EN

Integra®

Freedom Wrist Arthroplasty System

SURGICAL TECHNIQUE

INTEGRA®
LIMIT UNCERTAINTY

Table of Contents

Description....02
Indications....02
Contraindications....02
Preoperative Planning....02

Total Arthroplasty Surgical Technique....03
Step 1: Surgical Incision....03
Step 2: Joint Exposure....03
Step 3: Preparation of Carpus....04
Step 4: Preparation of Radius....06
Step 5: Trial Reduction....08
Step 6: Implantation....08
Closure....11
Postoperative care/ Therapy....11

Hemiarthroplasty Surgical Technique....12
Step 1: Surgical Incision....12
Step 2: joint Exposure....12
Step 3: Preparation of Carpus....13
Step 4: Preparation of Radius....13
Step 5: Trial Reduction....16
Step 6: Implantation....16
Closure....17
Postoperative Care/Therapy....17

Training....17
Ordering Information....18
Instrumentation Set....19

Description

The system consists of components to replace the articulation of the distal radius and proximal row of carpal bones of the wrist joint and corresponding instrumentation. The components are intended to be implanted together as a system, or as a hemiarthroplasty to replace the articulation of the distal radius in conjunction with a proximal row carpectomy.

The radial component is made of Cobalt Chrome Molybdenum Alloy (CrCoMo) and has a concave articulating surface and is fixed by means of a stem which is inserted into the radial intramedullary canal. The carpal implant is an assembly consisting of a titanium carpal plate, which is fixed into the carpal bones with a central peg and two titanium screws and locking caps. Both the radial and carpal components are intended to be implanted with or without bone cement. A convex Ultra-High-Molecular-Weight Polyethylene (UHMWPE) bearing is locked onto the carpal plate to articulate with the radial component.

Instrumentation is provided to assist in the surgical implantation of the Integra Freedom Wrist Arthroplasty System. It is important that the instruments and trial implants used are those specifically designed for this device to ensure accurate installation.

Indications

The Integra Freedom Wrist Arthroplasty System, when used as a total wrist arthroplasty is indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, and trauma-induced osteoarthritis of the radial/carpal joint and is intended to replace functionality of the joint due to deformity or elements stated above.

When used as a hemiarthroplasty, the system is indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, and trauma-induced osteoarthritis of the radial/carpal joint and is intended to replace functionality of the joint due to deformity or elements stated above.

The Integra Freedom Wrist Arthroplasty System is intended for cemented or cementless use.

Contraindications

Contraindications for the use of the Integra Freedom Wrist Arthroplasty System include any condition which would contraindicate the use of joint replacement in general, including:

- Poor bone quality which may affect the stability of implants
- Severe tendon, neurological, or vascular deficiencies which could compromise the affected extremity
- Any concomitant disease which may compromise the function of the implants
- Infections; acute or chronic, local or systemic

Preoperative Planning

The proper implant size is estimated preoperatively using x-rays of the wrist. With the carpal plate stem aligned with the center of the capitate on the posteroanterior (PA view), the ulnar screw should enter the proximal pole of the hamate at the level of resection. In general, select the smaller implant size when deciding between two sizes.

Surgical Technique

This technique has been developed with the help of Brian D. Adams, MD.

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Total Arthroplasty Surgical Technique

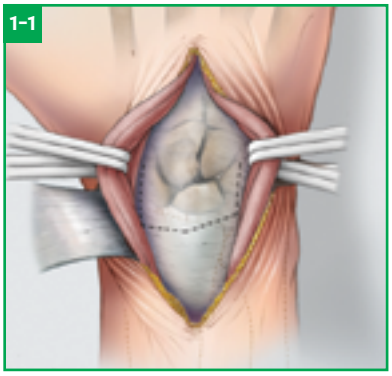
Step 1 • Surgical Incision

1-1 A dorsal longitudinal incision is made over the wrist in line with the 3rd metacarpal, extending proximally from its midshaft to approximately 8cm proximal to the wrist joint.

The skin and subcutaneous tissue are elevated together off the extensor retinaculum, with care to protect the branches of the superficial radial nerve and the dorsal cutaneous ulnar nerve.

The EDQ extensor compartment is opened and the entire retinaculum is elevated radially to the septum between the 1st and 2nd extensor compartments. Each septum is divided carefully to avoid creating rents in the retinaculum, especially at Lister's tubercle.

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). Quarter inch Penrose tubing is used to retract the extensor tendons, with the EDQ and EDC tendons pulled ulnarly and the EPL, ECRB, and ECRL pulled radially.

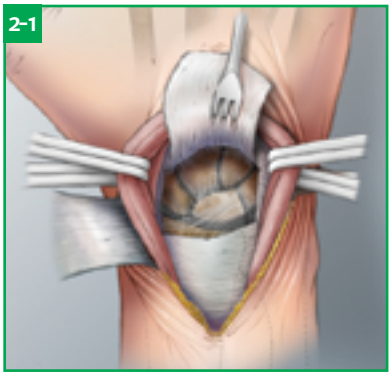


Step 2 • Joint Exposure

2-1 The dorsal wrist capsule is raised as a broad distally-based rectangular flap to the level of the mid-capitate. The capsule is raised in continuity with the periosteum over the distal 1cm of the radius to create a longer flap for closure. The radial side of the flap is made in the floor of the 2nd extensor compartment and the ulnar side extends from the radius to triquetrium.

The 1st extensor compartment is elevated subperiosteally from the distal 1cm of the radial styloid. The remaining dorsal wrist capsule is elevated ulnarly from the triquetrum.

The wrist is fully flexed to expose the joint. If necessary, a synovectomy is performed. If the distal ulna is to be resected, a separate capsulotomy is made proximal to the triangular fibocartilage complex (TFCC).



