ParametricsMedical

ensuring physicians have the best solutions for their patients

EnduriFuse™

Advanced Bone Matrix

Allograft bone containing three key elements ideal for bone formation

Welcome to Parametrics Medical

Parametrics Medical provides the latest advancements in allograft tissue, biologic implants, and regenerative medicine designed to enhance surgical outcomes and improve patient quality of life while honoring the gift of donated human tissue.

Our Mission

Ensuring physicians have the best solutions for their patients.

Customer Service

Parametrics Medical provides world-class customer service. Historically, we fill over 98% of orders placed, and we respond to requests in less than three minutes.

Place Your Order with Parametrics Medical

- Orders must be placed by 4 PM CST for next-day arrival
- sales@parametricsmedical.com
- 1-888-494-2240
- 1-719-941-9766
- Normal business hours are 8 AM to 5 PM CST

Shipping Options

PO-Shipping | Priority Overnight, Frozen (10:30am)

FO-Shipping | First Overnight, Frozen (8:00am)

5Day-Shipping | 5 Day, Extra Ice, Weekend, Frozen

FD-Shipping | Freeze Dried Overnight (10:30am)

Return Policy Overview

Parametrics Medical will not accept tissue for return without a return authorization number. Contact customer service for a return authorization number and additional details regarding the Parametrics Medical Return Policy.

Bone Grafting Epidemiology

Bone grafting in general is a surgical procedure that replaces missing bone and provides a scaffold for new bone growth in numerous clinical applications, including but not limited to fusion. Bone grafts may be autologous (obtained from the patient's body), allogenic (obtained from a donor), or synthetic. Successful bone grafts are designed to have one or more of these three properties:

- **Osteoconductive:** graft acts as a scaffold for the growth of natural bone
- **Osteoinductive:** graft contains growth factors that recruit immature cells and stimulate those cells to develop into active bone-forming cells called osteoblasts
- **Osteogenic:** graft directly provides living cells that contribute to the growth of natural bone

Autograft has long been accepted as the gold standard graft material for these procedures because it possesses all three key properties needed for new bone growth.

Bone Grafting Clinical Challenges Using Autograft

While the use of autograft typically results in high fusion rates, autograft varies in both quality and quantity depending on the patient and site of harvest. Additional concerns associated with autograft harvest include increased surgical time, limited volume availability, surgical site morbidity, potential for blood loss, and infection[1]. A wide range of alternative allogeneic and synthetic graft materials have been made available to surgeons in response to these challenges.

An Alternative to Autograft

EnduriFuse advanced bone matrix contains viable spine-derived cells. EnduriFuse is safe and non-immunogenic[2], providing an ideal alternative to autograft in various orthopedic and spine applications. When combined with the bone component, our cells provide a basis for tissue supplementation that carries the intentions of autograft without the complications associated with its harvest. The EnduriFuse advanced bone matrix utilizes a novel cryoprotectant to preserve the cell component that is DMSO-free, so there is no need to rinse or decant during the preparation of the product.

Donor Recovery and Processing

EnduriFuse advanced bone matrix is recovered from qualified tissue donors that meet strict testing and screening criteria. Testing includes medical and social history, physical examination, medical record review, and serology testing.

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.

The Medical Director reviews all results, and all tissue must be deemed suitable for transplantation.

Donor Criteria and Screening

Test	Symbol
Human Immunodeficiency Virus (HIV)	
HIV-1/2 Antibodies	HIV-1/2-Ab
Nucleic Acid Test for HIV-1 RNA	HIV-1 NAT
Hepatitus B Virus (HBV)	
HBV Surface Antigen	HBsAg
HBV Core Antibody (IgG & IgM)	HBcAb
Nucleic Acid Test for HBV DNA	HBV NAT
Hepatitis C Virus (HCV)	
HCV Antibody	HCVab
Nucleic Acid Test for HCV RNA	HCV NAT
Human T Cell Lymphotrophic Virus I/II (if applicable)	
HTLV-I/II Antibody	HTLV-I/II-Ab*
Syphilis	
Rapid Plasma Reagin Screen	RPR**
T. Pallidum IgG	T. pallidum IgG
Cytomegalovirus CMV Ab (igG & IgM)	

Aseptic Tissue Processing

EnduriFuse advanced bone matrix is processed in compliance with FDA's Human cells, tissues, and cellular and tissue-based products under CFR Title 21 Part 1271. EnduriFuse is processed in current good tissue practice conditions at a state-of-the-art manufacturing facility.

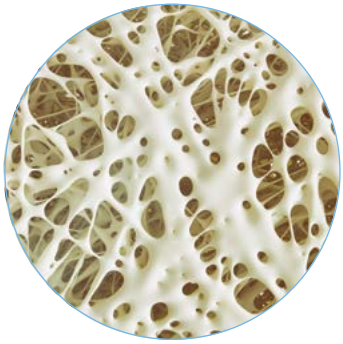
EnduriFuse is processed in an aseptic manner in ISO 5 (Class 100) cleanrooms using procedures and screening criteria that meet the American Association of Tissue Banks (AATB) requirements. Microbiological testing is performed before and after processing to ensure the safety of the final product. EnduriFuse advanced bone matrix has an impeccable record of quality and has been associated with zero disease transmissions.

