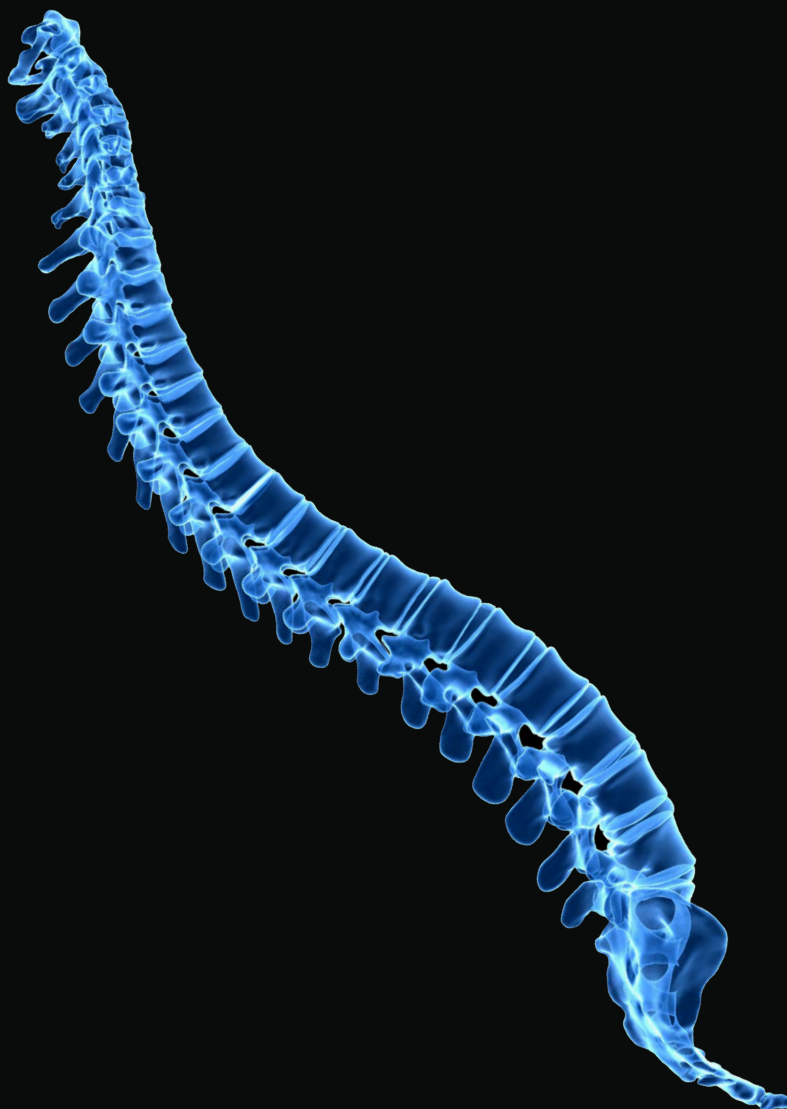




ZAVATION

UniFuze™

SPINE SOLUTIONS



ZAVATION

UniFuze™ Portfolio of Bone Graft Products

Bone Graft Product	Composition	Form	BMA: Product Mixing Ratio	Handling Characteristics	Absorbency	Where to Use***
UniFuze™ Block	80% Mineral* 20% Collagen**	Rectangular shaped blocks	1ml : 1cc	Compression resistant, Flexible	Moderate	-Posterolateral gutters
UniFuze™ Conformable Putty	55% Mineral* 45% Collagen**	Cylinder shaped pucks	1ml : 1cc	Moldable	High	-Posterolateral gutters -Around surgical hardware -Vertebral body defects

*Anorganic carbonate apatite bone mineral

**Type I Collagen

***See instructions for use of the products for specific indications.

Why Use a Bone Graft Matrix?

Bone grafts provide a scaffold for the patient's body to grow new bone. A common use for bone grafts is in spinal fusion surgeries where two or more vertebrae are fused together. Spine surgeons also use bone grafts to stabilize a corrected spinal deformity or to repair spinal fractures.



UniFuze™ Biocomposites-Perfect Partnership

The biocomposite bone graft matrices are a combination of two components that are derived from natural sources, highly purified bovine type I collagen and bovine anorganic carbonate apatite bone mineral.

When combined, they provide an optimal and successful scaffold to support the body's natural ability to regenerate new bone.



