

PART OF THE
TECHNICAL DOCUMENTATION

PRODUCT DESCRIPTION

HIP HEADS

PRODUCT-GROUP:
PRIMARY AND REVISION ARTHROPLASTY

RISK-CLASS: III

LOCATION: HIP

REV.10, DATE: 04.12.2017

TABLE OF CONTENTS

LISTS..... 2
 IC-HEADS..... 3
 IC-BIPOLAR HEAD 9
 IC- UNIPOLAR HEAD 11
 DOCUMENT REVISION HISTORY 12

LISTS

LIST OF TABLES

TABLE 1 NECK LENGTHS OF IC-HEADS CoCrMo / TITANIUM 4
 TABLE 2 NECK LENGTHS OF IC-HEADS DELTA / FORTE..... 4
 TABLE 3 SPECIFICATIONS OF THE COLLARLESS IC-HEADS..... 5
 TABLE 4 SPECIFICATIONS OF THE COLLARED IC-HEADS 5
 TABLE 5 SPECIFICATIONS OF THE IC-HEADS BIOLOX® FORTE 6
 TABLE 6 SPECIFICATIONS OF THE IC-HEADS BIOLOX® DELTA..... 6
 TABLE 7 SPECIFICATIONS OF TAPER ADAPTER FOR IC-HEAD REVISION BIOLOX® DELTA..... 6
 TABLE 8 COATING SPECIFICATIONS 7
 TABLE 9 IC-HEADS SIZES AND DIMENSIONS..... 8
 TABLE 10 IC-BIPOLAR HEADS SIZES AND DIMENSIONS 10
 TABLE 11 IC-UNIPOLAR HEADS SIZES AND DIMENSIONS 11

LIST OF FIGURES

FIGURE 1 IC-HEAD CoCrMo 3
 FIGURE 2 IC-HEAD TITANIUM 3
 FIGURE 3 IC-HEAD BIOLOX® DELTA..... 3
 FIGURE 4 IC-HEAD BIOLOX® FORTE 3
 FIGURE 5 TAPER ADAPTER FOR IC-HEAD REVISION BIOLOX® DELTA 12/14 AND IC-HEAD REVISION
 BIOLOX® DELTA 3
 FIGURE 6 (EXAMPLE) SPECIFICATIONS FOR: 5
 FIGURE 8 FEMORAL HEAD TAPER ANGLE..... 7
 FIGURE 9 IC-BIPOLAR HEAD CoCrMo 9
 FIGURE 10 IC-UNIPOLAR HEAD TAPER 12/14 11

IC-HEADS

DESIGN DESCRIPTION



FIGURE 1 IC-HEAD
CoCrMo

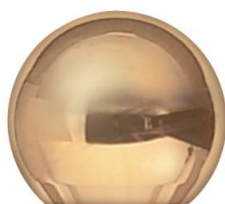


FIGURE 2 IC-HEAD
TITANIUM



FIGURE 4 IC-HEAD
BIOLOX® FORTE



FIGURE 3 IC-HEAD
BIOLOX® DELTA

The ic-heads are spherical modular femoral heads for the connection with the hip stems of the implantcast company. The heads are available in various sizes and neck lengths to match the individual patients' anatomy. The head sizes with the longest neck length provide a collar.

The ic-heads articulate with either with a monoblock acetabular cup, a liner of a modular acetabular cup, a bipolar head or a dual mobility head such as EcoFit® 2M.

The heads are available in various materials.



FIGURE 5 TAPER ADAPTER FOR IC-HEAD REVISION BIOLOX® DELTA 12/14 AND IC-HEAD REVISION BIOLOX® DELTA

Among the various ic-heads, there are also available ic-heads revision BioloX® delta in a range of sizes. It consists of a titanium alloy sleeve (taper adapter) and an ic-head BioloX® delta with a conical bore, which is matched to the taper adapter. The taper adapter is attached to the stem taper.

