



Amnion-Chorion Allograft

Product Guide

maxxeus™
by CTS

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 Vascularization
- Recruits Mesenchymal and Hematopoietic Stem Cells
- Hastened Epithelialization
- Hastened Flap Reattachment
- More Keratinized Tissue
- 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 other'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 Augmentation/Perforation Repair
- Gingival Perforation Repair
- Neural Protection/Regeneration
- Adhesion Barrier
- Guided Bone Regeneration
- Non-Surgical Periodontal Therapy

BioXclude® Reinvents the Membrane “Rules”



Keep It Minimally Invasive

- No flap elevation required
- Simply tuck BioXclude® 1.0 mm 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

- Unique ability to adhere to the Schneiderian membrane
- Easily applied dry, naturally hydrates and seals the perforation like a patch
- No need for further fixation

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.

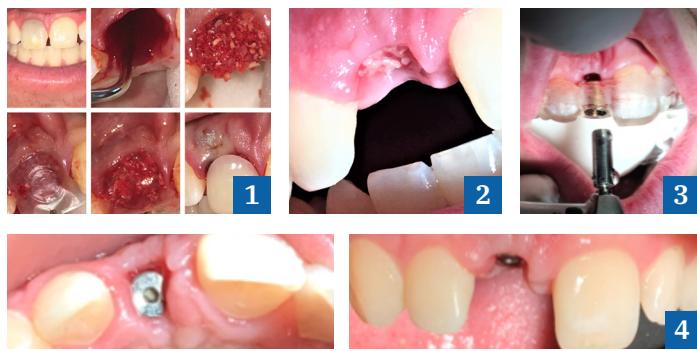
Witness the unique and beneficial handling characteristics that make BioXclude® more efficient and effective.

- 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 soft tissue donor site
- 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

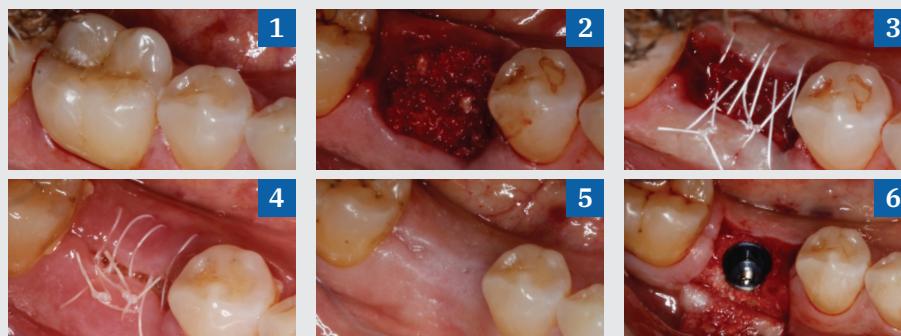
- 1 Allograft Bone + BioXclude®
- 2 4 Day Healing
- 3 5 Month Re-Entry
- 4 Implant Placement



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

Posterior Socket Preservation: Minimally-Invasive

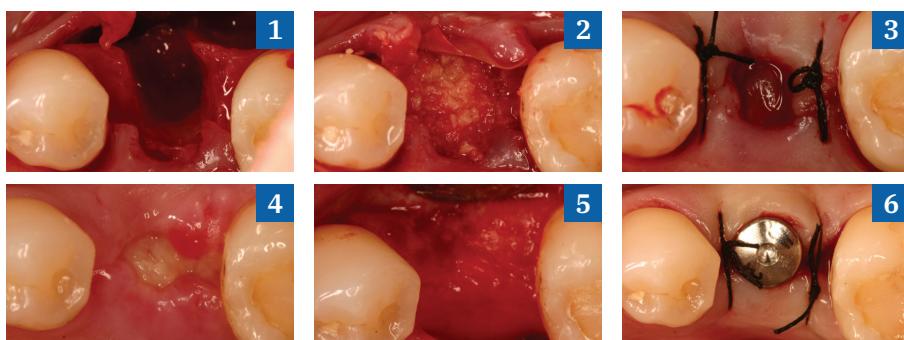
- 1 Pre-Op PA
- 2 Allograft Bone + BioXclude®
- 3 (2) Reverse Figure-Eight Sutures
- 4 10 Day Post-Op
- 5 6 Month Post-Op
- 6 Implant Placement



