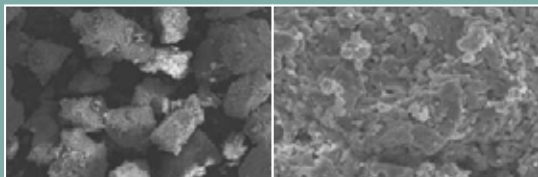


SynthoGraft™

Pure Phase Beta-Tricalcium Phosphate



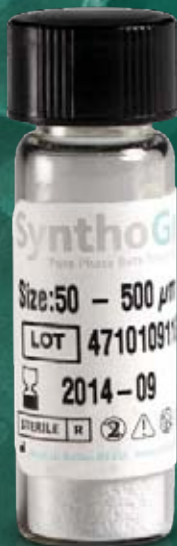
PROCEDURE MANUAL AND CATALOG

Why SynthoGraft?

SynthoGraft offers a unique structure which provides stability, while its micro-porosity allows for rapid vascularization and subsequent resorption. Although several varieties of beta-tricalcium phosphate are now commercially available, their bone regenerating capabilities are not equal. The differences can affect not only the rate and quality of bone regeneration, but also the rate of resorption and replacement with autogenous bone during the healing process.

SynthoGraft™

Pure Phase Beta-Tricalcium Phosphate



SynthoGraft offers:

- ▶ Increased patient acceptance
- ▶ Elimination of the inherent risks associated with biologically-derived bone graft materials
- ▶ Greater surface area compared to other synthetic bone grafting materials
- ▶ Rapid vascularization and subsequent resorption when mixed with the patient's own blood
- ▶ Nanometer-scale porosity
- ▶ Available in two particle sizes: 50-500µm and 500-1000µm

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SynthoGraft is manufactured, packaged, sterilized and sold at ISO certified facilities.

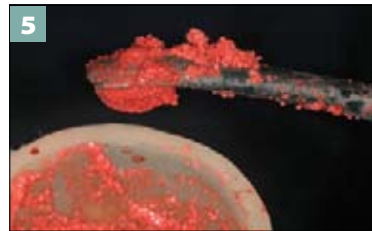
BASIC PROCEDURES

PRODUCT PREPARATION:

1. Remove glass vial of SynthoGraft from sterile package.
2. Use anesthesia without epinephrine. Place patient's blood into dappen dish. Blood is most easily obtained from the surgical site or venipuncture of the antecubital fossa.
3. Progressively pour SynthoGraft into dappen dish allowing the blood to be absorbed by the material.

SynthoGraft must only be wetted with the patient's blood.

4. Mix SynthoGraft with a periosteal elevator for two minutes or until its consistency is putty-like.
5. SynthoGraft is ready for use when it adheres to a periosteal elevator.



KEYS TO SUCCESS:

- It is not recommended to mix SynthoGraft with any other bone grafting material.
- Conventional flap and curettage techniques are used to assure that the site is completely debrided and that the root surfaces are thoroughly planed and decontaminated.
- Suctioning should be limited to the excess fluid from the graft and the periphery of the site.
- Use of a membrane may be indicated.
- Clinicians are encouraged to place implants 3 to 5 months after grafting.
- Peel and use vial label for easy charting and record keeping.