NECK LENGTHS

For ic-head CoCrMo and ic-head titanium:

Four neck lengths (short, medium, long and extra-long) are available in diameter 22mm to adjust neck length. Six neck lengths (S, M, L, XL, XXL and XXXL) are available in diameter 28, 32 and 36 mm to adjust neck length.

The short (S) neck lengths provide a neck length 3.5 mm / 4 mm shorter than the standard neutral medium (M) length (0 mm) while the long (L) neck length provides +3.5 mm / +4 mm and the extra-long (XL) provides +7.0 mm / +8 mm in neck length. The XXL neck lengths provide a neck length +10.5 mm / +12 mm and the XXXL provides +14 / +16 mm in neck length.

The 22 mm diameter heads have a neck base / collar in all neck length sizes as do all of the XL-length heads in all diameters.

TABLE 1 NECK LENGTHS OF IC-HEADS CoCrMo / TITANIUM

IC-HEADS CoCrMo / TITANIUM		
NECK LENGTH	OFFSET	
	OD 28 mm	OD 22 / 32 / 36 mm
S	-3.5 mm	-4 mm
M	0 mm	0 mm
L	+3.5 mm	+4 mm
XL	+7.0 mm	+8 mm
	OD 28 mm	OD 32 / 36 mm
XXL	+10,5 mm	+12,0 mm
XXXL	+ 14,0 mm	+16,0 mm

OD = OUTER DIAMETER

For ic-head BIOLOX® delta and forte:

TABLE 2 NECK LENGTHS OF IC-HEADS DELTA / FORTE

IC-HEADS BIOLOX® DELTA / FORTE		
NECK LENGTH	OFFSET	
	OD 28 mm	OD 22 / 32 / 36 / 40* / 44* mm
S	-3.5 mm	-4 mm
M	0 mm	0 mm
L	+3.5 mm	+4 mm
XL*	NOT AVAILABLE	+8 mm (+7 mm FOR BIOLOX® DELTA, 32mm)

OD = OUTER DIAMETER, * = AVAILABLE ONLY FOR DELTA

For taper adapter for ic-head revision BIOLOX® delta:

The ic-head revision BIOLOX® delta system consists of a BIOLOX® delta femoral head with 28 to 44 mm diameter and a metal sleeve (taper adapter) for one of the following dimensions:

S = - 3.0 mm

M = 0 mm

L = + 4.0 mm

XL = + 7.0 mm

COLLAR

The following tables show dimensions of the collar (if available), taper contact lengths and head space distances.

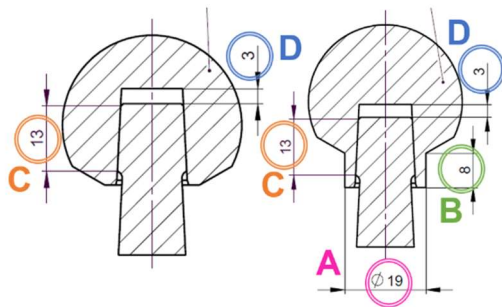


FIGURE 6 (EXAMPLE) SPECIFICATIONS FOR:
LEFT: COLLARLESS HEAD
RIGHT: COLLARED HEAD

A: COLLAR DIAMETER
B: COLLAR LENGTH
C: TAPER CONTACT LENGTH
D: HEAD SPACE DISTANCE

For ic-head CoCrMo and ic-head titanium:

Except for the ic-heads with \varnothing 22mm, all ic-heads with neck lengths S, M, L are collarless.
All ic-heads with neck lengths XL, XXL, XXXL and ic-heads \varnothing 22mm with neck lengths S, M, L have collars.

The following tables show dimensions of the collar (if available), taper contact lengths and head space distances for ic-heads CoCrMo and ic-heads titanium.

