INTERNATIONAL STANDARD

ISO 7206-1

Third edition
2008-04-01

Implants for surgery — Partial and total hip joint prostheses —

Part 1: Classification and designation of dimensions

Implants chirurgicaux — Prothèses partielles et totales de l'articulation de la hanche —

Partie 1: Classification et désignation des dimensions

Reference number
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Foreword

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ISO 7206-1 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 7206-1:1995), which has been technically revised.

ISO 7206 consists of the following parts, under the general title *Implants for surgery — Partial and total hip joint prostheses*:

— *Part 1: Classification and designation of dimensions*

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

— *Part 4: Determination of endurance properties and performance of stemmed femoral components*

— *Part 6: Determination of endurance properties of head and neck region of stemmed femoral components*

— *Part 8: Methods of determining endurance performance of stemmed femoral components*

— *Part 10: Determination of resistance to static load of modular femoral heads*

Introduction

Partial and total hip joint prostheses are designed to transmit load and allow movement under high stress conditions. Many different designs of hip joint prosthesis are used around the world and this first part of a series of test standards gives a comprehensive description of the most common hip joint prostheses by a detailed classification system. Dimensions of selected types of hip joint prosthesis will be the basis for all the test standards in this series.

Implants for surgery — Partial and total hip joint prostheses —

Part 1: Classification and designation of dimensions

1 Scope

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

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 21535, *Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21534 and ISO 21535, together with the following, apply.

3.1
bipolar femoral component
component(s) of a hip joint replacement consisting of a concave surface insert to articulate with a femoral head and a convex surface to articulate with the biological acetabulum

3.2
bone cement
acrylic resin cements used for fixation of implant components whether with radio-opaque or non-radio-opaque properties and supplied as units containing pre-measured amounts of sterile powder and of sterile liquid in forms suitable for mixing at the time of implantation

3.3
cemented hip joint replacement
component(s) of a hip joint replacement intended to be fixed to the bone by bone cement

3.4
cementless hip joint replacement
component(s) of a hip joint replacement intended to be fixed to the bone either by pressfit and/or bone ingrowth into the components' surface structure

3.5
modular femoral stem
femoral stem that is composed of two or more components (not counting a modular femoral head and neck) intended to be assembled to form a femoral stem before or during implantation of the stem

3.6
monobloc stem
femoral stem that is a single part including the head, with no modularity

3.7
modular head stem
stem designed to be used with a separate femoral articulating head that has a locking feature that engages with corresponding feature on the most proximal aspect of the stem

3.8
press fit fixation
cementless fixation of hip joint replacement components to the bone by elastic frictional connection due to pre-stress

3.9
in-/ongrowth fixation
cementless fixation of hip joint replacement components through bone in-/ongrowth into/on the components' surface structure like macro/micro-structures or porous coatings

3.10
primary hip joint component
implant used to replace one or both of the articulating surfaces of the hip joint in primary surgery designated as:

— surface replacement (components having no stem)

— short stem with CT $\leqslant$ 120 mm

— medium stem (120 mm $<$ CT $\leqslant$ 200 mm)

where CT is the distance from centre of head “C” to tip of stem “T” as designated in Figures 6 to 10

NOTE These implants can also be used for revision surgery.

3.11
reconstruction hip joint component
implant used to replace one or both of the articulating surfaces of the hip joint and adjacent bone structures in revision or tumour surgery

3.12
revision hip joint component
implant used to replace one or both of the articulating surfaces of an artificial hip joint in revision surgery

3.13
spherical design
acetabular component either of pressfit or screw ring fixation with a spherical outside contour of the cup

3.14
spherical flattened design
acetabular component either of pressfit or screw ring fixation with a spherical outside contour and a flattened pole of the cup

3.15
conical design
acetabular component either of pressfit or screw ring fixation with a conical outside contour

4 Classification

4.1 Description

Hip joint prostheses shall be classified as follows:

a) femoral component (consisting of one or more components);

b) acetabular component (consisting of one or more components);

c) a combination of a) and b).

Both femoral and acetabular components shall be sub-grouped according to the intended use as

— primary;

— revision;

— reconstruction.

NOTE A primary implant can be used for revision.

4.2 Coating

For easy handling of the classification system all parameters are coded. The code gives a clear description of the total hip joint replacement by using an alphanumerical system for femoral component, acetabular component and articulating surface, e.g. as shown in Figure 1.

Further classification parameters shall be “fixation” and “articulated surface” as given in the classification chart in Figure 2.

4.3 Advanced classification

For a more detailed classification the “Advanced Classification Chart of Total Hip Joint Replacement” (Figures 3 to 5) should be used.

