

# Orthopaedic joint prostheses —

**Part 6: Method for determination of  
endurance properties of stemmed  
femoral components of hip joint  
prostheses without application of  
torsion**

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The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/25, upon which the following bodies were represented:

- British Institute of Surgical Technologists
- British Medical Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association Incorporated
- Department of Health
- Department of Trade and Industry (National Engineering Laboratory)
- Royal College of Surgeons of England
- Scottish Office
- Coopted members

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# National foreword

This Part of BS 7251 has been prepared under the direction of the Health Care Standards Policy Committee and is identical with 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”*, published by the International Organization for Standardization (ISO). A related method of testing with the application of torsion is given in BS 7251-5. *Textual error*. When adopting the text of the International Standard the textual error given below was discovered. It has been marked in the text and has been reported to the International Organization for Standardization in a proposal to amend the text of the International Standard.

In Figure B.2, the dimension “50 ± 2” (distance between the centre of the head of the prosthesis and the top of the specimen holder) should read “80 ± 2”.

### Cross-references

| International Standard | Corresponding British Standard                                                |
|------------------------|-------------------------------------------------------------------------------|
| ISO 3696:1987          | BS 3978:1987 <i>Specification for water for laboratory use</i><br>(Identical) |

The Technical Committee has reviewed the provisions of ISO 4965, ISO 5833-1, ISO 7206-1 and ISO 7500-1, to which reference is made in the text and has decided that they are acceptable for use in conjunction with this standard. It should be noted that the definitions in ISO 7206-1, referred to in clause 3 of this standard are identical with those given in BS 7251-3, and the acrylic bone cement specified in ISO 5833-1 (referred to in 5.2 of this standard) is identical to the normal setting cement specified in BS 7253-1.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**

### Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

## 1 Scope

This part of ISO 7206 describes 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 joint replacement, without the application of torsion. 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 test method has been developed for prostheses that have a plane of symmetry, and may not be suitable for other designs of prosthesis, e.g. those having preformed anteversion or double curvature of the stem.

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 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 listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specifications and test methods*.

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

ISO 5833:1979, *Implants for surgery — Acrylic resin cements — Part 1: Orthopaedic applications*.

ISO 7206-1:1985, *Implants for surgery — Partial and total hip joint replacements — 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 Definitions

For the purposes of this part of ISO 7206, the definitions given in ISO 7206-1 apply.

## 4 Principle of the test method

Embedding of the lower portion 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 specimen 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

### 5.1 Fluid test medium

*Solution of analytical grade sodium chloride* [ $\rho(\text{NaCl}) = 9 \text{ g/l}$ ], continuously aerated, in distilled or deionized water of grade 3 as specified in ISO 3696.

### 5.2 Embedding medium

A casting medium, which should

- a) not be affected by the fluid test medium (5.1);
- b) not crack or break under the load applied during testing;
- c) not exhibit excessive deformation or creep;
- d) be reproducible in strength and other characteristics.

Three media that appear satisfactory are acrylic bone cement (see ISO 5833-1), epoxy casting resin and high-alumina cement (see Annex A which contains guidance on a satisfactory composition of high-alumina cement).

## 6 Apparatus

**6.1 Testing machine** having the following characteristics:

- a) error in applied load: not greater than  $\pm 1 \%$  at maximum load (see ISO 7500-1 and ISO 4965);
- b) dynamic loading waveform: sinusoidal;
- c) 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  $\pm 2 \%$  and to record the number of cycles or the elapsed time of operation.

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