



SJO NON-SILICONE IMPLANTS

150820-1

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*The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.

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June 2018

Printed in U.S.A.

Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

**WRIGHT MEDICAL
SMALL JOINT ORTHOPEDIC (SJO)
NON-SILICONE IMPLANTS
(150820-1)**

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I. DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry

	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation
	Sterilized using gas plasma
	Sterilized using aseptic processing techniques
	For prescription use only
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

II. GENERAL PRODUCT INFORMATION

Through the advancement of partial and total joint replacement, the surgeon has been provided a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal, ceramic materials, and ultra high molecular weight polyethylene, and that no joint replacement system can be expected to withstand the activity levels and loads as would normal, healthy bone. In addition, the system will not be as strong, reliable, or durable as a natural human joint.

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

In using joint prostheses, the surgeon should be aware of the following:

- **The correct selection and sizing of the prosthesis is extremely important.** Selection of the proper size, shape, and design of the prosthesis increases the potential for success in joint replacement. Joint prostheses require careful seating and adequate bone support.
- **In selecting patients for joint replacements, the following factors can be critical to the eventual success of the procedure:**
 1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
 2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
 3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. PATIENT SELECTION

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

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

See Section II for specific product information.

B. 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

See Section II for specific product information.

C. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the prosthesis requiring revision surgery
- Bone resorption or over-production
- 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
- Embolism

Some degree of particle formation is inevitable with all implants. The amount will vary with factors such as patient activity, joint stability or instability post-implantation, implant position and the amount of soft tissue support. The patient's biological response to these particles is variable, but could include local host tissue response or bone lysis in contiguous bones.

See Section II for specific product information.

D. PRECAUTIONS

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the

potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

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

One of the goals of implant surgery is to minimize production of wear particles. It can never be eliminated because of all the 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 force will further increase clinically significant wear.

Abnormal force loading and subsequent wear may be caused by:

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

NON-CEMENT APPLICATION

Proper fixation at the time of surgery is critical to the success of the procedure. The intramedullary stem component must properly fit into the prepared canal, which necessitates precise operative technique and the use of specified instruments. Intra-operative fracture of the canal can occur during the seating of the prosthesis. Bone stock must be adequate to support the device.

Some preventative measures to consider 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
- Avoid K-wires and sutures through the implant

Avoid flawing implant surfaces to minimize the potential for wear debris generation and tissue sensitivity. Complete cleaning prior to closure (complete removal of bone chips, bone fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.

If complications develop, possible corrective procedures include:

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

Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.
- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;
 - e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Concerning Magnetic Resonance Environments

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

See Section II for specific product information.

E. HANDLING AND STERILIZATION

IMPLANTS

The implants described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Implants that are presented in instrument trays are provided non-sterile.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

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

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized according to the following parameters:

Cleaning & Disinfection

Clean to remove gross contamination and disinfect to reduce the number of viable microorganisms.

1. **Disassemble** as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly/flush with deionized/reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly/flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.

12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Sterilization

1. Double wrap the component in CSR wrap or a similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 °F (132 °C)	Exposure Temperature	270 °F (132 °C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and tested using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your

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

For additional information see Wright's "Cleaning and Handling of Wright Medical Instruments".

F. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

III. SPECIFIC PRODUCT INFORMATION

A. SWANSON TITANIUM AND LPT™ GREAT TOE

INDICATIONS

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

- Hallux valgus: mild to moderate only (for larger inter-metatarsal angles, an adjunctive metatarsal osteotomy should be considered)
- Painful hallus rigidus, stage 2 and 3
- Revision Bunionectomy for arthrofibrotic or painful hallux limitus
- When an alternative to first MTP arthrodesis is considered
- Good condition of the patient
- Good neurovascular status
- Adequate skin mobility and coverage
- Functional great toe flexor power

Angled Great Toe is also indicated for:

increased proximal articular set angle (PASA) on the metatarsal head in combination with the above-mentioned indications

CONTRAINDICATIONS

- Rheumatoid arthritis
- Non-reduced, high, inter-metatarsal angles
- Unreduced cavus foot deformity
- Absence of both sesamoids
- Absence of great toe flexor power

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B. STA-PEG SUBTALAR ARTHRORISIS IMPLANT

DESCRIPTION

The STA-Peg (Smith* Design) is a one-piece ultra-high molecular weight polyethylene implant, designed for use in selective cases, where subtalar arthrorisis is indicated. The implant is placed into the dorsal lateral surface of the calcaneus just anterior to the posterior facet (not in the sinus tarsi). The stem of the implant is inserted into a prepared hole, and is secured with bone cement. The anterior leading edge of the talus contacts the superior surface of the implant to prevent excessive pronation of the subtalar joint.

