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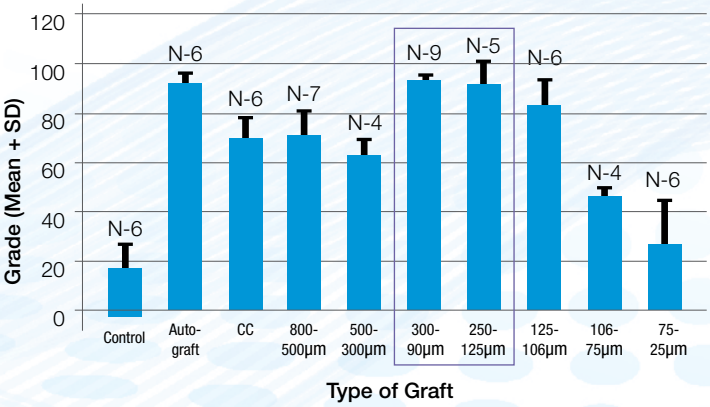
ensuring physicians have the best solutions for their patients

EnduriFuse™

EnduriFuse™ is allograft bone containing three key elements ideal for bone formation

- An **osteoconductive** three-dimensional scaffold with cortical and cancellous components.
- A demineralized bone scaffold with **osteoinductive** potential.[1]
- Viable spine-derived cells to **support osteogenesis.**



Particle Size Makes a Difference

EnduriFuse provides an osteoconductive bone scaffold composed of demineralized cortical and mineralized cortical and cancellous bone. The optimized microparticulate bone scaffold size range of **100-300 µm** has been shown to induce simultaneous activity of osteoclasts and osteoblasts, supporting rapid bone formation in bone defects.[2]

Figure 1: 100-300 µm optimized particle size for bone regeneration has been shown to support direct ossification, with results comparable to autograft.[2]

A Differentiated Technology

Proper preservation of cellular allografts requires strict adherence to recovery and processing protocols. In the EnduriFuse advanced bone matrix, viable spine-derived cells are collected from the vertebral body region of 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[1] (Figure 2). 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.[3,4,5]

The patented and proprietary cryoprotectant is a differentiated technology. This protective coating utilized to preserve EnduriFuse provides distinct advantages over DMSO-based cryoprotectant technology used in competitive products. DMSO-based cryoprotectant requires multiple rinsing and decanting steps which may result in the loss of cells that remain in the rinsing solution.

This innovative cryoprotectant provides a surgical procedure advantage over other cryoprotectants containing DMSO. EnduriFuse advanced bone matrix experiences minimal cell loss and retains, on average, over 80% cell viability after thaw[1], may be used up to four hours after thawing and can be stored for up to three years at or below -65°C.

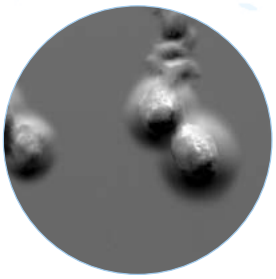


Figure 2*: Cells protected with DMSO-free cryoprotectant prevent crystalline damage (previously frozen)

*Image captured by SEM

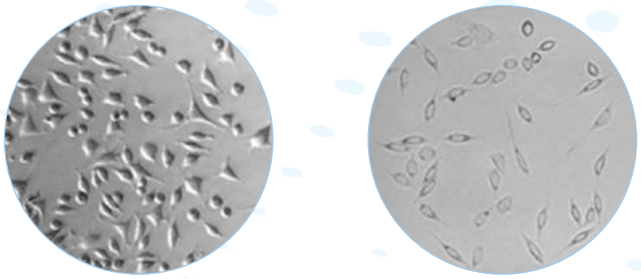


Figure 3: Cytotoxicity assay showing higher number of viable cells in media containing up to 10% DMSO-free cryoprotectant (left) compared to media containing 2.5% DMSO (right) after 48 hours incubation

A Viable Structural Allograft

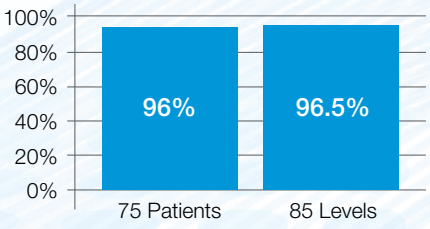
The cell component of EnduriFuse is collected from the vertebral body region of the donor. Strict donor criteria and quality control processes, including cell count and viability, ensure a favorable safety profile and support a viable cell population for osteogenic supplementation of the allograft bone matrix.

