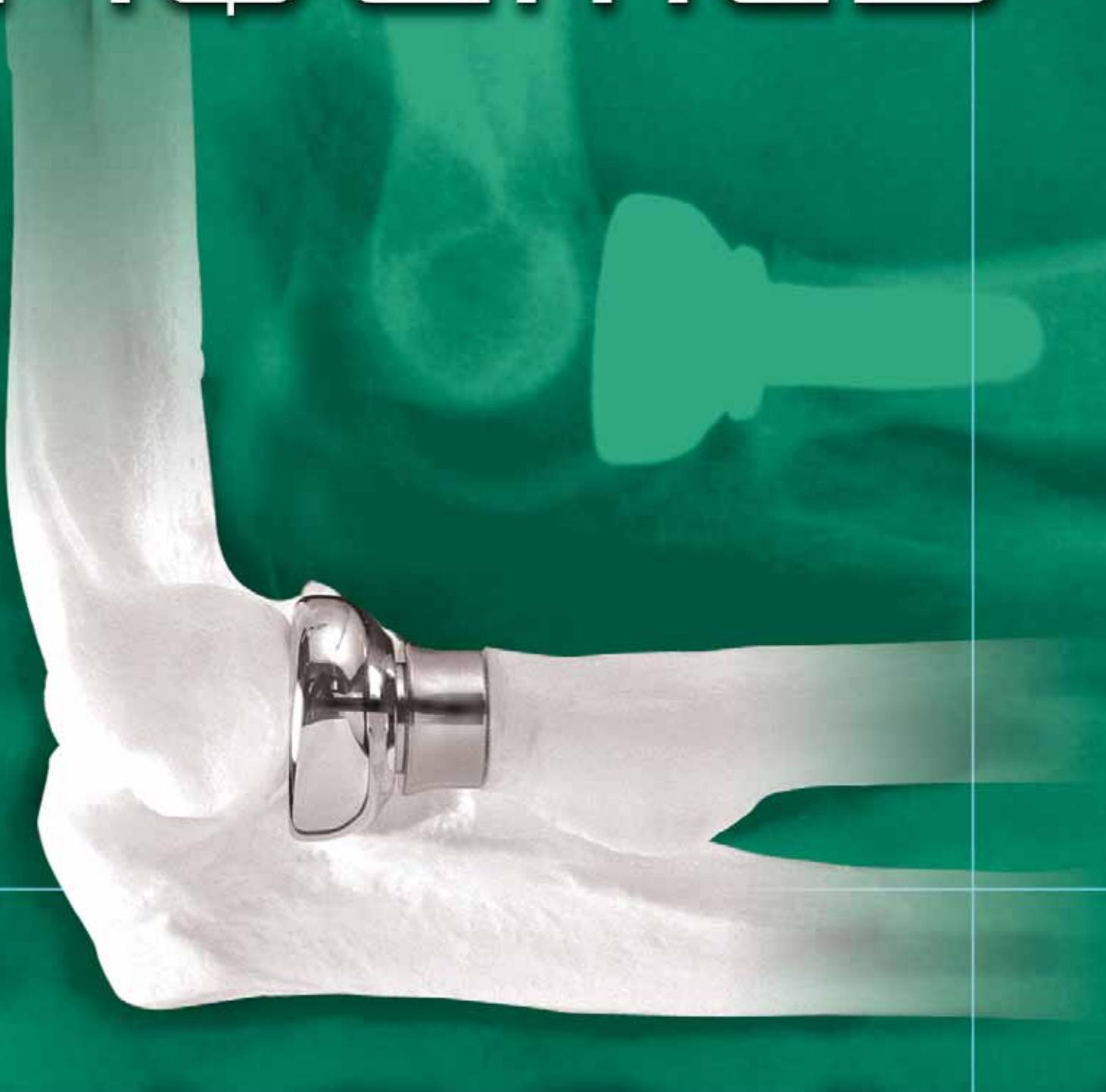


A&U MED[®]



ANATOMIC RADIAL HEAD SYSTEM

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Since 1988 Acumed has been designing solutions to the demanding situations facing orthopedic surgeons, hospitals and their patients. Our strategy has been to know the indication, design a solution to fit, and deliver quality products and instruments.

