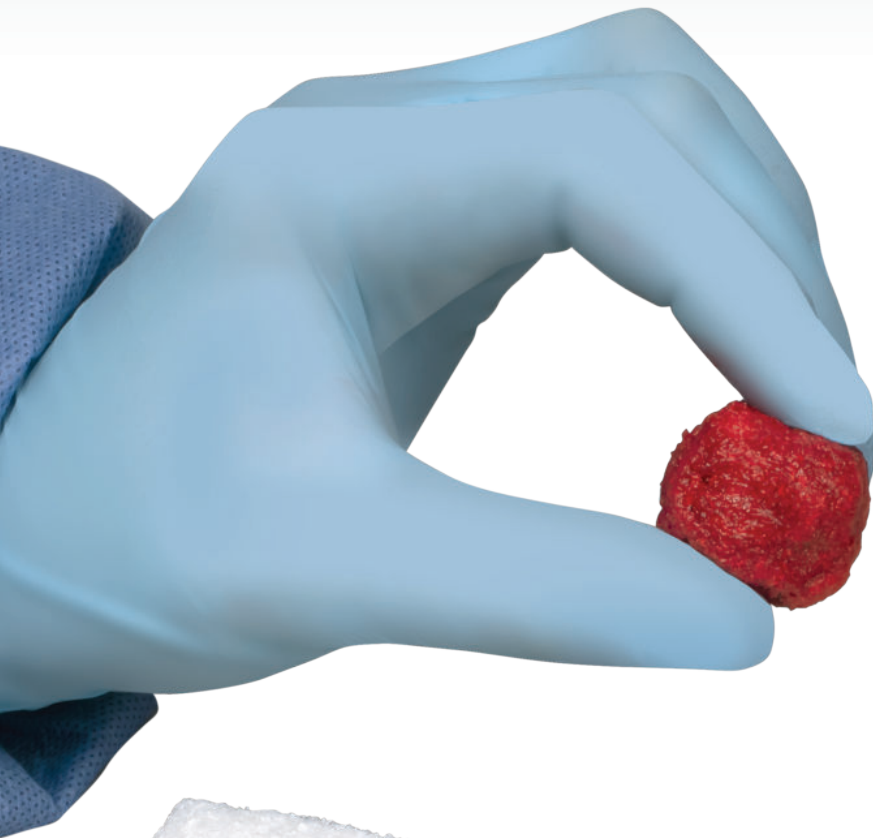




An outstanding trio of components  
molded to fit bone defects



# PlatFORM™ BG

Moldable Bone Graft Matrix





## Evolution of our PlatFORM Products



○ 2007  
PlatFORM CM  
Strips and Pads



○ 2008  
PlatFORM CM  
Putty



○ 2009  
PlatFORM CM  
Block



○ 2019  
PlatFORM BG  
Bioactive

# PlatFORM BG Moldable

## Our Bioactive Solutions

The evolution of our mineral and collagen composite bone grafts has advanced with the launch of our bioactive glass, mineral, and collagen composite bone graft solutions. We have a wide range of mineral and collagen composite bone grafts with a variety of adjustable characteristics, and we have expanded even further to offer bioactive moldable bone graft solutions.

## Composition

The bioactive composite bone graft matrices are a combination of three components: carbonate apatite anorganic bovine bone mineral, 45S5 bioactive glass, and Type 1 collagen. When combined, they provide an optimal scaffold to support the body's natural ability to regenerate new bone.



