Surgical Technique

Elbow Prosthesis

TORNIER
SURGICAL IMPLANTS

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The RHS Surgical Technique has been developed in conjunction with:
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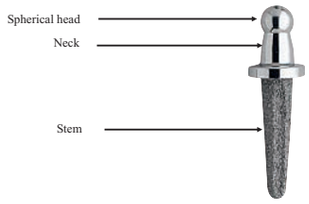
Proper surgical procedures and techniques are the responsibility of the medical professional. Individual surgeon evaluation of the surgical technique should be performed based on his or her personal medical training and experience. This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling on package insert for all necessary information.

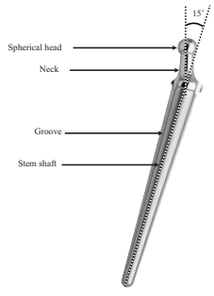
DESIGN RATIONALE

- The RHS implant has been designed to maintain optimal congruence between the prosthesis, distal humerus and proximal ulna.

- The radial head is a key anatomic structure of the elbow; 60% of the compressive axial loads are transferred across the radio-humeral joint. In addition, the radial head is a major stabilizer of the elbow resisting valgus forces.



The press-fit short stem is CoCr with Ti plasma spray for optimal bone fixation. The straight neck enables ± 10° bipolarity. Stem diameters of 6, 7, 8, 9, and 10 mm have a stem length ranging from 21 – 24 mm and accommodate neck resection levels of 13 mm and 16 mm.



The long stem design features a CoCr stem with 15° angulation of the neck relative to the stem axis in order to reproduce the anatomic offset of the proximal radius (supination curvature) and allows ± 17.5° bipolarity. Stem diameters of 6.5 mm and 8.0 mm, with stem lengths of 55 mm and 60 mm respectively, each accommodate neck resection levels of 19 mm and 22 mm. The long stem can be used for primary or revision arthroplasty. In primary fracture cases the long stem is ideal for more distal fractures that involve comminution of the radial neck.

The modular heads are CoCr with a polyethylene liner that offers a choice of 18 mm, 20 mm, 22 mm and 24 mm diameters.

INTRODUCTION

Indications

1. Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral 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.

The long stem is for single cemented use only. The short stem coated with titanium plasma-spray is for single use with or without cement.

Contraindications

Known contraindications to date:

- Acute or chronic infectious diseases of any etiology and localization.
- Unsuitable or insufficient bone support preventing proper anchoring of the prosthesis.
- Neuromuscular or psychiatric disorders, which might jeopardize fixation and postoperative care.
- Bone immaturity.
- Known allergy to one of the materials.
- Pregnancy.

Preoperative Planning

1. Radiographs of the contralateral elbow may be helpful in determining the radial head stem sizes.

2. If fracture line position < 16mm use a press-fit short stem.
If fracture line position > 16mm use a cemented long stem.

Surgical Approach

The surgical approach should facilitate access and exposure to any structure that may require repair or reconstruction in conjunction with the radial head replacement. The skin incision can be made either posteriorly, directly over the olecranon, or over the lateral aspect of the elbow. In a case that only requires access to the lateral side of the elbow the patient can be positioned supine with the elbow at the side and the shoulder internally rotated. Alternatively, the patient can be placed in a "lazy lateral" position, supine with a roll behind the affected side thorax, and the arm draped across the chest. A full lateral decubitus position can also be used. An upper arm tourniquet is used to maintain a relatively bloodless surgical field.

Full thickness faciocutaneous flaps are elevated to approach the lateral aspect of the elbow. The interval between the anconeus and the extensor carpi ulnaris muscles is identified. The anconeus muscle is elevated off of the underlying lateral elbow capsule. In case of elbow dislocation the lateral ligament complex and extensor origins are usually avulsed or elevated off of the lateral aspect of the distal humerus. If the extensor origin is intact a portion may need to be elevated off of the humerus to facilitate the exposure. The lateral capsule is incised obliquely and the annular ligament is divided to expose the radial head and neck. Care is taken to incise the annular ligament at a distance from the proximal ulna to facilitate repair.

