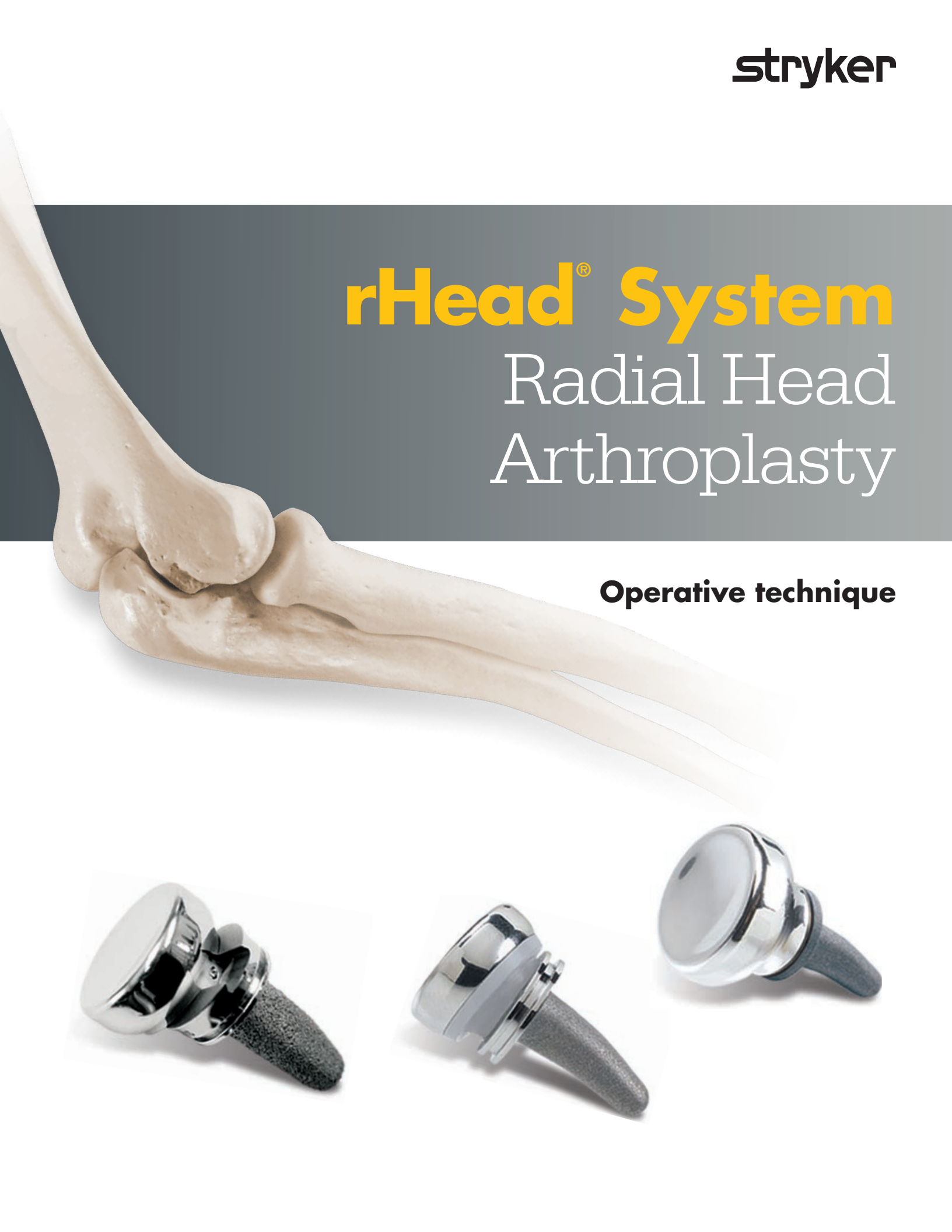
stryker

rHead® System
Radial Head Arthroplasty

Operative technique



rHead System
Radial Head Arthroplasty

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This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multicomponent instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling (Instruments and Sizers (V15106) or Elbow Management Solutions Tray V15137)

See package insert (Instruction for Use) (V15130) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

Indications and contraindications

Indications

When the rHead System is used in a hemiarthroplasty application with a standard stem:

rHead, rHead Recon, and rHead Lateral Implants are intended for replacement of the proximal end of the radius:

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:

- Joint destruction or subluxation visible on x-ray
- Resistance to conservative treatment

Primary replacement after fracture of the radial head

- Symptomatic sequelae after radial head resection

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 and Precautions

Please see package insert for Warnings, Precautions, Adverse Reactions, and other essential product information.