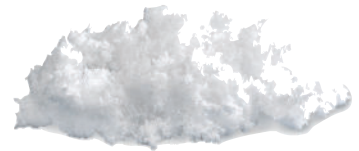
**30%**  
45S5 Bioactive Glass

+



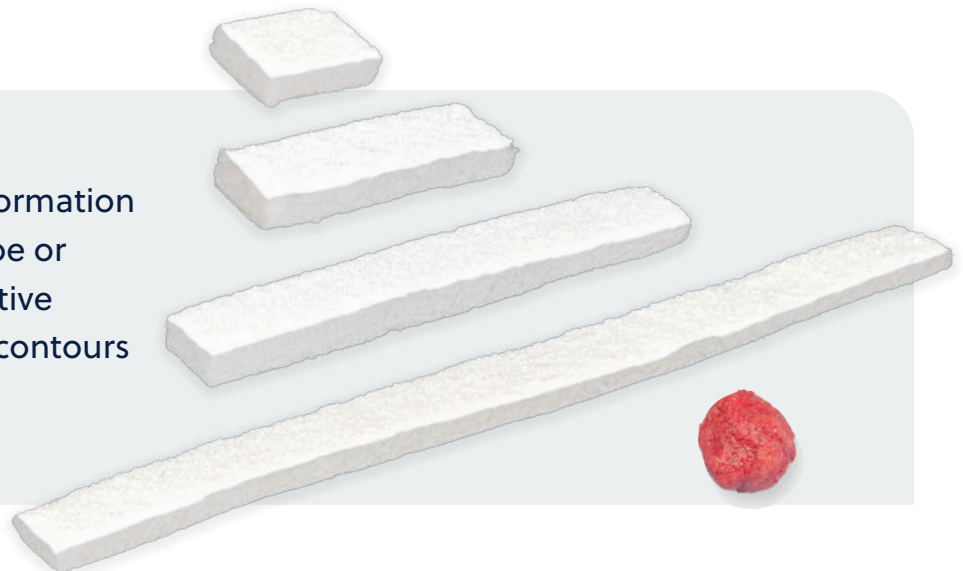
**50%**  
Carbonate Apatite  
Anorganic Bone Mineral

+



**20%**  
Highly Purified Bovine-Derived  
Type 1 Collagen

Upon hydration, the strip conformation can be used in its original shape or optionally molded into alternative shapes to address the unique contours of each defect.





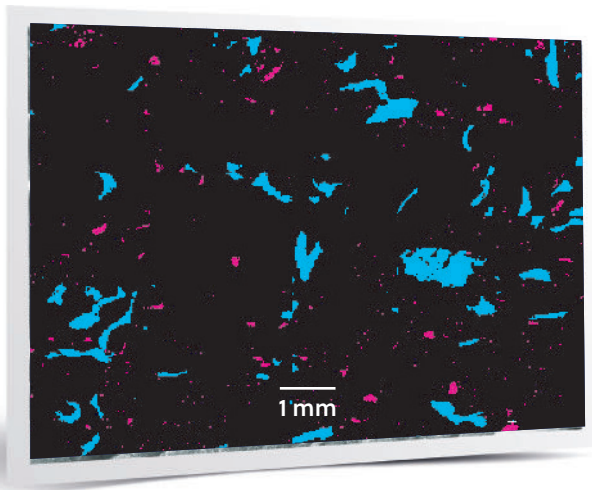
# PlatFORM BG

## Moldable Bone Graft Matrix




PlatFORM BG Moldable Bone Graft Matrix is composed of carbonate apatite anorganic bone mineral, bioactive glass, and Type 1 collagen that can be molded to fit the bone defect. It is an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site. The bone graft matrix is slowly resorbed and replaced by new bone tissue during the natural healing process.

### Why PlatFORM BG Moldable?

- An outstanding trio of components: 50% carbonate apatite anorganic bone mineral, 30% 45S5 bioactive glass, 20% Type 1 collagen
- Uniform distribution of bioactive glass and mineral particles throughout the matrix, achieved through our proprietary manufacturing process<sup>1</sup>



An SEM/EDX Analysis of PlatFORM BG Moldable polished cross sections showing mineral and bioactive glass

-  45S5 Bioactive Glass Particles
-  Carbonate Apatite Anorganic Bone Mineral
-  Porous Type 1 Collagen Matrix

### PlatFORM BG Glass Component

- **30% is optimal:** Less is more. Bioactive glass is incorporated into PlatFORM BG within a suggested critical range of 5-40% for optimal osteoblast growth and calcium phosphate formation in a composite<sup>2</sup>
- Ideal particle range: A narrow particle size distribution limited to 100-300  $\mu\text{m}$  to provide a more controlled rate of ion dissolution and surface reactivity, and a more consistent rate of bone bonding and proliferation<sup>3,4</sup>
- Exemplary particle size (100-300  $\mu\text{m}$ ): Larger sized particles may not fully resorb. Smaller particles may resorb away quickly and impede the upregulation of osteoprogenitor cells<sup>4,5</sup>

