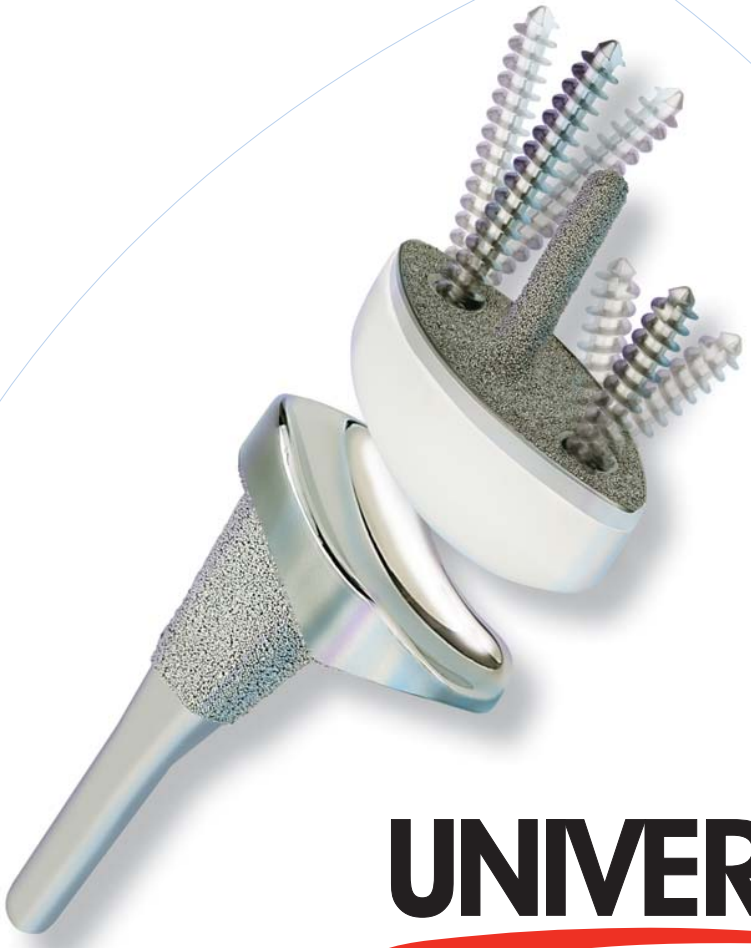
SURGICAL TECHNIQUE



UNIVERSAL2™

Total Wrist Implant System

KINETIKOS MEDICAL INC.

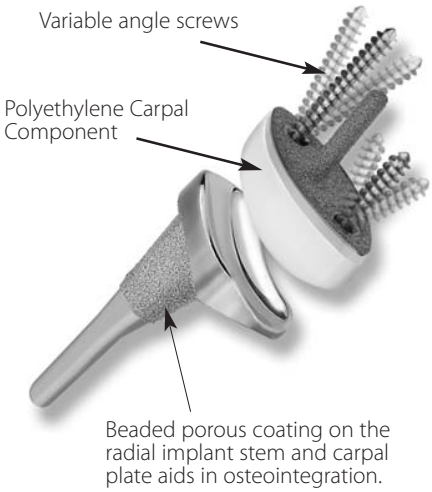
"Elegant Solutions for Extremity Challenges"

DESCRIPTION

The Universal2 Total Wrist System is designed for substantial improvements over earlier generation wrist implants, including a unique articular geometry that provides good balance and immediate stability for improved range of motion and early return to activities.

THE UNIVERSAL2 SYSTEM

- Porous coated, titanium carpal plate with a fixed central peg and two variable angle screws create stability that is supported by intercarpal fusion.
- Cobalt chrome radial component is contoured to conform to normal distal radius anatomy for superior balance and motion.
- A bevel on the ulnar side of the radial component porovides the option to preserve the ulnar head.
- Both the radial and carpal component stems have a volar offset to improve joint stability and wrist extension.
- Beaded porous coating on the carpal plate and radial implant stem aids in osteointegration.
- Minimal bone resection is needed to accommodate implants.
- Broad ellispsed-shape articulation provided excellent stability and a functional range of motion.

