BEZNOSKA
We bring back joy to movement

Hip Joint Stem
Type BEZNOSKA TRIO

Primary Hip Joint Implants
Femoral Components

ARTHRLOPLASTY

Implant Description

Cemented stem with centralizer
The centralizer ensures the balanced bone cement thickness from 1.0 mm to 1.5 mm. The thickness is determined by the sizes of rasp and stem (both).

Characteristics of implants:

Optionally, cemented or cementless stems can be used for implantation, depending on the type of stem.
Cemented stems require combination with a centralizer.
Cementless stem, Cementless modular stem.
Cementless options allow for making a choice between a stem with fixed neck or modular one.
Modular stems are set up with a range of necks having different angles.
Cemented option is polished to mirror-like gloss.
Upper third of the cementless option is plasma-coated with a layer of bioactive titanium oxide that ensures full biocompatibility of the implant.
Same basic instruments can be used for all stem types.

Caution for the surgeon: Before opting for implantation of the cemented stem, type Beznoska TRIO, sizes 1 & 2, it is essential to consider the patient's weight and motion activities. The manufacturer does not recommend to use stems in sizes 1 & 2 for implantation in patients either weighing over 80 kg or being exposed to excessive motion activities.

Fatigue Test of Stems Type BEZNOSKA TRIO

Fatigue tests of TEP hip joints are provided by European standards ISO 7206-4. The BEZNOSKA TRIO stem was tested at the Technical University in Liberec with the aid of a testing facility named Elektropulse, made by Instron. The tests took place in 2009 and 2010 and were conducted as follows:

- The stems were fastened in a basic braced frame and sloped at angles defined in the said standards;
- The stems were exposed to stress with the aid of axial ball bearing to avoid "parasitic" stress;
- Pulsing sinus stress: Fmin=200 N, Fmax=2300 N, mean value 1250 N;
- Stress frequency 20 Hz;
- Total number of stress cycles: 5 x 10^6.

Test Results

During the tests (three sets were tested) no damage to the stems was recorded (fracture or visual defect). In compliance with the said standards, it means that stem dimensions of hip joint replacement, type BEZNOSKA TRIO, are sufficiently proportioned. These test results were corroborated by means of MKP durability calculation.

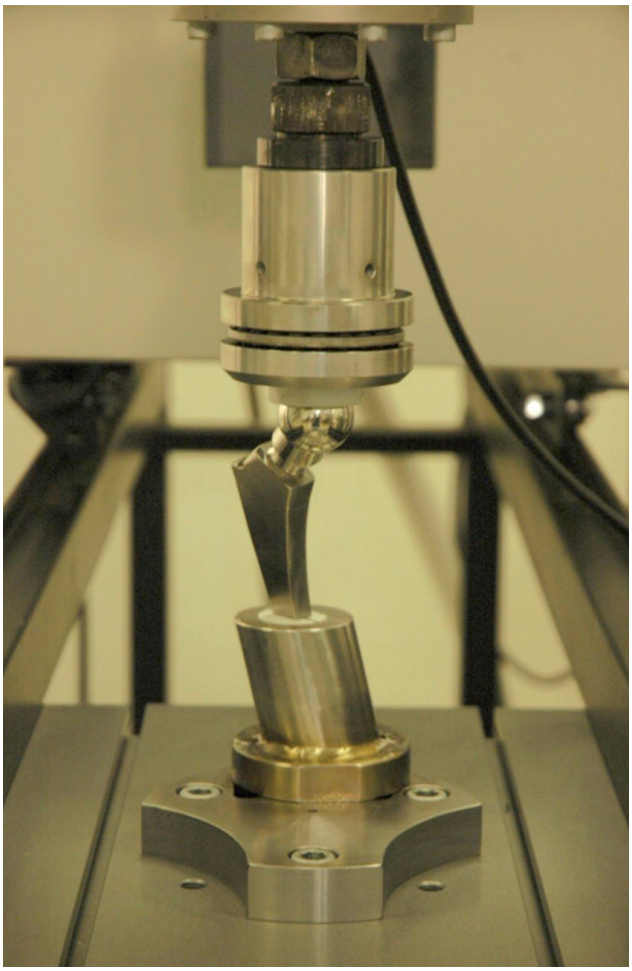


Fig. 1: Mounting a stem in the loading stand

Introduction

he complete assembly of the cementless total hip replacement is composed of the femoral component (stem and neck), head, and acetabular component (cup).

The type TRIO and TRIO/HA cementless stem for total hip replacement is designed using expertise and experience with cementless implants, and can be used in a hip TEP assembly with any acetabular component (cup) and head, provided that the diameter of the hip TEP head corresponds to the internal diameter of the articulation insert, and that the stem, head and cup meet the requirements for the flawless functioning of the arthroplasty assembly. The assembly can be used in combination with the entire available size spectrum without any limitation, provided that the stem is coupled with a 12/14 head.

For the abovementioned reasons, we only recommend using heads and cups manufactured by Beznoska company in the assembly with stem.

The stem is made of a titanium alloy and is surfaced using sophisticated technology on CNC-operated machining equipment. The surface of the proximal part of the stem is finished with a plasma coating consisting of a bioactive titanium oxide layer, which in the HA variant is supplemented with a hydroxyapatite layer. This HA layer ensures accelerated osteointegration of the implant.

The stem is designed in two versions; the first type of stem is a mono-block, while the alternative to this is a modular concept, where the neck is a separate part and is coupled together with the stem during surgery.

There is a broad spectrum of stem sizes available that enable virtually all cases of primo-implantation to be addressed. The instrumentation provided by the manufacturer for surgery allows simple and precise implantation.

