Discovery™
Elbow System

SURGICAL TECHNIQUE

Lima Corporate
Orthopaedic motion

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figure 1

figure 2

POSITIONING AND INCISION

Place the patient in a supine or lateral position. Lay the affected arm across the patient's chest to give access to the posterior aspect of the joint. Towels may be placed under the scapula to elevate the operative site. Drape the arm free to expose the posterior elbow and apply a tourniquet (sterile or non-sterile per surgeon preference).

Make a 12–15cm longitudinal incision slightly lateral to the medial epicondyle and just medial to the tip of the olecranon (Figure 1). Identify the ulnar nerve and decompress the cubital tunnel. Mobilize and carefully control the nerve along the medial/anterior border of the skin incision. Excise the intermuscular septum to ensure proper transposition of the nerve. Pay careful attention to the location of the ulnar nerve throughout the entire procedure (Figure 2). Eventual handling of the nerve should be individualized. The developing surgeons advocate anterior transposition.

This brochure is presented to demonstrate the surgical technique and postoperative rehab protocol of Hill Hastings, II, M.D. and Thomas J. Graham, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.

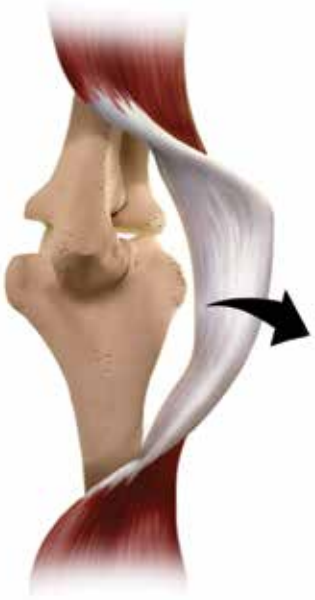


figure 3

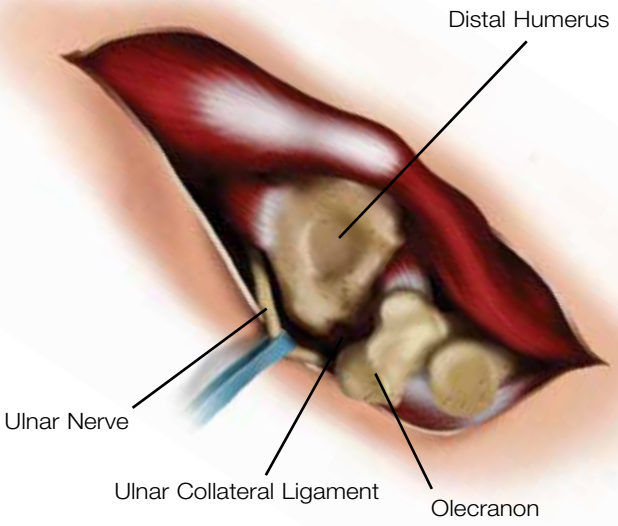


figure 4

TRICEPS-OFF APPROACH

Make an incision in the fascia over the ulnar head of the flexor carpi ulnaris muscle from the cubital tunnel out to a point on the ulnar shaft 7–10cm distal to the olecranon. Elevate the fascia over to the lateral subcutaneous border of the ulna. After anterior transposition of the ulnar nerve, carry sharp scalpel dissection down to the humerus, posterior to the intermuscular septum. Elevate the triceps proximally from the humerus with a periosteal elevator and distally from the olecranon fossa with a scalpel. Sharply elevate the triceps fibers of attachment to the ulna and mark with a 3-0 braided polyester suture to facilitate later repair. With elbow flexion, expose the joint.

Subperiosteal release of the lateral collateral ligament origin from the humerus and anterior capsulectomy provides additional exposure by allowing further flexion and supination of the forearm from the humerus (Figure 3). Attempt to preserve the integrity of the ulnar collateral ligament. However, severe elbow contractures may require proximal release of its origin for enhanced exposure.

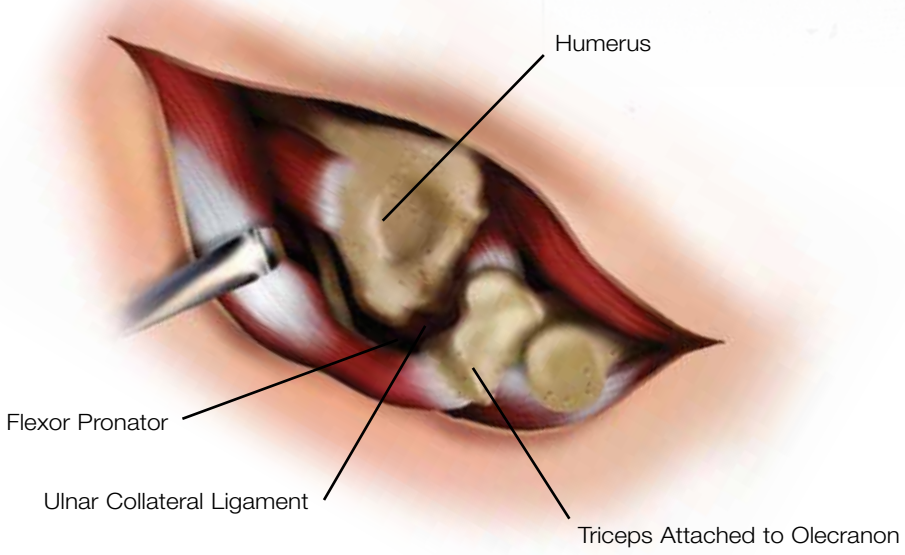


Figure 5

TRICEPS ON APPROACH

Make an incision on the medial and lateral sides of the triceps. Extend the incision distally to the ulna. On the lateral side, extend the dissection between the anconeus and the triceps. Completely detach the flexor-pronator and ulnar collateral ligament origins from the medial epicondyle and condyle. Similarly detach the extensor-supinator and lateral collateral ligament origins on the lateral side. In the case of a distal humeral fracture, excise the fracture condyles. “Button-hole” the distal humerus lateral to the triceps. This exposure allows for easy visualization of the humerus. However, the coverage of the triceps over the proximal ulna compromises visualization of the ulna.

Excise the entire olecranon tip and proximal portion of radial head, deep to the point of triceps attachment. Rotate the forearm into pronation to expose the proximal ulna articular surface.