Stryker systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling

The safety of rHead System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

Operative technique

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 (Fig. 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.

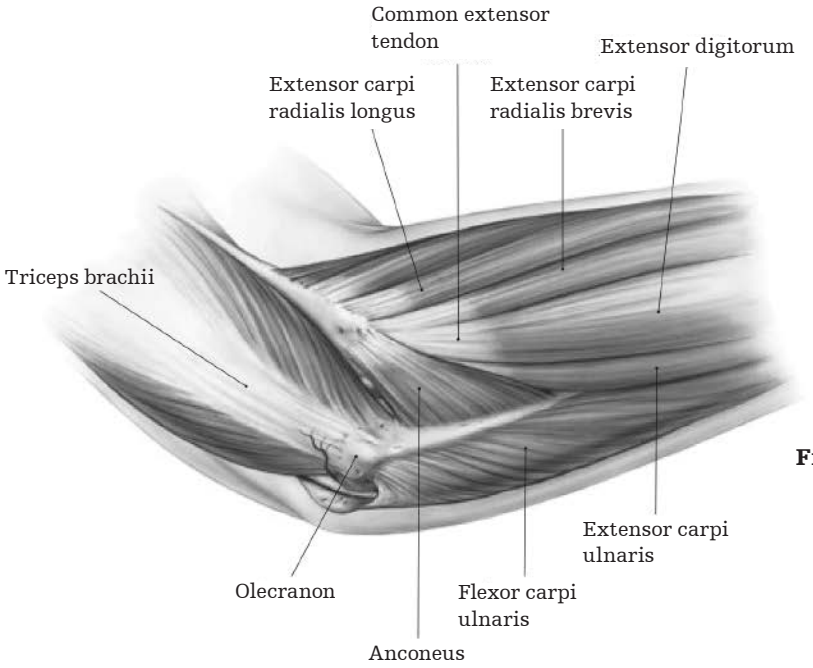


Fig. 1

Capsular 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 (Fig. 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 radiohumeral joint. The common extensor tendon and elbow joint capsule are retracted as needed to maximize exposure (Fig. 2B).