The radial head fragments are excised and any additional debris or clot is removed from the elbow joint. Careful visual examination of the joint is also carried out to identify other injuries. Some coronoid fractures can be reduced and fixed from the lateral side of the elbow.

Figure 1: Lateral incision

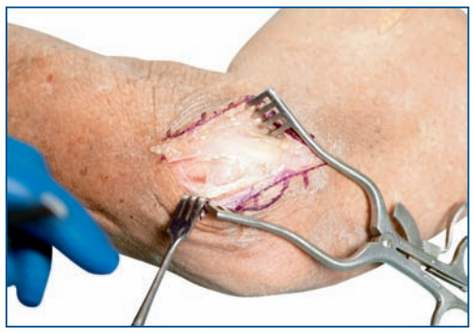


Figure 2: Lateral dissection

Figure 3: Posterior incision

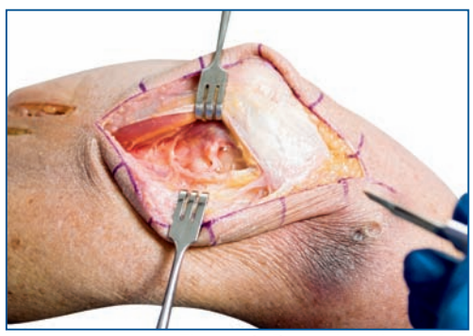


Figure 4: Posterior dissection

SURGICAL TECHNIQUE

1. Resection of the Radial Head

The radial neck is cut using a sagittal saw to create a flat surface perpendicular to the radial neck axis. A high-speed burr can also be used to remove irregularities or prominences at the end of the radial neck. The neck length gauges are used to determine the position of the radial neck cut or the length of the required neck when there is a radial fracture (Figures 5 and 6).

Figure 5: Press-Fit Short Stem

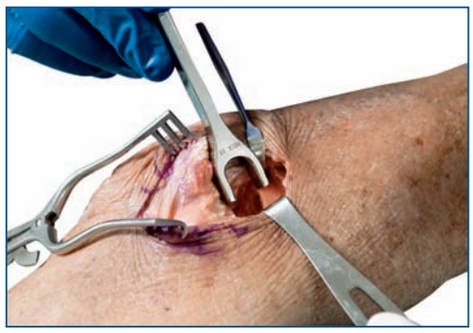


Figure 6: Cemented Long Stem

2. Preparation of the Radial Canal

Retractors are placed around the radial neck to expose the cut end and the intramedullary canal. Care must be taken to protect the posterior interosseous nerve, which courses slightly more distally along the radius under the supinator muscle. Pronating the forearm moves the nerve away from the operative site. The intramedullary canal is opened with the 6.5 mm reamer (Figure 7). The radial neck planer can be used to create a smooth contact surface for the stem collar (Figure 8).

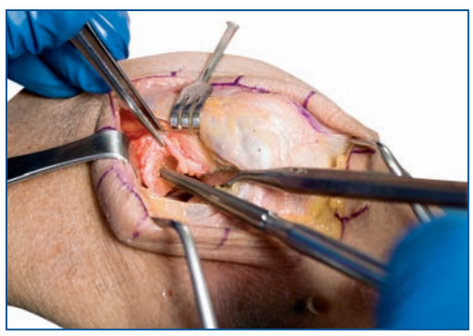


Figure 7

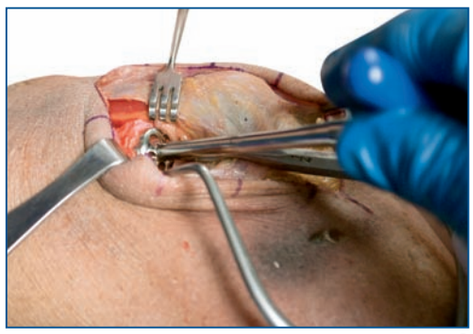


Figure 8

Press-Fit Short Stem:

Further preparation of the radius, for the press-fit short stem, involves compacting the bone against the cortex. Start with the compactor of the smallest size and progress sequentially, while manually inserting each compactor to the machined groove .
If the compactor cannot be inserted to the full depth in a younger patient with healthy dense bone, then you may want to select the implant size corresponding to the previous compactor size. Avoid using excessive force, but if the patient is elderly with osteoporotic bone, then light tapping on the compactor with a mallet may be necessary.

