TC 150

International Standard ISO 7207/1

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Implants for surgery — Partial and total knee joint prostheses — Part 1 : Classification, definitions and designation of dimensions

Implants chirurgicaux — Prothèse partielle et totale de l'articulation du genou — Partie 1 : Classification, définitions et désignation des dimensions

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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.

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Implants for surgery — Partial and total knee joint prostheses — Part 1 : Classification, definitions and designation of dimensions

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 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.

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 have features or ancillary items 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 7206/1.

1 Scope and field of application

This part of ISO 7207 classifies 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 a floating joint interposition are not included in this 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 7206/1, *Implants for surgery — Partial and total hip joint prostheses — Classification, designation of dimensions and requirements.*

3 Definitions

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

3.1 unicondylar 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).

3.2 bicondylar 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 — 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 replacements.

3.3 unicondylar partial replacement of the knee joint: Procedure of replacing the bearing surface of one condyle (normally of the tibia).

3.4 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).

3.5 total replacement of the knee joint: Procedure of replacing the femoral and tibial bearing surfaces in both compartments of the knee (see figure 1, position A, B, C and D).

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

3.6 non-constrained total knee joint prosthesis: A total knee joint prosthesis in which there is no mechanical attachment between the tibial and femoral components and that allows movement in all three planes (see figures 2, 3 and 4).

3.7 partially-constrained total knee joint prosthesis: A total knee joint prosthesis having some mechanical constraint between the tibial and femoral components and allowing movement in more than one plane (see figure 5).

3.8 fully-constrained total knee joint prosthesis: A total knee joint prosthesis in which the two parts are mechanically articulated and that allows movement principally in one plane (see figure 6).

3.9 effective bone resection distance: Minimum distance between resected surfaces of the femur and/or tibia in contact with the plateau(x) of the implant.

3.10 stem: Part of bicondylar component designed to enter the medullary cavity (see figures 2, 5 and 6, dimensions t and f).

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

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

3.13 intra-condylar projection: Portion of condylar component for locating and fixing the component in the condyle, (see figures 3 and 4, dimensions t_p and f_p).

3.14 overall width: Maximum dimension in the transverse plane (see figures 2 to 5, dimension w).

3.15 overall depth: Maximum dimension in the antero-posterior plane with the joint fully extended (see figures 2 to 5, dimension d).

3.16 implant plateau: That part of the component in contact with transected bone and/or bone cement.

3.17 bone plateau: Transected surface of the bone which may be in contact with the plateau of the implant and/or bone cement.

3.18 patella bearing surface: Surface that is intended to articulate with the patella or resurfacing component of the patella.

3.19 bearing surface: Those areas through which load is transmitted from the femoral to the tibial component.

4 Classification

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

The intended use of the prostheses shall be classified as follows :

a) partial joint replacement

1) unicondylar

2) unicompartmental

b) total joint replacement

For total joint replacement the assembled components shall be classified according to the function of the joint in the unloaded condition as follows :

a) non-constrained (see figures 2, 3 and 4)

b) partially constrained (see figure 5)

c) fully constrained (see figure 6)

5 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.

NOTE — 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 the standard.

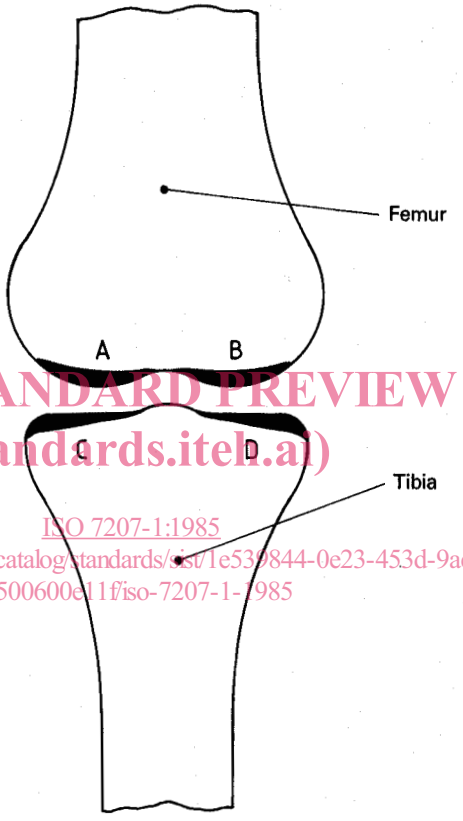

Figure 1 — Human knee joint showing positions in which condylar prostheses may be used

