SICAGE® System

IMPORTANT MEDICAL INFORMATION FOR THE SICAGE® SYSTEM

ENGLISH

The following contains important medical information on the SICAGE® System.

DESCRIPTION

The SICAGE implant is a fully threaded, self-drilling/self-tapping bone screw having an array of circular fenestrations placed helically along its shaft. It is offered in a single diameter and various lengths to accommodate variability in patient anatomy. The SICAGE implant is manufactured from medical grade titanium (Ti-6Al-4V ELI per ASTM F136), packaged as a single unit and sold sterile.

The SICAGE instruments are provided non-sterile, and must be cleaned and sterilized prior to use. All instruments are reusable with the exception of the Quick Connect Drills (10-2-9002), Implant Filling Tube (10-2-9011) and Guide Pins (10-2-9013, 10-2-9014, and 10-2-9015), which are single use devices and must be discarded after use.

INDICATIONS

SICAGE is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CONTRAINDICATIONS

- Documented or probable allergy, intolerance or sensitivity to component material.
- Patients with medical conditions which would preclude the potential benefit of the surgical outcome; including, but not limited to the following: Fever, fracture of ilium and/or sacrum involving the sacroiliac joint, infection, mental illness, open wounds, osteopenia and/or osteoporosis, pregnancy, and tumors at or near the surgical site.
- Deformities, abnormalities or anatomic variations that may interfere with or prevent accurate placement of the implant.
- Conditions not described in the Indications for Use

WARNINGS

- The implantation of the SICAGE device should be performed only by experienced surgeons with specific training in this procedure because this is a technically demanding procedure presenting a risk of serious injury to the patient. Accurate implant position is critical to the outcome of the procedure and particular attention should be paid to this. The SICAGE Surgical Technique can be obtained at no charge by contacting Customer Service at (800) 890-4489.
- Vaginal delivery of a fetus may not be advisable following implantation of the SICAGE device. Women of childbearing potential should be warned of this. Delivery options should be reviewed with an obstetrician if pregnancy does occur.

PRECAUTIONS

- Carefully read and follow all instructions prior to use. *Copies of the SICAGE Surgical Technique can be obtained at no charge by contacting Customer Service at (800) 890-4489.*
- Patient selection is important. Patients with previous surgery and a patient's ability to comply with post-operative instructions may affect the long term surgical outcome.
- The patient should be made aware of the implant limitations and instructed that immediate postoperative activity should be limited to reduce the risk of implant related complication.
- Correct implant selection is an important factor in achieving a successful surgical outcome. Review of X-rays and CT scans during the pre-operative planning phase may be helpful in selecting the correctly sized implant.
- Inspect the implant and its packaging prior to use.
- Do not use an implant if the package is opened or damaged.
- Do not use an implant if expiration date provided on the labelling has passed.
- The SICAGE System should not be used with components from other systems.
- The SICAGE implant is single use only and should never be reused under any circumstances.
- Do not attempt to reprocess or re-sterilize an implant.

POTENTIAL ADVERSE EVENTS

As with all surgical procedures there are associated risks when using the SICAGE procedure to treat SI joint conditions, these include but are not limited to;

1. Anesthetic risk
2. Gastrointestinal complications (i.e. Ileus or bowel perforation)
3. Vascular injury or damage that may result in catastrophic or fatal bleeding, hematoma or seroma or other cardiovascular system compromise
4. Neurological deficit, nerve root or peripheral nerve injury, irritation or damage
5. Neurovascular injury
6. Damage to lymphatic vessels and/or lymphatic fluid exudation
7. Injury to intra-pelvic structures, reproductive system compromise, urological compromise
8. Infection of the wound, deep infection, peritonitis
9. Wound dehiscence
10. Pulmonary or systemic embolism
11. Thrombosis, thrombophlebitis
12. Muscle damage
13. Loss of spinal mobility and/or persistent low back pain
14. Localized swelling
15. Malfunction of the implants and/or instruments
16. Radiation exposure
17. Sepsis
18. Death

