ENG

Integra®

First Choice™ Partial Ulnar Head Implant

SURGICAL TECHNIQUE

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LIMIT UNCERTAINTY

Products for sale in Europe, Middle-East and Africa only

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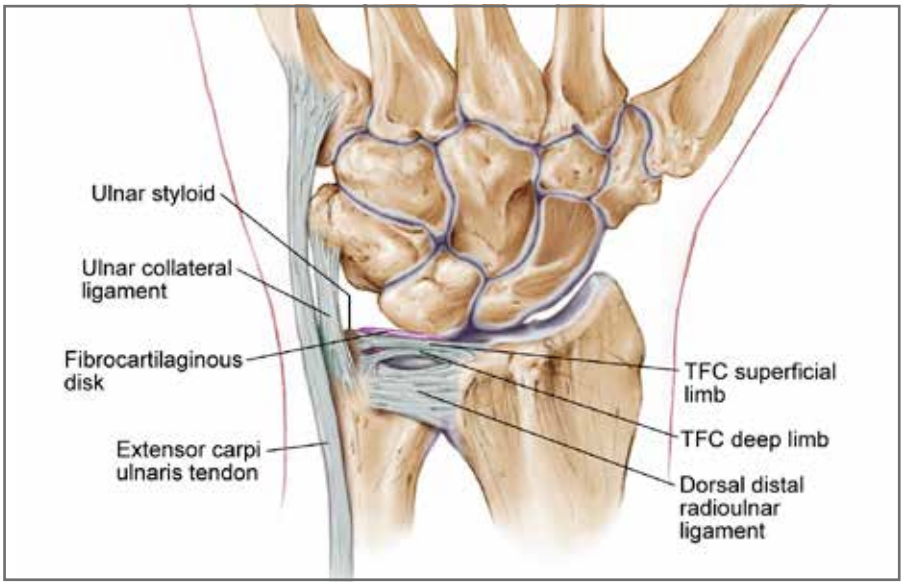
System Overview

The Integra First Choice™ Partial Ulnar Head Replacement allows retention of the ulnar neck, ulnar styloid, extensor carpi ulnaris groove, ulnocarpal ligament attachments, extensor carpi ulnaris sheath, and the triangular fibrocartilage complex (TFCC) attachments to the ulnar styloid. Therefore, while all articular surfaces of the ulnar head are replaced, nearly all of the ligaments and bony anatomy for the DRUJ are maintained. The procedure is performed with minimal exposure and immediate implant fixation can be achieved. The First Choice™ Partial Ulnar Head implant is a one-piece cobalt chrome implant with a grit blasted stem and is available in four head sizes and three stem sizes, providing intraoperative choices to match patient anatomy.

Triangular Fibrocartilage Complex (TFCC) Anatomy

The First Choice™ Partial Ulnar Head implant preserves the ulnar styloid attachments of the TFCC, including the palmar and dorsal distal radioulnar ligaments, fibrocartilaginous disk, extensor carpi ulnaris subsheath, and ulnocarpal ligaments. The deep radioulnar ligament attachment to the fovea is released to gain access to the ulnar medullary canal. Special care should be taken during surgical dissection to preserve these structures and their attachments, as well as protecting other surrounding soft tissues and vasculature.



First Choice™ Partial Ulnar Head Implant Indications for Use:

First Choice™ Partial Ulnar Head Implant is intended for partial replacement of the distal ulna for rheumatoid, degenerative, or posttraumatic arthritis presenting with pain and weakness localized to the distal radioulnar joint and not improved by conservative treatment. The First Choice™ Partial Ulnar Head implant is intended for press-fit use.

