GRAFT
Biomaterials

SCIENCE THAT NURTURES WELLNESS

A NOVEL REVOLUTION IN BONE REGENERATION

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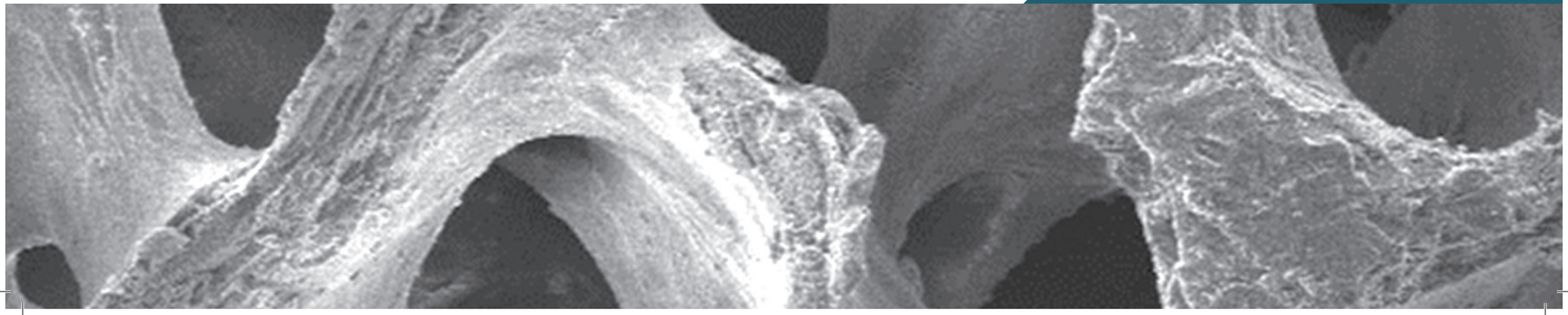
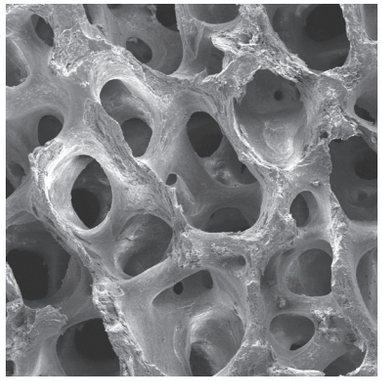
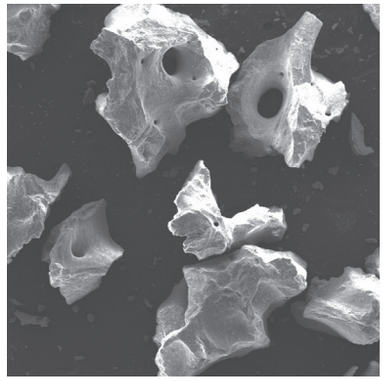
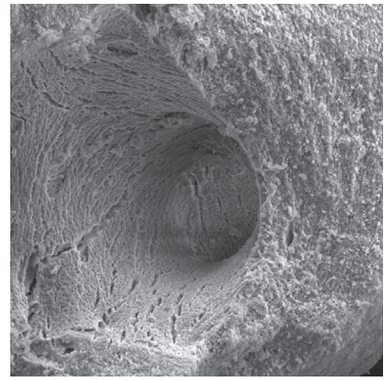
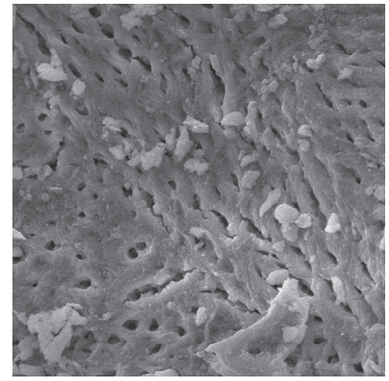


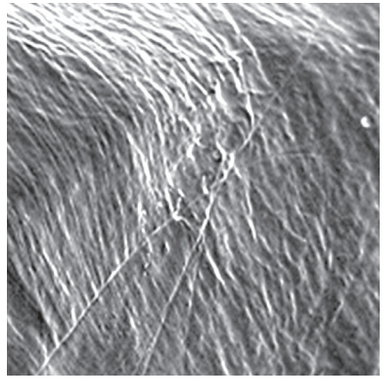


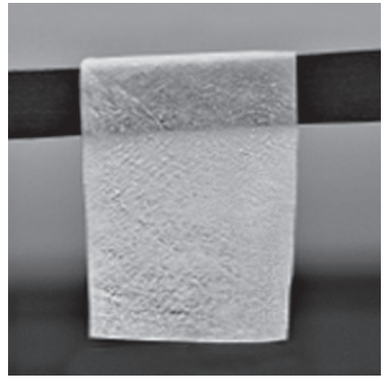


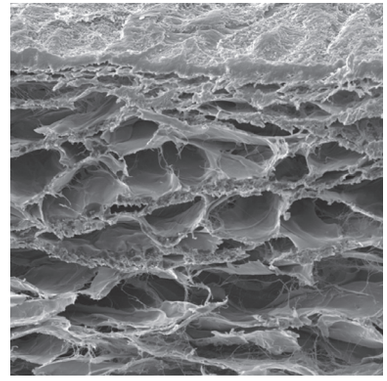
InterOss®





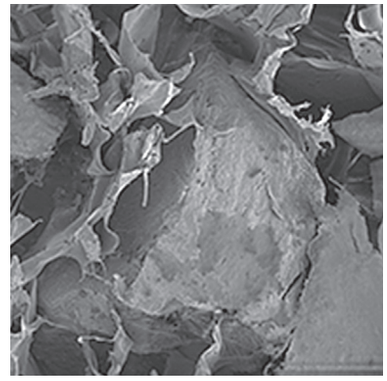


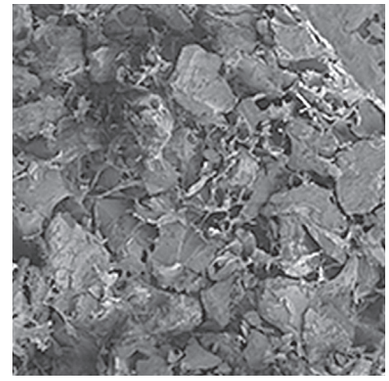




InterCollagen® Guide

InterOss® Collagen





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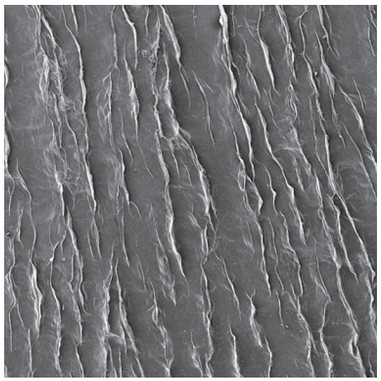