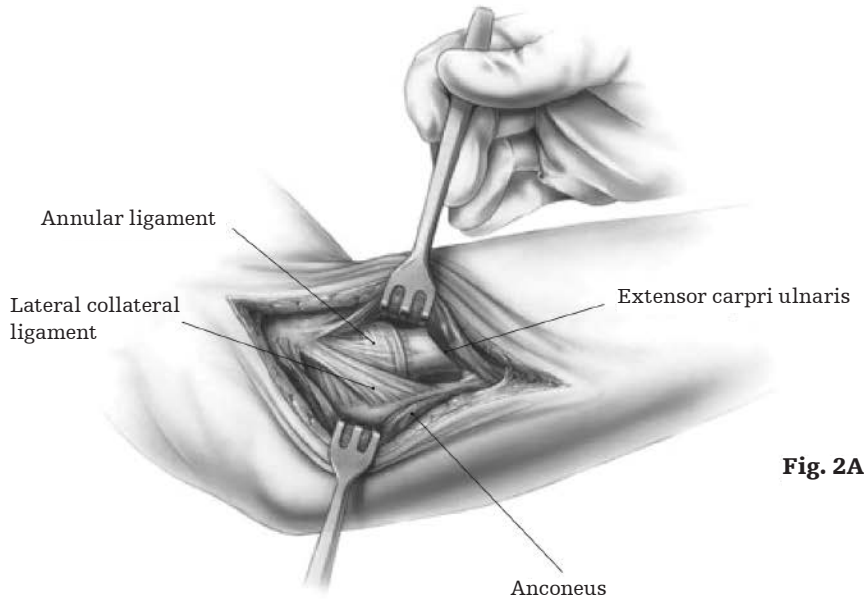


Fig. 2A

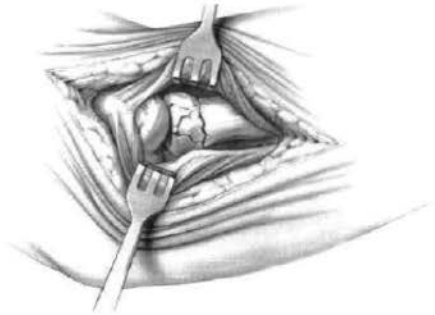


Fig. 2B

Operative technique

Using the radial head resection guide, standard collar

The radial neck cut requires a resection guide. The device is inserted over the capitellum with the axis of the alignment rod oriented over the ulnar styloid (Fig. 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 (Fig. 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.

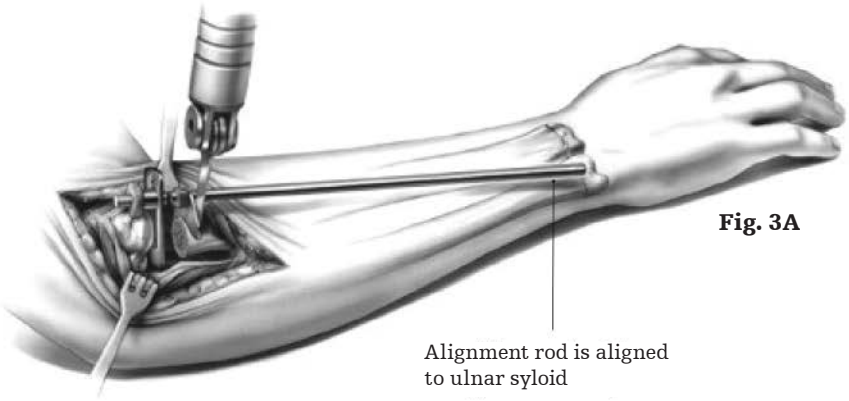


Fig. 3A

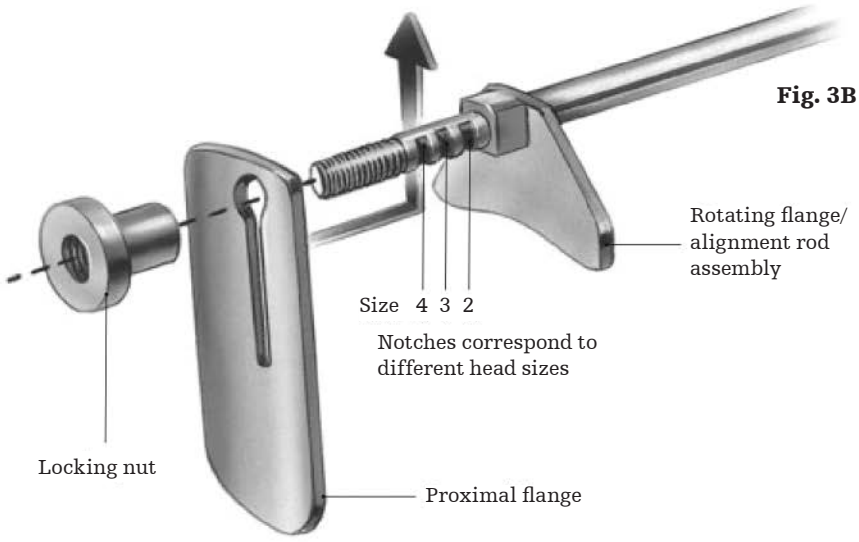


Fig. 3B

Operative technique

Using the radial head resection guide, 6mm extended collar

If X-Ray templating is performed, 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" (Fig. 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.

Resecting the radial head

Using the resection guide, the blade should be guided by the distal surface of the rotating flange (Fig. 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 (Fig. 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 (Fig. 4C). This includes at least the margin articulating with the ulna at the radial notch. When the rHead is to be used after radial head resection was previously performed, the guide is employed to "freshen" the resected proximal radius.

