

BioXclude™

Amnion Chorion Allograft

The unique physical and biologic properties of BioXclude give it the benefits of a barrier membrane **AND** growth factor.

Physical

- Lacks rigidity and is self-adhering with excellent adaption
- Place over exposed roots and seated implants
- Place up or down and may fold over itself
- No trimming required
- Extremely thin



Biological

- Can be left exposed
- Suppresses inflammation
- Aids in the formation of clinical attachment
- Allows for rapid establishment of blood supply
- Cellular occlusive with rapid sealing of protected space



What Is BioXclude™

BioXclude is minimally manipulated amnion chorion allograft tissue for use as a wound covering in dental surgery. Since its introduction in 2010, SNOASIS Medical has distributed over 32,000 grafts of BioXclude. This allograft represents a paradigm shift in regenerative technology. Its unique physical and biologic properties provide the benefits of a growth factor and a barrier membrane. The placental tissue used in BioXclude is obtained from consenting mothers who donate their placentas after elective caesarian section delivery. The tissue is then processed using Purion®, a patented, tissue processing technology designed to cleanse and maintain the delicate structures of the tissue. Following processing, the allografts are packaged and terminally sterilized (SAL¹⁰⁻⁶). This methodology allows for retention of the biological factors found within BioXclude with over 55 identified to date¹⁻⁴.



Dry BioXclude prior to placement; orientation does not matter; the allograft can be placed UP or DOWN.

Biological Factors	BioXclude
PDGFα, β	X
TGFα, β	X
βFGF	X
EGF	X
GCSF	X
IL-1ra, 4, 6, 8, 10	X
VEGF	X
PLGF	X
TIMP-1, 2, 4	X
Laminin, 5	X

Barrier Membrane Properties

BioXclude's physical properties allow clinicians to avoid many of the drawbacks associated with traditional collagen and synthetic membranes, which can help simplify the procedure, allow for less invasive surgery, and reduce chair time⁵⁻⁷.



Excellent Adaption [A]: The literature reports gaps of up to 2.25mm when using a traditional membrane around periodontal defects⁸. In contrast, BioXclude can fold over itself and bunch up interproximally, conform to root concavities, and tightly adhere to proximal bone.

Benefits

- No trimming required
- Extremely thin; does not add meaningful bulk to the site
- Lacks rigidity and is self-adherent with excellent adaption
- Place dry or after flash hydration
- Place UP or DOWN and may fold onto itself
- Can be placed over exposed roots and seated implants
- May be placed over or under other membranes, meshes, or palatal tissue



Minimal Bulk [B]: Does not add meaningful bulk to the site when placed over a block graft; making it easier to obtain primary closure.



Self-Adherent [A]: BioXclude tightly adapts over a sinus perforation, forming a tight seal.



Over Collagen [A]: When additional stability is needed, BioXclude can be placed over a collagen membrane to aid in healing without over bulking the site.



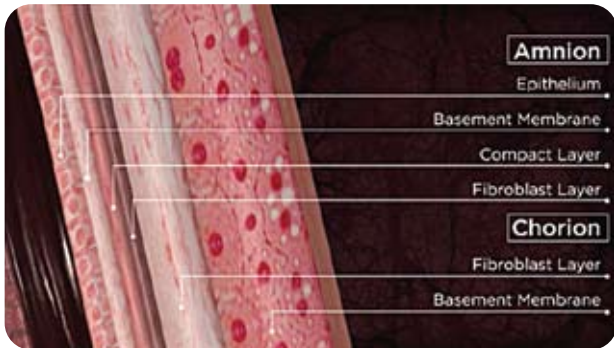
Multiple Pieces [A]: To further aid healing, or when covering irregular sites, multiple pieces may overlap or be stacked on to one another.

Safety

BioXclude is safe for patients. The placental tissue used in BioXclude is procured and processed according to regulations established by the FDA and the standards of the AATB. The medical use of amniotic tissue dates back over 100 years. During that time, there has never been a report of disease transmission, graft rejection, or an immune response^{10, 15}.

