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Instructions for Use—OSKAR/OSKAR-II Radial Head Prostheses

This document applies to OSKAR Radial Head Implant (Sterile) OR OSKAR-II Radial Head Implant (Sterile) manufactured by Chetan Meditech Pvt. Ltd. (BIOTEK).

Description
BIOTEK manufactures Radial Head prostheses intended for primary and revision joint arthroplasty for use in uncemented press fit applications.

Materials used
Titanium Ti-6Al-4V (ISO 5832-3) OR CoCr alloy (ASTM F75)

Indications
The indications for use of Radial Head Replacement Devices include:
1. Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio- humeral and/or proximal radio-ulnar joint with:

a. Joint destruction and/or subluxation visible on x-ray
b. Resistance to conservative treatment
2. Primary replacement after fracture of the radial head.
3. Symptomatic sequelae after radial head resection.
4. Revision following failed radial head arthroplasty.

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, 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 implants, to avoid crevice corrosion and improper seating. Use clean gloves when handling implants. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing surgery.

1. Properly align and properly seat components, including tapers. Failure to properly align and completely seat the components can lead to disassociation. Thoroughly clean and dry all components, including tapers to avoid crevice corrosion and improper seating.
2. Complete preclosure cleaning and removal of metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

BIOTEK 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, and trauma and can lead to 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 prostheses 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, which 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.

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 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 especially those involving open procedures.
5. Nerve injures, including injuries to the Ulnar nerve.
6. Loosening or migration 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 and improper positioning. 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. Wear and/or deformation of articulating surfaces.
14. Intraoperative or postoperative bone fracture and/or postoperative pain.

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

Magnetic Resonance Imaging/ Electromagnetic field/ Magnetic field
Implants made from non-ferromagnetic materials i.e. Titanium Ti-6Al-4V (ISO 5832-3) 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. 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. 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*** 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
EC REP CMC MEDICAL DEVICES & DRUGS S.L. Address: C/ Horacio Lengo Nº 18, CP 29006, Málaga, SPAIN Ph: +34 951 214 054 info@cmcmedicaldevices.com Authorized Representative in the European Community	Batch Code
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By Prescription Only	CE 2265 European Conformity