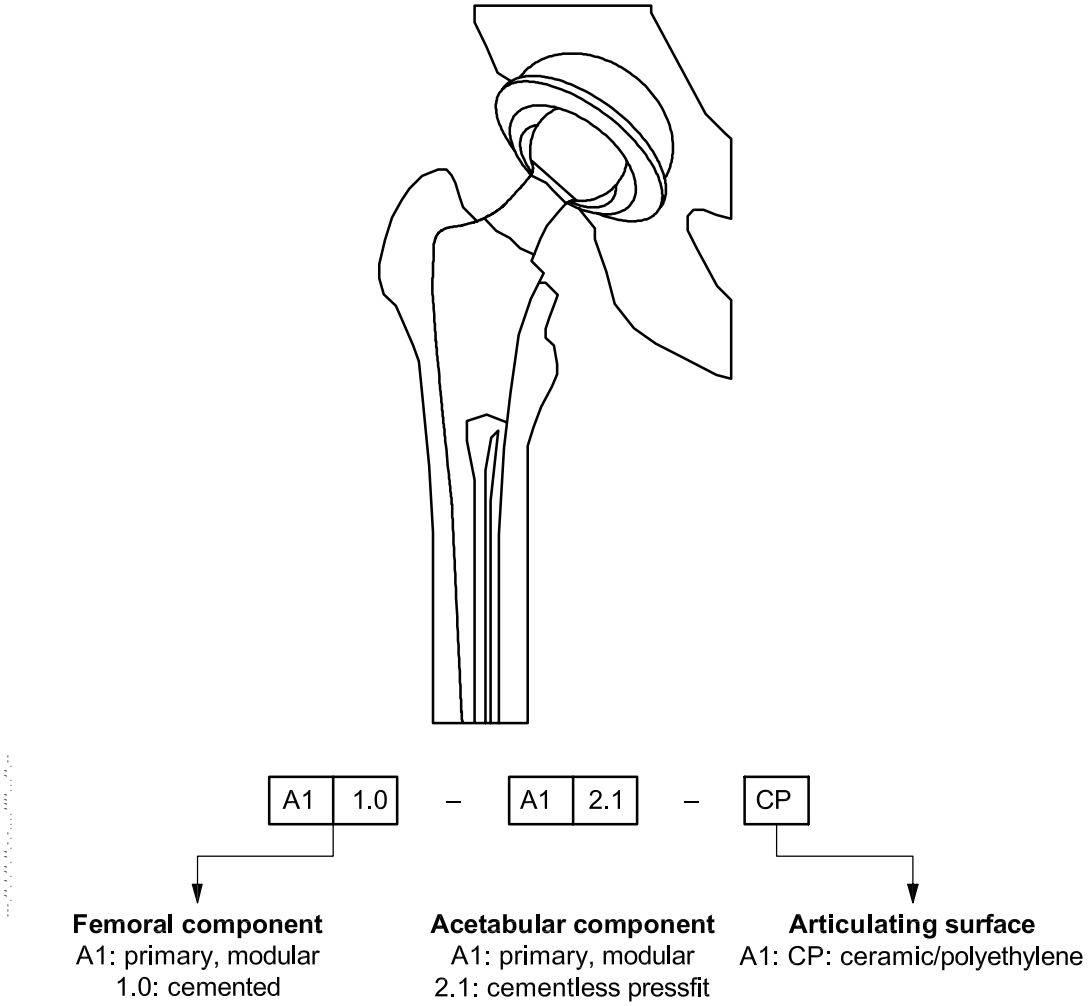


Figure 1 — Example of alphanumeric code

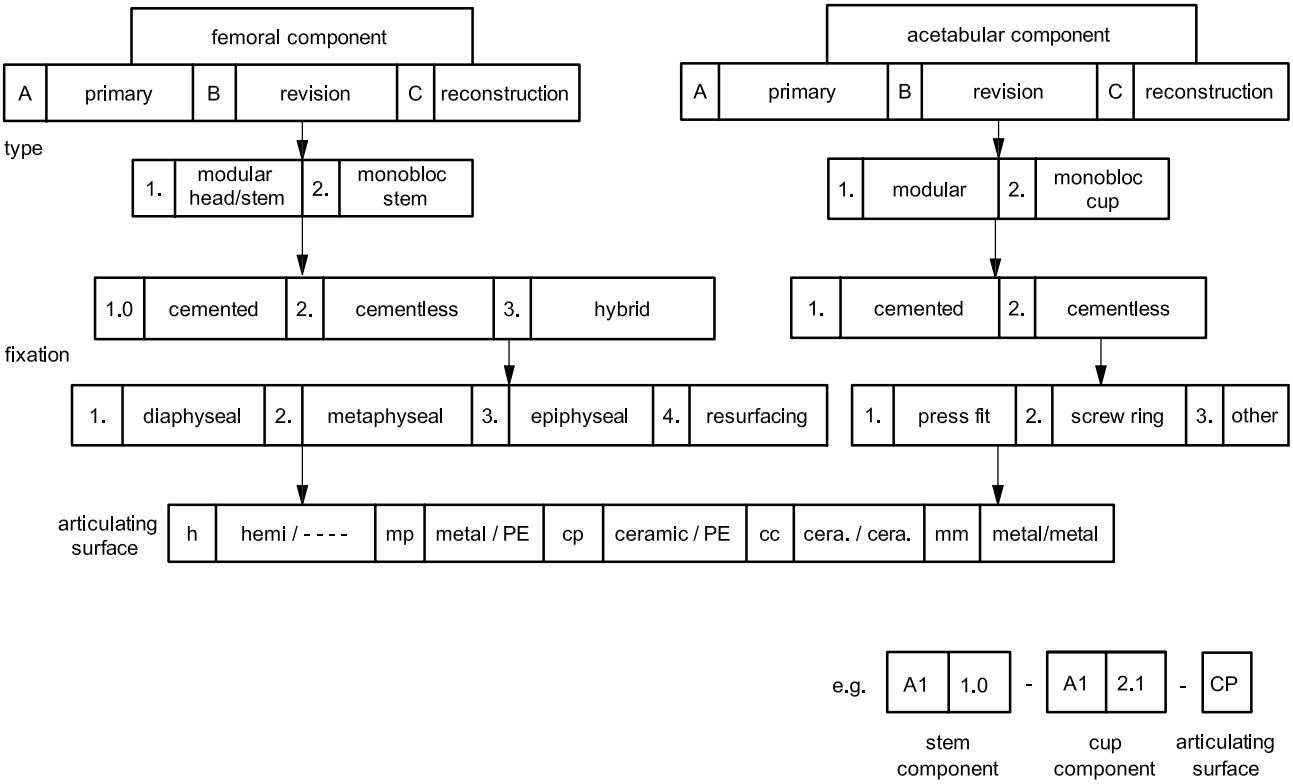


Figure 2 — Classification chart and code of total hip joint replacement

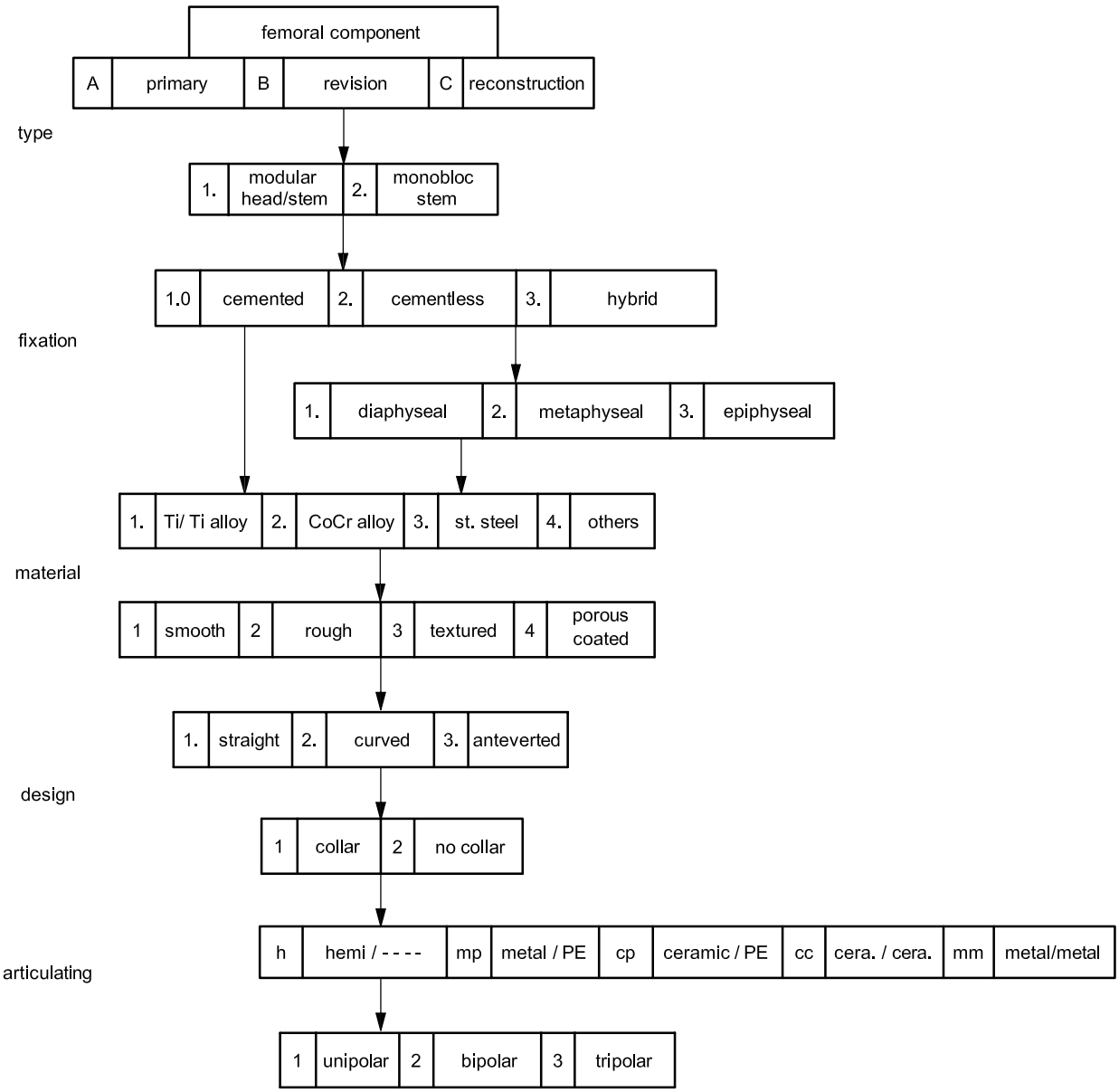


Figure 3 — Advanced classification chart and code of total hip joint replacement (femoral component)