Type I Collagen

+



**Anorganic Carbonate
Apatite Bone Mineral**

=



UniFuze™ Biocomposites

UniFuze™ Comprehensive Solutions



**UniFuze™
Conformable Putty**



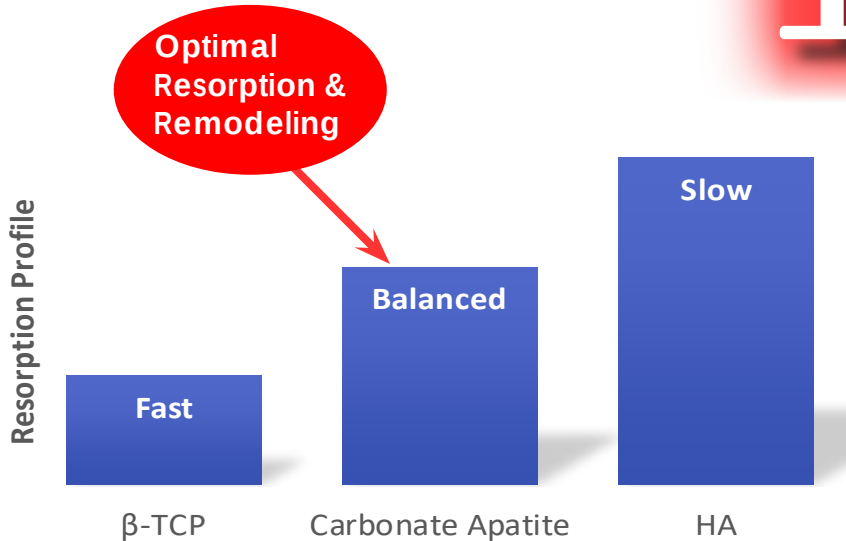
UniFuze™ Block



Five Reasons Why Carbonate Apatite is Optimal

1

Optimal Resorption & Remodeling^{1,2}



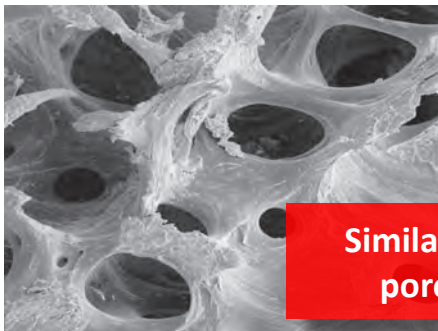
- Not fast like beta-tricalcium phosphate (β -TCP)
- Not slow like hydroxyapatite (HA)
- Ideally, the rate of the bone graft resorption is balanced to the rate of bone remodeling
- Carbonate apatite resorption and remodeling are similar to human bone^{1,2}

2

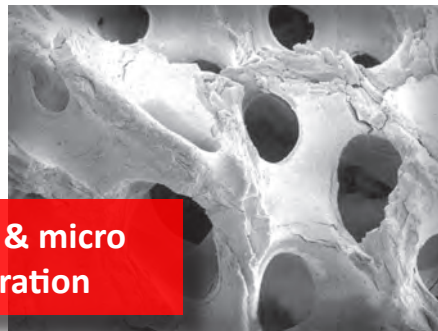
Natural Mineral Structure Similar to Human Bone Mineral

- Pores provide pathways for cell migration and attachment to lay down new bone
- Carbonate apatite is a better osteoconductive material than HA³

Human Bone



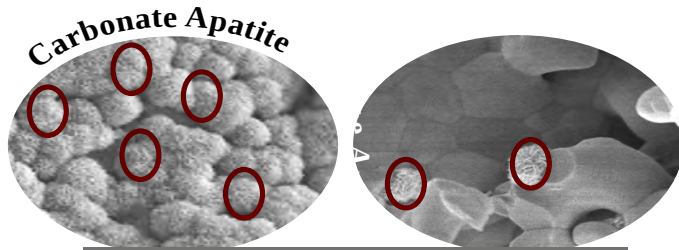
Carbonate Apatite



Similar sized macro & micro pores for cell migration

3

More Calcium Phosphate Deposition than β -TCP⁴



Calcium phosphate surface molecules

- More calcium phosphate molecules are deposited on a carbonate apatite surface than a β -TCP surface⁴
- Osteoblasts prefer attaching to calcium phosphate to lay down new bone

