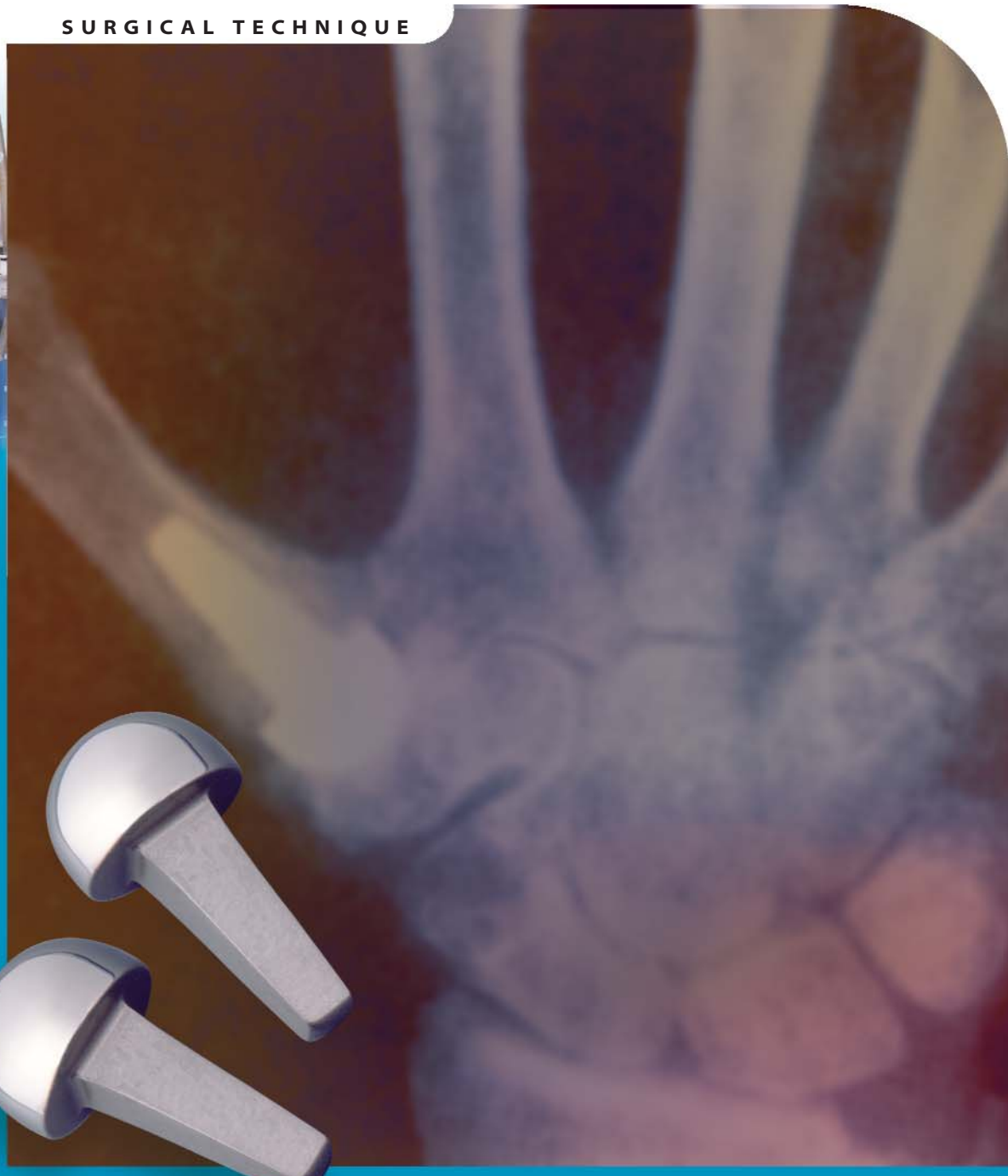
SWANSON

BASAL THUMB IMPLANT

SURGICAL TECHNIQUE



WRIGHT MEDICAL TECHNOLOGY

A Wright Medical Group Company

SWANSON
BASAL THUMB
IMPLANT SYSTEM

surgical technique presented by

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GRAND RAPIDS, MICHIGAN.

SWANSON
basal thumb 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.