Growth Factor Properties

Amniotic tissue consists of a thin inner amnion layer and a thick outer chorion layer. Amnion tissue is composed of a single layer of epithelium cells, a basement membrane, a thick compact layer, and a fibroblast layer. Amnion contains collagen types III, IV, and V⁹. Chorion tissue consists of a reticular layer, a basement membrane containing a layer of dense connective tissue and a trophoblast layer. The reticular and basement membrane layers contain collagen Types I, III, IV, V, and VI¹⁰. These tissues contain over 55 ECM proteins, interleukins, cytokines, and TIMPs. In-vitro, in-vivo, and clinical research demonstrate the following^{1-3, 5, 11-14}:



Benefits

- Rapid wound closure when left exposed
- Cellular occlusive with rapid sealing of protected space
- Aids in the formation of clinical attachment
- Allows for rapid establishment of blood supply
- Shown to recruit mesenchymal stem cells
- Suppresses inflammation
- Allows for excellent early healing

Supports Angiogenesis: A key determinant of success in any procedure is adequate blood supply. Koob et al. demonstrated soluble angiogenic growth factors within the allograft stimulated the proliferation and migration of human microvascular endothelial cells and caused the production and release of all 30 tested angiogenic growth factors². When using BioXclude, the combination of angiogenic growth factors, neovascularization, and subsequent resorption of the allograft, allows for rapid establishment of blood supply^{2, 11, 12, 15}.

Role of Laminin-5: BioXclude provides a protein enriched matrix, which includes a high concentration of the ECM protein, laminin-5⁴. Laminin-5 is important due to its high affinity for the cellular adhesion of gingival epithelial cells and the prominent role it plays in the migration and attachment of directly attached tooth cells (DAT cells) to the root of the tooth^{16, 17}. This helps explain why BioXclude may be placed over exposed roots, aids in the formation of clinical attachment, and allows for rapid wound closure when left exposed to the oral environment^{5, 6, 10, 13-15}.

BioXclude vs. Bovine Collagen



Laminin-5: Immunohistochemical analysis for laminin-5 scores BioXclude 4.2 out of 5 (left). In contrast, bovine collagen (BioGide®) scores 0 out of 5 (right)⁴.

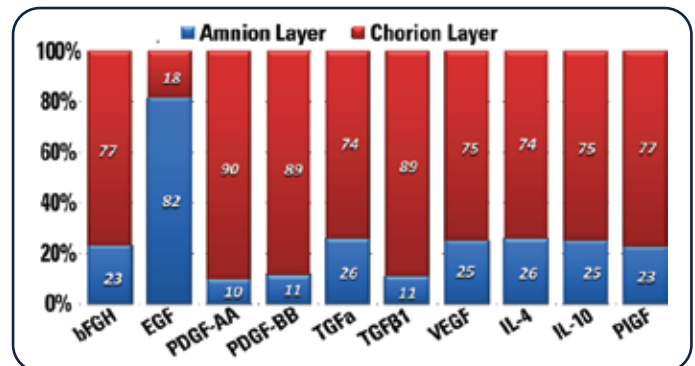
Hastens Flap Re-Attachment: In repeating the classic 1968 Hiatt attachment study, Holtzclaw et al. preformed osseous recontouring of the entire maxilla on a 54 year old male smoker, with chronic periodontitis¹³. BioXclude was placed on one side, nothing on the other (control), and the flaps reapproximated and secured. The tensile strength (in grams) required to separate the gingival flap from the underlying structures was measured at different time points. At one week, the control side was easily displaced, whereas the BioXclude side had nearly 500% greater resistance, with only a small amount of gingival displacement. Another study has shown amnion allograft prevented post-operative gingival recession¹⁸. These studies support why clinicians can reflect a larger flap when using BioXclude.

Tensile Strength to Separate Gingival Flap

	72 hours	1 week	2 weeks	3 weeks
Control	200	350	1,600	2,100*
BioXclude	325	1,700	2,000*	2,200*

* Sutures pulled through without flap dislodgement

The Benefit of the Chorion Layer: The use of amnion only allografts dates back over 100 years. BioXclude was the first, and still is the only amniotic tissue allograft composed of both the amnion and chorion tissue layers. In addition to being much thicker than the amnion layer, an analysis of these tissues revealed the chorion layer contains over 80% more cytokines and structural non-collagenous proteins (right)¹⁹. For this reason, amnion chorion allografts (BioXclude) are not only more durable from a physical perspective, but also possess greater amounts of biological factors compared to amnion only allografts.



Applications

The unique biologic and physical properties of amnion and amnion chorion (BioXclude) allograft allow it to be used as a wound covering, in a multitude of dental implant / periodontal / oral maxillofacial applications which include 5, 6, 10, 14, 20-24:

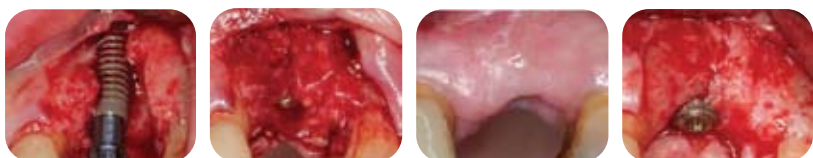
- Socket Preservation
- Peri-Implantitis
- Ridge Augmentations
- Oral Wounds
- Adhesion Barrier
- Implants
- Periodontal
- Sinus/Flap Perforations
- Growth Factor
- Nerve Repair

Clinical Cases

Below are three cases highlighting the use of BioXclude in dental surgery. Please visit www.SnoasisMedical.com/Applications to review additional cases and published scientific and clinical research.



