

THE  
ALL-NATURAL  
EFFECT

# OssiMend®



**OssiMend®**  
Mineral-Collagen Composite  
Bone Graft Matrix



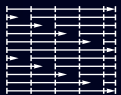
**OssiMend® Putty**  
Mineral-Collagen Composite  
Bone Graft Matrix



**OssiMend® Block**  
Mineral-Collagen Composite  
Bone Graft Matrix



**OssiGuide™**  
Cancellous Granules



**Collagen Matrix, Inc.**  
*Science, Technology, Innovation*

# Comparative Animal Study of OssiMend® and Healos® 13,14

## Objective

This study was conducted to evaluate the use of OssiMend® as compared with Healos® in combination with autologous bone marrow as a bone grafting material in a critical size segmental defect of radial bones in rabbits. No repair (empty defect) was included as a negative control.

## Methods/Surgery

Bilateral surgeries were performed on 6 month old New Zealand White rabbits with 6 week intervals between the surgeries. Products were soaked with bone marrow aspirated from the femur. Osteotomies were performed and a 1.5cm bone segment was removed. Periosteum covering bone ends was removed and the bone marrow saturated implants placed in the defects. Implants (15mm x 2mm x 5mm) were sutured at both ends to the periosteum. Muscle and skin were closed. Defects, six (6) each, were repaired with OssiMend® (Collagen Matrix Inc., Oakland, NJ) and Healos® (Depuy Spine, Raynham, MA)<sup>15</sup> at each time point. Three (3) empty defects were used as negative controls at each time point.

## Results

All animals survived for 6 and 12 weeks without complication and all surgical sites remain closed with no evidence of infection or adverse tissue reaction to the implant materials. Radiographs at 6 and 12 weeks (Figure 1) show progressively more dense bone over time with formation of cortical bone for both OssiMend® and Healos®. Histologically, using the cross-sections through the middle of the defect, there are no significant differences between OssiMend® and Healos® (Figure 3). Statistically, both products show significantly greater new bone formation than empty defect (Figure 2).

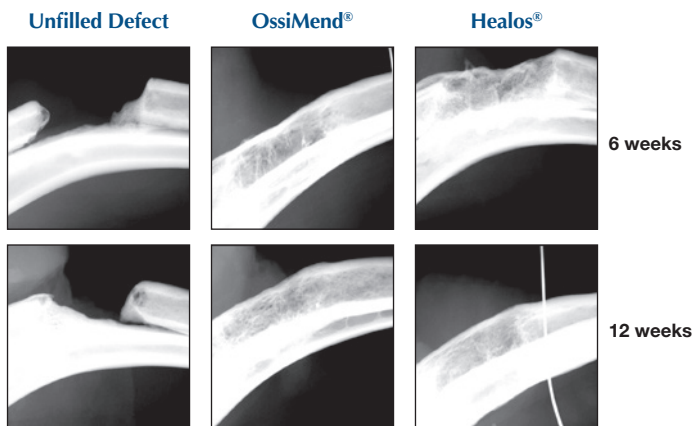


Figure 1: Radiographs of OssiMend®, Healos®, and empty defect at 6 weeks and 12 weeks.

## Conclusion

OssiMend® and Healos® in combination with autologous bone marrow successfully repaired critical size defects in the rabbit radius with the implant achieving axial regeneration of radius-like bone and synostosis at the junction of the implant and native bone. Complete new bone formation was observed at all 12 implant sites for both OssiMend® and Healos®.

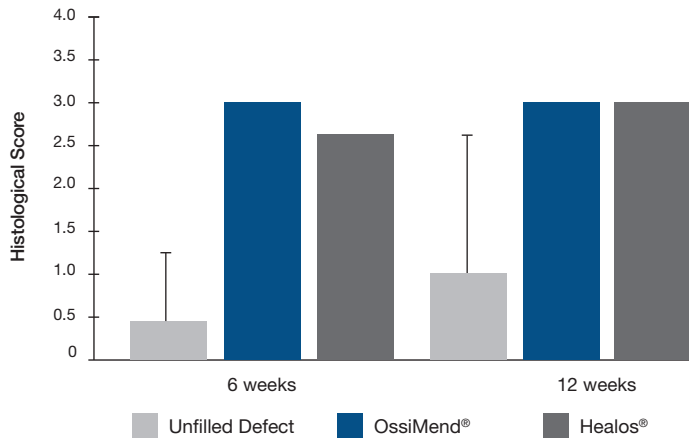


Figure 2: New bone formation at 6 weeks and 12 weeks of OssiMend®, Healos® as compared to empty defect.