Acumed's 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 and patient outcome.

The Anatomic Radial Head System is a comprehensive solution for radial head fractures. The Acutrak 2 Mini System can be included in the base of the tray, as well as the Mayo Clinic Radial Head Plate if needed upon request.

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.

For more detailed information refer to the Anatomic Radial Head System Technical Monograph. **CPS60-02**



Designed in conjunction with Shawn O'Driscoll, Ph.D, M.D., Acumed's Anatomic Radial Head System provides a comprehensive solution for radial head replacement. Featuring 10 left and right anatomically shaped radial head implants and 20 stem options, the system provides 200 head/stem combinations to accommodate each patient's anatomy.

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 is less pain for the patient and a lower 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. An advanced surgical technique aids with accurate implant insertion and placement. Innovative implant design and insertion procedure makes Acumed's Anatomic Radial Head System the next generation in radial head replacement.

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 neck angle is 4 degrees, preventing implant loosening and maintaining 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 are included in the system to create a perpendicular neck surface for the stem collar.

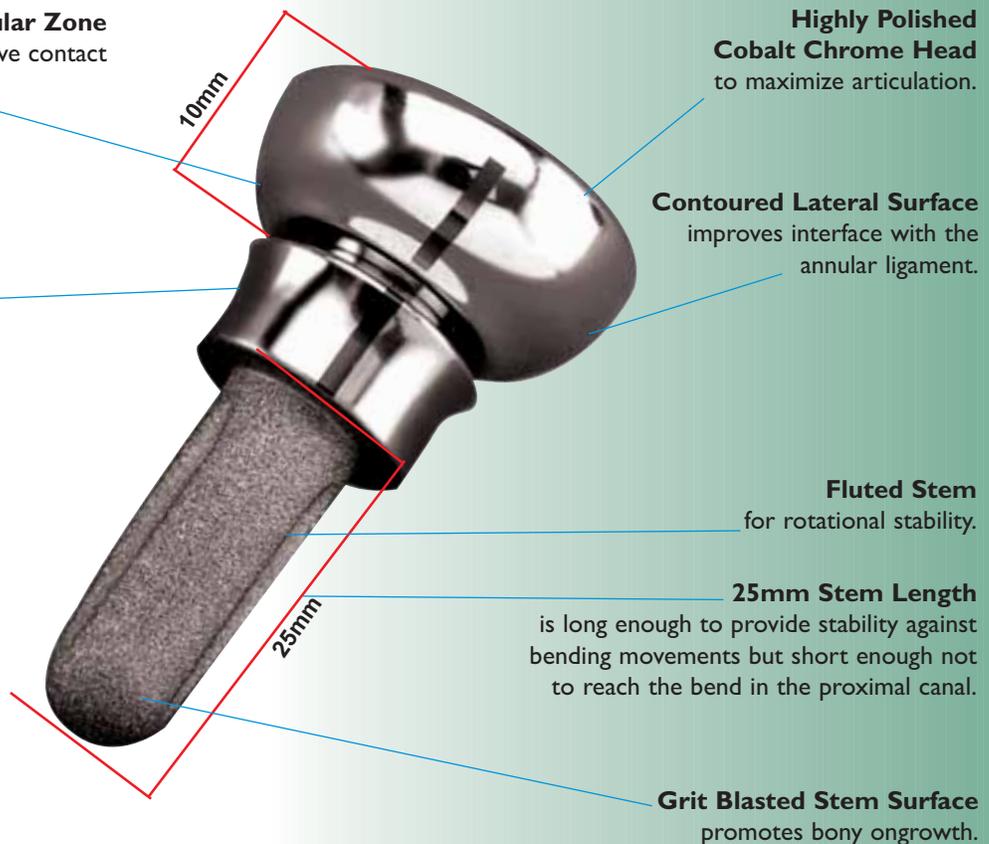


200 Head and Stem Combinations provide the surgeon with an implant that matches the patient's natural anatomic radial head shape. 20 stem options in five diameters, each with four collar height options provide proper restoration of the overall length of the radius. The anatomical heads are provided in five sizes, left and right, to accommodate various patient sizes.



