

BIOLOGICS

PRODUCT CATALOG

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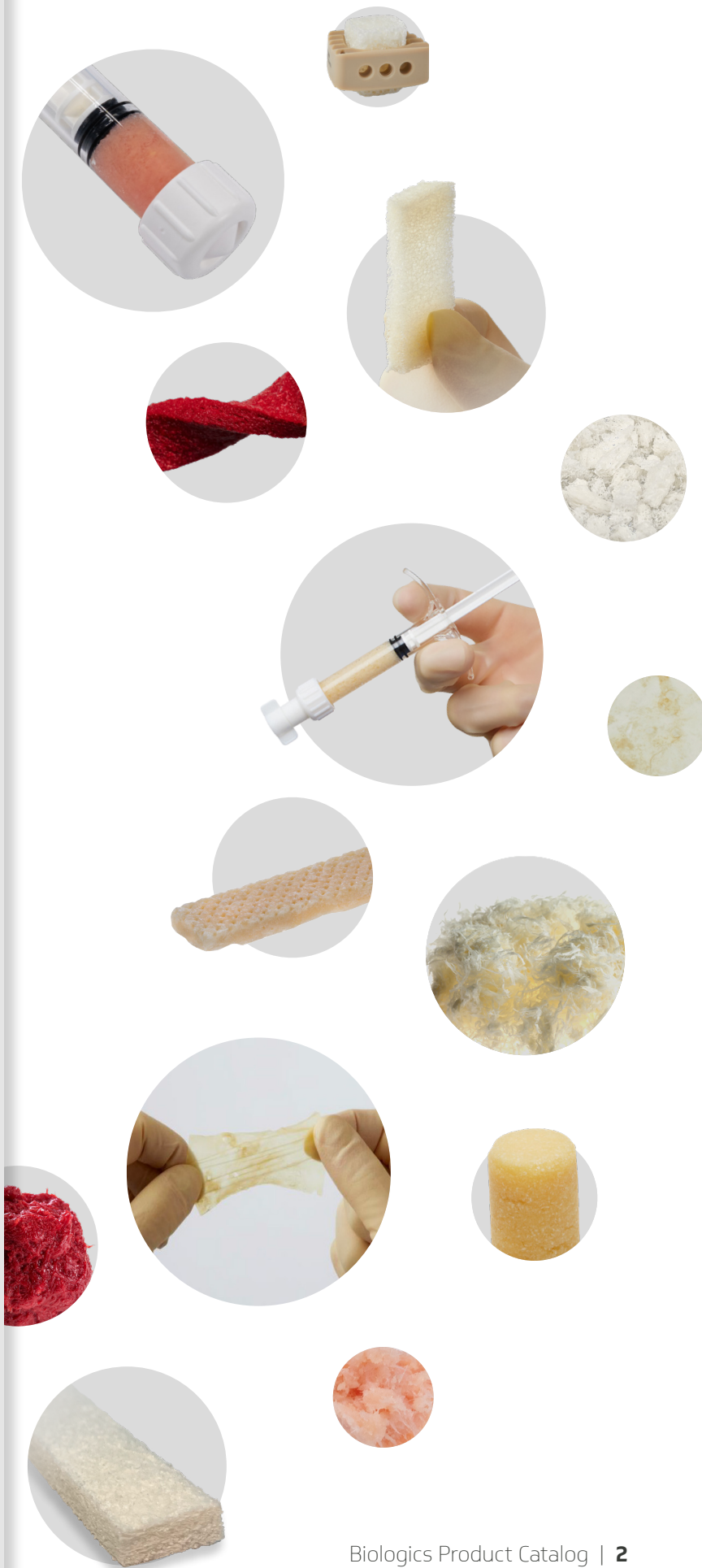
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ATEC Spine is a distinguished provider of solutions concerning spinal surgery. Since 1990, ATEC has focused on Revolutionizing the Approach to Spine Surgery with the ultimate vision of becoming The Standard-Bearer in Spine. Offering a wide berth of products and services, ATEC is committed to delivering improved patient care through high performance and clinical distinction.

ATEC's Biologics portfolio has a variety of offerings ranging from tissue-based to synthetic products. The portfolio is designed to the highest quality standards to aid in the healing of bony defects, while considering all three components necessary for new bone formation: osteogenesis, osteoinduction, and osteoconduction.