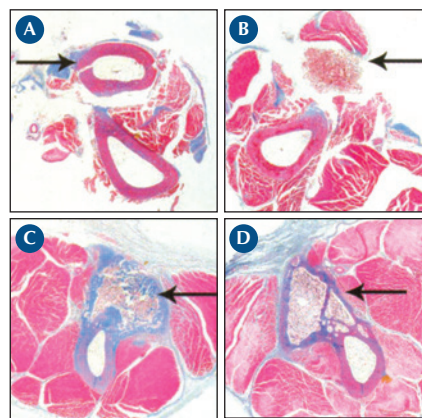


Figure 3A: Histology of Radius  
 A) Intact radius, no defect,  
 B) OssiMend® in place at day 0  
 C) OssiMend® / new bone at 6 weeks  
 D) OssiMend® / new bone at 12 weeks

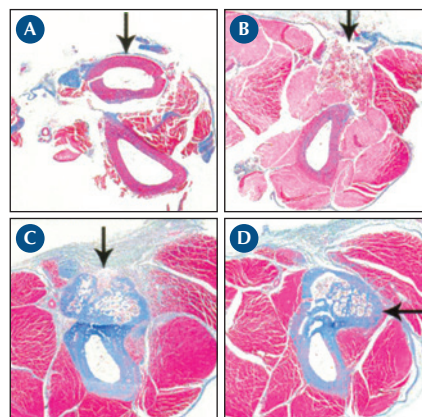


Figure 3B: Histology of Radius  
 A) Intact radius, no defect,  
 B) Healos® at day 0  
 C) Healos® / new bone at 6 weeks  
 D) Healos® / new bone at 12 weeks

# OssiMend®

THE ALL-NATURAL EFFECT

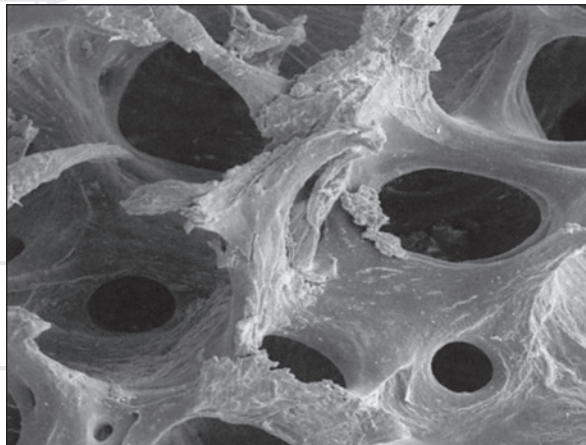


OssiMend® is a mineral-collagen composite matrix processed into strips, pads, blocks and putty for bone grafting procedures. The bone mineral and collagen in OssiMend® are derived from bovine bone and tendon. The natural mineral and collagen are highly biocompatible. The resorption and remodeling profiles of OssiMend® are more similar to normal human bone than those of synthetic materials, such as hydroxyapatite or tricalcium phosphate.

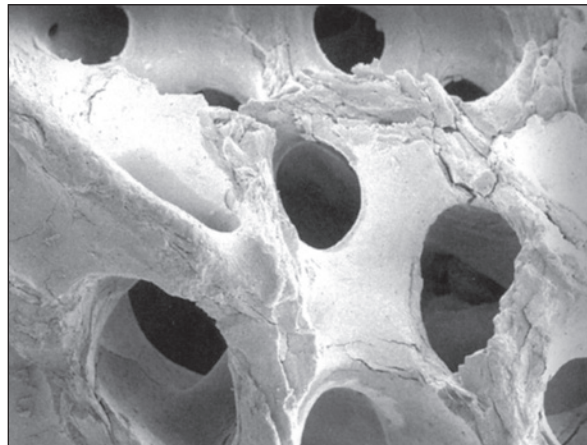
## Composition Based On Natural Bone

### Mineral Component – Carbonate Apatite Structure

- Carbonate apatite structure is the same as human bone
- Carbonate apatite structures are better osteoconductive materials than hydroxyapatite<sup>1,2,3</sup>
- Resorption and remodeling are similar to that of human bone<sup>2</sup>



Scanning Electron Micrograph of Processed Human Bone magnification x50



Scanning Electron Micrograph of Mineral component of OssiMend® (OssiGuide™) magnification x50

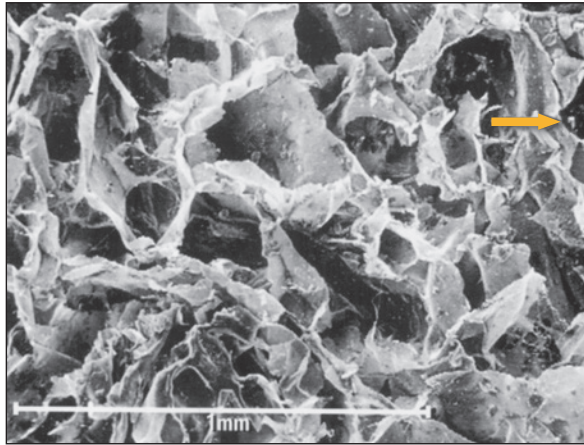
### Collagen Component - Type I Collagen


