INTERNATIONAL STANDARD

ISO 7206-4

Second edition
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Implants for surgery — Partial and total hip joint prostheses —

Part 4: Determination of endurance properties of stemmed femoral components

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

Partie 4: Détermination des propriétés d'endurance 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 7206 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 7206-4 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 7206-4:1989), which has been technically revised.

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

— *Part 8: Endurance performance of stemmed femoral components with application of torsion*

— *Part 10: Determination of resistance to static load of modular femoral heads*

Implants for surgery — Partial and total hip joint prostheses —

Part 4:
Determination of endurance properties of stemmed femoral components

1 Scope

This part of ISO 7206 specifies a test method for determining the endurance properties, under specified laboratory conditions, of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joints. It also defines the conditions of testing 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 is applicable to prostheses that have a plane of symmetry, or have preformed anteversion or double curvature of the stem, and to prostheses designed for use in revision surgery.

This part of ISO 7206 does not specify methods of examining the test specimen.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 7206. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 7206 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 4965:1979, *Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique*

ISO 7206-1:1995, *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 part of ISO 7206, the terms and definitions given in ISO 7206-1 apply.

4 Principle of the test method

The lower portion of the test specimen is embedded in a solid medium. A cyclic load is applied to the head of the test specimen, producing two-plane bending and torsion, until the specimen exhibits failure or until the chosen number of cycles has been attained. The specimen is subsequently examined for defects caused by the loading regime.

Methods of examining the test specimen should be agreed between the test laboratory and the party submitting the specimen for test.

5 Materials

5.1 Embedding medium: a casting medium, which shall

— not crack or break under the load applied during testing,

— not exhibit excessive deformation or creep,

— be reproducible in strength and other characteristics.

NOTE Media that have been found to be satisfactory have a modulus of elasticity between 3 GPa and 6 GPa.

6 Apparatus

6.1 Testing machine, having the following characteristics:

— error in applied load not greater than ± 2 % at maximum load (see ISO 4965);

— dynamic loading waveform sinusoidal at the primary frequency;

— instrumentation to monitor the values of the maximum and minimum loads and the deflection of the head of the test specimen to an accuracy of 0,5 mm, to stop the machine if deflection exceeds a prescribed value and to record the corresponding number of cycles or the elapsed time of operation.

6.2 Specimen holders, having a construction and dimensions to suit the testing machine and test specimens. An example of a suitable holder is shown in Figure 1.

In some cases (circular or near-circular elliptical stems) additional rotation stabilization may be used. This should only be applied near the tip of the stems.

6.3 Means of loading the test specimen, which maintains loading through the centre of the head of the specimen, along the axis of the testing machine, and which incorporates a low-friction mechanism that minimises loads not coincident with the axis of the testing machine.

Attention is drawn to the importance of lubricating the loading mechanism correctly.

6.4 Device to grip the test specimen by the head or neck, which retains the specimen in the orientation specified in 7.3. An example of a suitable device to grip the head of the specimen is shown in Figure 2.

7 Procedure

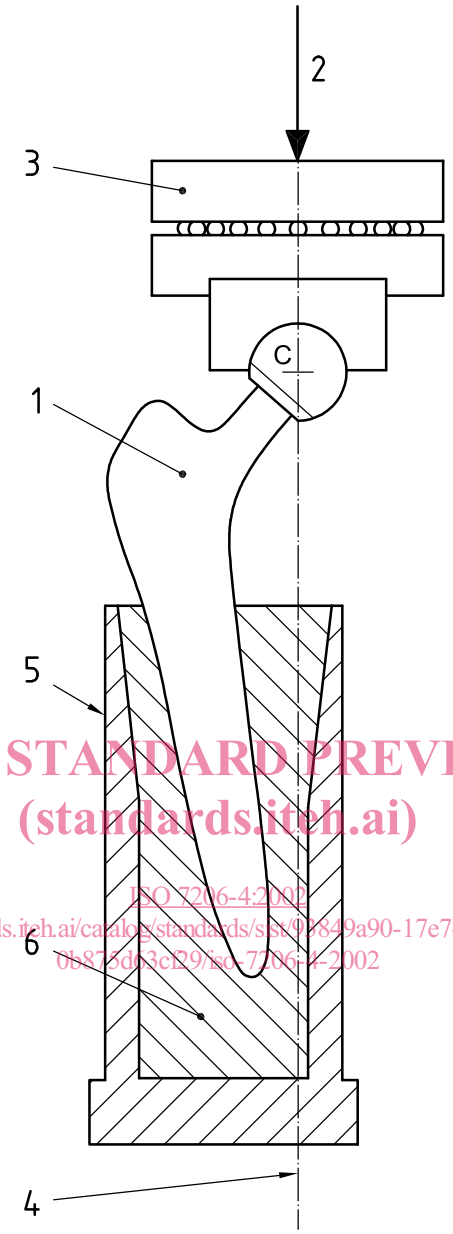
7.1 Measure the distance between the centre of the head and the most distal point of the stem, length CT as shown in Figures 3 to 5.

