

extremities solutions



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SWANSON

Flexible Hinge Toe Implant
with SWANSON Flexible Hinge Grommet

SWANSON
flexible
HINGE TOE IMPLANT

with SWANSON
Flexible Hinge Grommet

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

SWANSON

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

Some preventive 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
- Avoid pins and screws through the implant

If complications develop, possible corrective procedures include:

- Implant removal
- Synovectomy
- Bone grafting of cysts
- Limited intertarsal fusion
- 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.

specific 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.

potential complications AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists.

The risks and complications with the Swanson Flexible Hinge Toe Implant and the Swanson Flexible Hinge Toe Joint Grommet include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the grommet, the implant stem and/or the hinge
- Loosening or dislocation of the prosthesis requiring revision surgery
- Bone restoration or over-production
- Allergic reactions(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, metatarsal 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 judgement 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. Please write or call Wright Medical Technology, Inc.

DESCRIPTION FLEXIBLE IMPLANT

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 Implant is made of silicone elastomer and the design of this implant is based on that of the load distributing, flexible hinge finger joint implant. The midsection however, is thicker and wider to meet the anatomical and physiological requirements of the metatarsophalangeal joint. The proximal (longer)

DESCRIPTION
-continued

stem fits into the intramedullary canal of the metatarsal and the distal (shorter) stem into the proximal phalanx. The flexural concavity or open portion of the hinge is placed superiorly or dorsally to allow greater range of dorsiflexion of the toe. The proximal and distal stems have a rectangular cross section to help provide rotational stability in the intramedullary canals.

The Swanson Flexible Hinge Toe Implant is available in two stem sizes, standard and small. Sizes 0 through 7 (standard design) and OS through 5S (small stem design) will adequately meet most operative requirements in the first metatarsophalangeal joint. Size 7.0 through 0 are usually preferred in the lateral toe joint. In the small stem design, the hinge portion is identical to the standard implant but the stems are proportionately smaller for use in those cases in which less reaming of the intramedullary canal is required to insert an implant. Three separate sizing sets (supplied non-sterile and not suitable for implantation) corresponding to sizes 0 through 7 for use in the first toe, sizes OS through 5S for use in the lateral toes, are available for proper size determination during surgery.

GROMMETS

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. Grommets are available in 12 sizes corresponding to sizes 0 to 5 and OS to 5S of the Swanson Flexible Hinge Toe Implants. The outer surface of each grommet is marked with a numeral,

indicating the size of flexible hinge toe joint implant the grommet fits, as well as the letters “P” or “D”, indicating whether it is a proximal or distal grommet.

RATIONALE FLEXIBLE IMPLANT

Designed for metatarsophalangeal joint implant arthroplasty, the Swanson Flexible Hinge Toe Joint Implant acts as a dynamic spacer to preserve proper joint space and alignment while early motion is started. The flexible hinge intramedullary-stemmed implant in association with encapsulation provides adequate lateral stability with minimal flexion-extension restriction. It acts as an internal mold to support the new capsuloligamentous system that develops around it and becomes functionally oriented through early guided motion.

Because the implant is designed as a load-distributing hinge, fabricated from low-elastic modulus silicone elastomer, and not fixed to bone, the compressive loading forces are effectively distributed to the resected end of the bone and cortical shaft. This encourages favorable bone remodeling, which is evidenced by maintenance of bone length, preserved shape of the amputated bone end, cortical thickening and new bone formation next to the implant midsection and intramedullary stem.

GROMMETS

The function of the press-fit grommet is to provide an unattached, smooth and durable interpositional titanium shield between the silicone elastomer implant and contiguous bone. Typically, grommets are placed on the distal and proximal stem of the implant to protect the implant from sharp bone ends in areas where abrasion, wear, and

specific advantages OF THE IMPLANT



This radiograph shows the foot of a 69 year-old man with rheumatoid arthritis with a hallux valgus deformity and lateral toe involvement



This radiograph shows the postoperative result one year following resection arthroplasty with a double stemmed flexible hinge toe implant protected by grommets. This patient also had resection arthroplasties of the lateral metatarsophalangeal joints. He has a pain-free, mobile and stable arthroplasty with excellent functional and cosmetic result.

cutting are most likely to occur due to forces exerted on the implant during flexion and extension. Use of the grommet does not alter the function of the implant, patient indications and contraindications, nor reduce the need for careful attention to the arthroplasty technique.

