BEZNOSKA

We bring back joy to movement

Humeral head resurfacing

Primary Implants

ARTHROPLASTY

Preface

The surface finish of the humeral head implant has been developed using state-of-the-art knowledge and experience with the finishes of non-cemented implants. It is made of a cobalt alloy using the latest finishing technology. Facets that come into contact with bone tissue are covered with bioactive porous coating of titanium oxide to ensure optimal integration of the implant. The head's external surface is polished to mirror-like gloss. The use of instruments from the implant's manufacturer facilitates the implantation process and ensures perfect fixation of the implant. The instruments are available in a broad range of dimensions, enabling the surgeon to accommodate practically all common anatomical dispositions.

Implant characteristics:

- Assorted dimensions
  - a lower or higher variant can be chosen for each of the five sizes
- Perfectly prepared humeral head
  - excellent primary fixatione
- Bioactive coating
  - confirmed fast secondary fixation by osteointe gration

Indication:

- omarthrosis
- rheumatoid arthritis
- avascular necrosis
- "cuff tear" arthropathy
- collapse of humeral head surface (post-trauma condition)

A. The Surgical approach

For implantation of the humeral head surface replacement we use the deltopectoral approach. The incision begins below the A-C joint and continues medially with a straight cut towards the insertion of the delta muscle, cutting simultaneously through the clavipectoral fascia.

With a dull instrument, we clear the space between the delta and pectoral muscle by pushing the delta muscle away laterally, along with vena cephalica. Thereupon we abduct the arm to 40-60° with external rotation of 20° and induce the retractor into the subacromial space between the delta muscle and rotator cuff. Another retractor is convenient to be placed also above the upper end of the acromion.

This is followed by careful visualization of the nervus axillaris. Thereupon we identify the sulcus bicipitalis and the insertion of musculus subscapularis that we loosen sharply from the small node, thus gaining access to the glenohumeral joint.

Thereupon we cut through the subscapular ligamentous complex above the humeral head and then the joint's capsule. Upon exposing the glenohumeral ligaments, we loosen them and dislocate the loosened head of the humerus on the front side, Fig. A.

B. Preparing the humeral head resurfacing

B1. Size of the head and its anatomical cente

Using a gauge, we assess the right size of the head, preliminarily, and then – depending on the size – we use the aiming device for determining the anatomical center of the humeral head, Fig. 1, 2. Using the aiming device, we induce the guiding wire, Fig. 3a, 3b.

Fig.: A

Fig. 1: Making preliminary assessment of the size of the head

Fig. 2: Determining the anatomical center of the head

Fig. 3a: Aiming and inducing the guide wire

Fig. 3b: Aiming and inducing the guide wire

B2. Milling the head surface

Using a suitable milling cutter (according to x-ray and gauge), we remove the layer of cartilage on the head so that the thickness of the cartilage left corresponds to the thickness of the surface replacement selected. Fig. 4, 5

Using a rake cutter, we grind off the remaining surface on the top of the head Fig. 6, 7.

Thereupon we examine the head's surface to see whether all the damaged parts have been removed, using a control cap to make sure that the head's upper facet is properly prepared for the selected size of implant, Fig.8.

Fig. 4: Removing cartilage from the head

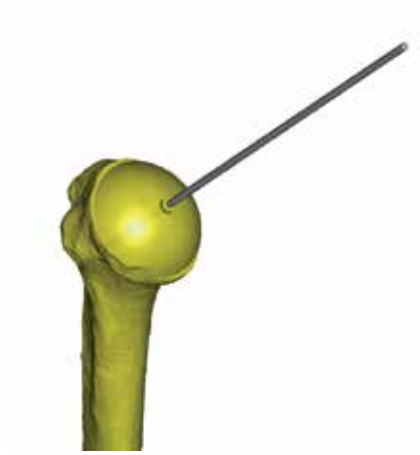


Fig. 5: Removing cartilage from the head

Fig. 6: Cutting off residual parts

Fig. 7: Cutting off residual parts

Fig. 8: Checking the head surface

B3. Milling a hole for the anchoring stem of the humeral head resurfacing

Using a milling cutter of corresponding size, we create a canal for the anchoring stem of the humeral head surface replacement, Fig. 9,10. After removing the cutter and the guiding wire, we may start trial fitting of the joint.