7.2 Define the axis of the distal stem as the line KL joining the centres of cross-sections distant 0,1 × CT and 0,4 × CT from the distal end (Figure 3).

7.3 Hold the head or neck of the test specimen by means of the gripping device (6.4) and position the specimen so that the axis LK of the stem is oriented at angles α and β as shown in Figure 3 for a straight stem without anteversion, Figure 4 for a straight stem with an anteverted neck, Figure 5 for an “anatomical” stem with non-planar curvature and Figure 6 for a revision prosthesis. Values of angles α and β are specified in Table 1.

7.4 Mount the holder and specimen in the aligning device (6.4) so that the load line of the testing machine will intersect the centre of the head, point C of the specimen, as designated in ISO 7206-1. Clamp the holder firmly in position and ensure that the correct orientation of the specimen is maintained. Measure and record the head offset length, as designated in Figures 3 to 5 and the anteversion offset, as designated in Figures 4 and 5.

The angles α and β should be measured relative to the load line of the test machine.

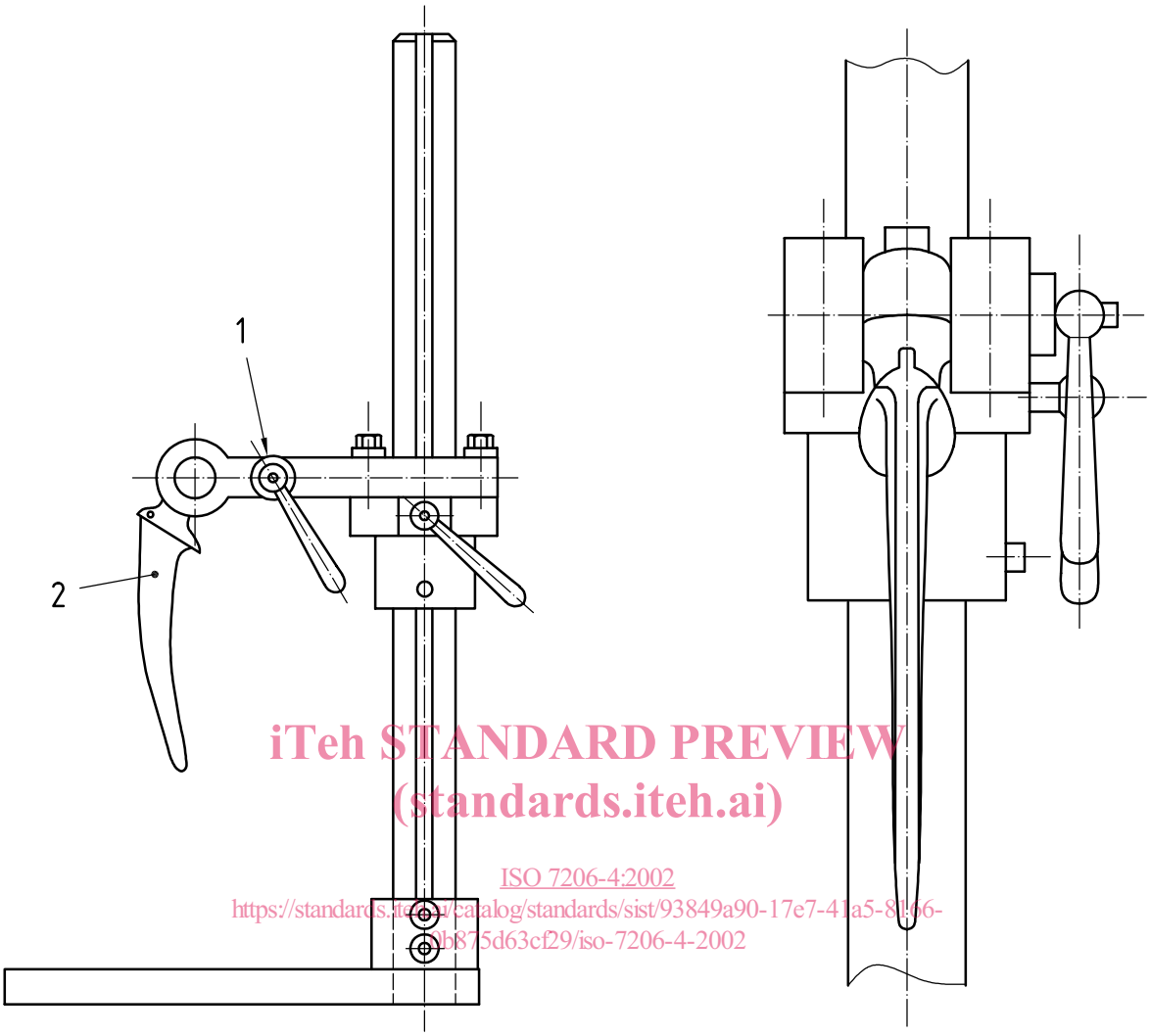


Key

1 Test specimen
2 Load
3 Loading mechanism (see 6.3)
4 Load line
5 Example of test specimen holder (construction and dimensions to suit test specimen and testing machine)
6 Embedding medium

NOTE Point C is designated in ISO 7206-1.

