

Document No. 0400-1017	Rev. C	Pg. 1 of 6	Approvals / Date
Title: INSTRUCTIONS FOR USE - DJO SURGICAL® DISCOVERY® ELBOW JOINT REPLACEMENT PROSTHESES			Deann Rector 31-Aug-2018
			Reference DC-11834 for electronic signatures.

Revision	ECO Date	ECO	Summary of Changes
C	31AUG2018	DC-11834	INITIAL RELEASE IN THE DJO SURGICAL QUALITY SYSTEM.



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1. Product Handling

Implants are provided sterile and should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage that may compromise sterility. If packaging has been opened or damaged upon receipt, contact the manufacturer's representative. Also inspect the labeling to verify that the expiration date has not passed. If the product is expired, contact Customer Service and do not use the implant. When unpacking the implant, verify the labeling for correct Reference No. and size. When removing the implant from its packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage. This implant is part of a system and should be used only in combination with other original DJO Surgical® product belonging to the same elbow system, unless otherwise specified.

2. Product Description and Implant Materials

Component	Fixation Method	Material	Applicable ASTM Standard	Applicable ISO Standard
DISCOVERY® ELBOW Humeral Stem*	Cemented	Ti6Al4V alloy	ASTM F1472	N/A
DISCOVERY® ELBOW Ulna Stem*	Cemented	Ti6Al4V alloy	ASTM F1472	N/A
DISCOVERY® ELBOW Bearing Components*	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F648	N/A
DISCOVERY® ELBOW Condyles*	Cemented	CoCrMo alloy	ASTM F75	N/A
DISCOVERY® ELBOW Locking Screws*	Cemented	Ti6Al4V alloy	ASTM F1472	N/A
DISCOVERY® ELBOW Lock Pin*	Cemented	Ti6Al4V alloy	ASTM F1472	N/A
*Note: Not available for sale or distribution in the European Union (EU) Note: See Discovery Elbow Surgical Technique for information on compatibility of X-small and Standard size components.				

3. Indications

Joint replacement is indicated for patients suffering from disability due to:

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

All Discovery® Elbow components are intended for use with bone cement. These devices have not received FDA clearance for non-cemented application in the USA.

4. Intended Use

DJO Surgical® Discovery® Elbow Joint Replacement Prostheses devices are intended for treatment of patients who are candidates for elbow arthroplasty per the Indication for use. While elbow joint replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

5. Contraindications

Joint replacement is contraindicated where there is:

- Infection (or a history of infection), acute or chronic, local or systemic;
- Uncooperative patient or patient with neurologic disorders who is incapable of following directions;
- Osteoporosis;
- Metabolic disorders which may impair bone formation;
- Osteomalacia;
- Distant foci of infections which may spread to the Implant site;
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.

6. Precautions and 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. Do not modify implants.

Patient selection factors to be considered include:

- Need to obtain pain relief and improve function;
- Ability and willingness of the patient to follow instructions, including control of weight and activity levels;
- A good nutritional state of the patient, and;
- The patient must have reached full skeletal maturity.

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.

An implant should never be reused. Although the implant may appear undamaged, previous stresses could create imperfections that may lead to mechanical failure. It is advised to utilize new prostheses of current design.

Familiarity with, and attention to the surgical technique recommended for this device is imperative for best results. The correct selection as well as the correct seating/placement of the prosthetic implant is extremely important. Only DJO Surgical® (or Zimmer-Biomet) Discovery® Elbow Joint Replacement Prostheses, instruments, and trial prostheses should be used.

Care must be taken to protect mating surfaces (i.e. tapers) and polished bearing surfaces from nicks and scratches which could become the focal point for failure. Contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load. An implant must not be tampered with, as tampering will adversely affect the performance of the implant.

DJO Surgical® (Hip, Knee, and Extremity) systems have not been evaluated for safety and compatibility in the Magnetic Resonance environment. The (Hip, Knee, and Extremity) systems have not been tested for heating or migration in the Magnetic Resonance environment.

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

7. Preoperative Planning and Postoperative Care

Preoperative planning provides essential information regarding the appropriate prosthesis and likely combinations of components. Use instrument trial components for fit verification (where applicable) and extra implant components for backup. X-ray templates for all sizes of the DJO Surgical® Discovery® Elbow Joint Replacement Prostheses are available upon request.

