
ALLOCYTE®+
Advanced Viable Bone Matrix

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HARNESSING NATURE & TECHNOLOGY WITH EASE

YOU ASKED FOR AN EASY-TO-USE, STREAMLINED PREPARATION PROCESS, AND WE HEARD YOU!

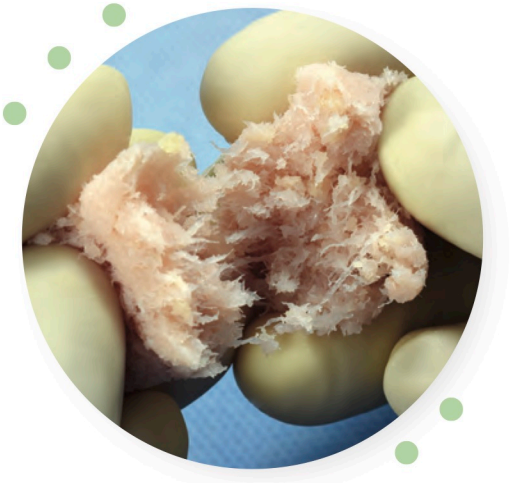
ALLOCYTE® ***Plus*** allograft is the next generation solution for bone formation to support a variety of potential clinical applications. The allograft is packaged in an easy-to-use syringe with minimal preparation time of under 15 minutes. A proprietary process preserves the native bone cells in a DMSO-free (free of dimethyl sulfoxide) cryoprotectant, requiring no rinsing or decanting — just thaw and use!

ALLOCYTE® Plus Provides the Three Key Elements Ideal for Bone Formation

- An osteoconductive three-dimensional scaffold with cortical and cancellous components.
- A demineralized cortical bone scaffold. Demineralized cortical bone has been identified to have osteoinductive potential.[1]
- Viable endogenous bone cells to support osteogenic healing processes.

KEY FEATURES AND BENEFITS

- Average cell viability exceeds 92% post-thaw[2]
- Average of 1.5 Million viable cells per cc of allograft[2]
- No rinsing or decanting steps required — native bone cells are preserved in a DMSO-free cryoprotectant
- Four-hour working window for implantation after thaw without loss of cell viability
- Packaged in easy-to-use syringe



Bone Scaffold Delivers Osteoconductive and Osteoinductive Potential

ALLOCYTE® ***Plus*** provides an osteoconductive bone scaffold composed of mineralized cancellous bone along with demineralized cortical fibers. Bone fibers offer superior osteoconductivity when compared to powder due to the increased ability for cells to migrate along fibers, creating “cellular highways” for bone formation.[3] In contrast, particulate-based demineralized bone matrices (DBMs) have gaps between the particles that osteoblasts cannot always bridge across.[3] The demineralized cortical fibers are supplemented with cancellous chips to deliver a 100% human-derived product that mimics the particulate structure of native bone.

Cells Protected by Proprietary Cryoprotectant

- Protective coating preserves allograft and prevents crack propagation and membrane lysis[2]
- Retains over 92% cell viability after thaw[2]
- Non-cytotoxic, non-DMSO
  - Reduces concerns about cytotoxicity and negative effects on cell differentiation[4,5,6]
  - Does not require rinsing or decanting

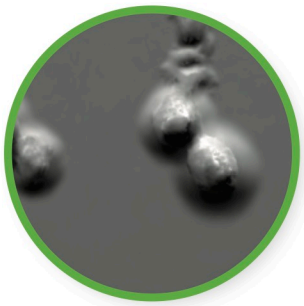


Figure 1*: Cells protected with cryoprotectant to prevent crystalline damage (previously frozen)

**Image captured by SEM*

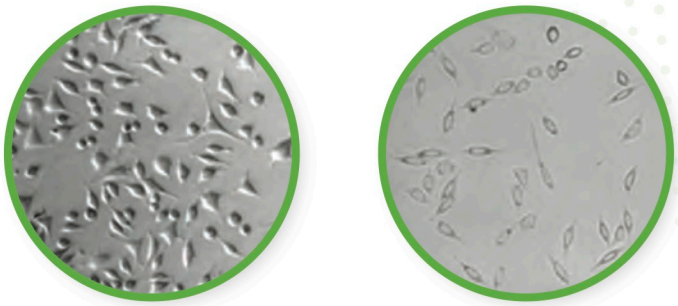


Figure 2: Cytotoxicity assay showing higher number of viable cells in media containing up to 10% cryoprotectant (left) compared to media containing 2.5% DMSO (right), after 48 hours incubation