- Both FLEXSPAN™ elastomer and unalloyed titanium have acceptable biocompatibility.
- The Swanson grommet is durable and abrasion resistant to shield the implant from sharp bone ends.
- Available in twenty sizes to adequately meet most operative requirements.
- Neither the flexible implant nor the grommet require fixation to bone.
- The flexible intramedullary stemmed implant allows the joint to find its own axis of rotation and allows proper distribution of forces.
- The Swanson Flexible Hinge Toe Implant and Swanson Flexible Hinge Toe Joint Grommet have been sterilized.
- Both flexible implant and grommet are visible on X-rays.
- 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.

CLINICAL ADVANTAGES OF THE PROCEDURE

- Improves toe dynamics and helps to relieve pain and maintain stability, mobility, and toe length.
- Offers improved stability for maintenance of alignment in reconstruction of the severely deformed metatarsophalangeal joint.
- Acts as a space filler; maintains joint space and allows capsule/ligament reconstruction to correct the deformities.
- Improves cosmetic appearance.
- Facilitates postoperative rehabilitation.

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

CLINICAL INDICATIONS

Use of the Swanson Flexible Hinge Toe Implant may be considered:

- 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.

The use of a Swanson Flexible Hinge Toe Grommet 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.

GENERAL 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

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

instructions FOR USE **SURGICAL TECHNIQUE**

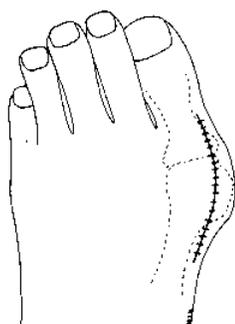


FIGURE 2 | A dorsomedial approach through a slightly curved longitudinal incision along the medial aspect of the metatarsophalangeal joint is used for surgery of the great toe

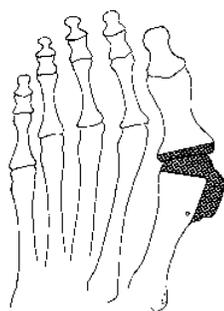


FIGURE 3 | The metatarsal head is excised distal to the metaphyseal flare at the largest diameter of the head with a 10 degree valgus angle. The base of the proximal phalanx may be removed to provide a wider joint space.

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 profession. Each surgeon must evaluate the appropriateness of the technique used based on personal medical training and experience. A description of the procedure used by Alfred B. Swanson, M.D.*, follows.

FIRST METATARSOPHALANGEAL JOINT IMPLANT ARTHROPLASTY INCISION AND EXPOSURE

The joint is exposed through a slightly curved, longitudinal incision made over the dorsomedial aspect of the first metatarsophalangeal joint. | **FIGURE 2** Additional longitudinal incisions are used when reconstruction of the lateral toes is indicated as frequently needed in a rheumatoid foot. Care must be taken to avoid injury to the small dorsal sensory nerves and veins in the area. The fascia and medial capsule of the joint are exposed and incised medial to the extensor hallucis longus tendon to prepare a capsuloligamentous flap for later closure and correction of the deviation deformity. This flap is usually proximally based on the proximal phalanx. If the anatomical attachments appear weakened these can be reinforced with a suture through the bone either proximally or distally. If a bursa is present, it is resected. The metatarsophalangeal joint is opened by flexing the toe and incising the dorsal capsular reflections. The capsular attachments to the neck of the metatarsal contain an important vascular supply to the bone and must be protected.

BONE PREPARATION

The head of the first metatarsal is excised distal to the metaphyseal flare at the longest diameter of the metatarsal head. | **FIGURE 3** A sagittal saw or other power equipment is used to resect this portion of the head in 10 degrees valgus to conform to normal valgus. This way the implant will not be pinched by the lateral bone edge. The intramedullary canal is shaped in a rectangular fashion to accept the implant stem. An air drill, broach, curette, or rasp may be used. A portion of the base of the proximal phalanx is removed to provide a wider joint space.