4

Half the Crystallinity than HA, More Soluble⁵

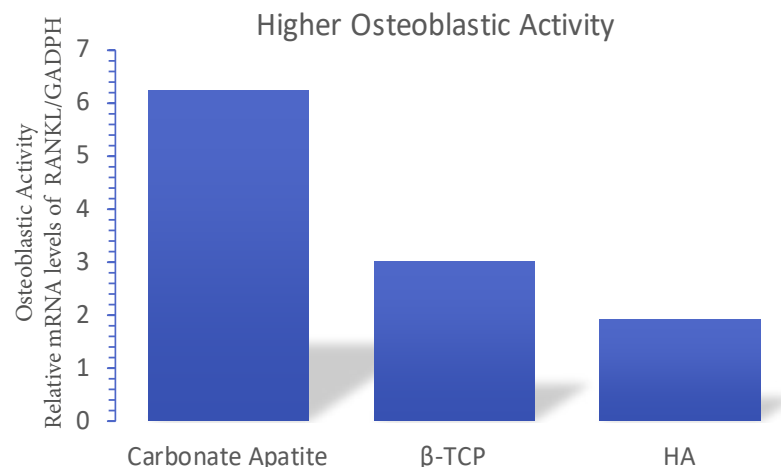
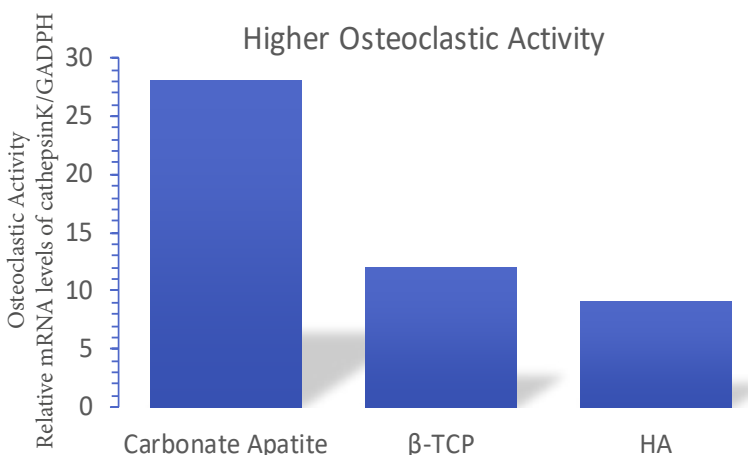
- Carbonate apatite has half the crystallinity than HA, which enables optimal resorption and remodeling because it more easily resorbs⁵



5

Independent Studies have shown Higher Osteoclastic & Osteoblastic Activity than β -TCP & HA⁶

- Osteoclasts break down bone
- Carbonate apatite shows higher levels of osteoclastic activity than β -TCP & HA⁶
- Osteoblasts secrete new bone
- Osteoblast proteins are most upregulated with carbonate apatite than β -TCP & HA⁶



UniFuze™ Block

Bone Graft Matrix

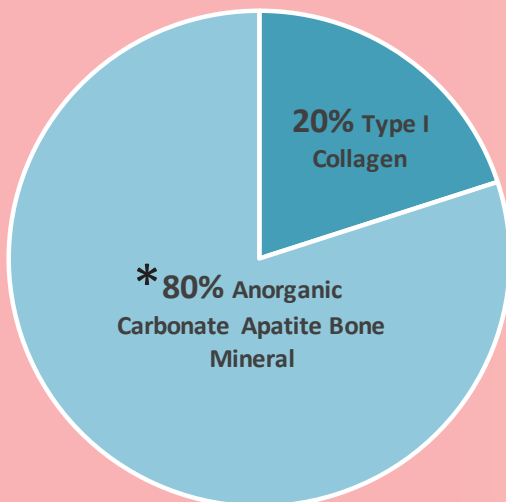
A mechanically strong, compression resistant biocomposite matrix that is easily cut and customized and is fully resorbed during bone remodeling. It is osteoconductive and when mixed with autogenous bone marrow becomes osteoinductive and osteogenic.

Compression resistant

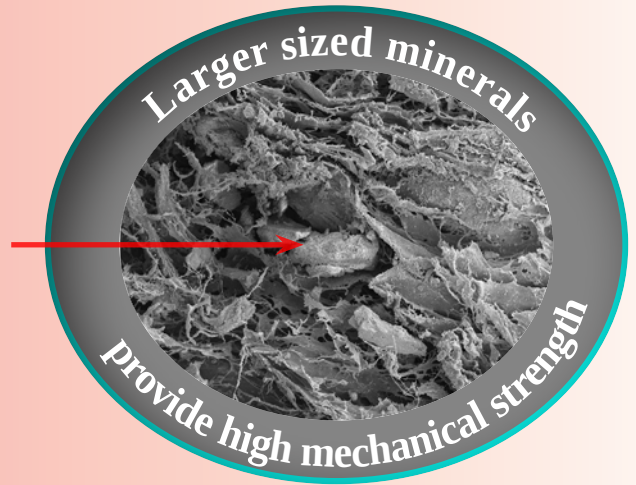
- High mechanical strength
- Retains integrity upon implantation

Optimal porosity

- 78% of pores are optimal size (100-400µm) for tissue regeneration⁷
- Absorptivity allows retention of rich stem cells



*See 5 Reasons Why Carbonate Apatite is Optimal on pages 3-4



Scanning Electron Micrograph of Block magnification x50, arrow indicates mineral particle (particle size range 0.25-1.25mm)

Almost **2x more absorbent** than Vitoss® Foam Strip⁷

	Absorbency (ml/g)
UniFuze™ Block	3.8 ± 0.2
Vitoss® Foam Strip	2.1 ± 0.1

Vitoss® is a Registered Trademark of Orthovita, Inc.