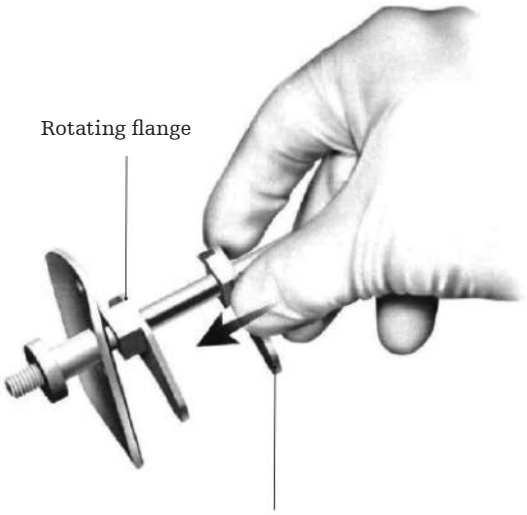


Fig. 3C

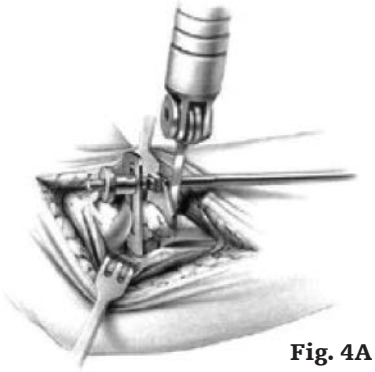


Fig. 4A

Fig. 4B

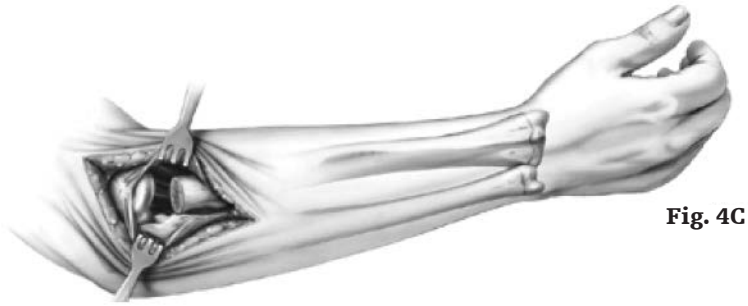


Fig. 4C

If the medullary canal is not obvious after the radius has been recut, it should be thus identified with a tool such as a curved needle holder or a high speed burr. In addition, radial length should be restored (axial traction) using a lamina spreader if there is a positive ulnar variance.

Operative technique

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 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 (Fig. 5). The curve of the broach should be directed away from the bicipital tuberosity and towards the radial styloid (Fig. 6A). Care should be taken not to rotate or twist the broach during the broaching process. 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.

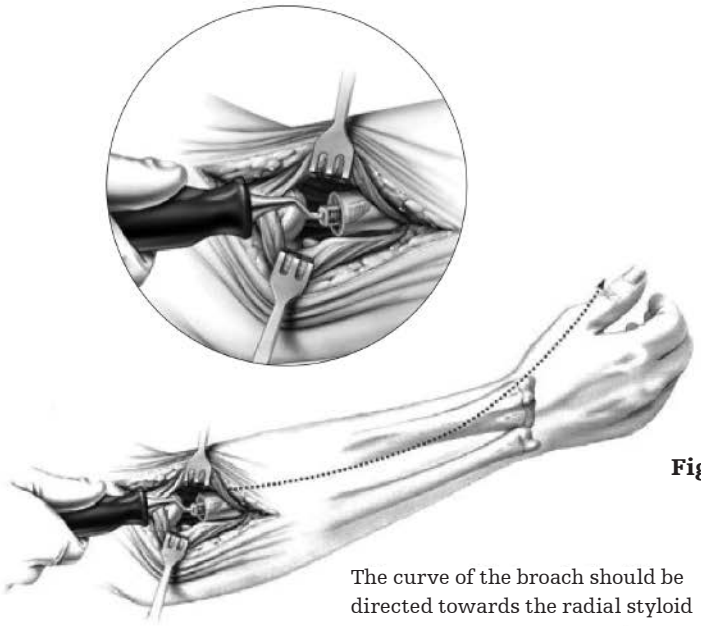


Fig. 5

The curve of the broach should be directed towards the radial styloid

Trial stem and head insertion

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

Fig. 6A

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 (Fig. 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.

