MEDGAL-HIP

OPERATIVE TECHNIQUE

Bipolar Hip Endoprothesis

TERAZ POLSKA

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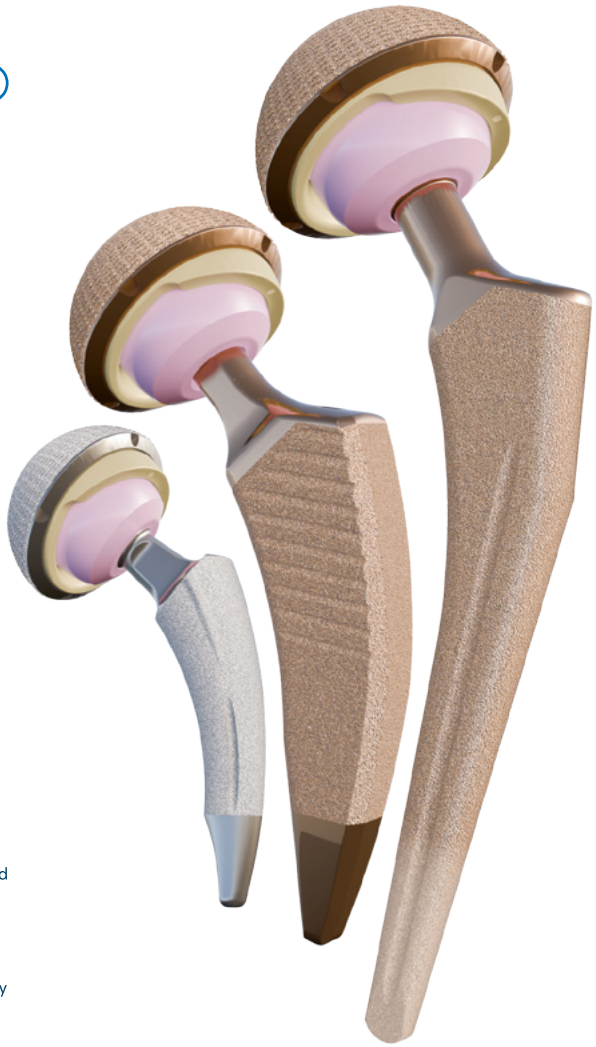
MEDGAL®

ORTHOPAEDIC IMPLANTS & INSTRUMENTS



Silicon-carbon coating

The Si-DLC coating inscreases the biocompatibility of the implants, creates better conditions for bone fusion and osseointegration.

Increased bacteriostaticity

Microstructural properties of the DLC coating are the main factor of the bacteriostatic mechanism [1-2].

Decreased ion migration

The Si-DLC coating prevents the migration of the element ions from the implant to the body, consequently reducing the possibility of allergic reactions [3-5]

Better osseointegration

The use of the silicon increases the bone formation on the implant by more than 12% compared to hydroxyapatite. Silicon also stimulates the synthesis of type I collagen [6-9].

Higher biocompatibility

The Si-DLC coating increases the biotolerance of the implant, intensifies the hemocompatibility and the adhesion of human cells, without causing the cytotoxicity [10-12].

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Publications Si-DLC:

[1] F.R. Marciano, L.F. Bonetti, L.V. Santos, N.S. Da-Silva, E.J. Corat, V.J. Trava-Airoldi (2009) Antibacterial activity of DLC and Ag-DLC films produced by PECVD technique. Diamond & Related Materials 18, 1010-1014.

[2] J.M. Gutiérrez B., K. Conceição, V. M. de Andrade, V.J. Trava-Airoldi, G. Capote (2019) High antibacterial properties of DLC film doped with nanodiamond. Surface & Coatings Technology 375, 395-401.

[3] A. Ordine, C. Achete, O. Mattos, I. C. Margarit, S. Camargo, & T. Hirsch (2000) Magnetron sputtered SiC coatings as corrosion protection barriers for steels. Surface and Coatings Technology, 133-134, 583-588.

[4] D. Batory, A. Jedrzejczak, W. Kaczorowski, L. Kolodziejczyk, B. Burnat (2016) The effect of Si incorporation on the corrosion resistance of a-C:H:SiOx coatings. Diam Relat Mater 67:1-7.

[5] DD. Rylska, J. Sokołowski, M. Łukomska, M. Pers, L. Klimek (2006) Influence of protective Al2O3 and SiC coatings on corrosion resistance of Wirobond C alloy

[6] D. M. Reffitt, N. Ogston, R. Jugdaohsingh, H. F. Cheung, B. A. Evans, R. P. Thompson, J. J. Powell & G. N. Hampson (2003) Orthosilicic acid stimulates collagen type 1 synthesis and osteoblastic differentiation in human osteoblast-like cells in vitro. Bone, 32(2), 127-135.

[7] G. Lehmann , I. Cacciotti, P. Palmero, L. Montanaro, A. Bianco, L. Campagnolo, & A. Camaioni (2012)Differentiation of osteoblast and osteoclast precursors on pure and silicon-substituted synthesized hydroxyapatites. Biomedical Materials 7(5), 055001.

[8] K. Koryszewski, D. Bociąga & R. Skowroński (2015) Results of peritrochanteric fracture treatment with carbon (DLC) and silicon-carbon (Si-DLC) coated Gamma nail - preliminary report

[9] M. Navarro, A. Michiardi, O. Castaño & J. A. Planell (2008) Biomaterials in orthopaedics. Journal of the Royal Society, Interface, 5(27), 1137-1158.

[10] A. Grill (2003) Diamond-like carbon coatings as biocompatible materials—an overview. Diamond and Related Materials, 12(2), 166-170.

[11] D. Bociaga & K. Mitura (2008) Biomedical effect of tissue contact with metallic material used for body piercing modified by DLC coatings. Diamond and Related Materials 17(7-10), 1410-1415.

[12] D. Bociąga, A.Olejnik, K.Jastrzębski, A. Jędrzejczak, L. Świątek, J. Grabarczyk, A. Sobczyk - Guzenda, M. Kamińska, W. Jakubowski, P.Komorowski, P.Niedzielski (2016) Control of the biological response to metallic biomaterials through application of the dlc coatings with dopants. ENGINEERING OF BIOMATERIALS 138 94.

Table of contents

THE INSTRUCTIONS PROVIDED ARE NOT A DETAILED OPERATING MANUAL!

SELECTION OF APPROPRIATE SURGICAL TECHNIQUE IS AT THE DISCRETION OF THE PHYSICIAN.

The first part of the catalog numer	Materials	
1-XX-XX-XX	titanium alloy	**ISO 5832-3**
4-XX-XX-XX	implantation steel (M30NW)	**ISO 5832-9**
9-XX-XX-XX	UHMWPE polyethylene with vitamin E	**ASTM F2695-12**
41-XX-XX-XX	titanium alloy coated with Ti + Hap	**ISO 5832-3**
61-XX-XX-XX	titanium alloy coated with Ti + Si-DLC	**ISO 5832-3**
103-XX-XX-XX	cobalt-chromium-molybdenum alloy	**ISO 5832-12**

INTENDED TO USE

Endoprosthesis can be used in the following cases:

- Degenerative changes or serious ailments in the course of hip rheumatoid disease,
- Extensive hip damage that significantly reduces the efficiency of the musculoskeletal system,
- Joint post-traumatic changes,
- Femoral head necrosis,
- Non-promising union of a hip fracture.

CONTRAINDICATIONS:

- Infection of a joint or joint area,
- Bone defect that prevents the primary stability of the joint stem as a result of alloplasty,
- Patient's allergic reactions to the implant's alloying components,
- Body infection,
- Cardiovascular disease,
- Anticipated overload of the hip endoprosthesis (e.g. overweight or excessive physical activity of the patient),
- Patients unable or willing to cooperate during treatment,
- Limited patient's ability to understand doctor's recommendations and not to follow them in the postoperative period.

