TORNIER
TECHNOLOGY

TORNIER
LATITUDE EV™
Total Elbow Arthroplasty

SURGICAL TECHNIQUE

WRIGHT™
FOCUSED EXCELLENCE

Table of Contents:

Indications and Contraindications

Indications:

The LATITUDE EV™ Total Elbow Arthroplasty system is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using other techniques. The LATITUDE EV Total Elbow Arthroplasty system is intended for cemented use only.

Contraindications:

Systemic infection is an absolute contraindication. Every effort should be made to rule out the possibility of preoperative sepsis in patients who have one or more of the following abnormalities: fever and/or local inflammation; rapid joint destruction or bone resorption apparent on roentgenograms; elevation of sedimentation rate unexplained by other disease; elevation of WBC count; distant foci of infection from genitourinary, pulmonary, skin and other sites, dental focus infection which may cause hematogenous spread to the implant site; skeletally immature patients; cases where there is inadequate neuromuscular status, poor bone stock, or poor skin coverage around the elbow joint that would make the procedure unjustifiable; neuromuscular or psychiatric disorders which might jeopardize fixation and postoperative care; known allergy to one of the materials; pregnancy.

Radial Head Replacement Considerations

The LATITUDE EV Total Elbow Arthroplasty system can be used with or without its radial head replacement component. The native radial head always needs to be resected prior to final implantation. The humeral and ulnar components must always be used in the procedure. The radial head component needs to be carefully considered in all cases, particularly when lateral joint load sharing needs to be reasonably recreated, such as in the case of unlinked arthroplasty.

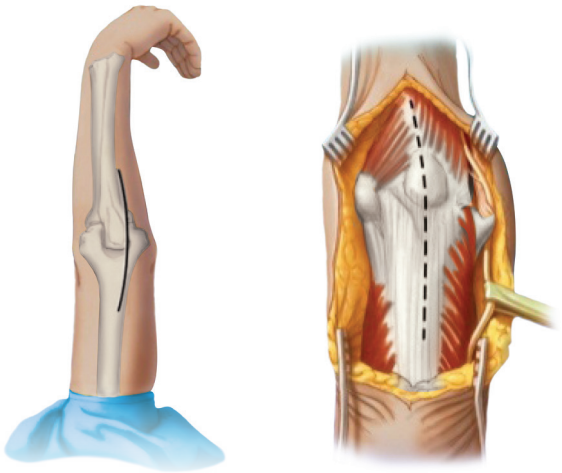
Surgical Steps

Elbow Exposure and Sizing

Step 1: Exposure

Patient Position:

The patient may be positioned in a lateral decubitus position or a supine position based upon surgeon preference. It is important to have full mobility of the elbow during the procedure. A sterile tourniquet is employed.



Incision:

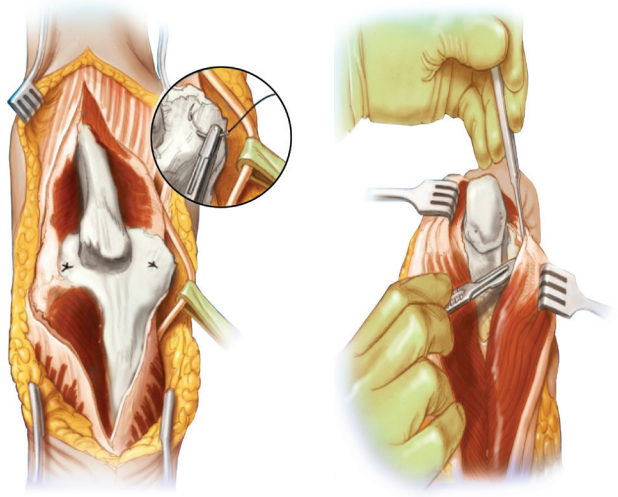
A straight incision is made approximately 15 centimeters in length and centered just medial to the tip of the olecranon. Full thickness medial and lateral flaps are elevated on the deep fascia.

Ulnar Nerve Transposition:

The medial aspect of the triceps mechanism is identified and the ulnar nerve is isolated. The medial intermuscular septum is excised. The ulnar nerve is mobilized and transposed anteriorly into the subcutaneous tissue.

Triceps Management:

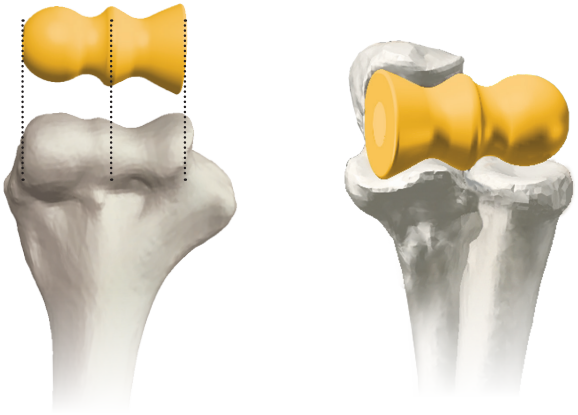
Management of the triceps mechanism is at the surgeon's discretion. If the surgeon does not have extensive experience with the elbow, a triceps-splitting approach is recommended. In this case, the distal 6 to 8 cm of the triceps is split in line with the center of the olecranon. The triceps is then kept in continuity with the distal forearm fascia as it is split distally along the subcutaneous border of the ulna. Both the medial and lateral triceps flaps are then elevated subperiosteally over the medial and lateral epicondyles respectively, exposing the elbow joint. Both medial and lateral ulnar collateral ligaments are elevated off the humeral insertions subperiosteally with sharp dissection, allowing dislocation of the elbow.



Note: For surgeons with greater experience, a triceps-on approach (not shown) is compatible with the instrumentation.

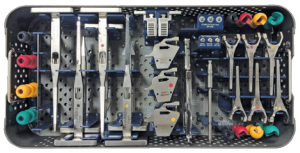
Step 2: Sizing

Size the width of the humeral articular surface using the Sizing Spools. Start by comparing the Sizing Spools to the patient's capitellum and trochlear groove. Then verify that the spool fits precisely into the trochlear groove of the ulna and aligns with the center of the radial head. Small, Medium, Large and Large+ sizes are available. The selected size will be used throughout the procedure; the humeral, ulnar and radial component sizes are not interchangeable. The Large+ spool is used with a Large humeral stem.



Tip: If the patient is between sizes, select the smaller size.

Note: Size is important for this implant as it has a radial head component. Ensure that the implant capitellum properly articulates with the radial head to facilitate the restoration of the natural kinematics of the elbow.



Tray 1 Top

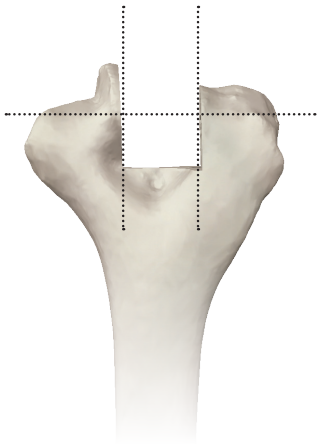
Small Sizing Spool | Medium Sizing Spool | Large Sizing Spool | Large+ Sizing Spool

Tip: Consider starting the procedure with the ulna if there are any concerns about sizing - the ulna typically provides the size limitation for the implant.

Humeral Preparation

Step 3: Initial Cut

Make a cut between the medial and lateral posterior trochlear ridges and a coronal cut at the center of the fossa. The initial cut should be wide enough to accommodate the stem of the humeral broach to allow access to the medullary canal. Nearly all of the trochlea needs to be removed in order to accommodate the humeral broach.



Tip: The osteotome in the tray can be used as a reference for how wide to make the initial cut in the distal humerus. Consider creating a bone graft (autograft) for the flange with the bone resected from the distal humerus prior to making the full cut.

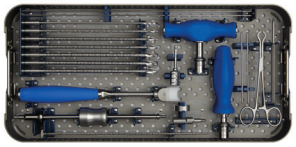
Step 4: Initial Entry

Use a high speed burr to open the medullary canal. If preferred, cannulated Flexible Reamers may be used to further open the canal prior to broaching and are recommended if using a revision stem. Guide Wires are provided if desired when utilizing a flexible reamer.

Humeral Component	Reamer Size
Small	Up to 6mm
Medium	Up to 8mm
Large	Up to 10mm

Tip: Use the base of the fossa as a landmark for how deep to make the initial entry.

Tip: Listen for diaphyseal chatter, not entry chatter, when using the reamers to know that the canal has been sized up appropriately.



