CITRELOCK® ACL- INSTRUCTIONS FOR USE

CAUTION – Federal Law (USA) restricts these devices to sale by or on the order of a physician.

DEVICE DESCRIPTION:

The CITRELOCK ACL device is a multiple lead helical thread form style design with an extended taper. The external surface of the device presents a blunt surface geometry suitable for engaging soft tissue. A cannula through the central axis of the implant allows for engagement with an insertion instrument, facilitating alignment into the prepared site. The CITRELOCK ACL device is to be used with CITRELOCK ACL instruments.

The CITRELOCK ACL device is made from CITREGEN® biomaterial, which is a resorbable, homogeneous biocomposite comprised of 60 wt.-% unsintered hydroxyapatite (HA) and 40 wt.-% polyester. CITREGEN'S polymer component is a citrate-based network of completely amorphous polymer chains crosslinked together to form an elastomeric material. As water penetrates the subject device, surface erosion of the polymer phase occurs through hydrolysis of the ester bonds located between the monomers and at the crosslink sites.

MATERIALS:

POC-HA: poly (octamethylene citrate) hydroxyapatite

INDICATIONS:

The CITRELOCK® ACL is intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, foot/ankle, knee, and hand/wrist. More specifically:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tendon Reattachment, Acromion-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist.

CONTRAINDICATIONS:

Include, but are not limited to:

1. Fever or leukocytosis.
2. Infection, local to the operative site.
3. Mental illness.
4. Morbid obesity.
5. Pregnancy.
6. Insufficient quantity or quality of bone.
7. Signs of local inflammation.
8. Blood supply limitations and previous infections which may retard healing.
9. Any active infection or blood supply limitations.
10. Any patient unwilling to co-operate with postoperative instructions.
11. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
12. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
13. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
14. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
15. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant.
16. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
17. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, limit their ability to follow postoperative restrictions. These patients may place undue stresses on the implant during bony healing and may be at higher risk of implant failure.
18. Any condition not described in the indications for use.

POTENTIAL ADVERSE EVENTS:

All adverse events or complications associated with surgery are possible. A listing of these along with those associated with the CITRELOCK ACL device include, but are not limited to:

1. Infections, both deep and superficial.
2. Bone loss or decrease in bone density, possibly caused by stress shielding.
3. Inability to perform the activities of daily living.
4. Change in mental status.
5. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
6. Gastrointestinal complication.
7. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
8. Delayed healing.
9. Scar formation possibly causing neurological compromise around nerves and/or pain.
10. Death.
11. Foreign body (allergic) reaction to the implant's, debris, resorption products; including osteolysis, staining, tumor formation and/or autoimmune disease. These reactions have sometimes necessitated the removal of the implant. Patient sensitivity to device materials must be considered prior to implantation.
12. Breakage of any or all of the components.
13. Implant migration.
14. Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any bone above, and/or below the level of surgery.
15. Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNING:
Surgeons must apply their professional judgment when determining the appropriate implant size based on the specific indication, preferred surgical technique, and patient history. Implant sizes that are smaller than 7mm may not be appropriate for the knee indication.

A successful result is not always achieved in every surgical case. This fact is especially true where other patient conditions may compromise the results. No implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good alignment are important considerations in the success of surgery. Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of delayed healing. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for surgery.

DO NOT USE devices that are received in open or damaged packages.

DO NOT USE past the expiration date.

No implant should be reused once the sterile packaging has been opened.

PRECAUTIONS:
Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. The manufacturer provides detailed surgical techniques.

1. Under insertion of the device may leave the proximal end of the implant protruding beyond the cortical bone, which could potentially cause soft tissue irritation and/or pain post-operatively.
2. Use the appropriate size reamer to create a pilot hole in the bone.
3. It is important to completely seat the inserter to prevent potential fracturing of the implant during insertion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patients.

MR SAFETY INFORMATION:
CITRELOCK ACL is MR Safe.

IMPLANT SELECTION:
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Polymeric implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PRE-OPERATIVE:
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. Further information on the use of this system will be made available on request.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRA-OPERATIVE:
1. The instructions in the applicable surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the nerves and soft tissue. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Bone cement should not be used since this material will make removal of the components difficult or impossible.

POST-OPERATIVE:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to healing, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or any sudden jolt.
2. To maximize the chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume excess alcohol during the bone healing process.
3. The patient should be advised of their inability to bend at the point of surgery and taught to compensate for this potentially permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used and should be returned to the manufacturer.

CLEANING AND DECONTAMINATION:
Unless just removed from an unopened package provided by the manufacturer, all instruments must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to the manufacturer.
All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION:
The contents of the implant package for the CITRELOCK ACL device are provided sterile via Ethylene Oxide Gas sterilization. The reusable instruments for the CITRELOCK ACL device are provided non-sterile. The CITRELOCK ACL device must not be resterilized.

Please refer to the instrument package insert for processing instructions. All instruments must be sterilized prior to use in surgery. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment.

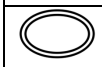
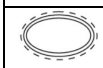
Only sterile implants and instruments should be used in surgery. No implant should be reused once the sterile packaging has been opened. Always immediately clean and re-sterilize reusable instruments that have been used in surgery. This process must be performed before handling or (if applicable) returning to the manufacturer.

PRODUCT COMPLAINTS:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the manufacturer. Further, if the implanted CITRELOCK ACL device ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the manufacturer should be notified immediately. If any product of the manufacturer ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone, email or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the manufacturer is requested.

STORAGE CONDITIONS:
Store in a cool, dry place out of direct sunlight. Prior to use, inspect product package for signs of tampering, damage or water contamination.

INFORMATION:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact the manufacturer.

Packaging Labels Legend:

	Manufactured by
REF	Catalog Number
LOT	Manufacturer's Lot number
UDI	Unique Device Identifier
EO LOT	Sterilization Lot number
	Caution
	Consult instructions for use
	Use by date
QTY	Quantity
	Do not reuse / Single use only
	Do not use if package is damaged
	Keep Dry
STERILE EO	Sterile unless the package is damaged or open. Method of sterilization - EO
Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician.
MR	MR Safe
	Double sterile barrier system
	Double sterile barrier system with protective packaging outside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