

# SWANSON

## TRAPEZIUM IMPLANT

### SURGICAL TECHNIQUE



**SWANSON**  
trapezium  
IMPLANT

surgical technique

surgical technique presented by  
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# SWANSON

trapezium IMPLANT

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

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## device DESCRIPTION

The Swanson Trapezium Implant is a flexible, one-piece intramedullary-stemmed implant developed to help restore function to thumbs disabled by degenerative arthritis or post-traumatic arthritis (e.g., following an old Bennett's fracture).

The Swanson Trapezium Implant is fabricated from silicone elastomer and is available in 5 sizes. The stem of the implant fits into the intramedullary canal of the first metacarpal and has a triangular cross section to prevent rotation of the stem in the intramedullary canal. The head of the implant has a slightly concave surface to provide better seating on the articular surface of the scaphoid. An autoclavable sizing set, supplied nonsterile, and not suitable for implantation, is available for proper size determination during surgery.



## treatment CONSIDERATIONS

The problems presented at the basal joint of the thumb differ in osteoarthritis and rheumatoid arthritis. Accurate evaluation of the location of the arthritic involvement and alignment of adjacent bones are essential in selecting the appropriate treatment. The disease can involve the trapeziometacarpal joint alone or also affect the peritrapezium or other carpal bone articulations, with or without absorption or displacement of adjacent carpal bones. Treatment methods can be selected from either resection arthroplasty of the trapeziometacarpal joint or resection of the entire trapezium with or without a trapezium implant.

Implant resection arthroplasty of the basal joint of the thumb helps maintain a smooth articulating joint space with improved joint stability, mobility, pain relief, and strength. Selection of the appropriate treatment, meticulous surgical technique including capsuloligamentous stabilization, medialization of the implant, and correction of associated deformities of the thumb ray are essential for a good result.

Trapezium implants made of conventional silicone elastomer are preferred in cases of pantrapezium involvement in osteoarthritic patients. In isolated trapeziometacarpal involvement in osteoarthritic patients, titanium basal thumb implants are recommended. In the rheumatoid patient, or in cases of severe erosive osteoarthritis, simple resection arthroplasty is preferred. These alternative techniques are described in separate product literature pamphlets.

## indications

Any joint implant arthroplasty requires consideration of the following generation 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

Use of the Swanson Trapezium Implant may be considered in degenerative or post-traumatic (e.g. following an old Bennett fracture) disabilities of the thumb basal joint with:

- Localized pain and palpable crepitation at the base of the thumb on the "grind test" (circumduction with axial compression of the thumb)
- Decreased motion, pinch, and grip strength
- X-ray evidence of arthritic changes of the trapeziometacarpal, trapezioscapoid, trapeziotrapezoid, and trapezium-second metacarpal joints, singly or in combination.
- Associated unstable, stiff, or painful distal joints of thumb or swan neck deformity

## contraindications

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Severe displacement, absorption, or involvement of contiguous carpal bones

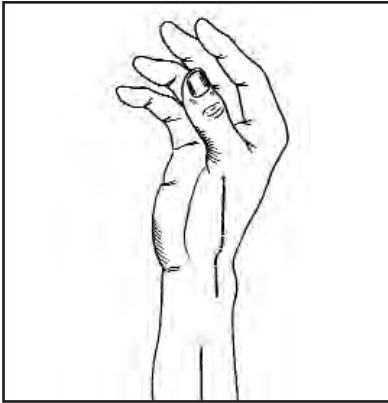
**Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.**

## surgical PROCEDURE

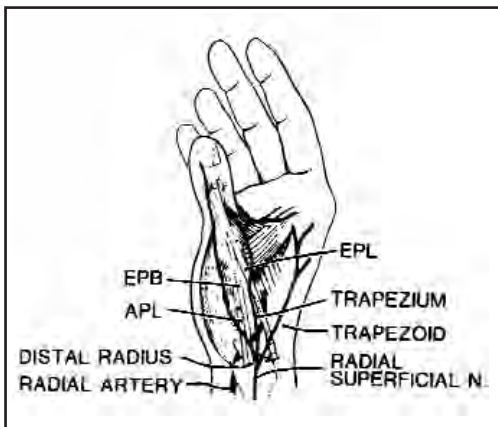
Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The following procedure is furnished for informational purposes only and is the technique used by Dr. Alfred B. Swanson.<sup>1</sup> Each surgeon must evaluate the appropriateness of the procedure based on personal medical training and experience.