- Animal type I collagen is homologous to human type I collagen<sup>4</sup>
- Purified type I collagen is highly biocompatible
- Degradants during resorption are metabolized through normal metabolic pathways<sup>5,6</sup>
- Implantable collagen products have a long clinical history<sup>5</sup>
- Intact type I collagen fibers have intrinsic hemostatic properties to control minor bleeding<sup>5,7</sup>



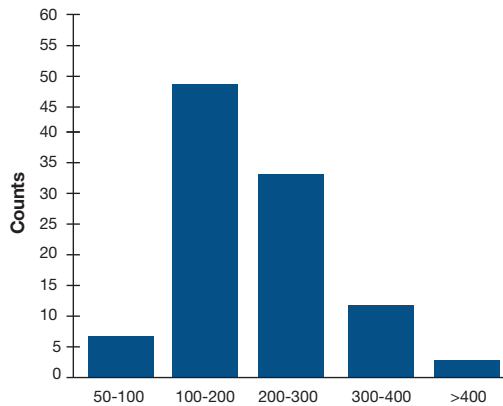
### Optimal Porosity<sup>8,9,10,11</sup>

- Pore size plays a role in effectiveness to support host tissue regeneration
- 100 - 400  $\mu\text{m}$  pore size is optimal for tissue regeneration<sup>8,12</sup>
- OssiMend<sup>®</sup> products have pore sizes within the optimal range<sup>14</sup>



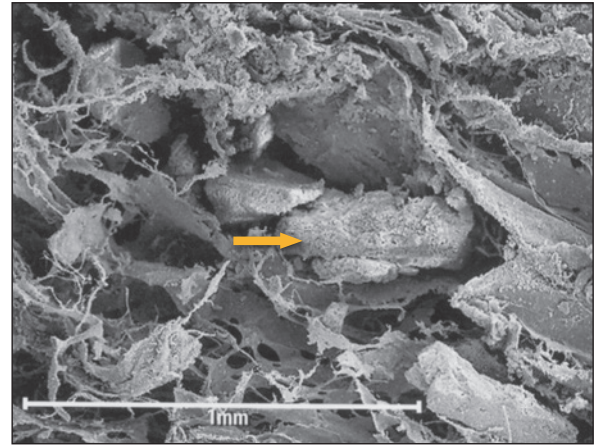
Scanning Electron Micrograph of OssiMend<sup>®</sup> Strip magnification x50 (  ) Mineral particle (Particle size range <0.125mm)


Pore Size Distribution OssiMend<sup>®</sup>



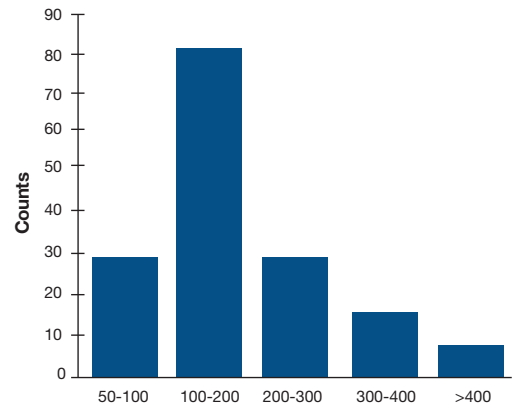
Pore Size (microns)

OssiMend<sup>®</sup> - 92% pores within the optimal range



Scanning Electron Micrograph of OssiMend<sup>®</sup> BLOCK magnification x50 (  ) Mineral particle (Particle size range 0.25-1.25mm)

Pore Size Distribution OssiMend<sup>®</sup> Block



Pore Size (microns)

OssiMend<sup>®</sup> Block - 78% pores within the optimal range

### Highly Absorbent Delivery Matrix

- OssiMend<sup>®</sup> absorbs fluid, such as bone marrow aspirate, to deliver the osteoinductive, osteogenic, “bioactive” stem cell rich composite matrix locally to the injury site
- Absorption Capacity<sup>14</sup>

	Absorbency (ml/g)
OssiMend <sup>®</sup>	12.2 $\pm$ 0.7
OssiMend <sup>®</sup> Block	3.8 $\pm$ 0.2
OssiMend <sup>®</sup> Putty	12.0 $\pm$ 0.1
Vitoss <sup>®</sup> Foam Strip	2.1 $\pm$ 0.1

## Handling Alternatives

- Available in pads, strips, blocks and putty to meet surgeon handling preferences



