

MEDGAL-H/P



Bipolar Hip Endoprosthesis



MEDGAL[®]

ORTHOPAEDIC IMPLANTS & INSTRUMENTS

Silicon-carbon coating



The Si-DLC coating increases 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]



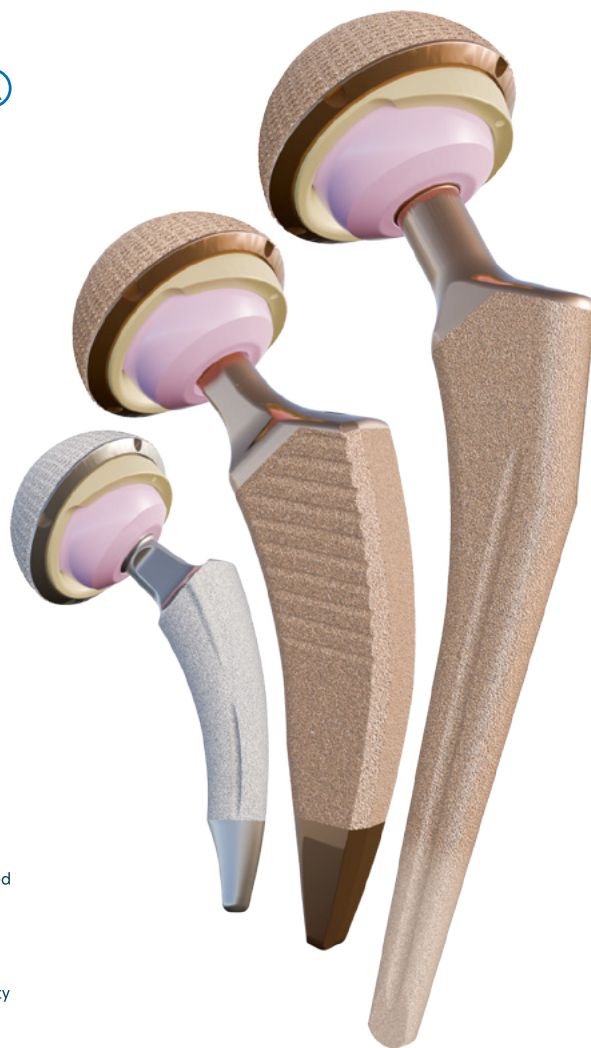
Better osseointegration

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. Jędrzejczak, W. Kaczorowski, L. Kołodziejczyk, B. Burnat (2016) The effect of Si incorporation on the corrosion resistance of α -C:H:SiO_x coatings. *Diam Relat Mater* 67:1-7.
- [5] DD. Ryłska, 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. Cimaioni (2012) Differentiation of osteoblast and osteoclast precursors on pure and silicon-substituted synthesized hydroxyapatites. *Biomedical Materials* 7(5), 055001.
- [8] K. Koryszewski, D. Bociągga & 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. Bociągga & 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. Bociągga, 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.

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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

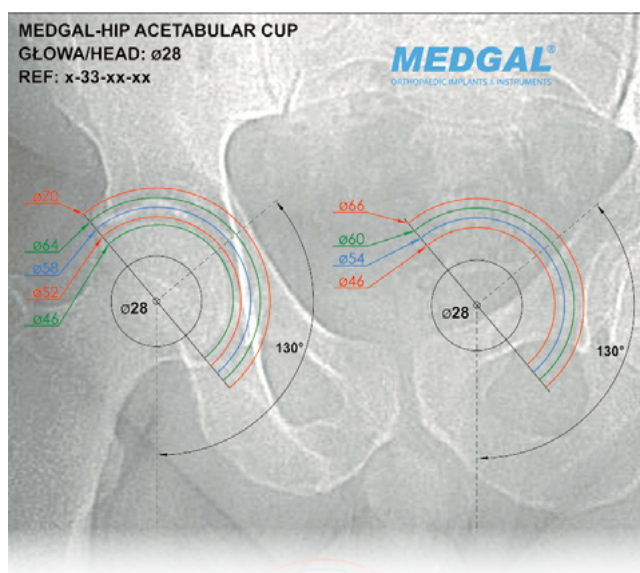
Preoperative planning is key stage to determining the appropriate stem size and bipolar head offset prior to alloplasty.

