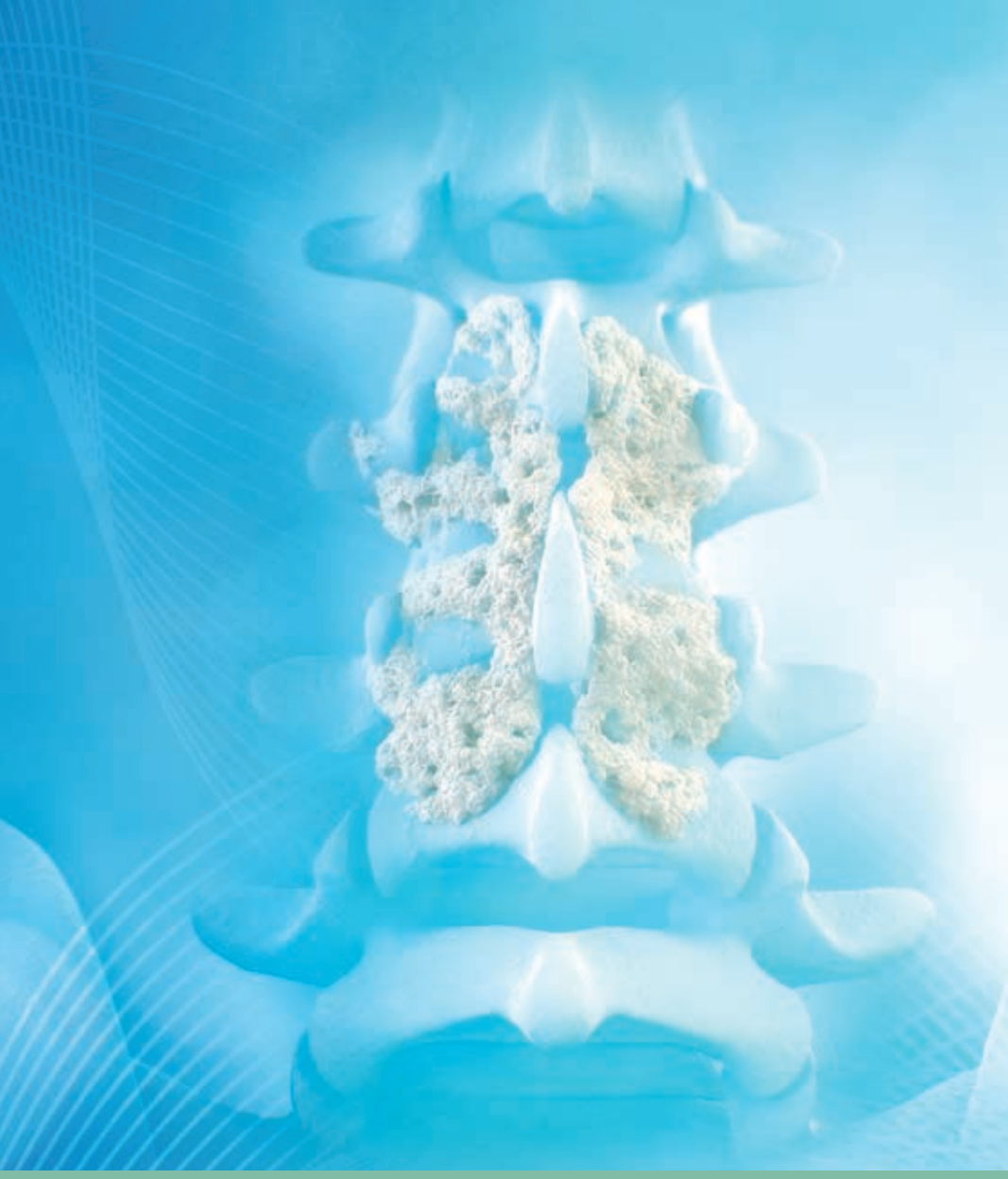


ViaCell®

Viable Cell Allograft

SURGICAL TECHNIQUE GUIDE

GLOBUSMEDICAL.COM/BIOMATERIALS | *Life moves us*

GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us

SURGICAL TECHNIQUE GUIDE

ViaCell®

ViaCell®

Viable Cell Allograft

ViaCell® is a natural cellular bone allograft containing viable cells including inherent mesenchymal stem cells and osteoprogenitor cells, which are essential requirements for bone formation. ViaCell® has many of the same characteristics as the current gold standard of bone grafting, iliac crest bone graft, without the morbidity associated with autograft harvesting.