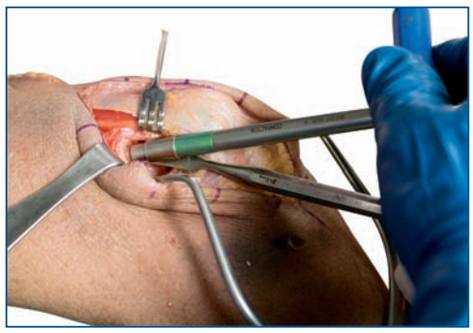


Figure 9

Cemented Long Stem:

The canal preparation for the cemented long stem involves removing the cancellous bone from the intramedullary canal of the radius in order to optimize the strength at the bone-cement interface. Start with the 6.5 mm reamer followed by the 8 mm reamer, if the canal is large enough (Figure 10).

Figure 10

3. Insertion of the Trial Component

Press-Fit Short Stem:

Insert the trial radial stem using the stem holder followed by the stem impactor (Figure 11). The size of the head is chosen with respect to the anatomy of the operative elbow and templating from the contralateral side. If between sizes, the smaller size should be used. The selected trial head is placed on the stem and the elbow is reduced with the trials in place (Figure 12).

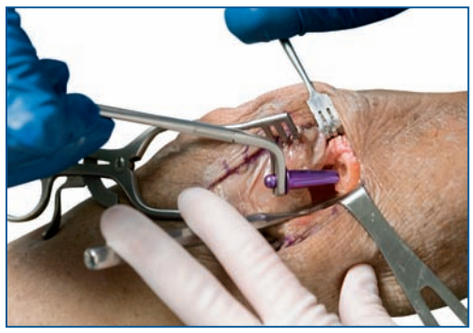


Figure 11

Figure 12

Cemented Long Stem:

The orientation of the prosthetic neck must be in the anatomic plane of the thumb in extension. The angulated neck of the trial stem is oriented towards the radial styloid. Insert the trial radial stem using the stem holder followed by the stem impactor (Figure 13). The size of the head is chosen with respect to the anatomy of the operative elbow and templating from the contralateral side. If between sizes, the smaller size should be used. The selected trial head is placed on the stem and the elbow is reduced with the trials in place (Figure 14).

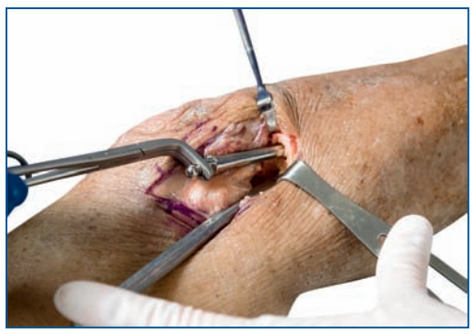


Figure 13

Figure 14

4. Range of Motion

Once reduced, the elbow should be placed through a full range of elbow flexion/extension and forearm pronation/supination. The stability of the radial head is checked by ensuring that its concave surface remains positioned against the capitellum in all positions. Varus, valgus, and posterior lateral rotatory stability are also assessed.

