Explor® Modular Radial Head





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INDICATIONS

The indications for use of Radial Head Replacement Devices include:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radiohumeral and/or proximal radio-ulnar joint with:
 - a. Joint destruction and/or subluxation visible on x-ray
 - b. Resistance to conservative treatment
- 2. Primary replacement after fracture of the radial head.
- 3. Symptomatic sequelae after radial head resection.
- 4. Revision following failed radial head arthroplasty.

This device is intended for single use with or without bone cement.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include:

1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.



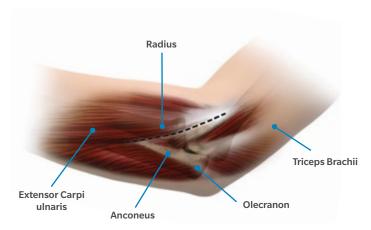


Figure 1

Figure 2

Patient Positioning

Position the patient supine on the operating table, using an arm table. Ensure the arm is mobile and unencumbered by the drapes. Use a pneumatic tourniquet placed far enough proximally to allow adequate exposure to the lateral elbow. Flex the elbow and pronate the forearm (Figure 1).

Surgical Approach

An anterolateral approach (Kaplan/Thompson) to the elbow between the extensor digitorum communis (EDC) and the extensor carpi radialis longus/brevis (ECRL, ECRB) is preferred and allows for preservation of the lateral collateral ligament (Figure 2). To facilitate the surgeon's determination of proper soft tissue tension, preservation of the lateral collateral ligament is important. An alternate posterolateral (Kocher) approach can be used for better exposure of the lateral column. The anconeus and extensor carpi ulnaris (ECU) interval should be identified to protect the posterior interosseus nerve.

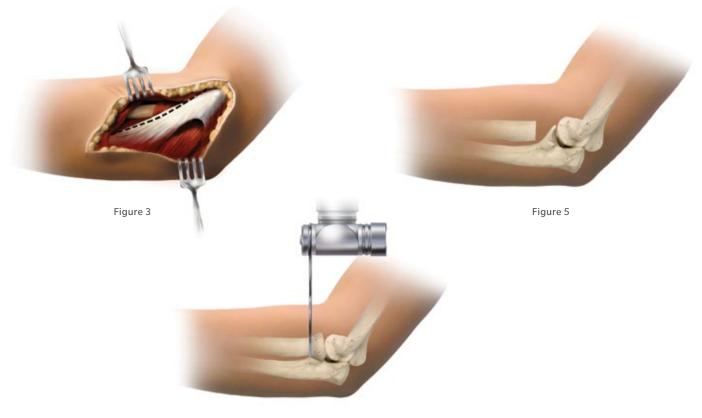


Figure 4

Surgical Approach (cont.)

For the anterolateral approach, make the skin incision along the lateral elbow starting approximately 2 cm proximal to the lateral epicondyle and along the supracondylar ridge. Extend the incision distally to the lateral epicondyle overlying the EDC-ECRL interval (Figure 3). Carry down the dissection to the ECRB, which is split longitudinally from its origin at the lateral epicondyle. Perform a longitudinal radiocapitellar capsular arthrotomy to gain access to the radiocapitellar joint. If further surgical exposure is needed, the annular ligament can be released as the dissection is extended distally.

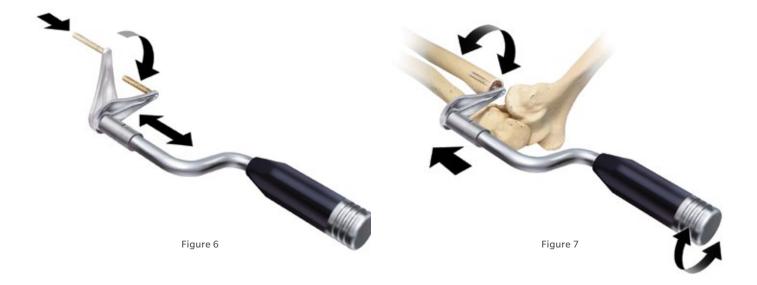
If using the posterolateral approach, extend the incision along the interval between the anconeus and ECU. Elevate the ECU off the lateral aspect of the proximal ulna, allowing for exposure of the radiocapitellar joint. Divide the annular ligament to mobilize the radial head.

Resection of the Radial Neck

If the radial head is fractured, remove and reconstruct the pieces to ensure all bone is removed from the joint. Use an oscillating saw or a rongeur to evenly resect the proximal radius perpendicular to the axis of the radial neck (Figure 4).