First Choice™ Partial Ulnar Head Implant Contraindications:

- Inadequate bone stock or soft tissue coverage
- Previous open fracture or infection in the joint
- Skeletal immaturity
- Physical interference with or by other prostheses during implantation or use
- Procedures requiring modification of the prosthesis
- Skin, bone, circulatory and/or neurological deficiency at the implantation site

Partial Ulnar Head Replacement Surgical Technique

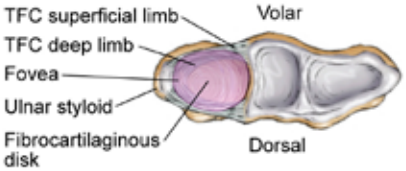
This technique has been developed for the partial ulnar head replacement. As the manufacturer of this device, Ascension does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for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

Step 1 • Preoperative Assessment (PA)

1-1 Use the X-ray sizing template on a PA X-ray to estimate the prosthetic stem and head size to best match the patient's distal radioulnar joint (DRUJ) anatomy. **Note the presence and magnitude of any ulnar variance.** Ulnar variance is measured by comparing the proximal-distal alignment of the distal articular surface of the ulna to the distal edge of the sigmoid notch. In neutral variance, these articular landmarks are aligned. Positive ulnar variance is defined as the ulna presenting more distal while in negative ulnar variance it presents more proximal.

The instrumentation has the capability to either replicate or alter preoperative ulnar variance, with the goal in most cases to create approximately -1 to -2 mm negative ulnar variance following implantation in order to avoid ulnar impaction, which is the term used to describe excessive loading across the ulnocarpal articulation. In rare cases of extreme ulnar negative variance such as from an acquired deformity, the surgeon may choose to decrease the negative variance towards more neutral in order to create a more congruous articulation between the implant and sigmoid notch.

1-1



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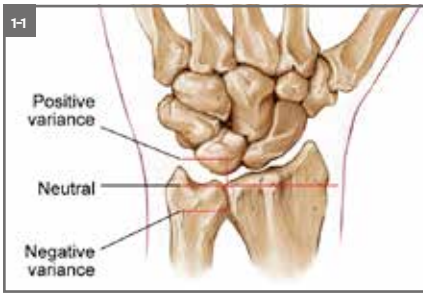


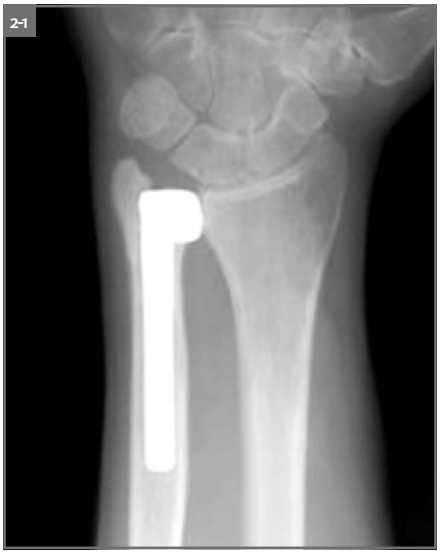
Step 2 • Patient Position

2-1 The patient is positioned supine with the shoulder abducted and elbow flexed, with the forearm and dorsal wrist in pronation.

Step 3 • Initial Incision

3-1 Make a straight 5 cm dorsal skin incision centered over the dorsal aspect of the ulnar head and neck.

2-1



Palmar view

3-1

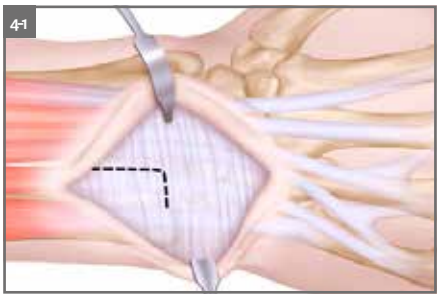
Dorsal view

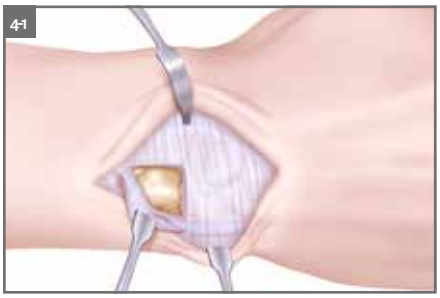
Step 4 • Retinaculum and Capsule Incision

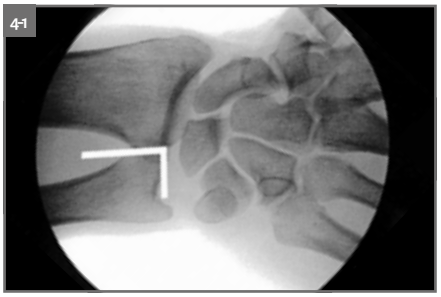
4-1 Using a combination of blunt and sharp dissection, elevate the skin and subcutaneous tissues with care to protect the branches of the dorsal sensory ulnar nerve. Identify the Extensor Carpi Ulnaris (ECU) and the Extensor Digiti Minimi (EDM) tendons. Open the 5th extensor compartment and extract the EDM tendon.

