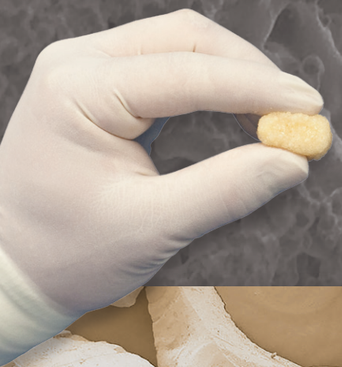
NanoFuse®
BIOACTIVE MATRIX

The Mix That Mends.



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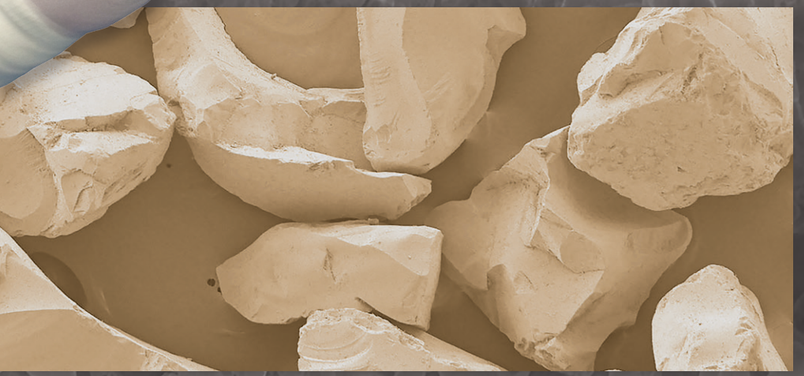
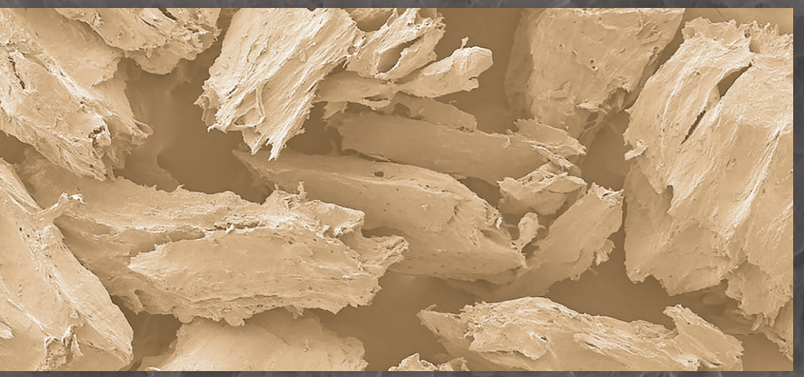
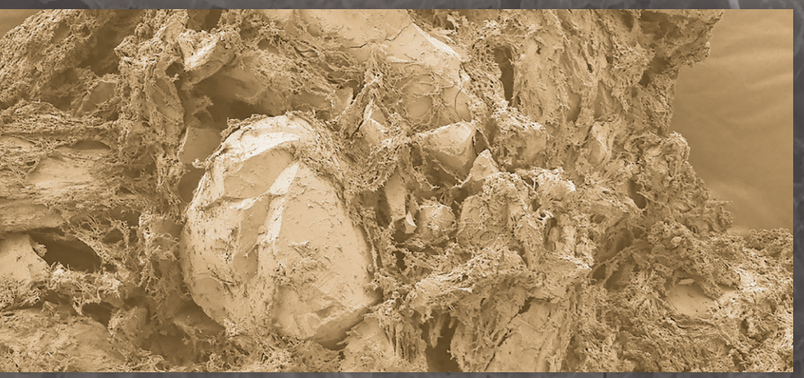


Bioactive Glass



Demineralized Allograft Bone



Gelatin Encapsulation

A Synergistic Combination of Bioactive Glass, DBM and Gelatin

NanoFuse® Bioactive Matrix is a novel bone graft substitute expressly designed to optimize surgical handling, graft stability and osteoproductivity in orthopedic and spine surgery.

