

SURGICAL TECHNIQUE

STABILITY *PGT*[™]
SIGMOID NOTCH
TOTAL DRUJ SYSTEM *WITH PRECISE
GUIDANCE TECHNOLOGY*



SBi
SMALL BONE INNOVATIONS

SURGICAL TECHNIQUE

- 1 Exposure**

The ulnar incision is made along the ulnar or medial shaft of the distal ulna in line with the ulnar styloid. The extensor retinaculum is incised along the medial border of the distal ulna between the extensor carpi ulnaris (ECU) and flexor carpi ulnaris (FCU). The dorsal cutaneous branch of the ulnar nerve must be identified and carefully preserved. With the extensor retinaculum reflected, the ECU tendon sheath is elevated subperiosteally off the distal ulna along with the triangular fibrocartilage (TFC) and ulnar collateral ligament distally. The extensor retinaculum should remain intact during reflection in both radial-to-ulnar and ulnar-to-radial directions (**FIGURE 1**).
- 2 Ulnar Head Resection**

After adequate exposure, retractors are placed under the ulnar head to protect the underlying structures. The level of resection is based upon a preoperative assessment for size and the use of a cutting template. The head of the distal ulna is resected using a saw. The undersurface of the TFC is inspected for any tears. The combination of the periosteal sleeve elevation, ECU subsheath, ulnar collateral ligaments, and TFC forms a pocket of the support of the distal ulna.
- 3 Intramedullary Canal Preparation**

The intramedullary canal is identified with the Starter Awl. Broaches are then used to ream the canal to the appropriate stem size.
- 4 Trial Insertion and Trial Reduction**

The appropriate size Trial Stem is inserted into the shaft of the distal ulna and secured using the Impactor. The collar should seat firmly against the resected surface of the bone. The ulnar head trial is placed onto the Trial Stem. There should be a smooth articulation of the ulnar head prosthesis with the sigmoid notch. The level of the head with respect to the radius should be evaluated. If an ulna plus variance exists, additional resection of the ulna may be required. Conversely, if an ulna minus condition exists, a build up collar of bone may be required (**FIGURE 2**).
- 5 Preparation**

In cases where the STABILITY Implant is indicated, the corresponding size Saddle Spacer is assembled to the trial head component. Once the Saddle Spacer is seated against the sigmoid notch, forearm rotation should be accessed. The thickness of the Saddle Spacer corresponds to the thickness of the STABILITY implant. If pronation or supination is limited, a reduction in head size should be considered. A .062 K-wire is drilled through the Insertion hole on the Saddle Spacer. The K-wire should lie in the coronal plane and be angulated to approximate the ulnar inclination of the distal radius. The K-wire is driven into the radius and the placement is verified using fluoroscopy. Care should be taken not to extend the K-wire past the deep cortex. The K-wire, Trial Head with Saddle Spacer, and the Trial Stem are removed. The K-wire is re-inserted and a 3.5mm cannulated drill is used to prepare the hole into the radius to accept the stem of the STABILITY Implant. The drill should be advanced no more than 2.0cm. (**FIGURES 3 AND 4**).

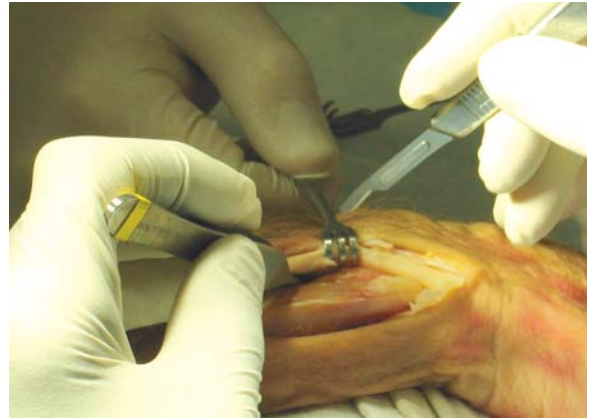


FIGURE 1



FIGURE 2



FIGURE 3



FIGURE 4

6 **Implantation of Radial Plate**

Two sizes of Radial Plates are available, Large and Small. Plate size is determined by patient anatomy. The Radial Plate is attached to the corresponding size impaction tool and is inserted into the radius. Proper rotational alignment should be assessed visually and under fluoroscopy. A 2.0mm drill is used to prepare the hole for the radial screw. Bi-cortical screw purchase should be achieved if possible. Proper screw length is measured and the appropriate screw is inserted and tightened. The Insert Component is attached to the corresponding size Insertion Tool. The insert engages the Radial Plate in a proximal to distal direction. The Insert is locked into place on the Radial Plate when fully advanced. (FIGURES 5 AND 6).

7 **Implantation of the Ulnar Stem**

The appropriate size Stem is impacted into the distal ulna. Care should be taken not to damage the Morse taper of the stem or the articulating surface of the STABILITY Implant.

8 **Implantation of the Ulnar Head**

Non-absorbable sutures are used to secure the ulnar head to the TFC and/or the ulnar capsule and ECU subsheath. Care should be taken to assure the tapers of the head and stem component are dry and free of tissue. The ulnar head implant is gently placed over the stem implant. The rotational position of the head component can be assessed by aligning the suture holes with the olecranon of the elbow. After proper alignment has been achieved, the impactor is used to secure the head to the stem via a Morse Taper Lock (FIGURE 7).

9 **Closure**

The remaining capsule over the distal ulna should be closed and imbricated, if possible, replacing the ECU tendon and tendon subsheath dorsally and closing the FCU-ECU interface. Stability of the prosthesis in prono-supination can be assessed at this time. The extensor retinaculum is closed over the capsule and restores the normal anatomic position of the extensor tendons.

10 **Postoperative Care**

The forearm is immobilized in mid-rotation and held in a supportive long arm or Muenster-type splint or cast for 3 weeks. Active range of motion of the wrist and forearm are then initiated after 3 weeks. Therapy is then advanced as tolerated, beginning strengthening when the patient achieves a functional range of wrist and forearm motion.

Small Bone Innovations does not recommend a particular surgical technique when using the implant. Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

Caution: United States federal law restricts this device to sale by or on the order of a physician.

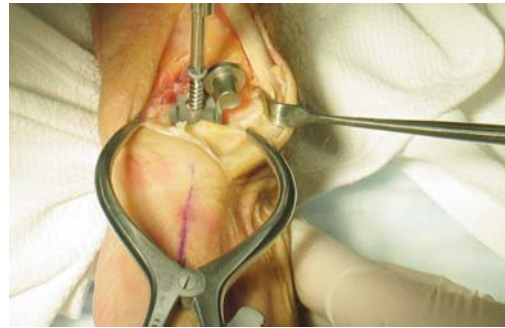


FIGURE 5



FIGURE 6

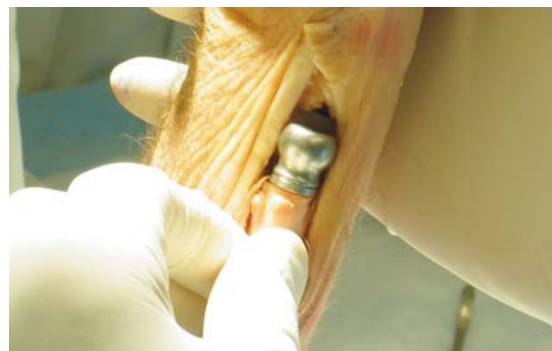


FIGURE 7

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