

SWANSON
silicone RADIAL HEAD IMPLANT
surgical technique

surgical technique presented by
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SWANSON

silicone RADIAL HEAD IMPLANT

as described by
Alfred B. Swanson, MD

description



The Swanson* 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.

Designed specifically for radiohumeral arthroplasty, the Swanson Radial Head Implant is fabricated from silicone elastomer. It serves to help restore and maintain the physiological length of the radius by providing a smoother surface for its proximal end.

The Swanson Radial Head Implant has been sterilized and is available in five standard and three extra-long sizes to adequately meet various operative requirements. A sizer 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

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Complete indications, contraindications, warnings, and precautions are listed in the implant package insert and should be viewed by the physician and operating room personnel.

specific INDICATIONS

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

- Replacement of the radial head for rheumatoid, degenerative or posttraumatic 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

NOTE | The use of extra long radial head implant is indicated when there is a lack of bone stock at the radial neck and the distance between the capitellum and the proximal radius is too long for the conventional style implant. This situation can be seen when there has been a comminuted radial head fracture including the neck or following an overzealous bone removal in radial head excision procedures. Evidence of joint narrowing secondary to radiohumeral joint synovitis is not a contraindication to radial head implant replacement combined with elbow synovectomy.

general CONTRAINDICATIONS

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

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

specific CONTRAINDICATIONS

- Growing children with open epiphyses
- Dislocations of radius on ulna that would not allow a radiohumeral articulation

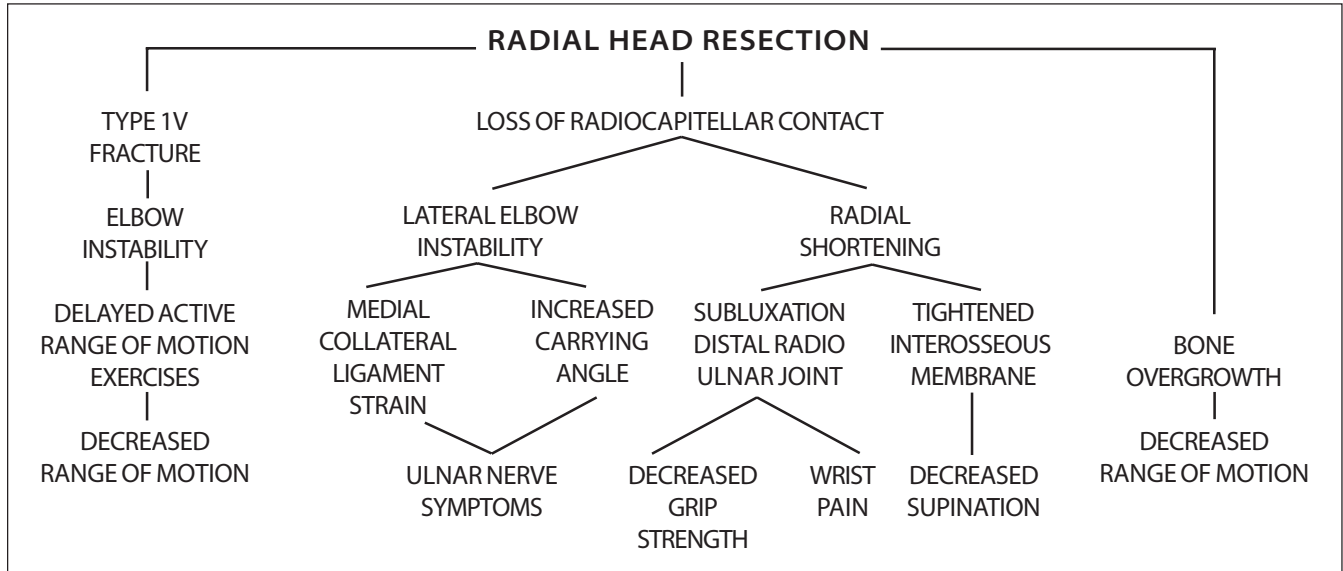


TABLE 1 | Radial Head Resection

SURGICAL PROCEDURE

Proper surgical procedure and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for information purposes only as a technique used by Dr. Alfred B. Swanson. 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 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, 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.

Use blue sizers to select the largest size that will provide lapping of the cuff

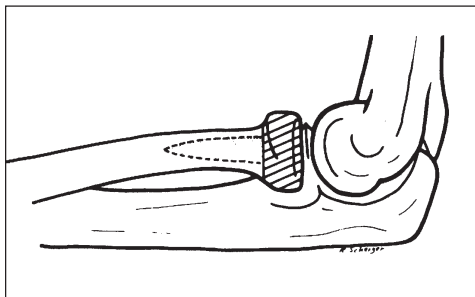


FIGURE 1 | The radial head is resected, preserving as much as possible of the annular ligament. Using a curette, broach or drill, the intramedullary canal of the radius is shaped to accommodate the implant stem.

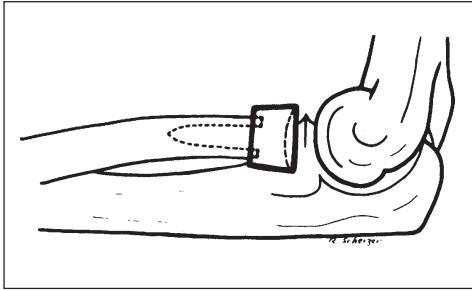


FIGURE 2 | The implant cuff should overlap the radius end, and fit snugly in the canal. Smooth rotation of the implant head should be noted on passive flexion and rotation of the forearm.

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 blue sizer with the capitellum and smooth rotation should be noted on passive flexion and rotation of the forearm. The blue 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 nonabsorbable 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.



FIGURE 3A | 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.

FIGURE 3B | 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.