A radial cutting jig may be used for resecting the flattest surface possible. Ideally, the proximal 14 mm is resected (Figure 5).

The shortest construct possible with the modular radial head prosthesis is 12 mm. Take care to avoid excessive head resection.

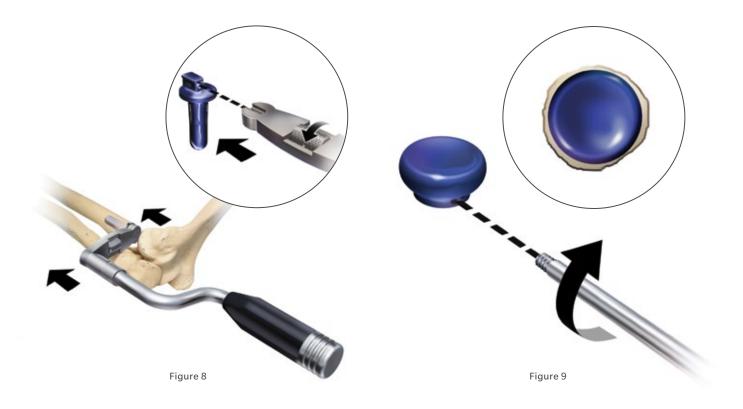


Preparation of the Radial Canal

Sequentially rasp the proximal radial canal using progressively larger rasps that are exchanged on the offset handle (Figure 6). Because excessive rasping of the canal may produce or propagate a longitudinal radial neck fracture, utilize special care.

Rasp using a gentle back and forth twisting motion (Figure 7). Take care to concentrically and evenly broach the canal to ensure proper seating of the implant. If necessary, use a mallet to fully seat the rasp.

Aim the rasp handle at the capitellum during rasping to facilitate appropriate alignment of the prosthesis (Figure 7). Rasp until there is a tight fit (just short of cortical chatter to accommodate for the bond coating on the radial stem).



Trial Reduction

Using the stem inserter, place the trial or implant stem in the canal corresponding to the last rasp size used (Figure 8 & 8 inset). Stem trial should fully seat with minimal effort. If the stem trial will not fully seat, remove and re-rasp the canal.

Following stem placement, assess trial head components. Using the available head inserter handle, guide the trial head from the lateral aspect onto the trial stem (Figure 9).

The trial and implant stem are designed with a 2 mm flange around the top of the stem; therefore, the first head height chosen should be 2 mm less than the original resection level. The radial head trial should be chosen to match the diameter of the articulation surface of the native radial head (Figure 9 inset). If the patient's radial head diameter is between two available sizes, the smaller of the two radial heads should be used.

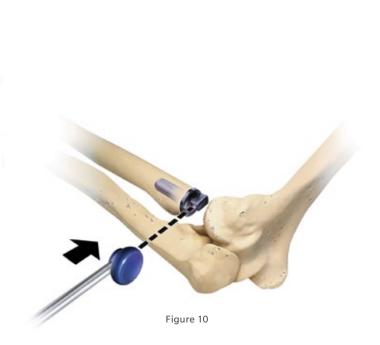




Figure 11

Trial Reduction (cont.)

Slide the slot located on the undersurface of the radial head along the ridge located on the proximal radial stem until the head is fully seated (Figure 10). If necessary, use a provisional set screw to secure the radial head to the radial stem.

The screw can be inserted using the screw driver available in the set by assembling the handle and the 2.4MM X-lock STD Blade.

Following placement of the trial head, place the elbow through a full range of elbow flexion-extension and forearm pronation-supination. The radial head implant should articulate with the capitellum smoothly through a full arc of motion (Figure 11). Take care to avoid impingement of the implant along the anterior distal humerus with elbow flexion. Assess varus-valgus stability of the elbow. A mismatch in the implant-capitellum articulation may be a result of improper implant size or eccentric placement of the stem.



Implantation of Prosthesis

The ExploR prosthesis may be press-fit or cemented. When press-fitting the implant, there will be approximately 0.5 mm of press-fit surrounding the implant stem. When cementing the implant, it is recommended to use an implant stem 1 size smaller than the last rasp size used to allow for an appropriate (approximately 0.5 mm) cement mantle. For example, rasping to 7 x 26 mm results in a 6 x 24 mm implant.

Once the radial head has been fully seated on the radial stem, place the set screw packaged with the stem to secure the head to the stem (Figure 12).

