





InterOss®

Anorganic Cancellous Bone Granules

InterOss® is a natural hydroxyapatite bone grafting material for use in dentistry. Made from a proven multi-step purification process which leaves only a bone composition, it is a highly purified osteoconductive material for bone regeneration.

Having an interconnected network of macro and micro pores and large inner surface areas that provides an ideal environment for cell attachment, InterOss® is chemically and structurally comparable to mineralized human bone. It is available in sterilized granule form and is dedicated for single uses.

Indications of Use

InterOss® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge including the filling of extraction sockets
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Elevation of the maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for guided tissue regeneration (GTR) and guided bone regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for guided bone regeneration (GBR)

Available in the following options Small Granules (0.25 - 1.0 mm)

VIAL	Volume	Weight
IOSG025	0.54 сс	0.25 g
IOSG050	1.08 cc	0.5 g
IOSG100	2.16 cc	1.0 g
IOSG200	4.32 cc	2.0 g

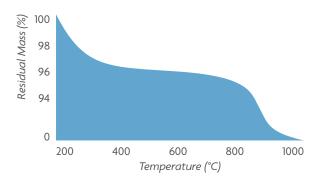
SYRINGE	Volume
IOSGS025	0.25 cc
IOSGS050	0.5 cc
IOSGS100	1.0 cc
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Features & Benefits

Biocompatible

Highly purified bone mineral resulting from a long annealing process. A plateau region observed in the Thermogravimetric Analysis curve below shows extremely low residual organic substances.

The same of



Micro & Macro Porous

- Porosity enhances osteogenesis and promotes attachment and proliferation of bone forming cells
- Micropososity facilitates proliferation of osteoblasts
- Macroporosity allows vascularization and plays important role in the osteoconductivity

Large Granules (1.0 - 2.0 mm)

VIAL	Volume	Weight	
IOLG050	2.0 cc	0.5 g	
IOLG100	4.0 cc	1.0 g	
IOLG200	8.0 cc	2.0 g	

SYRINGE	Volume
IOLGS050	0.5 cc
IOLGS100	1.0 cc

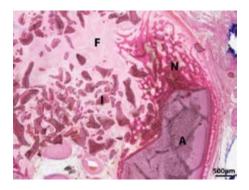
Features & Benefits (cont'd)

Osteoconductive

A preclinical trial was conducted to treat 54 mandibular critical-sized alveolar ridge defects in 27 canines. The study confirmed InterOss®' osteoconductivitiy as it was clinically and histologically successful in forming new bone.

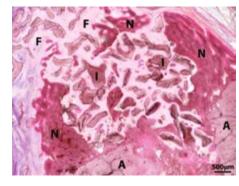
At 4 weeks:

Residual material with some woven bone formation (N) was observed.



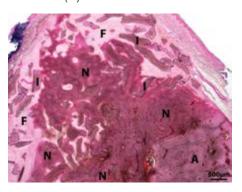
At 8 weeks:

A significant amount of new bone formation (N) was observed.



At 12 weeks:

A mixture of mature and woven bone formation (N) was observed.



InterOss® Bio-Oss®

A Comparison Study with Bio-Oss®

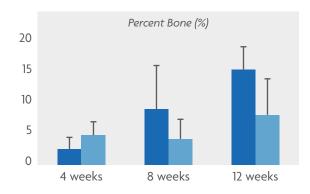


Figure 1, Histomorphometry

Percent Bone by Area (BA/DA)

While not statistically different, on average InterOss® had more than twice the mean amount of bone present at 8 and 12 weeks (8.88% and 14.76%, respectively) as compared to Bio-Oss® (3.58% and 7.54%, respectively).

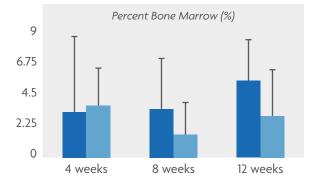


Figure 2, Histomorphometry

Percent Residual Graft by Area (GA/DA)

Overall, both InterOss® and Bio-Oss® were very similar throughout the study; no statistical differences in percent residual graft were observed between the two treatment groups. At 12 weeks, the values were 5.78% ffl 2.83 for InterOss® and 5.73 ffl 4.43 for Bio-Oss®.

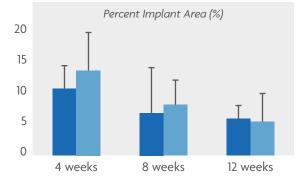


Figure 3, Histomorphometry

Bone Formation Density (BA/BMA)

Bone formation density is the ratio of newly formed bone to newly formed bone marrow area and can be used to understand bone formation densities.

Application & Handling



Hydration

InterOss® can be hydrated in blood or sterile saline solution.

Wound Closure

Ensure that the grafted site is securely closed with the soft tissue free of tension.

