SWANSON II

wrist JOINT IMPLANT

surgical technique 1-12
The Swanson II Wrist Joint Implant is a one-piece intramedullary stemmed implant fabricated from implant grade silicone elastomer. It is designed for use in implant resection arthroplasty of the radiocarpal joint. The Swanson II Wrist Joint Implant is available in five sizes to satisfy most anatomical requirements. It has a wide mid-section to match the width of the radius. The shorter distal stem extends through the carpus into the base of the third metacarpal. The stems usually do not require shortening. This implant design was previously known as "wide with Shortened Distal Stem." The former "Regular" and "Wide" designs (both with long distal stems) have been discontinued.

The size of each implant is identified by a number 1 through 5 followed by the letters "WS": indicating wide mid-section and short distal stem. A color coded sizing set supplied nonsterile and not suitable for implantation is available for proper size determination during surgery.

Stability of the wrist is important for normal function of the extrinsic muscles of the fingers. Reconstruction of a disabled wrist should provide reasonable stability and strength with enough mobility to assist in hand adaptations. Such a result can be achieved with the flexible implant resection arthroplasty procedure in the arthritic patient.

The Swanson II Wrist Joint Implant has been used as an adjunct to resection arthroplasty of the wrist in patients who have demonstrated marked instability of the wrist joint with absorptive changes of the proximal carpal row and subluxation of the radiocarpal joint. The purpose of the implants is to maintain an adequate joint space and alignment while supporting the development of a new capsuloligamentous system. It allows vertical and lateral movements through its flexible midsection and stems. The implant is used with a proximal row resection the includes resection of the base of the capitate. The distal implant stem is directed through the capitate into the third metacarpal and the proximal stem into the intramedullary canal of the radius.
This positions the implant well in respect to the normal flexural area. It has been demonstrated that the axis of motion of the wrist is at the level of the head of the capitate bone. However, most of the wrists are severely diseased, and the normal radiocarpal and intercarpal articular movements have been altered. The flexible hinge implant, because of its flexibility, can adjust to the required axis of rotation with little resistance. Because the stems are not fixed, this is further facilitated as demonstrated on cinefluoroscopy studies. Furthermore, this procedure is essentially retrievable. If necessary, the implant is easily replaced and if fusion becomes indicated, it can easily be done with a bond graft.

The degree of stability and mobility obtained with this technique to date has been most encouraging. It would appear that a properly done implant resection arthroplasty of the wrist, including a proper capsuloligamentous reconstruction around the implant and balancing of the muscle power to obtain adequate active movements in all planes, is superior to arthrodesis, pseudarthrodesis, or other simple arthroplasty procedures for the arthritic.

GROMMET

The Swanson II Wrist Joint Grommet is a thin, titanium shield designed to modify the Swanson II Wrist Joint Implant in selected cases. It is contoured to conform to the shape of the midsection of the flexible implant and is fabricated from unalloyed titanium for surgical application. The distal grommet is normally used on the dorsal surface, and the proximal grommet on the palmar surface to protect the implant from the shearing forces of sharp bone edges. Use of the grommet-modified implant is indicated in patients where cutting or abrasion of the flexible implant from contact with resected bone is likely to occur.

The outer surface of each grommet is marked with a numeral, indicating the size of wrist joint implant it fits, as well as the letter “P” or “D”, indicating whether it is a proximal or a distal grommet.