AlphaGRAFT[®]

CELLULAR BONE MATRIX

AlphaGRAFT CBM is a minimally manipulated, advanced allograft comprised of growth factor-rich cortical bone fibers and natively occurring living cancellous bone particles. Viable, endogenous, osteogenic cells, including mesenchymal stem cells, are present. Proprietary processing and cryopreservation creates a balanced cellular bone matrix that possesses all three essential components of bone remodeling: osteogenesis, osteoinduction, and osteoconduction.



FREQUENTLY ASKED QUESTIONS

REGULATORY STATUS

Human Cells, and Cellular and Tissue-Based Product (HCT/P) Section 361, following criteria in 21 CFR Part 1271

INTENDED USE

100% human tissue restricted to homologous use for the repair, replacement, or reconstruction of bony defects

SHELF-LIFE

2 or 3 years (refer to package label)

STORAGE & SHIPPING

Frozen, at or below -70°C (-94°F)

PREPARATION

Thaw in 8 minutes or less.
No rinsing or decanting is required.

STERILIZATION

Aseptically processed

- DMSO-free cryoprotectant eliminates the need to rinse the tissue. Simply thaw and go.
- High amounts of osteoinductive, angiogenic, and proliferative growth factors are readily available *in situ*.¹
- Cortical bone fibers designed for optimized handling properties



AlphaGRAFT®

DBM FIBER AND FIBER STRIP

ATEC'S advanced fiber technology combines the regenerative capacity of interconnected fibers with the maximum availability of growth factors endogenous to bone. Composed of 100% demineralized fibers, AlphaGRAFT DBM Fibers and Fiber Strip offer moldable, cohesive handling characteristics and an innovative solution for posterolateral spinal fusion. Interconnected fibers provide an osteoconductive scaffold for the delivery of autologous stem cells.



FREQUENTLY ASKED QUESTIONS

REGULATORY STATUS

HCT/P Section 361, following criteria 21 CFR Part 1271

INTENDED USE

100% human tissue restricted to homologous use for the repair, replacement, or reconstruction of bony defects

SHELF-LIFE

5 years

STORAGE & SHIPPING

Ambient temperatures 15°C to 30°C (59°F to 86°F)

PREPARATION

1:1 hydration with BMA, blood, or saline is required before implantation.

STERILIZATION

Gamma irradiation (terminal)

- Demineralized to expose innate osteoinductive growth factors²
- Delivers osteogenic cells when hydrated with the patient's bone marrow aspirate³
- Cohesive handling that enables combination with allograft or autograft⁴
- Graft expands *in situ* and can promote endplate coverage⁵



AlphaGRAFT®

DBM FIBER FLOW

AlphaGRAFT DBM Fiber Flow is an advanced allograft composed of 100% demineralized bone with a proprietary combination of demineralized bone fibers and demineralized bone particulate. ATEC's technology combines the regenerative capacity of interconnected fibers with robust handling characteristics. The moldable, cohesive scaffold is ready to use in syringe packaging with no need for graft preparation or hydration.



FREQUENTLY ASKED QUESTIONS

REGULATORY STATUS

HCT/P Section 361, following criteria 21 CFR Part 1271

INTENDED USE

100% human tissue restricted to homologous use for the repair, replacement, or reconstruction of bony defects

SHELF-LIFE

3 years

STORAGE & SHIPPING

Ambient temperatures 15°C to 30°C (59°F to 86°F)

PREPARATION

No rehydration is required prior to implantation.

STERILIZATION

Gamma irradiation (terminal)

- This post-packing solution offers procedural integration with Calibrate™ Expandable Interbody Systems.
- Flowable and cohesive handling, supporting ease of delivery
- Ready-to-use graft; no need for graft preparation or hydration
- Engineered for enhanced regenerative capacity of DBM fibers compared to particulate DBM⁶



AlphaGRAFT®

DBM PUTTY & GEL

AlphaGRAFT DBM Putty and Gel are ready-to-use bone graft substitutes made of demineralized bone powder and a thermosensitive reverse phase medium (RPM), which allows for product thickening *in situ* to minimize the likelihood of graft migration.⁷ AlphaGRAFT DBM provides an osteoconductive scaffold with osteoinductive potential⁸ and is designed for excellent handling properties. The products can be used as a bone graft extender and are available in a variety of sizes.



