

SWANSON

Hammertoe Implant

SURGICAL TECHNIQUE



A red line graphic consisting of a vertical line on the left and three horizontal lines extending to the right from the vertical line at different heights.

SWANSON
hammertoe IMPLANT

surgical technique presented by
LOWELL SCOTT WEIL, DPM

HANDLING AND STERILIZATION

This product 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:

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° 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.
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 wrapping material/pouch 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 sterilized after contact with body tissues or fluids.

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

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

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SWANSON

hammertoe IMPLANT

as described by Lowell Scott Weil, DPM

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.

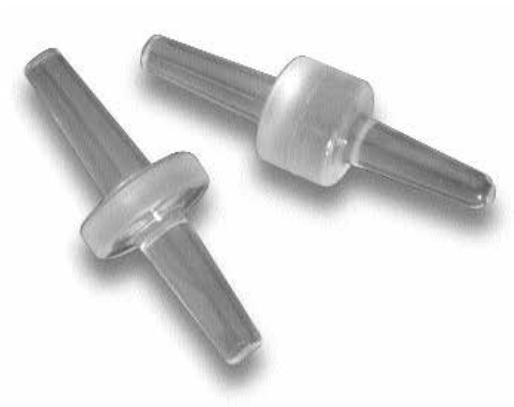
It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations 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 may be caused by:

- Uncorrected 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 below:
- 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

- 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.

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

potential complications AND ADVERSE REACTIONS

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

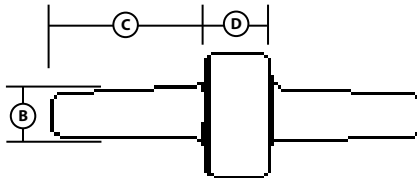
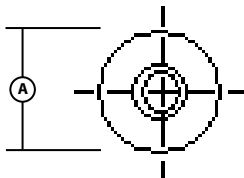
Implant include:

- 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

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

HOW SUPPLIED

The Hammertoe Implant (Swanson Type) Weil Design has been sterilized and packaged as follows:



TYPICAL DIMENSIONS

SIZE	A	B	C	D
1S	.25 (6.4)	.10 (2.5)	.36 (9.1)	.078 (2.0)
1	.25 (6.4)	.10 (2.5)	.36 (9.1)	.13 (3.3)
1L	.25 (6.4)	.10 (2.5)	.33 (8.4)	.18 (4.6)
1W	.30 (7.6)	.10 (2.5)	.36 (9.1)	.15 (3.8)
2S	.30 (7.6)	.12 (3.0)	.36 (9.1)	.09 (2.3)
2	.30 (7.6)	.12 (3.0)	.36 (9.1)	.15 (3.8)
2L	.30 (7.6)	.12 (3.0)	.33 (8.4)	.21 (5.3)

SMALL STEM

QUANTITY	DESCRIPTION	CATALOG #
1 Box	1 Each, Size 1S	431-001S
1 Box	1 Each, Size 1	431-0001
1 Box	1 Each, Size 1L	431-001L
1 Box	1 Each, Size 1W	431-001W
1 Box	1 Each, Size 2S	431-002S
1 Box	1 Each, Size 2	431-0002
1 Box	1 Each, Size 2L	431-002L
1 Sizing Set	1 Each, sizes: 1S, 1, 1L, 1W, 2S, 2, 2L Numerically marked, color coded (non-sterile) NOT FOR IMPLANTATION.	441-0000



PRE-OPERATIVE | Hammertoe 2, 3, and 4



2 ½ YEARS POST-OPERATIVE | Hammertoe Implant toes 2, 3, and 4.
 Note | Excellent toe alignment in spite of phalangeal regeneration.