Make a "L" or "C"-shaped dorsal capsulotomy flap over the DRUJ, beginning proximally at the ulnar neck and extending to the distal ulnar head with care to preserve the dorsal radioulnar ligament of the TFCC and the ECU sheath. Leave a small rim of capsule attached to the sigmoid notch to facilitate closure.

The TFCC fibers inserting into the ulna fovea are sharply released at their insertion but all other ligament attachments can be retained.







Step 5 • Ulnar Variance and TFCC Assessment

5-1 Confirm the Preoperative assessment of native ulnar variance by direct inspection of the ulnar head in relation to the sigmoid notch and correlate with fluoroscopy. Determine the preferred ulnar variance; a -1 to -2 mm negative variance is typically recommended (see discussion under Step 1: Preoperative Assessment).

5-2 Assess the sigmoid notch for arthritic changes or degeneration which could impact implant articulation. Resect any substantial ridges or other irregularities of the articular surface but avoid weakening the subchondral bone.

5-3 Through direct visualization and DRUJ manipulation assess the TFCC for degenerative changes or injury, with emphasis on its ligamentous attachments to the ulnar styloid.

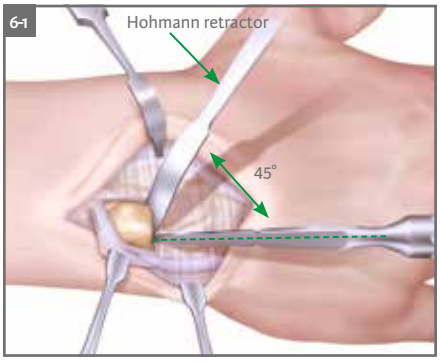
5-4 During manipulation, the DRUJ should be stable and the TFCC should show appropriate tension. If the TFCC's stabilizing function is compromised, other surgical options should be considered (e.g. resectional arthroplasty or Modular Ulnar Head implant).

Step 6 • Medullary Canal Preparation

6-1 The forearm is hyperpronated while the wrist is flexed maximally over a bump to directly view the fovea. A Hohmann retractor is placed beneath the ulnar head under direct visualization at a 45° angle to the head on the radial side. Gently elevate the ulnar head to visualize the fovea.

Note
The retractor protects the dorsal radioulnar ligament, extensor retinaculum, and the extensor tendons beneath the retinaculum throughout the procedure.

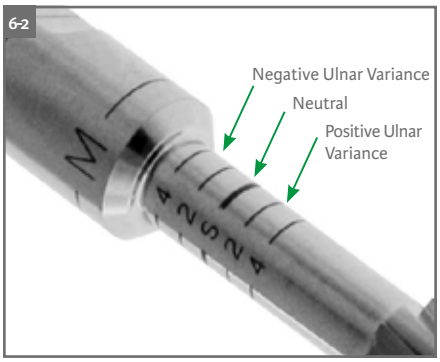
Caution
Proper placement of the retractor will help prevent ulnar styloid fracture or avulsion of the TFCC from the styloid.



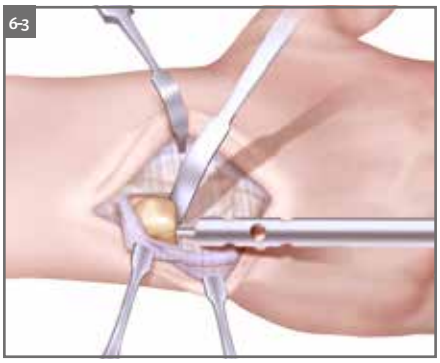
6-2 Using the starter awl or k-wire, penetrate at or near the fovea in alignment with the medullary canal of the ulna shaft. Insert the 3.5 mm starter reamer using a 360° forward twisting motion until the appropriate reamer marking is flush with the articular surface of the distal ulna. The reamer markings correspond to the ulnar variance that will be created relative to the native ulnar head.