Tray 2 Top

4mm Straight Reamer

5mm -10mm Flexible Reamers

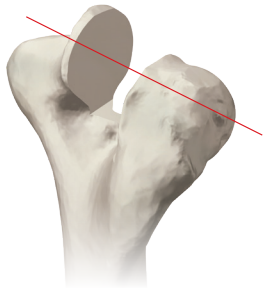
Guide Wire

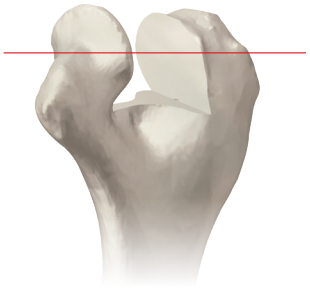
Step 5: Humeral Broaching

Using a mallet, insert the Starting Broach until the Flexion/Extension (F/E) line on the posterior surface is lined up with the patient's F/E axis.

Tip: If the patient has healthy bone stock, consider tapping the broach 2-3 times, removing, and then repeating. This will reduce the bone that gets pushed down the canal and will help reduce the possibility of cracking.

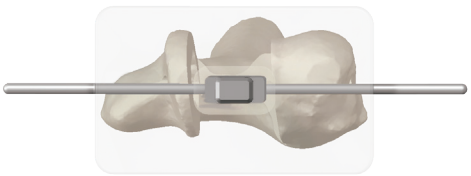
Tip: If broaching becomes difficult, use the flexible reamers to further open the diaphyseal canal.





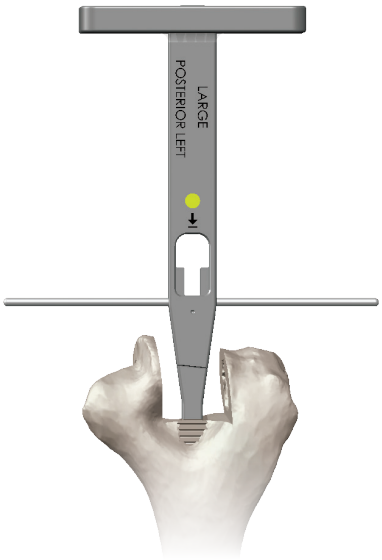
The F/E axis can be approximated in several ways:

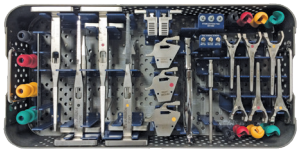
1. The easiest way is to impact the Broach until the F/E line on the posterior surface of the Broach lines up with the anteroinferior portion of the medial epicondyle (origin of the medial collateral ligament).
2. When viewing the internal cut surface of the trochlea it will approximate a circle. The center of the circle will be the approximate F/E axis.
3. The internal cut surface of the capitellum on the lateral side can also approximate a circle and the center of this is approximately the F/E axis.



If performing a left elbow replacement, the words POSTERIOR LEFT should be visible. If performing a right elbow replacement, the words POSTERIOR RIGHT should be visible. The F/E Alignment Pin can be used to aid rotational alignment by inserting it through the medial/lateral hole in the Humeral Broach. Humeral broaching should be done sequentially to the selected humeral component size. Broaches are color coded to match the correct spool size.

Tip: The Humeral Broaches allow for a 1mm cement mantle. If the Broach is too tight, avoid fractures by either reaming the canal with a Flexible Reamer or using a Broach one size lower than the definitive implant.





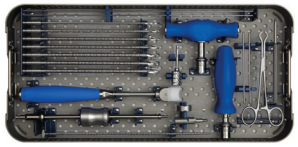
Tray 1 Top

Humeral Broach Starting Size

Humeral Broach Small Size

Humeral Broach Medium Size

Humeral Broach Large Size

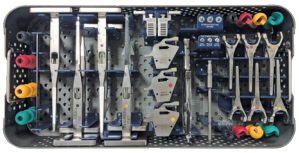


Tray 2 Top

F/E Alignment Pin

Step 6: Trochlear Cut

Attach the Broach Adaptor to the Humeral Broach and push it down to lock it in place. Attach the Trochlear Cut Guide to the Broach using the Broach Adaptor. Depress the lever on the guide and slide it on until it touches bone. Use a 3mm Drill Bit to drill through the two holes in this guide and insert a Stabilization Pin into each hole in order to secure it. **The distal cut extension on the Trochlear Cut Guide should be over the capitellum indicating that the mediolateral and rotational orientation is correct**. Care should be taken not to place the cutting guide too proximal as it may result in a very thin medial column susceptible to fracture. Thus, it is important to line up the F/E axis correctly on the original Broach to prevent overly proximal placement of the Trochlear Cut Guide. If the medial column appears to be very thin, consider downsizing the component or shifting the Humeral Broach more laterally.



Tray 1 Top

Humeral Broach Adapter: Right & Left

Small Trochlear Cut Guide

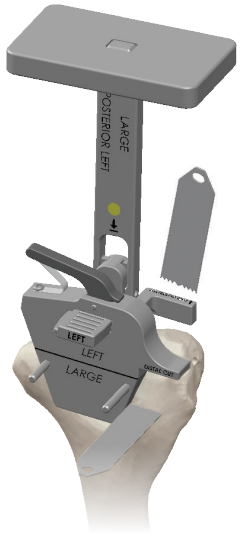
Medium Trochlear Cut Guide

Large Trochlear Cut Guide

Stabilization Pins

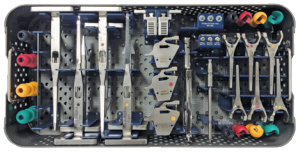
Use a reciprocating or oscillating saw to cut along the outside edges of the Trochlear Cut Guide. There are five trochelar cuts:

1. Bottom middle cut. Be sure to stop prior to hitting the broach and avoid notching the corners as this may lead to stress risers and predispose to a column fracture.
2. Lateral cut.
3. Medial cut.
4. Distal capitellum cut. Cut along the bottom surface marked DISTAL CUT.
5. Anterior cut. Use the back of the Broach Adaptor marked ANTERIOR CUT.



Tip: It may be easier to use the guide to score the cuts and then complete the cuts once it is removed. Be sure to complete all five cuts - often the anterior cut is missed.

Use the Pin Puller to remove the Stabilization Pins from the Trochlear Cut Guide, and then remove the Trochlear Cut Guide, Broach Adaptor and Humeral Broach. Finish the bottom cut with an oscillating saw.



Tray 1 Top

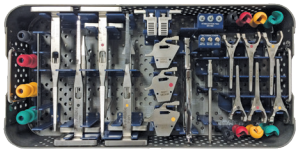
Pin Puller

Note: In situations where distal humeral landmarks are not present due to previous trauma or bony erosions, several different strategies can be used to obtain a reasonable approximation of appropriate humeral positioning:

1. If the proximal portion of the olecranon fossa is still present, it can be used for a landmark as the location of the proximal portion of the yoke of the humeral component.
2. Internal rotation of the humeral component 15 degrees relative to the flat posterior surface of the distal humerus approximates the correct rotational alignment.
3. If no distal humeral landmarks are present, appropriate positioning can be estimated by soft tissue tensioning with respect to the proximal ulna. This is better approximated with triceps-on approaches.
4. Appropriate size of the component can be estimated based on radiographic templating of the uninvolved contralateral elbow.
5. When distal humeral landmarks are not present, generally a linked component will be employed and sizing is not quite as important. Sizing can be based more on ulnar fit or intramedullary fit.

Step 7: Humeral Gusset Broaching

To prepare the humerus for the fins of the humeral component, use the Humeral Gusset Broach that matches the final Humeral Broach used (Small, Medium, or Large). Align the tip of the Gusset Broach into the canal, checking for correct alignment and rotation, with the correct RIGHT or LEFT visible. Use a mallet to insert the Humeral Gusset Broach until the F/E mark lines up with the natural F/E axis.



Tray 1 Top

Small Humeral Gusset Broach

Medium Humeral Gusset Broach

Large Humeral Gusset Broach

Step 8: Humeral Trial

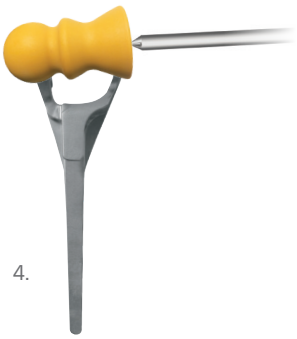
Select the appropriate side, size and length Trial Humeral Stem and corresponding Trial Humeral Spool. Place the capitellum of the Trial Humeral Spool on the left for a left trial stem and on the right for a right trial stem. An "M" is marked on the medial side and an "L" is marked on the lateral side. Insert the appropriate size Trial Humeral Screw from medial to lateral, and tighten using the 3.5mm Screwdriver on the 3Nm Torque Driver.