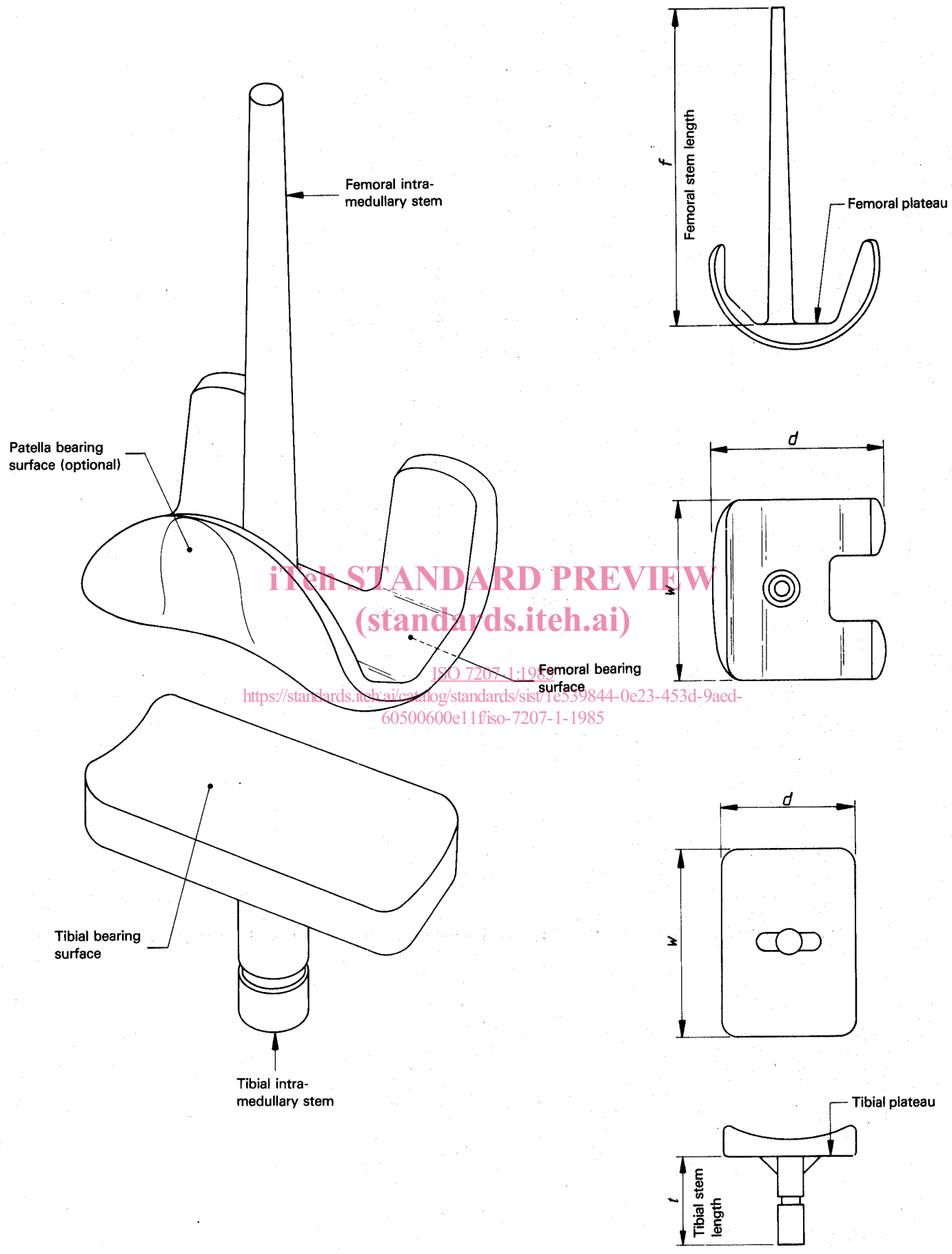

Figure 2 — Typical non-constrained bicondylar total knee joint prosthesis with intra-medullary stems (see note to clause 5)

