DJO Surgical
Encore Medical L.P.
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0400-1017
Revision A
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Discovery® Elbow Joint Replacement Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION
DJO Surgical 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. Components are available in a porous titanium plasma spray finish. Small diameter cement plugs are available as specialty components.

MATERIALS:

Humeral stem	Titanium alloy
Ulnar stem	Titanium alloy
Bearing components	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Condyles	CoCrMo alloy
Surface coating	Titanium alloy
Locking Screws	Titanium alloy
Lock Pin	Titanium alloy
Small Diameter Cement Plugs	UHMWPE

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.

All Discovery Elbows components are intended for use with bone cement.

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 components, prior to attachment of components to minimize the risk of crevice corrosion and improper seating. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissues 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 surgical technique, 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 components prior to assembly. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry all connections, prior to attachment of modular components to minimize the risk of 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 reduce the risk of 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. X-small humeral components should only be used with x-small ulnar components.
4. X-small humeral condyles should only be used with x-small humeral components.
5. X-small bearing kits should only be used with x-small ulnar components.

DJO Surgical 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, unusual and/or awkward movement and/or activity, trauma excessive weight, and/or obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation 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 in advance, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

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.

Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

PRECAUTIONS
Specialized instruments are designed for DJO Surgical 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, incorrect 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. DJO Surgical recommends that all instruments be regularly inspected for wear and disfigurement and prior to surgery.

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

- Patient must avoid placing excessive loads on the implant.
- Patient must avoid lifting more than 5 lbs 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/or 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. Intraoperative or postoperative bone fracture and/or postoperative pain.
15. Bearing and/or condyle 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.

MRI INFORMATION

DJO Surgical Elbow components have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only. Do Not Reuse. 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., DJO Surgical, 9800 Metric Blvd., Austin, TX 78758.

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Symbol Legend
Manufacturer

	Date of manufacture
	Do not reuse
	Consult IFU
	Keep Dry
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE	Sterile
STERILE A	Sterilized using aseptic processing techniques
STERILE	Sterilized using steam or dry heat
	Use by date
	WEEE device
REF	Catalogue number
LOT	Batch code
FLAMMABLE	Flammable
EC REP	Authorized representative in the European Community