PRE-OPERATIONAL RECOMMENDATIONS

- The treatment should be carefully planned.
- The size of the endoprosthesis (stem and head) must be carefully selected for the anatomical structure of the hip, based on X-Ray tests using appropriate MEDGAL templates.
- In the pre-operative period, any existing infectious outbreaks in the body should be eradicated.
- The physician should carry out allergy tests of the patient's body on the components of the implants.
- The use of an endoprosthesis is not allowed if allergy tests show positive reactions.
- Please read the instructions for using the instruments and follow the recommendations contained therein.
- The physician is responsible for choosing the appropriate surgical technique for a particular clinical case.

Before the procedure, the doctor should make sure that:

- all implants to be implanted in the operating room,
- surgical instruments / tools are completed and functional.

PRE-OPERATIVE PLANNING

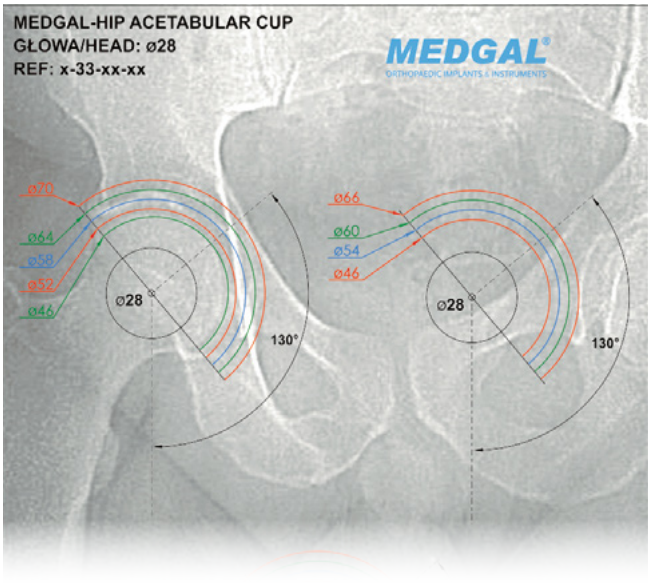
Preoperative planning is key stage to determining the appropriate stem size and bipolar head offset prior to alloplasty.

The template should define the resection area necessary to restore the anatomical center of rotation in the hip joint. The selection of the height and angle of the femoral head resection defines the length and angle of the head neck and the correct bipolar head offset.

Necessary to carry out preoperative planning are:

- x-ray machine;
- templates containing the contours of the stems, femoral heads and shell heads in various sizes;

The femur should be placed in the neutral rotation position so that its orientation on the x-ray image corresponds to the template plane. The developed x-ray scan should have sufficient femoral stem length to determine the steml length. An adequate stem size should be selected by applying the template to an X-ray scan and finding the optimal implant adaptation to anatomical structures - neck angle and stem length. The center of rotation of the femoral head determines which head to choose - by selecting the appropriate offset. The template with bipolar heads allows you to adjust the head to the patient's natural acetabulum. The coverage line is specified on each of the templates.



BIPOLAR HIP ENDOPROTHESIS

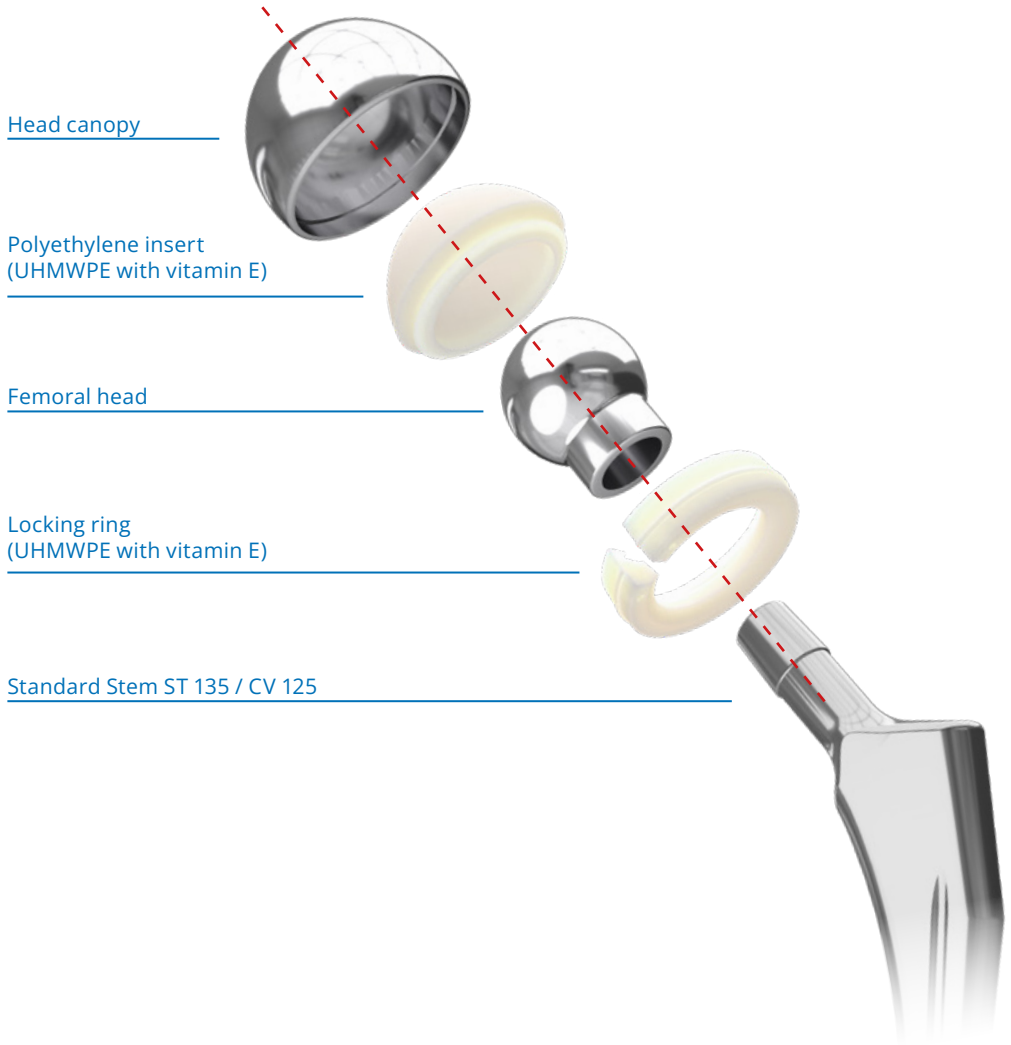
A bipolar (hemiprosthetic) prosthesis is most commonly used to treat femoral cervical fractures in elderly patients who have not been diagnosed with advanced degenerative changes in the acetabulum. It consists of a femoral stem placed in the intramedullary canal and a bipolar head system that has two pivot points, thereby limiting acetabular protrusion.