Three Key Elements of Bone Formation

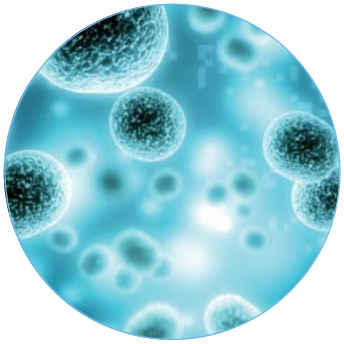
EnduriFuse is allograft bone containing viable spine-derived cells. This innovative graft contains the three key elements that are ideal for bone formation:

- An osteoconductive three-dimensional scaffold with cortical and cancellous components.
- A demineralized bone scaffold with osteoinductive potential which provides exposure of signaling molecules and bone morphogenetic proteins.[3]
- Spine-derived cells to support osteogenic healing processes.

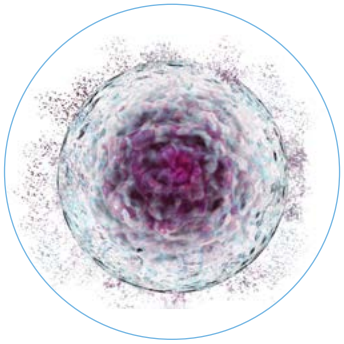
Bone Healing



Osteoconductive



Osteoinductive



Osteogenic

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.[4]

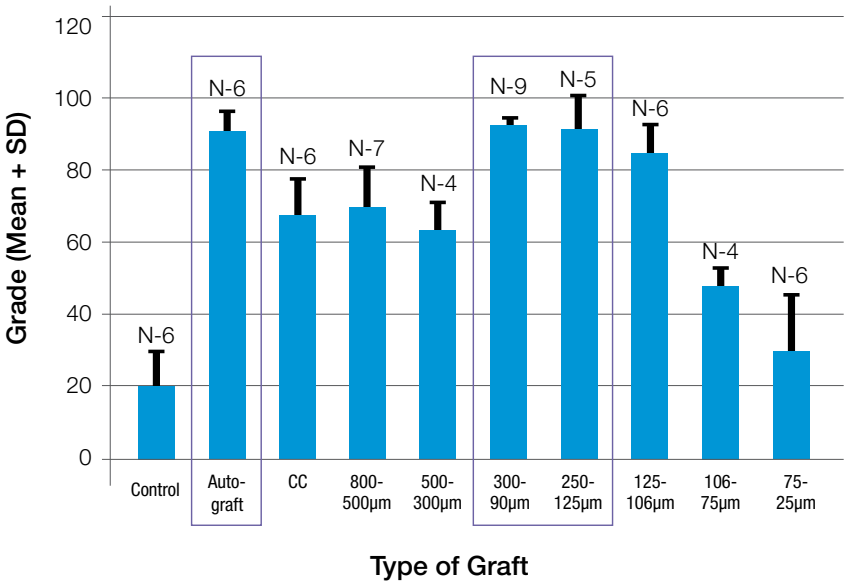


Figure 1: 100-300 µm optimized particle size for bone regeneration has been shown to support direct ossification with results comparable to autograft.[4]

Cell Preservation: 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 using a novel DMSO-free cryoprotectant, which uses an extracellular protective coating on the cell to prevent crack propagation and membrane lysis[2] (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.[5,6,7]

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[2], may be used up to four hours after thawing, and can be stored for up to three years at or below -65°C.

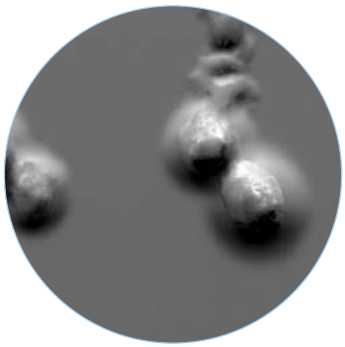


Figure 2*: Cells protected with DMSO-free cryoprotectant prevent crystalline damage (previously frozen)

*Image captured by SEM

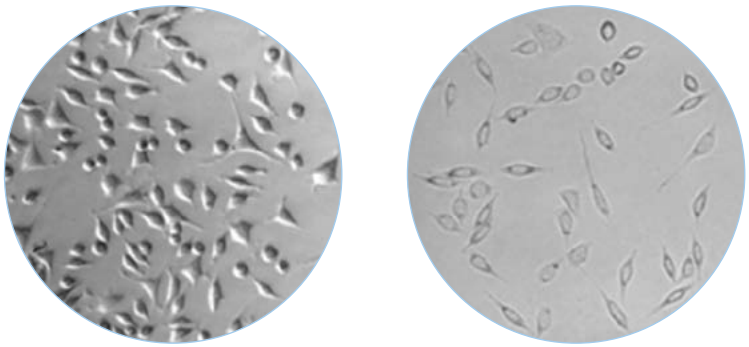
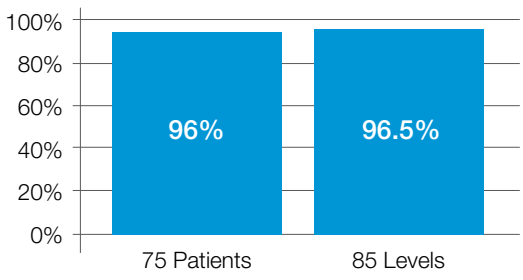