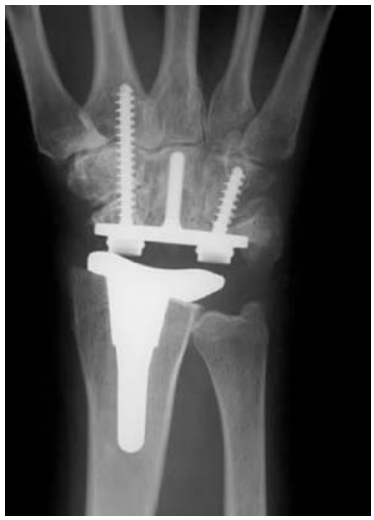


INDICATIONS

The Universal2 Total Wrist System is indicated for use in patients suffering pain and/or loss of function due to:

- Rheumatoid arthritis
- SLAC wrist
- Osteoarthritis
- Traumatic arthritis

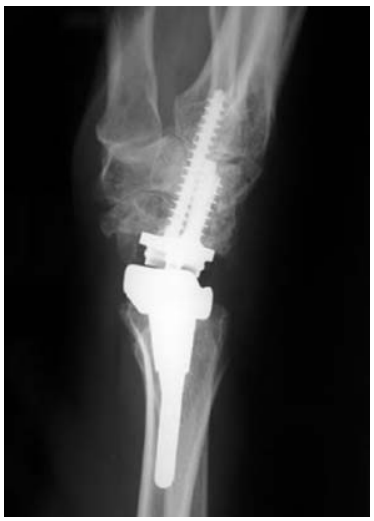
The Universal2 Total Wrist implant may also be indicated in the revision of a failed implant or in situations where clinical experience indicates that other reconstructive efforts are not likely to achieve satisfactory results.



CONTRAINDICATIONS

The Universal2 implant is contraindicated in cases involving:

- Poor bone quality which may effect the stability of implants.
- Severe tendon, neurological, or muscular deficiencies that would compromise implant function.
- Infections; acute or chronic, local or systemic.
- Any concomitant disease which may compromise the function of the implant.
- Current highly active inflammatory disease of the wrist.



PRE-OPERATIVE PLANNING

The proper implant size is estimated preoperatively using x-ray templates. With the carpal system aligned with the center of the capitate, the Ulnar Screw should enter the proximal pole of the hamate. In the AP view, the radial component should not extend beyond the edge of the radial styloid. The carpal component should not extend more than 2 mm over the margins of the carpus at the level of the osteotomy. In general, select the smaller implant size when deciding between two sizes.

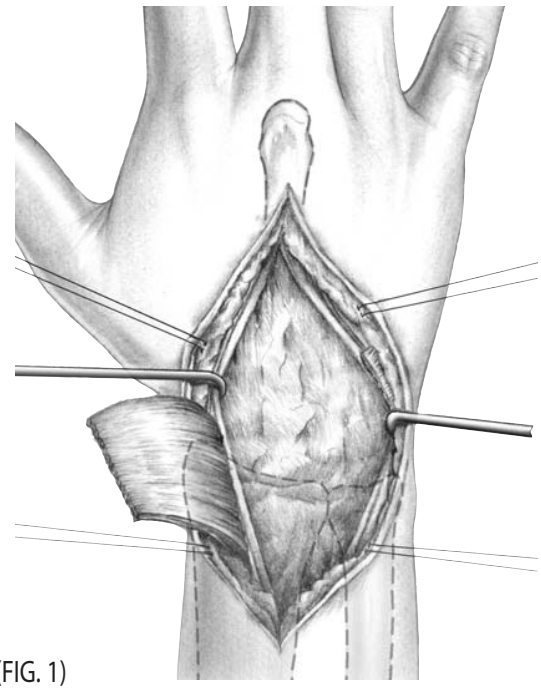
GENERAL RECOMMENDATIONS

Prophylactic antibiotic is administered. Either general or regional anesthesia is appropriate. A nonsterile tourniquet is used. A strip of transparent adhesive film is applied to the dorsum of the hand and wrist to protect the skin from damage during instrumentation. Fluoroscopy is a helpful adjunct to confirm positions of the guides and implants. Save all resected bone during the procedure for use in bone grafting the carpus to achieve an intercarpal arthrodesis.

STEP 1

SURGICAL INCISION

- A dorsal longitudinal **incision** is made over the wrist in line with the **3rd metacarpa**l, extending proximally from its midshaft.
- The skin and subcutaneous tissue are **elevated together** off the **extensor retinaculum**, with care to protect the superficial **radial nerve** and the **dorsal cutaneous branch** of the ulnar nerve.
- The **ECU compartment is opened** along its volar margin and the **entire retinaculum is elevated radially** to the septum between the **1st and 2nd** extensor compartments (**Figure 1)**.
- Each septum is **divided carefully** to avoid creating rents in the retinaculum, especially at Lister's tubercle, which may need to be osteotomized.
- An **extensor tenosynovectomy** is performed if needed, and the tendons are inspected. The **ECRB must be intact or repairable** (preferably the ECRL is also functional). Vessel loops are used to retract the extensor tendons.