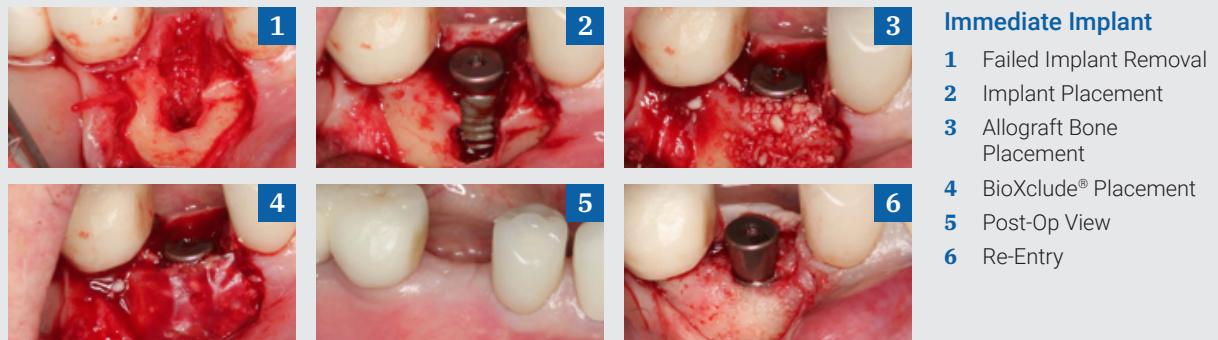
Photos courtesy of: Dan Cullum, DDS, Coeur D'Alene, ID

Socket Preservation: Significant Bony Defect

- 1 Buccal Defect
- 2 Allograft Bone + 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



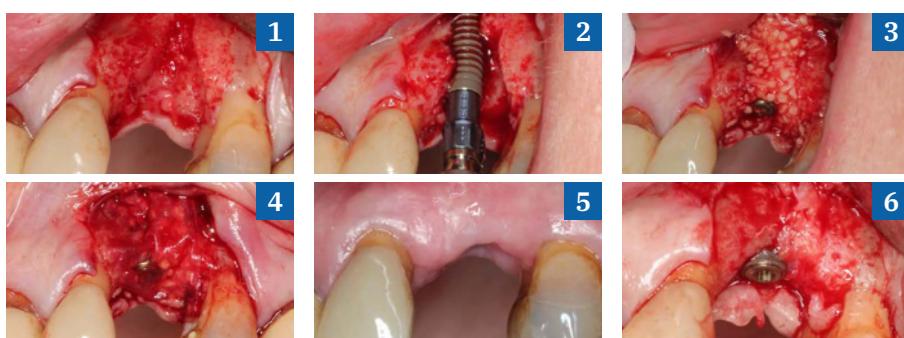
Photos courtesy of: Robert Miller, DMD, Plantation, FL

Immediate Implant

- 1 Failed Implant Removal
- 2 Implant Placement
- 3 Allograft Bone Placement
- 4 BioXclude® Placement
- 5 Post-Op View
- 6 Re-Entry

Immediate Implant: Moderate Facial Defect

- 1 Buccal Defect
- 2 Implant Placement
- 3 Allograft Bone 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® Placement
- 5 12 Month Post-Op
- 6 12 Month PA