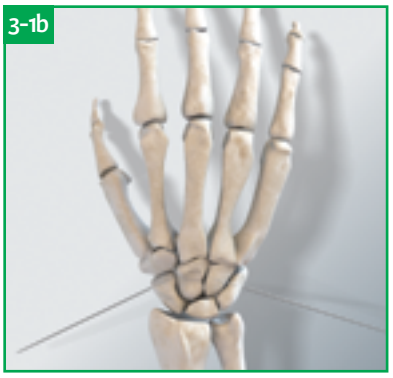
Step 3 • Preparation of Carpus

3-1a 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 maximum joint contact. The Tissue Protective Sleeve is used to protect the soft tissues when inserting .054" (1.4mm) K-wires. A single transverse K-wire or **3-1b** two oblique K-wires are used. The K-wires are inserted so as not to impede the carpal osteotomy or screw placements, and can be left in place through final carpal component implantation when advantageous. Excise the lunate by sharp dissection and rongeur.

3-2 Place Carpal Sizer just distal to intended level of resection, centering on the long axis of the capitate. The resection should cut through the proximal 1.5mm of the hamate, the capitate head, scaphoid waist, and mid-triquetrum. The Integra Freedom Total Wrist is available in three sizes: 1, 2 and 3. Size is determined by the line on the Carpal Sizer that most closely matches up with the center of the proximal pole of the hamate. This site corresponds to the ulnar screw insertion point.

3-3 Insert K-wire Sleeve into barrel of Modular Drill Guide. Apply Modular Drill Guide with barrel pressed against center of capitate head and the saddle on the 3rd metacarpal shaft, either on top or under the skin. If necessary, remove the most proximal portion of scaphoid to facilitate seating Modular Drill Guide on capitate. Drive a .054" (1.4mm) K-wire through the capitate and into the 3rd metacarpal base. Remove K-wire Sleeve first, then remove Modular Drill Guide. Check position of K-wire using fluoroscopy to ensure it is directed down the center of the capitate into the metacarpal.

3-4 Place the 3.5mm Cannulated Drill Bit over K-wire. Drill to first laser mark for size 1, second mark for size 2, and third mark for size 3. Remove drill bit and K-wire.



Step 3 • Preparation of Carpus (continued)

3-5 Insert Carpal Guide Bar into capitate. Mount Carpal Resection Guide on Carpal Guide Bar. Insert Hamate Feeler into the holes in the Carpal Resection Guide closest to proximal pole of hamate. Slide Carpal Resection Guide distally with minimal force until Hamate Feeler just contacts proximal pole of hamate. At this position, the saw blade will cut through the proximal 1.5mm of hamate (the cut will also pass through the capitate head, scaphoid waist, and mid-triquetrum).

3-6 Pin Carpal Resection Guide to capitate with two .054" (1.4mm) K-wires inserted through the two innermost holes. Insert additional K-wires as needed into scaphoid and triquetrum to stabilize Carpal Resection Guide to the carpus. Remove Hamate Feeler and Carpal Guide Bar. Slide Carpal Resection Guide down against carpus. Confirm the cut will be made nearly perpendicular to the 3rd metacarpal shaft at proper level through carpus. Cut K-wires above Carpal Resection Guide. An oscillating saw blade is used to make the carpal resection. If necessary, remove the Carpal Resection Guide to complete the cut. Retain resected bone for future bone grafting.

3-7 Remove Carpal Resection Guide and its securing K-wires. Select the appropriate size Carpal Reamer to prepare capitate for Carpal Plate Trial. Connect Carpal Reamer to AO Handle and ream until Carpal Reamer flange abuts capitate. If flange on Carpal Reamer does not fully abut capitate, drill hole deeper and ream again.

Warning
Carpal Reamers are not intended to be connected to power equipment.

3-8 Attach Carpal Plate Impactor to Broach Handle. Select appropriate size Carpal Plate Trial and impact into capitate, aligning its dorsal edge with the dorsal contour of the carpus. Carpal Plate Trial may be left in place to protect carpus during radial preparation.

Step 4 • Preparation of Radius

4-1 Align Radial Template with dorsal and radial edges of radius. Using notch on Radial Template, mark K-wire insertion site for entry into radial canal. K-wire insertion site will typically be below Lister's tubercle and in the dorsal/ulnar quadrant of the scaphoid fossa.

The distal radius' articular surface and Lister's tubercle may be distorted by chronic wear, trauma, or rheumatoid disease. In this case, the Radial Template may be used as a reference point for insertion of a K-wire, but fluoroscopy should be used to facilitate accurate placement.

4-2 Insert K-wire Sleeve into barrel of Modular Drill Guide. Position Modular Drill Guide with saddle beneath subcutaneous tissue and on top of musculature on dorsal radius. Insert a .054" (1.4mm) K-wire into radius. Using fluoroscopy, confirm K-wire is centered in radial canal in both PA and lateral views. If K-wire is not centered in radial canal, reposition K-wire. Remove K-wire Sleeve to facilitate removal of Modular Drill Guide.

4-3 Place 3.5mm Cannulated Drill over K-wire and drill to highest laser mark near end of flutes. Remove drill and K-wire. Insert Radial IM Guide Rod into radius. Confirm position with fluoroscopy.

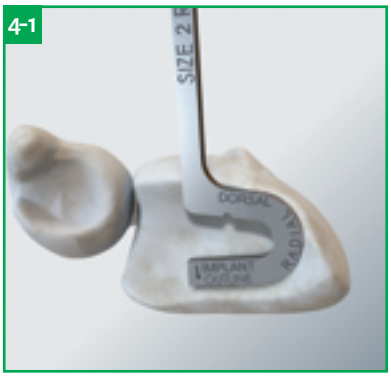
4-4 Slide Radial Feeler over Radial IM Guide Rod until it abuts radius. If necessary, remove Lister's tubercle to facilitate placement of Radial Feeler.