Fig. 9: Cutting a channel for the implant's anchoring stem

B4. Trial fitting

Remove the stem's cutter and the guiding wire. Depending on the size of the cutter, the head, and the trial cap, select the appropriate size of humeral head surface replacement.

Insert the trial head with the aid of the stem into the prepared opening and tap it into position using the tapping block, Fig.11,12,13. The trial replacement.

Fig. 10: Cutting a channel for the implant's anchoring stem

The transition between the definitive humeral head surface replacement and the surrounding bone tissue has to be smooth, i.e., it must not overlap over the edge to prevent impingement.

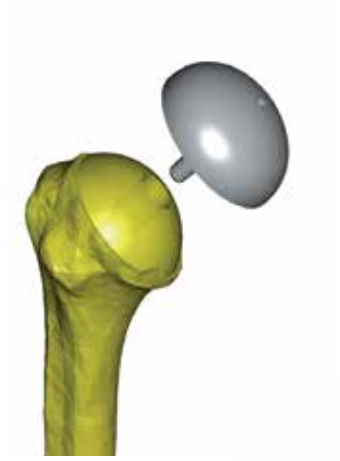


Fig. 11: Inserting the trial head

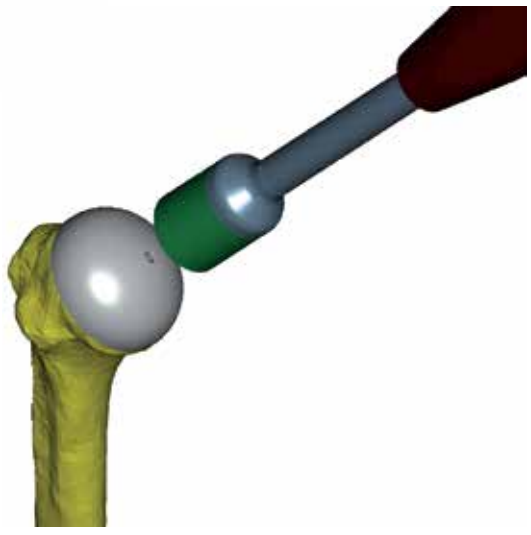


Fig. 12: Inserting the trial head

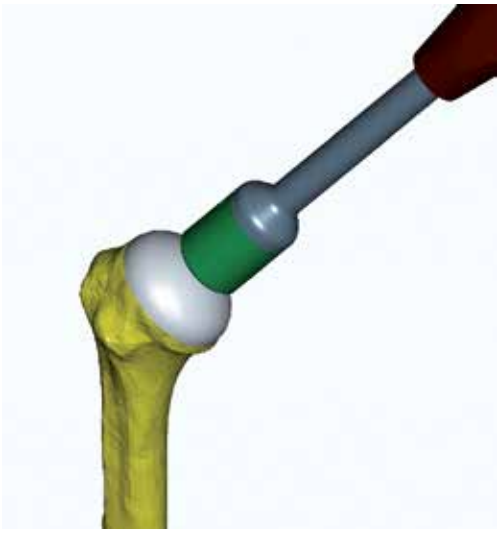


Fig. 13: Inserting the trial head

B5. Removing the trial head

Take out the trial head with the aid of the extractor, Fig.14,15.

If the trial head reaches over the edge of the surrounding bone tissue or if we decide to choose a head of a different size, we can work on the head's surface a little more using the right milling cutter, see below, Fig. B6.

