MEDGAL-HIP
REVISION

MREVISION STEM
- OPERATIVE TECHNIQUE

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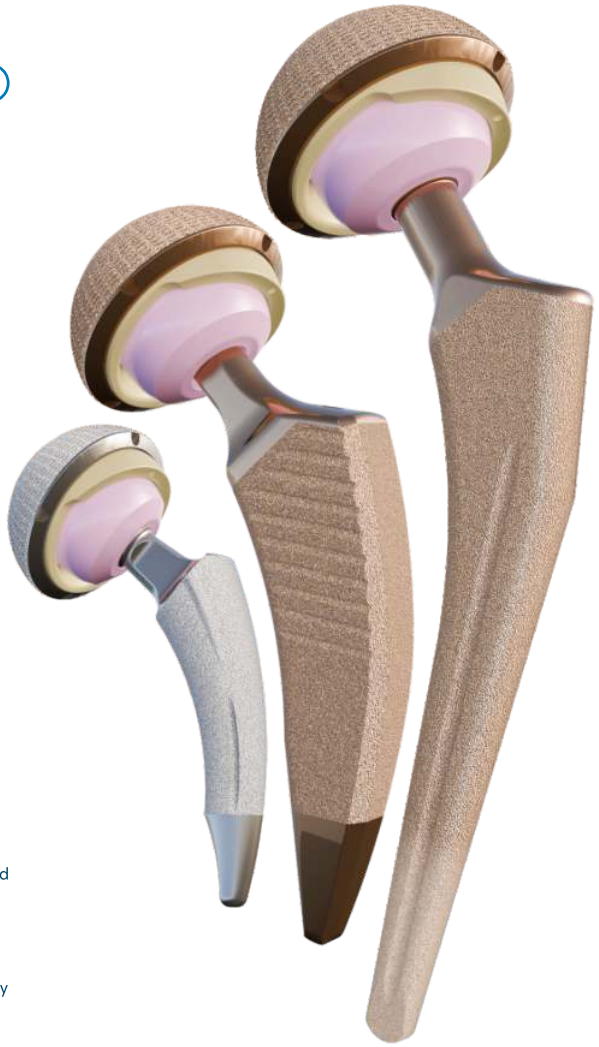
MEDGAL®

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.

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- Surgical Technique 5

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First part of the catalogue number	Materials
1 -XX-XX-XX	titanium alloy
4 -XX-XX-XX	implantation steel
9 -XX-XX-XX	UHMW-PE polyethylene with witamin E
41 -XX-XX-XX	titanium alloy coated with Ti + Hap
61 -XX-XX-XX	titanium alloy coated with Ti + Si-DLC
103 -XX-XX-XX	cobalt-chromium-molybdenum alloy

Revision hip joint endoprosthesis system

INTENDED TO USE

The MEDGAL-HIP SIMPLE REVISION hip revision system is recommended for patients with poor bone stock or inadequate for primary reconstructive techniques due to deficiencies in the femoral head, neck, or fragments of the femur near the joint. It is intended for cementless revision hip arthroplasty after femoral implants.

The SIMPLE REVISION system is intended for the treatment of patients who are candidates for total surgery hip replacement surgery in accordance with indications for use. However, the system is not designed to last activity levels and loads normal for healthy bones. They provide a way to restore mobility and reduce pain for patients.

CONTRAINDICATIONS

- Insufficient bone quality,
- Muscular, neurological or vascular deficiencies,
- Patients with an immature skeleton and cases in which there is loss of abductive muscle, poor bone stock, insufficient coverage of the skin around the hip joint,
- Osteolysis,
- Rapid joint destruction or bone absorption,
- Hypersensitivity to materials,
- Pathological diseases of the acetabulum that prevent the achievement of an appropriate range of motion, adequate head stability and/or well-set and supported, smooth articulation of the head in the socket,
- Alcoholism or other addictions,
- Loss of ligament structures,
- High level of physical activity (e.g. competitive sports, heavy physical work).

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.