A 7 to 8 centimeter longitudinal incision centered over the trapezium is made, starting approximately 2 centimeters above the trapeziometacarpal joint and paralleling the extensor pollicis brevis tendon | **FIGURE 1A**. This incision is carried proximally and ulnarward and has a short transverse arm over the distal wrist crease to continue proximally. The flexor carpi radialis tendon is exposed in the distal forearm through a separate incision.

<sup>1</sup>Swanson, Alfred B. M.D., F.A.C.S., Professor of Surgery, Michigan State University, Lansing, Michigan; Director of Orthopaedics Surgery Training Program of the Grand Rapids Hospitals; and Director of Hand Fellowship and Orthopaedic Research Blodgett Memorial Medical Center, Grand Rapids, Michigan.



**FIGURE 1A** | Incision centered over trapezium, parallel to extensor pollicis brevis tendon, has short transverse arm over distal wrist crease to continue proximally. FCR tendon exposed through separate incision.



**FIGURE 1B** | Anatomical relationships of the superficial radial nerve, abductor pollicis longus tendon, extensor pollicis longus and brevis, and radial artery at the base of the thumb. Careful identification and preservation of these structures in the surgical procedure are necessary.

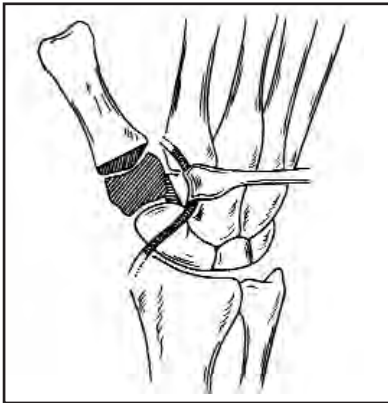
The skin flaps and subcutaneous tissue are carefully dissected to expose the branches of the superficial radial nerve in the proximal wound. Its branches are carefully traced distally, particularly the thumb palmar branch, which crosses over the abductor pollicis longus tendon. The fascia of the abductor pollicis brevis muscle is incised to allow the radial nerve to be safely retracted palmarward with the skin flap | **FIGURE 1B**. Small transverse veins may be ligated. However, longitudinal veins are spared.

The retinaculum of the first dorsal compartment is incised longitudinally and the dissection is carried out between the abductor pollicis longus and the extensor pollicis brevis tendons to expose the adventitial tissue and fatty layer overlying the radial artery, which is carefully exposed and mobilized for proximal retraction. The artery can be retracted safely with a small, flexible, rubber tube. Branches off the radial artery are carefully dissected. A small branch going to the trapezium is ligated with a 6-0 Dacron<sup>2</sup> suture and the small, more palmar branch going toward the scaphoid is preserved. The artery should also be dissected away from the underlying capsular tissues around the dorsal surface of the trapeziometacarpal joint.

The trapeziometacarpal joint is identified by palpation and manipulation of the thumb in traction. The capsule over the scaphoid, trapezium, and base of the metacarpal is then incised longitudinally, or in a "T" fashion, and the flaps are carefully incised off the underlying bone to retain all capsular tissue. The trapezioscapoid joint and the trapeziometacarpal joint are identified by placing blunt dissectors into them, and with traction on the thumb, further freeing of the capsular attachments around the trapezium on its dorsal surface can be done. It is important to stay close to the bone during this dissection to avoid injury to the artery, overlying tendons, or capsule. Trapeziectomy is a difficult procedure and must be done carefully, saving all the surrounding capsule by a sharp dissection from the bone.

