SURGICAL TECHNIQUE

rHead™
Radial Implants

SBi
SMALL BONE INNOVATIONS, INC.

rHead™ Radial Implants

SURGICAL TECHNIQUE

CONTENTS

Introduction

The radial head is an important component of both normal elbow as well as forearm function contributing to the radiocapitellar and proximal radioulnar joints. Stability testing has demonstrated that the radial head is an important "second line" constraint to resist valgus loads (after the medial collateral ligament).

Radial head resection, while occasionally necessary from fracture, osteochondrosis, or secondary arthritis, is not without adverse effect on both elbow and forearm function. In-depth laboratory studies have demonstrated the important role of the radial head in elbow kinematics, force distribution, and load transfer across the forearm and elbow joint.

Radial head resection has been implicated in persistent elbow instability in elbow fracture-dislocation, rotational instability injuries, and medial-lateral translation injury. Forearm axial instability can result from radial head excision if the remaining stabilizers have been compromised (the Essex-Lopresti lesion). The common thread in all of the instabilities of the forearm and elbow is one of ligament injury in association with bone loss. Once the secondary stabilizer is removed (i.e. radial head) and elements of the soft tissues (collateral ligaments, interosseous membrane of the forearm and/or distal and proximal radio-ulnar joints) are compromised, joint instability is noted to increase.

Replacement of the radial head is an anatomic and functional solution to acute elbow and forearm instability when internal fixation of the radial head fractures cannot be performed. It is also indicated in instances in which residual symptoms of pain or instability prompt the use of the delayed insertion of a radial head implant as a reconstruction procedure.

rHead™

rHead Recon

rHead Lateral

rHead Design Rationale

The rHead™ Standard, Recon, and Lateral styles make up a family of anatomically designed radial head implants. They are offered in multiple sizes to duplicate the anthropomorphic differences of the radial head and can be used to correct complex elbow instabilities or for elbow reconstruction. These implants are made up of a head and a stem component and are modular within each of the rHead styles.

The heads are designed with a concave articular surface to articulate with the convexity of the capitellum. There are three sizes offered. The circumference approximates the normal proximal radioulnar joint articulation, preserves the annular ligament, and minimizes release of the important lateral collateral ligaments.

The stems are designed with a curve to match the anatomical geometry of the proximal radius and to ease insertion into the intramedullary canal. The stems are cement optional. There are four sizes of stems, each of which are offered with two collar lengths. The extended collared stems are used with distally migrated fractures or where poor bone quality makes proper implantation problematic.

A comprehensive instrument set is provided for the rHead System including trials sizers, broaches, and impactors. A radial head resection guide is also included and is used to establish the anatomical axis of rotation of the forearm and the proper position of the osteotomy. This prevents rotational malalignment that may cause poor radio-capitellar contact leading to instability and/or cartilage wear.

Note that the anatomy of the proximal radial head and neck are offset 15° laterally to the shaft of the radius with the forearm in supination (SEE FIGURE B, PAGE 4)

The rHead™ Standard is designed with a Morse taper coupling mechanism to firmly attach the head onto the stem. The rHead Standard was SBi's first radial head implant developed and has been on the market since 1998.

The rHead™ RECON is designed with a "ball/socket" (bipolar) coupling mechanism between the head and stem which adds an element of alignment flexibility. This facilitates proper radio/capitellar contact through a functional range of flexion & extension during forearm rotation. The rotational flexibility allows for the adaptation/correction of alignment variations between the radius and capitellum. This is especially true in reconstructive situations when proper axial alignment is difficult to attain.

The rHead™ Lateral is designed using a dovetail coupling mechanism. This side-loading feature allows for easier insertion of the head while it is being assembled to the stem using a specially designed assembly tool. The rHead Lateral implant is tissue sparing by requiring a less invasive approach and exposure, minimizing possible ligament disruption or damage. The dove-tail locking mechanism allows for easy insertion without the use of a set screw.

Surgeon Preferences

Recommended clinical situations for potential use of this device are as follows:

Acute Trauma

1. Comminuted radial head fracture requiring resection associated with ligament injury
   a) Elbow dislocation
   b) Distal radioulnar joint injury (Essex-Lopresti injury)

2. Comminuted radial head fracture requiring resection with associated fracture(s)
   a) Coronoid type II or III fracture (single or comminuted more than half of the coronoid process)
   b) Olecranon type III fracture (displaced or comminuted and unstable)

After radial head excision with evidence of medial collateral ligament insufficiency.

Reconstruction

Malalignment of the resected proximal radius under the following circumstances:

1. Instability after radial head resection in the context of:
   a) Medial collateral deficiency or reconstruction
   b) Lateral collateral deficiency or reconstruction
   c) Axial (Essex-Lopresti) stabilization

2. Failed prior radial head replacement.

3. With interposition arthroplasty if the radial head is excised and residual elbow instability is enhanced by replacement.

In general the rHead™ Recon was designed for use in circumstances in which the proximal radius cannot be anatomically aligned with the capitellum.

Clinical situations where the use of this device should be avoided:

Acute Trauma

1. Older patient with a comminuted radial head fracture requiring radial head excision without evidence of elbow instability or other associated injury (greater than age 65)

2. Open fracture of the radial head, olecranon or associated elbow disolcation with high risk for sepsis

3. Mason type I or II radial head fractures

4. Mason type II radial head fracture not associated with elbow or forearm instability.

Reconstruction

1. Severe malalignment of forearm, proximal radius or ulna (e.g. congenital radial head dislocation or malunion Monteggia fracture).

2. Lack of proper alignment with trial insertion.

3. Disease or injury of the capitellum (e.g. Osteochondrosis of the capitellum).

General

1. Prior sepsis or concern regarding wound contamination

2. Known allergy to implant constituents

3. Skeletal immaturity

4. Bone, tendon or muscle, or adjacent soft tissue compromised by disease, trauma or prior implantation which cannot provide adequate elbow stability or fixation for the prosthesis.

Anatomy of the Radial Head

1. The radial head articulates with the capitellum and radial (greater sigmoid) notch of the ulna (**FIGURE A**).

2. The radial head makes a 15° lateral angle to the radial shaft away from the tuberosity (**FIGURE B**).

3. Ligaments about the radial head provide important soft tissue support and are essential to elbow stability after radial head replacement (**FIGURE C**).

4. Stress distribution varies in pronation and supination but averages 60% radiohumeral and 40% at the ulnohumeral articulation.

5. Elbow stability is related to articular geometry and ligament constraint.

6. Loss of medial collateral ligament and/or radial head produces primary or secondary elbow instability. Radial head replacement aids in restoring elbow stability (**FIGURE D**).

7. **Recon only:** After radial head resection, or following ulnar fracture, the proximal radius may not align with the capitellum.