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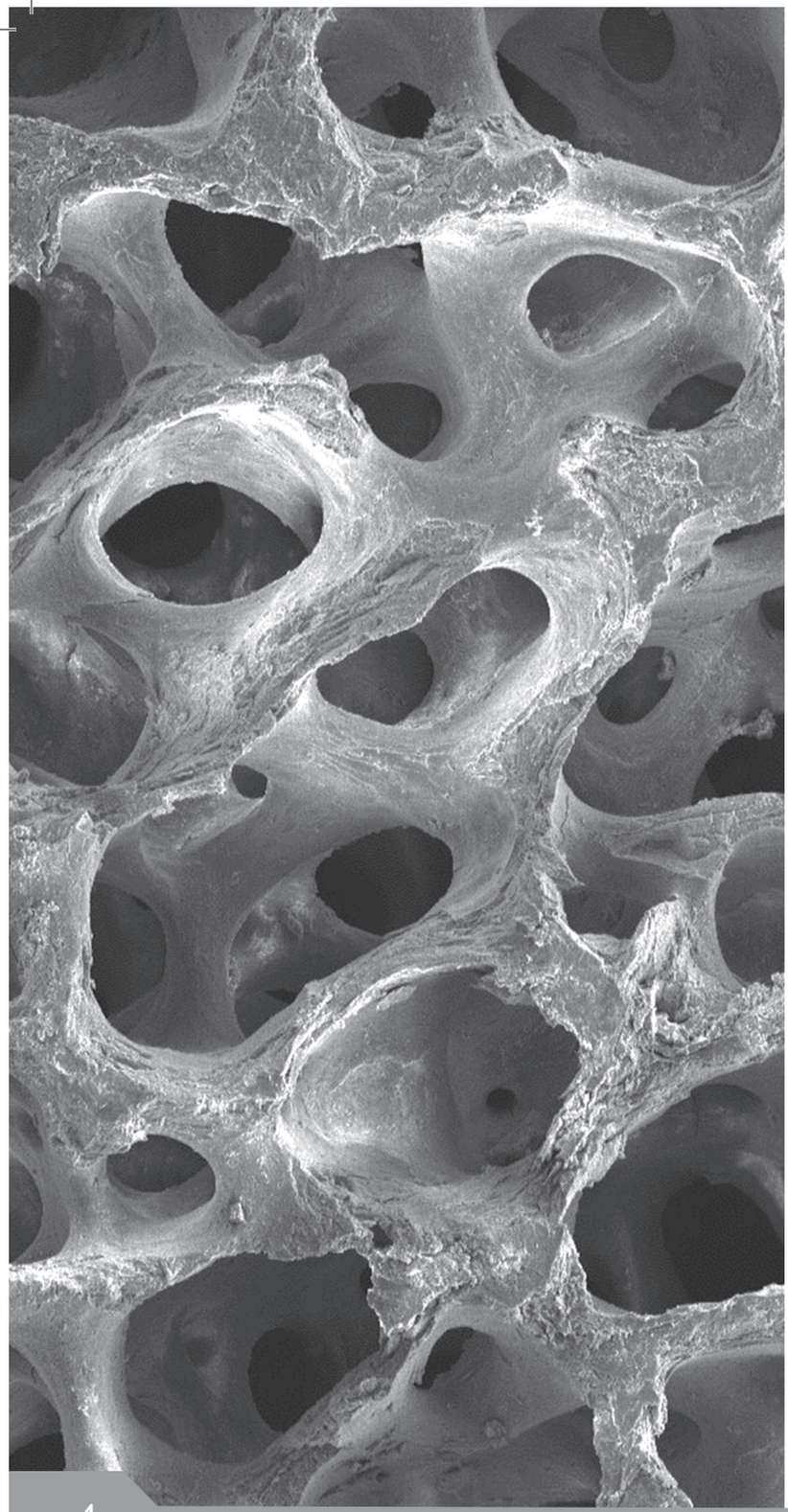


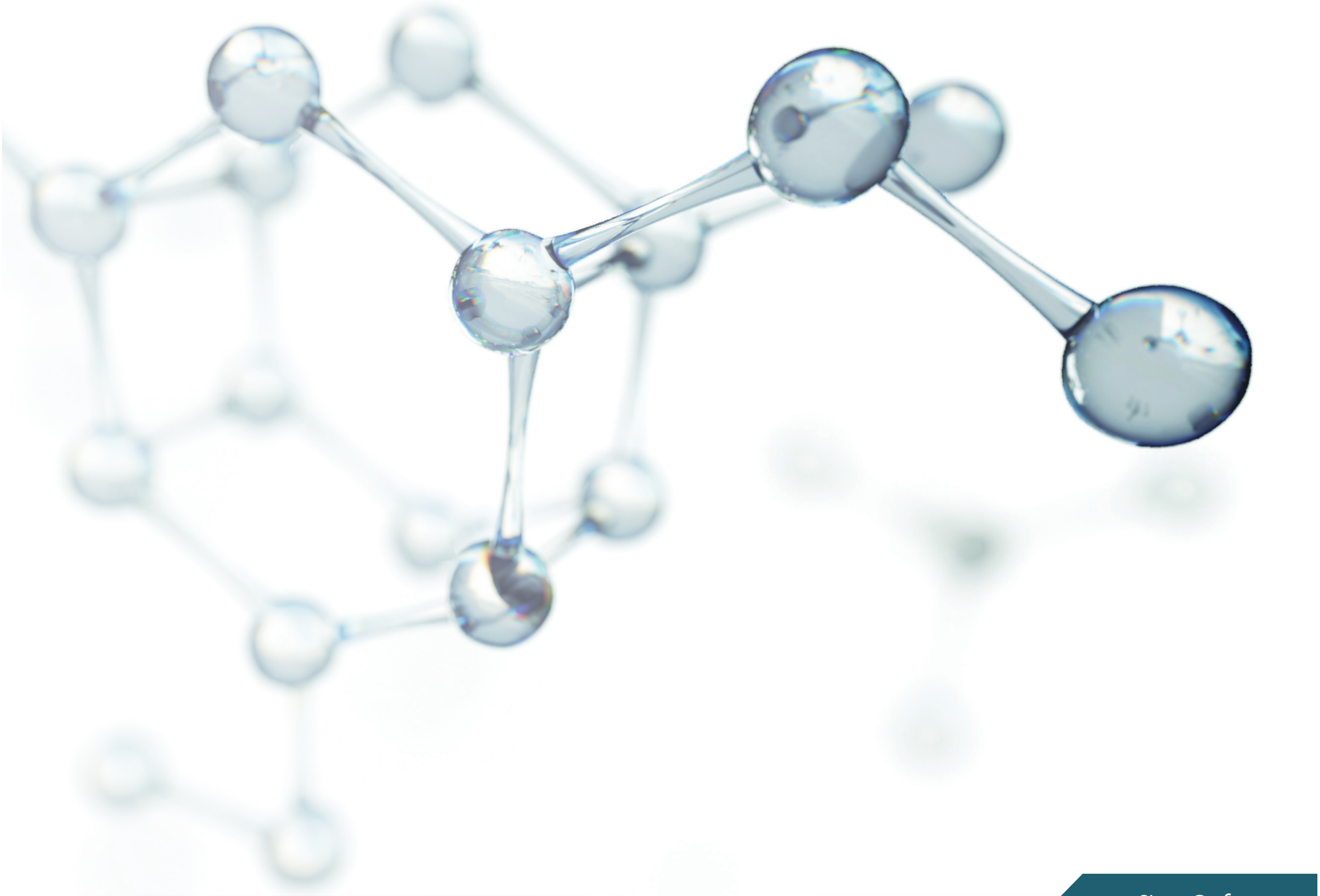
ABOUT US

SigmaGraft is a United States Manufacturer of dental and orthopedic biomaterials used in bone regeneration.
We manufacture bone grafting materials as medical devices and biomaterials in the areas of dental and orthopedic implant surgery. Our materials are used in surgical procedures that allow new bone growth in a region of loss due to diseases or injuries.

We specialize in the production of two types of grafiting material. The first is a xenograft product that consists of anorganic bovine bone. The second is synthetic bone graft products that are available in two forms, Biphasic Calcium Phosphate and β-tricalcium Phosphate. Additionally, we produce and provide synthetic raw bio-ceramic materials such as hydroxapatite (HAp), beta-tricalcium phosphate (β-TCP), and biphasic calcium phosphate (BCP) for various bone graft applications.

We are committed to providing innovative solutions to bone grafting surgeries.

Our mission is to focus our time and investment in researching, developing, and manufacturing the highest quality products for medical device business and distributors.