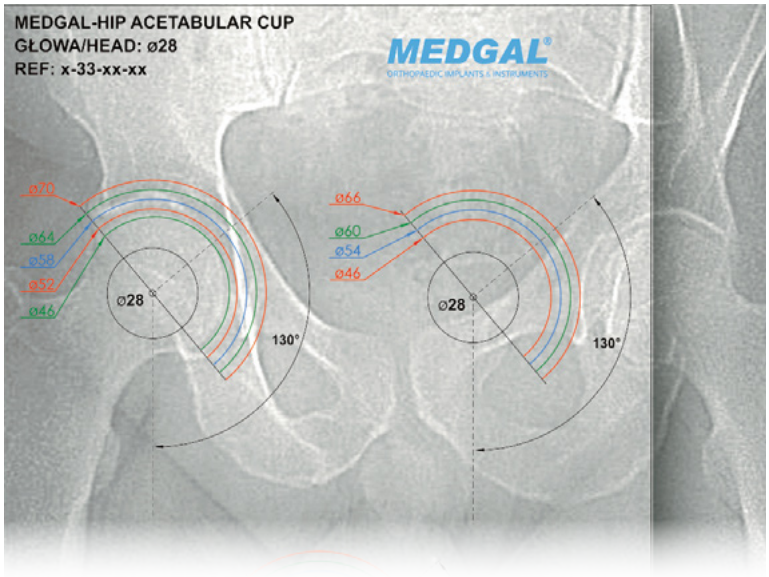
Indications:

- Femoral neck fractures

Contraindications:

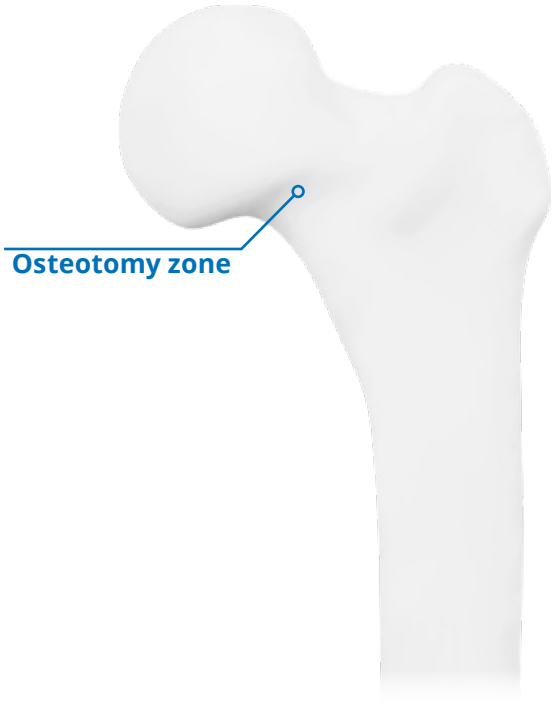
- Severe soft tissue, nerve or vascular insufficiency that compromises the function and long-term stability of the implant
- Primary or secondary osteoarthritis of the hip
- Hypersensitivity to any of the materials used
- Local or systemic infection
- Patients for whom another type of reconstructive surgery or treatment is likely to be successful



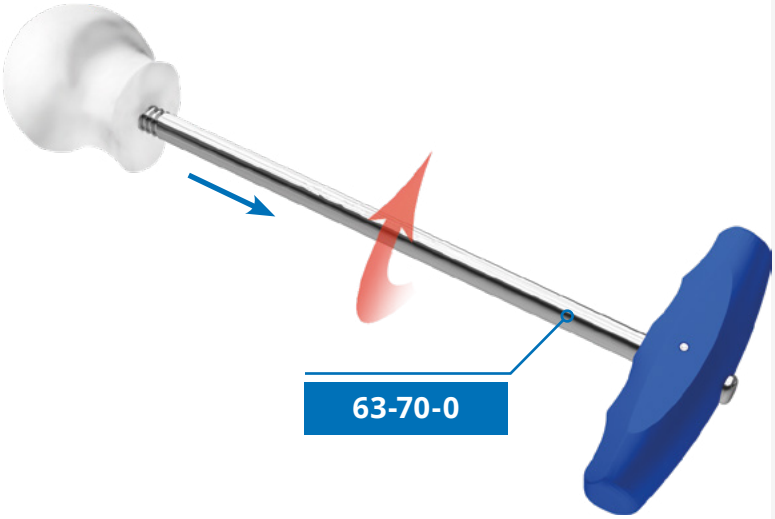


PREOPERATIVE PLANNING

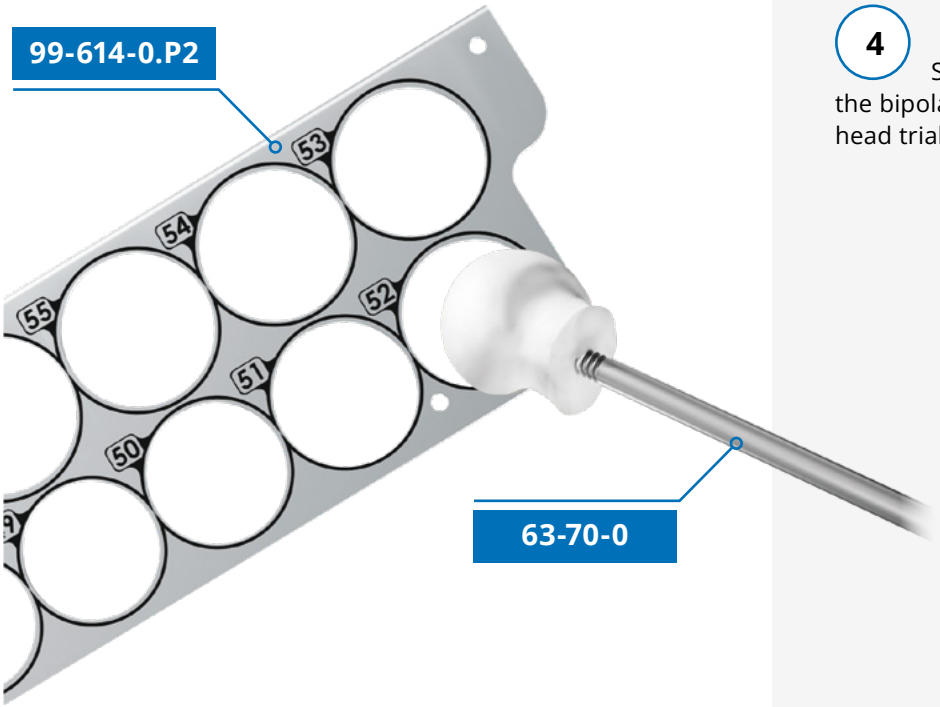
1 Before the surgery, the size of the endoprosthesis components should be selected using X-ray templates or software.



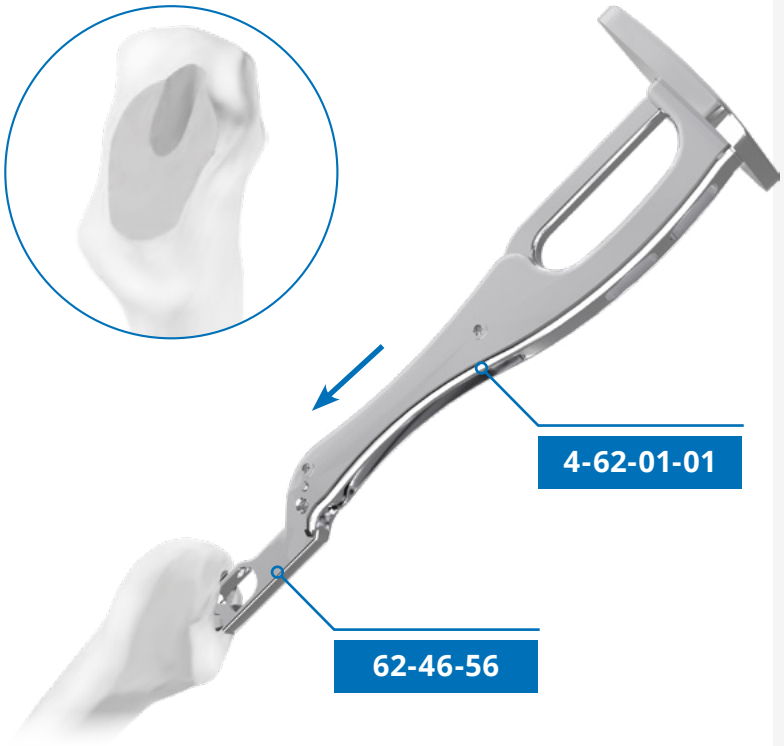
2 Perform severing of the femoral head using a trial and saw.



