C·GRAFT PUTTY™ C·BLAST PUTTY™

Demineralized Bone Matrix with Cancellous Bone Putty

Demineralized Bone Matrix Putty

Distributed by **Citagenix Inc.**
3300 Autoroute Jean-Noël-Lavoie (A-440) O
Laval, Qc H7T 2H6
Tel : +1-450-688-8699 Fax : +1-450-688-1977
info@citagenix.com www.citagenix.com

CITAGENIX
The Regen Company

1

DESCRIPTION

C-Graft Putty™ is composed of human demineralized bone (DBM) mixed with a resorbable carrier; carboxymethylcellulose (CMC). C-Blast Putty™ is composed of DBM, CMC and processed human cancellous bone powder. These are provided in sterile single patient use packages.

INDICATIONS

The C-Graft Putty™ and C-Blast Putty™ products are indicated for bony voids or defects that are not intrinsic to the stability of the bony structure. They are intended to be gently packed into bony voids or defects of the skeletal system (extremities and spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

CONTRAINDICATIONS

- Active or latent infection in or about the surgical site
- Vascular disease
- Neurological disease
- Degenerative bone disease
- Uncontrolled diabetes
- Renal impairment
- Do not use in patients with metabolic disorders known to adversely affect the skeletal system (e.g. hypercalcemia)

INSTRUCTIONS FOR USE

C-Graft Putty™ and C-Blast Putty™

Keep the surgical site as dry as possible. Do not irrigate during or after placement of C-Graft Putty™ or C-Blast Putty™ grafts.

C-Graft Putty™ and C-Blast Putty™ requires no reconstitution prior to use.

1. Peel open outer pouch using proper sterile technique
2. Pass sterile pouch into sterile field.
3. Peel open inner pouch and remove syringe.
4. Remove protective cap from syringe end.

2

5. Dispense C-Graft Putty™ or C-Blast Putty™ from syringe.

Once the inner pouch has been opened, the tissue must either be transplanted, if applicable, or discarded.

Bone grafting procedures can experience extremely variable results. Factors to be considered in selecting the bone grafting material and the surgical technique to be utilized are as follows:

- Location of the defect
- Age of the patient
- Quality of the patient's bone
- Anticipated loading conditions
- Proximity of the graft to a suitable blood supply
- Elimination of gaps in the graft site
- Ability to suitably stabilize the graft site
- Ability to achieve direct apposition of the graft to viable host bone

PREOPERATIVE PREPARATION

Fluids such as water, saline solution, bone marrow aspirate, or blood may alter the consistency of handling characteristics of grafts. The addition of fluid may cause the graft to have a consistency that is too watery and not ideal for handling and placement. Irrigation of the graft site during or after graft placement may remove or displace graft materials.

POSTOPERATIVE CARE

Standard postoperative practices should be followed, particularly as applicable to defects involving the use of fixation devices. The patient should be cautioned against early weight bearing and premature movement which could lead to loosening and/or failure of the fixators or loss of reduction. The length of healing time may depend on the patient's physical condition and the complexity of the defect site.

SINGLE PATIENT USE

Each C-Graft Putty™ and C-Blast Putty™ package is intended for single patient use only. To prevent cross-infection of graft recipients and graft contamination, do not use the contents of any

3

C-Graft Putty™ and C-Blast Putty™ package for multiple patients.

C-Graft Putty™ and C-Blast Putty™ have been tested for sterility. Do not subject to additional disinfection or sterilization procedures. Empty C-Graft Putty™ and C-Blast Putty™ packages and excess or unused C-Graft Putty™ and C-Blast Putty™ should be disposed in accordance with recognized procedures for discarding medical waste material.

STORAGE

Store C-Graft Putty™ and C-Blast Putty™ at room temperature (1° C to 30° C). No refrigeration or freezing is required.
It is the responsibility of the tissue distributing service and user to maintain the product under appropriate conditions prior to use. The circulation (shelf-life) period is 2 years from the date of manufacture.

STERILIZATION

After the complete processing and packaging procedure, C-Graft Putty™ and C-Blast Putty™ have been sterilized by electron beam irradiation. This irradiation procedures has been validated to reduce the level of bacterial and fungal contamination. DO NOT RE-STERILIZE. The product must not be used beyond the expiration date.

PRECAUTIONS

In order to avoid the use of a potentially contaminated package, C-Graft Putty™ and C-Blast Putty™ must not be used under any of the following conditions:
-if any of the package or product elements appear to be missing, tampered with, or damaged;
-if the expiration date shown on the package label has passed

If any of the above conditions exists or are suspected, the package of C-Graft Putty™ or C-Blast Putty™ should not be used.

