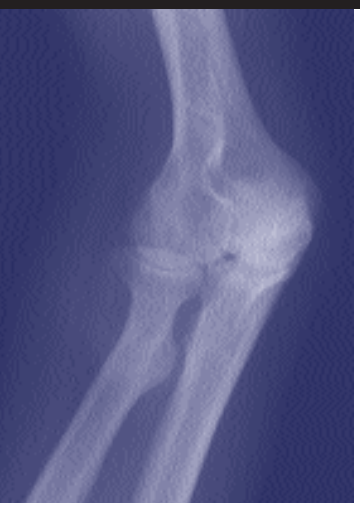
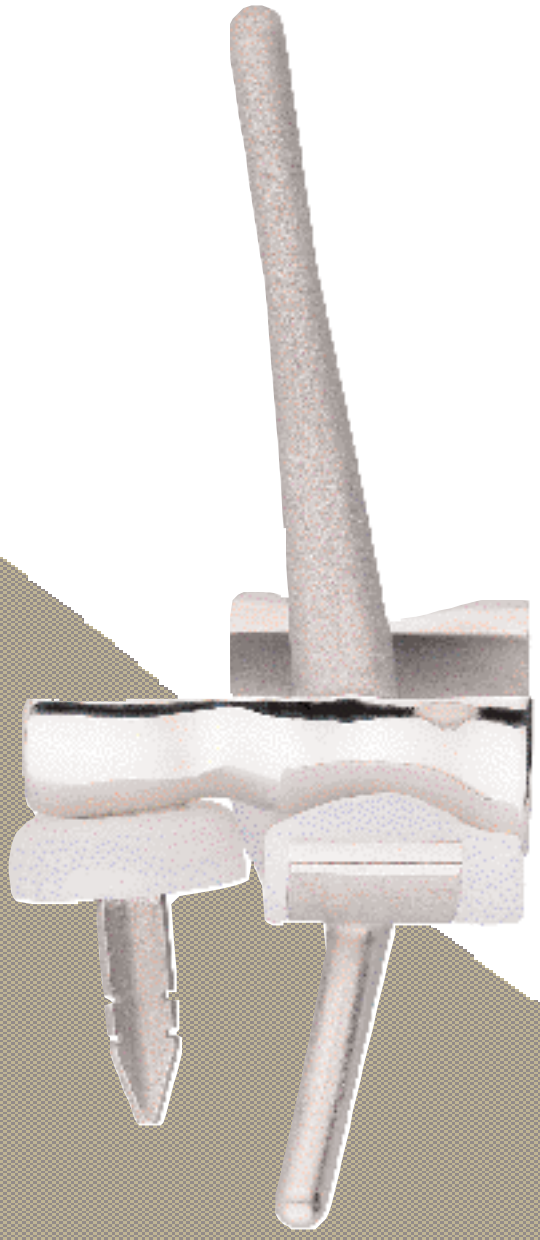


The Sorbie - Questor Total Elbow System

SURGICAL TECHNIQUE



WRIGHT.

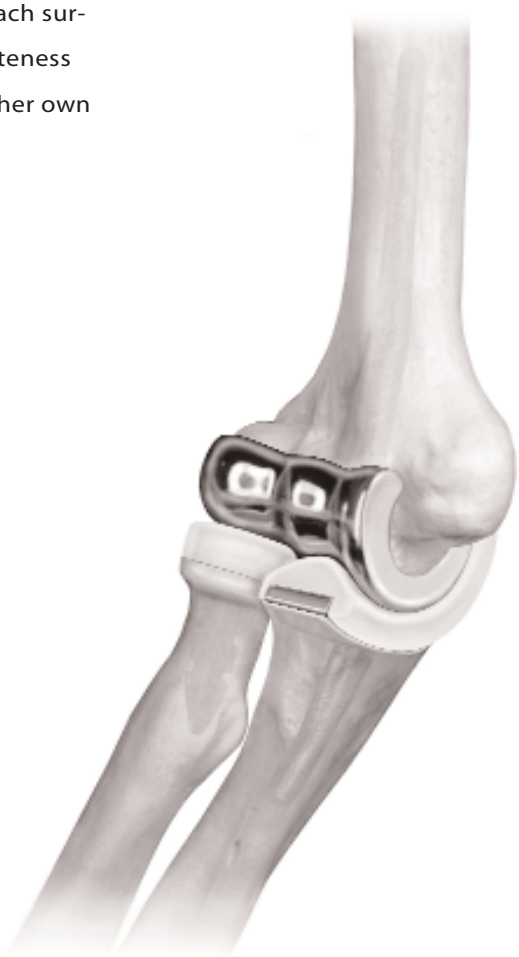
WE BRING SOLUTIONS TO THE TABLE

TABLE OF CONTENTS

The Sorbie - Questor Total Elbow System

SURGICAL TECHNIQUE

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines used by Charles Sorbie, MD, are furnished for informational purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her own medical training and experience.

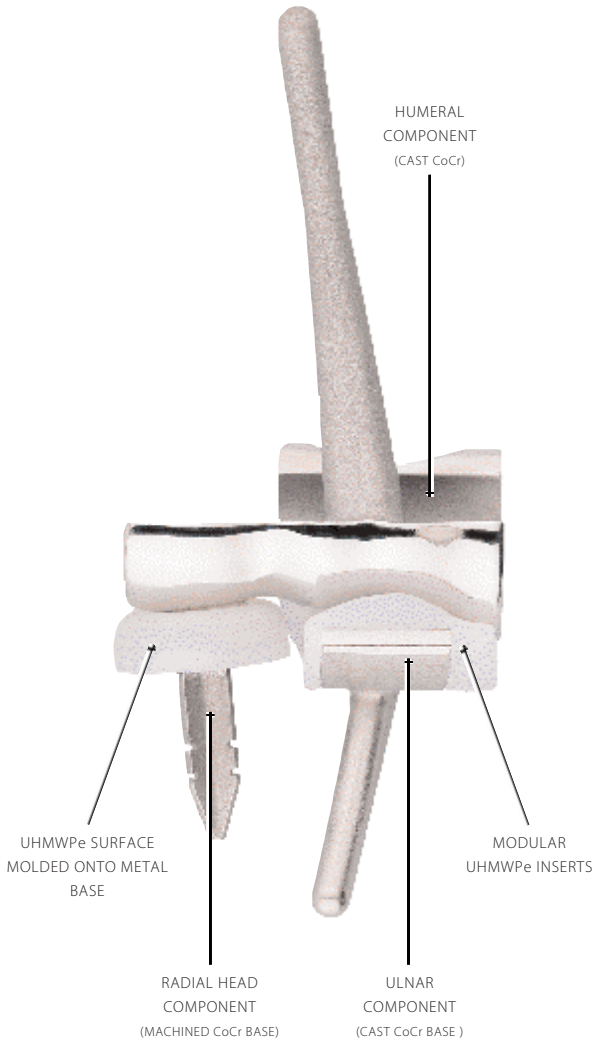


INTRODUCTION

The Sorbie-Questor® Total Elbow System offers true to form surface geometry, or an Idemorph™* of the elbow's natural articulating surfaces. Combined with precision instrumentation as well as a radial head component, the Idemorph™ technology allows for maximum elbow function.

Referencing the central axes of flexion and extension (CAFE), the instrumentation allows for proper implant alignment, which increases joint stability and reduces the risk of dislocation. This design concept complements our goals to promote accurate joint tracking, proportionate distribution of forces between the humerus, ulna and radius, and the replication of the elbow's natural anatomic structure.

This system is the most comprehensive available, allowing the surgeon to confidently implant technologically advanced elbow prostheses. The Sorbie-Questor® Elbow, in combination with a skillful technique, will help take total elbow arthroplasty to the next level of patient and surgeon satisfaction.



*Idemorph: Derived from latin and greek terminology meaning same (idem) - form (morph).

DESIGN RATIONALE

The Sorbie-Questor® Elbow System's design rationale was based on these fundamental principles:

ANATOMICAL SURFACING

Replicating anatomic structures of the joint requires that each component duplicate the original surfaces of the elbow with the goal of providing increased stability and reduced risk of dislocation.

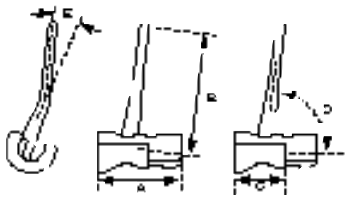
RADIAL HEAD COMPONENT

The radial head helps distribute load forces transferred through the elbow joint. Removing the radial head may lead to the redistribution of forces through the ulna or soft tissue. The inclu-sion of a separate radial head component can more ana-tomically and proportionally enhance load distribution and further reduce the risk of dislocation.