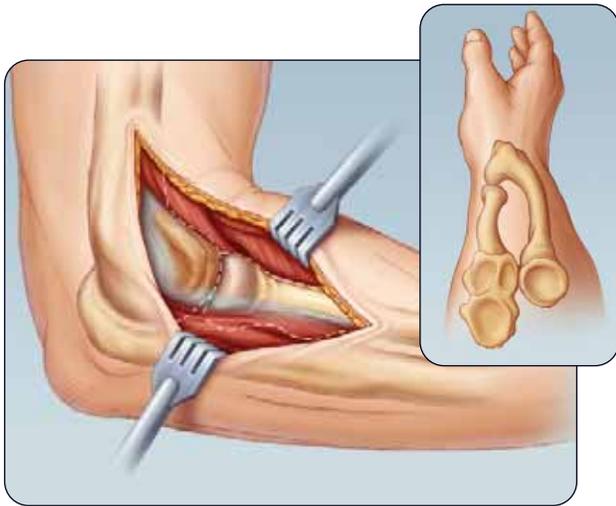
Medial Defined Ulna Articular Zone is angled and smooth to improve contact with the radial notch.

Multiple Collar Heights to restore radial length.



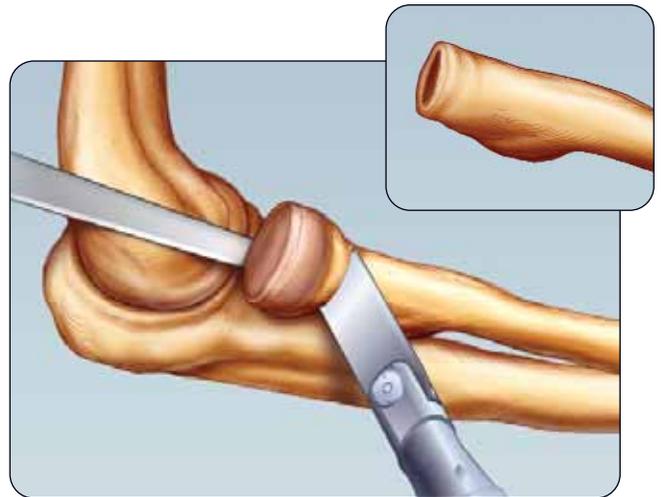
By Shawn O'Driscoll, Ph.D., M.D.

The following is Acumed's suggested method for implanting the Anatomic Radial Head Prosthesis. For specific questions not addressed here, please contact your local Acumed representative or Acumed by phone at 888 627-9957 or on the web at www.acumed.net.



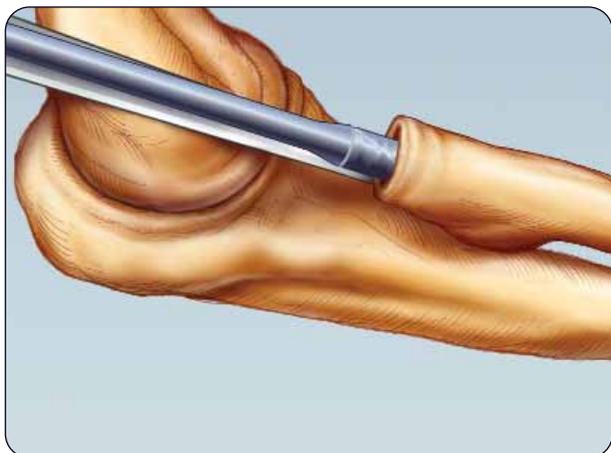
Step 1: Incision and Dissection

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.



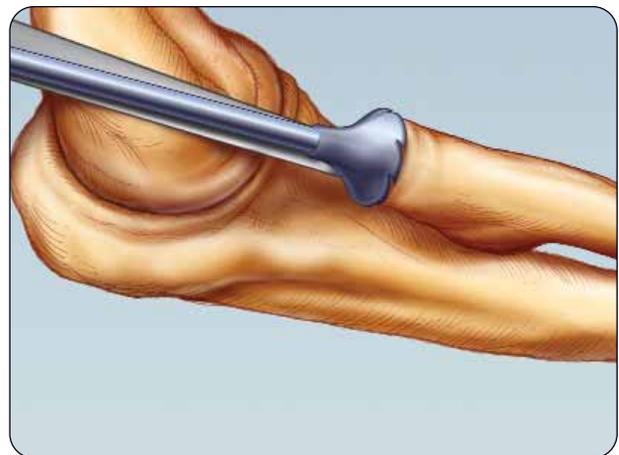
Step 2: Radial Head Resection

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 17mm of the radius can be replaced. **This 17mm includes the radius length reamed with the Collar Reamer in Step 4.**