Bone edges are carefully smoothed. A trial fit is made with the appropriate color coded sizer. The implant should fit well into the canal so that the transverse midsection of the implant abuts against the bone ends. The end of the implant stems must not impinge against the end of the intramedullary canals. When the lateral metatarsal heads are not resected, it is important to retain a portion of the first metatarsal head to avoid shifting of the weight bearing to the second metatarsal head. In these cases, to obtain the necessary joint space, additional bone is removed from the base of the proximal phalanx. In patients selected to receive titanium grommets, the sizer is removed and the bone canals are prepared to allow a press-fit of the appropriate size grommet. The resected surfaces of the metatarsal and proximal phalanx are shaped so that the grommet fits well into the bone and the shoulders seat directly against resected bone without protruding so that contact with overlying soft tissue is avoided. The grommet sizing corresponds to the implant sizing. Final seating of the grommet is done by gentle pressure or tapping with the grommet seater or a curved instrument held against the exposed surface of the grommet. This is done with care to avoid bending or distorting the grommet. 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 size is never used. With grommets in place, the sizer is inserted in the joint space and flexion-extension assessed.

CAUTION | Fitting of the grommet requires a good press-fit and presence of adequate bone stock. It must be accurately centered, otherwise it may impinge the intramedullary canal on one side and could cause bone resorption. In certain cases of severe metatarsophalangeal joint dislocation, considerable bone must be removed to obtain joint reduction and the implant should be used without the grommet. The seating must be exact with regard to centering and rotation. The joint space must be adequate to accommodate the implant midsection. An evaluation of how well the implant/grommet fits in the joint space should be made in both flexion and extension. The implant must slide and not be impinged by the grommet. Impingement is usually caused by the joint being too narrow. The principle of the flexible hinge as a dynamic joint spacer must be respected. The grommet and sizing unit are removed to permit soft tissue reconstruction. A 0.5mm drill hole is made in the medial portion of the metatarsal and

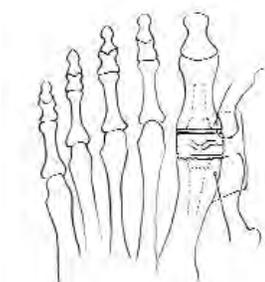


FIGURE 4A | A medial capsuloligamentous flap is carefully prepared and later reattached to bone either proximally or distally or both with 3-0 Dacron sutures to correct the valgus deformity.

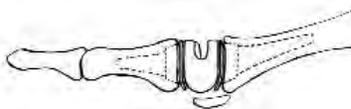


FIGURE 4B | The implant and grommets should fit flush with the cut bone ends without protruding medially or laterally or dorsally or plantarly

proximal phalanx neck and 3-0 Dacron sutures are passed through these holes in preparation for capsular closure. | **FIGURE 4A, 4B**

NOTE | A non-sterile set of color coded sizing units in either the standard or small stem design is available to assist in size determination during surgery.

IMPLANT INSERTION

After the capsular sutures are placed and the wound is copiously irrigated, the grommets are firmly seated if used. The proximal (longer) stem of the implant is inserted in the intramedullary canal of the first metatarsal with the open portion of the hinge positioned dorsally. The toe is then flexed and the distal (shorter) stem is inserted into the proximal phalanx. The proper size implant is determined by the size of the remaining metatarsal and the intramedullary canal.

The distal stem may be shortened if it abuts the distal end of the intramedullary canal of the proximal phalanx but in the small design, modification of the implant is usually not necessary.

Avoid other reshaping of the implant.

