ACUMED®

Anatomic Radial Head System

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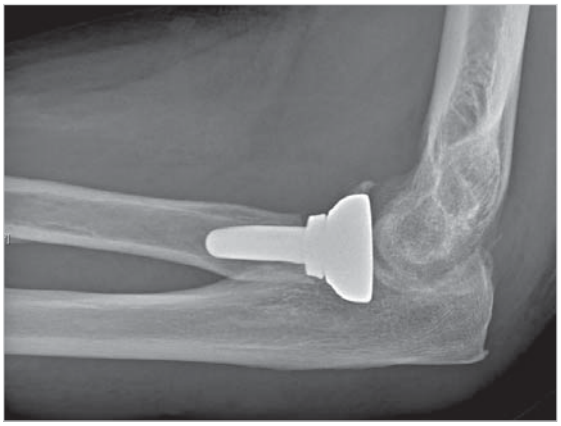
Acumed® is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to developing products, service methods and approaches that improve patient care.



The Acumed® Anatomic Radial Head Prosthesis is designed to provide a precise anatomical implant to replace the patient's native radial head. Many innovative design features are incorporated into the implant heads and stems, as well as the instrumentation to improve the surgical technique.

The Anatomic Radial Head System is a comprehensive solution for radial head fractures. The Acutrak 2® Mini and Micro Instruments are included in the base of the tray, as well as the Locking Radial Head Plate System.

With the Anatomic Radial Head System, the surgeon is equipped with the tools needed to properly restore the patient's anatomy in a radial head replacement surgery.

Designed in conjunction with Shawn W. O'Driscoll, Ph.D, M.D., the Acumed® Anatomic Radial Head System provides a comprehensive solution for radial head replacement.

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Radial head fractures are the most common bony injury to the adult elbow.[4] Current and past designs of radial head prostheses have had a round radial head component. The radial head is clearly not round but has a more ellipsoidal shape.[4] The Acumed® Anatomic Radial Head Prosthesis is a unique implant that closely replicates the natural anatomy of the patient's radial head.

Surgeons have emphasized the importance of restoring the biomechanical properties of the native radial head when radial head replacement is indicated.[9] The Acumed® system restores proper radial head geometry along with the proper height and placement in the radial canal. Dr. O'Driscoll hypothesized that if he could not possibly fix the radial head then it should be replaced with a prosthesis that best replicates the anatomy of the patient. This could improve "tracking" with the capitellum, reduction in implant loosening and thus result in an improved patient outcome.

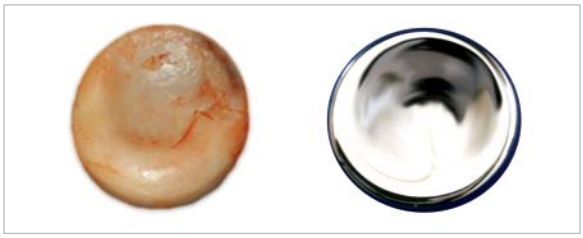
There are three potential areas of clinical importance of an anatomic (noncircular) radial head prosthesis: kinematics and stability, radiocapitellar contact forces, and stresses on the prosthesis-bone interface.[9] There is a growing concern among surgeons that suggests a need for an anatomic prosthesis. A round radial head prosthesis is non-anatomic and therefore does not track properly against the capitellum, the altered kinematics could affect joint function and elbow stability. More importantly, eccentric loading can potentially alter radiocapitellar contact stresses leading to either insufficient or excessive load bearing. Finally, eccentric loading will increase stress on the prosthesis-bone interface, increasing the risk for loosening.[3]

By providing the patient with an anatomical prosthesis, wear on the capitellum is theoretically reduced due to the improved biomechanics and balancing within the elbow. The result may be less pain for the patient and a reduced chance of long-term prosthesis loosening.

For radial head fractures that indicate joint replacement, this system provides the surgeon with advanced instrumentation that is designed to properly determine the overall length of the radius. A straightforward, reproducible surgical technique aids with accurate implant insertion and placement. Innovative implant design and insertion procedure makes the Acumed® Anatomic Radial Head System the next generation in radial head replacement.