WRIGHT MEDICAL TECHNOLOGY DOES NOT RECOMMEND A PARTICULAR SURGICAL PROCEDURE. PROPER SURGICAL PROCEDURES AND TECHNIQUES ARE NECESSARILY THE RESPONSIBILITY OF THE MEDICAL PROFESSION. EACH SURGEON MUST EVALUATE THE APPROPRIATENESS OF THE PROCEDURE 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, MD.*

potential complications and ADVERSE REACTIONS

There have been some reports of patients with metal sensitivity reactions following joint replacement. Clinical data have not established the long term effects of these reactions. Implantation of materials such as titanium may result in foreign body reaction adjacent to the implant site. The clinical significance of such a reaction is uncertain. The risks and complications with this trapeziometacarpal joint replacement are similar to those of other small joint replacements and include:

- Fracture of the stem and/or the articular surface
- Late loosening of the prosthesis requiring revision surgery
- Fracture or absorption of the bone leading to the need for further surgery
- The generation of metal wear debris.

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 in each specific case.

warnings and RECOMMENDATIONS

Implants are mechanical devices that can be worn away, fatigued, or broken. An implant site may become infected, painful, swollen, or inflamed. Strenous implant loading, excessive mobility, the presence of articular instability, implant oversizing, and patient over-activity or misuse increase the potential for complications including wear or fracture of the implant and particle formation. Excessively mobile joints are generally less stable and an implant alone cannot provide long-term stability in a joint that lacks functional stability; complications necessitating revision surgeries are thus more frequent in unstable joints. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate in time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.
Therefore, surgeons must balance many considerations to achieve the best result in individual patients. Providing each patient scheduled for implant surgery with documented counseling of potential complications is required.

STERILIZATION

The Swanson Titanium Basal Thumb Implant has been sterilized. The sizing set is supplied non-sterile. The following sequential steps are suggested to clean and sterilize the sizing set or to resterilize implants:

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 such as Ivory soap. Do not use synthetic detergents or oil-based soaps, as these may be absorbed and subsequently leached 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 by standard hospital steam sterilization procedures.

GAS STERILIZATION (ETHYLENE OXIDE) IS NOT RECOMMENDED FOR THE SIZING SET. THE RESIDUAL STERILANT MAY CAUSE ADVERSE TISSUE REACTION.

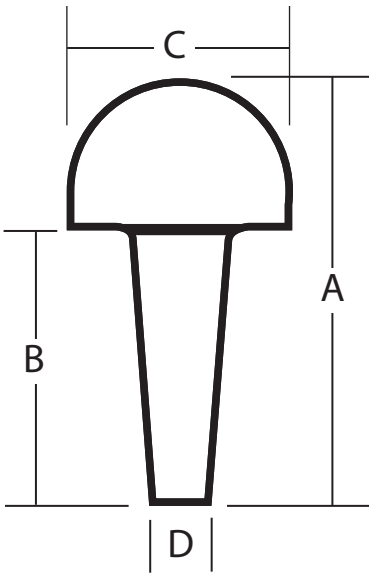
DESCRIPTION

The Swanson Titanium Basal Thumb implant is a one-piece intramedullary-stemmed implant developed to be used as an adjunct to resection arthroplasty of the trapeziometacarpal joint in cases of degenerative arthritis, or post-traumatic arthritis limited to that joint. The implant can provide a stable, pain-free, functional thumb joint. The implant stem fits in the intramedullary canal of the first metacarpal and the convex head into a concave surface made in the distal surface of the trapezium. The Swanson Titanium Basal Thumb implant is fabricated from unalloyed titanium for surgical applications (ASTM F67).
The intramedullary stems are anatomically sized and designed to resist rotation of the implant. The smooth convex articulating surface helps restore and maintain motion and maintain the joint space. An autoclavable plastic sizing set, supplied non-sterile and not suitable for implantation, is available for proper size determination during surgery.

HOW SUPPLIED

The Swanson Titanium Basal Thumb implant has been sterilized and packaged as follows:

QUANTITY	DESCRIPTION	CATALOG #
1 Box	1 Each, Size 1	428-3001
1 Box	1 Each, Size 2	428-3002
1 Box	1 Each, Size 3	428-3003
1 Box	1 Each, Size 4	428-3004
1 Box	1 Each, Size 5	428-3005
1 Sizing Set	1 Each, implant sizes: 1, 2, 3, 4 and 5 for the Basal Thumb, Numerically marked, color coded (non-sterile) NOT FOR IMPLANTATION.	438-3000



