KATALYST™

Bipolar Radial Head System

KATALYST™ • ENGLISH

Surgical Technique

ORTHOPEDICS
UPPER
EXTREMITY

INTEGRA™

Introduction

Description

The Katalyst™ Telescoping Bipolar Radial Head implant restores the support and bearing surface of the radial head in the face of fracture, arthritis or failed prior radial head implantation.

The Katalyst™ system offers three unique features

- Telescoping shaft allows correct length and tension of the soft tissues.
- Bipolar neck provides optimal load transfer to the humerus and decrease the potential for capitellar wear.
- Anatomic curvature of the head recreates normal anatomy.

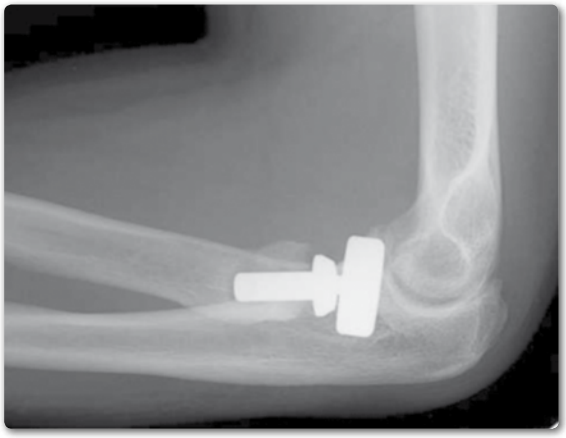
These features allow the surgeon to recreate appropriate tension in situ with an implant that articulates with the capitellum and sigmoid notch in an anatomic fashion. In addition, the modular design allows for radial head replacement without surgical disruption of the lateral ligament complex from the humerus.

Indications

- Comminuted radial fracture with or without associated elbow instability
- Comminuted radial fracture with associated failure of the interosseous membrane; the Essex-Lopresti lesion
- Post-traumatic or primary osteoarthritis involving the radiocapitellar or proximal radioulnar joint
- Rheumatoid arthritis involving the radiocapitellar joint or proximal radioulnar joints
- Revision of failed radial head implant

Contraindications

- Inadequate bone and surrounding soft-tissues to accept and support the implant
- Neurological, metabolic or other medical conditions that might compromise the bone, soft tissues or proprioception about the elbow joint
- Open physes in the radius, ulna and distal humerus
- Infection



Integra as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Surgical technique

Step 1 • Assessment of elbow stability

Valgus stability, posterolateral stability and longitudinal stability are determined using commonly accepted practices such as preoperative radiographs, intraoperative inspection, and stress radiographs.

Surgical approach

- After the skin incision is performed (Fig. 1), the radial head is exposed via a modified lateral approach designed to preserve the lateral ligaments.
- The approach **splits** the thick common extensor tendon origin in the midline.

Step 2 • Exposure

- The appropriate plane can be identified by **palpating** the lateral condylar ridge and radial head.
- A full-thickness **incision** is made through the common tendon and ligament origin along the **longitudinal axis** of the radial head and neck (Fig. 2).
- The origin of the radial wrist extensors and the joint capsule may be **elevated** from the anterolateral aspect of the distal humerus as needed for exposure.
- Extend the split of the lateral complex **distally** to the metaphysis of the radial neck. In the atraumatic setting, the exposure can be performed without destabilizing the elbow since the posterior half of the extensor origin and lateral ligament complex remain intact.

NOTE:

When the radial head has fractured in association with a dislocation of the elbow, the lateral complex will often be stripped from its origin on the lateral epicondyle. This should be noted during the exposure, and a plan should be formulated to repair or reconstruct the complex at the end of the case. (Text on file)