The function of the grommet modification to the flexible Swanson II Wrist Joint Implant is to provide an unattached, smooth and durable metallic shield between the silicone elastomer implant and contiguous bone. Typically, grommets are placed on the dorsal surface of the distal stem and palmarward on the proximal stem to protect the implant from sharp bone in areas where wear, abrasion and cutting are most likely to occur. The grommet modification does not alter the function of the implant, patient indications and contraindications, nor reduce the need for careful attention to the arthroplasty technique.
WARNING | RECOMMENDATIONS
In some patients, particulate associated synovitis and related cystic bone changes can occur around abraded silicone implants due to the so-called “frustrated macrophage” which, after ingesting particles, releases a variety of detrimental enzymes. This phenomenon has been reported especially with: carpal bone implants overloaded with excessive compressive and shear stress; implant oversize or subluxation; inadequate intercarpal bone stabilization; and excessive activity. These complications have been reported to occur to a lesser degree with trapezium or other spacer implants.
Although there have been a few reports in the literature suggesting a relationship between silicone implants and a broad spectrum of connective tissue diseases, system illness and autoimmune phenomena, the causal relationship has not been proven. It has been shown that rheumatoid patients are at greater risk to develop lymphomas, leukemia and myelomas possibly due to the immunological abnormality of rheumatoid arthritis. The participation of antigen-specific lymphocytes or antibodies in silicone particle-induced macrophage reactions has not been demonstrated in ongoing studies.

PRECAUTIONS
It is the responsibility of each surgeon to evaluate the medical and surgical status and requirements of each patient, to know all aspects of implant procedures, and to inform the patient on alternative procedures, potential expectations and complications.
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 surgery following implant procedures is not uncommon. Surgeons must balance many considerations to achieve the best result in individual patients.

STERILIZATION
The Swanson II Wrist Joint Implants and Grommets are supplied sterile. The sizing sets are supplied nonsterile.
The following sequential steps are recommended to clean and sterilize the sizing:
1. Scrub thoroughly with a 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 the soaps may be absorbed and subsequently leach out to cause a tissue reaction.
2. Rinse thoroughly with distilled water.
3. Wrap in a lint-free cloth or place on a clean open tray, and autoclave according to the following guidelines:

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<th>EXPOSURE</th>
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<td>Steam</td>
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<td>270°F (132°C)</td>
<td>10 minutes</td>
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BIBLIOGRAPHY
A bibliography may be obtained by writing Wright Medical Technology, Inc. or by contacting your WMT representative.

NOTE | Evidence suggests that repeated sterilization may affect the physical characteristics of the implant. Accordingly, resterilization of the implant in excess of three times is contraindicated.
The foregoing statement does not apply to the colored sizers where ultimate physical properties are medically irrelevant.

IMPORTANT | Do not sterilize by ethylene oxide as the residual sterilant may cause adverse tissue reaction.
SPECIFIC ADVANTAGES OF THE IMPLANTS

• Pliable implant grade silicone elastomer with low-elastic modulus (softer than bone) dampens force-loading and minimizes potential for necrosis or bone resorption. Cortical bone density typically increases postoperatively. These benefits are retained with grommet-modified implants.

• Neither the flexible implant nor the grommet requires artificial fixation to bone. Micro-pistoning of the flexible implant intramedullary stems results in less stress to bone and the implant; allows joint to find its own axis for center of rotation.

• Both flexible implant and grommet are visible on x-ray evaluation.

• Design characteristics of load-distributing hinges include: intramedullary-stemmed, flexible one-piece hinge-like construction of homogeneous material with stiffness/flexibility balance of implant material, and proper compression-tension force distribution in midsection.

• The flexible implant orients and supports joint encapsulation.

• The flexible implant makes results of arthroplasty more predictable, reproducible, and durable.

TREATMENT CONSIDERATIONS

CLINICAL ADVANTAGES

• Allows reconstruction and rebalance of musculotendinous structures.

• Good pain relief.

• Provides a reasonable stable wrist.

• Provides adequate wrist motion in all planes, especially extension.

• Maintains AP and lateral relationship of the carpus and radius, joint space, and alignment.

• Facilitates postoperative rehabilitation.

• Essentially a salvageable procedure.

• Does not interfere with later fusion of the wrist if the implant arthroplasty does not meet functional requirements.
Any joint implant reconstruction requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate bone stock to receive implant
- Availability of postoperative therapy
- Cooperative patient

Rheumatoid arthritic changes in the radiocarpal joint are frequent and are especially disabling when associated digit deformities are present. They may affect the soft tissues and the joints of the wrist including the radiocarpal, intercarpal and radioulnar, singly or in combination. Associated ruptures of the extensor tendons are common.

