# INTERNATIONAL STANDARD

# ISO 7207-1

Third edition
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## Implants for surgery — Components for partial and total knee joint prostheses —

## Part 1: Classification, definitions and designation of dimensions

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

*Partie 1: Classification, définitions et désignation des dimensions*

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# Foreword

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

This third edition cancels and replaces the second edition (ISO 7207-1:1994) which has been technically revised.

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

— *Part 1: Classification, definitions and designation of dimensions*

— *Part 2: Articulating surfaces made of metal, ceramic and plastics materials*

# Introduction

Partial and total knee joint prostheses are designed to transmit loads and allow movement under high stress conditions. They are intended to replace anatomical structures and provide structure and function to provide as closely as possible the attributes of the normal natural joint. The structure and functions required in a specific implant depend on the amount of anatomical structure or function which is attenuated or absent, and a system of classification of the attributes of various types of implant is presented.

Many different designs of knee joint prostheses are used all over the world and ISO 7207 gives a comprehensive description of the most common knee joint prostheses in accordance with this detailed classification system, definition of components and the designation of dimensions. These classifications assist the surgeon in selection of the appropriate implant for a specific case.

# Implants for surgery — 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, tibial and patellar components for knee joint prostheses in which the bearing surfaces of one or more compartments of the knee are replaced. It also gives definitions of components and the designation of dimensions.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21534, *Non-active surgical implants — Joint replacement implants — Particular requirements*

ISO 21536, *Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants*

## 3 Terms and definitions and symbols

For the purposes of this document, the terms and definitions given in ISO 21534 and ISO 21536 and the following apply.

### 3.1 Types of knee joint prosthesis

**3.1.1**
**total knee joint prosthesis**
bi-compartmental or tri-compartmental knee joint prosthesis

NOTE A bi-compartmental total knee joint prosthesis is shown in Figure 1. A tri-compartmental total knee joint prosthesis is shown in Figure 7c).

**3.1.2**
**uni-compartmental knee joint prosthesis**
set of implant components used to replace the femoral and tibial articulating surfaces in either the medial or the lateral compartment of a knee joint

NOTE A uni-compartmental knee joint prosthesis is shown in Figure 2.

**3.1.3**
**bi-compartmental knee joint prosthesis**
set of implant components used to replace the femoral and tibial articulating surfaces in both the medial and the lateral compartments of a knee joint

NOTE Bi-compartmental knee joint prostheses are shown in Figures 3 to 5.

**3.1.4**
**tri-compartmental knee joint prosthesis**
set of implant components used to replace the femoral and tibial articulating surfaces in the medial and the lateral compartments of a knee joint and also the patellar and femoral articulating surfaces in the patello-femoral compartment

NOTE A tri-compartmental knee joint prosthesis is shown in Figure 7c).

**3.1.5**
**patello-femoral knee joint prosthesis**
set of implant components used to replace patellar and femoral articulating surfaces in the patello-femoral compartment of a knee joint

**3.1.6**
**mobile-bearing knee joint prosthesis**
total or uni-compartmental knee joint prosthesis which allows relative motion between the mobile-bearing component and both the femoral component and the tibial tray

NOTE Mobile-bearing knee joint prostheses are shown in Figures 2 a) and 4.

**3.1.7**
**fixed-bearing knee joint prosthesis**
total or uni-compartmental knee joint prosthesis which allows articulation of a fixed-bearing component with the femoral component only

NOTE A fixed-bearing knee joint prosthesis is shown in Figure 3.

**3.1.8**
**cemented knee joint prosthesis**
knee joint prosthesis designed to be attached to the supporting bones using bone cement

**3.1.9**
**unconstrained total knee joint prosthesis**
**non-constrained total knee joint prosthesis**
total knee joint prosthesis in which there is no mechanical attachment between the tibial and femoral components, allowing relative movement in all three planes

NOTE Unconstrained total knee joint prostheses are shown in Figures 3 and 4. In the previous edition, the term non-constrained was used for this definition. A non-constrained joint prosthesis is used for partial or total joint replacement and minimally restricts prosthesis movement in one or more planes. Its components have no across-the-joint linkage.

**3.1.10**
**uncemented knee joint prosthesis**
knee joint prosthesis designed to be attached to the supporting bones without using bone cement

**3.1.11**
**posterior stabilized total knee joint prosthesis**
semi-constrained total knee joint prosthesis which is intended to limit antero-posterior movement

NOTE A posterior stabilized total knee joint prosthesis is shown in Figure 5.