UniFuze™ Conformable Putty

Moldable Bone Graft Matrix

This highly absorbent moldable biocomposite putty is available in cylinder shaped pucks and when hydrated with autogenous bone marrow can be molded. It maintains its integrity upon post-surgical irrigation and is fully resorbed during bone formation and remodeling. It is osteoconductive and when mixed with autogenous bone marrow becomes osteoinductive and osteogenic.

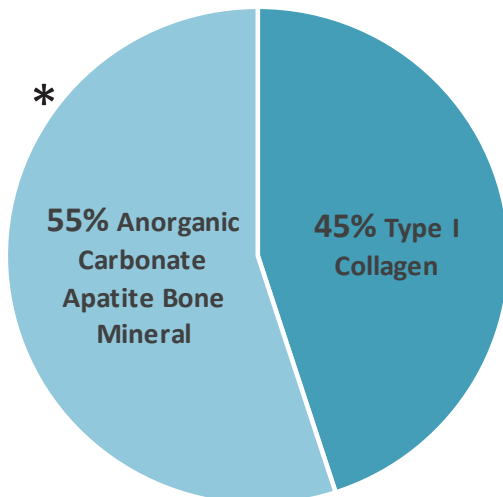


More than double the collagen than other leading brands

- 45% collagen, compared to 20% collagen which is typically found in other matrices
- Highly absorbent which enables retention of rich stem cells

Robust & cohesive handling

- Highly moldable to fit defect sites
- Larger mineral size provides stable handling
- Resistant to irrigation, does not wash away



Over 4x more absorbent than Vitoss® Foam Strip⁷

	Absorbency (ml/g)
UniFuze™ Conformable Putty	9.1 ± 0.5
Vitoss® Foam Strip	2.1 ± 0.1

Vitoss® is a Registered Trademark of Orthovita, Inc.

*See 5 Reasons Why Carbonate Apatite is Optimal on pages 3-4



ZAVATION

UniFuze™ Block

CATALOG NO.	DIMENSIONS			QUANTITY
	Length	Width	Thickness	
801-0005	6.25cm	2cm	0.4cm	5cc, 1 Block
801-0010	6.25cm	2cm	0.8cm	10cc, 1 Block
801-0020	6.25cm	2cm	0.8cm	20cc, 2 Blocks
802-0005	12.5cm	1cm	0.4cm	5cc, 1 Block
802-0010	12.5cm	2cm	0.4cm	10cc, 1 Block



UniFuze™ Conformable Putty

CATALOG NO.	QUANTITY
804-0025	2.5 cc Cylinder Shaped Puck
804-0005	5 cc Cylinder Shaped Puck



References:

1. Matsuura A, Jubo T, Doi K, Hayashi H, Hirata I, Okazaki M, and Akagawa Y. 2009. Bone Formation Ability of Carbonate Apatite-Collagen Scaffolds with Different Carbonate Contents. Dental Materials Journal 28(2): 234-242. 2. Ellies LG, Carter JM, Natiella JR, Featherstone JDB, Nelson DGA. 1988. Quantitative Analysis of Early In Vivo Tissue Response to Synthetic Apatite Implants. J Biomed Mater Res 22:137-148. 3. Spense G., Patel N., Brooks R., Rushton N. 2009. Carbonate Substituted Hydroxyapatite: Resorption by Osteoclasts Modifies the Osteoblastic Response. Journal of Biomedical Materials Research Part A 217-224. 4. In vitro data on file at Collagen Matrix, Inc. 5. Li, S.T., Chen, H.C., Yuen, D, investors; 2011 Sept. 29. Method of Preparing Porous Carbonate Apatite from Natural Bone. United States patent US 8,980,328. 6. Kanayama, K., Sriarj, W., Shimokawa, H., Ohya, K., Doi, Y., Shibutani, T, 2011. Osteoclast and Osteoblast Activities on Carbonate Apatite Plates in Cell Cultures. J Biomater Appl 2011 26:435-436. 7. Data on file at Collagen Matrix, Inc.

