










RADIAL HEAD PROSTHESIS

- *IMPLANTS*
- *INSTRUMENT SET 15.1000.101*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTION

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

www.chm.eu

Document No ST/20E
Date of issue 06.12.2021
Review date P-001-06.12.2021

*The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu*

I. INTRODUCTION	5
II. INDICATIONS AND CONTRAINDICATIONS FOR RADIAL HEAD REPLACEMENT	5
II.1. INDICATIONS	5
II.2. CONTRAINDICATIONS	5
III. IMPLANTS	6
IV. INSTRUMENTS	7
V. SURGICAL TECHNIQUE	11
V.1. SURGICAL APPROACH TO THE HUMERORADIAL JOINT	11
V.2. PROSTHESIS IMPLANTATION	12
V.3. PROSTHESIS REMOVAL	17
V.4. PROSTHESIS REIMPLANTATION	17

I. INTRODUCTION

The radial head is an essential anatomical and biomechanical element of the elbow joint. Significant restriction of elbow joint movement can be a reason of high percentage of disability especially for patients who have professions requiring precise movements.

In the case of multifragmental radial head fracture, radial head resection is still performed, but many complications are observed after this operation. The indication for radial head replacement is a multifragmental, comminuted fracture of the radial head where stable osteosynthesis is not possible.

The presented prostheses are made of cobalt alloy (*in accordance with ISO 5832*), UHMWPE polyethylene (*in accordance with ISO 5834*) and PEEK OPTIMA® Wear Performance (*in accordance with ISO 10993-1*). Compliance with the requirements of Quality Management Systems and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

Implants and the instrument set have been developed in cooperation with Professor S. Pomianowski, Head of the Department of Traumatology and Orthopaedics, Postgraduate Medical Center in Otwock.

System for radial head replacement consists of:

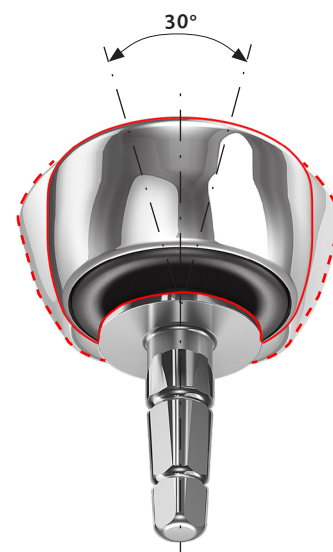
- implants,
- instrument set,
- instructions for use and surgical techniques.

The radial head prosthesis is a bipolar implant; the stem is connected to the head as a socket joint, which enables the prosthesis head to rotate and tilt 15° against the stem axis in both directions. Total range of tilting is 30°.

The prosthesis stem has a collar which should rest against a stump of the radial neck which has been cut during surgery.

The prosthesis head has convex, "barrel-shaped" exterior surface to contact concave surface of the radial notch of the ulna.

From above the surface is concave to contact convex shape of the humerus capitulum.



II. INDICATIONS AND CONTRAINDICATIONS FOR RADIAL HEAD REPLACEMENT

II.1. INDICATIONS

Indications for the radial head replacement in the case of comminuted fracture (*Type III according to Mason Classification*) are the following coexisting injuries:

- dislocation of the elbow joint together with radial head fracture (*Type IV*);
- injury of the medial collateral ligament;
- injury of the lateral collateral ligament;
- Monteggia type injury with the olecranon fracture and the radial head fracture;
- fracture of the major part of the coronoid process (*Types II and III*);
- coexisting injury of the distal radioulnar joint (*Essex-Lopresti type*) or injury of the interosseus membrane;
- as a combination of the above - complex injury and instability.

II.2. CONTRAINDICATIONS

The conditions mentioned below are considered contraindications for implantation of radial head prosthesis:

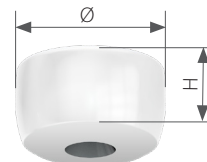
- damage to articular cartilage of the humeral head,
- arthritis, even as a chronic inflammation of the synovium.