**3.1.12**
**semi-constrained total knee joint prosthesis**
**partially-constrained total knee joint prosthesis**
total knee joint prosthesis having some mechanical constraint between the tibial and femoral components limiting movement in one or two planes

NOTE A semi-constrained total knee joint prosthesis is shown in Figure 5. In the previous edition, the term partially-constrained was used for this definition. A semi-constrained joint prosthesis is used for partial or total joint replacement and limits translation and rotation of the prosthesis in one or two planes.

**3.1.13**
**constrained total knee joint prosthesis**
**fully-constrained total knee joint prosthesis**
total knee joint prosthesis in which the tibial and femoral components are mechanically linked to restrict movement to either one (hinged) or two (rotating hinged) planes

NOTE A constrained total knee joint prosthesis is shown in Figure 6. In the previous edition, the term fully-constrained was used for this definition. A constrained joint prosthesis is used for joint replacement and prevents dislocation of the prosthesis's articulating surfaces in more than one anatomical plane.

**3.1.14**
**hinged total knee joint prosthesis (with and without rotation)**
constrained total knee joint prosthesis with a hinged or rotating hinged attachment between the tibial and femoral components

NOTE A hinged total knee joint prosthesis is shown in Figure 6.

**3.1.15**
**porous coated knee joint prosthesis**
uncemented knee joint prosthesis with some non-articulating surfaces coated to encourage bony in-growth

**3.1.16**
**hybrid knee joint prosthesis**
knee joint with fixation comprising at least one component cemented and at least one component uncemented

## 3.2 Components of knee joint prostheses

**3.2.1**
**monobloc component**
femoral, tibial or patellar component which is supplied as a single unit and which is not intended to be disassembled by the user

**3.2.2**
**modular component**
femoral, tibial or patellar component which is supplied as a number of sub-components and which is intended to be assembled by the user

**3.2.3**
**femoral component**
component of a total, patello-femoral or uni-compartmental knee joint prosthesis intended to be secured to the femur to replace its articulating surface(s)

NOTE It can be monobloc or modular.

**3.2.4**
**femoral intramedullary stem**
part of the femoral component designed to enter the medullary cavity of the femur

NOTE A femoral intramedullary stem is shown in Figure 6. It can be monobloc or modular.

**3.2.5**
**tibial component**
component of a total or uni-compartmental knee joint prosthesis intended to be secured to the tibia to replace its articulating surface(s)

NOTE It can be monobloc or modular.

**3.2.6**
**tibial intramedullary stem**
part of the tibial component designed to enter the medullary cavity of the tibia

NOTE Tibial intramedullary stems are shown in Figures 3, 5 and 6. They can be monobloc or modular.

**3.2.7**
**tibial fixation elements**
parts of the tibial component extending distally from the tibial plateau to engage in holes formed in the cut section of the tibia to assist fixation

**3.2.8**
**tibial tray**
sub-component of a modular tibial component of a total or uni-compartmental knee joint prosthesis used to support the tibial insert or mobile-bearing component

NOTE A tibial tray is shown in Figures 1, 2, 3 and 5.

**3.2.9**
**tibial insert**
sub-component of a modular tibial component of a total or uni-compartmental knee joint prosthesis which is attached to the tibial tray and which articulates with the femoral component

NOTE A tibial insert is shown in Figures 1, 2, 3, 4 and 5.

**3.2.10**
**mobile-bearing component**
component of a total or uni-compartmental mobile-bearing knee joint prosthesis which articulates with both the femoral component and the tibial tray

NOTE A mobile-bearing component is shown in Figure 4a).

**3.2.11**
**rotating platform**
mobile-bearing component which articulates with the tibial tray in axial rotation only

**3.2.12**
**floating platform**
mobile-bearing component which articulates with the tibial tray in a combination of rotation and translation

NOTE A floating platform is shown in Figure 4b).

**3.2.13**
**patellar component**
component of a total or patello-femoral knee joint prosthesis which is used to replace the articulating surface of the patella

NOTE A patellar component is shown in Figure 7. It can be monobloc or modular.

**3.2.14**
**patellar tray**
sub-component of a modular patellar component of a total knee joint prosthesis used to support and secure the patellar insert

**3.2.15**
**patellar insert**
sub-component of a modular patellar component of a total knee joint prosthesis which is attached to the patellar tray and which articulates with the femoral component or the femur

**3.2.16**
**augmentation elements**
augmentation device made of metal or plastic fitted onto a tibial or femoral component to fill the space between the bone and the implant component

## 3.3 Symbols

Symbols used in the Figures are given in Table 1.