Fig. 1

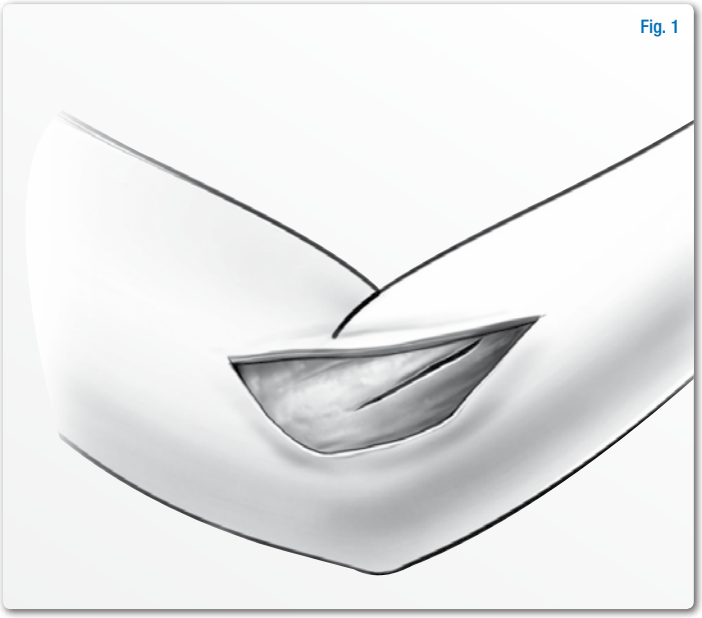


Fig. 2

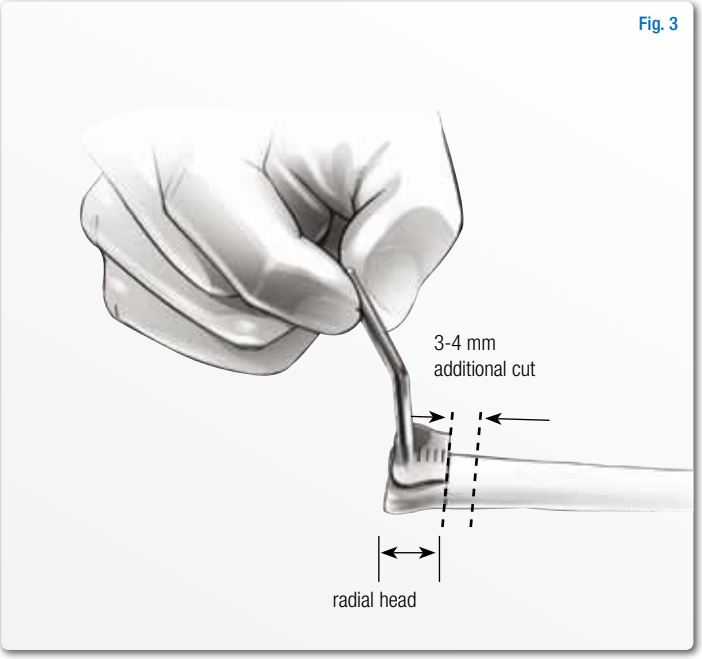
Step 3 • Radial head resection

- Radial head resection at **the proximal articular margin** at this level will prevent impingement between the cut end of the proximal radius and the sigmoid notch.
- An additional **3-4 mm** of the proximal radius is resected for the implant. The appropriate location for resection can be determined by using **the Cutting Template** (Fig. 3); this location corresponds with the disection of the head using the **1mm (4.5")** shim.

NOTE:

Once the cut in the neck is made, measure the distance from the coronoid to the cut edge of the proximal radius and re-create that distance with the head and neck (see Step 7).

Fig. 3



Step 4 • Opening intramedullary canal

The Starter Awl is used to open the intramedullary canal of the proximal canal. (Fig. 4)

Fig. 4

Step 5 • Broaching

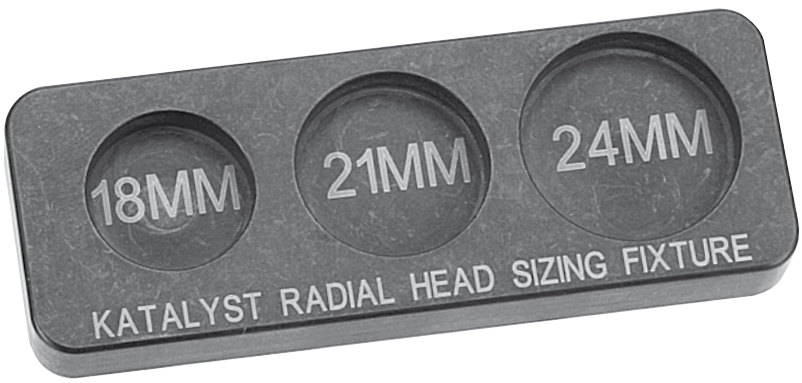
- The combination **Broach** with **End Cutting Mill** is used to create a smooth cut end of the proximal radius intramedullary canal that is **perpendicular** to the long axis of the radius (Fig. 5)
- It is recommended to start with the **6.5mm** Broach prior to using the **7.5mm** Broach.

Fig. 5

Step 6 • Choosing trial head

- Once the canal is broached up to the appropriate size, the corresponding Trial Stem is placed into the intramedullary canal with the black line on the side of the trial stem facing the surgeon.
- The Broaches and trial stems are **color coded** for convenience.
- The appropriate **diameter** Trial Head is chosen based on pre-operative templating and/or reassembly of the fracture components using **the Head Sizing** Fixture as a template (Fig. 6).
- In cases where there is a question between 2 head sizes, the smaller implant is chosen.

