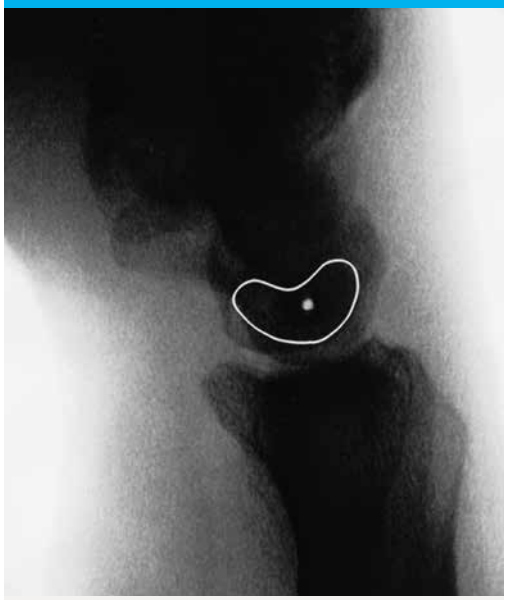
Value Analysis Committee Resource Guide

acumed® | SLIC Screw System

Acumed is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to developing products, service methods, and approaches that improve patient care.



Acumed® SLIC Screw System

The Acumed Scapholunate Intercarpal Screw (SLIC Screw) System has a cannulated cylinder-in-cylinder design for adjunct fixation of acute scapholunate instability and specific instrumentation. The included specialized targeting guide is designed to be used in correspondence with K-wires for anatomical reduction of the scaphoid and lunate carpals while allowing simplified targeting of the central third of the scaphoid and lunate in the lateral view.

SLIC Screw Design Surgeon
William B. Geissler, M.D.

SL Targeting Guide
Design Surgeon
Michael G. McNamara, M.D.

Contents

Our mission is to aid the afflicted through the ingenuity of our minds, the labor of our hands, and the compassion of our hearts.

About Acumed®

Acumed began as a family business in 1988 and evolved to become a market leader in developing innovative orthopaedic and medical solutions to improve patient care around the world. Acumed strives to advance the art and science of orthopaedics for the collective good and understands that innovation cannot come at the expense of value. Acumed blends knowledge, ingenuity and skill to develop devices that solve real orthopaedic challenges to benefit the patient, surgeon and hospital.

The company was founded as Accurate Machine and Design (Acumed) in an 1100-square-foot space in Butler, New Jersey, with a single machinist as the first employee. Accurate Machine and Design started out engineering prototypes for companies like Howmedica, Kirschner and Exactech®, in addition to designing test machines and creating prototypes of hip stems, acetabular cups, and knee implants.

In 1991 the company relocated to Oregon as Acumed and launched the Oregon Fixation Screw. Intended for repair of ACL ligaments in the knee, the Oregon Fixation Screw was the first line of arthroscopy screws created by Acumed. The success of the product allowed Acumed to expand from the arthroscopy market into trauma. Acumed has continued to research, design, and manufacture products to improve patient care while adding new product lines each year, including Acutrak 2® Screws, Acu-Loc® 2, Clavicle Plating System, Elbow Plating System, and the Fibula Rod System.

In 1999, The Marmon Group purchased Acumed. This allowed for investments in equipment and the purchase of a new building for additional onsite design and manufacturing. In 2002, after five decades of leading The Marmon Group as CEO, Robert Pritzker stepped down and created Colson Associates. This move allowed more time and attention to be focused on Colson businesses, including Acumed.

Today, Acumed is a multi-award-winning company dedicated to delivering innovative and quality medical device solutions. Committed to the highest standards of manufacturing, Acumed is proud to produce over 90% of our implants in the U.S.A.

Throughout our history, Acumed has stayed true to our founders' vision of addressing the challenges facing orthopaedic surgeons and their patients. Acumed will continue to fulfill this vision by designing and developing innovative products and instruments to meet even the most complex indications and demanding procedural needs.

Acumed is headquartered in Hillsboro, Oregon, with a global distribution network and offices worldwide.

Dedicated to Excellence

From manufacturing to business practices to product innovation, Acumed has an unwavering commitment to excellence. It is reflected in the honors received from industry peers and in the performance of our suite of surgical fixation solutions.

The AME Manufacturing Excellence Award

In 2011, Acumed received the AME Manufacturing Excellence Award, an honor recognizing North American manufacturing sites that have demonstrated operational excellence through continuous improvement, best practices, creativity, and innovation. This award supports AME's vision, mission and values of inspiring commitment to enterprise excellence through shared learning and access to best practices.

The Association for Manufacturing Excellence is North America's premier organization for the exchange of knowledge in Organizational Excellence through the implementation of techniques such as Lean Tools, Leadership, Lean Product Development, Lean Supply Chain and Lean Accounting.

The Frost & Sullivan Manufacturing Leadership 100 Operational Excellence Award

In 2013, Acumed received the Frost & Sullivan Manufacturing Leadership 100 award for Operational Excellence, an honor recognizing the top 100 global manufacturing companies who are shaping the future through projects that deliver outstanding value, innovation, and return on investment.

Frost & Sullivan Manufacturing Leadership 100 is the world's first member-driven leadership network with knowledge in manufacturing leadership. It was created through a global community of executives working within the manufacturing industry.

A Leader in Product Development and Innovation

Acumed began developing a product for scapholunate instability treatment in 2006. Acumed will continue to devote resources to the development of implants that aid in improving patient outcomes and advancing the field of orthopaedic surgery.

Industry Compliance

As a logo member of the Advanced Medical Technology Association (AdvaMed), Acumed endorses the AdvaMed Code of Ethics. Adherence to this Code ensures ethical interaction with healthcare professionals. Acumed requires anti-corruption training for employees interacting with healthcare professionals or government officials (foreign or domestic). In addition, Acumed sales representatives in the United States as well as international distribution partners must complete anti-corruption training programs.

Acumed also supports the United Nations Global Compact and Boston College Center for Corporate Citizenship organizations.