Select Radial Resection Guide that corresponds to Carpal Plate Trial size.

4-5 Apply Radial Resection Guide onto Radial Feeler ensuring label, LEFT or RIGHT, is aligned distally with proposed resection. Slide Radial Resection Guide into a position to resect the dorsal portion of the radial articular surface. For reference, the laser line on the Radial Feeler corresponds to where its barrel contacts the articular surface. The cut will typically be at or just proximal to this line. The cut need not remove the entire articular surface, particularly its volar portion.

Align Radial Resection Guide with dorsal surface of radius. Insert two or three .054" (1.4mm) K-wires into distal radius through any holes in Radial Resection Guide, with at least one on each side of the Radial Feeler.

Remove Radial IM Guide Rod and Radial Feeler. Slide Radial Resection Guide against radius. Cut K-wires above Radial Resection Guide.



Step 4 • Preparation of Radius (continued)

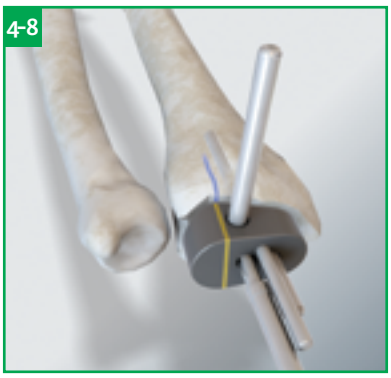
4-6 The Radial Score Guide is used to mark ulnar extent of radial resection to maintain integrity of the DRUJ. Attach Radial Score Guide to Radial Resection Guide and score radius 1-2mm in depth using a saw blade. Remove Radial Score Guide.

4-7 Resect radius with oscillating saw blade. To complete the cut, Radial Resection Guide may need to be removed.

Remove remaining prominence of radius at its dorsal ulnar rim adjacent to the sigmoid notch and any large osteophytes on volar rim using a rongeur. Remove Radial Resection Guide and K-wires.

4-8 Reinsert Radial IM Guide Rod. Select appropriate Radial Drill Guide (left or right) and place it over Radial IM Guide Rod and against radius in proper rotational alignment.

The Radial Drill Guide and Box Punch have corresponding lines to match rotation during their sequential use. A pen is used to mark the bone adjacent to line on Radial Drill Guide. Using 4.0mm Stop Drill Bit, drill radial hole to drill stop. Insert Anti-Rotation Pin into drilled hole. Drill ulnar hole to drill stop. Remove Anti-Rotation Pin and Radial Drill Guide.



4-9 Slide appropriate Box Punch (left or right) over Radial IM Guide Rod. Align volar corners of Box Punch with the two drilled holes and use mark on bone to assist with rotational alignment. Drive Box Punch into radius with a mallet until fully seated. Remove Box Punch and Radial IM Guide Rod. Remove any remaining bone left by Box Punch with a small curette.

4-10 Attach appropriate Size 1 Radial Broach (left or right) to Broach Handle. Insert nose of Size 1 Broach into radial canal hole. Ensure Radial Broach is in correct longitudinal alignment with the radius and drive Radial Broach with a mallet until its dorsal collar is flush with bone. The Radial Broach teeth extend beyond the level of the collar and are not intended to be fully impacted. Use fluoroscopy to confirm the broach is centered in the canal and aligned with the long axis of the radius. Sequentially broach up to size of selected Radial Trial.

Step 5 • Trial Reduction

5-1 Assemble Radial Impactor to Broach Handle and impact Radial Trial.

5-2 Place the standard Carpal Poly Trial over the Carpal Plate Trial.

Reduce joint and assess range of motion and stability. The joint should be stable and demonstrate approximately 35° of extension and 35° of flexion with modest tightness at full extension.

If the volar capsule is too tight and limiting extension, the radius can be shortened by approximately 1.5mm using the previously described radial preparation. If a severe preoperative flexion contracture was present, a step-cut tendon lengthening of flexor carpi ulnaris (FCU) and flexor carpi radialis (FCR) may help achieve proper balance and motion. If volar instability is present, the volar capsule should be inspected and if detached then repaired to rim of distal radius. If volar capsule is intact, a thicker Carpal Poly Trial may be used to improve joint stability. There are three thicknesses of carpal poly trials for each implant size (Standard, +2 mm, +4 mm). A mild dorsal instability should respond to capsule closure but a thicker poly is considered for marked instability.

Remove Carpal Poly Trial and Carpal Plate Trial. A towel clip may be used to remove the Carpal Plate Trial. Remove Radial Trial with Radial Trial Remover.

Step 6 • Implantation

The three sizes of the Integra Freedom Wrist system are not interchangeable; the same size radial and carpal component must be used.

Cemented Technique for Implant Placement

To prepare for the cement mantle, broach radius one size larger than the selected implant size. For example, the size 4 Radial Broach is used for a size 3 radial implant. Use the Carpal Cement Reamer to prepare for cementation of the carpal stem. The Carpal Cement Reamer has two laser marks. Ream to first mark for size 1, second mark for size 2, and fully insert reamer head for size 3.

Three horizontal 2-0 polyester sutures are placed through small bone holes made along dorsal rim of distal radius for later capsule closure.

To prepare for final implant insertion, assemble Radial Impactor onto a Broach Handle and the Carpal Plate Impactor onto other Broach Handle. Thoroughly irrigate the wound of all debris.

6-1 Inject cement with a syringe into radius and capitate. Insert Radial Implant and use Radial Impactor to fully seat. Insert Carpal Plate Implant and use Carpal Plate Impactor to fully seat. Remove excess cement and continue with screw preparation while cement cures.

Warning
Avoid using excessive force when impacting final implants.