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

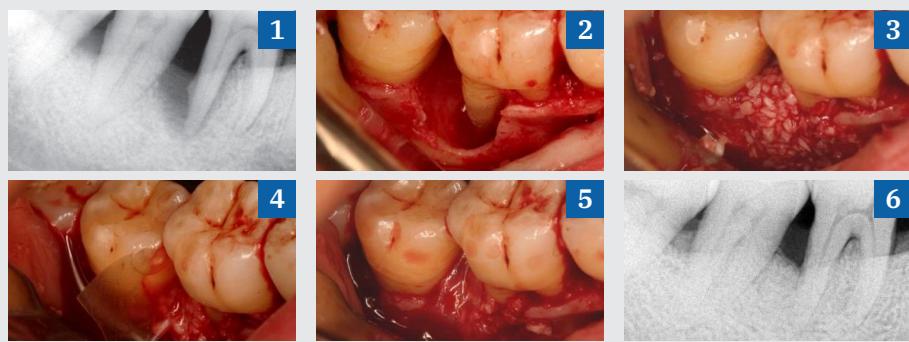
Guided Tissue Regeneration

- 1 Pre-Op #30
- 2 Defect
- 3 Allograft Bone Placement
- 4 BioXclude® Placement Interproximally - Can Flash Hydrate
- 5 BioXclude® Hydrated
- 6 16 Month Post-Op

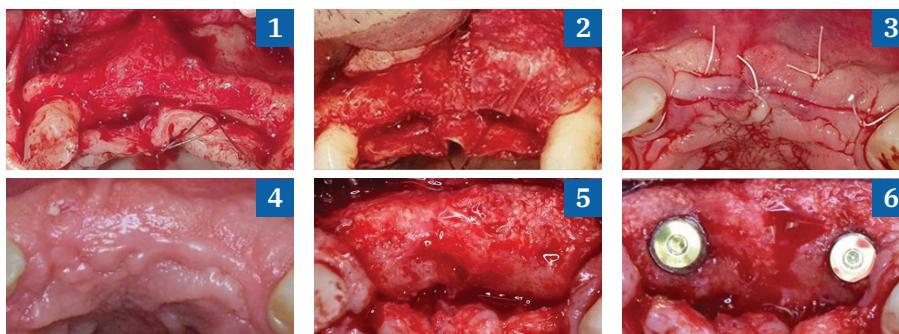
Probing Depth:

Pre-Op = 12.0 mm

3 Months = 3.0 mm



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



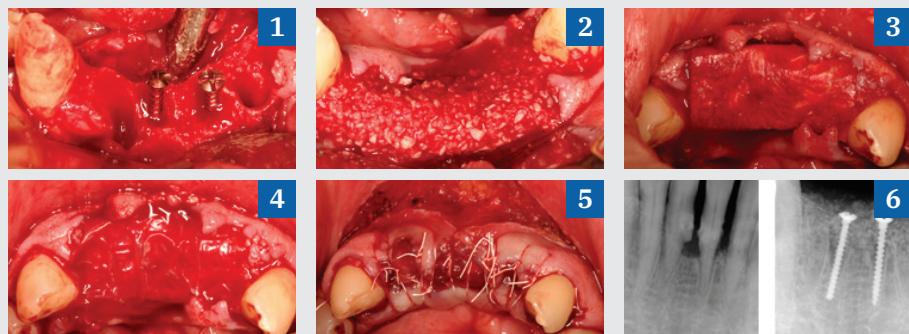
Guided Bone Regeneration: BioXclude® Only

- 1 Pre-Op Defect
- 2 Autogenous Scrapings, Xenograft Bone & BioXclude® Placement
- 3 Primary Closure with PTFE
- 4 8 Month Healing
- 5 8 Month Re-Entry
- 6 Implants Placement

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

Guided Bone Regeneration: Double Membrane

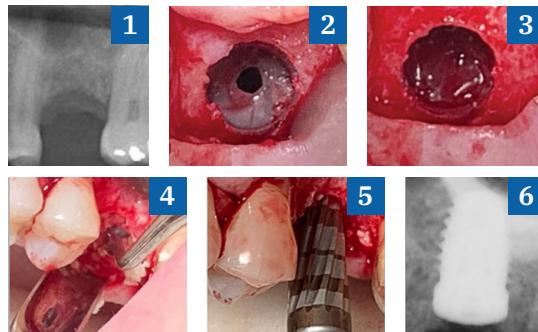
- 1 Extraction #23-26; Tenting Screw Placement
- 2 Allograft Bone Placement
- 3 Collagen Membrane Placement
- 4 BioXclude® Placed OVER Collagen
- 5 Non-Primary Closure (Vestibular Dissection into Chin Performed to Close the Site)
- 6 Pre-Op/Post-Op PA