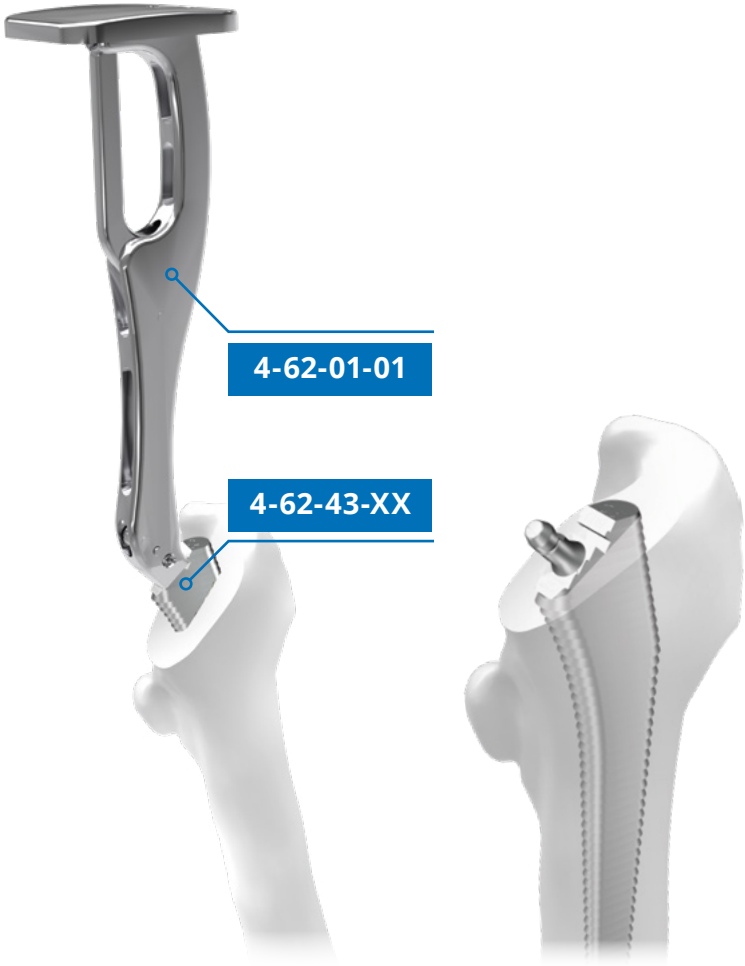
3 Remove the femoral head from the acetabulum with an extractor **63-70-0**.



4 Select the outer diameter of the bipolar head using the femoral head trial **99-614-0.P2.**

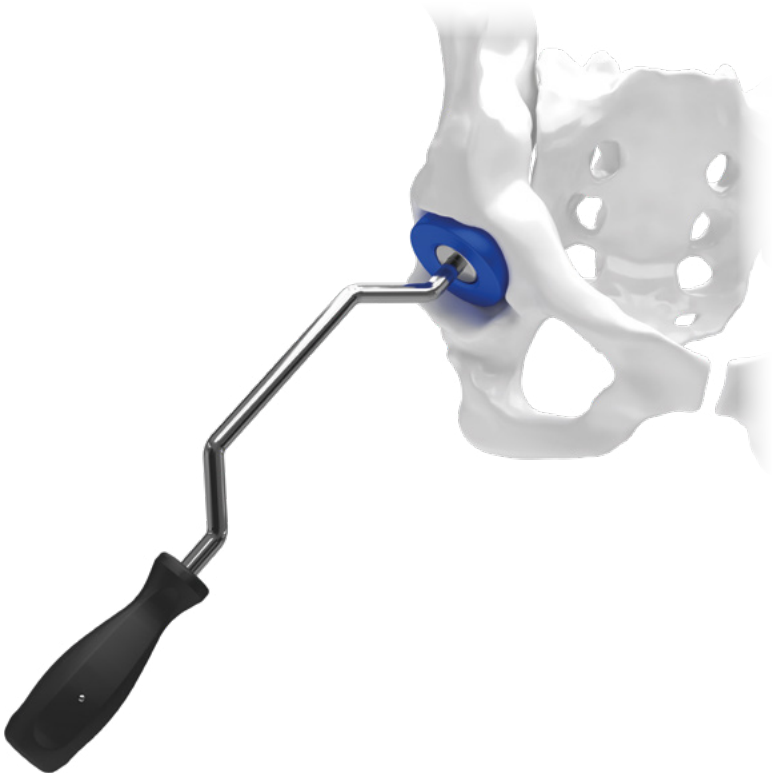


5 Remove part of a cancellous bone at the femoral neck dissection site using osteostarter **4-62-46-56** on a holder **4-62-01-01** and a hammer. In case of difficulty in inserting the first size of the rasp, optionally use the opening of the marrow canal with a hand drill.

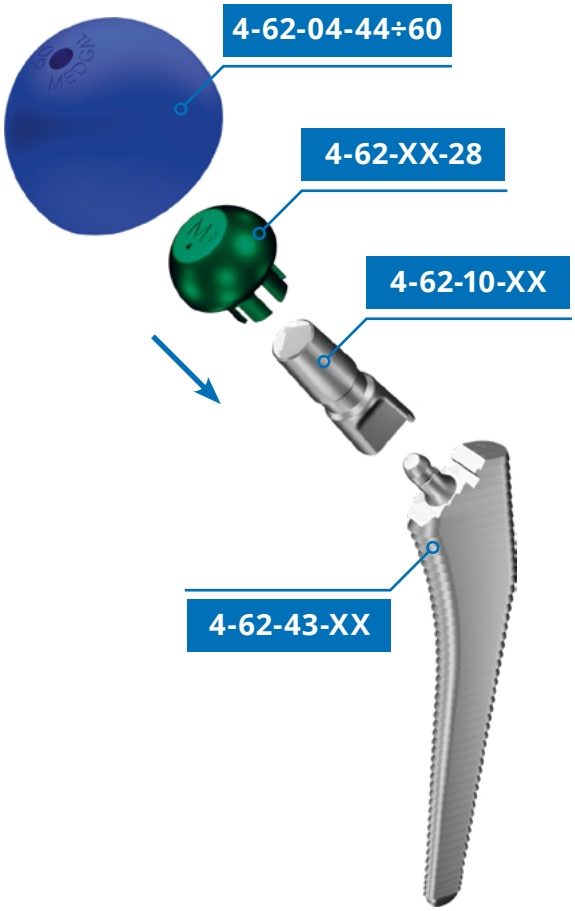


6 Prepare the femoral marrow canal for the endoprothesis stem using rasps **4-62-43-XX**, mounted on a rasp holder **4-62-01-01**. Start from the smallest size of rasp, increasing the size by one until the desired canal size is reached.

