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Radial Head Replacement

Primary Implants | ALLOPLASTY

Introduction

This publication is to be used as orientation instructions for the specified implant and set of instruments. It focuses strictly on issues related to the application of the specific implant, on the presumption that the surgeon and other personnel are thoroughly acquainted with the general rules applicable to radial head replacement operations. The objective of this publication is to facilitate the use of the individual instruments by surgeons and theater nurses, so that they may attain optimal results quickly and properly, and, last but not the least, prevent unnecessary damage and depreciation of the instruments or the implant itself.

Description of the Implant

The implant is designated for radial head replacement.

The implant consists of a head and a stem that must be assembled inseparably during the operation, using a self-clamp cone at the connection point.

Indication for implantation

- Primary implantation in cases involving comminuted irreconstructible fracture of the head of the radius with plus-variant of the ulna or simultaneous injury of:
  - medial ligament (primary stabilizer)
  - radioulnar interosseal membrane (Essex-Lopresti)
    membrány (Essex-Lopresti)
  - coronoideous ulnae and olecranum ulnae

- Chronic indication:
  - status after extensive deliberation ofthe elbow with medial instability with deformity of the head

  - status after resection of the head:
    - with progressing valgosity of the elbow or narrowing of the radial half of the ulnohumeral joint
    - with proximation of the radius and secondary plus-variant of the ulna with symptomatic distal radioulnar instability

Surgical procedure

General Principles

Prior to every operation, it is necessary to do pre-operation planning to determine the estimated size of the implant.
Final determination of the implant's size is done during the operation, as it depends on the dimensions of the resected radial head, which is determined with the aid of the calibration gauge that is part of the set of instruments.

Access

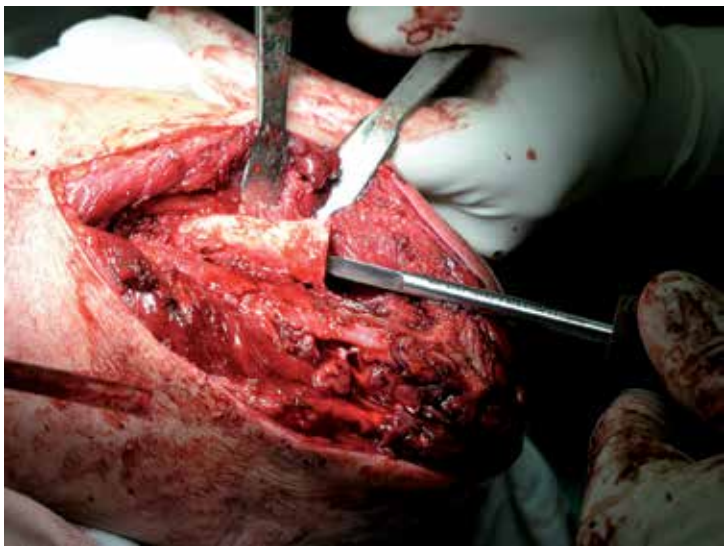
We start the operation by lateral incision using Kocher or Boyd method of access.

Resecting Damaged Radial Head

Incision of lig. anulare radii with arthrotomy of the radiohumeral joint exposes the radial head. Next, the radial head is resected using the oscillation saw (below the fracture). The resection angle must be perpendicular (right angle) to the axis of the forearm. Thereupon we put the resected head into the gauge (see set of instruments) to determine its size. The head sizes of implants are marked on the gauge – available are 3 heights (S, M, L) for 4 diameters (20 to 26 mm, differing by 2 mm).

Preparing the Cavity

Induce the puncher into the diaphysis of the radius approx. 1.5 cm deep.



Next, work on the cavity using drills starting from a diameter of 4.5mm, increasing the drill size gradually until the cavity's diameter is 1mm larger than the diameter of the stem we plan to implant. Keep the depth of drilling to the limit line marked on the drill, as per following table:

Implant's Stem	Drills
Ø5	Ø4,5 ▸ Ø6 (1st line)
Ø7	Ø4,5 ▸ Ø8 (2nd line)
Ø9	Ø4,5 ▸ Ø10 (3rd line)

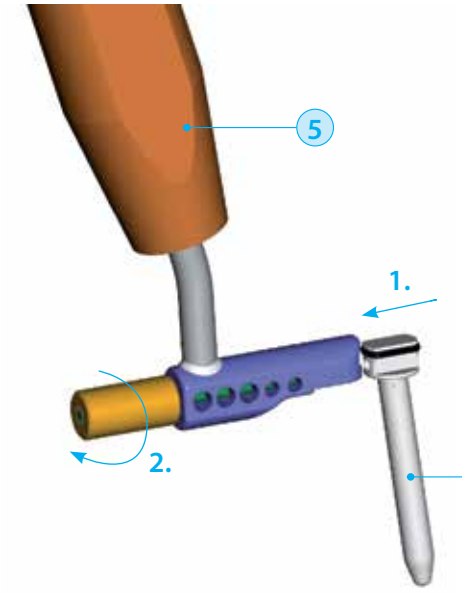
Drills are available with diameters ranging from 4.5 to 10 mm, at 0.5mm increments.

