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**C € 0482**

**Primaro Pfanne**

Deutsch 3

**Primaro Cup**

English 16

**Cotyle Primaro**

Français 28

**Cotile Primaro**

Italiano 41

**Cótilo Primaro**

Español 54

**Primaro Kom**

Nederlands 66

**Caixa Primaro**

Português 78

**Κυπέλιο Primaro**

Ελληνικά 91

**Panewka Primaro**

Polski 105

**Jamka Primaro**

Česky 120

**Primaro Vápa**

Magyar 133

**Acetabul Primaro**

Română 146

**Primaro ацетабуларна чашка**

Български 160

**Primaro kalça kemiği**

Türkçe 175

**Чашка-западина Primaro**

Українська 188

**Gūžduobė „Primaro“**

Lietuvių k. 204

**Вертлужная впадина Primaro**

Русский 217

**Primaro 髌臼**

中文 234



## IMPLANT

### Primaro Cup

Before using the product, the user is under obligation to carefully study the following recommendations and information along with the information specific to the product.

The party introducing this product into circulation accepts no liability for direct or consequential damage or injury resulting from careless use or handling, particularly noncompliance with the following user instructions or improper care or maintenance. These implants may be used only by physicians with appropriate experience and practice in hip arthroplasty. Familiarity with the surgical technique recommended for this system and its diligent application are indispensable in order to achieve the best possible result.

#### 1. Product description and implant materials

The Primaro Cup is an acetabular cup endoprosthesis for cementless fixation in the acetabulum. The Primaro Cup consists of an outer shell made of titanium alloy Ti6Al4V (ISO 5832-3) with TPS coating (according to ASTM F1580), an optional Bonit® coating, an inlay made of highly cross-linked PE (XL-PE 75) or UHMWPE (ISO 5834-2) and screw lids made of Ti6Al4V (ISO 5832-3). If necessary, self-tapping flat-head screws made of titanium alloy Ti6Al4V (ISO 5832-3) with a cancellous bone screw thread Ø6.5 mm are available in varying lengths from 15 mm to 60 mm for an improved fixation of the outer shell in the acetabulum. The outer shell comes in outside diameters of 44 mm to 68 mm. The internal contour of the outer shell is designed to facilitate the use with every cup size of the PE inlays made of UHMWPE according to ISO 5834-2 or XL-PE 75, which are specially designed for this system. The PE inlays are available in standard and dysplasia variants for femoral head diameters measuring 28 mm, 32 mm and 36 mm. Ceramic inlays are also available for femoral head diameters of 28 mm, 32 mm and 36 mm.

Product, packaging contents and materials used are specified on the product label. The implant must be implanted using a suitable surgical technique familiar to the surgeon. In this regard, attention must be given to the explanations concerning the particular surgical technique.

#### 1.1 Implant overview

Name	Material	Reference number
<b>Primaro Cup</b>		
Primaro Cup size 44 (XX/37G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1190
Primaro Cup size 46 (XX/39G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1191
Primaro Cup size 48 (XX/39G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1192
Primaro Cup size 50 (XX/39G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1193
Primaro Cup size 52 (XX/44G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1194
Primaro Cup size 54 (XX/44G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1195
Primaro Cup size 56 (XX/48G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1196