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 stem 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

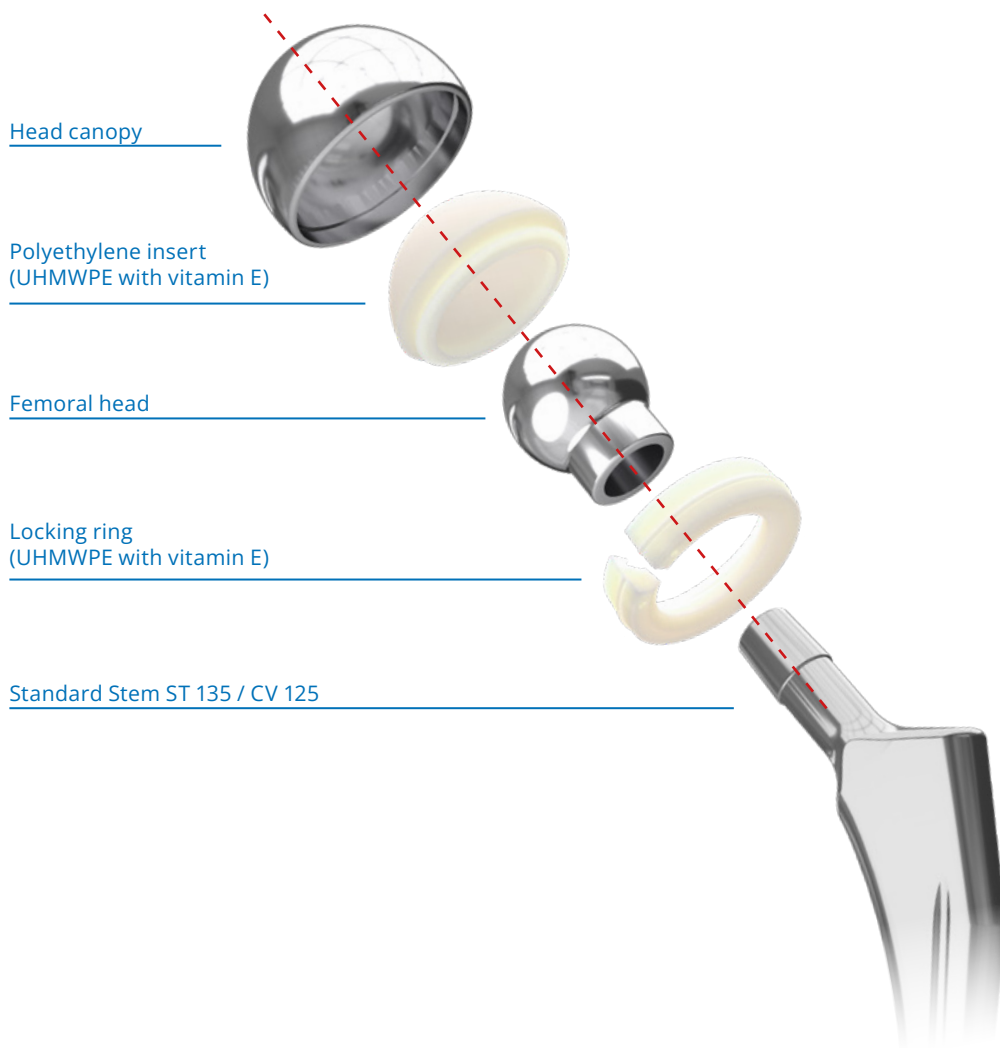
A bipolar (hemiprosthetic) prosthesis is most commonly used to treat femoral cervical fractures in elderly patients who have not been diagnosed with advanced degenerative changes in the acetabulum. It consists of a femoral stem placed in the intramedullary canal and a bipolar head system that has two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

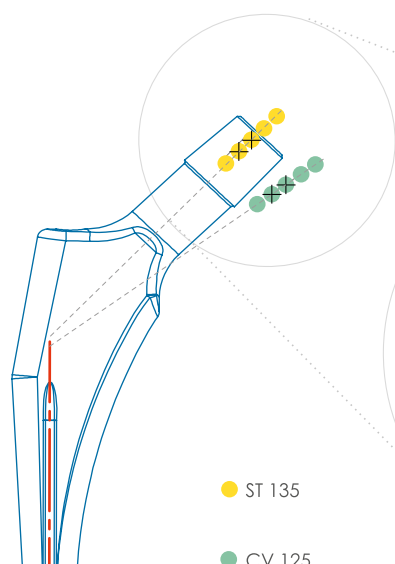
Indications:

- Femoral neck fractures

Contraindications:

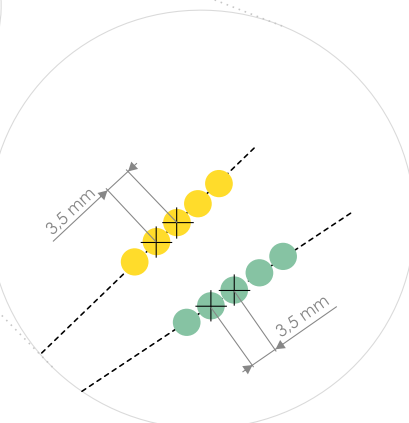
- Severe soft tissue, nerve or vascular insufficiency that compromises the function and long-term stability of the implant
- Primary or secondary osteoarthritis of the hip
- Hypersensitivity to any of the materials used
- Local or systemic infection
- Patients for whom another type of reconstructive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





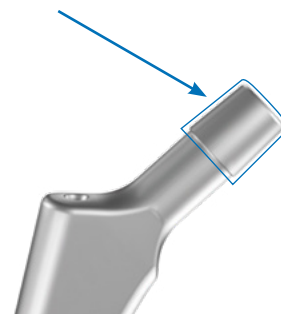
● ST 135

● CV 125

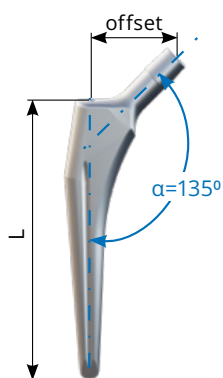


- Optimal offset and two neck angles: 135°, 125°
- Femoral head can be adjusted to 10 different positions (including type of stems)

Standard 12/14 taper

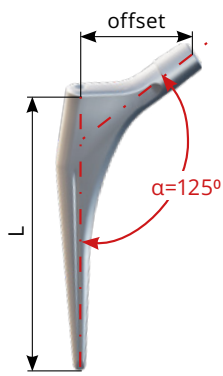


STANDARD STEM ST 135

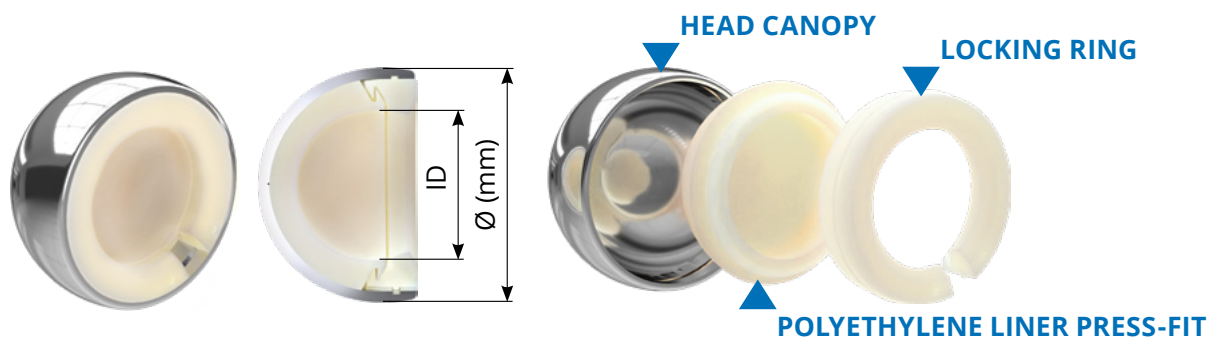


Offset (mm)	Length L (mm)	REF		
		Titanium alloy +Ti+HAp	Titanium alloy +Ti+Si-DLC	Titanium alloy - cemented
37,4	128	-	-	1-35-07-01
37,8	130	41-35-07-01	61-35-07-01	1-35-07-02
38,3	133	41-35-07-02	61-35-07-02	1-35-07-03
39,0	136	41-35-07-03	61-35-07-03	1-35-07-04
39,5	139	41-35-07-04	61-35-07-04	1-35-07-05
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