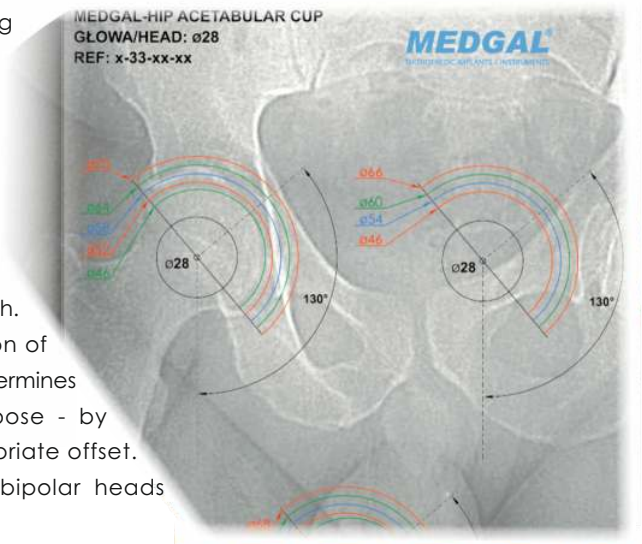
PRE-OPERATIVE PLANNING

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;

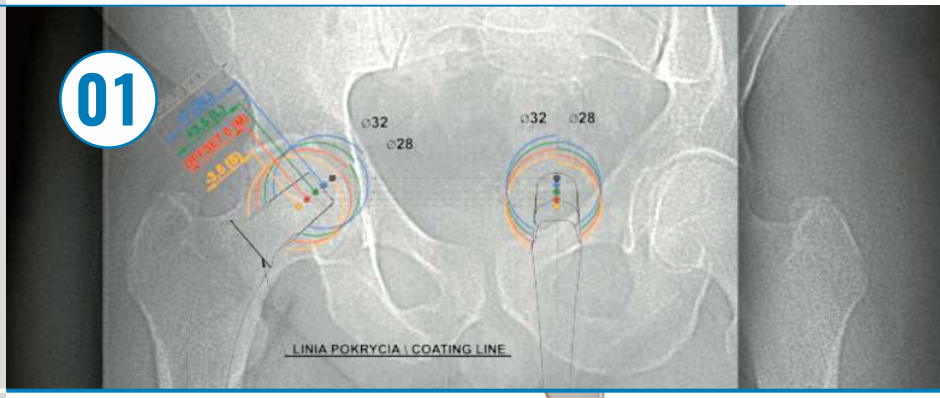
The femur should be placed in the neutral rotation position so that its orientation on the x-ray image corresponds to the template plane. The developed x-ray scan should have sufficient femoral stem length to determine the steml length. An adequate stem size should be selected by applying the template 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.



REVISION STEM - SURGICAL TECHNIQUE

PREOPERATIVE PLANNING

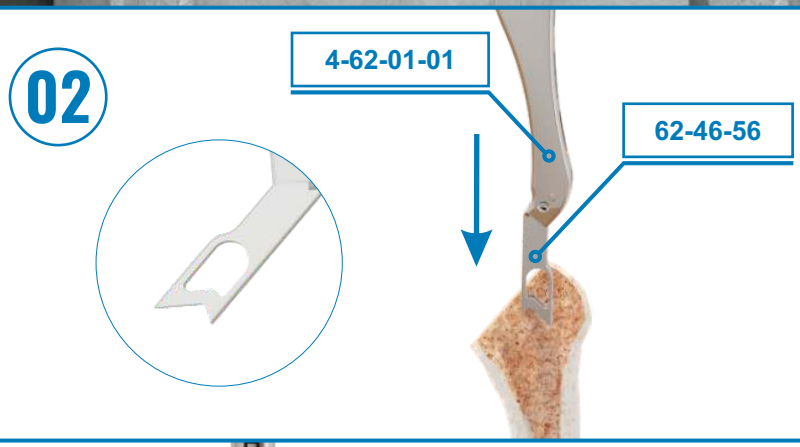
Before the surgery, the size of the endoprosthesis components should be selected using X-ray templates or software.



Prepare the medullary canal for the insertion of the rasp.

IMPORTANT: The initial path of the tools should be parallel to the axis of the femoral shaft.