Step 6 • Implantation (continued)

Cementless Technique for Implant Placement

To prepare for final implant insertion, assemble Radial Impactor onto a Broach Handle and the Carpal Plate Impactor onto other Broach Handle. Thoroughly irrigate the wound of all debris.

Insert Radial Implant and use Radial Impactor to fully seat. Insert Carpal Plate Implant and use Carpal Plate Impactor to fully seat.

Warning
Avoid using excessive force when impacting final implants.

Cemented and Cementless Technique for Implant Placement

6-2 Position the barrel of the Modular Drill Guide into the radial hole of the carpal plate and its saddle on 2nd metacarpal. Insert K-wire Sleeve and drive a .054" (1.4mm) K-wire into base of 2nd metacarpal. Confirm position using fluoroscopy. Remove K-wire Sleeve.

6-3 Slide K-wire Depth Gauge over K-wire to measure screw length. Place a 2.5mm Cannulated Drill Bit over the K-wire and drill to the measured depth. Remove Cannulated Drill Bit and K-wire. Remove Modular Drill Guide.

Attach the 2.5mm Hex Driver to the AO Handle. The 2.5mm Hex Driver is not intended to retain screws.

Warning
Screws and Locking Caps are not intended to be inserted with power equipment. Screws and Locking Caps are not interchangeable with implants from other manufacturers or other Integra implant systems.

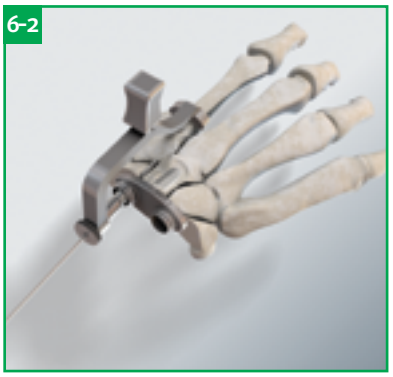
6-4 Insert a 4.5mm screw corresponding to measured depth into radial hole of the Carpal Plate. Do not fully tighten yet.

Position barrel of Modular Drill Guide into ulnar hole of Carpal Plate and its saddle on 4th metacarpal. Insert K-wire Sleeve into Modular Drill Guide. Manually extend the 4th and 5th CMC joints to facilitate proper K-wire insertion. Drive a .054" (1.4mm) K-wire into the hamate to its distal cortex and confirm position using fluoroscopy. Remove K-wire Sleeve and use K-wire Depth Gauge to measure the K-wire's depth. Place a 2.5mm Cannulated Drill Bit over the K-wire and drill to the measured depth. Insert a 4.5mm screw corresponding to measured depth into ulnar hole of the Carpal Plate. The screw should not penetrate the 4th CMC joint.

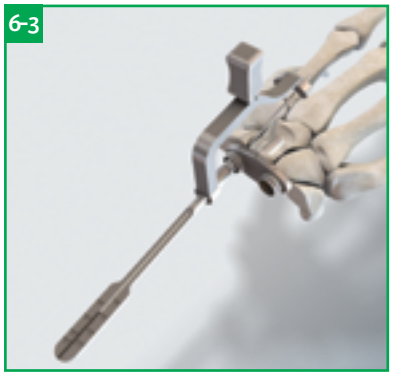
6-5 Alternately advance screws until tightened.

Warning
Do not overtighten screws. Do not remove and reinsert screws.

6-2



6-3



6-4

6-5

Step 6 • Implantation (continued)

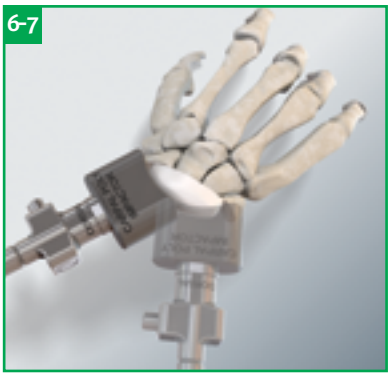
6-6 Attach T15 Star Driver to AO Handle. Place a Locking Cap on T15 Star Driver with concave portion of Locking Cap directed towards Carpal Plate. If Locking Cap will not thread into Carpal Plate, further insert the screw. Fully tighten Locking Caps.

Confirm appropriate Carpal Poly thickness using Carpal Poly Trials.

Apply Carpal Poly and ensure soft tissue is not trapped between Carpal Poly and Carpal Plate.

6-7 Attach Carpal Poly Impactor to Broach Handle. Sequentially angle Carpal Poly Impactor radially and ulnarly to impact one side of the Carpal Poly at a time. The Carpal Poly is fully seated when the Carpal Poly lip circumferentially covers the Carpal Plate.

6-8 Reduce the joint and make a final assessment of wrist motion, balance and stability.



Bone Grafting and Closure

Perform an intercarpal fusion to stabilize the carpus. The dorsal half of each intercarpal articular surface between the triquetrum, hamate, capitate, scaphoid and trapezoid are removed using a curette or burr (avoid the Carpal Plate stem and screws). Cancellous chips from previously resected bone are packed into the interspaces.

The dorsal capsule is reattached to the distal margin of the radius using the previously placed sutures. 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 lengthen the capsule. The entire implant must be covered to achieve proper stability and function and to avoid extensor tendon irritation. The remaining extensor retinaculum is repaired over the EDC tendons to prevent bowstringing, however, the EPL, ECRB and ECRL are typically left superficial to the retinaculum. A suction drain may be placed and the skin is closed. A bulky gauze dressing and a short arm plaster splint are applied.

Postoperative Care/ Therapy

Strict elevation and early passive and active digital motion are encouraged to reduce swelling and stiffness. At approximately 14 days, the sutures are removed and an x-ray is obtained to confirm prosthetic reduction. Gentle wrist exercises are begun, including active flexion and extension, radial and ulnar deviation, and pronation and supination. (A removable wrist splint is used when not performing exercises.) A therapist may be engaged to ensure progress. The splint is weaned 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 must be advised against impact loading of the wrist and repetitive forceful use of the hand.