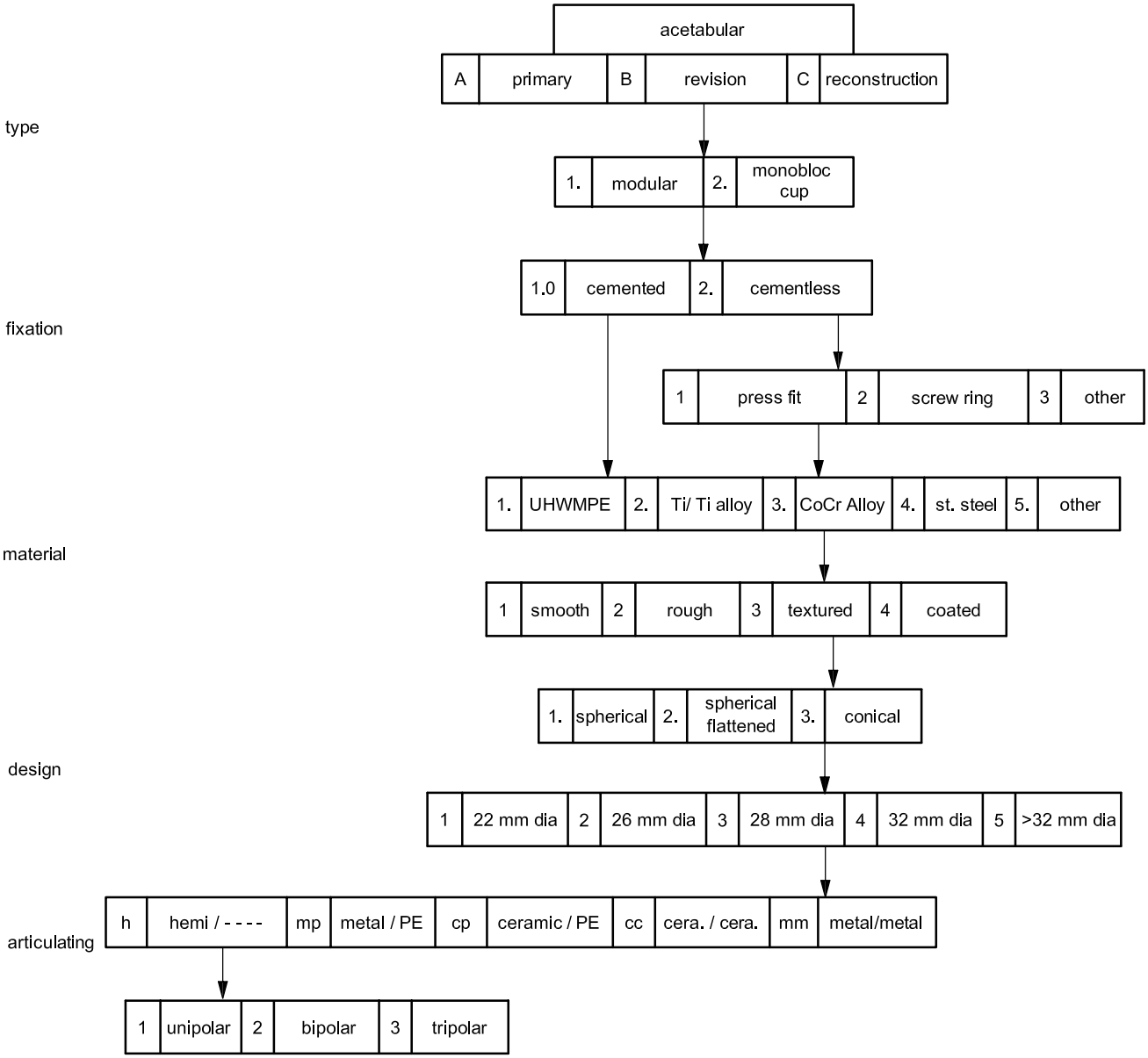


Figure 4 — Advanced classification chart and code of total hip joint replacement (acetabular component)

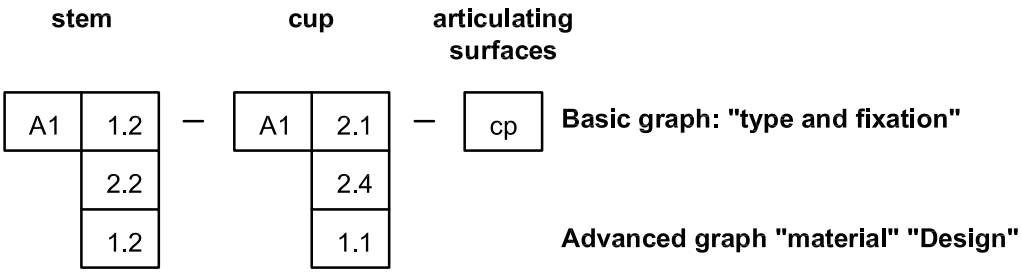


Figure 5 — Advanced classification chart and example of the code for a total hip joint replacement