Flexible wrist implant resection arthroplasty is indicated in cases of arthritic or traumatic disability resulting in:

1. Instability of the wrist due to subluxation or dislocation of the radiocarpal joint.
2. Severe deviation of the wrist causing musculotendinous imbalance of the digits.
3. Stiffness or fusion of the wrist in a non-functional position
4. Stiffness of the wrist where movement is a requirement for hand function.

Reconstruction of the wrist should be performed before surgery of the finger joints unless there are extensor tendon ruptures.

The use of Swanson II Wrist Joint Grommets is indicated in selected patients to prevent cutting of the implant by sharp bone edges. Grommets can be used both distally and proximally to protect the surfaces of the flexible implant. The proximal grommet is placed palmarly and the distal grommet dorsally.

- Young patients with open epiphyses
- Physiologically or psychologically inadequate patients
- Inadequate skin, bone and/or neurovascular status
- Irreparable tendon system
- Patients who plan heavy manual work
- Presence of infection
- Possibility for conservative treatment
- Infection

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.
A straight, longitudinal incision is made over the dorsal wrist, taking care to preserve the superficial sensory nerves. The extensor retinaculum is incised as to prepare a radially-based flap between the first and second dorsal compartments | FIGURE 1A, 1B. A narrow proximal flap is prepared for later resuture over the extensor tendons to prevent bow-stringing. Another retinacular ligament flap can be prepared to relocate the extensor carpi ulnaris tendon in associated implant reconstructions of the ulnar head. Synovectomy of the extensor compartments is performed taking care to remove the synovium only. The dorsal capsuloligamentous structures are carefully preserved for later resuture, reflecting them from the radius leaving a distally based flap | FIGURE 1C.

A part of the proximal carpal row is usually absorbed, and the remnants are displaced palmarward on the radius. Resection of the remaining lunate is carefully done with a rongeur. Part of the distal scaphoid, capitate, and triquetrum can be retained in some cases. Injury to the underlying tendons and neurovascular structures should be avoided. The end of the radius is squared off to fit against the distal carpal row. The distal row of carpal bones should be left intact because of their importance in maintaining the stability of the metacarpal bases. The radiocarpal subluxation should be completely reduced | FIGURE 2A, 2B.

The intramedullary canal of the radius is prepared with a broach, curette or air drill to receive the proximal stem of the implant. If there has been a marked radiocarpal dislocation with subsequent soft tissue contracture, it is preferable to shorten the distal radius rather than remove more of the carpal bones.
IMPORTANT POINTS TO OBSERVE

- Handling of the flexible hinge implant should be done with blunt instruments to avoid trauma to its surface or contamination with foreign bodies. Rinse the implant thoroughly with saline solution before insertion. Reshaping of the implant should be avoided because modification might create mechanical weakness. Shortening of the end of the stem should be done if it abuts the end of the intramedullary canal.

- Fitting of the grommet requires a precise press fit. It must be accurately centered, otherwise it may impinge the cortex in the intramedullary canal on one side and could cause bone absorption. Unless the shoulders of the grommet can be fitted into metaphyseal bone, rotation of the grommet could occur. In certain cases of severe metacarpophalangeal joint dislocation, more bone must be removed to obtain joint reduction and the implant may have to be used without the grommet.

The distal stem of the implant fits through the capitate bone into the intramedullary canal of the third metacarpal which is carefully prepared by passing a wire or very thin broach through the capitate bone and the base of the third metacarpal. A Kirschner wire can be passed into the base of the metacarpal and out through its head to verify the intramedullary orientation. The bones are usually very soft and this preparation is performed quite easily. An air drill may be used for the final reaming procedure. The distal stem should not be distal to the metaphysis of the third metacarpal in most cases and should be shortened accordingly | FIGURE 2B. Sizers are used as the canals are being prepared and to determine correct implant size.