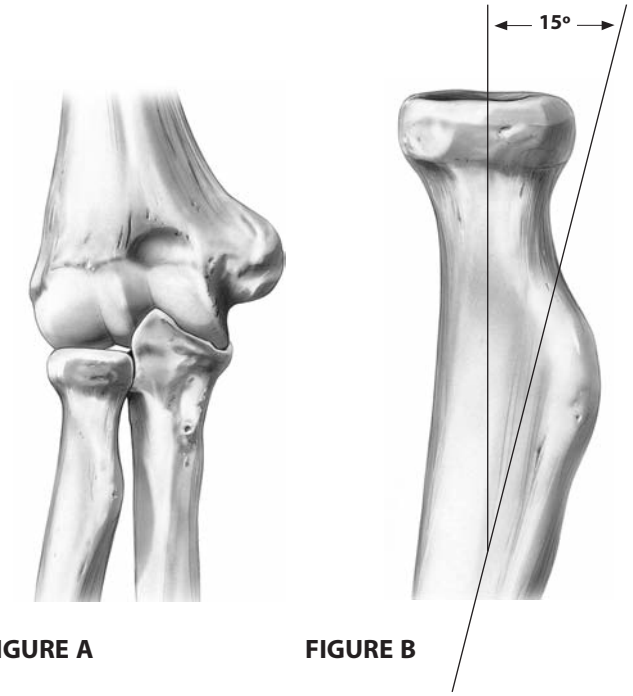


FIGURE A **FIGURE B**

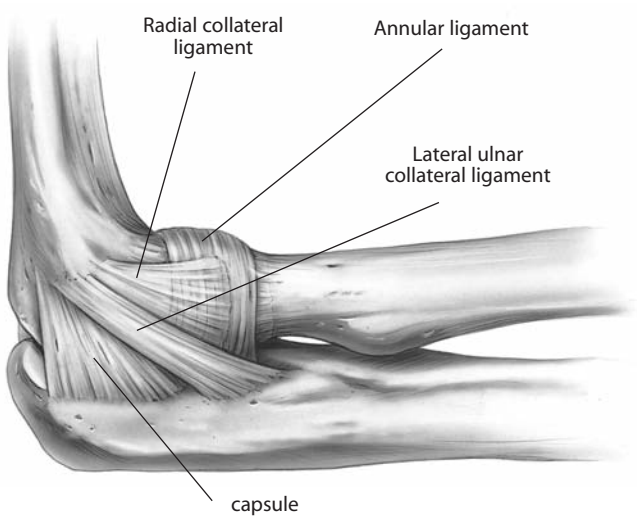


FIGURE C

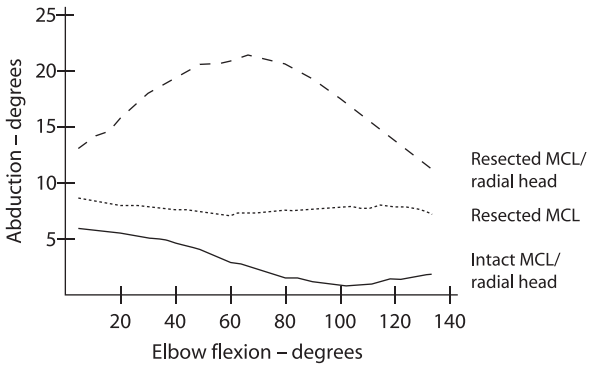


FIGURE D

Disorders of the Proximal Radioulnar Joint

The proximal radioulnar and radiocapitellar joint articulations may be affected by traumatic and acquired disorders. Traumatic injury is common. Injuries include:

1. Radial head fractures (Mason types I-III) and Mason Type IV — complex radial head fracture associated with ligament injuries

2. Combined proximal ulna fracture with radial head dislocation or fracture (Monteggia lesions I-IV)

3. Radial head fracture associated with dislocation of the elbow (anterior, posterior or lateral)

4. Forearm and elbow injuries (radial head fracture and interosseous membrane disruption) — The Essex-Lopresti lesion.

Elbow Instability
All but one of these above conditions relate to elbow instability and are classified as:

1. Dislocation of the elbow with radial head fracture

2. Monteggia variant with olecranon and radial head fracture

3. Concurrent medial collateral ligament disruption

4. Fracture of a major portion of the coronoid.

Treatment, rHead:
Comminuted radial head fractures Type III (**FIGURE E**) associated with medial collateral ligament injury require stabilization by medial collateral ligament repair and internal fixation of the radial head or radial head replacement. Excision of comminuted fracture of the radial head requires radial head replacement if elbow instability is present. Radial head fracture with dislocation or Type III coronoid fractures also require treatment based on the type of radial head replacement.

Delayed Treatment, Recon Only:
If the injury was not successfully treated initially, a delayed reconstruction of the radio-humeral joint is sometimes required. This is especially true in instances of residual angular or axial instability.

Essex-Lopresti Injury
Forearm disassociation (Essex-Lopresti injury) requires careful diagnosis and initial or delayed radial head stabilization.

The following should be considered:

1. History of axial loading forearm injury

2. Radial head fracture (often comminuted)

3. Tenderness and pain over DRUJ and forearm.

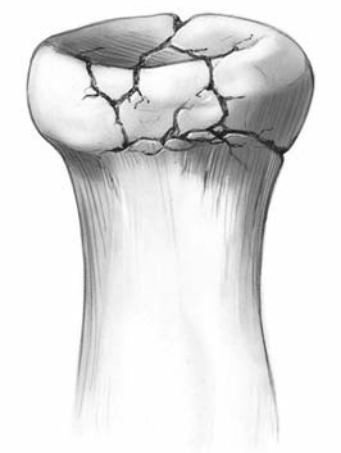
Treatment:
1. Stabilization of the radial head
   a) Open reduction & internal fixation
   b) Radial head prosthesis

2. Immobilization of forearm

3. Operative repair of TFCC

4. Repair or late reconstruction of interosseous membrane.

Radial head replacement is indicated to restore elbow and forearm stability in these conditions.



Mason Type III

FIGURE E

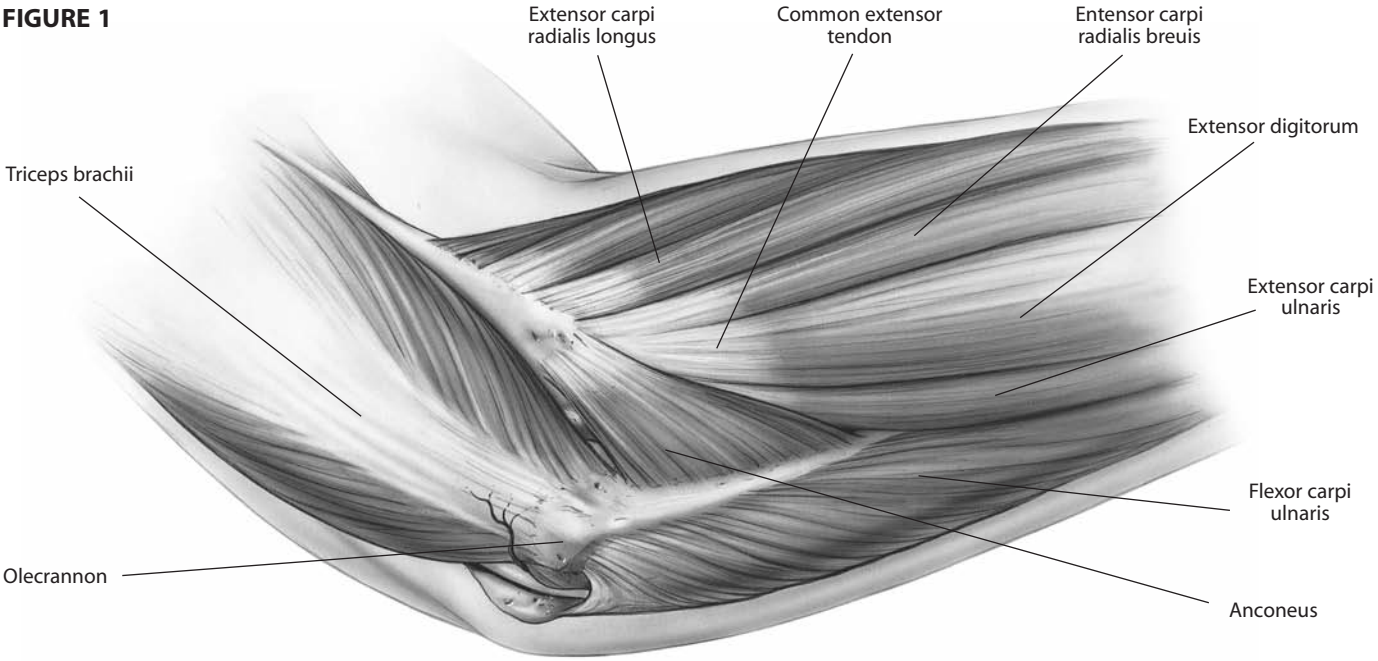
Surgical Procedure

1 ***The Initial Incision***

The patient is placed under a general or a regional anesthesia. The extremity is prepped and draped in the usual sterile fashion. A sterile tourniquet is often a good option. An arm table may be used if the patient is in a supine position or the arm may be brought across the chest.

A classic Kocher skin incision is made identifying the interval between the anconeus and the extensor carpi ulnaris (**FIGURE 1**). The incision extends approximately 6-7cm. The dissection is carried down to the joint capsule. The origin of the anconeus can be released subperiosteally and retracted posteriorly to permit adequate exposure of the capsule.