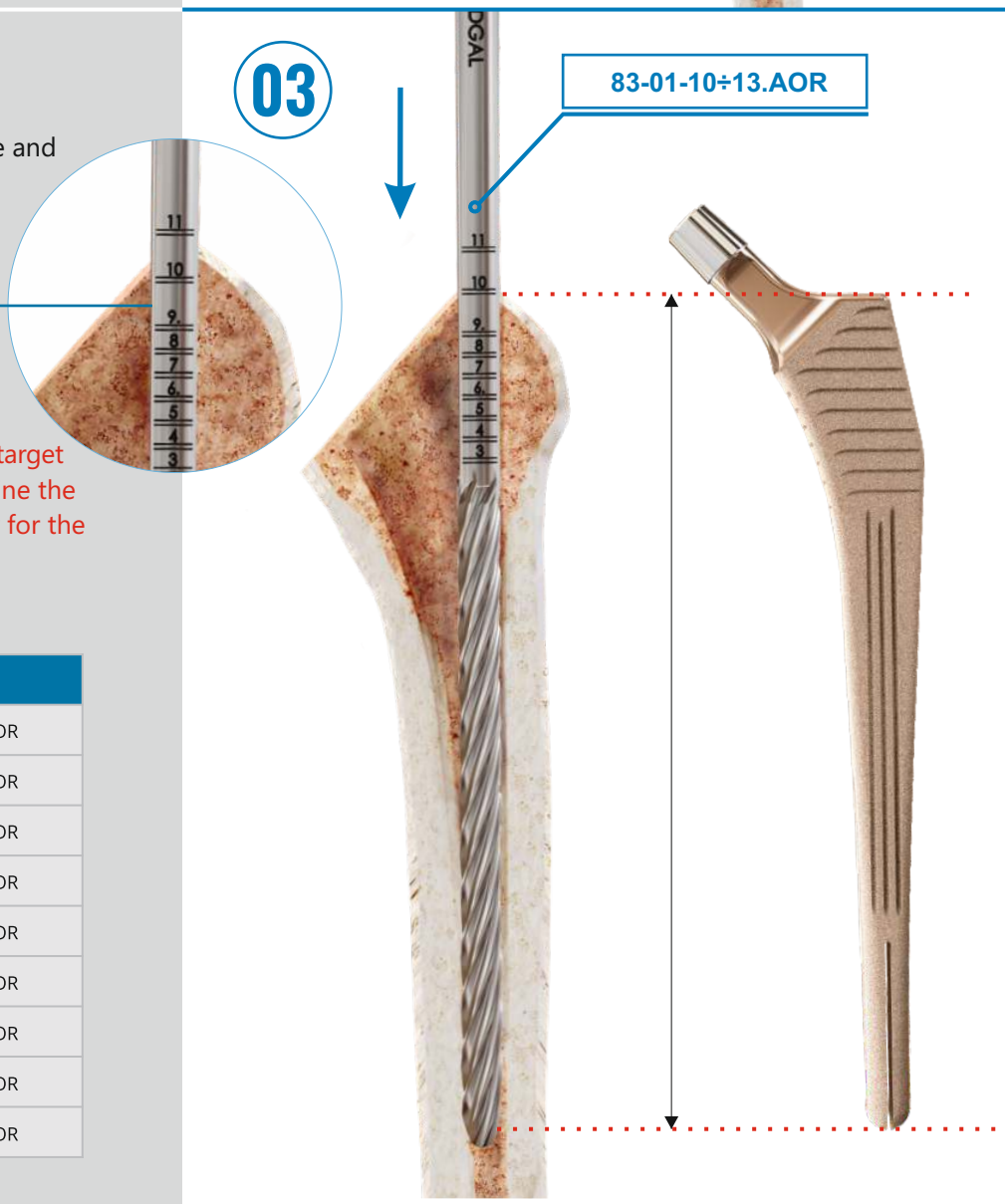
If it nesesary prepare medullary canal using osteostarter **62-46-56.**



Ream the bone using reamer **83-01-10÷13.AOR.**
Select the cutter based on the table and the selected stem size during presurgical planning, or use only the smallest one.