Transparency in Business Practice

In 2012, the company began preparing to track and report spending in accordance with the Physician Payment Sunshine Act. In order to become an Acumed partner, all distributors must go through a due diligence analysis and a robust training and education program to ensure they share Acumed's values with respect to anti-corruption and compliance. Acumed maintains ethical behaviors with respect to compliance standards and laws.

Green Initiatives

Acumed has formed a cross-functional group dedicated to preserving the environment and educating Acumed employees on the benefits of being "green". The Green Team's purpose statement is:

We empower Acumed and the global community through education, encouragement, and execution of sustainable business practices. By doing this, we engage our sphere of influence to deliver innovative products that respect the community's natural systems, support ethical equity, and drive customer loyalty.

The Acumed vision includes being respectful stewards of our local community and global environment, and a large part of this is our commitment to "green" initiatives.

No Bottled Water Pledge

The Green Team sponsored a "no bottled water" pledge program to reduce the consumption of bottled water by Acumed. To date, over 230 employees have pledged to avoid drinking bottled water while on site or traveling domestically on behalf of Acumed. In addition, during on site sales rep trainings, attendees are provided with reusable water bottles.

Papercut

Acumed is committed to reducing paper consumption in our daily business operations. The Green Team drove projects to reduce paper consumption and will expand this to reduce overall landfill waste by 10%. Activities include eliminating paper stubs, defaulting to double-sided printing, copying, and providing compostable lunchroom supplies.

The Facts on Scapholunate Instability

Incidence and Patient Demographics

According to recent clinical literature on the incidence of soft tissue injuries of the wrist, up to 54% of distal radius fractures have associated scapholunate instability. Despite this statistic, it has been shown that it is not common for soft tissue injuries to be recognized in patients with fractures of the distal radius.[1] Conversely, Richards et al. discussed findings of the presence of scapholunate injuries in 21.5% of intra-articular fractures and 6.7% of extra-articular fractures in a study of 118 acute fractures.[2]

In addition, an analysis by Rockwood and Green details the projected incidence rate of distal radius fractures as 195.2 cases per 100,000 in the population per year.[3] Based off of multiple studies, the projected incidence rate of scapholunate injuries associated with distal radius fractures is 117.8 cases per 100,000 in the population per year.[4-6]

Classification of Scapholunate Instability

Treatment Algorithm

An article published in 2006 by Garcia-Elias et al. through the Journal of Hand Surgery presented a scapholunate instability treatment algorithm. Acumed based the SLIC Screw treatment model after this article.[7]

Staging of Scapholunate Dissociations	1	2	3	4	5	6
Is there a partial rupture with a normal dorsal SL ligament?	●					
If ruptured, can the dorsal SL ligament be repaired?	●	●				
Is the scaphoid normally aligned (radioscaphoid angle ≤ 45°?)	●	●	●			
Is the carpal malalignment easily reducible?	●	●	●	●		
Are the cartilages at both RC and MC joints normal?	●	●	●	●	●	

Garcia-Elias et al, Three-Ligament Tenodesis for the Treatment of Scapholunate Dissociation: Indications and Surgical Technique, JHS, 2006, 31(1), 125-134.

The SLIC Screw is recommended for acute injuries and should only be used for Stages 1-4 of the algorithm.

Staging of Scapholunate Dissociations	1	2	3	4	5	6
SLIC Screw Recommended	●	●	●	●		

Stage 1: Partial Scapholunate Ligament Injury

Patient Presentation

- Partial scapholunate ligament injury
- No dynamic or static gapping present
- No abnormal kinematics, but there is pain
- Associated distal radius fracture and TFCC injury may be present as well

Treatment Option Using SLIC Screw

- Percutaneous SLIC Screw fixation across the scapholunate interval

Postoperative Rehabilitation Protocol: Per individual surgeon's discretion. Remove SLIC Screw at 6-9 months.

STAGE 2A: Complete Scapholunate Ligament Injury with Repairable Dorsal Scapholunate Ligament (Acute)

Patient Presentation

- Complete scapholunate ligament disruption
- No dynamic or static gapping present
- No rotator subluxation, but there is pain
- The dorsal ligament is repairable
- Associated distal radius fracture and TFCC injury may be present as well

Treatment Option Using SLIC Screw

- Open repair of dorsal scapholunate ligament with anchors
- SLIC Screw fixation across the scapholunate interval

Postoperative Rehabilitation Protocol: Per individual surgeon's discretion. Remove SLIC Screw at 6-9 months.

STAGE 2B: Perilunate Dislocation with Repairable Dorsal Scapholunate Ligament (Acute)

Patient Presentation

- Perilunate dislocation
- Dislocation of the lunate
- Complete scapholunate ligament disruption
- Radioscaphocapitate ligament ruptured
- Possible lunotriquetral ligament disruption
- Possible scaphoid fracture
- The dorsal scapholunate ligament is repairable

Treatment Option Using SLIC Screw

- Open reduction of bones, followed by repair of dorsal scapholunate ligament with anchors
- SLIC Screw fixation across the scapholunate interval
- Fixation of the lunotriquetral interval may be appropriate as well
- The scaphoid is stabilized in a trans-scaphoid perilunate dislocation and a SLIC Screw may be placed across the lunotriquetral interval

Postoperative Rehabilitation Protocol: Per individual surgeon's discretion. Remove SLIC Screw at 6-9 months.

STAGE 2C: Complete Scapholunate Ligament Injury with Repairable Dorsal Scapholunate Ligament and Reducible Rotatory Scaphoid Subluxation

Patient Presentation

- Complete scapholunate ligament disruption
- Dynamic and/or static gapping present
- Rotatory subluxation
- The dorsal scapholunate ligament is repairable
- Associated distal radius fracture and TFCC injury may be present as well

Treatment Option Using SLIC Screw

- Open repair of dorsal scapholunate ligament with anchors
- SLIC Screw fixation across the scapholunate interval and stabilize the scaphoid distally (e.g. ECRL tendon transfer, dorsal capsulodesis, dorsal intercarpal ligament capsulodesis, scaphocapitate pin/screw)

Postoperative Rehabilitation Protocol: Per individual surgeon's discretion. Remove SLIC Screw at 6-9 months.