If necessary, the distal ulna may be managed via a Darrach or similar procedure. The hand is then centralized over the radius. Enough bone should have been removed so that 20°-30° extension and 20°-30° flexion of the wrist can be obtained on passive manipulation. Usually 1.0 to 1.5cm of separation between the radius and carpus is adequate.
In patients selected to receive Swanson II Wrist Joint Grommets, the sizer is removed and the bone canals are prepared to allow a press-fit of the appropriate sized grommet. The resected surfaces of the radius and capitate are shaped so that the grommet fits well into bone and the curvilinear profile of the grommet is covered by bone so that contact with overlying soft tissues is avoided. The distal grommet is normally used on the dorsal surface, and the proximal grommet on the palmar surface to protect the implant from the shearing forces of sharp bone edges [FIGURE 3]. The grommet sizing corresponds to implant sizing. Final seating of the grommet is done by gentle pressure or tapping against a curved instrument held against the exposed surface of the grommet. This is done with care to avoid bending or distorting the grommet. The grommet shoulders are seated directly against resected bone and inspected to assure the grommet does not protrude. If too loose, the next larger size is selected. When necessary, using a grommet one size larger than the flexible implant is permissible but a grommet smaller than the implant is never used. With grommets in place, the sizer is inserted and joint space and flexion-extension assessed. If the joint space is too small the proximal grommet is removed and it is reseated more deeply to create a larger joint space. The wound is thoroughly irrigated with triple antibiotic solution. The proximal stem of the wrist joint implant is inserted into the intramedullary canal of the radius first, and the distal stem is then introduced through the capitate and into the intramedullary canal of the third metacarpal.

Repair of both the palmar and dorsal capsuloligamentous structures around the implant is critical to obtain an adequate result. the palmar ligaments are reefed proximally or distally or both, according to where they are loose [FIGURE 4A, 4B].
The proximal palmar reefing is done by passing 2.0 Dacron sutures on a PR-4 needle through two small drill holes made in the palmar distal edge of the cut end of the radius. The distal palmar reefing is done by passing a 2.0 Dacron sutures on a PR-4 needle passed through three small drill holes made in the dorsal cortex of the radius | FIGURE 4C.

The sutures are placed prior to implant insertion. After implant insertion and closure, the repair should be tested so that approximately 30° of extension and flexion and 10° of ulnar and radial deviation are possible on passive manipulation. More than 30° postoperative extension or flexion may increase the potential for implant failure and does not improve wrist function significantly. In patients with significant bone loss or loose ligaments who may have excessive extension, radial or ulnar deviation after implant arthroplasty, it may be necessary to add sutures to the palmar, radial and ulnar cortex of the radius to tighten the capsule in these areas. Adequate ligamentous repair is very important to proper function and durability with this type of arthroplasty.

The previously prepared extensor retinaculum flap is brought down over the wrist joint under the extensor tendon and sutured in place to provide further capsular support. The pull of the extensor tendons of the wrist joint are then evaluated, and they are shortened or transferred as required to obtain wrist extension without lateral deviation. The extensor carpi radialis longus may be transferred under the brevis to attach to the third metacarpal by a suture through the bone or interwoven into the brevis tendon distal attachment. The extensor tendons of the digits are repaired if necessary. We frequently may use one of the flexor superficialis muscles as a tendon transfer to reconstruct ruptured extensor digitorum communis tendons. If isolated extensor tendons are ruptured, side-to-side suture can be performed. Ruptures of the extensor pollicis longus tendon can be repaired by transferring the extensor indicis proprius tendon. The small proximal flap is placed over the extensor tendons to prevent bowstringing | FIGURE 1B.

