ACUITIVE TECHNOLOGIES

CITREGRAFT™ INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION:

CITREGRAFT is a synthetic, highly porous, resorbable bone void filler that is used to fill bony voids or gaps of the skeletal system.

CITREGRAFT is comprised of 60 wt.-% polymer and 40 wt.-% Bioactive Glass. The polymer component is a citrate-based network of completely amorphous polymer chains crosslinked together to form an elastomeric material. Bioactive Glass is a biologically compatible synthetic material consisting of silicates, sodium and calcium oxides, and phosphates.

CITREGRAFT is a pre-formed bone graft substitute that will facilitate new bone formation across the graft site and throughout the interconnected porous structure. As body fluids penetrate the device, surface erosion of the polymer phase occurs through hydrolysis of the ester bonds located between the monomers and at the crosslink sites.

CITREGRAFT is Bioactive, as upon implantation, the Bioactive Glass component of CITREGRAFT undergoes a surface modification that provides for direct bonding to surrounding bone via an apatite layer.

CITREGRAFT is provided in a variety of pre-formed shapes and sizes.

MATERIALS:

POC: poly (octamethylene citrate)

45S5 Bioactive Glass

INDICATIONS:

CITREGRAFT™ is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. CITREGRAFT is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. CITREGRAFT is intended to be used for filling bony voids or gaps of the skeletal system (i.e., extremities and pelvis) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, CITREGRAFT resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS:

Include, but are not limited to:

1. Conditions in which general bone grafting is not advisable.
2. Infection, local to the operative site.
3. Fever or leukocytosis.
4. Signs of local inflammation.
5. Any previous or active blood supply limitation which may retard healing.
6. Any previous or active infection which may retard healing.
7. Any systemic or metabolic disorder that may retard healing.
8. Pregnancy.
9. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
10. The physician should carefully assess the location of the void with respect to the growth plate prior to performing orthopedic surgery on patients who are skeletally immature. The use of this device and the placement of adjunctive hardware or implants must not bridge, disturb, or disrupt the growth plate.
11. Where stabilization of the defect is not possible.
12. Use in segmental defects without adjunctive fixation.
13. In cases where the defect is in direct contact with the articular space, the device should not impinge on the joint or otherwise compromise motion in any way.
14. Any patient having inadequate tissue to cover the operative site.
15. Conditions where the defect site may be subjected to excessive stress or impact.
16. Conditions that may place excessive stresses on bone and the device, 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 considering the risks versus the benefits to the patient.
17. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness and/or alcoholism limits 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. Conditions that tend to limit the patient's ability or willingness to co-operate with postoperative instructions and to restrict activities during the healing period.
19. 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 those associated with the CITREGRAFT device includes, but is not limited to:

1. Inability to perform the activities of daily living.
2. Change in mental status.
3. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
4. Gastrointestinal complication.
5. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
6. Wound necrosis or wound dehiscence.
7. Delayed healing.
8. Scar formation causing neurological compromise and/or pain.
9. Superficial wound infection, deep wound infection, osteomyelitis.
10. Foreign body (allergic) reaction to implants, 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.
11. Transient hypercalcemia
12. Tissue or nerve damage, irritation, joint impingement, and/or pain caused by improper preparation for and placement of the implant.
13. Incomplete or lack of bone formation
14. Fracture of newly formed bone
15. Delayed union or nonunion
16. Loss of fracture reduction or refracture
17. Cyst recurrence
18. Fracture of the device with or without particulate formation
19. Device migration or extrusion

Note: Additional surgery may be necessary to address the adverse event.

WARNING:

A successful result is not always achieved in every surgical case. This fact is especially true where other patient conditions may compromise the results. Preoperative and operating procedures, including knowledge of surgical techniques, proper selection, and placement of the implant are key factors in determining the success of surgery. Further, the proper selection and compliance of the patient will 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 patients that abuse alcohol are also poor candidates for surgery.

Care should be taken when treating patients with other preexisting conditions that may have a negative impact on healing the defect.

CITREGRAFT does not possess sufficient mechanical strength to stabilize a defect site. Rigid mechanical fixation, with adjunctive hardware as needed, is required to assure stabilization of the defect in all planes.

CITREGRAFT cannot be used to obtain purchase for screws. Screws, if used for adjunctive fixation, must engage the host bone.

CITREGRAFT must not be used to repair bone defects where soft tissue coverage cannot be achieved.

CITREGRAFT is intended for single patient use only. Do not reuse, reprocess or resterilize this device.

DO NOT USE devices that are received in open or damaged packages or are past the expiration date.

PRECAUTIONS:

Pre-operative and operating procedures, including knowledge of bone grafting techniques with adjunctive fixation, proper implant selection and placement, are important considerations in the successful utilization of this device. Preparation of the defect site using appropriate instrumentation is required for proper implantation of the device.

