surgical technique as described by
ALFRED B. SWANSON, MD, FACS,
GRAND RAPIDS, MICHIGAN.
The potential for complications or adverse reactions with any implant can be minimized by following the instructions for use provided in the 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 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 carpal instability
- Oversized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity
- Intraoperative fixation
Some preventative measures considered 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

If complications develop, possible corrective procedures include:

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

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.

In any surgical procedure, the potential of complications exists. The risks and complications with the Swanson Titanium Carpal Lunate implant and Swanson Titanium Carpal Scaphoid implant include:

- Infection or painful, swollen, or inflamed implant site
- Breakage of the implant
- Implant rotation or subluxation
- Progressive carpal instability or collapse, and progression of disease to other carpal articulations or to the radiocarpal joint
- 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
SWANSON TITANIUM CARPAL LUNATE IMPLANT
This implant essentially has the same anatomical configuration as the lunate bone, the concavities being more pronounced to provide for stability. The implant has a pair of suture holes designed for use in suture fixation through the scaphoid and triquetrum to provide temporary postoperative stability while a capsuloligamentous system forms around the implant. The design of this implant includes a deep articular concavity on the distal surface to receive and secure the head of the capitate.

SWANSON TITANIUM CARPAL SCAPHOID IMPLANT
This implant is designed to replace the carpal scaphoid bone. The implant has a beak on the distal pole which fits under a shelf formed in the carpal trapezium or trapezoid bone, and a suture hole on the proximal hole for suture fixation. These temporarily help maintain anatomical position during the early postoperative period until a firm capsuloligamentous system has formed around the implant.

Both the Swanson Titanium Carpal Lunate implant and Swanson Titanium Carpal Scaphoid implant has been designed to act as an articulating spacer to help maintain the relationship of the adjacent carpal bones after excision of the lunate or scaphoid, while preserving mobility of the wrist. It is particularly important to achieve a meticulous repair of the palmar aspect of the carpus, to provide adequate support of the implant. The palmar ligaments should be reconstructed if they have been injured either preoperatively or during the removal of the lunate or scaphoid bone. In cases of collapse deformity or carpal instability, associated limited intercarpal bone fusions are indicated to improve the distribution of forces across the wrist and consequently the hand.

The Swanson Titanium Carpal Lunate implant and Swanson Titanium Carpal Scaphoid implant is fabricated from unalloyed titanium for surgical application which conforms to ASTM F67, and is available in five anatomically-graduated right and left sizes to adequately meet various surgical requirements.

Autoclavable color coded plastic sizing sets, supplied non-sterile and not suitable for implantation, are available for proper size determination during surgery.
Aseptic necrosis and arthritic changes of the lunate or scaphoid, either primary or secondary to trauma, are frequent causes of wrist joint disability.

**SWANSON TITANIUM CARPAL LUNATE IMPLANT**

Many cases develop progressive bone collapse followed by:

- Loss of carpal height with rotation and shifting of associated carpal bones
- Ulnar translation of the hand on the wrist
- Intercarpal and radiocarpal arthritis

**SWANSON TITANIUM CARPAL SCAPHOID IMPLANT**

Conservative methods of treatment of Preiser’s disease have met with unpredictable results. Complications following fractures, fracture dislocations, and dislocation of the scaphoid include:

- Nonunion
- Aseptic necrosis of a fragment
- Cystic and degenerative arthritic scaphoid changes
- Lunate dorsiflexion
- Carpal height collapse
- Intercarpal and radiocarpal arthritis

The resultant loss of function, stiffness, pain and weakness of the wrist interfere with activities of daily living, work and sports performance.

The ideal goal of reconstructive procedures of the wrist and carpus is to provide pain relief with reasonable stability, strength, and mobility for hand adaptations. Proper evaluation of the patient’s symptoms and findings, including age, severity of disease and functional requirements, is essential in selecting the best treatment from the wide range of available procedures. Treatment methods have included conservative methods, localized bone grafting, resection arthroplasty, implant arthroplasty, intercarpal fusions, and total wrist implant arthroplasty or fusion.
The following tables provide classification of pathological severity based on bone status, carpal height collapse, angular alterations of the carpal bones' relationships, and arthritic involvement of contiguous carpal bones. A classification of various possible treatments according to the situation presented may be obtained by writing Wright Medical Technology, or by contacting your local Wright Medical Technology representative.