TYPICAL DIMENSIONS | Millimeters

SIZE	1	2	3	4	5
A	19.3	20.9	22.8	24.5	26.3
B	13.0	14.0	15.0	16.1	17.3
C	9.5	10.4	11.5	12.6	13.6
D	2.5	2.8	3.0	3.2	3.4

TREATMENT CONSIDERATIONS

Many patients who have disabilities of the basal joints of the thumb due to rheumatoid arthritis have destructive changes of the contiguous carpal bones which make the standard trapezium implant arthroplasty difficult; frequently, the trapezium may be fused to the scaphoid or the scaphoid may be fused or shifted ulnarly. A silicone implant arthroplasty of the trapeziometacarpal joint may be indicated in these cases to preserve motion and stability at the thumb basal joints. A Swanson Titanium Basal Thumb implant is used for isolated trapeziometacarpal joint involvement from degenerative or post-traumatic arthritis. Instead of carrying out a trapeziectomy, a limited resection of the base of the metacarpal and of the distal facet of the trapezium is carried out. The stem of the basal thumb implant is inserted into the intramedullary canal of the first metacarpal and the capsule is reinforced with a slip of the abductor pollicis longus tendon.

ADVANTAGES

- Available in five sizes to adequately meet various operative requirements.
- Acts as a spacer to preserve joint relationship and allow appropriate capsuloligamentous reconstruction to correct deformities.
- Provides improved stability, range of motion and relief of pain.
- Fixation in the intramedullary canal is not required.

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 and support the implant
- Availability of postoperative therapy
- A cooperative patient

Trapeziometacarpal joint implant arthroplasty with the SWANSON Titanium Basal Thumb implant may be considered in cases of isolated trapeziometacarpal joint involvement from either degenerative or post-traumatic arthritis presenting:

- Localized pain and palpable crepitation during circumduction movement with axial compression of involved thumb ("grind test")
- Decreased motion, normal pinch and grip strength
- X-ray evidence of arthritic changes at the trapeziometacarpal joint only
- Subluxation of the trapeziometacarpal joint
- Associated unstable, stiff, or painful distal joints

NOTE | A TRAPEZIUM IMPLANT OF SILICONE MATERIAL IS PREFERRED IN CASES OF PANTRAPEZIAL INVOLVEMENT DUE TO DEGENERATIVE ARTHRITIS.

CONTRAINDICATIONS

- Pantrapezial arthritic involvement
- Rheumatoid or erosive osteoarthritis
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, and/or neurovascular status
- Irreparable tendon system
- Presence of infection

NOTE | EACH PATIENT MUST BE EVALUATED BY THE SURGEON TO DETERMINE THE RISK/BENEFIT RELATIONSHIP.

surgical PROCEDURE

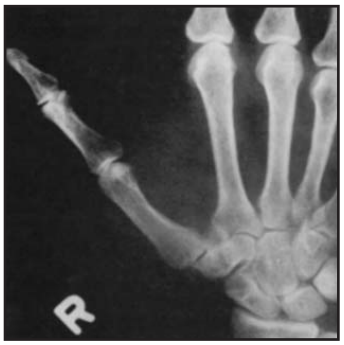


FIGURE 1 | Preoperative x-ray of hand of a 65-year-old female with isolated osteoarthritic involvement of the trapezial metacarpal joint. Note joint subluxation.

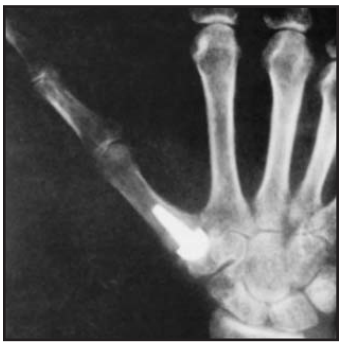


FIGURE 2 | Postoperative x-ray shows a well tolerated titanium basal thumb implant in place. Trapezium was shaped to fit the head of the implant and the base of the metatarsal was resected. All osteophytes were removed and the capsule was reconstructed with a slip of abductor pollicis longus tendon. Patient has a pain free functional thumb.

