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Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

"जानने का अधिकार, जीने का अधिकार"
Mazdoor Kisan Shakti Sangathan
“The Right to Information, The Right to Live”

"पुराने को छोड़ नये के तरफ"
Jawaharlal Nehru
“Step Out From the Old to the New”

[MHD 2: Orthopaedic Instruments, Implants and Accessories]
Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL HIP JOINT PROSTHESSES

PART 9 DETERMINATION OF RESISTANCE TO TORQUE OF HEAD FIXATION STEMMED FEMORAL COMPONENTS

ICS 11.040.40
NATIONAL FOREWORD

This Indian Standard which is identical with ISO 7206-9 : 1994 'Implants for surgery — Partial and total hip joint prostheses — Part 9 : Determination of resistance to torque of head fixation of stemmed femoral components' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

<table>
<thead>
<tr>
<th>International Standard</th>
<th>Corresponding Indian Standard</th>
<th>Degree of Equivalence</th>
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<tbody>
<tr>
<td>3696 : 1987</td>
<td>IS 1070 : 1992 Reagent grade water (third revision)</td>
<td>Technically equivalent</td>
</tr>
<tr>
<td>7206-1 : 1985</td>
<td>IS 12375 (Part 1) : 1987 Partial and total hip joint prostheses: Part 1 : Classification, designation of dimensions and requirements</td>
<td>Identical</td>
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This standard has been issued in 9 parts. Other parts of this standard are:

Part 1 Classification, designation of dimensions and requirements
Part 2 Bearing surfaces made of metallic and plastic 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 without application of torsion
Part 8 Endurance performance of stemmed femoral components with application of torsion

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.
Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL
HIP JOINT PROSTHESSES

PART 9 DETERMINATION OF RESISTANCE TO TORQUE OF HEAD FIXATION OF
STEMMED FEMORAL COMPONENTS

1 Scope

This part of ISO 7206 describes a method of determining the torque required, under specified laboratory conditions, to loosen the fixation of the head of hip joint prostheses in which the head is not intended to rotate relative to the neck. It applies to the femoral component of total or partial hip joint replacements in which the head and arm are secured together by a locking conical taper or any other means and in which the head and neck are separate components, and which are made of metallic and non-metallic materials.

This part of ISO 7206 does not cover methods of examining 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.


3 Definitions

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

4 Principle

Mounting of the head on a firmly fixed neck unit. Immersion of the assembly in liquid at a controlled temperature. Application of an axial load to the assembly. Application of a torque to the head and the measurement of the torque required to initiate rotation of the head on the neck.

5 Reagent

Fluid test medium, comprising either:

a) distilled or deionized water of Grade 3 in accordance with ISO 3696; or

b) liquid of a composition stated by the party submitting the specimen for test.
6 Apparatus

See figure 1 for an example of test apparatus.

6.1 Specimen holder, of a corrosion-resistant material, and having a construction and dimensions to suit the testing machine and test specimen.

6.2 Testing machine, capable of applying an axial load through the axis of the head/neck assembly, with accuracy of 1 % of full scale reading, and of applying a torque to the head in a plane at right angles to the axial load, with an accuracy of 1 % of full scale reading.

6.3 Means of transmitting the axial load, e.g. an acetabular cup of ultra-high-molecular-weight polyethylene.

6.4 Means of maintaining the temperature of the fluid test medium at 37 °C ± 1 °C.

6.5 Means of continuously aerating the fluid test medium, e.g. a small air pump of the type used for aquaria.

6.6 Means of measuring the torque applied to the head of the assembly, with an accuracy of 1 %.

6.7 Neck unit, comprising a neck/stem of the type to which the head is to be fitted in service, or a dummy neck having the same dimensions and being made of the same material, by the same manufacturing process and to the same specification.

NOTE 1 The use of a dummy neck is convenient and economical compared with fully finished femoral components: however in cases of dispute the test should be performed using the complete stemmed femoral component.

Figure 1 — Example of equipment for determination of resistance to torque of head/neck assembly
7 Procedure

7.1 If the head is not in place on the stem, mount the head to be tested on the neck unit (6.7) in the manner recommended by the manufacturer, and mount the assembly in the specimen holder (6.1). If the head is in place on the stem, mount the assembly in the specimen holder.

7.2 Mount the specimen holder and assembly in the testing machine (6.2).

7.3 Apply and maintain a load of 1 000 N axially to the head through the loading device (6.3).

7.4 Circulate heated fluid test medium through the specimen holder until the temperature of the holder and contents stabilizes at 37 °C ± 1 °C. Maintain this temperature and maintain aeration of the fluid test medium (6.4 and 6.5). Allow all electronic amplifiers, recorders, etc. that form part of the test equipment to reach a stable operating temperature.

7.5 Apply (6.2) an incrementally increasing torque to the head until the head begins to rotate on the neck, continuously recording the torque applied. Note the maximum torque applied before rotation commences. Record or calculate from the recording the rate of application of torque.

If fixation is achieved by the use of a screw thread the torque should be applied in the loosening direction.

NOTE 2 Depending on the means used for gripping the head, it may be necessary to grind small flats on the surface of the head, especially in the case of hard materials such as ceramics.

7.6 Remove the head/neck assembly from the testing machine and specimen holder.

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

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 maximum torque applied before the head commenced to rotate on the neck;

d) the torque application rate;

e) the results of the examination requested by the party submitting the specimen for test.

9 Disposal of test specimens

No part of the prosthesis shall be used for clinical purposes after testing.

This test normally results in the transfer of material from one component to the other and changes the nature of both mating surfaces. Care should be exercised in the use of the specimen for further mechanical tests because the loading regime may have altered the mechanical properties. In particular, it is recommended that neither the neck/stem components nor the head are used for further testing by the method given in this part of ISO 7206.
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This Indian Standard has been developed from Doc : No. MHD 2 (2709).

Amendments Issued Since Publication

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