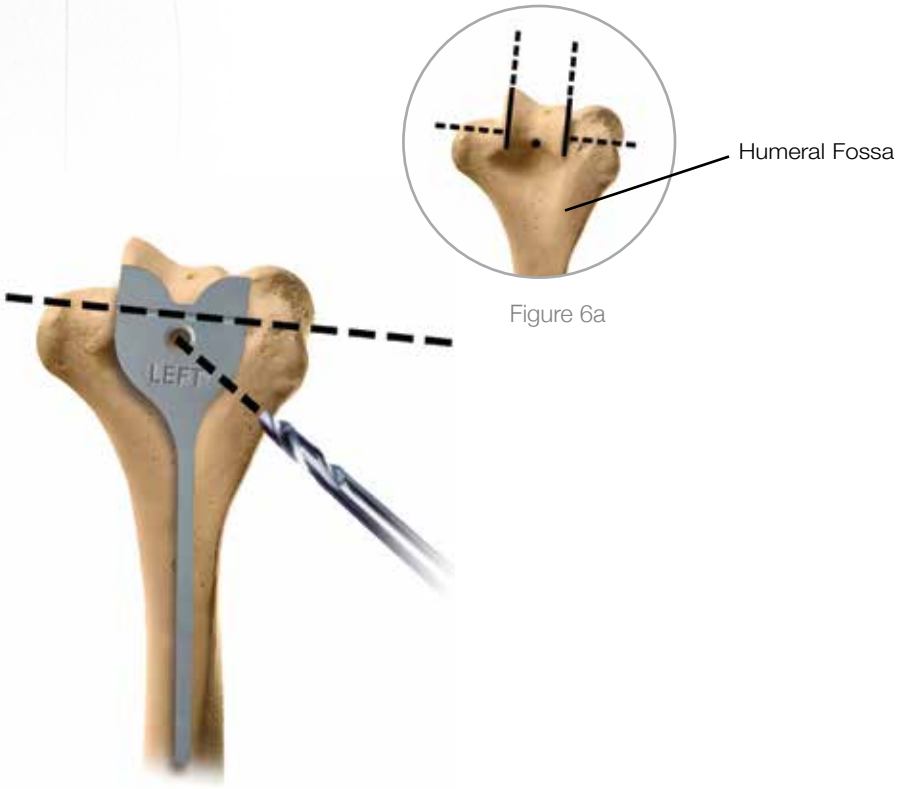


Figure 6a

Figure 6

EXTRAMEDULLARY RESECTION METHOD

Position the external fossa guide over the distal humerus to identify the location for intercondylar resection. Align the medial border of the guide with the medial extent of the trochlea while aligning the proximal stem over the midline of the humeral shaft (Figure 6).

Place a drill bit through the hole in the fossa guide and into the humeral fossa, perpendicular to the slightly internally rotated plane of the flexion-extension axis. With the drill bit in place, mark the humerus on the medial and lateral sides of the guide using electrocautery (Figure 6a).

Figure 9a

Figure 7

Figure 8

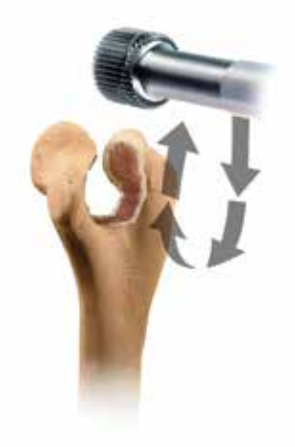


Figure 9

Insert a 5-step fossa reamer into the drill hole in the olecranon fossa (Figure 7). Ream until outermost teeth contact the humeral fossa. Use a saw to cut distal to the outermost circular groove made by the reamer to remove the remains of the trochlea along the previously marked lines (Figure 8).

Remove the trochlea and use the barrel reamer to round out the proximal part of the U-shaped area of resection (Figure 9 and 9a).

Note: *The barrel reamer should be spinning clockwise prior to contact with the bone to prevent jumping and the potential for bone chipping.*

DISCOVERY™ ELBOW SYSTEM
Extramedullary Resection Method

Figure 10

Figure 11

Figure 12

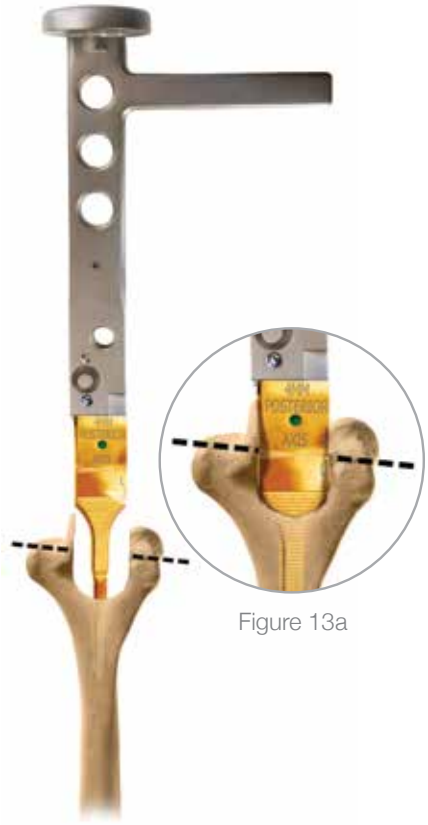


Figure 13a

Figure 13

Use a high speed bur and the starter awl to gain access into the humeral canal at the proximal part of the olecranon fossa with the opening enlarged to 4mm (Figure 10). Using the rasp handle, insert the 3mm proximal starter rasp with the posterior curve of the rasp matching the posterior bow of the humerus (Figure 11).

Note: *On the proximal area of the rasp, "P" faces posterior and "A" faces anterior. Rasp the humerus with progressively larger rasps until cortical resistance is met. At minimum, the 4mm rasp must be used to fit the smallest humeral implant into the canal. Use a mallet to impact and disimpact the rasps until the teeth of the rasp disappear into the canal (Figure 12). If the rasp will not advance, choose the implant based on the last fully seated rasp.*

Choose one of the three color coded distal humeral broaches corresponding to the size of the last proximal humeral rasp used.

Note: *A green dot is present on the 4 x 100 proximal rasp. Similarly, a green dot can be found on the 4mm distal broach. This color coding allows for easier recognition of the proper broach to use.*

Insert the rasp into the canal with the engraving marks positioned posteriorly until the respective left or right axis line aligns with the level of elbow axis, which passes through the most inferior part of the medial epicondyle (Figure 13 and 13a).

Figure 14

Figure 15

Figure 16

INTRAMEDULLARY RESECTION METHOD

Resect a small section of the central trochlea, centered just above the isthmus of the olecranon fossa (Figure 14). Use a high speed bur and starter awl at the proximal aspect of the olecranon fossa to gain entry to the medullary canal (Figure 15).