STAGE 3: Complete Non-repairable Scapholunate Ligament Injury with Normally Aligned Scaphoid

Patient Presentation

- Complete scapholunate ligament disruption
- No static gapping present
- No carpal mal-alignment, but there is pain
- The dorsal ligament is not repairable or has limited healing capacity

Treatment Option Using SLIC Screw

- Open procedure to visualize dorsally
- SLIC Screw fixation across the scapholunate interval
- Soft tissue repair that bridges the scapholunate interval (e.g. reverse or modified Mayo capsulodesis, burring scapholunate interval to form neoligamentous tissue at the interval)

Postoperative Rehabilitation Protocol: Per individual surgeon's discretion. Remove SLIC Screw at 6-9 months.

STAGE 4: Complete Non-repairable Scapholunate Ligament Injury with Reducible Rotatory Scaphoid Subluxation

Patient Presentation

- Complete scapholunate ligament disruption and disruption of the secondary stabilizing ligaments (e.g. DIC, RSL, STT, SC ligaments)
- Radioscaphoid angle is greater than 45°
- Lunate is extended (pathologic)
- Static and/or dynamic gapping may be present
- Scaphoid may displace dorsally (scaphoid clunk) during motion, and there is pain
- Dorsal ligament is not repairable or has limited healing capacity
- Rotatory mal-alignment must be easily reducible, defined as being able to reduce scaphoid using a 0.045" K-wire, and no cartilage damage can be present

Treatment Option Using SLIC Screw

- Open reduction of the scaphoid and lunate dorsally, using k-wire joysticks to reduce the bones
- To be easily reducible, the scaphoid must allow reduction with a 0.045" or 0.054" K-wire
- After reduction, SLIC Screw fixation across the scapholunate interval is performed, along with a soft tissue reconstruction that bridges the scapholunate interval (e.g. reverse or modified Mayo capsulodesis, burring scapholunate interval to form neoligamentous tissue at the interval) and stabilizes the scaphoid distally (e.g. ECRL tendon transfer, dorsal capsulodesis, dorsal intercarpal ligament capsulodesis, scaphocapitate pin/screw)

Postoperative Rehabilitation Protocol: Per individual surgeon's discretion. Remove SLIC Screw at 6-9 months.

The SLIC Screw is not recommended for the following stages:

Stage 5: Complete Non-repairable Scapholunate Ligament Injury with Irreducible Rotatory Malalignment but Normal Cartilage

Patient Presentation

- Complete scapholunate ligament disruption
- Disruption of the secondary stabilizing ligaments (e.g. DIC, RSL, STT, SC ligaments)
- Radioscaphoid angle is greater than 45°
- Lunate is extended (pathologic)
- Significant static gapping is typically present
- Scaphoid may displace dorsally (scaphoid clunk) during motion, and there is pain
- Dorsal ligament is not repairable or has limited healing capacity
- Rotatory mal-alignment is not easily reducible, defined as being able to reduce scaphoid using a 0.045” K-wire, and no cartilage damage can be present

Treatment Option Using SLIC Screw

The SLIC Screw is not recommended for Stage 5 scapholunate instability and is contraindicated in the absence of potential for soft tissue healing. In these cases, soft tissue reconstructions and screws across the scapholunate interval will probably fail.

Stage 6: Complete Non-repairable Scapholunate Ligament Injury with Irreducible Rotatory Malalignment and Cartilage Degeneration

Patient Presentation

- Complete scapholunate ligament disruption
- Disruption of the secondary stabilizing ligaments (e.g. DIC, RSL, STT, SC ligaments)
- Radioscaphoid angle is greater than 45°
- Lunate is extended (pathologic)
- Static and/or dynamic gapping may be present
- Scaphoid may displace dorsally (scaphoid clunk) during motion, and there is pain
- Dorsal ligament is not repairable or has limited healing capacity
- Rotatory mal-alignment is not easily reducible, defined as being able to reduce scaphoid using a 0.045” K-wire and cartilage damage can be present

Treatment Option Using SLIC Screw

The SLIC Screw is not recommended for Stage 6 scapholunate instability and is contraindicated in the presence of cartilage degeneration on the bone.

Arthroscopic Classification

SLIC Screw System designing surgeon, Dr. William Geissler published a classification system for scapholunate instability in 2013 through the Journal of Wrist Surgery. Per the Geissler Arthroscopic Classification, gapping at the scapholunate interval is present in Grades II and III.[8]

Geissler Arthroscopic Classification System

Grade	Description	Detail	Management
1	"Attenuation/hemorrhage of interosseous ligament as seen from the radiocarpal joint. No incongruency of carpal alignment in the midcarpal space."	"There is a loss of the normal concave appearance of the interosseous ligament from the scaphoid and the lunate as the ligament bulges with a convex appearance, as seen with the arthroscope in the radiocarpal space. In the midcarpal space, the scapholunate interval is still tight and congruent. It is thought these are minor wrist sprains and usually will resolve with simple immobilization."	Immobilization
2	"Attenuation/hemorrhage of interosseous ligament as seen from the radiocarpal joint. Incongruency/step off of carpal alignment is seen in both the radiocarpal and midcarpal spaces. A slight gap (less than width of a probe) between carpals may be present."	"The interosseous ligament continues to stretch and a convex appearance is seen between the scaphoid and the lunate with the arthroscope in the radiocarpal space. In the midcarpal space, the scapholunate interval is no longer congruent. The scaphoid starts to flex palmarly and its dorsal lip is rotated distal to the level of the lunate."	Arthroscopic reduction and pinning
3	"Incongruency/step off of carpal alignment is seen in both the radiocarpal and midcarpal spaces. The probe may be passed through the gap between the carpals."	"The interosseous tear has progressed from a stretch to a tear to a gap is seen between scaphoid and the lunate with the arthroscope in the radiocarpal and midcarpal spaces. This gap can be appreciated from both the radiocarpal and the midcarpal space."	Arthroscopic/ open reduction and pinning
4	"Incongruency/step off of carpal alignment is seen in both the radiocarpal and midcarpal spaces. Gross instability with manipulation is noted. A 2.7 mm arthroscope may be passed through the gap between carpals."	"There is complete tear to the SLIL. The arthroscope can be freely translated between the radiocarpal and midcarpal spaces."	Open reduction and repair

