



ZAVATION®

ZAVATRIX®

Viable Bone Allograft



Product Brochure

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Harnessing Nature & Technology with Ease

Zavatrix 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. The native bone cells are preserved in a DMSO-free (free of dimethyl sulfoxide) cryoprotectant, VIA Coat™, requiring no rinsing or decanting—just thaw and use!

Provides 3 Key Elements Ideal for Bone Formation

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



Bone Scaffold Delivers Osteoconductive & Osteoinductive Potential

Zavatrix 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.

Features & Benefits

- No rinsing or decanting steps required—native bone cells preserved in a DMSO-free cryoprotectant
- Four-hour window for implantation after thaw without loss of cell viability
- Packaged in easy-to-use syringe
- Average cell viability exceeds 92% post-thaw²
- Average of 1.5 million viable cells per cc of allograft²

Cells Protected By Proprietary VIA Coat™ Cryoprotectant

- Protective coating preserves allograft and prevents crack propagation and membrane lysis²
- Retains over 92% cell viability after thaw²
- Non-cytotoxic, non-DMSO
 - Reduces concerns about cytotoxicity and negative effects on cell differentiation^{4,5,6}
 - Does not require rinsing or decanting



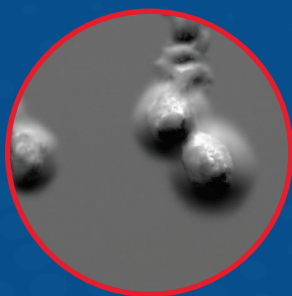
Proper preservation of cellular allografts requires strict adherence to recovery and processing protocols. To manufacture Zavatrix, viable endogenous bone cells are collected from the donor and preserved with the use of a novel DMSO-free cryoprotectant, VIA Coat, which uses an extracellular protective coating on the cell to prevent crack propagation and membrane lysis² (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.^{4,5,6}

The patented and proprietary VIA Coat cryoprotectant is a differentiated technology that is applied to a number of products in our portfolio. The VIA Coat technology provides our products with distinct advantages over DMSO-based cryoprotectant technology used in competitive products. As an added bonus, because VIA Coat is DMSO-free, it does not require the multiple rinsing and decanting steps of DMSO-based cryoprotectants. Rinsing steps can diminish both the cell viability and the inherent regenerative properties of allografts.

VIA Coat provides a surgical procedure advantage over other cryoprotectants containing DMSO. Allografts treated with VIA Coat experience minimal cell loss and retain, on average, over 80% cell viability after thaw². VIA Coat also allows for usage up to four hours after thawing and VIA Form+ 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.

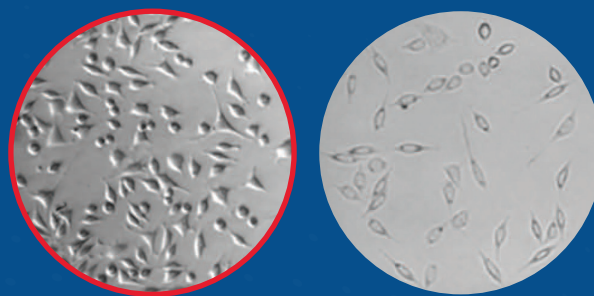
Figure 1*



Cells protected with VIA Coat to prevent crystalline damage (previously frozen)

*Image captured by SEM

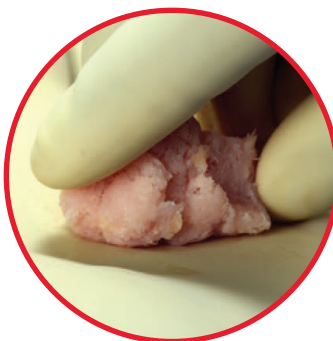
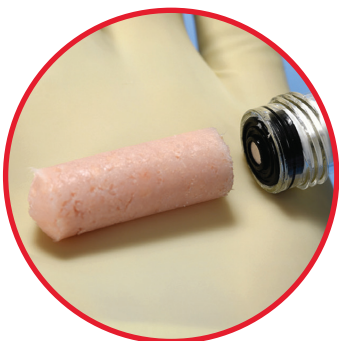
Figure 2



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

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, VIA Coat, 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

Customer Service

For product or ordering information, contact us at (601) 919-1119 or (888) 349-7808.

Set Request

For any set requests, email setrequest@zavation.com

Product Offering	
Catalog No.	Description
850-02	Zavatrix Viable Bone Allograft, 2.5cc
850-05	Zavatrix Viable Bone Allograft, 5cc
850-10	Zavatrix Viable Bone Allograft, 10cc

Sales Orders

For sales orders, email salesorders@zavation.com

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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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