

**DISCOVERY<sup>®</sup>** ELBOW SYSTEM  
POLYETHYLENE EXCHANGE

SURGICAL TECHNIQUE



# DISCOVERY<sup>®</sup> ELBOW SYSTEM

## POLYETHYLENE EXCHANGE



Figure 1

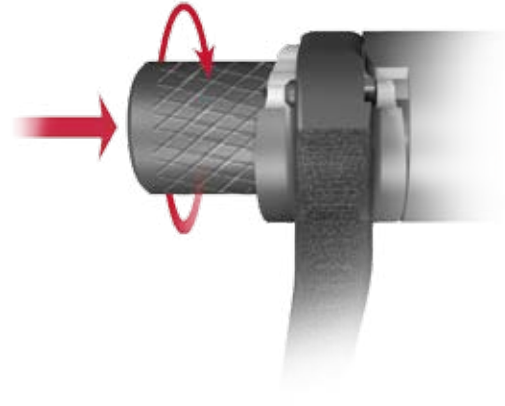


Figure 2

### PREOPERATIVE PLANNING

Place two ulna bearing kits in a freezer for a minimum of three hours. Freezing causes the bearing to constrict, making it easier to insert into the ulna ring. The temperature should be between -13° F and 14° F (-25° C and -10° C). A lower freezer temperature will increase the handling time of the bearing. Do not remove the bearing from the freezer until ready for assembly, as it will begin to expand immediately and reach full expansion within two minutes of removal. The second bearing kit should remain in the freezer as reserve.

### BEARING REMOVAL

Insert the threaded end of the bearing removal tool through the center hole of the ulna component. Push the T-handle toward the ulna component as far as possible, turning the T-handle to allow the threaded shaft to pass through the bearing if necessary. The ledge of the ulna component should fit into the recess on the body of the bearing removal tool (Figure 1). With the jagged end toward the polyethylene, tighten the end cap onto the bearing removal tool (Figure 2).

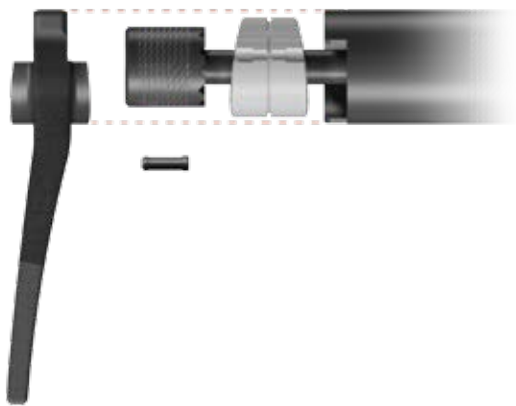


Figure 3

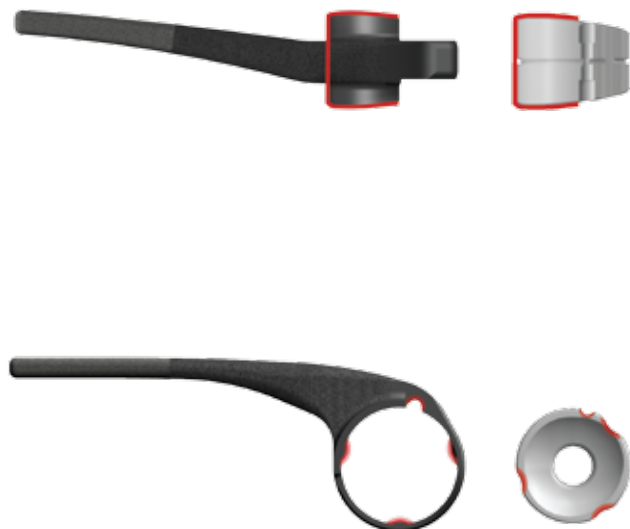


Figure 4

While holding the body of the removal tool, rotate the T-handle clockwise. The polyethylene will be pulled from within the ulna component onto the threaded shaft of the removal tool. Continue rotating until the polyethylene is removed from the ulna stem and the locking pin falls free (Figure 3). Discard the pin and polyethylene; irrigate and remove any small polyethylene particles.