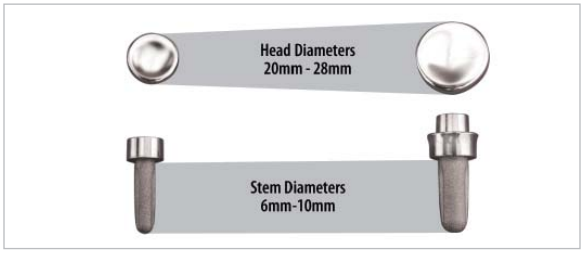
Anatomic Radial Head Features

Anatomic Radial Heads and Stems replicate the patient's natural radial head geometry. The offset anatomic dish on the proximal end of the radial head implant provides improved articulation with the capitellum. The 4° neck angle maintains the proper angled relationship between the radial neck and the plane of the head.



Straightforward Instrumentation includes a unique collar height gauge for an improved method of determining overall length of the radius. Color-coded broaches, trial heads and stems provide quick distinction between system components and sizes. Collar reamers, included in the system, create a perpendicular neck surface for the stem collar.

200 Head and Stem Combinations provide the surgeon with an implant that matches the patient's natural anatomic radial head and neck shape. Twenty standard stem options in five diameters, each having four collar height options, provide proper restoration of the overall length of the radius. The anatomical heads are provided in five diameters, left and right, to accommodate various patient sizes.

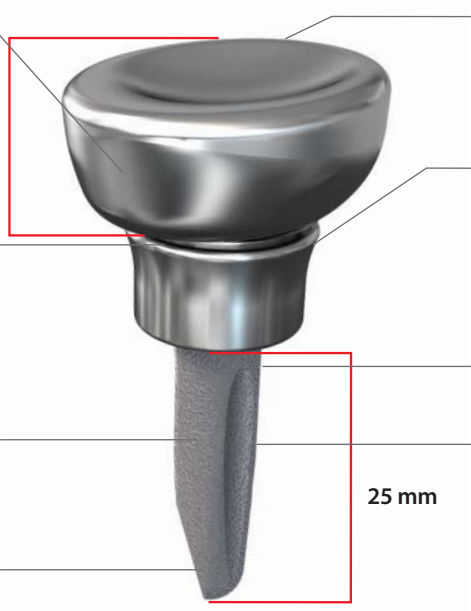


Medial Defined Ulna Articular Zone is angled and smooth to improve contact with the radial notch

Multiple Collar Heights to restore radial length

Grit Blasted Stem Surface promotes bony ongrowth

Tapered Titanium Stem to aid insertion



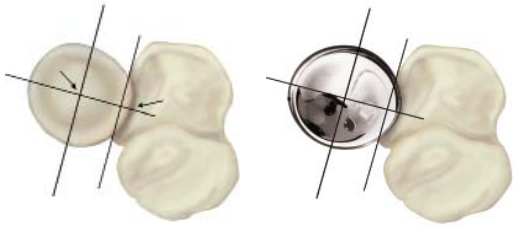
Highly-Polished Cobalt Chrome Head to maximize articulation

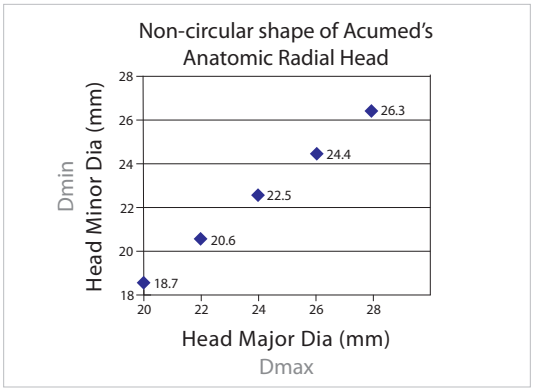
Contoured Lateral Surface improves interface with the annular ligament

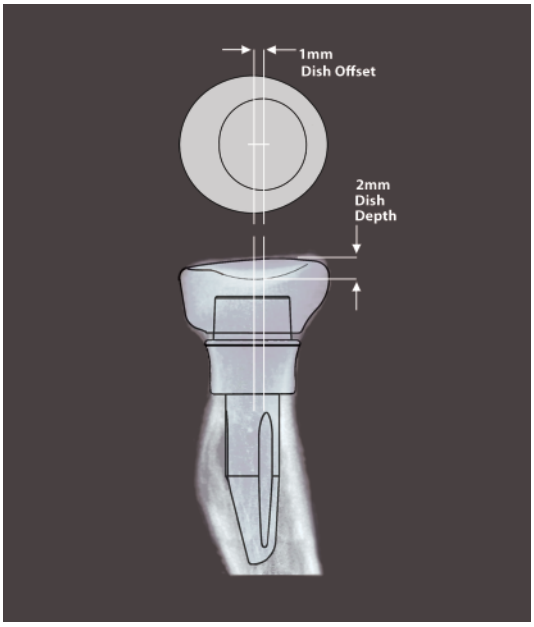
Fluted Stem for rotational stability

25 mm Stem Length is long enough to provide stability against bending movements but short enough not to reach the bend in the proximal canal

