### INTERNATIONAL STANDARD

ISO 7207-1

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# Implants for surgery — Femoral and tibial components for partial and total knee joint prostheses —

iTeh STANDARD PREVIEW

Classification, definitions and designation of dimensions, 1994

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Implants chirurgicaux — Éléments fémoral et tibial de prothèses partielle et totale de l'articulation du genou —

Partie 1: Classification, définitions et désignation des dimensions



#### **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.

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.

International Standard ISO 7207-1 was prepared by Technical Committee ISO/TC 150, Implants for surgery, Subcommittee SC 4, Bone and joint replacements.

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This second edition cancels and replaces 1-7the4/isfirst07-edition (ISO 7207-1:1985), of which it constitutes a technical revision.

ISO 7207 consists of the following parts, under the general title *Implants* for surgery — Femoral and tibial components for partial and total knee joint prostheses:

- Part 1: Classification, definitions and designation of dimensions
- Part 2: Bearing surfaces made of metallic and plastics materials

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#### 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.

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### Implants for surgery — Femoral and tibial components for partial and total knee joint prostheses —

#### Part 1:

Classification, definitions and designation of dimensions

#### 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.

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).

Patellar components and prostheses that include any-1:199NOTE 2 Provision for articulation with the patella may or interposed floating component are not included in this ards/sis/may/not be provided 91d6-part of ISO 7207. 6783bde74714/iso-7207-1-1994

#### 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 bicompartmental 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

- **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 figures 2, 3 and 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 figures 2, 5 and 6, dimensions *t* and *f*).

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- 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.
- 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 figures 3 and 4, dimensions  $t_{\rm p}$  and  $f_{\rm p}$ ).
- 2.13 overall width: Maximum dimension in the transverse plane (see figures 2 to 5, dimension w).
- 2.14 overall depth: Maximum dimension in the antero-posterior plane with the joint fully extended (see figures 2 to 5, dimension d).
- 2.15 implant plateau: That part of the component in contact with transected bone and/or bone cement. DA
- 2.16 bone plateau: Transected surface of the bone and site air non-constrained (see figures 2, 3 and 4) plant and/or bone cement.
- 2.17 patella bearing surface: Surface sthatai(sat)pg/standards/sist/c91f7661-845f-4bd4-91d6 tended to articulate with the patella or resurfacing 74714/iso-7207-1-1994 component of the patella.
- 2.18 femorotibial bearing surface: Those areas through which load is transmitted from the femoral to the tibial component.

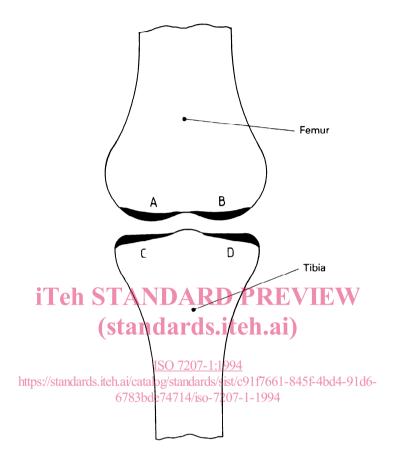
#### Classification 3

Prostheses used to replace some or all of the bearing surfaces in the knee joint shall be classified as follows:

- a) unicondylar (see figure 4)
  - 1) femoral
  - 2) tibial
- b) bicondylar (see figures 2, 3, 5 and 6)
  - 1) femoral
  - 2) tibial
- 3.2 The intended use of the prostheses shall be classified as follows:
- a) partial joint replacement
  - 1) unicondylar
  - 2) unicompartmental
- b) total joint replacement
- **3.3** For total joint replacement the assembled components shall be classified according to the function of the joint in the unloaded condition as follows:
- partially constrained (see figure 5)
- ISO 7207)1:1fully constrained (see figure 6)
- - **Designation of dimensions**

The dimensions of partial and total knee joint prostheses shall be designated in accordance with figures 2, 3, 4 or 5 as appropriate.

Figures 2 to 6 are intended to be illustrative of typical knee joint prostheses and to designate dimensions and illustrate nomenclature, but representation of the components does not otherwise form part of ISO 7207.