FIGURE 1



2 Capular Exposure

If the elbow is stable, the capsule is exposed by elevating a portion of the extensor carpi ulnaris sufficiently to allow identification of the lateral collateral ligament complex (**FIGURE 2A**). Alternatively, the extensor carpi ulnaris may be split longitudinally in line with its fibers staying anterior to the attachment of the lateral collateral ligament. The lateral capsule is divided slightly anteriorly to the collateral ligament and the annular ligament and capsule are reflected anteriorly and posteriorly to expose the radial head.

A portion of the lateral collateral ligament and anterior capsule can be reflected off the lateral epicondyle and anterior humerus to expose the capitellum if necessary. The lateral ulnohumeral ligament must not be disturbed. If the ligament has been disrupted, then the exposure progresses through the site of disruption to expose the resected proximal radius. The common extensor tendon and elbow joint capsule are retracted as needed to maximize exposure (**FIGURE 2B**).

FIGURE 2A

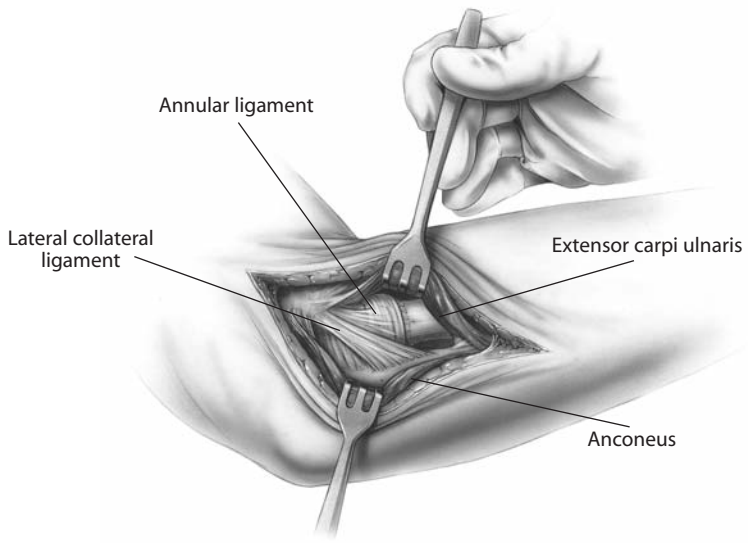
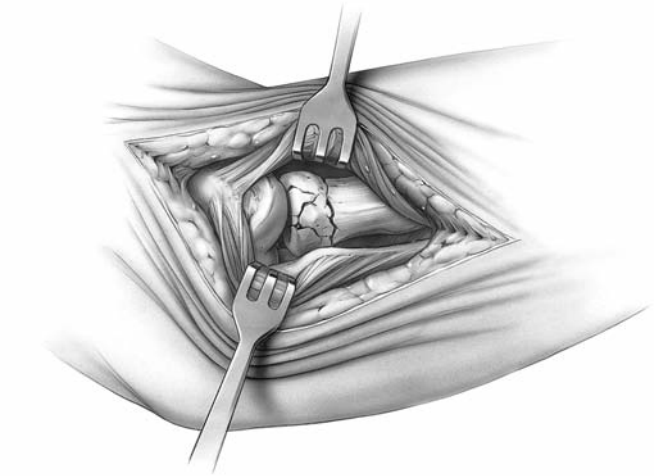


FIGURE 2B



3 *Using the Radial Head Resection Guide, Standard Collar*

The radial neck cut requires a resection guide (17-0967). The device is inserted over the capitellum with the axis of the alignment rod oriented over the ulnar styloid (**FIGURE 3A**). This alignment reflects the anatomic axis of forearm rotation. Test forearm rotation with the guide in place to ensure proper alignment. The proximal flange of the guide is placed against the articular surface of the capitellum and the rotating flange/alignment rod assembly is then guided proximally or distally to the desired length of radial shaft resection (**FIGURE 3B**).

Each notch on the threaded portion of the rod corresponds to a different head size. The rotating flange placement direction must be matched to the anticipated radial head implant size and the axis of forearm rotation. Once the desired length has been established, the proximal flange is secured by tightening the locking nut. The guide must be again aligned to the ulnar styloid (the axis of forearm rotation), not the radial shaft.

FIGURE 3A

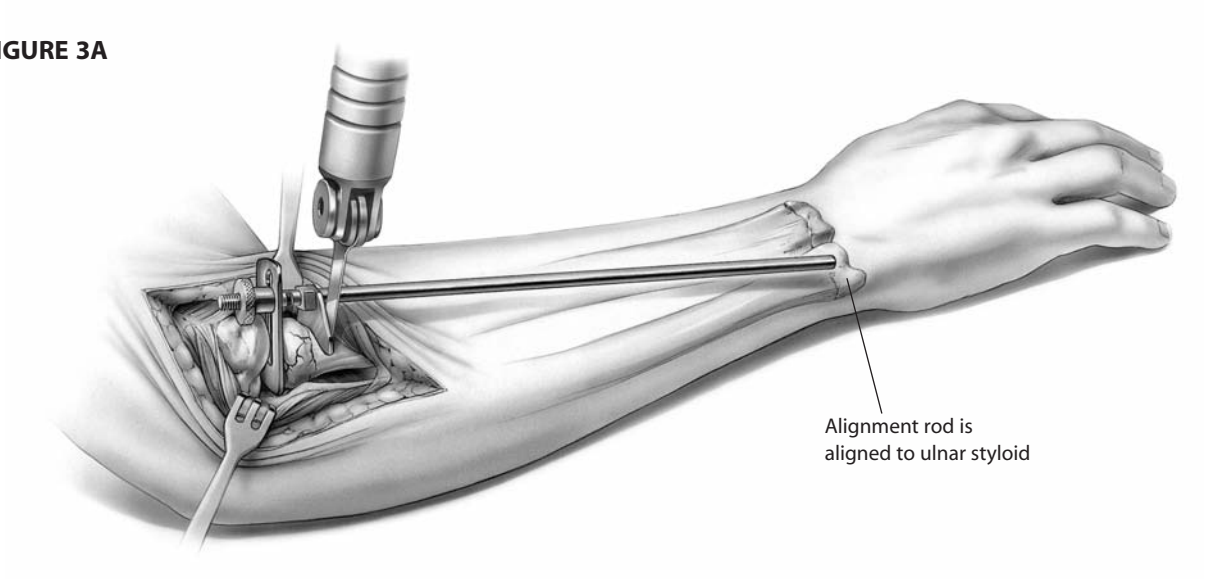
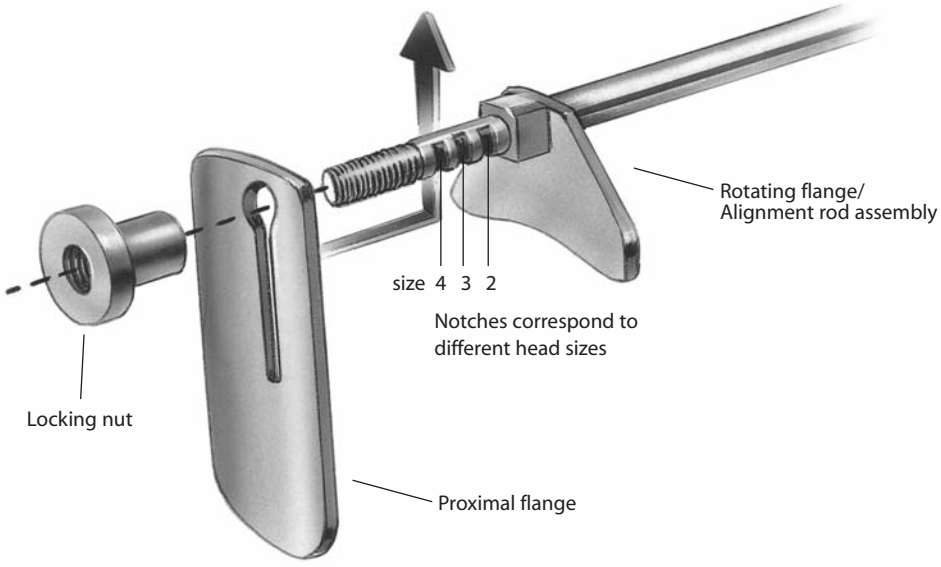


FIGURE 3B



3.1 *Using the Radial Head Resection Guide, 6mm Extended Collar*

During X-Ray templating it may become apparent that the fracture incurred by the patient is distally migrated and the standard 2mm rHead™ stem collar will not restore adequate neck length. For this specific situation the rHead system is also offered in a 6mm extended collar. This 6mm extended collar is intended to be used with distally migrated fractures of the proximal radius.