A 7 to 8cm longitudinal incision centered over the trapezium compartment is made parallel to the extensor pollicis brevis tendon. The incision starts approximately 2 cms above the trapeziometacarpal joint and is carried proximally and ulnarly to the distal wrist crease. To expose the abductor pollicis longus at the wrist, the incision can be prolonged proximally or the tendon can be approched through a separate incision. The skin flaps and subcutaneous tissues are carefully dissected to expose the branches of the superficial radial nerve which are identified and retracted. Small transverse veins may be ligated; however, longitudinal veins are spared. The retinaculum of the first dorsal compartment is incised longitudinally to expose the abductor pollicis longus and the extensor pollicis brevis tendons. These two tendons are retracted from each other, and dissection is carried down between them to expose the adventitial tissue and fatty layers overlying the radial artery. The radial artery is then carefully dissected and mobilized so that it can be retracted proximally and protected during the dissection. The artery can be safely retracted with a small flexible rubber tube. The capsule overlying the base of the metacarpal and trapezium is then incised longitudinally over the radial size of the trapeziometacarpal joint. Approximately 2 to 4mm of the base of the metacarpal is resected. The articulating projection of the trapezium to the second metacarpal must also be resected. The distal facet of the trapezium is shaped in a slightly concave contour with a bur and air drill to accommodate the implant head.

A sufficient bone resection must be carried out to provide a joint space of approximately 4mm and allow at least 45° of radial abduction of the first metacarpal. To achieve this goal, either more bone may be resected from the metacarpal base, or the origin of the adductor pollicis may be released from the third metacarpal through a separate palmar incision if indicated. The intramedullary canal of the metacarpal should be probed first with a thin broach or small curette to avoid perforation through its side wall and consequent extrusion of the implant stem through this defect. Special blunt tip leader point burs are then used to develop a square intramedullary shape, which should be no larger than necessary to receive the implant stem. The appropriate size implant is then selected.

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 THEIR USE, FOLLOW INSTRUCTIONS UNDER SECTION, "STERILIZATION".

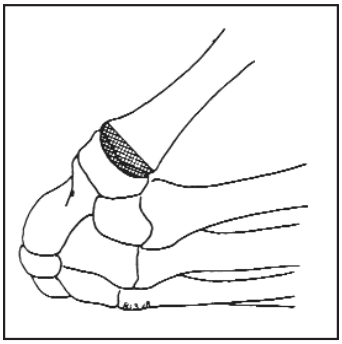


FIGURE 3 | Bone resection for arthroplasty of the trapeziometacarpal joint..

There is usually a radial subluxating tendency in these cases, which can be corrected by a firm capsuloligamentous reconstruction using a slip of the abductor pollicis longus tendon; this technique can provide an excellent stabilizing effect.

An 8cm in length and 2mm in width distally based slip of the abductor pollicis longus tendon is prepared; its insertion on the radial aspect of the base of the first metacarpal is preserved. The slip is then looped into the intramedullary canal of the first metacarpal and the end of the slip is pulled out with a wire loop through a 2 to 3mm drill hole in the radiodorsal aspect of the metacarpal. A similar hole is made in the trapezium and the end of the slip is then drawn from inside the trapezium to the outside using a wire loop. (The slip should be inside-out - inside-out.)

The implant is placed in position after a thorough irrigation of the wound with saline to eliminate all debris and bony fragments.

The thumb is then held in 45° abduction as the slip is pulled up tight and securely interwoven to reinforce the capsular closure. The distal end of the slip is passed through or under the insertion of the abductor pollicis longus tendon and sutured to the radial capsular structures of the trapezium using a few 3-0 Dacron sutures and an inverted knot technique. It can be noted that when the slip is pulled up tight, this tendon slip reconstruction forces the metacarpal slightly ulnarward, providing an excellent checkrein to radial subluxation of the base of the metacarpal and is routinely used. If a secure capsular closure can be achieved with 3-0 Dacron sutures passed through small drill holes in the base of the first metacarpal, reinforcement with a slip of abductor pollicis longus is not always necessary. The abductor pollicis longus insertion, however, is always advanced distally, and the short extensor tenodesed. Any associated deformities of the thumb ray must be corrected.

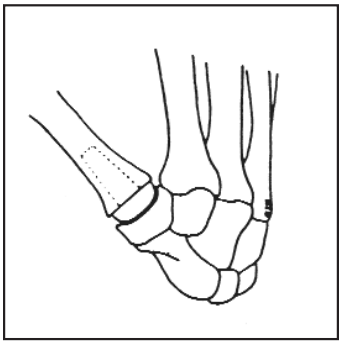


FIGURE 4 | Titanium basal thumb implant fits into the prepared concave surface of the trapezium.

