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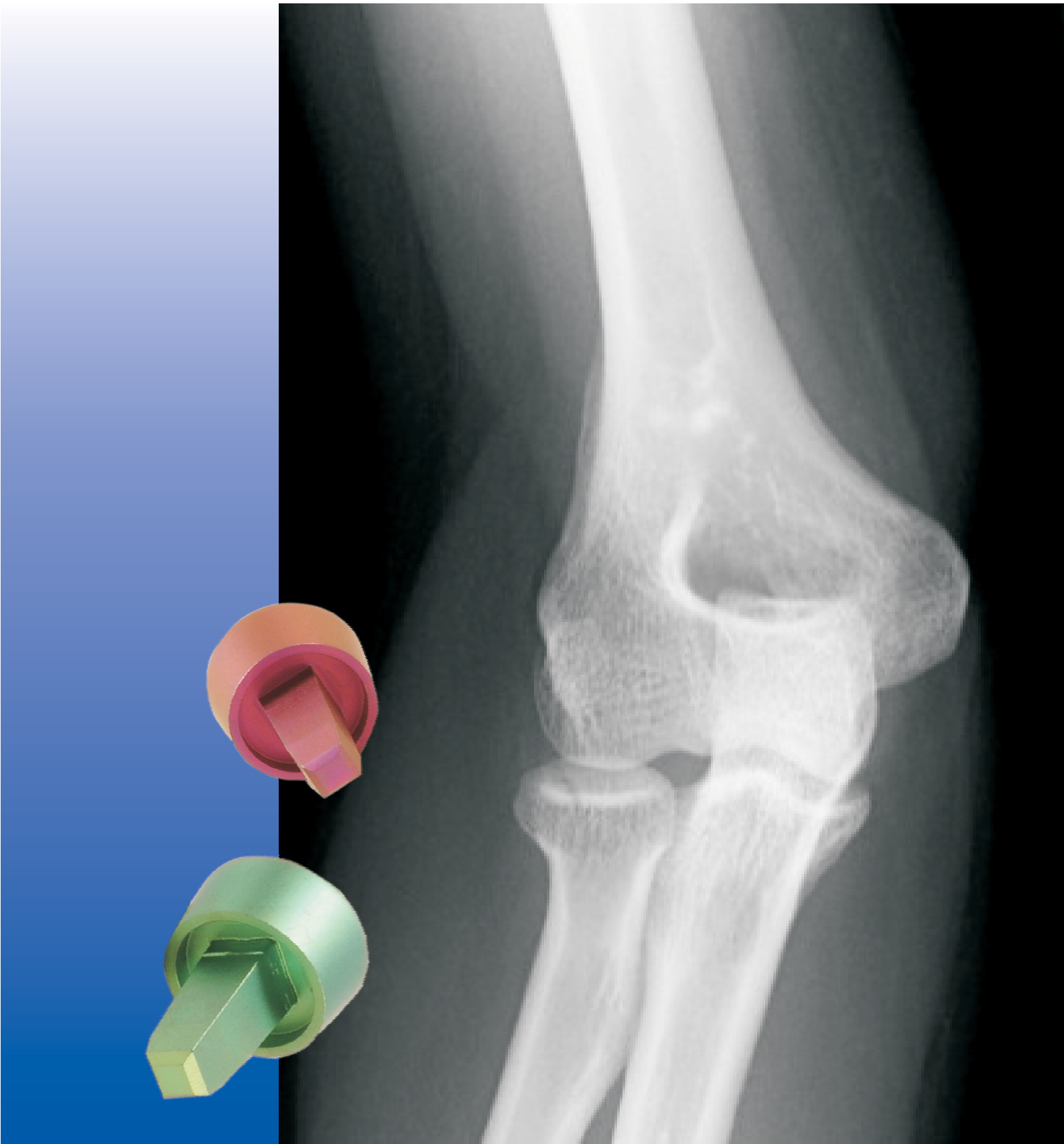
Technique Guide

OSKAR

Radial Head Prosthesis



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DESCRIPTION

The **OSKAR** Radial Head Implant is a pliable, one-piece intramedullary-stemmed cuffed implant designed to help preserve the joint space and relationships of the radiohumeral and proximal radioulnar joints following radial head resection for rheumatoid, degenerative, or traumatic arthritis. It has also been used as a primary replacement following radial head resection for fractures.