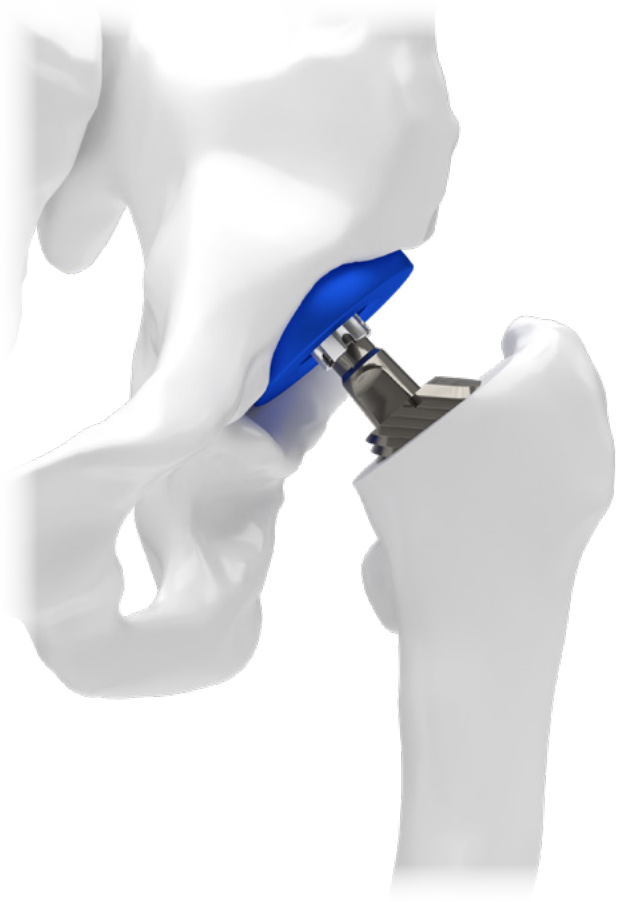
7 The size of the used rasp should correspond to the stem number in the table.



8 Check the outer diameter of the bipolar head using a gauge. Insert the appropriate trial canopy of bipolar head **4-62-04-XX** to the cup using the trial canopy holder **4-62-37-00** and check its mobility. Remove the trial canopy from the acetabulum.



9 Fit the following to the rasp:
- a trial neck **4-62-10-XX** with the correct angle (CV 125/ST 135),
- a trial head **4-62-XX-28** with the correct offset (S-XXL),
- a matching trial canopy of bipolar head **4-62-04-44÷60.**

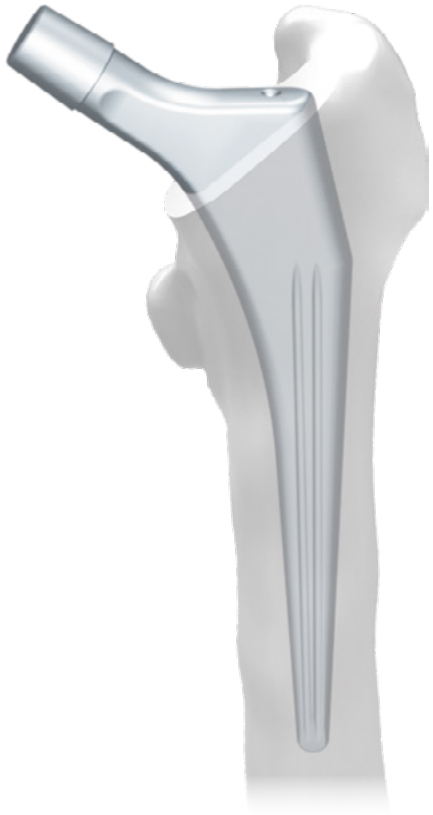


10 Place the assembled prosthesis in natural acetabulum. Check the range of motion of the hip joint and verify the length of the limb. If necessary, adjust the trial components until optimal joint biomechanics are achieved.

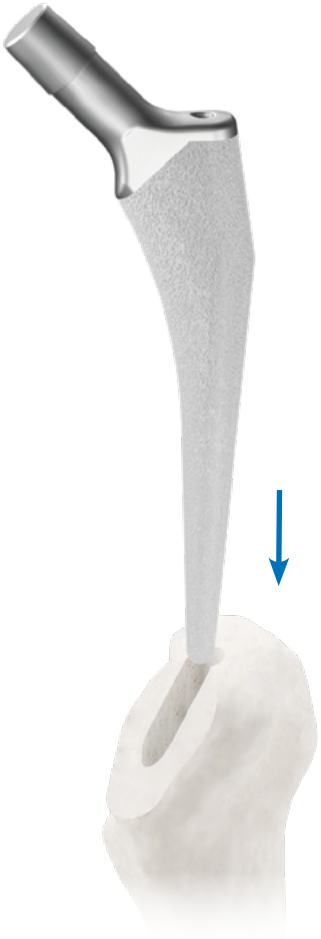
CEMENTED STEM IMPLANTATION

1 Insert cement limiter into prepared canal. Apply cement into the hole in the bone, in the manner recommended by the bone cement manufacturer.

2 Insert stem.

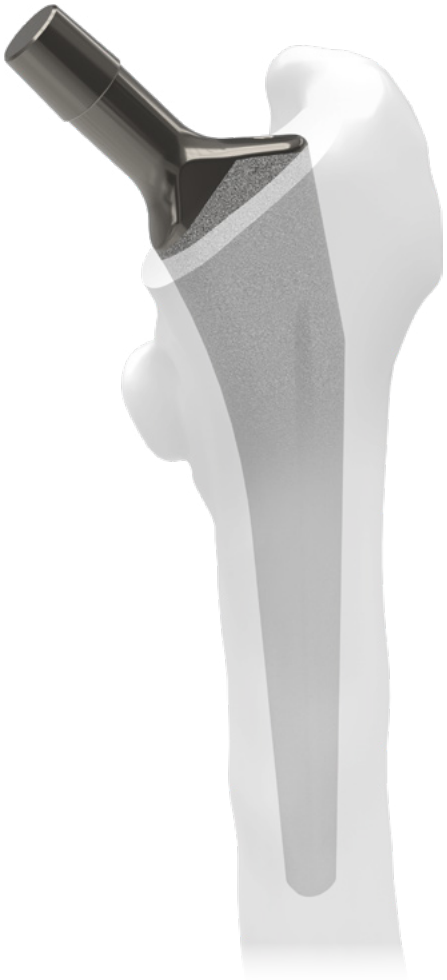


3 After stem insertion, remove excess cement. After completion of stem implantation, it is recommended to recheck the mobility of the hip joint by attaching stem to the trial head placed in the natural acetabulum.



CEMENTLESS STEM IMPLANTATION

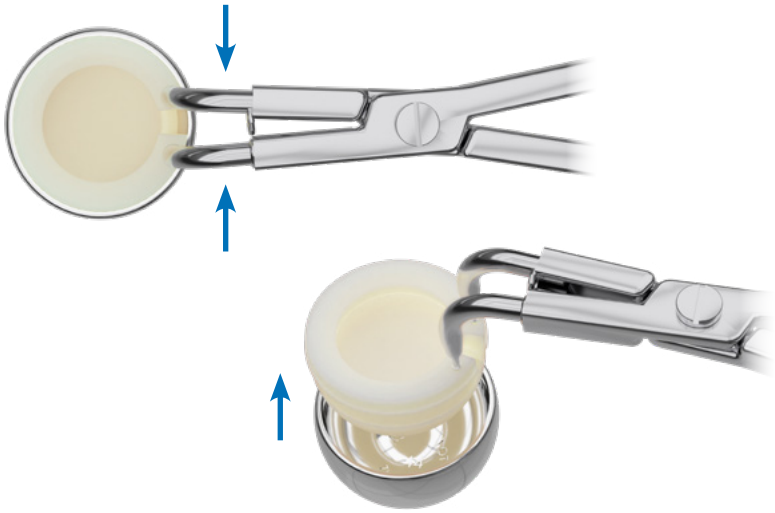
1 Place the cementless endoprothesis stem in the hole prepared in the bone.

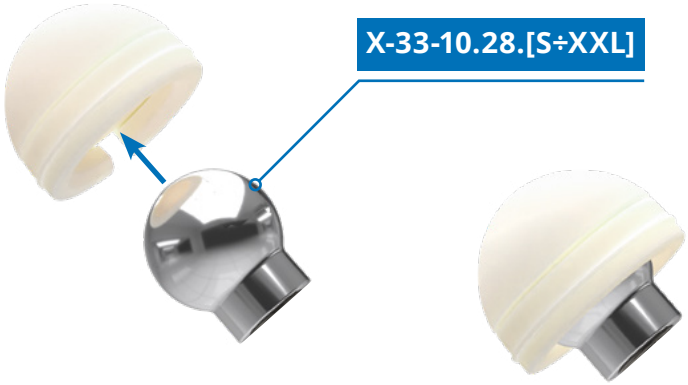


2 Implant the stem of the endoprothesis into the femur using a stem impactor **4-62-39-00**. After completion of stem implantation, it is recommended to recheck the mobility of the hip joint by attaching the stem to the trial head placed in the natural acetabulum.