III. IMPLANTS

Radial head prosthesis consists of:

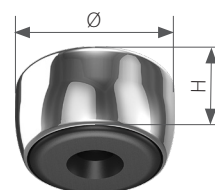
Solid head of radial head prosthesis

H [mm]	Catalogue no.		
	Ø20	Ø22	Ø24
10	7.3696.010	7.3697.010	7.3698.010
12	7.3696.012	7.3697.012	7.3698.012
14	7.3696.014	7.3697.014	7.3698.014



Modular head of radial head prosthesis

H [mm]	Catalogue no.		
	Ø20	Ø22	Ø24
10	4.3692.010	4.3693.010	4.3694.010
12	4.3692.012	4.3693.012	4.3694.012
14	4.3692.014	4.3693.014	4.3694.014



Stem of radial head prosthesis [4.3690.000]



Angular stem of radial head prosthesis (*reconstructive*) [4.3691.000]





The radial head prosthesis components are packed in separate sterile packages and are put together during surgical procedure.

IV. INSTRUMENTS

For radial head replacement and radial head prosthesis removal, the instrument set **[40.5231.000]** shall be used.

The instrument set comprises the following devices:

	Name	Catalogue no.	Pcs.
	Rasp for radial bone	40.5232.100	1
	Rectangular curved file	40.5233.100	1
	Rhb prosthesis stem impactor	40.5234.100	1
	Rhb prosthesis stem holder	40.5235.100	1
	Radial head bone trial	40.5236.100	1
  	Rhb head prosthesis trial 20 H10	40.5237.110	1
	Rhb head prosthesis trial 22 H10	40.5238.110	1
	Rhb head prosthesis trial 24 H10	40.5239.110	1
  	Rhb head prosthesis trial 20 H12	40.5237.112	1
	Rhb head prosthesis trial 22 H12	40.5238.112	1
	Rhb head prosthesis trial 24 H12	40.5239.112	1
  	Rhb head prosthesis trial 20 H14	40.5237.114	1
	Rhb head prosthesis trial 22 H14	40.5238.114	1
	Rhb head prosthesis trial 24 H14	40.5239.114	1

	Name	Catalogue no.	Pcs.
	Tray for rhb trials	14.1000.201	1
	Resection guide 10	40.5242.310	1
	Resection guide 12	40.5242.312	1
	Resection guide 14	40.5242.314	1
	Resection guide 10R	40.5242.320	1
	Resection guide 12R	40.5242.322	1
	Resection guide 14R	40.5242.324	1
	Resection guide	40.5242.100	1
	Container lid for rhb prosthesis 4x4	14.1000.102	1
	Container for rhb prosthesis 4x4H	14.1000.101	1



Name

Catalogue no.

Pcs.

Perforated aluminum lid 1/2 306x272x15mm gray

12.0751.200




1




Container with solid bottom 1/2 306x272x85mm




12.0751.100

1

Rhb head prosthesis trial

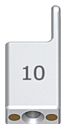


H [mm]	Ø [mm]	Catalogue no.	
10	20	40.5237.110	
	22	40.5238.110	
	24	40.5239.110	

H [mm]	Ø [mm]	Catalogue no.	
12	20	40.5237.112	
	22	40.5238.112	
	24	40.5239.112	

H [mm]	Ø [mm]	Catalogue no.	
14	20	40.5237.114	
	22	40.5238.114	
	24	40.5239.114	




Resection guide

(in the case of using the stem [4.3690.000])

H [mm]	Catalogue no.	
10	40.5242.310	
12	40.5242.312	
14	40.5242.314	

Resection guide

(in the case of using the stem [4.3691.000])

H [mm]	Catalogue no.	
10	40.5242.320	
12	40.5242.322	
14	40.5242.324	

Instruments for radial head prostheses
[15.1000.101]

V. SURGICAL TECHNIQUE

Surgical technique has been developed in cooperation with Professor S. Pomianowski, Head of the Department of Traumatology and Orthopaedics, Postgraduate Medical Center in Otwock. The experience of the medical center as well as the experience of the surgeon are the most important aspects when selecting the treatment method.

V.1. SURGICAL APPROACH TO THE HUMERORADIAL JOINT

Operation should be performed in Esmarch's clamp. Anterior-lateral operative approach should be used.

Straight skin incision is made 1cm above the lateral epicondylus of the humerus and 2cm distal from palpable radial head.