The purpose of the STA-Peg Subtalar Arthrorisis Implant is to prevent this anterior movement of the talus. The other components of pronation will then also be affected in a like manner since all of the components of pronation occur simultaneously; preventing anterior movement of the talus prevents the other components of pronation from functioning. The net result is a limitation of pronation and consequently reduction of heel valgus.

The STA-Peg Subtalar Implant is available in five (5) sizes to satisfy most anatomical requirements. The STA-Peg (Smith design) is available in two (2) sizes, small and medium. The STA-Peg (Angled) Smith Design is available in three (3) sizes, small, medium and large. A sizing set, supplied non-sterile and not suitable for implantation, is available for proper size determination during surgery.

- * Stephen D. Smith, D.P.M., F.A.C.F.S., Diplomat - A.B.P.S. and A.B.P.O.; Clinical Professor, California College of Podiatric Medicine; Director of Podiatric Education and Residency Training, Health Care Medical Center of Tustin, California.

INDICATIONS

- Severely pronated foot
 - a) Calcaneal stance position greater than 5°
 - b) Loss of arch on weight-bearing
 - c) Manually correctable deformity
 - d) No contributing torsional deformity of the extremity
 - e) Forefoot varus greater than 10°
 - f) Mid-tarsal breach (talonavicular ptosis)
- Radiographic signs:
 - a) X-ray finding of lateral talocalcaneal angle greater than 40°
 - b) Dorsal-plantar talocalcaneal angle greater than 30°
 - c) Talonavicular joint less than 50% articulated
 - d) Anterior break of the Cyma line
 - e) Talonavicular and/or naviculo-cuneiform breach (lateral view)

- In children one to three years of age, surgery should be undertaken only if there has been no improvement after one or two years in a heel control orthotic.
- In patients older than six years of age who have not yet reached skeletal maturity, subtalar implant arthrorisis is indicated initially.

C. SWANSON TITANIUM RADIAL HEAD AND EVOLVE™ MODULAR RADIAL HEADS

DESCRIPTION

The Radial Head Implant is available as a one-piece, intramedullary-stemmed, cuffed implant or a modular, two-piece, intramedullary-stemmed, uncuffed implant. Both act as a spacer in the radio-humeral joint.

The Radial Head Implants have been sterilized. A sizing set, supplied non-sterile and not suitable for implantation, is available for proper size determination during surgery.

INDICATIONS

Use of the Radial Head Implant may be considered for:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
 - joint destruction and/or subluxation visible on x-ray; and/or
 - resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

CONTRAINDICATIONS

- Growing children with open epiphyses.
- Dislocations of radius on ulna that would not allow a radio-humeral articulation.
- Rheumatoid arthritis.

Evidence of joint narrowing secondary to radio-humeral joint synovitis is not a contraindication to radial head implant replacement combined with elbow synovectomy.

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D. E-CENTRIX™ MODULAR ULNAR HEAD IMPLANT

DESCRIPTION

The E-CENTRIX™ Ulnar Head Implant is available as a modular, two-piece, intramedullary-stemmed, implant. It acts to restore the articular geometry of the distal radial ulnar joint and the normal length of the ulna. In addition, it allows for the reattachment of soft tissues.

INDICATIONS

Use of the E-CENTRIX™ Ulnar Head Implant may be considered

for: Replacement of the distal ulnar head for disorders of the distal radioulnar joint in rheumatoid, degenerative and post-traumatic arthritis presenting with the following findings:

- pain and weakness of the wrist joint not improved by non-operative treatment;
- instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint;
- failed ulnar head resection, e.g. Darrach resection;
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

CONTRAINDICATIONS

Use of the Metallic Ulnar Head Implants are contraindicated for:

- Children with open epiphyses; i.e. skeletally immature
- Extensive loss of the distal ulnar shaft
- Charcot joint

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E. SWANSON TITANIUM BASAL THUMB IMPLANTS

DESCRIPTION

The Swanson Titanium Basal Thumb Implant is a one-piece intramedullary-stemmed implant developed to help restore function to smaller joints disabled by rheumatoid arthritis, degenerative arthritis, or post-traumatic arthritis. The implant is designed to replace the convex condylar portion of diseased or destroyed joints as an adjunct to resection arthroplasty.

The Swanson Titanium Basal Thumb is manufactured from unalloyed titanium for surgical application (ASTM F67). The intramedullary stem is 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.