Step 3: Determine Stem Diameter

Use the 5mm awl (TR-0206) to initially enter the canal. Starting with the smallest broach (6mm, 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 0.5mm undersized from the implant stem to ensure a tight press fit.



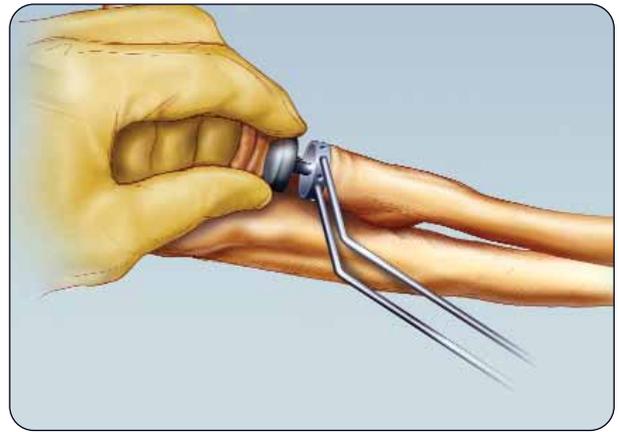
Step 4: Ream with Collar Reamer

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.



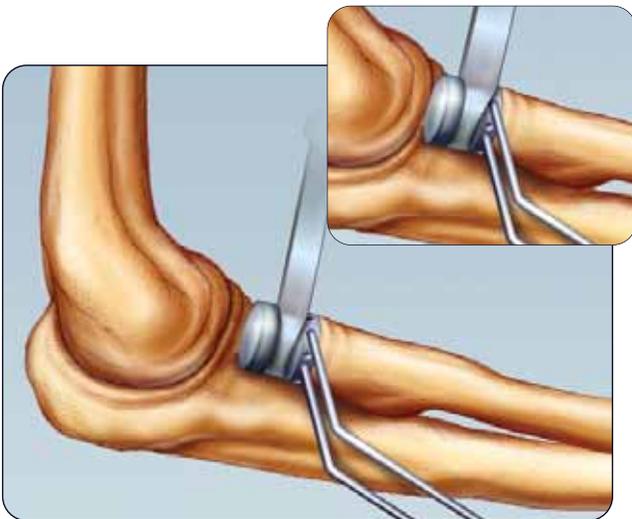
Step 5: Determine Head Diameter

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.



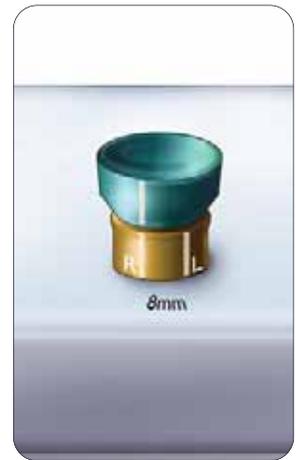
Step 6: Assemble Head and Stem Gauge

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



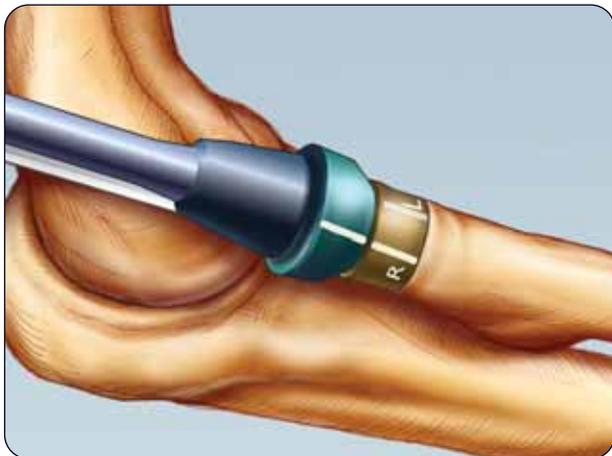
Step 7: Determine Collar Height

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, 8mm) will correspond to the collar height on the stem.