IMPLANTATION OF BIPOLAR HEAD

1 Prepare the components of bipolar head **X-32-14-28.XX** / **X-32-14-32.XX** and **X-33-10-28.XX** / **X-33-10-32.XX** to assemble, using forceps **4-62-31-00**. Check the correct sizing of the components.





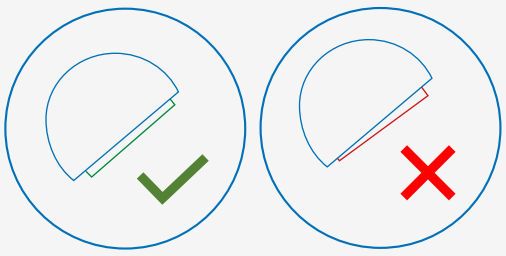
IMPLANTATION OF A BIPOLAR HEAD

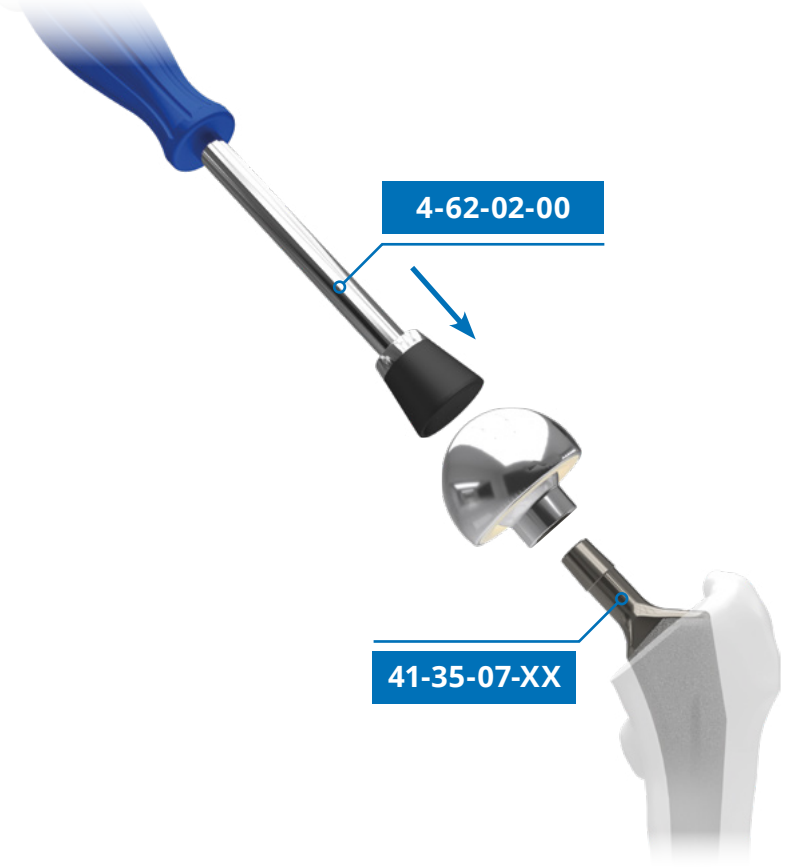
1 Prepare the previously selected components of the **X-32-14-28.XX** bipolar head and the **X-33-10.28 [S–XXL]** femoral head for assembly, using forceps **4-62-31-00**. Check that the correct sizes of the components have been selected.

2 Press the femoral head **X-33-10.28.[S÷XXL]** into the assembly of the polyethylene insert and locking ring.

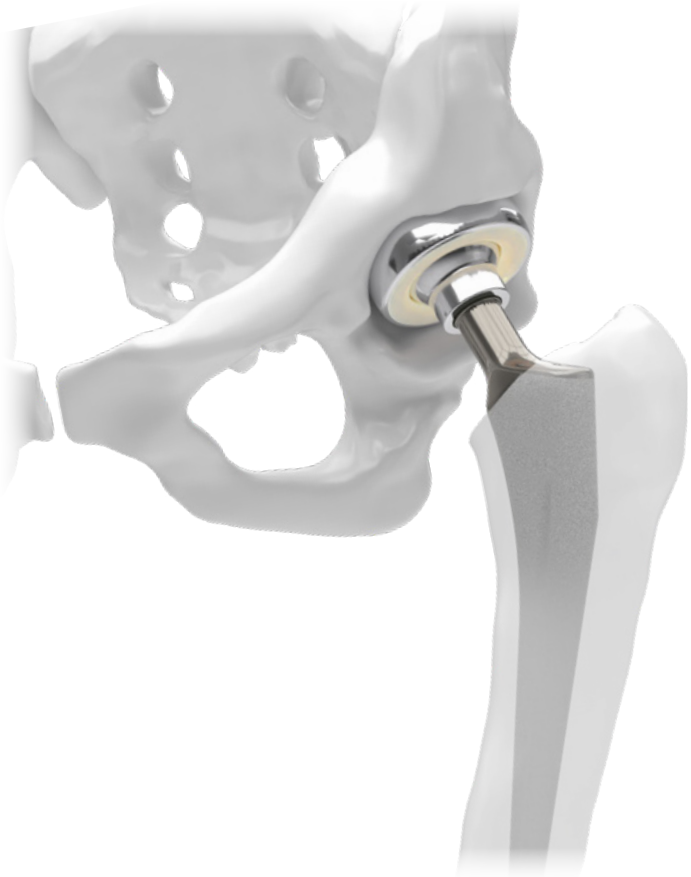
3 Assemble the set and check that the assembly moves freely.

Diagram showing the correct positioning of the cup on the polyethylene insert.





4 Fit the assembly onto the prosthesis stem and tap it into place using a tap **4-62-02-00.**



5 Insert and fit the prosthesis into the natural acetabulum. Check the final range of motion of the hip joint.

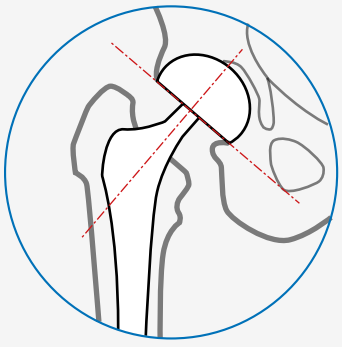
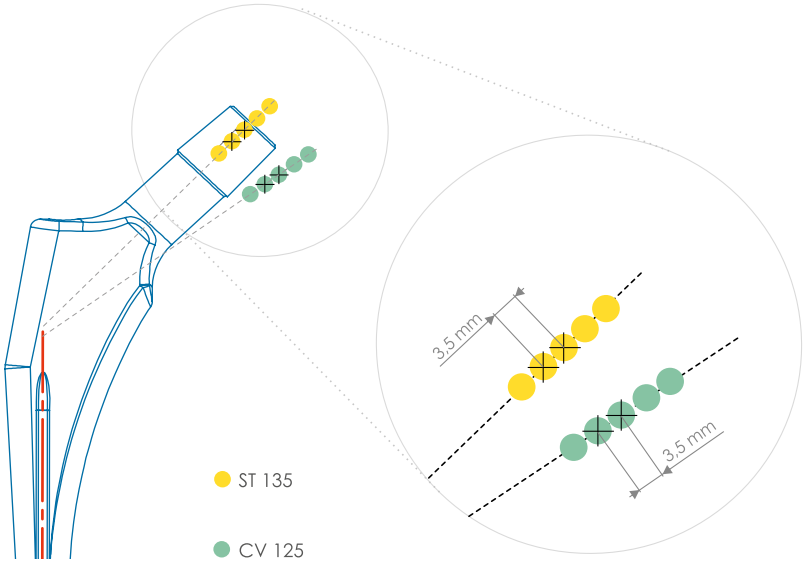


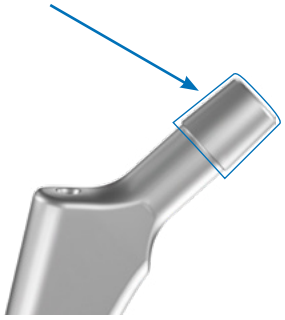
Diagram showing the correct placement of a bipolar hip prosthesis.