## NEW BEARING INSERTION

Remove one ulna bearing revision kit from the freezer. The widest portion of the bearing should face toward the widest portion of the ulna ring (Figure 4). Locate the four notches on the outer edge of the bearing and align the cylindrical notch (pin groove) posteriorly.

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## POLYETHYLENE EXCHANGE



Figure 5



Figure 6



Figure 7

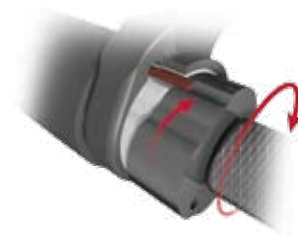


Figure 8

Align the three shallow notches in the bearing with the three tabs inside the ulna stem ring (Figure 5). Insert the bearing into the middle of the stem ring by pushing it until the bearing freely spins/rotates. Rotate the bearing until the cylindrical notch (pin groove) aligns with the pin groove of the ulna stem (Figure 6).

### OPTIONAL BEARING INSERTION METHOD

The bearing rotation tool may be used to rotate the bearing if it does not spin freely when inserted into the ulna ring. To use, insert the tool from the medial side of the bearing, allowing the long metal tab to slide into the groove on the bearing reserved for the locking pin (Figure 7). Rotate the bearing until the cylindrical notch in the bearing is aligned with the pin groove of the ulna stem (Figure 8).



Figure 9



Figure 11



Figure 10

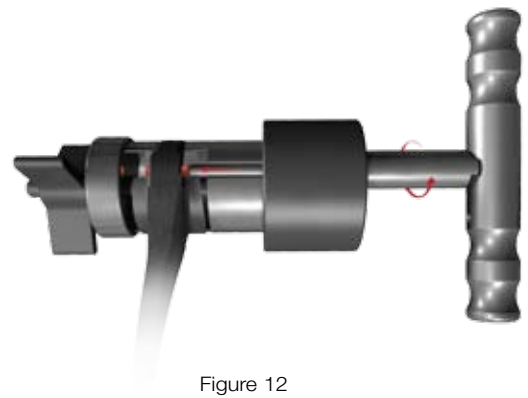


Figure 12








## PIN INSERTION

Insert the ulna pin inserter body through the bearing from the medial side until the ledge of the ulna component fits into the recess on the body of the pin inserter. Secure the ulna component into place using the lock body and lock nut. The push rod should be backed out enough to place the locking pin into the small canal (Figure 9). The tapered end of the pin should be facing toward the ulna component (Figure 10).

The hole in the lock body, groove in the ulna component and pin should be aligned (Figure 11). Attach the T-handle and turn clockwise to drive the pin into the ulna component (Figure 12). Ensure the pin does not become dislodged during insertion. Once the pin is fully inserted into the ulna component, bearing exchange is complete.

# DISCOVERY® ELBOW SYSTEM

## ORDERING INFORMATION – INSTRUMENTATION

Product	Part Number	Description	Size
	114800*	Discovery® Ulna Bearing Revision Kit	—
	414892**	Discovery® T-handle	—
	414922**	Screwdriver Handle	2.0/2.7mm
	414923**	X-lock Standard Blade (Screwdriver Shaft)	2.4mm
	414950**	Discovery® Bearing Removal Tool	—
	414951**	Discovery® Bearing Ulna Pin Inserter	—
	414952**	Discovery® Bearing Rotation Tool	—

\*Contains one polyethylene bearing and locking pin

\*\*Available from loaners

**Biomet Orthopedics, Inc.**  
P.O. Box 587  
56 East Bell Drive  
Warsaw, Indiana 46581 USA

**01-50-0901**  
Date: 05/07

## **Biomet® Elbow Joint Replacement Prostheses**

### **ATTENTION OPERATING SURGEON**

#### **DESCRIPTION**

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.

#### **Materials:**

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

#### **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 involvement, which are unmanageable using other treatment methods.

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 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.

#### **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 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.

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.

#### **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 be a result of 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 impeding 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.

#### **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.

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**CE** 0086

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

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