Please avoid compression in closed cavities which could produce fat embolism or embolization of the graft into blood stream; and extrusion past treatment site which could damage surrounding tissues.

This product is for single use only

Restricted to use by a licensed clinician

4

Adverse outcome potentially attributable to the product must be promptly reported to your distributor

WARNINGS

As a biological product, the tissue has the potential to transmit infectious agents in spite of processing treatments, donor screening, tissue selection and laboratory tests. To date, there have been no reports of experimental or clinical viral seroconversion using demineralized bone matrix.

As with any surgical procedure, the possibility of infection exists.

PROCESSING

C-Graft Putty™ and C-Blast Putty™ are banked human tissue that has been demineralized and combined with our own carrier using a process that results in an allograft with a putty-like consistency. Demineralized tissues are processed so that the resulting bone matrix has a calcium content of less than 8 %. CMC is combined with the DBM to form the final allograft products. Cancellous bone powder is also added to form C-Blast Putty™. C-Graft Putty™ and C-Blast Putty™ tissue grafts are prepared via a proprietary processing service of Hans Biomed Corp.

DONOR ELIGIBILITY

Donor eligibility (screening and testing) is performed in accordance with AATB standards, and FDA regulations and MFDS regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor eligibility has been determined by HansBiomed Medical Director.

SEROLOGICAL TESTING

The following required testing was performed and found to be negative or non-reactive. Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II), may have been performed at the time of donor screening, and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed can be provided upon request. Serological testing is performed using FDA-licensed test kit by a laboratory registered with FDA to

5

perform donor testing and certified to perform such testing on human specimens in accordance with the clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services(CMS).

- Antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2)
- Nucleic acid test (NAT) for HIV-1
- Hepatitis B surface antigen (HBsAg)
- Nucleic acid test(NAT) far the hepatitis B virus (HBV)
- Total antibodies to hepatitis B core antigen (anti-HBc-total, meaning IgG and IgM)
- Antibodies to the hepatitis C virus (anti-HCV)
- Nucleic acid test (NAT) for HCV
- Syphilis (a non-treponemal or treponemal-specific assay may be performed.)

MICROBIOLOGICAL TESTING

Tissue is subjected to microbiological testing at recovery and in the course of processing, and must be free of specific aerobic / anaerobic bacteria and fungi contaminants whose presence would preclude tissue processing or transplantation.

RECIPIENT RECORD

Product recipient records must be maintained by the physician, transplant facility or hospital for the purpose of tracing tissue post-implantation. A Traceability record and peel-off chart labels have been included in the packaging of this product. This record must be completed at the time of the surgical procedure. Please record the name and address of the transplant facility, physician name, allograft tissue information (use a chart label), and comments on use of the product. The original form or copy must be sent back to Citagenix Inc., when completed and the rest should be retained by the transplant facility or physician for future reference. If the entire tissue product is discarded, filled out the reason and method for discarding the product and this record must be sent back to Citagenix Inc.

6

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

LABELING SYMBOLS

Symbols used on some package labeling for easy identification.

REF	Catalogue number
LOT	Lot number
STERILE R	Sterilization using irradiation
	Do Not Re-use
	See Instructions for Use
	Temperature Limitation
	Use by
	Manufacturer

HOW SUPPLIED

	Syringe size	Cat. #
C·GRAFT PUTTY™	0.3 cc	CG-P03
	0.5 cc	CG-P05
	1 cc	CG-P10
	3 cc	CG-P30
C·BLAST PUTTY™	0.3 cc	CB-P03
	0.5 cc	CB-P05
	1 cc	CB-P10
	3 cc	CB-P30

HANS Biomed

HansBiomed Corp.
64, Yuseong-Daero 1628beon-gil,
Yuseong-gu, Daejeon,
Republic of Korea (34054)
Tel. 82-42-478-9001 Fax 82-42-478-9006
www.hansbiomed.com

CITAGENIX

Distributed by Citagenix Inc.
3300 Autoroute Jean-Noël-Lavoie (A-440) O
Laval, Qc, Canada H7T 2H6
Toll free : 1 877-243-6724 (North America)
Tel.: +1-450-688-8699
Fax : +1-450-688-1977
info@citagenix.com
www.citagenix.com

GP-3021.4 (2018/01)
Document # : CB059-1801R4