Operating Room Ease of Use

- No rinsing or decanting steps required
- Average cell viability consistently exceeds 80% post-thaw[1]
- Minimum of 150,000 viable cells per cc of allograft[1]
- Four-hour working window for implantation after thaw without loss of cell viability

A Growing Body of Evidence

MIS-TLIF study demonstrated 96% fusion at 12 months.[6]



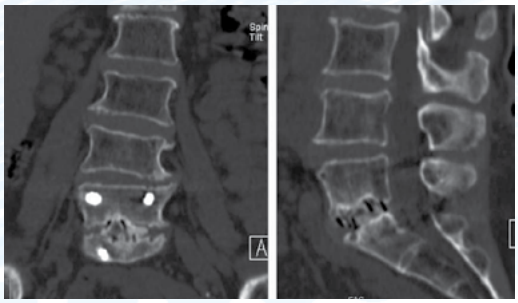
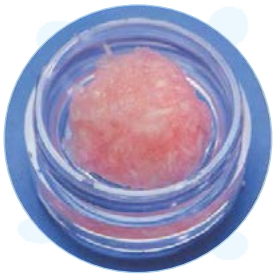


Figure 4: A 54-year-old woman underwent treatment for radiculopathy secondary to disc herniation. Bridging bone is apparent at the L5-S1 intervertebral level.

Advantages of EnduriFuse Advanced Bone Matrix:

- An allogeneic, osteoconductive scaffold with osteoinductive potential.[1]
- A viable cell population to support osteogenic processes.
- A proprietary DMSO-free cryoprotectant that allows for consistent delivery of viable allograft to the patient.

Product Number	Description	Size
EFCBM0250	EnduriFuse, Advanced Bone Matrix	2.5cc
EFCBM0500	EnduriFuse, Advanced Bone Matrix	5cc
EFCBM1000	EnduriFuse, Advanced Bone Matrix	10cc



EnduriFuse™ Advanced Bone Matrix

Preparation Guide

1. Prepare a sterile saline or sterile water bath at room temperature for thawing of the bone gel jar and cell vial.

2. Remove the bone gel jar from the inner pouch using standard aseptic technique and place in the bath to thaw.

3. Remove the cell vial(s) from the inner pouch using standard aseptic technique and place the vial in the bath for 3-5 minutes, or until the contents of the cell vial have completely thawed.

4. While the bone gel jar and cell vial are both thawing, remove the chevron peel pouch containing the bone particulate jar and spatula.

5. Remove the liner from the inside of the bone particulate jar, and add sterile saline directly to the bone particulate jar. Refer to the table below for specific volumes of saline for each size.

EnduriFuse™ Size	2.5cc	5 cc	10 cc
Saline Volume	0.5 mL	1 mL	2 mL

6. Using the spatula, mix the contents of the saline and bone particulate thoroughly.

7. After the contents of the cell vial have completely thawed, carefully invert the cell vial at least three times.

8. Pour the contents of the thawed cell vial directly into the jar containing the bone particulate/saline mixture.

9. Using the spatula, mix the contents of the cell vial and the bone particulate/saline thoroughly.

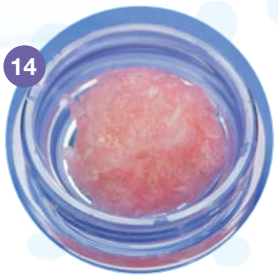
10. Once the bone particulate and cell vial(s) contents are mixed thoroughly, remove the bone gel jar from the bath and place the bone gel onto the palm of the hand.

11. Using the spatula, press and spread the bone gel into the hand repeatedly until a smooth and homogenous paste consistency is obtained.

12. Transfer the mixture of cells/bone particulate onto the prepared bone gel in the hand.

13. Mix the cell/bone particulate/bone gel mixture thoroughly until all components are incorporated and a uniform consistency is obtained.

14. The prepared allograft should be placed back into the jar and capped until ready for use and must be implanted within 4 hours from the time of initial cell thaw.



Note: Please refer to the EnduriFuse package insert for complete allograft preparation instructions and any additional product information.

1. Data on file at Vivex Biologics, Inc.
2. Malinin, T.I., et. al., Particulate bone allograft incorporation in regeneration of osseous defects; importance of particle sizes. The Open Orthopeadics Journal, 2007. 1:19-24.
3. Best, Benjamin. P. Cryprotectant Toxicity: Facts, Issues, and Questions. Rejevenation Research, 2015. Vol. 18, No. 5.
4. Renzi, S., et al., Mesenchymal stromal cell cryopreservation. Biopreservation and Biobanking, 2012. 10(3): p. 276-281.
5. Asghar, W., et al., Preserving human cells for regenerative, reproductive, and transfusion medicine. Biotechnology Journal, 2014. 9: p. 895-903.
6. Tally, William C, et al., Transforaminal Lumbar Interbody Fusion with Viable Allograft: 75 Consecutive Cases at 12-Month Follow-Up. International Journal of Spine Surgery, 2018. Vol. 12, No. 1 pp 76-84.

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