Specifications are subject to change without prior notice. Some products to be launched in the market after necessary approvals are also listed in this catalog.
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Application of OSTEON™ Collagen

- Ridge augmentation
- Extraction site & osteotomy
- Cystic cavities
- Sinus lift
- Periodontal defect

Description

OSTEON™ Collagen is a bone void filler composed of synthetic bone, (OSTEON™) and natural Type I collagen.

Characteristics of OSTEON™ Collagen

- Collagen coating enables easy handling, and thus shortened operation time
- Moldable to various defect shape after being wet
- Collagen dissolves after helping the initial handling
- Excellent new bone formation and space maintenance
- Hemostatic function
**In vitro cell test**

Cell adhesion test

Osteoblasts spread well on the OSTEON™ Collagen

**In vitro test**

1. Animals: New Zealand white rabbit
2. Implantation Area: Calvaria
3. Period: 8 weeks
4. Staining method: Goldner Trichrome

**Products**

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**Clinical Case**

Clinical Case 1

Clinical Case 2
Application of OSTEON™ II

- Ridge augmentation
- Extraction site & osteotomy
- Cystic cavities
- Sinus lift
- Periodontal defect

Composition of OSTEON™ II

Osteoconductive biphasic calcium phosphate with higher ?-TCP

**OSTEON™ II = HA 30% + ?-TCP 70%**

Characteristics of OSTEON™ II

- Highly resorbable due to higher ?-TCP content
- Easy manipulation
- Excellent wettability
- Osteoconductive synthetic bonegraft
- Pore size: 200~300 μm
- Porosity: 70%
Cell adhesion test
Osteoblasts attached & spreaded well

In vitro dissolution test

Animal test
12-weeks follow up in rabbit calvaria model

Products

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Application of OSTEON™

- Ridge augmentation
- Extraction site
- Cystic cavities
- Sinus lift
- Periodontal defect

Composition of OSTEON™

100% Synthetic bone graft: HA scaffold coated with ?-TCP

OSTEON™ = HA 70% + ?-TCP 30%

Specification of OSTEON™

- 100% Synthetic bone graft
- Interconnected porous structure similar to that of human cancellous bone
- Osteoconductive material as a bone growth scaffold

Cell adhesion test

In vitro test of OSTEON™

Osteoblast was well attached and spreaded on OSTEON™ surface.
Human Histology

6.5 months after Sinus graft surgery

OSTEON™ area = 1.24\,mm² (17.1\%)
New bone area = 1.63\,mm² (22.7\%)

10 months after Sinus graft surgery

OSTEON™ area = 3.04\,mm² (35.5\%)
New bone area = 2.38\,mm² (27.7\%)

21 months after Sinus graft surgery

OSTEON™ area = 6.30\,mm² (40.4\%)
New bone area = 5.12\,mm² (33\%)
**OSTEON™ Sinus & Lifting**

### Products

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### Syringe

- **O.D.**: Syringe outer diameter
- **I.D.**: Syringe inner diameter

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Instruction for OSTEON™ Sinus & Lifting

① Slightly retract the plunger and gently tap to loosen particles. Gently push plunger back into place.

② Place syringe into a sterile dappen dish and retract plunger to draw liquid into the syringe.

③ To optimize delivery, OSTEON™ should be wetted and loosened sufficiently.

④ Expel excess liquid by applying very gentle pressure on the plunger.

⑤ When sufficiently hydrated, OSTEON™ will expel with ease from the syringe. Before injecting OSTEON™, remove the cap from the syringe.

⑥ Deliver OSTEON™ directly into the surgical site with the syringe.

Clinical Case

OSTEON™ Sinus Case

OSTEON™ Lifting Case

After 9 months
Application of ORTHOPEDIC OSTEON™

- Bone filling
- Fractures with bone defects
- Pseudoarthrosis with or without bone defects
- Tibial osteotomy
- In certain cases of arthroplasty revision

Products

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GOBG0510, GOBG1020, GOBG2030, GOBG3040, GOBG4050 are available.

In vivo Test-Rabbit Femur Model

- 12 weeks after bone grafting in rabbit femur.
- After bone grafting in rabbit femur for 12 weeks, new bone was well formed in the pores and around ORTHOPEDIC OSTEON™.