Note: *On the proximal area of the rasp, "P" faces posterior and "A" faces anterior. Rasp the humerus with progressively larger rasps until cortical resistance is met. Leave the last rasp used in the canal (Figure 16).*

DISCOVERY™ ELBOW SYSTEM
Intramedullary Resection Method

Figure 17

Figure 17a

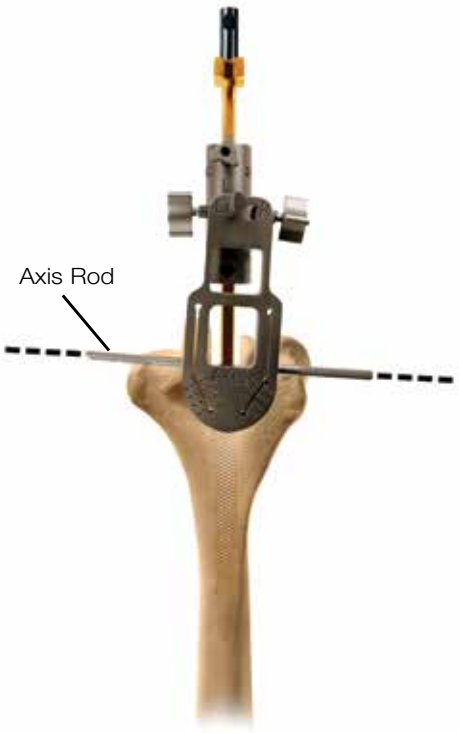


Figure 18

Insert the resection guide boom onto the rasp handle from medial/lateral and rotate 90 degrees posterior (Figure 17 and 17a).

Attach the resection cut guide on to the guide boom and orient it for the proper resection. Position the guide so the axis rods are slightly proximal to the distal edge of the medial epicondyle. Make proper height adjustments and lock into place using the imbedded screws (Figure 18). (These may be tightened using an optional 3.5mm hex driver.)

Place two 0.062 inch Kirschner wires through the pin holes on each side of the resection guide and into the humerus. The proximal rasp maintains the same contour as the humeral implant so the guide will position the area of resection to accurately match the subsequent implant.

Figure 19

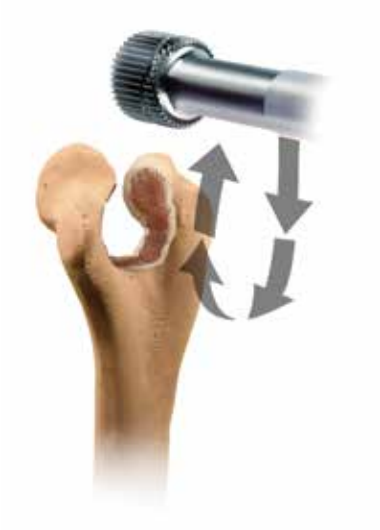


Figure 20

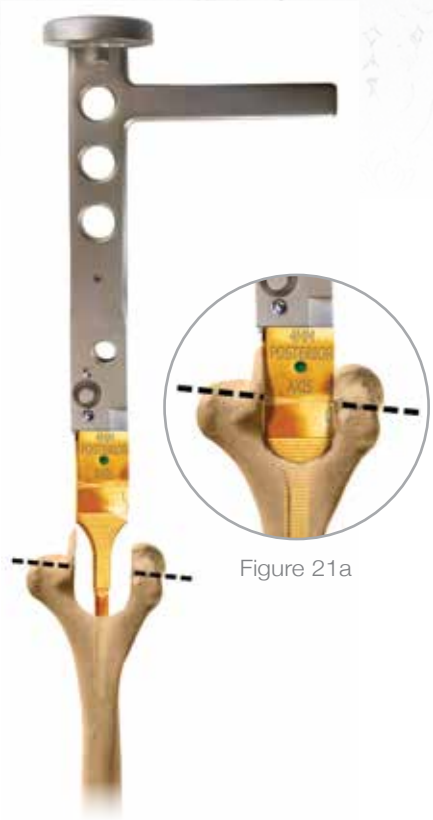


Figure 21

Figure 21a

Remove the trochlea by making four saw cuts through the resection guide (Figure 19), and round out the proximal portion of the resected area with the barrel reamer (Figure 20).

Choose one of the three color coded distal humeral broaches corresponding to the size of the last proximal humeral rasp used.

Note: *A green dot is present on the 4 x 100 proximal rasp. Similarly, a green dot can be found on the 4mm distal broach. This color coding allows for easier recognition of the proper broach to use.*

Note: *The barrel reamer should be spinning clockwise prior to contact with the bone to prevent jumping and the potential for bone chipping.*

Insert the rasp into the canal with the engraving marks positioned posteriorly until the respective left or right axis line aligns with the level of elbow axis, which passes through the most inferior part of the medial epicondyle (Figure 21 and 21a).