LEFT

1.

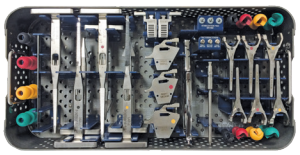
2.

3.



4.

Position the trial stem assembly in the humeral shaft and use the Impactor to seat the trial implant flush with the capitellum. Appropriate distal proximal and rotational positioning of the Trial Stem can be verified by ensuring the Humeral Screw of the trial component lines up with anteroinferior aspect of the medial epicondyle.



Tray 1 Top

Small Trial Humeral Spool

Medium Trial Humeral Spool

Large Trial Humeral Spool

Large+ Trial Humeral Spool

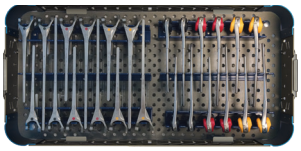
Right & Left

Small Trial Screw

Medium Trial Screw

Large Trial Screw

3.5mm Screwdriver



Tray 2 Bottom

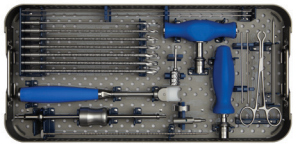
Small Trial Humeral Stem

Medium Trial Humeral Stem

Large Trial Humeral Stem

Right & Left, Standard, 150mm & 200mm (Tray 2 Bottom)

WARNING: The 3.5mm Screwdriver must only by used with the 3Nm Torque Driver. Deviation from this technique could result in screw or instrument breakage.



Tray 2 Top

3Nm Torque Driver

Impactor

Ulnar and Radial Head Preparation

There are two options for Ulnar Preparation:

Step 9a: Ulnar Preparation Option 1 – Ulnar Jig

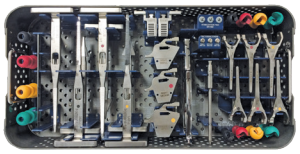
This option is used most commonly when proximal ulnar bonestock is preserved.

Select the correct Ulnar Jig, LEFT or RIGHT, and assemble by placing the Sizing Spool into the greater sigmoid notch of the ulna; the capitellar portion should align and articulate with the center of the radial head where available. Slide the post of the Ulnar Jig into the sizing spool. Tighten the clamp until the Ulnar Jig is secure.

Tip: The foot of the jig should sit on the flat portion of the olecranon to aid in stability and accuracy of the cut.

Caution: Be sure to irrigate or tap the bell saw during the cut to reduce heat build-up

Caution: Do not restart the bell saw in the jig if it doesn't move freely

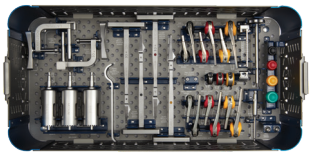

Tray 1 Top


Small Sizing Spool


Medium Sizing Spool


Large Sizing Spool


Large+ Sizing Spool


Tray 1 Bottom


Ulnar Jig: Right & Left

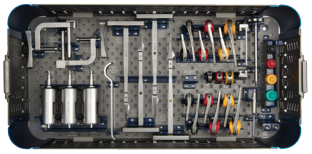
There are two points in the procedure in which the radial head can be resected.

If removing the radial head at this point in the procedure, use the cutting surface on the Ulnar Jig marked RADIAL HEAD to resect the radial head.

Note: The alternative option for radial head resection is described in the section titled Radial Head Resection - Option 2 (Pg. 15). If using this option and deciding not to resect the head at this point in the procedure, continue on to the steps detailed on the next page and resume preparation of the ulna using the Ulnar Jig.

Step 9a: Ulnar Preparation Option 1 – Ulnar Jig (Continued)

Select the correct Bellsaw size (Small, Medium, or Large) and attach to power. With the appropriate size Bellsaw, cut the ulna. Ensure the ulnar nerve is protected when making this cut. After the cut is made, remove the Ulnar Jig assembly and Bellsaw. If there is any additional bone on the ulna that needs to be removed, use the Barrel Reamer to refine this cut.



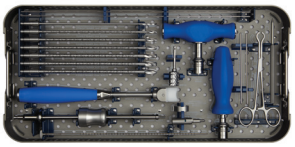
Tray 1 Bottom

Small Bellsaw

Medium Bellsaw

Large Bellsaw

Radial Head Protector



Tray 2 Top

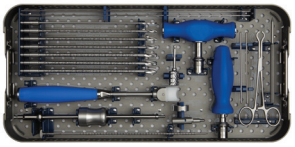
Barrel Reamer

Step 9b: Ulnar Preparation Option 2 – Barrel Reamer

Used in the setting of proximal ulnar bone loss.

Barrel Reamer:

Attach the Barrel Reamer to power and use it to shape the ulna into C-shape that will accommodate the appropriate Ulnar Trial. The Ulnar Trial can be used as a visual aid to help in appropriate ulnar preparation when utilizing this option.



Tray 2 Top

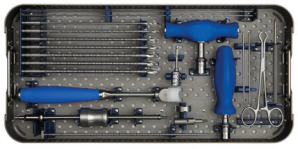
Barrel Reamer

Step 10: Initial Entry

Open up the ulnar canal using a burr at the base of the coronoid. If preferred, cannulated Flexible Reamers may be used to further open the canal prior to broaching and are recommended if using a revision stem. If the flexible reamers are used, be sure to use them sequentially to avoid potential perforation.

Ulnar Component	Reamer Size
Small	Up to 5mm
Medium	Up to 6mm
Large	Up to 7mm

Caution: Do not use the flexible reamers in the ulna without a guide wire to reduce the possibility of perforation.

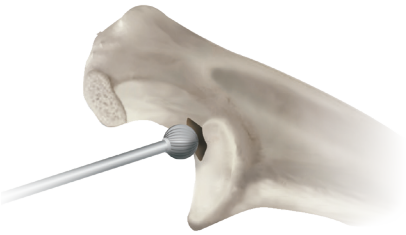


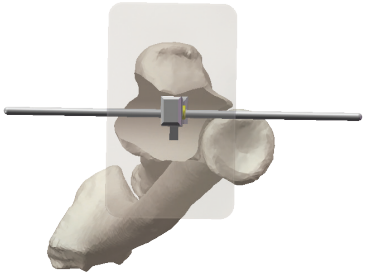
Tray 2 Top

Guide Wire

4mm Straight Reamer

5mm -10mm Flexible Reamers





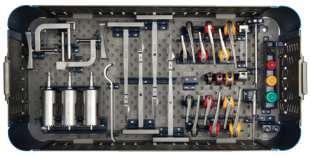
Step 11: Ulnar Broaching

Broach the ulnar canal beginning with the Starting Ulnar Broach and proceeding sequentially to the Broach sizes that match the selected ulnar component size. Insert the Ulnar Broach in the ulnar canal respecting the radial inclination of the proximal ulnar shaft. The Broach should be parallel to the flat posterior portion of the proximal ulna. The F/E Alignment Pin can be used to aid in alignment by inserting it through the medial/lateral hole in the Ulnar Broach.

Tip: Align the flat portion of the broach with the flat spot of the bone. Look from the top for version and the laser line for the depth.

Tip: Hold the trial stem up to the bone to determine how deep to broach.

Impact with a mallet and Broach until the apex of the fin is in contact with the bone.



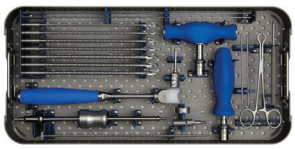
Tray 1 Bottom

Starting Ulnar Broach

Small Ulnar Broach

Medium Ulnar Broach

Large Ulnar Broach



Tray 2 Top

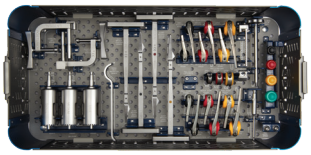
F/E Alignment Pin

Step 12: Ulnar Trial

Select the correct Trial Ulnar Stem and impact it using a mallet and the Impactor. Version is established by holding the spool in alignment with the radius. Use the barrel reamer to remove any osteophytes or other abnormalities that will cause misalignment of the axis.

Note: There is no Large+ ulnar component; use the Large if using Large+ radial and humeral components.

Tip: If there are challenges seating the trial, consider trialing with the short stem. If that seats, then additional diaphyseal reaming is needed. If the short stem does not work, then check that the broach has been completed sufficiently.