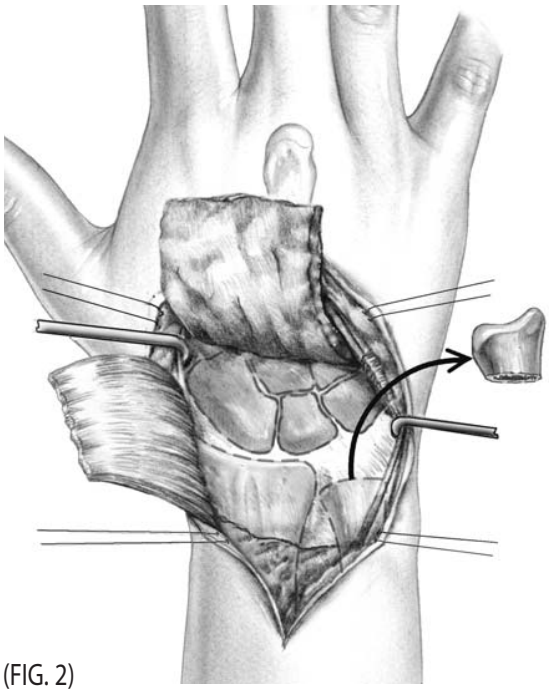


(FIG. 1)

STEP 2

JOINT EXPOSURE

- The dorsal wrist **capsule is raised** as a distally based rectangular flap.
- If the ulnar head is to be resected, the capsule is **raised in continuity** with the dorsal DRUJ capsule and the periosteum over the distal 1cm of the radius to create a broad exposure and long flap for closure **(Figure 2)**.
- The sides of the flap are made in the floors of **1st and 6th** extensor compartments.
- If the distal ulna is to be preserved, the capsule on the ulnar side of the wrist is incised distal to the triangular fibocartilage complex (TFCC).
- The brachioradialis and **1st extensor** compartment are elevated subperiosteally from the distal styloid.
- The wrist is fully flexed to expose the joint. **Synovectomies of the radiocarpal and distal radioulnar joints** are performed when needed.
- If the distal **radioulnar joint** is arthritic or if there is severe erosion of the distal radius, the distal ulna is resected through its neck, or contoured into a cylinder.

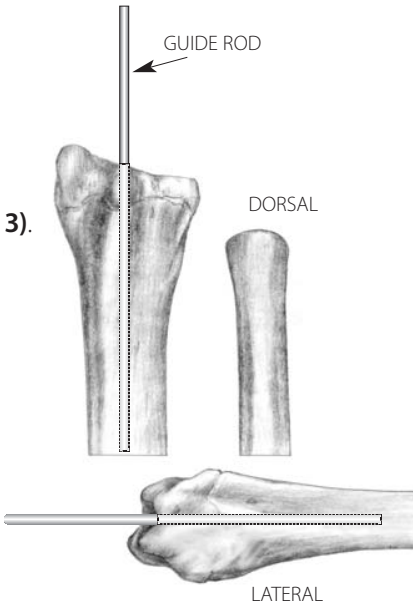


(FIG. 2)