DISCOVERY™ ELBOW SYSTEM
Humeral Trialing/ Ulnar Preparation

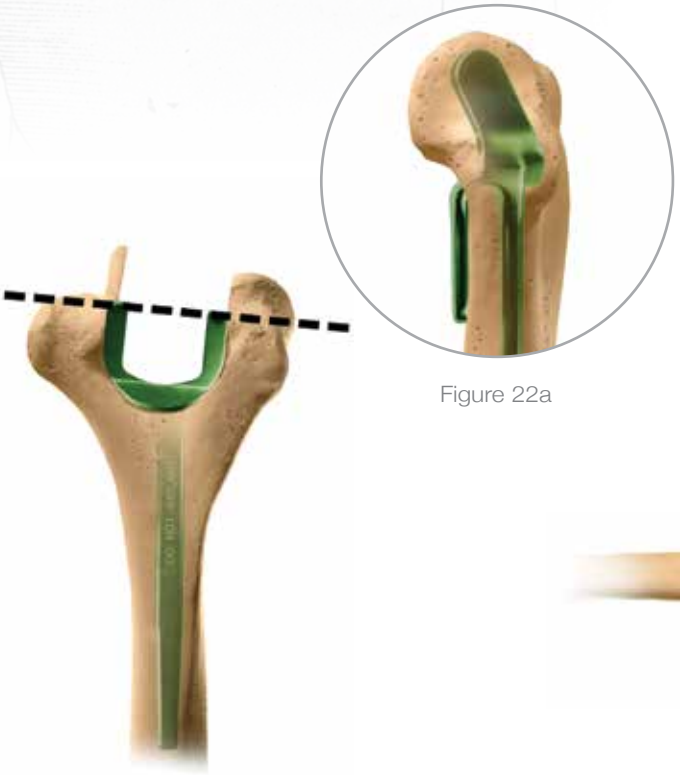


Figure 22

Figure 22a

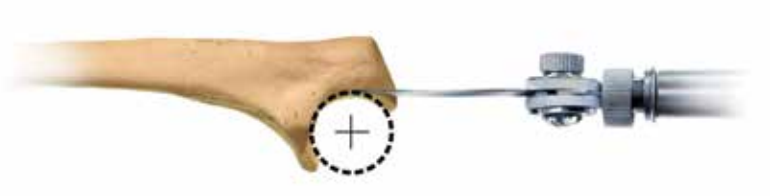


Figure 23

HUMERAL TRIALING

Select the humeral provisional that corresponds to the size of the last proximal/distal humeral rasp used, and insert it into the canal to check the fit (Figure 22). If obstructions are encountered, use a small rotating bur to contour or remove any bony obstructions and allow full seating of the provisional. The barrel reamer may also be used to help contour the resection to receive the provisional.

The humeral implant has an anterior flange that provides an additional cortex to push against when a load is applied. It may be necessary to remove 3–4mm of the central anterior humeral cortex for the flange to rest in the proper position (Figure 22a).

When humeral preparation is complete, remove the provisional, using the humeral extractor to remove if necesary.

ULNAR PREPARATION

If not performed earlier, use an oscillating saw to remove the tip of the olecranon along a line tangent to the posterior-most portion of the olecranon articulation (Figure 23). In addition, it may be necessary to remove any ectopic or excessive bone (2-3mm) from the tip of the coronoid. An anterior capsulectomy may also be done at this time.

Ulnar Preparation

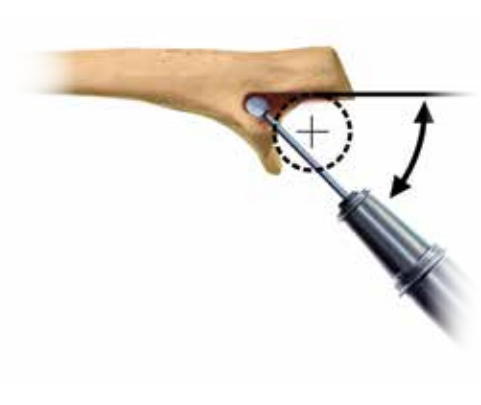


Figure 24

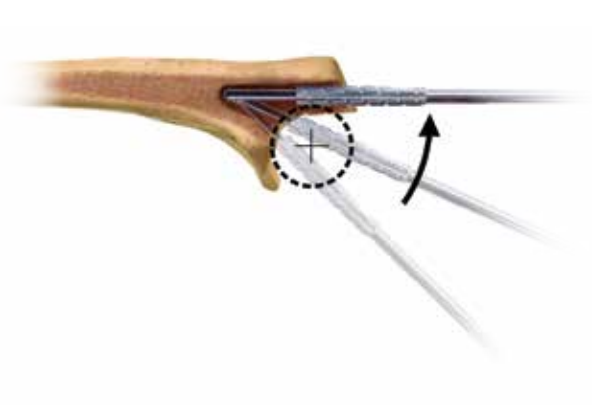


Figure 25

Figure 26*

Begin opening the ulnar canal at the intersection of the olecranon with the coronoid. The bur should be aimed parallel to the ulnar canal and 55 degrees anteriorly (Figure 24).

Once the canal is located, use the olecranon trough reamer and flexible reamers to prepare a channel through the olecranon to gain straight access to the ulnar canal.

Note: *The olecranon trough reamer may be used with the modular T-handle or the power adaptor. The smooth tip of the reamer is designed to act as a pivot point to drive this side-cutting instrument in a posterior direction (Figure 25). This instrument is not to be driven distally as a reamer.*

Create a trough in the olecranon by moving the rotating trough reamer to a position parallel to the axis of the ulna (Figures 26).

DISCOVERY™ ELBOW SYSTEM
Ulnaire Reaming\Ulnar Rasping

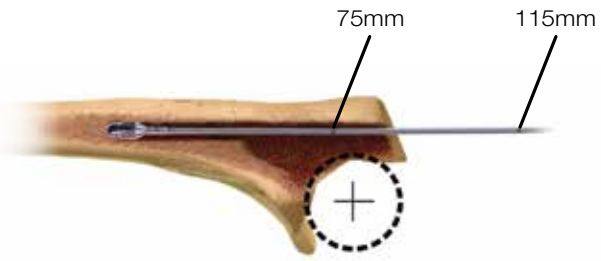


Figure 27

Figure 28

ULNAIRE REAMING

Attach the smallest ulnar flex reamer to the modular T-handle or power adaptor. Carefully drive the reamer to one of the two guide markers corresponding to the desired implant stem length (Figure 27).

Continue sequentially reaming until cortical contact is achieved.

Note: *The purpose of the ulnar flex reamers is to remove/ dislodge the soft cancellous bone inside the canal to enhance the integrity of the cement mantle.*

ULNAR RASPING

Attach the appropriate left or right 3mm ulnar rasp to the modular rasp handle. Drive the rasp distally until it is seated against the coronoid. Position the rasp in a slightly posterior direction while tapping back and forth, using the hole in the rasp to determine the natural axis of rotation. Continue this back and forth motion, keeping the rasp posterior, until final seating occurs (Figure 28).

Figure 29

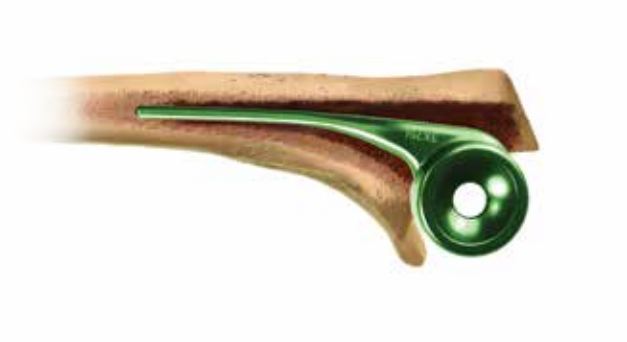


Figure 30

If the desired placement is not obtained, a high-speed rotating bur may be used to carefully enhance the trough in the bed of the trochlea and coronoid process. This technique, used in conjunction with the rasps, should yield the desired placement of the ulnar component.

Continue sequentially rasping until cortical contact is achieved. The largest rasp that fully seats indicates the size of implant to be used.

