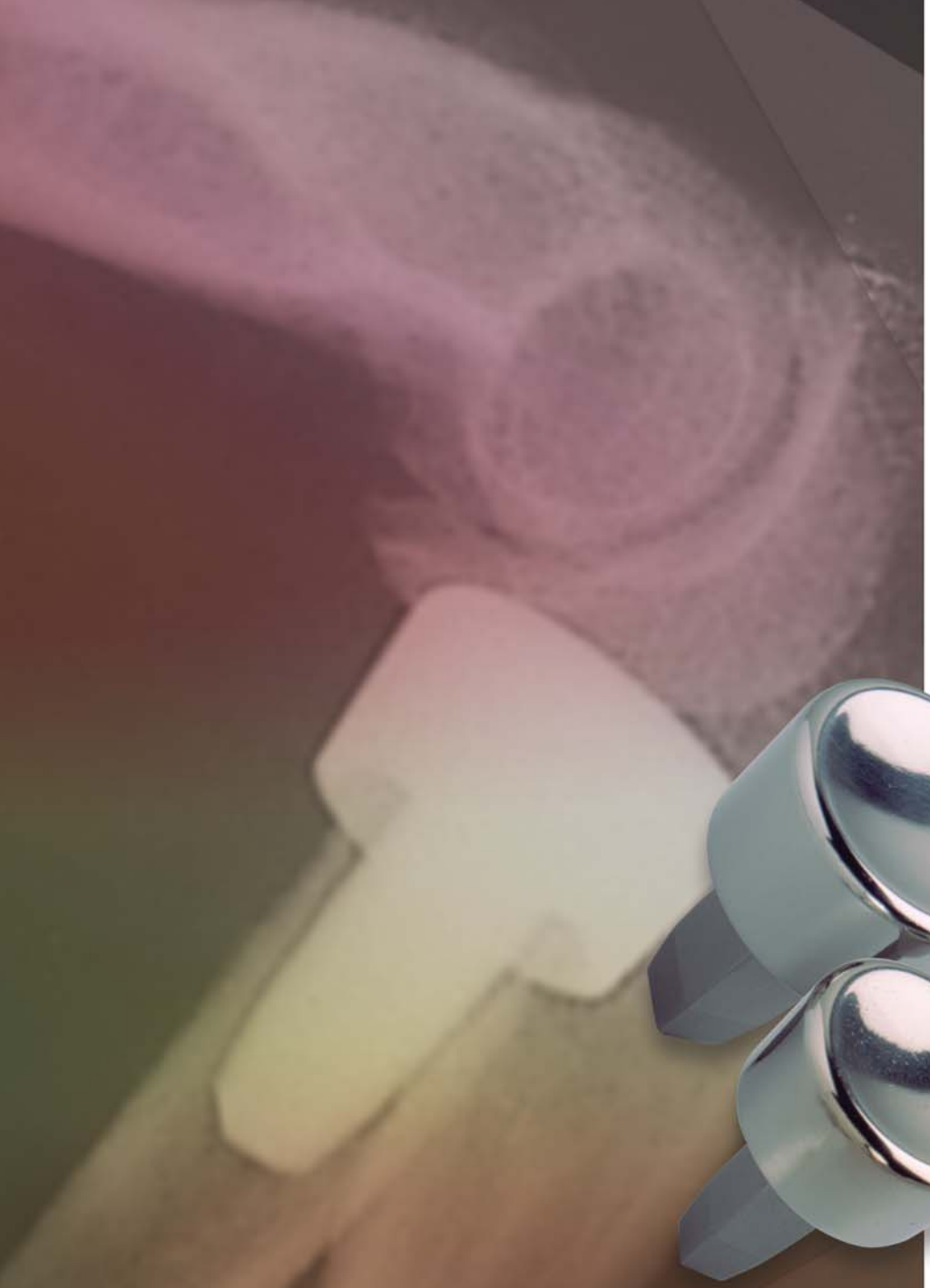
extremities solutions



SURGICAL TECHNIQUE

WRIGHT.

SWANSON

Titanium Radial Head Implant

SWANSON
titanium
RADIAL HEAD IMPLANT

regular and narrow stem

surgical technique presented by
ALFRED B. SWANSON, MD, FACS,
GRAND RAPIDS, MICHIGAN.

