



# Surgical Orthobiologics

Where patient needs are met through innovation.

## Relationships in Sync with Technology

Our desire to build positive relationships with our reps and physicians drives our daily business decisions. We also pursue innovative technology that will put us at the forefront of our industry. Relationships in sync with that technology set AlexiGen apart from the rest. We pride ourselves in meeting patients' needs with the latest innovations in the biologics market.

Our focus is to harness the full potential of our biologics line to address the full spectrum of patients' needs. Our adherence to strict quality standards helps to ensure the safety, efficacy, and reliability of our biologics products.

## Our Foundation

AlexiGen staff believes we should responsibly steward the opportunity we have to bring new ideas and innovations to the medical community and ultimately to their patients and their families. This opportunity stands on the foundation of relationships. Our strict standards permeate every aspect of our daily business, from product testing, delivery, correspondence with physicians, and relationships with our reps.

## AlexiGraft Dual Layer Amnion Patch

AlexiGraft is dehydrated human amniotic membrane derived from the submucosa of placental tissue.

All of these grafts are natural, non-steroidal, and can be used in spinal, reconstructive, and general orthopedic applications.

Part Number	Description
AB-8223	AlexiGraft DL Amnion Patch (2x3cm)
AB-8234	AlexiGraft DL Amnion Patch (3x4cm)
AB-8244	AlexiGraft DL Amnion Patch (4x4cm)
AB-8246	AlexiGraft DL Amnion Patch (4x6cm)
AB-8248	AlexiGraft DL Amnion Patch (4x8cm)

### Potential Benefits:

- may help reduce scarring
- may aid in repairing damaged tissue
- may alleviate pain caused by joint injuries
- may decrease inflammation



# AlexiFuse Demineralized Cancellous Strips

Demineralized Cancellous Strips can be used in general orthopedic, reconstructive, and spine surgery. Upon compression, the strip will expand to its original state, filling the void and minimizing the space between the graft and the host bone. Consisting of 100% demineralized bone matrix, this product has various applications.

## Potential Benefits:

- Osteoinductive & osteoconductive potential
- Room temperature storage
- Variety of sizes available
- Easy to use
- Resists irrigation
- Sponge-like consistency
- Sterilized to SAL 10<sup>-6</sup>
- Stays in place

Part Number	Description
AB-3201	AlexiFuse Demin Strip 10x7x7mm (1 per pk) FD
AB-3202	AlexiFuse Demin Strip 20x7x7mm (1 per pk) FD
AB-3203	AlexiFuse Demin Strip 50x5x5mm (1 per pk) FD
AB-3204	AlexiFuse Demin Strip 50x10x5mm (1 per pk) FD
AB-3205	AlexiFuse Demin Strip 50x20x5mm (1 per pk) FD
AB-3206	AlexiFuse Demin Strip 50x20x5mm (2 per pk) FD
AB-3207	AlexiFuse Demin Strip 50x20x7mm (1 per pk) FD
AB-3208	AlexiFuse Demin Strip 26x19x7mm (1 per pk) FD
AB-3209	AlexiFuse Demin Strip 30x20x5mm (1 per pk) FD
AB-3210	AlexiFuse Demin Strip 50x5x7mm (1 per pk) FD
AB-3211	AlexiFuse Demin Strip 25x10x7mm (1 per pk) FD
AB-3212	AlexiFuse Demin Strip 50x10x7mm (1 per pk) FD





## AlexiFuse Demineralized Cortical Fibers

Our bone fibers are made with 100% demineralized cortical fibers. Our bone fibers are an excellent bone graft contact for orthopedic and void-filling applications. Their high surface area allows for excellent cell absorption, retention, and viability. There are no anatomical restrictions to the size or shape of the implants. AlexiFuse Fibers will not wash away with irrigation.