Fig. 6



Step 7 • Using spacers to adjust separation

- Once the Trial Head is **snapped** in place on the stem, the two components are **extended** to re-create the appropriate distance from the coronoid, to the edge of the proximal radius **as determined in Step 3.**
- This separation is achieved by inserting **the First Spacer** which will position the implant in the first **extended position.** For each additional extension required, **2mm** Spacers are used (Fig. 7).

NOTE:

The forearm must be in 90° of flexion and at full pronation when determining the appropriate tension via the spacer forks.

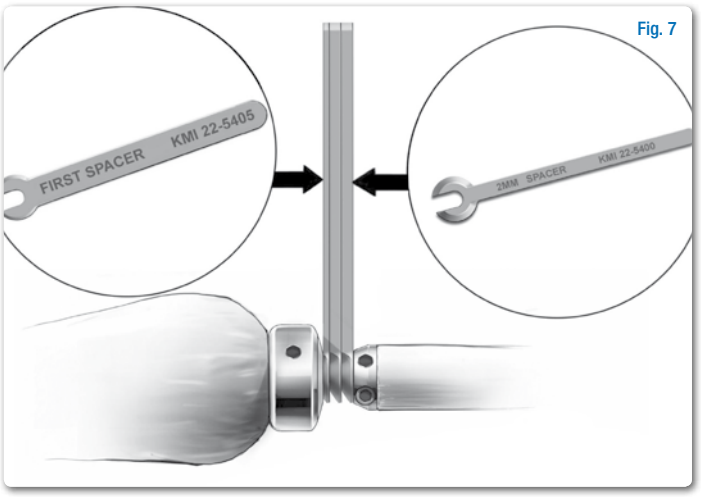


Fig. 7

Step 8 • Appropriate separation

- Determining the appropriate separation in the head-neck construct is more difficult when the lateral complex has torn. This can be accomplished by provisional reduction of the tendon and ligament origin to the humerus with the ulno humeral joint reduced by flexion and pronation of the forearm.
- Length can also be checked by evaluating the radial head implant relative to the measurements between the coronoid and the cut edge of the proximal radius **(as determined in Step 3)**.
- The proximal margin of the implant should line up with **the articular surface** of the coronoid when viewed from the lateral side.

Step 9 • Locking the stem

- Once the appropriate tension is achieved, the Trial Stem is **locked** in place by turning **the Set Screw** in a clockwise fashion for 3/4 of a turn (Fig. 8).

NOTE:

The set screw in the trial is captured in place and cannot be removed.


Fig. 8

Step 10 • Implant alignment

- Intraoperative radiographs may be used to confirm appropriate **size and position** of the implant.
- The stem should be aligned with the longitudinal axis of the radius. The head should **match the capitellum and seat** in a congruent fashion against the sigmoid notch.
- **The medial joint space** of the ulnohumeral articulation should be **symmetrical** and **not converge** on the anteroposterior projection (Fig. 9).; if so, the elbow may have been forced into a valgus position by an "overstuffed"implant (Fig. 10).
- Move the elbow through **a full arc** of flexion and fore arm rotation. A lack of motion may be additional evidence of an oversized or over-distracted trial implant.

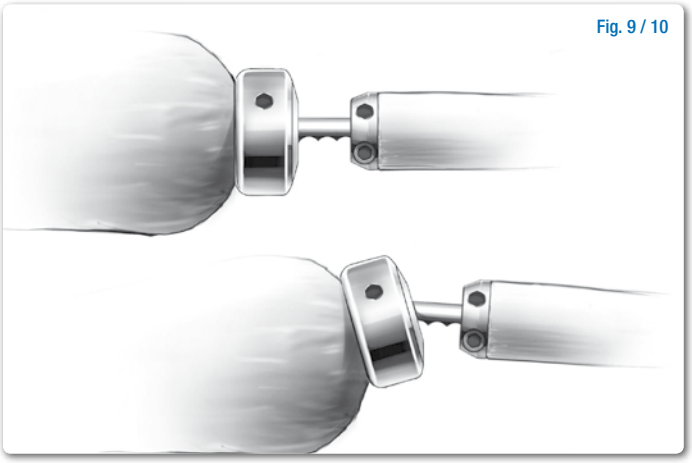


Fig. 9 / 10

Step 11 • Stem insertion

- **The Trial Implant** is removed and **the Permanent Implant** of the same size is placed. Prior to placing the Stem in the surgical field, **the Set Screw** is removed from the side of the Stem. **The Stem is fully inserted** into the canal, again ensuring that the black line on the implant faces the surgeon (Fig. 11).