**Table 1 — Symbols for dimensions**

| Symbol | Dimension | Definitions and notes (where applicable) |
|---|---|---|
| $a$ | femoral depth | Maximum dimension of the femoral component in the antero-posterior direction with the joint fully extended. See Figures 2, 3 and 5. |
| $b$ | femoral width | Maximum dimension of the femoral component in the transverse plane. See Figures 2, 3 and 5. |
| $c$ | femoral intracondylar depth | Distance between the anterior and posterior internal surfaces of the femoral component. See Figures 3 and 5. |
| $d$ | femoral height, anterior | |
| $e$ | femoral height posterior | |
| $f$ | femoral thickness, posterior | |
| $g$ | femoral thickness, distal | |
| $h$ | tibial tray thickness | |
| $i$ | diameter of the hinge | |
| $k$ | tibial component thickness | Minimum thickness in the load-bearing area of a monobloc or modular tibial component. See Figures 2 and 3. |
| $k_f$ | femoral intramedullary stem diameter | |
| $k_t$ | tibial intramedullary stem diameter | |
| $l_f$ | femoral intramedullary stem length | |
| $l_t$ | tibial intramedullary stem length | |
| $m$ | tibial depth | Maximum dimension of the tibial component in the antero-posterior plane. See Figures 2, 3, 5 and 6. |
| $n$ | tibial width | Maximum dimension of the tibial component in the transverse plane. See Figures 2, 3, 5 and 6. |
| $r$ | global gap | |
| $s$ | jumping distance | Effective length of the feature of a posterior stabilized knee which prevents luxation. See Figure 5. |
| $t$ | tibial insert thickness (mobile-bearing component thickness) | Minimum thickness of the tibial insert (mobile-bearing component) in the load-bearing area. See Figures 2, 3, 4, 5 and 6. |
| $u$ | patellar component thickness/patellar insert thickness/patellar tray thickness | Minimum thickness of the patellar component in the load-bearing area. See Figure 7a). |
| $v$ | patellar component width | |
| $\alpha$ | range of flexion angle | |

## 4 Classification

Prostheses used to replace some or all of the bearing surfaces in the knee joint shall be classified as follows (see Figure 8):

a) uni-compartmental knee replacement;

b) bi-compartmental knee replacement;

c) tri-compartmental knee replacement.

Additionally, the stability provided to the knee joint replacement implant by the ligaments is described as follows:

— anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) sparing;

— PCL sparing;

— ACL and PCL sacrificing;

— ACL and PCL and collateral ligament sacrificing.

With the degree of instability of the natural knee joint, the knee joint prostheses shall be classified in addition according to the function of the joint as follows:

— unconstrained: without mechanical connection between components, free movement;

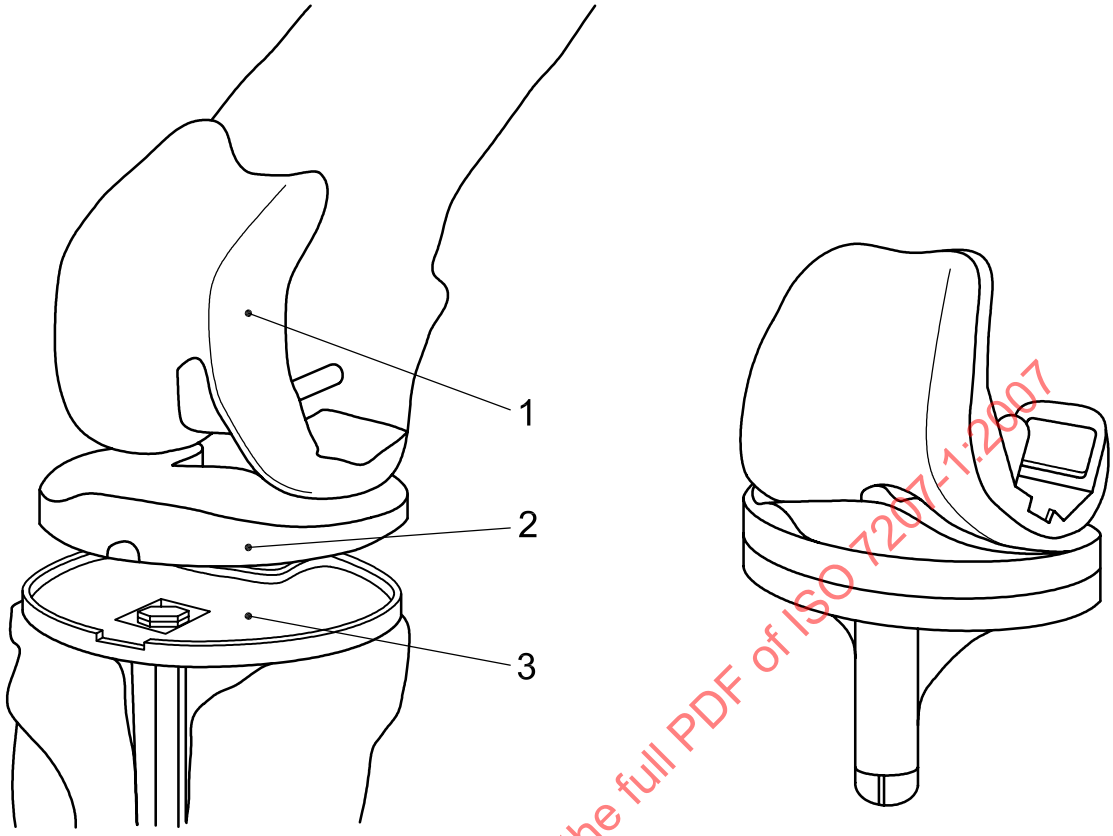
— semi-constrained: with some mechanical connection between components, limited movement;