COMPREHENSIVE INSTRUMENTATION

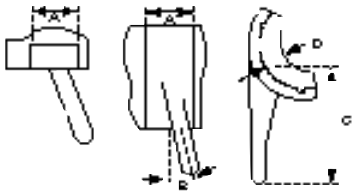
Elbow joint replacement surgery demands that precise alignment be of foremost concern if proper stability is to be accomplished. The com-prehensive, specialized instrumentation of the Sorbie-Questor® Elbow System promotes the precise orientation of the components on the original anatomic axes of motion.

HUMERAL COMPONENT



	A	B	C	D	E
S	45.8	68.5	26.8	85°	14°
M	46.0	68.5	28.2	85°	14°
L	48.5	68.5	29.6	85°	14°

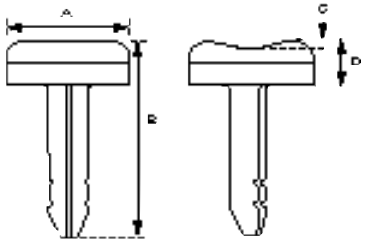
ULNAR COMPONENT



	A	B	C	D
S	14.6	15°	34.9	6.5 or 9.4
M	15.5	15°	34.9	6.9 or 9.9
L	16.5	15°	34.9	7.4 or 10.4

RADIAL HEAD COMPONENT

DIMENSIONS IN MM



	A	B	C	D
S	20.3	32.2	1.0	6.8 or 9.9
M	21.5	32.5	1.1	7.1 or 10.2
L	25.3	32.7	1.5	7.5 or 10.5

PREOPERATIVE ASSESSMENT

Total elbow replacement is an operation designed to provide a long wearing, artificial surface to replace damaged joint cartilage and its supporting bone. The success of the replacement is determined by the remaining amount of supporting bone, the integrity of the capsule, and the integrity of the ligaments.

Patients suitable for elbow replacement have joint surfaces damaged by primary arthritis, both rheumatoid and degenerative, or incidental to diseases such as hemophilia. It is also suitable for traumatic arthritis and for restoring a mobile joint fused by disease or prior surgery.

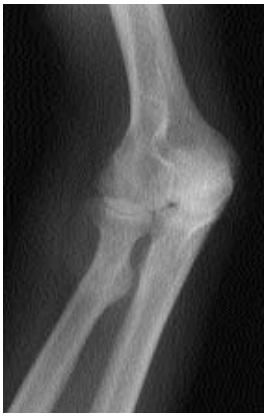
X-ray films of the diseased elbow are essential when assessing the extent of cartilage and bone damage. Although it is hard to define precisely, sufficient bone should be present to support the implants; that is, enough trochlear base to engage the concavity of the trochlear side of the humeral implant by at least 3mm. This prevents rotation of the implant before cementing and ensures resist-ance to forces associated with pushing medially or laterally using the arm with the elbow flexed at 90°.

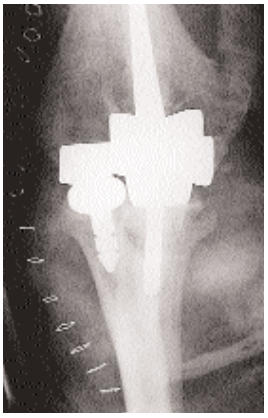
The remaining ulnar bone should have enough olecranon thickness to support the implant. 5mm is adequate.

An absent radial head may be compensated for by the inherent stability of the contact surfaces of the humeral and ulnar components. However, the forces distributed to the radial head in normal elbows are significant and thus, the radial head should be replaced when possible.

The patient may be given the choice of general or regional anaesthetic for the procedure, which is usually performed with the assistance of a tourniquet.

To avoid disappointment, the patient should be warned that local discomfort will be experienced during the first days after surgery, that resisted elbow extension should be minimized until the triceps tendon has reattached to the olecranon, and that there may be a period of ulnar nerve dysesthesia due to post-operative swelling.





INDICATIONS AND CONTRAINDICATIONS

IV

INDICATIONS

This device is indicated for use in total elbow arthroplasty for reduction or relief of pain and/or improved elbow function in skeletally mature patients with the following conditions:

1. Noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis;
2. Inflammatory degenerative joint disease including rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and
5. Treatment of fractures that are unmanageable using other techniques.

CONTRAINDICATIONS

Absolute contraindications include:

1. Overt infection;
2. Distant foci of infections (which may cause hematogenous spread to the implant site);
3. Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4. Skeletally immature patients; and
5. Cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate muscle strength), poor bone stock, or poor skin coverage around the elbow joint that would make the procedure unjustifiable.

CONDITIONS PRESENTING INCREASED RISK OF FAILURE INCLUDE:

1. Uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2. Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
3. Metabolic disorders that may impair bone formation or cause bone loss;
4. Osteomalacia; and
5. Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

THIS PRODUCT IS FOR USE WITH BONE CEMENT ONLY

See package insert for additional information including warnings and precautions.

V 1

INITIAL INCISION: POSTERO—LATERAL APPROACH

An incision is made on the postero-lateral aspect of the elbow. It begins opposite the junction of the middle and distal thirds of the humerus in the midline of the posterior surface of the arm. The incision curves laterally one centimeter posterior to the lateral epicondyle and then medially to end over the subcutaneous border of the ulna (Figure 1).

The interval between the brachio-radialis and the lateral edge of the triceps is defined and the muscles separated.

The separation is continued down the lateral border of the humerus to the origin of the anconeus and the interval between the anconeus and the extensor carpi ulnaris.

The extensor muscles are eased off the anterolateral aspect of the humerus. The common extensor origin is lifted off the lateral epicondyle and the lateral collateral ligament by sharp dissection.

The surgeon should take care at all times to avoid damaging nerves and other critical tissues.

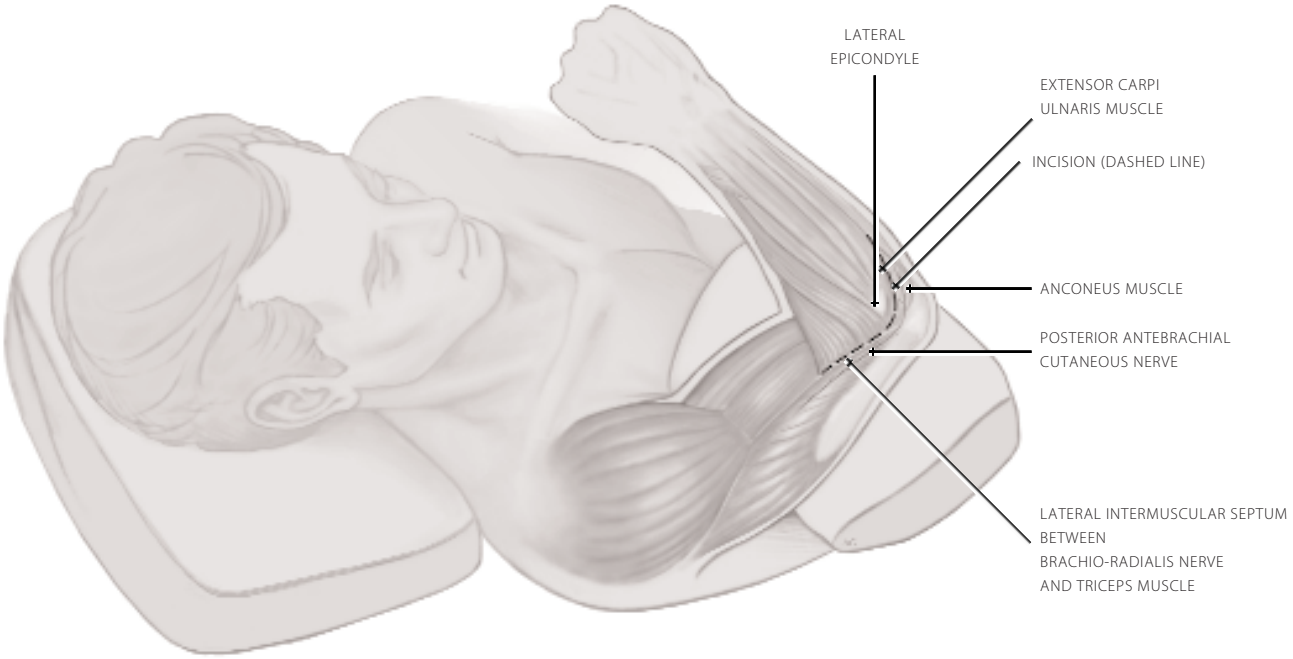


Figure 1

CAPSULAR INCISION

2 The capsule of the elbow and the annular ligament are incised to expose the neck of the radius (Figure 2).

The anconeus muscle is sharply dissected from its origins behind and below the lateral epicondyle and separated from the extensor carpi ulnaris distally to the ulna. The nerve to the anconeus is a continuation of the branch of the radial nerve which begins at the upper end of the spiral groove and passes through the medial head of the triceps, which it supplies. Damage to the nerve can be avoided by taking the anconeus postero-medially with the triceps.