TABLE I

CLASSIFICATION FOR AVASCULAR NECROSIS OF LUNATE AND TREATMENTS

<table>
<thead>
<tr>
<th>CLASS</th>
<th>PATHOLOGY</th>
<th>TREATMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Sclerosis of lunate with:</td>
<td>Splinting and rest&lt;br&gt;Revascularization&lt;br&gt;Ulna &amp; radius lengthening/shortening</td>
</tr>
<tr>
<td></td>
<td>Minimal symptoms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal carpal bone relationships</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Sclerosis of lunate with cystic changes with:</td>
<td>Lunate implant replacement&lt;br&gt;Ulna &amp; radius lengthening/shortening</td>
</tr>
<tr>
<td></td>
<td>Clinical symptoms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal carpal bone relationships</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Sclerosis, cysts, and fragmentation of lunate with:</td>
<td>Lunate implant replacement with/without intercarpal fusions</td>
</tr>
<tr>
<td></td>
<td>Scaphoid-radius angle 40-60°</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carpal height collapse 0-5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carpal translation minimal</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>Sclerosis, cysts, fragmentation of lunate with:</td>
<td>Lunate implant replacement with scaphoid stabilization (distal fusion)</td>
</tr>
<tr>
<td></td>
<td>Scaphoid-radius angle &lt;70°</td>
<td>Intercarpal fusions if early changes in contiguous bones</td>
</tr>
<tr>
<td></td>
<td>Carpal height collapse 5-10%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carpal translation moderate</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Sclerosis, cysts, fragmentation of lunate with:</td>
<td>Lunate implant replacement and intercarpal fusions&lt;br&gt;Wrist arthrodesis</td>
</tr>
<tr>
<td></td>
<td>Scaphoid-radius angle &gt;70°</td>
<td>Ulna impingement treatment PRN</td>
</tr>
<tr>
<td></td>
<td>Carpal translation severe</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cystic changes severe in contiguous bones</td>
<td></td>
</tr>
<tr>
<td>VI</td>
<td>Sclerosis, cysts, fragmentation of lunate with:</td>
<td>Total wrist implant arthroplasty&lt;br&gt;Wrist arthrodesis&lt;br&gt;Ulna impingement treatment PRN</td>
</tr>
<tr>
<td></td>
<td>Scaphoid-radius angle &gt;70°</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carpal height collapse &gt;15%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carpal translation severe</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cystic changes in contiguous bones</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Significant intercarpal &amp; radiocarpal degenerative arthritic changes</td>
<td></td>
</tr>
<tr>
<td>CLASS</td>
<td>PATHOLOGY</td>
<td>TREATMENTS/OPTIONS</td>
</tr>
<tr>
<td>-------</td>
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<td>--------------------</td>
</tr>
</tbody>
</table>
| I     | Acute scaphoid fractures  
          Acute scaphoid fracture/dislocation | Immobilization  
          Open or closed reduction |
| II    | Nonunion of scaphoid | Bone graft  
          Bone Stimulator |
| III   | Avascular necrosis of a fragment with:  
          Carpal height collapse 0-5%  
          Lunate dorsiflexion minimal (R-L angle* 0-10°) | Partial implant replacement  
          Scaphoid implant replacement |
| IV    | Comminuted or grossly displaced fracture  
          Avascular necrosis with scaphoid degenerative arthritic changes  
          Subluxation of scaphoid with cystic changes with:  
          Carpal height collapse 5-10%  
          Lunate dorsiflexion minimal (R-L angle* 10-30°)  
          Mild degenerative arthritic changes of contiguous bones (particularly between lunate and capitate) | Scaphoid implant replacement with/without intercarpal bone fusions |
| V     | Category IV pathology of scaphoid with:  
          Carpal height collapse greater than 10%  
          Lunate dorsiflexion moderate (R-L angle* >30°) | Scaphoid implant replacement with/without intercarpal bone fusions  
          Proximal row carpectomy  
          Fusion proximal carpus to radius  
          Hemiarthroplasty |
| VI    | Category VI pathology of scaphoid or previous surgery with:  
          Carpal height collapse greater than 15%  
          Lunate dorsiflexion severe (R-L angle* >30°)  
          Severe intercarpal and radiocarpal degenerative arthritic changes | Total wrist implant arthroplasty  
          Wrist arthrodesis  
          Ulna impingement treatment PRN |