FREQUENTLY ASKED QUESTIONS

REGULATORY STATUS

FDA Class II Medical Device, 510(k) number: K071849

INDICATIONS

Indicated for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structures. AlphaGRAFT DBM is indicated to be packed gently into bony gaps in the skeletal system as bone graft extender (extremities, spine, and pelvis) and as a bone void filler of the extremities and pelvis. These defects may be surgically created or from the result of traumatic injury to the bone.

SHELF-LIFE

Putty: 2 years
Gel: 3 years

STORAGE & SHIPPING

In a clean, dry place at ambient temperatures 15°C to 30°C (59°F to 86°F)

PREPARATION

No rehydration is required prior to implantation.

STERILIZATION

Electron beam irradiation (terminal)

- Moldable and cohesive handling characteristics to pack into a variety of defects
- Thickens *in situ* to resist graft migration
- No preparation needed for ready-to-use application



3D ProFuse[®]

BIOSCAFFOLD

3D ProFuse is a demineralized, osteoconductive bioscaffold, carefully processed to retain proteins and growth factors essential for osteoinduction. The scaffold is conducive to cell migration and attachment, and highly compressible, enabling the endplate-to-endplate contact necessary to promote fusion.



FREQUENTLY ASKED QUESTIONS

REGULATORY STATUS

HCT/P Section 361, following criteria 21 CFR Part 1271

INTENDED USE

Human musculoskeletal allograft may be used in several orthopedic, reconstructive, and dental applications. Allograft bone may be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or it may be used as a standalone bone graft.

SHELF-LIFE

5 years

STORAGE & SHIPPING

Ambient temperatures 15°C to 30°C (59°F to 86°F)

PREPARATION

Reconstitution in isotonic solution required prior to implantation.

STERILIZATION

Gamma irradiation (terminal)

- Available in both blocks and strips
- Absorbs and retains fluids (blood, bone marrow aspirate, etc.)
- Becomes compressible upon hydration



BioCORE[®]

MOLDABLE BIOACTIVE GRAFT

BioCORE Moldable Bioactive Graft is an advanced mineral-collagen composite matrix that creates an osteoconductive, bioactive, and porous environment allowing for bony ingrowth across the graft site. BioCORE is composed of carbonate apatite, bioactive glass, and type I collagen that can be molded to fit the bone defect. Each component provides unique functional benefits to the product and allows for optimal resorption and remodeling.



FREQUENTLY ASKED QUESTIONS

REGULATORY STATUS

FDA Class II medical device, 510(k) number: K182074

INDICATIONS

BioCORE combined with either autogenous bone marrow or autograft with saline is indicated for bony voids or gaps, that are not intrinsic to the stability of the bony structure. BioCORE can also be used as a bone graft extender.

SHELF-LIFE

3 years

STORAGE & SHIPPING

Ambient temperatures 15°C to 30°C (59°F to 86°F)

PREPARATION

Rehydration with BMA or physiological saline mixed with autograft is required prior to implantation.

STERILIZATION

Gamma irradiation (terminal)

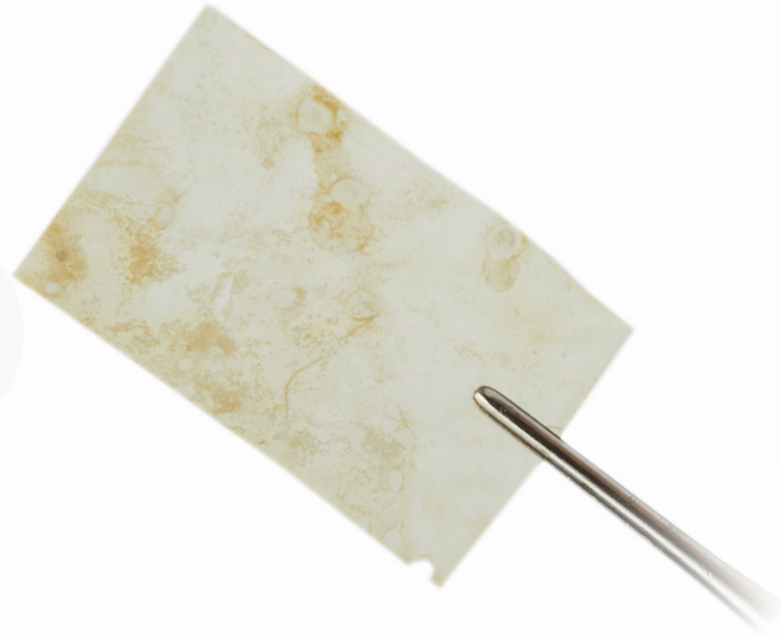
- Through ion exchange and release, bioactive glass creates a favorable microenvironment for bone regeneration and osteoblast attachment.⁹
- Upon hydration, BioCORE can be used as a strip or molded into a variety of shapes.