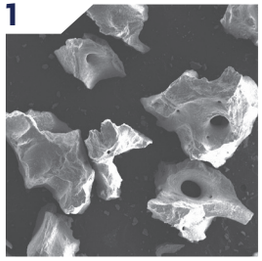


InterOss®

ANORGANIC CANCELLOUS GRANULES

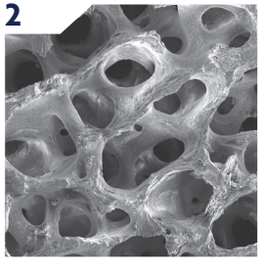
Granules

1



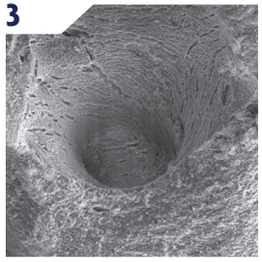
Macropore (>100µm)

2



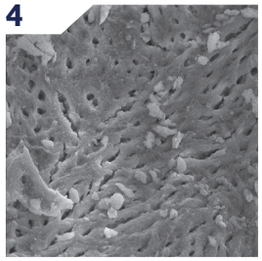
Mesopore (10 - 100µm)

3



Micropore (<10µm)

4



Storage: InterOss® should be stored in a dry, clean and well ventilated place at ambient temperature (15-25°C/59-77°F). Keep the product in aseptic conditions until using the product.

Sterilization: InterOss® is sterilized using gamma irradiation. Appropriate aseptic technique should be observed in all operations. The package should be inspected prior to use to ensure that the sterile barrier has not been compromised.

Caution: Federal (USA) law restrict this device to sale by or on the order of a licensed dentist.

InterOss® is a natural hydroxyapatite bone grafting material derived from Australia bovine (BSE free). The highly purified osteoconductive material is produced from natural bone through a multi-step purification process. Due to its natural origin, **InterOss®** is chemically, as well as structurally, comparable to mineralized human bone (nanocrystalline natural apatite). **InterOss®** is available in granule form. It is supplied sterile and is dedicated for single-use.

The presence of a macroporous structure favors cell ingrowth while the micropores allow the penetration of body fluids into the implant. The microporosity can also be a strategy to manipulate resorption and dissolution rate: the greater the microporosity, the greater the degradation rate.

The pore structure and interconnected pore system of **InterOss®** allow the grafting material to act as a guide for body fluids, grown factors, blood vessel, bone marrow, and bone cells.

Granule Size	Small granules (0.25-1mm)				Large granules (1-2mm)		
Volume	0.25 g	0.50 g	1.0 g	2.0 g	0.50 g	1.0 g	2.0 g
Reference	IOSG025	IOSG050	IOSG100	IOSG200	IOLG050	IOLG100	IOLG200

● Small granules (0.25-1mm) ● Large granules (1-2mm)

InterOss® Syringe

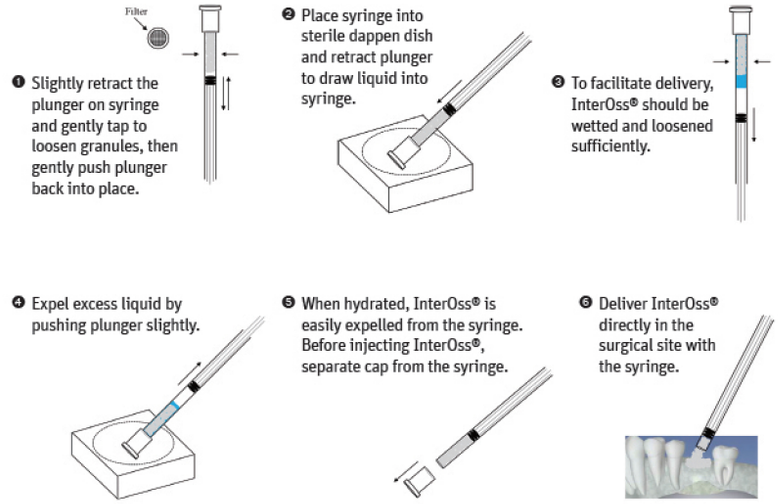
ANORGANIC CANCELLOUS GRANULES

InterOss® Syringe is a natural mineral derived from bovine bone originating from BSE-free Australia. The bovine cancellous bone is purified into an osteoconductive mineral, in a series of chemically-refining steps. This bone mineral is a single-use gamma sterilized product available in granule form. Due to its natural origin, this product is structurally and chemically similar to mineralized human bone. **InterOss®'s** inorganic bone matrix is constituted by macropores and micropores, characteristics that play a critical role in maintaining blood supply to the defect, promoting osteoconductivity,and contributing to tissue integration and wound stability.

In addition, high interconnectivity of pores ensures a high surface area for fast resorption and enhanced cells adhesion and proliferation. Overtime, the irregular- shaped **InterOss®** particles (0.25-2.0mm) incorporate with the living bone to provide long term volume support and promote angiogenesis and migration of osteoblasts.

Granule Size	Small granules (0.25-1mm)		Large granules (1-2mm)
Volume	0.25 cc	0.50 cc	0.50 cc
Reference	IOSGS025	IOSGS050	IOLGS050

● Small granules (0.25-1mm) ● Large granules (1-2mm)



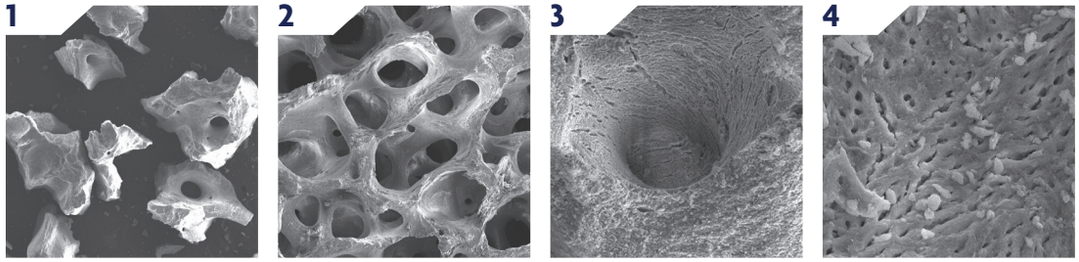
Storage: InterOss® should be stored in a dry, clean and well ventilated place at ambient temperature (15-25°C/59-77°F). Keep the product in aseptic conditions until using the product.

Sterilization: InterOss® is sterilized using gamma irradiation. Appropriate aseptic technique should be observed in all operations. The package should be inspected prior to use to ensure that the sterile barrier has not been compromised.

Caution: Federal (USA) law restrict this device to sale by or on the order of a licensed dentist.

InterOss®

ANORGANIC CANCELLOUS GRANULES

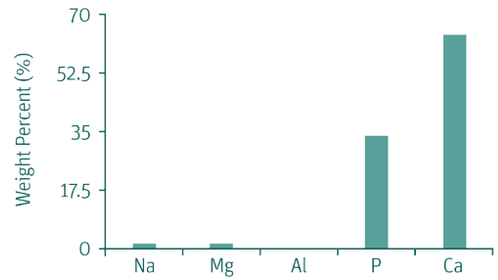


	InterOss®
Ca/P ratio Comparison (ICP-MS)	1.57
Crude Protein (%) (Protein Analyzer)	0.04
Inner Surface Area (m^2/g) (BET)	88.2

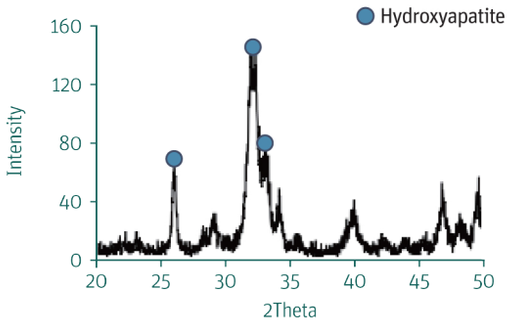
Energy-dispersive X-ray spectroscopy (EDS)

Element	App Conc.	Intensity Corrn.	Weight %	Weight %	Atomic %
Na K	0.13	1.0461	1.65	0.59	2.56
Mg K	0.11	0.9132	1.56	0.47	2.29
Al K	0.01	0.9883	0.07	0.39	0.10
P K	3.80	1.5103	33.21	1.03	38.36
Ca K	5.01	1.0408	63.51	1.13	56.69
Totals			100.00		