<b>Name</b>	<b>Material</b>	<b>Reference number</b>
Primaro Cup size 58 (XX/48G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1197
Primaro Cup size 60 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1198
Primaro Cup size 62 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1199
Primaro Cup size 64 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1200
Primaro Cup size 66 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1201
Primaro Cup size 68 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1202
Primaro Cup size 44 (XX/37G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1203
Primaro Cup size 46 (XX/39G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1204
Primaro Cup size 48 (XX/39G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1205
Primaro Cup size 50 (XX/39G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1206
Primaro Cup size 52 (XX/44G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1207
Primaro Cup size 54 (XX/44G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1208
Primaro Cup size 56 (XX/48G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1209
Primaro Cup size 58 (XX/48G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1210
Primaro Cup size 60 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1211
Primaro Cup size 62 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1212
Primaro Cup size 64 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1213
Primaro Cup size 66 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1214
Primaro Cup size 68 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1215
<b>Primaro Cup with screw fixation</b>		
Primaro SF Cup size 44 (XX/37G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1216
Primaro SF Cup size 46 (XX/39G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1217
Primaro SF Cup size 48 (XX/39G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1218
Primaro SF Cup size 50 (XX/39G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1219
Primaro SF Cup size 52 (XX/44G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1220
Primaro SF Cup size 54 (XX/44G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1221
Primaro SF Cup size 56 (XX/48G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1222
Primaro SF Cup size 58 (XX/48G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1223
Primaro SF Cup size 60 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1224
Primaro SF Cup size 62 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1225
Primaro SF Cup size 64 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1226
Primaro SF Cup size 66 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1227
Primaro SF Cup size 68 (XX/52G) coating: TPS	ISO 5832-3 Ti6Al4V	367-1228
Primaro SF Cup size 44 (XX/37G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1229
Primaro SF Cup size 46 (XX/39G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1230
Primaro SF Cup size 48 (XX/39G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1231
Primaro SF Cup size 50 (XX/39G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1232
Primaro SF Cup size 52 (XX/44G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1233

<b>Name</b>	<b>Material</b>	<b>Reference number</b>
Primaro SF Cup size 54 (XX/44G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1234
Primaro SF Cup size 56 (XX/48G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1235
Primaro SF Cup size 58 (XX/48G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1236
Primaro SF Cup size 60 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1237
Primaro SF Cup size 62 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1238
Primaro SF Cup size 64 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1239
Primaro SF Cup size 66 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1240
Primaro SF Cup size 68 (XX/52G) coating: TPS+Bonit®	ISO 5832-3 Ti6Al4V	367-1241
<b>Primaro PE Inlay</b>		
PE Inlay Primaro Cup, size 44 KD28 STD	ISO 5834-2 UHMWPE	367-1252
PE Inlay Primaro Cup, size 46-50 KD28 STD	ISO 5834-2 UHMWPE	367-1253
PE Inlay Primaro Cup, size 52-54 KD28 STD	ISO 5834-2 UHMWPE	367-1254
PE Inlay Primaro Cup, size 56-58 KD28 STD	ISO 5834-2 UHMWPE	367-1255
PE Inlay Primaro Cup, size 60-68 KD28 STD	ISO 5834-2 UHMWPE	367-1256
PE Inlay Primaro Cup, size 46-50 KD32 STD	ISO 5834-2 UHMWPE	367-1257
PE Inlay Primaro Cup, size 52-54 KD32 STD	ISO 5834-2 UHMWPE	367-1258
PE Inlay Primaro Cup, size 56-58 KD32 STD	ISO 5834-2 UHMWPE	367-1259
PE Inlay Primaro Cup, size 60-68 KD32 STD	ISO 5834-2 UHMWPE	367-1260
PE Inlay Primaro Cup, size 52-54 KD36 STD	ISO 5834-2 UHMWPE	367-1261
PE Inlay Primaro Cup, size 56-58 KD36 STD	ISO 5834-2 UHMWPE	367-1262
PE Inlay Primaro Cup, size 60-68 KD36 STD	ISO 5834-2 UHMWPE	367-1263
PE Inlay Primaro Cup, size 44 KD28 DYS	ISO 5834-2 UHMWPE	367-1264
PE Inlay Primaro Cup, size 46-50 KD28 DYS	ISO 5834-2 UHMWPE	367-1265
PE Inlay Primaro Cup, size 52-54 KD28 DYS	ISO 5834-2 UHMWPE	367-1266
PE Inlay Primaro Cup, size 56-58 KD28 DYS	ISO 5834-2 UHMWPE	367-1267
PE Inlay Primaro Cup, size 60-68 KD28 DYS	ISO 5834-2 UHMWPE	367-1268
PE Inlay Primaro Cup, size 46-50 KD32 DYS	ISO 5834-2 UHMWPE	367-1269
PE Inlay Primaro Cup, size 52-54 KD32 DYS	ISO 5834-2 UHMWPE	367-1270
PE Inlay Primaro Cup, size 56-58 KD32 DYS	ISO 5834-2 UHMWPE	367-1271
PE Inlay Primaro Cup, size 60-68 KD32 DYS	ISO 5834-2 UHMWPE	367-1272
PE Inlay Primaro Cup, size 52-54 KD36 DYS	ISO 5834-2 UHMWPE	367-1273
PE Inlay Primaro Cup, size 56-58 KD36 DYS	ISO 5834-2 UHMWPE	367-1274
PE Inlay Primaro Cup, size 60-68 KD36 DYS	ISO 5834-2 UHMWPE	367-1275
<b>Primaro XL-PE Inlay</b>		
XL-PE Inlay Primaro Cup, size 44 KD28 STD	XL-PE 75	367-1276
XL-PE Inlay Primaro Cup, size 46-50 KD28 STD	XL-PE 75	367-1277
XL-PE Inlay Primaro Cup, size 52-54 KD28 STD	XL-PE 75	367-1278