After use, the instruments must be properly prepared for cleaning by removing any remaining bone fragments. Perform the cleaning process and re-sterilisation.

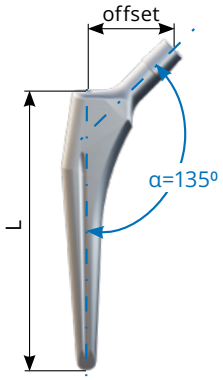


- Optimal offset and two neck angles: 135°, 125°
- Femoral head can be adjusted to 10 different positions (including type of stems)

Standard 12/14 taper

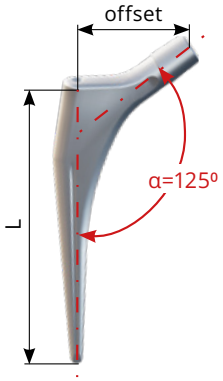


STANDARD STEM ST 135

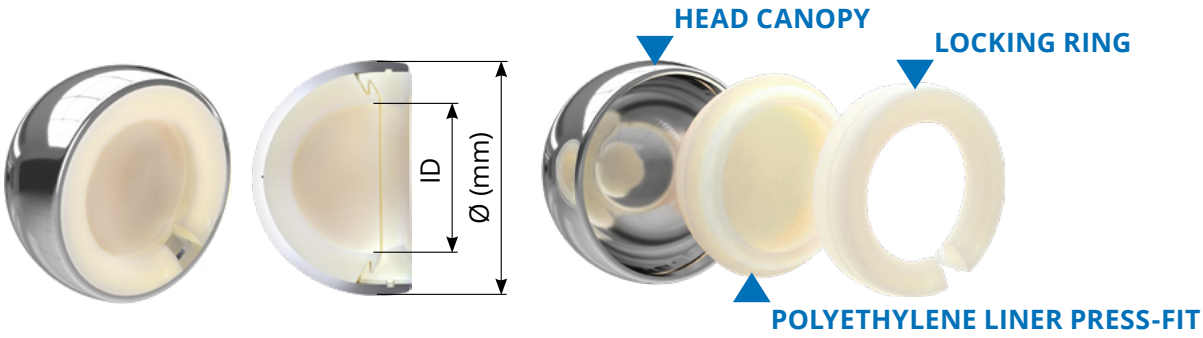


Offset (mm)	Length L (mm)	REF		
		Titanium alloy +Ti+HAp	Titanium alloy +Ti+Si-DLC	Titanium alloy - cemented
37,4	128	-	-	1-35-07-01
37,8	130	41-35-07-01	61-35-07-01	1-35-07-02
38,3	133	41-35-07-02	61-35-07-02	1-35-07-03
39,0	136	41-35-07-03	61-35-07-03	1-35-07-04
39,5	139	41-35-07-04	61-35-07-04	1-35-07-05
40,0	143	41-35-07-05	61-35-07-05	1-35-07-06
40,7	146	41-35-07-06	61-35-07-06	1-35-07-07
41,2	150	41-35-07-07	61-35-07-07	1-35-07-08
41,8	155	41-35-07-08	61-35-07-08	1-35-07-09
42,5	160	41-35-07-09	61-35-07-09	1-35-07-10
43,2	165	41-35-07-10	61-35-07-10	1-35-07-11
43,9	170	41-35-07-11	61-35-07-11	-

STANDARD STEM CV 125



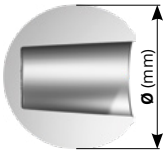
Offset (mm)	Length L (mm)	REF		
		Titanium alloy +Ti+HAp	Titanium alloy +Ti+Si-DLC	Titanium alloy - cemented
43,1	128	-	-	1-35-08-01
43,5	130	41-35-08-01	61-35-08-01	1-35-08-02
44,0	133	41-35-08-02	61-35-08-02	1-35-08-03
44,7	136	41-35-08-03	61-35-08-03	1-35-08-04
45,2	139	41-35-08-04	61-35-08-04	1-35-08-05
45,7	143	41-35-08-05	61-35-08-05	1-35-08-06
46,4	146	41-35-08-06	61-35-08-06	1-35-08-07
46,9	150	41-35-08-07	61-35-08-07	1-35-08-08
47,5	155	41-35-08-08	61-35-08-08	1-35-08-09
48,2	160	41-35-08-09	61-35-08-09	1-35-08-10
48,9	165	41-35-08-10	61-35-08-10	1-35-08-11
49,6	170	41-35-08-11	61-35-08-11	-



Cup size	REF Stal implantacyjna/ stop kobalt-chrom-molibden + wysokousieciowiony UHMWPE z witaminą E ID=28
43	X-32-14-28.43*
44	**X-32-14-28.44**
45	**X-32-14-28.45**
46	**X-32-14-28.46**
47	**X-32-14-28.47**
48	**X-32-14-28.48**
49	**X-32-14-28.49**
50	**X-32-14-28.50**
51	**X-32-14-28.51**
52	**X-32-14-28.52**
53	**X-32-14-28.53**
54	**X-32-14-28.54**
55	**X-32-14-28.55**
56	**X-32-14-28.56**
57	**X-32-14-28.57**
58	**X-32-14-28.58**
59	**X-32-14-28.59**
60	**X-32-14-28.60**
61	X-32-14-28.61*
62	X-32-14-28.62*
63	X-32-14-28.63*
64	X-32-14-28.64*
65	X-32-14-28.65*
66	X-32-14-28.66*
67	X-32-14-28.67*
68	X-32-14-28.68*
69	X-32-14-28.69*
70	X-32-14-28.70*
71	X-32-14-28.71*
72	X-32-14-28.72*
73	X-32-14-28.73*

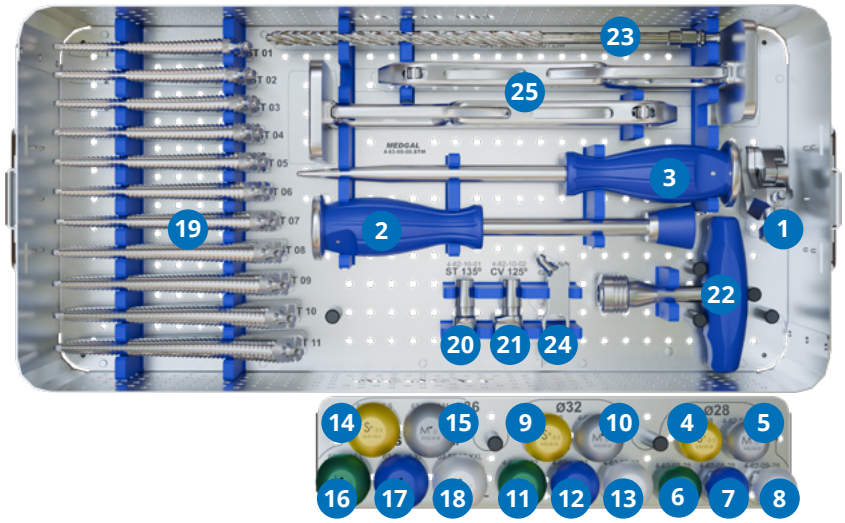
*Available on request

FEMORAL HEAD (METAL)



