Integra®

First Choice[®] DRUJ System

Partial Ulnar / Modular Ulnar Head Implant

SURGICAL TECHNIQUE





System Overview

The Integra® First Choice® DRUJ System was developed through the international collaboration of several prominent extremity surgeons. Design surgeons include Drs. Philippe Kopylov and Magnus Tagil from Lund, Sweden, Dr. Brian Adams from Iowa City, Iowa, and Professor John Stanley from Wigan, England. These surgeons all shared the desire to bring an innovative distal radioulnar joint (DRUJ) system to the market that is straight forward and addresses both primary and revision cases with reproducibility.

The Integra First Choice DRUJ System provides instrumentation for both a partial and a modular ulnar head replacement. The system allows an intraoperative choice between the two implants and a conversion option from the partial to the total head if necessary.



Indications For Use

Partial Ulnar Head

The Integra First Choice Partial Ulnar Head implant is intended for partial replacement of the distal ulna for rheumatoid, degenerative, or post-traumatic 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.

Modular Ulnar Head

The Integra First Choice MUH Implant is intended for replacement of the distal radioulnar joint:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or posttraumatic 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

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



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 DRUJ System 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 DRUJ System implants have not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. The First Choice DRUJ System implants have not been tested for heating or migration in the MR environment.

Partical Ulnar Head Replacement Surgical Technique

This technique has been developed for the partial ulnar head replacement



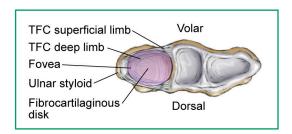
As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device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

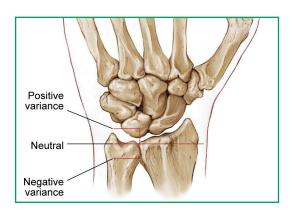
Step 1: Pre-Operative Assessment



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 reate a more congruous articulation between the implant and sigmoid notch.





Step 2: Patient Position



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



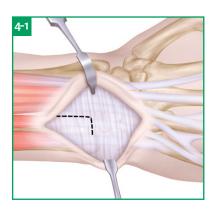
Step 3: Initial Incision

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

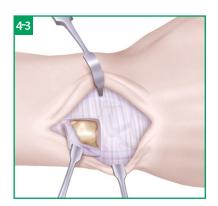


Step 4: Retinaculum and Capsule Incision

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 ECU and the 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 ease of 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

- 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).
- 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.
- Through direct visualization and DRUJ manipulation assess the TFCC for degenerative changes or injury, with emphasis on its ligamentous attachments to the ulnar styloid.
- During manipulation, the DRUJ should be stable and the TFCC should show appropriate tension. If the TFCC's stabilizing function is found to be compromised, other surgical options should be considered (e.g. resectional arthroplasty or Modular Ulnar Head implant).

Step 6: Medullary Canal Preparation



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.

Hohmann Retractor 45°

Caution

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



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 neurtral 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.

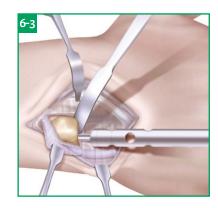


Note

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.



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

- 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.
- 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.



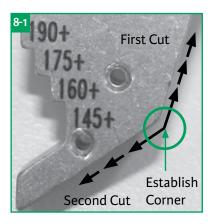
Step 8: Resection of the Radial Aspect of the Distal Ulna

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.

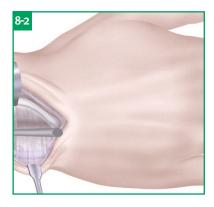
Perform a second cut that extends from the proximal end of the first osteotomy through the radial aspect of the ulna.

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.



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



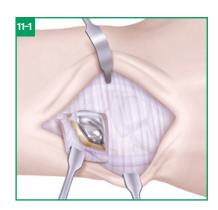
Inspect the sigmoid fossa and resect any remaining marginal osteophytes. Select the appropriate stem/head size trial and insert into the medullary canal. During trial insertion, ensure proper rotation of the implant so that the collar aligns with the ulnar head cuts. Gently impact the trial into place.

Step 10: Trial Reduction

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

Upon successful trial reduction and assessment, use the trial extractor to remove the trial. Insert the final Partial Head trial, ensuring proper rotation of the implant so that the collar aligns with the ulnar head cuts, and impact into place. The trial stems, unlike the definitive implant, have a hole through the head in which a K-wire or pick-ups can be placed to aid in rotational control.



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.



7

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.

Closure and Stabilization

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.

Modular Ulnar Head Surgical Technique

This technique has been developed for the modular ulnar head

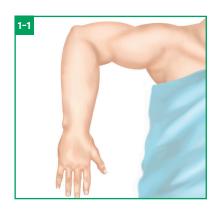


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Step 1: Pre-Operative Assessment and Patient Position

1-1

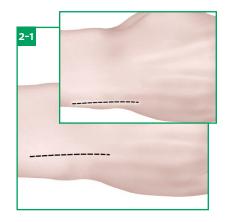
Use the x-ray sizing template on a PA x-ray to estimate the proper size implant and head to best match the patient's distal radioulnar joint (DRUJ) anatomy. The patient should be supine with the shoulder abducted to 90°, elbow flexed to 90°, and palm down, thus presenting the wrist in near neutral pronation/supination.



Step 2: Incision and Exposure



Either a dorsal approach as used for the partial ulnar head replacement or an ulnar approach can be used. In primary cases, the dorsal approach is typically preferred because it better preserves the soft tissue joint restraints. For patients with prior DRUJ operations, the ulnar approach may be easier, especially if that approach was used previously since this would likely better preserve the remaining soft tissues.



2-2

In the dorsal approach, a 5 cm longitudinal incision is made over the ulnar head and neck. Using a combination of blunt and sharp dissection, elevate the skin and subcutaneous tissues while protecting the cutaneous nerve branches. Identify the extensor carpi ulnaris and extensor digiti minimi tendons. The 5th extensor compartment is opened and the extensor digiti minimi tendon is retracted. An "L" or "C"-shaped dorsal capsulotomy flap is made over the DRUJ extending distally to the ulnar head and ulnarly to the styloid. Proximally it can be reflected from the ulnar neck.

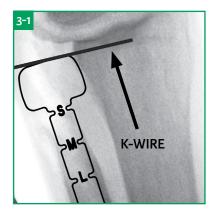


Continue to raise the flap ulnarly and volarly around the distal ulna, elevating the extensor carpi ulnaris sheath and releasing soft tissue attachments to the ulnar styloid (if present). The dissection will create a continuous soft tissue sleeve for subsequent closure over the implant.



Step 3: K-Wire Placement

To determine the best position for the ulnar osteotomy, insert a 0.045" (1.1 mm) k-wire at the most distal point of the sigmoid notch articulating surface. The k-wire is placed perpendicular to the long axis of the radius. Place the resection guide next to the sigmoid notch and aligned with the inserted k-wire.



The resection guide will help determine the appropriate collar to be used - standard, medium or long and assist with determining whether an additional resection is needed. The resection level, S, M, or L, can be marked on the ulnar neck.



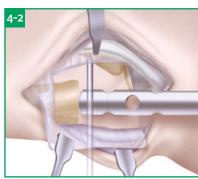
Step 4: Medullary Canal Preparation

The forearm is hyperpronated while the wrist is flexed acutely over a bump. Place a Hohmann retractor under the ulnar shaft to provide better visualization of the medullary canal or ulnar head if this is a primary procedure. Use a

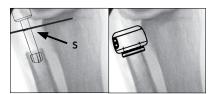
K-wire follow by the starter awl to penetrate the center of the medullary canal, approximately 2.0 cm



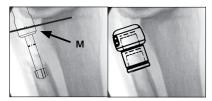
- Insert the 3.5 mm starter reamer, using a 360° forward twisting motion until the appropriate mark on the reamer S, M, or L, as previously determined by the resection level guide. The K-wire inserted into the edge of the sigmoid notch should be aligned with the appropriate mark on the reamer.
- Repeat the reaming with sequentially larger reamers as necessary until cortical contact within the medullary canal is felt. Always ensuring to align the K-wire with the appropriate mark on the reamer.







Placement of reamer for standard collar implant



Placement of reamer for medium collar implant



Placement of reamer for long collar implant

11

Step 5: Osteotomy Guide Placement



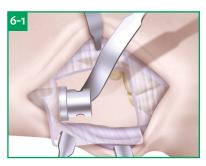
Place the First Choice Modular Ulnar Head osteotomy guide on the last reamer used. If sufficient bone stock exists, stabilize the guide with a 0.045" (1.1mm) k-wire. Using a sagittal saw with the blade held flush against the surface of the osteotomy guide, cut to the level of the reamer. Remove the osteotomy guide and reamer, and complete the osteotomy.



Step 6: Trial Reduction



It is important to note that the trials are provided in three separate pieces: stem, collar and head for ease of use. The final implant is provided in two pieces which are secured together through a Morse tapered between the collar and head. Choose the stem trial that corresponds to the last reamer used.



6-2

If a resection for a medium or long collar was made, place the medium or long collar trial onto the trial stem.



