

AUGMATRIX™

Biocomposite Bone Graft



AUGMATRIX™ BIOCOMPOSITE BONE GRAFT

PAD

STRIP

BLOCK

PLUG

PASTE

NEEDLE



Versatility by design AUGMATRIX™ Biocomposite Bone Graft is available in multiple forms to suit an array of bone grafting challenges.



More collagen, better handling

Reject ordinary with a more natural bone mineral and more collagen.

AUGMATRIX™ Biocomposite Bone Graft is comprised of 55% carbonated apatite (a type of calcium phosphate) and 45% bovine Type I collagen (w/w). Carbonated apatite more closely resembles the mineral phase of natural bone in chemical composition and structure than common minerals found in ordinary matrices, such as pure phase beta tricalcium phosphate (β -TCP) and hydroxyapatite (HA). And 45% collagen is more than double the amount found in ordinary matrices, which typically contain $\leq 20\%$ collagen.

Quick absorption to the core

AUGMATRIX™ is 95% porous. Its interconnected pore structure provides efficient absorption of fluid and stem cell retention. Bone marrow aspirate (BMA) penetrates all the way to the core of shaped devices almost instantaneously – no more dry, brittle shapes.

Maximum flexibility

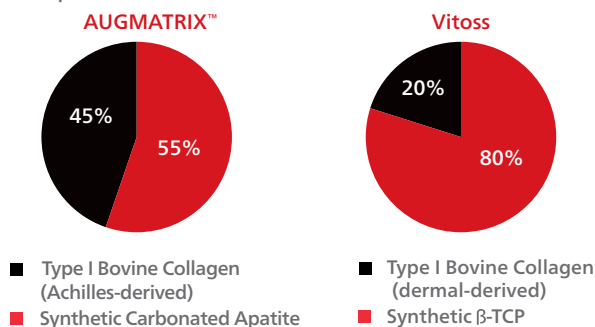
Upon saturation with BMA, AUGMATRIX™ offers maximum flexibility and ease of implantation to fit even the most challenging applications.



Flexible, pliable, and easy to handle AUGMATRIX™

AUGMATRIX™ – Compositional Advantages

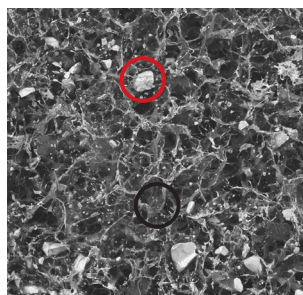
AUGMATRIX™ Biocomposite Bone Graft has a unique composition relative to other synthetic bone grafts. Laboratory studies were conducted to examine the physical and chemical properties of AUGMATRIX™ compared to Vitoss Foam¹.



Homogeneous, Not Heterogeneous

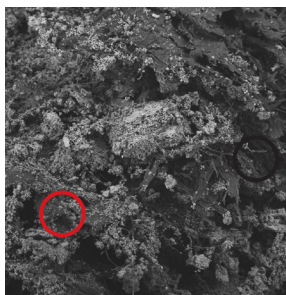
AUGMATRIX™ has an interconnected network of collagen with a uniform pore size and a homogeneous distribution of carbonated apatite, compared to heterogeneous characteristics found in Vitoss.

AUGMATRIX™



Collagen matrix provides relatively uniform pore size and distribution of pores

Vitoss



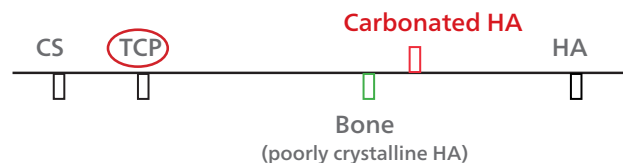
Collagen matrix fills area between β-TCP resulting in inconsistent pore size and distribution

Scanning Electron Microscopy: 100x

○ - mineral component ○ - collagen component

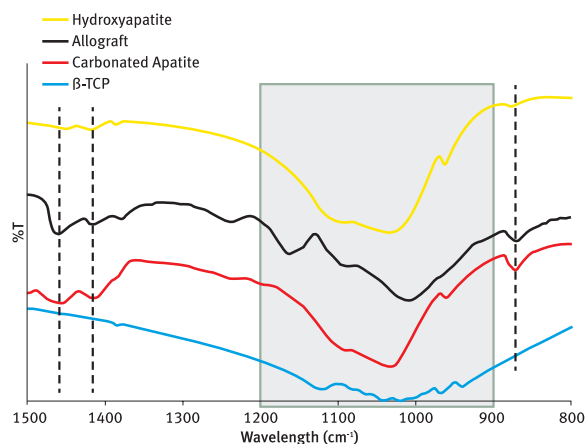
Carbonated Apatite is More Similar to Natural Bone

As depicted in the schematic below, the relative crystallinity and solubility of the carbonated apatite in AUGMATRIX™ is more consistent with the mineral phase of natural bone than the β-TCP in Vitoss.