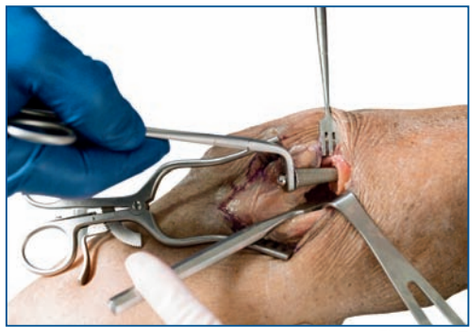


Figure 15

5. Placement of the Final Implants

Press-Fit Short Stem:

The press-fit short radial stem is 1 mm in diameter larger than the corresponding bone compactor. The stem is inserted into the intramedullary canal using the stem holder followed by the impactor and should be at the exact level of the radial cut, making sure the collar is in contact with the resected surface (Figure 15). If a firm fixation is not obtained at the time of the insertion (i.e. stem can be easily extracted from or rotated in the medullary canal) then the use of cement is recommended. The appropriate size head is then snapped onto the stem (Figure 16).

Figure 16

Cemented Long Stem:

The intramedullary canal is first plugged, beyond the tip of the implant stem, by impacting bone fragments from the head using the reamer corresponding to the selected prosthesis size.

Cement is injected into the canal and the prosthesis is introduced using the stem holder taking care to position the implant with respect to the anatomical orientation. The stem holder can be positioned onto the neck of the prosthesis to rotate the stem into the proper orientation. Using the impactor the prosthesis is inserted to the exact level of the radial cut with the collar in contact with the resected surface. Once the cement has hardened the radial head is snapped onto the stem (Figure 17).

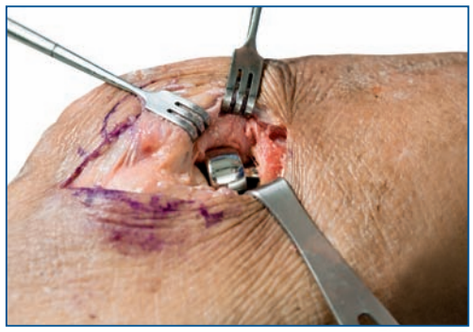


Figure 17

Closure

Once the radial head has been reduced, careful closure of the lateral soft tissues and management of other injured elbow structures is essential to restoring elbow stability. The annular ligament and lateral capsule are repaired with number 0 braided non-absorbable suture. At this point elbow motion and stability are reassessed both grossly and with fluoroscopic imaging. If the extensor origin was disrupted by the trauma or has been elevated for exposure it is repaired back to the distal humerus with either suture anchors or trans-osseous sutures. The anconeus is repaired to the edge of the extensor carpi ulnaris muscle with number 0 braided absorbable suture. The subcutaneous tissues and skin are closed according to surgeon preference (Figures 18, 19, 20). Post-operative splinting or immobilization is dependent upon the specific injury patterns. A radial head replacement is more stable than a radial head that has undergone open reduction and internal fixation. This usually allows for earlier range of motion.