Hemiarthroplasty

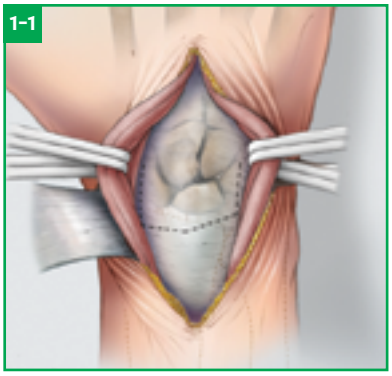
Step 1 • Surgical Incision

1-1 A dorsal longitudinal incision is made over the wrist in line with the 3rd metacarpal, extending proximally from its midshaft to approximately 8cm above the wrist joint.

The skin and subcutaneous tissue are elevated together off the extensor retinaculum, with care to protect the branches of the superficial radial nerve and the dorsal cutaneous ulnar nerve.

The EDQ extensor compartment is opened and the entire retinaculum is elevated radially to the septum between the 1st and 2nd extensor compartments. Each septum is divided carefully to avoid creating rents in the retinaculum, especially at Lister's tubercle.

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). Quarter inch Penrose tubing is used to retract the extensor tendons, with the EDQ and EDC tendon pulled ulnarly and the EPL, ECRB, and ECRL pulled radially.

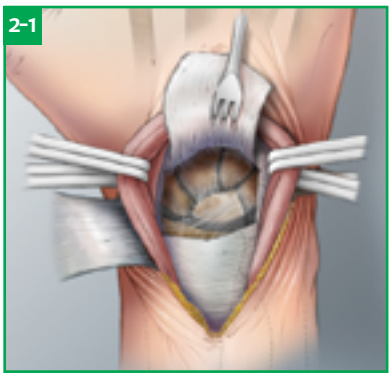


Step 2 • Joint Exposure

2-1 The dorsal wrist capsule is raised as a broad distally-based rectangular flap to the level of the mid-capitate. The capsule is raised in continuity with the periosteum over the distal 1cm of the radius to create a longer flap for closure. The radial side of the flap is made in the floor of the 2nd extensor compartment and the ulnar side extends from the radius to triquetrium.

The 1st extensor compartment is elevated subperiosteally from the distal 1cm of the radial styloid. The remaining dorsal wrist capsule is elevated ulnarly from the triquetrum.

The wrist is fully flexed to expose the joint. If necessary, a synovectomy is performed. If the distal ulna is to be resected, a separate capsulotomy is made proximal to the triangular fibocartilage complex (TFCC).



Step 3 • Preparation of Carpus

3-1 A proximal row carpectomy is performed with care to preserve the capitate head and volar wrist capsule. No further carpal preparation is required.

The capitate head should not have any erosions or cysts that would lead to structural weakening. However, articular cartilage is not a requirement for a hemiarthroplasty.

Using the Radial Trials, apply their articular surface against the capitate head to determine the appropriate size. The capitate head must fit easily into the articular surface of the Radial Trial and allow volar-dorsal translation throughout all ranges of motion.

Step 4 • Preparation of Radius

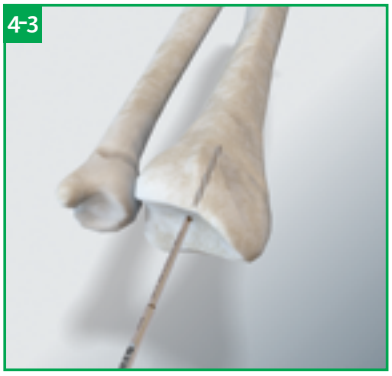
4-1 Align Radial Template with dorsal and radial edges of radius. Using notch on Radial Template, mark K-wire insertion site for entry into radial canal. K-wire insertion site will typically be below Lister's tubercle in the dorsal/ulnar quadrant of the scaphoid fossa.

The distal radius' articular surface and Lister's tubercle may be distorted by chronic wear, trauma, or rheumatoid disease. In this case, the Radial Template may be used as a reference point for insertion of a K-wire, but fluoroscopy should be used to facilitate accurate placement.

4-2 Insert K-wire Sleeve into barrel of Modular Drill Guide. Position Modular Drill Guide with saddle beneath subcutaneous tissue and on top of musculature on dorsal radius. Insert a .054" (1.4mm) K-wire into radius. Using fluoroscopy, confirm K-wire is centered in radial canal in both PA and lateral views. If K-wire is not centered in radial canal, reposition K-wire. Remove K-wire Sleeve to facilitate removal of Modular Drill Guide.

Step 4 • Preparation of Radius (continued)

4-3 Place 3.5mm Cannulated Drill over K-wire and drill to highest laser mark near end of flutes. Insert Radial IM Guide Rod into radius. Radial!M Guide Rod should easily slide into radial canal.



4-4 Slide Radial Feeler over Radial IM Guide Rod until it abuts radius. If necessary, remove Lister's tubercle to facilitate placement of Radial Feeler.

Select Radial Resection Guide that corresponds to Carpal Plate Trial size.

4-5 Apply Radial Resection Guides onto Radial Feeler ensuring label, LEFT or RIGHT, is aligned distally with proposed resection. Slide Radial Resection Guide into a position to resect the dorsal portion of the radial articular surface. For reference, the laser line on the Radial Feeler corresponds to where its barrel contacts the articular surface. The cut will typically be at or just proximal to this line. The cut need not remove the entire articular surface, particularly its volar portion.

Align Radial Resection Guide with dorsal surface of radius. Insert two or three .054" (1.4mm) K-wires into distal radius through any holes in Radial Resection Guide, with at least one on each side of the Radial Feeler.