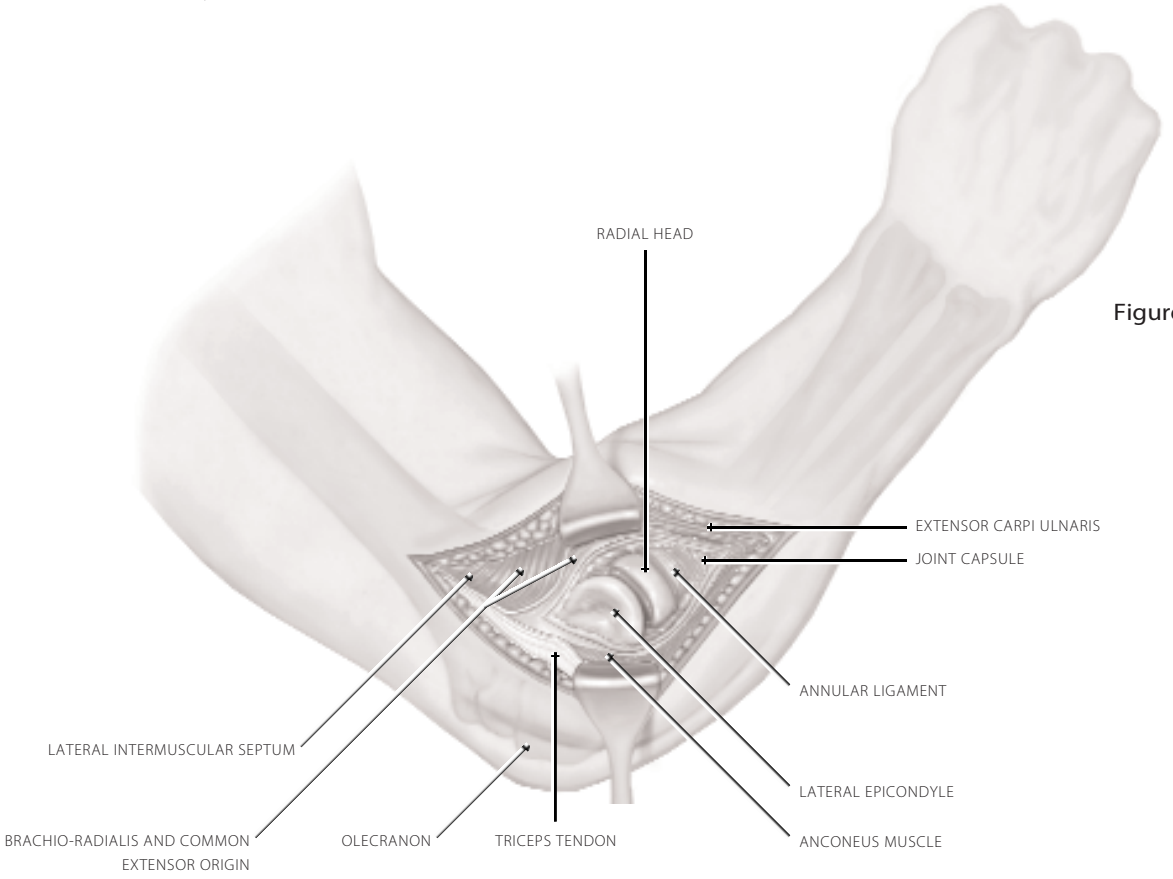


Figure 2

DISLOCATION AND RADIAL HEAD EXPOSURE

3 As part of the same posterior flap, the triceps insertion is dissected from the olecranon and moved postero-medially (Figure 3).

The elbow may then be dislocated to expose the entire radial head, the sigmoid fossa of the ulna and the distal end of the humerus.

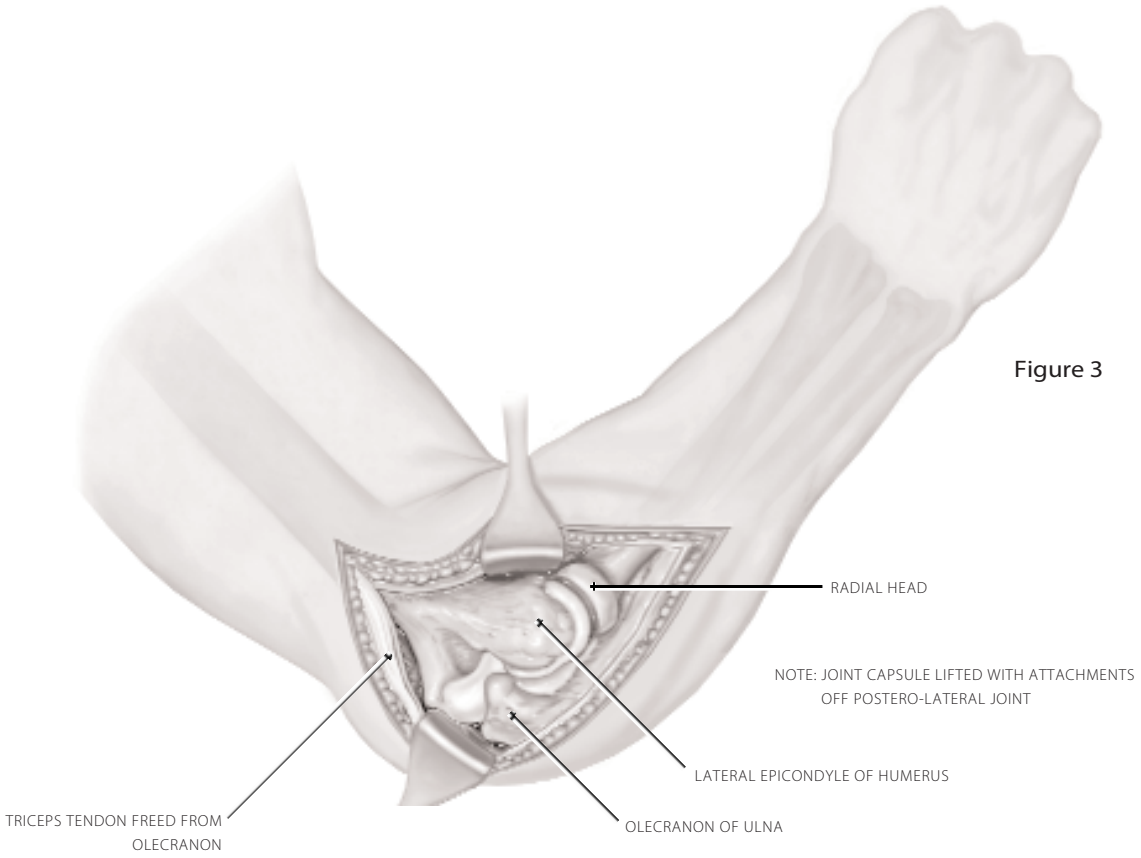
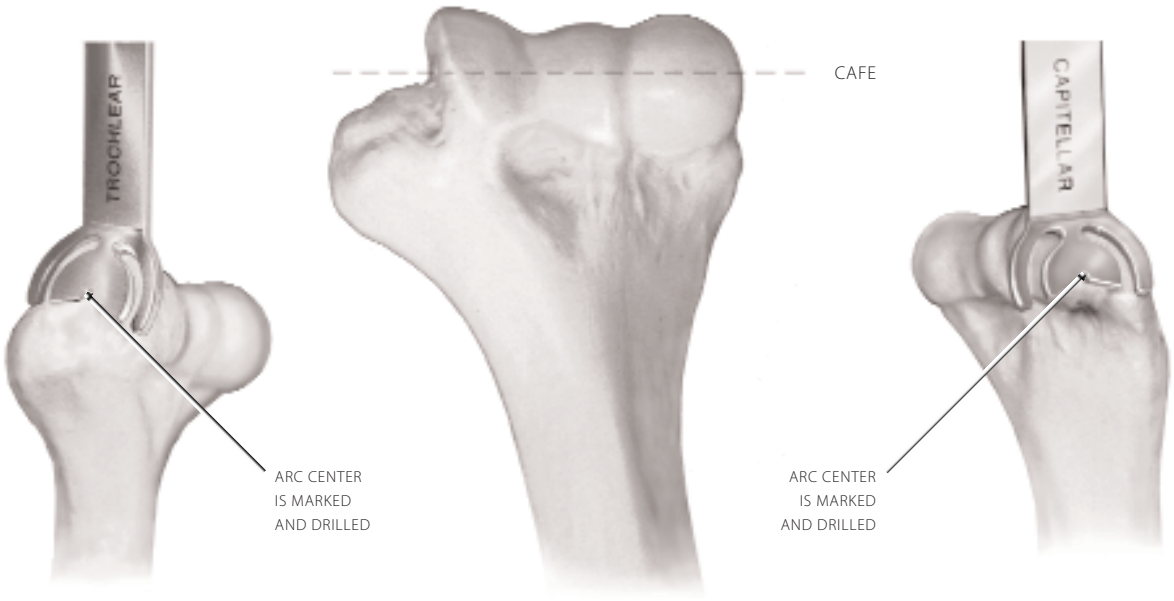


Figure 3

SIZING OF THE HUMERUS

4 The trochlea and capitellum sizing and centering template is applied to the medial surface of the trochlea and the lateral surface of the capitellum. The curvature of the trochlear and capitellar surfaces are matched to the template arcs. The arc centers are marked and drilled using a 1/8" or 3.2mm drill bit. These centers are on the central axis of flexion and extension (CAFE) of the lower end of the humerus (Figure 4).