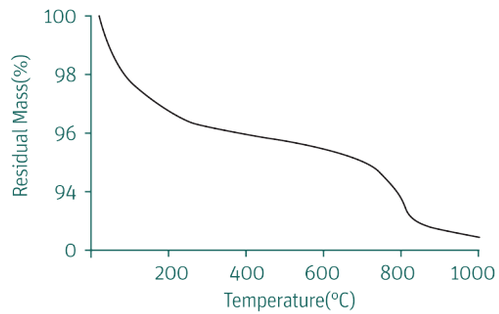
Quantitative Results



X-ray Diffraction

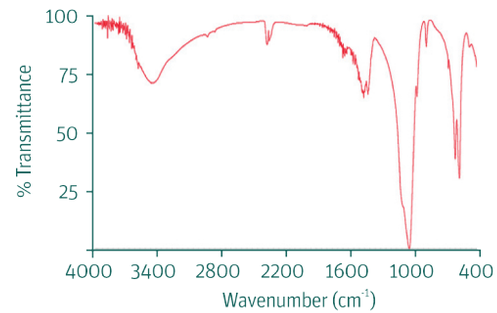


Thermogravimetric Analysis (TGA)



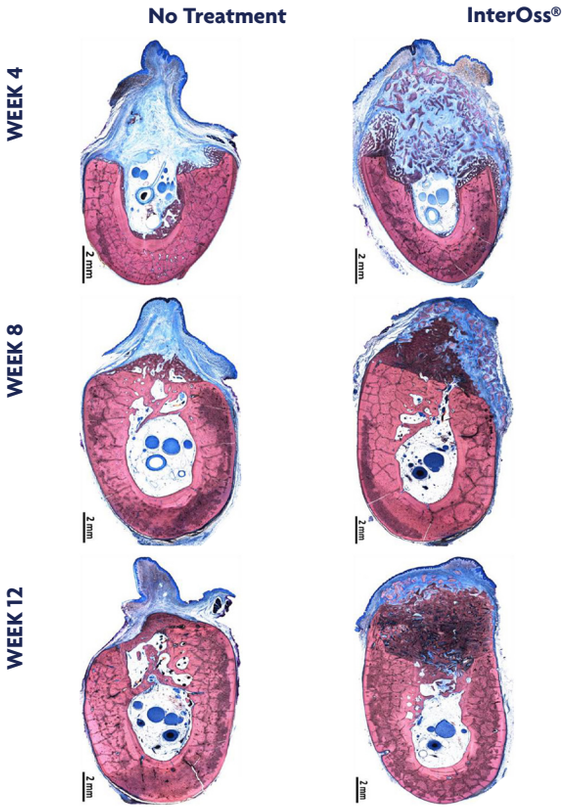
H_2O (%) (25-280°C)	3.36
CO_2 (%) (550-1000°C)	2.29
Carbonate (%)	6.64

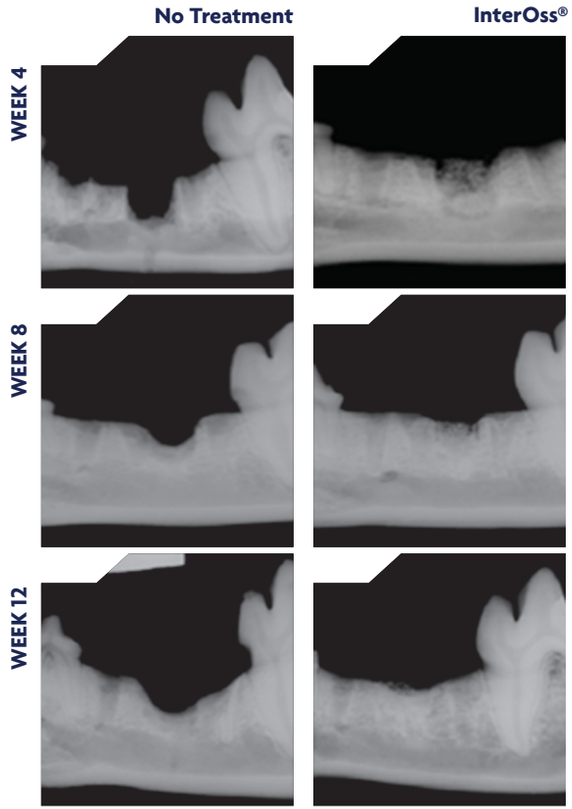
FTIR

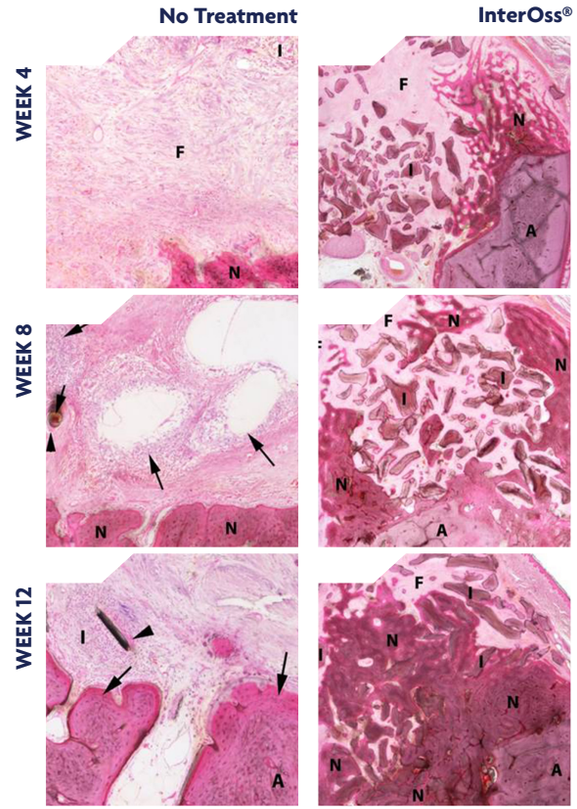


InterOss®

ANORGANIC CANCELLOUS GRANULES







Residual Implant Material, and New Bone formation and were scored as follows:

0 - Absent
1 - Minimal
2 - Mild
3 - Moderate
4 - Marked

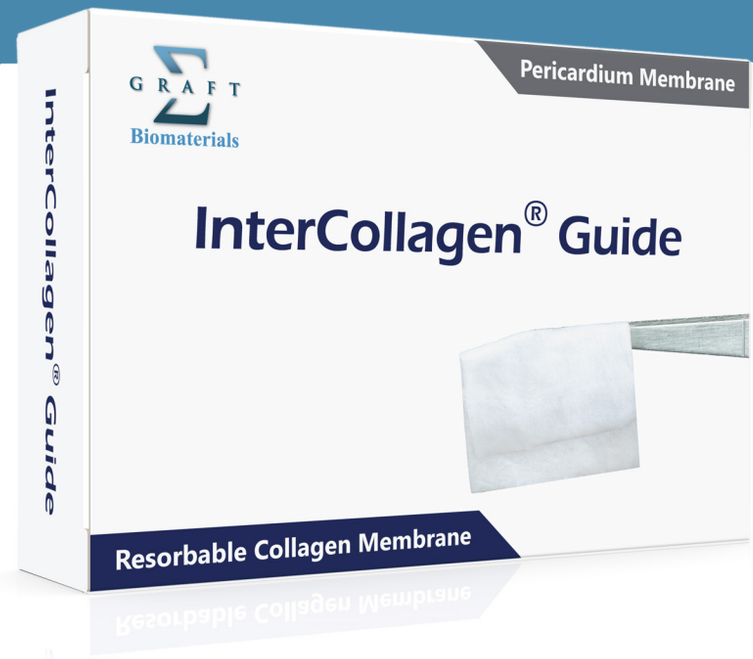
Bone Maturation was scored as follows:

0 - Predominantly woven bone
1 - More woven than mature
2 - 50% mature and 50% woven
3 - More mature than woven
4 - Mature alveolar bone

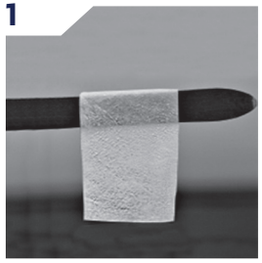
	InterOss®			Deefect - No Treatment		
	Week 1	Week 8	Week 12	Week 1	Week 8	Week 12
Residual Implant Material	3.0±0.0	2.3±0.5	2.5±0.5	0.0±0.0	0.0±0.0	0.0±0.0
Bone Maturation	0.0±0.0	0.2±0.1	2.3±0.5	0.0±0.0	0.2±0.1	3.0±0.0
New Bone formation	1.0±0.0	2.0±0.9	3.0±0.0	1.2±0.1	1.3±1.0	2.5±0.5

InterCollagen® Guide

RESORBABLE COLLAGEN MEMBRANE

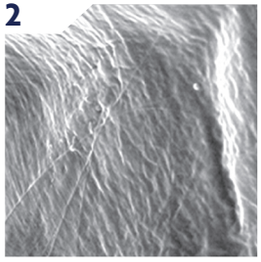


1



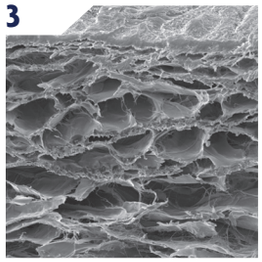
Macropore (>100µm)

2



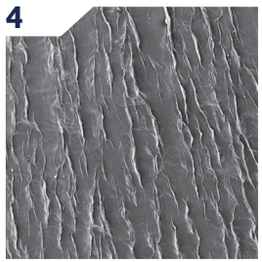
Mesopore (10 - 100µm)

3



Micropore (<10µm)

4



Storage: InterCollagen® Guide should be stored in a dry, clean and well-ventilated place at ambient temperature (15-25c/59-77F).

Sterilization: InterCollagen® Guide is sterilized using gamma irradiation. Appropriate aseptic technique should be observed in all operations. The package should be inspected prior to use to ensure that the sterile barrier has not been compromised.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed dentist.

InterCollagen® Guide is a cross-linked porcine derived resorbable collagen membrane used in periodontal and/or dental surgical procedures. One advantage of the collagen membrane is its dense fibrous architecture that prevents the infiltration of epithelial tissue into the bon defect. This dense fibrous architecture also enhances mechanical strength, increasing durability while still being easily sutured. The collagen membrane can be trimmed to the appropriate size, and once hydrated conforms easily to the defect site. **InterCollagen® Guide** will be available to the United States market in 2 versions: 15X20mm30x40mm. The Collagen membrane is gamma irradiated, supplied sterile, non-pyrogenic, and intended for single use only.

	InterCollagen® Guide	
Size	15x20mm	30x40mm
Reference	ICG1520	ICG3040

Benefits include:

- High mechanical strength (>5MPa)
- Easily hydrated (90 seconds for 30 x 40 mm sheet)
- Durable when hydrated or dry
- Any face of the membrane may be in contact with the defect

InterOss® Collagen

RESORBABLE COLLAGEN BLOCK

InterOss® Collagen Block is a resorbable type I collagen- anorganic bone composite block for regenerative dental applications. It consists of 80% InterOss® bone graft small granules (250µm to 1000 µm) and 20% porcine collagen. InterOss® bone grafts are used to replace or enhance bone growth in order to repair bone defects or bone fractures. Combining InterOss® with highly purified collagen will enhance its handling characteristics making **InterOss® Collagen Block** formable and easy to handle. Additionally, the scaffold matrix has a similar structure to natural bone that provides a biocompatible environment for bone-growth as well as osteoconductive characteristics. The InterOss Collagen™ Block will be available in 100mg, 250mg, and 500mg block sizes for ease of use.

Benefits include:

- Mechanical strength to maintain bone void space and resist soft tissue pressure
- Absorbs well in the body
- Assists in tissue healing/guided tissue and bone regeneration
- Encloses grafting material so that it does not migrate from the placement site
- Biocompatible and safe
- Does not cause inflammation
- Has high surface area and interconnected pores to provide suitable environment for bone regeneration
- Provides high osteoinductivity
- Preserves the natural structure of bone

Storage: InterOss® should be stored in a dry, clean and well ventilated place at ambient temperature (15-25°C/59-77°F). Keep the product in aseptic conditions until using the product.

Sterilization: InterOss® is sterilized using gamma irradiation. Appropriate aseptic technique should be observed in all operations. The package should be inspected prior to use to ensure that the sterile barrier has not been compromised.

Caution: Federal (USA) law restrict this device to sale by or on the order of a licensed dentist.

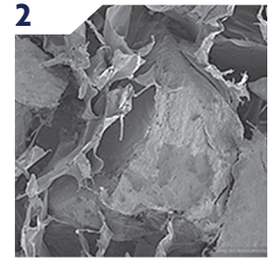
	InterOss® Collagen Block		
Weight	100mg	250mg	500mg
Reference	IOC100	IOC250	IOC500

1

1

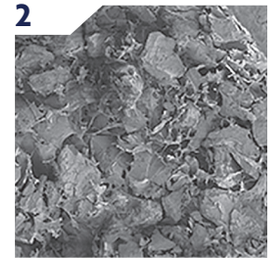
Macropore (›100µm)

2



Mesopore (10 - 100µm)

2

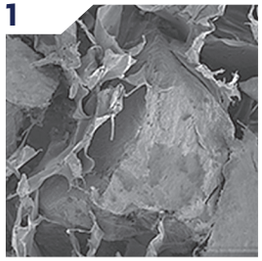


InterOss® Collagen

RESORBABLE COLLAGEN PLUG

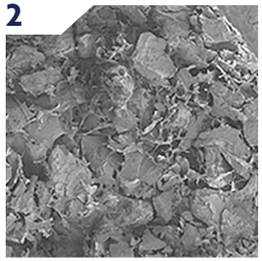
Macropore (>100µm)

1



Mesopore (10 - 100µm)

2



Storage: InterOss® Collagen Plug should be stored in a dry, clean and well-ventilated place at ambient temperature (15-25c/59-77F).

Sterilization: InterOss® Collagen Plug is sterilized using gamma irradiation. Appropriate aseptic technique should be observed in all operations. The package should be inspected prior to use to ensure that the sterile barrier has not been compromised.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed dentist.

	InterOss® Collagen Plug		
Size	Small	Medium	Large
Reference	IOCP100	IOCP250	IOCP500

InterOss® Collagen Plug is a resorbable type I collagen – anorganic bone composite plug for regenerative dental applications. It consists of **InterOss®** bone graft small granules (250 um to 1000 um) and porcine collagen. The **InterOss®** bone graft is used to replace or enhance bone growth in order to repair bone defects or bone fractures. Combining **InterOss®** with highly purified collagen will enhance its handling characteristics making **InterOss®** Collagen formable and easy to handle. Additionally, the scaffold matrix that is similar to a natural bone structure will provide a biocompatible environment for the bone-growth and osteoconductive characteristic.