The components of ViaCell® provide the three essential elements of bone formation:

- **Osteogenic cells**
- **Osteoconductive scaffold**
- **Osteoinductive growth factors**

ViaCell® is a cohesive putty that can easily be molded and delivered to the treatment site.

By **Unlocking The Cell™**, ViaCell® has been designed and developed to expose the cell's inherent regenerative properties.

ViaCell® is minimally processed human tissue regulated by the FDA under 21 CFR Part 1271 and Section 361 of the Public Health Service Act.

Unlocking the Cell™

ViaCell® has been shown to contain 3 million or more cells per cc, including inherent mesenchymal stem cells and osteoprogenitor cells.[1]

The **OSTEOGENIC**, **OSTEOCONDUCTIVE**, and **OSTEOINDUCTIVE** properties of ViaCell® work together to facilitate bone healing and new bone regeneration.

Osteogenic Cells

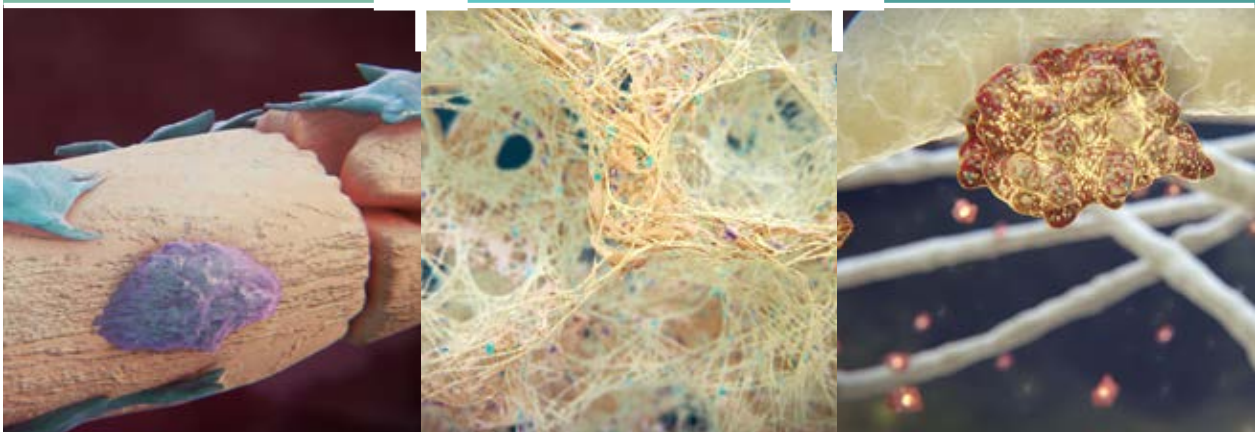
Mesenchymal stem cells (MSCs) and osteoprogenitor cells (OPCs) are naturally found in cancellous bone and are capable of differentiating into osteoblasts.[2-6]

Osteoconductive Scaffold

The cancellous chips and partially demineralized cortical fibers provide a natural bone matrix for cellular attachment and bone growth.[6]

Osteoinductive Growth Factors

Inherent growth factors provide the signals necessary for osteoprogenitor cells to differentiate into osteoblasts and form new bone.[7-8]



SURGICAL TECHNIQUE

ViaCell®

STEP 1 SITE PREPARATION

Proper positioning of the patient is determined by the surgical approach. Determine the amount of ViaCell® to be used based on the size or volume of the site.