INDICATIONS

The titanium basal thumb implant may be considered for:

- Disabilities of the thumb basal joint with localized bony changes
- Localized pain and palpable crepitation during circumduction movement with axial compression of the involved thumb ("grind test")

- Decreased motion, decreased pinch, and decreased grip strength
- X-ray evidence of arthritic changes of the trapeziometacarpal joint
- Subluxation of the trapeziometacarpal joint
- Associated unstable, stiff, or painful distal joints

F. ORTHOSPHERE™ CERAMIC SPHERICAL IMPLANT

DESCRIPTION

The ORTHOSPHERE™ Ceramic Spherical Implant is a one-piece implant developed to be used as an adjunct to resection arthroplasty of the carpometacarpal (CMC) or tarsometatarsal (TMT) joint in cases of degenerative arthritis, or post-traumatic arthritis limited to those joints. It acts as a spacer to preserve joint relationship and allow appropriate capsuloligamentous reconstruction to correct deformities.

The ORTHOSPHERE™ Ceramic Spherical Implant is a highly polished sphere. This spherical implant will rest in a spherical cavity created by two hemispherical shapes in the adjoining bones. The implant will articulate directly on bone. The ORTHOSPHERE™ Ceramic Spherical Implant is manufactured from zirconia ceramic. Autoclavable sizing instruments are available for proper size determination during surgery. These sizing instruments are supplied non-sterile and are not suitable for implantation.

INDICATIONS

The ORTHOSPHERE™ Ceramic Spherical Implant is indicated for use in cases of isolated carpometacarpal (CMC) or 4th/5th tarsometatarsal (TMT) joint involvement from either degenerative or post-traumatic arthritis presenting:

- Decreased motion
- X-ray evidence of arthritic changes and/or subluxation of the carpometacarpal joint

- Localized pain and palpable crepitation during circumduction movement with axial compression of the involved thumb (“grind test”)
- Associated unstable, stiff, or painful distal joints
- Decreased pinch and grip strength
- Degenerative joint disease of the midfoot associated with gout or pseudogout

Only sizes 9mm-12mm are indicated for use in the tarsometatarsal (TMT) joints. Sizes 9mm-14mm are indicated for use in the carpometacarpal (CMC) 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
- Charcot foot
- Peripheral vascular disease
- Neuropathic foot

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G. SWANSON TITANIUM CARPAL LUNATE IMPLANT

DESCRIPTION

The Swanson Titanium Carpal Lunate Implant is an implant that has essentially 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.

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

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

INDICATIONS

The carpal lunate implant may be considered for:

- Presence of avascular necrosis-Kienbock's disease
- Localized osteoarthritic changes
- Long-standing dislocations

CONTRAINDICATIONS

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

The procedure is contraindicated in the following situations:

- 1) arthritic involvement not localized to the lunate articulations;
- 2) presence of inadequate bone to support the implant;
- 3) ligamentous instability and carpal collapse that cannot be corrected at the time of surgery;

- 4) following fracture dislocations of the wrist with injury to the lunate and associated disruption of ligaments, especially the radiocarpal ligament, unless the carpal relationships and ligamentous integrity can be reestablished;
- 5) when there is severe diminution in the size of the lunate space through long-standing disease, there may be inadequate room for placing the implant; and
- 6) in presence of advanced pathology.

H. SWANSON TITANIUM CARPAL SCAPHOID IMPLANT

DESCRIPTION

The Swanson Titanium Carpal Scaphoid Implant is a 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 pole for suture fixation. These temporarily help maintain anatomical position during the early postoperative period until a firm capsuloligamentous system has formed around the implant.

The implant has been designed to act as an articulating spacer to help maintain the relationship of the adjacent carpal bones after excision of the scaphoid, while preserving mobility of the wrist. 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 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 Scaphoid Implant is fabricated from unalloyed titanium for surgical application which conforms to ASTM F 67, and is available in five graduated right and left sizes to adequately meet various operative requirements.

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

INDICATIONS

Use of the Swanson Titanium Carpal Scaphoid Implant may be considered in the following situations:

- 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

CONTRAINDICATIONS

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

The procedure is contraindicated in the following situations:

- 1) arthritic involvement not localized to the scaphoid articulations;
- 2) presence of inadequate bone to support the implant and following radial styloidectomy;

- 3) ligamentous instability and carpal collapse that cannot be corrected at the time of surgery;
- 4) following fracture dislocations of the wrist with injury to the scaphoid and associated disruption of ligaments, especially the radiocarpal ligament, unless the carpal relationships and ligamentous integrity can be reestablished;
- 5) when there is severe diminution in the size of the scaphoid space through long-standing disease, there may be inadequate room for placing the implant; and
- 6) in presence of advanced pathology.

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