An osteoinductive and osteopromotive material that causes new bone formation

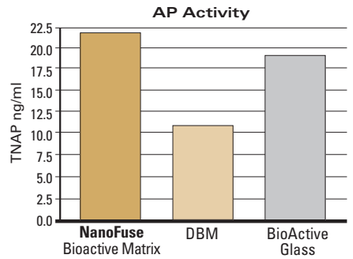
- Forms an exceedingly strong interfacial bond between the graft and adjacent boney tissue within minutes[1]
- Triggers the mechanisms that cause differentiation and proliferation of osteoblasts[2]
- Boosts the activity of critical growth factors needed for bone formation[3]
- Accelerates the process of osteogenesis[4]
- Additionally, in vitro studies demonstrate that ionic release (Ca++) and local pH changes inherent to bioactive glass create an unfavorable environment for growth of certain microbes[5]

Indications for Use:
NanoFuse Bioactive Matrix is indicated to be gently placed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure (i.e., the extremities, pelvis and posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NanoFuse Bioactive Matrix must be used with autograft as a bone graft extender in the posterolateral spine. The product provides a bone graft substitute that remodels into the recipient's skeletal system.

NanoFuse Bioactive Matrix has a history of safe and effective clinical use. Biocompatibility testing and in vitro bench testing was conducted to evaluate the biological safety and performance characteristics of the device formulation. The performance of NanoFuse Bioactive Matrix in the extremities and posterolateral spine was evaluated in vivo.[4]

DBM has inherent osteoconductive and osteoinductive properties and contains numerous bone morphogenic proteins (BMPs) that initiate the cascade of new bone formation

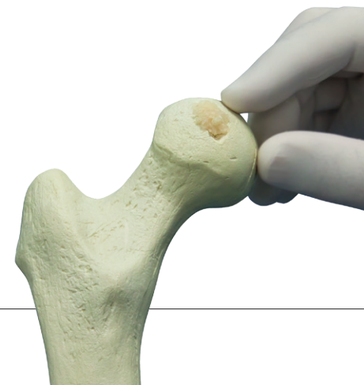
- 100% testing of each lot for osteoinductivity
- Processed to achieve a sterility assurance level (SAL) of 10-6
- Surface roughness of DBM particles drives the migration and proliferation of the osteogenic cells[7]
- Natural BMPs bind to mesenchymal stem cell receptors resulting their proliferation and differentiation into osteoblasts and subsequent osteogenesis[8]



Graph of Alkaline Phosphate activity demonstrates the synergy of the combination and picture of cell attachment to the combination[9]

A novel and patented process that encapsulates the osteoinductive and osteoconductive elements of the product

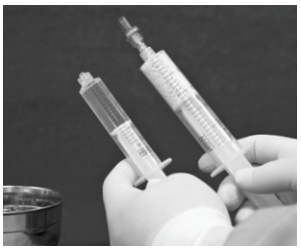
- Rapidly reconstitutes and is easily prepared
- Product is moldable, extrudable and can be packed into osseous defects
- Resists migration during irrigation allowing the active components to stay in place



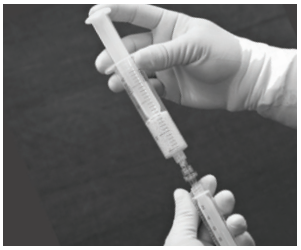
Familiar, Easy Preparation with Improved Handling.

1. Fill the transfer syringe with sterile fluid.

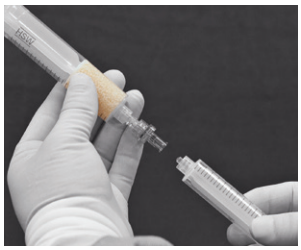
Package Size	Fluid
2cc	1.5cc
5cc	3.5cc
10cc	7.0cc



2. Attach transfer syringe to female luer port on the product syringe and hold the assembly vertically with the product syringe on top. Inject the sterile fluid into the product syringe.



3. Once the fluid is transferred compress the plunger of the product syringe until all of the air is removed and the powder is wetted. Wait 30 seconds for the fluid to be completely absorbed into the powder.



4. Remove the fluid transfer syringe and the valve from the product syringe.

5. Extrude the product directly into bony voids or gaps, or into moist gloves.

6. Mold and handle putty as desired. NanoFuse Bioactive Matrix handles best when used within 12 minutes of reconstitution.

References

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6. BervenS, TayBK, KleinstueckFS, Bradford DS(2001)Clinical applications of bone graft substitutes in spine surgery: consideration of mineralized and demineralized preparations and growth factor supplementation. *Eur Spine J* 10(Suppl 2):S169–S177. doi:10.1007/s005860100270
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9. Kirk T. J, (2012) Osteoconductivity and osteoinductivity of NanoFuse DBM. Cell Tissue Bank DOI 10.1007/s10561-012-9297-1

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