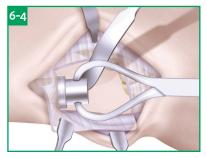
6-3

Choose the head trial that best fits the sigmoid notch and provides proper DRUJ stability. If the fit is between sizes, it is usually best to use the smaller size to avoid overstuffing the joint. Place it on the neck, and reduce the joint.



6-4

Reduce the trial into the sigmoid notch and evaluate DRUJ stability and forearm pronation and supination. Proper positioning should be checked using fluoroscopy with particular attention to ulnar variance as positive ulnar variance should be avoided. Use the trial extractor to remove the trial implant components.



Step 7: Assemble and Implant the DRUJ



Using the black assembly pad, place the chosen ulnar head implant in the matching hole with its opening facing up. Place the taper portion of the correct stem into the head taper and use the gray stem impactor to impact the stem into the head. Figure 7a.

There are two holes on the side of the implant head for optional suturing to the adjacent soft tissue to help stabilize the implant. If the integrity of the capsule and sigmoid notch are good then sutures are not usually necessary. Typically, when suturing is done, one or two double-armed sutures are inserted through these holes before inserting the implant into the canal for technical ease.



7-1

Regardless if sutures are used, the implant should be inserted into the canal with the suture sites facing the subcutaneous ulnar border of the forearm and away from the sigmoid notch. Figure 7b.

When sutures are used, it is important they are tied to the capsule or other surrounding tissue at the proper location and with these tissues under proper tension, which will reduce the risk of creating a joint tether and imbalance. The optional sutures can be placed through the capsule volar to the extensor carpi ulnaris, with care to avoid trapping the tendon, and tie the sutures iver the capsule. In most cases, sutures are not necessary as closure of the capsule provides proper stability and joint motion.

Reduce the implant into the sigmoid notch and evaluate DRUJ stability and forearm pronation and supination. Final radiographic imaging is used to verify that proper alignment of the DRUJ has been achieved, including slight negative ulnar variance.



Closure and Stabilization

Close the capsule and retinaculum either separately or as one layer. Imbricate if necessary to improve DRUJ stability, but avoid excessive imbrication as this will decrease joint motion and may cause subluxation. A long arm splint with wrist and forearm in neutral positions is applied.

Postoperative Management Following Surgery

Immobilize the forearm and wrist for two weeks in neutral positions of rotation, flexion-extension, and deviation using a long arm plaster splint to protect the capsule repair.

2 Weeks Postoperatively

The progression of splinting and rehabilitation depends on the quality of the capsular repair and joint stability achieved at surgery. If there was evidence of DRUJ instability then rehabilitation should be delayed and extended beyond the typical program by approximately two weeks at each stage. Conversely, if the joint was stable and early stiffness is occurring then the program can be accelerated slightly.

Long arm plaster splinting in neutral forearm rotation is applied for an additional two weeks to maintain joint position and improve capsular healing, especially if surgery was performed for a failed distal ulna resection. In some cases a short arm cast can be used at this time.

4 Weeks Postoperatively

The long arm splint is changed to a well-molded short arm cast, which will naturally allow some forearm rotation. Alternatively, if the patient can be minimally active and a strong capsule repair was achieved then a removable wrist splint can be used instead, but it should only be removed sparingly for gentle active range of motion exercises.

6 Weeks to One Year Postoperatively

A removable wrist splint is applied and used for an additional 4 weeks during which range of motion exercises for both the forearm and wrist are begun but forceful passive motion is to be avoided.

Full activities as tolerated without the splint are allowed at 10 to 12 weeks postoperative. Begin mobilization earlier if stiffness occurs or delay as necessary to avoid instability, e.g., a rheumatoid patient with laxity.

Conduct clinical and radiographic examinations at 6 weeks and 6 months postoperatively, and then yearly intervals to assess joint stability and motion, implant fixation and sigmoid notch condition.



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



Total Modular Ulnar Head Implants

Available in 27 sizes

3 Head Sizes: 16.0 mm, 17.5 mm, 19.0 mm 3 Stem Sizes: 4.5 mm, 5.5 mm, 6.5 mm

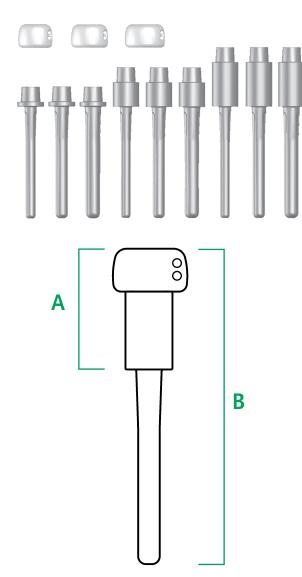
Material: CoCr head / Ti stem

Length of collar + head "A"