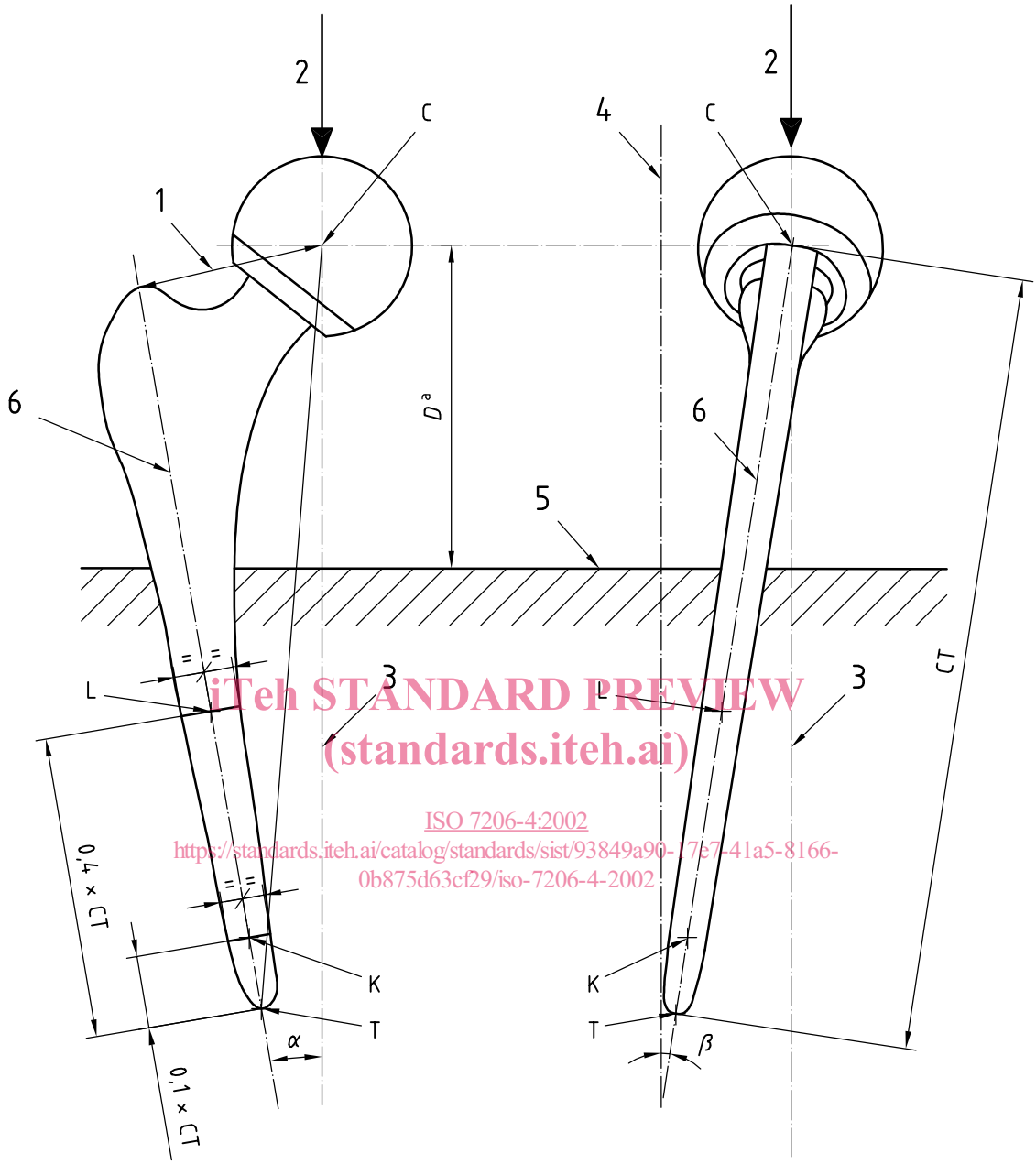
Figure 1 — General arrangement of specimen for testing



Key

1 Clamping mechanism
2 Test specimen

Figure 2 — Example of a device for gripping the head of the test specimen during setting up



Key

C	Centre of the head
T	Tip of stem
1	Head offset length
2	Load point
3	Load axis
4	Line parallel to load axis
5	Cement level
6	Axis KL

[a] See 7.5 for explanation.

Figure 3 — Orientation of specimen under test — Implant with no anteversion