*Radiolunate angle
The Swanson Titanium Carpal Lunate implant and Swanson Titanium Carpal Scaphoid implant acts as an articulating spacer to help maintain the relationship of the adjacent carpal bones after resection while allowing some wrist mobility. Attention to the indications, contraindications, alternative and/or associated procedures, operative techniques and postoperative care are essential for good results. It is particularly important to achieve a meticulous repair of the capsuloligamentous system, especially on the palmar aspect of the carpus, to provide adequate support of the implant. The palmar ligaments should be reconstructed if they have been injured either preoperatively or during the removal of the scaphoid bone. In cases of collapse deformity of carpal instability, associated limited intercarpal bone fusions are indicated to improve the distribution of forces across the wrist and consequently the hand.

**clinical ADVANTAGES**

- Designed to help provide improved stability and joint space relationship
- Acts as an articulating spacer to help prevent carpal bone migration which may occur following simple resection arthroplasty
- Made of unalloyed titanium to enhance durability and lessen the risk of wear debris
- Suture hole(s) in the implant allows early stabilization
- Available in five graduated right or left sizes to meet various operative requirements
- Prolonged immobilization is not required and can usually be discontinued after eight weeks
- Essentially salvageable procedure

**general INDICATIONS**

- Any joint implant arthroplasty requires consideration of the following:
  - General condition of the patient
  - Good neurovascular status
  - Adequate skin coverage
  - Possibility of a functional musculotendinous system
  - Availability of postoperative therapy
  - Cooperative patient
specific INDICATIONS

Use may be considered in the following situations:

**SWANSON TITANIUM CARPAL LUNATE IMPLANT**
- Presence of avascular necrosis-Kienbock’s disease
- Localized osteoarthritic changes
- Long-standing dislocations

**SWANSON TITANIUM CARPAL SCAPHOID IMPLANT**
- Acute fractures
  a. Comminuted
  b. Grossly displaced
- Pseudarthrosis, especially with small proximal fragments, not responsive to conservative therapy
- Preiser’s disease
- Avascular necrosis of a fragment
- Failures due to previous surgery

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.

- Usage of metal suture/wire for implant fixation
- Usage of two titanium carpal implants in adjacent articulations
specific CONTRAINDICATIONS

The procedure is contraindicated in the following situations:
1) arthritic involvement not localized to the lunate/scaphoid articulations
2) presence of inadequate bone to support the implant; and following radial styloidectomy (scaphoid)
3) ligamentous instability and carpal collapse not correctable at time of surgery
4) following fracture dislocations of wrist with injury to lunate/scaphoid and associated disruption of ligaments, especially the radiocarpal ligament, unless carpal relationships and ligamentous integrity can be reestablished long-standing disease, there may be inadequate room for placing the implant
6) in presence of advanced pathology

surgical PROCEDURE

Wright Medical Technology, Inc. does not recommend a particular surgical technique when using the implant. Proper surgical 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. A description of the procedure used by Alfred B. Swanson, M.D., follows:
SWANSON TITANIUM CARPAL LUNATE & CARPAL SCAPHOID IMPLANTS

A 7 to 10cm dorsal longitudinal incision across the radiocarpal area and centered at Lister’s tubercle is used to expose the lunate bone. A transverse skin incision may be made over the radiocarpal joint in some of the uncomplicated cases, especially on the female. A volar approach is recommended when the lunate bone is dislocated volarly. Longitudinal veins are protected; transverse veins may be ligated. Careful dissection of the subcutaneous layer down to the retinaculum should be done to avoid the superficial sensory branches of the radial and ulnar nerves | FIGURE 1A.

The extensor retinaculum is incised over the extensor pollicis longus tendon which is retracted radially. The extensor digitorium communis tendons are retracted ulnarward.