Figure 4



MEDIAL SURFACE ANTERIOR VIEW LATERAL SURFACE

TROCHLEA RESECTION

5 The humeral caliper is attached to the humerus by placing the pin arms in the pre-drilled holes prepared in Step 4. When applying the caliper, one arm pin should first be placed deeply in position and held firmly in place while tightening the caliper and engaging the pin on the other arm. The caliper bar is centralized in the trochlea on its posterior surface with its free end pointing in a proximal direction (Figure 5).

A saw is used to remove a section of the trochlea equal to the width of the caliper bar. If the trochlea and capitellum are badly eroded, the saw cut should be made at an appropriate place on the lateral half of the remaining trochlea.

The cut segment of the trochlea is removed with a rongeur until the distal end of the medullary cavity is exposed.

A 3mm burr may be useful to locate and begin the opening of the medullary cavity.

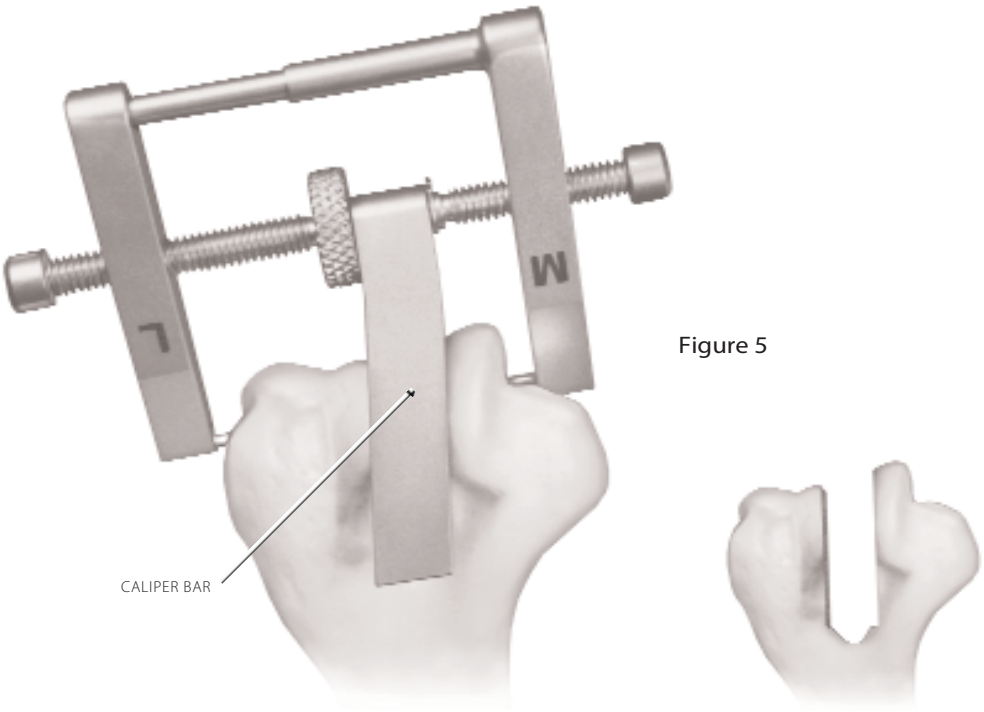


Figure 5

POSTERIOR VIEW

HUMERAL INTRAMEDULLARY CANAL PREPARATION

6

The intramedullary canal of the humerus is further opened and reamed using the humeral starter reamer (Figure 6).

The larger humeral stem reamer may then be used to slightly widen the canal by inserting the reamer half-way down the cutting fin surface.

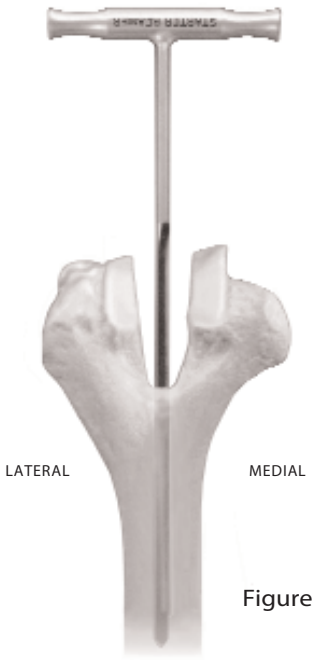


Figure 6

INTRAMEDULLARY ROD INSERTION

7

The appropriate size intramedullary (IM) rod (long should be used whenever possible) and IM rod inserter are assembled and inserted into the canal (Figure 7).
The IM rod should not be inserted unattached in patients with wide intramedullary canals.

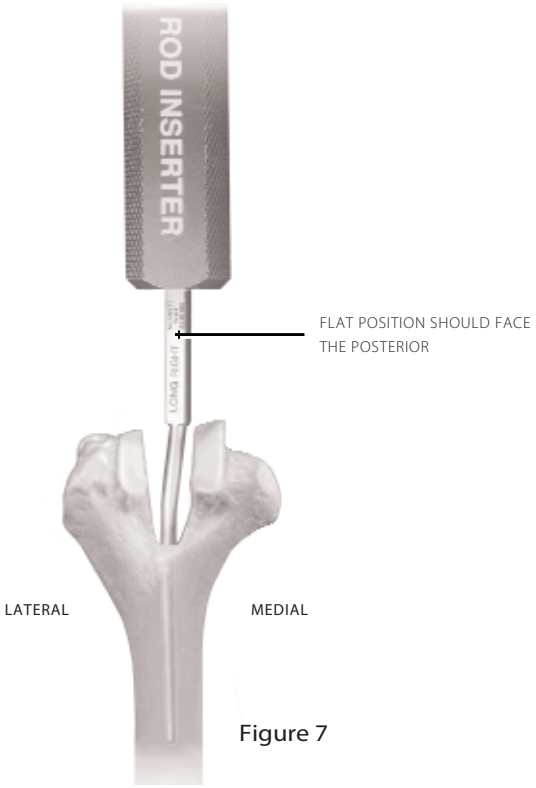


Figure 7

DISTAL, ANTERIOR, POSTERIOR AND BEVEL CUTS

8

With the IM rod properly inserted in the canal, the appropriate size humeral cutting guide is attached to the rod. The cutting guide arms are inserted deeply into the pre-drilled holes on the CAFE prepared in Step 4. Should the cut block require adjustment to align the cut guide arms, the IM rod may be inserted further into or extracted slightly from the medullary cavity until proper alignment is achieved. The lock screws on the guide arms are tightened. The guide block is then further secured by tightening the locking screw on its posterior side to the flat surface of the IM rod (Figure 8.1).

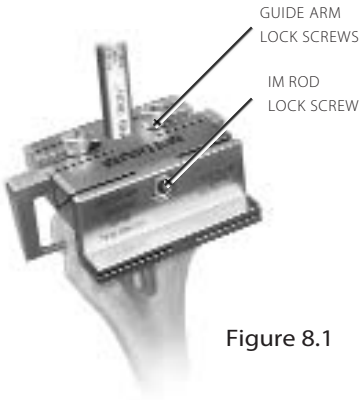


Figure 8.1

Saw cuts are made through the slots in the humeral cutting guide (Figure 8.2).

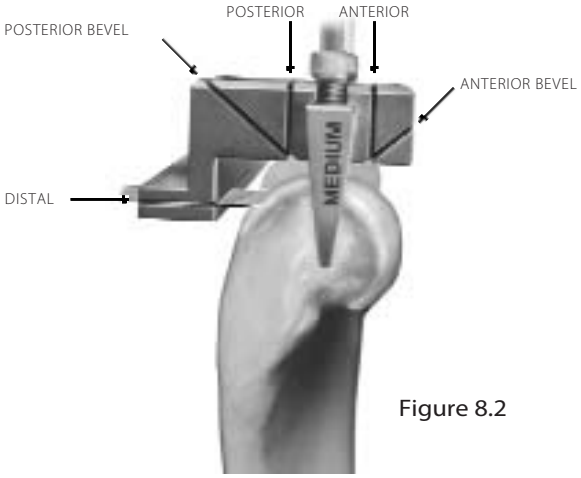


Figure 8.2

Caution: A cut is not made to the postero-lateral region of the humerus behind the capitellum (origin of the anconeus).