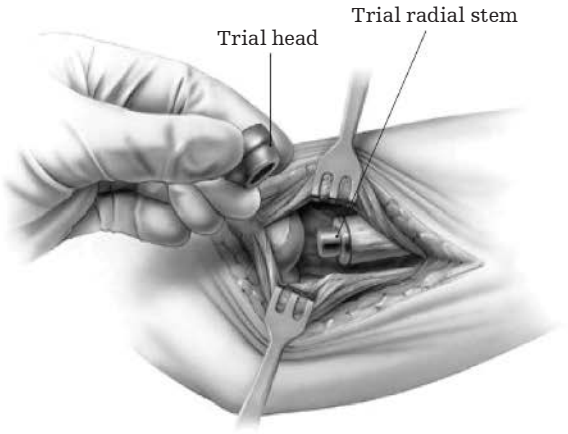


Fig. 6B

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

Operative technique

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 (Fig. 6A) the radial stem is placed in the medullary canal and tapped into place with the impactor (Fig. 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 (Fig. 7B).

The elbow is then reduced (Fig. 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.

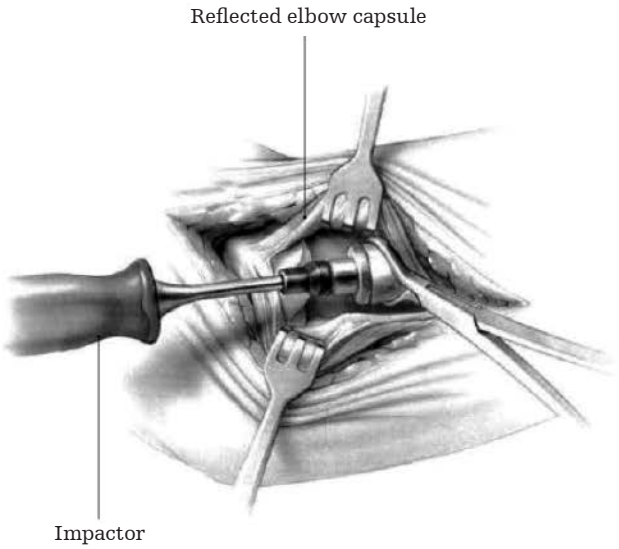


Fig. 7A

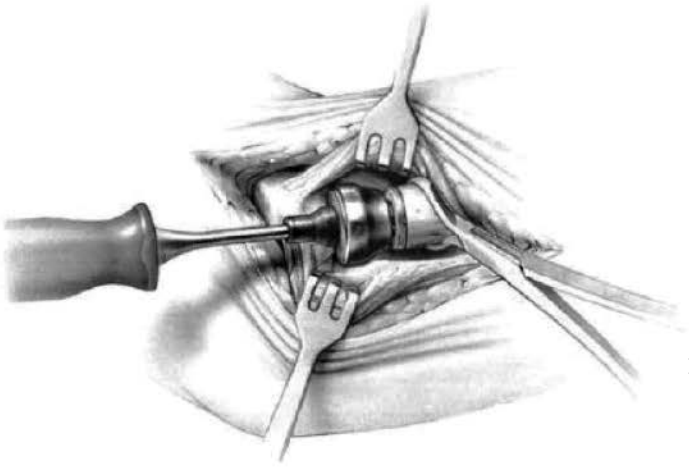


Fig. 7B

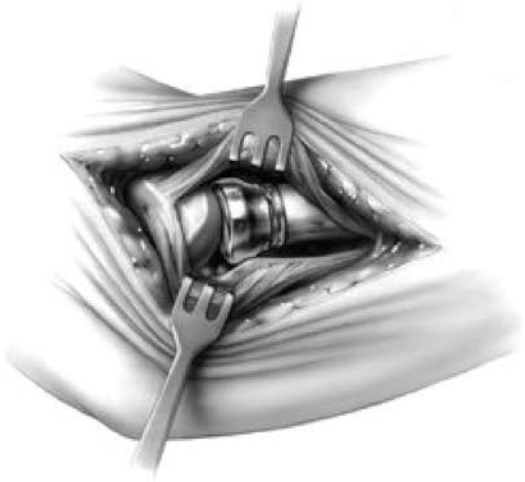


Fig. 7C

Operative technique

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 (Fig. 6A), the implant stem is placed in the medullary canal and tapped into place with the impactor (Fig. 7D). lf 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 (Fig. 7E).