The trapezium is sectioned into four pieces with an osteotome and then removed piecemeal with a rongeur, including its ulnar distal projection which is often seen between the first and second metacarpals. It is best to use a small sharp osteotome and direct it distally and not towards the depths of the wound in order to avoid injury to the underlying flexor carpi radialis tendon and capsule. Traction on the thumb or distal retraction with a small, two-pronged retractor on the base of the metacarpal will facilitate the exposure. A thin bony shell remnant of the trapezium is left with the underlying capsule to maintain a good palmar capsuloligamentous support. However, this must not be so large as to interfere with the implant.

<sup>2</sup>Dacron is a registered trademark of E. I. DuPont de Nemours & Co. for polyester.



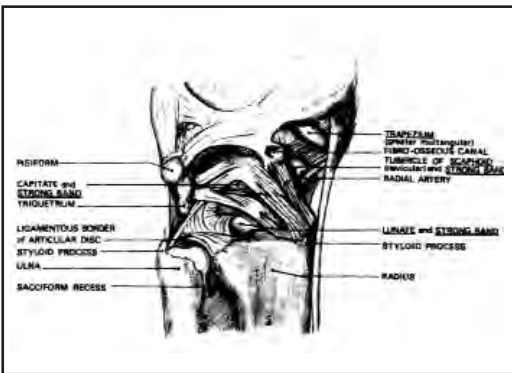
**FIGURE 1C** | Radial artery branch is identified and protected. Trapezium is removed, base of first metacarpal resected, and partial trapezoidectomy is performed.

This is especially true on the radial palmar aspect of the trapezium bone where it attaches to the transverse carpal ligament and to the underlying thenar musculature. Any osteophytes or irregularities on the distal end of the scaphoid, trapezoid, or base of the first and second metacarpals are trimmed to assure proper medialization of the first metacarpal.

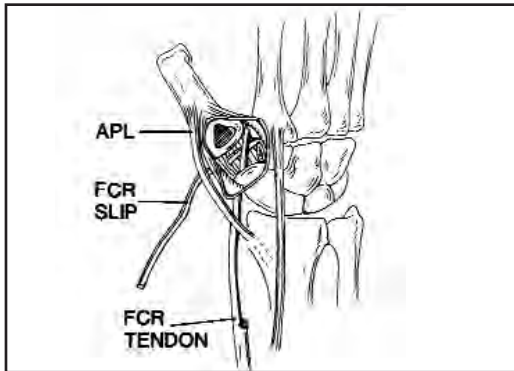
Care should be taken to selectively identify the trapezium bone to prevent the removal of portions of the other surrounding bony structures. Frequently, there is a shift of the trapezoid radially that prevents proper seating of the implant on the scaphoid facet; a portion of the radial aspect of the trapezoid is usually removed to allow the implant to fit better over the scaphoid | **FIGURE 1C**.

The partial trapezoidectomy is done by lifting the trapezoid from the scapoid with a small dissector and using a rongeur to remove bone. The dorsal prominence of the scaphoid should be left intact because it provides attachment for the dorsal capsule, which is important for a secure capsuloligamentous closure. The cut surface of the trapezoid is smoothed with round burs. The scaphoid, trapezoid, second metacarpal, and the base of the first metacarpal joint surfaces are inspected to note the degree of arthritic change, surface irregularity, or cyst formation.

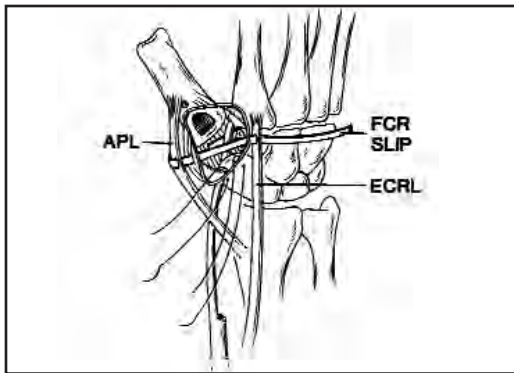
The base of the metacarpal is brought into the wound with one or two small, two-pronged retractors which are placed under its distal medial (ulnar) portion. The base of the metacarpal is squared off with a rongeur or power saw, leaving most of the cortical and subchondral bone intact and preserving the ligament attachments. Any osteophytes, especially on the medial aspect, should be removed. The intramedullary canal is then prepared to receive the implant stem. The canal should not be entered with a drill, but should first be probed with a small tapered broach or curette to prevent inadvertent perforation through the side wall of the metacarpal and extrusion of the implant stem through this defect. Using special burs with a leader point, a triangular intramedullary shape is developed. Trapezium rasps are also available to form the triangular shape. The canal should not be any larger than necessary to receive the stem of the implant easily. If the canal is enlarged, bone chips are inserted to provide intramedullary stability of the stem.