Part Number	Description
AB-3051	AlexiFuse Demin Cortical Fibers, 1.0cc
AB-3052	AlexiFuse Demin Cortical Fibers, 2.5cc
AB-3053	AlexiFuse Demin Cortical Fibers, 5.0cc
AB-3054	AlexiFuse Demin Cortical Fibers, 10.0cc
AB-3055	AlexiFuse Demin Cortical Fibers, 20.0cc

### Potential Benefits:

- Osteoinductive & osteoconductive potential
- Hydrates quickly and uniformly
- Minimal graft migration
- Shape-conforming
- Easy to use
- Longer strands
- Sterilized to SAL 10<sup>-6</sup>



## AlexiFuse DBM Putty

AlexiGen offers DBM in several different putty sizes to efficiently address a variety of procedures. These procedures include trauma, extremities, hips, knees, foot, ankle, spine, and more. Ease of use and resistance to irrigation were priorities in the development of our DBM putty.

### Potential Benefits:

- Osteoinductive & osteoconductive potential
- Room temperature storage
- Stays in place
- Quick preparation
- Easy to use
- Malleable
- Sterilized to SAL 10<sup>-6</sup>
- Resists irrigation



Part Number	Description
AB-7401	AlexiFuse DBM Putty 0.50cc
AB-7402	AlexiFuse DBM Putty 1.00cc
AB-7403	AlexiFuse DBM Putty 2.50cc
AB-7404	AlexiFuse DBM Putty 5.00cc
AB-7405	AlexiFuse DBM Putty 10.0cc
AB-7451	AlexiFuse DBM Putty Crunch 0.50cc
AB-7452	AlexiFuse DBM Putty Crunch 1.00cc
AB-7453	AlexiFuse DBM Putty Crunch 2.50cc
AB-7454	AlexiFuse DBM Putty Crunch 5.00cc
AB-7455	AlexiFuse DBM Putty Crunch 10.0cc

## Donor Screening and Recovery

The common goal of AlexiGen and its strategic partners is to treat each donor and their family with unmatched honor and respect. We go to extensive lengths when screening, recovering, processing, storing, and distributing donor tissue in order to maximize the benefit for our allograft patients.

Each prospective donor is put through a comprehensive screening process, including medical and social history evaluations that are in accordance with Food and Drug Administration (FDA) regulations and American Association of Tissue Banks (AATB) standards. When screening donors and recovering tissue, the highest standards must be adhered to. After receiving consent from the donor's family, qualified personnel perform and document a physical examination of the prospective donor. A full review of the donor's medical records is performed following the physical examination. Upon the final approval of the donor, the donor tissue is then tested by a CLIA certified, FDA-registered laboratory.

These tests include, but are not limited to the following:

- **Anti-HBc**
- **Anti-HIV Type 1 & 2**
- **HIV-1 and HCV (NAT)**
- **Anti-HCV**
- **HBsAg**
- **Syphilis**

### Quality Assurance:

**Policies are often updated to assure that we are in complete compliance with all applicable standards and regulations. Quality assurance audits are routinely performed on all internal and external processes and procedures. Providing the highest quality biologics to our patients and their physicians is our main focus. Along with our strategic partners, AlexiGen adheres to strict policies and detailed standard operating procedures in all aspects of the donor screening and tissue recovery process.**



## Sterilization Methods

The revolutionary PASCO2 sterilization process is a new and improved way to sterilize allograft tissues. This new, advanced process allows for sterilization without the use of irradiation. The process relies on supercritical carbon dioxide to extract and remove unwanted compounds from soft tissue.

Using an optimal balance of pressure and temperature, the allograft tissue is prepared to help facilitate a problem-free tissue transplant. The PASCO2 process maximizes the biocompatibility and mechanical integrity in donor tissue and does not jeopardize the tensile strength and elastic properties of the connective tissue. The PASCO2 process is excellent for use in sports medicine and other soft tissue allografts. Additionally, we also use low gamma irradiation on some products in our portfolio. Low gamma irradiation ensures the utmost quality and sterility. This virtually eliminates the occurrence of donor tissue with an unacceptable bioburden. This time-tested technique helps ensure quality and sterility of tissue for our patients.

### AlexiGen BioTech, LLC

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