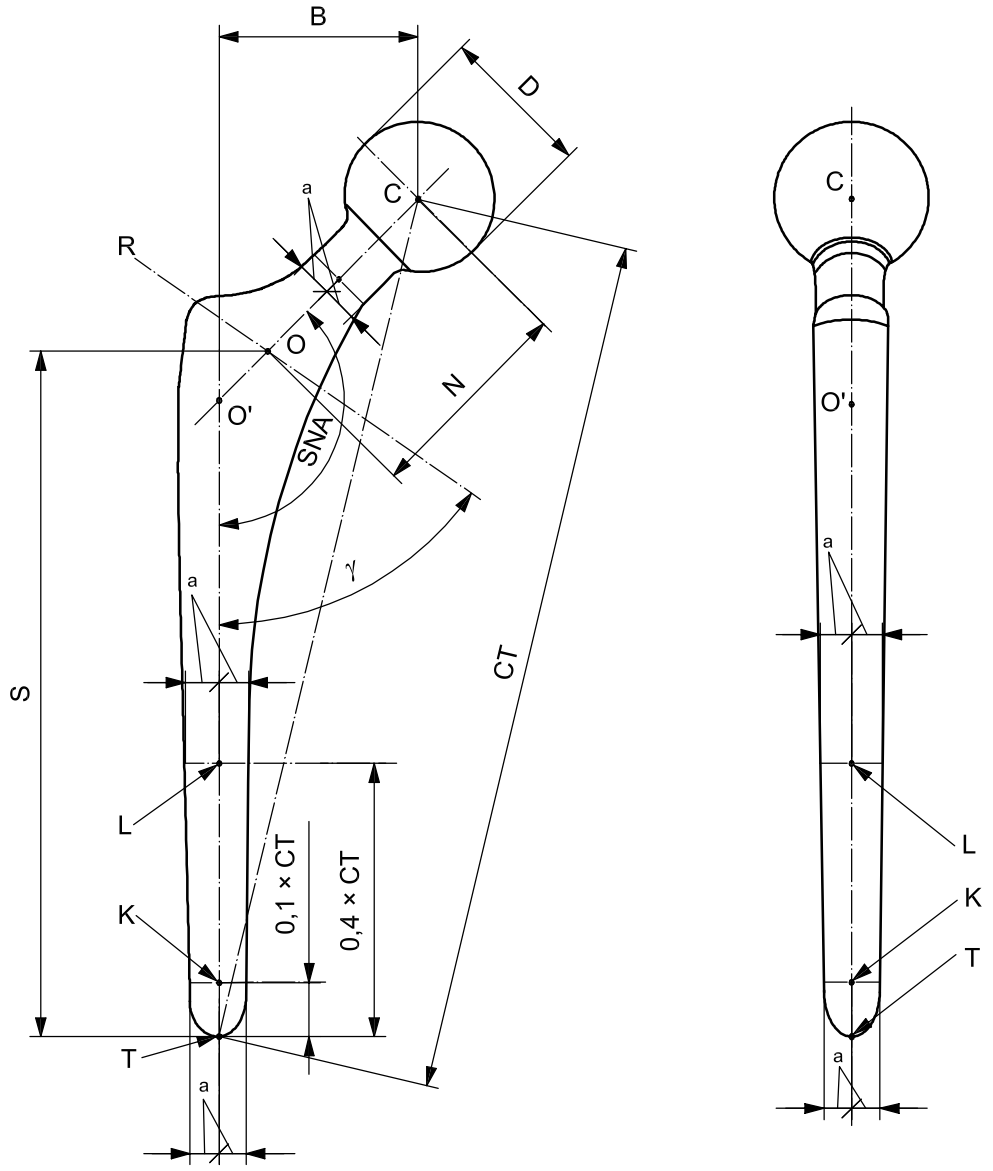
5 Designation of dimensions

5.1 Femoral components

Dimensions of femoral components shall be designated in accordance with Figures 6 to 12.

5.2 Acetabular components

Dimensions of acetabular components shall be designated in accordance with Figures 13 and 14.

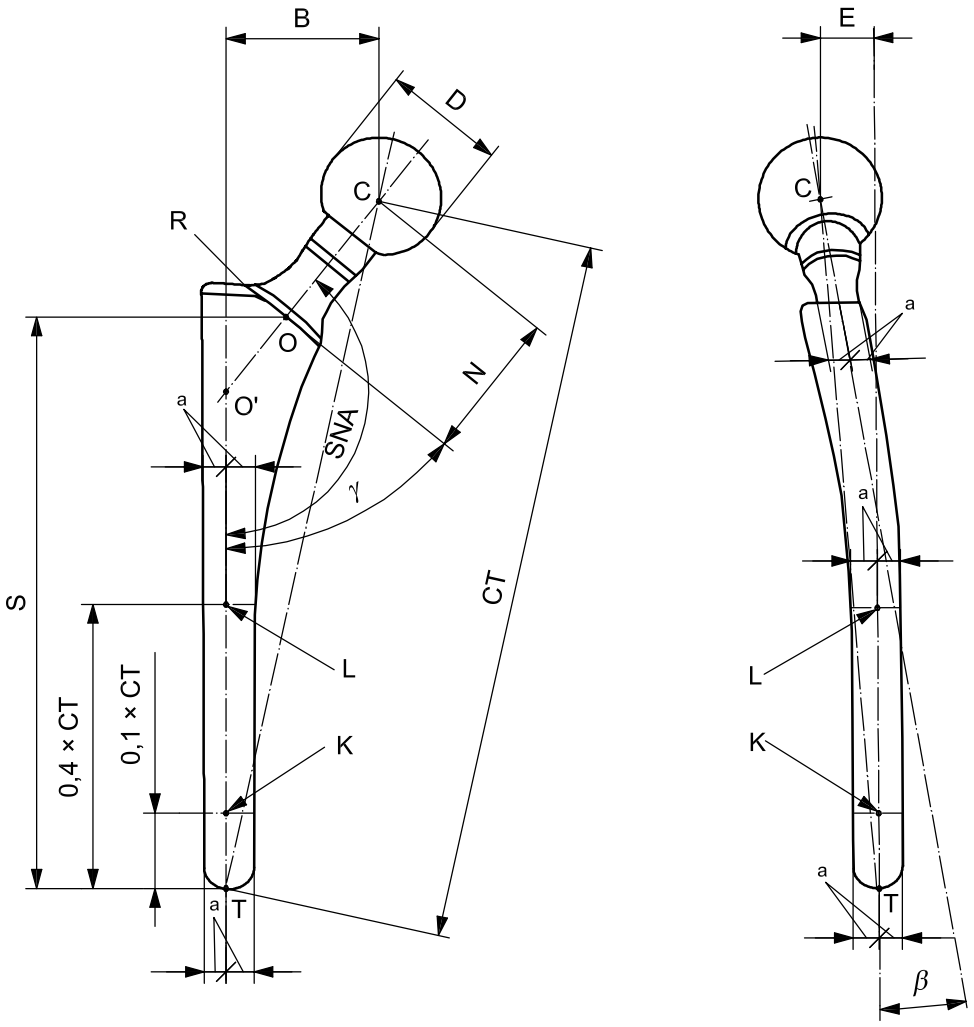


Key

B	head offset length	K, L	points at specific distances from T defining the stem axis	S	stem length
C	nominal centre of the head (medium neck length in case of modular heads)	O	intersection of neck axis and intended resection line	SNA	stem/neck angle
CO	neck axis	O'	intersection of neck axis and stem axis	T	tip of stem (most distal point)
CT	distance from centre of head to tip of stem	N	neck length	TKL	stem axis
D	diameter of head	R	intended resection line (shall be defined by the manufacturer)	γ	resection angle

[a] The two dimensions indicated are equal.