<b>Name</b>	<b>Material</b>	<b>Reference number</b>
XL-PE Inlay Primaro Cup, size 56-58 KD28 STD	XL-PE 75	367-1279
XL-PE Inlay Primaro Cup, size 60-68 KD28 STD	XL-PE 75	367-1280
XL-PE Inlay Primaro Cup, size 46-50 KD32 STD	XL-PE 75	367-1281
XL-PE Inlay Primaro Cup, size 52-54 KD32 STD	XL-PE 75	367-1282
XL-PE Inlay Primaro Cup, size 56-58 KD32 STD	XL-PE 75	367-1283
XL-PE Inlay Primaro Cup, size 60-68 KD32 STD	XL-PE 75	367-1284
XL-PE Inlay Primaro Cup, size 52-54 KD36 STD	XL-PE 75	367-1285
XL-PE Inlay Primaro Cup, size 56-58 KD36 STD	XL-PE 75	367-1286
XL-PE Inlay Primaro Cup, size 60-68 KD36 STD	XL-PE 75	367-1287
XL-PE Inlay Primaro Cup, size 44 KD28 DYS	XL-PE 75	367-1288
XL-PE Inlay Primaro Cup, size 46-50 KD28 DYS	XL-PE 75	367-1289
XL-PE Inlay Primaro Cup, size 52-54 KD28 DYS	XL-PE 75	367-1290
XL-PE Inlay Primaro Cup, size 56-58 KD28 DYS	XL-PE 75	367-1291
XL-PE Inlay Primaro Cup, size 60-68 KD28 DYS	XL-PE 75	367-1292
XL-PE Inlay Primaro Cup, size 46-50 KD32 DYS	XL-PE 75	367-1293
XL-PE Inlay Primaro Cup, size 52-54 KD32 DYS	XL-PE 75	367-1294
XL-PE Inlay Primaro Cup, size 56-58 KD32 DYS	XL-PE 75	367-1295
XL-PE Inlay Primaro Cup, size 60-68 KD32 DYS	XL-PE 75	367-1296
XL-PE Inlay Primaro Cup, size 52-54 KD36 DYS	XL-PE 75	367-1297
XL-PE Inlay Primaro Cup, size 56-58 KD36 DYS	XL-PE 75	367-1298
XL-PE Inlay Primaro Cup, size 60-68 KD36 DYS	XL-PE 75	367-1299
<b>Ceramic Inlay</b>		
Bilox® delta Inlay XLW 18 28/37G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-894
Bilox® delta Inlay XLW 18 28/39G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-1307
Bilox® delta Inlay XLW 18 28/44G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-1308
Bilox® delta Inlay XLW 18 28/48G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-1309
Bilox® delta Inlay XLW 18 28/52G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-1310
Bilox® delta Inlay XLW 18 32/39G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-895
Bilox® delta Inlay XLW 18 32/44G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-896
Bilox® delta Inlay XLW 18 32/48G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-897
Bilox® delta Inlay XLW 18 32/52G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-1311
Bilox® delta Inlay XLW 18 36/44G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-898
Bilox® delta Inlay XLW 18 36/48G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-899
Bilox® delta Inlay XLW 18 36/52G	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	367-1312
ELEC®plus Inlay Ø28/37-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-012
ELEC®plus Inlay Ø28/39-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-013
ELEC®plus Inlay Ø28/44-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-014
ELEC®plus Inlay Ø28/48-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-015