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 (Fig. 7F). 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

(Fig. 7G) 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.

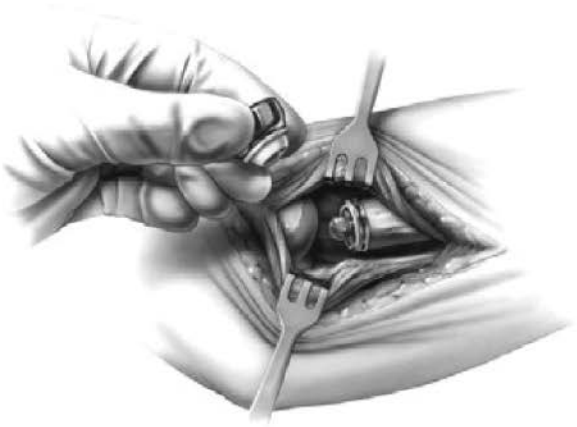


Fig. 7D

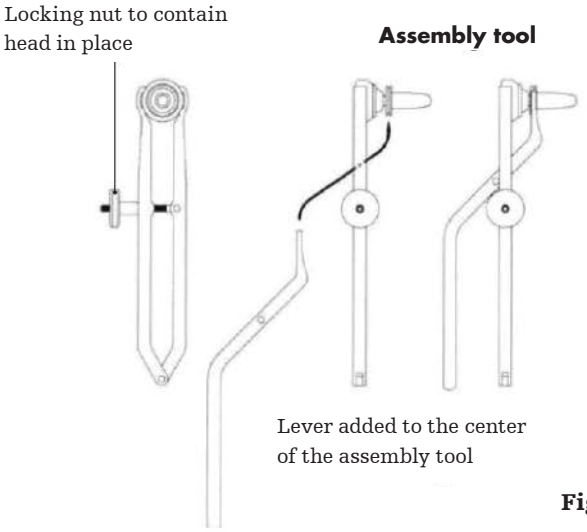


Fig. 7E

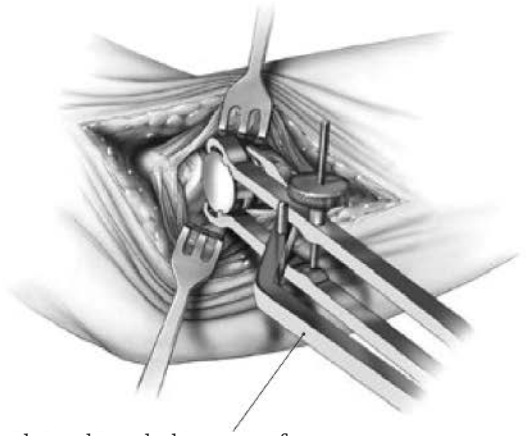


Fig. 7F

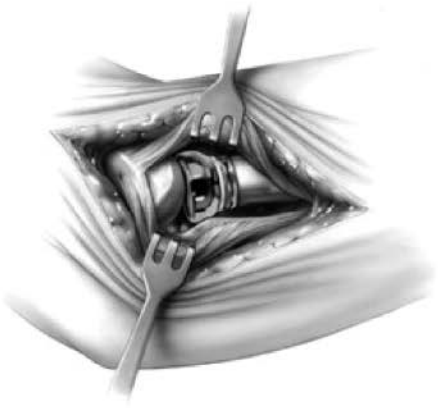


Fig. 7G

Operative technique

rHead lateral: Implanting the final components

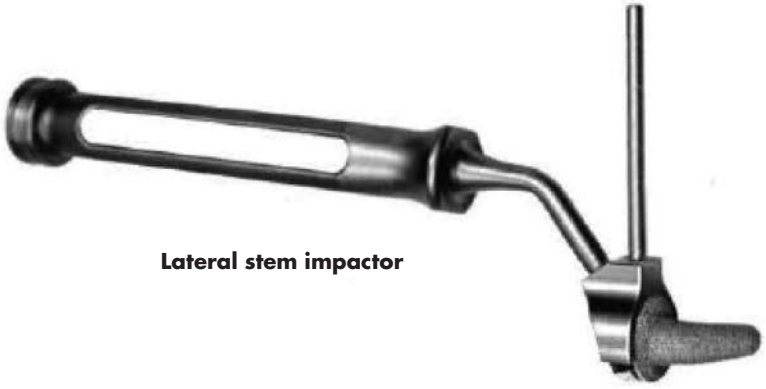
Connect the rHead Lateral Stem Impactor to the collar of the appropriate size stem to be implanted (Fig. 8).

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 (Fig. 9).

The stem should be inserted in an arc-like fashion, facilitated by the curve of the stem (Fig. 6A). Tap the end of the rHead Lateral Stem Impactor until the stem is firmly seated in the medullary canal. 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.