The length of the stem is represented by the marking on the cutter

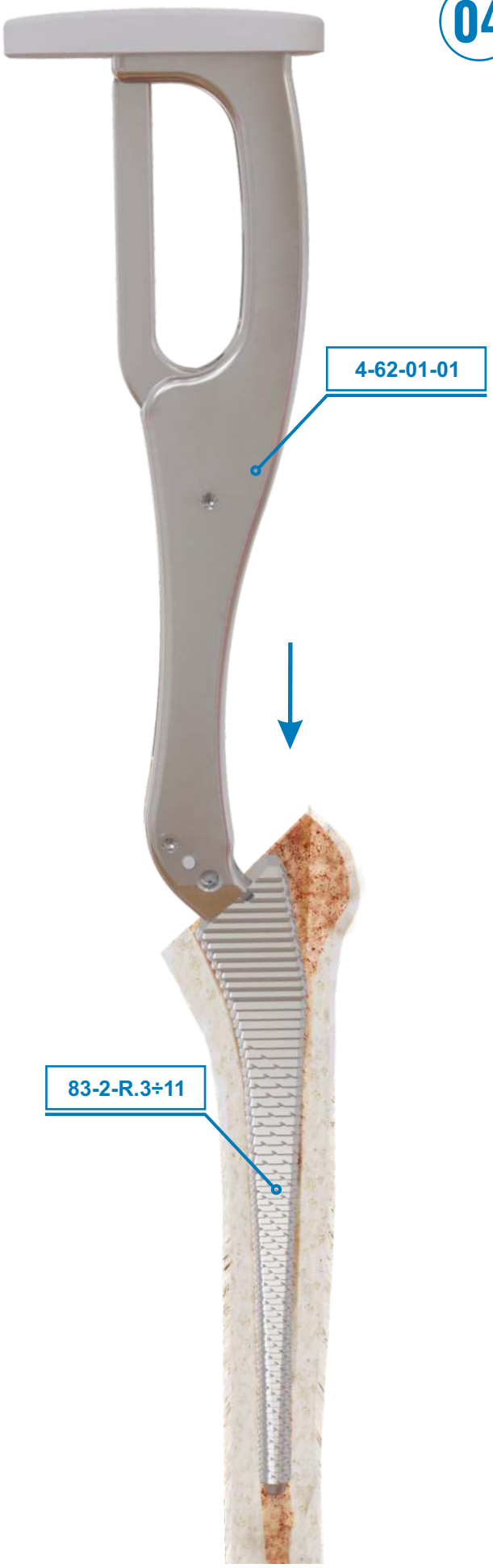
*The cutter does not determine the target stem size. A rasp is used to determine the target stem. The cutter is used only for the initial preparation of the canal.



Stem selection table:

Stem size	Cutter
3	83-01-10.AOR
4	83-01-10.AOR
5	83-01-10.AOR
6	83-01-10.AOR
7	83-01-10.AOR
8	83-01-11.AOR
9	83-01-11.AOR
10	83-01-11.AOR
11	83-01-12.AOR

04



Prepare the femoral marrow canal for the endoprosthesis stem using rasps attached to a rasp holder.

Start with the smallest size of the rasp, increasing the size by one until the top surface of the rasp is aligned with the resection line and the final rasp is firmly placed.

Check rotational stability and stability in the Medial-Lateral direction.

Caution: the orientation of the rasp insertion should respect the position of the marrow canal (medial-lateral or anterior-posterior).

Attach the trial head neck on the rasp.

Type of trial neck:

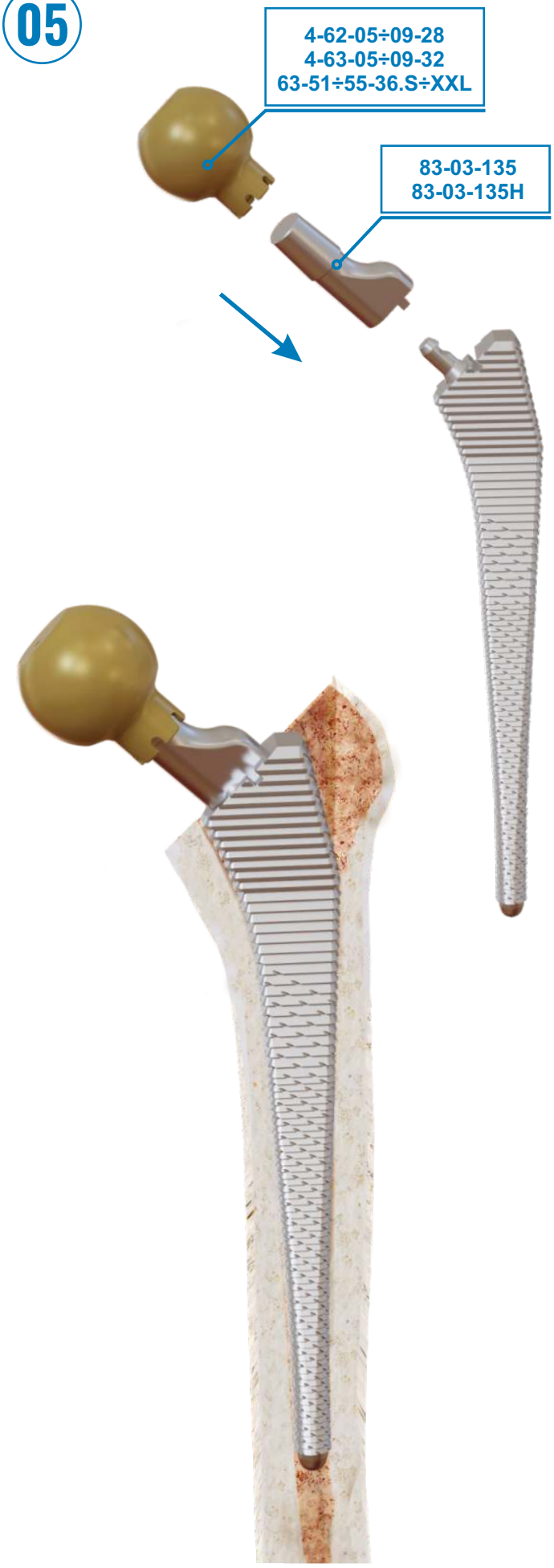
83-03-135

or

83-03-135H

Select size of the trial head before implantation.
Put on the trial head.

05



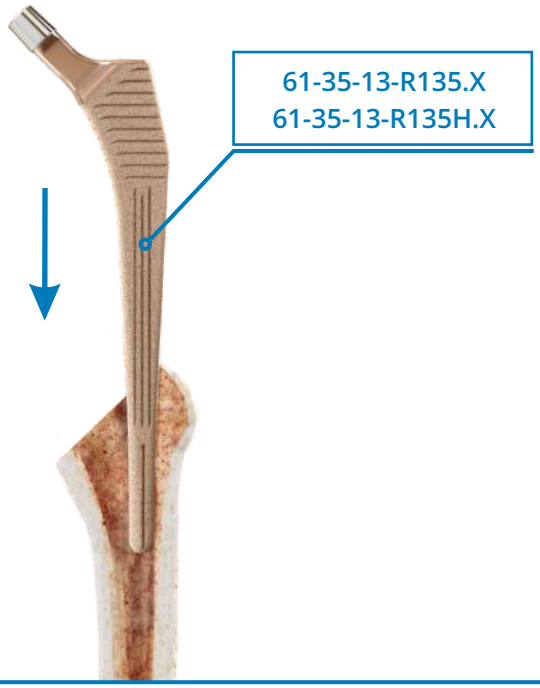
06

Check hip mobility and assess limb length. If necessary, change trial elements until optimal joint biomechanics is achieved.

CEMENTLESS STEM IMPLANTATION

Insert the stem into the hole prepared in the bone.

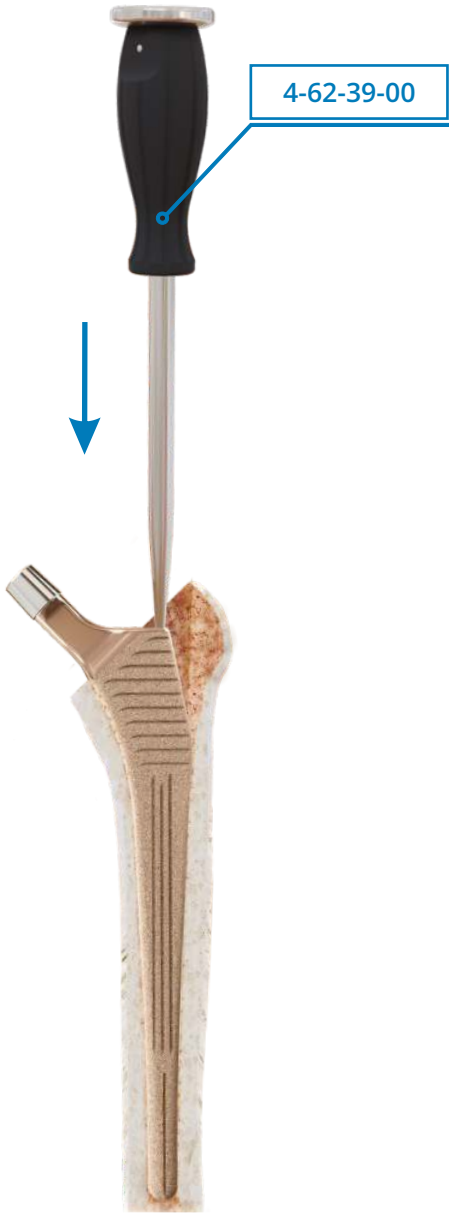
07



Implant the stem of the prosthesis into the femur using the stem impactor and the hammer. The covered part of the stem should be level with the line of resection.