Head Design Rationale







While more simple fractures of the radial head are managed with conservative treatment or internal fixation, radial head replacement may be necessary for more complex fractures. The Acumed® Anatomic Radial Head Prosthesis was designed to treat those fractures not amenable to internal fixation. During the design of the prosthesis, Dr. Shawn W. O'Driscoll hypothesized the following:

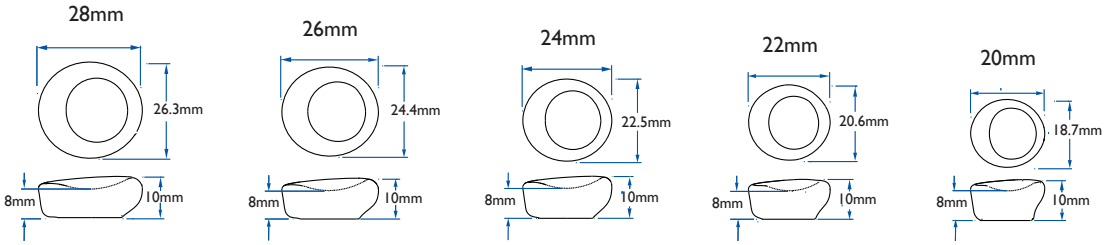
1. If perfect anatomy could be restored with rigid internal fixation, that would be the best
2. If we knew which aspects of the radial head shape and orientation were important, and if we could reproducibly position the prosthesis and assure fixation in the shaft, we might achieve #1
3. PERFECT replication of anatomy is not critical, but some elements are necessary
4. With more research, we will determine which factors are critical
5. Current trend of bipolar design is only necessary if we cannot achieve #4

With two hundred standard implant options and precise instrumentation, the Acumed® Anatomic Radial Head System is the first system that has design features that most closely replicate the patient's anatomy.

The Acumed® Anatomic Radial Head Prosthesis features an elliptical-shaped head. Results of several studies, including an in-house study, have shown a strong correlation between the radial head's major diameter (Dmax) and minor diameter (Dmin) measured in cadaveric radial heads.[11] As shown in the figure to the left, the orientation of the major diameter axis is perpendicular to the radial notch when the forearm is neutral position.[1-5,10]

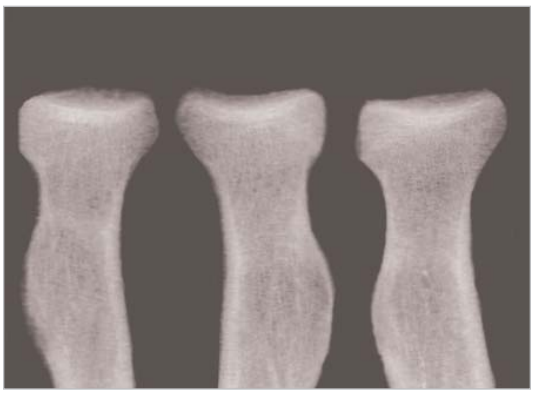
A laser mark on the prosthesis head and stem components allows for proper alignment during assembly and insertion. The laser mark is located 30° from the major axis. When inserting the prosthesis, the laser mark is then oriented laterally with the forearm in neutral position.[4] Lister's tubercle may also be used as a landmark for laser mark orientation.

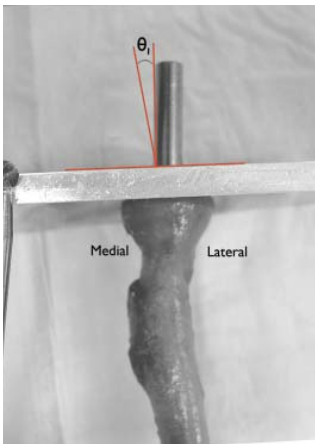
The dish is offset 1 mm laterally from the center of the radial head to properly accommodate the patient's anatomy. The dish depth is 2 mm and is consistent amongst all implant diameters. A head height of 10 mm was found to most closely replicate cadaveric radii. This was confirmed on the same 24 cadaver radii and in the referenced literature. [3,5,6]