TISSUE RELEASE AND ASSOCIATED PROCEDURES

The surgical details of the procedure and attention to the complete release of contractures, realignment of the toe ray and correction of the deformities of the lateral toes are of great importance to obtain the desired results. The extensor hallucis longus is lengthened in a manner similar to a Z-plasty in cases that present a moderate to severe valgus angle and/or claw toe deformity. The tendon ends are sutured together with 5-0 Dexon sutures inverting the knots. The adductor tendon, the lateral capsule and the short extensor tendon should also be released. If cut, care must be taken to reattach the short flexor to the medial inferior aspect of the cut proximal phalanx through a drill hole to obtain flexion of the metatarsophalangeal joint. In milder cases of claw toe deformity, the interphalangeal joint can be pinned with a Kirschner wire for 3 to 4 weeks. In cases of moderate to severe claw or pronation deformity, the interphalangeal joint may require fusion. In cases of severe hallux valgus deformity, the correct alignment can be maintained in the early postoperative period by placing a .045" Kirschner wire across the toe ray in the intramedullary canals dorsal to the implant. With the implant in position, the wire is inserted in a retrograde fashion first through the intramedullary canals of the proximal and distal phalanges and then through the first metatarsal. The end of the wire extrudes 1 cm from the toe and is removed after 10 days. If the intermetatarsal angle is greater than 15°, an osteotomy of the base of the first metatarsal should be considered.

TISSUE REEFING AND CLOSURE

With the toe held in proper alignment, including rotation, the medial fascial-capsular flap is firmly sutured proximally and/or distally with the previously passed Dacron sutures, inverting the knots. The aponeurosis of the long extensor tendon, which may be released on its lateral aspect, is sutured to the medial capsule with 4-0 Dacron sutures and a buried knot technique.

The cutaneous incision is closed and Incision Drains are placed in the wound. A voluminous conforming dressing is applied to the foot. Cotton or Dacron batting is used for padding. A longitudinal splint such as a tongue blade, may be incorporated in the medial aspect of the dressing to support the toe in position. A posterior molded plaster splint and a conforming bandage such as a Kling are then applied. The foot is elevated with the patient at bed rest for 2 to 5 days to decrease postoperative swelling.

POSTOPERATIVE CARE

After 3 to 5 days the initial dressing is removed and a dynamic splint** is applied to maintain the alignment of the toe while allowing early and active flexion-extension exercises. | **FIGURE 5** An exercise program is prescribed. The dynamic splint is either attached to a cast, or a removable type splint may be used. It is worn continuously for 3 to 4 weeks and then used as a night splint for approximately 3 to 6 weeks. The patient may walk on his heel or on a wooden-soled shoe in a week. The use of a ½ inch thick foam rubber inner sole extending to the distal metatarsal level is important to allow flexion exercises. Exercises over a step or other solid objects are prescribed to encourage flexion. Guarded weight bearing is allowed 3 weeks post operatively. Appropriate nonconstrictive shoe wear is prescribed. It is also important to avoid extraneous movements of pins extending through the skin and giving the patient adequate instructions to keep clean and dry feet and avoid abusive foot use postoperatively.



FIGURE 5 | Appearance of the dynamic toe splint worn with the wooden-soled shoe. The shoe is fitted with a ½ inch-thick foam rubber inner sole extending to the distal metatarsal level to allow flexion exercises.



FIGURE 6 | The metatarsal heads are exposed through separate longitudinal incisions placed in intermetatarsal area.

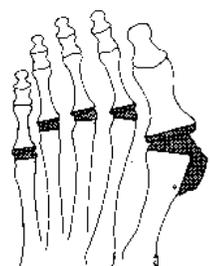


FIGURE 7 | The head of the metatarsal is resected at the metaphyseal flare.

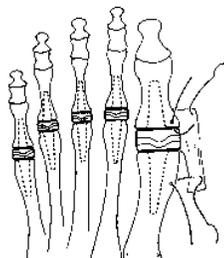


FIGURE 4A | The appropriate size implant is selected to obtain a snug fit of the stems in the intramedullary canals and to maintain the appropriate joint space. Firm reattachment to bone of a loose medical capsule either proximally or distally is of absolute importance for correction of valgus deformity.