S = 13.0 mm M = 22.0 mmL = 31.0 mm

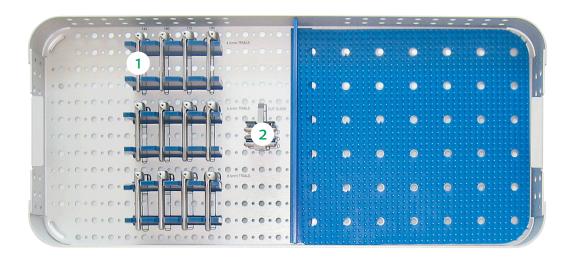
TOTAL Length of implant "B"

S = 63.0 mm M = 72.0 mmL = 81.0 mm

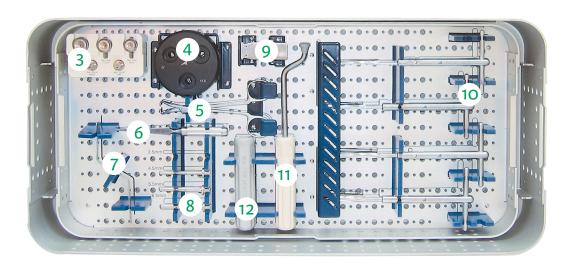


Instrument Tray Layout

- 1. Partial Ulnar Head Replacement Sizing Trials
- 2. Partial Ulnar Head Replacement Osteotomy Guide



- 3. MUH Head & Collar Trials
- 4. MUH Assembly Pad
- 5. Trial Extractor
- 6. Starter Awl
- 7. MUH Resection Guide
- 8. MUH Stem Trials
- 9. MUH Osteotomy Guide
- 10. Reamers
- 11. Implant Impactor
- 12. MUH Assembly Impactor



Partial Ulnar Head Implants

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



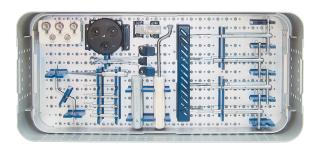
Partial Ulnar Head Instruments

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

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

Modular Ulnar Head Implants

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Catalog Number	Description
MUH-600-H160-WW MUH-600-H175-WW MUH-600-S45S-WW MUH-600-S55S-WW MUH-600-S65S-WW MUH-600-S45M-WW MUH-600-S55M-WW MUH-600-S65M-WW MUH-600-S45L-WW MUH-600-S55L-WW MUH-600-S65L-WW	16.0mm head 17.5mm head 19.0mm head 4.5mm standard stem 5.5mm standard stem 6.5mm standard stem 4.5mm medium stem 5.5mm medium stem 6.5mm medium stem 4.5mm long stem 5.5mm long stem 6.5mm long stem



Modular Ulnar Head Instruments

Catalog Number	Description
INS-600-00	Instrument Set
AWL-100-01	Starter Awl
TRL-600-H160	MUH Head Trial Size 16.0
TRL-600-H175	MUH Head Trial Size 17.5
TRL-600-H190	MUH Head Trial Size 19.0
TRL-600-S45	MUH Stem Trial Size 4.5
TRL-600-S55	MUH Stem Trial Size 5.5
TRL-600-S65	MUH Stem Trial Size 6.5
TRL-600-MED	MUH Trial Collar Medium
TRL-600-LNG	MUH Trial Collar Long
OSG-600-00	MUH Resection Guide
BRH-600-45	MUH Reamer Size 4.5
BRH-600-55	MUH Reamer Size 5.5
BRH-600-65	MUH Reamer Size 6.5
IMP-600-00	MUH Stem Impactor
IMP-600-01	MUH Assembly Pad
OSG-600-01	MUH Osteotomy Guide
IMP-300-00	Implant Impactor
EXT-200-00	Trial Extractor
UH-DIS-STR	Disposable Pack (Stryker)*
UH-DIS-HAL	Disposable Pack (Linvatec/Hall)*
*Contain 2 K-Wires 1 sa	w Blade

*Contain 2 K-Wires, 1 saw Blade



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.

- \blacksquare Always refer to the appropriate instructions for use for complete clinical instructions.
- Non contractual document. The manufacturer 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.

For more information or to place an order, please contact:

United States, Canada, Asia, Pacific, Latin America
USA 800-654-2873 = 888-980-7742 fax
International +1 609-936-5400 = +1 609-750-4259 fax
integralife.com/contact

Manufacturer:



Ascension Orthopedics, Inc. 8700 Cameron Road Austin, Texas 78754 USA