use, coincides with the transection level of the femur recommended by the manufacturer (see figures 1 and 3).

b) Set the testing machine or other instrument to give an indication if the vertical or horizontal component of the specimen deflection exceeds a value of 3 mm greater than the deflection occurring in the first minute of running at test load.

7.2 Test with load applied non-parallel (with torsion effect) to plane of neck

Carry out the test as described in ISO 7206-4, except as follows:

a) Embed the specimen so that the embedding medium extends up the stem to the level which, in clinical use, coincides with the transection level of the femur recommended by the manufacturer (see figures 2 and 3).

b) Set the testing machine or other instrument to give an indication if the vertical or horizontal component of the specimen deflection exceeds a value of 3 mm greater than the deflection occurring in the first minute of running at test load.

8 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 embedding medium used;

d) the minimum and maximum loads applied and whether applied parallel or non-parallel to the plane of the neck;

e) the duration of the test, in cycles;

f) the loading frequency;

g) the offset angle in degrees;

h) a statement of results including location of fracture (if applicable), description of test specimen at the end of the test, and the results of the examination requested by the party submitting the specimen for test;

i) a record of if and why the test was terminated.

9 Disposal of test specimens

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

Care should be exercised in the use of the specimens for further mechanical tests, including endurance tests, because the loading regime may have altered the mechanical properties.

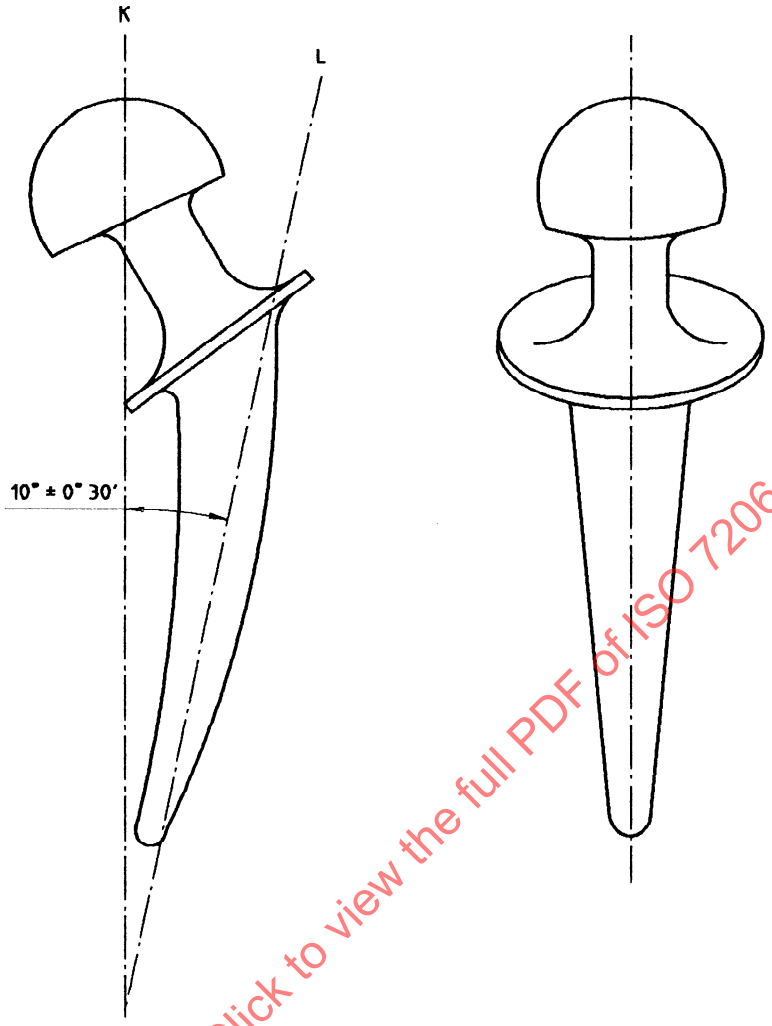

Figure 1 — Orientation of specimen with load applied parallel (with no torsion effect) to plane of neck