Healing Time and Re-entry

Healing time depends on the patient, nature and the size of the defect site and thus must be determined by the clinician based on the initial diagnosis. For a safe re-entry, it is recommended to let the surgical site heal for at least six months to ensure the graft material has been integrated properly.

For Use with Allograft

The long-term stability of InterOss® coupled with the biological potential of allograft may yield enhanced bone regeneration.

For Use with Autologous Bone

InterOss® helps achieve a natural biological activity due to the osteoinductivity and osteogenesis of autologous bone which in turn may encourage faster regeneration.

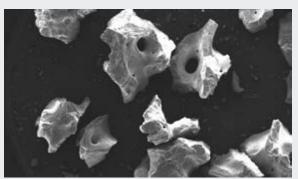
Application

- InterOss® can be adminstered to the surgical site after hydration using a surgical currette or periosteal elevator.
- For maximum results, the graft material should make sufficient contact with the bleeding bone surface to facilitate ingrowth of new blood vessels and bone forming cells.
- A resorbable membrane should be used in conjunction with the graft material by placing over it to minimize particulate migration

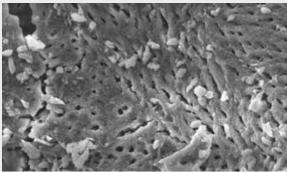
Properties

Attribute	Description
Composition	Calcium phosphate (100% pure hydroxyapatite, mineral phase)
Integration time	6 - 9 months (depending on defect)
Storage temperature	59 - 77 °F / 15 - 25 °C
Degradation profile	Bovine hydroxyapatite provides osteoconductive surface enabling a slow degradation and enhanced osseointegration of particles into a new bone.

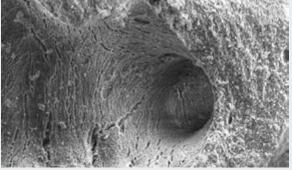
The existence of mesopores and micropores in the granules increases the inner surface area enhancing osteoconduction thus encouraging bone growth inside the pores.



→ 300μm



— 3um



--→ 30μm

Objective

Patient was missing tooth number 42. It was determined that the missing tooth should be restored by implant restoration.

Conclusion

InterOss® actively induced new bone formation, and implant placement surgery was successful. Decalcified section showed a trabecular bony network with thick osteophyte formation.

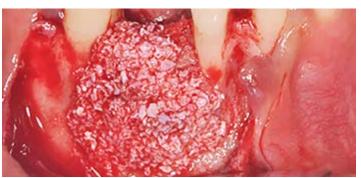


Pre-operative view.



A view of the bone defect.





InterOss® placement.



Membrane placement and immediate post-operative view.



Post-operative view at 5 months.



Implant placement.



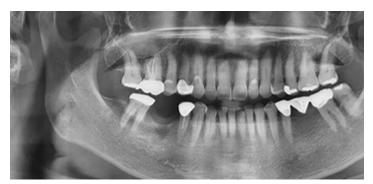
Post-operative view at 10 months.



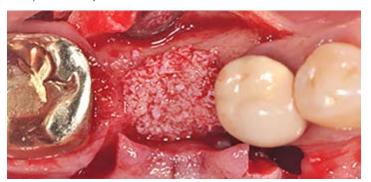
Post-operative view at 10 months with crown installed.

Objective

Patient was missing tooth number 46. It was determined that ridge augmentation was needed for implant placement.



Pre-operative X-ray.



InterOss® placement.



Post-operative X-ray at 4 months.



Implant placement.

Conclusion

After 5 months of healing, implant placement surgery was performed and successful. Decalcified section showed active new bone formation on InterOss®. As InterOss® gradually resorbed, it subsequently induced osteogenic effect for excellent bone formation.



A view of the bone defect.



Membrane placement and immediate post-operative view.



View at re-entry.



Immediate post-loading view and 4 weeks after.

Objective

Patient suffered from missing tooth number 15 and 16. It was determined sinus augmentation was necessary for implant placement surgery.



Pre-operative X-ray and view.

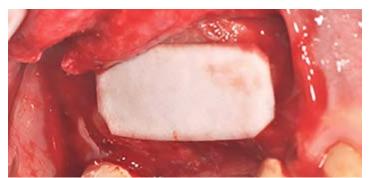


Exposure of the defect site.

Conclusion



Sinus cavity exposure.



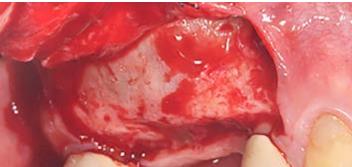
Membrane placement.

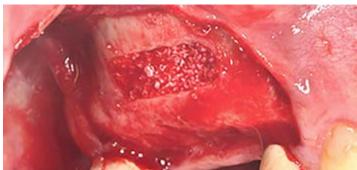


Post-operative X-ray at 1 week.



Decalcified section showed active new bone deposition on the xenogeneic graft bone (InterOss®). This graft lesion was clearly





InterOss® placement.



Immediate post-operative view.



Post-operative X-ray at 7 months.