Risks more specifically related to the use of the SICAGE System include, but are not limited to;

1. Infection
2. Pain, discomfort, or abnormal sensations due to presence of an implant
3. Malposition of the implant
4. Implant failure resulting in a complication
5. Migration, bending, loosening or fracture of an implant
6. Muscle pain related to altered biomechanics
7. Nerve irritation due to local swelling or altered biomechanics
8. Loss of fixation / stabilization
9. Metal sensitivity or allergic reaction
10. Failure to improve symptoms and/or function

11. Increased pain at treated or adjacent levels
12. Need for re-operation or removal of the implant(s)
13. Implant rejection
14. Response to wear debris
15. Osteoarthritis
16. Decreased bone density due to stress shielding
17. Pseudarthrosis or failure to achieve SI joint fusion

HOW SUPPLIED AND HANDLED

The SICAGE implants are provided sterile in single units. The implants are packaged in a sealed dual barrier system and should be intact upon receipt and stored at room temperature. If sterility is compromised prior to use (e.g., the package is damaged or the expiration date has passed), the product should be returned to Sicage, LLC. Do not alter the implant as alterations may lead to breakage of the implant. Notches or scratches put in the implant during the course of surgery may also contribute to breakage. The implant should never be re-sterilized.

The SICAGE instruments are designed specifically to implant the SICAGE device. The SICAGE instruments are provided separately and are non-sterile. Prior to use, the instruments must be cleaned and sterilized per the cleaning and sterilization instructions provided below.

Prior to use, thoroughly check all instruments for completeness and to ensure the instruments are free from damage. Do not use damaged products. Damaged products should be returned to Sicage, LLC.

Handle the SICAGE implant(s) and instruments with care at all times to prevent scratches or damage. Store the implant(s) in their protective packaging and do not open until ready for use. Inspect each implant and instrument prior to use.

If surface or configuration damage is identified, return the implant(s) and/or instruments to Sicage, LLC. See Section "Product Complaints" for more information.

REPROCESSING

Instruments are provided non-sterile and must be cleaned and sterilized prior to introduction into a sterile surgical field. Following use of the instruments, all reusable instruments must be must be thoroughly cleaned and sterilized before reuse.

Dispose of any Guide Pin(s), Implant Filling Tube(s), and Quick Connect Drill(s) that were used in the procedure.

1. PRE-CLEANING

Clean instruments as soon as possible after use and keep used instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.

Rinse instruments thoroughly, for a minimum of 1 minute, with a steady stream of cold water (below 110°F/43°C). Remove gross contaminants using a soft bristled, nylon brush. Particular attention should be taken to remove all debris from all cannulations, crevices, obscured holes and other hard to clean areas. A lumen brush may be used to clean the lumens and hard to reach areas. Do not use saline or chlorinated solutions.

All instruments must be disassembled (if applicable) prior to cleaning and sterilization. See the following table for Assembly and Disassembly Instructions.

ASSEMBLY AND DISASSEMBLY INSTRUCTIONS

Part Number	Description	Assembly Instructions	Prior to Cleaning and Re-sterilization
10-2-9002	Quick Connect (QC) Drill	Attach to QC Handle	Remove from QC Handle
10-2-9003	Tissue Protector	NA	No Disassembly/Reassembly Required
10-2-9005	Implant Driver Shaft	Attach to QC Handle	Remove from QC Handle
10-2-9006	Offset Guide	NA	No Disassembly/Reassembly Required
10-2-9007	Tissue Dilator	NA	No Disassembly/Reassembly Required
10-2-9010	Plunger Rod	NA	No Disassembly/Reassembly Required
10-2-9011	Implant Filling Tube	NA	No Disassembly/Reassembly Required
10-2-9012	Quick Connect (QC) Handle	Attach to Implant Driver or Drill, as necessary	Remove from Implant Driver or Drill
10-2-9013	Ø3.2mm x 229mm Sharp Guide Pin	NA	No Disassembly/Reassembly Required
10-2-9014	Ø3.2mm x 229mm Short Blunt Guide Pin	NA	No Disassembly/Reassembly Required
10-2-9015	Ø3.2mm x 457mm Long Blunt Guide Pin	NA	No Disassembly/Reassembly Required