The OSKAR Radial Head Implant is available in five to adequately meet various operative requirements.

ADVANTAGES

- Permanent fixation in the intramedullary canal is not required
- Available in five sizes to adequately meet the various operative requirements.
- Improves elbow stability, joint relationship and motion.

INDICATIONS

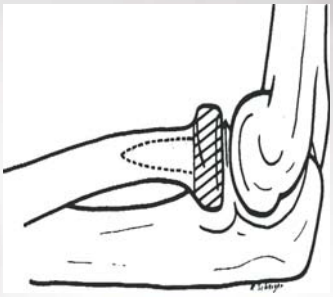
Any joint implant arthroplasty requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bond stock to receive implant
- Availability of postoperative therapy
- Cooperative patient

SURGICAL PROCEDURE

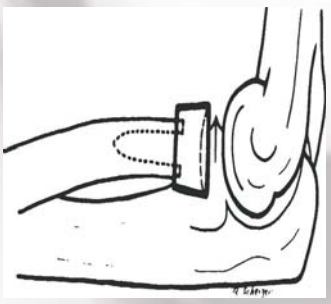
Proper surgical procedure and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

Through a dorsolateral incision, the radiohumeral joint is exposed between the anconeus and extensor carpi ulnaris muscles, carefully preserving the motor branch of the radial nerve (posterior in-terosseous nerve) that passes at the radial neck. Under the protection of retractors, the radial head is resected at the epiphyseal-metaphyseal junction. The annular and collateral ligaments must be preserved. Synovectomy of the anterolateral and posterior aspects of the elbow joint may be performed at the same time, and all excres-cences and marginal osteophytes are trimmed. The intramedullary canal of the radius is shaped to fit the stem of the implant using a curette, broach, or drill. The flare of the neck of the radius may be circumferentially trimmed to accommodate the implant collar. The bone resection preparation must be sparing.



The radial head is resected, preserving as much as possible of the annular ligament. Using a curette, broach or drill, the intramedullary canal of the radius is shaped to accommodate the implant stem.

Select the largest sizer that will provide lapping of the cuff over the resected bone end of the radius and a snug fit of the stem in the intramedullary canal. Good contact of the sizer with the capitellum and smooth rotation should be noted on passive flexion and rotation of the forearm. The sizer is removed, and the joint is thoroughly irrigated with saline solution. The implant is inserted with a no-touch technique and blunt instruments. The capsule, ligaments, and anconeus and extensor carpi ulnaris muscles are sutured in layers with nonabsorb-able sutures burying the knots. An incision drain is inserted, the fascial layers are closed over the muscles, and the skin is sutured. A bulky conforming dressing, including a posterior plaster splint, is applied with the elbow in 90 degrees flexion. If there are any symptoms of ulnar nerve entrapment, or if there is significant synovitis about the medical epicondyle, a synovectomy of the ulnar nerve is transposed anteriorly as necessary. The medial collateral ligament should be resutured if incised.



The implant cuff should overlap the radius end, and fit snugly in the canal. Smooth rotation of the implant head should be noted on passive flexion and rotation of the forearm.

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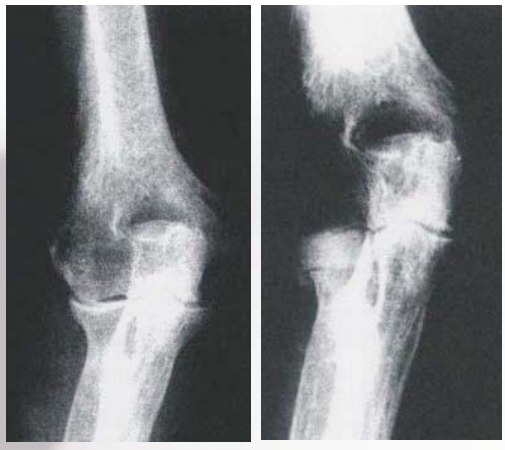
POST OPERATIVE CARE



Preoperative radiogram of a 49-year-old rheumatoid woman, presenting for disabling pain and crepitation at the elbow due to elbow joint synovitis and arthritic changes at the proximal radioulnar joint.