In addition to a complete set of 6mm extended collar stem trials, a spacer is included for use with the rHead resection guide. This additional spacer is placed over the distal tip of the resection guide with the raised block facing the proximal portion of the resection guide. The spacer is slid proximal until it makes contact with the "Rotating flange" (**FIGURE 3C**). The remainder of the technique is unchanged. The addition of this spacer assures that the proper amount of bone is resected for the extended collar implant

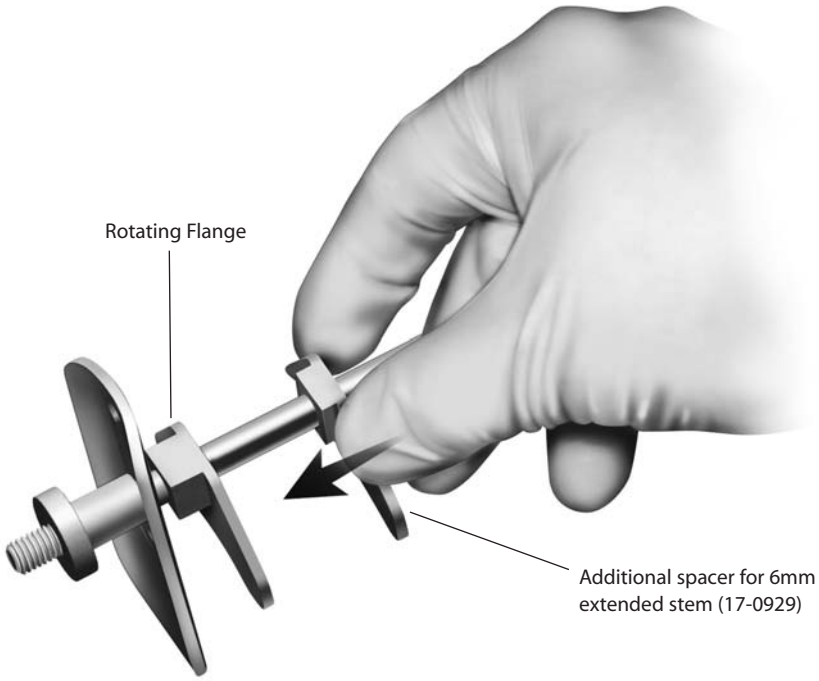


FIGURE 3C

4 Resecting the Radial Head

Using the resection guide, the blade should be guided by the distal surface of the rotating flange (**FIGURE 4A**). During the resection, the forearm is pronated and supinated while the cutting guide is used to align the sawblade perpendicular to the axis of rotation (**FIGURE 4B**). Once initial alignment cuts have been made, the guide is removed and the resection is completed. The distal extent of resection is the minimal amount that is consistent with the restoration of function (**FIGURE 4C**). This includes at least the margin articulating with the ulna at the radial notch.

When the rHead™ Recon is to be used, after radial head resection was previously performed, the guide is employed to "freshen" the resected proximal radius. If the medullary canal is not obvious after the radius has been recut, a high speed bone burr is employed to identify the proxmial radial canal.

In addition, radial length should be restored (axial traction) using a lamina spreader if there is a positive ulnar variance.

FIGURE 4A

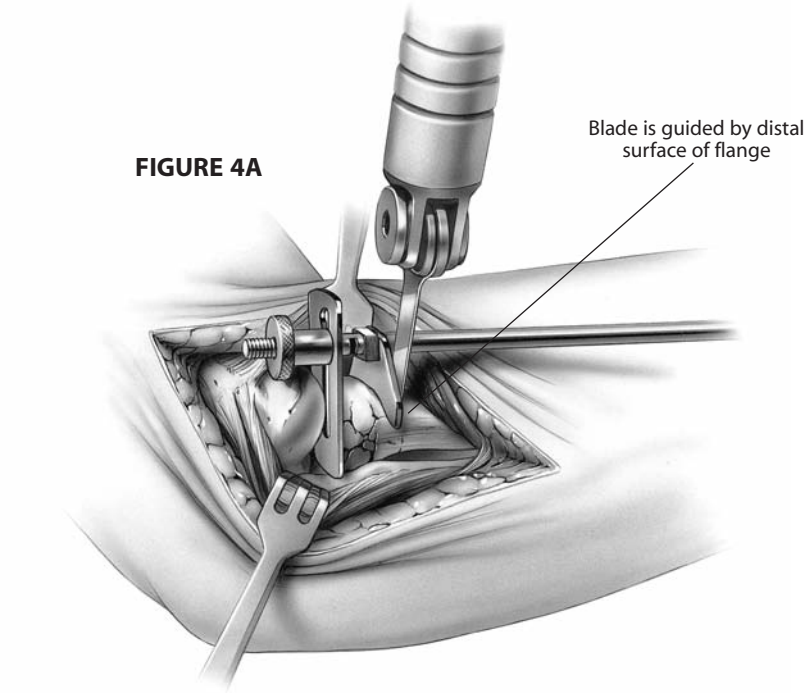
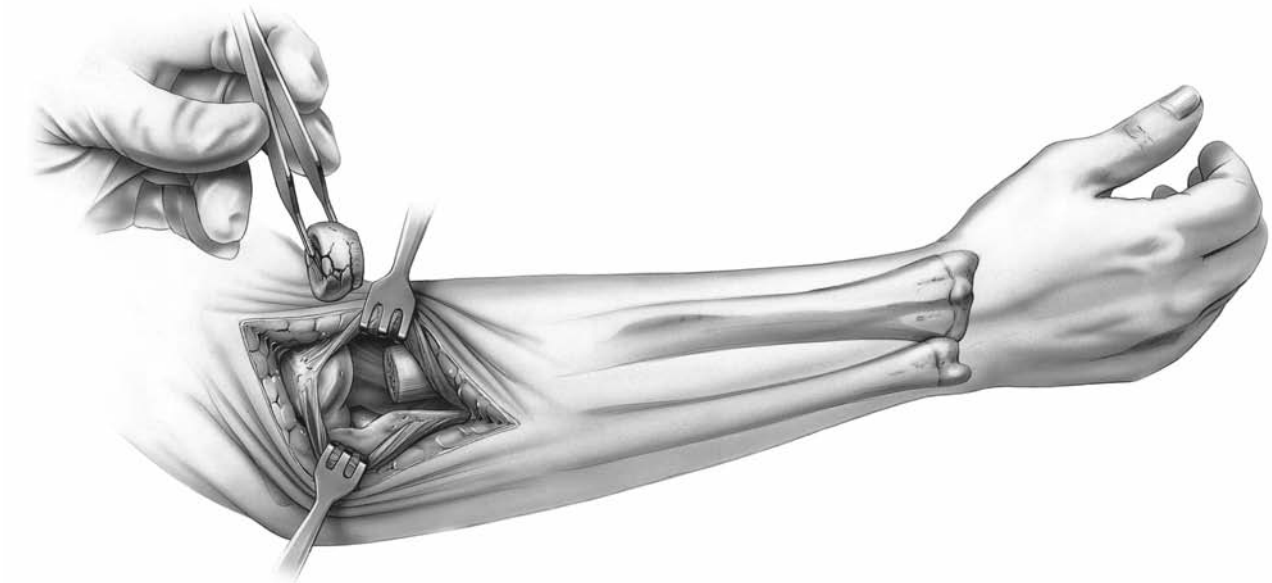