<b>Name</b>	<b>Material</b>	<b>Reference number</b>
ELEC <sup>®</sup> plus Inlay Ø28/52-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-016
ELEC <sup>®</sup> plus Inlay Ø32/39-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-017
ELEC <sup>®</sup> plus Inlay Ø32/44-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-018
ELEC <sup>®</sup> plus Inlay Ø32/48-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-019
ELEC <sup>®</sup> plus Inlay Ø32/52-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-020
ELEC <sup>®</sup> plus Inlay Ø36/44-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-021
ELEC <sup>®</sup> plus Inlay Ø36/48-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-022
ELEC <sup>®</sup> plus Inlay Ø36/52-18	ISO 6474-2 Al <sub>2</sub> O <sub>3</sub> +ZrO <sub>2</sub>	013-023
<b>Flat-head screws</b>		
Flat-head screw Ø 6.5 x 15 mm	ISO 5832-3 Ti6Al4V	000-290-15
Flat-head screw Ø 6.5 x 20 mm	ISO 5832-3 Ti6Al4V	000-290-20
Flat-head screw Ø 6.5 x 25 mm	ISO 5832-3 Ti6Al4V	000-290-25
Flat-head screw Ø 6.5 x 30 mm	ISO 5832-3 Ti6Al4V	000-290-30
Flat-head screw Ø 6.5 x 35 mm	ISO 5832-3 Ti6Al4V	000-290-35
Flat-head screw Ø 6.5 x 40 mm	ISO 5832-3 Ti6Al4V	000-290-40
Flat-head screw Ø 6.5 x 45 mm	ISO 5832-3 Ti6Al4V	000-290-45
Flat-head screw Ø 6.5 x 50 mm	ISO 5832-3 Ti6Al4V	000-290-50
Flat-head screw Ø 6.5 x 55 mm	ISO 5832-3 Ti6Al4V	000-290-55
Flat-head screw Ø 6.5 x 60 mm	ISO 5832-3 Ti6Al4V	000-290-60
<b>Spare part</b>		
Screw lid M9x0.75, flat	ISO 5832-3 Ti6Al4V	367-1019

## 1.2 Instrument overview

The instruments of the OHST Medizintechnik AG listed below must be used exclusively for implantation:

<b>Name</b>	<b>Reference number</b>
Acetabulum reamer instrument set	367-147
Equatorial size tester instrument set	367-1464
Cementless cup instrument set	367-149
Primaro Cup instrument set	367-1341
<b>Optional:</b>	
Primaro Cup insertion instrument set (not to be used in combination with ceramic inlays)	367-1477
Primaro trial cups instrument set	367-1342
CERA-Guide insertion instrument set, Primaro Cup	367-1479
Cup Positioning Guide Ø8 to Ø24	506-010
Primaro Trial Insert DYS Ø 44 (28/37G) PPSU green, with pole screw	367-1494
Primaro Trial Insert DYS Ø 46-50 (28/39G) PPSU green, with pole screw	367-1495
Primaro Trial Insert DYS Ø 52-54 (28/44G) PPSU green, with pole screw	367-1496
Primaro Trial Insert DYS Ø 56-58 (28/48G) PPSU green, with pole screw	367-1497

