
International Standard



7206/1

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

Implants chirurgicaux — Prothèse partielle et totale de l'articulation de la hanche — Partie 1 : Classification, désignation des dimensions et spécifications

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 7206/1 was prepared by Technical Committee ISO/TC 150,
Implants for surgery.

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Implants for surgery — Partial and total hip joint prostheses —

Part 1 : Classification, designation of dimensions and requirements

0 Introduction

Orthopaedic joint prostheses are designed to transmit load and translate movement under high stress conditions. The task of preparing International Standards to cover all eventualities is complicated by the limited range of biologically suitable materials.

The purpose of this part of ISO 7206 and of other International Standards relating to joint prostheses is to provide direction in the control of manufacture and standard specifications for the different components of prostheses.

The insertion and removal of a prosthesis for the purposes of trial fitting at the time of the operation can damage the prosthesis. For this reason reduction tests shall be carried out using a test prosthesis, except in those cases where the prostheses are designed with protection for the bearing areas of the components. It is important, once implantation has been completed, that no components are used again after their removal.

Attention is drawn to ISO 5833/1, ISO 5839 and ISO 7207/1.

1 Scope and field of application

This part of ISO 7206 specifies general requirements for partial and total hip joint prostheses, provides a means of classification and standardizes the designation of dimensions.

NOTE — Bearing surfaces and methods of test will form the subject of a future International Standard.

2 References

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

ISO 5839, *Implants for surgery — Orthopaedic joint prostheses — Basic requirements.*

ISO 6018, *Implants for surgery — General requirements for marking, packaging and labelling.*¹⁾

ISO 7207/1, *Implants for surgery — Partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions.*

3 General

Components of hip joint prostheses shall be in accordance with ISO 5839 and shall be packaged and labelled in accordance with ISO 6018.

4 Radio-opacity of acetabular cups made of plastics material alone

Acetabular cups made of plastics materials alone shall carry at least one radio-opaque marker which shall be situated so as to

- enable the position of the acetabular cup to be determined by means of radiography, and;
- indicate the position of the bearing surface relative to the head of the femoral component.

NOTE — It is recommended that one radio-opaque marker should be situated circumferentially in relation to the largest diameter of the cup.

5 Classification

Hip joint prostheses shall be classified as follows:

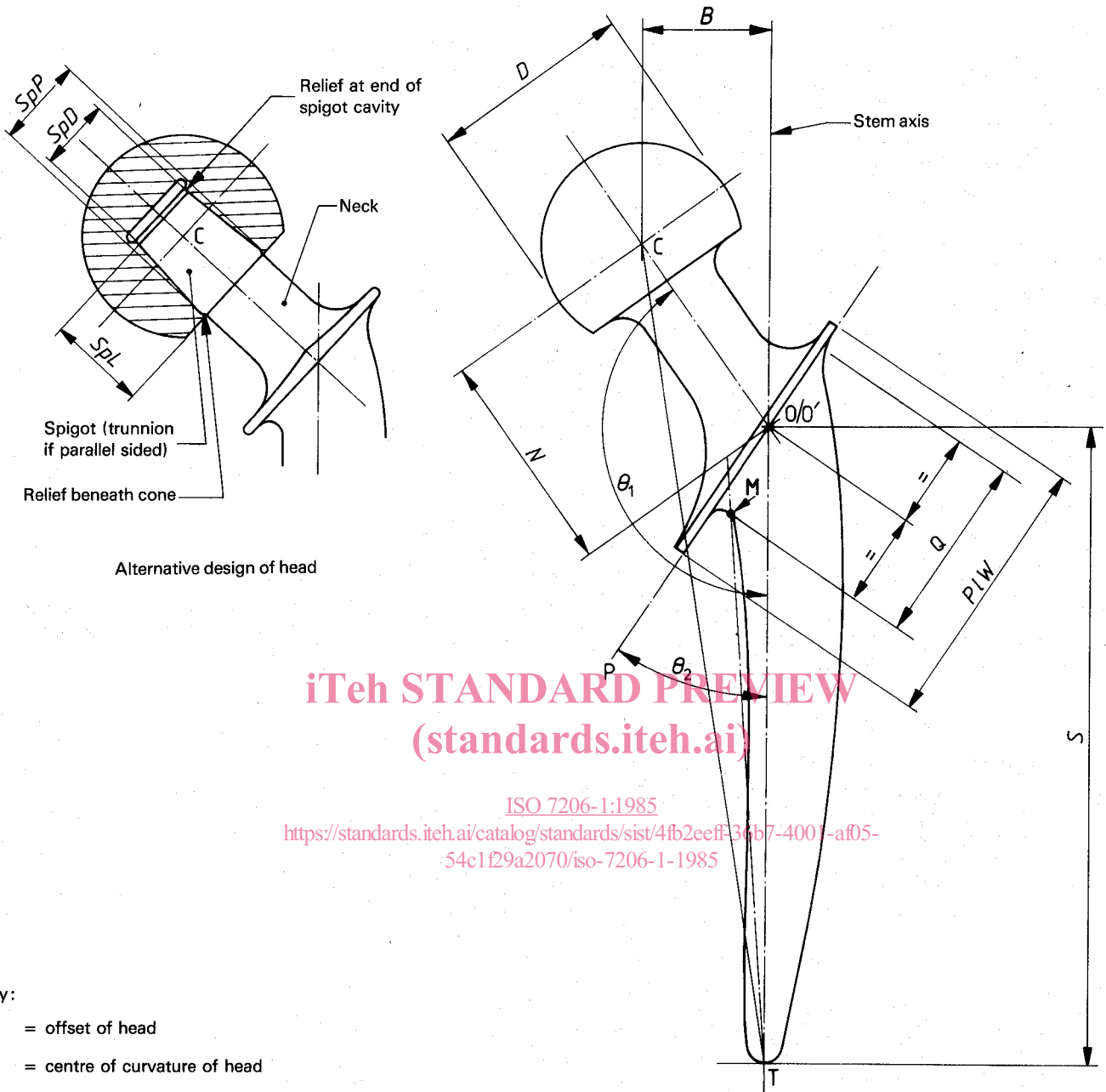
- femoral prosthesis (consisting of one or more components);
- acetabular prosthesis (consisting of one or more components);
- a combination of a) and b).

6 Designation of dimensions

Dimensions of hip joint prostheses shall be designated in accordance with figures 1 to 4.

NOTE — Figures 1 to 4 are intended to be illustrative of typical hip joint prostheses and to designate dimensions, but representation of the components does not otherwise form part of the standard.

1) At present at the stage of draft.



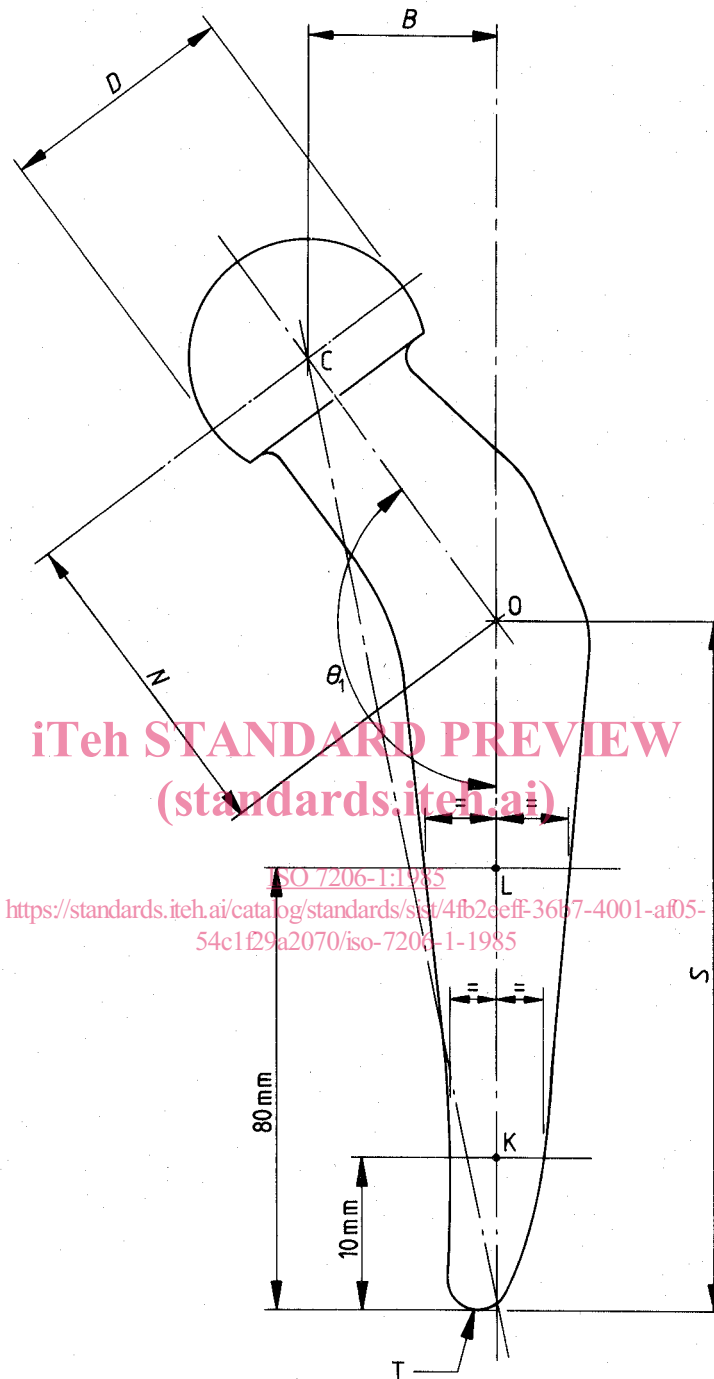
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Key:

- B = offset of head
- C = centre of curvature of head
- CO' = axis of symmetry of neck (O' is not necessarily coincident with O)
- D = diameter of head
- N = neck length (OC) (not necessarily coincident with the neck axis)
- O = centre of stem on plateau (not necessarily coincident with O')
- θ_1 = neck angle (COT)
- θ_2 = plateau angle (POT)
- PO = major axis of plateau
- Q = width of stem adjoining plateau
- SpD = minimum diameter of spigot
- SpP = maximum diameter of spigot
- SpL = length of spigot

- Stem axis = that line from the centre of the tip of the stem to the centre of the stem in the plane of intersection of the plateau
- Mid-line axis of stem = straight line passing through the centres of two sections, 10 mm and 80 mm from the tip respectively (see figure 2)
- S = stem length [distance between tip and plateau (OT)]
- T = tip of stem
- M = mid-point of radius of junction of medial side of stem with plateau
- MT = medial stem length
- CT = length from centre of head to tip of stem
- PIW = mediolateral diameter of plateau