STEP 2 IMPLANT PREPARATION

Open the nested pouches and remove the jar.

Note: The outside of the vial and pouch packaging are not sterile.

STEP 3 IMPLANT THAWING

Place the jar containing ViaCell® in a sterile basin containing warm (35°C to 39°C; 95°F to 102.2°F) sterile saline. The jar should remain in the saline until the contents are able to move freely throughout the jar when overturned. Remove the vial from the warm saline once it is thawed. ViaCell® thaws in approximately 20 minutes.

Note: ViaCell® should not be implanted prior to thawing, and is recommended for use within 2 hours of thawing.

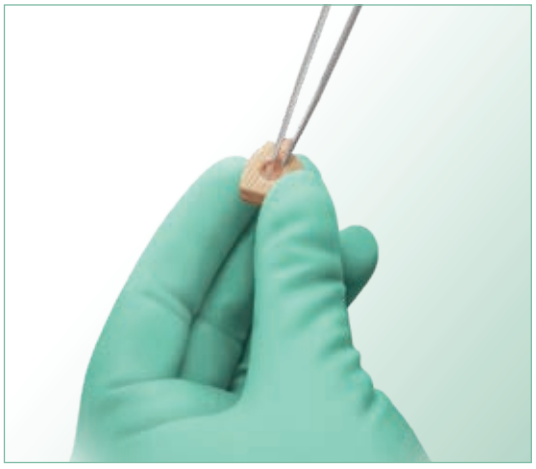
STEP 4 DECANT CRYOPROTECTANT

Decant the cryoprotectant just prior to use.

Note: Rinsing is not required prior to use. If rinsing is performed, avoid vigorous agitation.

STEP 5 IMPLANT INSERTION

Gently pack the site with ViaCell®, avoiding overfilling the bony defect or compressing the treatment site. ViaCell® can be molded and contoured as desired.



ViaCell®
IMPLANT LIST

Part No.	Description
8137.0001S	ViaCell® 1cc
8137.0005S	ViaCell® 5cc
8137.0010S	ViaCell® 10cc

REFERENCES

1. Data on file.
2. Yusuke S et al. Suspended cells from trabecular bone by collagenase digestion become virtually identical to mesenchymal stem cells obtained from marrow aspirate. *Blood*. 2004; 104: 2728–2735.
3. Knight M et al. Mesenchymal stem cells in bone regeneration. *Adv Wound Care*. 2013; 2(6): 306–316.
4. Tuli R et al. A simple, high-yield method for obtaining multipotential mesenchymal progenitor cells from trabecular bone. *Mol Biotechnol*. 2003; 23(1): 37–49.
5. Chamberlain G et al. Concise review: mesenchymal stem cells: their phenotype, differentiation capacity, immunological features, and potential for homing. *Stem Cells*. 2007; 25(11): 2739–2749.
6. Kraus K et al. Mesenchymal stem cells and bone regeneration. *Vet Surg*. 2006; 35(3): 232–242.
7. Hinsenkamp M et al. Growth factors in orthopaedic surgery: demineralized bone matrix versus recombinant bone morphogenetic proteins. *Int Orthop*. 2015; 39(1): 137–147.
8. Holt D et al. Demineralized bone matrix as a vehicle for delivering endogenous and exogenous therapeutics in bone repair. *Adv Drug Deliv Rev*. 2012; 64(12): 1123–1128.

IMPORTANT INFORMATION ON ViaCell® VIABLE CELL ALLOGRAFT

DESCRIPTION

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.

ViaCell® is a viable cellular allograft packaged in a cryoprotectant and stored frozen.

ViaCell® is supplied by GLOBUS MEDICAL and is processed and prepared by Bone Bank Allografts (BBA). All recovery, processing and distribution costs were reimbursed in part by GLOBUS MEDICAL in accordance with NOTA.

This allograft is aseptically processed. Representative product from each lot undergoes destructive microbiological verification testing per USP <71> and must show "no growth" following 14 days on culture.