SWANSON
titanium radial head IMPLANT

as described by Alfred B. Swanson, MD

general 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.

IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

One of the goals of implant surgery is to minimize production of wear particles. It can never be eliminated because all moving parts, e.g., implants which articulate against bone, wear to some degree. In an implant arthroplasty, clinically significant wear can result from normal biomechanical forces. Abnormal or excessive force will further increase clinically significant wear.

Abnormal force loading may be caused by:

- Uncorrected instability
- Oversized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity
- Intra-operative fixation

The following are some preventive measures to consider to minimize the potential for complications:

Follow guidelines for indications and contraindications provided below:

- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant

| WARNING Avoid flawing implant surfaces to minimize the potential for wear debris generation and tissue sensitivity.

If complications develop, possible corrective procedures include:

- Implant removal
- Synovectomy
- Bone grafting of cysts
- Replacement of the implant
- Removal of the implant with fusion of the joint

Clinical results depend on surgeon and technique, pre-operative and post operative care, the implant, patient pathology, and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

potential complications AND ADVERSE REACTIONS

Any implant site may become infected, painful, swollen, or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant or may deteriorate with time resulting in instability, deformity, or both. Excessively mobile joints are generally less stable and an implant alone cannot provide long-term stability in a joint that lacks functional stability; complications necessitating revision surgeries are more frequent in unstable joints.

DESCRIPTION

The Swanson Titanium Radial Head Implant is an alternative to the silicone elastomer radial head implant. The implant is manufactured from commercially pure titanium that features nitrogen ion implantation for increased surface hardness. The overall profile of the implant head is unchanged from the silicone radial head implant design. The stem of the titanium radial head implant has been shortened in length and enlarged in cross-section for improved ease of placement.

The Swanson Titanium Radial Head Implants have been sterilized and are available in five sizes to meet various operative requirements. A sizing set, supplied nonsterile and not suitable for implantation, is available for proper size determination during surgery.

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.

GENERAL 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 bone stock to receive implant
- Availability of postoperative therapy
- Cooperative patient

SPECIFIC INDICATIONS

Use of the Swanson Titanium Radial Head Implant may be considered for:

- Replacement of the radial head for degenerative or post traumatic disabilities presenting pain, crepitation, and decreased motion at the radiohumeral and/or proximal radioulnar joint with:
  - A. joint destruction and/or subluxation visible on X-ray and/or
  - B. resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

GENERAL CONTRAINDICATIONS

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.

SPECIFIC CONTRAINDICATIONS

- Growing children with open epiphyses
- Dislocations of radius on ulna that would not allow a radio-humeral articulation
- Evidence of joint narrowing secondary to radiohumeral joint synovitis is not a contraindication to radial head implant replacement combined with elbow synovectomy.

SPECIFIC COMPLICATIONS

As in any surgical procedure, the potential for complications exists. The risks and complications with the Titanium Radial Head Implant includes:

- Infection or painful, swollen, or inflamed implant site
- Breakage of the implant
- Loosening or dislocation of the prosthesis requiring revision surgery
- Fracture or resorption of the bone leading to the need for further surgery
- Allergic reactions(s) to prosthetic material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response

HANDLING AND STERILIZATION

This product has been sterilized and should be considered sterile unless the package has been opened or damaged. Remove from the 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 of 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. This product is for single use only. An implant should never be resterilized after contact with body tissues or fluids.

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 non-woven 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 10^4 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.

BIBLIOGRAPHY

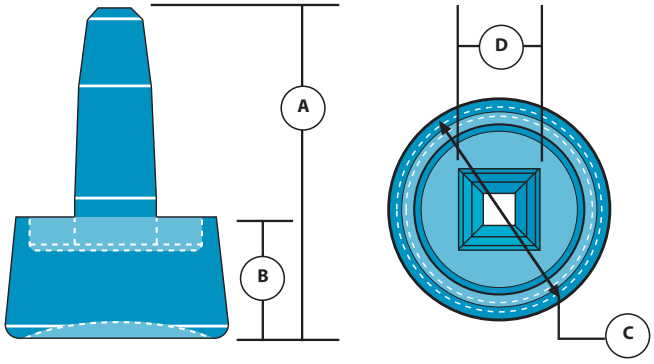
A bibliography may be obtained by writing Wright Medical Technology, Inc., or by contacting your Wright Medical representative.

