Product Information

Bio-Oss®
natural bone grafting material

Bio-Oss Collagen®
natural bone grafting material plus collagen

Bio-Gide®
resorbable bilayer membrane
Bio-Oss®

natural bone grafting material

Hi-tech at its best: reliable and precise Bio-Oss® production at Geistlich Biomaterials' company headquarters in Switzerland.

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The Master's Choice

Bio-Oss® Natural Bone Grafting Material

→ The leading bone graft substitute in bone and tissue regeneration
→ Used successfully for oral and maxillofacial defects for over 20 years
→ Studied in over 100 universities by leading dental surgeons
→ Developed to fulfill the needs of clinicians for a wide range of grafting indications
→ More than 500 peer reviewed studies demonstrate long-term reliability and effectiveness in even the most challenging clinical situations
→ Widely regarded as the standard of care in oral and maxillofacial bone regeneration

In the following pages, you will find out why.

Did you know...

Approximately one procedure is performed with Bio-Oss® somewhere in the world every 38 seconds.
Biofunctionality

Natural remodeling.
The human body interacts best with a material it is familiar with. The physical and chemical properties of Bio-Oss® are particularly similar to those of human bone. It is this very close similarity to human bone that allows Bio-Oss® to be a highly effective osteoconductive grafting material.

As in human cancellous bone, Bio-Oss® is a highly porous structure that facilitates vascular ingrowth and osteoblastic cell migration throughout the Bio-Oss® matrix.1 The precise microstructure of the Bio-Oss® surface supports optimal adhesion of osteoblasts, cells responsible for bone formation.

In addition to its role as an excellent osteoconductive matrix, facilitating effective bone formation, Bio-Oss® also serves to preserve the architectural integrity of grafted sites. Bio-Oss®, by virtue of its slow remodeling and low substitution rate, becomes anatomically integrated with newly forming bone.2,3,4 Bio-Oss® evokes no foreign body or inflammatory response and is readily accepted as “normal” within grafted areas.

Increased bone mineral density
Because Bio-Oss® remains stable and well integrated within grafted sites, treatment with Bio-Oss® results in an increased level of bone mineral density of grafted defect sites.

Dimensional stability of the graft site.
The long-term presence of Bio-Oss® particles stabilizes the resulting graft, leading to retention of both volume and desired architectural form of augmented sites, factors especially important when grafting in the esthetic zones of the maxilla and mandible.

Biofunctionality through beneficial product characteristics

The Bi-modal pore structure of Bio-Oss® is similar to natural bone.

"Pores in the nanometer range: Penetration of Bio-Oss® with tissue fluid.

**Pores in the micrometer range: Enables cell adhesion
(Measurement: Research Analysis Department, R&D Geistlich Biomaterials, Wolhusen, Switzerland 2006).

The interconnecting pore system of Bio-Oss® enables absorption of blood, sprouting of blood vessels and good growth of new bone throughout the bone substitute (© Dr. M. Bufler).

The pore size and thus the associated inner surface areas of bone substitutes influence their in vivo behavior.

(Measurement: Gas adsorption).

Natural remodeling rather than rapid resorption

- Dimensional stability at the graft site
- Increased bone mineral density
- High porosity and large internal surface area
- Optimal adhesion of bone forming cells and absorption of blood
Long-term success

Extensive testing plus years of successful clinical use equals product reliability and confidence

True success is rarely achieved overnight. The biocompatible, highly functional characteristics of Bio-Oss® took years of clinical development and testing followed by years of successful clinical use. Over 500 publications are currently in print, many documenting long-term successful treatment with Bio-Oss®.

Xenographic bone substitutes – the most successful material

The implant survival rate with xenogenic materials shows the highest success rate in long-term follow-up. Consequently, high reliability and good predictability can be achieved with xenogenic material.

Predictability of the implant survival rates in lateral window sinus floor elevation

<table>
<thead>
<tr>
<th>Material</th>
<th>Percentage (±)</th>
<th>Implant Survival (%)</th>
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<tbody>
<tr>
<td>Synthetic</td>
<td>81.0</td>
<td>n=190</td>
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<tr>
<td>Iliac crest</td>
<td>88.0</td>
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<tr>
<td>Autogenous</td>
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<tr>
<td>Allotopic</td>
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<td>n=189</td>
</tr>
<tr>
<td>Xenogenic</td>
<td>95.6</td>
<td>n=443</td>
</tr>
</tbody>
</table>

9 Sculean A. et al., J Clin Periodontal Vol. 34, 2007; 72–77
11 Aghaloo et al., Int J Oral Maxillofac Implants Vol. 22(Suppl), 2007: 49–70
Long-term success due to gradual remodeling and long-term volume preservation