**FIGURE 1D** | Complete resection of the carpal bone (trapezium, scaphoid, or lunate) may leave "holes" in the palmar ligaments as illustrated. A thin wafer of bone is behind to maintain the integrity of the ligament support. A capsular reinforcement with a slip of the flexor carpi radialis tendon is indicated.



**FIGURE 2A** | Slip made of FCR tendon (preserving metacarpal insertion), passed under FCR tendon and laterally through radial capsule and abductor pollicis brevis muscle.



**FIGURE 2B** | FCR slip is passed medially through APL tendon, lateral capsule across trapeziectomy site, through medial capsule, under radial artery branch, and through distal portion of extensor carpi radialis (ECRL). 3-0 Dacron<sup>2</sup> sutures are passed through capsular reflections off scaphoid for capsular closure.

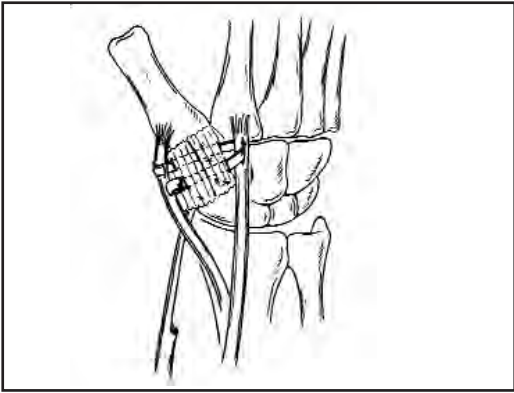
Trial color coded sizers are used to determine the proper implant size, starting usually with size two. A sizer should fit the space left by the resection of the trapezium, and allow full circumduction of the thumb, maintaining stability over the scaphoid bone. The implant base should fit well over the distal scaphoid facet. The collar of the implant should seat properly on the base of the metacarpal. The wound must be thoroughly irrigated with saline to remove all debris before inserting the implant.

Before inserting the implant, the palmar capsule and ligaments should be inspected in the depths of the wound for inadvertent tears or "holes". If present, these should be sutured so there is a firm supporting capsule on the palmar surface of the implant. Leaving a small bony shell on the ligament floor in the depths of the wound will help assure the maintenance of the ligament structures | **FIGURE 1D**.

### LIGAMENTOUS REINFORCEMENT

It is important to localize the implant over the scaphoid facet by reconstruction of the capsuloligamentous structures around the implant. A ligamentous reconstruction using a tendon slip from the flexor carpi radialis is recommended for most cases. Rarely are the abductor pollicis longus, the extensor carpi radialis longus, or palmaris longus tendons used. The flexor carpi radialis (FCR) tendon is exposed in the forearm, and a 7 to 8 cm tendon slip is developed from its radial third. The slip is dissected distally to the fibro-osseous canal, pulled into the trapeziectomy site, and freed to its insertion on the second metacarpal which is carefully preserved. Great care should be taken to avoid transverse lacerations of the tendon slip. The radial artery is carefully retracted. A small hemostat is passed through the abductor pollicis brevis muscle to pull the tendon slip radialward under the residual flexor carpi radialis tendon and then through the capsule and the abductor pollicis brevis muscle | **FIGURE 2A**. The slip is then brought back anteriorly and ulnarward through the abductor pollicis longus tendon and the radial capsule | **FIGURE 2B**.