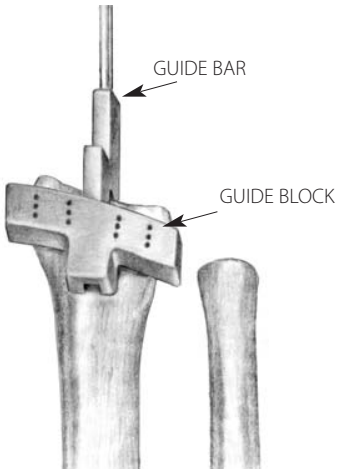
STEP 3

PREPARATION OF RADIUS

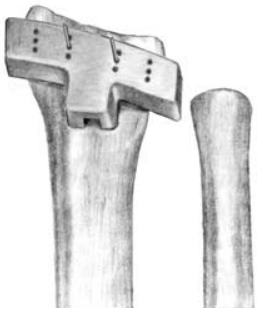
- Using a **Bone Awl**, a hole is made through the articular surface of the radius about **5mm** below its dorsal rim and just radial to Lister's tubercle. Enlarge the hole with a curette.
- The **Radial Alignment Guide Rod** is inserted in the hole and advanced far into the medullary canal. The rod should slide easily without bending **(Figure 3)**. Fluoroscopy is used to confirm the **Guide Rod** is centered within the canal.
- The **Radial Guide Bar** is slid over the rod until it abuts the radius.
- The radial cutting **Guide Block** (left or right) is mounted onto the guide bar and slid into proper position. It is positioned to **guide** the saw cut just beneath the articular surface. **(Figure 4)**
- While the **Cutting Block** is held aligned with the dorsal surface of the radius, **two or three 1.1mm K-Wires** are inserted through the holes in the Cutting Block and drilled into the distal radius. The Cutting Block has four rows of **three holes spaced 2mm apart**. By using the middle holes in the rows, the Cutting Block can be adjusted proximally or distally if necessary **(Figure 5)**.
- The alignment rod and guide bar are removed and the **Cutting Block** is slid down against the radius. Lister's tubercle may have to be removed to fully seat the Cutting Block. The **K-Wires** are cut above the cutting block **(Figure 5)**.
- The position of the cutting block is checked for proper level of resection and adjusted if needed. A small, oscillating **saw blade** is used to make the **radial cut.** To complete the cut through the volar cortex, the **cutting block** may have to be removed.
- The Cutting Block and K-Wires are removed. If a large **osteophyte** remains on the volar rim of the distal radius, it should be resected.
- The Alignment Rod is reinserted into the **medullary canal** of the radius. The proper size **Broach Head** is inserted into the **Broach Handle** and set to the position marked for either "standard" or "minimal" broaching. The Broach is slid over the **Alignment Rod** and its sides are aligned parallel to the sigmoid notch and volar rim of the radius **(Figure 6)**.
- Using a **mallet**, the broach is driven into the distal radius until its collar is flush with the cortex **(Figure 7)**. The Broach and Alignment Rod are removed.
- **A Trial Radial Component** is inserted using the **Impactor**, with care to maintain proper alignment within the prepared metaphysis. For removal the **Extractor Tool** (T-handle) is applied and the Trial Radial Component is removed.



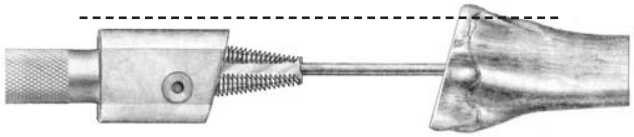
(FIG. 3)



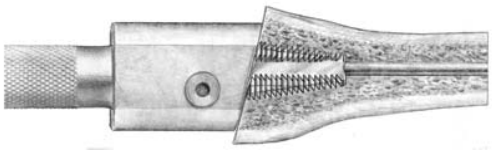
(FIG. 4)



(FIG. 5)



(FIG. 6)



(FIG. 7)

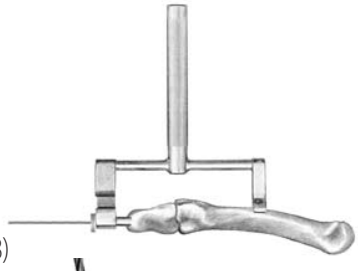
STEP 4

PREPARATION OF CARPUS

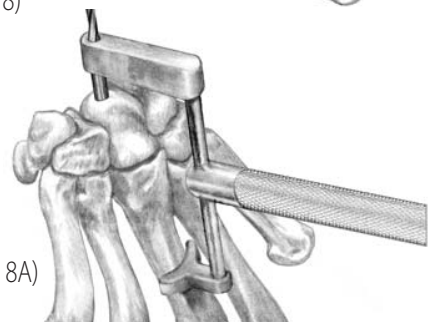
- If the **scaphoid and triquetrum** are mobile, carpus preparation is facilitated by first temporarily pinning these bones to the **capitate and hamate** in positions that create the most joint contact. The **K-Wires** can be left in place through final Carpal Component implantation.

STEP 4 (CONTINUED)