— constrained: mechanical connection between components, restricted movement.

## 5 Designation of dimensions

The dimensions of knee joint prostheses shall be designated in accordance with Figures 1 to 7 as appropriate.

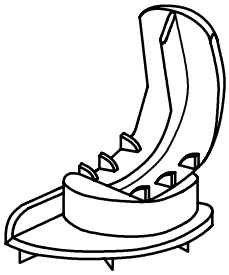
NOTE Figures 1 to 7 are intended to be illustrative of typical knee joint prosthesis for designation of dimensions and to illustrate nomenclature. Representation of the detailed features of the components does not otherwise form part of this part of ISO 7207.



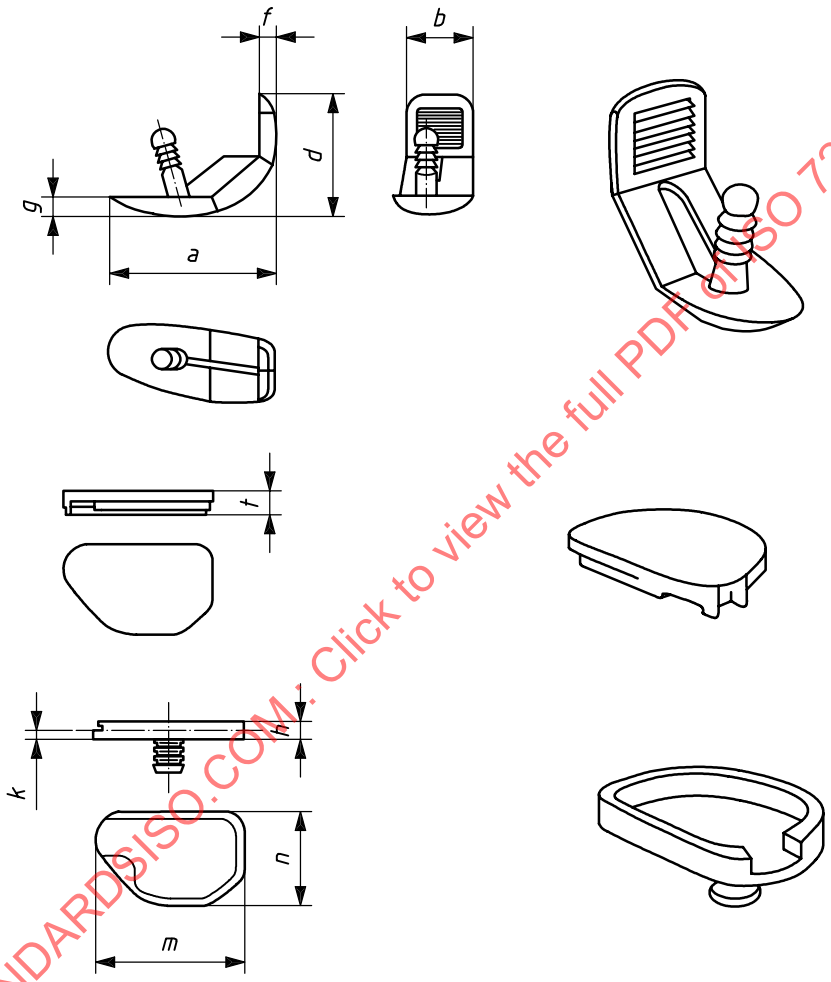