HOW SUPPLIED

QUANTITY	DESCRIPTION	PART NUMBER(R)	PART NUMBER(N)
1 Box	1 Each, Size 1	486-0001	486-001N
	1 Each, Size 1.5	486-0015	486-015N
	1 Each, Size 2	486-0002	486-002N
	1 Each, Size 2.5	486-0025	486-025N
	1 Each, Size 3	486-0003	486-003N
1 Sizing Set	1 Each, Size: 1, 1.5, 2, 2.5, 3 NON-STERILE Numerically marked color coded **NOT FOR IMPLANTATION**	486-1000	486-100N
1 Instrument Tray	Contains 1 set of color coded sizers and one set of rasps for implant sizes: 1, 1.5, 2, 2.5, 3 NON-STERILE	2486-7211	2486-711N

TYPICAL DIMENSIONS (Millimeters)

SIZE	A	B	C	D (Regular)	D (Narrow)
1	27	10	19	7.0	6.0
1.5	28	11	20	7.2	6.2
2	29	11.5	21	7.5	6.5
2.5	30.5	12.5	22	7.7	6.7
3	32	13.5	23	8.0	6.9



CAUTION: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician

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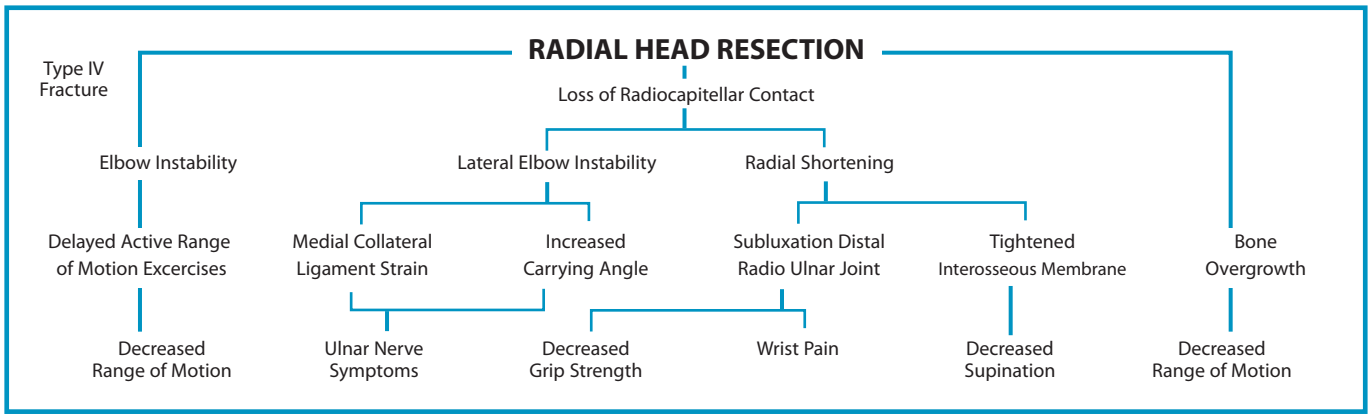

TABLE 1

INSTRUCTIONS FOR USE

Wright Medical Technology, Inc. does not recommend a particular surgical technique when using the implant. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience. The following procedure is a technique used by Dr. Alfred B. Swanson* and is furnished for information purposes only.

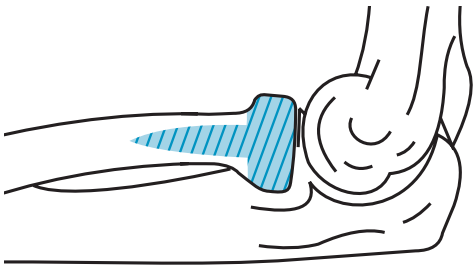

FIGURE 1 | The radial head is resected, preserving as much as possible of the annular ligament. Using a curette, broach, or drill, the intramedullary canal of the radius is shaped to accommodate the implant stem.