FIGURE 4B

FIGURE 4C

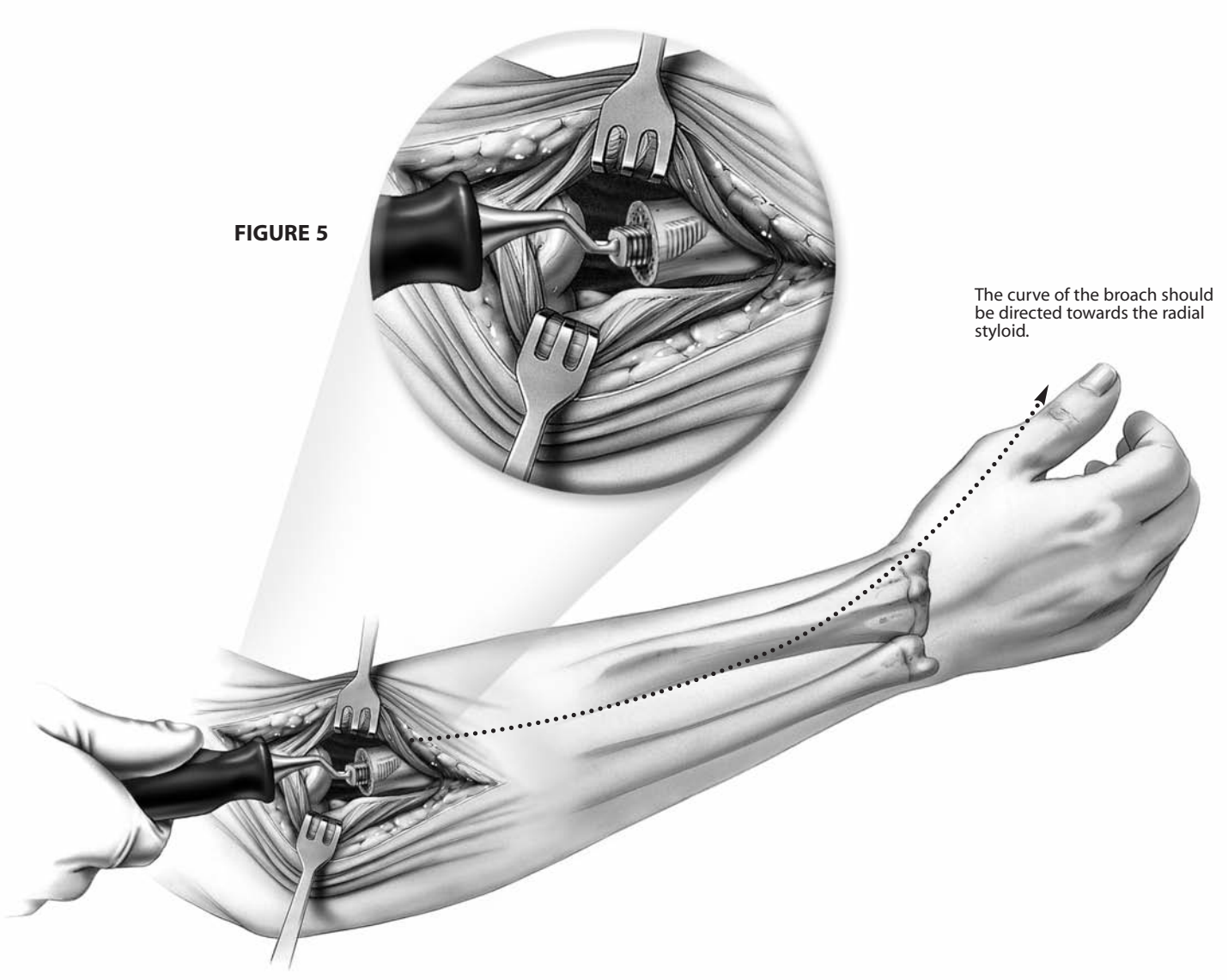


5 Intramedullary Preparation

If the elbow is unstable, varus stress and rotation of the forearm into supination allows improved access to the medullary canal. If the elbow is stable but the exposure is not adequate to access the medullary canal, careful reflection of the origin of the collateral ligament from the lateral epicondyle may be necessary to permit subluxation to the medullary canal. The canal can be entered with a starter awl using a twisting motion, the tip of a pair of curved needle holders or a high speed bone burr, so the broaching process can be initiated. The canal is then broached as allowed by the pathologic anatomy of the proximal radius (**FIGURE 5**).

The curve of the broach should be directed away from the bicipital tuberosity and towards the radial styloid (see **FIGURE 6A**, page 12). If the position of the tuberosity cannot be easily assessed, it generally is opposite of the radial styloid. Serial sized broaches are used until the broach fits snugly in the canal at the appropriate depth.

FIGURE 5



6

Trial Stem and Head Insertion

The appropriate sized trial stem is inserted in an arc-like fashion, facilitated by the curve of the stem (**FIGURE 6A**). Assure the collar is flush with the resection.

Choosing the Correct Head Size

Use the resected native head to properly determine the head size to be trialed. To avoid overstuffing, if the native head is between two sizes, it is generally preferable to select the smaller rather than the larger size.

The trial head is attached to the trial stem (**FIGURE 6B**), and tracking, both in flexion and extension and forearm rotation, should be carefully assessed. Malalignment of the osteotomy will cause abnormal tracking during flexion/extension and forearm pronation/supination.

NOTE: In some instances adequate tracking cannot be attained. In this circumstance the implant should not be used.

FIGURE 6A

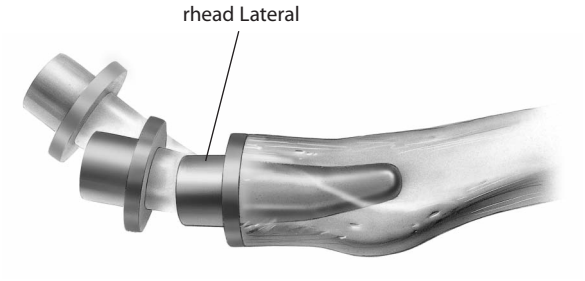
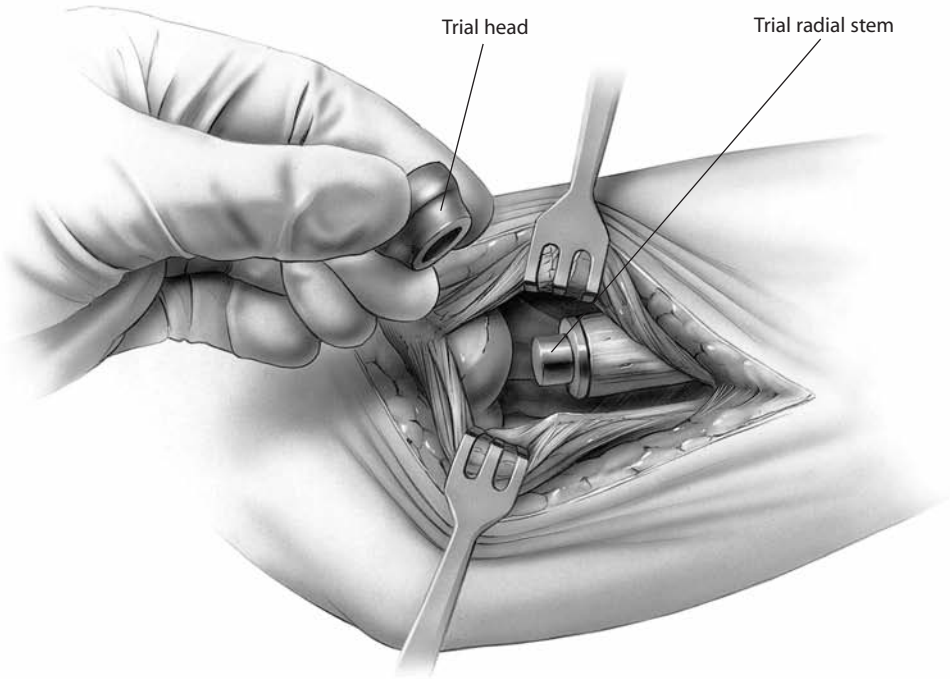


FIGURE 6B



IMPORTANT: Please Take Note

"Implanting the Final Components"

The approach will vary slightly, depending on the rHead™ Radial Implant that is used—

rHead technique,

rHead Recon technique, or

rHead Lateral technique.