**Key**

1 femoral component
2 tibial insert
3 tibial tray

**Figure 1 — Bi-compartmental knee joint prosthesis**



**a) Mobile-bearing uni-compartmental knee joint prosthesis**



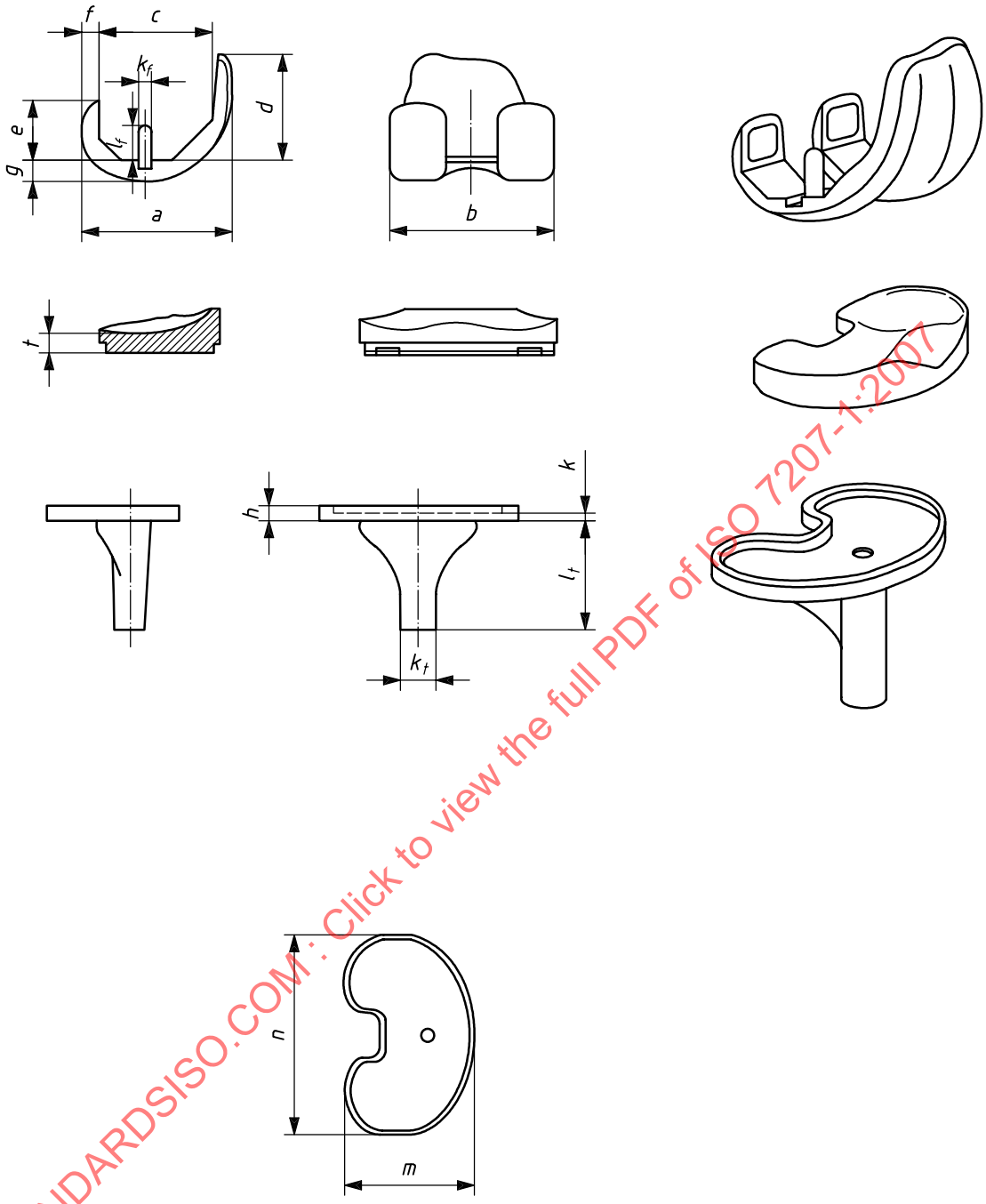



**Key**

| | | | |
|---|---|---|---|
| *a* | femoral depth | *h* | tibial tray thickness |
| *b* | femoral width | *k* | tibial component minimum thickness |
| *d* | femoral height, anterior | *m* | tibial depth |
| *f* | femoral thickness, anterior | *n* | tibial width |
| *g* | femoral thickness, distal | *t* | tibial insert thickness |

