

PRODUCT GUIDE

BioXclude®

AMNION-CHORION ALLOGRAFT

BARRIER MEMBRANE + GROWTH FACTOR



IMMUNOPRIVILEGED
ANTI-INFLAMMATORY
ACCELERATED HEALING
ANTIBACTERIAL

LEAVE IT EXPOSED • SAFE TO TOUCH TOOTH SURFACES • REGENERATIVE

SNOASIS
MEDICAL
BORN TO SMILE

What is BioXclude®



BioXclude® is the only minimally manipulated dehydrated human deepithelialized amnion-chorion membrane available for use in a variety of dental, endodontic, oral maxillofacial, and periodontal regenerative procedures as a barrier, conduit, connector or cushion. Amnion-chorion tissue contains biological factors which aid in healing, promote angiogenesis, reduce inflammation and accelerate flap reattachment. It also possesses inherent anti-bacterial properties and the tissue is non-immunogenic. ^(1-4, 7, 8, 16)

The Bioactive Advantage

Over 280 preserved growth factors, cytokines and chemokines have been identified within BioXclude. BioXclude's complex extracellular matrix composition combined with these retained biological factors offer critical advantages over other membrane materials, demonstrated in-vitro and in-vivo. ^(1-3, 5, 7, 8, 11-14, 16)

- Safely Exposed to the Oral Environment
- Cell Occlusive Barrier
- Growth Factors
- Anti-inflammatory
- Decreased Post-Operative Pain
- Facilitates Rapid Vascular Growth
- Recruits Mesenchymal and Hematopoietic Stem Cells
- Hastened Epithelialization
- Hastened Flap Reattachment
- More Keratinized Tissue
- Stem Cell Magnet
- Antimicrobial
- Angiogenic

Composition

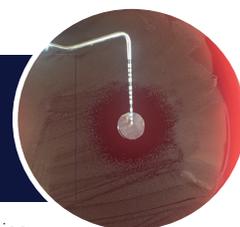
BioXclude is composed of allograft amnion and chorion tissue. These layers represent the inner and outermost layers of the amniotic membrane, the only barrier between the mother and fetus, protecting both from each another's immune system and infection. It also serves as a shock absorber, prevents adhesion and regulates fetal temperature. Amnion tissue is rich in collagen types III, IV, and VI.⁹ 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 VI.¹⁰

A Paradigm Shift In Resorption Kinetics

BioXclude jump starts the natural wound healing process. It allows for rapid gingival epithelial cell migration and promotes neovascularization, enabling the rapid establishment of blood supply by activating the migration of human mesenchymal and hematopoietic stem cells. BioXclude stimulates the proliferation and migration of human microvascular endothelial cells and causes these cells to produce and release angiogenic growth factors. The high concentration of Laminin-5 provides an ideal substrate for the attachment of gingival epithelial cells and Directly Attached Tooth cells (DAT cells), which supports why BioXclude may be placed over exposed roots and is safe to leave exposed. **BioXclude resorbs in 8-12 weeks**, as demonstrated with histology.¹⁷ BioXclude is truly a paradigm shift in resorption kinetics. It is a bioactive barrier, recruiting mesenchymal stem cells to the site, which differentiate between hard and soft tissues before the matrix resorbs. Once this process begins, it's faster resorption profile is ideal, allowing the periosteum to take over. This process challenges the established theories regarding barrier membrane characteristics which have been based solely on an inert scaffold model. ^(2, 5, 6, 10-12, 13-15)

Proven Bactericidal

Placental tissues are inherently antibacterial, offering a safer, superior material to leave exposed to the oral environment and placed in the maxillary sinus. In two separate studies, BioXclude was proven bactericidal, in contrast to porcine collagen, which promoted bacterial growth, and porcine pericardium demonstrating no antimicrobial activity. ^(7,8)



Aggregatibacter actinomycetemcomitans * Note the zone of inhibition around the BioXclude disc

One Product. Simple. VERSATILE.