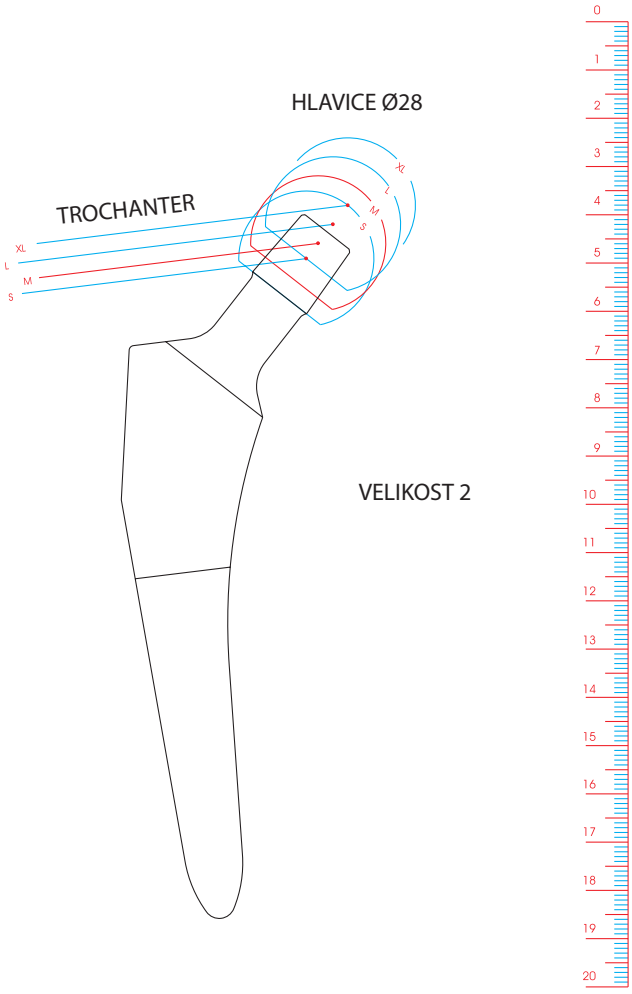
The TRIO and TRIO/HA cementless stem is indicated especially in active and cooperative patients in case of primary and secondary osteoarthritis of the hip, femoral head necrosis, inflammatory and post-inflammatory conditions (progressive polyarthritis, ankylosing spondylitis Bechtěrev), post-traumatic conditions (pseudoarthrosis of the femoral neck, acetabular fractures…), and for certain bone tumours.

Surgical Technique - General Rules

Before each total hip replacement surgery, it is necessary to do pre-surgery planning that enables us to determine the right size of femoral components.

For pre-surgery planning we need an X-ray of pelvis and both hip joints in A/P and axial projections to be able to assess the width of metaphysis. Planning of the size of femoral components is done with the aid of templates, delivered by the manufacturer. Full-size transparent templates are provided, i.e. a scale of 1:1. To determine the correct size of the components, it is necessary to have the x-rays calibrated such that both the bone and the control element used are located the same distance from the x-ray source. We recommend using a metal gauge with a scale, or a round-shaped gauge with precisely defined dimensions.

Different approaches can be applied in a TEP surgery, depending on the given surgeon's experience. The same principle is applied to the MIS technique. Due to the fact that the surgical technique of femoral components (cemented, cementless, modular) is concerned with here, we do not mention techniques used in implantation of acetabular components.



Example of supplied template comparing the size of cementless stem to its X-ray.

Surgical Technique - Femoral Component Implantation

1. Opening the bone marrow canal

When using the posterior approach to the hip joint, it is advised to open the bone marrow canal with the aid of "T" 28 head perforator 26 (Fig. 1).

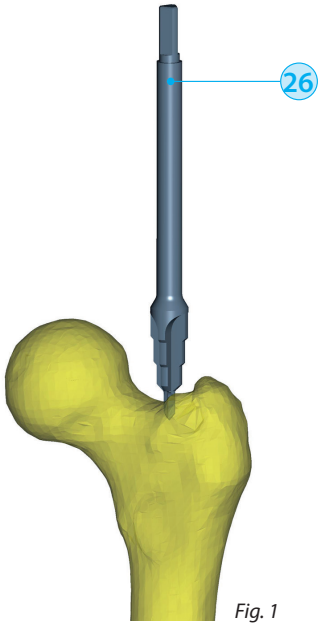


Fig. 1

2. Resecting the femoral neck

After having disarticulated the hip joint head and inserted the suitable elevatory instruments 39 to 44 all the way up to the line where we intend to do the neck osteotomy, we take the oscillatory saw to perform the resection (Fig. 2).

Note: *Neck osteotomy can also be performed in situ without previous head dislocation. It is gentler on soft tissue.*

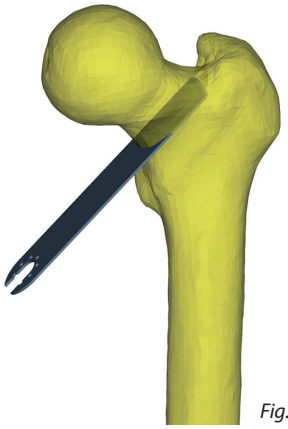


Fig. 2

- references on instruments correspond to their layout(s) in the trays (see pp. 13-16)

3. Preparing access into the bone marrow cavity

To open the bone marrow canal, we use the wicket chisel 29 mounted on the rasp snapon handle 27. The chisel point is contouring the inner lateral facet of metaphysis. In this leg, it is essential to respect the femoral component anteversion (Fig. 3).

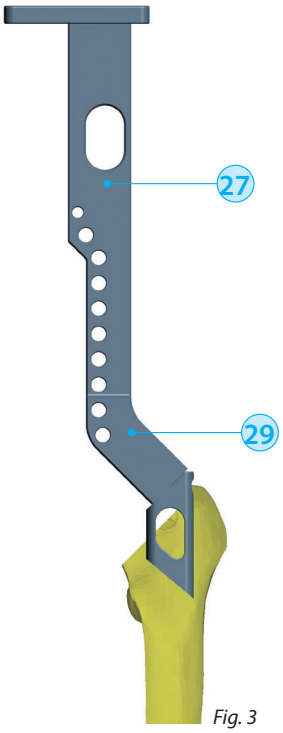


Fig. 3

4. Rasping of the bone marrow cavity

For preparation of the bone marrow canal, there is a set of ten rasps 1 to 10 with a cylindrical neck tail-piece for mounting in a snap-on handle 27 and, for the next step, there are 21 to 25 metal trial necks and 11 to 20 plastic heads (or 30 to 35 for ceramics).
In the handle there are holes for inserting the targeting pin 36 that determines the rasp anteversion. The trial necks differ upon the type of implant – five different trial necks are available. The basic, straight neck corresponds to cemented and cementless stems, type monoblock. The other four ones differ as their names indicate: varus, valgus, ante, retro.
These necks match the modular necks of cementless modular stem. The shape of rasp corresponds to the profile of bone marrow cavity. The rasp dimensions are identical for all types of BEZNOSKA TRIO stems (cemented, cementless, modular). Preparation of the bone marrow cavity begins with the smallest rasp. As we continue working the bone marrow canal on, we increase step-by-step the size until full contact with the cortical bone is reached and, simultaneously, the osteotomy line is even with the toothed part of rasp (Fig. 4).