The head and stem components are coupled together using the rHead Lateral Assembly Tool. 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 (Fig. 10).



Lateral stem impactor

Fig. 8

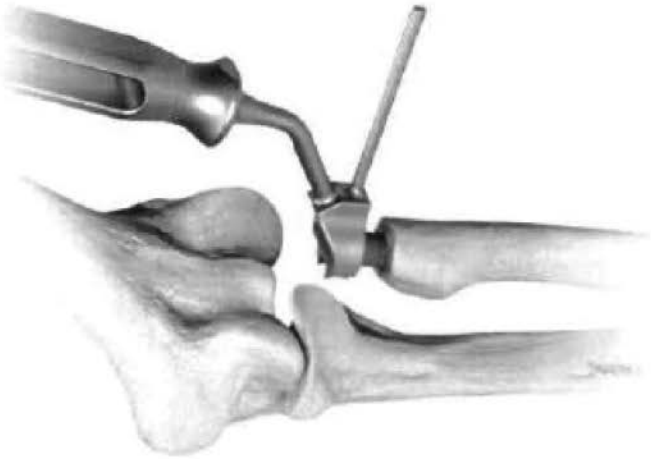
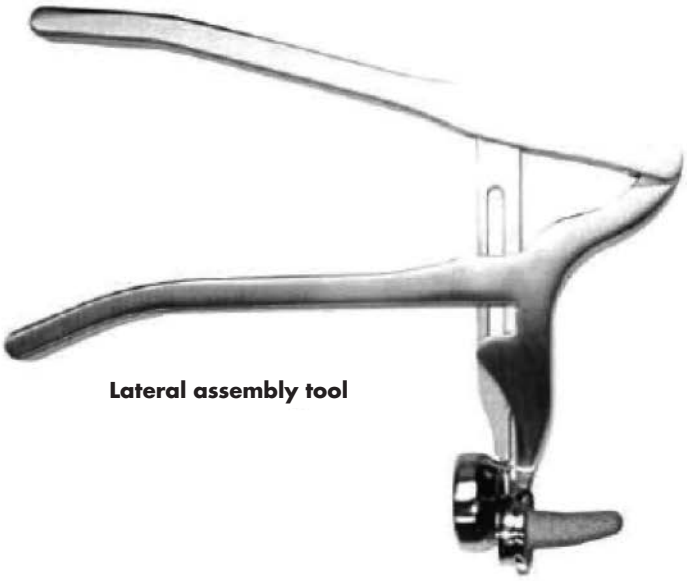


Fig. 9



Lateral assembly tool

Fig. 10

Operative technique

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 (Fig. 11A). 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 (Fig. 11B). The Assembly Tool can now be removed.

If disassembly should be needed, rotate the forearm and 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 (Fig. 12B). Compress the trigger on the rHead Lateral Assembly Tool until the radial head implant disengages from the stem (Fig. 12A).