Benefits include:

- Maintain bone void space and bear soft tissue pressure
- Absorbs well into the body
- Assist in tissue healing/guided tissue and bone regeneration
- Enclose grafting material preventing migration
- Biocompatible and safe
- Does not cause inflammation
- Provide high osteoinductivity
- Preserve the natural bone structure

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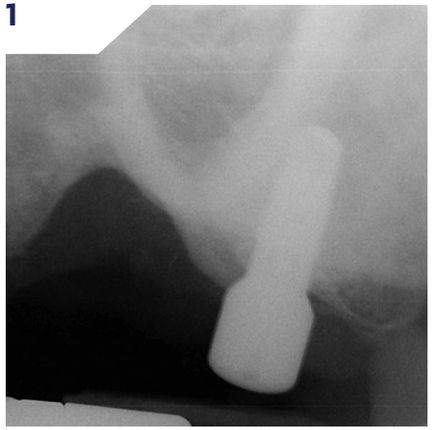
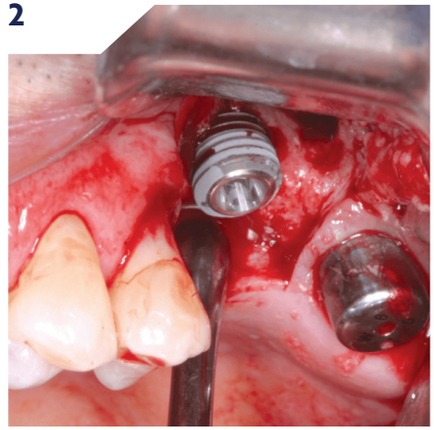
InterOss®

ANORGANIC CANCELLOUS GRANULES

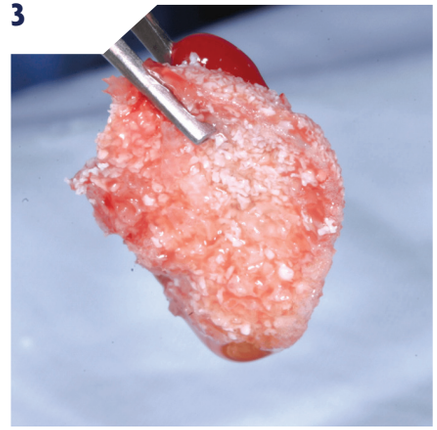
1 Preoperative X-ray



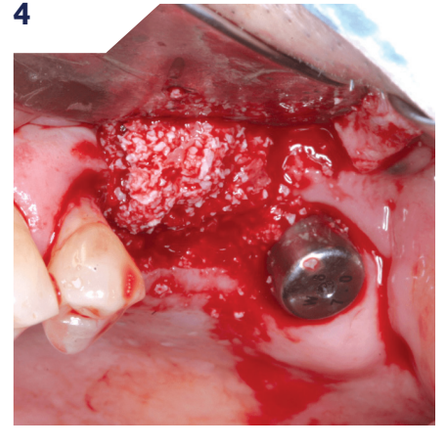
2 Immediate implant placement at -26



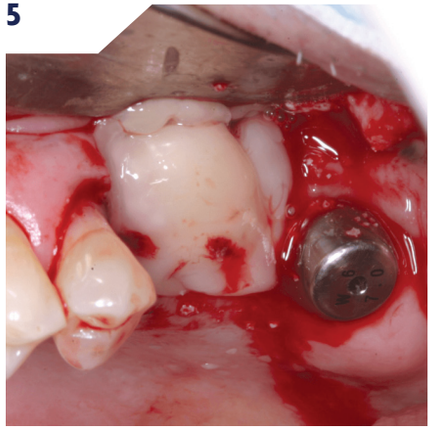
3 InterOss® - mixed with allograft



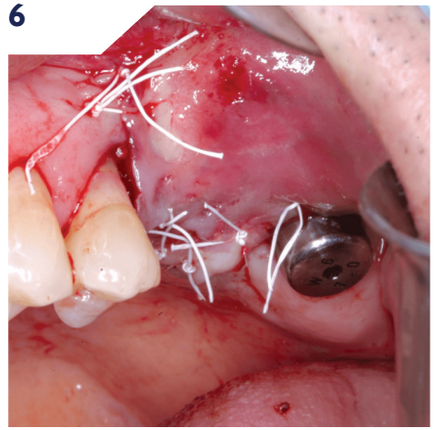
4 Ridge augmentation with InterOss- allograft mixture



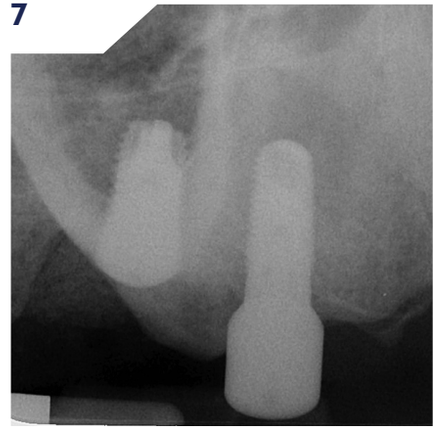
5 InterOss® - allograft mixture was covered with platelet rich fibrin