After the distal, anterior, posterior and bevel cuts have been made, remove the rod and cutting block (Figure 8.3).

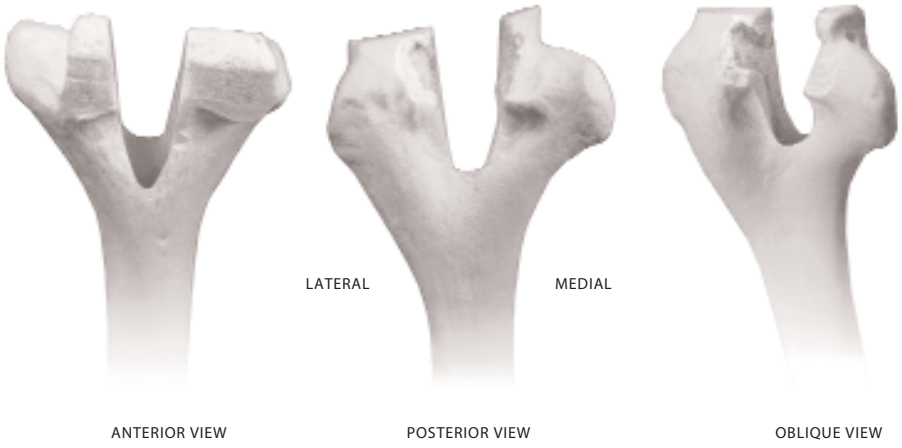


Figure 8.3

HUMERAL STEM RASPING

9

The IM canal is further enlarged using the humeral stem reamer, reaming the full length of the cutting fins.

Beginning with the humeral starter rasp, the medullary canal is rasped allowing for a 1mm cement mantle. The humeral stem rasp may then follow to enlarge the canal providing for a 2mm cement mantle (Figure 9).

Any remaining articular surface on the posterior capitellum may be removed with a rongeur.

The humeral trial of appropriate size (small, medium, large) is inserted and the fit and position are checked.

Figure 9

RADIAL HEAD RESECTION AND TRIAL PREPARATION

10

Using an oscillating saw, the minimum amount of radial joint surface is removed at 90° to the long axis of the neck (Figure 10.1).

The radial head broach is inserted through the center of the cut surface to its full depth.

The radial head trial is inserted and checked for position and fit.

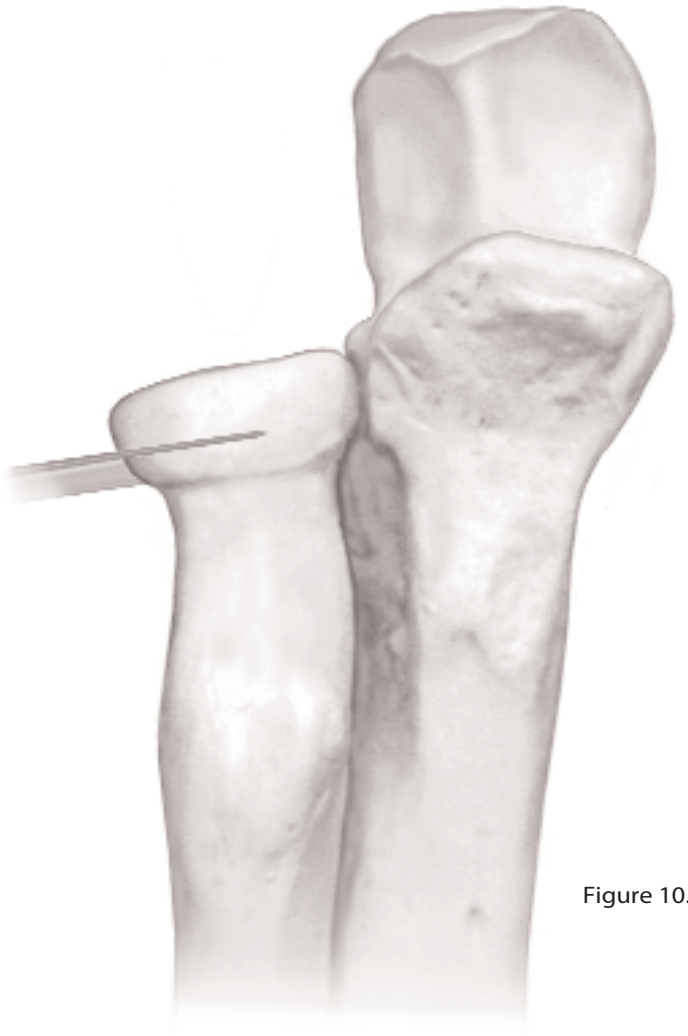


Figure 10.1

ULNAR ALIGNMENT GUIDE

11

The ulnar alignment guide is applied parallel to the shaft of the ulna. The sharp pin at the upper end of the guide is impacted in the center of the area of the olecranon process. The impaction should be done using a plastic ended mallet on the broad portion of the guide (Figure 11).

With a velcro strap, the wrist is secured in its holder which has been adjusted to a suitable length for the forearm.

The whole guide is rotated in a medial or lateral direction to be aligned parallel with the subcutaneous border of the ulna. The spring clamp on the guide is lightly tightened on the upper ulna.

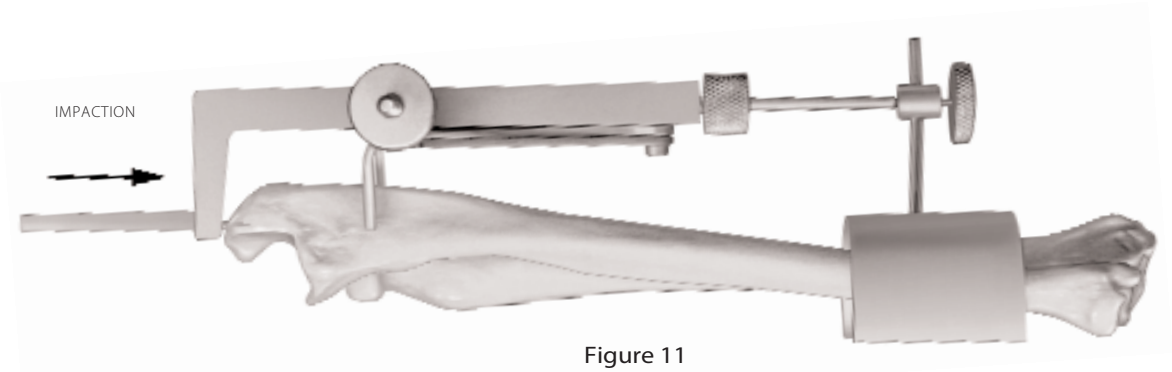


Figure 11

ULNAR PREPARATION (WITH CAM)

12

The ulnar cut guide holder is slid onto the ulnar rotation guide shaft. The ulnar rotation guide is then slid onto the shaft (Figure 12.1). This assembly is then attached to the ulnar cut guide locator (Figure 12.2). Once assembled, the angle adjuster can be loosened allowing the carrying angle of the joint to be determined by the patient's anatomy, then tightened.

All arrows on the assembly should point in the same direction, that is, toward the radial side (lateral) of the ulna (Figures 12.1 and 12.2).