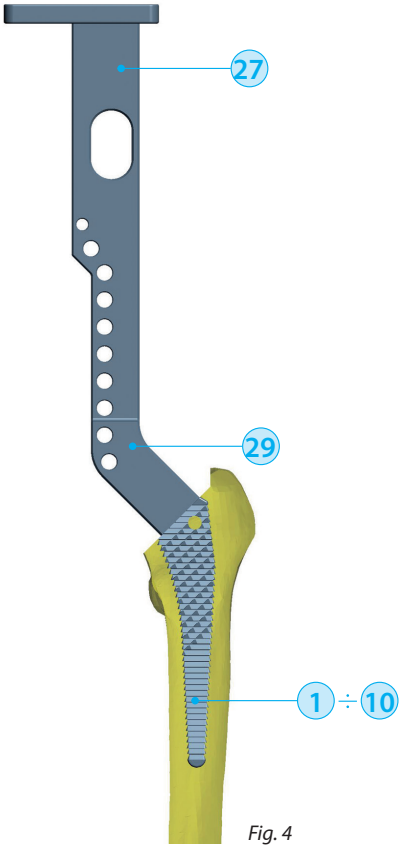


Fig. 4

Note: *Prior to inserting the first rasp, it is useful first to verify the shape and position of the modular canal using a small perforator, and to determine the direction for inserting the rasp. In a situation when a modular canal deformity, such as femoral dysplasia, does not allow the insertion of the rasp in the correct anteversion, preparations should be aimed at implantation with a modular femoral component.*

5. First Trial Articulation

The first-fitting procedures may vary, depending on the type of planned (preferred) component:

a) If we want to apply a cemented or cementless stem with a fixed neck, we opt for a straight-neck rasp (135°/0°), selecting a metal trial neck 21 with a plastic head of the selected size (S, M, L, XL, XXL) and 11 to 20 diameter (or 30 to 35 for ceramics) (Fig. 5a).

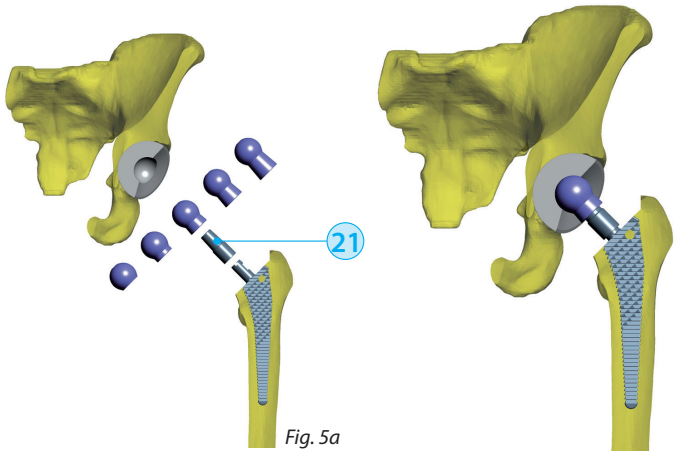


Fig. 5a

b) If a modular stem is used, we fit the rasp neck with the metal modular trial neck 22 to 25 and plastic trial head of the chosen size (S, M, L, XL, XXL) and 11 to 20 diameter (or 30 to 35 for ceramics) (Fig. 5b).

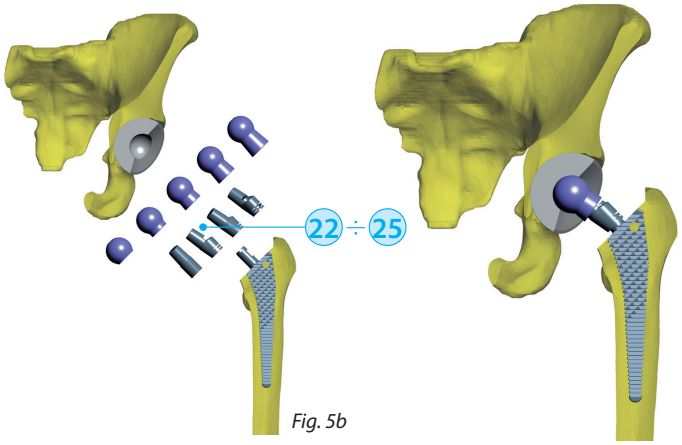


Fig. 5b

During trial articulation we evaluate the hip joint stability and scope of mobility. At this leg we decide definitively about the type of stem to be implanted, as well as the mode of its fixation (according to the bone tissue quality). Other decision-making factors to be taken into consideration include less-than-perfect stability during the articulation, atypical anatomical properties of acetabulum, or other atypical features impacting on the choice of implant for the surgery.

Well-done trial articulation optimizes the subsequent decision-making.

6. Definitive Stem Insertion

a) inserting a cemented stem
b) inserting a cementless stem
c) inserting a cementless modular stem

Ad a)

The definitive cemented stem corresponding to the size of rasp used last may now be inserted into the bone marrow cavity, after inserting a centralizer of the size in question. Before inserting the stem,

the distal end of the bone marrow cavity is to be closed (blinded) with a plug of cancellous bone tissue extracted with the aid of a tubular drill bit 57. Insert the plug with the aid of the inserter 61 up to the very end of the bone marrow cavity/canal. Into the bone marrow cavity – properly flushed and thoroughly dried – we insert a Redon drain. Next, we fill the bone marrow cavity with a bone cement. While inserting the stem, we simultaneously remove the Redon drain. The stem is inserted with the aid of a guiding instrument that is fitted with a mobile positioning fork. The depth of the stem depends on the collar prominence which is marked on it (Fig. 6a).

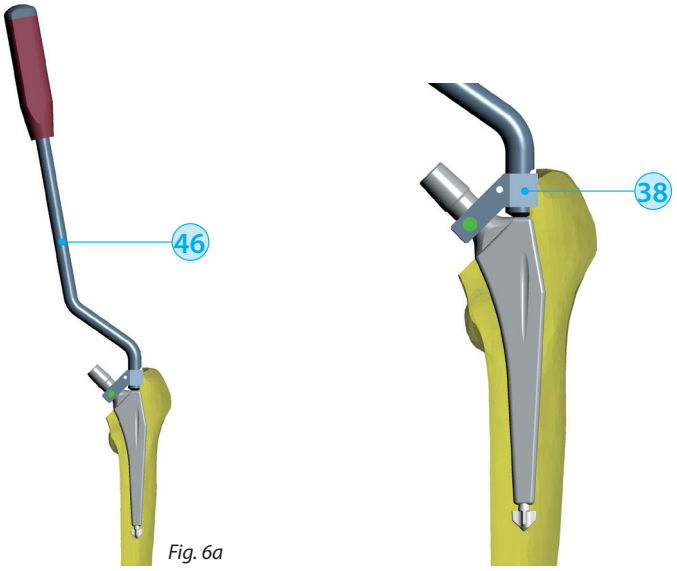


Fig. 6a

Note:
How to set the centralizer on a cemented stem up
The cross-cut profile of the distal stem section is shaped like an isosceles trapezoid, making the centralizer look like a cross with unequal arms. When setting the centralizer up, we make sure that its longer arms are parallel to with the trapezoid shorter arms, whereupon we turn the centralizer by 90° while simultaneously pressing it in the direction of the stem axis. If properly positioned, all of the centralizer arms have to overlap the stem circumferential contour by 1.0 mm –1.5 mm.
The surgeon inserts the stem into the bone cement manually; the specially forked inserter 46 is used only in the final stage for correcting the stem anteversion by means of the inserter driven 53 into the positioning fork 38.