CLINICAL APPLICATIONS

BUCCAL DEFECT



Anterior defect



Graft in place



Post graft

EXTRACTION SITE



Failed root canal

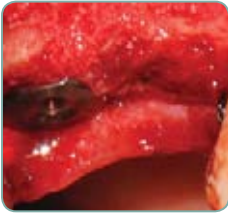


Extraction

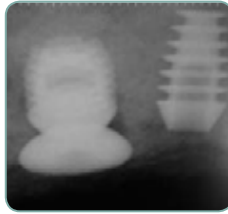


Post graft

INTERNAL SINUS LIFT

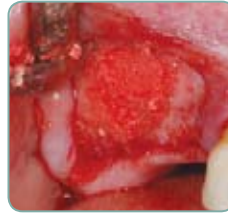


Graft in place

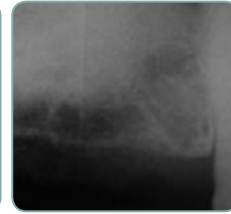


Post graft

LATERAL SINUS LIFT



Graft in place

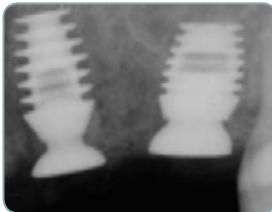


Post graft

CREST AUGMENTATION



Graft in place



Post graft

PERIODONTAL DEFECT



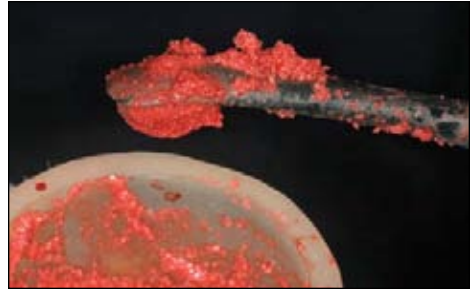
Site of defect



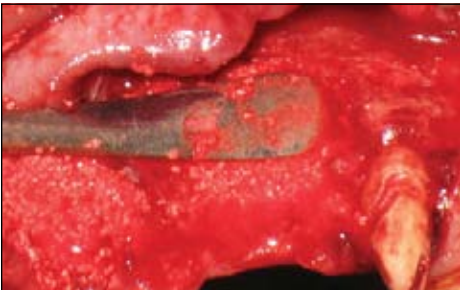
Graft in place

| CLINICAL APPLICATION | PARTICLE SIZE (µm) | TYPICAL QUANTITY |
|----------------------|---------------------------|------------------|
| Buccal Defect | 50–500 | 0.25–0.50 grams |
| Extraction Site | 50–500 | 0.25–1.00 grams |
| Internal Sinus Lift | 50–500 | 0.25–1.50 grams |
| Lateral Sinus Lift | 50–500 <i>or</i> 500–1000 | 1.50–5.00 grams |
| Crest Augmentation | 50–500 | 0.25–1.50 grams |
| Periodontal Defect | 50–500 | 0.10–0.50 grams |

SMALL BONE DEFECT



SynthoGraft is ready for use when it adheres to a periosteal elevator.



Apply SynthoGraft over the bony defect with a periosteal elevator.

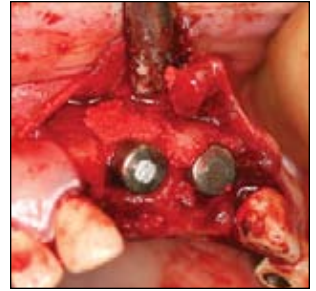
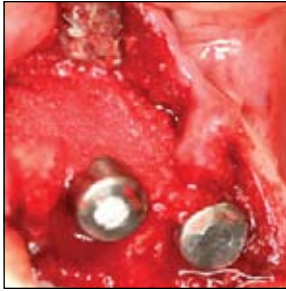


Compress SynthoGraft with periosteal elevator. Use gauze to absorb excess fluid.

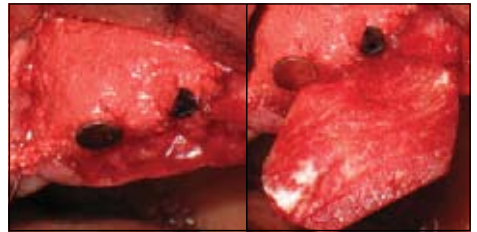


Compression provides mechanical stability to the graft.

SANDWICH TECHNIQUE



If autogenous bone is collected, place it first on the bony defect and then apply SynthoGraft on top of it. Do not mix the SynthoGraft with the harvested bone.



For a small-sized defect or the one-stage implant placement technique, the flap may be closed over the grafted area without a membrane.

Use a membrane for a large defect or when a horizontal augmentation of the buccal plate is required.



The mucoperiosteal flaps should be sutured to achieve primary closure.

LATERAL SINUS LIFT



Mix SynthoGraft with a periosteal elevator for two minutes or until its consistency is putty-like.



Use a Graft Delivery Instrument to place SynthoGraft against the mesial, distal, and medial walls of maxillary sinus.



Wet resorbable collagen membrane with patient's blood prior to its placement.



Place membrane over the antrostomy.



Suture site with resorbable sutures.

INDICATIONS FOR USE:

- Filling and/or reconstruction of a traumatic or degenerative multi-walled bone defect.
- Augmentation of the sinus floor.
- Augmentation of an atrophied alveolar ridge.
- Filling of a periodontal or other alveolar bone defect, tooth sockets, and osteotomies.
- Preservation of the alveolus for an implant osteotomy.

WARNINGS:

- SynthoGraft should only be used by or under the supervision of trained personnel with experience in surgical techniques.
- Do not use SynthoGraft if package has been opened, damaged, or if the expiration date has passed.
- Do not compromise blood supply to the surgical site.
- Do not apply SynthoGraft unless it is wetted with the patient's blood.
- Do not wet SynthoGraft with any solution (e.g. physiological saline, NaCl or antibiotics) other than the patient's blood.
- Do not mix SynthoGraft with any other bone grafting material.
- Do not overfill surgical site.
- Do not re-sterilize SynthoGraft.
- Discard any unused SynthoGraft particles.
- Use sutures and/or membranes to prevent migration of particles.
- SynthoGraft is packaged and sterilized for single use only.

CONTRAINDICATIONS:

SynthoGraft should not be used for patients with the juvenile form of chronic periodontitis, uncontrolled systemic diseases, infections, endocrinopathies, coagulopathies, psychological and neurological concerns, or in any other instance where the clinician believes that surgery or the use of SynthoGraft is inappropriate.