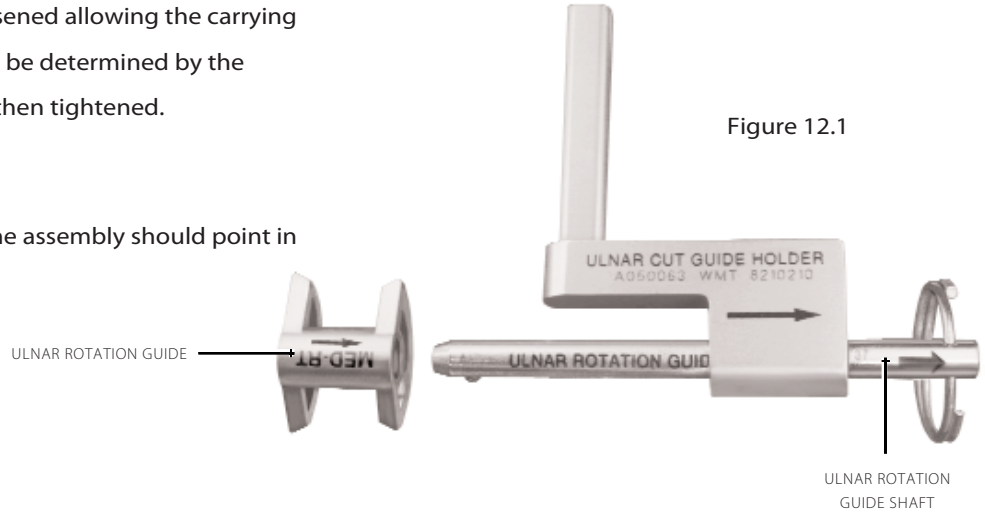


Figure 12.1

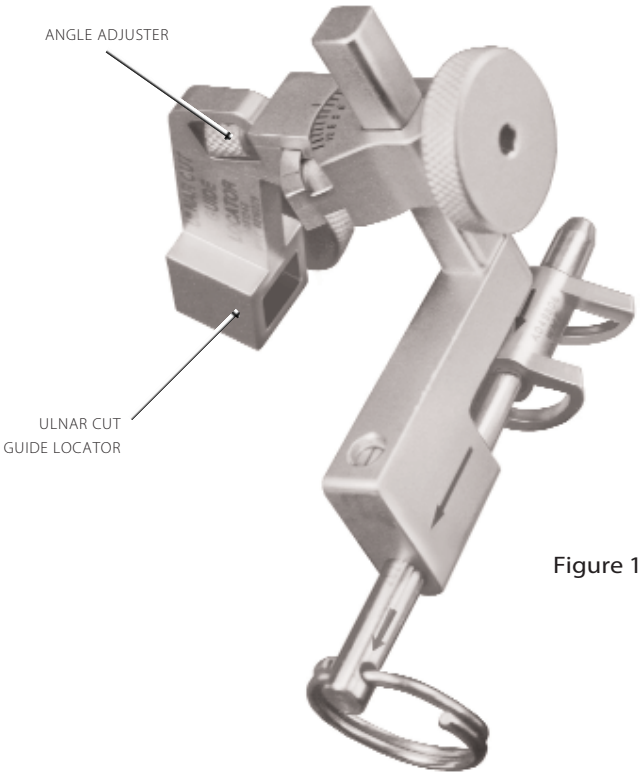


Figure 12.2

ULNAR CUTTING GUIDE AND ALIGNMENT GUIDE ASSEMBLY

13 The assembled cutting guides are attached to the upper protruding bar on the ulnar alignment guide and eased into position with the ulnar rotation guide firmly pressed into the trochlear notch (Figure 13). Knurled knobs are hand tightened only.

The spring clamp on the ulnar alignment guide is tightened. Minor adjustments may be made to suit individual clinical situations. All knurled knobs are then tightly secured using the hex wrench.

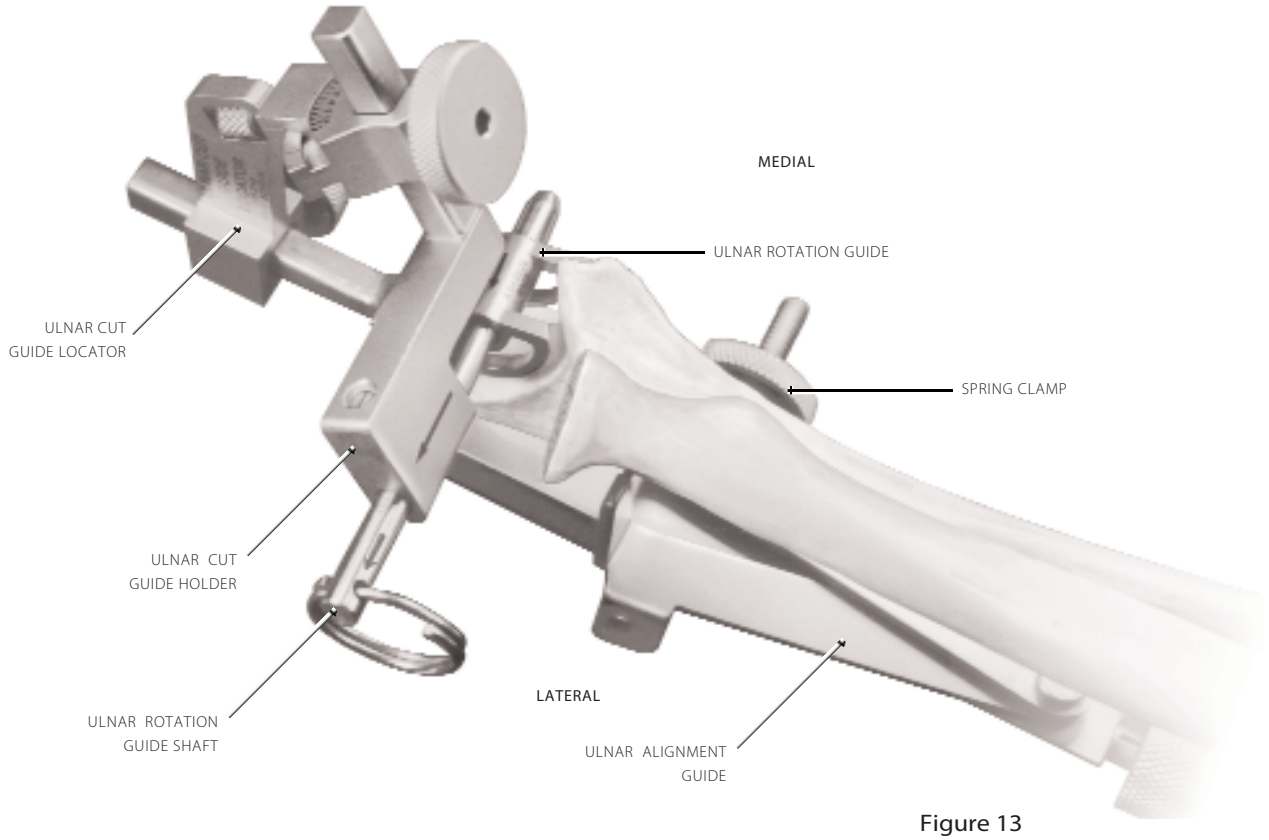


Figure 13

ULNAR CAM INSERTION

14 The ulnar rotation guide shaft and the ulnar rotation guide are removed. The ulnar cam of appropriate size (small, medium, large) is inserted into the ulnar cut guide holder (Figure 14).

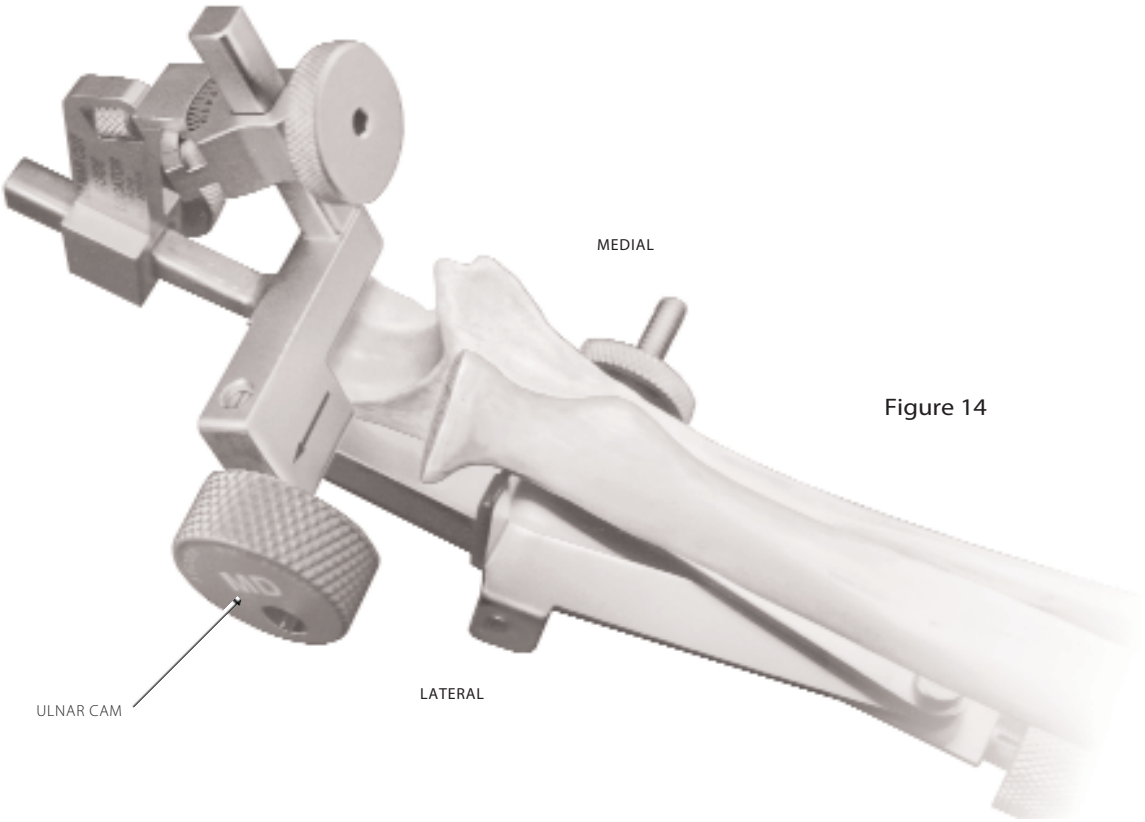


Figure 14

15

The high speed cutting burr is passed through the cam and an arc is scribed against the lateral side of the trochlear notch of the ulna (Figure 15). Small adjustments can be made to ensure a coincident cutting arc and the amount of bone to be removed.