A proven product that you can rely on over time

- Long-term implant survival rates greater than 95%
- Long-term dimensional stability of grafted sites

Histomorphometric analysis of bone and Bio-Oss® in a patient demonstrates that Bio-Oss® is gradually integrated and remodeled into bone.5

After sinus floor augmentation with a mixture of Bio-Oss® and autologous bone, the percentage bone volume is preserved throughout the study period, while the height of a purely autologous bone graft diminishes markedly.6

The long-term implant survival rate in Bio-Oss® grafted sites is similar to the survival rate of implants placed in native bone (112 implants, 5 years follow-up).8
Natural bone grafting material plus collagen

As with Bio-Oss®, the mineral structure of Bio-Oss Collagen® is highly porous, possesses a large internal surface area, and functions as an effective scaffold for bony ingrowth and cell adhesion.

The collagen component enables convenient handling and simple application of the Bio-Oss® particles. In addition, the collagen fibers adhere to the bony recipient site, facilitating formation of a well-formed blood clot. Suspended within a 10% collagen matrix, the Bio-Oss® particles are highly stabilized when placed within a defect site. When moistened with saline or the patient’s blood, Bio-Oss Collagen® becomes readily pliable and moldable, facilitating placement within a wide configuration of bony defect sites.

Site Preservation Made Simple

Following tooth removal, crestal alveolar bone loss, especially in the anterior esthetic zone of the maxilla, is an undesirable but predictable process. Bio-Oss Collagen® is an ideal grafting solution for ridge preservation procedures. When placed immediately into the extraction socket and onto the marginal portion of the buccal cortex, Bio-Oss Collagen® promotes new bone formation, compensating for predictable crestal bone loss.23

Bio-Oss Collagen®, when placed into the socket, conforms readily to the defect site, facilitating preservation of bone and soft tissue architecture. Additionally, the composite nature of the graft material virtually eliminates particle migration from the grafted area.

Maintaining Dimensional Stability Following Tooth Extraction

Decreased alveolar ridge surface area and volume along with hard and soft tissue anatomical distortion are predictable sequelae following tooth removal, especially in the critical anterior esthetic zones of the jaws. Labial and buccal crestal bone loss is especially severe following tooth extraction. By actively promoting new bone growth within the crestal third of extraction sockets, Bio-Oss Collagen®, when grafted immediately, restores ridge anatomy, surface area and volume back to normal, preserving the critical soft tissue profile needed for natural looking, esthetic restorations.

All the benefits of Bio-Oss® in an easy-to-use, moldable block

Excellent stabilization of Bio-Oss® particles and blood clot

Favorable handling properties particularly in site preservation procedures

Superior results when combined with Bio-Gide® in treatment of Class II furcations
Indications

Effective in both routine and challenging defects

Bio-Oss®, with unique physical and chemical characteristics and close similarity to human cancellous bone, has an extremely wide range of clinical indications.

Implantology indications

In order to meet the functional and esthetic demands when placing implants, bone grafting regenerative procedures are often needed, especially in the esthetic zones of the maxilla and mandible. Guided bone regeneration (GBR) procedures with Bio-Oss® and Bio-Gide® are considered standard of care therapy and widely accepted worldwide.

- Peri-implant defects
- Extraction sockets
- Sinus floor elevation
- Horizontal augmentation
- Vertical augmentation

12 Hämmerle CH. / Lang N.P., Clin Oral Implants Res. 12, 2001; 9-18
14 Zuhr O. et al., Implantologie 2006; 14(4); 339-353
15 Weng D. et al., Implantologie 2006; 14(4); 355-363
18 Van Arx T. / Buser D., Clin Oral Implants Res. 17, 2006; 359-366
21 Sculean A. et al., J Clin Periodontol Vol. 34, 2007; 72-77
22 Linares A. et al., J Clin Periodontol Vol. 33, 2006; 351-358
24 Houser B.E. et al., Int J Periodontics Restorative Dent. Vol. 21, 2001; 161-169
**Periodontal indications**
The gold standard of periodontal care is regeneration of new cementum, new periodontal ligament and new supporting alveolar bone. Regenerating the complete attachment apparatus requires an effective barrier membrane capable of preventing a long junctional epithelium as well as an effective bone graft matrix that effectively supports formation of new alveolar bone. Multiple studies, including those with human histology, document the regenerative potential of Bio-Oss® and Bio-Gide® in promoting regeneration of new cementum, periodontal ligament and supporting alveolar bone in periodontal defects.