POSTOPERATIVE CARE

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.

| FIGURE 3

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.

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



FIGURE 4A | Preoperative radiogram of the elbow of a 52-year-old surgeon who, ten years previously, had a radial head resection for comminuted fracture. He presented proximal migration of the radius with increased valgus angle, elbow instability, ulnar nerve symptoms, distal radioulnar joint disability, and decreased motion and strength, with severe pain at the elbow, forearm, and wrist.

FIGURE 4B | The postoperative radiogram shows an extra-long radial head implant in place, well-tolerated by bone. The patient at ten-years' follow-up has a pain-free, stable elbow with freedom of pain at the wrist and return of normal strength in the hand.

radioulnar joint will develop from proximal migration of the radial shaft. This may be avoided by the use of the radial head implant.

| FIGURE 4

As in radial head resection alone for a comminuted fracture, radial head resection and silicone 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 silicone 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 quadratus ligament and protecting the posterior interosseus nerve. The radial head is resected at the metaphyseal flare or is resected to preserve as much of the bone of the radius as possible. Using a power-driven bur, the end of the bone is smoothed, as sharp edges can cut the implant. The intramedullary canal is reamed with a blunt-tipped reamer. The correct size of the implant is determined by a trail fitting with the blue 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 issue on the head of the implant when the elbow and forearm is moved. The implant should articulate accurately on the capitellum.

Long-head implants are available to correct for increased loss of bone stock due to comminution. 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 blunt forceps utilizing a no-touch technique. An anatomical closure is done using nonabsorbable sutures in the annular ligament.

In Type III fractures, active range-of-motion exercises of the elbow are begun on the third postoperative day, and a sling is used for three weeks.

In Type-IV fractures, active range-of-motion exercises are begun on the fifteenth postoperative day or as stability of the elbow dictates.

A study of 18 cases of radial head replacement for comminuted fractures of

the radial head, operated by Dr. A. B. Swanson, has been reported. It was shown that 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 in whom maintenance of good radiocapitellar contact is important.

Other investigators have also reported good results using the implant for primary replacement in comminuted fractures of the radial head.

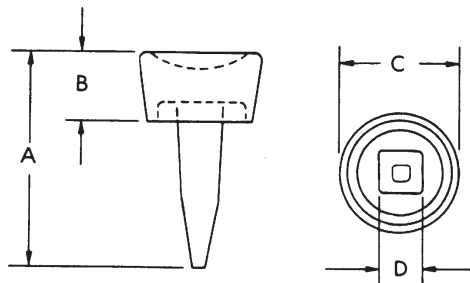
BIBLIOGRAPHY

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

HOW SUPPLIED

The Swanson Radial Head Implant has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	One each, size 1	484-0001
1 box	One each, size 1.5	484-0015
1 box	One each, size 2	484-0002
1 box	One each, size 2.5	484-0025
1 box	One each, size 3	484-0003
1 sizing set	One each, sizes, 1, 1.5, 2, 2.5, 3 non-sterile, numerically marked, color blue NOT FOR IMPLANTATION	494-0000
1 box	One each, size 1XL	484-0101
1 box	One each, size 2XL	484-0102
1 box	One each, size 3XL	484-0103
1 box	One each, sizes 1XL, 2XL, 3XL nonsterile, numerically marked, color blue NOT FOR IMPLANTATION	494-00XL



TYPICAL DIMENSIONS (millimeters)

Size	1	1.5	2	2.5	3	1XL	2XL	3XL
A	32.0	34.8	36.3	38.8	39.9	45.5	53.3	55.0
B	10.4	11.2	11.9	13.2	14.0	15.2	19.1	21.8
C	19.1	20.1	20.8	21.8	22.6	18.5	21.0	22.5
D	6.9	7.4	7.6	8.6	8.9	7.4	7.9	8.6

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 and subsequent wear may be caused by:

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

Some preventive measures to consider to minimize the

potential for complications:

- Follow guidelines for indications and contraindications
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft preexisting cysts
- Use a properly sized implant
- Avoid K-wires and sutures through the implant

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, preoperative 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.

WARNING | Reshaping of the implant should be avoided because it can compromise or destroy the structural integrity and the functionality of the implant.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with the

Swanson Radial Head Implant include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the prosthesis requiring revision surgery
- Bone restoration or overproduction
- Allergic reaction(s) to prosthesis material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response

Some degree of particle formation is inevitable with all implants including those made of silicone elastomer. The amount will vary with factors such as patient activity, carpal stability or instability post-implantation, implant position and the amount of soft tissue support. The patient's biological response to these particles is variable, but can include local synovitis and bone lysis in contiguous bones. Another potential concern with silicone implants arises from case reports in the literature suggesting an association between silicone implants and immunological abnormalities and autoimmune rheumatic disorders, although these reports have been contradicted and the association has not been proven conclusively.

RISK / BENEFIT DECISION BY SURGEON

The judgment by a surgeon to implant silicone elastomer implants is a complicated risk/benefit decision which must take into account the patient's needs and desire in addition to the surgeon's knowledge of expected results and complications as well as therapeutic alternatives. Wright Medical Technology, Inc. can provide a bibliography of articles on the use and complications of silicone elastomer implants to any physician.

HANDLING & STERILIZATION

The Swanson 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. 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 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 270° F flash sterilization cycle, place the component on a standard mesh sterilization tray.
4. If using a 270° F gravity or 270° 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	270° F/121° C	45 minutes
Steam	Flash	270° F/132° C	15 minutes
Steam	Pulsing-Vacuum	270° F/132° 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, re-sterilization in excess of three times is contraindicated.

The Swanson Radial Head Implant is for single use only.

An implant should never be re-sterilized after contact with body tissues or fluids.

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

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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