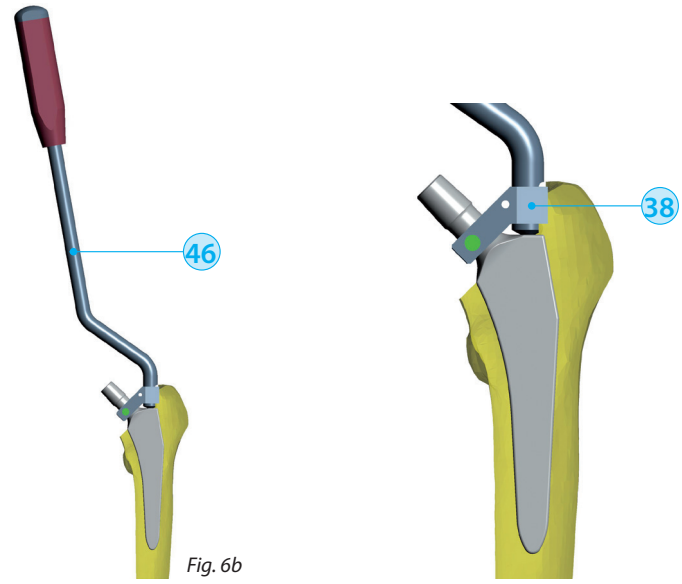


Fig. 6b

Ad b)
As above, the definitive cementless stem, too, corresponds to the size of rasp used last, except that – due to the greater dimensions of the stem (overlapping) compared to the dimensions of the rasp – the guiding instrument (as under par. [a]) 46

and the 300g hammer has to be used from the very beginning of the implantation procedure. The insertion itself is done with the aid of hammer. Only gentle taps are allowed. The correctness of the required anteversion has to be rechecked conscientiously. The depth of the insertion depends on the upper edge of the porous titanium coating with HA (Fig. 6b).

Ad c)
Inserting a definitive modular stem is, in essence, identical to inserting the cementless stem. However, its implantation requires a different inserter 45 designed specifically for modular stems.Its protruding points have to be fitted into the stem grooves; once in place, we screw them in with the aid of a ball screwdriver 47 and tighten the connecting screw. Then, in order to prevent penetration of dirt, insert a plastic plug 54 into the oval hole. As above, modular stems are inserted up to the upper edge of porous titanium coating with HA. Next, we carefully evaluate the anteversion reached, as any deviation could exert influence oup the choice of the neck module (Fig. 6c).

Plastic plug is removed after final implementation of the modular stem.

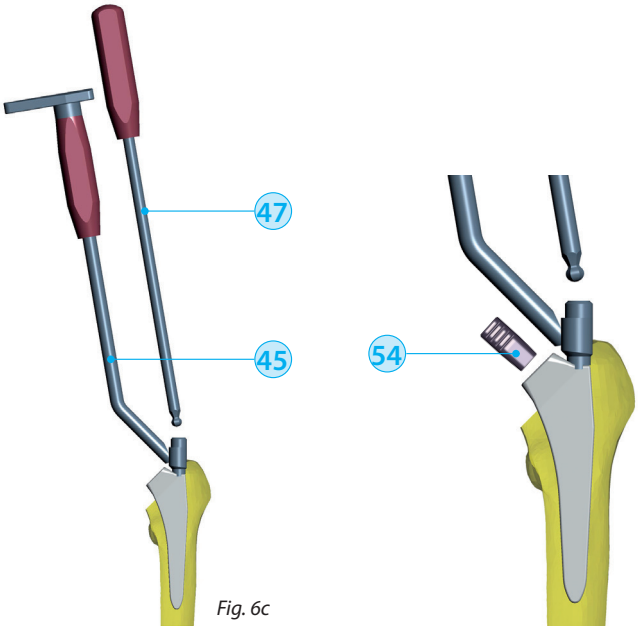


Fig. 6c

7. Second Trial Articulation

After definitive insertion of the stem, the second trial leg of surgery follows.

a) On stems with a fixed neck (cemented or cementless), we put a plastic trial head of our choice (S, M, L, XL, XXL) and 11 to 20 diameter (or 30 to 35 for ceramics) and perform final trial articulation (Fig. 7a).

b) The inserted modular stem has an oval aperture in its proximal part which we insert the metal trial modular neck 48 to 52 into – selected according to the results of the first trial articulation on the rasp. The color of the metal trial neck differs from that of the definitive implant. On this neck, we put the plastic trial head of the size chosen (S, M, L, XL, XXL) and 11 to 20 diameter (or 30 to 35 for ceramics). Once again, final trial articulation follows (Fig. 7b).

Note:
At this stage, we can still change the neck position by choosing a more suitable module. In this phase, the position of the neck can still be changed by selecting a more appropriate module at the cost of opening another sterile implant package. Extraction of unfitting neck is performed using a special modular neck extractor. For extracting the improper neck, we use a special extractor designed for modular necks 55.

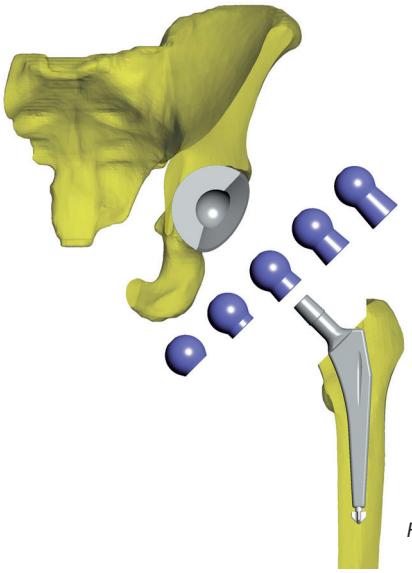


Fig. 7a

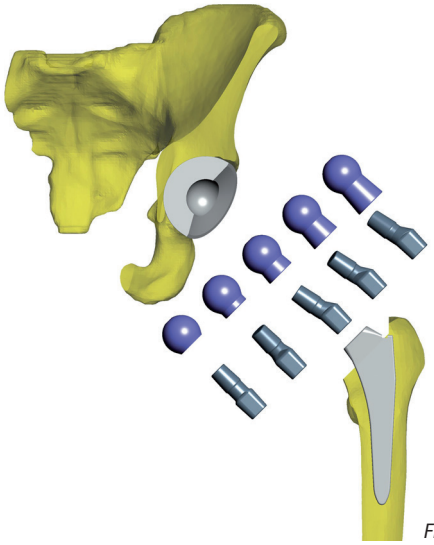


Fig. 7b

8. Definitive Articulation

Before final articulation, we have to remove the plastic trial head to be able to apply the definitive metal or ceramic head, Prior to final articulation, the test plastic heads must be removed, the final metal or ceramic heads assembled, and the final PE or ceramic cup inserts implanted, with final articulation performed using a special tool (impactor with a plastic cuff) and to perform definitive articulation using a special instrument 63 (stamper with a plastic support).

The total endoprosthesis surgery is finalized with a stability check and a verification of mobility scope (Fig. 8).

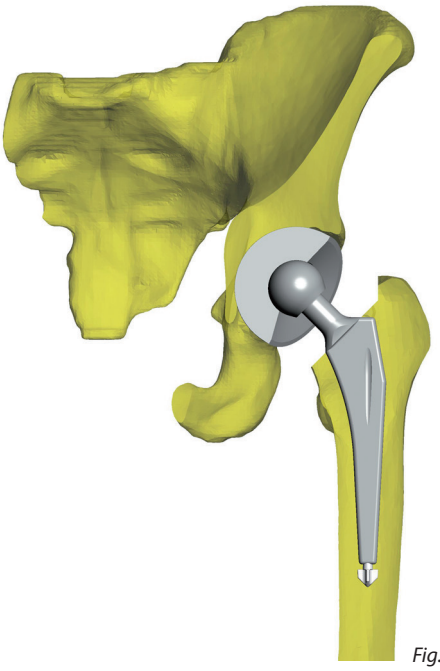
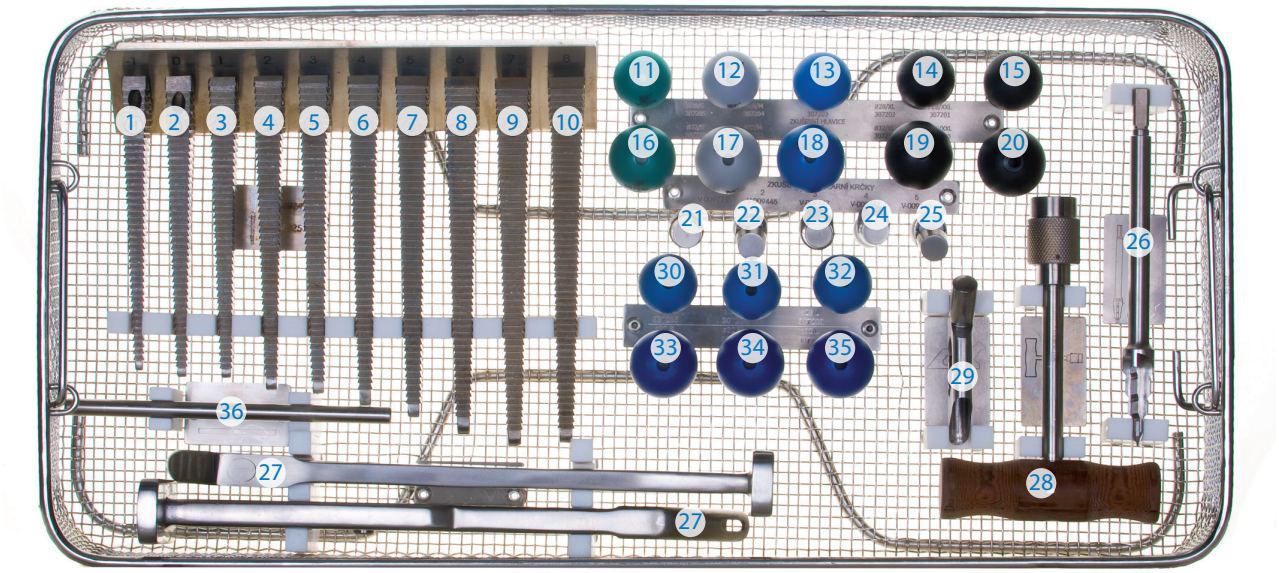


Fig. 8

Note:
If it is necessary to replace a stem with a fixed neck or modular type of neck, always use a special extractor (55, 56, 59, 60) and a spanner for stem extractor 62.

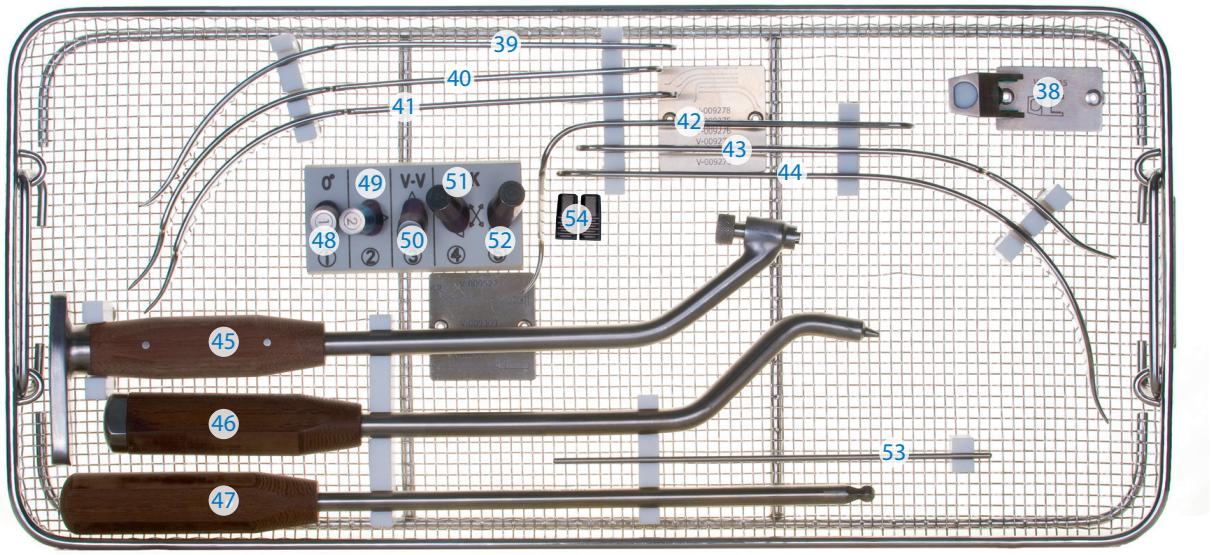
Instrumentation Set

The instrumentation set (art. 300006) is laid out into three trays being well-arranged not merely for transportation, storage, and preparation, but also for easy orientation and use during surgery theatre. The numerical identification of instruments corresponds to illustrations (Fig.) in the surgical technique. During transportation, the trays are stored in a sterilizable container.

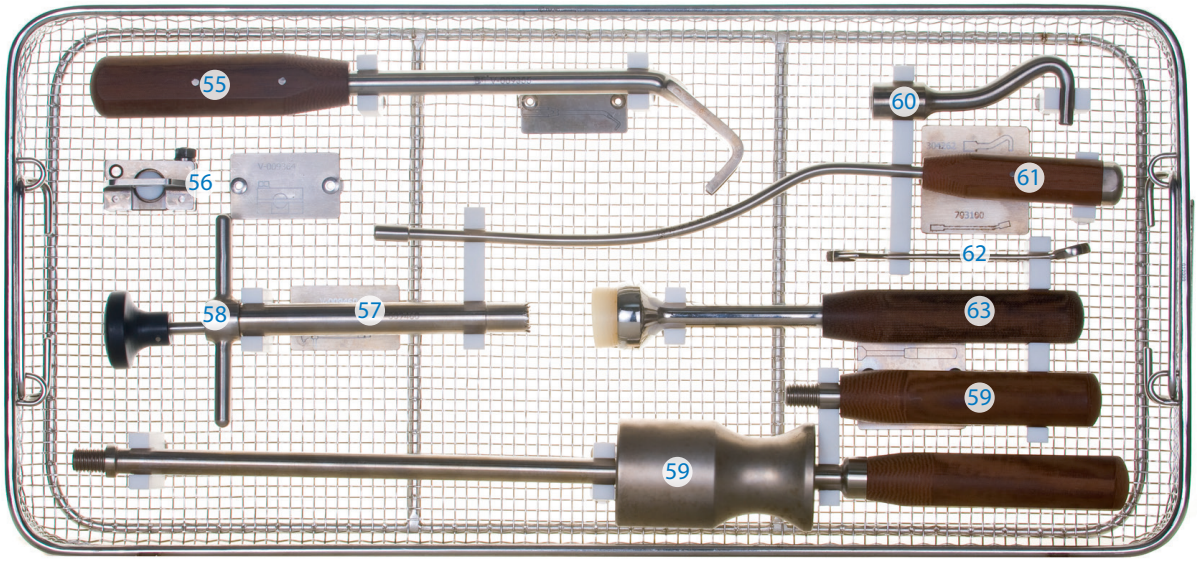


INSTRUMENTATION SET FOR HIP STEM, TYPE BEZNOSKA TRIO LAYOUT - TRAY 1			
	Denomination	**Qty**	**Order number**
	Tray		300015
1	Rasp size 01	1pc	301209
2	Rasp size 0	1pc	301210
3	Rasp size 1	1pc	301211
4	Rasp size 2	1pc	301212
5	Rasp size 3	1pc	301213
6	Rasp size 4	1pc	301214
7	Rasp size 5	1pc	301215
8	Rasp size 6	1pc	301216
9	Rasp size 7	1pc	301217
10	Rasp size 8	1pc	301218
11	Trial head 28/S	1pc	307205
12	Trial head 28/M	1pc	307204
13	Trial head 28/L	1pc	307203
14	Trial head 28/XL	1pc	307202
15	Trial head 28/XXL	1pc	307201
16	Trial head 32/S	1pc	307210
17	Trial head 32/M	1pc	307211
18	Trial head 32/L	1pc	307212

	Denomination	Qty	Order number
19	Trial head 32/XL	1pc	307213
20	Trial head 32/XXL	1pc	307214
21	Trial on-rasp neck, type 1	1pc	301221
22	Trial on-rasp neck, type 2	1pc	301222
23	Trial on-rasp neck, type 3	1pc	301223
24	Trial on-rasp neck, type 4	1pc	301224
25	Trial on-rasp neck, type 5	1pc	301225
26	Perforator	2pcs	304000
27	Handle of easy clamping rasp	1pc	301202
28	„T“ head	1pc	304002
29	Wicket chisel	1pc	301203
30	Trial head for ceramics 28/S	1pc	307220
31	Trial head for ceramics 28/M	1pc	307221
32	Trial head for ceramics 28/L	1pc	307222
33	Trial head for ceramics 32/S	1pc	307225
34	Trial head for ceramics 32/M	1pc	307226
35	Trial head for ceramics 32/L	1pc	307227
36	Guiding pin	1pc	301248



INSTRUMENTATION SET FOR HIP STEM, TYPE BEZNOSKA TRIO LAYOUT - TRAY 2			
	Denomination	**Qty**	**Order number**
	Tray		300016
38	Mobile positioning fork	1pc	301242
39	Crowbar MIS-dull	1pc	202402
40	Crowbar MIS-Homan 2	1pc	202404
41	Crowbar MIS-Müller	1pc	202403
42	Crowbar MIS-90°	1pc	202401
43	Crowbar MIS-Homan 1	2pcs	202406
44	Crowbar MIS-Cobra	1pc	202407
45	Inserter for modular stem	1pc	301243
46	Inserter for stem with neck	1pc	301241
47	Ball screwdriver - 8mm	1pc	102446
48	Trial neck for stem type 1	1pc	301231
49	Trial neck for stem type 2	1pc	301232
50	Trial neck for stem type 3	1pc	301233
51	Trial neck for stem type 4	1pc	301234
52	Trial neck for stem type 5	1pc	301235
53	Guiding wire 3-200	1pc	301246
54	Plug of modular stem	2pc	301226

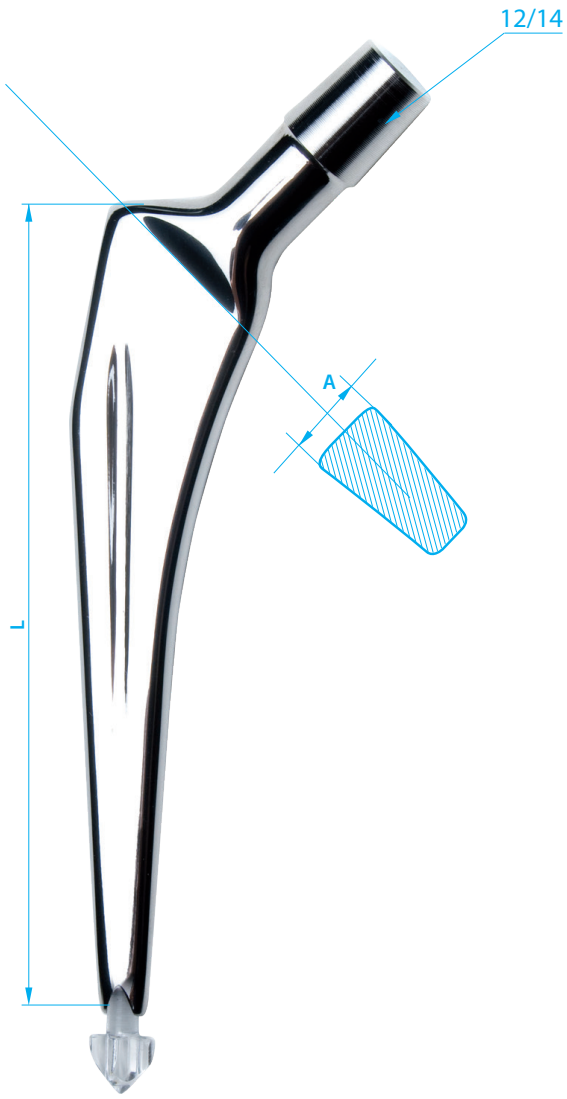


INSTRUMENTATION SET FOR HIP STEM, TYPE BEZNOSKA TRIO LAYOUT - TRAY 3			
	Denomination	**Qty**	**Order number**
	Tray		300017
55	Extractor for modular neck	1pc	301245
56	Extractor for stem with neck	1pc	301244
57	Tubular drill bit 11	1pc	301240
58	Tubular drill piston	1pc	301247
59	Extractor	1pc	301512
60	Extractor hook	1pc	304262
61	Plug inserter - size 11	1pc	301250
62	Flat-eyelet spanner 10	1pc	703100
63	Head inserter	1pc	304075

Note: *The tray layout is only of an informative character and may be amended depending on future innovation.*

Cemented stem type BEZNOSKA TRIO

Material: Stem – high-nitrogen stainless steel (ISO 5832-9)
Centralizer – PMMA



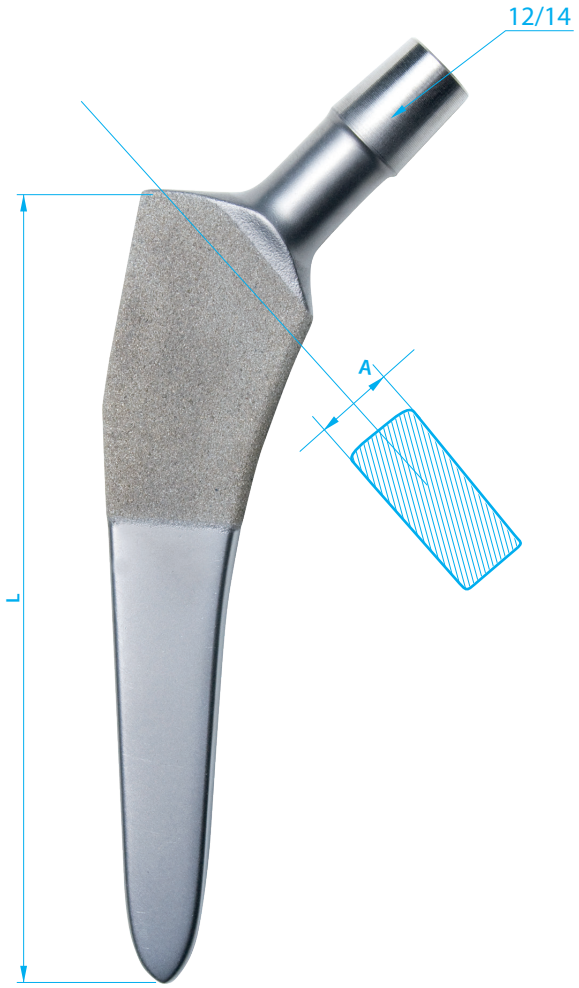
Cemented Stem			
Size	**L [mm]**	**A [mm]**	**Order number**
01	115	11,0	321999
0	115	11,5	322000
1	115	11,0	322001
2	120	11,5	322002
3	125	11,7	322003
4	130	12,0	322004
5	135	12,3	322005
6	140	12,5	322006
7	145	13,0	322007
8	150	13,5	322008

Centralizer PMMA	
Size	**Order number**
01	317019
0	317020
1	317021
2	317022
3	317023
4	317024
5	317025
6	317026
7	317027
8	317028

Note: *CCD angle - 135°*

Cementless stem type BEZNOSKA TRIO

Material: Titanium alloy Ti6Al4V (ISO 5832-3)

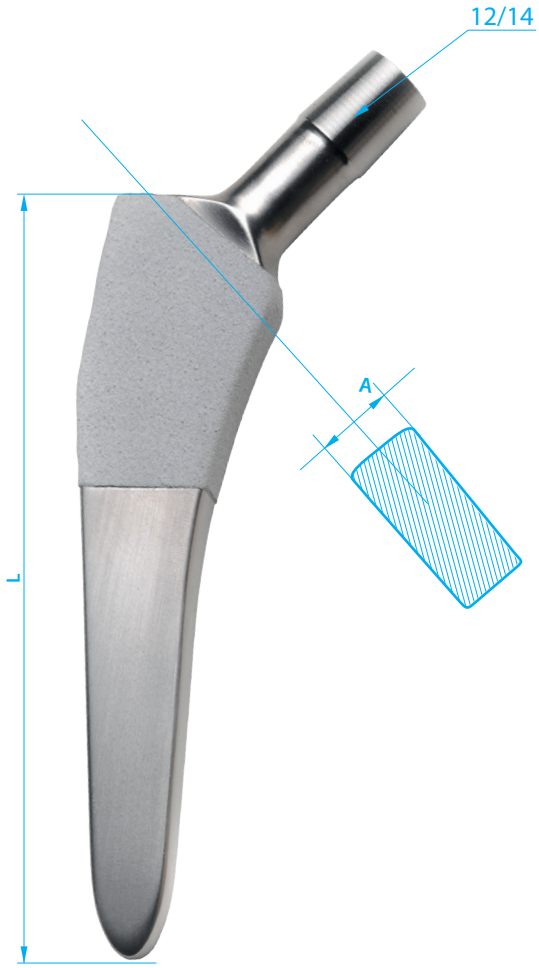


Cementless Stem			
Size	**L [mm]**	**A [mm]**	**Order number**
01	115	12,0	322013
0	115	12,5	322014
1	115	13,0	322015
2	120	13,5	322016
3	125	14,0	322017
4	130	14,5	322018
5	135	15,0	322019
6	140	15,5	322020
7	145	16,0	322021
8	150	16,5	322022

Note: *CCD angle - 135°*

Cementless stem type BEZNOSKA TRIO HA

Material: Titanium alloy Ti6Al4V (ISO 5832-3)

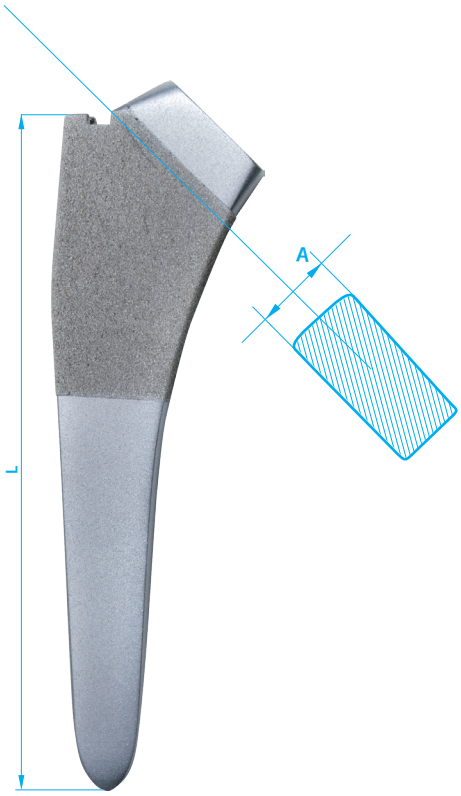


Cementless stem HA			
Size	**L [mm]**	**A [mm]**	**Order number**
01	115	12,0	321913
0	115	12,5	321914
1	115	13,0	321915
2	120	13,5	321916
3	125	14,0	321917
4	130	14,5	321918
5	135	15,0	321919
6	140	15,5	321920
7	145	16,0	321921
8	150	16,5	321922

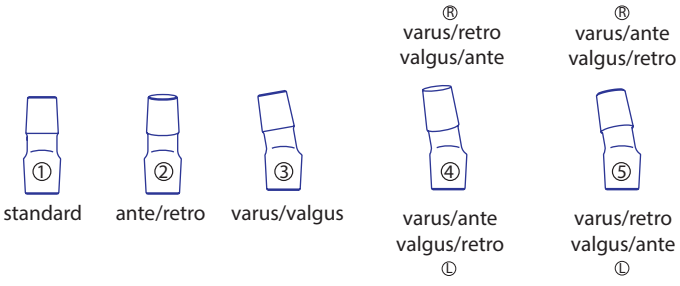
Note: *CCD angle - 135°*

Cementless Modular Stem Type BEZNOSKA TRIO

Material: Stem – Titanium alloy Ti6Al4V (ISO 5832-3)
Neck – Titanium alloy Ti6Al4V (ISO 5832-3)



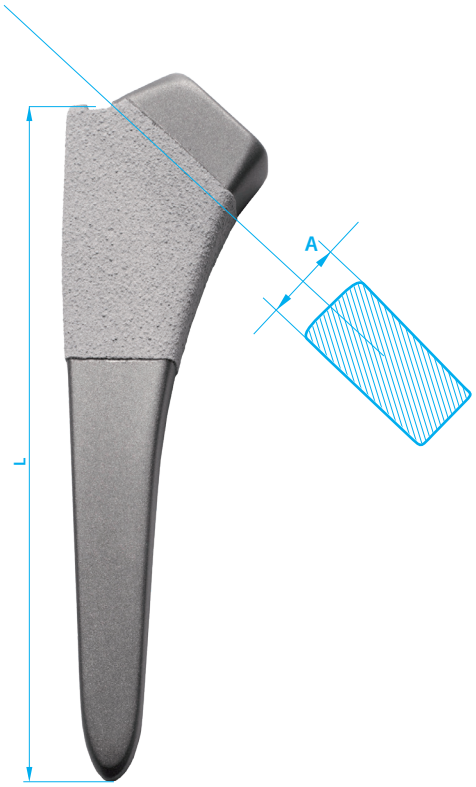
Modular Stem			
Size	**L [mm]**	**A [mm]**	**Order number**
01	115	12,0	322033
0	115	12,5	322034
1	115	13,0	322035
2	120	13,5	322036
3	125	14,0	322037
4	130	14,5	322038
5	135	15,0	322039
6	140	15,5	322040
7	145	16,0	322041
8	150	16,5	322042



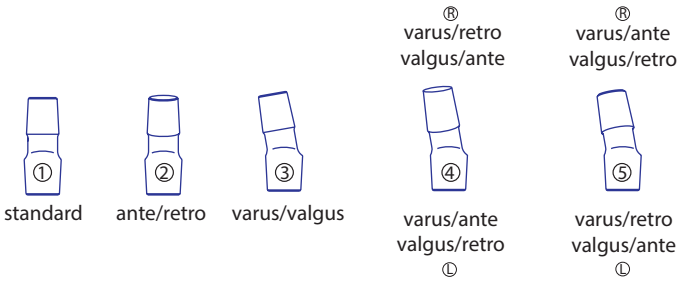
Neck type	Neck description		Implant reference		Order number
1	STANDARD		135°/ 0° T		321991
2	ANTE/RETRO		135°/ 10°	A ◄► R	321992
3	VARUS/VALGUS		125°/ 0° T	145°/ 0° T	321993
4	® VARUS/RETRO VALGUS/ANTE	Ⓛ VARUS/ANTE VALGUS/RETRO	125°/ 10° A (L) R (R)	145°/ 10° R (L) A (R)	321994
5	® VARUS/ANTE VALGUS/RETRO	Ⓛ VARUS/RETRO VALGUS/ANTE	125°/ 10° A (R) R (L)	145°/ 10° R (R) A (L)	321995

Cementless Modular Stem Type BEZNOSKA TRIO HA

Material: Stem – Titanium alloy Ti6Al4V (ISO 5832-3)
Neck – Titanium alloy Ti6Al4V (ISO 5832-3)



Modular Stem			
Size	**L [mm]**	**A [mm]**	**Order number**
01	115	12,0	321933
0	115	12,5	321934
1	115	13,0	321935
2	120	13,5	321936
3	125	14,0	321937
4	130	14,5	321938
5	135	15,0	321939
6	140	15,5	321940
7	145	16,0	321941
8	150	16,5	321942



Neck type	Neck description		Implant reference		Order number
1	STANDARD		135°/ 0° T		321991
2	ANTE/RETRO		135°/ 10°	A ◄► R	321992
3	VARUS/VALGUS		125°/ 0° T	145°/ 0° T	321993
4	® VARUS/RETRO VALGUS/ANTE	Ⓛ VARUS/ANTE VALGUS/RETRO	125°/ 10° A (L) R (R)	145°/ 10° R (L) A (R)	321994
5	® VARUS/ANTE VALGUS/RETRO	Ⓛ VARUS/RETRO VALGUS/ANTE	125°/ 10° A (R) R (L)	145°/ 10° R (R) A (L)	321995

Combination of stems BEZNOSKA TRIO with other implants manufactured by BEZNOSKA company

Metal head

Cobalt head

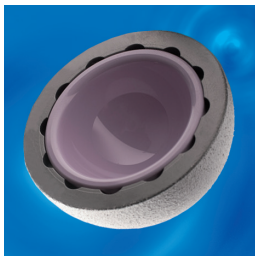
Ceramic head

Cemented cup
type 02

Cemented cup
type Poldi

Cementless cup
type SF

Cementless cup
type DUO



Reconstruction
cage type BS

Oval revision
shell type TC

BEZNOSKA
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