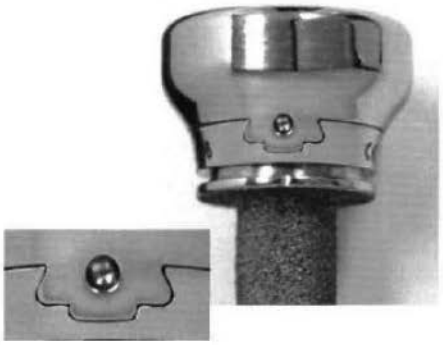
Note that the radial head implant is intended for one time use. The radial head implant may not be reused once it is disengaged from the stem. A new radial head implant must be used if the original head is disengaged for any reason.

Note:
In the Elbow Management Solutions Tray, 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 on page 7. In the rHead Combination tray, the head and stem components (not pictured) are a morse taper design and should be utilized as explained on page 7.

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.

Assembly

Fig. 11A

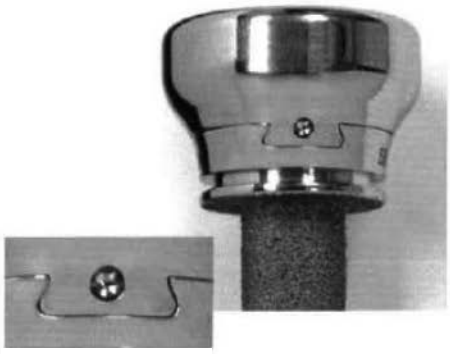


Assembly side

Fig. 11B

Disassembly

Fig. 12A



Disassembly side

Fig. 12B

Operative technique

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 (Fig. 13A and 13B). 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.

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.

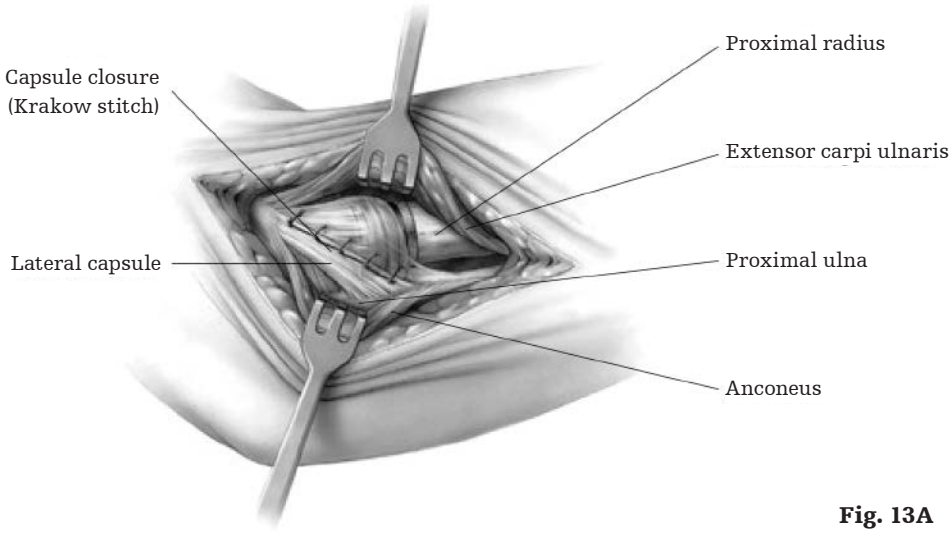


Fig. 13A

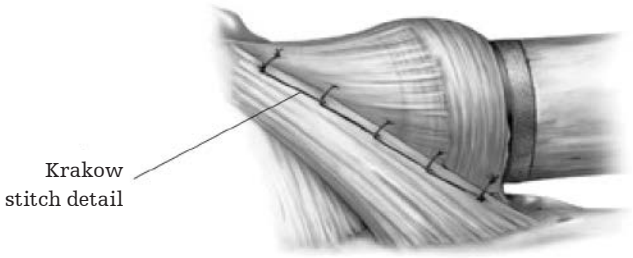


Fig. 13B

Notes:

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stryker

Trauma & Extremities

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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