Proper preservation of cellular allografts requires strict adherence to recovery and processing protocols. To manufacture **ALLOCYTE® *Plus***, viable endogenous bone cells are collected from the donor and preserved with the use of a novel DMSO-free cryoprotectant, which uses an extracellular protective coating on the cell to prevent crack propagation and membrane lysis[2] (Figure 1). Industry standard DMSO penetrates the cell and prevents crystal formation from within. At room temperature, DMSO-based cryoprotectants raise concerns about cytotoxicity and negative effects on cell differentiation (Figure 2).[4,5,6]

The cryoprotectant in **ALLOCYTE® *Plus*** provides a surgical procedure advantage over other cryoprotectants containing DMSO. Allografts treated with cryoprotectant experience minimal cell loss and retain, on average, over 80% cell viability after thaw[2]. It also allows for usage up to four hours after thawing and **ALLOCYTE® *Plus*** allografts can be stored for up to one year at or below -65°C.

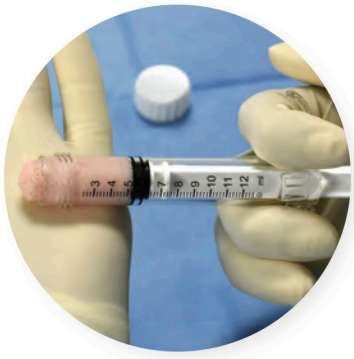
The bone cells are endogenous to the cancellous bone, remaining attached throughout the donor tissue processing event. Strict donor criteria and quality control processes verify a viable cell population for osteogenic supplementation as a viable structural allograft.

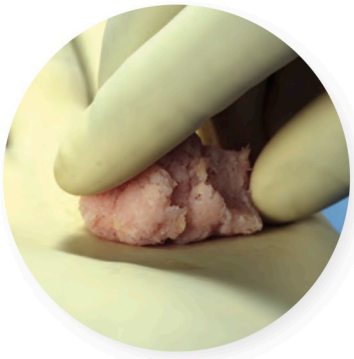
IT ALL ADDS UP

- Improved storage container streamlines preparation: thaw product in provided syringe and use
- A natural, 100% tissue scaffold of demineralized cortical bone fibers coupled with chips rich with endogenous bone cells provides an optimal microenvironment for osteogenesis and excellent handling
- A proprietary DMSO-free cryoprotectant that protects and allows for consistent delivery of viable allograft to the patient
- A viable cell population for osteogenic supplementation as a viable structural allograft

ORDERING INFORMATION

Product Code	Product Description	Size
ACBMP-010	**ALLOCYTE**® ***Plus*** Advanced Viable Bone Matrix	1.0cc
ACBMP-025	**ALLOCYTE**® ***Plus*** Advanced Viable Bone Matrix	2.5cc
ACBMP-050	**ALLOCYTE**® ***Plus*** Advanced Viable Bone Matrix	5.0cc
ACBMP-100	**ALLOCYTE**® ***Plus*** Advanced Viable Bone Matrix	10.0cc





Sanara MedTech has used reasonable efforts to provide accurate and complete information herein, but this information should not be construed as providing clinical advice, dictating reimbursement policy, or as a substitute for the judgment of a health care provider. It is the health care provider's responsibility to determine the appropriate treatment, codes, charges for services, and use of modifiers for services rendered and to submit coverage or reimbursement-related documentation.

References: 1. Gruskin, E. et.al., Demineralized bone matrix in bone repair: history and use. Advanced Drug Delivery Reviews, 2012. 64:1063-1077 **2.** Data on file at Vivex Biologics, Inc. **3.** Martin GJ Jr, Boden SD, Titus L, Scarborough NL, "New formulations of demineralized bone matrix as a more effective graft alternative in experimental posterolateral lumbar spine arthrodesis.", Spine. 1999 Apr 1;24(7):637-45. **4.** Best, Benjamin. P. Cryoprotectant Toxicity: Facts, Issues, and Questions. Rejuvenation Research, 2015. Vol. 18, No. 5. **5.** Renzi, S., et al., Mesenchymal stromal cell cryopreservation. Biopreservation and Biobanking, 2012. 10(3): p. 276-281. **6.** Asghar, W., et al., Preserving human cells for regenerative, reproductive, and transfusion medicine. Biotechnology Journal, 2014. 9: p. 895-903.

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