The extensor retinaculum is incised over the extensor pollicis longus tendon which is mobilized for radial retraction. Further dissection is carried down to the fourth extensor compartment of the extensor digitorium communis tendons. These are carefully dissected and retracted ulnarward to expose the dorsocarpal ligament. With the wrist flexed, the dorsocarpal ligament is incised in a “T” shape placing its vertical extension over the lunate in the direction of the capitate and third metacarpal, and its horizontal extension at the insertion of the capsule over the distal radius | FIGURE 1B.

The capsule is dissected close to bone to preserve enough material for later reattachment. Positive identification of the lunate bone is essential. The scaphoid and lunate, at their junction, may appear as if they are one bone; after incising the interosseous scapholunate ligament, identification of the two bones is easy. Radiograms are taken if necessary, for proper identification of the carpal bones.

FIGURE 1A | The extensor retinaculum is incised over the extensor pollicis longus tendon which is retracted radially. The extensor digitorium communis tendons are retracted ulnarward.

FIGURE 1B | The wrist dorsal capsule is incised in a “T” fashion. The vertical extension of the “T” is placed over the lunate in the direction of the capitate and 3rd metacarpal. The horizontal extension of the “T” is placed over the distal radius at the insertion of the dorsal capsule.
The lunate is removed piecemeal with great care to avoid injury to the dorsal and palmar carpal ligaments. A thin, bony shell remnant of the lunate is left with the palmar ligaments to assure their important continuity. The integrity of the palmar capsuloligamentous structures must be verified and obtained to prevent palmar subluxation of the implant. If the lunate is completely removed, the two strong bands of the palmar ulnocarpal and radiocarpal ligaments, which are attached on each side of the lunate bone, become separated [FIGURES 1C & 1D].

If weak, the ligament structures are brought together with 3-0 Dacron sutures to assure a firm capsular support. A defect in this area can be repaired with a tendon graft or a slip of flexor carpi radialis tendon.

The associated bones should be evaluated for presence of arthritic changes, loss of cartilage, surface irregularities, cystic changes, and collapse patterns. Traction and compression of the hand across the wrist joint can help appreciate instability patterns, particularly vertical rotation of the scaphoid bone. Preoperative radiograms are useful in evaluating collapse patterns, but these can also be confirmed at surgery. In presence of collapse patterns or instability of the carpus, associated limited carpal bone fusions are very important to improve the distribution of forces across the wrist joint and subsequently the hand. Rotary subluxation of the scaphoid must be corrected and the carpus stabilized either by triscaphe or scaphocapitate fusion.

Carpal bones are fused with a spline-type bone graft, preferably iliac bone, keyed into a slot made in the two adjacent bones. Resected bone, if healthy, can also be used. Firm internal fixation is obtained with staples, Kirschner or threaded wires, or preferably a Herbert™ bone screw. Any preexisting cyst is curetted and bone grafted.

Approximately one cm of the posterior sensory branch of the posterior interosseous nerve is resected to provide some sensory denervation of part of the carpal area. Care is taken to avoid injury to the small arteries and veins in the area.
Selection of the correct implant size is most important. Lunate implants are made in 5 sizes for the right or left hand. Implant sizing is started with the smallest trial size implant. The implant size selected should comfortably fit in the lunatectomy space. It is important to avoid using an oversized implant as this could result in excessive implant force-loading and displacement. The deep concavity of the lunate implant straddles the head of the capitate distally. The shorter flat implant surface articulates with the scaphoid and the longer flat surface, with the triquetrum. A small hole is made through the articular surface of the proximal pole of the scaphoid and triquetrum in a palmer direction to pass #2 Dacron studies to stabilize the implant | FIGURES 1C & 1E.

One suture is passed through the triquetrum bone and looped through the implant body | FIGURES 1E & 1F. The other suture is passed through the scaphoid, and also looped through the implant holes. A wire loop is used to pass the sutures through the holes in the bones. Note that the short flat implant surface articulates with the scaphoid and that the long flat surface articulates with the triquetrum.

**THE USAGE OF METAL SUTURES/WIRE FOR IMPLANT FIXATION IS CONTRAINDICATED**

The preserved dorsocarpal ligament is securely sutured by passing 2-0 Dacron sutures through two small drill holes made through the dorsal distal radius prior to implant insertion | FIGURES 1C & 1F. The repair is firmly secured with additional Dacron and Dexon sutures. All knots are tied with an inverted technique to present a smooth gliding surface for the extensor tendons. A strip of extensor retinaculum can be used to reinforce the dorsal carpal ligaments if necessary. The retinaculum is sutured over the extensor tendons except for the extensor pollicis longus, which is left free in the subcutaneous tissues | FIGURE 1G.