SOCKET PRESERVATION

IMPLANTS

PERI-IMPLANTITIS

GUIDED TISSUE REGENERATION

SINUS / FLAP PERFORATION REPAIR

NEURAL PROTECTION / REGENERATION

ADHESION BARRIER

ORAL WOUNDS

NON-SURGICAL PERIODONTAL THERAPY



KEEP IT MINIMALLY INVASIVE

- No flap elevation required
- Simply tuck BioXclude 1mm under gingival margin
- Easily achieved with a reverse (inverted) suturing technique

NO NEED TO TRIM

- Allow BioXclude to drape and adhere
- This allows a larger piece to bunch up between the teeth adjacent to the site, while also extending over the buccal portion of the graft, and onto native bone

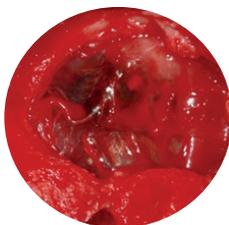


NO NEED TO FIXATE

- BioXclude will stick to any hydrated surface
- Place dry and allow it to hydrate to the site, or hydrate over the top with sterile saline
- BioXclude adheres like shrink wrap

UNMATCHED ADHESION

- No other product adheres to the Schneiderian membrane like BioXclude
- Easily applied dry, naturally hydrates and seals the perforation like a patch
- No need for further fixation



BioXclude Reinvents the Membrane “Rules”

The physical properties of BioXclude allow clinicians to avoid many of the drawbacks associated with traditional collagen and synthetic membranes. This allows for a simplified, less invasive procedure resulting in less chair time.

Witness the unique and beneficial handling characteristics that make BioXclude more efficient and effective.

- **NO NEED TO TRIM - LET BIOXCLUDE TOUCH ADJACENT TEETH**
- **NO ORIENTATION - PLACE UP OR DOWN, FOLD IT, ALLOW TO “BUNCH” UP**
- **SAFELY TOUCH ROOT SURFACES**
- **SAFELY TOUCH IMPLANT SURFACES**
- **PLACE OVER OR UNDER OTHER MEMBRANES, MESH OR PALATAL TISSUE**
- **LACKS RIGIDITY, EASILY ADAPTS AND ADHERES**
- **NO NEED TO TACK OR SUTURE**
- **THIN PROFILE - EASIER TO OBTAIN PRIMARY CLOSURE**
- **NO PRE-HYDRATION NECESSARY**
- **NO RETRIEVAL - FULLY RESORBS IN 8-12 WEEKS**
- **STORES AT AMBIENT CONDITIONS WITH A 5 YEAR SHELF LIFE**

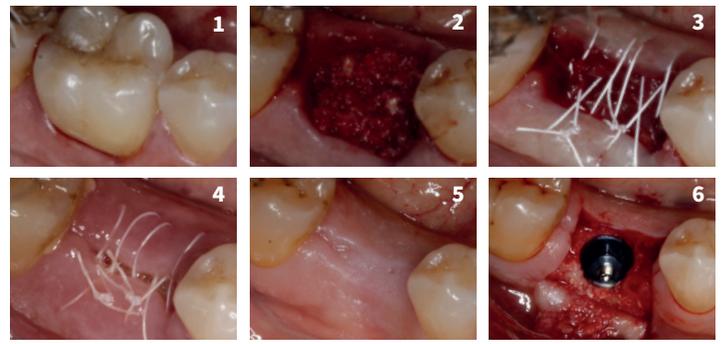
Photos courtesy of: 1)Jin Sub Oh, DMD, MS; (2,3)John Kim, DMD, MS, PA; 4)Arthur Yagudayev, DDS, MS