SYNTHOGRAFT PRODUCT INFORMATION

| PARTICLE SIZE (µm) | GRAMS PER VIAL | VIALS | PART NUMBER |
|--------------------|----------------|-------|-------------|
| 50–500 | 0.25g | 5 | 260-400-125 |
| 50–500 | 0.50g | 5 | 260-400-150 |
| 50–500 | 1.00g | 5 | 260-400-151 |
| 50–500 | 2.00g | 5 | 260-400-152 |
| 500–1000 | 0.25g | 5 | 260-400-525 |
| 500–1000 | 0.50g | 5 | 260-400-500 |
| 500–1000 | 1.00g | 5 | 260-400-501 |
| 500–1000 | 2.00g | 5 | 260-400-502 |


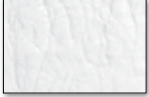
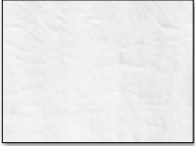
Dappen Dish

| DESCRIPTION | PART NUMBER |
|----------------------|-------------|
| Silicone Dappen Dish | 260-103-030 |



COLLAGEN PRODUCT INFORMATION


Resorbable Collagen Membrane

| DESCRIPTION | SIZE (mm) | PART NUMBER | |
|------------------------------|---------------|-------------|--|
| Resorbable Collagen Membrane | 15 x 20 x 0.3 | 260-509-600 |  |
| Resorbable Collagen Membrane | 20 x 30 x 0.3 | 260-509-300 |  |
| Resorbable Collagen Membrane | 30 x 40 x 0.3 | 260-509-800 |  |

MEMBRANE CONSIDERATIONS

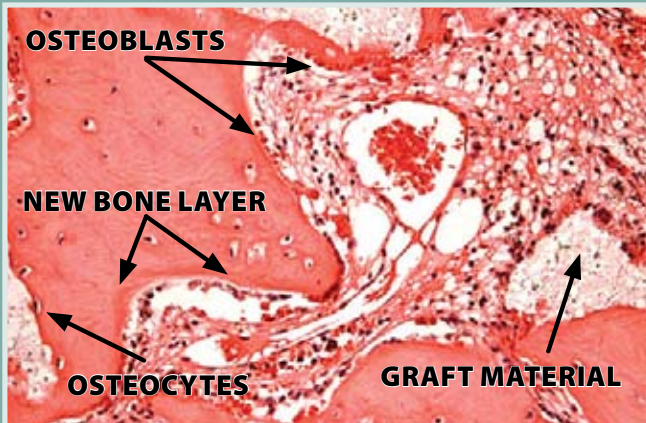
- Intended for use in oral surgical procedures as a resorbable or non-resorbable material for placement in the areas of dental implants, bone defects and ridge augmentation procedures.
- Ensure that the membrane is stable and securely placed under the tissue.
- Primary closure is desirable to allow for full coverage of the membrane.
- Dissecting and suturing the buccal aspect of the flap will allow for the coronal movement of the flap facilitating primary closure.
- Each membrane can be easily trimmed during surgery for an appropriate clinical adaptation.

Resorbable Collagen Plug

| DESCRIPTION | SIZE (mm) | PART NUMBER | |
|-------------------------------|-----------|-------------|--|
| Resorbable Collagen Plug (10) | 10 x 20 | 260-509-400 |  |

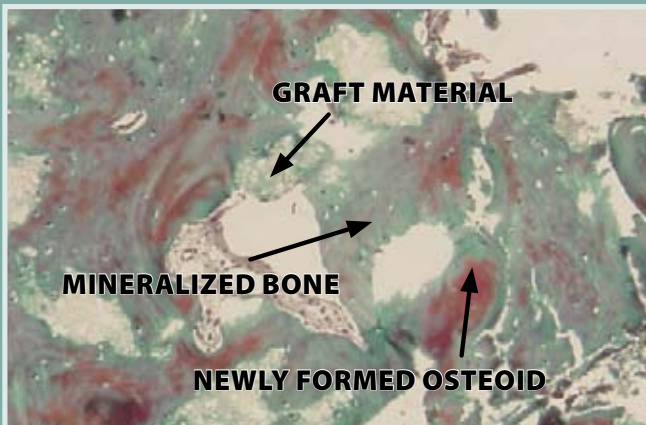
COLLAGEN PLUG CONSIDERATIONS

- The Resorbable Collagen Plug is fully absorbed in 10 to 14 days.
- Its cylindrical shape adapts easily to surgical sites.



Courtesy of Ziedonis Skobe, Ph.D., Forsyth Institute and Harvard University

3 MONTH HISTOLOGY



Courtesy of Serge Dibart, D.M.D., Boston University School of Dental Medicine

6 MONTH HISTOLOGY

SynthoGraft[™]
 Pure Phase Beta-Tricalcium Phosphate

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