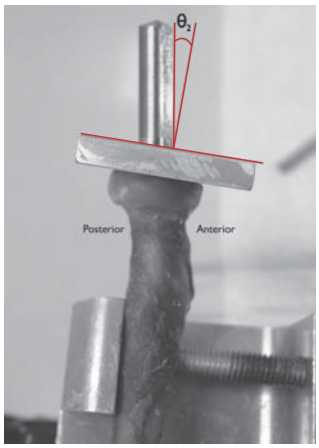


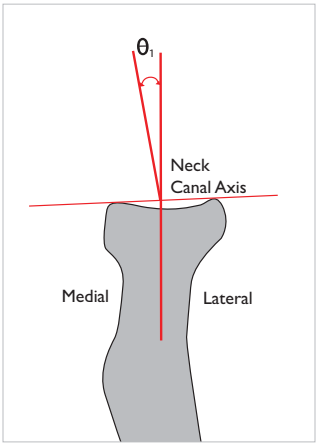
Head Design Rationale

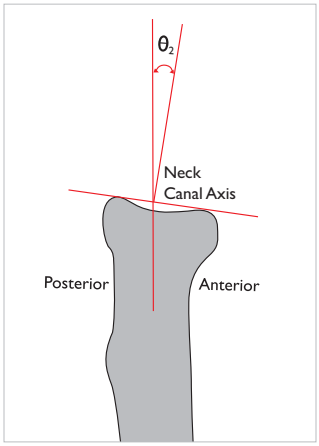
The Anatomic Radial Head was designed with 4° of tilt in two planes: anterior/posterior and medial/lateral. The head tilt relative to canal axis was measured in 24 cadaver radii by drilling an oversized hole in the radial head and sequentially broaching until canal cortex met. The oversized hole allowed the broach to self align with the neck canal axis. A flat plate with a central hole was inserted over the broach and placed flat on top of the head. The angle of the head relative to the neck canal axis in the M/L plane (θ1) and A/P plane (θ2) was recorded along the major and minor axes. As a result of these measurements, a 4° M/L and A/P tilt was selected, thus creating a need for both left and right heads.[11]











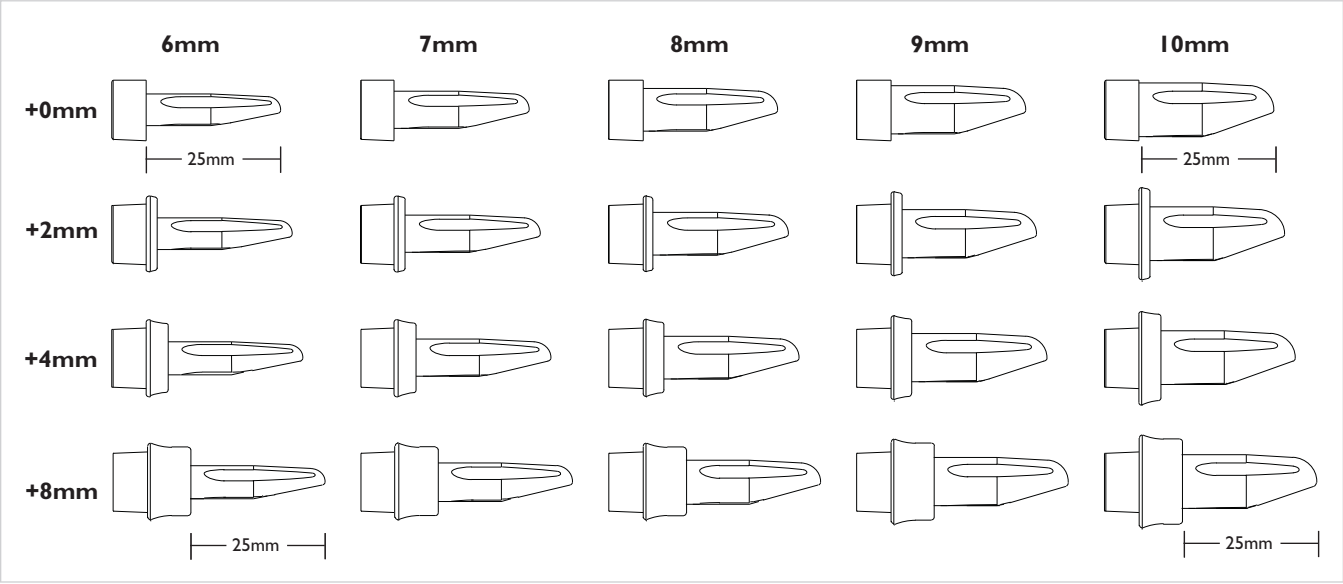
Stem Design Rationale

With the Anatomic Radial Head Prosthesis, height is restored by collar height, not the head height. Studies show the length of the radial neck affects the valgus/varus position of the ulna throughout the flexion arc in each of the forearm rotations. Restoration of proper axial length of the radius is critical to avoid a number of complications such as residual instability.[7,8] The shape of the collar helps to restore the natural shape of the bone. The highly polished collar minimizes soft tissue irritation.