Anterior Socket Preservation: Minimally-Invasive

1. FDDB + BioXclude
2. 4-day healing
3. 5-month re-entry
4. Implant placement



Photos courtesy of: Anthony Del Vecchio, DDS, Yorktown Heights, NY



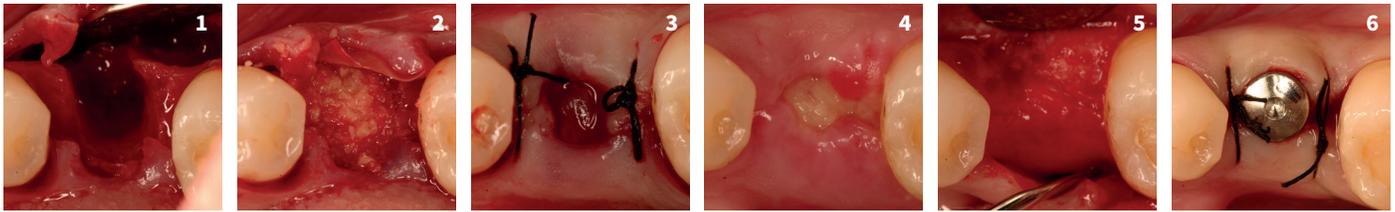
Photos courtesy of: Dan Cullum, DDS, Coeur D'Alene, ID

1. Pre-op PA
2. FDDB + BioXclude
3. (2) Reverse figure-eight sutures
4. 10-day post-op
5. 6 month post-op
6. Implant placement

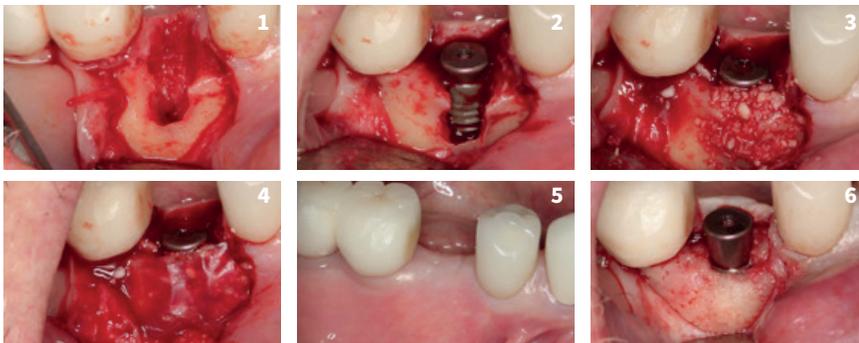
Posterior Socket Preservation: Minimally-Invasive

Socket Preservation: Significant Bony Defect

1. Buccal defect
2. FDDB + BioXclude
3. Site left exposed
4. 10-day healing
5. 3-month re-entry
6. Implant placement



Photos courtesy of: Dan Holtzclaw, DDS, MS, Austin, TX



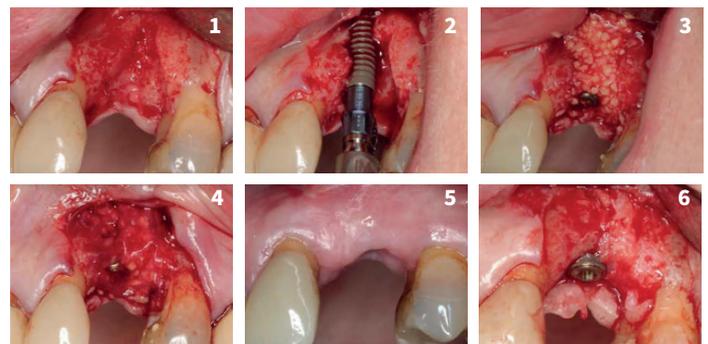
Photos courtesy of: Robert Miller, DMD, Plantation, FL

Immediate Implant

1. Failed implant removal
2. Implant placement
3. Bone graft placement
4. BioXclude placement
5. Post-op view
6. Re-entry