Figure 6 — Designation of dimensions of straight femoral components of hip joint prostheses with and without collar

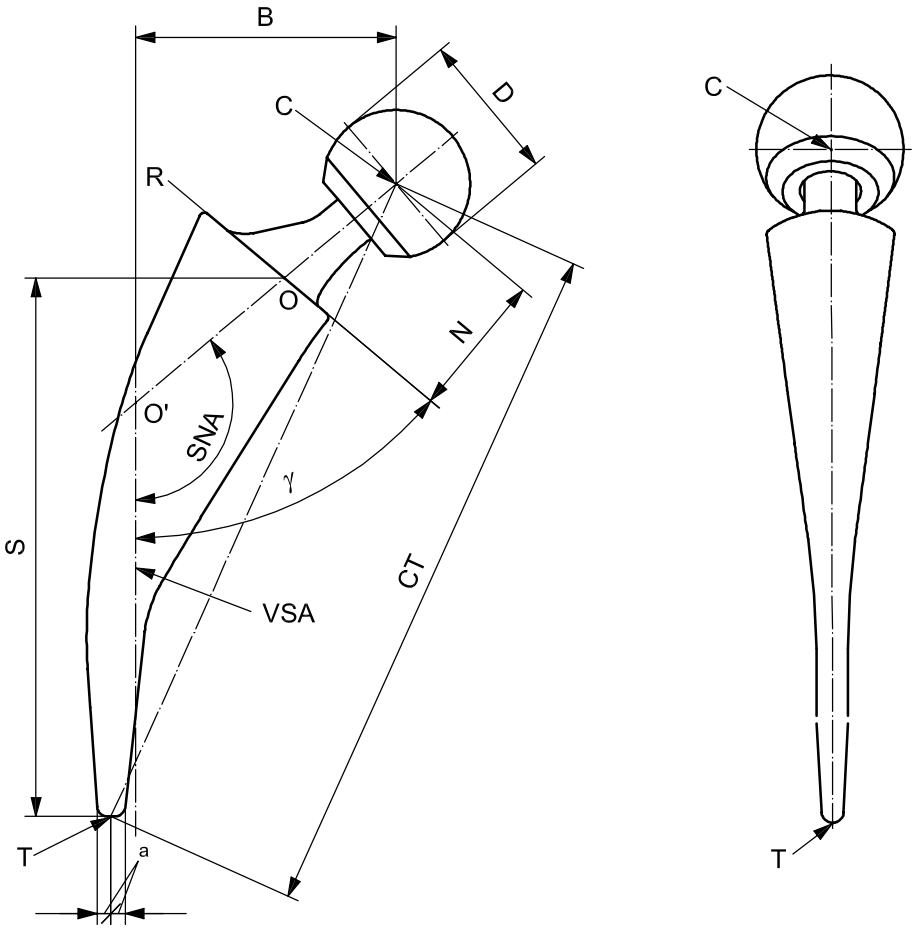


Key

B	head offset length	K, L	points at specific distances from T defining the stem axis	SNA	stem/neck angle
C	nominal centre of the head (medium neck length in case of modular heads)	N	neck length	T	tip of stem (most distal point)
CO	neck axis	O	intersection of neck axis and intended resection line (frontal)	TKL	stem axis
CT	distance from centre of head to tip of stem	O'	intersection of neck axis and stem axis (frontal)	β	anteversion angle
D	diameter of head	R	intended resection line (shall be defined by the manufacturer)	γ	resection angle
E	anteversion offset	S	stem length		

[a] The two dimensions indicated are equal.

Figure 7 — Designation of dimensions of curved femoral components of hip joint prostheses