**FIGURE 2C** | Implant is inserted and slip folded under dorsal capsule, looped through APL, and sutured. Capsular reflections are sutured proximally and distally. APL is advanced distally on metacarpal.

It is important that this slip not be pulled too tightly, as it may have a tendency to tent up and lift the implant from the floor of the wound. This can be prevented by placing the tendon slip under the flexor carpi radialis tendon, suturing it to this tendon and the palmar capsule. As the radial artery is retracted, two 3-0 Dacron<sup>2</sup> sutures are placed through the capsular reflection off the scaphoid bone to obtain a secure closure of the radial capsule. The remaining portion of the tendon slip is brought over and through the radial capsule to exit through the ulnar capsule. The tendon slip is then passed through the distal portion of the extensor carpi radialis longus tendon, avoiding the overlying radial artery | **FIGURE 2B**. After implant insertion, the slip of the flexor carpi radialis tendon is pulled out and folded across the dorsal capsular repair and sutured in position | **FIGURE 2C**.

In some cases, sutures may be required in the proximal end of the metacarpal to securely close the distal portion of the capsular repair. The longitudinal dorsal capsular incision is repaired with 3-0 Dacron<sup>2</sup> sutures or other non-absorbable material using multiple interrupted sutures and inverting the knots. The abductor pollicis longus is advanced distally on the metacarpal and the extensor pollicis brevis is tenodesed by suture to the abductor tendon insertion. This ligamentous repair provides a firm capsular reinforcement on the palmar, ulnar, radial, and dorsal sides. It is noted again that a portion of the trapezoid bone may have to be removed for proper seating of the implant. If the dissection has been near the radial artery, the tourniquet is released at this point to verify its integrity or release any area of restriction by the overlying fascia.

The first dorsal compartment is loosely closed over the abductor pollicis longus and extensor pollicis brevis tendons. Dorsal bow stringing of the extensor pollicis brevis tendon could result in an increased moment arm and produce hypertension of the MP joint of the thumb, however, increasing the moment arm of the abductor pollicis longus tendon has advantages for thumb abduction and can be accomplished by advancing its distal insertion on the metacarpal. Tenodesis of the extensor pollicis brevis over the metacarpal helps abduction and also helps restrict its tendency to hyperextend the metacarpophalangeal joint.

On closure, care is taken to avoid branches of the superficial radial nerve which must not lie over the tendon edges or directly underneath the wound. We frequently prefer to transfer it slightly dorsally away from the line of skin closure. The skin is closed in layers, using 6-0 Dexon sutures for the subcutaneous tissues and interrupted 5-0 nylon for the skin. Small drains are inserted subcutaneously. A secure dressing, including an anterior and posterior plaster splint, is then applied with the thumb in palmar abduction. It is also possible to apply a plaster cast at the end of the operative procedure. The cast should be bivalved and the extremity elevated because of potential postoperative swelling. During the application of the dressing, it is essential to avoid grasping the operated hand through the carpal area so as to avoid applying pressure against the base of the thumb. This could result in displacement of the implant over the scaphoid facet. If the tourniquet is left on for more than 90 minutes, a stellate ganglion block is usually given, unless previously contraindicated.

### postoperative CARE

The extremity is kept elevated for two to three days with a sling that can be attached to an intravenous infusion stand. The drains are removed in approximately 48 hours. After two to three days, depending on the amount of soft tissue swelling, a short arm thumb spica-type cast is applied. After two to three weeks, sutures are removed through a window in the cast. The cast is worn for a total of six weeks, and adjusted or replaced as needed. When it is removed, the patient is instructed to start a guarded range of motion, and pinch, and grasp activities. A small dowel (2.5 cm in diameter) can be grasped in the first web space to improve abduction and is a good exercise device. Heavy pinch activities are to be avoided for three months after surgery | **FIGURES 3A & 3B.**