Immediate Implant: Moderate Facial Defect

1. Buccal defect
2. Implant placement
3. Bone graft placement
4. BioXclude placement
5. Post-op view
6. Re-entry

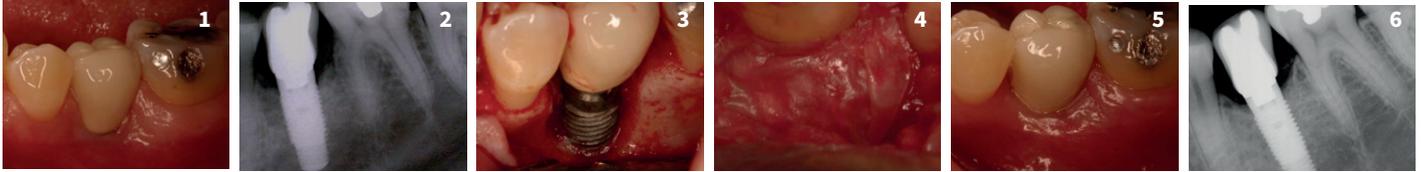


Photos courtesy of: Robert Miller, DMD, Plantation, FL

Clinical Cases

Implant Repair: Peri-implantitis

1. Pre-op implant #20
2. Pre-op PA
3. Defect
4. BioXclude in place (Grafted with Accell® Bone Putty)
5. 12-month post-op
6. 12-month PA



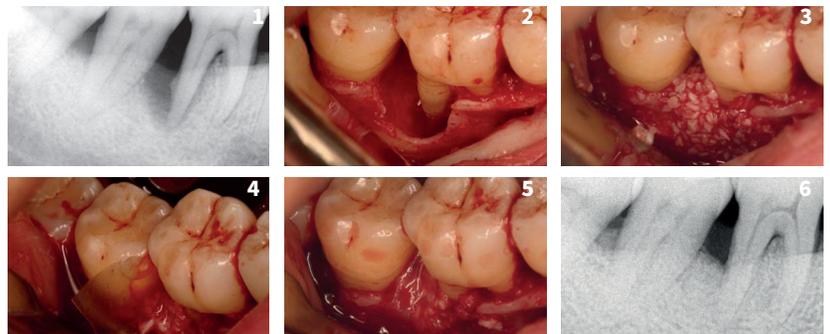
Photos courtesy of: Dan Holtzclaw, DDS, MS, Austin, TX

Guided Tissue Regeneration

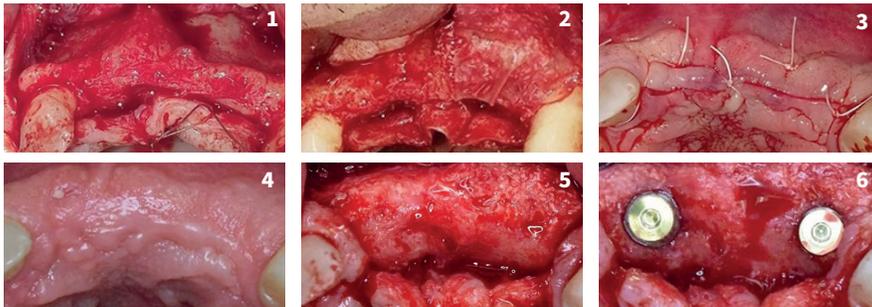
1. Pre-op #30
2. Defect
3. Grafted with FDDB
4. BioXclude placed interproximally - can flash hydrate
5. BioXclude hydrated
6. 16-month post-op

Probing Depth

Pre-Op = 12 mm
3 Months = 3 mm



Photos courtesy of: Dan Holtzclaw, DDS, MS, Austin, TX



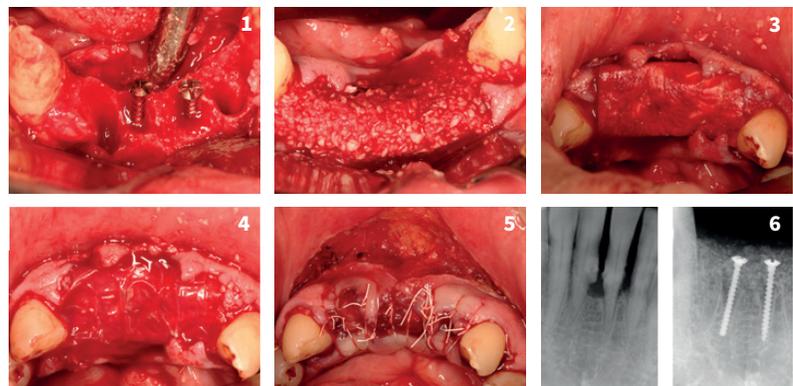
Photos courtesy of: Vinay Bhide, DDS, MSc, Ontario, CAN