Clinical Case

Bone void filler
Description

- Non-resorbable GBR membrane
- Biocompatible polymer PCL
- Thin for easy manipulation
- Porous membrane

Products

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Composition of OSTEOGUIDE™

Bio-compatible polymer
= 100% PCL (Polycaprolactone)

- The porous outer surface of the OSTEOGUIDE™ allows easy entry of the adjacent cells assuring rapid and good tissue attachment.
- Good nutrient flow and blood vessel formation supported by the porous structure.

In vivo Test-Rabbit Calvaria Model

- New bone was well formed on the bottom of the OSTEOGUIDE™ and cells did not penetrate into the defect.
**Characteristics of Collagen Membrane**

- Easy manipulation
- Dual-sided usage
- Barrier function lasting for 4-6 months

- Thinner membrane (300 μm) with multiple layers for easy manipulation and sufficient mechanical strength in surgery.
- Resorption period of 4-6 months to provide enough time for stabilizing graft materials and supporting bone growth.
- Multiple-layered structure enables more effective bone regeneration by sparing enough space for hard tissue formation and facilitates proliferation of osteoblast.

**Application of collagen Membrane**

Biodegradable barrier membrane for guided bone/tissue regeneration

- Periodontal/infrabony defects
- Ridge augmentation
- Extraction sites (implant preparation/placement)
- Sinus lift
## Products

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## Preclinical Data

- Rabbit Calvaria Model, 6-12 weeks

- Degradation character in collagenase solution

![Graph showing degradation character](image)

## Clinical Case

![Clinical case images](image)
Documentation Summaries

Bone Graft Material
This is the summary of Clinical Evaluations OSTEON as a New Alloplastic Material in Sinus Bone Grafting and its effects on Bone Healing’ which is published at Journal of Biomedical Material Research Part B, written by Prof. Young-Kyun Kim.

**Introduction.**
Placement of implant prosthesis in the maxillary posterior region is known to be difficult on many aspects and has lowest success rate. In many clinical situations, the maxillary region is made of type III or IV bone with porous and insufficient bones for implant placement. The advancement in implant surgical techniques, improved bone graft, and recent development in implant surface treatments have resulted in predictable sinus bone graft success, thereby allowing implant placement in the maxillary molar region.

However, controversy still exists on what constitute an ideal sinus graft materials. Ideally, the bone graft material used for implant reconstruction should (a) maintain space an optimal period of time to achieve bone in growth and implant healing, (b) remain stable for the period of graft consideration, during implant integration, and after the implants are restored, (c) promote osteoconduction of the neighboring cells to form bone within the graft materials, (d) remodel itself into long-lasting bone, (e) facilitate easy placement to avoid morbidity, and (f) have predictable success rate.

Alloplastic materials are recently used as bone substitute. They are biologically acceptable, allowing bone ingrowths and bone remodeling while maintaining volume. Additionally, alloplastic materials have several advantages, such as (a) the lack of required donor site, (b) ample supply, and (c) the nonexistence of disease transmission.

OSTEON is one of the alloplastic materials composed of hydroxyapatite (HA) 70% and beta-tricalcium phosphate (β-TCP) 30% which are most close to major mineral components of human bone, and have interconnected porosity structure (scaffolding) which is similar to that of human cancellous bone.

**Figure 1.** SEM morphology of OSTEON with interconnected pore structure (x120). The pore size is from 300 to 500 μm, which is similar to human cancellous bone and the porous bone graft is beneficial to osteoblast cell ingrowth to OSTEON.

**Clinical Evaluation of OSTEON® as New Alloplastic Material in Sinus Bone Grafting and Effect on Bone Healing**

Young-Kyun Kim,1 Pil-Young Yun,1 Sung-Chul Lim,2 Su-Gwan Kim,3 Hyo-Jung Lee,4 Joo L. Ong 5

*Journal of Biomedical Materials Research Part B. Applied Biomaterials. 2008. vol 86 page 270~277*

The objective of this study was to clinically evaluate the use of OSTEON as a sinus graft material and to measure the effect of healing at 4 and 6 months after surgery.