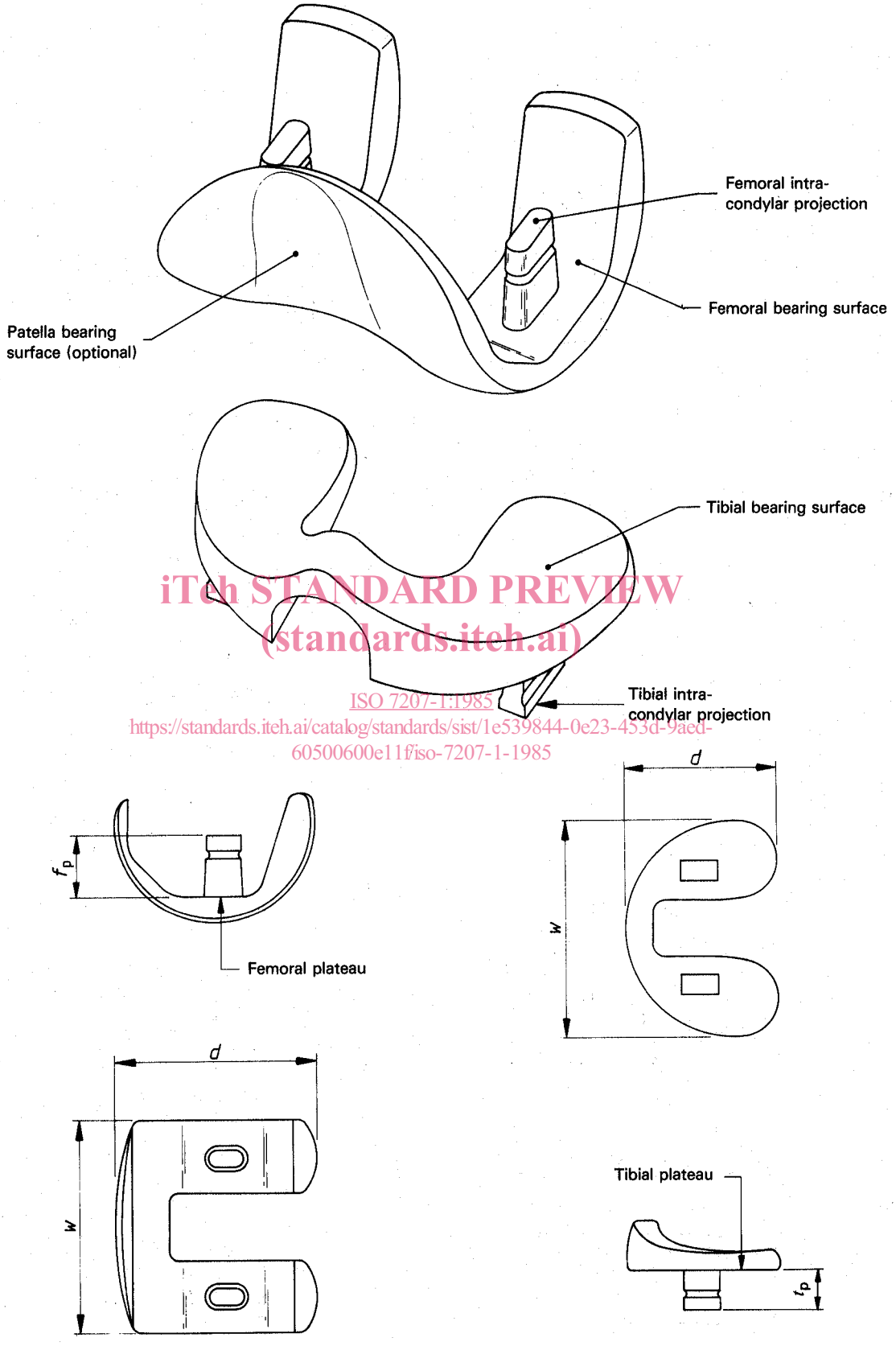

Figure 3 — Typical non-constrained bicondylar total knee joint prosthesis with intra-condylar projections, and patella bearing surface (optional) (see note to clause 5)

