Osteobiologic

BONE GRAFTING SOLUTIONS

AlloSource®

Delivering Powerful Possibilities™

The AlloSource® Advantage

Delivering Quality and Safety

AlloSource is one of the nation's largest nonprofit providers of bone, skin and soft tissue allografts for use in surgical procedures. The company maintains the highest standards in the recovery, processing and storage of human tissue while working to develop new therapeutic technologies. All tissue processed by AlloSource is derived from voluntary human tissue donation.

AlloSource maintains a Quality Assurance Program in compliance with the following federal and state regulations and voluntary standards:

- FDA Human Cells, Tissues, and Cellular and Tissue-Based Products, 21 CFR Part 1271
- FDA Human Tissue Intended for Transplantation, 21 CFR Part 1270
- AATB Standards for Tissue Banking
- Clinical Laboratory Improvements Amendments (CLIA) Certification
- State of California Health and Safety Code
- State of Florida Statutes
- State of Maryland Code
- State of New York Public Health Law
- State of Oregon Registration
- Health Canada CTO Registration Certificate

AlloSource is compliant with ISO 9001:2000, an internationally-recognized quality assurance standard, for the manufacture and distribution of tissue for transplant and the design, manufacture and distribution of tissue-based products.

Precision at Every Step of the Process

AlloSource has established multiple safeguards in our manufacturing process to assure allograft safety. These include:

- Tissue donation process initiated by a certified organ procurement organization (OPO)
- Rigorous donor screening in accordance with FDA regulations and standards published by the AATB, including verification of donor medical records and social history
- Rigid recovery procedures carried out by highly trained and qualified tissue recovery teams
- Extensive donor testing, including serological and microbiological testing, during recovery, processing and packaging
- Aseptic processing and packaging; microbial testing is performed on final products by a CLIA-certified lab to assure the safety of the allograft for transplantation in accordance with CLIA and AATB regulations
- Comprehensive post-processing review, including visual inspection of final allografts
- Post processing sterilization using low dose, low temperature irradiation when appropriate
- Allograft distribution after verification of labeling, sizing and expiration date

Strict Donor Screening and Tissue Testing

AlloSource requires a comprehensive donor physical assessment and a complete medical and social history to identify and eliminate donors that are at risk of being carriers of certain viruses and diseases. Donor acceptance criteria are based on FDA regulations and AATB Standards as well as additional standards set by the AlloSource Medical Advisory Board.

Donors must test negative or non-reactive in the following assays:

- Antibody to Hepatitis C (HCV)
- Antibody to Human Immunodeficiency Virus 1 & 2 (HIV 1 & 2)
- Antibody to Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II)
- Hepatitis B Core IgG/IgM Antibody (HBcAb)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis C Virus (HCV NAT)
- Human Immunodeficiency Virus Type 1 (HIV-1 NAT)
- Rapid Plasma Reagin or Serologic Test for Syphilis (RPR or STS)

All tests are conducted using FDA-approved test kits.

** Allografts labeled Sterile R are aseptically processed and packaged and then subjected to gamma irradiation. AlloSource has validated the sterility of its irradiated allografts in accordance with a technical standard published jointly by the American National Standards Institute (ANSI), the Association for the Advancement of Medical Instrumentation (AAMI), and the International Organization for Standardization (ISO). The FDA Standards Program recognizes the standard, ANSI/AAMI/ISO 11137, as a Consensus Standard. The Sterility Assurance Level (SAL) of tissue labeled Sterile is 10^{-6}.*

AlloSponge® and AlloFlex®

Versatile Bone Grafting Materials that Support Matrix Formation

AlloFlex®

AlloSponge® Block

AlloSponge® Strip

AlloSponge supports the creation of a structural matrix for bone formation while encouraging cellular ingrowth. Its unique sponge-like structure is flexible enough to be compressed to fill a challenging space and resilient enough to expand to its original size without compromising its strength.

AlloSponge is valued by surgeons for its versatile benefits, including:

- Compressible and flexible enough to fill bone defects of nearly any shape or size
- Capable of absorbing fluids like blood and serum
- Can be used as adjunct in spine surgery as a PEEK cage filler, in multi-level fusion or to fill a bone or tumor void
- Excellent delivery tissue for biologic agents like bone marrow aspirate, synthetic bone morphogenic proteins, DBM gels and other bone-forming biologic concentrations

AlloFlex strips are flexible and can contour to any anatomical curvature – an optimal solution for many craniofacial surgery applications as a bone defect wrap.

AlloFlex®

Product Code	Product Description
60715510	AlloFlex Small 10 x 50 x 2 – 4 mm
60715515	AlloFlex Medium 15 x 50 x 2 – 4 mm
60715520	AlloFlex Large 20 x 50 x 2 – 4 mm
60715750	AlloFlex Ex-Large 50 x 70 x 2 – 4 mm

AlloSponge® Blocks

Product Code	Product Description
60515008	AlloSponge Block (8 mm)^3
60515010	AlloSponge Block (10 mm)^3
60515012	AlloSponge Block (12 mm)^3
60515014	AlloSponge Block (14 mm)^3