Guided Bone Regeneration: BioXclude Only

1. Pre-op defect
2. Autogenous scrapings / xenograft bone, BioXclude placed
3. Primary closure with PTFE
4. 8-month healing
5. 8-month re-entry
6. Implants placed

Guided Bone Regeneration: Double Membrane

1. Extraction #23-26; tenting screws placed
2. Grafted w/FDDB
3. Collagen membrane placed
4. BioXclude placed OVER collagen
5. Non-primary closure (vestibular dissection into chin performed PA to close the site).
6. Pre-op/post-op PA

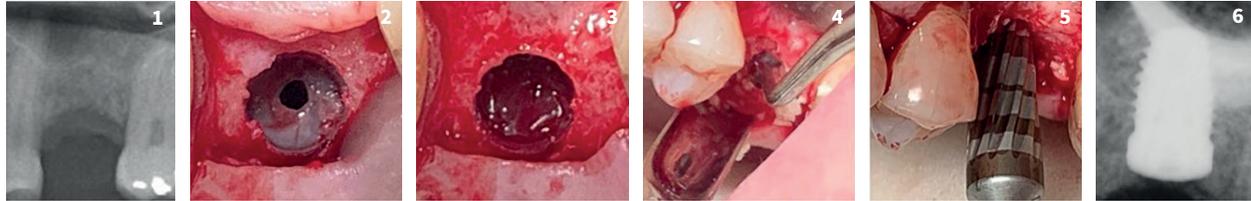


Photos courtesy of: Dan Holtzclaw, DDS, MS, Austin, TX

Perforation Repair: Crestal Sinus Lift

1. Pre-op PA
2. Sinus perforation
3. BioXclude in place

4. FDDBA
5. Versah® bur used. Implant placed.
6. Immediate post-op PA

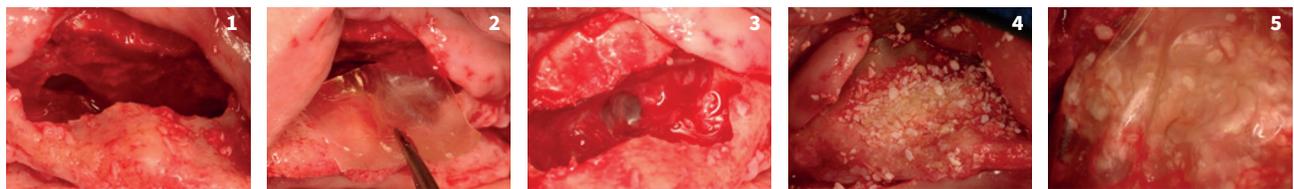


Photos courtesy of: Anthony Del Vecchio, DDS, Yorktown Heights, NY

1. Sinus membrane perforation
2. BioXclude placed dry
3. BioXclude adheres to sinus and seals perforation

4. FDDBA placed
5. Lateral sinus window covered with BioXclude

Perforation Repair: Lateral Sinus Lift

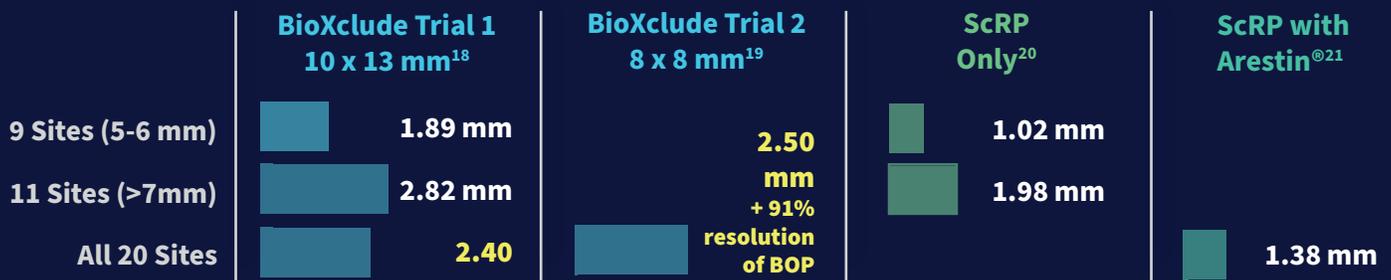


Photos courtesy of: Dan Holtzclaw, DDS, MS, Austin, TX

Non-Surgical Periodontal Therapy Adjunct

These studies followed patients at 5-12 week re-evaluation of probing depth following ScRP with BioXclude condensed into periodontal pockets of 5mm or greater. Note the consistent improvement achieved with BioXclude regardless of the change in graft size.

MEAN PROBING DEPTH IMPROVEMENT



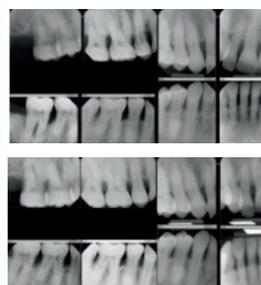
Initial One Week Post-Op

Decreased post-op pain and inflammation + accelerated healing

Soft Tissue Donor Site Application

Photos courtesy of: Nicholas Poulos, DDS, MS, Denver, CO

Periodontal Laser Therapy + BioXclude Adjunct

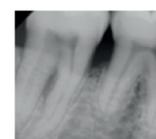


Pre-Op



Initial PD
Average: **4.99 mm**

Post-Op



Post-Op PD
Average: **3.03mm**
Post-Op PD Improvement
Average: **1.96mm**

Photos courtesy of: Nicholas Poulos, DDS, MS, Denver, CO

Safety, Procurement and Processing

Our placental tissue is sourced in the United States with informed consent from pre-screened mothers following elective cesarean section deliveries only. The tissue is procured, processed, and distributed according to standards and regulations established by the American Association of Tissue Banks and the United States Food & Drug Administration.