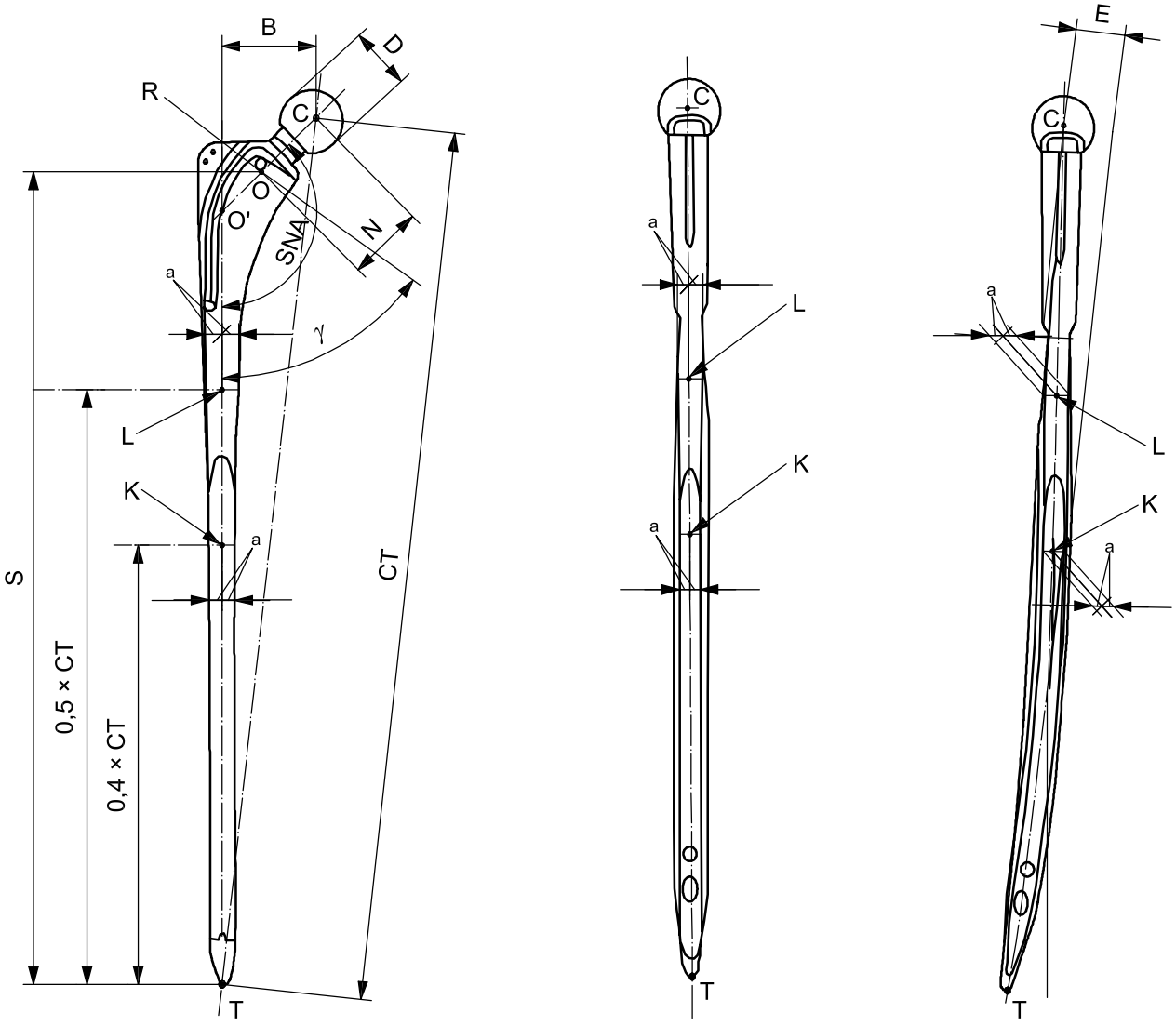


Key

B	head offset length	O′	intersection of neck axis and virtual stem axis (frontal)
C	nominal centre of the head (medium neck length in case of modular heads)	R	intended resection line (shall be defined by the manufacturer)
CO	neck axis	S	stem length
CT	distance from centre of head to tip of stem	SNA	stem/neck angle
D	diameter of head	T	tip of stem (most distal point)
N	neck length	VSA	virtual stem axis corresponding to the intended femoral bone axis
O	intersection of neck axis and intended resection line (frontal)	γ	resection angle

[a] The two dimensions indicated are equal.

Figure 8 — Designation of dimensions of short femoral components of hip joint protheses



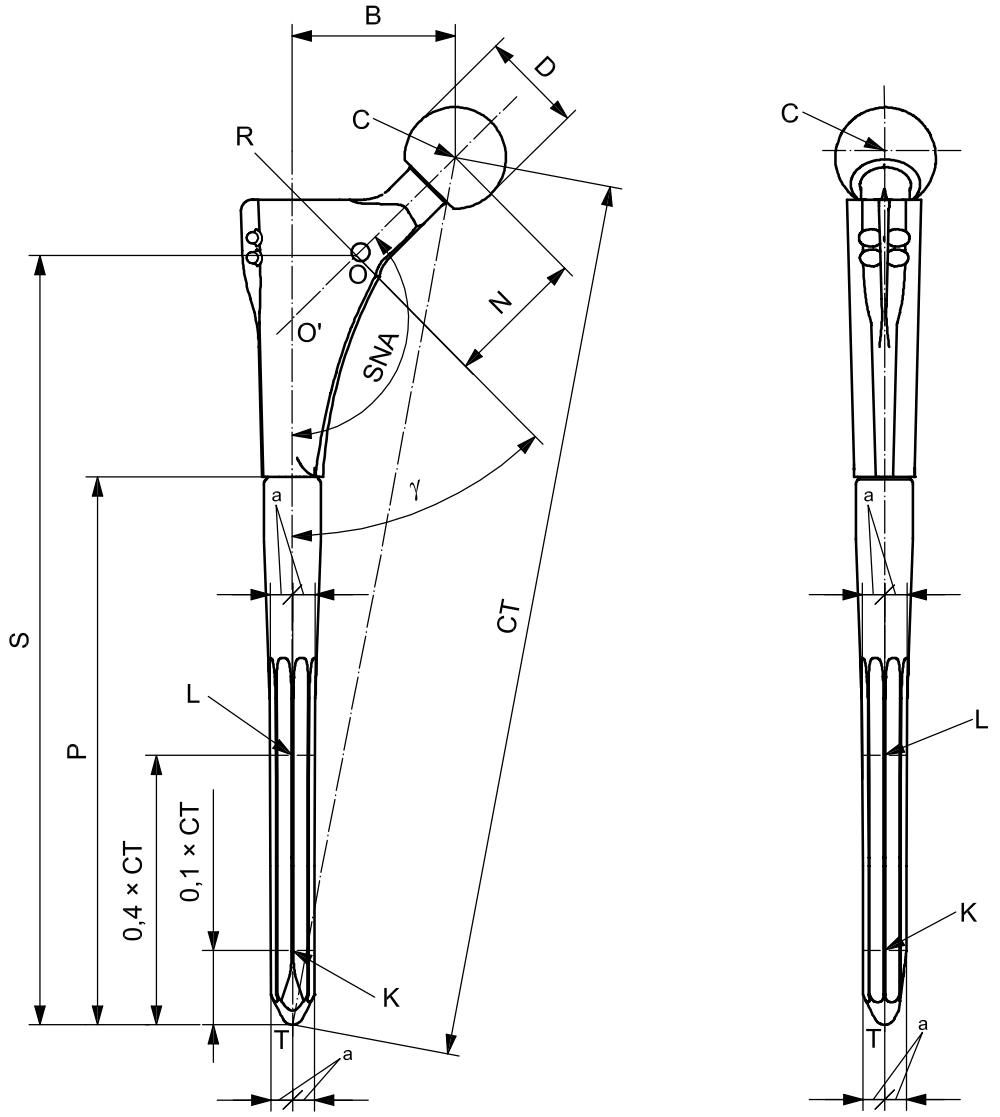
a) Straight stem **b) Curved stem**

Key

B	head offset length	K, L	points at specific distances from T defining the stem axis	S	stem length
C	nominal centre of the head (corresponding to medium neck length for implants with modular heads)	N	neck length	SNA	stem/neck angle
CT	distance from centre of head to tip of stem	O	intersection of neck axis and intended resection line (frontal)	T	tip of stem (most distal point)
D	diameter of head	O'	intersection of neck axis and stem axis (frontal)	TKL	stem axis
E	anteversion offset	R	intended resection line (shall be defined by the manufacturer)	γ	resection angle

[a] The two dimensions indicated are equal.

Figure 9 — Designation of dimensions of femoral components of hip joint prostheses for revisions (CT > 200 mm)