The subcutaneous tissues are closed with absorbable sutures and the skin with interrupted sutures. Multiple small incision drains are inserted subcutaneously. A secure voluminous conforming dressing, which includes anterior and posterior plaster splints, is made of Dacron batting and a conforming Kling bandage wrap.
The extremity is elevated for one to two days and the patient is instructed to move the shoulder and fingers. A short or long-arm thumb spica type cast is applied, depending upon the stability of the carpal bones. If a cast has been applied at surgery, it should be bi-valved.

When the implant arthroplasty is done for patients with palmar dislocation of the lunate, a palmar exposure can be used. The lunate is usually displaced into the carpal canal and is easily exposed. The capsuloligamentous structures should be very carefully dissected from the lunate and preserved for later repair. A meticulous repair of the palmar radiocarpal ligaments must be performed to achieve good stability of the implant. A free graft of palmaris longus tendon can be used to stabilize the carpus volarly and reinforce the radiocarpal ligaments. The graft can be threaded through the ligament structures or through drill holes in the radius, scaphoid, capitate, and back across the lunate implant to the radius. The transverse carpal ligament is left unsutured to decompress the carpal canal. The lunate implant may be introduced through the palmar wound or through a separate dorsal incision.

**postoperative CARE**

Skin sutures are removed at two to three weeks through a window in the cast. The cast is worn for six to eight weeks, and may be tightened or changed as needed. The rehabilitation program includes isometric gripping exercises to strengthen the extrinsic and intrinsic muscles of the hand and forearm, and movements of the shoulder. Use of the wrist is usually resumed at twelve weeks, unless an intercarpal fusion was done which requires a long immobilization.

Postoperative roentgenograms are made to evaluate the position of the implant and the bone status | **FIGURES 2A - 2C.**

**FIGURES 2A** | Preoperative radiogram of the wrist of a 31 year-old male with Kienböck’s disease without rotatory subluxation of the scaphoid.

**FIGURES 2B & 2C** | Postoperative radiograms, 4 1/2 years after replacement of the lunate (2B)/scaphoid (2C) with a titanium implant. Note the excellent bone tolerance and position of the implant. The patient has an excellent functional result and is able to perform heavy activities without wrist pain.
HOW SUPPLIED
Each implant has been sterilized, and packaged as follows:

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<thead>
<tr>
<th>QUANTITY</th>
<th>DESCRIPTION</th>
<th>CATALOG NUMBER</th>
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<tr>
<td>1 Box</td>
<td>One each, Size 3</td>
<td>481-3003</td>
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<tr>
<td>1 Box</td>
<td>One each, Size 4</td>
<td>481-3004</td>
</tr>
<tr>
<td>1 Box</td>
<td>One each, Size 5</td>
<td>481-3005</td>
</tr>
<tr>
<td>1 Sizing Set</td>
<td>One each, Size 1, 2, 3, 4, &amp; 5 Numerically marked, Color-coded (non-sterile) NOT FOR IMPLANTATION</td>
<td>491-3000</td>
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TYPICAL DIMENSIONS (mm)

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<td>16.2</td>
<td>17.4</td>
<td>18.3</td>
<td>19.5</td>
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</table>
An 8 to 10cm dorsoradial longitudinal incision is made across the radiocarpal joint midway between the tip of the radial styloid and Lister's tubercle. Dissection is carried to the retinaculum taking care to preserve the longitudinal veins and branches of the superficial radial nerve. The extensor retinaculum is incised over the extensor pollicis longus tendon, which is released proximally and retracted radially.

The extensor retinaculum is elevated from the third compartment radially to expose the second compartment. The extensor carpi radialis longus and brevis tendons are mobilized to their insertion for retraction. The transverse metacarpal vessels located immediately under the insertion of the wrist extensor tendons are protected. The extrinsic extensors of the fingers are mobilized ulnarward. The dorsocarpal wrist ligament and capsule are incised in a "T" shape.