Made from titanium alloy, the stem is designed to press fit into the neck canal. The distal portion of the stem is angled, allowing for easier insertion. This angle also allows the stem length to be longer within the radial canal for stability and to resist loosening.

The stem is grit blasted for bony ongrowth. Flutes have also been added to the stem to allow for rotational stability upon bony ongrowth. A Morse taper ensures a secure fit between the collar and the head, and 20 standard and five optional stem options give the surgeon a wide range of choices when choosing proper stem diameter and collar height. A threaded hole is located in the top of the stem to allow for implant removal when used in conjunction with the removal tool, included in the system.

Anatomic Radial Head Prosthesis Sizes



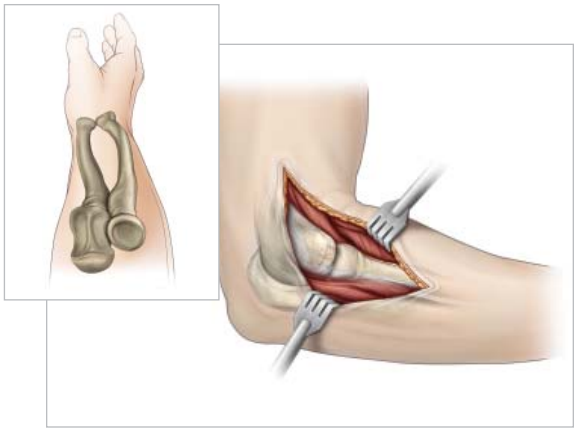
*Optional +6 mm stems and trials are available upon request.

The innovative broaches in the Anatomic Radial Head System allow the surgeon to create a precise opening in the radial canal for proper insertion of the implant. The broaches enter the radial canal in a straight direction and are less likely to broach the canal at an angle, resulting in improper implant placement. Spiral flutes on the broach are designed to displace bone during broaching. The implant stem is 0.5 mm oversized from the broach diameter. The trial stem diameter is 0.5 mm undersized of the broach diameter to allow for ease of trial insertion and removal.

A mallet should be used to insert the broach. Side Pegs are provided for removal with a mallet and also provide a T-Handle to ease broach insertion and extraction. Furthermore, the broaches are color-coded for ease of trial implant selection. Collar reamers are included in the system to create a perpendicular neck surface for the stem facilitating accurate placement of the stem.

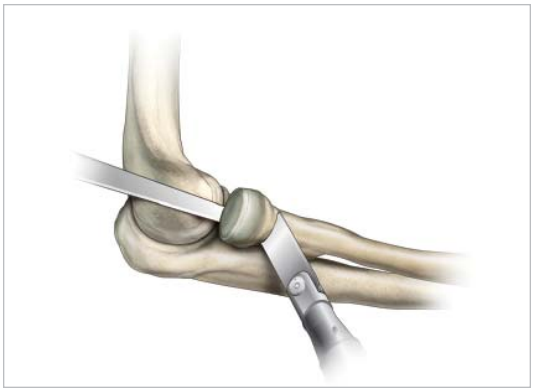
A unique guide allows the surgeon to determine proper collar height. A sizing gauge is placed in the radial canal and then ratcheted proximally with the collar sizing gauge. The measurement corresponds to proper collar height for accurate restoration of radial length.

Anatomic Radial Head



1 INCISION AND DISSECTION

While there are many acceptable exposure methods, the Kaplan interval in a line from the lateral epicondyle toward Lister's tubercle, with the forearm in neutral rotation, permits the collateral ligament to be left intact. In fracture dislocations, the exposure is through the traumatic opening in the ligament complex. Proximally, the ECRL origin is released with the anterior capsule to permit direct access to the front of the radial head.



2 RADIAL HEAD RESECTION

Template the radial head prior to surgery to determine the appropriate level of resection. Resect the radial head with a microsagittal saw as close to the surgical neck as possible. A maximum length of 17 mm of the radius can be replaced. This 17 mm includes the radius length reamed with the collar reamer in Step 4.