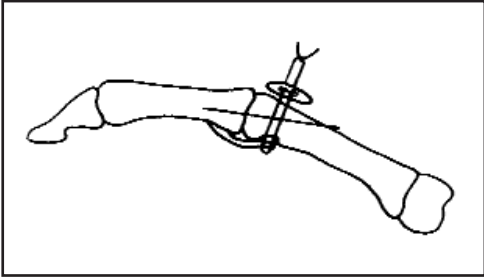
**FIGURE 3A |**



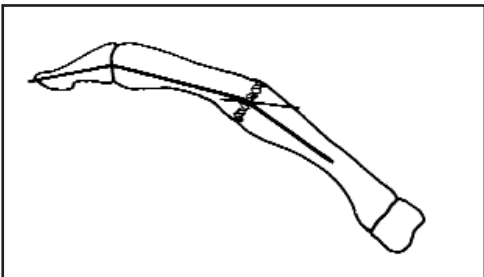
**FIGURE 3B |**

Pantrapezial degenerative arthritis with subluxation of carpometacarpal joint. **(B)** Result 13 years after trapezium implant arthroplasty with the original silicone elastomer. Note partial trapezoidectomy, excellent host tolerance, and implant position. The patient is pain-free and has an excellent clinical result.

## special CONSIDERATION



**FIGURE 4** | Capsulodesis of the metacarpophalangeal joint of the thumb: the palmar aspect of the joint is exposed through a lateral incision. The proximal membranous insertions of the palmar plate are incised. The tendinous attachments on the sesamoid bones are left intact. The periosteum is stripped from the volar aspect of the neck of the metacarpal. Two small drill holes are made vertical to the bone and converted into a cavity with a small curette. The dorsal aspect of the palmar plate is roughened and fixed in the bony depression with a pull-out wire suture exiting dorsally over a button. The tension of the palmar plate flap must be such as to obtain 10° to 15° of flexion of the metacarpophalangeal joint. The desired degree of flexion of the joint is maintained with a Kirschner wire left in place for 6 weeks. The pull-out wire is removed after 3 weeks.



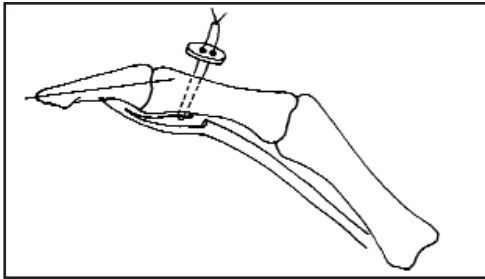
**FIGURE 5** | Joint fused in functional position of 10° flexion, 5° abduction and slight pronation. Permanent cross wire and temporary longitudinal Kirschner wire inserted to further stabilize joint.

Adduction contracture of the first metacarpal is a frequently associated problem in arthritic disabilities of the basal joint of the thumb. If severe and untreated, it will unbalance the thumb and seriously affect the result of resection arthroplasties of the trapezium. If the angle of abduction between the first and second metacarpals does not reach at least 45°, the origin of the adductor pollicis muscle may be released from the third metacarpal through a separate palmar incision. Once sufficient abduction has been achieved, proper seating of the implant on the scaphoid should be established.

Hyperextension deformity of the metacarpophalangeal joint contributes to the adduction tendency of the metacarpal and prevents proper abduction of the metacarpal and seating of the implant. If the metacarpophalangeal joint extends less than 10°, no treatment is necessary except to apply the postoperative cast so that the metacarpal is abducted - not the proximal phalanx. If the metacarpophalangeal joint hyperextends from 10° to 20°, a Kirschner wire is placed obliquely across the joint while it is held in 10° flexion. The wire is extracted when the cast is removed six weeks postoperatively. If hyperextension of the metacarpophalangeal joint is greater than 20°, stabilization is an absolute necessity.

If hyperextension of the metacarpophalangeal joint is greater than 20° with near normal flexion, good lateral stability, and adequate articular surfaces, a palmar capsulodesis of the metacarpophalangeal joint can be indicated to preserve available flexion and restrict hyperextension | **FIGURE 4**. Fusion of the metacarpophalangeal joint should be done for hyperextension deformities when there is no flexion or when there is lateral instability due to collateral ligament disruption or when there is articular destruction.