## Moldable Advantage

- **2 for 1 versatility:** Upon hydration, the strip conformation can be used in its original shape or optionally molded into alternative shapes to address the unique contours of each defect
- Combined with either autogenous bone marrow or autograft with saline
- Can also be used with autograft as a bone graft extender
- Puck conformation option is ideal for molding
- Moldable, flexible, absorbent, resists migration upon irrigation
- A lengthy 40 cc size option unlike any other bioactive moldable bone graft

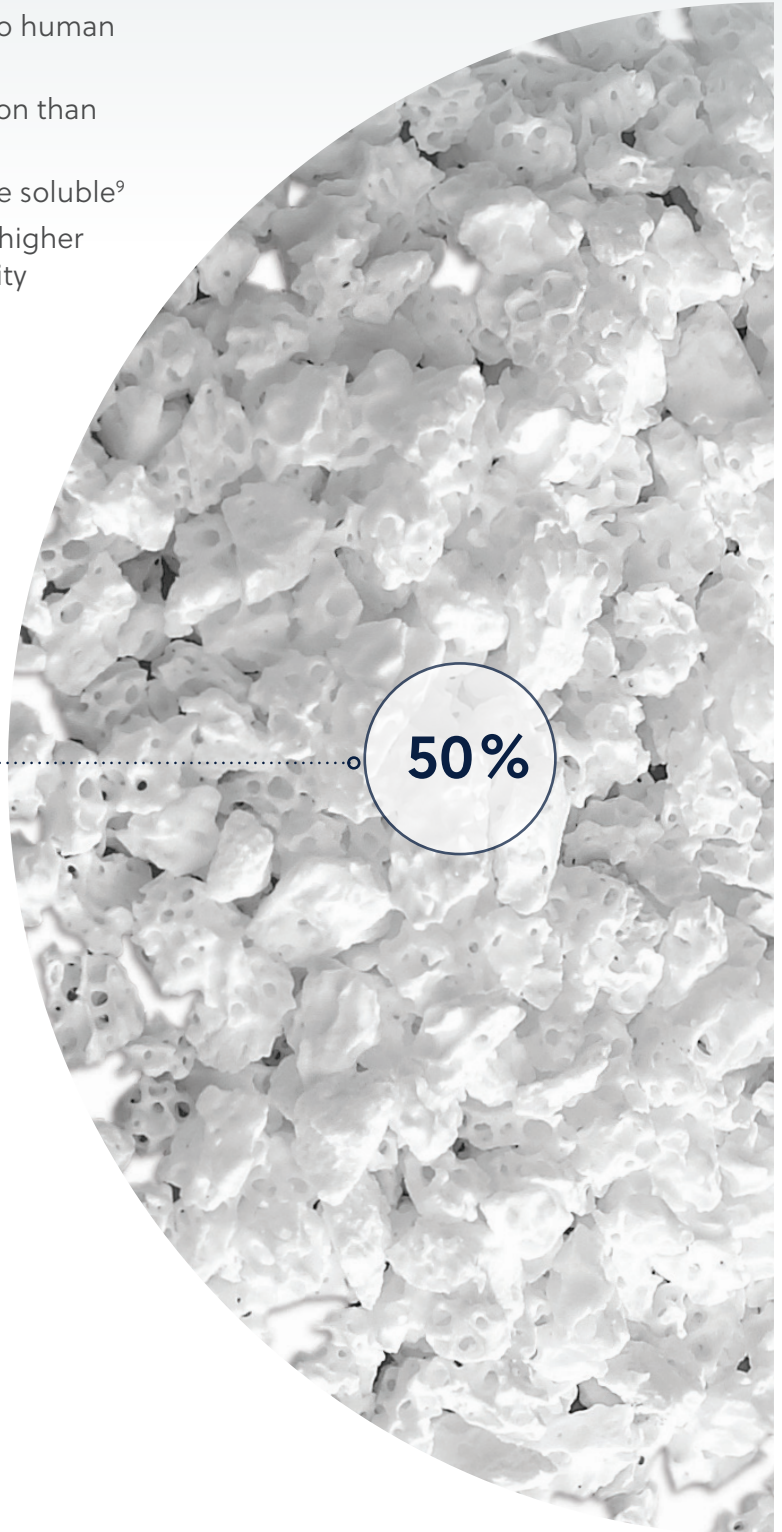


- Almost **2x more absorbent** than Vitoss® Bioactive Foam<sup>1</sup>