Remove Radial IM Guide Rod and Radial Feeler. Slide Radial Resection Guide against radius. Cut K-wires above Radial Resection Guide.

4-6 The Radial Score Guide is used to mark ulnar extent of radial resection to maintain integrity of the DRUJ. Attach Radial Score Guide to Radial Resection Guide and score radius 1-2mm in depth using a saw blade.

Step 4 • Preparation of Radius (continued)

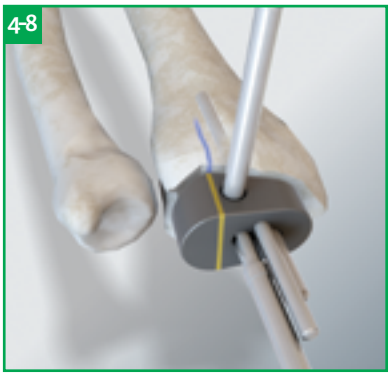
4-7 Resect radius with oscillating saw blade. To complete cut, Radial Resection Guide may need to be removed.

Remove remaining prominence of radius at its dorsal ulnar rim adjacent to the sigmoid notch and any large osteophytes on its volar rim using a rongeur.

4-8 Reinsert Radial IM Guide Rod. Select appropriate Radial Drill Guide (left or right) and place it over Radial IM Guide Rod and against radius in proper rotational alignment. Radial Drill Guide and Box Punch have corresponding lines to match rotation during their sequential use. A pen is used to mark the bone adjacent to line on Radial Drill Guide. Using 4.0mm Stop Drill Bit, drill radial hole to drill stop. Insert Anti-Rotation Pin into drilled hole. Drill ulnar hole to drill stop. Remove Anti-Rotation Pin and Radial Drill Guide.

4-9 Slide appropriate Box Punch (left or right) over Radial IM Guide Rod. Align volar corners of Box Punch with the two drilled holes and use mark on bone to assist with rotational alignment. Drive Box Punch into radius with a mallet until fully seated. Remove Box Punch and Radial IM Guide Rod. Remove any remaining bone left by Box Punch with a small curette.

4-10 Attach appropriate Size I Radial Broach (left or right) to Broach Handle. Insert nose of Size 1 Broach into radial canal hole. Ensure Radial Broach is in correct longitudinal alignment with the radius and drive Radial Broach with a mallet until its dorsal collar is flush with bone. The Radial Broach teeth extend beyond the level of the collar and are not intended to be fully impacted. Use fluoroscopy to confirm the broach is centered in the canal and aligned with the long axis of the radius. Sequentially broach up to size of selected Radial Trial.

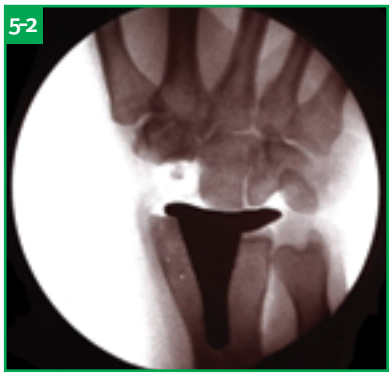


Step 5 • Trial Reduction

5-1 Assemble Radial Impactor to Broach Handle and impact Radial Trial.

5-2 Capitate head is reduced against the radial implant articular surface. Range of motion and stability are assessed, confirming volar-dorsal translation throughout all ranges of motion.

Remove Radial Trial with Radial Trial Remover.



Step 6 • Implantation

6-1 Three horizontal 2-0 polyester sutures are placed through small bone holes made along dorsal rim of distal radius for later capsule closure. If the ulnar head was resected, place sutures through its dorsal neck.

Thoroughly irrigate the wound of all debris.

Cemented Technique for Implant Placement

To prepare for the cement mantle, broach radius one size larger than the selected implant size. For example, the size 4 Radial Broach is used for a size 3 radial implant.

To prepare for final implantation, assemble Radial Impactor onto Broach Handle.

Inject cement with a syringe into radius. Insert Radial Implant and use Radial Impactor to fully seat. Remove excess cement and allow cement to cure.

Cementless Technique for Implant Placement

Assemble Radial Impactor onto Broach Handle and impact Radial Implant until sealed.

Reduce the joint and make a final assessment of wrist motion, balance and stability.

Warning
Avoid using excessive force when impacting final implants.

Closure

The dorsal capsule is reattached to the distal margin of the radius using the previously placed sutures. If the ulnar head was resected, the capsule is reapproximated to the ulnar neck using the previously placed sutures. 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 lengthen the capsule. The entire prosthesis must be covered to achieve proper stability and function and to avoid extensor tendon irritation. The remaining extensor retinaculum is repaired over the EDC tendons to prevent bowstringing, however, the EPL, ECRB and ECRL are typically left superficial to the retinaculum. A suction drain may be placed and the skin is closed in layers. A bulky gauze dressing and a short arm plaster splint are applied.

Postoperative Care/ Therapy

Strict elevation and early passive and active digital motion are encouraged to reduce swelling and stiffness. At approximately 10 days, the sutures are removed and an x-ray is obtained to confirm prosthetic reduction. Gentle wrist exercises are begun, including active flexion and extension, radial and ulnar deviation, and pronation and supination. (A removable wrist splint is used when not performing exercises.) A therapist may be engaged to ensure progress. The splint is weaned 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 must be advised against impact loading of the wrist and repetitive forceful use of the hand.

Training

Surgeons may obtain training from a qualified instructor prior to implanting the Integra® Freedom Wrist Arthroplasty System to ensure thorough understanding of the implantation techniques and the instrumentation.