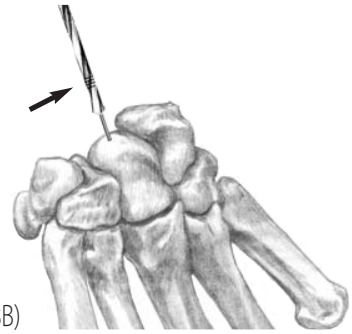
- The **lunate** is excised by sharp dissection or Rongeur.
- In applying the Modular Drill Guide, the barrel is pressed against the **capitate head** and the saddle is placed onto the **3rd** metacarpal shaft over the skin **(Figures 8 and 8A)**. The sleeve for the Guide Wire is inserted in the Drill Guide Barrel. The **1.4mm (.54") guide wire** is drilled through the capitate and into the **3rd** metacarpal. The Sleeve and Drill Guide are removed sequentially.
- The **3.5mm** cannulated drill for the **minimal hole** or the **4.5mm** Cannulated Drill for the **standard hole** is placed over the Guide Wire and a hole is made in the **capitate** to the proper depth marked on the drill bit (approx. 20-22mm) **(Figure 8B)**.
- The appropriate **Carpal Guide Bar**, for either a standard or minimal hole diameter, is inserted into the capitate hole to its full depth.
- The **Carpal Cutting Guide Block** is mounted onto the Guide Bar and slid into proper position. It is positioned to **guide** the saw cut through the proximal **1mm (.45")** of the hamate, which will pass through the capitate head, scaphoid waist, and mid-triquetrum **(Figure 9)**.
- While the **Cutting Block** is held aligned with the dorsal surface of the carpus, two to four **1.1mm** K-Wires are inserted through the holes in the Cutting Block and drilled into the carpus. The Cutting Block has four rows of two holes spaced **2mm** apart. By using the distal holes in the rows, the **Cutting Block** can be adjusted distally to resect more carpus if necessary. The **K-Wires** are cut above the Cutting Block.
- The position of the Cutting Block is checked for **proper level** of resection. Confirm that the cut will be made nearly perpendicular to the **3rd** metacarpal shaft. A small, oscillating saw blade is used to make the carpal cut. To complete the cut, the Cutting Block may have to be removed, but the **K-wires** should be retained **(Figure 10)**. The Cutting Block can be reapplied to help stabilize the carpal bones during the remaining carpal preparation.
- The **countersink** is used to enlarge the opening of the drill hole to accommodate the "shoulder" of the carpal component's stem.
- A Trial Carpal Component is inserted into the **capitate hole** and its dorsal edge is aligned with the dorsal surface of the carpus.
- The Modular Drill Guide is applied with its **barrel in the radial hole** of the trial carpal component and its **saddle on the 2nd metacarpal** shaft over the skin. A **2.5mm** hole is drilled across the scaphoid, trapezoid, and **2nd CMC** joint to a depth (marked on the drill bit) of **30mm to 35mm (Figure 11)**. This hole is typically not perpendicular to the carpal component, however the component and screw heads are designed to accommodate screw insertions at oblique angles.
- A **4.0mm** Self-tapping Trial Screw (blue color) can be inserted but not firmly tightened **(Figure 12)**.
- A similar technique is used for the ulnar side, with a few important differences. The saddle is placed on the **4th** metacarpal shaft over the skin. The mobile **4th** metacarpal must be held elevated (4th CMC extended) while drilling to ensure the hole is not directed volarly. The hole is drilled through the hamate but does not cross the mobile **4th** CMC joint. Its depth is typically **20mm** but a small wrist may accommodate only **15mm.**
- Optional: A **4.0mm** Self-tapping Trial Screw (blue color) may be inserted but not firmly tightened.



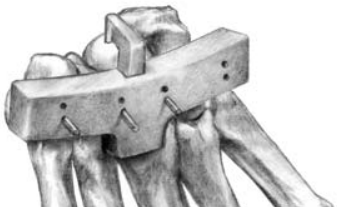
(FIG. 8)



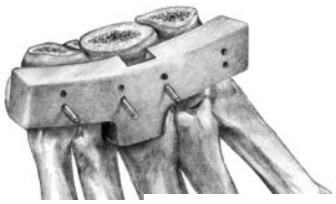
(FIG. 8A)



(FIG. 8B)



(FIG. 9)



(FIG. 10)

(FIG. 11)

(FIG. 12)