Geissler, W.B. Arthroscopic Management of Scapholunate Instability. Journal of Wrist Surgery. 2013, 2, 129-135

Scapholunate Instability Treatment Options

Surgical Vs. Non-Surgical Intervention

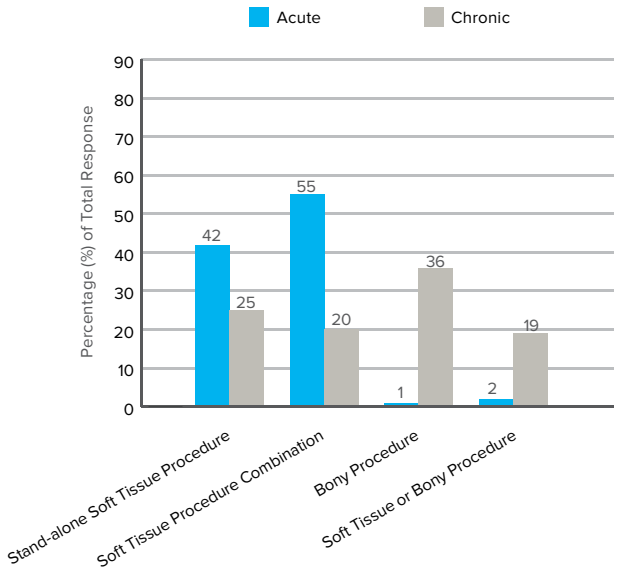
According to the literature, scapholunate instability is a common injury that can potentially lead to further injuries yet it remains an often underestimated injury that is treated non-operatively or poorly managed when treated surgically.[9]

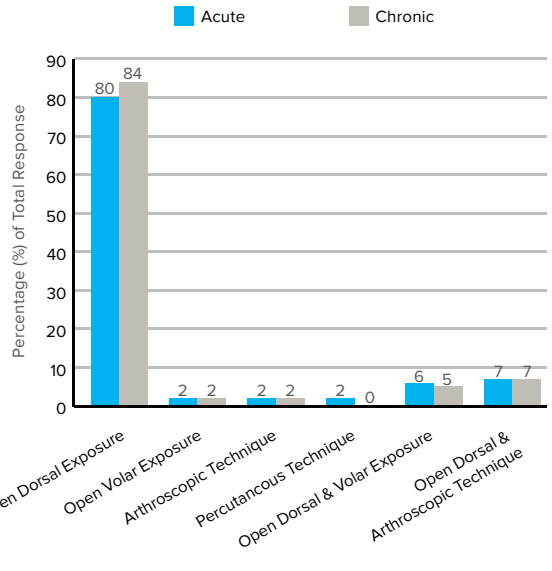
"Irreparable damage of the scapholunate (SL) interosseous ligament is a relatively injury that leads to joint instability, potentially causing painful arthritis. The best surgical approach for this challenging lesion is unclear." [10]

"A history of a fall or sudden load on the wrist should alert the clinician to consider in particular a radial-side wrist injury, such as a scaphoid fracture or SL instability." [11]

Recent studies have shown that when a scapholunate instability injury is detected, surgical intervention is the preferred treatment option for most scapholunate instability injuries including both acute and chronic cases.[12] This can be attributed to an improved understanding of the biomechanics of the injury and anatomy.[13] Surgical treatment varies depending on the stage of the injury but some options include K-wires, screws, suture anchors, or soft tissue repair.[14-15]

In addition, an analysis by Zarkadas et al. in the Journal of Hand Surgery details survey findings from over 400 surgeons to determine whether or not they would surgically treat scapholunate instability. Based on the findings in the study, more than 99% of all surgeons considered some kind of surgical intervention for both acute and chronic scapholunate instability cases presented in the survey which ranged from soft tissue procedure, bony procedure, or a combination of both. As shown in the next figure, the most common surgical approach identified for the scapholunate instability case presented was an open dorsal approach.[16]



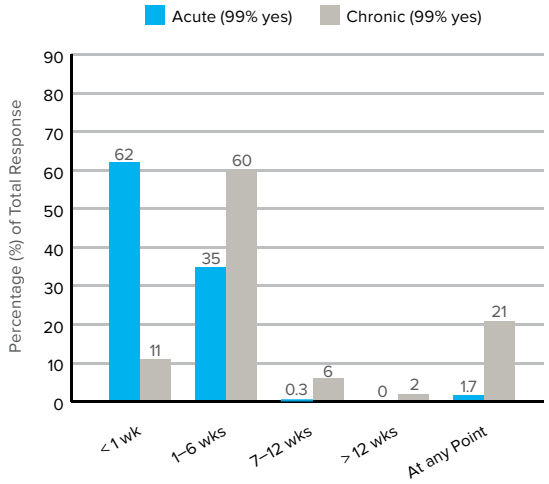


Acute vs. Chronic Soft Tissue Repair

Scapholunate instability is a soft tissue procedure when surgical intervention is employed. In the acute setting, a direct repair of the scapholunate interosseous ligament (SLIL) can be performed with small suture anchors, while in the chronic setting a reverse capsulodesis or tenodesis can be performed.

Some other examples of soft tissue procedures commonly conducted in scapholunate instability cases are direct repair of SL ligament, reverse (modified Mayo) capsulodesis, burring scapholunate interval, ECRL tendon transfer, dorsal (Blatt) capsulodesis, dorsal intercarpal ligament capsulodesis, and/or free ligament to SL.[17]

In the same analysis by Zarkadas mentioned above, findings describe whether surgeons will perform surgical intervention on scapholunate instability injuries based on whether the injury is acute or chronic and when surgeons typically perform the surgery based on the stage of the injury, as shown in the next figure.[18]



The Acumed SLIC Screw System is intended to provide fixation and anatomically reduce the scaphoid and lunate in association with acute soft tissue repair. Acumed defines acute as the ability to repair or reconstruct the soft tissue injury by bridging the scapholunate interval while achieving reduction of the scaphoid and lunate carpals.