REGULATORY CLASSIFICATION

This allograft is a human tissue product for transplantation. It is processed and distributed by Bone Bank Allografts, an American Association of Tissue Banks (AATB) accredited institution, in accordance with FDA requirements for Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271) and State regulations.

CAUTION: Federal Law restricts this product to sale by or on the order of a licensed practitioner. Human Tissue for transplant shall not be offered, distributed or dispensed for veterinary use.

APPLICATIONS FOR USE

- This allograft may be used for the treatment of musculoskeletal defects.
- This allograft is intended for single patient use only.

DONOR RECOVERY AND SCREENING

After authorization for donation is obtained, surgical recovery of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments. Donor eligibility is carefully evaluated as required by the US FDA, other regulatory standards, and applicable state guidelines. Tissue donors are evaluated for high risk behaviors and relevant communicable diseases. Screening includes a review of the donor medical and social history, a physical assessment of the donor, an autopsy review (if performed), serological screening, tissue recovery microbiology, and cause of death.

Each donor is tested and shown to be negative or nonreactive for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- HIV1/HCV/HBV Nucleic Acid Test (NAT)

Either of the following CMV testing has been performed and shown to be negative or nonreactive:

- CMV Total Ab
- CMV IgM

Additional CMV testing that may have been performed:

- CMV IgG

The following test(s) may have also been performed and shown to be negative or nonreactive:

- Human T-Cell Lymphotropic Virus Type I Antibody
- Human T-Cell Lymphotropic Virus Type II Antibody
- West Nile Virus Nucleic Acid Test (NAT)

This testing is performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

BONE BANK ALLOGRAFTS' Medical Director has determined this donor tissue to be suitable for transplantation. The testing and medical release records are maintained by BONE BANK ALLOGRAFTS.

PROCESSING

ViaCell® is processed in a controlled environment using methods designed to prevent contamination and cross contamination. Final products are packaged according to approved specifications and procedures and cryopreserved for safe, long-term storage and shipping.

NOTE: ViaCell® will naturally vary in color from pink, pale pink, and yellow to pale yellow.

CONTRAINDICATIONS

Trace amounts of antibiotics, antimycotic, and other reagents could remain after processing. Patients who have sensitivities to the substances used in the processing of ViaCell®, listed under warnings should not receive ViaCell®.

WARNINGS

Careful donor screening, laboratory testing, and tissue processing have been utilized to minimize the risk of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this graft cannot be guaranteed to be free of all pathogens.

Trace amounts of Povidone-iodine, Vancomycin, Meropenem, and Amphotericin B may be present. The product contains a cryopreservative consisting of an aqueous solution with 10% Dimethyl Sulfoxide (DMSO) in MEM-Alpha.

Do NOT reuse or sterilize.

Do NOT refreeze product if thawed.

Proprietary physiological buffers, acids, alcohols and surfactants are used during processing. Allograft tissue may contain traces of these processing agents.

Caution should be used for the following conditions:

- Severe neurological or vascular disease
- Hypercalcemia
- Pregnancy
- Local infection
- Systemic and/or metabolic disorders that affect the bone or wound healing
- Conditions in which general bone grafting is not advisable
- Any patient unwilling to follow postoperative instructions
- Any case not described in the applications for use

PACKAGING AND LABELING

Each allograft distributed by GLOBUS MEDICAL is identified by its own unique serial number. ViaCell® is packaged in a vial and is supplied frozen. Contents of the vial have been processed aseptically and have passed testing according to USP <71> sterility tests.

WARNING: If the double pouch packaging is compromised or shows evidence of being damaged or opened, DO NOT USE!

ViaCell® is supplied frozen.

TRANSPORT AND STORAGE OF FROZEN GRAFTS

ViaCell® is shipped frozen on dry ice via overnight courier. Upon arrival, product should be removed from the shipping container and placed in appropriate frozen storage. The recommended storage temperature for ViaCell® is -40°C or lower.

EXPIRATION

See package label for expiration date or observe the above indications for alternate tissue storage.