Materials and Methods
The two different commercially available OSTEON grafting materials (one with particle size of 0.5-1.0 mm and the other with particle size of 1.0-2.0 mm) were mixed in a ratio of 1:1, hydrated, followed by mixing with 10% autogenous bone chips and stabilized with tissue adhesive. After sinus graft (Fig. 3) using OSTEON in 17 patients, bone specimens were collected from lateral sinus using 2.0-mm trephine bur at the time of 4 or 6 months after surgery. Histology of the bone specimens was prepared and the percentage of newly formed bone fraction, lamellar bone/woven bone ratio (LB/WB), and newly formed bone/graft material ratio (NB/GM) were measured to indicate the suitability of the materials and the successful healing of the graft.

Results & Discussions.
The morphology of OSTEON was observed to be interconnected, with 77% porosity and a pore size of 300–500μm. This observed architecture was suggested to be similar to human cancellous bone, with the interconnected porosity and pore size capable of providing space for bone cell ingrowth (Fig. 1). After implantation, the mean percentage of newly formed bone fraction after 4 months and 6 months surgery was 40.6 and 51.9%, respectively (Table II). Statistical analysis indicated no significant difference (p = 0.135) in the newly formed bone fraction between the two postoperative periods.
As described in Table II, the mean LB/WB ratio after 4 months and 6 months surgery was 0.14 and 0.45, respectively, with significant difference observed between the two postoperative periods (p = 0.027). Additionally, the mean NB/GM ratio after 4 months and 6 months surgery was 1.95 and 7.72, respectively, with significant difference observed between the two postoperative periods (p = 0.046).

Like most commercially available xenogenic and alloplastic bone grafting materials, bone healing during sinus graft applications using OSTEON is induced via osteoconduction. The host osteoprogenitor and angiogenic cells use the graft as a scaffold to generate new bone across the defect. As the host cells differentiate and mature within the graft, a functional skeletal network develops and replaces the graft through a “creeping substitution” process. The reported survival rates for grafted xenografts and alloplastic materials are equivalent or better than the survival rates for grafted autogenous materials. Additionally, these studies also indicated that the nonresorbed residual graft materials did not hinder osseointegration but significantly increased the bony density. Caution has to be taken on the mesial side of the sinus wall as the graft material is pressed against it. Too much pressure against the mesial side of the sinus wall causes small particles to obstruct new blood vessel formation and delayed resorbing large particles to retard the formation of new bone.

**Summary and Conclusion**

In this study, OSTEON, a new alloplastic material was clinically evaluated as a sinus graft material. The morphology was observed to be interconnected, with 77% porosity and a pore size of 300~500 μm. No significant difference in the percentage of newly formed bone fraction was observed at 4 months and 6 months after grafting in 17 patients. However, significant differences in mean LB/WB ratio and the mean NB/GM ratio were observed after 4 months and 6 months surgery. As confirmed by observations using the SEM, bone biopsy indicated more lamellar bone after 6 months surgery as compared to biopsy obtained after 4 months surgery. In this short-term study, it was concluded that OSTEON is suitable for use in sinus graft application since desirable time-dependent healing was demonstrated.

For full report, please contact DENTIUM website [www.dentium.com](http://www.dentium.com)
Analysis of the healing process in sinus bone grafting using various grafting materials

Young-Kyun Kim, DDS, PhD, a Pil-Young Yun, DDS, PhD, a Su-Gwan Kim, DDS, PhD, b and Sung-Chul Lim, MD, PhD c SeongNam and GwangJu City, Korea

SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL AND CHOSUN UNIVERSITY

Objectives:
The purpose of this study was to compare differences in the healing process in the sinus bone grafting using various grafting materials.

Study design:
Maxillary sinus bone grafts were divided into 4 groups according to the graft material used: group I, a mixture of autogenous bone and BioOss (Osteohealth Co., Shirley, NY); group II, a mixture of BioOss and Orthoblast II (Greencross; Isotis); group III, BioOss only; and group IV, synthetic bone, Osteon (Genoss, Korea), only. To evaluate the healing status of the graft surgery, bone specimens were collected from the lateral sinus using a 2.0-mm trephine bur at 4 and 6 months after surgery. Histology of the bone specimens was prepared, and the percentage of newly formed bone fraction, lamellar bone/woven bone ratio (LB/WB), and newly formed bone/graft material ratio (NB/GM) were measured to indicate the suitability of the materials and the healing of the grafts.