AmnioShield[®]

AMNIOTIC TISSUE BARRIER

AmnioShield is a natural biologic barrier composed of human amnion and chorion membranes that comprise the innermost layer of the placenta tissue and the amniotic cavity. This Amniotic Tissue Barrier membrane may reduce scar tissue adhesion as a physical barrier which helps establish a clean plane of dissection.¹⁰



- Provides a dissection plane between overlying scar and underlying tissue
- Amniotic membranes can regulate scar tissue adhesion.^{10,11}
- Intact chorion layer provides rigidity to support robust handling characteristics.

FREQUENTLY ASKED QUESTIONS

REGULATORY STATUS

HCT/P Section 361, following criteria 21
CFR Part 1271

INTENDED USE

This product is intended for use as a barrier and protective cover to acute and chronic wounds.

SHELF-LIFE

5 years

STORAGE & SHIPPING

Ambient temperatures 15°C to 30°C
(59°F to 86°F)

STERILIZATION

Electron beam irradiation (terminal)



Allograft Chips

Cancellous bone chips are intended for homologous use for the repair, replacement, or reconstruction of bony defects. Available in various sizes and volumes, this allograft provides a porous matrix for cellular attachment and proliferation. Donor bone chips are stored at room temperature and terminally sterilized.



- Crushed cancellous chips (1-4 mm) are available in 15, 30, and 60 cc sizes.
- Cortical cancellous chips are available in 15 and 30 cc sizes.
- Cancellous chips (4-10 mm) are available in 15 and 30 cc sizes.

FREQUENTLY ASKED QUESTIONS

REGULATORY STATUS

HCT/P Section 361, following criteria 21 CFR Part 1271

INTENDED USE

This allograft bio-implant is intended for implantation.

SHELF-LIFE

5 years

STORAGE & SHIPPING

Ambient temperatures 15°C to 30°C (59°F to 86°F)

STERILIZATION

Gamma irradiation (terminal)



PRODUCT DESCRIPTION	SIZE	PART NUMBER
ALPHAGRAFT CBM	1 cc	210-010
	5 cc	210-050
	10 cc	210-100
ALPHAGRAFT DBM FIBER	1 cc	1008-010
	5 cc	1008-050
	10 cc	1008-100
ALPHAGRAFT DBM FIBER STRIP	100 x 10 mm	213-51010
	100 x 20 mm	213-52010
ALPHAGRAFT DBM FIBER FLOW	1 cc	2008-010
	2.5 cc	2008-025
	5 cc	2008-050
	10 cc	2008-100
ALPHAGRAFT DBM GEL	1 cc	1001-010
	5 cc	1001-050
ALPHAGRAFT DBM PUTTY	2.5 cc	1002-025
	5 cc	1002-050
	10 cc	1002-100
BIOCORE MOLDABLE BIOACTIVE GRAFT	21 x 21 mm block	214-0025-BK
	32 x 32 mm block	214-0060-BK
	50 x 20 mm strip	214-0060-ST
	100 x 20 mm strip	214-0120-ST
3D PROFUSE BIOSCAFFOLD	9 x 8 x 12 mm block	670-9812
	9 x 9 x 9 mm block	670-999
	13 x 11 x 11 mm block	670-131111
	20 x 6 x 16 mm block	670-20616
	22 x 8 x 17 mm block	670-22817
	25 x 6 x 16 mm block	670-25616
	25 x 3 x 16 mm block	670-25316
	50 x 20 x 5 mm strip	670-50205
	50 x 20 x 7 mm	670-010
CRUSHED CANCELLOUS (1-4 MM)	15 cc	CCH-1415
	30 cc	CCH-1430
	60 cc	CCH-1460
CANCELLOUS CHIPS (4-10 MM)	15 cc	CCH-41015
	30 cc	CCH-41030
CORTICAL CANCELLOUS CHIPS	15 cc	MIX-15
	30 cc	MIX-30
AMNIOSHIELD TISSUE BARRIER	2 x 2 cm	212-0202
	4 x 4 cm	212-0404
	4 x 6 cm	212-0406

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CUSTOMER SERVICE

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