Those variations are outlined in some detail on the next three pages.

7 rHead™:

Implanting the Final Components

Once acceptable alignment has been determined, the trials are removed and the permanent prosthesis is inserted in two steps. First, using the same arc-like motion as shown in (**FIGURE 6A**, page 12) the radial stem is placed in the medullary canal and tapped into place with the impactor (**FIGURE 7A**). If a firm fixation is not present at the time of the insertion of the trial stem (i.e. stem can be easily extracted from or rotated in the medullary canal), then bone cement (PMMA) is recommended. Second, the modular head is placed over the taper while applying longitudinal distraction and/or varus stress to distract the radiocapitellar interface sufficiently to permit the radial head to be inserted. Once inserted over the taper, the radial head is secured using the impactor (**FIGURE 7B**). The elbow is then reduced (**FIGURE 7C**) and tested again in flexion/extension and pronation/supination.

If exposure permits, the head and stem can be assembled on the "back table".

NOTE Care should be taken to protect the taper from any damage, including but not limited to scratches and contact with bone cement.

FIGURE 7A

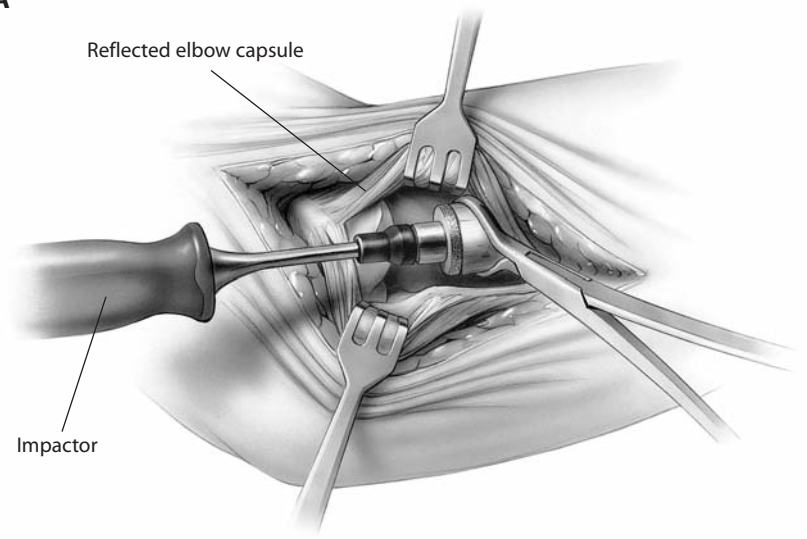


FIGURE 7B

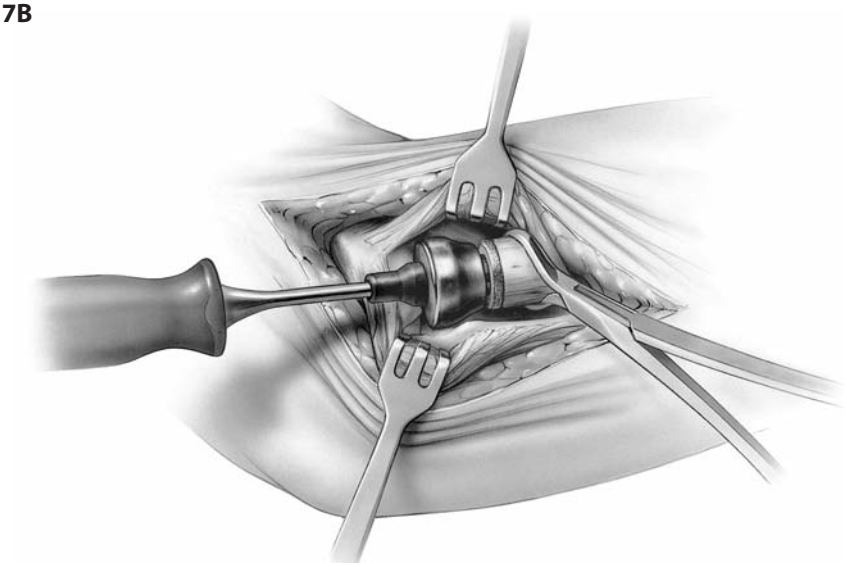


FIGURE 7C

7.1 rHead™ Recon (Bi-Polar):

Implanting the Final Components

Once acceptable alignment has been determined, the trials are removed and the permanent prosthesis is inserted in two steps. First, using the same arc-like motion as shown in (**FIGURE 6A** page 12), the implant stem is placed in the medullary canal and tapped into place with the impactor (**FIGURE 7A**). If a firm fixation is not present at the time of the insertion of the trial stem (i.e. stem can be easily extracted from or rotated in the medullary canal), then bone cement (PMMA) is recommended. Second, the implant head of the prosthesis is assembled to the implant stem. This is accomplished by carefully placing the implant head into the jaws of the assembly tool and tighten the locking nut (**FIGURE 7B**).

While applying longitudinal distraction and/or varus stress to distract the radiocapitellar interface, insert the implant head between the capitellum and the spherical ball of the implant stem. Place the lever through the center of the assembly tool and engage the collar of the stem (**FIGURE 7C**). Using the assembly tool like a plier, snap the implant head onto the stem. Carefully remove the assembly tool to avoid damage to the implant. The elbow is then reduced (**FIGURE 7D**) and tested again in flexion/extension and pronation/supination.

NOTE: Care should be taken to protect the articulating surfaces between the head and stem of any damage, including, but not limited to, scratches and contact with bone cement.

FIGURE 7A

FIGURE 7B

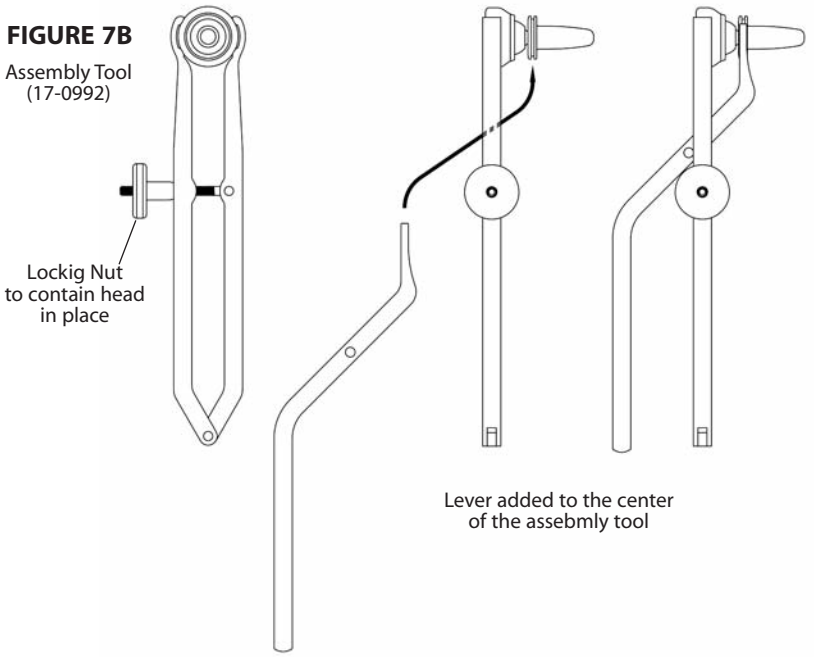
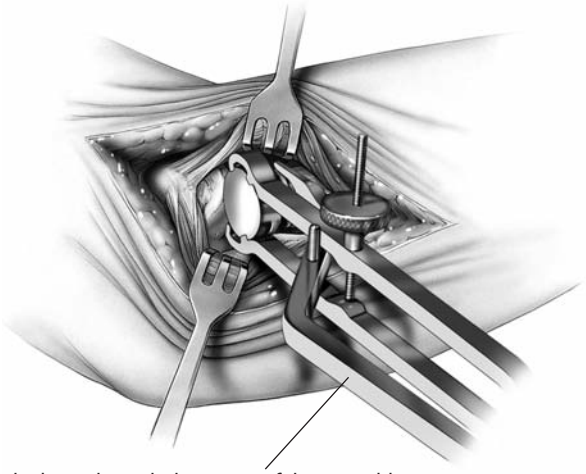
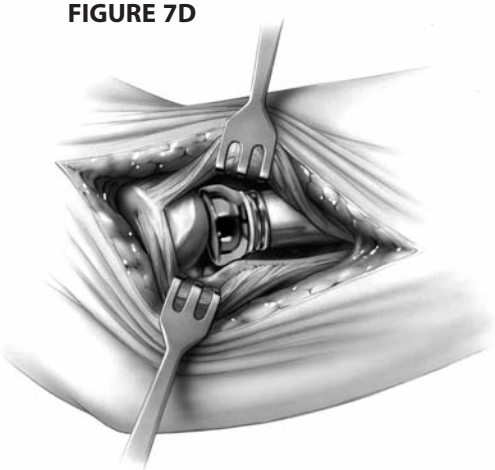