Surgical Intervention with Screw Fixation

K-Wires and Partially Threaded Screws vs. Fully Threaded Jointed Screws

Historically, studies have supported the belief that solid screw structure or a combination of K-wire fixation across the SL joint interval would help stabilize the area while the soft tissue healed.[19-20] Therefore, the industry standard has been to use a solid screw or K-wire fixation for carpal reduction with the chosen soft tissue repair for surgical intervention. Several studies have presented fair to poor results when using K-wire fixation or headed/headless solid screws with a soft tissue repair but these treatment options remain the chosen techniques by surgeons.[21-26] Acumed recognized the market need for a product addressing SL instability and designed a unique, jointed, cannulated headless screw to be used as an adjunct to the soft tissue repair.

The Acumed SLIC Screw was the first cannulated jointed headless screw with differential thread pitch to enter the market. It was suspected that for the soft tissue to have a chance to heal, there needed to be adequate reduction of the scapholunate interval while allowing for movement between the carpals in correspondence with a soft tissue repair. One way this may be achieved is with the introduction of a joint in the screw with differential pitch threads designed to create reduction between the carpals and biomechanically relevant toggle in the screw at the native joint space.

Key Features of Acumed SLIC Screw System:

- Machined stainless steel components for articulation of the joint of the screw and for the higher modulus of elasticity and strength as compared to titanium for implant removal capabilities.[27-30] Having the same biometal in both portions of the screw avoids the potential for galvanic corrosion resulting from two dissimilar metals in contact with one another.[31]
- Cylinder-in-cylinder jointed design to provide two points of contact at the maximum toggle angle for structural support within the screw.
- Cutting relief to aid in removal of the screw at the recommended time of 6-9 months or after biological healing of the soft tissue has occurred with minimal bony on-growth.
- Fully cannulated to be inserted percutaneously over a guide wire for recommended placement in the central middle third of the scaphoid and lunate from the lateral view.

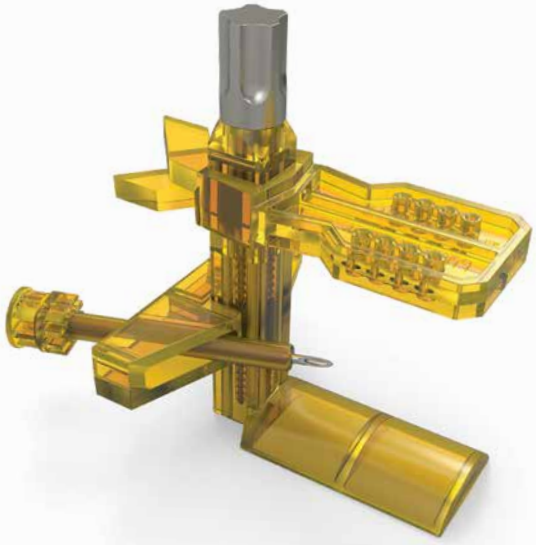
Anatomic Complexity

Several studies have shown the complexity of the scapholunate interosseous ligament (SLIL) as it is a C-shaped structure that connects three surfaces of the scaphoid and lunate together including the volar, dorsal, and proximal surfaces.[32-33] These three surfaces of the ligament provide different anatomic properties and depending on the direction and degree the hand is placed in, leads to different kinematic behaviors of the ligament construct.[34] The movement of the SLIL is also related to the motion of the ligaments of the surrounding carpal bones. The complexity of this anatomic region makes it advantageous to have multiple implant sizes specifically designed to mimic the normal biomechanics made available to surgeons. This accommodates varying patient anatomies which may aid in soft tissue healing when a soft tissue repair procedure is performed.

"Ligamentous or bony injury to the wrist has the potential to irreversibly disrupt the balance and to set the stage for an inexorable progression to abnormal motion, joint loading, and degenerative change." [35]

The Acumed Advantage

Differential pitch screw designs are utilized as additional support to the preferred soft tissue repair by the surgeon. The Acumed SLIC Screw System is a comprehensive system of screws and a targeting guide designed to provide stability and anatomic mobility while the soft tissue heals.



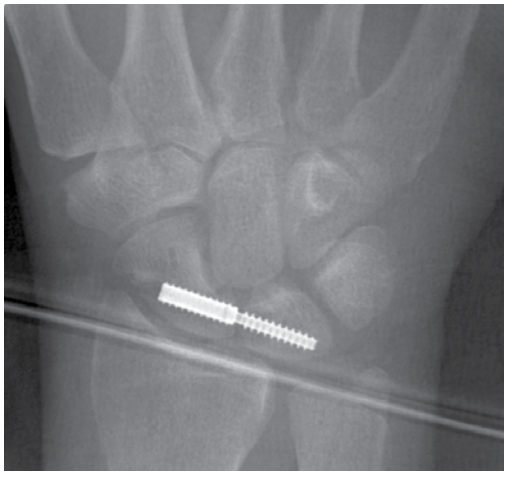
The Acumed® SLIC Screw System:

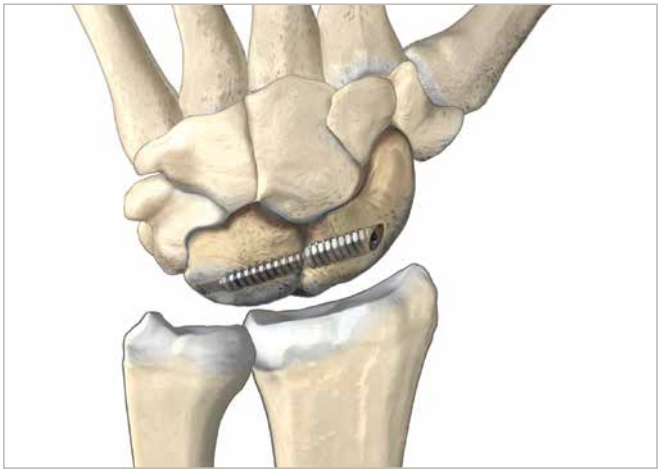
SLIC Screw

The SLIC Screw is an adjunct to the biological healing of soft tissue repair or reconstructions utilized to treat SL and LT instability. The SLIC Screw is utilized to provisionally hold the reduction of the scapholunate interval while the soft tissue repair heals. The jointed screw allows relative rotation and anatomic toggle between the scaphoid and lunate while holding reduction. Utilization of the SLIC Screw device should be limited to surgeons well versed in the treatment of intercarpal instability.