3 DETERMINE STEM DIAMETER

Use the 5 mm awl (TR-0206) to initially enter the canal. Starting with the smallest broach (6 mm, TR-BRA06), prepare the canal for the stem. Use sequentially larger broaches until a tight fit is achieved with the broach. Tap on the back end of the broach with a mallet. There is a groove on the broach just above the cutting flutes that indicates when to stop. Note that the broaches are 0.5 mm undersized from the implant stem to ensure a tight press fit.

4 REAM WITH COLLAR REAMER

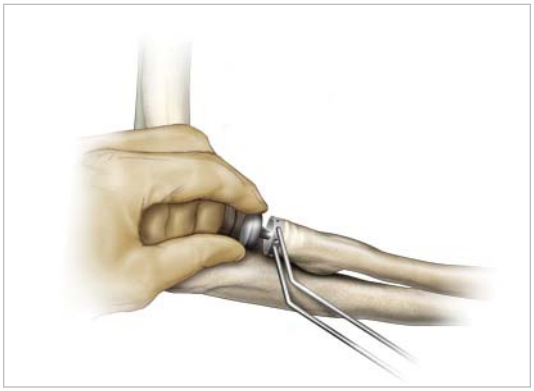
Select the collar reamer (TR-CRAxx) that matches the stem diameter determined by the broach in the previous step. Under power or by hand, ream to create a surface where at least 60% of the radial shaft is in contact with the reamer. To ream by hand, attach the collar reamer to the T-Handle (MS-T1212). Do not over-ream the radial shaft; removing too much bone will cause the radial head not to articulate properly with the capitellum.

5 DETERMINE HEAD DIAMETER

Determine head diameter by placing the resected head into the sizing pockets on the impactor base (TR-MS03). If between sizes, select the smaller diameter.

6 ASSEMBLE HEAD AND STEM GAUGE

Assemble the head gauge (TR-TG02) and stem gauge (TR-TGA06). The head gauge needs to be completely compressed.

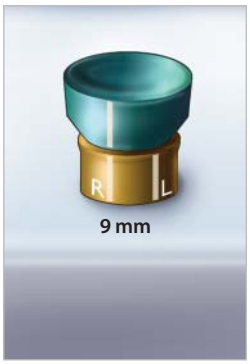


7 DETERMINE COLLAR HEIGHT

Insert stem gauge assembly (TR-TGA06) into the bone canal. Starting with the +0 end of the trial gauge (TR-TG01), sequentially increase the height by inserting the end of the gauge under the head of the assembly, until the head reaches the capitellum. It is critical that the coronoid contacts the trochlea during this process. The coronoid separated from the trochlea is an indicator that the collar is too large. The number on the trial gauge (+0, 2, 4, 8 mm) will correspond to the collar height on the stem.

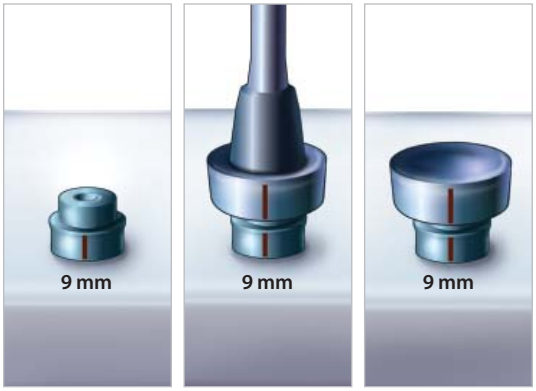
8 SELECT TRIAL IMPLANTS AND ASSEMBLE

After selecting the trial head and stem, align laser marks on the head and stem and assemble using hand pressure. The stem laser mark is indicated for Left and Right for proper orientation. If the trial head and stem are difficult to connect, apply saline solution prior to connecting.



9 TRIAL IMPLANT INSERTION

Insert the trial implant into the radius. Ensure that the laser marks on the head and stem are aligned with the lateral aspect of the radius when the forearm is in neutral position. Lister's tubercle may also be used as a landmark for laser mark orientation. Check for proper articulation with the capitellum and the coronoid. The coronoid needs to be in contact with the trochlea to ensure proper positioning of the trial. The trial stems are 0.5 mm undersized from the broaches for ease of insertion.