Site Preservation [A]: BioXclude left intentionally exposed over #20 grafted with Maxxeus 70/30 bone. Excellent healing at 9 days with granulation tissue covering the exposed portion of BioXclude. Healing at 7 weeks with healthy gingival tissue covering the site. At 6 months, the implant is surrounded with a wide zone of attached keratinized tissue.



Immediate Implant [C]: 84 year old male with a long / narrow buccal defect on #29. Once adapted over grafted implant, BioXclude adds minimal bulk to the site. Great contour of the gingiva at 4 months. Reentry at 4 months reveals excellent new bone formation.



Periodontal Defect [A]: Smoker, #18D 11mm PD, #19B 8mm PD (grade 2 furcation), #19M 7mm PD. BioXclude placed over exposed roots and defects grafted with Maxxeus 70/30 bone. At 12 months, the gingival margin is maintained with a small gain in root coverage. Defect resolution; #18D 4mm PD, #19B 3mm PD, #19M 3mm.

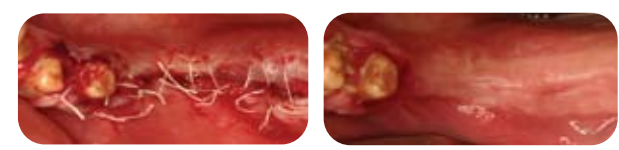
Leaving BioXclude Exposed

BioXclude may be left exposed to the oral environment when used on its own over grafted extraction sockets and immediate implants (left). It can also be left exposed in ridge augmentations when placed over a collagen membrane (below).



BioXclude over Collagen [D]: Augmented ridge using a collagen membrane with BioXclude placed over the top. Primary closure was not obtained the length of the site buccal/lingual. Excellent healing is observed at one week. The exposed portions of BioXclude are covered with granulation tissue.

When using BioXclude on its own for ridge augmentations, where its only physical requirement is to contain the graft material (particulate, putty, block), primary closure should be obtained. However, very small gaps present after closing the site, should heal over without incident (below).



Primary Closure [A]: Closure of a ridge split. The flaps are not fully reapproximated, leaving small amounts of BioXclude exposed to the oral environment. Healing at 11 weeks shows newly formed zone of attached keratinized tissue.

Sizing, Storage, and Ordering

Using a larger piece makes placement much easier as it can fold over itself and/or multiple pieces overlap one another. The allograft also contains biological factors to aid healing. For these reasons, clinicians are encouraged to order larger sizes of BioXclude than they would when purchasing a traditional barrier membrane. To place an order, please call us at 866-521-8247 or download an order form at www.SnoasisMedical.com/order. **Thank You!**

Size (cm)	1 x 1.3	1 x 2.5	1.5 x 2	2 x 3
Product Code	GB1130	GB1255	GB1125	GB1235
List Price*	\$89	\$105	\$119	\$179
Storage	Room Temp: -80° to 80° C			

* Contact Snoasis Medical for first time buyer specials, bulk discounts, and university and government pricing.

PHOTO / CASE CREDITS: [A] Dan Holtzclaw, DDS, MS, Austin, TX. [B] Vincent Wang, DDS, MS, Pasadena, CA. [C] Robert Miller, DMD, Plantation, FL. [D] Hsun-Liang Chan, MS, DDS, Ann Harbor, MI. ABBREVIATIONS: Platelet-derived growth factor-alpha (PDGFα), -beta (PDGFβ), transforming growth factor alpha (TGFα), -beta (TGFβ), basic fibroblast growth factor (bFGF), epidermal growth factor (EGF), interleukin-1 receptor antagonist (IL-1ra), interleukin (IL), vascular endothelial growth factor (VEGF), granulocyte-colony stimulating factor (G-CSF), placenta growth factor (PLGF), tissue inhibitor of metalloproteinases (TIMP), Food & Drug Administration (FDA), American Association of Tissue Banks (AATB), Maxxeus cortical mineralized / demineralized allograft bone 70/30 blend (Maxxeus 70/30), extracellular matrix (ECM). REFERENCES: [1] Koob T, Rennert R, Zabeck N, et al. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. 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