IMPORTANT: After insertion and finishing of the stem, it is recommended to recheck the biomechanics of the joint and the length of the limb using a trial head.

08

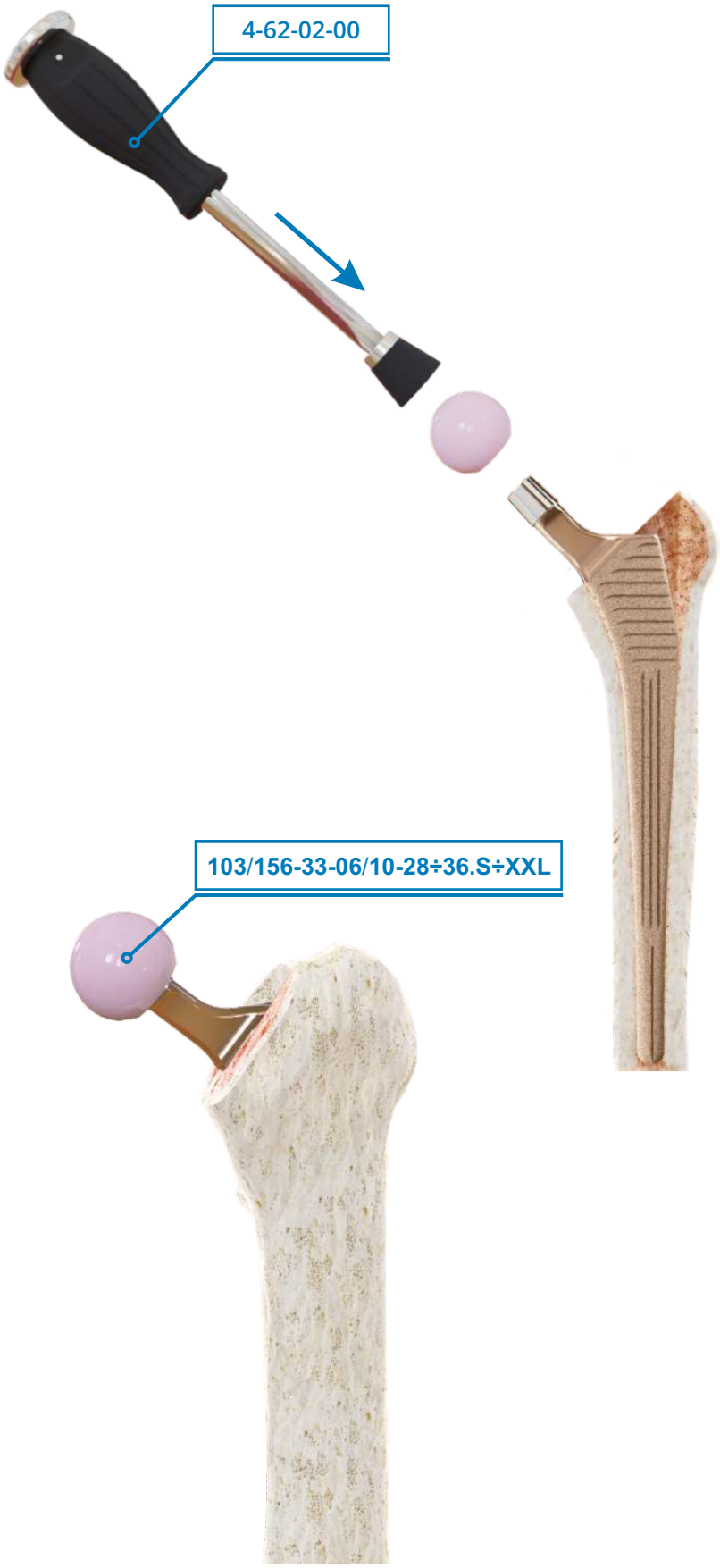


09

FEMORAL HEAD IMPLANTATION

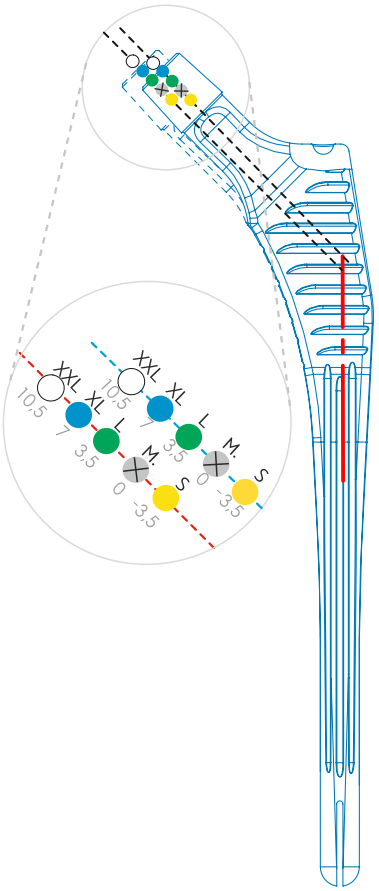
Place the head on the cleaned stem cone and finish it off using the head impactor and a hammer.

After use the instruments should be properly prepared for cleaning by removing the remaining bone fragments, carry out the cleaning process and re-sterilization.