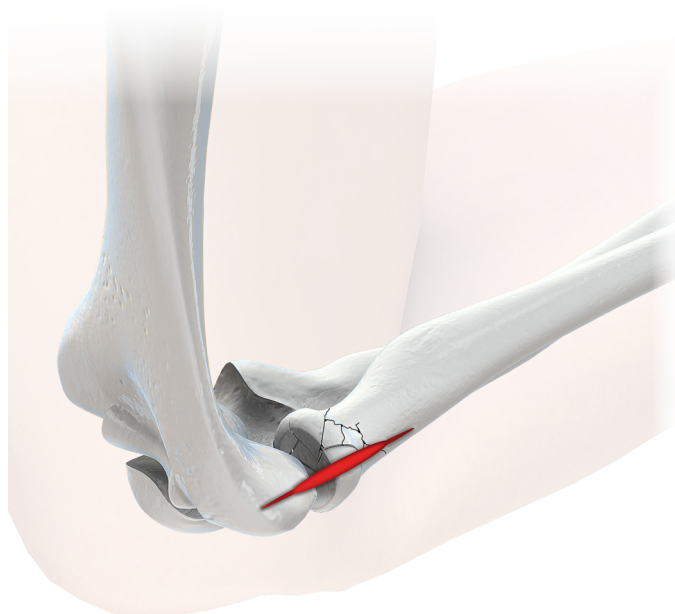
Incision is 8-10cm long. It is advised to mark osseous points: the lateral epicondylus of the humerus, the head of the radius, and the top of the olecranon. After skin and subcutaneous tissue incision, expose the fascia (*pic. a*). After it has been cut, partially release the attachment of the brachioradialis muscle for approx. 2cm. Then go forward to the radiohumeral joint between both carpi radialis extensors muscles and common extensor digitorum tendon. While making the approach, assistant should pronate forearm. This manoeuvre allows the posterior interosseous nerve (*the deep branch of the radial nerve*) to be away from the incision line by approximately 1cm. The joint capsule should be incised above the lateral collateral ligament avoiding any damage to its attachment, which is situated at the central point of curvature of the humerus capitulum from the lateral side.

Next, incise the joint capsule and the proximal part of the annular ligament unless it is damaged and the incision is unnecessary. In this manner the humeroradial joint is opened from the top, above the attachment of the lateral collateral ligament. Expose antero-lateral part of the humerus capitulum and the head of the radius. Due to radial head fracture, humerus capitulum is a better reference point than radial head, as the latter is often not directly visible in the operating field. From the joint side place Langenbecks's elevator up to the anterior surface of the distal humerus.

Next, place the second Langenbecks's elevator behind the remaining part of the radial head.

If fragments of the head are displaced, they should be found and removed. Keep the forearm pronated and incise the distal part of the annular ligament exposing the neck of the radius from the lateral side.

Carefully remove tissue with raspatory from lateral and anterior surfaces of the neck, place Langenbecks's elevator behind it. Remove all the remaining fragments of the radial head.



V.2. PROSTHESIS IMPLANTATION

1 Measurement of the radial head diameter

Fragments of the radial head should be put together into the radial head bone trial [40.5236.100] fitting head diameter to a hollow in the trial. Do this on the operating table. Select appropriate prosthesis head on the basis of measured diameter.

