

stryker[®]

Trauma & Extremities

uHead® System with Stability Sigmoid Notch

Distal Radial Ulnar Joint

Operative Technique



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This publication sets forth detailed recommended procedures for using

Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to performing your first surgery.

All non-sterile devices must be cleaned and sterilized before use. Multicomponent instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling (Unsterile Instruments and Sizers V15106).

See package insert (Instruction for Use V15127) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

Introduction

uHead System with Stability Signmoid Notch

This system allows for complete DRUJ (distal radial ulnar joint) replacement.

The sigmoid notch component is designed to be used in conjunction with the uHead prosthesis. The implants are available in various lengths and they are modular, meaning that any size sigmoid notch will fit with any size head.

Indications & Contraindications

Indications

The uHead Ulnar implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting the following:

- Pain and weakness of the wrist joint not improved by conservative treatment
- Instability of the ulnar head with X-Ray evidence of dorsal subluxation and erosive changes
- Failed ulnar head resection

Warnings and Precautions

Please see package insert for Warnings, Precautions, Adverse Effects, and other essential product information.

Contraindications

- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation which cannot provide adequate support or fixation for the prosthesis
- Any active or suspected infection in or around the joint
- Skeletal immaturity
- Physiologically or psychologically unsuitable patient
- Known sensitivity to materials used in this device
- Possibility for conservative treatment

Surgical Technique

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-toradial directions (Fig. 1).

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 ulnar 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.

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.

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 (Fig. 2).

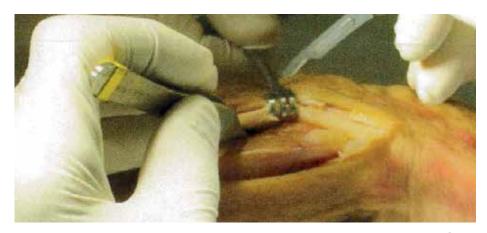


Fig. 1

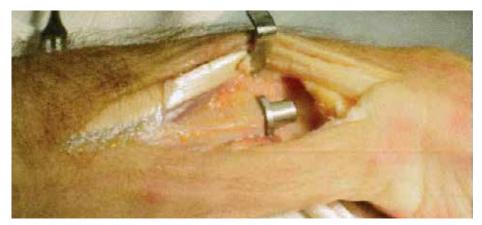


Fig. 2

For additional information, please reference uHead System Operative Technique.

Surgical Technique

Preparation

In cases where the uHead Ulnar implant is used in conjunction with the stability notch component 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 sigmoid notch component. If pronation or supination is limited, a reduction in head size should be considered.

A Ø1.5mm (.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 sigmoid notch plate. The drill should be advanced no more than 2.0cm (Fig. 3 & 4).

Implantation of Sigmoid Notch Plate

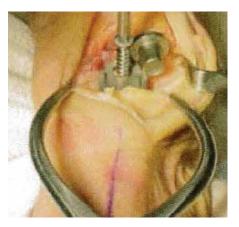
Two sizes of sigmoid notch plates are available, Large and Small. Plate size is determined by patient anatomy. The sigmoid notch plate is attached to the corresponding size impaction tool and is inserted into the radius. Proper rotational alignment should be assessed visually and under fluoroscopy. A 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 sigmoid notch insert is attached to the corresponding size Insertion Tool. The insert engages the sigmoid notch plate in a proximal to distal direction. The sigmoid notch insert is locked into place on the sigmoid notch plate when fully advanced. (Fig. 5 & 6).



Fig. 3



Fig. 4





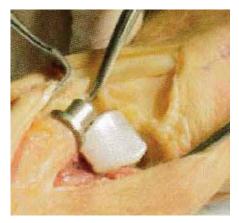


Fig. 6

Surgical Technique

Implantation of the uHead Ulnar Stem

The appropriate size uHead ulnar stem is impacted into the distal ulna.

Care should be taken not to damage the Morse Taper of the uHead ulnar stem or the articulating surface of the sigmoid notch component.

Implantation of the uHead 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 (Fig. 7).

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 pronosupination can be assessed at this time. The extensor retinaculum is closed over the capsule and restores the normal anatomic position of the extensor tendons.

Postoperative Care

The forearm is immobilized in midrotation 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 may then initiated after 3 weeks. Therapy may then be advanced as tolerated, beginning strengthening when the patient achieves a functional range of wrist and forearm motion.



Fig. 7



Reconstructive

Hips

Knees

Trauma & Extremities

Foot & Ankle

Joint Preservation

Orthobiologics & Biosurgery

MedSurg

Power Tools & Surgical Accessories

Computer Assisted Surgery

Endoscopic Surgical Solutions

Integrated Communications

Beds, Stretchers & EMS

Reprocessing & Remanufacturing

Neurotechnology & Spine

Craniomaxillofacial

Interventional Spine

Neurosurgical, Spine & ENT

Neurovascular

Spinal Implants

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Manufacturer:

Stryker GmbH Bohnackerweg 1 2545 Selzach Switzerland

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