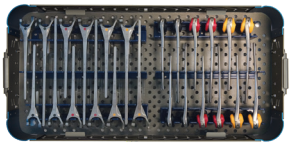
Tray 1 Bottom

Small
Trial Ulnar Stem

Medium
Trial Ulnar Stem

Large
Trial Ulnar Stem

Right & Left, Short, Standard, 125mm & 150mm

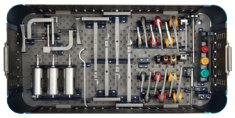


Tray 2 Bottom

Radial Head Resection Option 2

Note: If the radial head has already been resected, proceed to Step 13: Radial Preparation and Radial Trial.

With the Ulnar Stem Trial in place, insert the Radial Head Impactor (the Radial Head Impactor is also used in conjunction with the Trial Radial Stem to broach the radial canal) through the Radial Cut Guide Alignment Block and thread into the Ulnar Stem Trial. Insert the Radial Cut Guide into the Radial Cut Guide Alignment Block from the appropriate side and push it in until it touches bone. Use an oscillating saw to cut the radius using the surface marked "RADIAL CUT" as a guide. Remove the Radial Cut Guide, unscrew the Radial Head Impactor and remove the Radial Cut Guide Alignment Block.



Tray 1 Bottom

Radial Cut Guide Alignment Block

Radial Head Impactor

Radial Head Cut Guide

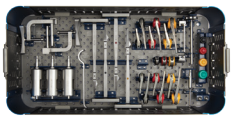
Step 13: Radial Preparation and Radial Trial

Caution: LATITUDE EV can be used with or without its radial head replacement component. The native radial head always needs to be resected prior to final implantation. The humeral and ulnar components must always be used in the procedure. The radial head component needs to be carefully considered in all cases, particularly when lateral joint load sharing needs to be reasonably recreated, such as in the case of unlinked arthroplasty.

Note: If the radial head component is not going to be implanted during the procedure, proceed to Step 14: Trial and Reduction, detailed on the next page.

Screw the Trial Radial Head Impactor to the Trial Radial Stem (Broach). Starting with the 5mm Trial Radial Stem, tap the handle until the collar of the Broach seats on the resected surface. If a large stem is desired, Broach next with the 6.5mm Broach.

Upon completion, unscrew the handle leaving the Broach seated in the canal. Using the same color code, select the appropriate size Trial Radial Head and snap onto the trial stem.



Tray 1 Bottom

Radial Head Impactor

Trial Radial Stems: 5mm & 6.5mm

Small Trial Radial Head

Medium Trial Radial Head

Large Trial Radial Head

Large+ Trial Radial Head

Trial, Reduction and Implant Assembly

Step 14: Trial and Reduction

The trial components can be placed unlinked or linked.

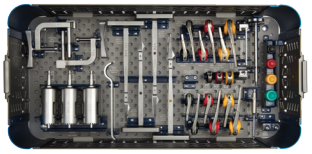
UNLINKED:

Reduce the Trial Humeral, ulnar and radial components. It is strongly recommended that the radial head component be carefully considered when leaving the prosthesis unlinked. Perform the initial trial reduction by placing the triceps in its anatomic position. The elbow should articulate through a full range of motion (ROM), testing for stability, articular tracking, axis of rotation, and ROM. Of particular concern is tracking of the prosthetic radial head to the capitellum. In general, for the elbow to be unlinked, lateral joint load sharing needs to be reasonably recreated. Radial capitellar articulation should be visualized through a flexion/extension arc and through supination/pronation to verify reasonable tracking. Additionally, there should be 10^0 of varus-valgus motion available through the elbow joint even in the presence of radial capitellar articulation. If there is less than this amount of valgus angulation possible, it indicates that the radial head component may be proud and thus, preventing normal varus-valgus freedom in the articulation. If the trial reduction is satisfactory, remove the trial components and prepare the elbow for the final implants. If the trial reduction is not satisfactory, check that the trial implants are correctly positioned and that no soft tissue impingement has occurred. Check for impingement of the coronoid process on the anterior flange of the humeral component in flexion and impingement of the olecranon process on the humeral component in extension, and resect as required. In case of an unstable elbow, use the trial cap to link the implant.

LINKED:

Assemble the Trial Ulnar Cap to the Trial Ulnar Stem and tighten the trial locking screw. Confirm appropriate component placement and perform another trial reduction. Perform the initial trial reduction by placing the triceps in its anatomic position. The elbow should articulate through a full ROM, testing for stability and axis of rotation. If the trial reduction is satisfactory, remove the trial components and prepare the elbow for the final implants. If the trial reduction is not satisfactory, check that the trial stems sit properly on the bone and that no soft tissue or boney impingement has occurred. Check for impingement of the coronoid process on the anterior flange of the humeral component in flexion and impingement of the olecranon process on the humeral component in extension, and resect as required.

If the Trial Radial Head has been utilized, check to make sure that the Trial Radial Head articulates congruently with the capitellum. If maltracking of the Trial Radial Head is evident, component positioning should be adjusted.



Tray 1 Bottom

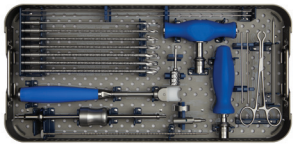
Small Trial Ulnar Cap

Medium Trial Ulnar Cap

Large Trial Ulnar Cap

Trial Ulnar Cap Screw

2.5mm Screwdriver



Tray 2 Top

3Nm Torque Driver

WARNING: The 2.5mm Screwdriver must only by used with the 3Nm Torque Driver. Deviation from this technique could result in screw or instrument breakage.

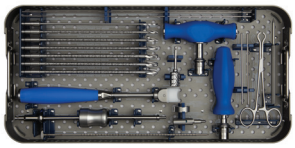
Step 15: Trial Stem Removal

Trial Radial Stems

To remove, screw radial head trial handle into screw hole of radial stem. Gently tap with mallet to extract.

Trial Ulnar Stems

Use the ulnar stem extractor tool.



Tray 2 Top

Small
Trial Ulnar Stem

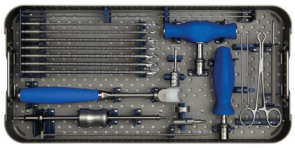
Medium
Trial Ulnar Stem

Large
Trial Ulnar Stem

Right & Left, Short, Standard, 125mm & 150mm

Trial Humeral Stems

Grasp the humeral trial spool with the humeral extractor clamp. Gently tap retrograde and remove the component.



Tray 2 Top

Small Trial
Humeral Stem

Medium Trial
Humeral Stem

Large Trial
Humeral Stem

Right & Left, Standard, 150mm & 200mm (Tray 2 Bottom)

Step 16: Final Implant Assembly

After all trial components have been removed, lavage and dry all medullary canals.

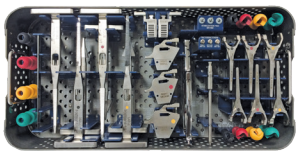
Cement Restrictors should be used for the humerus and ulna:

EBO101 Diameter range of 8-15mm
EBO102 Diameter range of 5-8mm

Assembly of Final Components:

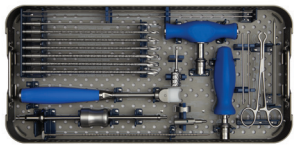
Assemble the Humeral Stem (side and size) to the appropriate Humeral Spool (side and size). Firmly tighten the implant Humeral Screw (cannulated) with the 3.5mm Hex Screwdriver using the 3Nm Torque Driver.

WARNING: The 3.5mm Screwdriver must only by used with the 3Nm Torque Driver. Deviation from this technique could result in screw or instrument breakage.



Tray 1 Top

3.5mm Screwdriver



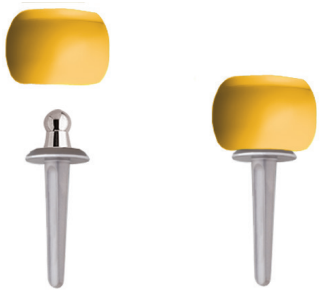
Tray 2 Top

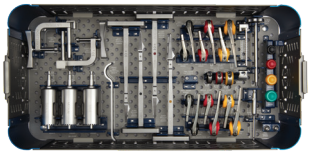
3Nm Torque Driver

Note: If the radial head component is not going to be used, proceed to the next page and follow the steps for the cement technique and the bone graft (autograft) resected from the distal humerus.

Assemble the radial components by snapping the Trial Radial Head onto its stem prior to implantation.

Note: Do not remove and reapply head on stem as repeated assembly reduces the disassembly force.