The SLIC Screw is contraindicated in the presence of active or latent infection, sepsis, osteoporosis, insufficient quantity, and/or quality of bone, presence of cartilage degeneration on the bones, absence of potential for soft tissue healing or soft tissue reconstruction spanning the bones, or with patients who are unwilling or unable to follow postoperative care instructions.

- The SLIC Screw System includes three different screw length options for varying patient anatomy.
  - 22 mm
  - 25 mm
  - 28 mm
- Cylinder-in-cylinder joint is designed to sit at the SL interval in order to allow for maximum relative rotation between the scaphoid and lunate while holding reduction and allows for a smaller screw diameter for varying patient anatomy.
- The SLIC Screw is made of stainless steel to aid in the removal of the screw.[36-39] SLIC Screw removal is recommended at 6-9 months or after biological healing of soft tissue has occurred.
- Two-part screw design:
  - The lunate portion is consistent across all three screw sizes while the scaphoid portion of the screw varies in length.
  - The three different scaphoid portion lengths allow the scaphoid portion of the screw to be inserted just under the radial cortex of the scaphoid to aid in removal of the screw 6-9 months post operation.[40]
- The scaphoid and lunate portions of the SLIC Screw have differential pitch which “reduces” the SL interval during insertion.
- Each screw size has specific instrumentation including a specific SLIC Screw Driver and Easyout to make contact with both the lunate and scaphoid portions of the screw.
- The SLIC Screw Stepped Drill has a step off feature in the drill flutes and measurement grooves to enable determination of depth of the drill and screw length.

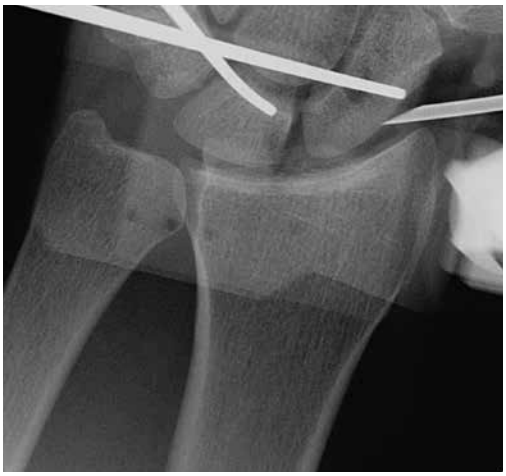


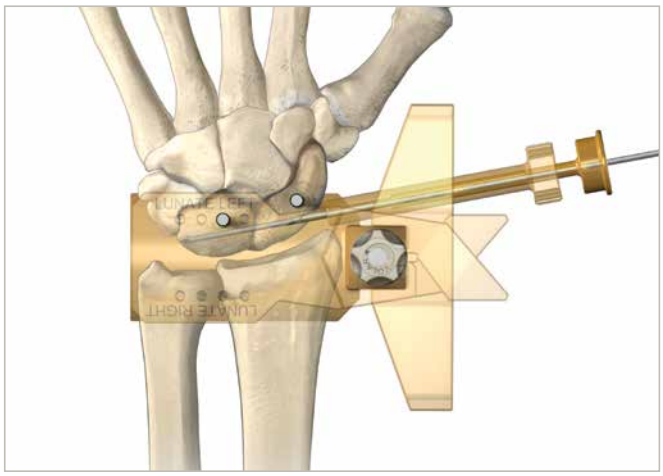


SL Targeting Guide

The SL Targeting Guide is designed to be used in correspondence with K-wires for anatomical reduction of the scaphoid and lunate while allowing simplified targeting of the central third of the scaphoid and lunate in the lateral view.

- The SL Targeting Guide provides specialized instrumentation designed to anatomically align the scaphoid and lunate carpals and target the scapholunate interval.
  - Targeting Wing is designed to hold the Soft Tissue Protector Cannula in place in order for the Scaphoid Needle to target the location of guide wire insertion.
  - Elevator Screw allows adjustment of the Targeting Wing to line up with the lateral position of the scaphoid for future 0.045” guide wire insertion.
  - Scaphoid Needle aids in preventing the 0.045” guide wire from skiving off the scaphoid during insertion and in both the PA and lateral view shows the projection of the guide wire path.
  - Soft Tissue Protector Cannula designed with a flat side feature to be used with the Trajectory Wing to target the scaphoid and lunate for 0.045” guide wire placement. When the correct trajectory is located, it is locked into place by turning it clockwise.
  - Dorsal Plate stabilizes the SL Targeting Guide construct for potential movement during fluoroscopy imaging as well as aid in maintaining placement of the lunate joystick guide wire.
  - Joystick Clip aids in anatomical reduction of the scaphoid and lunate by holding the lunate and scaphoid joystick guide wires in reduced position.
- Radiolucent material allows the surgeon to view the carpals and guide wires under fluoroscopy. SL Targeting Guide Scaphoid Needle and SL Targeting Guide Elevator Screw are exceptions as they are radio-opaque.
- SL Targeting Guide Elevator Body enables adjustments dorsally or palmarly to the SL Targeting Guide Targeting Wing by turning the Elevator Screw clockwise or counterclockwise. The correct location for the Targeting Wing in the lateral view is the center middle third of the lunate.
- The locking feature of the SL Targeting Guide Soft Tissue Protector Cannula allows the surgeon to determine the correct trajectory for 0.045” Guide Wire insertion by rotating and locking the Soft Tissue Protector Cannula in place.
- The oblique SL Targeting Guide Scaphoid Needle helps prevent the guide wire from skiving off the scaphoid when rotated so the oblique tip is at the most proximal position. In both the PA and lateral view, it shows the projection of the guide wire path.
- SL Targeting Guide is designed with multiple K-wire hole options including four designated holes to target the lunate, a cutout for a joystick approach to anatomically reduce the carpals, and a Scaphoid Needle to target the SL interval.