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

Perforation Repair: Crestal Sinus Lift

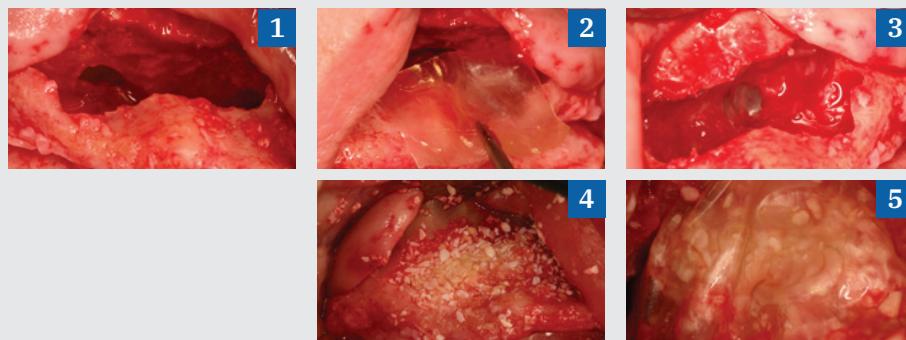
- 1 Pre-Op PA
- 2 Sinus Perforation
- 3 BioXclude® Placement
- 4 Allograft Bone Placement
- 5 Implant Placement
- 6 Immediate Post-Op PA



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

Perforation Repair: Lateral Sinus Lift

- 1 Sinus Membrane Perforation
- 2 BioXclude® Placement, Dry
- 3 BioXclude® Adheres to Sinus and Seals Perforation
- 4 Allograft Bone Placement
- 5 Lateral Sinus Window Covered with BioXclude®

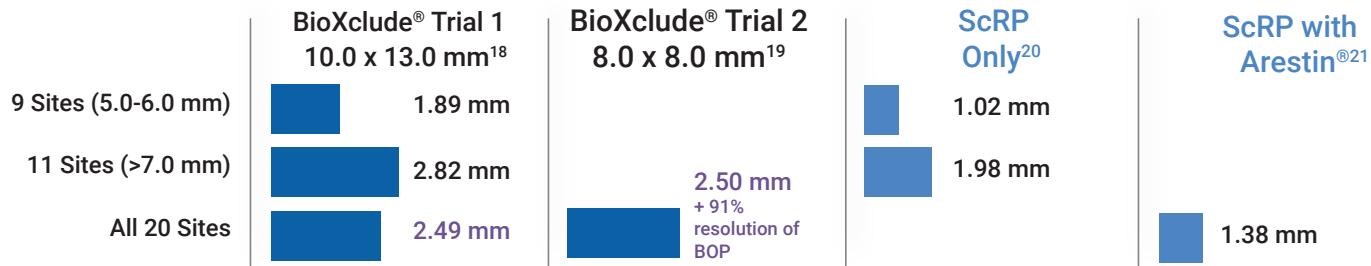


Photos courtesy of: Dan Holtzclaw, DDS, MS, Austin, TX

Non-Surgical Periodontal Therapy Adjunct Studies

These studies followed patients at 5-12 week re-evaluation of probing depth following ScRP with BioXclude® condensed into periodontal pockets of 5.0 mm of greater. Note: the consistent improvement achieved with BioXclude® regardless of the change in graft size.

Mean Probing Depth Improvement



Soft Tissue Donor Site Application

Decreased post-op pain and inflammation + accelerated healing



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

Periodontal Laser Therapy + BioXclude® Adjunct

Initial PD
Average: 4.99 mm



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

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).

BioXclude® Size Choices



Choosing The Right Size:

No Flap Elevation: Tuck 1.0 mm under gingival margin

Flap Elevation: Cover all graft material and extend onto native bone 3.0 mm

Sinus Perforation: Extend 5.0 mm past edge of perforation

* 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 and Barrier Membrane
- Immunoprivileged, similar to autologous grafts
- Accelerated early healing/attachment
- Anti-Inflammatory
- More: Bone, Keratinized Tissue
- Antibacterial



Clinical

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



Patient

- Safe and 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 DEHYDRATED
DEEPITHELIALIZED AMNION-CHORION
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