FIGURE 7C



Place the lever through the center of the assembly tool and engage the collar of the stem

FIGURE 7D



7.2 rHead™ Lateral:

Implanting the Final Components

Connect the rHead Lateral Stem Impactor (312-0805) to the collar of the appropriate size stem to be implanted **(FIGURE 1)**.

Use the Stem Impactor to maneuver the stem and insert it into the prepared canal of the radius. When the stem is inserted correctly into the canal, the Axis Alignment Bar on the shaft of the Impactor should align with the patient's radial styloid **(FIGURE 2)**. The stem should be inserted in an arc-like fashion, facilitated by the curve of the stem (**FIGURE 6A** page 12). Tap the end of the rHead Lateral Stem Impactor until the stem is firmly seated in the medullary canal. If the stem can be easily extracted or rotated in the canal, bone cement, (PMMA), is recommended.

The head and stem components are coupled together using the rHead™ Lateral Assembly Tool (312-0800). Prior to beginning assembly, all soft tissue must be cleared away from the locking mechanism. Position the appropriately sized radial head implant so that the male portion of the head locking mechanism is engaged by the female portion of the stem locking mechanism **(FIGURE 3)**.

FIGURE 1

Lateral Stem Impacter
(312-0805)

FIGURE 2

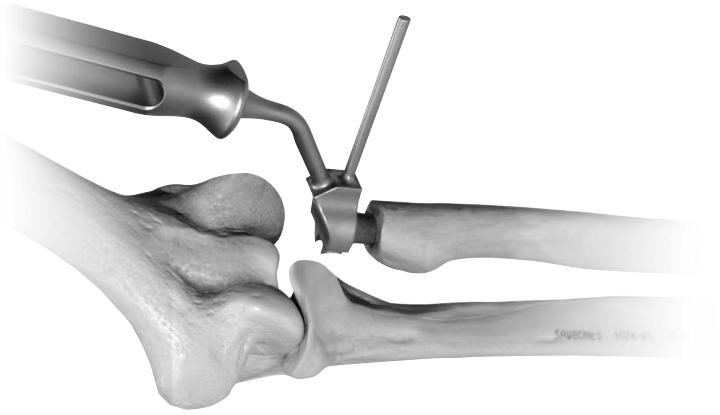


FIGURE 3

Lateral Assembly Tool
(312-0800)

Place the rHead™ Lateral Assembly Tool around the grooved collar of the stem and ensure the dimple on the radial head implant is engaged by the pin on the advancer of the rHead Lateral Assembly Tool **(FIGURE 4)**. The trigger on the rHead Lateral Assembly Tool is then compressed to advance the radial head implant until it is fully engaged by the stem. The head is fully locked to the stem when an audible "snap" is heard or felt. Visually, the head should be concentric with the stem when properly engaged **(FIGURE 4A)**. The Assembly Tool can now be removed.

If disassembly should be needed, reverse the rHead Lateral Assembly Tool until the pin on the advancer is aligned with the dimple on the opposite side of the radial head implant **(FIGURE 5).** Compress the trigger on the rHead Lateral Assembly Tool until the radial head implant disengages from the stem **(FIGURE 5A)**. Note that the radial head implant is intended for one time use. **The radial head implant may not be reused once it is disengaged from the stem.** A new radial head implant must be used if the original head is disengaged for any reason.

Note: the head and stem trial components (not pictured) are designed to be a "non-locking" lateral assembly mechanism. These components will be utilized as explained in step 6.