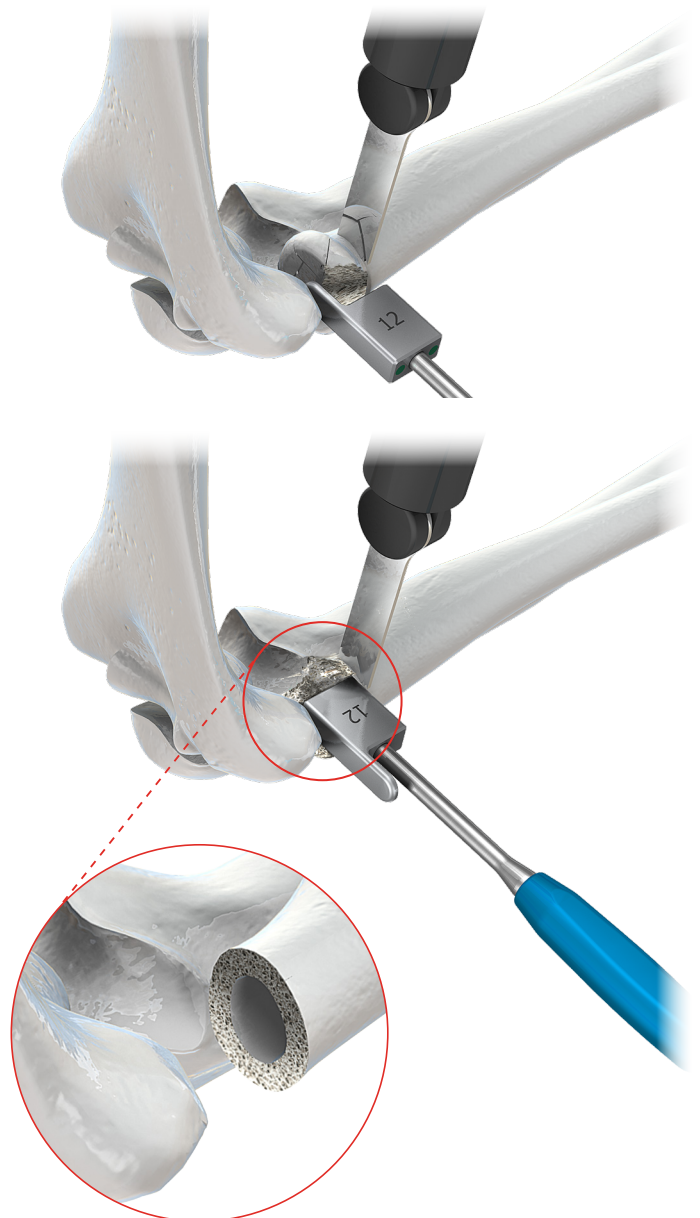
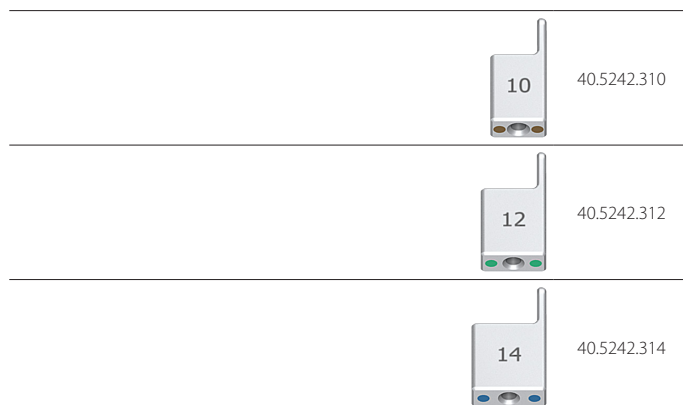


2 Resection of a radial head stump

Carefully rinse the joint with physiological saline. Using the resection guide, measure the distance from the cut radial neck stump to the humerus capitulum or from the cut radial neck stump to the proximal radial notch of the ulna (*in the case of using the stem* [4.3690.000]):

- The resection guide with cat. no. [40.5242.310] corresponds to 10mm of the heads of prostheses: [7.3696.010], [7.3697.010], [7.3698.010], [4.3692.010], [4.3693.010], [4.3694.010].
- The resection guide with cat. no. [40.5242.312] corresponds to 12mm of the heads of prostheses: [7.3696.012], [7.3697.012], [7.3698.012], [4.3692.012], [4.3693.012], [4.3694.012].
- The resection guide with cat. no. [40.5242.314] corresponds to 14mm of the heads of prostheses: [7.3696.014], [7.3697.014], [7.3698.014], [4.3692.014], [4.3693.014], [4.3694.014].

Cut the stump so it matches the closest size (*height*) of the radial head.



2a Establishing the size of prosthesis head

Measure the above-mentioned distance again. Choose the suitable size of the prosthesis head based on the measured distance, as well as on the measurement of removed radial head diameter.