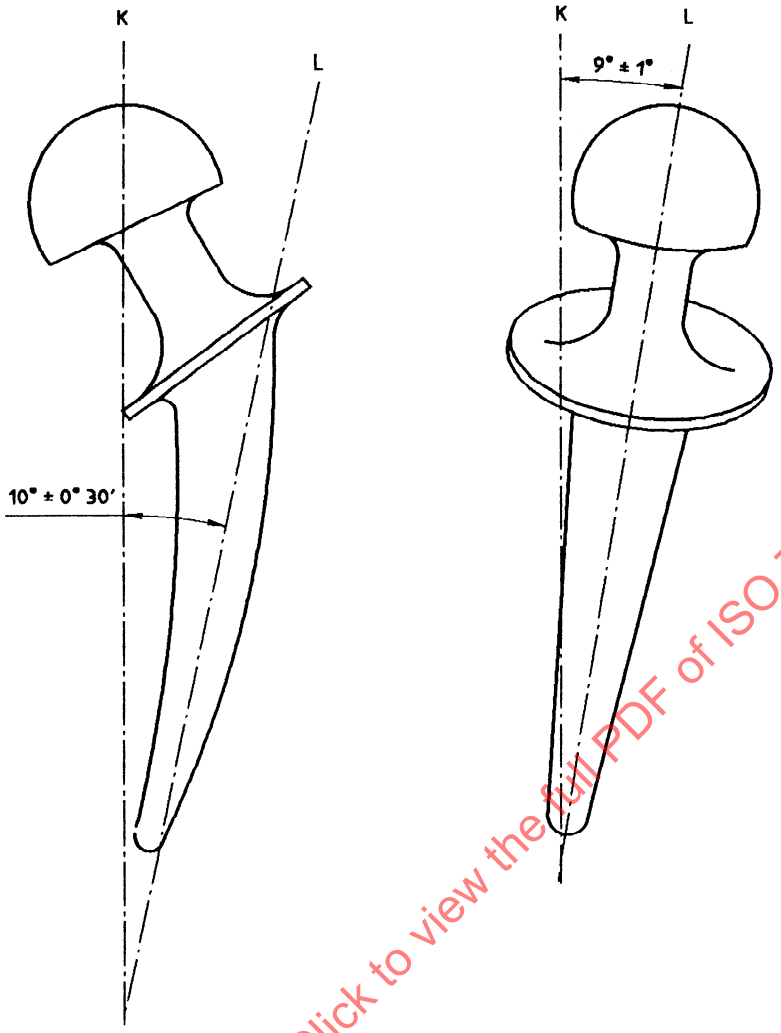

Figure 2 — Orientation of specimen with load applied non-parallel (with torsion effect) to plane of neck

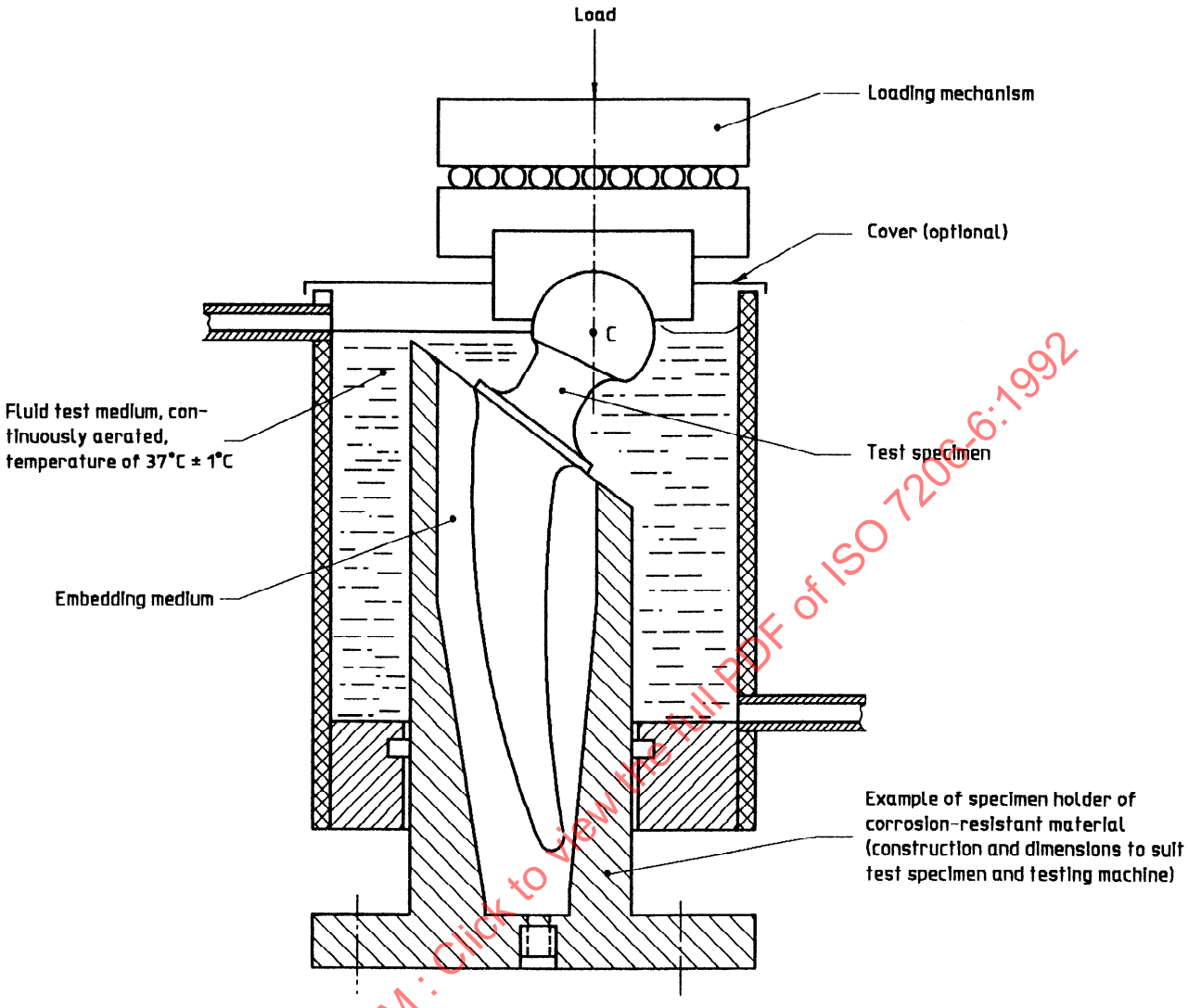

Figure 3 — General arrangement of specimen for testing