Accepted surgical practices should be followed for postoperative care. The patient should be made aware of the limitation of total joint reconstruction. 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 instruction of the treating physician including follow-up visits. The patient should be cautioned to govern his activities accordingly as the risk of implant failure increases with weight and activity levels of the patient.

8. Adverse Effects

Some of the adverse effects that could occur related to elbow arthroplasty are:

- 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 the 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;
- 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;
- Impairment due to injury of the ulnar nerve is a major concern in elbow procedures;
- Loosening, migration and/or fracture of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive activity;
- Periarticular calcification or ossification, with or without impediment of joint mobility;
- Inadequate range of motion due to improper selection or positioning of components;
- Undesirable shortening or lengthening of limb;
- 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;
- Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union or excessive weight;
- Fretting and crevice corrosion can occur at interfaces between components;
- Wear and/or deformation of articulating surfaces;
- Postoperative bone fracture and/or postoperative pain;
- Bearing and/or condyle components may disassociate causing the elbow to disarticulate;
- Revision and post-traumatic patients are susceptible to higher wear rate if varus/valgus constraints are compromised.

9. Sterilization

Unless opened or damaged, DJO Surgical® implants are supplied sterile in multiple pouches or barrier blister trays. Upon receipt, check all packaging for punctures or other damage. If packaging is opened or damaged, contact the manufacturer or manufacturer's representative for instructions.

Sterilization of implants is performed by gamma radiation at the minimum dose of 25 kGy to achieve a Sterility Assurance Level (SAL) of 10⁻⁶. Implants are single-use devices. Trials and other instruments are used to determine sizing before the sterile package needs to be opened. Should the original sterile package be inadvertently opened or compromised before implantation, the device cannot be implanted. Contact manufacturer or manufacturer's representative for instructions. Do not resterilize an implant or component that has been in contact with or contaminated by blood or other substances. Do not try to clean an implant since standard procedures cannot be relied upon to remove contamination from porous coating and storage of any opened implant or component should be avoided.

Instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines found in the DJO Surgical® Instrumentation Instructions for Use.

WARNING: DO NOT resterilize any elbow prosthesis distributed by DJO Surgical® (Encore Medical, L.P.) if sterile packaging is opened or damaged upon receipt. Return the implant with respective packaging to DJO Surgical® for inspection and disposition.

WARNING: Protect all porous coated and polished surfaces. Standard cleaning procedures cannot be relied upon to remove contamination from porous coating.

WARNING: DO NOT resterilize UHMWPE (ultra-high molecular weight polyethylene).

DJO Surgical® has validated sterilization cycle data on file.

NOTE: DJO Surgical® does not recommend Flash or Chemical Sterilization.













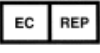


For further information regarding the use of the DJO Surgical® Discovery® Elbow Joint Replacement Prostheses, contact your DJO Surgical® representative or distributor.

DJO Surgical® Discovery® Elbow Joint Replacement Prostheses are manufactured by
ENCORE MEDICAL, L.P.

9800 Metric Blvd., Austin, TX 78758 USA (Made in the USA)

10. Trademarks and patents

Discovery® is a trademark of DJO Surgical®.

	Single use – do not reuse
	Expiration Date
	Keep Dry
	Store in a cool place: Do not store in environments with the potential for extreme heat or direct sunlight
	Lot number/Batch Code
	Sterile
	Sterility symbol: R: Sterile Using Irradiation
	Sterile symbol: H ₂ O ₂ : Sterilized Using Hydrogen Peroxide Gas Plasma
	Non-sterile
	See "Instructions for Use"
	Manufacturer
	Quantity of items in package
	Authorized Representative in European Community
	Catalog Number
	Federal Law (USA) restricts this device to sale by or on the order of a physician.

Bone Cement Usage – The following legends are displayed on the product labeling to indicate bone cement usage:

Usage	Legend
Implants intended to be used with bone cement	CEMENTED
Implants intended to be used without bone cement	CEMENTLESS
Implants intended to be used optionally	NO LEGEND