STEP 5

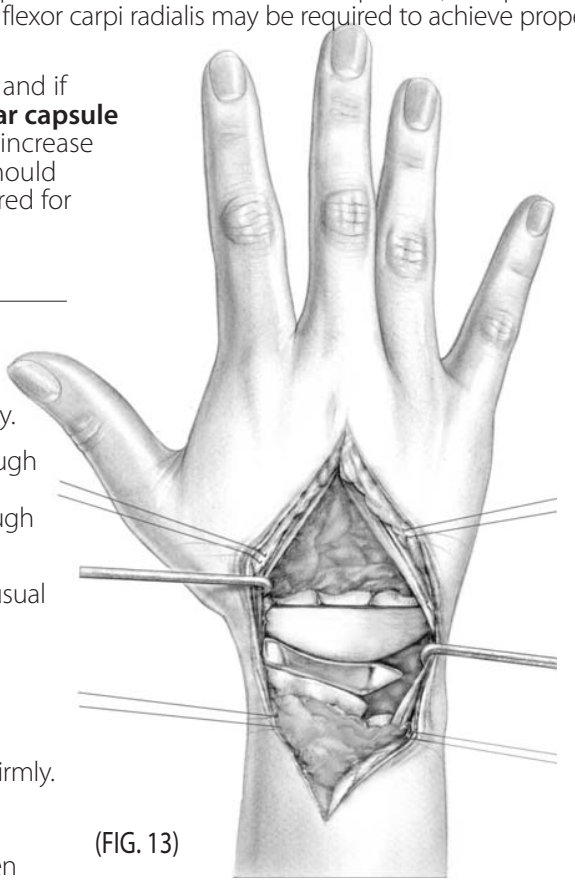
TRIAL REDUCTION

- The radial trial component is reinserted.
- A **Trial Polyethylene Carpal Component** is applied to the carpal plate, beginning with the standard thickness.
- The prosthesis is reduced and range of motion and stability are checked. The prosthesis is typically quite stable and should demonstrate approximately **35° of flexion and 35° of extension** with modest tightness at full extension.
- If the **volar capsule is tight and limiting extension**, the radius may need to be **shortened**, but will usually only require a couple of millimeter (avoid excessive shortening). If a severe preoperative flexion contracture was present, a step-cut tendon lengthening of the flexor carpi ulnaris and occasionally the flexor carpi radialis may be required to achieve proper balance and motion.
- When **volar instability** is present, the volar capsule is inspected and if detached it is repaired to the **rim of the distal radius**. If the **volar capsule is intact**, a thicker polyethylene component may be required to increase soft tissue tension and joint stability. A mild **dorsal instability** should respond to capsule closure but a thicker polyethylene is considered for marked instability.

STEP 6

IMPLANTATION

- **Remove the Trial Component**s and irrigate the wound thoroughly.
- Three horizontal mattress sutures of **2-0 polyester** are placed through small bone holes along the **dorsal rim** of the distal radius for later capsule closure. If the ulnar head was resected, place sutures through its **dorsal neck**.
- When indicated by the surgeon, **bone cement** is prepared in the usual manner and injected into the cavities for the carpal and radial component stems just prior to final implantation.
- Mount the Carpal Plate onto the **Impactor** and drive it into the capitate hole while maintaining proper position.
- Insert the **4.5mm** Bone Screws (radial and ulnar sides) and tighten firmly.
- Remove any remaining K-Wires from the carpus.
- Using the **Radial Impactor**, the Radial Implant Component is driven into the **metaphysis** with care to maintain proper alignment.
- **OPTIONAL:** Apply the **Trial Polyethylene Component** to confirm the proper size for joint motion and stability.
- Using the **Impactor**, the Polyethylene Component is snapped onto the plate with firm mallet taps. Confirm the Polyethylene Component is **completely engaged** onto the Carpal Plate **(Figure 13)**.
- **Reduce** the prosthesis and make a final assessment of wrist motion, balance and stability.



(FIG. 13)