The reconstruction of the distal radio-ulnar joint is completed by using a retinacular flap from the sixth dorsal compartment to relocate dorsally the extensor carpi ulnaris tendon.
The wound is closed in layers, and an appropriate drain is inserted subcutaneously. Extreme care must be taken to protect the wound from hematoma and the skin from necrosis. A straight line incision, careful tissue handling, proper wound drainage, a supportive, conforming, non-compressive dressing, elevation of the extremity, and proper wound care are essential. The usual voluminous conforming hand dressing is applied, including a plaster splint with the wrist in neutral position. This is worn for three to ten days. The extremity is maintained in an elevated position for three to ten days with an arm sling, the patient being at bed rest. A short arm cast, with the wrist in neutral position, is then applied and fitted with outriggers to hold rubber band slings to keep the fingers in extension if the tendons have been repaired. This is worn as desired for four to six weeks. If necessary, a dorsal window is made in the cast for wound inspection and/or protection. Adequate immobilization is essential to allow firm capsuloligamentous healing to occur in proper wrist position. We desire a good ratio of stability and mobility. A joint that is too loose may be unstable. We attempt to obtain 50% to 60% of normal flexion/extension movements as the ideal goal. The patient should be started on an exercise program following cast removal to obtain active flexion and extension. Postoperative therapy includes strength building of the forearm musculature, especially of the wrist extensors. The patient should be started on an exercise program following cast removal to obtain active flexion and extension. Postoperative therapy includes strength building of the forearm musculature, especially of the wrist extensors. The patient should be restricted from excessive and abusive activity. If there is a tendency for tightness, some active and passive stretching exercises are prescribed.
The Swanson II Wrist Joint Implant (Radiocarpal) has been sterilized and packaged as follows.

1 box One each, size 1WS with Grommets G498-0301
1 box One each, size 2WS with Grommets G498-0302
1 box One each, size 3WS with Grommets G498-0303
1 box One each, size 4WS with Grommets G498-0304
1 box One each, size 5WS with Grommets G498-0305
1 sizing set One each, implant sizes 1WS 2WS, 3WS, 4WS, 5WS. Numerically marked, color coded (non-sterile), NOT FOR IMPLANTATION

### TYPICAL DIMENSIONS FOR WIDE IMPLANT WITH SHORTENED DISTAL STEM

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### TYPICAL DIMENSIONS FOR WRIST JOINT GROMMETS

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POTENTIAL COMPLICATIONS

An implant site may become infected, painful, swollen or inflamed. Strenuous implant loading, excessive mobility, the presence of articular instability, implant oversizing, patient over-activity or misuse increases the potential for complications including wear or fracture of the implant and particle formation. 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.

ADVERSE REACTIONS

The risks and complications with the Swanson II Wrist Joint Implant and the Swanson II Wrist Joint Grommets are similar to those of other small joint replacements and include:

1. Fracture of the grommet, the implant stem and/or hinge
2. Late loosening of the prosthesis requiring revision surgery
3. Bone absorption or overproduction and
4. The generation of wear debris.

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 procedures 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. Revisions surgeries with implants are not uncommon. Surgeons must balance many considerations to achieve the best result in individual patients.

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 that articulate against bone, wear to some degree. In an implant arthroplasty, clinically significant wear can result from abnormal biomechanical forces which generate excessive loads.

Abnormal force loading and subsequent wear may be caused by:
- Uncorrected joint subluxation
- Poor implant sizing.
- Inadequate capsuloligamentous structures.
- 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 patient selection guidelines.
- Identify prior pathology.
- Stabilize collapse deformities.
- Bone graft pre-existing cysts.
- Use a properly sized implant.
- Sutures and K-wires are not recommended.

If complications develop, possible corrective procedures include:
- Implant removal.
- Synovectomy
- Bone grafting of cysts.
- Replacement of implant or joint fusion.

Clinical results depend on surgeon and technique, preoperative and postoperative care, the implant, patient pathology, and daily activity. It is suggested that surgeons use appropriate informed consent and discuss the potential for complications with each patient scheduled for surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

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

Avoid flawing implant surfaces to minimize the potential for tear propagation.