When the metacarpophalangeal joint is fused, it is placed in 10° of flexion, 5° of abduction, and slight pronation | **FIGURE 5**. Small cancellous grafts from the excised trapezium may be inserted. A longitudinal wire and oblique wire are used for fixation. These procedures are performed at the same time as the basal joint reconstruction.



**FIGURE 6** | A flexor tenodesis of the thumb interphalangeal joint can be carried out for certain flexible hyperextension deformities of this joint. A slip of the flexor pollicis longus is prepared, leaving its distal attachment to the distal phalanx intact. The periosteum is stripped from the volar aspect of the neck of the proximal phalanx, two small drill holes are made through the bone in a vertical direction and converted with a curette to form a small cavity to receive the tendon slip. The flexor slip is secured in position, using a pull-out type suture exiting dorsally over a button to obtain 10° to 15° flexion of the interphalangeal joint. A small Kirschner wire is placed across the joint to maintain the desired degree of flexion. The pull-out wire is removed in 3 weeks and the Kirschner wire in 6 weeks.

The interphalangeal joint may be involved in the arthritic process, and if unstable, may require fusion. If there is a flexible hyperextension deformity of this joint with good articular surfaces and lateral stability, a flexor tendon hemitenodesis can be done | **FIGURE 6**. If there is evidence of arthritic destruction and reasonably good stability and motion, a Swanson Flexible Hinge Finger Implant may be used to preserve pain-free joint movement.

A boutonniere deformity of the thumb is not usually associated with arthritis of the basal joints of the type that would require implant arthroplasty. However, when this situation does occur, fusion of the metacarpophalangeal joint and release of the extensor tendon at the distal joint may be performed along with the implant procedure. The use of a finger joint implant at the level of the thumb metacarpophalangeal joint is contraindicated when implants are inserted at the thumb basal or distal joints.

## DICTUMS FOR BASAL THUMB IMPLANT ARTHROPLASY

### 1. Implant Selection

There are definite separate indications for the use of the Swanson Trapezium implants. The CSE trapezium implant is preferred for cases of pantrapezium involvement due to degenerative or post traumatic arthritis, providing there is integrity of the contiguous carpal bones and possibility of good seating of the scaphoid facet.

### 2. Implant Positioning

Proper medialization of the trapezium implant is essential. The scaphoid facet should be large enough to accept the base of the implant. A partial trapezoidectomy and resection of exostoses at the base of the first metacarpal are important to assure a stable position of the implant over the contiguous bone.

### 3. Surgical Technique

The importance of a firm capsuloligamentous reconstruction must be stressed. A slip of flexor carpi radialis tendon is used in all cases of trapezium implant arthroplasty. Branches of the superficial radial nerve and the radial artery must be carefully identified, protected and preserved during surgery.

### 4. Correction of Associated Deformities

Associated imbalances of the thumb ray, especially hyperextension of the metacarpophalangeal joint and adduction contracture of the first metacarpal, must be corrected at the same time as the basal joint reconstruction. Palmar capsulodesis or fusion of the metacarpophalangeal joint is indicated where the joint hyperextends to more than 20°. Adduction contracture of the first metacarpal must be released.

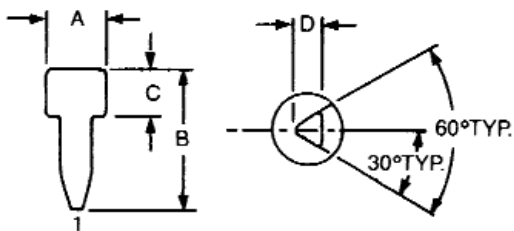
**HOW SUPPLIED**

The Swanson Trapezium Implant has been sterilized and packaged as follows:

Quantity	Description	Catalog Number
1 box	One each, Size 1	452-0001
1 box	One each, Size 2	452-0002
1 box	One each, Size 3	452-0003
1 box	One each, Size 4	452-0004
1 box	One each, Size 5	452-0005
1 sizing set	One each, Sizes 1, 2, 3, 4, 5. Numerically marked, color-coated (non-sterile). NOT FOR IMPLANTATION	462-0000