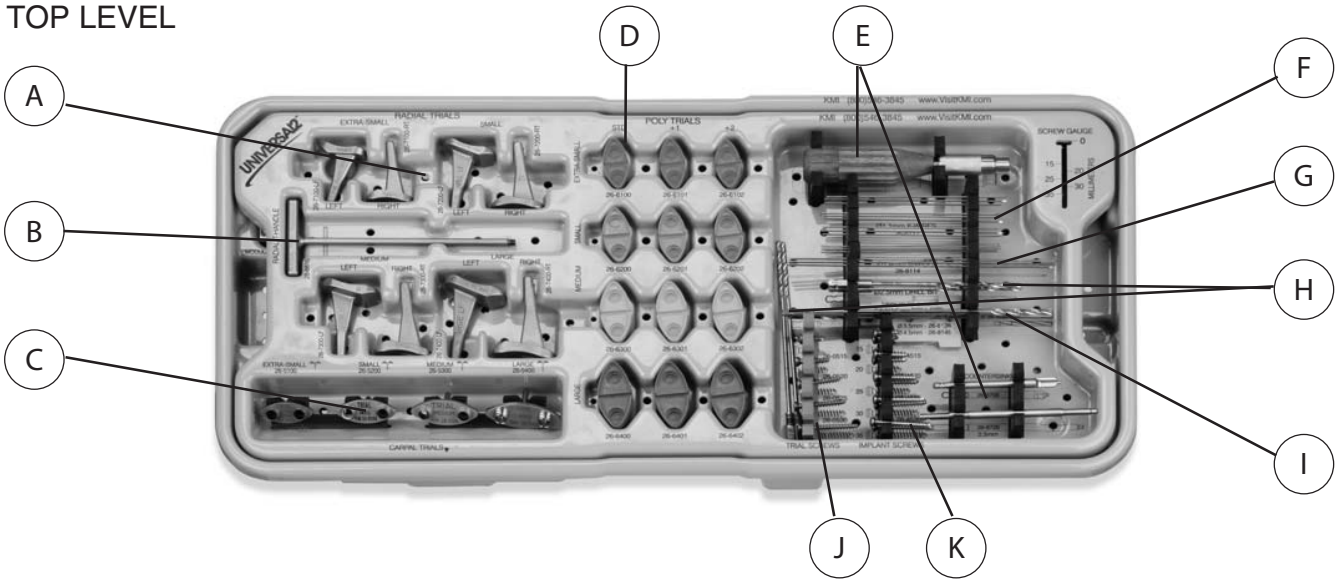
CLOSURE

The intercarpal articular surfaces of the triquetrum, hamate, capitate, scaphoid and trapezoid are removed using a curette or burr (Avoiding the carpal component fixation screws). Cancellous chips from previously resected bone are packed into the spaces. The dorsal capsule is reattached to the distal margin of the radius using the previously placed sutures. The capsule is reapproximated at the distal radioulnar joint or attached to the ulnar neck using the previously placed sutures if the head was resected. The medial and lateral aspects of the capsule are also closed. If the capsule is insufficient for closure with the wrist flexed 30°, the extensor retinaculum is divided in line with its fibers and one half is placed under the tendons to augment the capsule. The entire prosthesis must be covered to achieve its proper stability and function and to avoid extensor tendon irritation. The remaining extensor retinaculum is repaired over the tendons to prevent bowstringing, however, the EPL, ECRB and ECRL are typically left superficial to the retinaculum. If necessary to maintain the ECU dorsally over the ulna, a separate sling is made from the retinaculum. A suction drain is placed and the skin is closed in layers. A bulky gauze dressing and a short arm plaster splint are applied.

POSTOPERATIVE MANAGEMENT

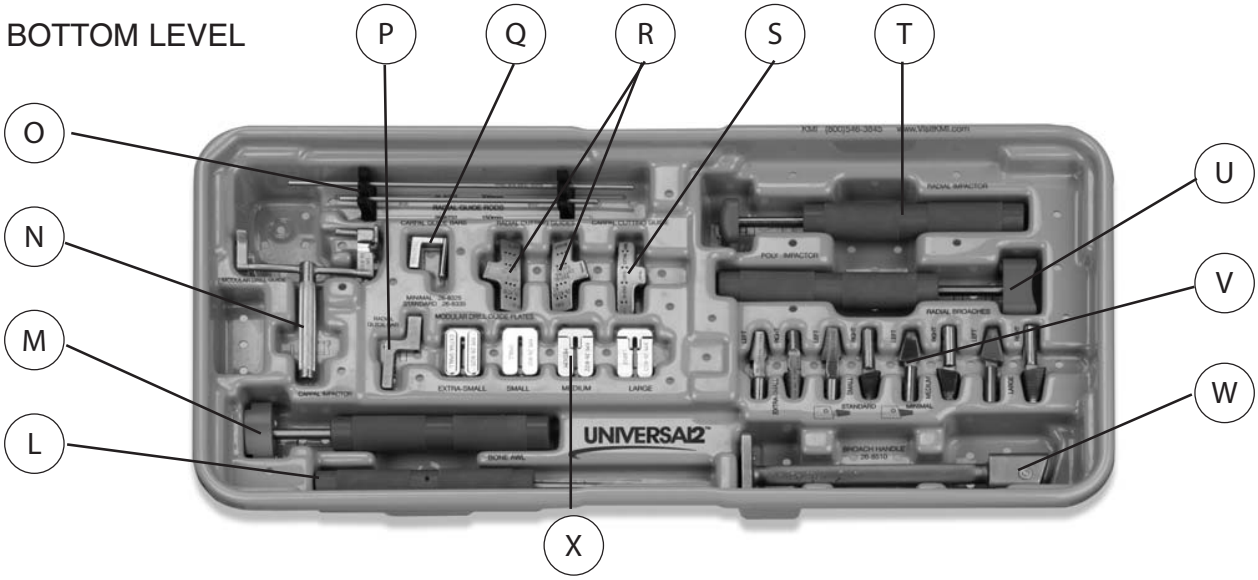
Strict elevation and early passive and active digital motion are encouraged to reduce swelling. At approximately 10 days, the sutures are removed and an x-ray is obtained to confirm prosthetic reduction. A removable wrist splint is fabricated and used when not performing exercises. Gentle wrist exercises are begun, including active flexion and extension, radial and ulnar deviation, and pronation and supination. A therapist may be engaged to ensure progress. The splint is discontinued at the 4th postoperative week and hand use advanced. The exercise program is continued and strengthening is added. Power grip and lifting is discouraged for the first 8 weeks. A dynamic splint is occasionally used if recovery of motion is difficult or incomplete. The patient is advised against impact loading of the wrist and repetitive forceful use of the hand.