Altering an ulnar-positive variance towards neutral will require deeper insertion of the reamer during preparation of the medullary canal while altering ulnar-negative variance towards neutral will require shallower insertion of the reamer into the medullary canal. These alterations are guided by the markings on the reamer.

Note
Native ulnar variance can be either reproduced or altered.
A -1 to -2 mm negative variance is typically recommended.
This technique reduces the risk of ulnar impaction syndrome.



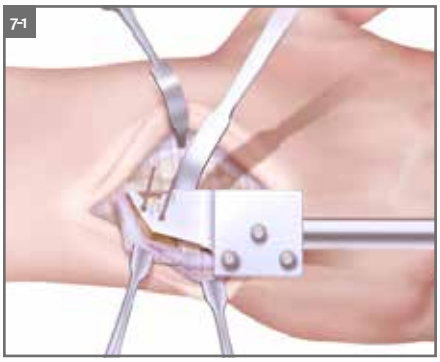
6-3 Repeat with increasing size reamers until cortical contact with the medullary canal is obtained, stopping at the same reamer marking with each reamer.



Step 7 • Osteotomy Guide Placement

7-1 With reamer in place, snap on the partial ulnar replacement osteotomy guide. Care is taken to ensure the proper side of the guide (right or left) corresponds to the DRUJ being resurfaced. For proper alignment of the osteotomy guide, use the true subcutaneous border of the ulna, which is defined by the ulnar styloid and olecranon tip.

7-2 While maintaining the reamer in proper position, insert one or two 0.045" (1.1 mm) k-wires through the osteotomy guide to secure the guide to the ulna. A wire cutter can be used to trim the k-wires.

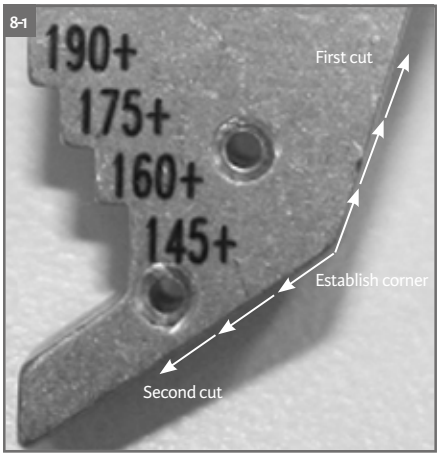


Step 8 • Resection of the Radial Aspect of the Distal Ulna

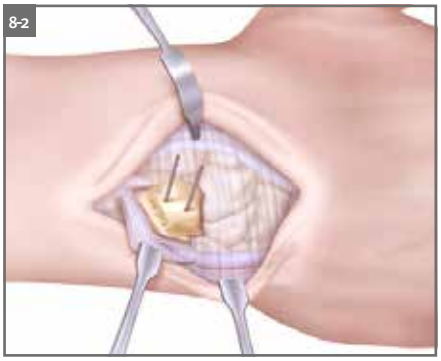
8-1 Using a sagittal saw with the blade held flush against the surface of the osteotomy guide, perform the oblique cut that extends distally through the ulnar head and proximally to the corner of the guide.

Perform a second cut that extends from the proximal end of the first osteotomy through the radial aspect of the ulna.

Caution
Do not extend the cuts beyond the corner of the guide as this could create an unwanted notch and potentially weaken the ulnar styloid



8-2 Remove the osteotomy guide followed by the reamer, and complete the osteotomy. Sharply dissect the articular fragment from any remaining soft tissue attachments.