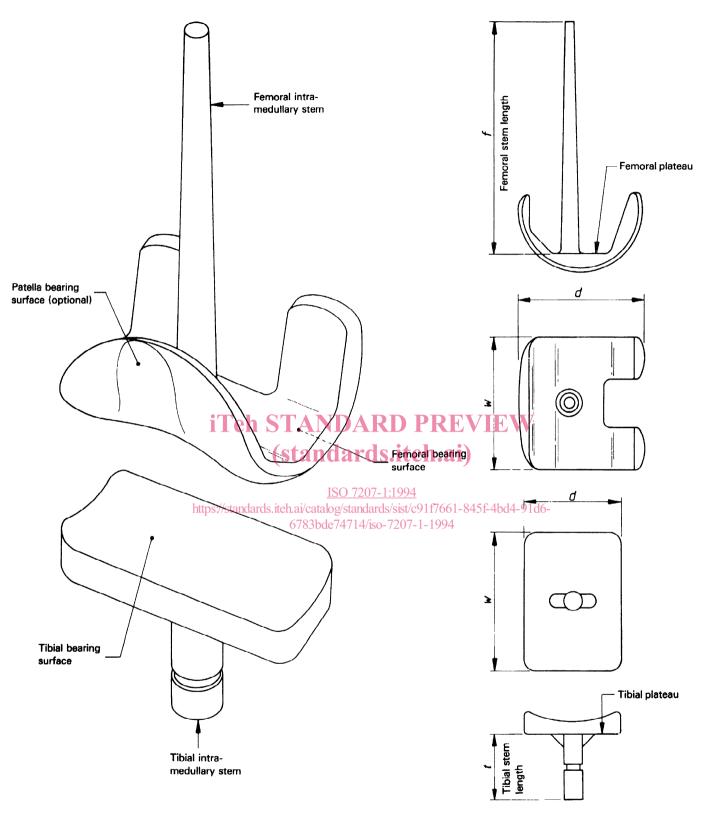
#### Key:

- Position of condylar prostheses on the femur Tibial plateau prostheses А, В
- C, D

NOTE — These may be medial or lateral.

Figure 1 — Human knee joint showing positions in which condylar prostheses may be used

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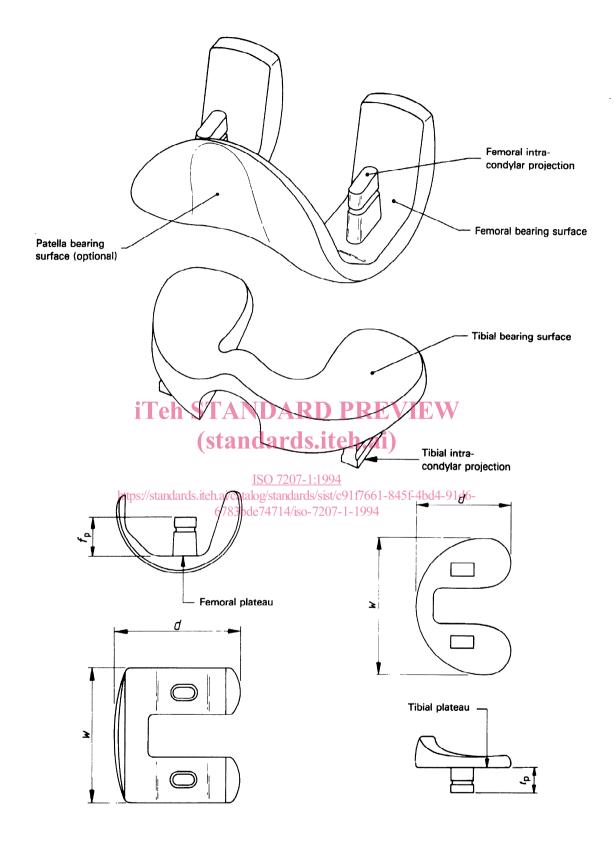
Key:

d overall depth

f stem (femoral stem length)

- stem (tibial stem length)
- w overall width

Figure 2 — Typical non-constrained bicondylar total knee joint prothesis with intramedullary stems (see note 4)



#### Key:

- overall depth
- length of femoral intracondylar projection
- length of tibial intracondylar projection  $t_{p}$  w
- overall width

Figure 3 — Typical non-constrained bicondylar total knee joint prosthesis with intracondylar projections, and patella bearing surface (optional) (see note 4)