ACUITIVE TECHNOLOGIES

CITREGRAFT™

General Operative Technique

CITREGRAFT

This publication sets forth detailed recommended procedures for using Acuitive Technologies devices.

It offers guidance you should heed, but as with any such technical guide, each surgeon must consider each patient's needs and make appropriate adjustments.

A workshop training is recommended before the first surgery. All non-sterile devices must be cleaned and sterilized before use.

For additional information, please refer to the instructions for use (IFU), Ref.-No. PI-014, delivered with each implant.

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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

WARNING:

A successful result is not always achieved in every surgical case. This 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 appropriate selection and patient compliance 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 ensure 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:

Preoperative 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 the 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 before 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 critical medical information given in this document should be conveyed to the patients

MR SAFETY INFORMATION:

CITREGRAFT is MR Safe.

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.

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 before implantation.
10. The physician should carefully assess the location of the void with respect to the growth plate before performing orthopedic surgery on skeletally immature patients. 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 of 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 cooperate with postoperative instructions and restrict activities during the healing period.
19. Any condition not described in the indications for use

Note: For additional information, please refer to the Instructions For Use (IFU), Ref.-No. PI-014 delivered with each implant.

System General Considerations

Note: This surgical technique is specific to using the CITREGRAFT device to fill bone defects. This guide does not include detailed instructions for all the potential anatomical locations per the indications for use. The surgical techniques described herein are limited to the proper preparation and placement of the device. This document does not cover patient positioning, surgical approaches, or exposing the bone for preparation. The surgeon is responsible for gaining proper surgical exposure and closure of the surgical site(s) for the given anatomical location and associated surgical procedure. Before using a CITREGRAFT device, it is important to familiarize yourself with preoperative and operating procedures, including knowledge of bone grafting techniques with adjunctive fixation. The surgeon should review the product-specific surgical technique described herein and the information, recommendations, warnings, and precautions provided in the package insert/instructions for use. Workshop training is recommended before the first surgery.

The CITREGRAFT system consists of sterile pre-formed implants in several sizes. The device is pliable and sponge-like and can be morselized by hand or using conventional instruments to fit the bony defect. At the surgeon's discretion, the device can be infused with saline, autogenous blood, and/or bone marrow aspirate at the time of surgery.

There are no implant-specific instruments; instead, the device and bone defect can be prepared with instruments readily available in the OR (e.g., curettes, rongeurs).

CITREGRAFT Sizing

12.5cc 6cc 3cc

- CITREGRAFT is greater than 80% porous with exceptional ability to absorb and retain fluids such as saline, autogenous blood, and bone marrow aspirate.
- CITREGRAFT is both Osteoconductive and Bioactive.
- Following placement in a bony void, CITREGRAFT provides Citrate to guide the healing process metabolically, is resorbed predictably, and replaced by the patient's bone.
- "Citrate, a critical intermediate in the Krebs cycle, is highly concentrated in native bone and is closely associated with bone metabolism and formation.[1]"
- "In response to citrate, human stem cells increase genetic signaling for metabolism, osteoinduction, osteoconduction, and extracellular matrix production.[1]"

1. A. Thirumaran, M.N. Doulgkeroglou, M. Sankar, J.T. Easley, B. Gadomski, A. Poudel, M. Biggs. Bioactive Materials 41 (2024), pp 207-220.

General Operative Technique

Defect Assessment

Pre-operatively evaluate the characteristics of the bony defect or fracture. Radiographic evaluation of the defect site is essential to accurately assess the extent of the traumatic defect and aid in selecting and placing the CITREGRAFT product and adjunctive fixation devices. Approximate the volume of CITREGRAFT necessary to address the defect or fracture.