  - Delivers stem cell rich BMA to fusion site

	ABSORBENCY (ml/g)
<b>PlatFORM BG Moldable</b>	4.59 ± 0.76
<b>Vitoss Bioactive Foam</b>	2.70 ± 0.35

## Why Carbonate Apatite Bone Mineral?

- Optimal resorption and remodeling<sup>6,7</sup>
- Natural mineral structure similar to human bone mineral
- More calcium phosphate deposition than  $\beta$ -TCP<sup>8</sup>
- Half the crystallinity than HA, more soluble<sup>9</sup>
- Independent studies have shown higher osteoclastic and osteoblastic activity than  $\beta$ -TCP and HA<sup>10</sup>



50%

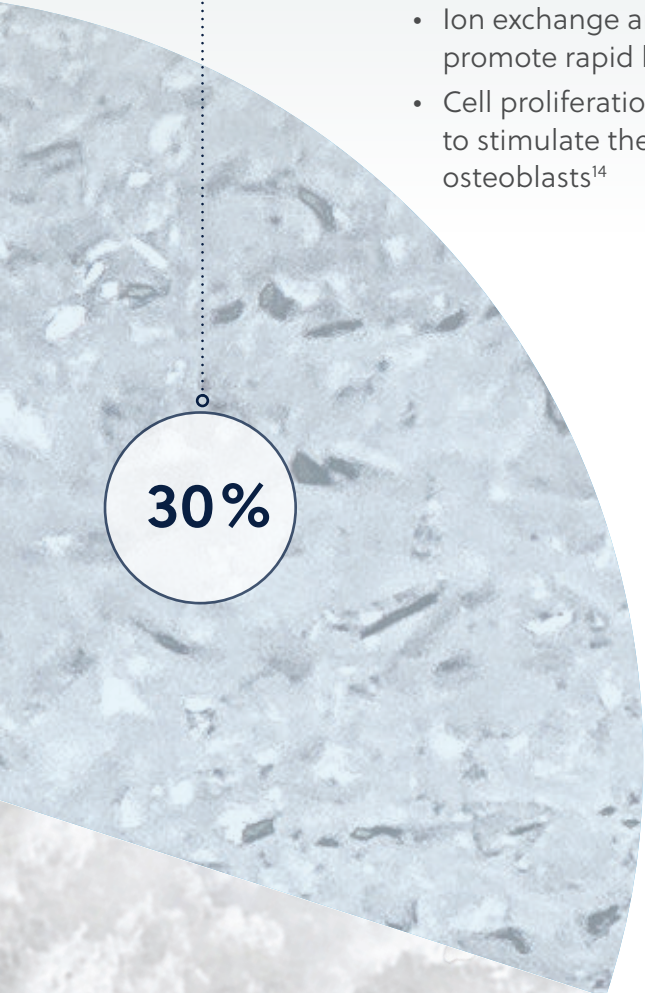
# Why 45S5 Bioactive Glass?