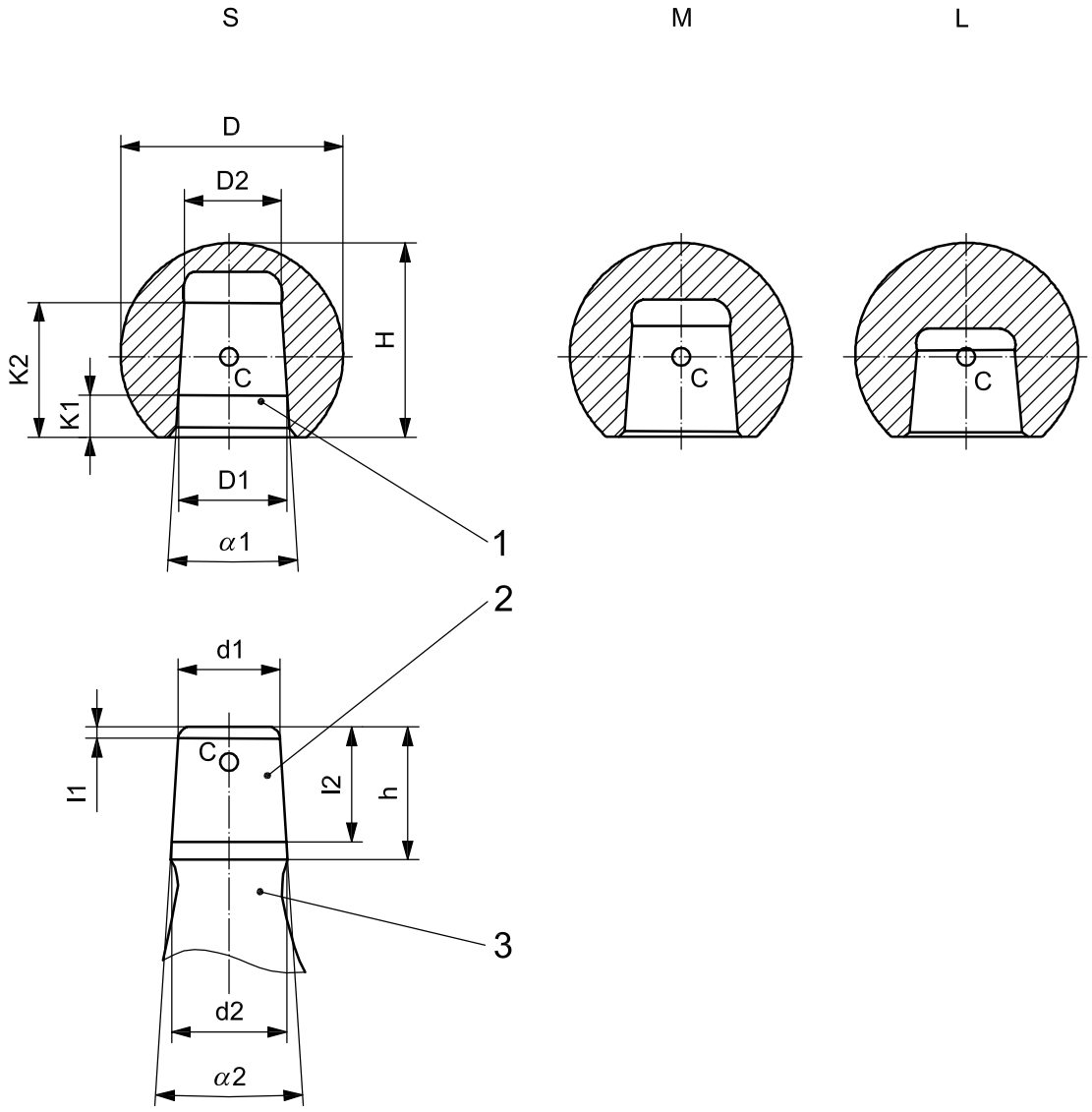


Key

B	head offset length	O´	intersection of neck axis and virtual stem axis (frontal)
C	nominal centre of the head (medium neck length in case of modular heads)	P	distance to surface of modular connection
CT	distance from centre of head to tip of stem	R	intended resection line (shall be defined by the manufacturer)
CO	neck axis	S	stem length
D	diameter of head	SNA	stem/neck angle
K, L	points at specific distances from T defining the stem axis	T	tip of stem (most distal point)
N	neck length	TKL	stem axis
O	intersection of neck axis and intended resection line (frontal)	γ	resection angle

[a] The two dimensions indicated are equal.

Figure 10 — Designation of dimensions of modular femoral components of hip joint protheses



Key

C	nominal centre of the head	h	full length of male cone	S	head with small neck length
D	diameter of head	K1	measurement distance 1, female cone	$\alpha 1$	female angle
D1	female cone diameter at K1	K2	measurement distance 2, female cone	$\alpha 2$	male angle
D2	female cone diameter at K2	L	head with large neck length		
d1	male cone diameter at n1 from end of implant	l1	measurement distance 1, male cone	1	female cone
d2	male cone diameter at n2 from end of implant	l2	measurement distance 2, male cone	2	male cone
H	head length	M	head with medium neck length	3	neck of implant

Figure 11 — Designation of dimensions of modular heads

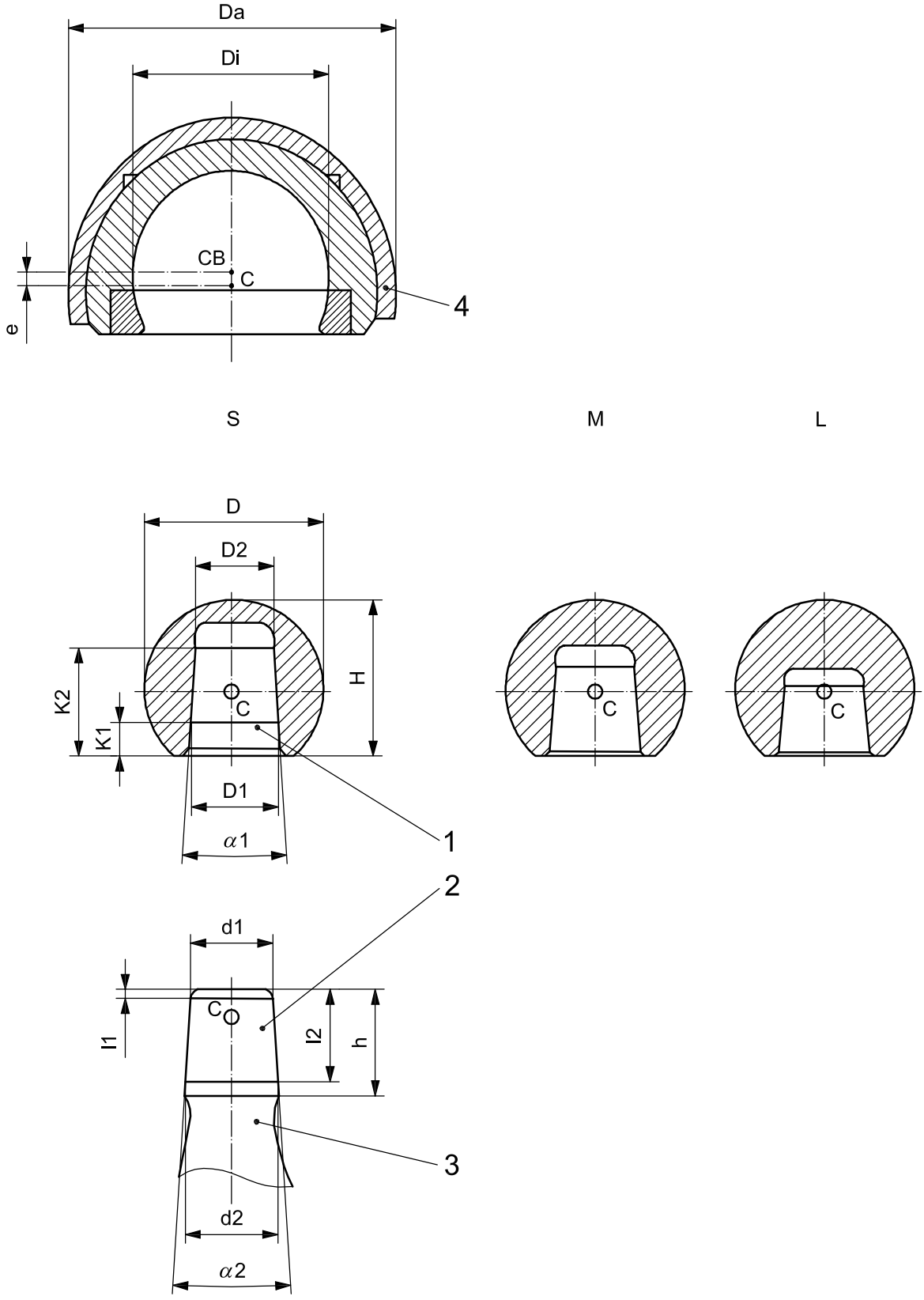
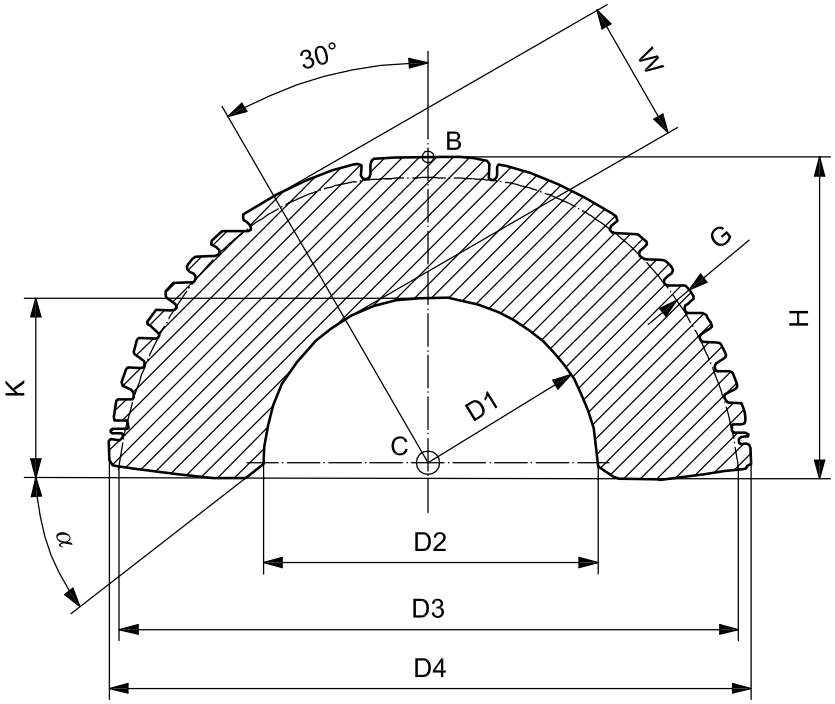