The patient underwent radial head resection, elbow synovectomy, and radial head implant replacement. The eight-year's postoperative radiogram shows the radial head implant in position. The patient has a stable, mobile and pain-free joint.

On the third postoperative day, the drain is removed. The plaster splint is discarded and a light dressing is applied. Active flexion/extension and pronation/supination exercises are allowed and the frequency progressively increased. The patient must avoid heavy lifting or stressful use of the elbow during the healing period. Full activity of the joint is resumed at six weeks. If necessary, gentle stretching exercises can be started at four to six weeks to increase the active range of motion. The early postoperative movements facilitate rehabilitation and increase the range of motion. Where radial head implant replacement is done for cases of radial fracture with posterior dislocation of the elbow, active flexion/ extension exercises are not started until the fifteenth postoperative day or as stability of the elbow dictates.

PRECAUTIONS

The potential for complications or adverse reactions with any implant can be minimized by following the instructions for use provided in product literature.

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/ or ability to follow postoperative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

HANDLING & STERILIZATION

The OSKAR Radial Head Implant has been sterilized and should be considered sterile unless the package has been opened or damaged. Remove from package, using accepted sterile technique, only after the correct size has been determined. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product.

Handling the implant should be done with blunt instruments to avoid surface trauma or contamination with foreign bodies. Rinse the implant thoroughly with sterile saline solution before insertion. The sizing set is supplied nonsterile. The following sequential steps are recommended to clean and sterilize the sizing set or to re-sterilize the implant:

1. Scrub thoroughly with clean, soft-bristled brush in a hot water-soap solution to remove possible surface contaminants. Use a non-oily, mild soap. Do not use synthetic detergents or oil-based soaps, as these soaps may be absorbed and subsequently leach out to cause a tissue reaction.
2. Rinse thoroughly with distilled water
3. If using a 270º F flash sterilization cycle, place the component on a standard mesh sterilization tray.
4. If using a 270º F gravity or 270º F pulsing vacuum sterilization cycle, double wrap the component in muslin or similar type nonwoven medical grade wrapping material or place in a sealed sterilization pouch.
5. Autoclave according to the following parameters:

Method	Cycle	Temperature	Exposure
Steam	Gravity	270º F/121º C	45 minutes
Steam	Flash	270º F/132º C	15 minutes
Steam	Pulsing-Vacuum	270º F/132º C	5 minutes

After sterilization, remove the component from its wrapping material/pouch or the sterilization tray using accepted sterile technique. Ensure that the component is at room temperature prior to implantation.

These recommendations have been developed and tested using specific equipment. The bioburden should not exceed 10* colony forming units (CFU) per device. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

Evidence suggests that repeated sterilization may affect the physical characteristics of the implant. Accordingly, resterilization in excess of three times is contraindicated.

The OSKAR Radial Head Implant is for single use only.

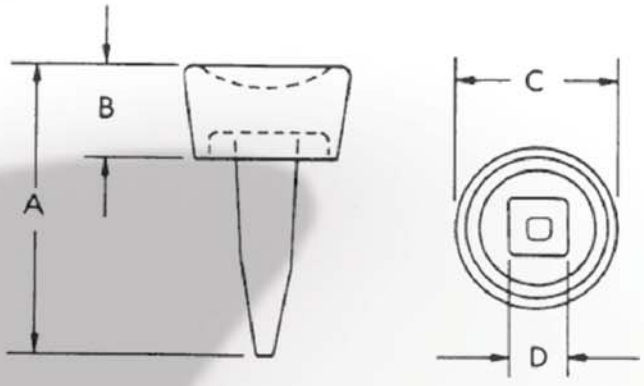
An implant should never be resterilized after contact with body tissues or fluids.

Do not sterilize by ethylene oxide as the residual sterilant may cause adverse tissue reaction.

CAUTION

Federal (India) law restricts this device to sale, distribution and use by or on the order of a physician.

DIMENSIONS (in millimeters)



SIZE	1	1.5	2	2.5	3
A	27.3	27.5	29.0	30.6	32.0
B	9.9	10.0	11.0	12.5	13.4
C	18.0	19.2	19.6	21.0	21.9
D	6.9	7.2	7.5	7.7	8.1

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