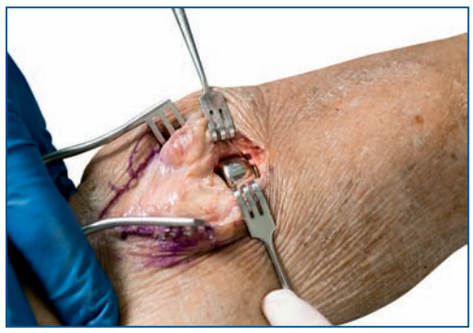


Figure 18

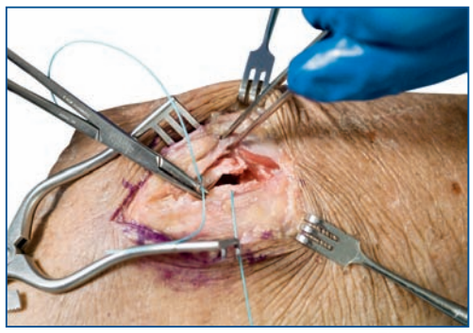


Figure 19

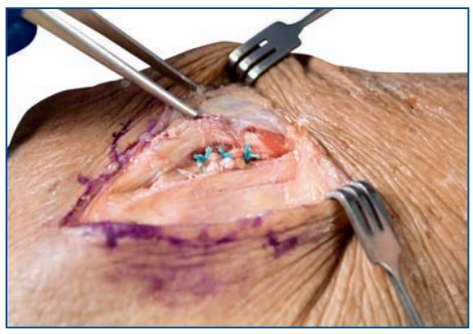


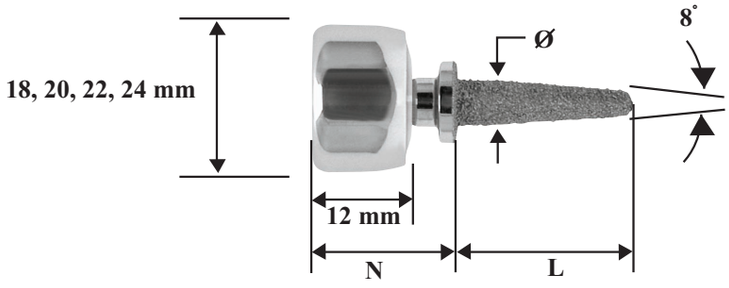
Figure 20

Rehabilitation

The post-operative rehabilitation protocol is dependent upon the specific injury. Elbows that have radial head replacement for a comminuted radial head without concomitant ligamentous or bony injury can begin immediate range of motion exercises. In these cases, although a splint can be used immediately after surgery for comfort, a sling provides sufficient support and protection. When there has been concomitant injury resulting in elbow instability, the pattern of injury as well as the results of the intraoperative assessment of elbow stability must be considered. Splinting may be required to protect tenuous bony fixation such as a comminuted proximal ulna fracture with involvement of the coronoid. If appropriate, night splinting in extension can be used to prevent flexion contracture. If the repairs of concomitant injuries are stable then early motion can be initiated. If the elbow is still unstable or the repairs are tenuous then splinting or external fixation may be required.

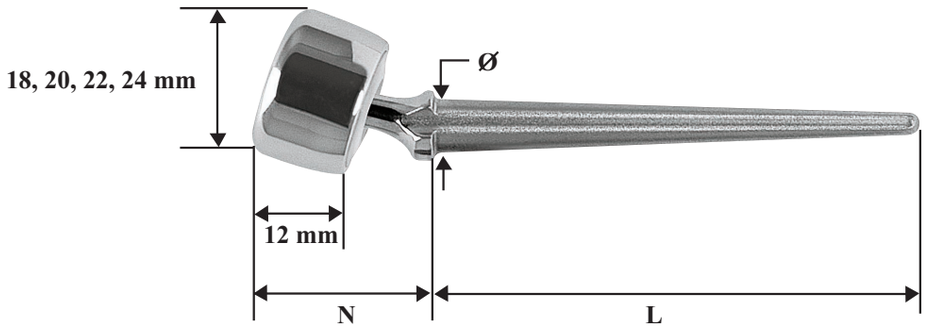
DIMENSION CHARTS

Short Stem



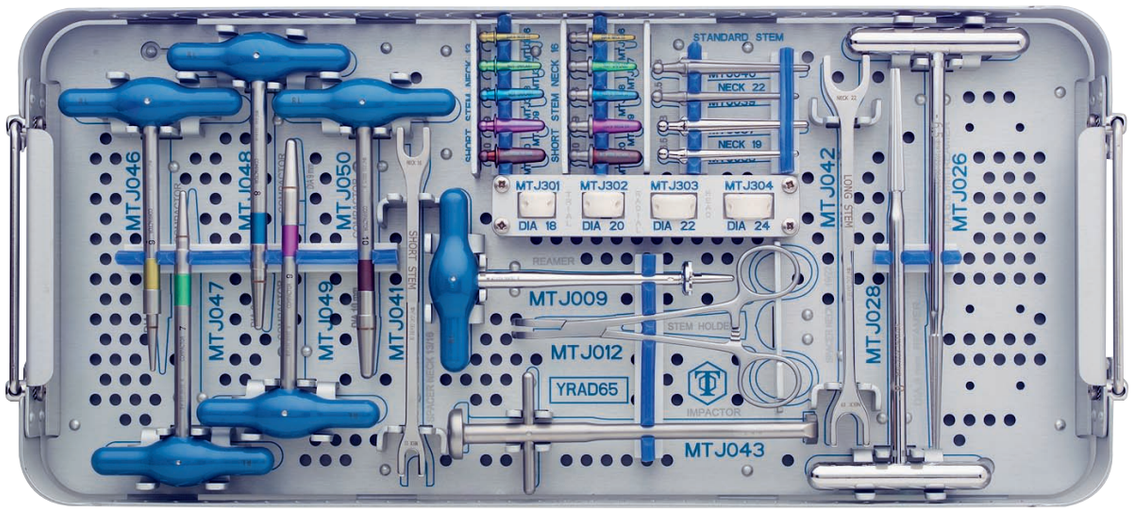
ø (mm)	N (mm)	L (mm)	Bipolarity
6	13 or 16	21	±10°
7	13 or 16	22	±10°
8	13 or 16	23	±10°
9	13 or 16	24	±10°
10	13 or 16	24	±10°