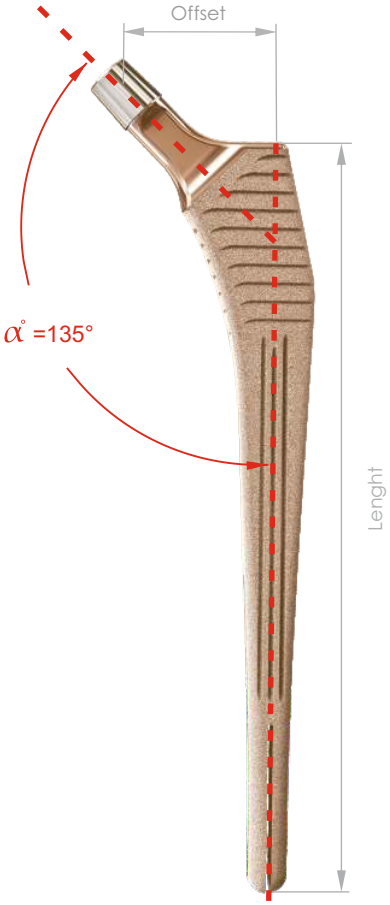


Revision Stem

HEAD OFFSET

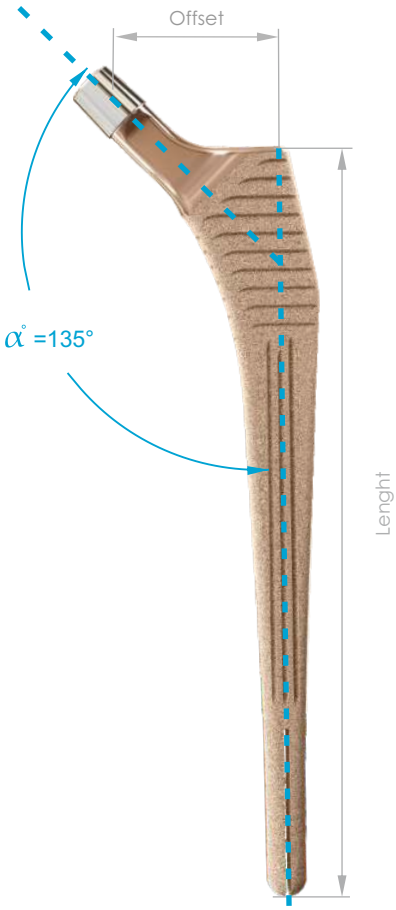


SIMPLE REVISION - STANDARD OFFSET



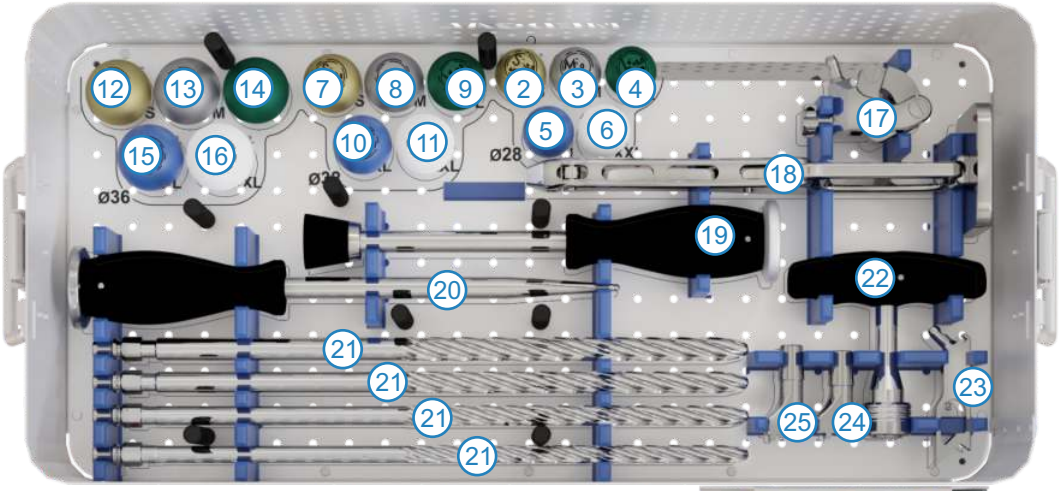
Offset	Length	REF No.
39,4	180	61-35-13-R135.3
39,9	185	61-35-13-R135.4
40,7	190	61-35-13-R135.5
41,2	195	61-35-13-R135.6
41,9	200	61-35-13-R135.7
42,6	205	61-35-13-R135.8
43,4	210	61-35-13-R135.9
44,4	220	61-35-13-R135.10
45,4	230	61-35-13-R135.11

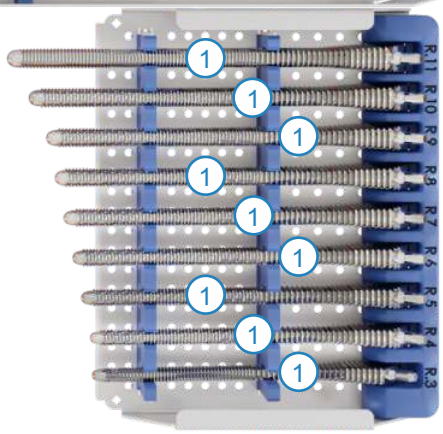
SIMPLE REVISION - HIGH OFFSET



Offset	Length	REF No.
44,4	180	61-35-13-R135H.3
44,9	185	61-35-13-R135H.4
45,6	190	61-35-13-R135H.5
46,2	195	61-35-13-R135H.6
46,9	200	61-35-13-R135H.7
47,6	205	61-35-13-R135H.8
48,4	210	61-35-13-R135H.9
49,4	220	61-35-13-R135H.10
50,4	230	61-35-13-R135H.11

INSTRUMENT SET - REVISION STEM
99-599-0





1	Rasp SIMPLE **3 - 11**	83-2-R.**3—11**
2	Trial head 28 mm S	4-62-05-28
3	Trial head 28 mm M	4-62-06-28
4	Trial head 28 mm L	4-62-07-28
5	Trial head 28 mm XL	4-62-08-28
6	Trial head 28 mm XXL	4-62-09-28
7	Trial head 32 mm S	4-63-05-32
8	Trial head 32 mm M	4-63-06-32
9	Trial head 32 mm L	4-63-07-32
10	Trial head 32 mm XL	4-63-08-32
11	Trial head 32 mm XXL	4-63-09-32
12	Trial head 36 mm S	63-51-36.S
13	Trial head 36 mm M	63-52-36.M
14	Trial head 36 mm L	63-53-36.L
15	Trial head 36 mm XL	63-54-36.XL
16	Trial head 36 mm XXL	63-55-36.XXL
17	Extractor	63-56-0
18	Rasp handle	4-62-01-01
19	Head impactor	4-62-02-00
20	Stem impactor	4-62-39-00
21	6-flute cutter Ø **10 - 13**	83-01-**10—13**.AOR
22	T handle (AO)	43-281-0.C
23	Osteostarter 56mm	62-46-56
24	Trial neck High Offset	83-03-135
25	Trial neck Standard Offset	83-03-135H

MEDGAL-HIP

POLISH PRODUCT

FIRST POLISH BIPOLAR AND REVISION
ENDOPROSTHESIS 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 make 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.
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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®

ORTHOPAEDIC IMPLANTS & INSTRUMENTS

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issue date: 27.06.2025 v. 5