<b>Name</b>	<b>Reference number</b>
Primaro Trial Insert DYS Ø 60-68 (28/52G) PPSU green, with pole screw	367-1498
Primaro Trial Insert DYS Ø 46-50 (32/39G) PPSU blue, with pole screw	367-1499
Primaro Trial Insert DYS Ø 52-54 (32/44G) PPSU blue, with pole screw	367-1500
Primaro Trial Insert DYS Ø 56-58 (32/48G) PPSU blue, with pole screw	367-1501
Primaro Trial Insert DYS Ø 60-68 (32/52G) PPSU blue, with pole screw	367-1502
Primaro Trial Insert DYS Ø 52-54 (36/44G) PPSU yellow, with pole screw	367-1503
Primaro Trial Insert DYS Ø 56-58 (36/48G) PPSU yellow, with pole screw	367-1504
Primaro Trial Insert DYS Ø 60-68 (36/52G) PPSU yellow, with pole screw	367-1505

### **1.3 Accessories**

<b>Name</b>	<b>Reference number</b>
Surgical technique Primaro Cup	50000349
X-ray template Primaro Cup	367-1338
Implant passport	50000572

## **2. Handling**

### **2.1 General information**

This implant is part of a system and must only be used with the appropriate original system components. Only the instruments of the system listed above must be used for implantation. Before using the instruments the attached instructions for use (50000354) must be considered.

**Caution:** Implants must always be kept in their complete, unopened protective packaging. The packaging containing the implant must not be exposed to direct sunlight. Before inserting the implant, the packaging must be examined for damage, as this could affect sterility.

When unpacking the implant, its conformity with the designation on the packaging (art. no. / serial no. / size) must be checked. Compliance is required with the appropriate hygiene regulations during removal of the implant from the packaging. Care must be taken to protect all implant surfaces against damage, since this could be decisive for possible failure. The prosthesis must not therefore come into contact with objects which could damage its surface. Before use, every implant must be visually inspected for damage. Machining an implant can not only reduce its service life, but can also lead to immediate or subsequent failure of the prosthesis under stress. The implant must therefore neither be mechanically nor otherwise processed. Implants from damaged packaging, unsterile, contaminated, damaged or carelessly handled implants or implants subjected to unauthorized machining must not be used.

**Caution:** Implants are intended for single use only! Individual loads on functional surfaces of an implant used for one patient modify the functional surfaces in a way that excludes any reuse. Detection of load-caused markings by visual methods only is not secured. Therefore, damage after explantation must be assumed which excludes any reuse.

### **2.2 Authorised component combinations**

We only guarantee compatibility of our products in combination with our own CE-marked products and with the products we have approved for combined use, for which the competent authority has issued its

approval. In this regard, please note the instructions for use of the endoprosthesis manufacturers and the combination matrix approved by OHST.

Due to reasons relating the product safety and product liability, it is prohibited to use implants manufactured by OHST Medizintechnik AG in combination with components of other manufacturer that have not been approved by OHST.

## **2.3 Information for use**

The application of the implant is done without cement.

**Caution:** The ball diameter of the femoral head prosthesis must agree perfectly with the spherical nominal diameter of the part of the acetabular cup implant which articulates as the sliding partner.

**Caution:** Please be hereby explicitly advised that, in case of an intraoperative change or revision of the femoral head, only femoral heads without a ceramic cone are to be used. This is valid irrespective of the materials used in the previous cone pairing.

**Caution:** If a ceramic component is damaged or fractured, complete revision of the prosthetic components at the earliest possible date is recommended. In this case, the use of metal femoral heads is contraindicated in revision surgery, as this may lead to serious and partly life-threatening complications. In the rare event of a fracture of the ceramic component, thorough debridement with removal of all visible ceramic particles as well as careful wound irrigation is absolutely essential during surgery.