Associated Acumed® Products

- Acu-Loc® Volar Distal Radius Plating System
- Acu-Loc® 2 Volar Distal Radius Plating System
- Acutrak Headless Compression Screw—Mini and Standard
- Acutrak® 2 Headless Compression Screw—Micro, Mini, and Standard
- ARC Wrist Tower System
- Forearm Fracture Solutions
- Hand Fracture System
- Modular Hand System
- Small Bone External Fixation System
- Stableloc External Fixation System
- Total Wrist Fusion System
- Ulna Shortening Plating System
- Wrist Spanning Plate

References

1. Forward, D.P., Lindau, T.R., & Melsom, D.S. Intercarpal Ligament Injuries Associated with Fractures of the Distal Part of the Radius. The Journal of Bone & Joint Surgery. 2007, 89, 2334-2340.
2. Richards, R.S., Bennett, J.D., Roth, J.H., & Milne Jr., K. Arthroscopic Diagnosis of Intra-articular Soft Tissue Injuries Associated with Distal Radial Fractures. The Journal Hand Surgery Am. 1997, 22(5): 772-776.
3. Rockwood, W.B., Heckman, J.D., & Court-Brown, C. Rockwood and Green's Fractures in Adults. Lippincott Williams and Wilkins. 2006, 6, 100.
4. Mehta, J.A., Bain, G.I., & Heptinstall, R.J. Anatomical Reduction of Intra-articular Fractures of the Distal Radius: An Arthroscopically-assisted Approach. The Journal of Bone and Joint Surgery (Br). 2000, 82B(1), 79-86.
5. Richards, R.S., Bennett, J.D., Roth, J.H., & Milne Jr., K. Arthroscopic Diagnosis of Intra-articular Soft Tissue Injuries Associated with Distal Radial Fractures. The Journal Hand Surgery Am. 1997, 22(5): 772-776.
6. Peicha, G. Seibert, F., Fellinger, M., & Grechenig, W. Midterm Results of Arthroscopic Treatment of Scapholunate Ligament Lesions Associated with Intra-articular Distal Radius Fractures. Journal of Knee Surgery Sports Traumatol Arthroscopy. 1999, 7(5), 327-333.
7. Garcia-Elias, M., Lluch, A.L., & Stanley, J.K. Three-Ligament Tenodesis for the Treatment Scapholunate Dissociation: Indications and Surgical Technique. The Journal of Hand Society. 2006, 31A, 125-134.
8. Geissler, W.B. Arthroscopic Management of Scapholunate Instability. Journal of Wrist Surgery. 2013, 2, 129-135.
9. Garcia-Elias, M., Lluch, A.L., & Stanley, J.K. Three-Ligament Tenodesis for the Treatment Scapholunate Dissociation: Indications and Surgical Technique. The Journal of Hand Society. 2006, 31A, 125-134.
10. Caloia, M., Caloia, H., & Pereira, E. Arthroscopic Scapholunate Joint Reduction. Is an Effective Treatment for Irreparable Scapholunate Ligament Tears? Clinical Orthopaedics and Related Research. 2012, 470(4), 972-978.
11. Walsh, J.J., Berger, R.A., & Cooney, W.P. Current Status of Scapholunate Interosseous Ligament Injuries. Journal of the American Academy of Orthopaedic Surgeons. 2002, 10, 32-42.
12. Zarkadas, P.C., Gropper, P.T., White, N.J., & Perey, B.H. A Survey of the Surgical Management of Acute and Chronic Scapholunate. The Journal of Hand Society. 2004, 29A(5), 848-857.
13. Caloia, M., Caloia, H., & Pereira, E. Arthroscopic Scapholunate Joint Reduction. Is an Effective Treatment for Irreparable Scapholunate Ligament Tears? Clinical Orthopaedics and Related Research. 2012, 470(4), 972-978.
14. Zarkadas, P.C., Gropper, P.T., White, N.J., & Perey, B.H. A Survey of the Surgical Management of Acute and Chronic Scapholunate. The Journal of Hand Society. 2004, 29A(5), 848-857.
15. Caloia, M., Caloia, H., & Pereira, E. Arthroscopic Scapholunate Joint Reduction. Is an Effective Treatment for Irreparable Scapholunate Ligament Tears? Clinical Orthopaedics and Related Research. 2012, 470(4), 972-978.
16. Zarkadas, P.C., Gropper, P.T., White, N.J., & Perey, B.H. A Survey of the Surgical Management of Acute and Chronic Scapholunate. The Journal of Hand Society. 2004, 29A(5), 848-857.

17. Zarkadas, P.C., Gropper, P.T., White, N.J., & Perey, B.H. A Survey of the Surgical Management of Acute and Chronic Scapholunate. The Journal of Hand Society. 2004, 29A(5), 848-857

18. Zarkadas, P.C., Gropper, P.T., White, N.J., & Perey, B.H. A Survey of the Surgical Management of Acute and Chronic Scapholunate. The Journal of Hand Society. 2004, 29A(5), 848-857.

19. Caloia, M., Caloia, H., & Pereira, E. Arthroscopic Scapholunate Joint Reduction. Is an Effective Treatment for Irreparable Scapholunate Ligament Tears? Clinical Orthopaedics and Related Research. 2012, 470(4), 972-978.

20. Zarkadas, P.C., Gropper, P.T., White, N.J., & Perey, B.H. A Survey of the Surgical Management of Acute and Chronic Scapholunate. The Journal of Hand Society. 2004, 29A(5), 848-857.

21. Caloia, M., Caloia, H., & Pereira, E. Arthroscopic Scapholunate Joint Reduction. Is an Effective Treatment for Irreparable Scapholunate Ligament Tears? Clinical Orthopaedics and Related Research. 2012, 470(4), 972-978.