Chemical Composition Comparison

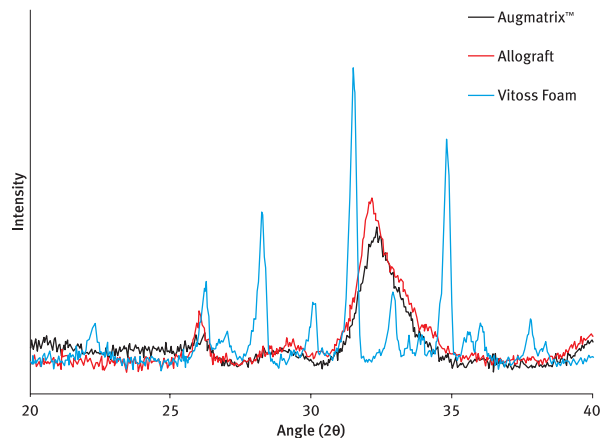
The chemical composition of the carbonated apatite in AUGMATRIX™ more closely resembles natural bone compared to the β-TCP in Vitoss. Fourier Transform Infrared (FTIR) spectra show the carbonate substitution at 840 and 1410-1450 cm⁻¹ occur in carbonated apatite (AUGMATRIX™) and allograft bone but not in HA or β-TCP (Vitoss).



Dotted lines = carbonate peaks; shaded box = phosphate peaks

Structural Comparison

The crystalline structure of the carbonated apatite in AUGMATRIX™ more closely resembles natural bone compared to the β-TCP in Vitoss. The X-ray Diffraction (XRD) pattern below (peak position, intensity, width, and shape) indicates carbonated apatite (AUGMATRIX™) more closely resembles the calcium phosphate phase of allograft compared to β-TCP (Vitoss).



¹Data on file. Vitoss is manufactured & distributed by Stryker Corp.

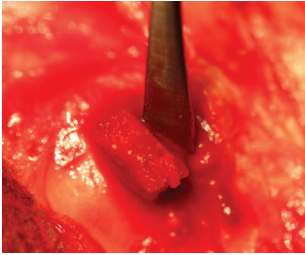
AUGMATRIX™ - Performance Advantages

In a laboratory study evaluating the early in vivo response in an ovine bone defect model, AUGMATRIX™ demonstrated excellent performance characteristics compared to Vitoss.

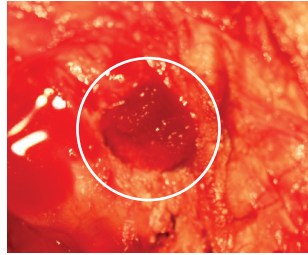
Easy to Implant

8 mm x 20 mm bilateral defects were made in the distal femur and proximal tibia of sheep. The defects were then filled with AUGMATRIX™ or Vitoss saturated with heparinized sheep BMA.

AUGMATRIX™



AUGMATRIX™ was easy to implant

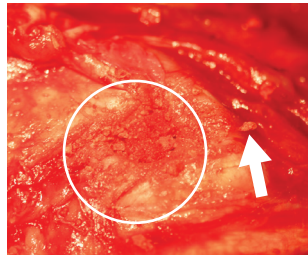


AUGMATRIX™ swelled to fit the defect

Vitoss



Due to stiffness, Vitoss required more manipulation to implant

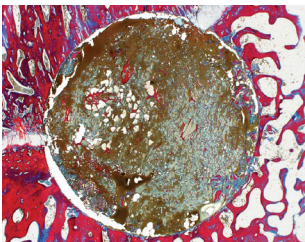


Due to brittle nature, stray Vitoss particles were observed outside the defect area (arrow).

Retains More BMA

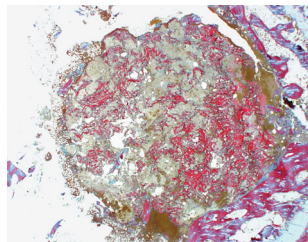
Histology images of filled defects 3 days post-implantation show improved infiltration of BMA in the AUGMATRIX™ group compared to the Vitoss group.