Note:
When drilling the bone marrow cavity, always start with drill diameter of 4,5mm, which has a sharp tip. The tips of the other drills are dull to eliminate the possibility of damaging the radius corticalis by penetration – they are used for gradual broadening of the cavity only.

The thickness of the stem's cement coating is 0.5mm.

Trial Fitting

Induce the trial stem of the appropriate size and angularity (5°or 12°) into the diaphysis, then put on a trial head of the appropriate size and check how it fits. For trial stem testing, the cavity must be drilled to its final dimensions. The thickness of the cement coating is calculated into the trial stem's diameter. The size of the definitive stem must therefore be identical to the size of the trial stem.



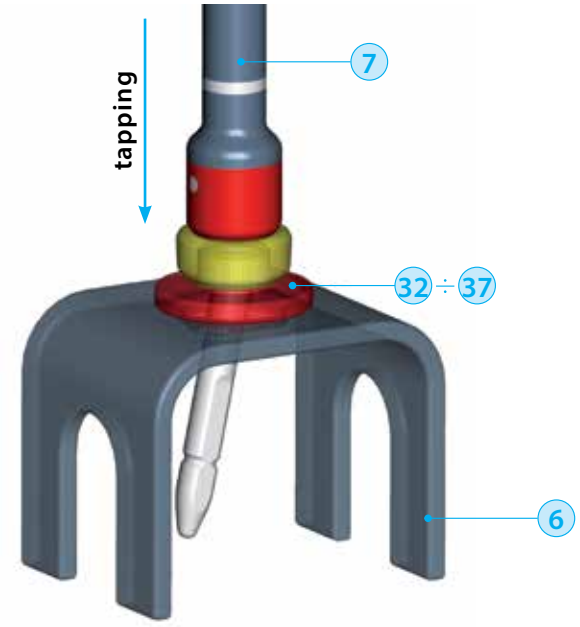
Trial Cemented Stem	
Size marked on trial stem	Drilled cavity's diameter
Ø5	Ø6
Ø7	Ø8
Ø9	Ø10

Use the inducer/extractor for inducing/extracting the trial head.

Next, check the mobility and stability in flexion, extension, supination, and pronation. Apart from having to determine the exact size of the radial head, it is also essential to choose the right axial angle of the stem, depending on individual anatomic conditions, and place it correctly both in terms of rotation and depth. After verifying proper functioning of the trial components, it is possible to induce definitive components (see following step).

Assembling and Inducing the Implant

The implant assembly, i.e., putting the head and the stem together, is done outside the surgical field (on a side table fitted with a plastic pad corresponding to the size of the stem).



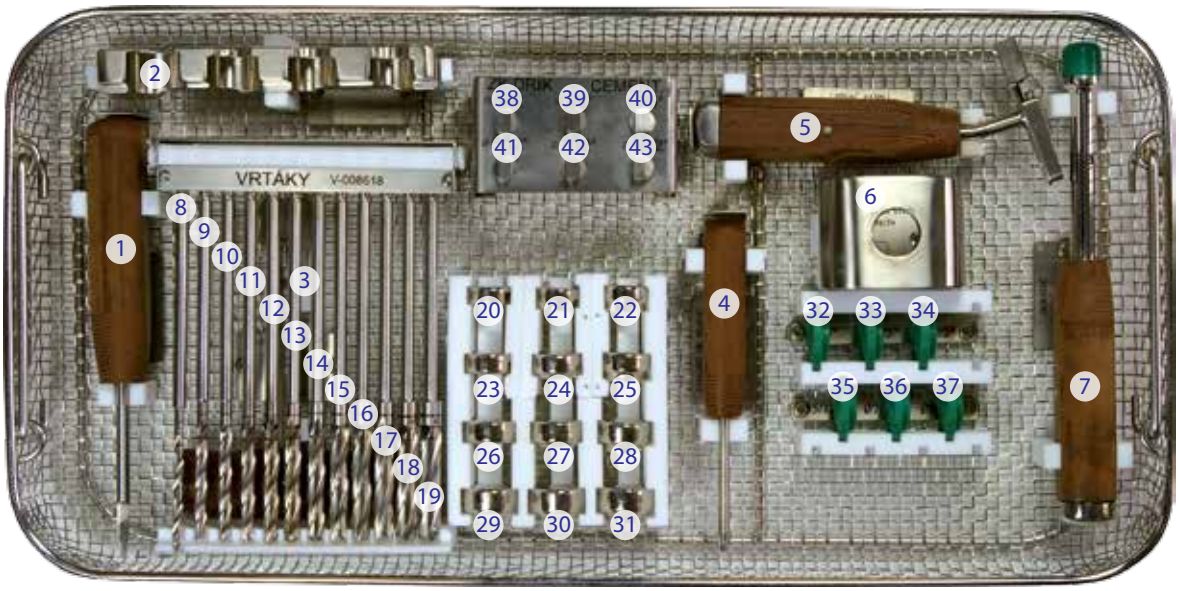
After filling the bone marrow cavity with cement, the implant can be induced, provided that any and all excess cement in the implant's proximity has been meticulously removed.