Figure 3: Cytotoxicity assay showing higher number of viable cells in media containing up to 10% DMSO-free cryoprotectant (left) compared to media containing 2.5% DMSO (right) after 48 hours incubation

A Growing Body of Evidence

Clinical studies have demonstrated this innovative technology provides a sufficient scaffold to support de novo bone formation resulting in clinically successful fusion.

MIS-TLIF study demonstrated 96% fusion at 12 months.[8]



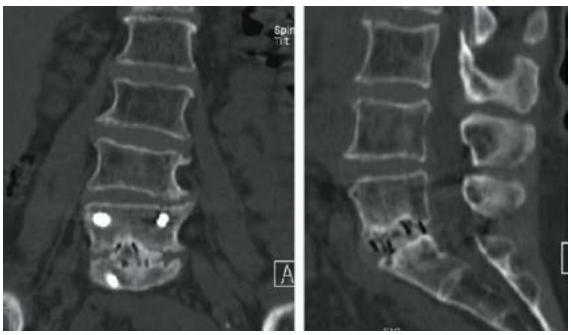
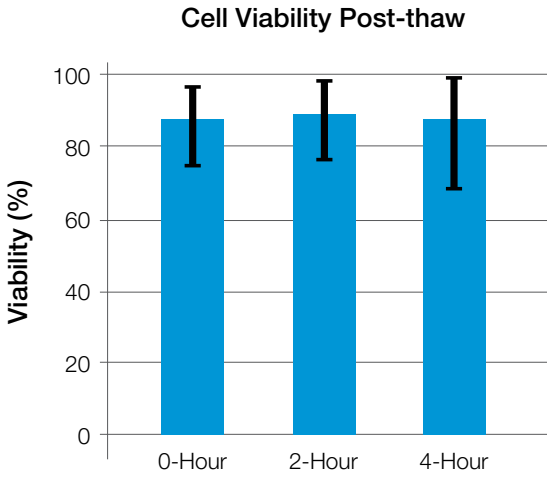


Figure 5: A 54-year-old woman underwent treatment for radiculopathy secondary to disc herniation. Bridging bone is apparent at the L5-S1 intervertebral level.

Clinical Efficiency

EnduriFuse advanced bone matrix offers optimal handling characteristics to provide clinical efficiency in the operating room with benefits which include:

- Proprietary, optimized bone microparticulate size range of 100-300 µm.
- Novel DMSO-free cryoprotectant, with no rinsing or decanting steps before use.
- Product ready to use immediately after thawing and preparation.
- Four (4) hour working window allows for flexible preparation time without loss of cell viability.
- Average cell viability of the cell component exceeds 80% post-thaw.
- Convenient handling and preparation in the OR, with total preparation time on the back table of less than 20 minutes.
- Product shelf-life is three (3) years.



Advantages of EnduriFuse Advanced Bone Matrix:

- An allogeneic, osteoconductive scaffold with osteoinductive potential.[4]
- A viable cell population to support osteogenic processes.
- A proprietary DMSO-free cryoprotectant that allows for consistent delivery of viable allograft to the patient.

EnduriFuse™

Product Number	Size
EFCBM0250	2.5cc
EFCBM0500	5cc
EFCBM1000	10cc

1. Grabowski, G. and R.N. Robertson, Bone allograft with mesenchymal stem cells: a critical review of the literature. Hard Tissue, 2013. 2(2).
2. Data on file at Vivex Biologics, Inc.
3. Gruskin, E., et al., Demineralized Bone Matrix in Bone Repair, History and Use. Advanced Drug Delivery Reviews, 2012. 64: 1063-1077.
4. 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.
5. Best, Benjamin. P. Cryoprotectant Toxicity: Facts, Issues, and Questions. Rejuvenation Research, 2015. Vol. 18, No. 5.
6. Renzi, S., et al., Mesenchymal stromal cell cryopreservation. Biopreservation and Biobanking, 2012. 10(3): p. 276-281.
7. Asghar, W., et al., Preserving human cells for regenerative, reproductive, and transfusion medicine. Biotechnology Journal, 2014. 9: p. 895-903.
8. 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.

ParametricsMedical

ensuring physicians have the best solutions for their patients

888.494.2240 | sales@parametricsmedical.com | 1501 Leander Dr. Ste. 140, Leander, TX 78641 | parametricsmedical.com