10 IMPLANT ASSEMBLY

After determining the correct size head and stem with the trials, place the implant stem into the appropriate size hole in the impactor base (TR-MS03). Align laser marks and impact the head and stem, then lock the Morse taper using the impactor (TR-MS05) and a mallet.

11 IMPLANT INSERTION

Insert the implant into the radius using the impactor (TR-MS05) and a mallet. Ensure that the laser mark on the head is aligned with the lateral aspect of the radius when the forearm is in neutral position. Lister's tubercle may also be used as a landmark for laser mark orientation. A stem removal tool (TRMS30) is available in the system if needed.

12 POSTOPERATIVE PROTOCOL

Postoperative management is determined by the overall management of the elbow and limb, more so than specifically the radial head. For isolated fractures of the radial head and neck without ligament injury, early motion is commenced in flexion and extension as well as pronation and supination. This usually begins within the first few days after surgery.

Ordering Information

Heads	
20.0 mm Head, Right	TR-H200R-S
22.0 mm Head, Right	TR-H220R-S
24.0 mm Head, Right	TR-H240R-S
26.0 mm Head, Right	TR-H260R-S
28.0 mm Head, Right	TR-H280R-S
20.0 mm Head, Left	TR-H200L-S
22.0 mm Head, Left	TR-H220L-S
24.0 mm Head, Left	TR-H240L-S
26.0 mm Head, Left	TR-H260L-S
28.0 mm Head, Left	TR-H280L-S

Stems	
6.0 mm x 0.0 mm Stem	TR-S0600-S
6.0 mm x 2.0 mm Stem	TR-S0602-S
6.0 mm x 4.0 mm Stem	TR-S0604-S
6.0 mm x 8.0 mm Stem	TR-S0608-S
7.0 mm x 0.0 mm Stem	TR-S0700-S
7.0 mm x 2.0 mm Stem	TR-S0702-S
7.0 mm x 4.0 mm Stem	TR-S0704-S
7.0 mm x 8.0 mm Stem	TR-S0708-S
8.0 mm x 0.0 mm Stem	TR-S0800-S
8.0 mm x 2.0 mm Stem	TR-S0802-S
8.0 mm x 4.0 mm Stem	TR-S0804-S
8.0 mm x 8.0 mm Stem	TR-S0808-S
9.0 mm x 0.0 mm Stem	TR-S0900-S
9.0 mm x 2.0 mm Stem	TR-S0902-S
9.0 mm x 4.0 mm Stem	TR-S0904-S
9.0 mm x 8.0 mm Stem	TR-S0908-S
10.0 mm x 0.0 mm Stem	TR-S1000-S
10.0 mm x 2.0 mm Stem	TR-S1002-S
10.0 mm x 4.0 mm Stem	TR-S1004-S
10.0 mm x 8.0 mm Stem	TR-S1008-S

Instruments	
6 mm Broach Assembly	TR-BRA06
7 mm Broach Assembly	TR-BRA07
8 mm Broach Assembly	TR-BRA08
9 mm Broach Assembly	TR-BRA09
10 mm Broach Assembly	TR-BRA10
Trial Gauge	TR-TG01
Head Gauge	TR-TG02
6.0 mm Stem Gage Assembly	TR-TGA06
20 mm Trial Head, Left	TR-TH20L
20 mm Trial Head, Right	TR-TH20R
22 mm Trial Head, Left	TR-TH22L
22 mm Trial Head, Right	TR-TH22R
26 mm Trial Head, Left	TR-TH26L
26 mm Trial Head, Right	TR-TH26R
28 mm Trial Head, Left	TR-TH28L
28 mm Trial Head, Right	TR-TH28R
6.0 mm x 0.0 mm Trial Stem	TR-TS60
6.0 mm x 2.0 mm Trial Stem	TR-TS62
6.0 mm x 4.0 mm Trial Stem	TR-TS64
6.0 mm x 8.0 mm Trial Stem	TR-TS68
7.0 mm x 0.0 mm Trial Stem	TR-TS70
7.0 mm x 2.0 mm Trial Stem	TR-TS72
7.0 mm x 4.0 mm Trial Stem	TR-TS74
7.0 mm x 8.0 mm Trial Stem	TR-TS78
8.0 mm x 0.0 mm Trial Stem	TR-TS80
8.0 mm x 2.0 mm Trial Stem	TR-TS82
8.0 mm x 4.0 mm Trial Stem	TR-TS84
8.0 mm x 8.0 mm Trial Stem	TR-TS88
9.0 mm x 0.0 mm Trial Stem	TR-TS90
9.0 mm x 2.0 mm Trial Stem	TR-TS92
9.0 mm x 4.0 mm Trial Stem	TR-TS94
9.0 mm x 8.0 mm Trial Stem	TR-TS98
10.0 mm x 0.0 mm Trial Stem	TR-TS100
10.0 mm x 2.0 mm Trial Stem	TR-TS102
10.0 mm x 4.0 mm Trial Stem	TR-TS104