## Over 30 Years of Presence in Tissue Engineering<sup>11,12</sup>

- Favorable environment for bone regeneration and osteoblast attachment<sup>13</sup>
- Ion exchange and release—including soluble tetrahedral silica, which may promote rapid bone formation<sup>2</sup>
- Cell proliferation and differentiation—45S5 bioactive glass has the ability to stimulate the growth and osteogenic differentiation of human primary osteoblasts<sup>14</sup>

### Composition of 45S5 Bioactive Glass

45%	Silicon Dioxide	SiO <sub>2</sub>
24.5%	Calcium Oxide	Ca <sub>2</sub> O
24.5%	Sodium Oxide	Na <sub>2</sub> O
6%	Phosphorus Pentoxide	P <sub>2</sub> O <sub>5</sub>



30%



20%

## Why Type 1 Collagen?

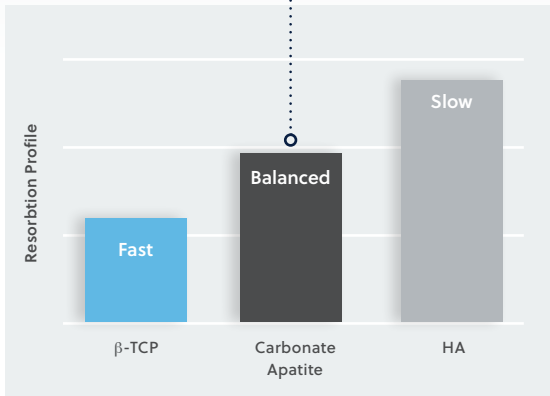
### Homologous Molecular Structure to Human Collagen<sup>15</sup>

- Highly purified for biocompatibility
- 100% resorbable through normal metabolic pathways<sup>16</sup>
- Intrinsic hemostatic properties control minor bleeding<sup>16,17</sup>
- Well-established long clinical history<sup>16</sup>
- Binds proteins and cells and retains biological factors<sup>18</sup>
- Single most abundant protein in the human body<sup>19</sup>



# Five Reasons Why Carbonate Apatite is Superior to HA and $\beta$ -TCP

Optimal Resorption and Remodeling



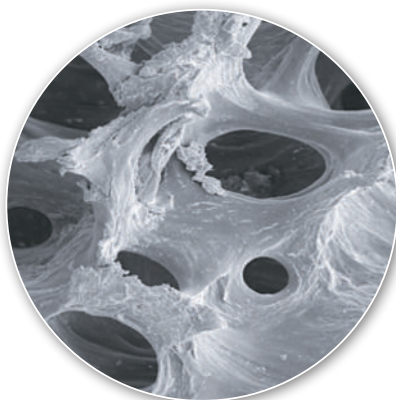
## 1 Optimal Resorption and Remodeling<sup>6,7</sup>

- Not fast like beta-tricalcium phosphate ( $\beta$ -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<sup>6,7</sup>

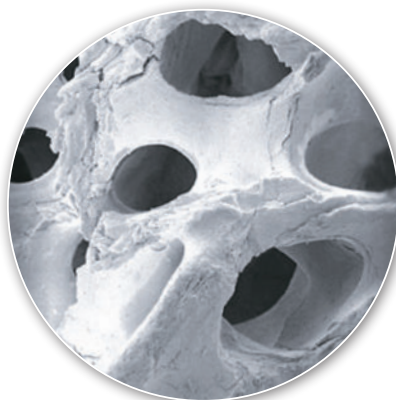
## 2 Natural Mineral Structure Similar to Human Bone Mineral

- Pores provide pathways for cell migration and attachment to lay down new bone
- Carbonate apatite is a better osteoconductive material than HA<sup>20</sup>

SIMILAR SIZED MACRO AND MICRO PORES FOR CELL MIGRATION



Human Bone

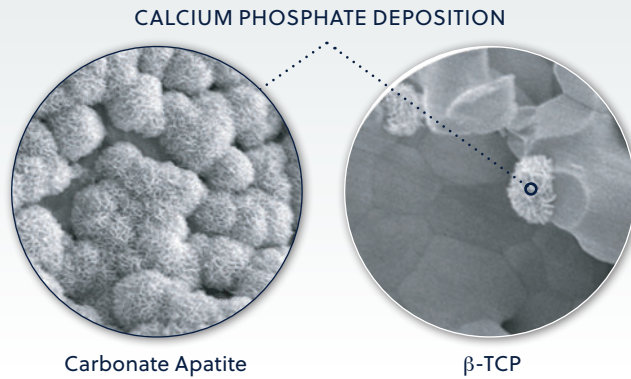


Carbonate Apatite



### 3 More Calcium Phosphate Deposition than $\beta$ -TCP<sup>8</sup>

- More calcium phosphate is deposited on the carbonate apatite surface as compared to  $\beta$ -TCP<sup>8</sup>
- Osteoblasts prefer attaching to calcium phosphate to lay down new bone



