

Orthopaedic joint prostheses —

**Part 2: Specification for classification,
definitions and designation of
dimensions of femoral and tibial
components for partial and total knee
joint prostheses**

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/25, Orthopaedic joint prostheses, upon which the following bodies were represented:

- Association of British Healthcare Industries
- British Industrial Ceramic Manufacturers' Association
- British Medical Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association
- Chemical Industries' Association
- Department of Health
- Royal College of Surgeons of England
- Scottish Office

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National foreword

This Part of BS 7251 has been prepared by Technical Committee CH/25. It is identical with ISO 7207-1:1994, *Implants for surgery — Femoral and tibial components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*, published by the International Organization for Standardization (ISO) and supersedes BS 7251-2:1990 which is withdrawn.

The specification for knee joint prostheses was first published as BS 3531-12:1982.

As a result of the development of so many disparate Parts of BS 3531 and because of the anticipated need to implement a number of published and forthcoming ISO standards that would have increased the diversity of BS 3531 still further, it was decided that BS 3531 should be restructured as five distinct standards which would enable the various aspects to be clearly differentiated. BS 3531 itself was limited to standards specific to implants for osteosynthesis and its title changed accordingly. Four new standards were published incorporating Parts of BS 3531 as well as new ISO standards.

BS 7251, *Orthopaedic joint prostheses*.

BS 7252, *Metallic materials for surgical implants*.

BS 7253, *Non-metallic materials for surgical implants*.

BS 7254, *Orthopaedic implants*.

The publication of BS 7251-2:1990 introduced editorial changes to reflect the restructuring, it also introduced information on the positions in which condylar prostheses may be used.

This revision of BS 7251-2 restricts the classification and designation of dimensions to the femoral and tibial components, includes additional definitions and with the introduction of a key to each diagram further identifies the figures given.

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.

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Summary of pages

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

Introduction

Partial and total knee joint prostheses are designed to transmit load and allow movement under high stress conditions. The task of preparing International Standards to cover all requirements is complicated by the limited range of biologically suitable materials.

The purpose of this part of ISO 7207 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.

Attention is drawn to ISO 5839, *Implants for surgery — Orthopaedic joint prostheses — Basic requirements*, in which the requirements for orthopaedic joint prostheses are specified.

1 Scope

This part of ISO 7207 classifies femoral and tibial components for knee joint prostheses in which one or both bearing surfaces of at least one compartment of the knee are replaced, and gives definitions of components and the designation of dimensions.

Patellar components and prostheses that include an interposed floating component are not included in this part of ISO 7207.

2 Definitions

For the purposes of this part of ISO 7207, the following definitions apply.

2.1

partial unicompartmental knee joint component

prosthesis designed to replace the bearing surface of one condyle of either the femur or the tibia (see Figure 1, position A, B, C or D)

2.2

partial bicompartamental knee joint component

prosthesis designed to replace the bearing surfaces of both condyles of either the femur or the tibia (see Figure 1, positions A and B, or C and D)

NOTE 1 In surgical practice unicondylar components may be used either for unicondylar replacements, for unicompartmental replacements, or for total replacements, whereas generally bicondylar components are used only for total knee joint replacement.

2.3

unicompartmental partial knee joint replacement

procedure of replacing the bearing surfaces of the contiguous condyles of the femur and tibia in one compartment of the knee (see Figure 1, positions A and C, or B and D)

2.4

total replacement of the knee joint

procedure of replacing the femoral and tibial bearing surfaces in both compartments of the knee (see Figure 1, positions A, B, C and D)

NOTE 2 Provision for articulation with the patella may or may not be provided.

2.5

non-constrained total knee joint prosthesis

total knee joint prosthesis in which there is no mechanical attachment between the tibial and femoral components and which allows movement in all three planes (see Figure 2, Figure 3 and Figure 4)

2.6

partially-constrained total knee joint prosthesis

total knee joint prosthesis having some mechanical constraint between the tibial and femoral components and which allows movement in more than one plane (see Figure 5)

2.7

fully-constrained total knee joint prosthesis

total knee joint prosthesis in which the two parts are mechanically articulated and which allows movement principally in one plane (see Figure 6)

2.8

effective bone resection distance

minimum distance between resected surfaces of the femur and/or tibia in contact with the plateau(x) of the implant

2.9

stem

part of bicondylar component designed to enter the medullary cavity (see Figure 2, Figure 5 and Figure 6, dimensions t and f)

2.10

femoral stem angle

acute angle between the axis of the femoral stem and the perpendicular to the plateau, as viewed in the antero-posterior direction

NOTE 3 The direction of this angle determines whether the prosthesis should be used in the right or left leg of the patient.

2.11

tibial stem angle

acute angle between the axis of the tibial stem and the perpendicular to the plateau, as viewed in the antero-posterior direction

2.12

intracondylar projection

portion of condylar component for locating and fixing the component in the condyle (see Figure 3 and Figure 4, dimensions t_p and f_p)