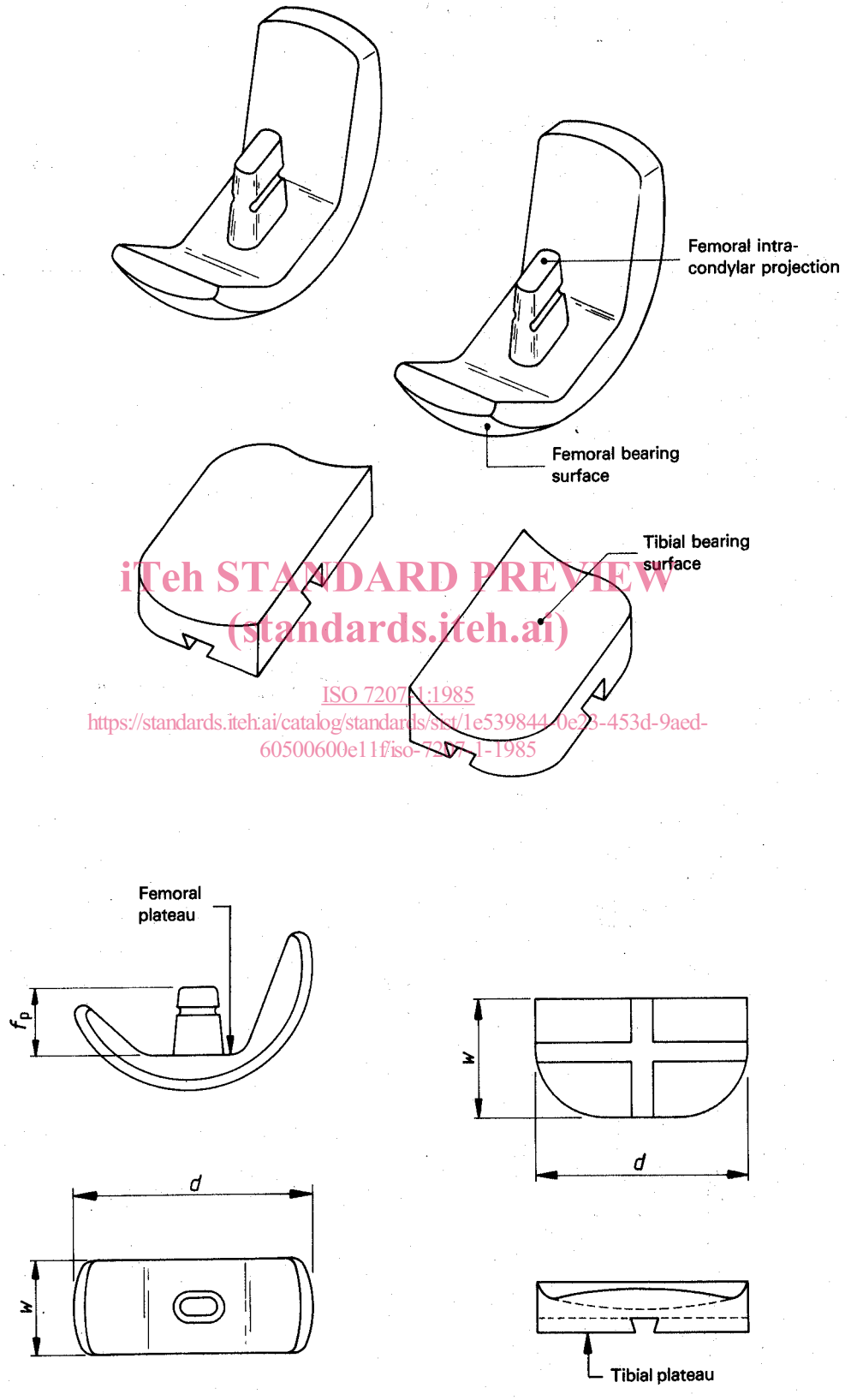

Figure 4 — Typical non-constrained unicondylar total knee joint prosthesis (see note to clause 5)