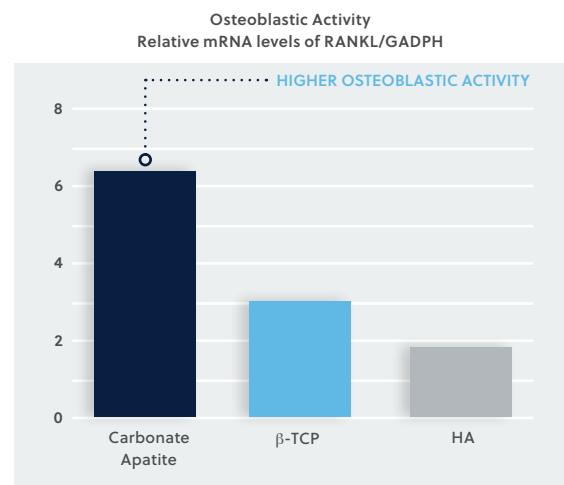
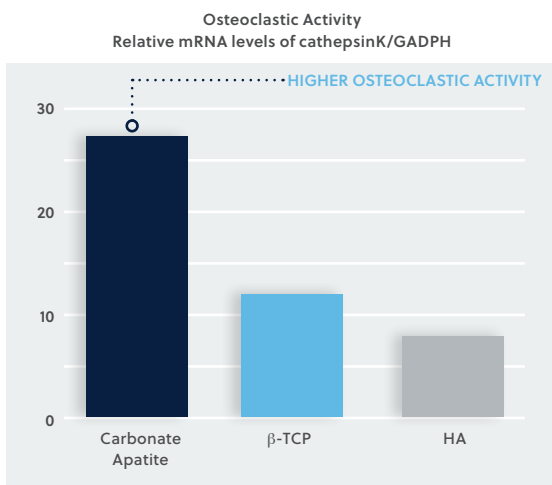
### 4 Half the Crystallinity than HA, More Soluble<sup>9</sup>

- Carbonate apatite has half the crystallinity than HA, which enables optimal resorption and remodeling because it more easily resorbs<sup>9</sup>

### 5 Independent Studies have shown Higher Osteoclastic and Osteoblastic Activity than $\beta$ -TCP and HA<sup>10</sup>

- Osteoclasts break down bone
- Carbonate apatite shows higher levels of osteoclastic activity than  $\beta$ -TCP and HA<sup>10</sup>

- Osteoblasts secrete new bone
- Osteoblast proteins are most upregulated with carbonate apatite than  $\beta$ -TCP and HA<sup>10</sup>