Freedom Wrist Implants

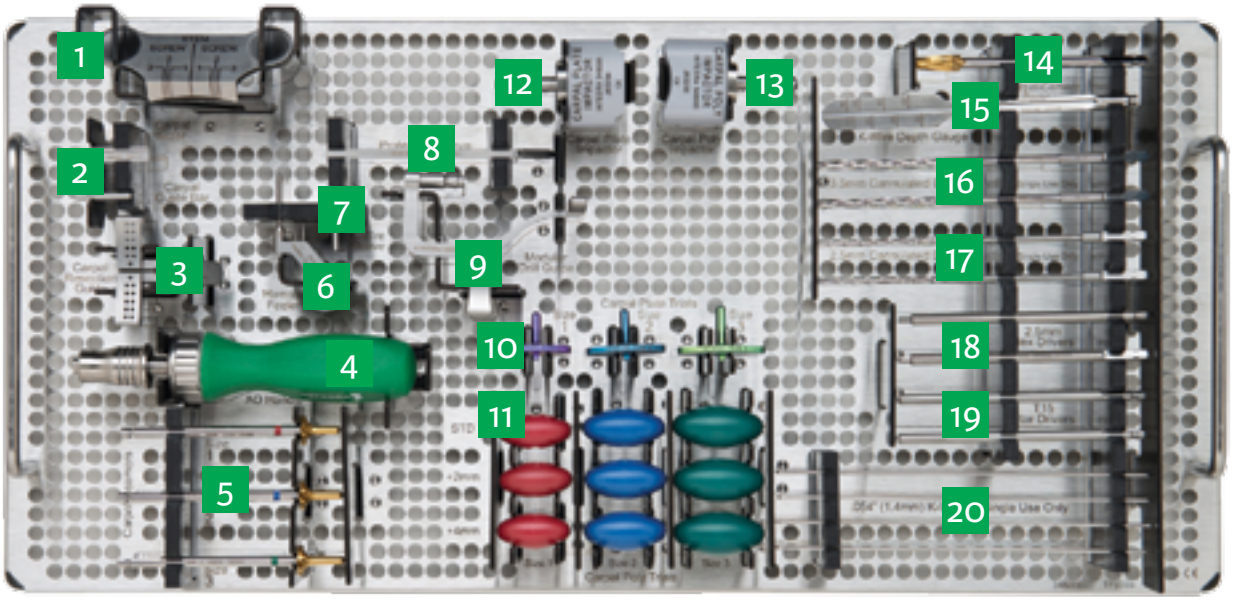
Reference	Description
348001E	Carpal Plate, Size 1
348002E	Carpal Plate, Size 2
348003E	Carpal Plate, Size 3
348291E	Carpal Poly, Size 1, Standard
348292E	Carpal Poly, Size 1, +2 mm
348293E	Carpal Poly, Size 1, +4 mm
348294E	Carpal Poly, Size 2, Standard
348295E	Carpal Poly, Size 2, +2 mm
348296E	Carpal Poly, Size 2, +4 mm
348297E	Carpal Poly, Size 3, Standard
348298E	Carpal Poly, Size 3, +2 mm
348299E	Carpal Poly, Size 3, +4 mm
348111E	Radial Implant, Size 1, Left
348112E	Radial Implant, Size 1, Right
348121E	Radial Implant, Size 2, Left
348122E	Radial Implant, Size 2, Right
348131E	Radial Implant, Size 3, Left
348132E	Radial Implant, Size 3, Right
348315E	4.5mm Screw and Locking Cap, 15 mm Long
348317E	4.5mm Screw and Locking Cap, 17.5 mm Long
348320E	4.5mm Screw and Locking Cap, 20 mm Long
348325E	4.5mm Screw and Locking Cap, 25 mm Long
348330E	4.5mm Screw and Locking Cap, 30 mm Long
348335E	4.5mm Screw and Locking Cap, 35 mm Long
348340E	4.5mm Screw and Locking Cap, 40 mm Long
348345E	4.5mm Screw and Locking Cap, 45 mm Long

Instruments

Reference	Description
348041	Carpal Plate Trial, Size 1
348042	Carpal Plate Trial, Size 2
348043	Carpal Plate Trial, Size 3
348044	Carpal Poly Trial, Size 1, Standard
348045	Carpal Poly Trial, Size 1, +2 mm
348046	Carpal Poly Trial, Size 1, +4 mm
348047	Carpal Poly Trial, Size 2, Standard
348048	Carpal Poly Trial, Size 2, +2 mm
348049	Carpal Poly Trial, Size 2, +4 mm
348050	Carpal Poly Trial, Size 3, Standard
348051	Carpal Poly Trial, Size 3, +2 mm
348052	Carpal Poly Trial, Size 3, +4 mm
348054	Carpal Sizer

