



SURGICAL TECHNIQUE



**SWANSON**  
Titanium Great Toe Implant

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titanium

GREAT TOE IMPLANT

surgical technique

surgical technique presented by  
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# SWANSON

titanium GREAT TOE IMPLANT

as described by Alfred B. Swanson, M.D.

## 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 procedures and the potential complications that may occur. The benefit 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 that articulate against bone, wear to some degree. In an implant arthroplasty, clinically significant wear can result from normal biomechanical forces. Abnormal or excessive forces 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 mal-position
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or over activity
- Intra-operative fixation

Some preventive measures to consider when minimizing 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

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

If complications develop, possible corrective procedures include:

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

Clinical results depend on surgeon and technique, preoperative and postoperative care, the implant, patient pathology and daily activity. It is important 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.

**potential** COMPLICATIONS

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

**specific** COMPLICATIONS

In any surgical procedure, the potential of complications exists. The risks and complications with the Swanson Titanium Great Toe Implant include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the stem and/or the articular surface
- Loosening of the prosthesis requiring revision surgery
- Fracture or resorption of the bone leading to the need for further surgery
- 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

**device** DESCRIPTION

The Swanson\* Titanium Great Toe Implant is a one-piece, intramedullary-stemmed implant developed to overcome the disadvantages of shortening, and occasional instability or painful stiffening which may follow simple resection arthroplasty procedures of the great toe.

The Swanson Titanium Great Toe is designed to supplement resection arthroplasty of the first metatarsophalangeal joint. The stem of the implant fits into the intramedullary canal of the proximal phalanx with the implant head replacing the proximal third of the proximal phalanx. It serves to provide a smooth articulating surface for the first metatarsal head, helps restore and maintain motion without loss of stability and preserves good cosmetic appearance. The implant is surrounded by a fibrous supporting capsule, which helps preserve joint space relationship and stability, resulting in early pain-free rehabilitation. The Swanson Titanium Great Toe Implant is fabricated from unalloyed titanium for surgical application (ASTM F 67), and is available in five anatomical sizes to meet various operative requirements.

An autoclavable plastic color coded sizing set, supplied non-sterile and not suitable for implantation, is available for proper size determination during surgery.

- Available in five sizes to adequately meet the various operative

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**clinical** ADVANTAGES

- requirements.
- Improves toe dynamics: provides stability, mobility, pain relief, and maintains toe length. The increased flexion power of the great toe assists in normal gait pattern.
- Provides a smooth articular surface for the first metatarsal head.
- Acts as a space filler: maintains joint space and allows capsule/ligament reconstruction to correct the deformities.
- Fixation in the intramedullary canal is not necessary.

**general** INDICATIONS

Any joint implant arthroplasty requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant
- Availability of postoperative therapy
- Cooperative patient

**specific** INDICATIONS

Use of the Swanson Titanium Great Toe Implant may be considered for cases of first metatarsophalangeal joint degenerative arthritis in the presence of good bone stock, integrity of the metatarsal head and the following clinical conditions:

- Hallux valgus: mild to moderate only
- Hallus rigidus
- Unstable or painfully still MP joint following Keller-type bunionectomy

**NOTE** | An associated osteotomy of the first metatarsal should be done for cases of metatarsus primus varus with an intermetatarsal angle greater than 15°.

**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.

- Rheumatoid arthritis

## specific CONTRAINDICATIONS

- Severe hallux valgus as seen in rheumatoid arthritis, in older patients, or following a Mayo-type resection
- Severe valgus deformity



FIGURE 1A



FIGURE 1B

**FIGURE 1A** | Preoperative x-ray showing degenerative joint changes of the first metatarsal phalangeal joint in a 49 year-old woman. She presented with decreased motion of first MTP joint with pain on walking short distances.

**FIGURE 1B** | Postoperative x-ray showing a well tolerated single stem titanium great toe implant replacing the base of the proximal phalanx. Patient has pain free functional motion and a good cosmetic result.



FIGURE 2A



FIGURE 2B

**FIGURE 2A** | Preoperative x-ray showing moderate hallux valgus deformity secondary to degenerative arthritis and metatarsus primus varus in a 56 year-old woman presenting pain, decreased motion, show wear problems and a cosmetic concern.

**FIGURE 2B** | Postoperative x-ray shows a titanium great toe implant replacing the base of the proximal phalanx. Exostoses were resected off the metatarsal head. Note osteotomy of base of first metatarsal to correct the metatarsus primus varus deformity. The implant is well tolerated by the bone and soft tissue. Patient has a good cosmetic and functional result with good pain free motion

## surgical PROCEDURE

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 surgical technique used based on personal medical training and experience. The following procedure is furnished for informational purposes only as a technique used by Alfred B. Swanson, M.D.

## INCISION AND EXPOSURE

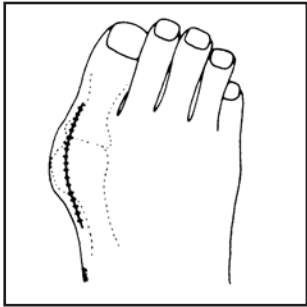


FIGURE 3A

A slightly curved longitudinal skin incision is made along the dorso-medial aspect of the metatarsophalangeal joint. Care must be taken to avoid injury to the small dorsal sensory nerves and veins in the area. The fascia and the medial joint capsule are incised medial to the extensor hallucis longus tendon to prepare a capsuloligamentous flap for later closure and correction of deformity. The flap is usually proximally based on the metatarsal and it is reflected for later resuture. If a bursa is present, it is excised and the metatarsophalangeal joint opened.