2b Extended fractures - Angular stem (reconstructive)

The fractures of radial head extended to fractures of the radial head's neck should be supplied with the angular stem [4.3691.000], whose construction allows reconstruction of the anatomical neck deviation in respect to the bone axis. In this case the neck should be resected just above the tuberosity of radius. Using the resection guide, measure the distance from the cut radial neck stump to the humerus capitulum or from the cut radial neck stump to the proximal radial notch of the ulna (in the case of using the stem [4.3691.000]):

- The resection guide with cat. no. [40.5242.320] corresponds to 10mm of the heads of prostheses: [7.3696.010], [7.3697.010], [7.3698.010], [4.3692.010], [4.3693.010], [4.3694.010].
- The resection guide with cat. no. [40.5242.322] corresponds to 12mm of the heads of prostheses: [7.3696.012], [7.3697.012], [7.3698.012], [4.3692.012], [4.3693.012], [4.3694.012].
- The resection guide with cat. no. [40.5242.324] corresponds to 14mm of the heads of prostheses: [7.3696.014], [7.3697.014], [7.3698.014], [4.3692.014], [4.3693.014], [4.3694.014].

Cut the stump so it matches the closest size (height) of the radial head.



	40.5242.320
	40.5242.322
	40.5242.324

3 Preparation of a medullary canal

Insert an elevator behind the neck of the radius and identify the bone marrow canal using a "frim" or a thin Wolszczan's chisel.

Next, using a reamer, a curette, and finally a rasp [40.5232.100] prepare the canal for implantation of the stem of the prosthesis. The canal should be wider by 0.5mm at both sides of the stem and longer than the stem by at least 0.5cm.

Plug the marrow canal with a bone block excised from the spongy portion of the removed radial head.

Carefully rinse the canal with saline.



If the angular stem is used, penetrate the bone marrow with the rasp [40.5232.100] to the marker signed RECON.
If the standard stem is used, penetrate the bone marrow with the rasp to the end of its filing part.



40.5232.100

4 Preparation of the frontal surface

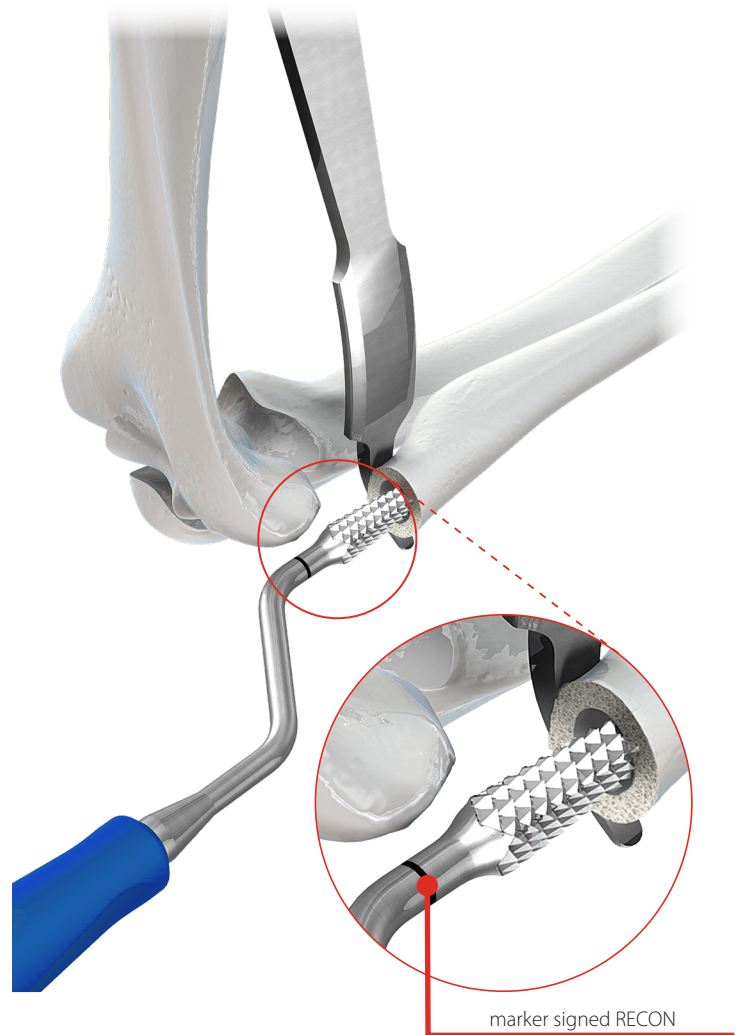
Using a rectangular curved file [40.5233.100] make the stump of the radial neck smoother.