- **Intraosseous defects**

- **Furcation defects**

![Bio-Oss® shown in a periodontal defect.](image1)

![Above photomicrograph demonstrates complete regeneration of cementum (dark purple, arrow) with perpendicularly inserting fibers of newly formed PDL. (Nevins et al., 1998)](image2)

**Did you know...**
The inner surface area measured in 1 gram of Bio-Oss® is roughly equivalent to the area of a tennis court (80m²).
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Hi-tech at its best: reliable and precise Bio-Gide® production
at Geistlich Biomaterials’ company headquarters in Switzerland.
More Than a Barrier

Bio-Gide® Resorbable Bilayer Membrane

→ Well documented success as a highly effective collagen membrane for bone and tissue regeneration
→ Worldwide clinical acceptance as the leading regenerative collagen membrane product
→ Backed by increasing numbers of respected scientific publications
→ Superior characteristics for GBR and GTR procedures
→ Positive effect on soft tissue wound healing
→ The number one choice for collagen membranes

In the following pages, you will find out why.
More than a barrier

The multi-functional collagen membrane
Membranes are essential components for effective Guided Bone (GBR) and Guided Tissue (GTR) regeneration procedures. Membranes perform several important functions and form the basis for predictable clinical results.26

Barrier function
During the initial phase of bone and tissue regenerative procedures, membranes act as barriers, excluding unwanted soft tissue cells from migrating into the grafted defect space. As an effective barrier membrane during this initial phase of healing, Bio-Gide® acts to protect and support the critically important early phases of bone regeneration. Once bone formation is initiated, further barrier function is no longer required for successful GBR and GTR to occur. Bio-Gide® is then naturally broken down enzymatically to its amino acid components in an inflammation-free process.

Supporting Regenerating Bone
The use of bone grafting materials, i.e. Bio-Oss®, in GBR procedures is considered standard of care in today’s clinical practice. Bio-Gide®’s unique bilayer anatomy, with a dense cell-occlusive upper layer and a porous, open-celled lower layer, prevents the migration of grafted particles, stabilizes the initial blood clot, and physically integrates with and supports newly forming bone during the regenerative process. 27, 28

Supporting wound healing
In addition to its barrier function, Bio-Gide® supports oral mucosal wound healing. Because Bio-Gide® is a natural collagen product without the addition of crosslinking, it readily supports vascular ingrowth into the grafted defect site. Its dense upper layer encourages overlying mucosal closure following flap reflection. In the anterior region of the maxilla, promoting healthy soft tissue healing is particularly important to a final esthetic result.

Use of a membrane increases the implant survival rate

The implant survival rate is higher when membranes are used to cover the sinus window osteotomy site26

Bio-Gide improves bone fill versus non-resorbable barriers

28 Wallace S. S. / Froum S. J., Ann Periodontal Vol. 8, 2003; 328–343
29 Nemcovsky C. E. / Artzi Z., J Periodontal 73, 2002; 754–761
Soft tissue dehiscences can occur in the presence of barrier membranes, especially if the membranes are non-resorbable or crosslinked. However, when properly used, soft tissue dehiscences rarely occur with Bio-Gide®. If dehiscences do arise, soft tissue wound closure almost always occurs within a few weeks without the need for removing the Bio-Gide® membrane.29, 30, 31

In contrast to cases treated with ePTFE membranes, dehiscences heal without complications with Bio-Gide® (Clinical study, Zitzmann N. U. et al., 1997).

→ Increases implant survival rate
→ Stabilizes graft particles and supports bone growth
→ Fewer dehiscences than non-resorbable or crosslinked membranes
→ Proven clinically for over 10 years
The bilayer matrix

Unique functional design
Bio-Gide®’s unique bilayer structure, without crosslinking, enables it to serve multiple functions that support optimal bone and soft tissue healing.

Excellent wound healing
The smooth dense layer of Bio-Gide® is cell occlusive, preventing unwanted soft tissue mucosal cells from invading the graft site as well as serving as a platform to support soft tissue healing. While occlusive to these soft tissue cells, Bio-Gide® does allow the ingrowth of blood vessels into the spaces between the collagen fibers, thereby promoting vascularization of the graft site.32, 33, 34, 35

Bio-Gide® retains the native collagen structure which is unaltered chemically or physically, and is thus highly biocompatible.36, 37 Even in rare cases of dehiscence, the soft tissue will typically heal without further complications.38 Consequently, open healing with Bio-Gide® is possible, although primary wound closure is generally recommended.

Bio-Gide® serves as an optimal surface for soft tissue regeneration. Above, fibroblasts shown on the smooth membrane surface.
**Undisturbed bone regeneration**

The rough porous layer of Bio-Gide®, with wide spaces between the collagen bundles, stabilizes the early blood clot as well as supports the newly regenerated bone. The first few weeks following GBR procedures are crucial for normal bone regeneration to occur. While providing a barrier function during this initial stage, Bio-Gide® acts as a scaffold for osteoblastic cell attachment. These functions are critical while early bone tissue, osteoid, is forming. Bio-Gide® is then broken down by enzymes into natural amino acids. Unlike membranes made with polylactide and polyglycolide, inflammation and foreign body reactions do not occur when Bio-Gide® is degraded, leaving the early regenerated tissues undisturbed.