It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to track expiration date accordingly.

USAGE INSTRUCTIONS

Before Usage:

Examine Allograft Package – Do Not Use This Allograft If:

1. Any of the package or product elements appear to be missing, tampered with or damaged.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed.
4. Frozen allograft has not been stored according to storage temperature requirements or the allograft has been prematurely thawed.

If any of the above conditions exist or are suspected, this allograft should NOT be used.

ViaCell® is packaged in a vial. The contents of the vial have been processed using an aseptic technique and have undergone destructive microbiological verification testing per USP <71> Sterility Tests. The test results must show "NO GROWTH" after 14 days.

Directions for Use:

ViaCell® is packaged in a screw top vial. The vial and double pouch packaging are sterilized prior to aseptic processing. The outer pouch is not sterile. Appropriate handling is required to avoid contamination of the product or the sterile operative field.

IMPORTANT INFORMATION ON ViaCell® VIABLE CELL ALLOGRAFT

Prepare the allograft for use using the following procedures:
1. Maintain at -40°C or lower until immediately prior to use. Open the package and remove the double pouches containing the vial from the carton.
2. Open the nested pouches and remove the vial.
3. In a clean product field, place the closed vial in a warm sterile water or saline bath (35°C-39°C). Thaw the vial for 20-30 minutes until the contents of the vial are in a flowable liquid state.
    - Once thawed, keep the ViaCell® allograft in the cryoprotectant solution.
    - When ready to implant, decant the cryoprotectant solution.
      NOTE: Implant ViaCell® within 2 hours of thawing for optimal cell viability

Frozen Tissues:
NOTE: Before use, the allograft must be thawed. The allograft must not be refrozen after thawing.

RETURNS

No ViaCell® returns will be accepted if the original container has been opened, the tamper evident seal has been compromised, or if the package has exceeded expiration of dry ice validation. All frozen tissue returns are at the sole discretion of Bone Bank Allografts.

PATIENT RECORD

Recipient records must be maintained for the purpose of tracking tissue post-transplant. IMPORTANT NOTICE TO END-USER: Please record this distinct graft identification code in your records and in the patient's medical record. It is also recommended that the following information be recorded in the patient's medical record:
1. Description of Tissue
2. Product Code
3. Expiration Date
4. Description of Procedure
5. Date and Time of Procedure
6. Surgeon Name
7. Any Other Pertinent Information

A Transplant Record has been included with each package of tissue. Please record the patient name, distinct graft identification code, date of birth, sex, name and address of the healthcare facility, name of the transplanting physician, date and type of surgery, name of the person filling out the Transplant Record and any comments. Once completed, the bottom copy of the Transplant Record should be returned to BONE BANK ALLOGRAFTS. Copies of this information should be retained by the transplant facility for future reference.

POTENTIAL COMPLICATIONS

ViaCell® contains allogeneic proteins and cells which have the potential for hypersensitivity, allergic reactions or other immune responses. All adverse outcomes potentially attributed to the ViaCell® must be promptly reported to GLOBUS MEDICAL.

Possible complications can occur with any surgical procedure including, but not limited to pain, infection, hematoma, incomplete or lack of bony growth at treatment site, and/or immune rejection of the introduced tissue.

Disease screening methods are limited; therefore, certain diseases may not be detected.

The following complications of tissue transplantation may occur:
- Transmission of diseases of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.
- Immune reaction to implanted HCT/P

DISPOSAL

Allograft disposal shall be in accordance with local, state, and federal regulations for human tissue.

INQUIRIES

For additional information, to place an order, or to report adverse reactions, contact:
GLOBUS MEDICAL Client Services at 1-866-GLOBUS1 (456-2871).

ALLOGRAFT TISSUE PROCESSED BY:

Bone Bank Allografts
5335 Castroville Road
San Antonio, Texas 78227

TRANSPLANT RECORD RETURNED TO:

Bone Bank Allografts
5335 Castroville Road
San Antonio, Texas 78227

EXT-190 (RO4)
9/2023

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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