TOP LEVEL



A. Radial Trials (left & right)
B. Radial T-Handle
C. Carpal Trials (x-small, small, medium, large)
D. Carpal Poly Trials (standard, +1, +2)
E. AO Screw Driver Handle/ Countersink / Hex Driver
F. 1.1mm (.045") K-Wires
G. 1.4mm (.054") K-Wires
H. 2.5mm Drill Bit (solid & cannulated)
I. 3.5mm / 4.5mm Cannulated Drill Bits
J. Trial Screws (15, 20, 25, 30, 35mm)
K. Implant Screws 4.5mm x (15, 20, 25, 30, 35mm)

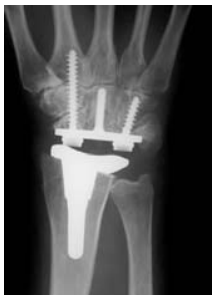
BOTTOM LEVEL

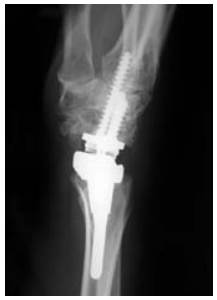


L. Bone Awl
M. Carpal Plate Impactor
N. Modular Drill Guide & Sleeve
O. Radial Guide Rods (200mm & 150mm)
P. Radial Guide Bar
Q. Carpal Guide Bar
R. Radial Cutting Guide (left & right)
S. Carpal Cutting Guide
T. Radial Impactor
U. Poly Impactor
V. Radial Broaches (all sizes, left & right)
W. Broach Handle
X. Modular Drill Guide Plates

UNIVERSAL2™

Total Wrist Implant System





FEATURES

- Minimal bone resection to accommodate implants.
- Radial component design optimal for the preservation of the ulnar head.
- Volar offset of radial articulation for ideal implant seating.
- Porous coating on radial and carpal implant surfaces.
- Central peg and two variable angle screws create stability through inter-carpal fusion.
- Complete range of carpal poly sizes to restore proper carpal height.
- Proven surgical techniques and refined instrumentation for precise and efficient implantation.

PART NO.	DESCRIPTION	SIZE
Implants - Radial Components		
26-3100-L	Radial Implant	X-Small, Left
26-3100-R	Radial Implant	X-Small, Right
26-3200-L	Radial Implant	Small, Left
26-3200-R	Radial Implant	Small, Right
26-3300-L	Radial Implant	Medium, Left
26-3300-R	Radial Implant	Medium, Right
26-3400-L	Radial Implant	Large, Left
26-3400-R	Radial Implant	Large, Right
Implants - Carpal Components		
26-1101	Carpal Implant	X-Small
26-1201	Carpal Implant	Small
26-1301	Carpal Implant	Medium
26-1401	Carpal Implant	Large
Implants - Carpal Poly Components		
26-2100	Carpal Poly Implant	X-Small Standard
26-2101	Carpal Poly Implant	X-Small +1
26-2102	Carpal Poly Implant	X-Small +2
26-2200	Carpal Poly Implant	Small Standard
26-2201	Carpal Poly Implant	Small +1
26-2202	Carpal Poly Implant	Small +2
26-2300	Carpal Poly Implant	Medium Standard
26-2301	Carpal Poly Implant	Medium +1
26-2302	Carpal Poly Implant	Medium +2
26-2400	Carpal Poly Implant	Large Standard
26-2401	Carpal Poly Implant	Large +1
26-2402	Carpal Poly Implant	Large +2
Implants - Bone Screws (Carpal Plate)		
26-4515	4.5mm Bone Screw	15mm length
26-4520	4.5mm Bone Screw	20mm length
26-4525	4.5mm Bone Screw	25mm length
26-4530	4.5mm Bone Screw	30mm length
26-4535	4.5mm Bone Screw	35mm length
System		
26-0100	Instrument Set	

INSTRUMENT SET

COMPONENT MATERIALS

- Radial Component & Porous Coating: Cobalt Chrome
- Carpal Component & Porous Coating: Titanium
- Carpal Poly Implant: Polyethylene (UHMWPe)
- Screws: Titanium (specifically designed for use with the Universal2 System)

CE 0197 TÜV ISO 13485 CERTIFIED

WARNING: Components are NOT modular. (Example: Size SMALL components are only interchangeable with other size SMALL components)

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