2. Automated Cleaning

Place the pre-cleaned items into the automated washer racks and/or trays. Items should not be placed in the sterilization case for automated cleaning, but in the racks and trays of the automated cleaner. Care should be taken to place difficult-to-clean parts near the center of the rack, with open sides down, and minimize touching between parts. Place small parts in baskets to prevent dislodging.

The instruments should be removed from the sterilization case prior to processing and placed in the racks, trays or baskets as appropriate.

The empty sterilization case and lid, along with items within the automated cleaner racks, trays and baskets should be cleaned using the following automated cleaning process steps:

TREATMENT	TIME (MM:SS)	TEMPERATURE	CLEANING SOLUTION
Enzymatic Wash	04:00	Hot tap water	Steris® Prolystica® 2X Concentrate Enzyme Presoak (1/8 oz. per fluid gallon)
Wash	02:00	65.5°C	Steris® Prolystica® 2X Concentrate Neutral Detergent (1/8oz. per fluid gallon)
Rinse	05:00	70°C	N/A
Dry	07:00	80°C	N/A

Note: Do not use cleaning solutions containing bleach or formalin since they may damage the device.

3. INSPECTION

Visually inspect cleaned instruments for any remaining soil to ensure they are visually clean. If necessary, using a soft brush, gently clean, paying close attention to lumens, crevices and other hard to clean areas, until all instruments are visually clean. Re-clean and rinse as described above, if manual re-cleaning is performed.

Visually inspect the instruments to ensure they are thoroughly dried. Instruments must be thoroughly dried and all residual moisture must be removed before they are returned to their designated locations in the sterilization tray. Allow to air dry, or use a soft, lint-free, absorbent towel/cloth to dry external surfaces.

Instruments must be inspected following cleaning and before each use. Inspect the instruments for non-functioning parts, wear, and/or possible damage. Damaged or defective instruments should not be used. Damage can include: pitting, corrosion, cracks, discoloration, wear etc. Contact Sicage, LLC for replacement and/or new parts.

Visually inspect and dispose of any disposable parts (Drills, Implant Filling Tube and Guide Pins) that show signs of previous use.

All products should be treated with care. Improper use of handling may lead to damage and possible improper functioning of the device.

4. STERILIZATION

Return the dry instruments to their designated locations in the SICAGE System Sterilization Case and steam sterilize the instruments prior to use. To achieve a 10^{-6} sterility assurance level, steam sterilize the instruments according to the parameter below.

A single wrap (or pouch) may be used for the pre-vacuum cycles. An FDA cleared wrap is recommended.

For instrument sterilization within the US, only the following method is recommended:

Instruments	Cycle	Temperature	Exposure Time	Drying Time
Method 1	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

NOTE: Medical facilities should verify that the sterilization equipment is properly installed, calibrated and maintained.

PRODUCT COMPLAINTS and CUSTOMER SERVICE
Phone (800) 890-4489

MRI INFORMATION
The SICAGE implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SICAGE implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

DIRECTIONS FOR USE AND DEVICE RETRIEVAL
Please see the SICAGE Surgical Technique manual for directions for use and instructions on the removal procedure if necessary. If you do not have a manual readily available, call Sicage, LLC for a replacement document (or visit www.sicage.com).

CAUTION: FEDERAL LAW RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

SYMBOL DESCRIPTION

Packaging Unit

Product Reference

Batch Number

Gamma Radiation Sterilization


Use By Date


Caution: Federal law restricts this device to sale by or on the order of a physician


Caution: See Instruction for Use


Do Not Reuse


Do Not Use if Package is Damaged


Manufactured For

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Patents Pending

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