Exposure

Physician preference can be utilized to expose the operative site in an open or arthroscopic manner. *Care should be taken to avoid injuring tendons, blood vessels, and nerves.*

Defect Stabilization and Preparation

Reduce and stabilize the defect or fracture site. Using preferred instruments (e.g., curette, rongeur), remove bone and tissue as desired to shape the defect site. Debride and irrigate the defect or fracture site, removing any clots, tissue, and bone debris. *Improper preparation may result in a fit that is too loose or tight and introduces the risk of device migration during or after insertion.*

CITREGRAFT Sizing

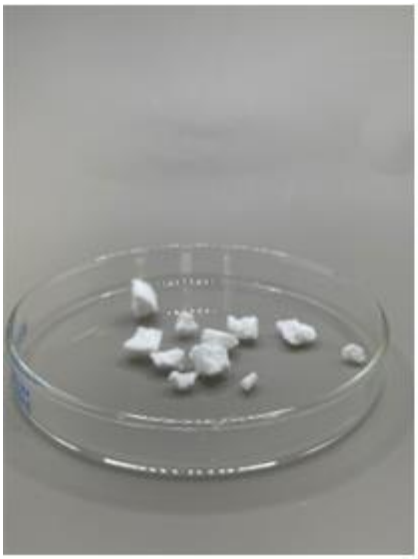
Choose the appropriate CITREGRAFT size (by volume) that best fills the defect (refer to sizing information on the previous page). Multiple units of different sizes can be combined as necessary. *The quantity of CITREGRAFT used should be limited to the amount required to treat the patient.*

Hydrating CITREGRAFT with Fluid

Use an intact device or morselize CITREGRAFT by hand or standard cutting instruments to the desired fragment size before hydrating with sterile saline, autogenous blood, and/or bone marrow aspirate. *Care should be taken to ensure exposed surfaces are free of excessive loose particles.*

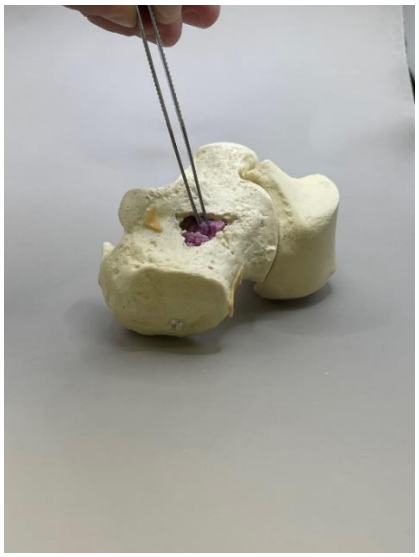
Contain the hydration fluid in a vessel in the sterile field (e.g., syringe). Place the CITREGRAFT device/fragments in a sterile container and introduce hydration fluid directly to the product, allowing excess liquid to pool. Allow the product to saturate with the preferred fluid. Stirring or flipping the product gently with sterile instruments can facilitate this process.

Once the intact CITREGRAFT or morselized fragments are placed in the defect, additional fluid can be injected directly into the graft if desired.



Inserting CITREGRAFT into the Defect

Place and gently pack CITREGRAFT into the defect cavity. Fill the defect and create contact with as much viable host bone as possible. *Incomplete insertion or overfilling of the defect may leave the device protruding beyond the bone cavity, which can cause device migration, soft tissue irritation, joint impingement, and/or postoperative pain.*



Completing the Repair

Verify through an appropriate imaging modality that any fracture has been reduced and that CITREGRAFT adequately filled the defect volume. CITREGRAFT possesses a slight degree of radiopacity; consider this when evaluating X-rays. *Anatomical reduction and rigid fixation of the defect or fracture in all planes must be obtained to ensure that* CITREGRAFT *is not supporting load.*

Closure

Proceed to close soft tissue using preferred methods. *The device should not be used on patients with inadequate tissue to cover the operative site.*

Ordering Information

Implants

Description	ID Number	Size	
3CC CITREGRAFT CYLINDER	36-106-0004	20x10mm	
6CC CITREGRAFT CYLINDER	36-106-0005	20x20mm	
12.5CC CITREGRAFT CYLINDER	36-106-0006	20x40mm	

This technique description is provided as an educational tool and clinical aid to assist properly licensed medical professionals in using specific Acuitive products. This document is intended solely for the use of healthcare professionals. A surgeon must always rely on their professional clinical judgment when deciding whether to use a particular product when treating a specific patient. Acuitive does not dispense medical advice and recommends that surgeons be trained to use any specific product before surgery.

The information presented is intended to demonstrate an Acuitive product. A surgeon must always refer to the package insert, product label, and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any Acuitive product. Products may not be available in all markets because product availability is subject to individual markets' regulatory and/or medical practices. Please contact your representative if you have questions about the availability of products in your area.

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ACUITIVE TECHNOLOGIES