The damaged joint surfaces of the ulna are removed by rotating the cam. When cutting is complete, all guides are removed as a unit. This allows all previously set angles to remain intact should minor adjustments need to be made at a later time.

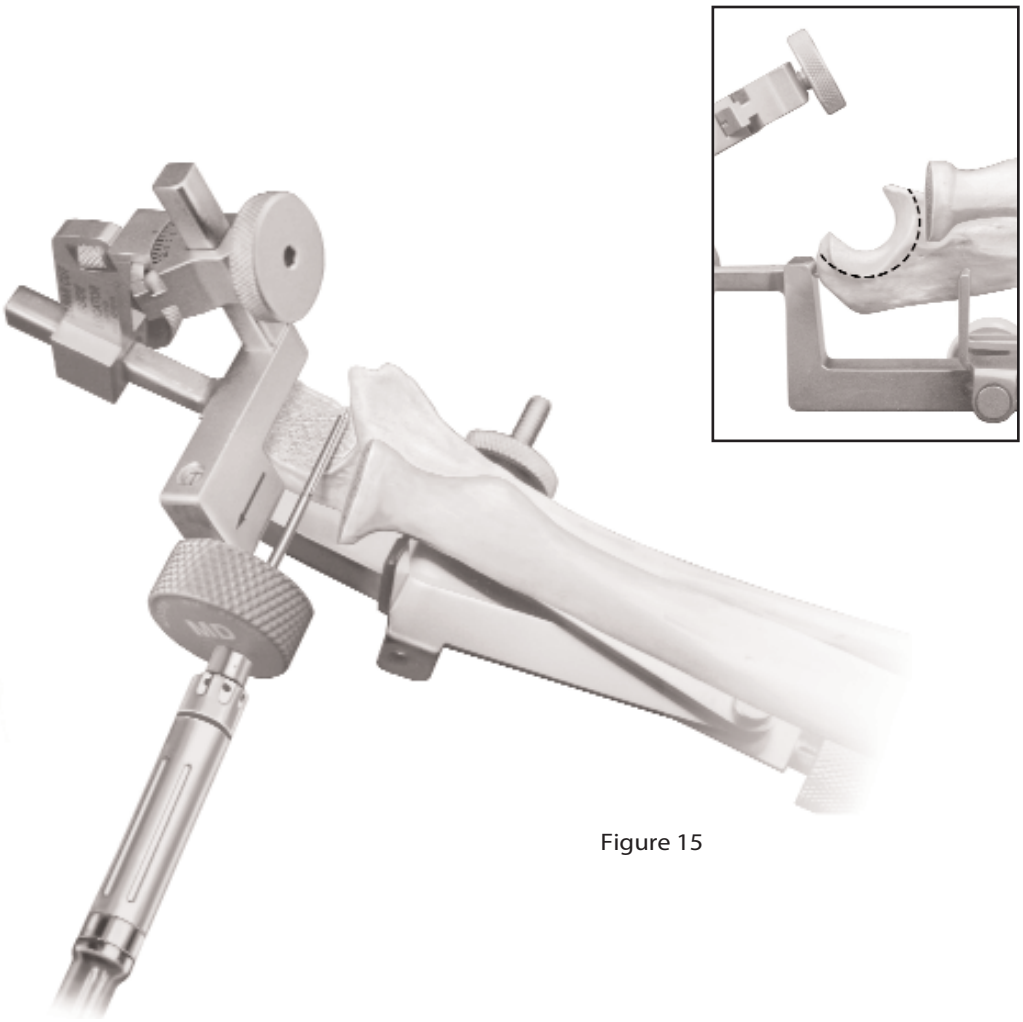


Figure 15

ALTERNATE ULNA PREPARATION: THE CYLINDRICAL ULNAR CUTTING GUIDE

15 ALTERNATE

Step 11 of previous method is followed. An appropriate size (small, medium, large) cylindrical ulnar cutting guide is attached to the ulnar cut guide locator.

The guides are assembled on the upper pro-truding bar on the ulnar alignment guide and eased into position. The surgeon adjusts the position of the cutting guide so that a suitable amount of the damaged articular surface can be removed using the high speed burr (Figure 15a.1 and 15a.2).

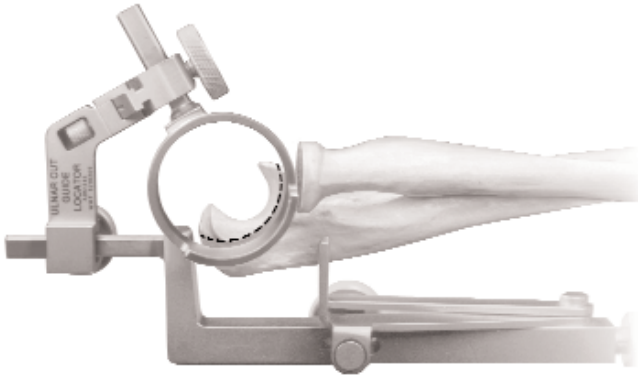


Figure 15a.1

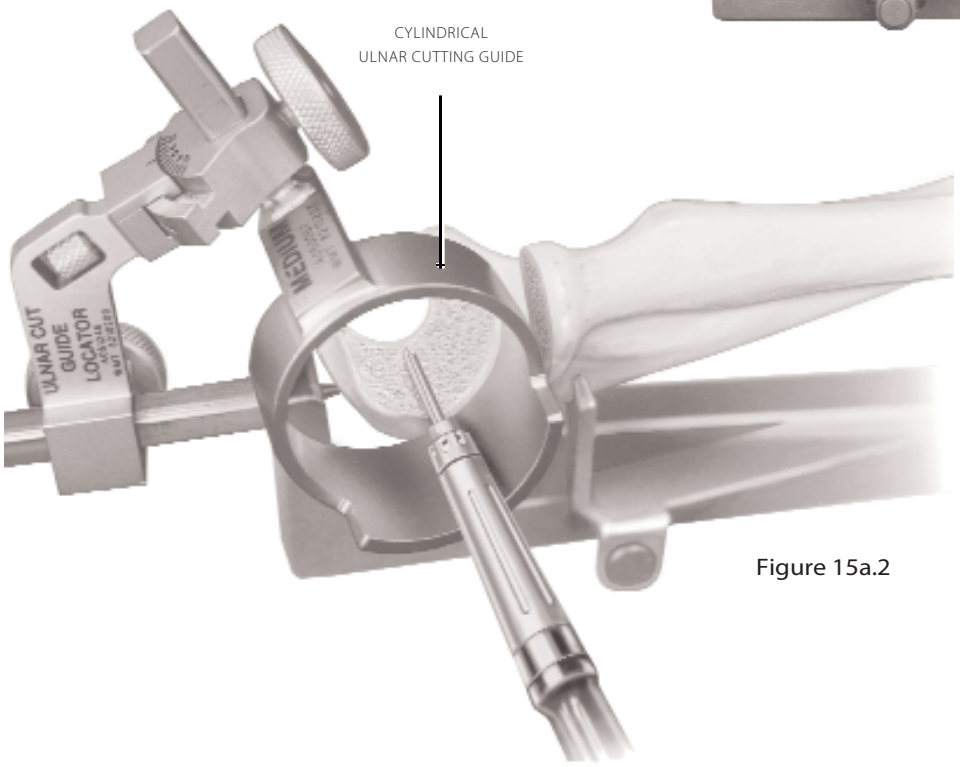


Figure 15a.2

FINAL ULNAR PREPARATION

16

The intramedullary canal of the ulna is opened with the supplied 3mm burr or the tip of the high speed cutting burr.

The hole is enlarged and the direction of the canal located with the starter reamer. The canal is then widened with the humeral stem reamer and rasped with the ulnar starter rasp, providing a 1mm cement mantle, and/or the ulnar stem rasp, providing a 2mm cement mantle (Figure 16.1). When a suitable amount of bone has been removed, the ulnar trial is inserted. For proper fit, it may be necessary to ensure the rasped area matches the contour of the back neck of the ulnar trial.

With a burr, 6 to 8 small pits about 1/8" or 3.2mm deep may be made on the cut ulnar surface to ensure better fixation of cement (Figure 16.2).