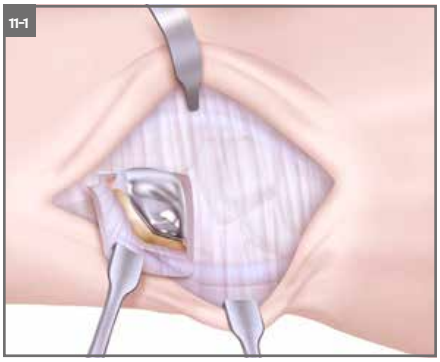


Step 9 • Sigmoid Fossa Inspection and Trial Placement

9-1 Inspect the sigmoid fossa and resect any remaining marginal osteophytes. Select the appropriate stem/head size trial and insert into the medullary canal. During trial insertion, ensure proper rotation of the implant so that the collar aligns with the ulnar head cuts. Gently impact the trial into place.

Step 10 • Trial Reduction

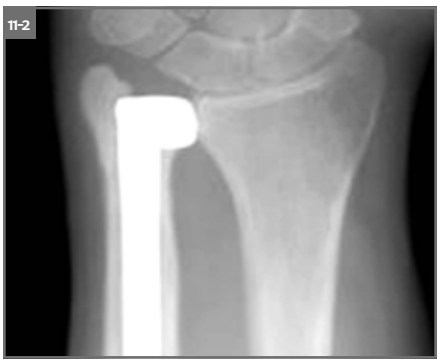
10-1 Reduce the trial into the sigmoid notch and evaluate DRUJ stability and forearm pronation and supination.
Proper positioning should be checked by x-rays. If the prosthesis is too distal, mark the required amount of additional ulna to resect. Using the same technique used to make the original osteotomy, reinsert the reamer and advance with a twisting motion, then remount the osteotomy guide. Ensure the guide is aligned with the reamer mark and is parallel to the existing cuts. Complete the revision cuts similar to the initial cuts.



Step 11 • Implant the Partial Ulnar Head

11-1 Upon successful trial reduction and assessment, use the trial extractor to remove the trial. Insert the final Partial Head implant, ensuring proper rotation of the implant so that the collar aligns with the ulnar head cuts, and impact into place.

11-2 Reduce the implant into the sigmoid notch and evaluate DRUJ stability and forearm pronation and supination. Final x-rays may be used to verify that anatomic alignment of the DRUJ has been achieved.



Closure and Stabilization

Close the capsule and retinaculum either separately or together. Imbricate if needed to improve DRUJ stability, but avoid excessive imbrication as this will decrease joint motion. Place a subcutaneous drain, if desired.
The patient is placed in sugar tong splint with the wrist and forearm in neutral positions.

Postoperative Management

2 Weeks Postoperative

The sugar tong splint is converted to a well-molded short arm cast applied with the forearm in neutral rotation. The cast will allow a short arc of forearm rotation, but will prevent full rotation.

4 Weeks Postoperative

The cast is removed. A removable wrist splint is applied and used for an additional 3-4 weeks while gentle motion exercises are initiated. The splint is removed for active but not passive forearm rotation and wrist motion during this time.

6-8 Weeks Postoperative

The patient is released from splint wear and activities gradually increased as tolerated. However, additional splint wear may be used for more stressful activities.

Essential Product Information

Indications For Use

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Contraindications

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Warnings

- Strenuous loading, excessive mobility, and articular instability all may lead to eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Do not modify the First Choice™ Partial Ulnar Head implants in any manner. Reshaping the implant using cutters, grinders, burrs, or other means will damage the structural integrity of the device.

Precautions

- Do not resterilize this device. Resterilization could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris.
- Do not reuse this device. Reuse of this product may result in infection or other systemic complication that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate and should be discarded.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and taper surfaces must not come in contact with hard or abrasive surfaces.
- The First Choice™ Partial Ulnar Head implants have not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. The First Choice™ Partial Ulnar Head implants have not been tested for heating or migration in the MR environment.