Fig. 11

Step 12 • Attaching radial head

- The appropriate sized Head is placed over the spherical end of the Stem. There is **a hex feature** on both the Head and the Stem. By placing **one Hex Driver** in each of these two holes and **pinching** the two Hex Drivers together, the Head will snap in place on the stem.
- **Pliers** are provided to assist with pinching the two drivers together when snapping the Head onto the Stem.

NOTE: DO NOT DISASSEMBLE

Once the head has been assembled to the stem, disassembly of these components will adversely affect retention strength between them and is not recommended.

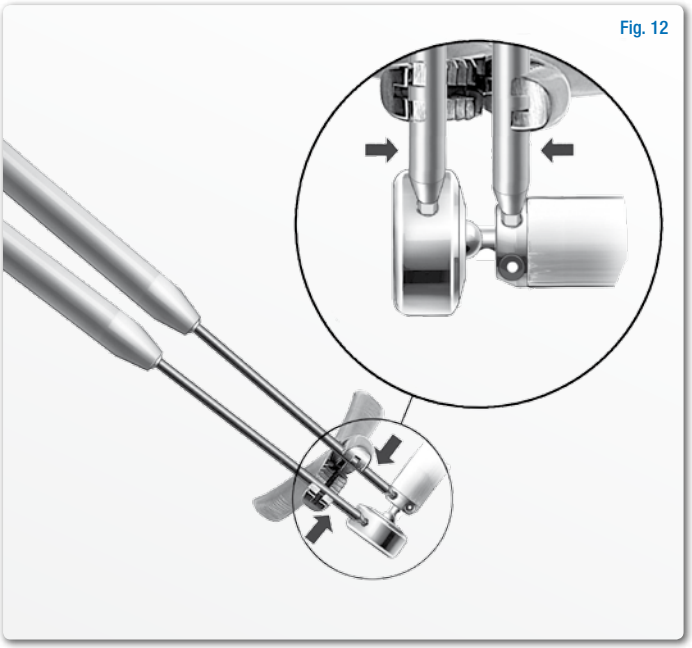
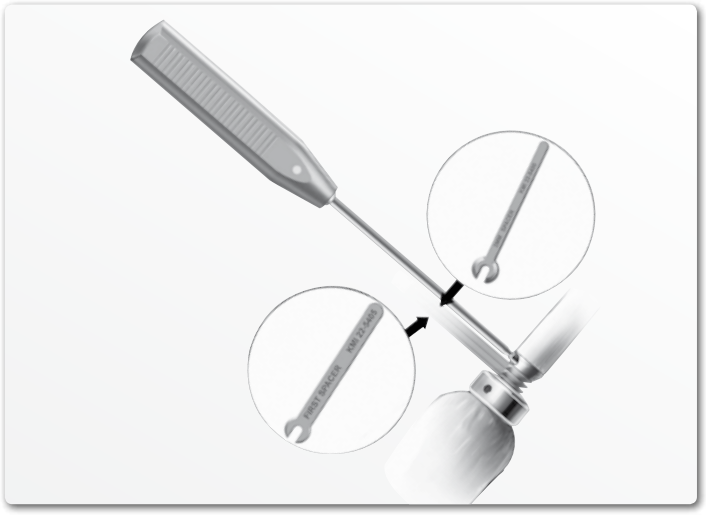


Fig. 12

Step 13 • Set screw locking

- Once in the correct position, **the Set Screw** is placed back into the stem, taking care **not to over-torque** the screw.
- Finally, **the Spacers** are removed from the implant.
- Repeat radiographs and intra-operative stress testing are now performed.



Step 14 • Repairing

- If **the posterior half** of the lateral complex is intact, the anterior half is repaired to the intact posterior limb.
- If **the lateral complex** was avulsed or released, it is repaired to **the lateral epicondyle**. The skin is closed and the elbow is placed in a posterior splint.

Step 15 • Final radiograph

In cases of unstable elbow fracture dislocations it is recommended that **a lateral radiograph** of the splinted elbow be obtained in the splint to ensure that **a concentric reduction** of the elbow has been maintained.