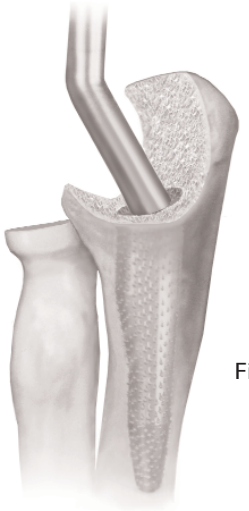


Figure 16.1

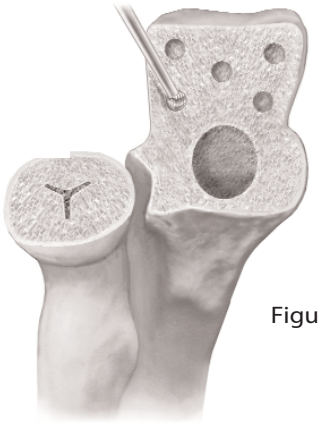


Figure 16.2

TRIAL REDUCTION

17

The three trial components are placed firmly in position, soft tissue is restored to original position, and the elbow joint is reduced. A full range of flexion and extension, supination and pronation is attempted to ensure general stability and proper orientation of the components.

It may be necessary to release the upper attachments of the anterior capsule from the front of the humerus using an elevator to gain full extension. If the muscles are very contracted, adjustments may also need to be made to tendons.

IMPLANTING THE HUMERAL COMPONENT

18

The cut bone surfaces and the humeral medullary canal are thoroughly lavaged.

The width of the interior of the humeral canal is measured using the bone plug sizer. The medullary cement restrictor of appropriate size is inserted using the bone plug inserter until the depth mark on the inserter shaft is aligned with the distal cut surface of the humerus (Figure 18.1).

Cement is injected into the medullary cavity of the humerus. Cement is further applied to the cut surfaces of the humerus as well as the contact surface of the humeral implant. The humeral component is inserted, tapped firmly into position with the humeral impactor and excess cement is removed (Figure 18.2).

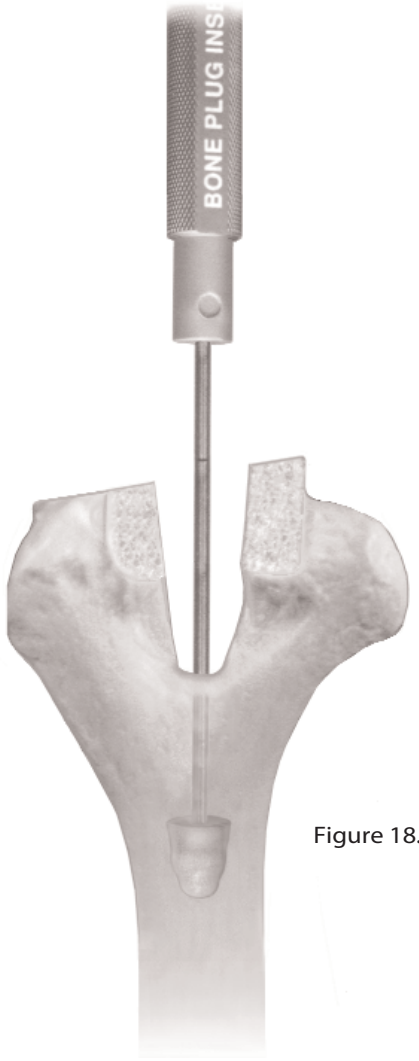


Figure 18.1

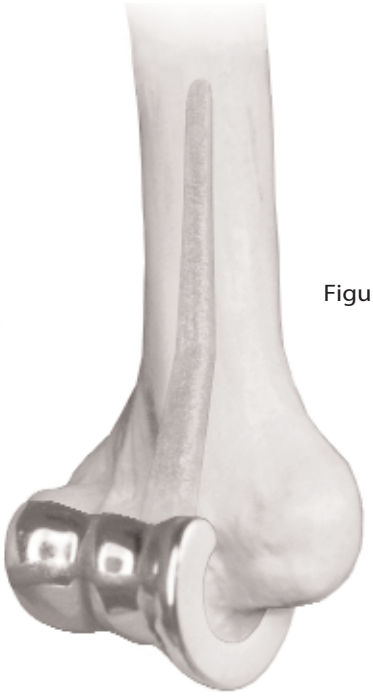


Figure 18.2

IMPLANTING THE ULNAR COMPONENT

19

The permanent ulnar implants are assembled. The ulnar polyethylene insert (6 or 9mm) must be firmly pressed into position in the metal base plate. When properly oriented, the mark on the insert will align with a corresponding mark on the base, and the snap fit will be firm. The assembly is performed by aligning the grooves on the proximal ends of the implants. One side of the polyethylene lock detail is fitted into the groove in the metal base and the remaining side of the polyethylene is pressed into place using the thumb.

A check for proper fit should show the stem of the base plate angled in the direction of the flat surface on the distal end of the polyethylene component. Cement is mixed and loaded into a cement insertion gun.

Cement is inserted into the ulna medullary cavity and pressed onto the remaining cut surface. Cement should also be applied to contact surface of the implant. The ulnar component is implanted and held in place with thumb pressure. Excess cement is removed (Figure 19).

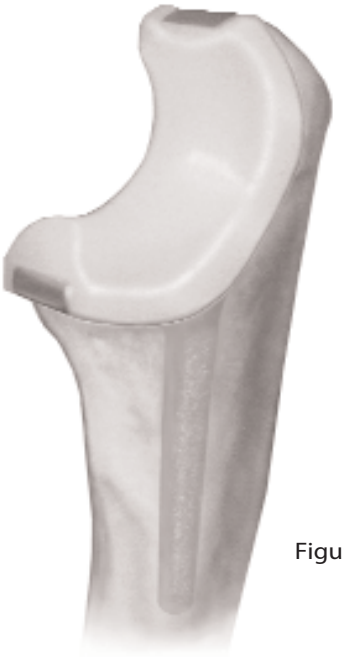


Figure 19

IMPLANTING THE RADIAL COMPONENT

20

Cement is pressed into the upper end of the radius prepared earlier by the broach. The radial component is positioned and impacted with the radial head seater. Excess cement is removed (Figure 20).

Figure 20

FINAL RANGE OF MOTION CHECK

21 The elbow is then reduced and moved through a full range of motion. Check for debris, especially between the radius and ulna. The cement is allowed to set with the bones of the joint held firmly together (Figures 21.1 and 21.2).

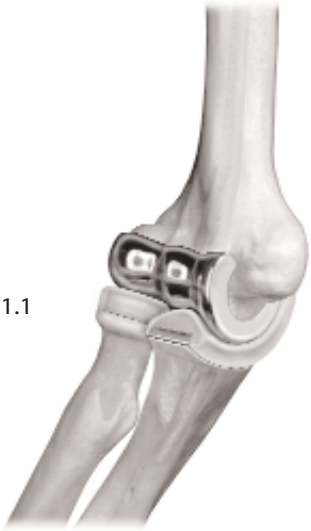


Figure 21.1

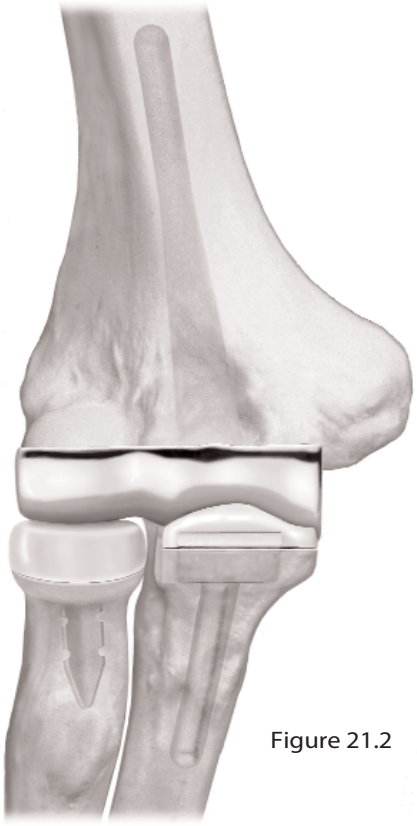


Figure 21.2

CLOSURE

22

1. Use of a vacuum drain is optional.
2. The tourniquet is released and bleeding points secured.
3. The triceps tendon is reattached to the ulna using two anchors or by drill holes and non-absorbable suture. It is important to assure a firm reattachment of the tendon.
4. The aponeurotic layer over the muscles is closed firmly with particular attention focused on the area of the lateral ligament. Some patients may require sutures passing through the lateral epicondyle.
5. The remainder of the wound is closed in layers.

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Warning: The Sorbie-Questor® Total Elbow System is intended for cemented use only.

Europe Patents: 0,201,010; 0,201,011
U.S. Patents: 4,624, 250; 4,718,414; 5,030,237

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