**b) Fixed bearing uni-compartmental knee joint prosthesis**

**Figure 2 — Modular uni-compartmental knee joint prosthesis**

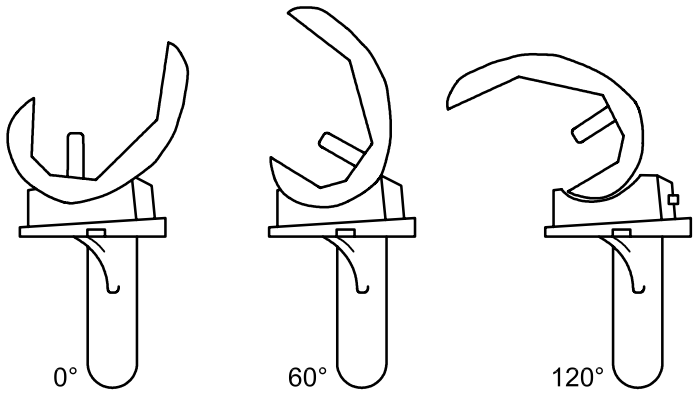




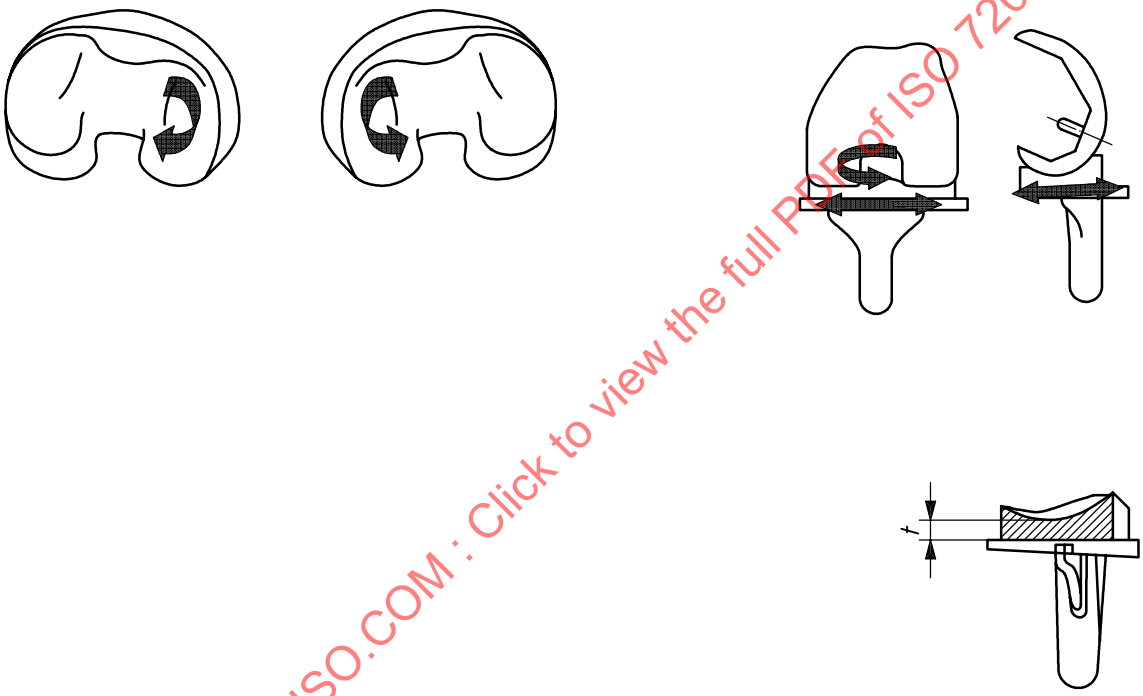

**Key**

| | | | |
|---|---|---|---|
| $a$ | femoral depth | $k$ | tibial component minimum thickness |
| $b$ | femoral width | $k_f$ | femoral intramedullary stem diameter |
| $c$ | femoral intracondylar depth | $k_t$ | tibial intramedullary stem diameter |
| $d$ | femoral height, anterior | $l_f$ | femoral intramedullary stem length |
| $e$ | femoral height, posterior | $l_t$ | tibial intramedullary stem length |
| $f$ | femoral posterior thickness | $m$ | tibial depth |
| $g$ | femoral distal thickness | $n$ | tibial width |
| $h$ | tibial tray thickness | $t$ | tibial insert thickness |