Tray 1 Bottom

Small Trial Radial Head

Medium Trial Radial Head

Large Trial Radial Head

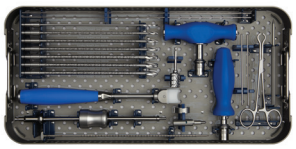
Large+ Trial Radial Head

Cement Technique and Bone Graft

Using a cement gun, antibiotic laden bone cement is injected retrograde into the humeral, ulnar and radial canals. The components are placed into position, removing all excess cement, particularly around the bipolar radial head component. Depending on preference, the radial and ulnar components can be cemented first and then the humerus or all three can be cemented simultaneously.

Note: Avoid movement of the elbow while cement is setting. Torque may reduce alignment accuracy.

Tip: Cement both the Radial Head and Ulnar Stem at the same time. To ensure that both components are seated at the same level, use the Trial Humeral Stem and Spool as a visual guide to correct insertion.



Tray 2 Top

Cement Restrictor Handle

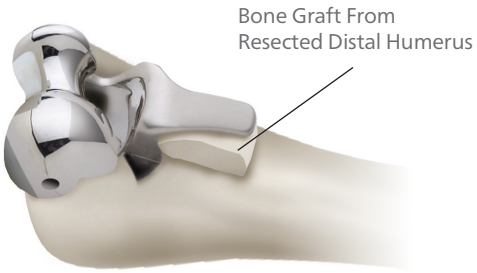
Cement each component according to the technique described. Remove any excess cement from around the components, avoiding cement in the bipolar articulation and the ulnar component in particular. Reduce the elbow to ensure correct alignment of the components to each other and wait until cement has set.

Remove the Trial Radial Head component and clear any residual cement from the bipolar articulation. Assemble the radial components by snapping the radial head onto its stem.

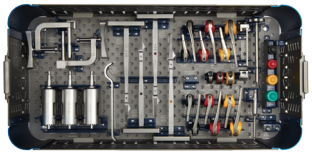
Note: Do not remove and reapply head on stem as repeated assembly reduces the disassembly force.

Cement Technique and Bone Graft (Continued)

Insert a cancellous bone fragment from the resected bone of the distal humerus (autograft) in between the humeral shaft and the anterior flange of the humeral component. The bone graft (autograft) is wedged firmly in place.

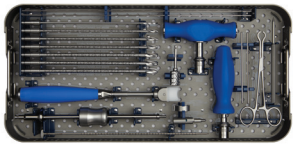


Leave protecting Ulnar Screw in its component to prevent cement from coming in contact with the threads during cementation. After the cement has completely set, remove the protecting Ulnar Screw with the 2.5mm Hex Screwdriver with the 3Nm torque handle and discard. Reduce humeral and ulnar components and flex to approximately 140°. If implanting a linked prosthesis, insert Ulnar Cap into the Ulnar Stem. Tighten the screw until the torque release is reached. Using the tab Bending Tool and a mallet, bend the cap tab over the screw.



Tray 1 Bottom

2.5mm Screwdriver



Tray 2 Top

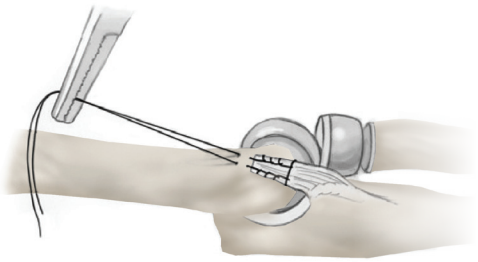
3Nm Torque Driver

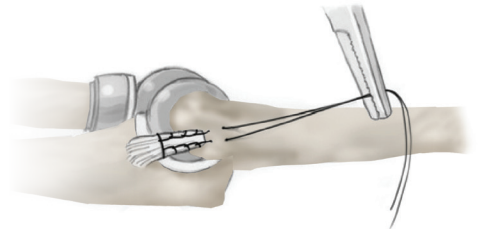
WARNING: The 2.5mm Screwdriver must only by used with the 3Nm Torque Driver. Deviation from this technique could result in screw or instrument breakage.

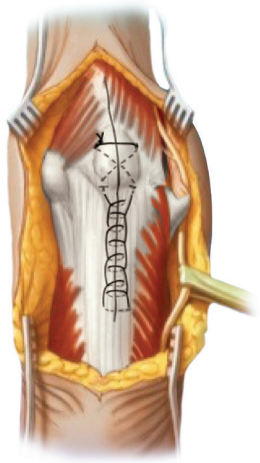
Closure

The tourniquet is deflated and hemostasis is secured. The LATITUDE EV™ Total Elbow Arthroplasty system has a cannulated humeral bolt allowing for repair of the collateral ligaments and common flexor/extensor origins to the implant and the adjacent epicondyle if desired. #2 FORCE FIBER™ sutures are placed into the medial and lateral collateral ligaments. A suture passer is used to pass these sutures across the axis bolt of the distal humerus. With the elbow reduced the end of these sutures are then passed through the contralateral collateral ligament as well as the common flexor and extensor origins and securely tied. The end of these sutures are left long and then passed over the posterior aspect of the olecranon to serve as a circumferential suture to prevent elbow subluxation or dislocation of an Unlinked implant in the post-operative period.

If the triceps had been detached it should be carefully repaired using non-absorbable locking Krackow sutures placed through drill holes in the ulna. Oblique and transverse drill holes are employed. Care should be taken to ensure that any knots are buried such that they will not be irritating to the patient. The ulnar nerve is secured in the anterior subcutaneous pouch using a #1 absorbable suture approximating the subcutaneous fat to the flexor pronator origin. The wound is closed in layers over a drain.







Postoperative Recommendation

UNLINKED TEA:

The elbow is immobilized at 60° in a well-padded splint for 2 to 10 days depending on skin quality. Active flexion and gravity assisted extension is performed with forearm in neutral rotation.

Active extension is avoided for 6 weeks to protect the triceps repair. If a triceps sparing approach was used, active extension is permitted as soon as the wound is stable. Prosupination is performed with the elbow in flexion. A collar and cuff or sling is used between exercises for the first 6 weeks. Extension splinting at night may be used to assist in regaining elbow extension after four weeks. Light strengthening is initiated 10 weeks postoperatively.

LINKED TEA:

The elbow is immobilized in full extension with a well-padded splint for 2 to 3 days depending on skin quality. Active flexion and prosupination is performed without restriction. Gravity assisted extension is used to protect the triceps repair for 6 weeks. If a triceps sparing approach was used, active extension is permitted immediately postoperatively. Light strengthening is initiated 10 weeks postoperatively.

Night extension splinting is initiated immediately postoperatively to maximize elbow extension.

Ulnar Bushing Revision Technique

Step 1

Remove the mantle of cement surrounding the ulnar polyethylene using a fine tipped burr.

Step 2

Locate the position of the Assembly Pin from the medial side.

Step 3

Using a burr, remove the polyethylene to gain full access to the pin. Grasp the pin with heavy pliers and remove.

Step 4

If the pin does not come out, use a tapered device, such as the tab Bending Tool, and a hammer, and tap from the lateral side to remove the pin.

Step 5

Once the pin has been removed, the ulnar polyethylene can be slid off the Ulnar Stem. It can be helpful to use a tapered tool and a hammer to assist.

Step 6

Position the new polyethylene bushing on the Ulnar Stem and rotate it on the slide channel until it is fully engaged.

Step 7

Assemble the Ulnar Cap to the Ulnar Stem after the polyethylene bushing is replaced, and bend the tab over the screw using the tab bender and a mallet. The Ulnar Cap secures the bushing on the Ulnar Stem.

Generational Compatibility and Incompatibilities

LATITUDE EV Total Elbow Arthroplasty Implant History:

Generation	Year Available	Implant Changes
1	2001-2002	
2	2003-Nov 2007	Redesigned Ulnar Stem and Cap
	Nov 2007-July 2012	Redesigned Humeral Stem and Spool
3 LATITUDE EV	July 2012	New Humeral and Ulnar Stems; New Plasma Coated Humeral Stems; Humeral Spools Centered only

When preparing for Revision Surgeries using the LATITUDE EV Total Elbow Arthroplasty system, it is important to take note of the original surgical date as well as the components used in order to ensure appropriate components are available. There are several known mating conflicts that can be avoided with adequate preparation.