BONE PREPARATION

Proper preparation of bone is very important. Bone size is small and care should be taken if power equipment is to be used. To prepare intramedullary canals for implant, the head of the proximal phalanx is resected approximately 7 to 8mm from its distal aspect. Using a wire, drill or preferably a small size Swanson Intramedullary Broach (Cat. #6480-0100) a centered, pilot hole is made by rotating the instrument into the proximal phalanx, followed by use of the Size 1 Compactor (Cat.#5431-0110) is used to compact the medullary canal and allow for an exact fit of the trial implant. The mid phalanx is prepared in a similar fashion making certain that the canal is formed along the longitudinal access of the toe. This canal opening may cross the distal interphalangeal joint into the distal phalanx in selected cases; therefore, the distal interphalangeal joint should be kept extended when drilling to maintain good position following implant insertion. All bone edges which contact the implant are left smooth, and a trial fit is made with the appropriate color coded sizer. If a larger implant is required, the canals can be enlarged using the Size 2 Reamer and Compactor (Cat. #543-0010 and Cat. #5431-0120 respectively).

IMPLANT INSERTION

All areas of the incision are thoroughly flushed and debris removed. The Hammertoe Implant is then placed into position using a no touch technique. The implant should be handled with blunt instruments to avoid traumatizing its surface or contamination with foreign bodies. The extensor apparatus is then repositioned and any redundant tissue is excised. The extensor apparatus is then secured under slight tension utilizing two interrupted sutures of 5-0 absorbable.

POSTOPERATIVE CARE

After ten days, sutures are removed followed by bathing and flexion exercises. Patients are allowed to return to their normal footwear when tolerated.

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 silicone elastomer implants to any physician. Please write or call Wright Medical Technology, Inc.

DESCRIPTION

The HAMMERTOE implant (Swanson* Type) Weil[†] Design is a double-stemmed flexible implant 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 HAMMERTOE implant is made of silicone elastomer and is constructed in a rod-shaped design with a thicker mid-section spacer or collar. The implant is symmetrical, therefore, there are no proximal/distal nor lateral/medial designations. Implants are available in 7 sizes with 2 stem sizes, 6 mid-section diameters to adequately satisfy sizing requirements with most patients. Stem and mid-section size should be selected to fit the bone. Mid-section diameter should be large enough to adequately maintain cortical bone contact. Mid-section length should be adequate to fill the void formed by resection arthroplasty and maintain the desired toe length. During the healing phase, the implant is encapsulated by a functionally oriented fibrous capsule providing stability, which can assist in the prevention of the "floppy toe" result, lateral angulation

deformities, or recurrence of the original deformity. In addition, the possible complications of arthrodesis (e.g., poor positioning, incomplete fusion, etc.) as well as the postoperative fixation required for arthrodesis are minimized.

A sizing set, supplied nonsterile and not suitable for implantation, is available for proper size determination during surgery. An instrument set which includes a hand reamer and a hand compactor is also available in two sizes. The reamer is used to drill the medullary canal, while the compactor is used to shape the canal to match the stem of the implant. The size "1" reamer/compactor sets should be used with the sizes 1S, 1, 1W and 1L implants. Similarly the size "2" reamer/compactor should be used with the size 2S, 2 and 2L implants.

ADVANTAGES

- Acts as a spacer to preserve joint relationship and allow appropriate capsuloligamentous reconstruction to correct deformities.
- Fixation in the intramedullary canal is not necessary.
- Available in seven sizes to adequately meet most operative requirements.

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 musculo-tendinous system
- Availability of postoperative therapy
- Cooperative patient

Use of the HAMMERTOES implant may be considered for:

- 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.

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.

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. The following procedure is furnished for information purposes only as a technique used by Dr. Lowell Scott Weil. Each surgeon must evaluate the appropriateness of the procedure based on his or her own medical training and experience.

INCISION AND EXPOSURE

Surgery may be performed under local anesthesia utilizing a digital block at the base of the involved digit. A total of 2cc of lidocaine hydrochloride 2% is sufficient to give adequate anesthesia. Two semi-elliptical incisions are made over the proximal interphalangeal joint of the hammertoe. The width of the semi-elliptical tissue removed corresponds to the severity of the hammertoe; the greater the deformity, the more tissue removed. The incision is carried to the extensor apparatus. Careful preservation of vascular supply is undertaken. The wedge of tissue is then excised in total. The joint capsule is opened by a transverse incision made over the dorsal aspect of the head of the proximal phalanx. The extensor tendon and apparatus is then dissected free from the head and shaft of the proximal phalanx, approximately 1 cm. The collateral ligaments of the proximal interphalangeal joint are then severed exposing the head of the proximal phalanx.



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