TABLE 3 SPECIFICATIONS OF THE COLLARLESS IC-HEADS

SIZE		COLLARLESS IC-HEADS	
OD [MM]	NECK LENGTH	TAPER CONTACT LENGTH [MM] (C)	HEAD SPACE DISTANCE [MM] (D)
28	S	13	1,6
28	M	13	1,6
28	L	9,5	1,6
32, 36	S	13	1,6
32, 36	M	13	3
32, 36	L	10,8	3

OD = OUTER DIAMETER

TABLE 4 SPECIFICATIONS OF THE COLLARED IC-HEADS

SIZE		COLLARED IC-HEADS			
OD [MM]	NECK LENGTH	COLLAR DIAMETER [MM] (A)	COLLAR LENGTH [MM] (B)	TAPER CONTACT LENGTH [MM] (C)	HEAD SPACE DISTANCE [MM] (D)
22	S	18	7.8	13	1,4
22	M	18	11.8	13	1,4
22	L	18	15.8	13	1,4
28	XL	19	7	13	1,6
28	XXL	19	10.5	13	1,6
28	XXXL	19	14	13	1,6
32,36	XL	19	8	13	3
32,36	XXL	19	12	13	3
32,36	XXXL	19	16	13	3

OD = OUTER DIAMETER

For ic-head BIOLOX® forte, ic-head BIOLOX® delta and ic-head revision BIOLOX® delta:

ic-heads BIOLOX® forte, ic-heads BIOLOX® delta and ic-heads revision BIOLOX® delta are collarless.

The following tables show the taper contact lengths and head space distances for ic-heads BIOLOX® products.

TABLE 5 SPECIFICATIONS OF THE IC-HEADS BIOLOX® FORTE

IC-HEADS BIOLOX® FORTE (COLLARLESS)			
SIZE		TAPER CONTACT LENGTH [MM]	HEAD SPACE DISTANCE [MM]
OD [MM]	NECK LENGTH		
28	S	11.8	2.2
28	M	12.6	3.9
28	L	10	4.5
32	S	11.8	2.3
32	M	13	3.9
32	L	10.1	4.5
36	S	13	3.5
36	M	13	6.5
36	L	10.2	6.5

TABLE 6 SPECIFICATIONS OF THE IC-HEADS BIOLOX® DELTA

IC-HEADS BIOLOX® DELTA (COLLARLESS)			
SIZE		TAPER CONTACT LENGTH [MM]	HEAD SPACE DISTANCE [MM]
OD [MM]	NECK LENGTH		
28	S	11.8	2.2
28	M	12.3	3.9
28	L	9.8	3.9
32	S	11.8	2.3
32	M	13	3.9
32	L	9.8	3.9
32	XL	8.3	8.3
36	S	13	3.5
36	M	13	6.3
36	L	10.2	6.3
36	XL	8.2	8.7
40, 44	S	12.8	5.3
40, 44	M	11.7	7.4
40, 44	L	8.9	7.4
40, 44	XL	8.1	8.3

TABLE 7 SPECIFICATIONS OF TAPER ADAPTER FOR IC-HEAD REVISION BIOLOX® DELTA

TAPER ADAPTER FOR IC-HEADS REVISION BIOLOX® DELTA (COLLARLESS)			
SIZE		TAPER CONTACT LENGTH [MM]	HEAD SPACE DISTANCE [MM]
OD [MM]	NECK LENGTH		
-	S	12.5	0.8
-	M	11.7	1.2
-	L	8.6	3.7
-	XL	7.1	6.7

SURFACE FINISH, SPHERICITY AND COATING

All ic-heads have a highly polished surface ($R_a \leq 0.05 \mu\text{m}$) and a roundness (sphericity) of 0.01 or 0.02 μm .

For ic-head CoCrMo and ic-head titanium:

The ic-heads titanium have an additional TiN coating. The specifications of this coating are given below.