Instruments	
10.0 mm x 8.0 mm Trial Stem	TR-TS108
Head Impactor	TR-MS05
Impactor Base	TR-MS03
6 mm Collar Reamer	TR-CRA06
7 mm Collar Reamer	TR-CRA07
8 mm Collar Reamer	TR-CRA08
9 mm Collar Reamer	TR-CRA09
10 mm Collar Reamer	TR-CRA10
Quick Release T-Handle	MS-T1212
5.5 mm Quick Release Awl	TR-0206
Stem Removal Tool	TR-MS30
Total Radial System Tray	TR-0001

Optional Items	
6.0 mm x 6.0 mm Stem	TR-S0606-S
7.0 mm x 6.0 mm Stem	TR-S0706-S
8.0 mm x 6.0 mm Stem	TR-S0806-S
9.0 mm x 6.0 mm Stem	TR-S0906-S
10.0 mm x 6.0 mm Stem	TR-S1006-S
6.0 mm x 6.0 mm Trial Stem	TR-TS66
7.0 mm x 6.0 mm Trial Stem	TR-TS76
8.0 mm x 6.0 mm Trial Stem	TR-TS86
9.0 mm x 6.0 mm Trial Stem	TR-TS96
10.0 mm x 6.0 mm Trial Stem	TR-TS106
ARH STD & Optional Trial Gauge	80-0832
ARH STD & Optional Trial Caddy Base	80-0833
ARH STD & Optional Trial Caddy Lid	80-0857
ARH Case Series	ELB70-03

Acutrak 2® Mini & Micro Instruments	
Acutrak 2® Tray Mini Screw Module	AT2-006
Acutrak 2® Micro Instrument Module	80-0405
Acutrak 2® Mini - Drill	AT2M-1813
Acutrak 2® Mini - Drill, Long	AT2M-L1813
Acutrak 2® Micro - Drill	AT2-1509
Acutrak 2® Micro - Drill, Long	80-0100
2.0 mm Cannulated Quick Release Driver Tip	HT-1120
1.5 mm Cannulated Quick Release Driver Tip	HT-0915
.045" x 6" ST Guide Wire	WS-1106ST
.035" x 5.75" ST Guide Wire	WS-0906ST
.045 Diameter, Parallel Wire Guide Assembly	AT2-4500
.035 Diameter, Parallel Wire Guide Assembly	AT2-3500

The Anatomic Radial Head System may also be used in combination with the following Acumed® Products:

- Locking Radial Head Plate System
- Acutrak 2® Headless Compression Screw System (Mini & Micro)

For ordering information, please contact your local Acumed® Sales Representative.

Notes:

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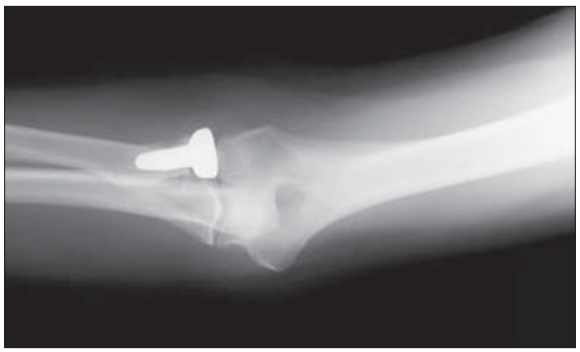

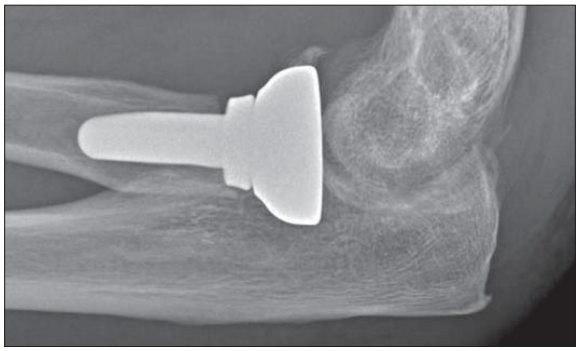

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