Assembly

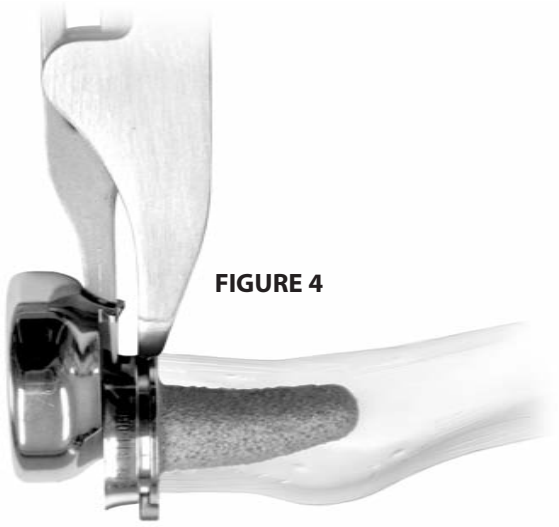


FIGURE 4

FIGURE 4A

Assembly Side

Disassembly

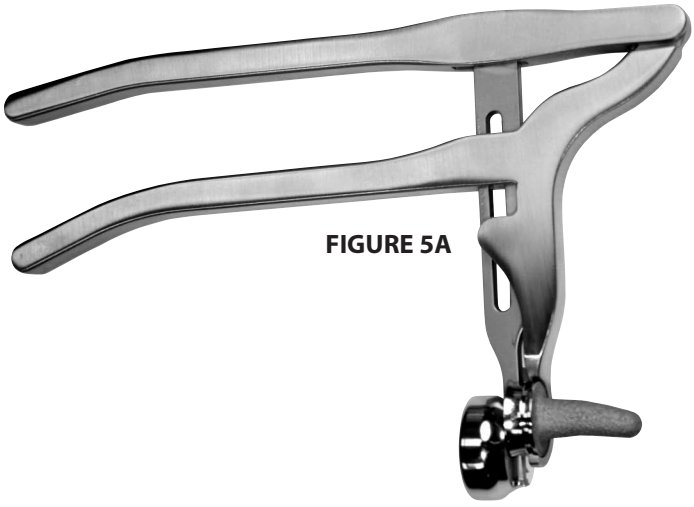


FIGURE 5A

FIGURE 5

Disassembly Side

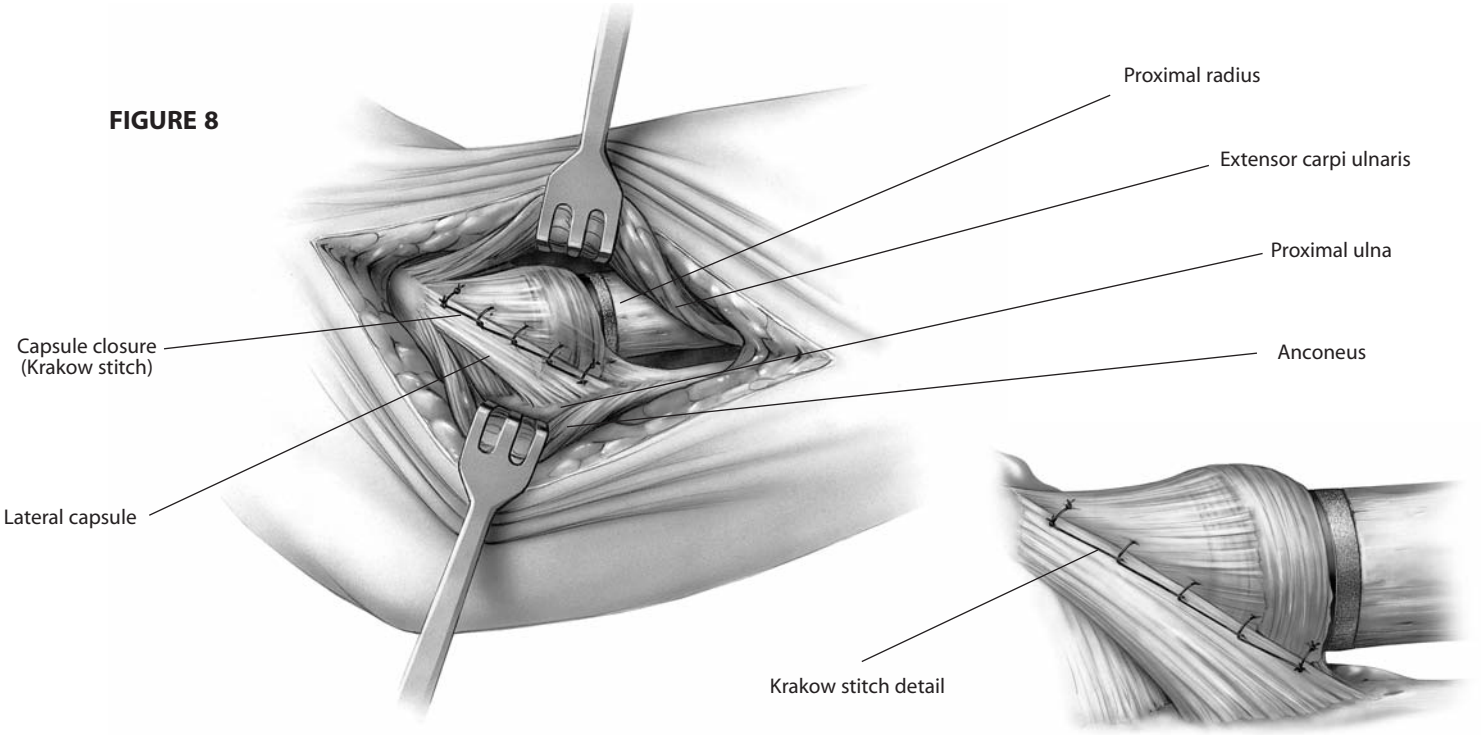
8 Closure

A simple closure is permitted if the collateral ligament is sufficient. If the collateral ligament has been disrupted, a Krakow stitch is used. A No. 5 absorbable suture is placed distally, crossing the site of the lateral ulnar collateral ligament and is then brought proximally.

Both ends of the suture are brought through a drill hole at the anatomic origin of the lateral collateral ligament complex and exit posteriorly.

The forearm is placed in full or partial pronation and the suture tied (**FIGURE 8**). The elbow is splinted at 90 degrees flexion and in neutral to full pronation. If ligamentous tissue is insufficient, a formal lateral collateral ligament reconstruction is done.

FIGURE 8



9 Aftercare

Passive flexion and extension is allowed on the second day assuming the elbow is considered stable. The goal of radial head replacement and soft tissue repair is to achieve elbow stability. Both flexion/extension and pronation/supination arcs are allowed without restriction. Active motion can begin by day five.

As with any prosthetic replacement, long term aftercare requires surveillance. If the implant is asymptomatic and tracks well, routine removal is not necessary.

IMPLANT DIMENSIONS

Radial Head Component

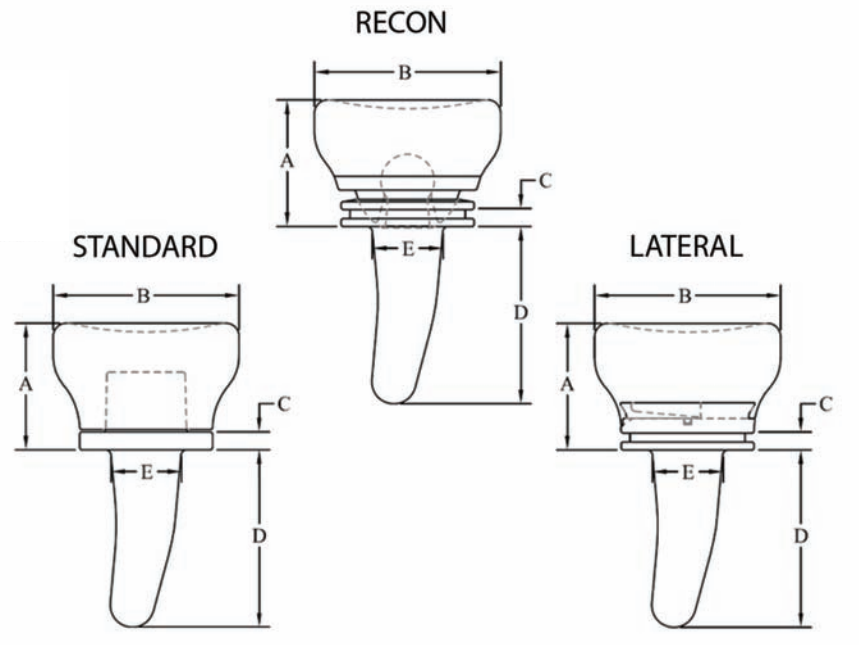
Size	Dimensions (mm) A STD. COLLAR	A EXT. COLLAR	B	Item # Standard	Recon	Lateral
2	11.3	15.3	18.0	RHA-H2	RCN-H2	310-0008
3	14.3	18.3	21.0	RHA-H3	RCN-H3	310-0009
4	17.3	21.3	24.0	RHA-H4	RCN-H4	310-0010

Standard Collar Stem Component

Size	Dimensions (mm) C	D	E	Item # Standard	Recon	Lateral
1	2.0	16.0	6.4	RHA-S1	RCN-S1	310-0000
2	2.0	18.0	7.2	RHA-S2	RCN-S2	310-0001
3	2.0	20.0	8.0	RHA-S3	RCN-S3	310-0002
4	2.0	22.0	8.8	RHA-S4	RCN-S4	310-0003

Extended Collar Stem Component

Size	Dimensions (mm) C	D	E	Item # Standard	Recon	Lateral
1	6.0	16.0	6.4	RHA-S160	RCN-S160	310-0004
2	6.0	18.0	7.2	RHA-S260	RCN-S260	310-0005
3	6.0	20.0	8.0	RHA-S360	RCN-S360	310-0006
4	6.0	22.0	8.8	RHA-S460	RCN-S460	310-0007



INDICATIONS

The SBi Radial Head implant is intended for replacement of the proximal end of the radius:

- Primary replacement after complex (comminuted) fracture of the radial head
- Symptomatic sequelae after radial resection
- Axial forearm instability
- Failed silicone radial head implant
- Elbow instability associated with radial head fracture or excision of radial head
- 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.

CONTRAINDICATIONS

- Bone musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation which cannot provide adequate support or fixation for the prosthesis
- Any active or suspected infection in or around the joint
- Skeletal immaturity
- Physiologically or psychologically unsuitable patient
- Known sensitivity to materials used in this device
- Possibility for conservative treatment

WARNINGS, PRECAUTIONS AND PATIENT COUNSELING INFORMATION

Warnings (See also the **Patient Counseling Information** Section)

- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

Precautions

- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.
- Meticulous preparation of the implant site and selection of the proper size implant increases the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and articulating surfaces must not come in contact with hard or abrasive surfaces.
- The head and stem should not be implanted if the ball and socket features are possibly damaged, this includes repeated attaching and detaching.
- The head of the prosthesis is assembled on to the head of the stem. Prior to assembly confirm that the ball and socket features are dry and free from contaminant.

Patient Counseling Information (See also **Warnings**)
In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient.

- While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.
- Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.

Please refer to implant package insert for additional product information including precautions and warnings.

Surgical Videos
For a surgical video DVD of this product contact Small Bone Innovations, Inc. or visit our website at www.totalsmallbone.com

Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

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CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

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