Figure 12 — Designation of dimensions of bipolar heads

Key

C	nominal centre of the head	e	eccentricity of bipolar head	S	head with small neck length
CB	nominal centre of the Bipolar head	H	head length	$\alpha 1$	female angle
D	diameter of head	h	full length of male cone	$\alpha 2$	male angle
D1	female cone diameter at K1	K1	measurement distance 1, female cone		
D2	female cone diameter at K2	K2	measurement distance 2, female cone	1	female cone
Da	outside diameter of bipolar head	L	head with large neck length	2	male cone
Di	inside diameter of bipolar head	l1	measurement distance 1, male cone	3	neck of implant
d1	male cone diameter at n1 from end of implant	l2	measurement distance 2, male cone	4	bipolar head
d2	male cone diameter at n2 from end of implant	M	head with medium neck length		

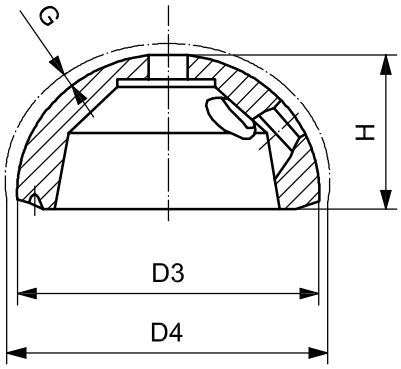
Figure 12 — Designation of dimensions of bipolar heads (*continued*)



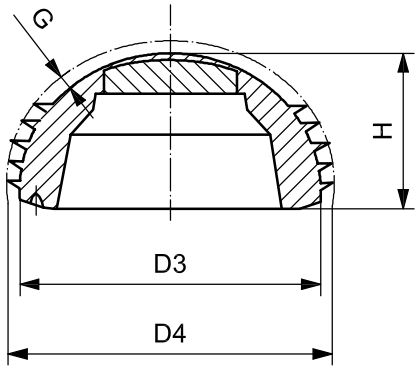
Key

B	top of the cup	D4	nominal outside diameter of the cup
BC	polar axis	G	retention system (macro-, micro structures)
C	nominal centre of the head	H	overall cup height
D1	diameter of spherical socket	K	inside depth
D2	retentive or non-retentive entry diameter	W	minimum wall thickness
D3	effective spherical external diameter	α	angle of entry chamfer

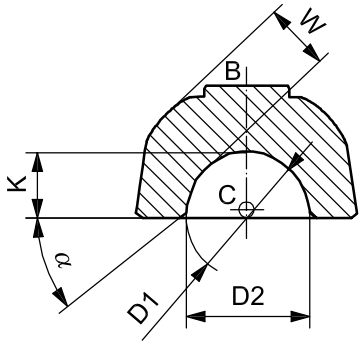
Figure 13 — Designation of dimensions of symmetrical cemented acetabular components of hip joint prostheses



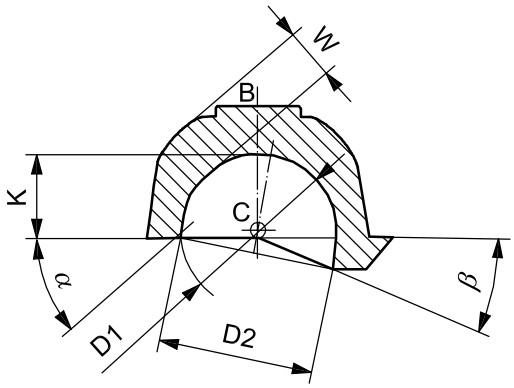
a) Metal backing — press fit cup



b) Metal backing — screw ring



c) Insert — primary



d) Insert — posterior wall insert

Key

B	top of the cup	G	retention system (macro-, micro-structures, coatings)
BC	polar axis	H	overall cup height
C	nominal centre of the head	K	inside depth
D1	diameter of spherical socket	W	wall thickness measured at 30°
D2	entry diameter	α	angle of entry chamfer
D3	effective spherical external diameter (the cup is not necessarily spherical shaped)	β	angle of posterior wall
D4	nominal outside diameter of the cup		

NOTE The reaming diameter should be specified by the manufacturer.

Figure 14 — Designation of dimensions of cementless acetabular components of hip joint prostheses

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