40.5233.100

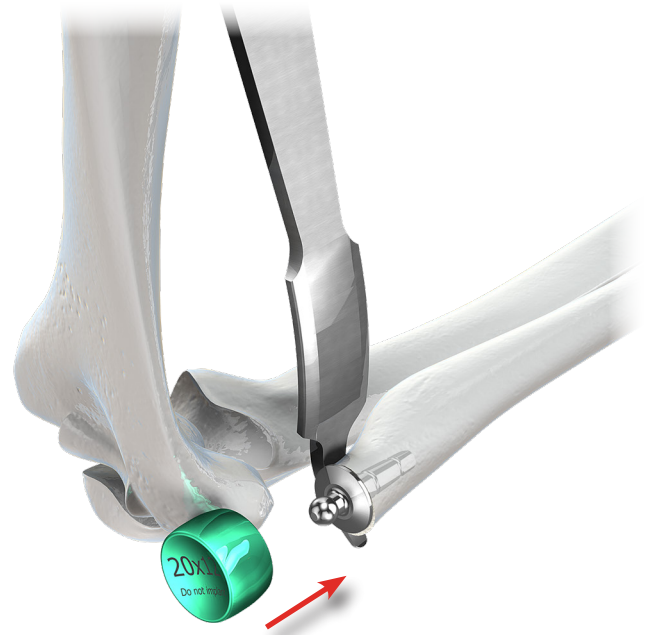


If the angular stem [4.3691.000] is used, omit the 5a and 5b steps, because collarless stem construction makes it impossible to carry the steps out.



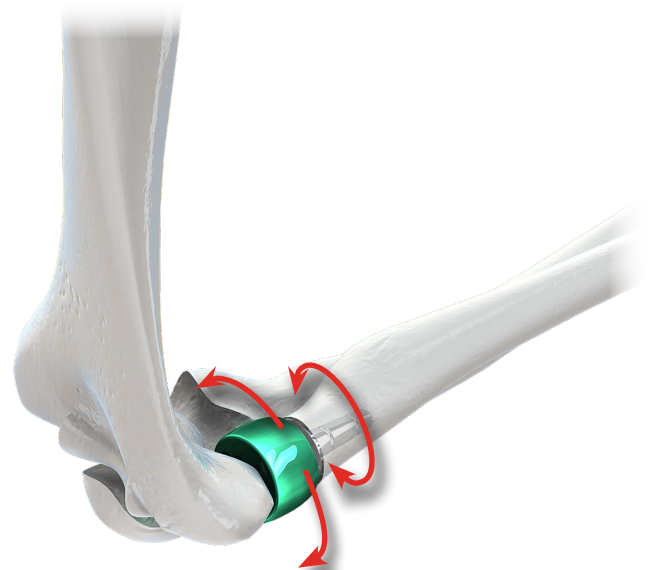
5a Implantation test

First insert the stem [4.3690.000] into previously prepared canal of the radial neck, and then put on it an appropriate trial of prosthesis head. Select diameter and height of the trial on the basis of: measured diameter of radial head (*see step 1*) and the distance from the cut radial neck stump to the humerus capitulum or to the proximal radial notch of the ulna (*see step 2*).

**5b Assessment of the elbow joint stability**

The collar of the stem should rest perfectly on the stump of the radial neck.

Check the joint stability and whether the head of prosthesis trial centers well on the humerus capitulum. Check the range of movement of the elbow joint: flexion, extension and rotation.



6 Implantation of the prosthesis final components

Carefully rinse the joint and then implant the stem [4.3690.000]. Using the rhb prosthesis stem impactor [40.5234.100], keep pushing the stem to the radial head stump until the bone cement has bound.