With the wrist flexed, the dorsal ligament is elevated from the radius by sharp dissection staying close to bone to preserve adequate tissues for reattachment. The wrist extensor tendons are retracted radially to identify the scapholunate junction and the capitate. The wrist extensor tendons are retracted ulnarward to visualize the distal portion of the scaphoid and its articulations with the trapezoid, trapezium and radius. If necessary, intraoperative radiograms can help identify the carpal bones. The scaphoid is removed piecemeal with a rongeur, avoiding injury to the underlying palmar ligaments. A thin bony wafer, remnant of the scaphoid, is left in the palmar ligament area distal to the radiocapitate ligament and up to the trapezium to assure the important ligamentous continuity.

The scaphoid is resected, leaving a small, bony wafer to preserve the continuity of the palmar radiocarpal ligaments. A bony shelf is made on the undersurface of the trapezium for stabilization of the implant distal pole. A suture hole is made through the lunate for passage of a fixation suture. Two drill holes are made in the distal radius to pass sutures for closure of the dorsocarpal ligament.
If the scaphoid distal pole is completely removed, there will be a hole left in the palmar supporting structures through which the implant could protrude | FIGURE 3D.

Prior to implant insertion, the integrity of the palmar ligaments is assessed; these are reefed or repaired as necessary.

The adjacent carpal bones are evaluated for presence of arthritic and cystic changes, cartilage loss, surface irregularities, and instability patterns. In the presence of collapse deformity or instability of the carpus, associated limited carpal bone fusions are important to improve the distribution of forces across the wrist joint. Rotation of the lunate must be corrected and the carpus stabilized by fusion of the lunate to the capitate and/or to the triquetrum and hamate. Carpal bones are fused with a spline-type bone graft, preferably iliac bone, keyed into a slot made in the two adjacent bones. Resected bone, if healthy, can also be used. Firm internal fixation is obtained with staples, Kirschner or threaded wires, or the Herbert™ bone screw. Any preexisting cyst is curetted and bone grafted.

Approximately one cm of the posterior sensory branch of the posterior interosseous nerve is resected to provide some sensory denervation of part of the carpal area. Care is taken to avoid injury to the small arteries and veins in the area.

Selection of the correct size implant is most important. Scaphoid implants are available in 5 sizes each for the right or left hand. Implant sizing is started with the smallest trial size implant. The implant size should be comfortably fit in the scaphoidectomy space. It is important to avoid using an oversized implant as this could result in excessive implant force-loading and displacement. The distal beak of the implant is stabilized in a bony channel prepared in the undersurface of the trapezium, or between the trapezium and trapezoid, according to individual carpal anatomy variations | FIGURES 3C & 3E.

The proximal hole is stabilized by passing a #2 Dacron suture first through a one mm drill hole made in the lunate and then through the suture hole in the proximal implant pole | FIGURES 3E & 3F. A wire loop is used to pass the suture through the hole in the lunate bone. Before inserting the implant, the wound is thoroughly irrigated with saline solution to remove all debris. The implant should be handled with blunt instruments. The implant position and stability are verified as the wrist is passively moved in all directions.
THE USAGE OF METAL SUTURES/WIRE FOR IMPLANT FIXATION IS CONTRAINDICATED

The preserved dorsocarpal ligament is securely sutured by passing 2-0 Dacron sutures through two small drill holes made through the dorsal distal radius prior to implant insertion | FIGURES 3C & 3F. The repair is firmly secured with additional Dacron and Dexon sutures. All knots are tied with an inverted technique to present a smooth gliding surface for the extensor tendons. A strip of extensor retinaculum can be used to reinforce the dorsal carpal ligaments if necessary. The retinaculum is sutured over the extensor tendons except for the extensor pollicis longus, which is left free in the subcutaneous tissues | FIGURE 3G.

The incision is closed and incision drains are inserted subcutaneously. A secure conforming dressing including a palmar wooden or plaster splint is applied.

The extremity is kept elevated for one to two days, and shoulder and finger movements are encouraged. A long-arm thumb spica cast is applied for four weeks and a short-arm spica cast is applied for an additional four weeks. Further casting or bracing will depend on the status of associated intercarpal fusions.