DRUJ

Partial Ulnar Head Implants

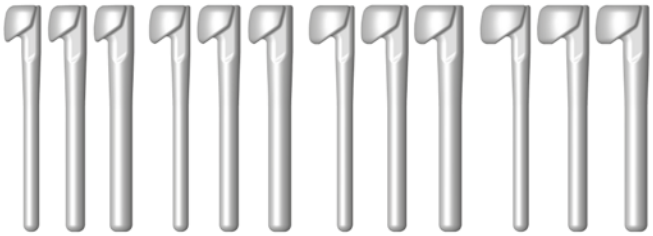
Reference	Description
DRUJ-610-1445-WW	14.5 mm head, 4.5mm standard stem
DRUJ-610-1645-WW	16.0 mm head, 4.5mm standard stem
DRUJ-610-1745-WW	17.5 mm head, 4.5mm standard stem
DRUJ-610-1945-WW	19.0 mm head, 4.5mm standard stem
DRUJ-610-1455-WW	14.5 mm head, 5.5mm standard stem
DRUJ-610-1655-WW	16.0 mm head, 5.5mm standard stem
DRUJ-610-1755-WW	17.5 mm head, 5.5mm standard stem
DRUJ-610-1955-WW	19.0 mm head, 5.5mm standard stem
DRUJ-610-1465-WW	14.5 mm head, 6.5mm standard stem
DRUJ-610-1665-WW	16.0 mm head, 6.5mm standard stem
DRUJ-610-1765-WW	17.5 mm head, 6.5mm standard stem
DRUJ-610-1965-WW	19.0 mm head, 6.5mm standard stem

Partial Ulnar Head Instruments

	Reference	Description
	INS-610-00	Instrument Set
A	OSG-610-00	DRUJ Osteotomy Guide
B	TRL-610-H145-S45	DRUJ Trial Size 14.5-4.5
B	TRL-610-H160-S45	DRUJ Trial Size 16.0-4.5
B	TRL-610-H175-S45	DRUJ Trial Size 17.5-4.5
B	TRL-610-H190-S45	DRUJ Trial Size 19.0-4.5
B	TRL-610-H145-S55	DRUJ Trial Size 14.5-5.5
B	TRL-610-H160-S55	DRUJ Trial Size 16.0-5.5
B	TRL-610-H175-S55	DRUJ Trial Size 17.5-5.5
B	TRL-610-H190-S55	DRUJ Trial Size 19.0-5.5
B	TRL-610-H145-S65	DRUJ Trial Size 14.5-6.5
B	TRL-610-H160-S65	DRUJ Trial Size 16.0-6.5
B	TRL-610-H175-S65	DRUJ Trial Size 17.5-6.5
	TRL-610-H190-S65	DRUJ Trial Size 19.0-6.5

Partial Ulnar Head Replacement Implants

- Available in 12 sizes



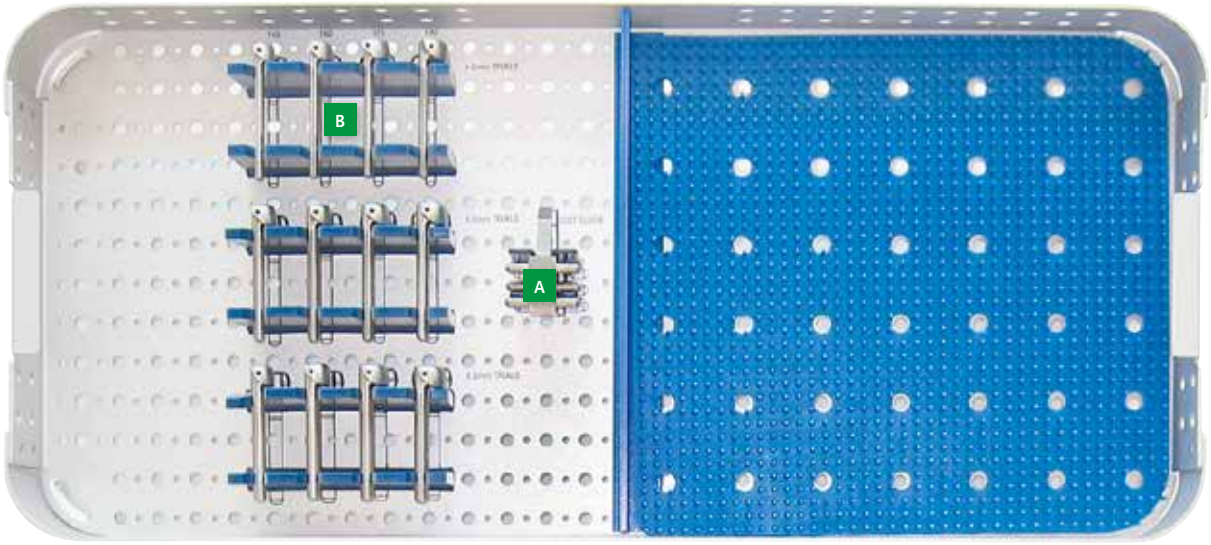
- 4 Head Sizes: 14.5 mm, 16.0 mm, 17.5 mm, 19.0 mm
- 3 Stem Sizes: 4.5 mm, 5.5 mm, 6.5 mm
- Material: CoCr
- Length of implant: 64.11 mm