**TYPICAL DIMENSIONS (millimeters)**

Size	1	2	3	4	5
A	12.2	12.9	14.0	14.7	15.7
B	27.4	31.2	35.3	39.1	43.3
C	8.6	9.9	10.9	11.9	13.2
D	5.8	6.3	6.6	7.1	7.6



## POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

The risks and complications with trapezium replacement are similar to those of other small joint replacements and include:

- 1) breakage of the implant
- 2) implant rotation or subluxation
- 3) progressive carpal instability or collapse, and progression of disease to other carpal articulations, or to the radiocarpal joint
- 4) infection, wound breakdown or neuroma formation
- 5) the generation of silicone wear particles
- 6) untoward histological responses possibly involving macrophages and fibroblasts.

One of the concerns of implant surgery is to minimize production of wear particles. It can never be eliminated because all moving parts, e.g., implants that articulate against bone, wear to some degree. In an implant arthroplasty, clinically significant wear can result from abnormal biomechanical forces which generate excessive loads. Abnormal force loading of the implant and subsequent formation of silicone wear particles may be caused by:

- Uncorrected carpal instability
- Oversized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

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

Some preventive measures to consider to minimize the potential for complications include:

- Follow patient selection guidelines
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant
- Avoid suturing or using K-wires through the implant
- Avoid flawing implant surfaces to minimize the potential for formation of silicone wear particles

If complications develop, possible corrective procedures include:

- Implant removal or replacement
- Synovectomy
- Bone grafting of cysts
- Joint fusion
- Soft tissue interposition arthroplasty

Clinical results depend on surgical technique, preoperative and postoperative 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 scheduled for surgery. This may include review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

## WARNINGS AND RECOMMENDATIONS

In some patients, particulate associated synovitis and related cystic bone changes can occur around abraded silicone implants due to the so-called "frustrated macrophage", which after ingesting particles releases a variety of detrimental enzymes. This phenomenon has been reported especially with: carpal bone implants overloaded with excessive compressive and shear stresses; implant oversize or subluxation; inadequate intercarpal bone stabilization; and excessive activity. These complications have been reported to occur more frequently with scaphoid and lunate replacement implants, and to a lesser degree with trapezium or other spacer implants.

Although there have been a few reports in the literature suggesting a relationship between silicone implants and a broad spectrum of connective tissue diseases, systemic illness and autoimmune phenomena, the casual relationship has not been proven. It has been shown that rheumatoid patients are at greater risk to develop lymphomas, leukemia and myelomas possibly due to the immunological abnormality of rheumatoid arthritis. The participation of antigen-specific lymphocytes or antibodies in silicone particulate-induced macrophage reactions has not been demonstrated in ongoing studies.

## PRECAUTIONS

It is the responsibility of each surgeon to evaluate the medical and surgical status and requirements of each patient, to know all aspects of implant procedures, and to inform the patient on alternative procedures, potential expectations and complications.

The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgery following implant procedures is not uncommon. Surgeons must balance many considerations to achieve the best result in individual patients.

## STERILIZATION

The Swanson Trapezium Implants are supplied sterile.

The color coded sizing sets are supplied nonsterile. The following sequential steps are recommended to clean and sterilize the color coded sizing set 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 the soaps may be absorbed and subsequently leach out to cause a tissue reaction.
- 2) Rinse thoroughly with distilled water.
- 3) Wrap in a lint free cloth or place on a clean open tray, and autoclave according to the following guidelines:

Method	Cycle	Temperature	Exposure
Steam	Gravity	250°F(121°C)	30 minutes
Steam	Gravity	270°F(132°C)	10 minutes
Steam	Vacuum	270°F(132°C)	10 minutes

## BIBLIOGRAPHY

A bibliography may be obtained by writing or by contacting your representative.

**IMPORTANT |** Do not sterilize by ethylene oxide as the residual sterilant may cause adverse tissue reaction.

**CAUTION |** Federal (U.S.) law restricts this device to sale by or on order of a physician.



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