22. Kalb, K. Blank, S., Van Schoonhoven, J. & Prommersberger, K.J. Stabilization of the Scaphoid According to Brunelli as Modified by Garcia-Elias, Lluch, and Stanley for the Treatment of Chronic Scapholunate Dissociation. Operative Orthopadie und Traumatologie. 2009, 21(4-5), 429-441.

23. Larson, T.B., Gaston, R.G., & Chadderdon, R.C. The Use of Temporary Screw Augmentation for the Treatment of Scapholunate Injuries. Techniques in Hand & Upper Extremity Surgery. 2012, 16(3), 135-140.

24. Pomerance, J. Outcome After Repair of the Scapholunate Interosseous Ligament and Dorsal Capsulodesis for Dynamic Scapholunate Instability Due to Trauma. The Journal of Hand Surgery AM. 2006, 31(8), 1380-1386.

25. Schadel-Hopfner, M. Junge, A. & Bohringer, G. Scapholunate Ligament Injury Occurring with Scaphoid Fracture—A Rare Coincidence? The Journal of Hand Surgery European Volume. 2005, 30(2), 137-142.

26. Talwalkar, S.C., Edwards, A.T.J., Hayton, M.J., John, H., Stilwell, I.A., & Stanley, J.K. Results of Tri-ligament Tenodesis: A Modified Brunelli Procedure in the Management of Scapholunate Instability. The Journal of Hand Surgery: British & European Volume. 2006, 31(1), 110-117.

27. Hayes, J.S., Seidenglanz, U., Pearce, S., Archer, C.W., & Richards, R.G. Reducing Implant Removal Related Morbidity with Surface Polishing—A Novel In Vivo Study. Orthopaedic Research Society. 2009.

28. Hover, A. Titanium for Fracture Fixation. Ace Medical Company. 1994. 1-11.

29. Langhoff, J.D., Maryer, J., Faber, L., Kaestner, S.B., Guibert, G., Zlinszky, K., & Auer, J.A. Does Surface Anodisation of Titanium Implants Change Osseointegration and Make Their Extraction from Bone Any Easier? Veterinary and Comparative Orthopaedics and Traumatology. 2008, 21, 202-210.

30. Pearce, A.I., Pearce, S.G., Schwieger, K., Milz, S., Schneider, E., Archer, C.W., & Richards, R.G. Effect of Surface Topography on Removal of Cortical Bone Screws in a Novel Sheep Model. Journal of Orthopedic Research. 2008. 26, 1377-1388.

31. Acumed® "Sales Representative Guide to Biometals." GEN60-01-B. Effective 10/2013.

32. Kuo, C.E. and Wolfe, S.W. Scapholunate Instability: Current Concepts in Diagnosis and Management. The Journal of Hand Society. 2008, 33A, 998-1013.

33. Walsh, J.J., Berger, R.A., & Cooney, W.P. Current Status of Scapholunate Interosseous Ligament Injuries. Journal of the American Academy of Orthopaedic Surgeons. 2002, 10, 32-42.

34. Kuo, C.E. and Wolfe, S.W. Scapholunate Instability: Current Concepts in Diagnosis and Management. The Journal of Hand Society. 2008, 33A, 998-1013.

35. Kuo, C.E. and Wolfe, S.W. Scapholunate Instability: Current Concepts in Diagnosis and Management. The Journal of Hand Society. 2008, 33A, 998-1013.

36. Hayes, J.S., Seidenglanz, U., Pearce, S., Archer, C.W., & Richards, R.G. Reducing Implant Removal Related Morbidity with Surface Polishing—A Novel In Vivo Study. Orthopaedic Research Society. 2009.

37. Hover, A. Titanium for Fracture Fixation. Ace Medical Company. 1994. 1-11.

38. Langhoff, J.D., Maryer, J., Faber, L., Kaestner, S.B., Guibert, G., Zlinszky, K., & Auer, J.A. Does Surface Anodisation of Titanium Implants Change Osseointegration and Make Their Extraction from Bone Any Easier? Veterinary and Comparative Orthopaedics and Traumatology. 2008, 21, 202-210.

39. Pearce, A.I., Pearce, S.G., Schwieger, K., Milz, S., Schneider, E., Archer, C.W., & Richards, R.G. Effect of Surface Topography on Removal of Cortical Bone Screws in a Novel Sheep Model. Journal of Orthopedic Research. 2008. 26, 1377-1388.

40. TR00981. "Proximal SLIC Screw Length Rationale." 8/2011. Data on file at Acumed®.

Relevant 510K Information

AUG 2 9 2011

5. 510(k) Summary

Device Trade Name: SLIC Screw Repair System

Manufacturer: Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

Contact: Ms. Lino Tsai
Regulatory Specialist
Phone: 503.627.9957

Prepared by: Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
Fax: (202) 552-5798

Date Prepared: June 8, 2011

Classification: 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener

Class: II

Product Code: HWC

Indications For Use:
The SLIC Screw Repair System is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

Device Description:
The SLIC Screw Repair System consists of a headless, cannulated two-piece screw assembly. The two-piece design incorporates the use of distal and proximal screw components to anatomically reduce two bones.

The purpose of this Special 510(k) is to modify the material, interconnection geometry and available sizes of the SLIC Screw. All components are made of 22-13-5 stainless steel conforming to ASTM F1314. These modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Predicate Device:
The modified SLIC Screw Repair System is substantially equivalent to the predicate ARC Surgical Bone Reduction System (K063244) with respect to indications, design, function, and materials.

Preclinical Testing:
The new components were subjected to insertion testing, pull-apart testing and pull-out strength testing. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Acumed, LLC
% Ms Lino Tsai
Regulatory Specialist
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

AUG 29 2011

Re: K111608
Trade/Device Name: SLIC Screw Repair System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bond fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 5, 2011
Received: August 8, 2011

Dear Ms. Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): _____

Device Name: SLIC Screw Repair System

The SLIC Screw Repair System is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Mellacom

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111608

GEN10-04-A
Effective: **3/2014**
U.S. Patent No. 7,951,198

Acumed®
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

Office: 888.627.9957
Fax: 503.520.9618
acumed.net