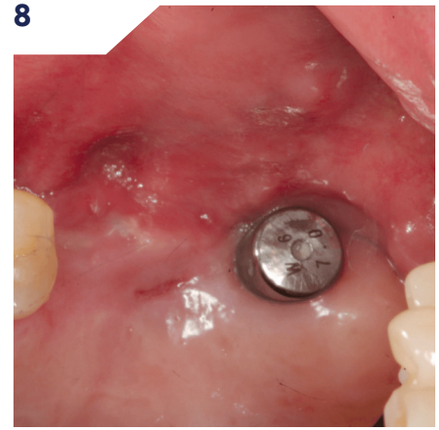
6 Site Closure



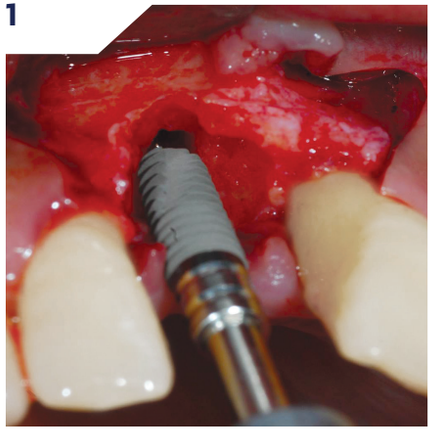
7 Postoperative X-ray



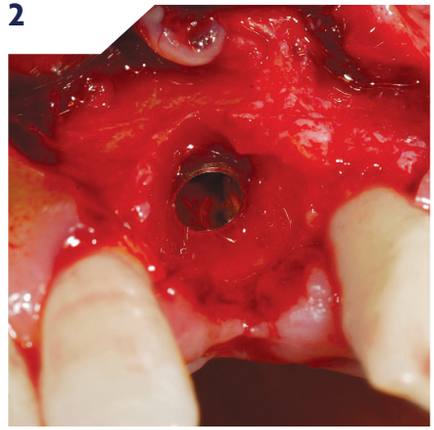
8 After 5 months healing time



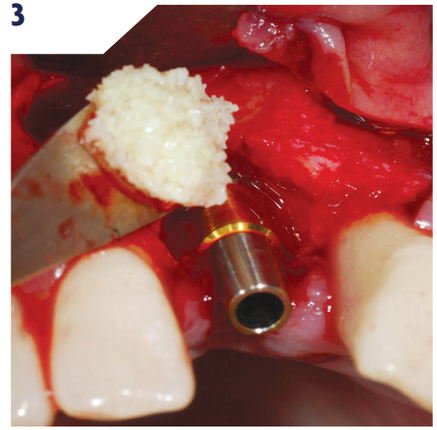
1 Implant Site



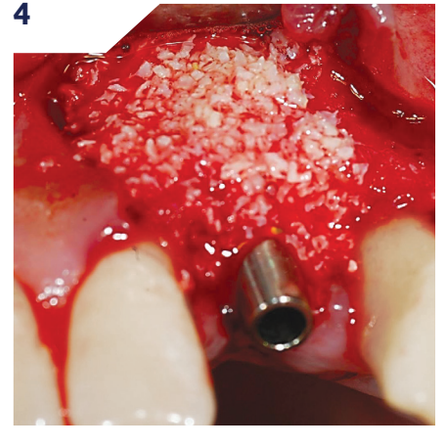
2 Implant Placement



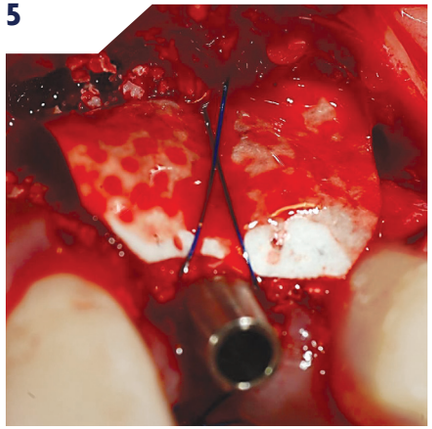
3 InterOss® Placement



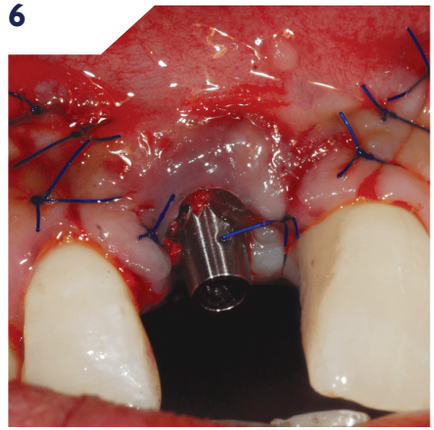
4 InterOss® Placement



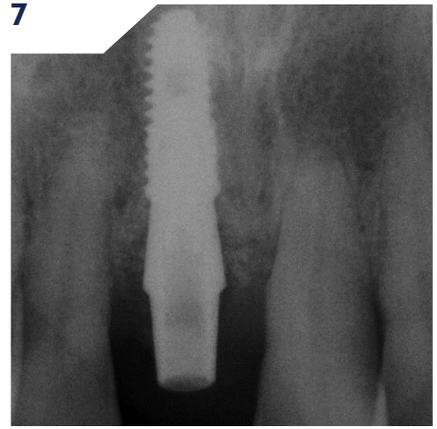
5 Collagen Membrane Placement



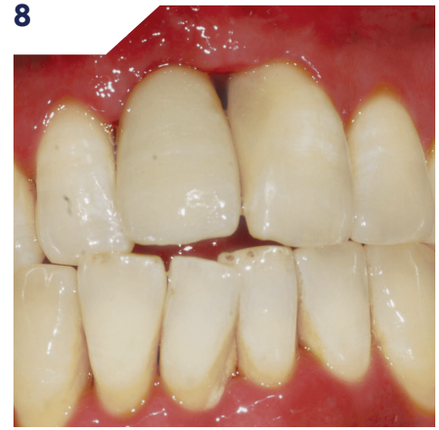
6 Site closure. The implant was immediately loaded with a temporary crown



7 X-ray at 2 Months



8 Second provisional restoration

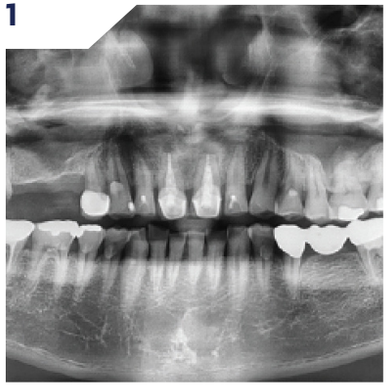


InterOss®

ANORGANIC CANCELLOUS GRANULES

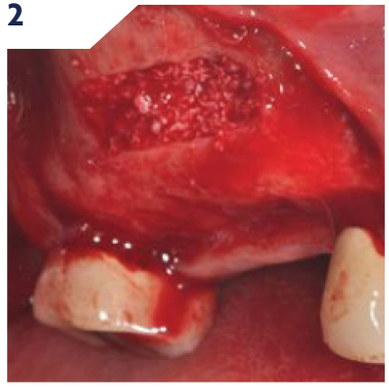
Initial Examination of missing #3 and #4. (Internationally #16 an #15) Panoramic View Radiograph

1



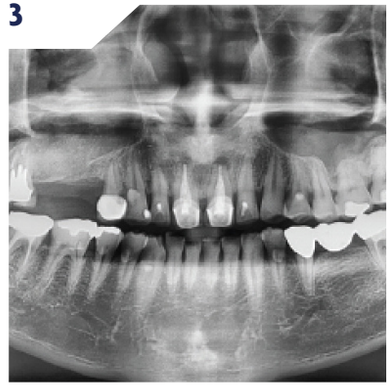
InterOss® Placement

2



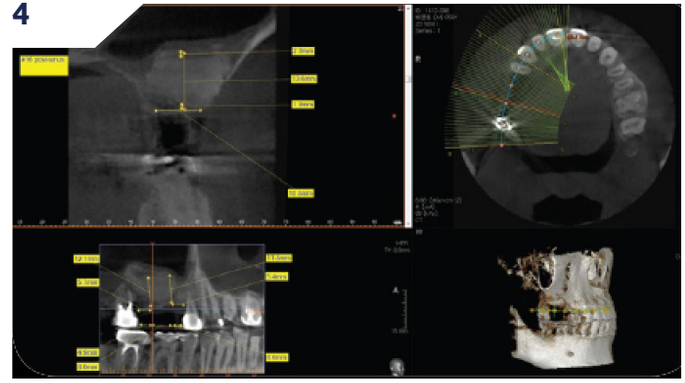
Panoramic view 1 week post Sinus Augmentatnion

3



CT scan (internationally #16) 4 months post Sinus Augmentatnion

4

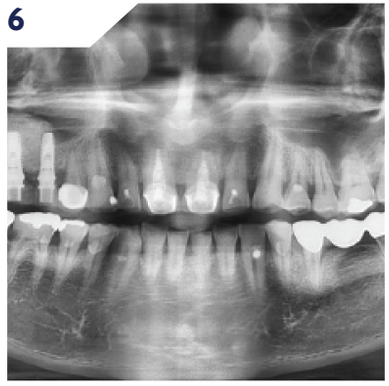


Implant Placement Surgery Implant Surgery #3 and #4 (7 months post graph placement)

5

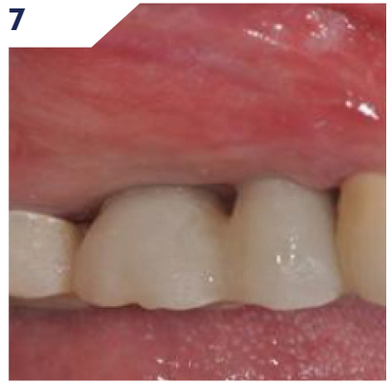
Panoramic view of #3 and #4 at Provisional Restoration (10 months post bone graph placement)

6



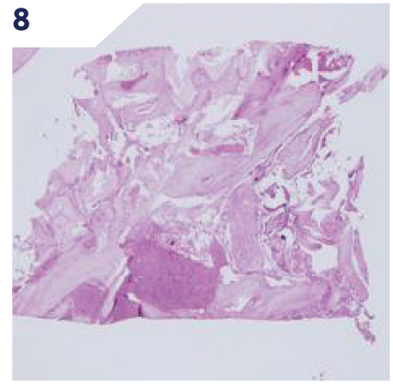
10 months post bone graph surgery

7



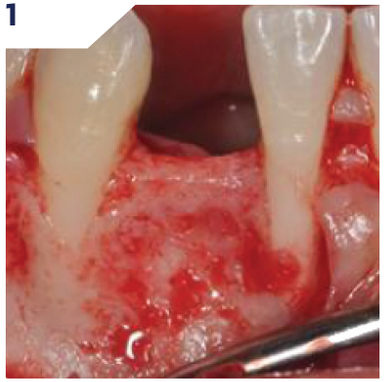
A core biopsy sample was taken from the graft site of #3. Biopsy was taken at the time of implant surgery 7 monts post-graft

