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. 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, 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

<table>
<thead>
<tr>
<th>Test</th>
<th>Symbol</th>
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<tbody>
<tr>
<td>Human Immunodeficiency Virus (HIV)</td>
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</tr>
<tr>
<td>HIV-1/2 Antibodies</td>
<td>HIV-1/2-Ab</td>
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<td>Nucleic Acid Test for HIV-1 RNA</td>
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<tr>
<td>HBV Surface Antigen</td>
<td>HBsAg</td>
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<tr>
<td>HBV Core Antibody (IgG &amp; IgM)</td>
<td>HBcAb</td>
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<td>Nucleic Acid Test for HBV DNA</td>
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<tr>
<td>Hepatitis C Virus (HCV)</td>
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<tr>
<td>HCV Antibody</td>
<td>HCVab</td>
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<td>Nucleic Acid Test for HCV RNA</td>
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<tr>
<td>Human T Cell Lymphotrophic Virus I/II (if applicable)</td>
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<td>RPR**</td>
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<td>T. Pallidum IgG</td>
<td>T. pallidum IgG</td>
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<tr>
<td>Cytomegalovirus CMV Ab (IgG &amp; IgM)</td>
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</table>

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.

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.\(^4\)
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°С.

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

*Image captured by SEM

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 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

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.  
- A viable cell population to support osteogenic processes.
- A proprietary DMSO-free cryoprotectant that allows for consistent delivery of viable allograft to the patient.

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**Cell Viability Post-thaw**

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<th>Time</th>
<th>Viability (%)</th>
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<tr>
<td>2-Hour</td>
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<td>4-Hour</td>
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2. Data on file at Vivex Biologics, Inc.