LATERAL METATARSOPHALANGEAL JOINT IMPLANT ARTHROPLASTY INCISION AND EXPOSURE

Flexible implant arthroplasty of the lateral metatarsophalangeal joints can be carried out at the same time as the reconstruction of the great toe. The metatarsal heads are exposed through separate longitudinal incisions as shown. | **FIGURE 6** Care must be taken to avoid injury to the small dorsal sensory nerves and veins in this area. Appropriate extensor tendon release is performed and the dorsal capsule is incised.

BONE PREPARATION

The head of the metatarsal is resected at the metaphyseal flare with sagittal saw or other power equipment to obtain a smooth transverse osteotomy. | **FIGURE 7** The intramedullary canal of the metatarsal is prepared to receive the implant stem, using a hand broach or the air drill with a small leader point burr to avoid perforation of the canal wall. A portion of the base of the proximal phalanx is removed to provide a wider joint space. The amount of bone removed is dependent upon the degree of contracture preoperatively. All bone edges which contact the implant are left smooth. The appropriate size implant is selected to obtain a snug fit of the stem in the intramedullary canals and to maintain the appropriate joint space. | **FIGURE 8**

NOTE | A non-sterile set of sizing units is available to assist in size determination during surgery.



Right foot preoperative radiograph of a 61 year old rheumatoid arthritis patient shows severe hallux valgus deformity with erosive arthritic changes at metatarsophalangeal joint. The lateral toes show dislocation of metatarsophalangeal joints with reasonably bone stock.



Postoperative radiograph shows correction of deformities of the great toe and the lateral toes following flexible (silicone) implant resection arthroplasty.

IMPLANT INSERTION

The wound is irrigated with saline to remove debris and bony fragments.

As in the first metatarsophalangeal joint, the proximal (longer) stem of the implant is inserted into the intramedullary canal of the metatarsal; with the open portion of the hinge positioned dorsally; the toe is then flexed and the distal (shorter) stem is inserted into the proximal phalanx. Reshaping of the implant should be avoided.

ASSOCIATED PROCEDURES AND CLOSING

In patients who present severe claw deformities and soft tissue contractures, the toe tray must be temporarily pinned in the corrected position. With the implant in position, a 0.45" Kirschner wire is inserted in a retrograde fashion first through the intramedullary canals of the proximal and distal phalanges and through the tip of the toe. The wire is then driven back across the top of the implant into the metatarsal canal. The end of the wire extrudes 1 cm from the toe end. The skin incisions are closed with interrupted 5-0 nylon sutures and incision drains are inserted subcutaneously. A voluminous, conforming foot dressing is applied and the foot is maintained in an elevated position in the postoperative course. The wires which have been left extruding from the tip of the toe are removed in about 10 days; no weight-bearing walking is allowed while the wires are in position. The usual postoperative regimen is then instituted for these patients. Exercises over a step or other solid objects are prescribed to encourage flexion. Guarded weight bearing is encouraged three weeks postoperatively in appropriate non-constrictive shoe wear.

IMPORTANT POINTS TO OBSERVE

- Using the color coded sizing set as a guide, select the largest implant that the bone can accommodate, at the same time being very careful that the implant is well seated.
- Rinse the implant and grommet thoroughly with saline solution before insertion.
- Blunt instruments should be used with a "no touch" technique when inserting Swanson Flexible Hinge Toe Implants and Swanson Flexible Hinge Toe Joint Grommets to avoid traumatization of the implant and contamination by foreign bodies.

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

BIBLIOGRAPHY

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

HANDLING AND STERILIZATION

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

Handling 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.

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 or grommets:

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 these soaps may be absorbed and subsequently leach out to cause a tissue reaction.

Rinse thoroughly with distilled water.

If using a 270°F flash sterilization cycle, place the component on a standard mesh sterilization tray.

If using a 250°F gravity or 270°F pulsing vacuum sterilization cycle, double wrap the component in muslin or a similar type non-woven medical grade wrapping material or place in a sealed sterilization pouch.