Results:
The LB/WB ratio and NB/GM ratio were markedly increased at 6 months compared with the values at 4 months. It was observed that good bone healing was achieved even for grafts of xenogeneic bone only or synthetic bone only. Cases grafted with a mixture of allogeneic and xenogeneic bone showed no great advantage regarding bone healing.

Conclusion:
The results indicated that grafts of xenogeneic or synthetic bone can be effective for sinus bone grafting.


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<th>LB/WB</th>
<th>NB/GM</th>
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<td>II. BioOss+Orthoblast II</td>
<td>37.89 ± 10.99</td>
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<td>1.82 ± 2.46</td>
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<td>6 months (n = 7)</td>
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<td>III. BioOss</td>
<td>35.60 ± 29.99</td>
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<td>0.78 ± 0.84</td>
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<td>6 months (n = 8)</td>
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<td>2.58 ± 1.96</td>
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<td>IV. OSTEON</td>
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<td>0.14 ± 0.15</td>
<td>1.95 ± 1.81</td>
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<td>6 months (n = 8)</td>
<td>51.88 ± 12.54</td>
<td>0.45 ± 0.35</td>
<td>7.72 ± 8.80</td>
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</table>

LB/WB, Lamellar bone/woven bone; NB, newly formed bone; NB/GM, newly formed bone/graft material.
Sinus bone graft using new alloplastic bone graft material (Osteon)—II: clinical evaluation

Ji-Hyun Bae, DDS, PhD, a Young-Kyun Kim, DDS, PhD, b Su-Gwan Kim, DDS, PhD, c Pil-Young Yun, DDS, PhD, d and Jae-Seung Kim, DDS, PhD, e Seongnam, Gwangju, and Seoul, Korea

SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL, CHOSUN UNIVERSITY, AND GUNGUK UNIVERSITY

Objectives:
The objective of this study was to clinically evaluate the use of Osteon as a sinus bone graft material and to measure the loss of sinus bone graft volume and marginal bone loss around the implants.

Study design:
Thirty-two implants were placed in 16 patients after maxillary sinus bone grafting. In 7 patients, maxillary sinus bone graft was performed first and 15 implants were placed after 4 months; in 9 patients, 17 implants were placed simultaneously with maxillary sinus bone grafting. Based on medical records and radiographs, intraoperative and postoperative complications were examined, and at 1 year after the placement of the upper fixture, the success rate of implants, peri-implant soft tissue condition, and the marginal bone loss were evaluated. Additionally, the sinus bone graft volume loss was evaluated by comparing the residual alveolar bone height of the preoperative maxillary sinus floor with that immediately after the operation and after 1 year.

Results:
Regarding intraoperative complications, perforation of the maxillary sinus membrane occurred in 6 cases (37.5%), and after surgery maxillary sinusitis developed in 2 cases. During the healing period, 1 implant failed in osseointegration. At the last follow-up observation, none of cases showed marginal bone loss of >1 mm and a 96.9% success rate was seen. The follow-up observation period after placement of the superstructure was 12-30 months (average 15). Between the simultaneous placement group and the delayed placement group, marginal bone loss showed no statistically significant difference (P=.455). In the entire patient group, the volume of sinus bone graft loss did not correlate with marginal bone loss (P=.568). Preoperative alveolar bone height was 0.8-8.8 mm (mean 4.64), postoperative alveolar bone height was 12-21.8 mm (mean 17.67), and the alveolar bone height 1 year after the operation was 11.2-20.8 mm (mean 16.78). Between the group with perforation of the maxillary sinus membrane and the group without, no difference in marginal bone loss was observed (P=.628). Additionally, no difference in the volume of sinus bone graft resorption between the two groups was observed (P=.970).

Conclusion:
It was concluded that Osteon is suitable for use in sinus graft application.