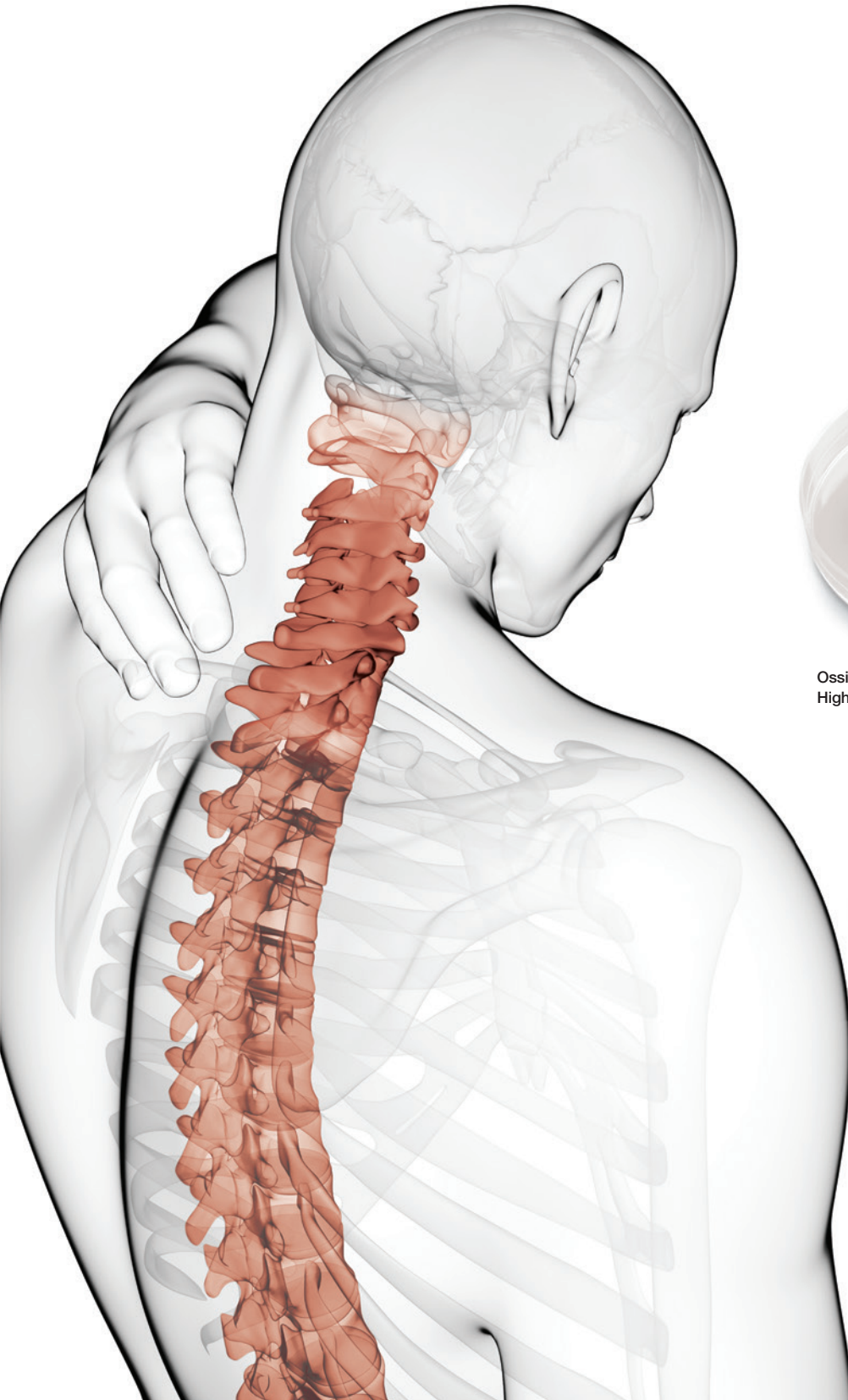
OssiMend® Pads and Strips  
Highly absorbent, conformable, and adaptable



OssiMend® Putty  
Highly absorbent, moldable when hydrated



OssiMend® Block  
Absorbent, flexible when hydrated, and  
compression resistant



## REFERENCES

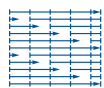
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## OssiMend® Strips, Pads, Putty, Block Bone Graft Matrix OssiGuide™ Anorganic Bone Mineral Cancellous Granules

### INDICATIONS

OssiMend® combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

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**Collagen Matrix, Inc.**  
*Science, Technology, Innovation*

Oakland Corporate Headquarters | 15 Thornton Road | Oakland, NJ 07436, USA  
Tel 201.405.1477 | Toll Free 888.405.1001 | Fax 201.405.1355

[www.collagenmatrix.com](http://www.collagenmatrix.com)