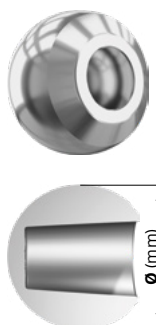
Offset (mm)	Length L (mm)	REF		
		Titanium alloy +Ti+HAp	Titanium alloy +Ti+Si-DLC	Titanium alloy - cemented
43,1	128	-	-	1-35-08-01
43,5	130	41-35-08-01	61-35-08-01	1-35-08-02
44,0	133	41-35-08-02	61-35-08-02	1-35-08-03
44,7	136	41-35-08-03	61-35-08-03	1-35-08-04
45,2	139	41-35-08-04	61-35-08-04	1-35-08-05
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	
	Implantation steel / cobalt-chromium-molybdenum alloy + highly cross-linked UHMWPE with vitamin 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

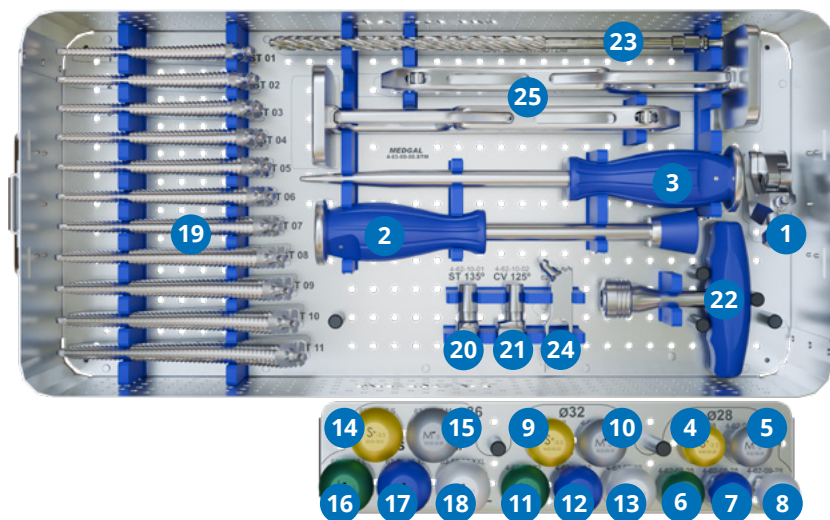
FEMORAL HEAD (METAL)



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*

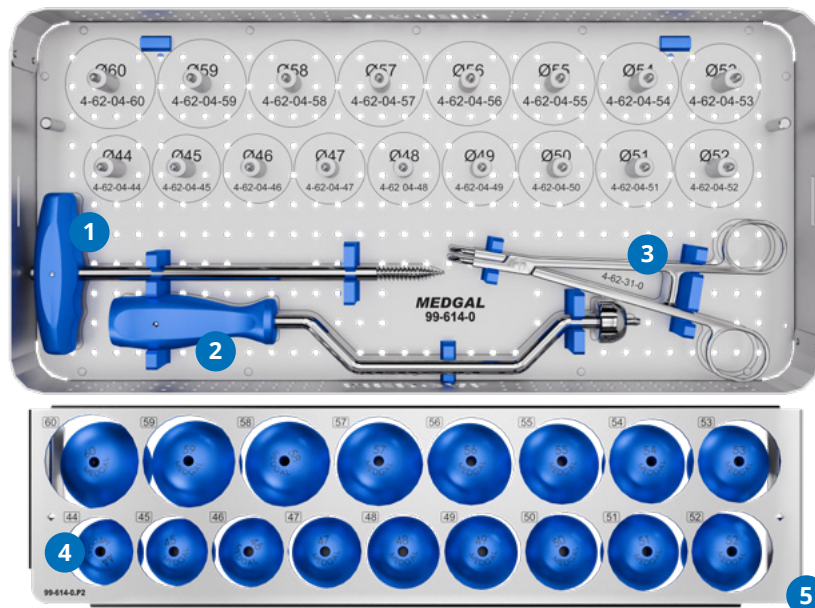


1	Mandrel remover	63-56-0
2	Head beater	4-62-02-00
3	Solid shaft beater	4-62-39-00
4	Test head 28 mm S	4-62-05-28
5	Test head 28 mm M	4-62-06-28
6	Test head 28 mm L	4-62-07-28
7	Test head 28 mm XL	4-62-08-28
8	Test head 28 mm XXL	4-62-09-28
9	Test head 32 mm S	4-63-05-32
10	Test head 32 mm M	4-63-06-32
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	43-281-0	83-01-08.AOR	62-46-56	4-62-01-01
4-63-00-00.STM.AOR.2.OL*				4-62-38-00*
4-63-00-00.STM.HUD.1.OL*	43-282-0*	83-01-08.HUD*	62-46-56*	4-62-01-01*
4-63-00-00.STM.HUD.2.OL*				4-62-38-00*
4-63-00-00.STM.ZIM.1.OL*	43-273-0*	83-01-08.ZIM*	62-46-56*	4-62-01-01*
4-63-00-00.STM.ZIM.2.OL*				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