→ Unique and multifunctional bilayer design
→ Supports healing of bone and soft tissue
→ Allows cell attachment of mucosal cells (smooth side) and osteoblasts (rough side)
**Excellent wound healing**

Bio-Gide®'s primary constituent is collagen. Unlike many of today's membranes, Bio-Gide® is a natural collagen product, without artificially produced crosslinking. Because Bio-Gide® is natural and without crosslinking, blood vessels are able to penetrate through all layers of the membrane structure, increasing vascularity to the regenerating bone. Also, since Bio-Gide® is not crosslinked, it is easily handled and adapts passively to underlying bone. Without crosslinking, soft tissue dehiscence rarely occurs with Bio-Gide® and when it does occur, the site almost always heals without the need for membrane removal.41, 42, 43, 44

Bio-Gide®'s unique bilayer structure, in combination with noncrosslinked collagen bundles, leads to a natural, 3-dimensional matrix that effectively promotes bone regeneration and excellent soft tissue healing.45, 46, 47, 48

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**Did you know...**

Bio-Gide® is the ONLY bilayer collagen membrane with dual functionality available for use in dentistry.

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41 Rothamel D. / Schwarz F., Clin Oral Implants Res. 15, 2004; 443–449
42 Rothamel D. / Schwarz F., Clin Oral Implants Res. 16, 2005; 369–378
43 Moses O. / Pitaru S. / Artzi Z. / Nemcovsky C. E., Clin Oral Implants Res. 16, 2005; 210–21
44 Friedmann A. / Strietzel F. P., J Periodontal 2001 Vol. 72; 1616–1623
45 Rothamel D. / Schwarz F., Clin Oral Implants Res. 15, 2004; 443–449
46 Von Arx T. / Buser D., Clin Oral Implants Res. 17, 2006; 359–366
47 Nemcovsky C. E. / Artzi Z., Clin Oral Implants Res. 13, 2002; 410–419
48 Nemcovsky C. E. / Artzi Z., J Periodontal 73, 2002; 754–761
Crosslinking vs. Biocompatibility

<table>
<thead>
<tr>
<th></th>
<th>Duration of Biodegradation</th>
<th>Biocompatibility, tissue integration, vascularization</th>
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<tbody>
<tr>
<td>Bio-Gide®</td>
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</tr>
<tr>
<td>BioMend®</td>
<td></td>
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<tr>
<td>BioMend Extend®</td>
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<tr>
<td>Ossix®</td>
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Conclusion: Bio-Gide® offers the optimal barrier function while at the same time providing the highest level of biocompatibility.

- Fewer dehiscences
- Natural degradation without irritating by-products
- Excellent wound healing
- Favorable handling properties
Bio-Oss® Cancellous
Small granules (0.25 - 1.0 mm)

Sizes: 0.25 g, 0.5 g, 2.0 g, 5.0 g

The small Bio-Oss® particles allow close contact with the surrounding bony walls. They are recommended for small to average size defects, i.e. extraction socket and periodontal defects, and for contouring autogenous block grafts.

Bio-Oss® Cancellous
Large granules (1.0 - 2.0 mm)

Sizes: 0.5 g, 2.0 g

The large Bio-Oss® granules have more space between the particles than the small granules. Particularly in large defects, this enables improved regeneration over large distances and provides enough space for the ingrowing bone.

Bio-Oss Collagen®
Bio-Oss® (small granules) + 10% Collagen (porcine)

Sizes: 100 mg, 250 mg, 500 mg

Bio-Oss Collagen® is indicated for use in periodontal defects and extraction sockets. Through the addition of collagen, Bio-Oss Collagen® can be tailored to the morphology of the defect and is particularly easy to apply.

Bio-Gide®
Resorbable bilayer membrane

Sizes: 13 x 25 mm, 25 x 25 mm, 40 x 50 mm

Bio-Gide® consists of porcine collagen (type I and III) and has a bilayer structure -- a rough porous side that faces the regenerated bone tissue and a dense smooth side that faces the soft tissue. Bio-Gide® is easy to handle: it can be positioned easily, adheres well to the defect, and is resistant to tension and tearing.

Also Available Bio-Oss® Cortical Small Granules (0.5 - 1.0 mm)

Sizes: 0.5 g, 2.0 g

Incorporate Bio-Oss®, Bio-Gide® and Bio-Oss Collagen® into your practice today by calling our Customer Service Representatives at 1-800-874-2334 or visit our web site at www.osteohealth.com