SURGICAL PROCEDURE

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 interosseous nerve) that passes at the radial neck. Under the protection of retractors, the radial head is resected at the epiphyseal-metaphyseal junction. | **FIGURE 1** 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 excrescences and marginal osteophytes are trimmed. The intramedullary canal of the radius is shaped to fit the stem of the implant using a curette, rasp, or drill. The proximal portion of the radius must be lifted up laterally to expose the intramedullary canal for fitting the implant. The radial nerve must be carefully protected during these maneuvers. When using the rasping technique, initially create the canal opening with the starter awl. The canal opening can be further enlarged with a leader point burr. Thereafter, rasping should progress sequentially until cortical bone is encountered.

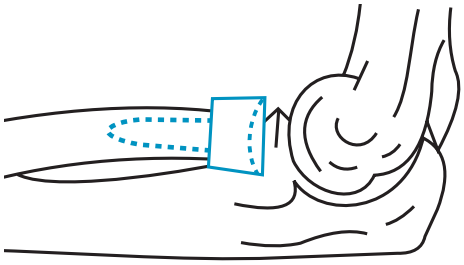

FIGURE 2 | The implant cuff should overlap the radius end, and fit snugly in the canal. Smooth rotation of the implant head should be noted on passive flexion and rotation of the forearm.

Bone debris may collect in the rasp teeth and prevent advancement. Routine rasp withdrawal and removal of bone debris may assist in fully seating the rasp. Use sizers to select the largest size 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. | **FIGURE 2** 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 and is fully seated. The capsule, ligaments, and the anconeus and extensor carpi ulnaris muscles are sutured in layers with non-absorbable 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 medial epicondyle, a synovectomy of the medical aspect of the elbow is performed, and the ulnar nerve is transposed anteriorly as necessary. The medial collateral ligament should be sutured if incised.

*Alfred B. Swanson, MD, FACS, Grand Rapids, Michigan.

postoperative CARE

On the first postoperative day, the drain is removed. The plaster splint is discarded and a light dressing is applied. The patient wears a sling for 1-2 weeks. 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 generally 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 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.

radial head fractures AND IMPLANT REPLACEMENT

In approximately one-third of the patients undergoing a simple radial head resection for fracture, a secondary disability of the distal radioulnar joint will develop from proximal migration of the radial shaft. This may be avoided by the use of the radial head implant

As in radial head resection alone for a comminuted fracture, radial head resection and replacement arthroplasty should be done soon after the fracture occurs, preferably within the first twenty-four hours. However, in patients with severe comminution, when the loss of bone stock would be considerable, a period of immobilization is indicated prior to resection and replacement arthroplasty. This is to allow healing of the neck of the radius so that a smooth osteotomy can be made.

The elbow is approached through a lateral (Kocher) incision. The annular ligament is incised, preserving the quadrate ligament and protecting the posterior interosseus nerve. The radial head is resected to preserve as much of the bone of the radius as possible. Using a power-driven burr, the end of the bone is smoothed. The intramedullary canal is reamed with a blunt-tipped reamer. The correct size of the implant is determined by trail fitting with the sizing set. The largest implant accepted by the intramedullary canal of the radius should be tight enough to prevent rotation of the implant. If the fit is too loose, a larger implant should be selected, or small bone grafts can be placed as shims in the radial intramedullary canal around the stem of the implant. There should be no impingement by bone or soft tissue on the head of the implant when the elbow and forearm is moved. The implant should articulate accurately on the capitellum.

The implant should have good contact with the capitellum, provide a good overlapping cuff to the underlying radius, and be centered over the center of the axis of rotation of the radius to prevent shearing forces at the base of the stem of the implant. The implant should be inserted with a light tap on the implant head using an impactor to complete implant seating. An anatomical closure is done using non-absorbable sutures in the annular ligament.

In Type-III fractures, active range-of-motion exercises of the elbow are generally begun on the third postoperative day, and a sling is used for approximately three weeks. In Type-IV fractures, active range-of-motion exercises are generally begun on the fifteenth postoperative day or as stability of the elbow dictates.

This procedure is a useful, safe, and reliable alternative in primary treatment of comminuted fractures of the radial head in adults. This procedure also has importance as a salvage procedure in patients with failed radial head resection. This is especially true in young, active people for whom maintenance of good radio-capitellar contact is important.

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