Radiographs can be taken to verify appropriate radial stem/head sizing and positioning.

Closure

Perform wound closure by capsular repair. The annular ligament, if released, can be repaired at the surgeon's discretion. If the lateral collateral ligament complex was avulsed from its lateral epicondyle origin, repair it using non-absorbable No. 2 braided sutures through bone holes in the lateral epicondyle. Repair the EDC-ECRL fascia and close the wound (Figure 13). A suction drain can be used.

Postoperative Rehabilitation

Immobilize the elbow in a long arm splint. If there are any signs of posterolateral elbow instability, immobilize the forearm in pronation. Begin active elbow flexionextension exercises within two to seven days following surgery. Continue immobilization in a removable long arm splint during the postoperative period.

Implants and Trials

ExploR Modular Radial Heads

Product	Description	Size	Trial Number	Part Number
	ExploR 20 mm Radial Head	10 x 20 mm	418022	11-210022
		12 x 20 mm	418023	11-210023
		14 x 20 mm	418024	11-210024
		16 x 20 mm	418025	11-210025
		18 x 20 mm	418026	11-210026
	ExploR 22 mm Radial Head	10 x 22 mm	418031	11-210031
	•	12 x 22 mm	418032	11-210032
		14 x 22 mm	418033	11-210033
		16 x 22 mm	418034	11-210034
		18 x 22 mm	418035	11-210035
	ExploR 24 mm Radial Head	10 x 24 mm	418041	11-210041
		12 x 24 mm	418042	11-210042
		14 x 24 mm	418043	11-210043
		16 x 24 mm	418044	11-210044
		18 x 24 mm	418045	11-210045

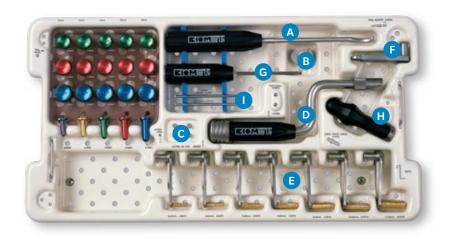
ExploR Modular Radial Stems

Product	Description	Size	Trial Number	Part Number
	ExploR Radial Stem	5 x 22 mm	418060	11-210060
E .		6 x 24 mm	418061	11-210061
		7 x 26 mm	418062	11-210062
		8 x 28 mm	418063	11-210063
		9 x 30 mm	418064	11-210064

ExploR Screw

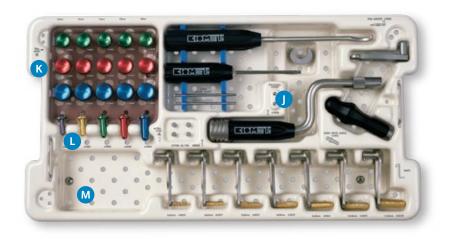
Product	Description	Size	Trial Number P	
	ExploR Screw	-	418098	11-210099

Trials, Instrumentation, and Accessories



Product	Description	Label	Size	Part Number
	Radial Hook	Α	_	408034
	Radial Head Cutting Jig	В	_	408030
1	Cutting Jig Pins (one each)	С	_	408033
	Offset Handle	D	-	418078
	Rasp	E	5 x 22 mm 6 x 24 mm 7 x 26 mm 8 x 28 mm 9 x 30 mm 10 x 32 mm	418070 418071 418072 418073 418074 418075
	Stem Inserter/Extractor	F	-	418092
	Head Inserter/Extractor	G	_	418082
	Screw Driver Handle	Н	-	414922
	2.4MM X-lock STD Blade (x2)	I	_	414923

Trials, Instrumentation, and Accessories (cont.)



Product	Description	Label	Size	Part Number
	Provisional Locking Screw	J		418098
>	Trial Head	K	10 x 20 mm	418022
			12 x 20 mm	418023
Q			14 x 20 mm	418024
			16 x 20 mm	418025
			18 x 20 mm	418026
			10 x 22 mm	418031
			12 x 22 mm	418032
			14 x 22 mm	418033
			16 x 22 mm	418034
			18 x 22 mm	418035
			10 x 24 mm	418041
			12 x 24 mm	418042
			14 x 24 mm	418043
			16 x 24 mm	418044
			18 x 24 mm	418045
3100	Trial Stem	L	5 x 22 mm	418060
			6 x 24 mm	418061
III.			7 x 26 mm	418062
III.			8 x 28 mm	418063
			9 x 30 mm	418064
	Instrument Case	М	_	595220

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Notes	

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