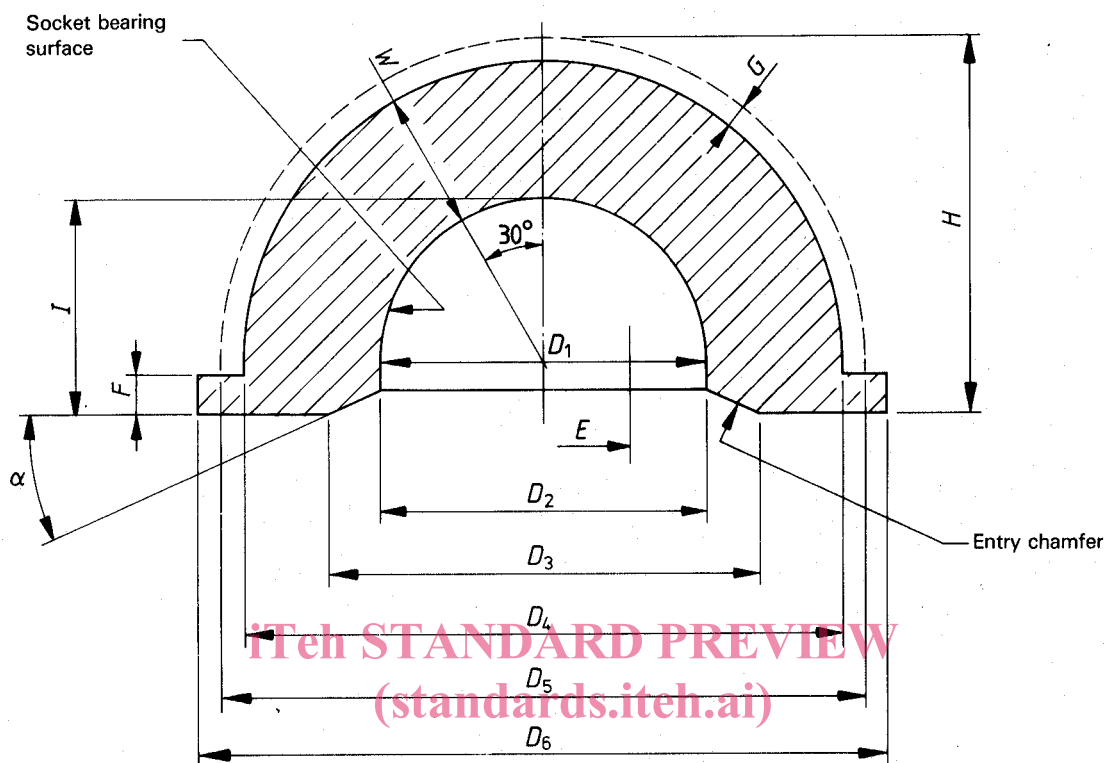
Figure 1 – Designation of dimensions of femoral components of hip joint prostheses provided with plateau



Key:

- | | |
|------------------------------------------------|----------------------------------------------------------------------|
| B = offset of head | O = intersection of nominal axis of neck and mid-line axis of stem |
| C = centre of curvature of head | S = effective stem length (OT) |
| CO = nominal axis of neck | T = tip of stem |
| CT = length from centre of head to tip of stem | θ_1 = neck angle (COL) |
| D = diameter of head | KL = mid-line axis of stem |
| N = neck length (OC) | |

Figure 2 — Designation of dimensions of femoral component of hip joint prostheses without plateau