Step 8: Select Trial Implants & 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.



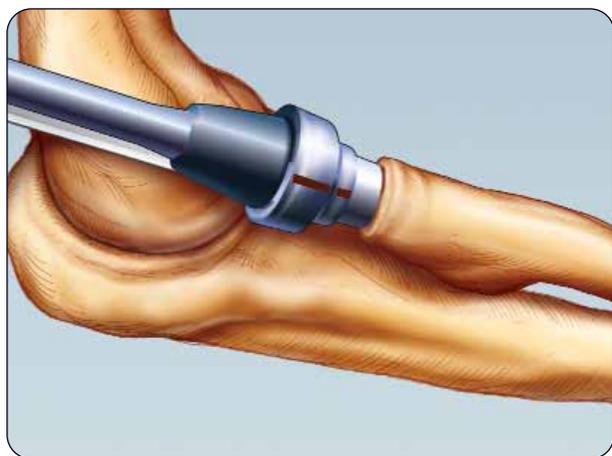
Step 9: Trial Implant Insertion

Insert the trial implant into the radius, ensure the laser etched line on the head and stem is aligned with the lateral aspect of the radius when the forearm is in neutral position. 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 0.5mm undersized from the broaches for ease of insertion.



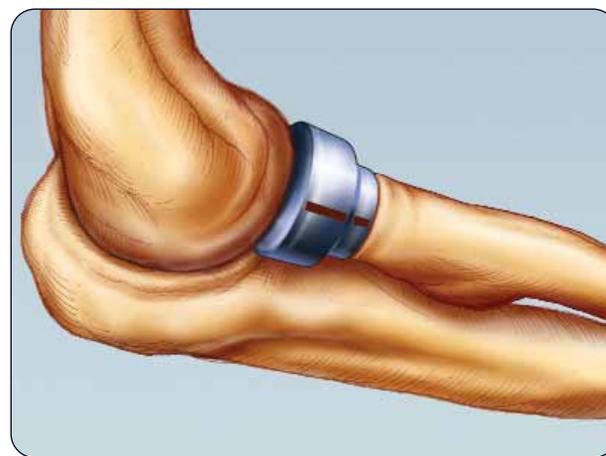
Step 10: Implant Assembly

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.



Step 11: Implant Insertion

Insert the implant into the radius using the impactor (TR-MS05) and a mallet. Ensure that the laser etched line on the head is aligned with the lateral aspect of the radius when the forearm is in neutral position. A stem removal tool (TR-MS30) is available in the system if needed.



Step 12: Post-Op 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.

Heads

20MM TR ANGLED HEAD RIGHT	TR-H200R-S
22MM TR ANGLED HEAD RIGHT	TR-H220R-S
24MM TR ANGLED HEAD RIGHT	TR-H240R-S
26MM TR ANGLED HEAD RIGHT	TR-H260R-S
28MM TR ANGLED HEAD RIGHT	TR-H280R-S
20MM TR ANGLED HEAD LEFT	TR-H200L-S
22MM TR ANGLED HEAD LEFT	TR-H220L-S
24MM TR ANGLED HEAD LEFT	TR-H240L-S
26MM TR ANGLED HEAD LEFT	TR-H260L-S
28MM TR ANGLED HEAD LEFT	TR-H280L-S