Autoclave according to the following parameters:

Method	Cycle	Temperature	Exposure
Steam	Gravity	250° F/121° C	30 minutes
Steam	Flash	270° F/132° C	10 minutes
Steam	Pulsing-Vacuum	270° F/132° C	10 minutes

After sterilization, remove the implant from its packaging or the sterilization tray using accepted sterile technique. Ensure that the implant is at room temperature prior to implantation. These recommendations have been developed and tested using specific equipment. The bioburden should not exceed 10⁴ colony forming units (CFU) per device. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials or equipment changes occur, the effectiveness of the sterilization process must be demonstrated. Evidence suggests that repeated sterilization may affect the physical characteristics of the implant. Accordingly, resterilization in excess of three times is contraindicated.

THIS PRODUCT IS FOR SINGLE USE ONLY. AN IMPLANT SHOULD NEVER BE RESTERILIZED AFTER CONTACT WITH BODY TISSUES OR FLUIDS.

DO NOT STERILIZE BY ETHYLENE OXIDE AS THE RESIDUAL STERILANT MAY CAUSE ADVERSE TISSUE REACTION.

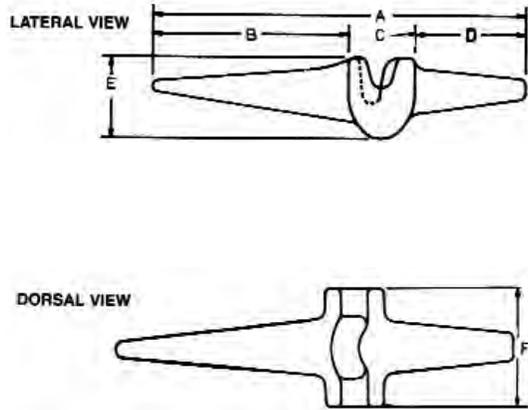
CAUTION: FEDERAL (UNITED STATES) LAW RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.

*Alfred B. Swanson, M.D., F.A.C.S.,
Grand Rapids, Michigan
†U.S. Patent No. 3,875,594.
††U.S. Patent No. 4,158,893; 4,198,713

**Cygnus Systems Productions
Suite 168, 2775 44th St. S.W.,
Grand Rapids, MI 49509

HOW SUPPLIED

The Swanson Flexible Hinge Toe Implant has been sterilized and packaged as follows:



TYPICAL DIMENSIONS

SIZE	A	B	C	D	E	F
7-0	28.1	14.2	3.9	9.9	4.7	8.5
6-0	31.6	16.0	4.4	11.2	5.3	9.6
5-0	34.8	17.7	4.8	12.3	6.0	10.7
4-0	38.3	19.4	5.3	13.6	6.7	11.8
3-0	41.7	21.2	5.7	14.7	7.1	12.8
2-0	45.4	23.1	6.2	16.1	7.7	14.0
OS	37.6	19.3	6.6	11.9	8.3	15.9
0	48.6	23.7	6.6	18.3	8.3	15.9
1S	40.2	20.9	7.2	12.4	8.9	16.6
1	52.2	26.0	7.2	18.9	8.9	16.6
2S	43.0	22.7	7.7	12.9	9.4	17.1
2	55.8	28.3	7.7	19.7	9.4	17.1
3S	45.6	24.2	8.3	13.4	10.2	18.0
3	58.9	30.5	8.3	20.1	10.2	18.0
4S	48.3	25.9	8.9	13.8	10.6	18.7
4	61.8	31.9	8.9	21.0	10.6	18.7
5S	51.1	27.5	9.7	14.3	11.0	19.6
5	65.5	34.0	9.7	21.8	11.0	19.6
6	69.3	36.1	10.0	23.2	11.6	20.3
7	72.8	38.5	10.7	23.6	12.2	21.2