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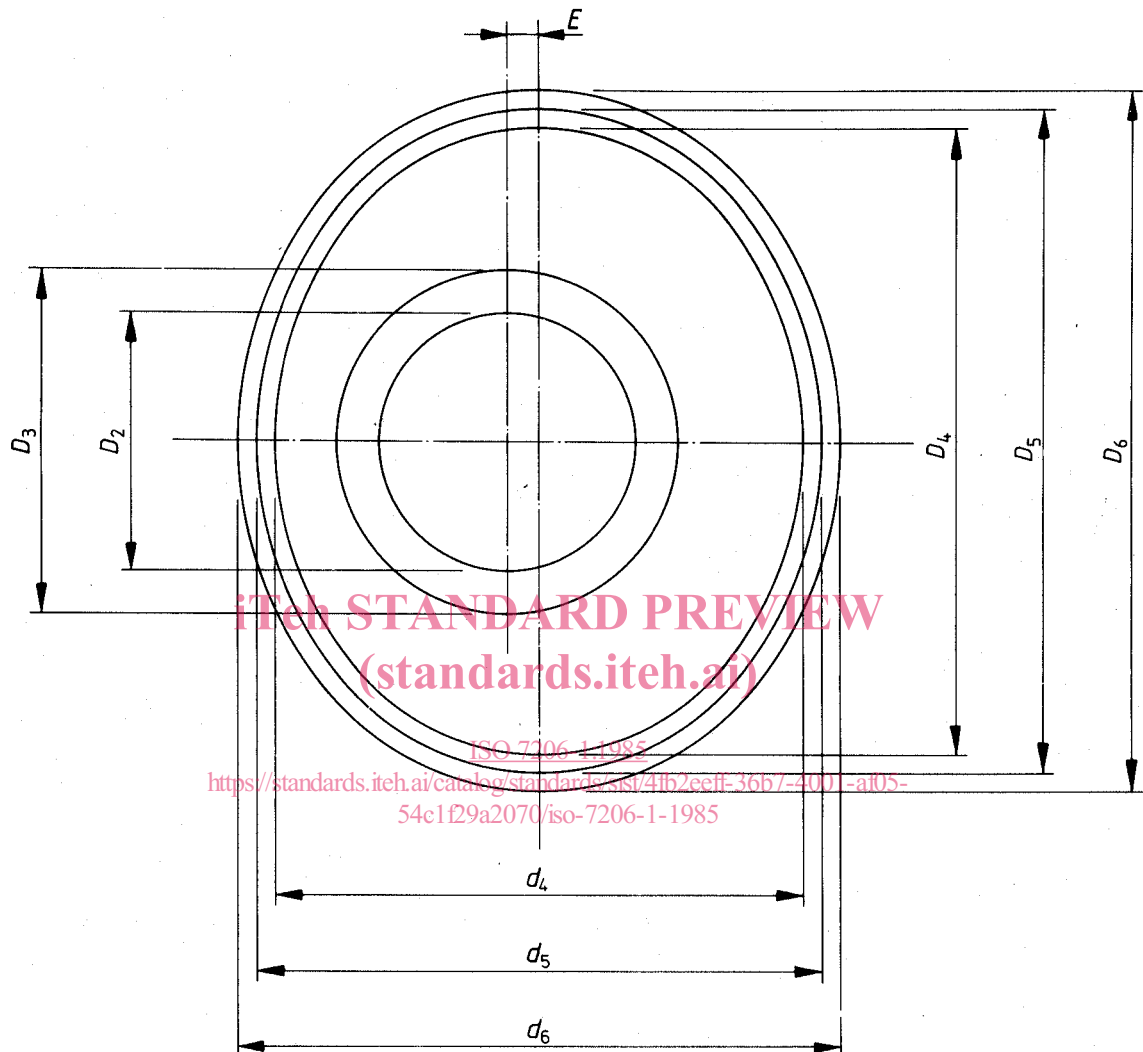
Key:

- D_1 = diameter of spherical socket
- D_2 = retentive or non-retentive entry diameter
- D_3 = relief diameter (the entry chamfer, if present, need not extend through the whole circumference)
- D_4 = effective spherical external diameter
- D_5 = outside diameter of the cup
- D_6 = flange diameter (when present)
- F = flange thickness (when present)
- W = minimum wall thickness
- G = retention system (grooves, ribs, spikes, etc.) depth may be variable
- H = overall height
- I = inside depth
- α = angle of entry chamfer

NOTE — The socket may be eccentrically disposed to the effective spherical external surface (circumscribed by D_5) in which case lateral displacement is denoted by eccentricity E [see figure 4 for designation of dimensions of oval/eccentric configurations (plan view)].

Various means to extend part of the wall of the cup may be incorporated.

Figure 3 — Designation of dimensions of acetabular components of hip joint prostheses



Key:

- D_2 = retentive or non-retentive entry diameter
- D_3 = relief diameter (the entry chamfer, if present, need not extend through the whole circumference)
- D_4 = major effective spherical external diameter
- D_5 = major outside diameter
- D_6 = major flange diameter (when present)
- d_4 = minor effective spherical external diameter
- d_5 = minor outside diameter of the cup
- d_6 = minor flange diameter (when present)
- E = eccentricity

Figure 4 — Designation of dimensions of acetabular components of hip joint prostheses — Plan view of oval/eccentric configuration