Use the barrel reamer in a perpendicular fashion to contour the olecranon and coronoid surfaces. This allows the ulnar component to properly seat and accurately reproduce the axis of rotation (Figure 29).

Note: *Move the barrel reamer clockwise to prevent jumping.*

ULNAR TRIALING

Select the ulnar provisional that corresponds to the last fully seated ulnar rasp. Fully seat the ulnar provisional into the ulnar canal (Figure 30). The hole in the ulna represents the ulnar axis of rotation. Ensure the axis is accurately reproduced.

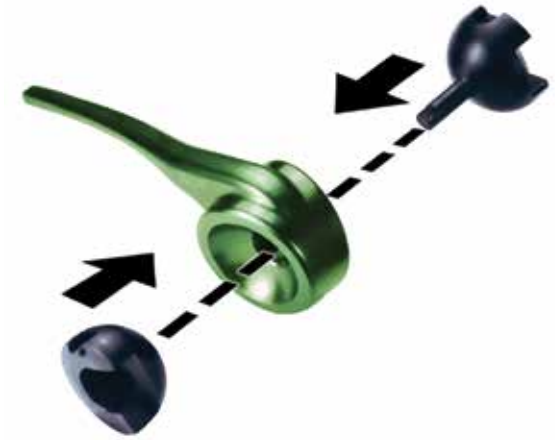


Figure 31

Figure 32

CONNECTING THE HUMERAL AND ULNAR PROVISIONAL COMPONENTS

Reinsert the humeral provisional. Assemble the hemispherical condyle provisionals through the hole in the ulnar provisional, making sure the recess for the screw heads are facing posterior with the spheres aligned to receive the humeral provisional (Figure 31).

Humeral and ulnar trials can be assembled before or after insertion.

Carefully relocate the joint while facilitating the assembly of the condyle provisionals onto the humeral provisional.

With the provisional components together, insert both provisional locking screws and tighten with the X-lock driver (Figure 32).

Perform a trial reduction and range of motion. Take care that the olecranon and/or coronoid do not impinge on bone or provisionals.

Figure 33

Figure 34

CEMENTING THE IMPLANTS

The humeral and ulnar components can be assembled before, during or after cementing. Two of the three possible methods of cementing are described.

- Before mixing the bone cement, ensure that the applicator tube will fit into the medullary canals. The applicator tube must be of sufficient length and flexibility to reach the distal end of each chosen stem in the medullary canals.

- Low viscosity bone cement is recommended.

- The provisionals are the same size as the substrate of the final implants but do not include the thin layer of plasma spray.

Note: *It is advised to trial the final implants prior to dispensing bone cement to be sure they will fit as expected. Clean and dry the implants before inserting them into the cement.*

- During the trialing of the final humeral implant, inspect the space between the anterior flange and the anterior cortex of the humerus. The typical fit of the flange with the anterior cortex requires little or no graft (Figure 33). If a space is present, a bone chip or artificial graft may be used in the space to establish contact between the flange and the bone (Figure 34). The graft may be placed during cementation. Conversely, if there is not enough space between the anterior flange of the implant and the anterior cortex, a bur may be used to create the proper fit.

DISCOVERY™ ELBOW SYSTEM
Cementing the Implants

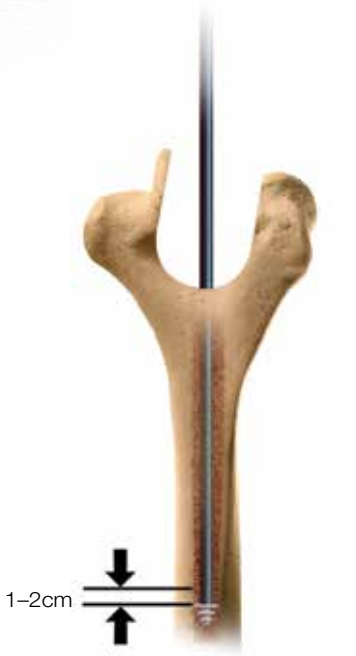


Figure 35

- Small diameter cement restrictors are available for use in the humerus and ulna. Preoperatively determine the diameter of the medullary canal during templating. Restrictor sizes range from 6 to 14mm. If the cement restrictor is too small it will not meet enough resistance to occlude the flow of cement down the canal. If the restrictor chosen is slightly large, it will deform to fit within the medullary canal.

  Caution: *An excessively large cement restrictor will deform and tilt off axis to the extent that it will not be able to stop the flow of cement. The restrictor should rest 1–2cm past the depth of the implant stem* (Figure 35).

- Attach the cement plug inserter onto the T-handle. Thread on the chosen cement restrictor and place in the canal. Depth markings on the inserter assist in determining proper canal placement. Unthread the inserter shaft to disengage from the restrictor.

Figure 36

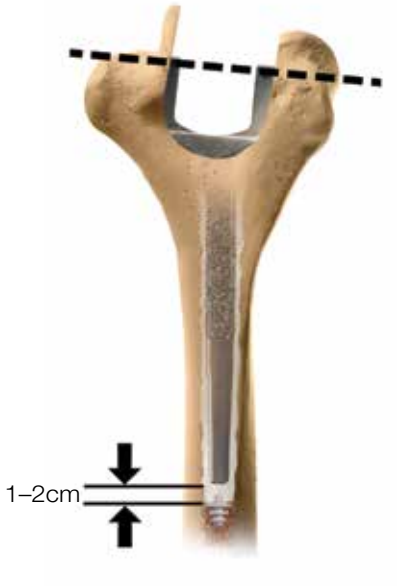


Figure 37

CEMENTING UNASSEMBLED COMPONENTS

HUMERAL COMPONENT

Dispense bone cement into the humerus to the opening of the canal. Insert the humeral implant, paying close attention to the orientation.

Use the humeral impactor to fully seat the implant (Figure 36). Assess implant position (Figure 37), and remove all excess cement.

If applicable, place a bone chip or artificial graft under the anterior flange to enhance stability. This may be done before or after the cement has cured, depending on preference.

Cementing Unassembled Components

Figure 38

Figure 39

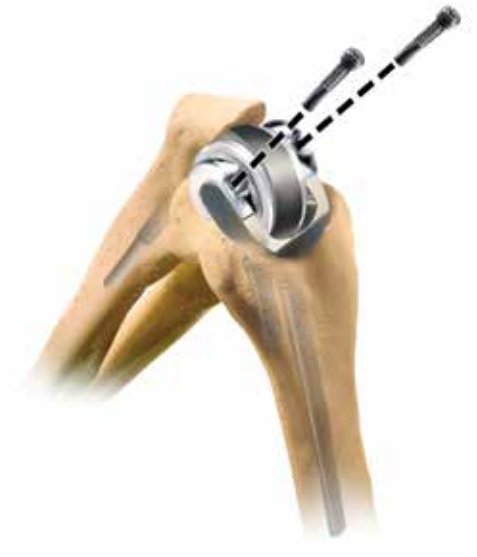


Figure 40

ULNAR COMPONENT

Dispense bone cement into the ulna to the opening of the canal. Press the ulnar implant into the canal, paying close attention to its orientation.