TABLE 8 COATING SPECIFICATIONS

SPECIFICATIONS OF TIN-COATING	
CHARACTERISTICS	VALUE
COATING THICKNESS	5.5 ± 1.5 µm
POROSITY	/
AVERAGE ROUGHNESS RA	< 0.05 µm
AVERAGE ROUGHNESS RT	/
TENSILE STRENGTH	≥ 22 MPa
SHEAR STRENGTH	/

For ic-head BIOLOX® forte, ic-head BIOLOX® delta and ic-head revision BIOLOX® delta:

The taper adapter for ic-head revision Biolox® delta is uncoated. The inner surface of the taper adapter has roughness Rz6.3 and the outer surface has between Rz6 to Rz20. The roundness of the taper adapter is 0.08 µm.

MORSE STYLE 12/ 14 TAPER

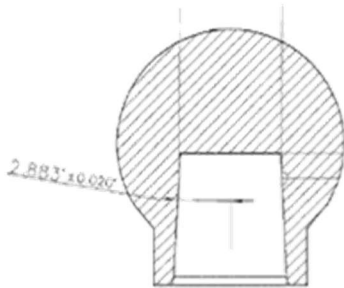


FIGURE 7 FEMORAL HEAD TAPER ANGLE

The femoral heads have a female 12/14 taper to mate with the male 12/14 taper of all implantcast hip stems. The female taper surface has a roughness of $Ra \leq 0.8 \mu\text{m}$. The taper angle is $2.883^\circ \pm 0.020^\circ$ measured from one end of the taper to the centreline.

The cone angle of the taper adapter for ic-head revision Biolox® delta is $5,767^\circ \pm 0,042^\circ$ ($5^\circ 46'0'' \pm 0^\circ 2'30''$) measured from one end to the other end of the taper.

MATERIALS

The ic-heads CoCrMo are manufactured from wrought Cobalt-Chrome-Molybdenum alloy conforming to ISO 5832-12 while the ic-head Titanium are made of TiAl₆V₄ alloy acc. to ISO 5832-3.

The ic-heads Biolox® forte are made of Aluminum Oxide meeting the requirements of ISO 6474-1 and the ic-heads Biolox® delta are manufactured from a mixed ceramic of high-purity alumina matrix with zirconia reinforcement acc. to ISO 6474-2.

The taper adapter for the ic-head revision Biolox® delta is wrought TiAl₆V₄ alloy complying with ISO 5832-3 and ASTM F136.

SIZES AND DIMENSIONS

The ic-heads are available in 22 mm, 28 mm, 32 mm, and 36 mm outer diameter sizes and have a highly polished surface to articulate with the corresponding 22 mm, 28 mm, 32 mm, or 36 mm inside diameter sizes of the PE and ceramic liners of the modular acetabular cups, the monoblock all polyethylene acetabular cups, the bipolar heads or dual mobility heads.

The ic-heads BioloX® delta and the ic-heads revision BioloX® delta are also available in 40 mm and 44 mm outer diameter sizes in addition.

The sizes of the respective head are given in the table below.

TABLE 9 IC-HEADS SIZES AND DIMENSIONS

IC-HEAD	OUTER DIAMETER	NECK LENGTH
ic-head CoCrMo	22 mm	S, M, L, XL
	28 mm, 32 mm, 36 mm	S, M, L, XL, XXL, XXXL
ic-head titanium	28 mm, 32 mm, 36 mm	S, M, L, XL, XXL, XXXL
ic-head BioloX® forte	28 mm, 32 mm, 36 mm	S, M, L
ic-head BioloX® delta	28 mm	S, M, L
	32 mm, 36 mm, 40 mm, 44 mm	S, M, L, XL
ic-head revision BioloX® delta (with its corresponding taper adapter)	28 mm, 32 mm, 36 mm, 40 mm, 44 mm	S, M, L, XL

IC-BIPOLAR HEAD

DESIGN DESCRIPTION



FIGURE 8 IC-BIPOLAR HEAD
CoCrMo

The ic-bipolar heads serve as a hemiarthroplasty that articulates directly with the natural (non-replaced) acetabulum on the outer side and with a femoral head on the inner side. Bipolar femoral heads are used in cases where the femoral head requires replacement but the acetabulum does not.