**Figure 3 — Unconstrained bi-compartmental knee joint prosthesis (fixed bearing)**




**a) Congruence of the mobile-bearing surface in different flexion angles**

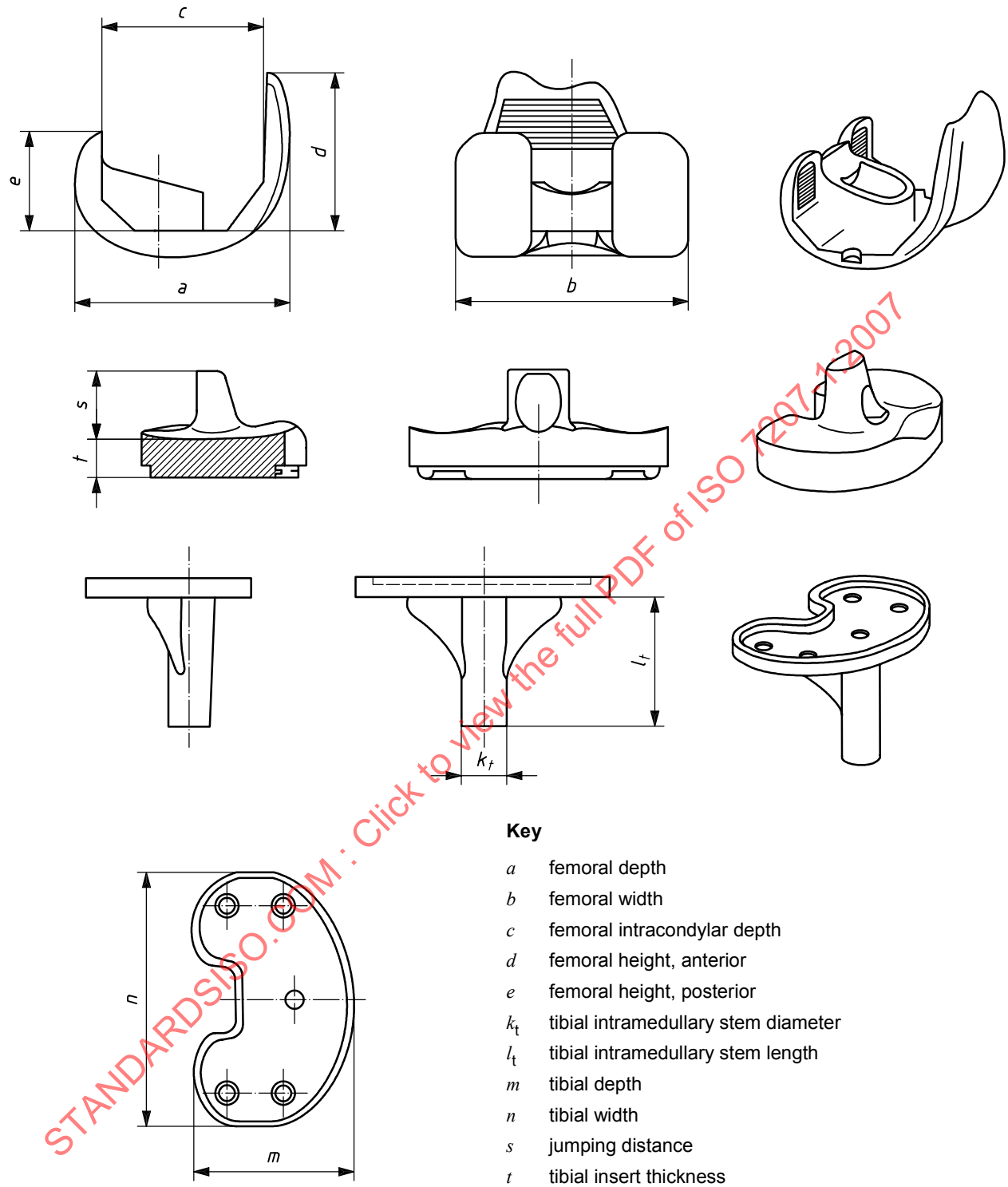



**Key**

*t* tibial insert thickness (mobile-bearing component thickness)

**b) Mobile-bearing component with tibial articulation in rotation, medial-lateral translation and anterior-posterior translation**