Use the ulnar impactor to fully seat the implant (Figure 38). Thoroughly remove all excess bone cement, especially where the polyethylene meets the metal.

Extend the arm and join the components using the cobalt chrome condyles. An alternate method is to join with trials until cement sets, then join with real condyles.

To assemble the condyles, place the condyles through the ulnar component (Figure 39). Ensure the screw pockets in the condyles reside on the posterior side of the assembled implant and are free of bone cement and debris. With the components together, insert both locking screws and thoroughly tighten using the screwdriver (Figure 40).

Note: *Alternate tightening lateral and medial screws until locked.*

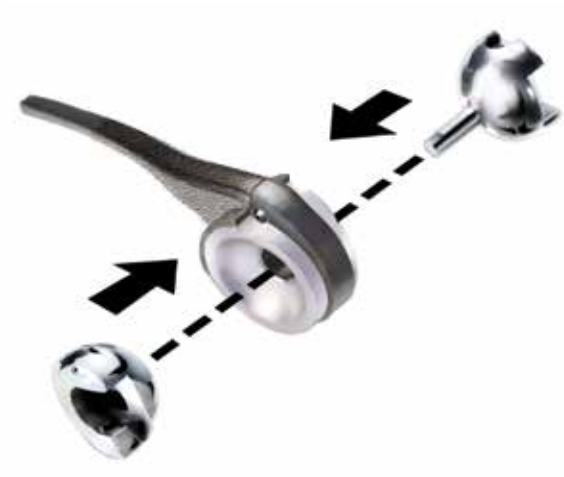


Figure 41

Figure 42

CEMENTING ASSEMBLED COMPONENTS

Note: *When using this method, take care to follow each step as there is only one opportunity to do it correctly once cement is dispensed.*

Assemble the components before inserting, using the condyles and screws provided (Figures 41 and 42). Thoroughly tighten the screws using the screwdriver.

Perform a trial insertion to verify fit before dispensing bone cement. Be sure to clean and dry the implants before inserting them into the cement.

Cementing Assembled Components

Figure 43

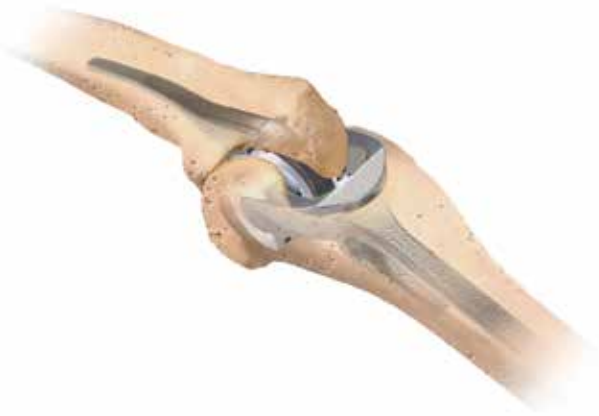


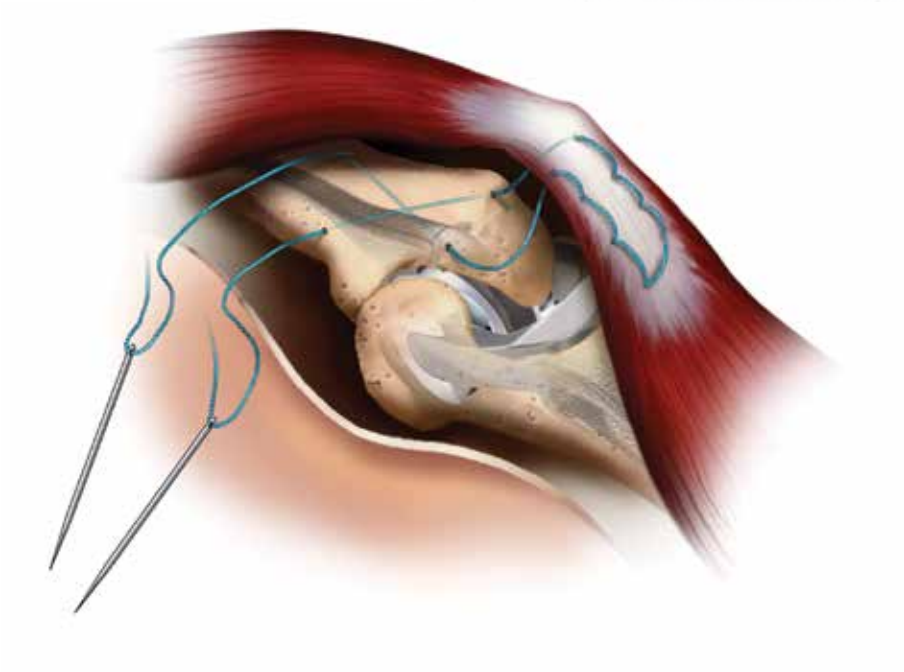
Figure 44

When the bone cement is mixed, fill the humerus and ulna to the openings of the canals. With the arm in full flexion, insert the assembled humeral and ulnar implants (Figure 43).

Gently extend the arm to fully seat the components. If necessary, use the humeral and ulnar impactors to help seat the components. Thoroughly remove all excess bone cement.

Hold the arm in extension until the cement has cured (Figure 44). Recheck for excess cement, as this technique will cause some of the cement to extrude around the implants. Thoroughly remove all excess bone cement from around the implants and allow the cement to cure.

If applicable, place a bone chip or artificial graft under the anterior flange of the humeral component to enhance stability.



WOUND CLOSURE

When the triceps attachment has not been violated, the only necessary deep soft-tissue closure is repair of the lateral collateral and common extensor origins back to the humeral condyle. This is done through two drill holes using No. 2 braided polyester with a polyethylene core and Kevlar.

When the triceps has been detached, repair it back to the olecranon with No. 2 polyester and Kevlar suture through two drill holes in the ulna. Repair the medial and lateral fascial sleeves with a running No. 2 bioabsorbable suture.