The ic-bipolar head consists of three components: the metal outer shell, the inner shell made of UHMWPE and the retaining ring. The latter is inserted into a slot of the inner shell to prevent luxation of the ball from the shell. The inner shell is attached to the outer shell by press fit.

SURFACE FINISH AND SPHERICITY

The bipolar heads have a polished surface finish of Ra of 0.05 μm and a roundness (sphericity) of 0.01 μm .

MATERIALS

The outer shell of the bipolar heads are manufactured from wrought Cobalt-Chrome-Molybdenum alloy conforming to ISO 5832-4 while the inner shell (inlay) and the retaining ring are made of UHMWPE according to ISO 5834-2.

SIZES AND DIMENSIONS

The bipolar heads are available in two inner diameters (22mm, 28 mm) matching the outer diameters of the ic-heads and 24 outer diameter sizes. The sizes of the respective head are given in the table below.

TABLE 10 IC-BIPOLAR HEADS SIZES AND DIMENSIONS

INNER DIAMETER	OUTER DIAMETER
22 mm	38 mm
	39 mm
	40 mm
	41 mm
	42 mm
28 mm	43 mm
	44 mm
	45 mm
	46 mm
	47 mm
	48 mm
	49 mm
	50 mm
	51 mm
	52 mm
	53 mm
	54 mm
	55 mm
	56 mm
	57 mm
	58 mm
	59 mm
60 mm	
62 mm	

IC- UNIPOLAR HEAD

DESIGN DESCRIPTION



FIGURE 9 IC-UNIPOLAR HEAD
TAPER 12/14

Contrary to the ic- bipolar head the design of the ic- unipolar head doesn't provide dual mobility. Unipolar heads have a fixed head which is available in various head diameters to accommodate for the acetabulum size of the patient. The ic-Unipolar head is combined with an implantcast hip stem and articulates with the natural acetabulum.

SURFACE FINISH AND SPHERICITY

The ic- unipolar heads have a polished surface finish of Ra of 0.05 μm and a roundness (sphericity) of 0.01 μm .

MATERIALS

The ic-Unipolar head is made of a wrought high nitrogen stainless steel according to ISO 5832-9.

SIZES AND DIMENSIONS

The ic- unipolar heads are given in 13 sizes:

TABLE 11 IC-UNIPOLAR HEADS SIZES AND DIMENSIONS

OUTER DIAMETER												
40mm	42mm	44mm	46mm	47mm	48mm	49mm	50mm	51mm	52mm	54mm	56mm	58mm

DOCUMENT REVISION HISTORY

DATE	REVISION	CHANGES	AUTHOR	COMMENTS
22.01.2009	1	----	J. Höppner	in German
18.08.2010	2	----	A. Kerber	in German
03.09.2012	3	- Table presentation	A. Kerber	in German + in English
27.02.2014	4	- Table presentation: ic-head titanium only	A. Kerber	in German
05.05.2014	5	- Design, layout - German->English	J. Höppner	----
21.07.2015	6	----	J. Höppner	in English
11.02.2016	7	----	I. Fateev	In English
20.09.2016	8	- Added neck length XXL, XXXL for ic-heads	I. Fateev	in English
12.06.2017	9	- Changes in "neck length": added collar sizes in section "ic-heads" - Added: - Table of contents - Revision History	S. Schlüter	in English
04.12.2017	10	- Added "ic-head revision BIOLOX® delta". - Changes in the section "collar" of "ic-heads" - The sections "surface finish and sphericity" and "coatings / surfaces" are combined to a section "surface finish, sphericity and coating". - Changes in layout	S. Schlüter	In English ÄA18-028