MEDGAL-HIP

POLISH PRODUCT

FIRST POLISH BIPOLAR AND REVISION
ENDOPROTHESIS SYSTEM
USED IN ALLOPLASTY
OF THE HIP JOINT

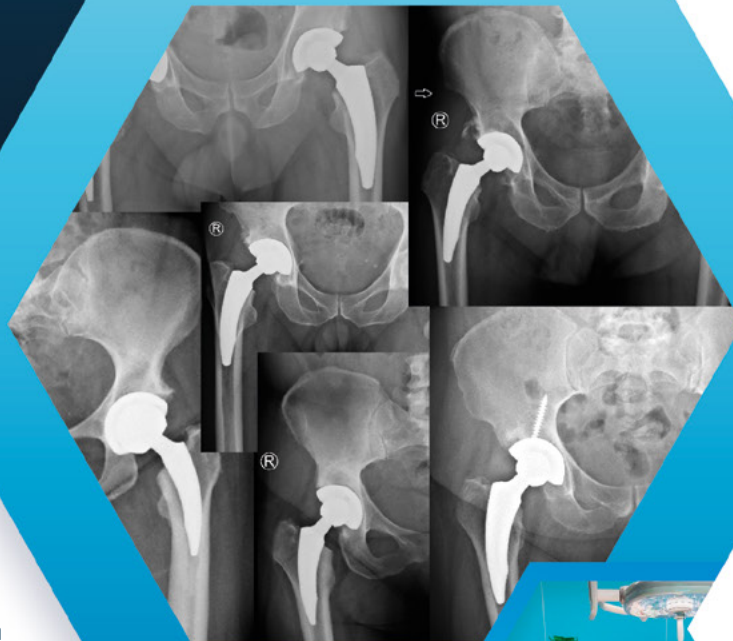
WE PROVIDE

- 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



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 makes up approximately 18, 5% of a healthy person's body weight.



Benefits of use



- 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)

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

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

III. Koryszewski, K., Bociaga, D., & Skowronski, R. (2015). Wyniki leczenia złamań okołokrętarzowych leczonych gwoździem Gamma pokrytym warstwą węglową DLC i węglowo-krzemową Si-DLC - doniesienie wstępne. *Chirurgia Narządów Ruchu i Ortopedia Polska*, 80(4), 171-175.

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

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

VI. Bociaga, D., & Mitura, K. (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.

VII. D. Bociaga, A. Olejnik, K. Jastrzębski, A. Jędrzejczak, L. Świątek, J. Grabarczyk, A. Sobczyk - Guzena, 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

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

IX. Batory D, Jędrzejczak A, Kaczorowski W, Kołodziejczyk L, Burnat B. The effect of Si incorporation on the corrosion resistance of a-C:H/SiOx coatings. *Diam Relat Mater*. 2016;67:1-7.

X. D. Ryśka, J. Sokołowski, M. Łukomska, M. Pers, L. Klimek. (2006) Wpływ powłok ochronnych Al2O3 i SiC na odporność korozyjną stopu Wirobond C. *Protetyka Stomatologiczna*, LVI, 1



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MEDGAL is a trusted manufacturer of high-quality medical products, with a strong commitment to safety, precision, and excellence. Our operations are guided by a robust and continually improved Quality Control System, ensuring full compliance with international standards for the production of medical implants and surgical instruments.

Our products are recognized and respected across Europe and in markets around the world. They carry the **CE Compliance Mark** and are certified according to **EN ISO 13485** for medical devices. These certifications have been issued by globally renowned institutions, including **TÜV Rheinland** and **PCBC**.

We maintain the highest standards by utilizing **premium BIO-compatible materials**, sourced from leading global suppliers of medical-grade steel and titanium. This commitment to quality materials is a cornerstone of our excellence in implant production.

MEDGAL's manufacturing processes are powered by cutting-edge CAD/CAM technology and an extensive range of advanced **CNC machining systems**, sourced from world-leading engineering companies. This technological foundation enables us to deliver products with outstanding precision, durability, and performance.

MEDGAL-HP



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