The ulnar nerve almost always remains stably located in an anterior position. Place one suction drain in the deep wound and one in the subcutaneous space and bring it out through the proximal skin. Approximate subcuticular tissues with No. 3-0 or 4-0 bioabsorbable sutures, and close the skin with staples or sutures. Apply a bulky dressing and splint with the elbow in 60 degrees of flexion to minimize posterior wound tension.

REHABILITATION

Continue postoperative antibiotics for 24 hours. Remove suction drains at 48 hours or when drainage has stopped. Patients are usually discharged on the second postoperative day. Between the third and fifth postoperative days, remove the dressing, check the wound and initiate active range of motion. Regardless of how the triceps was handled, instruct the patient on active and passive flexion exercises.

When the triceps has required repair, passive extension and active extension assisted by gravity are allowed.

When the triceps has not been detached, active and passive extension, even against resistance, is allowed. Employ weighted extension exercises to correct any residual tightness to extension. Use a long-arm splint in full extension at night to maintain extension.

Remove sutures or staples 10–14 days postoperatively and obtain routine radiographs. Initiate normal light use and strengthening at six weeks postoperative.

DISCOVERY™ ELBOW SYSTEM
Instrumentation

Discovery™ Humeral Components

PART NUMBER	PROVISIONAL	DESCRIPTION	SIZE
114904	414831	**Discovery** Humeral Component*	4 x 100mm, Left
114905	414836	**Discovery** Humeral Component*	4 x 100mm, Right
114906	414832	**Discovery** Humeral Component*	5 x 100mm, Left
114907	414837	**Discovery** Humeral Component*	5 x 100mm, Right
114908	414833	**Discovery** Humeral Component*	6 x 100mm, Left
114909	414838	**Discovery** Humeral Component*	6 x 100mm, Right
114914	414841	**Discovery** Humeral Component*	4 x 150mm, Left
114915	414846	**Discovery** Humeral Component*	4 x 150mm, Right
114916	414842	**Discovery** Humeral Component*	5 x 150mm, Left
114917	414847	**Discovery** Humeral Component*	5 x 150mm, Right
114918	414843	**Discovery** Humeral Component*	6 x 150mm, Left
114919	414848	**Discovery** Humeral Component*	6 x 150mm, Right

Discovery™ Ulnar Components

PART NUMBER	PROVISIONAL	DESCRIPTION	SIZE
114812	414871	**Discovery** Ulnar Component**	3 x 75mm, Left
114813	414876	**Discovery** Ulnar Component**	3 x 75mm, Right
114822	414872	**Discovery** Ulnar Component**	4 x 75mm, Left
114823	414877	**Discovery** Ulnar Component**	4 x 75mm, Right
114832	414873	**Discovery** Ulnar Component**	5 x 75mm, Left
114833	414878	**Discovery** Ulnar Component**	5 x 75mm, Right
114816	414881	**Discovery** Ulnar Component**	3 x 115mm, Left
114817	414886	**Discovery** Ulnar Component**	3 x 115mm, Right
114826	414882	**Discovery** Ulnar Component**	4 x 115mm, Left
114827	414887	**Discovery** Ulnar Component**	4 x 115mm, Right
114836	414883	**Discovery** Ulnar Component**	5 x 115mm, Left
114837	414888	**Discovery** Ulnar Component**	5 x 115mm, Right

*Includes Flange
**Includes Bearing

PART NUMBER	DESCRIPTION	SIZE
114700	**Discovery** Humeral Condyle Kit (includes two condyles and two screws)	-

114993	Extra Condyle Screw, Single	-

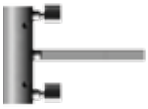
114800	**Discovery** Ulna Bearing Revision Kit (includes ulna bearing and two locking pins)	-

DISCOVERY™ ELBOW SYSTEM
Implants

PART NUMBER	DESCRIPTION	SIZE
414810	Proximal Humeral Rasp	3 x 100mm
414811	Proximal Humeral Rasp	4 x 100mm
414812	Proximal Humeral Rasp	5 x 100mm
414813	Proximal Humeral Rasp	6 x 100mm
414816	Proximal Humeral Rasp	4 x 150mm
414817	Proximal Humeral Rasp	5 x 150mm
414818	Proximal Humeral Rasp	6 x 150mm
414821	Distal Humeral Rasp	4mm
414822	Distal Humeral Rasp	5mm
414823	Distal Humeral Rasp	6mm
414896	Humeral Condyle Provisional	–
414912	Humeral Fossa Reamers, 5 Step	–
414915	Humeral Fossa Drill Guide	–
414921	Humeral Extractor	–
35-463012	Humeral Guide Drill Bit	3/16 x 5 inches
414890	Olecranon Trough Reamer	–
414891	Barrel Reamer	–
414800	Modular Rasp Handle	–
414892	T-handle	–
414893	1 to 1/2 x Standard Adapter	–
414894	Ulna Impactor	–
414924	Humeral Impactor	–
414925	Impactor Handle	–

DISCOVERY™ ELBOW SYSTEM

Instrumentation



PART NUMBER	DESCRIPTION	SIZE
414922	Screwdriver Handle	2.0/2.7mm
414923	X-lock Standard Blade	2.4mm
414926	Hexalobular Blade	–
430022	Slap Hammer	–
414851	Ulna Reamer	3mm
414852	Ulna Reamer	4mm
414853	Ulna Reamer	5mm
414854	Ulna Reamer	6mm
414855	Ulna Reamer	7mm
414856	Ulna Reamer	8mm
414861	Ulna Rasp	3mm, Left
414862	Ulna Rasp	3mm, Right
414863	Ulna Rasp	4mm, Left
414864	Ulna Rasp	4mm, Right
414865	Ulna Rasp	5mm, Left
414866	Ulna Rasp	5mm, Right
414935	I.M. Alignment Jig	–
414936	I.M. Resection Guide	–
414937	I.M. Axis Rod (2 Needed)	–
595327	Humeral Instrument Case Metal Outside Tray, Plastic Insert (2)	–
595328	Ulna Instrument Case Metal Outside Tray, Plastic Insert (2)	–

DISCOVERY™ ELBOW SYSTEM

Biomet Orthopedics, Inc.
P.O. Box 587
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Warsaw, Indiana 46581 USA

01-50-0991
Date: 05/07

BIOMET® ELBOW AND SHOULDER JOINT REPLACEMENT PROSTHESES

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet manufactures a variety of elbow and shoulder joint replacement prostheses intended for primary and revision joint arthroplasty for use in cemented applications.