REGULAR STEM

	QUANTITY	DESCRIPTION	CATALOG #
LATERAL	1 Box	1 Each, Size 7-0	426-0070
	1 Box	1 Each, Size 6-0	426-0060
	1 Box	1 Each, Size 5-0	426-0050
	1 Box	1 Each, Size 4-0	426-0040
	1 Box	1 Each, Size 3-0	426-0030
	1 Box	1 Each, Size 2-0	426-0020
	REGULAR	1 Box	1 Each, Size 0 with grommets
1 Box		1 Each, Size 1 with grommets	G426-0001
1 Box		1 Each, Size 2 with grommets	G426-0002
1 Box		1 Each, Size 3 with grommets	G426-0003
1 Box		1 Each, Size 4 with grommets	G426-0004
1 Box		1 Each, Size 5 with grommets	G426-0005
1 Box		1 Each, Size 6	426-0006
1 Box		1 Each, Size 7	426-0007
1 Sizing Set		1 Each, implant sizes: 0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0 for Lateral Toes, Numerically marked, color coded (non-sterile) NOT FOR IMPLANTATION.	436-0002
1 Sizing Set		1 Each, implant sizes: 1, 2, 3, 4, 5, 6, 7 for the Great Toe, Numerically marked, color blue (non-sterile) NOT FOR IMPLANTATION.	436-0001

SMALL STEM

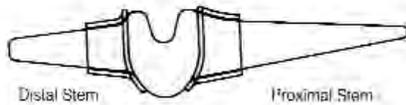
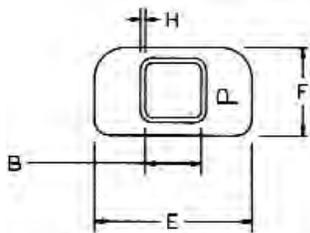
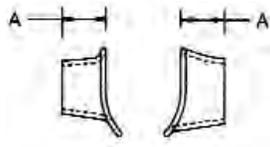
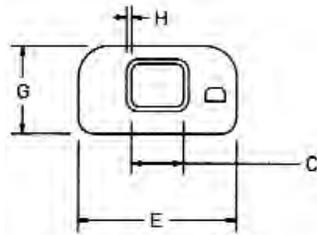
QUANTITY	DESCRIPTION	CATALOG #
1 Box	1 Each, Size OS with grommets	G426-0110
1 Box	1 Each, Size 1S with grommets	G426-0101
1 Box	1 Each, Size 2S with grommets	G426-0102
1 Box	1 Each, Size 3S with grommets	G426-0103
1 Box	1 Each, Size 4S with grommets	G426-0104
1 Box	1 Each, Size 5S with grommets	G426-0105
1 Sizing Set	1 Each, implant sizes: 0S, 1S, 2S, 3S, 4S, 5S for the Great Toe, Numerically marked, color coded (non-sterile) NOT FOR IMPLANTATION.	436-0100

NOTE | Sizes 0 through 7-0 are most often used for the lateral metatarsophalangeal joints and sizes OS and 0 through 7 for the great toe.

HOW SUPPLIED

The Swanson Flexible Hinge Toe Implant has been sterilized and packaged as follows:

TOE GROMMET DIMENSIONS



TYPICAL PLACEMENT OF SWANSON GROMMET
ON SWANSON FLEXIBLE HINGE TOE IMPLANT

SIZE / DIMENSION	A	B	C	E	F	G	H
0S	4.1	5.0	4.7	14.8	8.1	8.1	0.5
1S	4.3	5.3	5.1	15.4	8.5	8.5	0.5
2S	4.5	5.7	5.3	16.1	9.0	9.0	0.5
3S	4.6	6.1	5.6	16.8	9.7	9.7	0.5
4S	4.8	6.6	6.0	17.7	10.2	10.2	0.5
5S	4.9	7.0	6.4	18.4	10.7	10.7	0.5
0	4.1	5.9	5.6	14.6	8.5	8.1	0.5
1	4.3	6.2	5.9	15.2	9.0	8.5	0.5
2	4.5	6.8	6.3	15.8	9.3	9.1	0.5
3	4.6	7.3	6.7	16.6	10.6	9.8	0.5
4	4.8	7.8	7.2	17.4	10.6	10.3	0.5
5	4.9	8.4	7.7	18.3	10.9	10.8	0.5



Wright Medical Technology, Inc.

5677 Airline Road
Arlington, TN 38002
901.867.9971 phone
800.238.7188 toll-free
www.wmt.com

Wright Medical Europe SA

Rue Pasteur - BP 222
Zone d'Entreprise de La Farlède
83089 TOULON Cedex 9
France
+33 (0)4.94.08.77.88 phone