AUGMATRIX™



Paraffin histology with tetrachrome stain. Brown staining indicates bone marrow cells. Dense red staining in the defect indicates residual collagen from the matrix.

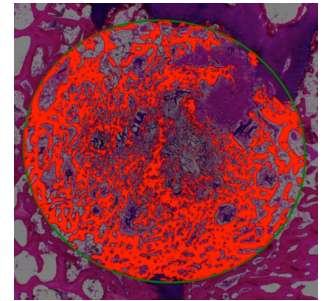
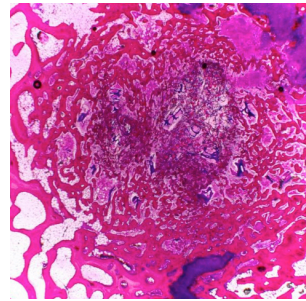
Vitoss



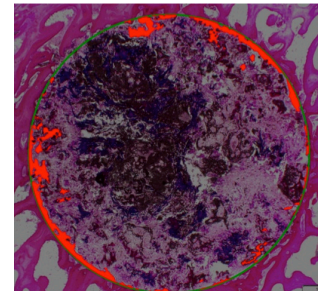
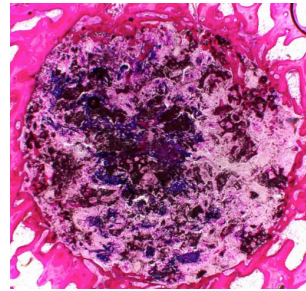
Significantly More Bone Formation at 4 Weeks

Histology images (below left) of filled defects 28 days post-implantation show more new bone within the defect in the AUGMATRIX™ group compared to the Vitoss group. Histomorphometry (below right) confirms.

AUGMATRIX™

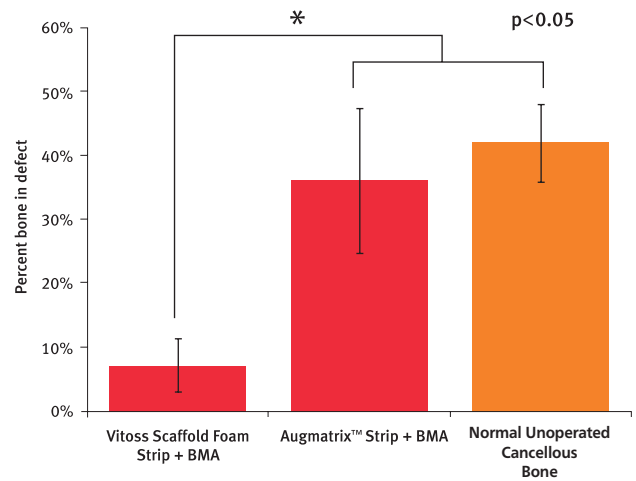


Vitoss




PMMA histology with methylene blue, basic fushin stains. Typical histomorphometry outputs.

Quantitative analysis of histomorphometry outputs shows AUGMATRIX™ demonstrates significantly more bone formation in the defect compared to Vitoss at 28 days.



Data on file. All claims based on an ovine cancellous bone defect model. It is unknown how results from this animal study relate to clinical results in humans.

Order Information

	Item	Size	Order Number	Dimensions	Qty
	Pad	2cc	M600-020-10	2cm l x 2cm w x 0.5cm h	1
		4cc	M600-040-10	2cm l x 2cm w x 0.5cm h	2
	Strip	5cc	M610-050-10	5cm l x 2cm w x 0.5cm h	1
		10cc	M610-100-10	5cm l x 2cm w x 0.5cm h	2
	Paste	2cc	M620-020-10		
		5cc	M620-050-10		
		10cc	M620-100-10		
	Block	10cc	M630-100-10	6.25cm l x 2cm w x 0.8cm h	1
		20cc	M630-200-10	6.25cm l x 2cm w x 0.8cm h	2
	Plug	12mm	M640-120-10	12mm d x 25mm l	1

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AUGMATRIX™ Biocomposite Bone Graft, combined with autogenous marrow, is intended for orthopaedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. AUGMATRIX™ is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities and pelvis. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

Please see the package insert for a complete list of warnings, precautions, possible adverse events and other important medical information.
Manufactured exclusively for BioMimetic Therapeutics, LLC by Collagen Matrix, Inc.