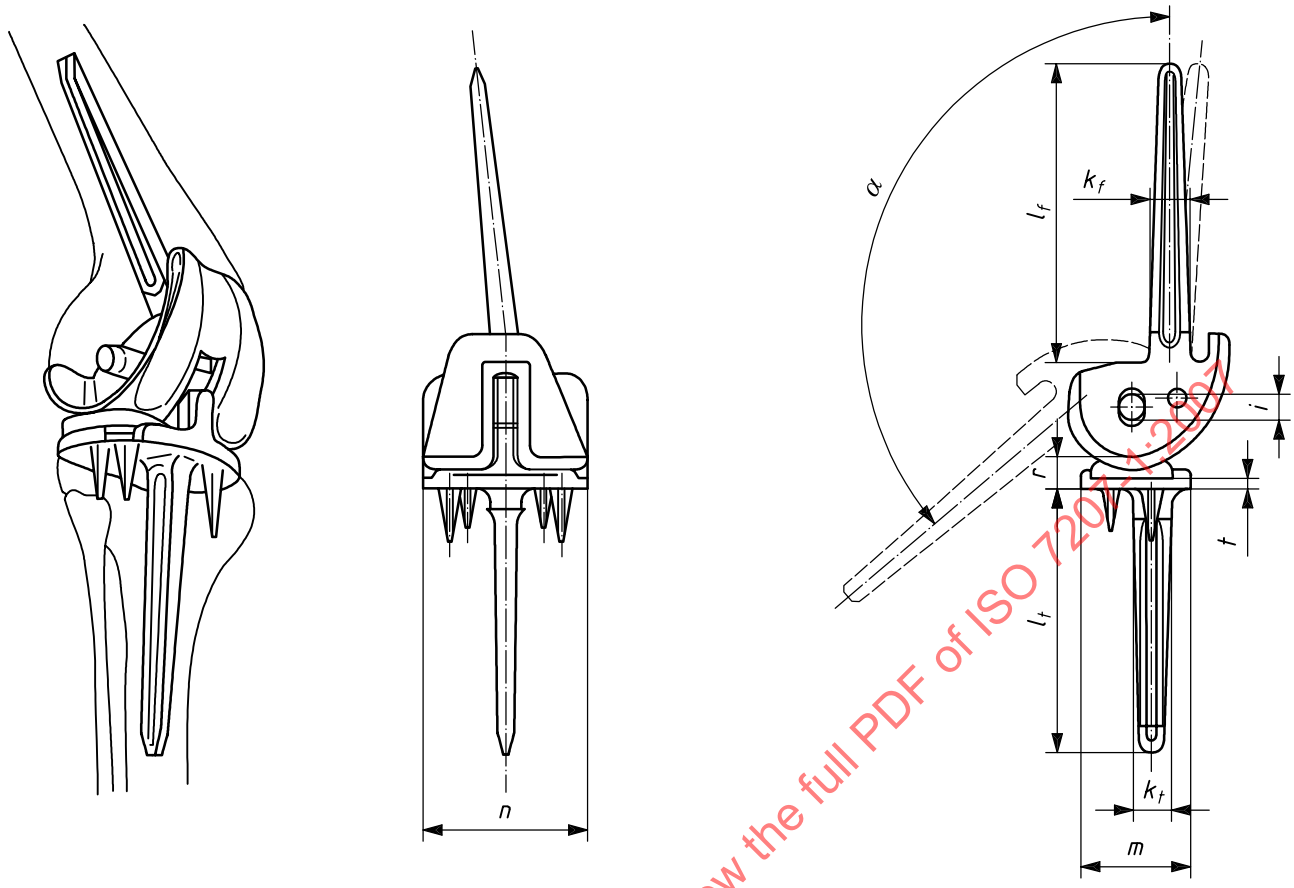
**Figure 4 — Unconstrained bi-compartmental knee joint prosthesis (mobile-bearing)**




**Key**

| | |
|---|---|
| $a$ | femoral depth |
| $b$ | femoral width |
| $c$ | femoral intracondylar depth |
| $d$ | femoral height, anterior |
| $e$ | femoral height, posterior |
| $k_t$ | tibial intramedullary stem diameter |
| $l_t$ | tibial intramedullary stem length |
| $m$ | tibial depth |
| $n$ | tibial width |
| $s$ | jumping distance |
| $t$ | tibial insert thickness |

**Figure 5 — Semi-constrained bi-compartmental knee joint prosthesis**
(fixed bearing, posterior stabilized)




**Key**

| | |
|---|---|
| $r$ | global gap |
| $i$ | diameter of the hinge |
| $t$ | tibial insert thickness |
| $k_t$ | tibial intramedullary stem diameter |
| $k_f$ | femoral intramedullary stem diameter |
| $l_t$ | tibial intramedullary stem length |
| $l_f$ | femoral intramedullary stem length |
| $m$ | tibial depth |
| $n$ | tibial width |
| $\alpha$ | range of flexion angle |

**Figure 6 — Constrained total knee joint prosthesis** (hinged concept)