LATITUDE EV Total Elbow Arthroplasty Revision Incompatibilities*

Mating Conflict	Component	Historic Item Number Reference	Options
LATITUDE EV Humeral Spool with Generation 1 Humeral Stem	Humeral Spool	**Generation 1** Humeral Stem: DKY-001, 002, 003, 006, 007, 008 Spool: DKY-011, 012, 013, 014, 016,017, 018, 019, 021, 022, 023, 024, 026,027, 028,029, 031,032, 033, 034, 036, 037, 038	• Revise the humeral stem with a LATITUDE EV Humeral Stem
LATITUDE EV Ulnar Cap with Generation 1 Ulnar components	Ulnar Cap	**Generation 1** Ulnar Stem: DKY039, 041, 042, 043, 046, 047,048 Cap: DKY051, 052, 053	• Revise the Ulnar Stem and Cap with LATITUDE EV components
LATITUDE EV Ulnar Bushing with Generation 1 Ulnar components	Ulnar Bushing	**Generation 1** Ulnar Stem: DKY-041,042,043,046,047,048 Cap: DKY-051,052,053	• Revise all Ulnar Stem and Cap with LATITUDE EV components

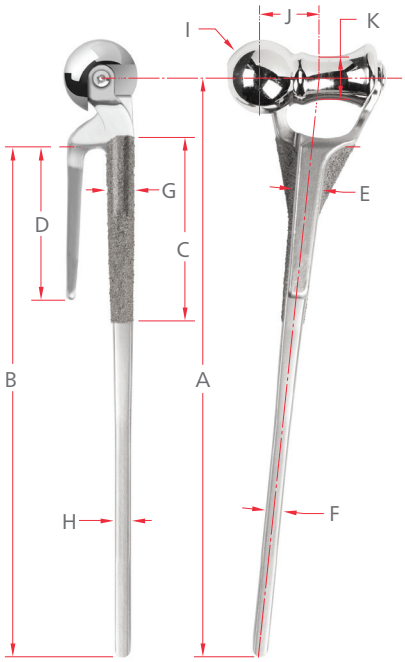
*All other revision combinations are compatible.

Product Dimensions

Humeral Stem & Spool Dimensions (In Millimeters)

Stems

Item	Description	Length	Small	Medium	Large
A	Stem Length *From Flexion/Extension Axis*	Standard	90	97	104
		150	150	150	150
		200	200	200	200
B	Stem Length *From Flange*	Standard	72	77	83
		150	132	130	129
		200	182	180	179
C	Plasma Spray Length	Standard	28	28	28
		150	42	42	42
		200	42	42	42
D	Flange Length	Standard	18	18	18
		150	45	45	45
		200	45	45	45
E	Stem Width *Medial/Lateral*	All	7.7	8.2	8.7
F	Stem Width *Distal*	All	4.4	4.7	5
G	Stem Depth *Anterior/Posterior*	All	6.5	6.7	7
H	Stem Depth *Distal*	All	4	4	4



Spools

Item	Description	Small	Medium	Large	Large +
I	Condyle Diameter	Ø19	Ø21	Ø23	Ø23
J	Trochlea/Condyle Distance	15.5	17.5	19.5	21.5
K	Trochlea Diameter	Ø10	Ø11	Ø12.5	Ø12.5

Using the corresponding size broach will create approximately .50mm cement mantle on the anterior, lateral and medial surfaces of the plasma spray coated areas. Downsizing one broach size will create a line to line fit on the anterior, posterior, lateral and medial surfaces of the plasma spray coated areas.

The Humeral Stem is made from Cobalt-Chromium alloy according to ASTM F-799 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539) or Cobalt-Chromium Molybdenum Alloy according to ISO 5832-7 Implants for Surgery-Metallic Materials-Part 7 (LATITUDE™). The LATITUDE EV Humeral Stem is coated according to ASTM F1580 Standard Specification for Titanium and Titanium-6Aluminum-4Vanadium Alloy Powders for Coatings of Surgical Implants.

The Humeral Spool is made of Chromium-Cobalt alloy (CrCo) according to ISO standard 5832-7 or ISO 5832-12 and of polyetheretherketone (PEEK-OPTIMA polymer) according to standard ASTM F 2026.

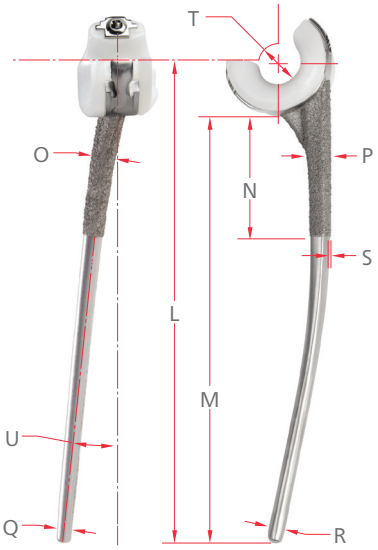
The Humeral Screw is made of stainless steel according to ISO 5832-9, ASTM F1586 or ASTM F1314.

Product Dimensions

Ulnar Stem Dimensions (In Millimeters)

Stems

Item	Description	Length	Small	Medium	Large
L	Stem Length *From Flexion/Extension Axis*	Short	41	47	52
		Standard	70	75	80
		125	125	125	125
		150	150	150	150
M	Stem Length *From Gusset*	Short	27	33	37
		Standard	56	61	65
		125	111	111	110
		150	136	136	135
N	Plasma Spray Length	Short	14	14	14
		Standard	20	20	20
		125	31	31	31
		150	31	31	31
O	Stem Width *Medial/Lateral*	All	6.2	6.7	7.3
P	Stem Depth *Anterior/Posterior*	All	6.2	6.6	7.2
Q	Tip Width *Medial/Lateral*	All	4.3	4.4	4.4
R	Tip Depth *Anterior/Posterior*	All	4.3	4.4	4.4
S	Plasma Spray Thickness	All	.3	.3	.3
T	Trochlea Notch Diameter	All	Ø10	Ø11.5	Ø13
U	Centerline Offset Angle	All	7°	7°	8°



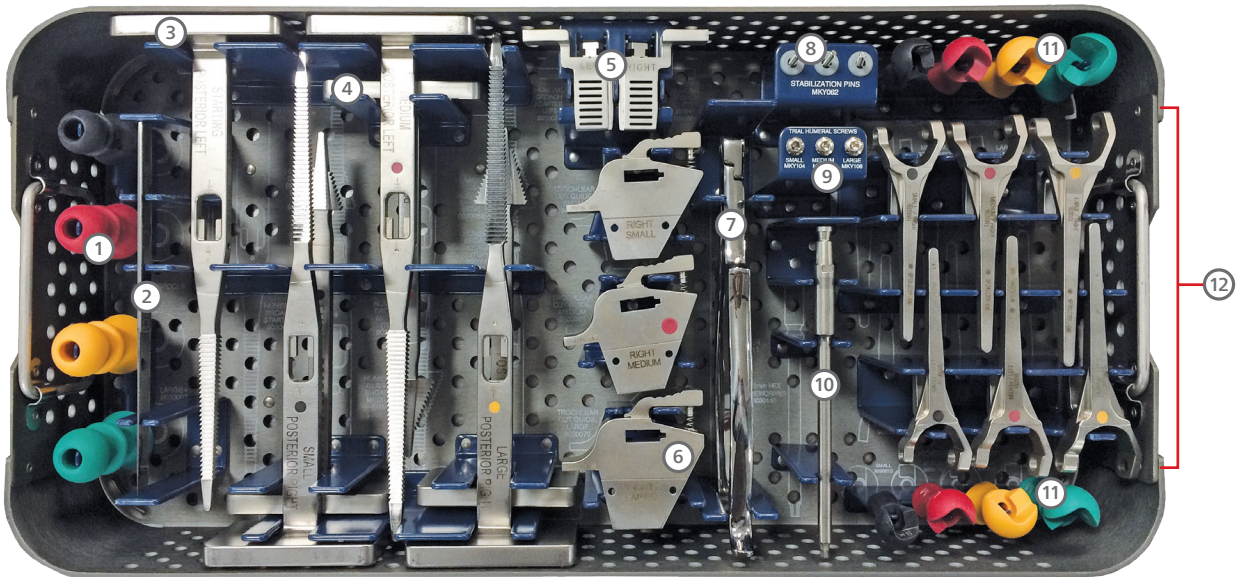
Using the corresponding size broach will create approximately .50mm cement mantle on the anterior, posterior, lateral and medial surfaces of the plasma spray coated areas.

The Ulnar Stem is made of Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants according to ASTM F-799 Standard Specification (UNS R31537, R31538, R31539) or, Cobalt-Chromium Molybdenum Alloy according to ISO 5832-7 Implants for Surgery-Metallic Materials- Part 7 and ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2. The LATITUDE EV Ulnar Stem is coated according to ASTM F1580 Standard Specification for Titanium and Titanium-6Aluminum-4Vanadium Alloy Powders for Coatings of Surgical Implants.

The Radial Head and Stem are made of Chromium-Cobalt alloy (CrCo) according to ISO standard 5832-7 or ISO standard 5832-12 and ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2.