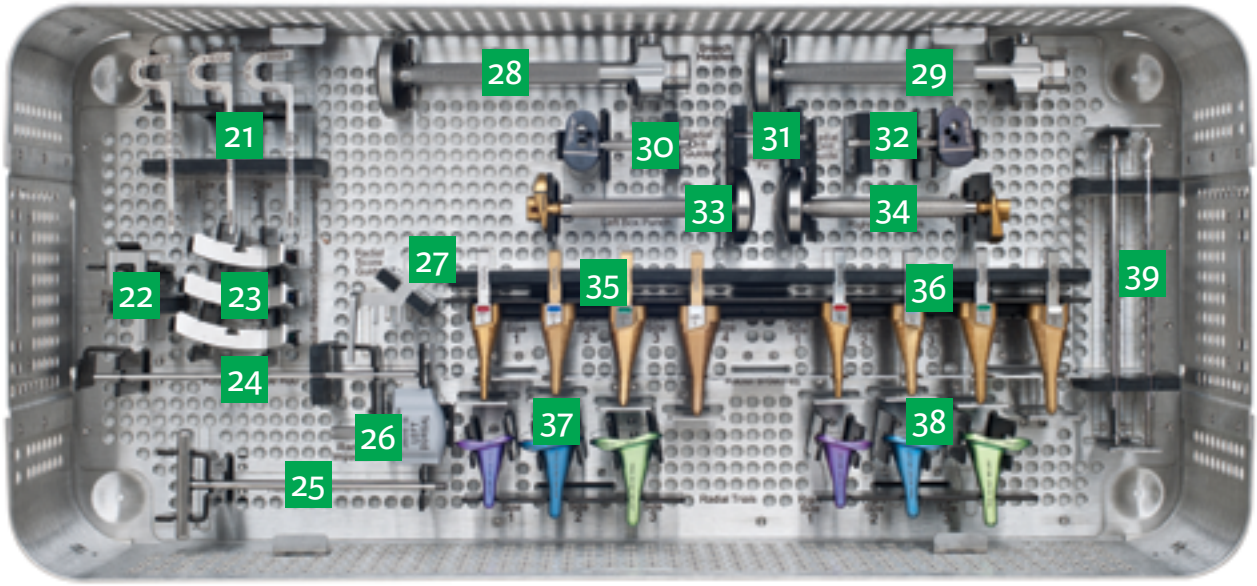
Instruments

Reference	Description
348055	Modular Drill Guide
348059	K-Wire Sleeve
348060	Carpal Guide Bar
348061	Carpal Resection Guide
348063	Hamate Feeler
348068	Carpal Reamer Size 1
348070	Carpal Reamer Size 2
348072	Carpal Reamer Size 3
348075	Carpal Cement Reamer
348081	Carpal Plate Impactor
348083	Carpal Poly Impactor
348088	Tissue Protective Sleeve Assembly
RM1011-SO3	AO Handle
348089	.054" (1.4 mm) K-wire
348090	K-wire Depth Gauge
348091	2.5mm cannulated drill bit
348092	3.5mm cannulated drill bit
348093	4.0mm Stop Drill Bit
348094	T15 Star Driver
348095	2.5mm Hex Driver
348101	Radial Trial, Size 1, Left
348102	Radial Trial, Size 1, Right
348103	Radial Trial, Size 2, Left
348104	Radial Trial, Size 2, Right
348105	Radial Trial, Size 3, Left
348106	Radial Trial, Size 3, Right
348137	Radial Score Guide
348138	Radial Template Size 1
348139	Radial Template Size 2
348140	Radial Template Size 3
348141	Radial IM Guide Rod
348142	Radial Feeler
348143	Radial Resection Guide Size 1
348144	Radial Resection Guide Size 2
348145	Radial Resection Guide Size 3
348146	Broach Handle
348154	Box Punch, Left
348156	Box Punch, Right
348160	Radial Broach Size 1 Left
348163	Radial Broach Size 1 Right
348166	Radial Broach Size 2 Left
348169	Radial Broach Size 2 Right
348172	Radial Broach Size 3 Left
348175	Radial Broach Size 3 Right
348178	Radial Broach Size 4 Left
348181	Radial Broach Size 4 Right
348184	Radial Impactor
348186	Radial Trial Remover
348189	Radial Drill Guide, Left
348191	Radial Drill Guide, Right
348195	Anti-Rotation Pin



Tray 1

1. Carpal Sizer
2. Carpal Guide Bar
3. Carpal Resection Guide
4. AO Handle
5. Carpal Reamers
6. Hamate Feeler
7. K-Wire Sleeve
8. Tissue Protective Sleeve
9. Modular Drill Guide
10. Carpal Plate Trials
11. Carpal Poly Trials
12. Carpal Plate Impactor
13. Carpal Poly Impactor
14. Carpal Cement Reamer
15. K-wire Depth Gauge
16. 3.5mm cannulated drill bit
17. 2.5 cannulated drill bit
18. 2.5mm Hex Driver
19. T15 Star Driver
20. 0.054” (1.4 mm) K-wire



Tray 2

21. Radial Templates
22. Radial Feeler
23. Radial Resection Guides
24. Radial IM Guide Rod
25. Radial Trial Remover
26. Radial Impactor
27. Radial Score Guide
28. Broach Handle
29. Broach Handle
30. Radial Drill Guide, Left
31. Anti-Rotation Pin
32. Radial Drill Guide, Right
33. Box Punch, Left
34. Box Punch, Right
35. Radial Broaches, Left
36. Radial Broaches, Right
37. Radial Trials, Left
38. Radial Trials, Left
39. 4.0mm Stop Drill Bit

Notes

Notes

Integra Contact - Sales & Marketing
EUROPE, MIDDLE-EAST and AFRICA
Integra LifeSciences Services (France) SAS
Immeuble Séquoia 2 ▪ 97 allée Alexandre Borodine
Parc technologique de la Porte des Alpes
69800 Saint Priest ▪ France
Phone: +33 (0)4 37 47 59 00 ▪ +33 (0)4 37 47 59 99 (fax)
emea.info@integralife.com

Integra Contact - Questions & Information

International: +33 (0)4 37 47 59 50 ▪ +33 (0)4 37 47 59 25 (Fax) ▪ csemea@integralife.com
Belgium: +32 (0)2 257 4130 ▪ +32 (0)2 253 2466 (fax) ▪ custsvcbenelux@integralife.com
Switzerland: +41 (0)2 27 21 23 30 ▪ +41 (0)2 27 21 23 99 (fax) ▪ custsvcsuisse@integralife.com
integralife.eu - integralife.com

Integra LifeSciences Corporation
4900 Charlemar Drive - Building A
Cincinnati ▪ OH 45227 ▪ USA

EC REP Integra LifeSciences Services France
Immeuble Séquoïa 2
97 allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest ▪ France

CE 0086 BSI

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.
- Please read carefully the instructions for use.
- Non contractual document. Integra reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

Additional information for EMEA Customers only:
Products mentioned in this document are CE class I, IIa & IIb devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED".