



SJO SILICONE IMPLANTS

150823-0

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Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

**SMALL JOINT ORTHOPEDIC (SJO)
(SILICONE IMPLANTS)
(150823-0)**











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I. DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture

	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation
	Sterilized using gas plasma
	Sterilized using aseptic processing techniques
	For prescription use only
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

II. GENERAL PRODUCT INFORMATION

Through the advancement of partial and total joint replacement, the surgeon has been provided a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from silicone, metal, and ceramic materials, and that any joint replacement system cannot be expected to withstand the activity levels and loads as would normal, healthy bone. In addition, the system will not be as strong, reliable, or durable as a natural human joint.

In using joint prostheses, the surgeon should be aware of the following:

- A. All products are manufactured from **silicone** elastomer, EXCEPT the finger, toe, and wrist grommets, which are manufactured from **titanium**.
- B. The **judgement by a surgeon** to implant silicone elastomer implants is a 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. Please write or call Wright Medical Technology, Inc.
- C. **The correct selection and sizing of the prosthesis is extremely important.** Selection of the proper size, shape, and design of the prosthesis increases the potential for success in joint replacement. Joint prostheses require careful seating and adequate bone support.
- D. 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.

- E. **Reshaping of the implant** should be avoided because it can compromise or destroy the structural integrity and the functionality of the implant.
- F. For all implants, a **sizing set** is available for proper size determination during surgery (supplied nonsterile and not suitable for implantation)
- G. **In selecting patients for joint replacements, the following factors can be critical to the eventual success of the procedure:**
 - 1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
 - 2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
 - 3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. PATIENT SELECTION

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 post-operative therapy
- Cooperative patient

See Section II for specific product information.

B. CONTRAINDICATIONS

- 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

See Section II for specific product information.

C. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with silicone implants 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 over-production
- 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
- Embolism

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, joint 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.

See Section II for specific product information.

D. PRECAUTIONS

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

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 post-operative 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 of all the moving parts, e.g., implants that 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
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity
- Intra-operative fixation

Some preventative measures to consider to minimize the potential for complications:

- Follow guidelines for indications and contraindications provided above
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing 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, 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.

Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.
- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.

- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;
 - e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Concerning Magnetic Resonance Environments

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

See Section II for specific product information.

E. HANDLING AND STERILIZATION

IMPLANTS

The implants described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Implants that are presented in instrument trays are provided non-sterile.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

This product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized according to the following parameters:

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.

5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly/flush with deionized/reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly/flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Sterilization

The minimum recommended steam sterilization conditions for Wright reusable instruments (and non-sterile implants) are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	Parameter	Set Point
Prevacuum 270 °F (132 °C)	Exposure Temperature	270 °F (132 °C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

- After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and tested using specific equipment. 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.

For additional information see Wright's "Cleaning and Handling of Wright Medical Instruments".

F. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

III. SPECIFIC PRODUCT INFORMATION

A. SWANSON RADIAL HEAD IMPLANT

DESCRIPTION

Available in Standard and Extra Long Sizes, 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 radio-humeral and proximal radio-ulnar 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. It is designed specifically for radiohumeral arthroplasty.

INDICATIONS

- Replacement of the radial head for rheumatoid, degenerative, or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
 - joint destruction and/or subluxation visible on X-ray and/or
 - 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 radio-humeral joint synovitis is not a contraindication to radial head implant replacement combined with elbow synovectomy.

CONTRAINDICATIONS

- Growing children with open epiphyses
- Dislocation of radius on ulna that would allow a radio-humeral articulation

B. SWANSON HAMMERTOE (WEIL DESIGN) IMPLANT

DESCRIPTION

The Swanson Hammertoe Implant is a flexible double stemmed implant specifically designed for the proximal interphalangeal joint of the lateral toes. It is used as an adjunct to resection arthroplasty in cases of moderate to severe hammertoe deformities of toes 2 through 5. The implant is symmetrical; therefore, there are no proximal/distal nor lateral/medial designations.

INDICATIONS

- Semi-rigid or rigid hammertoe deformity associated with degenerative arthritis
- Semi-rigid or rigid hammertoe deformity associated with rheumatoid arthritis
- Revision of a failed arthroplasty or arthrodesis

C. SWANSON FINGER JOINT IMPLANT AND GROMMET

DESCRIPTION

The Swanson Finger Joint Implant is a flexible, intramedullary-stemmed, one-piece implant developed for reconstruction of finger joints to help restore function to hands disabled by rheumatoid, degenerative or post-traumatic arthritis. The midsection of the load-distributing flexible hinge implant has been designed to flex easily while, at the same time, maintaining vertical stability: it acts as both a spacer and a flexible hinge.

The Swanson Finger Joint Grommet II is a thin, titanium shield designed for use with the Swanson Finger Joint Implant in severe rheumatoid arthritis patients where cutting or abrasion of the flexible implant from contact with thin, sharp bone edges could occur, or in patients who have high activity levels. It is contoured to conform to the shape of the stem and midsection of the flexible implant and is fabricated from unalloyed titanium for surgical application. The distal grommet is used on the distal stem and the proximal grommet on the proximal stem. Sizes 3-9 packages of the Swanson Finger Implant contains a pair of matching proximal and distal grommets.

INDICATIONS

- Metacarpophalangeal Joint
- Rheumatoid or post-traumatic disabilities with:
 - Fixed or stiff MP joints
 - X-ray evidence of joint destruction or subluxation
 - Ulnar drift, noncorrectable by surgery, of soft tissues alone
 - Contracted intrinsic and extrinsic musculature and ligament system
 - Associated stiff interphalangeal joints

- Proximal Interphalangeal Joint
- Rheumatoid, degenerative or post-traumatic disabilities with:
 - Destroyed or joints subluxed
 - Stiffened joints in which a joint tissue release alone would be inadequate

PRECAUTIONS

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 resorption. 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, additional bone must be removed to obtain joint reduction and the implant may have to be used without the grommet.

D. SWANSON FLEXIBLE HINGE TOE IMPLANT AND GROMMET (STANDARD AND SHORT STEM)

DESCRIPTION

The Swanson Flexible Hinge Toe Implant is a double stemmed flexible hinge implant designed to restore function to the metatarsophalangeal joints disabled by rheumatoid, degenerative, or post-traumatic arthritis. In the first metatarsophalangeal joint, the implant is used in cases of moderate to severe hallux valgus deformity secondary to rheumatoid arthritis, or to senile degenerative arthritis and in cases of bony destruction on both sides of the joint. In the lateral metatarsophalangeal joints, the implant is used in cases of dislocation and extension contracture of the metatarsophalangeal joint, in cases of bone destruction of one or both joint surfaces as in rheumatoid arthritis, and in cases of dislocation resulting from resection of the base of one or both joint surfaces as in rheumatoid arthritis.

The Swanson Flexible Hinge Toe Joint Grommet is a thin titanium shield designed for use with the Swanson Flexible Hinge Toe Implant in rheumatoid patients where cutting or abrasion of the flexible implant from contact with thin, sharp bone edges can occur, or in patients who have high activity levels. 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 used on the distal stem and the proximal grommet is used on the proximal stem to protect the implant from biomechanical shearing forces of sharp bone edges during joint motion.

INDICATIONS

- In cases of rheumatoid arthritis presenting a moderate to severe hallux valgus deformity, lateral toe involvement, radiographic evidence of erosion, cyst formation and narrowing of the first metatarsophalangeal joint and contractual deformities.
- In cases of severe senile hallux valgus deformity.
NOTE: Care must be taken to preserve part of the head to prevent shift of the weight bearing to the second toe.
- In cases of moderate to severe hallux valgus deformity secondary to degenerative or post-traumatic arthritis.
- For revision of previous procedures when there is evidence of bony destruction involving both sides of the joint and for revision of failed single stem arthroplasty.
- In cases of rheumatoid arthritis of the lateral toes presenting moderate to severe deformity and radiographic evidence of erosion, cyst formation, and narrowing of the metatarsophalangeal joint.

PRECAUTIONS

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 resorption. Unless the shoulders of the grommet can be fitted into metaphyseal bone, rotation of the grommet could occur. In certain cases of severe metatarsophalangeal joint dislocation, additional bone must be removed to obtain joint reduction and the implant may have to be used without the grommet.

E. SWANSON WRIST JOINT IMPLANT AND GROMMET

DESCRIPTION

The Swanson Wrist Joint Implant is a one-piece, intramedullary stemmed implant fabricated from silicone elastomer. It is designed for use in implant resection arthroplasty of the radiocarpal joint.

The Swanson Wrist Joint Grommet is a thin, titanium shield designed to modify the Swanson Wrist Joint Implant in selected cases. It is contoured to conform to the shape of the mid-section of the flexible implant and is fabricated from unalloyed titanium for surgical application. To protect the implant from the shearing forces of sharp bone edges, the distal grommet is normally used on the dorsal surface and the proximal grommet on the palmar surface. 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. Each package of the Swanson Wrist Joint Grommet contains matching proximal and distal pairs.

INDICATIONS

- Arthritic or traumatic disability resulting in:
 - instability of the wrist due to subluxation or dislocation of the radiocarpal joint
 - severe deviation of the wrist causing musculotendinous imbalance of the digits
 - stiffness or fusion of the wrist in a non-functional position
 - stiffness of the wrist where movement is a requirement for hand function

F. SWANSON TRAPEZIUM IMPLANT/TIE-IN® TRAPEZIUM

DESCRIPTION

The Swanson Trapezium Implant/TIE-IN® Trapezium is a flexible, one-piece, intramedullary stemmed implant developed to help restore function to thumbs disabled by degenerative arthritis or post-traumatic arthritis. It is designed to replace the trapezium bone in an attempt to preserve the anatomical relationships of the basal joints of the thumb after resection arthroplasty by acting as a space filler.

INDICATIONS

- Degenerative or post-traumatic arthritis (e.g., following an old Bennett fracture)
- Disabilities of the thumb basal joints with localized bony changes
- Localized pain and palpable crepitation during circumduction movement with axial compression of involved thumb ("grind test")

NOTE: Dr. Swanson has described a "grind test" which may be used in localizing the cause of the patient's complaint. To perform this test, the patient's thumb is held securely in the examiner's right hand, and the base of the patient's thumb

is held in the examiner left thumb and index finger. If the test is positive, passive circumduction of the thumb while axial compression is applied will produce pain, crepitation and subluxation localized at the carpometacarpal joint.

- Decreased motion, decreased pinch and decreased grip strength
- X-ray evidence of arthritic changes of the trapeziometacarpal, trapezioscapoid, trapezotrapezoid, and trapezium second metacarpal joints, singly or in combination
- Associated unstable, stiff or painful distal joints of thumb or swan-neck deformity

CONTRAINDICATIONS

- Severe displacement, resorption or involvement of contiguous carpal bones

G. SWANSON TENDON SPACER

DESCRIPTION

The Swanson Tendon Spacer is a temporary passive spacer used to facilitate two-stage reconstruction of flexor and extensor tendons of the hand.

INDICATIONS

- Reconstruction of flexor or extensor tendons of the fingers, thumb, and wrist
- Scarred or adherent tendons following trauma or failed primary repair
- Absence of tendon sheath
- Scarred or adherent non-functional tendon pulleys
- Ruptured tendon

H. SWANSON BONE PLUG (CEMENT RESTRICTOR)

DESCRIPTION

The Swanson Bone Plug is a flexible silicone elastomer plug designed to fit snugly into the intramedullary canal to restrict migration of poly (methyl) methacrylate bone cement. It can be used in total large joint replacement arthroplasty involving the hip, knee, shoulder or elbow joints which requires poly (methyl) methacrylate cement fixation of an intramedullary stem(s).

INDICATIONS

- Any total large joint replacement arthroplasty, which requires poly (methyl) methacrylate cement fixation of an intramedullary stem.

I. SWANSON INCISION DRAIN

DESCRIPTION

The Swanson Incision Drain is a thin, flat, flexible silicone elastomer drain designed for post-operative drainage of blood and fluids from incisions such as those involved with arthroplasty of the small joints of the upper and lower extremities.

INDICATIONS

- Drainage of smaller incisions, which do not require suction drainage, or as an adjunct to suction drainage in medium sized incisions. The drains may be useful in cases where decreased scar formation and tissue reaction are important, such as in hand and foot surgery or plastic surgery.

PRECAUTIONS

While the technique of insertion of the Swanson Incision Drain may vary among physicians, there are several important points to observe:

- Upon insertion, the drain should be wrinkled or twisted to form a path for drainage of fluids.
- When removing drain from package, immerse directly in sterile saline. The initial dressing should be moist so that it acts as a wick to draw the fluids out of the wound.
- Handling of the drain should be done with blunt instruments to avoid surface trauma or contamination with foreign bodies. Rinse the drain thoroughly with sterile saline solution before insertion.

The Swanson Hammertoe (Weil Design) Implant was designed by Lowell Scott Weil, D.P.M., F.A.C.F.S., Chicago, Illinois

All other Swanson Implants were designed by Alfred B. Swanson, M.D., F.A.C.S., Grand Rapids, Michigan

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