

## Instructions for Use—TEXX-21 Elbow Joint Replacement Prostheses

This document applies to TEXX-21 Elbow Joint Replacement Prostheses (Sterile) manufactured by Chetan Meditech Pvt. Ltd. (BIOTEK).

### Device Description

BIOTEK manufactures 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 locking pins.

### Materials used

Humeral stem SS 316L (ISO 5832-1) OR Titanium Ti-6Al-4V (ISO 5832-3) OR CoCr alloy (ASTM F75)  
Ulnar stem SS 316L (ISO 5832-1) OR Titanium Ti-6Al-4V (ISO 5832-3) OR CoCr alloy (ASTM F75)  
Bearing Components UHMWPE-Ultra-High Molecular Weight Polyethylene (IUPAC: Polyethylene) (ISO 5834-2)  
Locking Pins SS 316L (ISO 5832-1) OR Titanium Ti-6Al-4V (ISO 5832-3) OR CoCr alloy (ASTM F75)

### 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.

### 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. Misalignment 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 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 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. 5) 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. 6) 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.

BIOTEK 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 BIOTEK 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. Biotek 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, misalignment, bone resorption, and/or excessive activity.
7. Periparticular 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, misalignment, 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.

**Magnetic Resonance Imaging/ Electromagnetic field/ Magnetic field**

Implants made from non-ferromagnetic materials i.e. Titanium Ti-6Al-4V (ISO 5832-3) OR Polyethylene (ISO 5834-2) are safe or 'MR conditional' according to specific conditions for patients undergoing MR procedures.

However, patients who have implants made from ferromagnetic materials i.e. SS 316L (ISO 5832-1) OR CoCr alloy (ASTM F75) have potential risks of loosening and migration of the implant, heating of the metal with surrounding tissues, causing thermal damage, and artifactual distortion.

Patients who have implants made from ferromagnetic materials i.e. SS 316L (ISO 5832-1) OR CoCr alloy (ASTM F75) are warned not to enter areas with electromagnetic or magnetic fields.

**Disposal**

After use, this device may be a potential biohazard and should be decontaminated before disposal and handled in accordance with accepted medical practice and applicable local and national requirements.

**Warranty**

This product is warranted to be free from defects in material and workmanship.















**Documentation**

To ensure the implant's traceability at all times, attach/mention the information (batch no., etc) given in the product label to the patient's clinical history.

**For Further Information**

If further information on this product is needed, please visit [www.biotekortho.com](http://www.biotekortho.com) or contact BIOTEK Customer Service Department., or your authorized representative. In case of any queries, please put in to the knowledge of following organization. All trademarks herein are the property of BIOTEK or its subsidiaries unless otherwise indicated.

**Manufacturing unit: Chetan Meditech Pvt. Ltd. (BIOTEK), Kadi-Kalol Highway, Mehsana Dist.- 382715, Gujarat, India**

Symbol Legend	
 Manufacturer	 Date of Manufacture
 Do Not Reuse	 Caution
 Do Not Resterilize	 Sterilized Using Irradiation
 Catalogue Number	 Consult Instructions For Use
 CMC MEDICAL DEVICES & DRUGS S.L. Address: C/ Horacio Lengua Nº 18, CP 29006, Málaga, SPAIN Ph: +34 951 214 054 info@cmcmedicaldevices.com Authorized Representative in the European Community	 Batch Code
 Do not use if package is damaged	 Use By
 By Prescription Only	 European Conformity