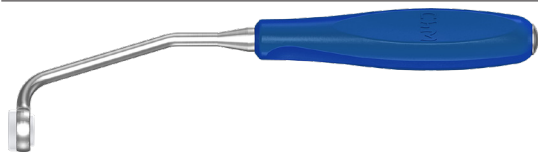
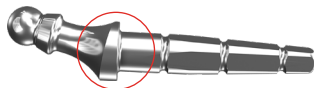
Next, put on the stem the appropriate prosthesis head. To put the head of the implant on the stem, slightly "stick out" the radial bone sideways. The step may be performed without releasing the attachment of the lateral collateral ligament complex since the intramedullary part of the stem of the implant is relatively short (*facilitated implantation*). It is possible thanks to bipolar structure of the implant.

During the implantation of the angular stem, position the stem in line with anatomical radial neck deviation, i.e.:

- set the forearm in the intermediate rotation (0°) - the abducted patient's thumb is then directed forward.
- insert the angular stem so that the curved proximal end of the stem is facing the direction indicated by the patient's thumb (while still in the intermediate rotation of the forearm).



Then softly push the stem until the bone cement has bound. Due to the collarless structure, immerse the stem in the cement up to the visible limiter.



40.5234.100

7 Final stage

Rinse the joint and apply Redon's drain.

It is recommended to put 2 mattress sutures on previously partially released attachment of the brachioradialis muscle.

Next, put on 2 or 3 sutures on the annular ligament; if it is seriously injured then stitch the articular capsule trying to "close" the joint. Sutures on fascia, subcutaneous tissue, and skin finish the operative procedure.

Put on a "cocoon" type sterile dressing with a thick layer of cotton and elastic bandage. There is no need to apply a plaster cast.

Put the limb in an elevated position and check the blood supply, sensation and fingers movement after the procedure.

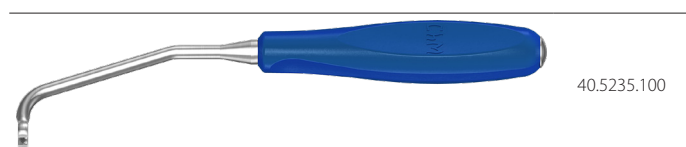


V.3. PROSTHESIS REMOVAL

- 8 In the case of infection of soft tissues around the implant it is recommended to remove the implant without performing reimplantation.

Having reached the humeroradial joint remove the prosthesis head, and then remove the stem with the use of rhb prosthesis stem holder [40.5235.100]. This instrument allows for grabbing and pulling with a minimum force, with a simultaneous tapping with a mallet into the curved part. At the same time use a thin chisel to remove the bone cement from the space between the collar and the stump of radial neck (*the surgeon decides about the tool used during the procedure*).

Pay special attention not to damage the radius and other structures of the elbow joint. After stem removal from the marrow cavity remove completely the bone cement using a special hook and chisel (*a surgeon performing the operation chooses an appropriate tool*).



V.4. PROSTHESIS REIMPLANTATION

In the case of:

- damage to the prosthesis head or stem,
- aseptic prosthesis loosening and/ or disconnection of its components,

the re-implantation of all the prosthesis elements (*stem with head*) is allowed.

Re-implantation indications

- joint instability (*valgization mainly*),
- distal radioulnar joint (DRUJ) subluxation,
- excessive valgus of the elbow joint resulting from lack of radial head (*previous prosthesis removal or resection*)



Contraindications for re-implantation are contained in the instructions for use for radial head prosthesis – chapter CONTRAINDICATIONS.

Implanted radial head prosthesis which stays in the body for a period of 3 to 6 months, enables the proper healing of damaged tissues (*prosthesis functions as a spacer*). After this period, when there is a need to remove the prosthesis, there is little chance of the occurrence of the complications such as: joint instability or valgus of the elbow joint, and/ or distal radioulnar joint (DRUJ) subluxation.

If the joint, despite the absence of radial head:

- is painless,
- achieves a functional range of motion,
- is stable,
- shows no clear axis disorder and there are no symptoms associated with the wrist,

there is no direct indications for re-implantation of the radial head prosthesis.

ChM sp. z o.o.

Lewickie 3b
16-061 Juchnowiec Kościelny
Poland
tel. +48 85 86 86 100
fax +48 85 86 86 101
chm@chm.eu
www.chm.eu



CE 0197