Sinus bone graft using new alloplastic bone graft material (Osteon)—II: clinical evaluation

Table 1. Summary of case I

<table>
<thead>
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<th>Implant</th>
<th>Length</th>
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<th>Marginal Bone Loss</th>
<th>Healing Period</th>
<th>Follow-up Observation Period</th>
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<td>2</td>
<td>M</td>
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Table 2. Summary of case II

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<th>Length</th>
<th>Diameter</th>
<th>Preoperative Alveolar Bone Height</th>
<th>Marginal Bone Loss</th>
<th>Healing Period</th>
<th>Follow-up Observation Period</th>
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<tr>
<td>11</td>
<td>F</td>
<td>25</td>
<td>Osteon</td>
<td>10</td>
<td>5.5</td>
<td>3.8</td>
<td>0.8</td>
<td>0.8</td>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td>12</td>
<td>M</td>
<td>25</td>
<td>Osteon</td>
<td>12</td>
<td>5.5</td>
<td>3.8</td>
<td>1.2</td>
<td>1.2</td>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>20</td>
<td>Osteon</td>
<td>10</td>
<td>5.5</td>
<td>3.8</td>
<td>0.8</td>
<td>0.8</td>
<td>6 months</td>
<td>12 months</td>
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<td>14</td>
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<td>1.2</td>
<td>6 months</td>
<td>12 months</td>
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<tr>
<td>15</td>
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<td>22</td>
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<td>3.8</td>
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<td>0.8</td>
<td>6 months</td>
<td>12 months</td>
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<tr>
<td>16</td>
<td>M</td>
<td>25</td>
<td>Osteon</td>
<td>12</td>
<td>5.5</td>
<td>3.8</td>
<td>1.2</td>
<td>1.2</td>
<td>6 months</td>
<td>12 months</td>
</tr>
</tbody>
</table>

Note: All cases were followed up for 12-30 months (average 15).
Effects of 4 Different Alloplastic Materials on Bone Regeneration in Rabbit Calvarial Defects

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Objectives:
The purpose of this study was to compare bone regeneration in 8-mm defects in 8 New Zealand White rabbit calvaria using 4 different alloplastic bone substitutes.

Materials and Methods:
Four 8-mm calvarial defects were made in the parietal bone of each animal. The defects were filled with Bongros-HA™ (Bioalpha, Seongnam, Korea), micro macroporous biphasic calcium phosphate (MBCP™, Biomatlante, France), Osteon™ (Dentium Co, Seoul, Korea) and Cerasorb® (Curasan, Kleinsthei, Germany). Two animals died after surgery. Two rabbits were sacrificed after 4 weeks, and the other 4 were sacrificed after 8 weeks. Data analysis included the qualitative assessment of the calvarial specimens.

Results and Discussion:
Histomorphometric analysis was performed to quantify the amount of new bone within the defects. It was found that Osteon™-treated defects had significantly more new bone after 8 weeks than all other groups. Osteon™ was an effective alloplastic bone substitute which showed reliable osseous healing of critical size defects in the rabbit calvarium.

Conclusion:
From the results of this study, it is suggested that HA and TCP alloplastic materials can be good bone substitutes for inducing new bone formation in rabbit calvaria in the early stage and that HA coated with TCP may have a better bone regeneration ability than HA, TCP or a mixture of HA and TCP.

KEY WORDS: Bongros-HA™, MBCP™, Osteon™, Cerasorb®, critical size defect, rabbit model

Table 1. For groups of alloplastic materials used in this study.

<table>
<thead>
<tr>
<th>Alloplastic Material</th>
<th>Manufacturing Company</th>
<th>Component (%)</th>
<th>HA (%)</th>
<th>TCP (%)</th>
<th>Particle size (μm)</th>
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<tr>
<td>1 Bongros-HA</td>
<td>Bioalpha(Korea)</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td>600-1000</td>
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<tr>
<td>2 MBCP</td>
<td>Biomatlante(France)</td>
<td>60</td>
<td>40</td>
<td>0</td>
<td>500-1000</td>
</tr>
<tr>
<td>3 Osteon</td>
<td>Dentium (Korea)</td>
<td>70</td>
<td>30</td>
<td>0</td>
<td>500-1000</td>
</tr>
<tr>
<td>4 Cerasorb</td>
<td>Curasan(Germany)</td>
<td>0</td>
<td>100</td>
<td>0</td>
<td>500-1000</td>
</tr>
</tbody>
</table>

Figure 1. Four different alloplastic materials were placed in each defect.
Figure 2. Histologic finding at 4 weeks after healing (x12). (a) Bongros HA, (b) MBCP, (c) Osteon and (d) Cerasorb.

Figure 3. Histologic finding 8 weeks after healing (x12). (a) Bongros HA, (b) MBCP, (c) Osteon and (d) Cerasorb.

Figure 4. Histomorphometric measurement of the percentages of newly formed bone. *p<0.05