Purion® Process

This proprietary process safely and gently separates placental tissues, cleans and reassembles layers, and then dehydrates the tissue to preserve the key elements associated with healing. The Purion® process removes blood components while protecting the delicate scaffold of the tissues, leaving an intact extracellular matrix. Following processing, the allografts are terminally sterilized (SAL 10⁻⁶)



CHOOSING THE RIGHT SIZE:

No flap elevation:

Tuck 1mm under gingival margin

Flap Elevation:

Cover all graft material; extend onto native bone 3mm

Sinus Perforation:

Extend 5 mm past edge of perforation

Size Choices



* most popular sizes

Innovation Supported By Research

Pioneering Placental Tissue Science and Regenerative Biomaterials

Snoasis Medical has pioneered the development and use of placental tissue products for tissue repair and regeneration in dental-oral maxillofacial surgery for over 10 years. For more information, review this sample of our **scientific** and **clinical studies**:

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The BioXclude® Advantage



BIOLOGICAL

- **Growth factors + Barrier Membrane**
- **Immunoprivileged**, like autologous grafts
- **Accelerated** early healing/attachment
- **Anti-inflammatory**
- **More:** Bone, Keratinized tissue
- **Antibacterial**



CLINICIAN

- **Lower cost** and less chair time
- **No rules:** No trimming, can touch tooth surfaces + leave exposed
- **Less** rejections, reactions, post-operative pain and contraindications
- **Consistent**, shelf stable product



PATIENT

- **Safe + Affordable**
- **No** need for venipuncture
- **Less** concern
- **Less** post-operative pain and inflammation
- **Less** unnecessary post-operative visits
- **Better clinical results = HAPPIER PATIENTS**

THE ONLY AMNION-CHORION
BIOACTIVE BARRIER MEMBRANE
AVAILABLE FOR USE IN THE DENTAL FIELD TODAY

**FOR MORE INFORMATION,
CONTACT US:**

Phone: 866-521-8247

Email: sales@snoasismedical.com

Fax: 720-259-1405

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