Size	Offset	REF Cobalt-chromium-molybdenum alloy (CoCrMo) Ø=28
S	-3.5	**103-33-10-28.S**
M	0	**103-33-10-28.M**
L	3.5	**103-33-10-28.L**
XL	7	**103-33-10-28.XL**
XXL	10.5	**103-33-10-28.XXL**

INSTRUMENT SET - STANDARD STEM
4-63-00-00.STM.AOR.1.OL/HUD.1.OL*/ZIM.1.OL*
4-63-00-00.STM.AOR.2.OL*/HUD.2.OL*/ZIM.2.OL*

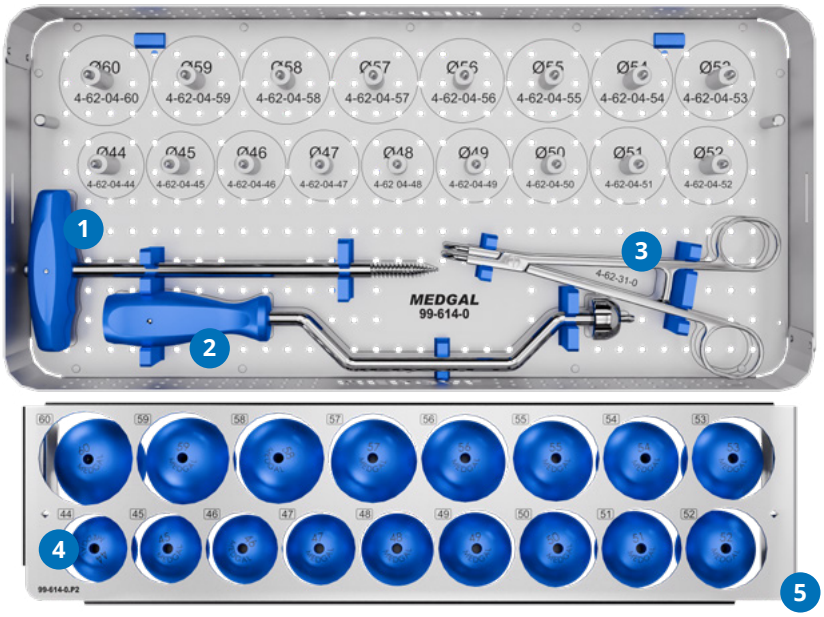


1	Mandrel remover	63-56-0
2	Head beater	4-62-02-00
3	Solid shaft beater	4-62-39-00
4	Test head 28 mm S	4-62-05-28
5	Test head 28 mm M	4-62-06-28
6	Test head 28 mm L	4-62-07-28
7	Test head 28 mm XL	4-62-08-28
8	Test head 28 mm XXL	4-62-09-28
9	Test head 32 mm S	4-63-05-32
10	Test head 32 mm M	4-63-06-32
11	Test head 32 mm L	4-63-07-32
12	Test head 32 mm XL	4-63-08-32
13	Test head 32 mm XXL	4-63-09-32
14	Test head 36 mm S	63-51-36.S
15	Test head 36 mm M	63-52-36.M
16	Test head 36 mm L	63-53-36.L
17	Test head 36 mm XL	63-54-36.XL
18	Test head 36 mm XXL	63-55-36.XXL
19	Rasp Standard ST 1÷11	4-62-43-01÷11
20	Test neck ST 135	4-62-10-01
21	Test neck CV 125	4-62-10-02

Instrument Set REF	22 T-handle with AO Reamer socket	23 6 - blade cutter	24 Osteostarter 56mm	25 Rasp picker
4-63-00-00.STM.AOR.1.OL 4-63-00-00.STM.AOR.2.OL*	43-281-0	83-01-08.AOR	62-46-56	4-62-01-01 4-62-38-00*
4-63-00-00.STM.HUD.1.OL* 4-63-00-00.STM.HUD.2.OL*	43-282-0*	83-01-08.HUD*	62-46-56*	4-62-01-01* 4-62-38-00*
4-63-00-00.STM.ZIM.1.OL* 4-63-00-00.STM.ZIM.2.OL*	43-273-0*	83-01-08.ZIM*	62-46-56*	4-62-01-01* 4-62-38-00*

*Optional

INSTRUMENT SET - BIPOLAR HEAD
99-614-0



1	Femoral head extractor	63-70-0
2	Trial canopy holder	4-62-37-00
3	Forceps	4-62-31-00
4	Trial canopy of bipolar head 44÷60	4-62-04-4460
5	Femoral bone head trial	99-614-0.P2

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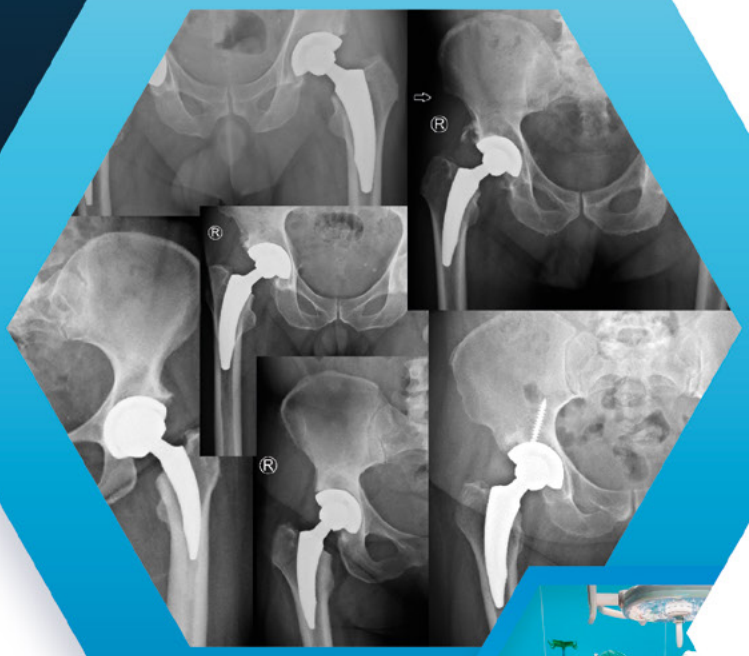
OF THE HIP JOINT



WE PROVIDE

- cementless acetabular cups coated with porous titanium with hydroxyapatite or Si-DLC layer
- polyethylene cup liners with vitamin E or ceramic (BIOLOX®delta)
- ceramic (BIOLOX®delta) and metal (CoCr) heads
- uniquely shaped or standard epiphyseal stems coated with porous titanium with hydroxyapatite or Si-DLC layer
- intuitive instrument set adapted to the individual needs of the operator

Si DLC

Innovative Si-DLC carbon-silicon layer coating.

SILICON stimulates the proliferation of osteoblasts, increases the expression of genes responsible for formation of callus through GMP-2 and can stimulate type I collagen synthesis.

CARBON is a basic and essential element included in all organic compounds. It make up approximately 18 , 5% of a healthy person's body weight.

Benefits of use

Si DLC

- increased biotolerance of the implant (V, VI, VII)
- prevention of migration of metal ions into the peri-implant area - no metallosis phenomenon (VIII, IX, X)
- very high corrosion resistance of the implanted implant in the body's tissue and its fluid environment (VIII, IX, X)
- minimisation of adverse toxic and allergic reactions to the organism and thus a significant reduction in post-operative complications (VIII, IX, X)

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(+48) 85 6632 344
medgal.com.pl
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Manufacturer:

MEDGAL® sp. z o.o.
ul. Niewodnicka 26A
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tel.:+48 85 663 23 44
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tel.:+48 85 663 29 99
fax +48 85 663 26 22
export@medgal.com.pl