Long Stem



ø (mm)	N (mm)	L (mm)	Bipolarity
6.5	19 or 22	55	±17.5°
8	19 or 22	60	±17.5°

INSTRUMENTATION



Instruments	Reference	Instruments	Reference
Spacer Neck 13/16	MTJ041	24 mm Trial Head	MTJ304
Spacer Neck 19/22	MTJ042	Trial Short Stem 6 mm x neck 13 mm	MTJ306
6.5 mm Reamer	MTJ026	Trial Short Stem 7 mm x neck 13 mm	MTJ307
8 mm Reamer	MTJ028	Trial Short Stem 8 mm x neck 13 mm	MTJ308
6 mm Compactor	MTJ046	Trial Short Stem 9 mm x neck 13 mm	MTJ309
7 mm Compactor	MTJ047	Trial Short Stem 10 mm x neck 13 mm	MTJ310
8 mm Compactor	MTJ048	Trial Short Stem 6 mm x neck 16 mm	MTJ316
9 mm Compactor	MTJ049	Trial Short Stem 7 mm x neck 16 mm	MTJ317
10 mm Compactor	MTJ050	Trial Short Stem 8 mm x neck 16 mm	MTJ318
Planer	MTJ009	Trial Short Stem 9 mm x neck 16 mm	MTJ319
Stem Holder	MTJ012	Trial Short Stem 10 mm x neck 16 mm	MTJ320
Stem Impactor	MTJ043	Trial Long Stem 6.5 mm x neck 19 mm	MTJ039
18 mm Trial Head	MTJ301	Trial Long Stem 8 mm x neck 19 mm	MTJ040
20 mm Trial Head	MTJ302	Trial Long Stem 6.5 mm x neck 22 mm	MTJ035
22 mm Trial Head	MTJ303	Trial Long Stem 8 mm x neck 22 mm	MTJ037

IMPLANTS

Press-Fit Short Radial Stems

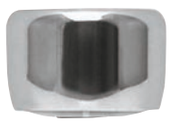
Description	Reference
6 mm x neck 13 mm	DTJ306
7 mm x neck 13 mm	DTJ307
8 mm x neck 13 mm	DTJ308
9 mm x neck 13 mm	DTJ309
10 mm x neck 13 mm	DTJ310
6 mm x neck 16 mm	DTJ316
7 mm x neck 16 mm	DTJ317
8 mm x neck 16 mm	DTJ318
9 mm x neck 16 mm	DTJ319
10 mm x neck 16 mm	DTJ320

Cemented Long Radial Stems

Description	Reference
6.5 mm x neck 19 mm	DTJ106
8 mm x neck 19 mm	DTJ105
6.5 mm x neck 22 mm	DTJ102
8 mm x neck 22 mm	DTJ101

Radial Heads

Description	Reference
18 mm	DTJ301
20 mm	DTJ302
22 mm	DTJ303
24 mm	DTJ304



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