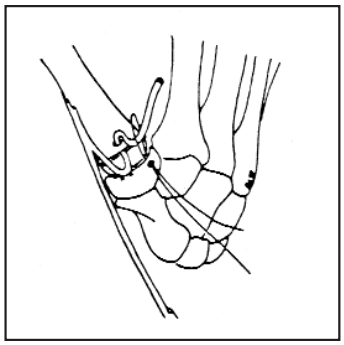


FIGURE 5 | Distally based abductor pollicis longus slip used for reinforcement of the capsule around the implant.

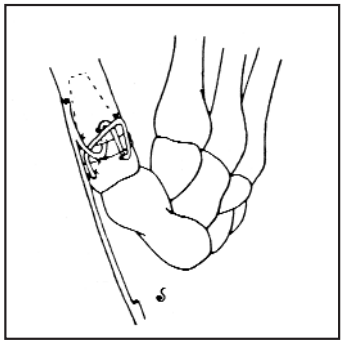


FIGURE 6 | The tendon is placed from inside to out of the metacarpal and from inside to out of the trapezium. This draws the metacarpal ulnarward when pulled tight, which helps prevent the radial subluxation tendency of the metacarpal.

The first dorsal compartment is loosely closed over the abductor pollicis longus and extensor pollicis brevis tendons. Dorsal bowstringing of the extensor pollicis brevis tendon could result in an increased moment arm and produce hyperextension of the metacarpophalangeal 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. Tenodesing the short extensor over the metacarpal will aid in abduction and restrict its tendency to hyperextend the metacarpophalangeal joint. On closure, the superficial radial nerve must not lie over the tendon edges or directly underneath the wound; it is frequently preferable to transfer it slightly away from the line of the skin incision. The wound is closed in layers, and a small drain is inserted subcutaneously. A secure conforming dressing, including an anterior and posterior plaster splint, is then applied.

postoperative CARE

The extremity is kept elevated for 3 to 5 days postoperatively; the drains are removed in approximately 48 hours. After 4 to 5 days, depending upon the amount of soft tissue swelling present, a short arm thumb spica cast is applied and the patient is allowed to leave the hospital. Sutures are removed through a window in the cast at 3 weeks. When the cast is removed after 4 to 6 weeks, the patient is instructed to start a guarded range of motion and pinch and grasp activities. A small dowel (1 1/2 to 2 inches in diameter) can be grasped in the web space between the first and second metacarpal to improve abduction, and build strength in the hand and forearm.

special CONSIDERATIONS

Adduction contracture of the first metacarpal, if severe and untreated, will unbalance the thumb and seriously affect the result of a basal thumb implant arthroplasty. If the angle of abduction between the first and second metacarpals is not at least 45° the origin of the adductor pollicis muscle should be released from the third metacarpal through a separate palmar incision. Rarely, a Z-plasty of the first web space can be indicated. Adduction deformity often causes secondary abduction deformity at the metacarpophalangeal joint with stretching of the ulnar collateral ligament. Fusion of the metacarpophalangeal joint may be required with arthroplasty of the basal joint. 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. This should be corrected at the same time as the basal joint reconstruction. If the metacarpophalangeal joint hyperextends more than 10° to 20°, the joint is pinned in 10° flexion for 4 to 6 weeks. The wire is extracted when the cast is removed, 4 to 6 weeks after surgery. If hyperextension of the metacarpophalangeal joint is greater than 20°, stabilization of the metacarpophalangeal joint is an absolute necessity. A palmar capsulodesis is recommended if there is lateral stability and the joint surfaces are preserved. A fusion of the metacarpophalangeal joint is recommended for hyperextension deformity when there is no available flexion, lateral instability due to collateral ligament disruption or articular destruction and in presence of radial deviation. The metacarpophalangeal joint is fused in 10° flexion, 5° abduction, and slight pronation. Small cancellous bone grafts from the excised bone may be inserted. A longitudinal wire and an oblique wire are used for fixation. 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 exist, fusion of the metacarpophalangeal joint and release of the extensor tendon at the distal joint may be performed along with the implant procedure. The distal 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 lateral stability and articular surfaces, a flexor tendon hemitenodesis may be indicated. If there is articular destruction with reasonably good stability and motion, a small, flexible, hinged implant may be used to preserve a pain free joint movement.

CAUTION | FEDERAL (UNITED STATES) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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