CITREGRAFT possesses a slight degree of radiopacity, consider this when evaluating X-rays.

CITREGRAFT should not be used to treat large defects that in the surgeon's opinion would fail to heal with autogenous bone grafting.

Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. The manufacturer and/or distributor provides detailed surgical techniques. Contact your local representative for an onsite demonstration.

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.

IMPLANT SELECTION:

Surgeons must apply their professional judgment when determining the appropriate implant size based on the specific indication, preferred surgical technique, and patient history.

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 contraindications should be avoided.
3. Care should be used in the handling and storage of the device. The device should be protected during storage, especially from corrosive environments.
4. The type and amount of the device to be used should be determined prior to beginning the surgery. An adequate inventory of devices should be available at the time of surgery. Additional sterile devices should be available in case of an unexpected need.
5. Additional information on the use of this system will be provided by the manufacturer and/or distributor on request.

INTRA-OPERATIVE:

1. The instructions in the applicable surgical technique should be carefully followed.
2. Familiarization with the device, proper bone grafting and rigid fixation techniques are extremely important. Radiographic evaluation of the defect site is essential to accurately assess the extent of the traumatic defect and to aid in the selection and placement of the bone void filler and fixation devices.
3. Use appropriate instrumentation as necessary to create a site for the device in the bone. Improper preparation may result in a fit that is too loose or too tight and introduces the risk of fracture of bone or migration of the device during or after insertion.
4. At all times, extreme caution should be used around the nerves and soft tissue. Damage to the nerves will cause loss of neurological functions.
5. Improper passage of the device into the sterile field may result in surgical delays and/or loss of sterility and increased risk of infection for the patient.
6. Use of a non-sterile implant or instrument during surgery may result in post-operative infection which may lead to device failure and need for reoperation.
7. The device may be trimmed to fit the defect. Care should be taken to ensure that exposed surfaces are smooth and free of loose particles.
8. The device should fill the defect and contact as many viable host bone as possible.
9. Incomplete insertion or overfilling the defect may leave the device protruding beyond the bone cavity. This has the potential to cause device migration, soft tissue irritation, joint impingement, and/or pain post-operatively.
10. The quantity of CITREGRAFT used should be limited to the amount necessary to treat the patient.
11. Anatomical reduction and rigid fixation of the defect or fracture in all planes must be obtained to ensure that the graft is not supporting load.

POST-OPERATIVE:

The physician's postoperative directions and warnings and the patient's corresponding compliance are extremely important.

1. Postoperative patient management should follow the same regimen as similar cases using autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.
2. Detailed instructions on the use and limitations of the device should be communicated to the patient. If partial weight bearing is recommended or required prior to healing, the patient must be warned of applying excessive weight bearing or muscular activity to the operative site. The patient should be warned to avoid falls or any sudden jolt.
3. Postoperatively and until healing is complete, the postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device and implantation site.
4. To maximize the chances for a successful surgical result the patient should be advised not to smoke or consume alcohol to excess during the bone healing process.
5. The device is made from a resorbable material that is intended to be replaced over time by the patient's own bone. There is a risk that new bone will not adequately replace the implant material as it resorbs. This risk can be increased if the patient has an adverse response to the material as it resorbs.
6. If the device migrates from the graft site consideration should be given to revise and/or remove the device before serious injury occurs.
7. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
8. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

MR SAFETY INFORMATION:

CITREGRAFT is MR Safe.

PACKAGING:
The package for the device should be intact upon receipt. If a loaner or consignment system is used carefully check it for completeness. All devices should be carefully checked to ensure that none are damaged. Damaged packages or products should not be used and should be returned to the manufacturer and/or distributor.

STERILIZATION:
The CITREGRAFT device is provided sterile via gamma irradiation sterilization. The CITREGRAFT device must not be resterilized by any method. Excess material and opened, unused product must be discarded.

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 and/or distributor. Further, if the implanted CITREGRAFT 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 and/or distributor should be notified immediately. If any product of the manufacturer and/or distributor ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer and/or distributor 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 and/or distributor 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 technique) are available at no charge upon request. If further information is needed or required, please contact the manufacturer and/or distributor.

Packaging Labels Legend:

	Manufactured by
	Catalog Number
	Manufacturer's Lot number
	Unique Device Identifier
	Sterilization Lot number
	Caution
	Consult instructions for use
	Use by date
	Quantity
	Do not reuse / Single use only
	Do not use if package is damaged
	Keep Dry
	Sterile unless the package is damaged or open. Sterilized using irradiation
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	MR Safe
	Double sterile barrier system
	Non-sterile protective packaging with double sterile barrier system inside


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