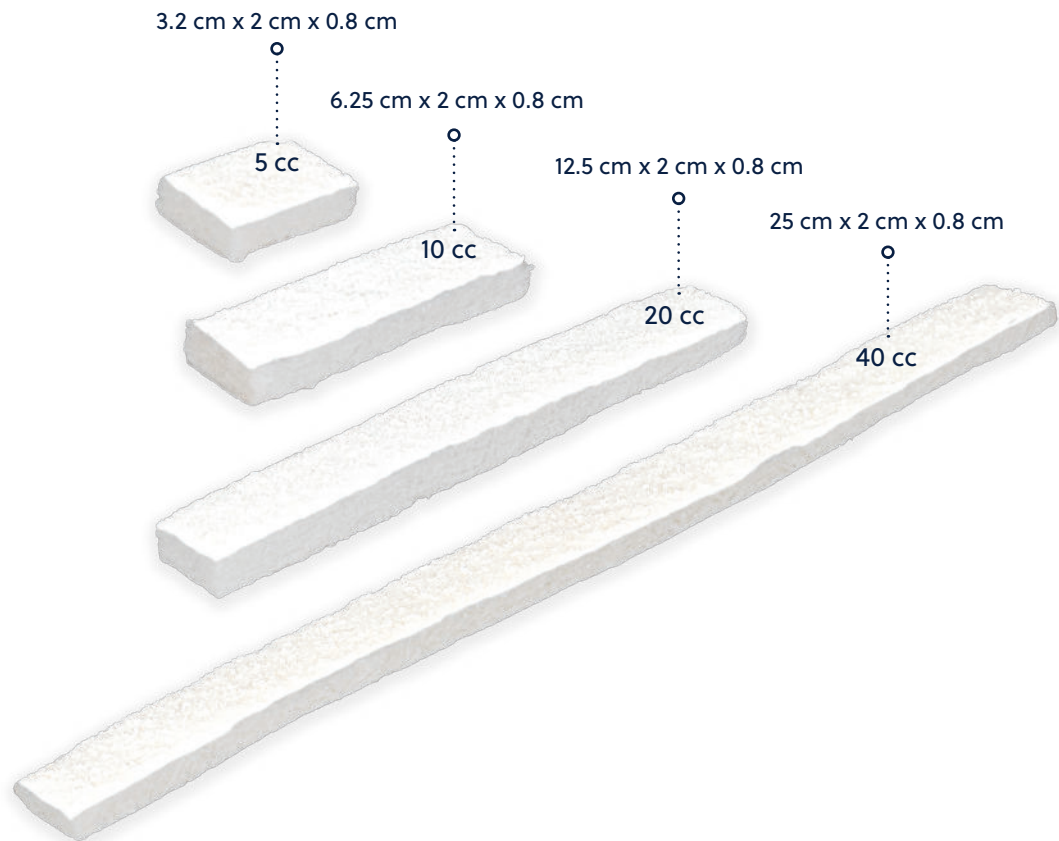




# Ordering Information

## PlatFORM BG Moldable Strips

Part Number	Dimensions			Quantity
	Length	Width	Thickness	
45-2115	3.2 cm	2 cm	0.8 cm	5 cc, 1 Strip
45-2125	6.25 cm	2 cm	0.8 cm	10 cc, 1 Strip
45-2515	12.5 cm	2 cm	0.8 cm	20 cc, 1 Strip
45-2525	25 cm	2 cm	0.8 cm	40 cc, 1 Strip