Skin sutures are removed at three weeks through a cast window. At eight weeks, isometric gripping exercises are started to strengthen the extrinsic and intrinsic muscles. Use of the wrist is usually resumed at 12 weeks | FIGURE 4A & 4B.
**HOW SUPPLIED**
Each implant has been sterilized, and packaged as follows:

**SWANSON TITANIUM CARPAL SCAPHOID IMPLANT**

<table>
<thead>
<tr>
<th>QUANTITY</th>
<th>DESCRIPTION</th>
<th>CATALOG NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Box</td>
<td>One each, Size 1 (right)</td>
<td>482-301R</td>
</tr>
<tr>
<td>1 Box</td>
<td>One each, Size 2 (right)</td>
<td>482-302R</td>
</tr>
<tr>
<td>1 Box</td>
<td>One each, Size 3 (right)</td>
<td>482-303R</td>
</tr>
<tr>
<td>1 Box</td>
<td>One each, Size 4 (right)</td>
<td>482-304R</td>
</tr>
<tr>
<td>1 Box</td>
<td>One each, Size 5 (right)</td>
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</tr>
<tr>
<td>1 Box</td>
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<td>482-301L</td>
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<td>482-302L</td>
</tr>
<tr>
<td>1 Box</td>
<td>One each, Size 3 (left)</td>
<td>482-303L</td>
</tr>
<tr>
<td>1 Box</td>
<td>One each, Size 4 (left)</td>
<td>482-304L</td>
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<tr>
<td>1 Box</td>
<td>One each, Size 5 (left)</td>
<td>482-305L</td>
</tr>
<tr>
<td>1 Sizing Set</td>
<td>One each, Size 1, 2, 3, 4, &amp; 5 Numerically marked,</td>
<td>492-30RH</td>
</tr>
<tr>
<td></td>
<td>Color-coded (non-sterile)</td>
<td>492-30LH</td>
</tr>
<tr>
<td></td>
<td><strong>NOT FOR IMPLANTATION</strong></td>
<td></td>
</tr>
</tbody>
</table>
HANDLING AND STERILIZATION

Each 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.

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 gravity or 270°F pulsing vacuum sterilization cycle, double wrap the place in a sealed sterilization pouch.

5. Autoclave according to the following parameters:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>250°F/121°C</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Flash</td>
<td>270°F/132°C</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Pulsing-Vacuum</td>
<td>270°F/132°C</td>
<td>10 minutes</td>
</tr>
</tbody>
</table>

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 testing 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 product sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

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

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

1) In the young, active or hard-laboring patient, associated procedures including limited intercarpal fusion, motion restriction by soft tissue capsular reconstruction, and strictly supervised postoperative care are indicated. Alternative nonimplant procedures such as soft tissue reconstruction or arthrodesis may be considered.

2) Identify prior pathology including preoperative collapse or instability patterns, bone cysts, and arthritis of other intercarpal joints. Failure to recognize and treat all preexisting pathology may result in its progression.

3) A meticulous surgical technique is essential.

4) If there is lunate/scaphoid instability in a wrist requiring an implant arthroplasty, a lunocapitate or lunotriquetrum/scaphocapitate or scaphotrapezio-trapezoid fusion may be considered. Intercarpal fusions are carried out with cancellous bone grafting (preferably iliac bone) and internal fixation.

5) Preexisting subchondral bone cysts must be treated at the time of carpal bone implant arthroplasty by curettage and cancellous bone grafting. Failure to recognize and treat preexisting cysts will result in their progression.

6) If there is inadequate space, an implant should not be used. Carpal bone implants must not be oversized.

7) Stabilization of the implant is obtained chiefly by capsuloligamentous reconstruction and fixation to the lunate bone.

8) Plaster cast immobilization for a minimum of eight weeks, and avoidance of excessive or abusive motion postoperatively.

Revision surgery for failed carpal bone implant arthroplasty is indicated if there is dysfunction, swelling, and disabling pain in the presence of cystic or degenerative bony changes. The ideal outcome of revision surgery should be a return to pain-free, functional, and stable movement. This can be achieved in most cases if sufficient bone stock is present. These procedures can include:

- Synovectomy
- Removal or replacement of implant
- Curettage of cysts with cancellous bone grafting
- Selective intercarpal bone fusions
- Implant substitution
- In some cases interposition resection arthroplasty, total wrist implant arthroplasty, or fusion is indicated.