Postoperative care

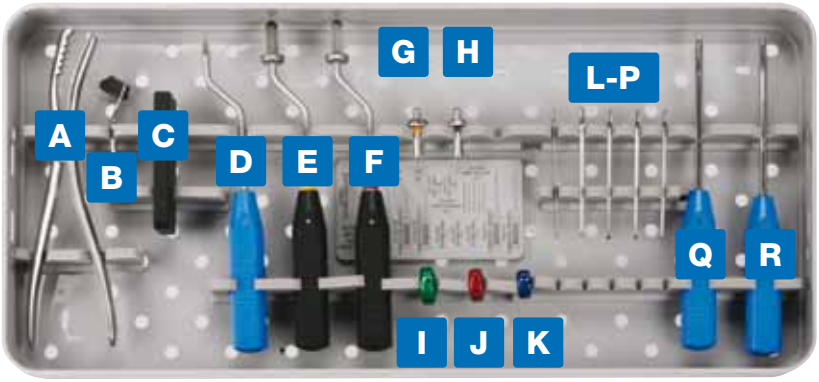
Elbow motion and forearm rotation are begun in the early postoperative period. Rehabilitation is guided by intraoperative stability. Serial follow-up radiographs should be examined for evidence of implant malposition or wear. Sclerosis in the bone at the implant-bone interface is evidence of appropriate load transfer through the implant.

NOTE: REVISION OR REMOVAL

To disengage the head from the stem, place one hex driver in the head component and a second hex driver in the stem component and lever the hex driver in the head away from the driver in the stem until the head is disassembled. Reusing a head component that has been previously assembled to a stem is not recommended as the retention force will be compromised.

Instrument tray

A	Pliers
B	Cutting Template
C	Head Sizing Fixture
D	Starter Awl
E	7.5 mm Stem Broach
F	6.5 mm Stem Broach
G	7.5 Trial Stem
H	6.5 Trial Stem
I	24 mm Trial Head
J	21 mm Trial Head
K	18 mm Trial Head
L	First Spacer (1 mm)
M	2 mm Spacer
N	2 mm Spacer



O	2 mm Spacer
P	2 mm Spacer
Q	2.5 mm Hex Driver
R	2.5 mm Hex Driver

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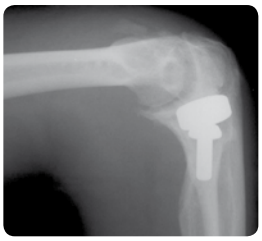
Features

- *In situ* telescoping shaft utilizes a First Spacer (1mm) and then spacers increase in 2 mm increments up to 10 mm.
- Two hex drivers are included in the instrument set to facilitate manipulating, assembling and disassembling both trials and implants.
- Cutting template tool available (Radial Head Sizing Block) to assist in accurate resection measurement for radial head implant.

These features allow the surgeon to recreate appropriate tension *in situ* in the supporting ligaments of the elbow with an implant that articulates with the capitellum and sigmoid notch in an anatomic fashion. In addition, the modular design allows for radial head replacement without surgical disruption of the lateral ligament complex from the humerus.

Component materials

- Head and poly Assembly: Cobalt Chrome with polyethylene liner
- Stem Assembly: Stainless Steel



Telescoping implant

with Multiple Head and Stem Sizes

Instrument set

Part N°	Description	Size
22-1418	Head and Poly Assembly	18 mm
22-1421	Head and Poly Assembly	21 mm
22-1424	Head and Poly Assembly	24 mm
22-1665	Stem Assembly	65 mm
22-1675	Stem Assembly	75 mm
22-1001	Instrument Set	

INTEGRA™

EC REP Integra LifeSciences Services (France) SAS
Sales & Marketing EMEA
Immeuble Séquoia 2 • 97 allée Alexandre Borodine
Parc technologique de la Porte des Alpes
69800 Saint Priest • FRANCE
t +33 (0)4 37 47 59 00 • fax +33 (0)4 37 47 59 99
emea.info@Integra-LS.com • www.Integra-LS.com

Distributed by

INTEGRA™

Integra LifeSciences Corporation
4900 Charlemar Drive
Cincinnati, OH, 45227
USA

Customer Service
International: +33 (0)4 37 47 59 50 • +33 (0)4 37 47 59 25 (Fax) • csemea@Integra-LS.com
France: +33 (0)4 37 47 59 10 • +33 (0)4 37 47 59 29 (Fax) • custsvcfrance@Integra-LS.com
Benelux: +32 (0)2 257 4130 • +32 (0)2 253 2466 (Fax) • custsvcbenelux@Integra-LS.com
Switzerland: +41 (0)2 27 21 23 30 • +41 (0)2 27 21 23 99 (Fax) • custsvcsuisse@Integra-LS.com

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