## References

1. Data on file at Collagen Matrix, Inc.
2. Gerhardt, L., Boccaccini, A.R. (2010). Bioactive Glass-Ceramic Scaffolds for Bone Tissue Engineering. *Materials*, 3, 3867-3910. Retrieved from <https://doi.org/10.3390/ma3073867>.
3. Oonishi, H., Kushitani, S., Yasukawa, E., Iwaki, H., Hench, L.L., Wilson, J., Tsuji, E., Sugihara, T. (1997). Particulate Bioglass Compared With Hydroxyapatite as a Bone Graft Substitute. *Clinical Orthopaedics and Related Research*, 334, 316-325, Lippincott-Raven Publishers, Philadelphia, PA.
4. Schepers, E.J.G., Ducheyne, P. (1997). Bioactive glass particles of narrow size range for the treatment of oral bone defects: a 1-24 month experiment with several materials and particle sizes and size ranges. *Journal of Oral Rehabilitation*, 24, 171-181.
5. Lindfors, N. C., Koski, I., Heikkilä, J. T., Mattila, K. and Aho, A. J. (2010), A prospective randomized 14 year follow-up study of bioactive glass and autogenous bone as bone graft substitutes in benign bone tumors. *J. Biomed. Mater. Res.*, 94B, 157-164. doi:10.1002/jbm.b.31636
6. Matsuura, A., Kubo, T., Doi K., Hayashi, K., Morita, K., Yokota, R., Hayashi, H., Hirata, I., Okazaki, M., Akagawa, Y. (2009). Bone formation ability of carbonate apatite-collagen scaffolds with different carbonate contents. *Dental Materials Journal*, 28(2), 234-242.
7. Ellies, L.G., Carter, J.M., Natiella, J.R., Featherstone, J.D.B., Nelson, D.G.A. (1988). Quantitative analysis of early in vivo tissue response to synthetic apatite implants. *J. of Biomed. Mater. Res.*, 22, 137-148.
8. In vitro data on file at Collagen Matrix, Inc.
9. Li, S.T., Chen, H.C., Yuen, D., inventors. (2011). United States patent US 8,980,328. Method of Preparing Porous Carbonate Apatite from Natural Bone.
10. 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. Biomaterials*, 26, 435-436.
11. Hench, L. L., & Jones, J. R. (2015). Bioactive Glasses: Frontiers and Challenges. *Frontiers in bioengineering and biotechnology*, 3, 194. doi:10.3389/fbioe.2015.00194
12. Hench, L.L. (2013). Chronology of Bioactive Glass Development and Clinical Applications. *New Journal of Glass and Ceramics*, 3(2), 67-73. doi: 10.4236/njgc.2013.32011.
13. Hench, L.L., Polak, J.M., Xynos, I.D., Buttery, L.D.K. (2000). Bioactive Materials to Control Cell Cycle. *Materials Research Innovations*, 3, 313-23. doi: 10.1007/s100190000055
14. Xynos, I.D., Hukkanen, M.V., Batten, J.J., Buttery, L.D.K, Hench, L.L., Polak, J.M. (2000). Bioglass 45S5 stimulates osteoblast turnover and enhances bone formation In vitro: Implications and applications for bone tissue engineering. *Calcif Tissue Int.* 67(4), 321-9.
15. Miller, E.J. (1984). Chemistry of the Collagens and Their Distribution. *Extracellular Matrix Biochemistry*, KA Piez, AH Reddi (eds.). 41-82. Elsevier, New York, NY.
16. Li, S.T. (2000). Biomedical Engineering Handbook, In JD Bronzino (Eds.), *Biologic Biomaterials: Tissue Derived Biomaterials (Collagen)* (1st ed.) 2, 42, 1-23, CRC Press, Boca Raton, FL.
17. Jaffe, R., Deykin, D. (1974). Evidence for a Structural Requirement for the Aggregation of Platelets by Collagen. *The Journal of Clinical Investigation*, 53, 875-883.
18. Geiger, M., Li, R.H., Friess, W. (2003). Collagen sponges for bone regeneration with rhBMP-2. *Science Direct / Elsevier*, 55, 1613-1629. <http://doi.org/10.1016/j.addr.2003.08.010>.
19. Ott S. (2003, October 21). Collagen and Bone Matrix. Retrieved from <https://depts.washington.edu/bonebio/ASBMRed/matrix.html>
20. Spence, G., Patel, N., Brooks, R., Rushton, N. (in press). Carbonate substituted hydroxyapatite: Resorption by osteoclasts modifies the osteoblastic response. *Wiley InterScience*. Retrieved from <https://doi.org/10.1002/jbm.a.32083>

For more information visit [ZimVie.com](https://www.ZimVie.com)

ZimVie Spine  
10225 Westmoor Drive  
Westminster, CO 80021  
[www.ZimVie.com](https://www.ZimVie.com)



Manufactured by:  
Collagen Matrix, INC.  
15 Thornton Road  
Oakland, NJ 07436



Unless otherwise indicated, as referenced herein, all trademarks and intellectual property rights are the property of ZimVie Inc. or an affiliate; and all products are manufactured by one or more of the spinal subsidiaries of ZimVie Inc. (Zimmer Biomet Spine, Inc., Zimmer Spine, LDR Medical, etc.) and marketed and distributed by ZimVie Spine and its authorized marketing partners. For additional product information, please refer to the individual product labeling or instructions for use. Product clearance and availability may be limited to certain countries/regions. This material is intended for clinicians only and does not comprise medical advice or recommendations. Distribution to any other recipient is prohibited. This material may not be copied or reprinted without the express written consent of ZimVie. ZV0337 REV A 02/23 ©2023 ZimVie. All rights reserved.