Before inserting the implant, the implant bed must be irrigated. During implantation, ensure that all loose particles (e. g. bone splinters, friction particles from the instruments) are removed from the prepared implant bed. The porous coating (TPS, Bonit®, CaP, HA) of the implant surfaces and the roughened surfaces must not come in contact with clothing or other fibre-shedding materials.

**Caution:** Whenever possible, avoid contact with the BONIT®-coated implant parts. These areas should be touched only with powder-free latex gloves.

**Caution:** When using high-frequency surgical instruments (e.g. cautery knife), it must be ensured that they do not come into contact with the implants or instruments. This can cause such severe damage to the implants or instruments that failure (e.g. fracture) may ensue. If an implant has been damaged, it must not remain in the patient but needs to be replaced by a new, intact implant. Damaged instruments may only continue to be used if they can still perform their intended function without compromise.

## **2.4 Surgical technique**

The resection of the femoral neck is carried out in accordance with the preoperative planning of the hip stem.

The acetabulum is prepared using cup reamers; the last reamer size used must be the same as the preoperative nominal size of the implant. Never apply force, always allow the reamer to move freely! In particular, the final reaming must not be distorted as a result of lateral pressure. The bony mass from the last reaming can be reserved to fill in any potential gaps between the implant and the acetabulum.

**Caution:** When implanting the Primaro Cup only the acetabulum reamers from size 44 to 68 mm must be used.



Equatorial size testers are available to determine the size of the cup needed. The size of the implant must be identical to the size of the last equatorial size tester used that fitted accurately. Trial cups can optionally be used for this. The outside diameter of the outer shell of the Primaro Cup is oversized compared to the size indication of the acetabulum reamer to achieve the desired primary stability. This oversize is also taken into account in the trial cups. The size of the implant must absolutely correspond to the size of the last trial cup used.

To implant the cup, connect the insertion head that fits the previously determined implant size with the straight handle or the MIS handle. After that, retract the spreader with the hook and position the cup onto the insertion head. The cup is locked when the hook is removed. Use moderate hammer blows to insert the cup into the pre-reamed dome. The insertion heads are not intended to be used for removing the cup. The cup is optimally positioned inside the acetabulum at an inclination of 35-45° and an anteversion of 10°. This is merely a recommendation. The individual anatomical conditions have to be taken into account for the exact alignment. If necessary, defects in the bony area are to be filled with cancellous bone. Alignment rods for the MIS handle are available as a guide for positioning the cup.

**Caution:** If the Primaro Cup requires fixation with screws owing to the condition of the bone, the user must ensure that the screw holes point towards the craniolateral side. Markings on the edge of the cup indicate the position of the screw holes for better guidance.

**Caution:** When inserting the Primaro Cup in combination with ceramic inlays, only impactors that support the cone from the inside must be used. In this case, driving in the cup with an insertion instrument that is connected to the cup only via the pole drill-hole is not permitted!

In order to place the screws, the covers of the screw holes (screw lids) have to be removed from the cup with the Cardan screwdriver. When using screws, pre-drill with a drill bit of Ø3.2 mm. A drilling gauge is available for the alignment of the drill.

A Cardan screwdriver is provided for insertion of the screws.

**Caution:** Only the flat-head screws (see 1.1. Implant overview) belonging to this system must be used for fixation of the screws.

**Caution:** The drill-holes and screws must be placed in such a way as to avoid damage of the pelvic vessels!

The femoral stem is prepared according to the surgical instructions of the hip stem system being used. Trial inlays corresponding to the inlay implant sizes that must be used together with the previously implanted cup are available for trial repositioning of the entire joint. First position the trial inlay into the cup manually and then tighten the pole screw with a screwdriver. In combination with a rasp, trial head and trial inlays, the function of the entire joint can be assessed. Afterwards, all trial components must be removed and the inlay inserted.