Elbow joint replacement components include: humeral and ulnar components, and a hinge component. Components are available in a variety of surface finishes including bond coat (a thin layer of titanium plasma spray) and Interlok® finish. Small diameter cement plugs are available as specialty components.

Shoulder joint replacement components include humeral stems, humeral heads, and glenoid components. Components are available in a variety of designs and size ranges for both primary and revision applications. Specialty components include glenoid screws, centering sleeves, bipolar heads, and intercalary segments.

MATERIALS

Elbow

Humeral Stem	CoCrMo alloy or titanium alloy
Ulnar Stem	CoCrMo alloy or titanium alloy
Bearing Components	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Axles	CoCrMo alloy
Surface Coating	Titanium alloy
Screws	Titanium alloy
Small Diameter Cement Plugs	UHMWPE

Shoulder

Humeral Stems	CoCrMo alloy or titanium alloy
Attachment Sleeves	CoCrMo alloy
Humeral Head	CoCrMo alloy
Glenoid Components	Ultra-High Molecular Weight Polyethylene (UHMWPE) / titanium alloy / 316 LVM stainless steel
Glenoid Screws	Titanium alloy
Centering Sleeves	Polymethylmethacrylate (PMMA)
Bipolar Heads	CoCrMo alloy / UHMWPE) / titanium alloy
Intercalary Segments	CoCrMo alloy or titanium alloy
Porous Coating	Titanium alloy

INDICATIONS

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement or humeral head (shoulder), which are unmanageable using other treatment methods.
6. Oncology applications.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, and/or 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.

WARNINGS

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Thoroughly clean and dry connecting segments, including taper, prior to attachment of components to avoid crevice corrosion and improper seating. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue has lower adhesion strength to cement than implants handled with clean gloves. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. Properly align and completely seat connecting components including tapers. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry all connectors, including tapers prior to attachment of modular components to avoid crevice corrosion and improper seating.
2. Disassociation of the humeral head component from the humeral stem component has been reported. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry tapers prior to attachment of modular head component to avoid crevice corrosion and improper seating.
3. Dislocation of the bipolar shoulder component has been reported. Closed reduction should be attempted with caution to prevent disassociation of the bipolar component. Do not use excessive force during closed reduction. The bipolar component may be impinged against the glenoid.
4. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

Biomet® joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PRECAUTIONS

Specialized instruments are designed for Biomet® joint replacement systems to aid in the proper implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

- Patient must avoid placing excessive loads on the implant.
- Patient must avoid lifting more than 5lbs with the operated arm after surgery.
- Patient must avoid putting full body weight on the operated arm when rising from a seated position.
- Patient must avoid sudden or strenuous pulling activities after surgery, as these can produce excessive stress on the operated arm.

POSSIBLE ADVERSE EFFECTS

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may result in loosening of the implant.
2. Early or late postoperative infection and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Infection is a rather common problem in elbow procedures
5. Impairment due to injury of the ulnar nerve is a major concern in elbow procedures.
6. Loosening, migration, and/or fracture of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive activity.
7. Periarticular calcification or ossification, with or without impediment of joint mobility.
8. Inadequate range of motion due to improper selection or positioning of components.
9. Undesirable shortening or lengthening of limb.
10. Dislocation and subluxation due to inadequate fixation, improper positioning, trauma, excessive range of motion, and/or excessive activity. Muscle and fibrous tissue laxity can also contribute to these conditions.
11. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
12. Fretting and crevice corrosion can occur at interfaces between components.
13. Wear and/or deformation of articulating surfaces.
14. Accelerated wear of glenoid articular cartilage.
15. Intraoperative or postoperative bone fracture and/or postoperative pain.
16. Axle or bearing components may disassociate causing the elbow to disarticulate.
17. Revision and post-traumatic patients are susceptible to higher wear rates if varus/valgus constraints are compromised.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date has passed.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

Authorized Representative: Biomet U.K., Ltd.
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CE 0086

DISCOVERY™ ELBOW SYSTEM

P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581 USA

Date: 08/07

Biomet manufactures a variety of elbow joint replacement prostheses intended for primary and revision joint arthroplasty for use in cemented applications. Elbow joint replacement components include humeral and ulnar components, and in some instances, hinge components. Components are available in a variety of surface finishes including bond coat (a thin layer of titanium plasma spray), porous titanium plasma spray and Interlok™ finish.

Humeral stem	CoCrMo alloy or titanium alloy
Ulnar stem	CoCrMo alloy or titanium alloy
Bearing components	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Axles	CoCrMo alloy
Connectors	CoCrMo alloy
Surface coating	Titanium alloy
Locking clips/screws	Titanium alloy

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Treatment of acute or chronic fractures with humeral epicondyle involvement, which are unmanageable using other treatment methods.

In addition to the above indications, BiAxial™ elbow components are also indicated for joints with both intact and limited soft tissue structure about the elbow.

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who is incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, and/or 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Thoroughly clean and dry connecting segments, including taper, prior to attachment of components to avoid crevice corrosion and improper seating. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing surgery.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

Elbow joint replacement prostheses have not received FDA clearance for non-cemented application (USA).

1. Properly align and completely seat connecting components including tapers. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry all connectors, including tapers prior to attachment of modular components to avoid crevice corrosion and improper seating.
2. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
3. BiAxial Elbow: Insertion of the axle clip must be performed properly. Complete seating of the clip using a new, unused clip is necessary to prevent disassociation. If an axle clip is removed for any reason, do not reuse.

Biomet® joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

Specialized instruments are designed for Biomet® joint replacement systems to aid in the proper implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

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1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
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4. Infection is a rather common problem in elbow procedures.
5. Impairment due to injury of the ulnar nerve is a major concern in elbow procedures.
6. Loosening, migration, and/or fracture of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive activity.
7. Periarticular calcification or ossification, with or without impediment of joint mobility.
8. Inadequate range of motion due to improper selection or positioning of components.
9. Undesirable shortening or lengthening of limb.
10. Dislocation and subluxation due to inadequate fixation, improper positioning, trauma, excessive range of motion, and/or excessive activity. Muscle and fibrous tissue laxity can also contribute to these conditions.
11. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
12. Fretting and crevice corrosion can occur at interfaces between components.
13. Wear and/or deformation of articulating surfaces.
14. Intraoperative or postoperative bone fracture and/or postoperative pain.
15. Axle or bearing components may disassociate causing the elbow to disarticulate.
16. Revision and post-traumatic patients are susceptible to higher wear rates if varus/valgus constraints are compromised.

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date has passed.

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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert or Biomet's website.

limacorporate.com

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