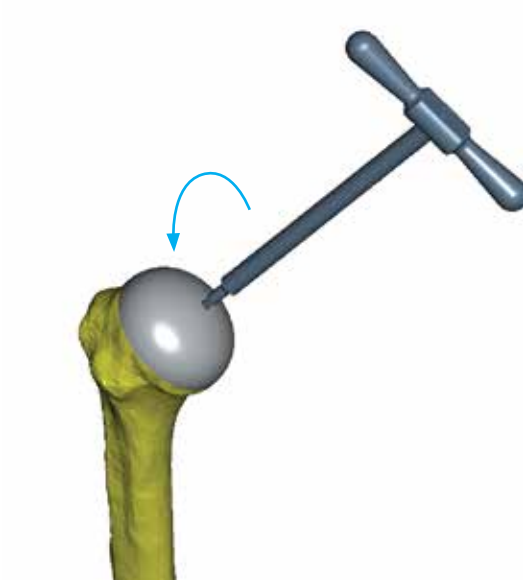


Fig. 14: Removing the trial head

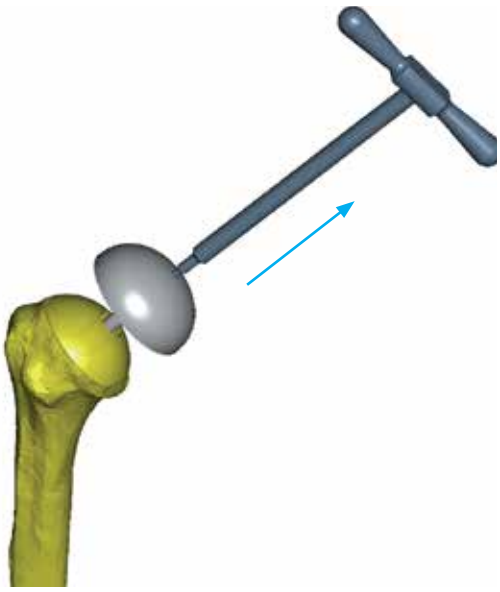


Fig. 15: Removing the trial head

B6. Additional preparation of the head's surface

Insert the guiding wire with the cone into the canal prepared for the anchoring stem and, using a milling cutter of appropriate size, we grind off excessive bone tissue until the transition between the cutter's surface and the remaining parts of the humeral head is smooth, Fig.16-19.

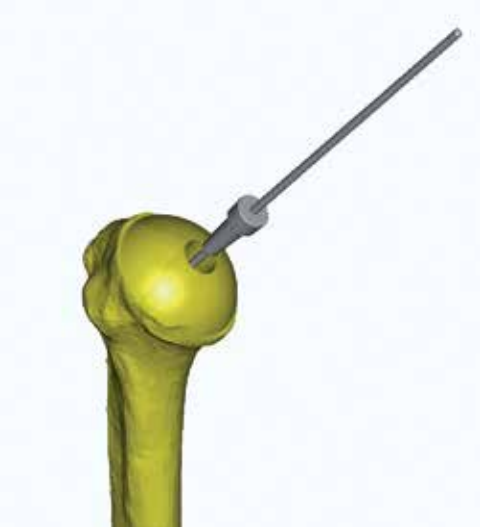


Fig. 16: Inducing the guide wire with a cone

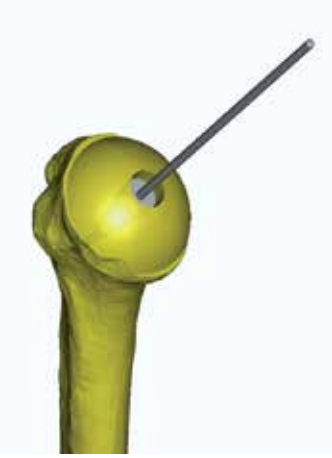


Fig. 17: Inducing the guide wire with a cone

Fig. 18: Cutting off excess surface

Fig. 19: Cutting off excess surface

Finally, we must not forget to rework the hole for the anchoring stem, Fig. 20, 21 and then we repeat trial fitting, Fig.11-15.

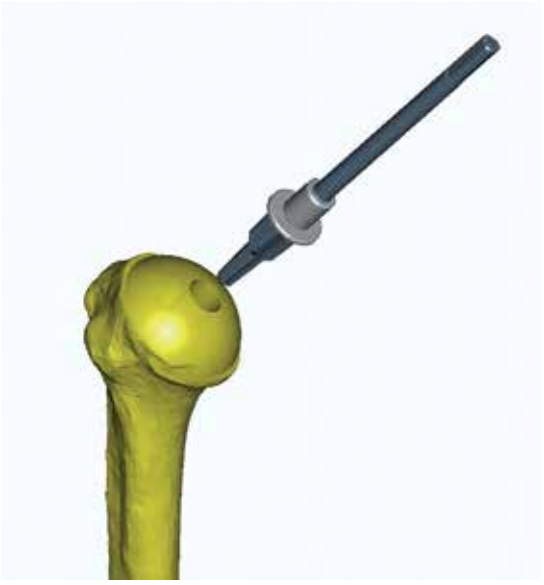


Fig. 20: Finishing the hole for the anchoring stem

Fig. 21: Finishing the hole for the anchoring stem

B7. Inducing the implant

Using the stem, we induce the implant into the prepared hole and tap it into position using the tapping block.

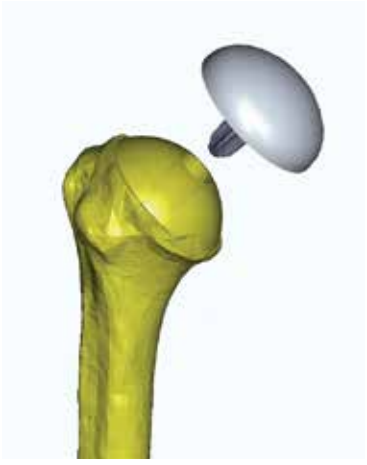


Fig. 22: Final insertion of the implant

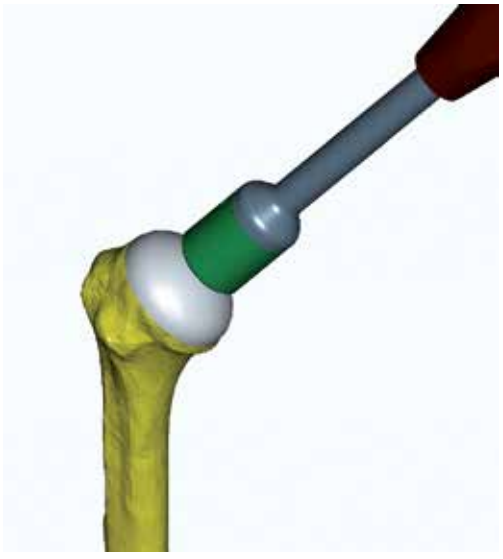
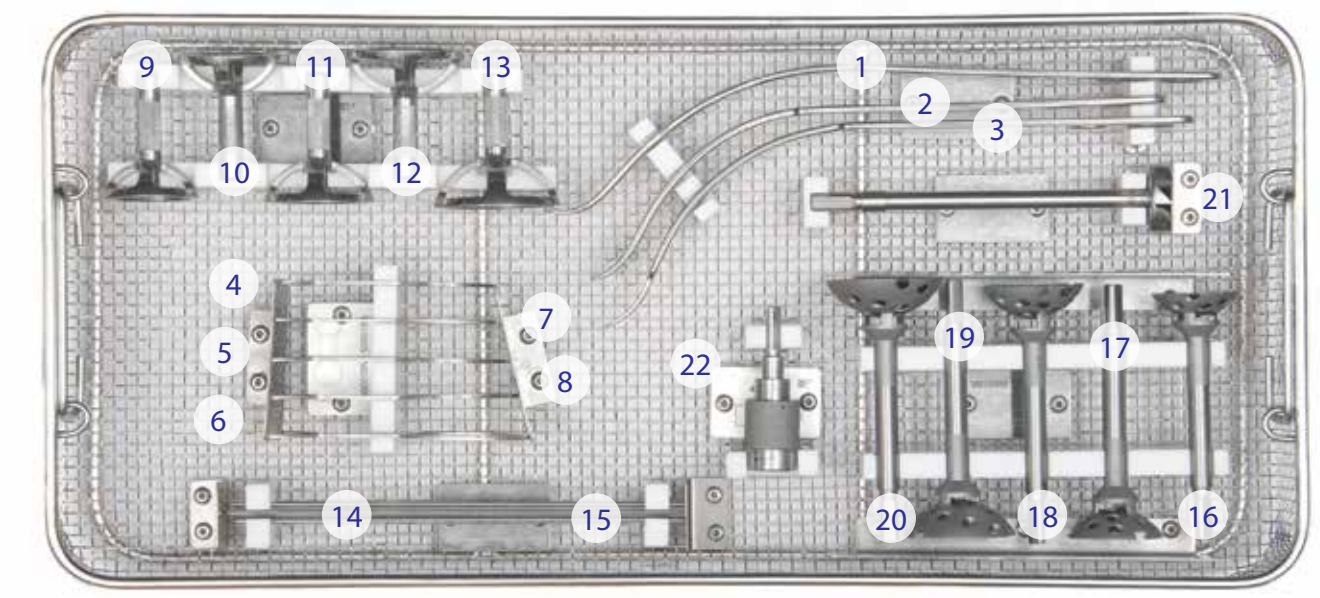


Fig. 23: Final insertion of the implant

Instruments

The set of instruments (Order No. 300030) is laid out on two nets that facilitate a practical layout of the instruments during transport, storage, preparation, as well as during surgery.
The nets are fitted into a container that can be used for sterilization.

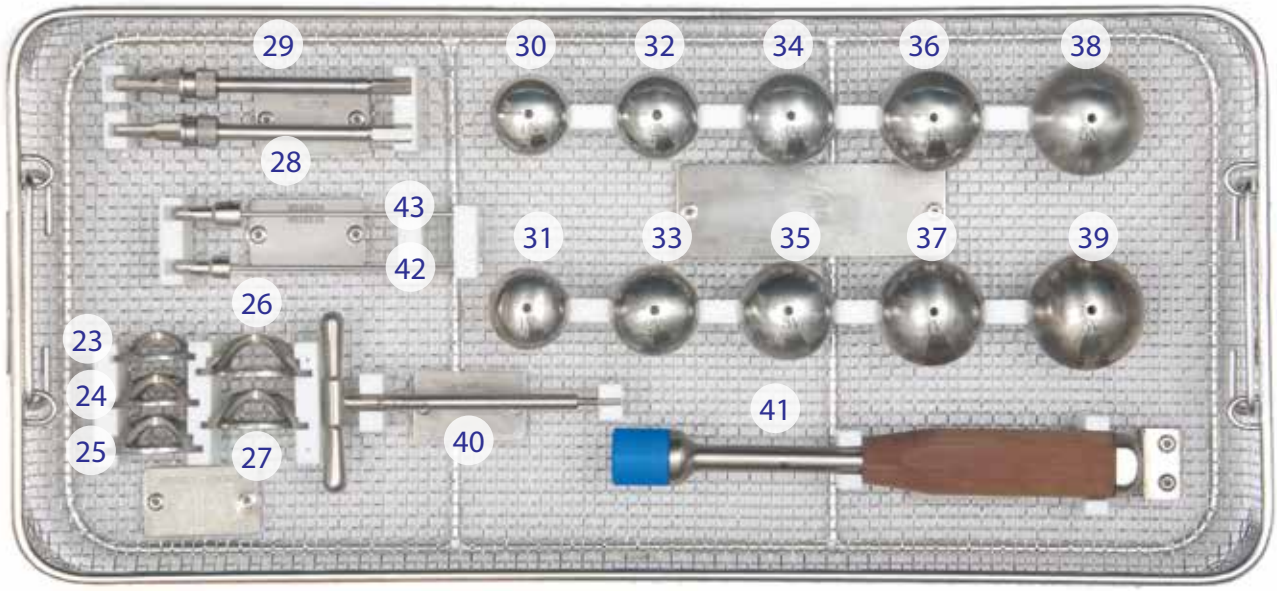


Set of instruments for application of Humeral head resurfacing.

CASSETTE LAY-OUT 1

	Name	Units	Order No.
	Cassette lay-out 1	1	300031
1	Elevatorium toupee	1	202210
2	Elevatorium MUELLER	1	202212
3	Elevatorium HOHMANN	1	202214
4	Head gauge, size 1	1	301801
5	Head gauge, size 2	1	301802
6	Head gauge, size 3	1	301803
7	Head gauge, size 4	1	301804
8	Head gauge, size 5	1	301805
9	Aiming device, size 1	1	301811
10	Aiming device, size 2	1	301812
11	Aiming device, size 3	1	301813
12	Aiming device, size 4	1	301814
13	Aiming device, size 5	1	301815
14	Guiding wire – arrow point	2	301841
15	Guiding wire – threaded point	2	301842
16	Head cutter, size 1	1	301821
17	Head cutter, size 2	1	301822
18	Head cutter, size 3	1	301823
19	Head cutter, size 4	1	301824
20	Head cutter, size 5	1	301825
21	Rake cutter	1	301843
22	Transition triangle	1	401205

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



Set of instruments for application of Humeral head resurfacing.

CASSETTE LAY-OUT 2

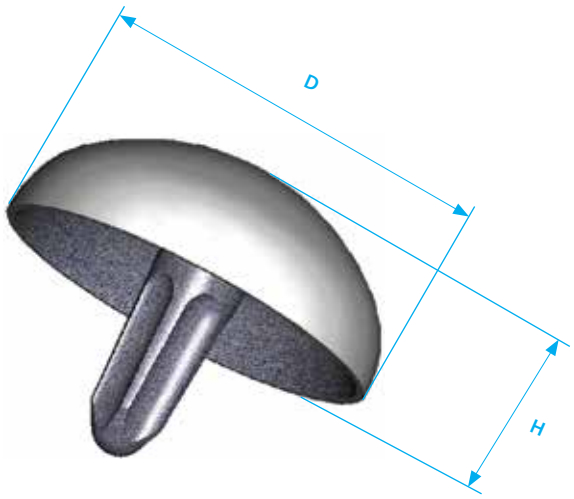
	Name	Units	Order no.
	Cassette lay-out 2	1	300032
23	Trial cap, size 1	1	301831
24	Trial cap, size 2	1	301832
25	Trial cap, size 3	1	301833
26	Trial cap, size 4	1	301834
27	Trial cap, size 5	1	301835
28	Head cutter stem, size 1-3	1	301844
29	Head cutter stem, size 4.5	1	301845
30	Trial head, size 1, low	1	301861
31	Trial head, size 1, high	1	301862
32	Trial head, size 2, low	1	301866
33	Trial head, size 2, high	1	301867
34	Trial head, size 3, low	1	301871
35	Trial head, size 3, high	1	301872
36	Trial head, size 4, low	1	301876
37	Trial head, size 4, high	1	301877
38	Trial head, size 5, low	1	301881
39	Trial head, size 5, high	1	301882
40	Extractor	1	301890
41	Tapping block	1	301891
42	Guiding wire with cone for size 1-3	1	301893
43	Guiding wire with cone for size 4.5	1	301894

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

Humeral head resurfacing

Material: Cobalt alloy ISO 5832-4

Size	Diameter [mm]	Height [mm]	Order No.
1 low	36	13,5	342300
high		15,5	342302
2 low	38,8	14,5	342304
high		17	342306
3 low	42,5	16	342308
high		18,5	342310
4 low	46,5	17,5	342312
high		20,5	342314
5 low	50	19	342316
high		22	312318



BEZNOSKA

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DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Beznoska, s.r.o.

Kladno, Czech Republic

Orthopaedics and Traumatology Implants

Further details are given overleaf

Høvik, 11 April 2008

11 April 2013

Notified Body No.: 0434

Steinar Kristiansen

Cecilie Gudesen Torp

DET NORSKE VERITAS

CERTIFIKÁT SYSTÉMU ŘÍZENÍ

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Dělnická 2727, 272 01 Kladno, Česká republika

ISO 13485:2003

Návrh, vývoj, výroba a prodej implantabilních zdravotnických prostředků a nástrojů.

23. listopadu 2003

23. listopadu 2012

Høvik, 6. listopadu 2009

Det Norske Veritas Certification AS, Norway

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