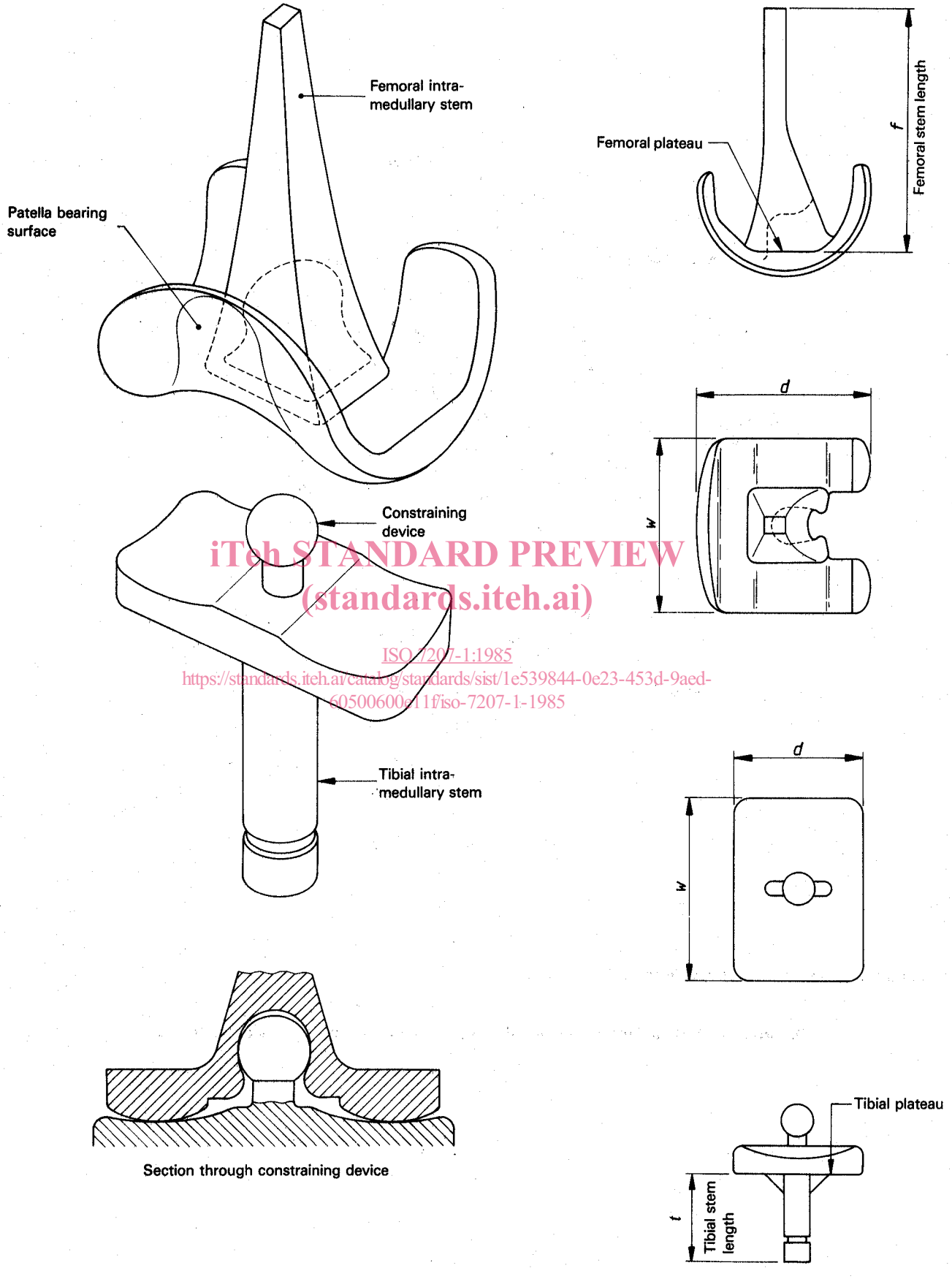

Figure 5 — Typical partially constrained total knee joint prosthesis with intra-medullary stems (see note to clause 5)