8



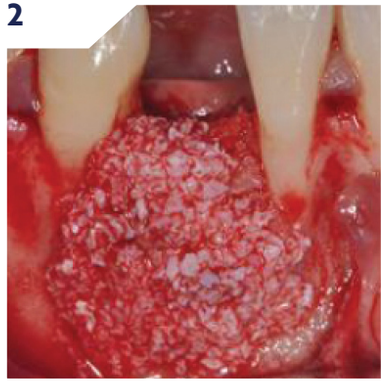
Ridge Augmentation
Horizontal Augmentation

1



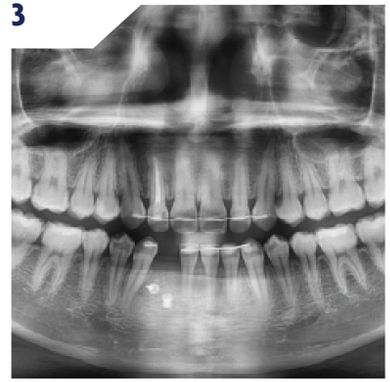
InterOss® Placement

2



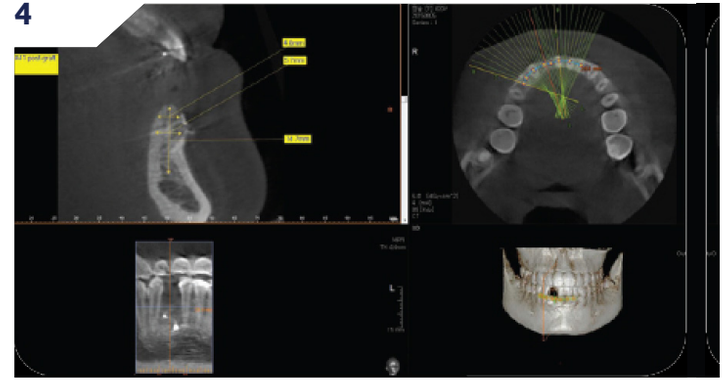
Panoramic view at 5 weeks post opperation showing #25 bone graft

3



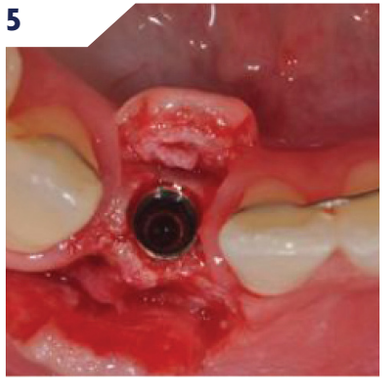
CT at 5 months 2 weeks postoppertion showing #26 bone graft

4



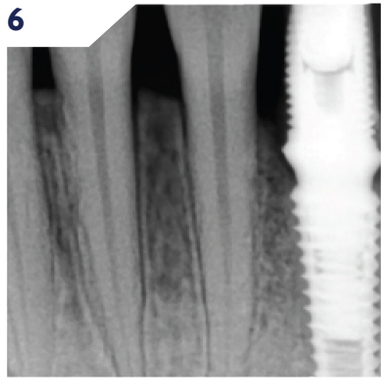
Implant Placement Surgery

5



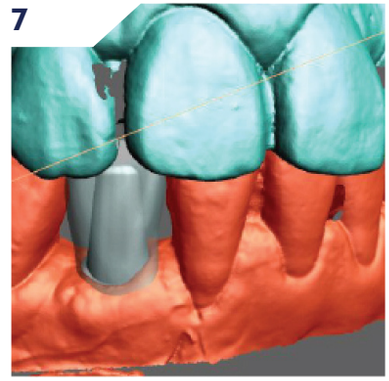
Panoramic view at 5 weeks post implant showing #26 bone graft and implant. (7 months post graft placement)

6



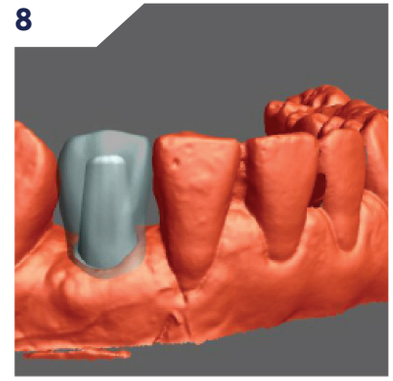
CAD/CAM

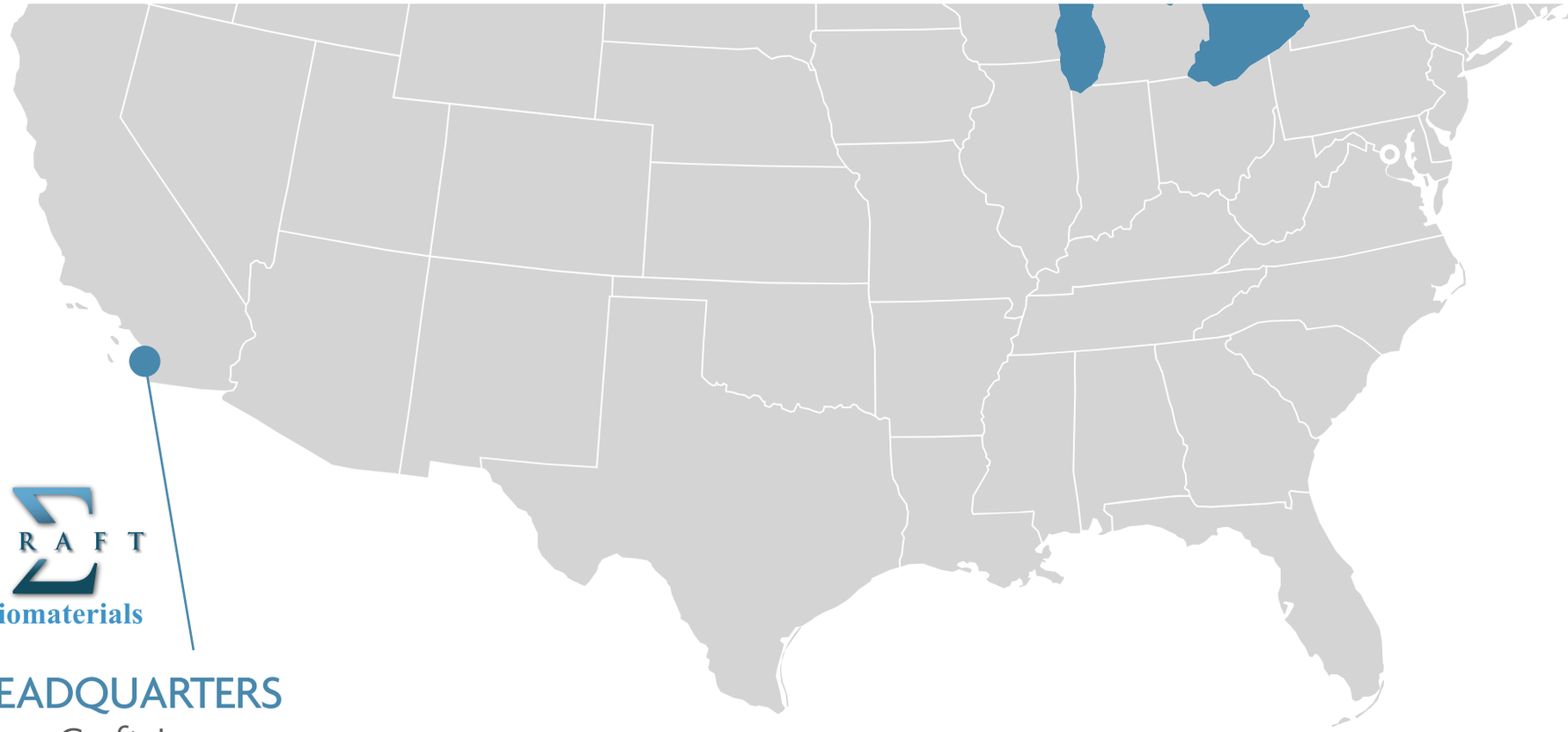
7



CAD/CAM

8





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