Stems

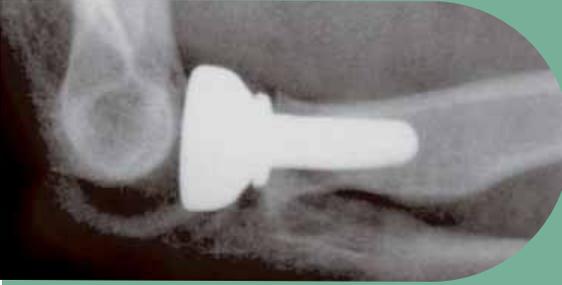
6MM DIA X 0.0MM TR STEM	TR-S0600-S
6MM DIA X 2MM TR STEM	TR-S0602-S
6MM DIA X 4MM TR STEM	TR-S0604-S
6MM DIA X 8MM TR STEM	TR-S0608-S
7MM DIA X 0.0MM TR STEM	TR-S0700-S
7MM DIA X 2MM TR STEM	TR-S0702-S
7MM DIA X 4MM TR STEM	TR-S0704-S
7MM DIA X 8MM TR STEM	TR-S0708-S
8MM DIA X 0.0MM TR STEM	TR-S0800-S
8MM DIA X 2MM TR STEM	TR-S0802-S
8MM DIA X 4MM TR STEM	TR-S0804-S
8MM DIA X 8MM TR STEM	TR-S0808-S
9MM DIA X 0.0MM TR STEM	TR-S0900-S
9MM DIA X 2MM TR STEM	TR-S0902-S
9MM DIA X 4MM TR STEM	TR-S0904-S
9MM DIA X 8MM TR STEM	TR-S0908-S
10MM DIA X 0.0MM TR STEM	TR-S1000-S
10MM DIA X 2MM TR STEM	TR-S1002-S
10MM DIA X 4MM TR STEM	TR-S1004-S
10MM DIA X 8MM TR STEM	TR-S1008-S

Instrumentation

6MM BROACH	TR-BRA06
7MM BROACH	TR-BRA07
8MM BROACH	TR-BRA08
9MM BROACH	TR-BRA09
10MM BROACH	TR-BRA10

Instrumentation Cont.

TRIAL GAUGE	TR-TG01
HEAD GAUGE	TR-TG02
6MM STEM GAUGE ASSY	TR-TGA06
20MM LEFT TRIAL HEAD	TR-TH20L
20MM RIGHT TRIAL HEAD	TR-TH20R
22MM LEFT TRIAL HEAD	TR-TH22L
22MM RIGHT TRIAL HEAD	TR-TH22R
24MM LEFT TRIAL HEAD	TR-TH24L
24MM RIGHT TRIAL HEAD	TR-TH24R
26MM LEFT TRIAL HEAD	TR-TH26L
26MM RIGHT TRIAL HEAD	TR-TH26R
28MM LEFT TRIAL HEAD	TR-TH28L
28MM RIGHT TRIAL HEAD	TR-TH28R
6MM DIA X 0.0MM TRIAL STEM	TR-TS60
6MM DIA X 2MM TRIAL STEM	TR-TS62
6MM DIA X 4MM TRIAL STEM	TR-TS64
6MM DIA X 8MM TRIAL STEM	TR-TS68
7MM DIA X 0.0MM TRIAL STEM	TR-TS70
7MM DIA X 2MM TRIAL STEM	TR-TS72
7MM DIA X 4MM TRIAL STEM	TR-TS74
7MM DIA X 8MM TRIAL STEM	TR-TS78
8MM DIA X 0.0MM TRIAL STEM	TR-TS80
8MM DIA X 2MM TRIAL STEM	TR-TS82
8MM DIA X 4MM TRIAL STEM	TR-TS84
8MM DIA X 8MM TRIAL STEM	TR-TS88
9MM DIA X 0.0MM TRIAL STEM	TR-TS90
9MM DIA X 2MM TRIAL STEM	TR-TS92
9MM DIA X 4MM TRIAL STEM	TR-TS94
9MM DIA X 8MM TRIAL STEM	TR-TS98
10MM DIA X 0.0MM TRIAL STEM	TR-TS100
10MM DIA X 2MM TRIAL STEM	TR-TS102
10MM DIA X 4MM TRIAL STEM	TR-TS104
10MM DIA X 8MM TRIAL STEM	TR-TS108
HEAD IMPACTOR	TR-MS05
IMPACTOR BASE	TR-MS03
6MM COLLAR REAMER	TR-CRA06
7MM COLLAR REAMER	TR-CRA07
8MM COLLAR REAMER	TR-CRA08
9MM COLLAR REAMER	TR-CRA09
10MM COLLAR REAMER	TR-CRA10
QUICK RELEASE T-HANDLE	MS-T1212
AWL	TR-0206
STEM REMOVAL TOOL	TR-MS30
TRAY	TR-0001



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