Instrumentation

Tray 1 Top



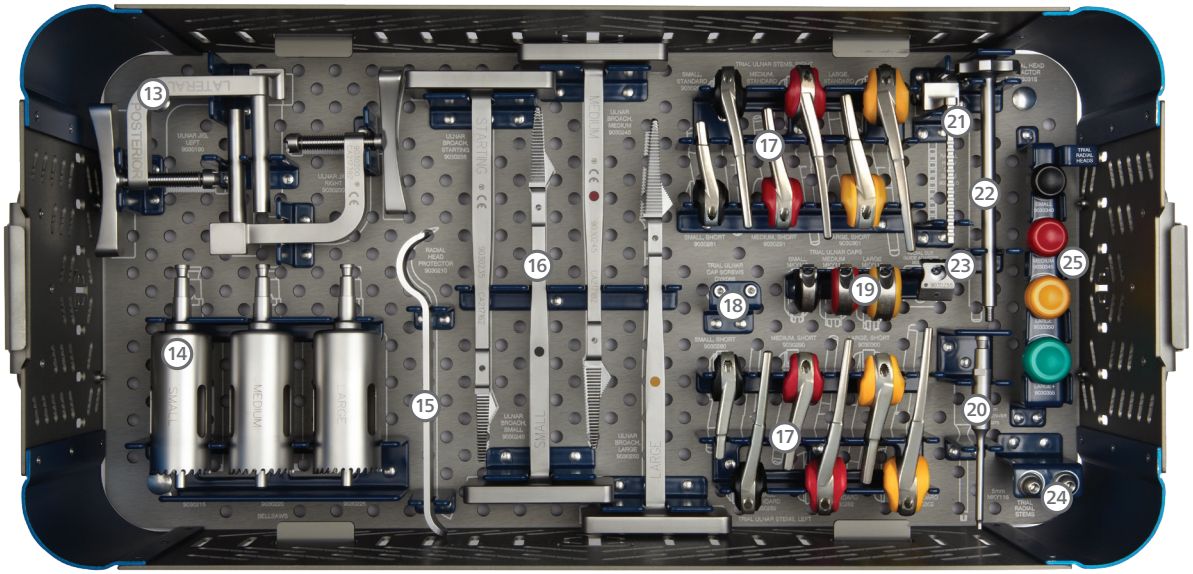
Tray 1 Top

Item	Instrument	Ref #	Quantity
1	Small Sizing Spool	9030001	1
	Medium Sizing Spool	9030003	1
	Large Sizing Spool	9030005	1
	Large+ Sizing Spool	9030007	1
2	Osteotome	MDU500	1
3	Humeral Broach, Starting Size	9030035	1
	Humeral Broach, Small Size	9030040	1
	Humeral Broach, Medium Size	9030045	1
	Humeral Broach, Large Size	9030050	1
4	Humeral Gusset Broach, Small	9030056	1
	Humeral Gusset Broach, Medium	9030057	1
	Humeral Gusset Broach, Large	9030058	1
5	Humeral Broach Adapter Left	9030030	1
	Humeral Broach Adapter Right	9030031	1
6	Trochlear Guide Small	9030060	1
	Trochlear Guide Medium	9030065	1
	Trochlear Guide Large	9030070	1
7	Pin Puller	MCI511	1
8	Stabilization Pin	MKY062	3
9	Trial Humeral Screw, Small	MKY104	1
	Trial Humeral Screw, Medium	MKY105	1
	Trial Humeral Screw, Large	MKY106	1
10	3.5mm Screwdriver	9030110	1

Tray 1 Top

Item	Instrument	Ref #	Quantity
11	Trial Humeral Spool, Small Left	9030010	1
	Trial Humeral Spool, Small Right	9030011	1
	Trial Humeral Spool, Medium Left	9030012	1
	Trial Humeral Spool, Medium Right	9030013	1
	Trial Humeral Spool, Large left	9030014	1
	Trial Humeral Spool, Large Right	9030015	1
	Trial Humeral Spool, Large+ Left	9030016	1
	Trial Humeral Spool, Large+ Right	9030017	1
12	Trial Humeral Stem, Standard Small, Left	9030080	1
	Trial Humeral Stem, Standard Small, Right	9030081	1
	Trial Humeral Stem, Standard Medium, Left	9030090	1
	Trial Humeral Stem, Standard Medium, Right	9030091	1
	Trial Humeral Stem, Standard Large, Left	9030100	1
	Trial Humeral Stem, Standard Large, Right	9030101	1

Tray 1 Bottom



Tray 1 Bottom

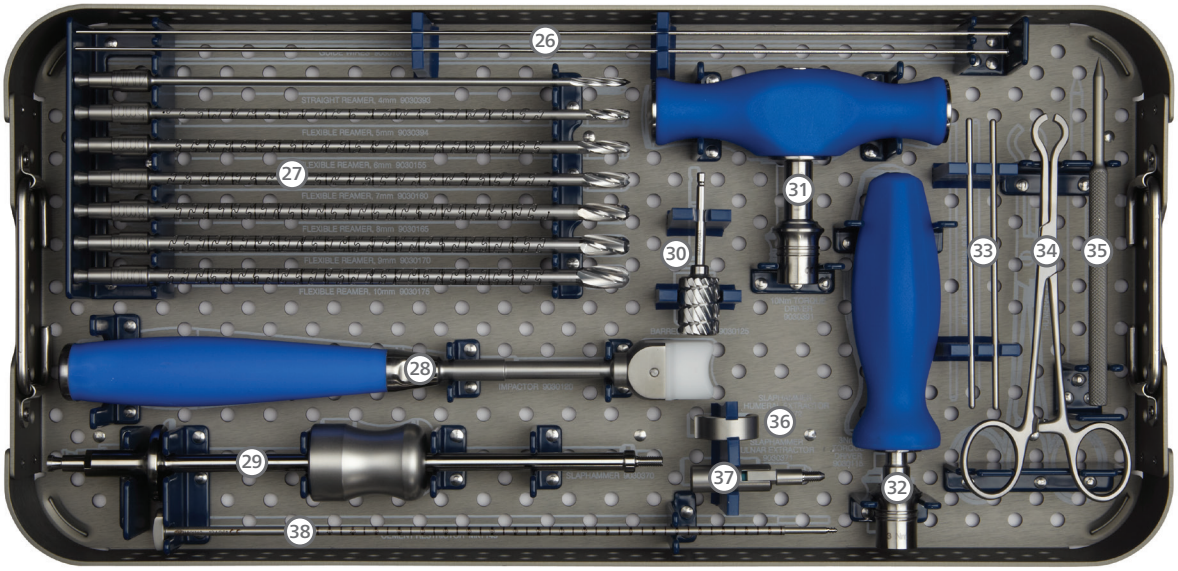
Item	Instrument	Ref #	Quantity
13	Ulnar Jig, Left	9030190	1
	Ulnar Jig, Right	9030200	1
14	Small Bellsaw	9030215	1
	Medium Bellsaw	9030220	1
	Large Bellsaw	9030225	1
15	Radial Head Protector	9030210	1
16	Ulnar Broach, Starting	9030235	1
	Ulnar Broach, Small	9030240	1
	Ulnar Broach, Medium	9030245	1
	Ulnar Broach, Large	9030250	1
17	Trial Ulnar Stem, Short Small, Left	9030280	1
	Trial Ulnar Stem, Short Small, Right	9030281	1
	Trial Ulnar Stem, Standard Small, Left	9030282	1
	Trial Ulnar Stem, Standard Small, Right	9030283	1
	Trial Ulnar Stem, Short Medium, Left	9030290	1
	Trial Ulnar Stem, Short Medium, Right	9030291	1
	Trial Ulnar Stem, Standard Medium, Left	9030292	1
	Trial Ulnar Stem, Standard Medium, Right	9030293	1
	Trial Ulnar Stem, Short Large, Left	9030300	1
	Trial Ulnar Stem, Short Large, Right	9030301	1
	Trial Ulnar Stem, Standard Large, Left	9030302	1
	Trial Ulnar Stem, Standard Large, Right	9030303	1

Tray 1 Bottom

Item	Instrument	Ref #	Quantity
18	Ulnar Cap Screw	DKY066	2
19	Trial Ulnar Cap, Small	MKY113	1
	Trial Ulnar Cap, Medium	MKY114	1
	Trial Ulnar Cap, Large	MKY115	1
20	2.5mm Screwdriver	9030375	1
21	Radial Head Cut Guide	9030310	1
22	Radial Head Impactor	9030315	1
23	Radial Cut Guide Alignment Block	9030255	1
24	Trial Radial Stem, 5mm	MKY116	1
	Trial Radial Stem, 6.5mm	MKY117	1
25	Trial Radial Head, Small	9030340	1
	Trial Radial Head, Medium	9030345	1
	Trial Radial Head, Large	9030350	1
	Trial Radial Head, Large +	9030355	1