Before inserting the inlay, the cup must be thoroughly rinsed and then dried. The inlay is then driven in with the insertion instrument. Insertion of the PE inlay is completed with an audible snap into the cup. The snap mechanism of the PE inlay is deformed, ensuring a tight fit inside the cup.

Dysplasia inlays have a raised edge for positioning in the cranial portion of the acetabulum.

**Caution:** When correctly installed, the PE inlay protrudes approximately 1.3 mm beyond the cup edge. In the event that the PE inlay ever needs to be removed, it must never be driven in a second time. This applies to both the standard and the dysplasia variants of the inlay.

Position and insert the ceramic inlays into the cup; when positioned correctly, the inlay is flush with the edge of the cup. Place the ceramic inlay with the impactor and corresponding impactor head according to the manufacturer's instructions. The CERA-Guide insertion instrument set is optionally available for ceramic inlays. The Primaro Cups are compatible with the ceramic inlays from CeramTec listed above (see 1.1 Implant overview).

**Caution:** When using ceramic inlays, the separate instructions for use of the components must also be observed. When a ceramic inlay is used, only a ceramic femoral head may be used as an articulation partner.

The insertion of the cup is concluded and the latter can be covered by small sterile compresses to avoid damage during the further course of the surgical procedure. The surgical procedure is continued with the implantation of a hip stem as per the surgical instructions of the hip step system being used. After implantation of the hip stem, the femoral head has to be reduced into the acetabulum. If a compress was used for covering, it has to be removed again prior to the reduction. The operation is routinely completed with the layer-by-layer wound closure.

### **Instruction for using optional Primaro Cup insertion instruments via pole drill hole**

The insertion instrument must be screwed as far as it will go into the drill hole on the pole of the cup. Use moderate hammer blows to insert the cup into the pre-reamed dome. If necessary, defects in the bony area are to be filled with cancellous bone. Refer to the surgical technique for the cup with respect to optimally positioning the cup in the acetabulum. However, for exact alignment the patient's anatomy must be taken into account.

The Primaro Cup MIS insertion instrument with screwdriver is designed for the anterior surgical approach.

The straight insertion instrument for pole drill hole M12x1 is not suitable for such an approach.

**Caution:** The Primaro Cup insertion instruments via pole drill hole may be used only in the case of PE inlays. Use with ceramic inlays is not permitted.

## **3. Packaging and sterility**

Depending on the sterilisation method used, implants are packaged in a triple transparent pouch made of plastic laminated film (sterilisation by irradiation at least 25 kGy) or in a double transparent pouch made of Tyvek® (ethylene oxide sterilisation) with a carton. The instruments are supplied unsterile in protective packaging. They must be cleaned and sterilised prior to use in accordance with the respective instructions for use (50000354). The stated expiry date presumes that the packaging is intact and unopened and that the product is stored under suitable conditions.

**Caution:** The implants may not be resterilized! The reconditioning of components that have not been implanted but the packaging of which has been opened is permitted only at the manufacturer, because the components must pass through individual validated processes once again.

The outer pouch of the triple transparent pouch packaging is to be removed by the non-sterile personnel together with the carton. For the double transparent pouch packaging, only the carton is to be removed by the non-sterile personnel. The second pouch must be opened such that the sterility of the inner pouch

is not compromised. The inner pouch is removed and opened by the sterile personnel. The implant must then be presented to the surgeon, who can then directly remove the sterile implant.

#### **4. Preoperative planning and postoperative care**

Preoperative planning by reference to X-rays, CT data and similar is indispensable and provides important information about suitable implants, placing and possible component combinations and enables the size of the implant to be used to be preselected. Surgery may only be performed once it has been established that the patient is able to tolerate the implant material. Use the X-ray templates for planning the operation. These are available for all sizes in a magnification of 1,15:1. In addition, X-ray templates with a 1:1 ratio are available in digital form. Trial prostheses for checking the correct seating (where applicable) and additional implants should be available should another size be required or the intended implant cannot be used. Recognized procedures must be used for postoperative care.