Modular Ulnar Head Instruments

	Reference	Description
	INS-600-00	Instrument Set
C	AWL-100-01	Starter Awl
D	TRL-600-H160	MUH Head Trial Size 16.0
D	TRL-600-H175	MUH Head Trial Size 17.5
D	TRL-600-H190	MUH Head Trial Size 19.0
E	TRL-600-S45	MUH Stem Trial Size 4.5
E	TRL-600-S55	MUH Stem Trial Size 5.5
E	TRL-600-S65	MUH Stem Trial Size 6.5
	TRL-600-MED	MUH Trial Collar Medium
	TRL-600-LNG	MUH Trial Collar Long
F	OSG-600-00	MUH Resection Guide
G	BRH-600-45	MUH Reamer Size 4.5
G	BRH-600-55	MUH Reamer Size 5.5
G	BRH-600-65	MUH Reamer Size 6.5
H	IMP-600-00	MUH Stem Impactor
I	IMP-600-01	MUH Assembly Pad
J	OSG-600-01	MUH Osteotomy Guide
K	IMP-300-00	Implant Impactor
L	EXT-200-00	Trial Extractor

*Contain 2 K-Wires, 1 saw Blade .

Note: To perform a Partial Ulnar Head procedure, both the MUH & Partial instrument sets are needed.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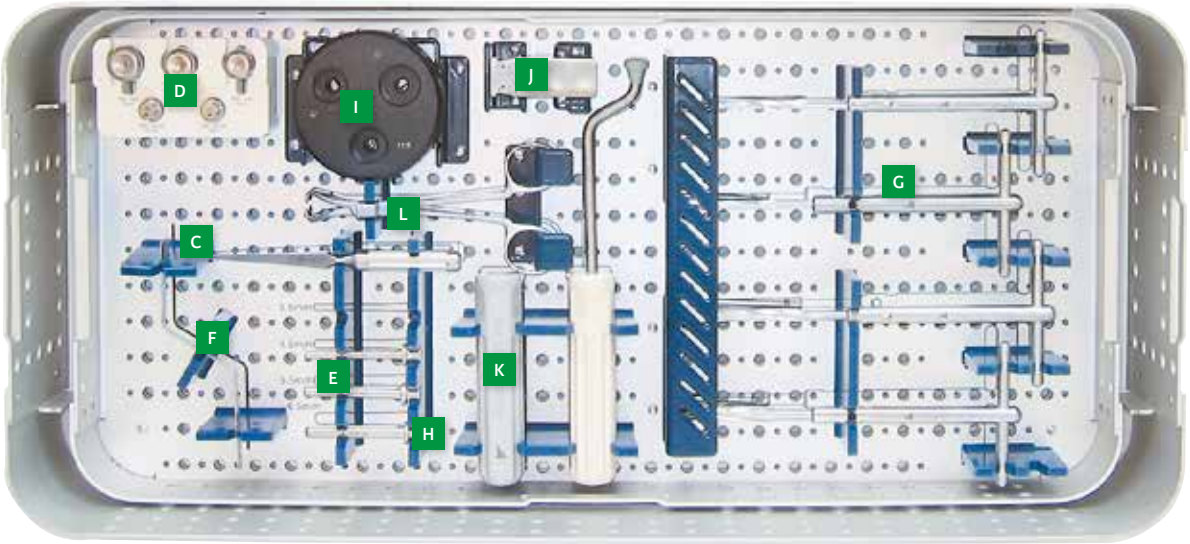
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