Finishing the operation

The operation ends with induction of a Redon drain, careful reconstruction of the joint capsule and ligament structures. Suture of subcutanea and skin follows.

Tools for Radial Head Reconstruction

The instruments are laid out in a net to facilitate easy orientation and handling during transport, storage, sterilization, and operation. The net is placed in a container. The layout of the instruments is depicted in the following illustration.



SET OF INSTRUMENTS FOR RADIAL HEAD REPLACEMENT NET LAYOUT			
	Name	**Units**	**Order Number**
	Complete Set		301102
1	Puncher	1	301144
2	Calibration gauge	1	301140
3	Drilling bit	1	301167
4	Inducer/Extractor	1	301142
5	Trial stem fastener	1	301146
6	Assembly table	1	301148
7	Tapping hammer	1	301165
8	Drill Ø4,5mm	1	301125
9	Drill Ø5,0mm	1	301126
10	Drill Ø5,5mm	1	301127
11	Drill Ø6,0mm	1	301128
12	Drill Ø6,5mm	1	301129
13	Drill Ø7,0mm	1	301130
14	Drill Ø7,5mm	1	301131
15	Drill Ø8,0mm	1	301132
16	Drill Ø8,5mm	1	301133

	Name	Units	Order Number
17	Drill Ø9,0mm	1	301134
18	Drill Ø9,5mm	1	301135
19	Drill Ø10mm	1	301136
20	Trial head Ø20/S	1	301175
21	Trial head Ø20/M	1	301176
22	Trial head Ø20/L	1	301177
23	Trial head Ø22/S	1	301180
24	Trial head Ø22/M	1	301181
25	Trial head Ø22/L	1	301182
26	Trial head Ø24/S	1	301185
27	Trial head Ø24/M	1	301186
28	Trial head Ø24/L	1	301187
29	Trial head Ø26/S	1	301190
30	Trial head Ø26/M	1	301191
31	Trial head Ø26/L	1	301192
32	Table pad Ø5/5°	1	301150
33	Table pad Ø7/5°	1	301155
34	Table pad Ø9/5°	1	301160
35	Table pad Ø5/12°	1	301151
36	Table pad Ø7/12°	1	301156
37	Table pad Ø9/12°	1	301161
38	Trial stem Ø5/5°	1	301110
39	Trial stem Ø7/5°	1	301115
40	Trial stem Ø9/5°	1	301120
41	Trial stem Ø5/12°	1	301111
42	Trial stem Ø7/12°	1	301116
43	Trial stem Ø9/12°	1	301121

Note: The layout of the net is informative only – it may vary in the future according to innovation changes.

The Head

The heads are made of nitrogen stainless steel (ISO 5832-9). The head surface is polished. The heads are available in four diameters (20, 22, 24, 26mm) and three heights per diameter (S, M, L).

Head				
Ø D [mm]	**A [mm]**	**Marking**	**VZP Code**	**Order Number**
20	9	20/S	108046	399930
	11	20/M		399932
	13	20/L		399934
22	10	22/S		399940
	12	22/M		399942
	14	22/L		399944
24	11	24/S		399950
	13	24/M		399952
	15	24/L		399954
26	13	26/S		399960
	15	26/M		399962
	17	26/L		399964

Cemented Stem

The stem is made of nitrogen stainless steel and its surface is polished. It is available in three diameters of the anchoring part (5, 7, 9mm) and two angular positions to the head (5° and 12°).

Cemented Stem				
Ø D [mm]	Stem Angle	Marking	VZP Code	Order Number
5	5°	5/5	108048	399972
	12°	5/12		399974
7	5°	7/5		399976
	12°	7/12		399978
9	5°	9/5		399980
	12°	9/12		399982

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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

Hovik, 11 April 2008

11 April 2013

Norway

CE

Notified Body No.: 0434

Cecilie Gudesen Torp

DET NORSKE VERITAS

CERTIFIKÁT SYSTÉMU ŘÍZENÍ

BEZNOSKA, s.r.o.

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

Evangelos Tavoulis

Hovik, 6. listopadu 2009

DET NORSKE VERITAS CERTIFICATION AS, NORWAY

Eugenie Wingård Hansbye

VALID SINCE: DECEMBER 9, 2011

Dělnická 2727, 272 01 Kladno, Czech Republic
tel.: +420 312 660 670, GSM: +420 602 666 503
fax: +420 312 660 216, +420 312 662 464
www.beznoska.com, export@beznoska.cz