Instrumentation

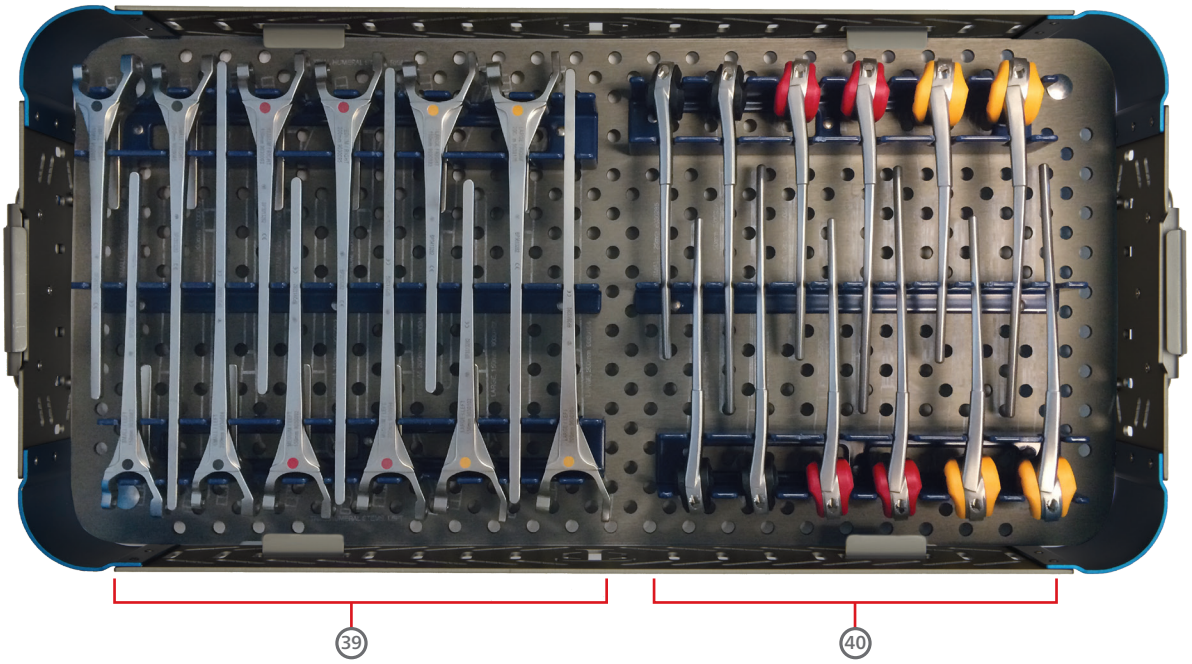
Tray 2 Top



Tray 2 Top

Item	Instrument	Ref #	Quantity
26	Guide Wire	9030150	2
27	Straight Reamer, 4mm	9030393	1
	Flexible Reamer, 5mm	9030394	1
	Flexible Reamer, 6mm	9030155	1
	Flexible Reamer, 7mm	9030160	1
	Flexible Reamer, 8mm	9030165	1
	Flexible Reamer, 9mm	9030170	1
	Flexible Reamer, 10mm	9030175	1
28	Impactor	9030120	1
29	Slaphammer	9030370	1
30	Barrel Reamer	9030125	1
31	10Nm Torque Driver	9030391	1
32	3Nm Torque Driver	9030115	1
33	F/E Alignment Pin	9030135	2
34	Humeral Extractor	MKY147	1
35	Ulnar Cap Bending Tool	MKY124	1
36	Slaphammer Humeral Extractor	9030372	1
37	Slaphammer Ulnar Extractor	9030371	1
38	Cement Restrictor Handle	MKY149	1

Tray 2 Bottom



Tray 2 Bottom

Item	Instrument	Ref #	Quantity
39	Trial Humeral Stem, 150mm Small, Left	9030082	1
	Trial Humeral Revision Stem, 150mm Small, Right	9030083	1
	Trial Humeral Revision Stem, 200mm Small, Left	9030084	1
	Trial Humeral Revision Stem, 200mm Small, Right	9030085	1
	Trial Humeral Revision Stem, 150mm Medium, Left	9030092	1
	Trial Humeral Revision Stem, 150mm Medium, Right	9030093	1
	Trial Humeral Revision Stem, 200mm Medium, Left	9030094	1
	Trial Humeral Revision Stem, 200mm Medium, Right	9030095	1
	Trial Humeral Revision Stem, 150mm Large, Left	9030102	1
	Trial Humeral Revision Stem, 150mm Large, Right	9030103	1
	Trial Humeral Revision Stem, 200mm Large, Left	9030104	1
	Trial Humeral Revision Stem, 200mm Large, Right	9030105	1
40	Trial Ulnar Revision Stem, 125mm Small, Left	9030284	1
	Trial Ulnar Revision Stem, 125mm Small, Right	9030285	1

Tray 2 Bottom

Item	Instrument	Ref #	Quantity
40	Trial Ulnar Revision Stem 150mm Small, Left	9030286	1
	Trial Ulnar Revision Stem 150mm Small, Right	9030287	1
	Trial Ulnar Revision Stem, 125mm Medium, Left	9030294	1
	Trial Ulnar Revision Stem, 125mm Medium, Right	9030295	1
	Trial Ulnar Revision Stem, 150mm Medium, Left	9030296	1
	Trial Ulnar Revision Stem, 150mm Medium, Right	9030297	1
	Trial Ulnar Revision Stem, 125mm Large, Left	9030304	1
	Trial Ulnar Revision Stem, 125mm Large, Right	9030305	1
	Trial Ulnar Revision Stem, 150mm Large, Left	9030306	1
	Trial Ulnar Revision Stem, 150mm Large, Right	9030307	1

Tray Ordering			
	LATITUDE™ Tray Lid	9030414	1
	LATITUDE™ Instrument Set Kit 1	9030421	1
	LATITUDE™ Instrument Set Kit 2	9030422	1

Implant Ordering Information

Humeral Spools	
DKY211	Small Right
DKY212	Small Left
DKY213	Medium Right
DKY214	Medium Left
DKY215	Large Right
DKY216	Large Left
DKY217	Large+ Right
DKY218	Large+ Left

Humeral Stems	
0030302	Small Standard Right
0030303	Small Standard Left
0030402	Medium Standard Right
0030403	Medium Standard Left
0030502	Large Standard Right
0030503	Large Standard Left
0030312	Small 150mm Right
0030313	Small 150mm Left
0030412	Medium 150mm Right
0030413	Medium 150mm Left
0030512	Large 150mm Right
0030513	Large 150mm Left
0030322	Small 200mm Right
0030323	Small 200mm Left
0030422	Medium 200mm Right
0030423	Medium 200mm Left
0030522	Large 200mm Right
0030523	Large 200mm Left

Ulnar Stems	
0030010	Small Short Right
0030011	Small Short Left
0030110	Medium Short Right
0030111	Medium Short Left
0030210	Large Short Right
0030211	Large Short Left
0030020	Small Standard Right
0030021	Small Standard Left
0030120	Medium Standard Right
0030121	Medium Standard Left
0030220	Large Standard Right
0030221	Large Standard Left
0030030	Small 125mm Right
0030031	Small 125mm Left
0030130	Medium 125mm Right
0030131	Medium 125mm Left
0030230	Large 125mm Right
0030231	Large 125mm Left
0030040	Small 150mm Right
0030041	Small 150mm Left
0030140	Medium 150mm Right
0030141	Medium 150mm Left
0030240	Large 150mm Right
0030241	Large 150mm Left

Ulnar Caps	
DKY067	Small
DKY068	Medium
DKY069	Large

Radial Heads and Stems	
DKY056	Small Head
DKY057	Medium Head
DKY058	Large Head
DKY059	Large+ Head
DKY061	5.0mm Stem
DKY062	6.5mm Stem

Cement Restrictors	
EBO101	Cement Restrictor (Diameter Range 8-15mm)
EBO102	Cement Restrictor (Diameter Range 5-8mm)

Single Use Items	
DKY090	Single Use Suture Passer
DWD060	3mm Drill Bit

LATITUDE EV Total Elbow Arthroplasty has been designed in conjunction with:
Graham King, MD (University of Western Ontario); Shawn O'Driscoll, MD, PhD (Mayo Foundation); Ken Yamaguchi, MD (Washington University)

Notes

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