AlloSponge® Filler

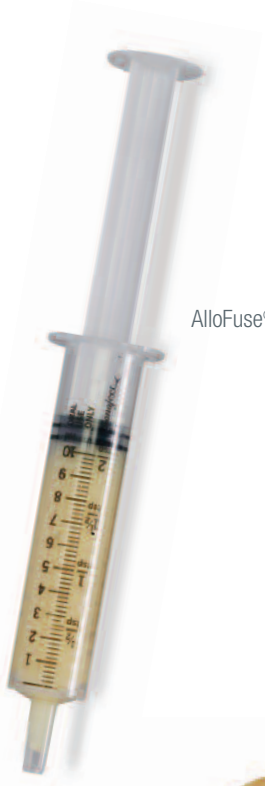
Product Code	Product Description
60815002	AlloSponge Filler 2.5 cc
60815005	AlloSponge Filler 5 cc
60815010	AlloSponge Filler 10 cc

AlloSponge® Strips

Product Code	Product Description
60615102	AlloSponge Strip 10 x 20 x 3 – 6 mm
60615154	AlloSponge Strip 15 x 40 x 3 – 6 mm
60615205	AlloSponge Strip 20 x 50 x 3 – 6 mm

AlloFuse® and AlloFuse® Plus

Easy-to-Use Bone Growth Solutions for Almost any Application



AlloFuse® DBM Gel

AlloFuse® DBM Putty

AlloFuse products are formulated to help stimulate natural bone formation processes in which mesenchymal cells differentiate into bone-forming cells. They offer a high level of DBM content provided in a reverse-phase polaxymer carrier for effective performance.

Used alone or in combination as a bone graft extender, AlloFuse and AlloFuse Plus provide:

- Proven osteoinductivity: Each lot of DBM is tested for its ability to stimulate new bone formation
- Superior handling: Available as a paste, putty or gel, AlloFuse is highly malleable and easy to mold and pack into any defect
- Excellent graft containment: AlloFuse thickens at body temperature and resists irrigation to minimize the likelihood of migration from the surgical site
- Ready-to-use application: AlloFuse can be used without thawing, mixing or other preparation, no refrigeration is needed

AlloFuse® DBM Gel

Product Code	Product Description
90138001	1 cc Injectable Gel
90138005	5 cc Injectable Gel
90138010	10 cc Injectable Gel

AlloFuse® DBM Putty

Product Code	Product Description
90038001	1 cc Putty
90038002	2.5 cc Putty
90038005	5 cc Putty
90038010	10 cc Putty

AlloFuse® Plus DBM Paste and Putty

Product Code	Product Description
90238001	1 cc Paste
90238003	3 cc Paste
90238008	8 cc Paste
9033800	5 cc Putty
90338010	10 cc Putty

To order call:

Customer Service 1 800 557 3587

AlloGro®, Cancellous Chips, AlloPac®, and CanPac

Products for Effective Bone Healing

AlloGro DBM is effective in procedures where augmented bone healing is desired, including:

- Bone voids and defects
- Structural allograft implants
- Non-unions and delayed unions
- Spinal fusion
- Fractures

Each lot of AlloGro DBM is tested for its osteoinductive potential and only allograft which demonstrates osteoinductivity is made available for distribution.

Other bone healing products from AlloSource include:

- Cancellous Chips
- AlloPac
- CanPac

AlloPac and CanPac undergo limited processing so more of the blood and lipid products remain with the bone. AlloPac is cortical-cancellous bone and CanPac is cancellous bone.

AlloPac®

AlloGro®

Cancellous Chips

AlloGro® Demineralized Bone Matrix

Product Code	Product Description
34910925	.25 cc
35010950	.50 cc
35110001	1 cc
35210003	3 cc
10111010	10 cc
10111015	15 cc
10111030	30 cc

Cancellous Chips

Freeze-dried	Frozen	Product Description
27615005		5 cc (approximately 4 – 9.5 mm)
27615015	27617015	15 cc (approximately 4 – 9.5 mm)
27615030	27617030	30 cc (approximately 4 – 9.5 mm)
27615060		60 cc (approximately 4 – 9.5 mm)
	27517050	50 cc (approximately 1 – 9 mm)
	27517090	90 cc (approximately 1 – 9 mm)
27615090		90 cc (approximately 4 – 9.5 mm)

AlloPac® (cortical-cancellous chips)

Product Code	Product Description
10216025	25 cc Non-purged, aseptic
10216050	50 cc Non-purged, aseptic
10216100	100 cc Non-purged, aseptic
10317025	25 cc Non-purged, irradiated
10317050	50 cc Non-purged, irradiated
10317100	100 cc Non-purged, irradiated

CanPac (cancellous chips)

Product Code	Product Description
24416025	25 cc Non-purged, aseptic
24416050	50 cc Non-purged, aseptic
24416100	100 cc Non-purged, aseptic
24417025	25 cc Non-purged, irradiated
24417050	50 cc Non-purged, irradiated
24417100	100 cc Non-purged, irradiated

AlloSource®
Delivering Powerful Possibilities™

AlloSource
6278 South Troy Circle
Centennial, Colorado 80111

720 873 0213
Toll Free 800 557 3587
Fax 720 873 0212

www.allosource.org

AlloSource is registered with the U.S. Food and Drug Administration (FDA) and accredited by the American Association of Tissue Banks (AATB). AlloSource is compliant with the AATB Standards for tissue banking and with all applicable state regulations and voluntary guidelines as required and is compliant with the ISO 9001:2000 standard. We support efforts to promote organ and tissue donation through our collaboration with Donate Life America.

M1S0717.00 – 06/2009