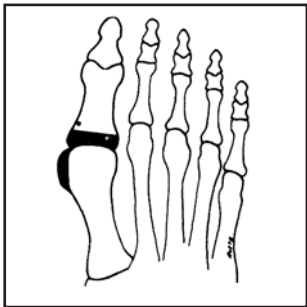


FIGURE 3B

### BONE PREPARATION

The proximal third of the basal phalanx is carefully resected with an air drill or motor saw. The exostoses of the metatarsal head are removed on both lateral and plantar surfaces so that a smooth rounded metatarsal head is presented. The cartilage and subchondral bone on the articulating surface of the metatarsal head should be preserved. The sesamoid bones are rarely excised. Using a drill, rasp, broach or curette, the canal of the proximal phalanx is shaped to accept the implant stem.

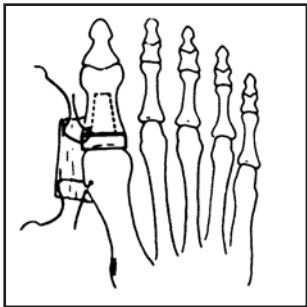


FIGURE 3C

**FIGURE 3A** | A dorso-medial approach through a slightly curved longitudinal incision along the medial aspect of the metatarsophalangeal joint is used when only surgery of the great toe is indicated.

**FIGURE 3B** | The proximal third of the basal phalanx is resected, exostoses on lateral and plantar surfaces are removed presenting a smoothed, rounded metatarsal head. Using curette, broach or drill, the proximal phalangeal canal is shaped to accept the implant stem.

**FIGURE 3C** | Implant stem should fit snugly in the canal with collar of implant fitting firmly against cut proximal surface of the phalanx. The curved portion of the stem should be placed plantarward. Firm reattachment to bone of the medial capsule proximally and distally is of absolute importance for correction of valgus deformity.

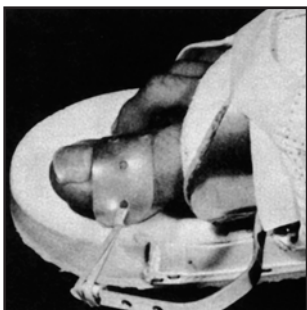


FIGURE 4

**FIGURE 4** | Appearance of the dynamic toe splint worn with the wooden-soled shoe. The shoe is fitted with a 1/2 inch-thick foam rubber inner sole extending to the distal metatarsal level to allow flexion exercises.

**NOTE** | A reusable sizing set is available to assist proper size determination. Numerically marked for easy identification, the sizing set is supplied non-sterile and is not suitable for implantation. For use, follow instructions under section "Sterilization".



### SOFT TISSUE RELEASE, REEFING AND CLOSURE

Complete correction of the deformity may require release of the lateral capsule and incision of the attachments of the adductor muscle to the basal phalanx. The short flexor attachments to the proximal phalanx should be reattached if released during the bone resection. Rerouting or lengthening of the long extensor tendon may also be necessary. It is often necessary to cut the short extensor tendon and lengthen the long extensor tendon in a manner similar to a Z-plasty. A loose and unrestricted passive range of motion of the joint must be obtained before closure. Rotation and angulation deformities must be completely corrected. If the intermetatarsal angle is greater than 15°, a metatarsal osteotomy is indicated.

A 0.5mm drill hole is made in the medial aspect of the neck of the metatarsal to pass a 3-0 Dacron suture for capsular closure. If the distal capsular attachments are weakened, they are similarly reinforced with a suture through bone. With the toe held in proper alignment (slight flexion and varus), the medial fascial-capsular flap is firmly sutured to drill holes in the proximal phalanx with the previously passed Dacron suture, using an inverted knot technique. The aponeurosis of the long extensor tendon which may be released on its lateral aspect, is sutured medially to the medial capsule using 4-0 Dexon sutures with a buried knot technique.

The skin is closed and a small Incision Drain is placed in the wound. A voluminous conforming dressing is applied to the foot. Dressings are placed with great care to avoid embarrassing the circulation postoperatively. 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 bandage are then applied. The foot is elevated with the patient as 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. An exercise program is carefully prescribed. The dynamic split 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/her heel or on a wooden-soled shoe in a week. The use of a 1/2-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 encouraged 3 weeks postoperatively. Appropriate non-constructive shoe wear is prescribed.

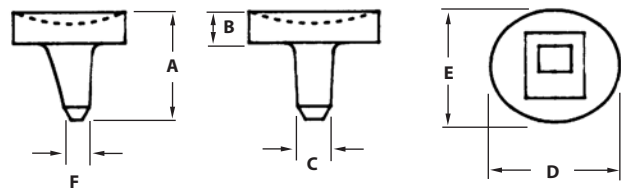
**HOW SUPPLIED**

The Swanson Titanium Great Toe Implant has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	One each, Size 0	483-3110
1 box	One each, Size 1	483-3101
1 box	One each, Size 2	483-3102
1 box	One each, Size 3	483-3103
1 box	One each, Size 4	483-3104
1 sizing set	One each, Sizes 0, 1, 2, 3 and 4. Numerically marked, color black (non-sterile) NOT FOR IMPLANTATION	483-3000

**TYPICAL DIMENSIONS** (millimeters)

Size	0	1	2	3	4
A	12.3	13.8	15.6	16.0	16.6
B	3.1	3.4	4.1	4.3	4.7
C	3.6	3.9	4.3	4.6	5.0
D	13.2	15.0	16.8	18.8	20.1
E	11.2	13.2	14.5	16.0	17.3
F	2.9	3.1	3.4	3.6	3.9



**HANDLING AND STERILIZATION**

The Swanson Titanium Great 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 non-sterile. The following sequential steps are recommended to clean and sterilize the sizing set or to re-sterilize the implant:

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 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 250°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.
5. 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.

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

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

**BIBLIOGRAPHY**

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



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