#### **5. Indications**

- Advanced degeneration of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis
- All types of primary and secondary coxarthrosis
- Sequelae of earlier surgical procedures, e.g. osteosynthesis, articular reconstruction, arthrodesis
- Osteoarthritis resulting from congenital or acquired intra-articular or extra-articular (axial) misalignments

#### **6. Contraindications**

- Acute or chronic infections, whether local or systemic
- Severe muscle, nerve or vascular diseases endangering the extremity concerned
- Missing bone substance or poor bone quality that threatens the stable fit of the prosthesis
- Any underlying condition that might compromise the function of the implant
- Hypersensitivity to the materials used
- Local bone tumours

When using Snap or Dysplasia cups or cup inserts, the movement range in flexion and extension is reduced by approximately 60° and in abduction and adduction by approximately 22° as compared to the standard application.

#### **7. Conditions that can impair the success of the operation**

Potential risks in connection with the operation are:

- Disorders of bone metabolism (osteoporosis, osteomalacia)
- Occurrence of fissures, in rare cases fractures
- Circulatory disorders of the affected limb
- Neurological disorders of the affected limb
- Muscle malfunction in the affected limb
- Overweight
- Alcohol or substance abuse
- Patient groups with mental disorders or addictions
- Pregnancy
- Growth in children and adolescents

- Anticipated extreme loading e.g. due to work and sport
- Epilepsy or other reasons for repeated trauma with an increased risk of fracture
- Joint deformities that make fixation of the implant difficult
- Weakening of the bearing structures by tumour
- High-dose ingestion of cortisone or cytostatics
- Previous or threatening infectious diseases with possible joint involvement
- Deep vein thrombosis and/or history of pulmonary embolism
- All general surgical risks

## **8. Possible negative effects**

The negative effects listed below are among the most typical and most frequently occurring consequences of total hip arthroplasty:

- Change in position and loosening of the prosthesis
- Dislocation of the prosthesis
- Implant breakage
- Infection
- Venous thrombosis and pulmonary embolism
- Cardiovascular disorders
- Haematomas
- Paresthesia
- Numbness
- Swelling
- Nerve damage
- Muscle spasm
- Stiffness,
- Implant noises
- Reduced quality of life (pain, sleep disorders, ROM limitations; in particular also when lying down)
- Inflammation
- Oedem/fluids
- Metallosis
- Elevated metal ions in blood
- Coxa vara
- Osteolysis
- Heterotopic ossification
- Pseudotumours

## **9. Patient information, documentation**

The serial numbers of the implants used must be recorded in the patient's records. Appropriate labels are included with the packaging of the sterile implants.

The patient must be informed of the advantages and risks of the procedure. If the implant is regarded as the best solution for the patient, although the contraindications described above partially apply to the patient, it is particularly important to point out to the patient the effects of these circumstances on the success. It must be explained to patients receiving a hip replacement that the life of the implant will depend on their weight and degree of activity. The patient has to be informed about activities with which he can reduce the effects of these aggravating circumstances.

All the information given to the patient must be documented in writing by the surgeon. After surgery, the patient must be given an implant pass containing all necessary information concerning the implant. Adhesive labels are enclosed for documenting the implant used. Adverse effects that are harmful to patients can arise during MRI investigations. Artefacts, heating of implant, induction of electrical currents and implant loosening are among the possible effects. The equipment manufacturer's instructions should be carefully studied before use. In case of doubt, comparable implants should be checked for their specific MRI suitability as part of an individual risk assessment. Patients should be informed of the risks.

## **10. Key to label symbols**

An explanation of the symbols used by OHST Medizintechnik AG can be found in the annex (p. 246).