BioXclude®

Processed Human Amnion Chorion
Allograft Information / Instructions for Use

SNOASIS MEDICAL
-BORN TO SMILE-

Snoasis Medical
Golden, Colorado
1-866-521-8247
www.snoasismedical.com

BX100.007

BioXclude® Description

Human amnion-chorion membrane is a thin, collagenous allograft derived from the placenta; the structure in which the human fetus grows and develops within the mother's uterus. BioXclude is a minimally manipulated, dehydrated, non-viable cellular amnion-chorion membrane that contains multiple extracellular matrix proteins, growth factors, cytokines and other specialty proteins present in the allograft that enhance healing.

BioXclude allografts are human tissue products and appearance may vary between donors. Variations in color (tan to light brown), opacity, and thickness are normal due to the nature of human tissue.

Tissue Uses

BioXclude is intended for homologous use in the treatment of dental, endodontic, maxillofacial, oral, and periodontal diseases and defects to provide a barrier, conduit, connector, or cushion, enhance healing, modulate inflammation and reduce scar tissue formation.

Precautions/Warnings

- BioXclude should not be used on:
  (1) Areas with active or latent infection; and/or
  (2) A patient with a disorder that would create an unacceptable risk of post-operative complications.
- BioXclude allografts remain suitable for transplantation in an unopened, undamaged package, under proper storage conditions.
- Please inspect the integrity of the package upon receipt. If package and contents appear defective or damaged in any way, immediately contact Snoasis Medical.
- This allograft is intended for single-patient use only. Discard all unused material.
- The procedure should be performed by an authorized dental/medical professional.
- Strict donor screening and laboratory testing, along with dedicated processing and sterilization methods, are employed to reduce the risk of any disease transmission. However, as with all biological implants, an absolute guarantee of tissue safety is not possible. This allograft has the potential to transmit infectious disease to the recipient.
- The reaction of the body to any biological implant is not completely understood.
- Caution should be used when treating patients with a known sensitivity to aminoglycoside antibiotics.
- Discard all damaged, mishandled or potentially contaminated tissue.
- DO NOT RE-STERILIZE.

Preparation

Prior to implantation, carefully follow the BioXclude allograft preparation steps below using aseptic technique:

- The outer peel pouch is NOT sterile. The inner pouch that contains BioXclude is sterile (unless the pouch is damaged or compromised).
- Carefully open the peelable corner of the outer pouch and remove the inner pouch using aseptic technique. Ensure the inner pouch does not come in contact with any portions of non-sterile surface of the outer pouch.
- Using aseptic technique, SLOWLY peel a corner of the inner peel pouch and grasp BioXclude with DRY non-toothed, sterile forceps.
- PLEASE TAKE GREAT CARE WHEN REMOVING THE PRODUCT FROM THE INTERNAL POUCH. BIOXCLUDE IS THIN AND EXTREMELY LIGHTWEIGHT.
- Use the allograft promptly after opening the inner sterile pouch.

Surgical Use

Due to unique physical properties, BioXclude has its own set of guidelines for sizing and placement. It is important that the treating clinician and surgical assistant read the guidance below outlining the instructions for use of BioXclude in dental implant and periodontal surgery.

Trimming: BioXclude does not need to be trimmed prior to use in most procedures. After placement, excess allograft can be folded over itself, lay over exposed tooth roots, implant collar threads, seated dental implants, and / or internal fixation. When trimming is required, use sharp dry scissors. Trimming BioXclude can be done in a less precise manner.

Hemostasis: Excessive bleeding can cause BioXclude to slide and prevent intimate contact with the underlying defect / graft material. Hemostasis should be achieved prior to placement. Damp gauze may be applied following BioXclude placement to absorb the excess fluid and help it adhere to the underlying defect.

Instrumentation: Use DRY instruments when BioXclude is dry and WETTED instruments once BioXclude is wet.

Orientation: During placement orientation does not matter. BioXclude may be placed UP or DOWN.

Placement: BioXclude may be placed dry or after flash hydration wherein the membrane is passed briefly through irrigant prior to placement. To speed up hydration, drops of irrigant may be placed on the membrane after placement.

- **Interproximal Spaces / Layering:** BioXclude should be placed dry or flash hydrated into the interproximal space. As it hydrates, it will fold onto itself, covering the crestal aspects and "fan out" apically over the proximal walls. In the event of very small embrasure spaces, place one piece of BioXclude from the facial side and the other piece from the lingual side to cover the crest of the grafted defect. Layering can also be used around circumferential defects.

- **Covering Sinus Perforations:** BioXclude should be placed dry on the moist sinus membrane with extension at least 5 mm beyond the perforation. It is important to make sure BioXclude is hydrated with good adhesion to the sinus membrane prior to placement of graft material.

Positioning: A blunt instrument can be used to tuck and position the allograft following placement. To help steady BioXclude, the surgical assistant can apply a second blunt instrument to the center of the allograft to hold it in place while the clinician tucks and positions BioXclude over the site. Once in position and fully hydrated, damp gauze or a wetted instrument is applied to BioXclude so the assistant's holding instrument can be retracted. This prevents it from sticking to the holding instrument and ensures BioXclude is in intimate contact with the underlying site.

Stabilization: No sutures or tacks are required to stabilize BioXclude.

Space Maintenance: BioXclude should be used with appropriate graft materials which can provide space maintenance when used as the sole barrier membrane. If required, BioXclude may be applied before and / or after placement of other membranes such as titanium reinforced polytetrafluoroethylene (PTFE), or titanium mesh.

Intentional Non-Primary Closure

General Guidelines: BioXclude may be intentionally left exposed to the oral environment in situations similar to extraction socket preservation, around dental implants and in situations similar to horizontal ridge augmentation when placed over a secondary collagen membrane.

Nothing on Top: Do not cover exposed portions of BioXclude with anything that could interfere with cell migration including adhesives, collagen plug, periodontal dressing, platelet gels and membranes.

Socket Preservation Without Flap Elevation: If the tooth is extracted without flap elevation. BioXclude should be tucked approximately 1 mm underneath gingival margins. Place two separate reverse figure eight sutures over the membrane for a molar site or one for a non-molar site. Due to its persistent tensile strength, use of PTFE suture is required for molar socket preservations and recommended in any case where BioXclude is intentionally left exposed to the oral environment.

First 3 Days Postoperative: The patient should refrain from rinsing, sucking, and spitting for three days following surgery. Overly aggressive rinsing with any solution during this early phase of healing can dislodge BioXclude.

Post-Operative Care: On days 4-7 gentle rinsing with ONLY TAP WATER is allowed. The patient should not use any oral rinse the first week after treatment. This includes antiseptics; chlorhexidine (Peridex®), chlorhexidine without alcohol, essential oils and methyl salicylate (Listerine®), hydrogen peroxide, and anti-inflammatories; natural antioxidants (AO ProRinse®) and botanicals (PerioActive®), and salt water rinses. Oral rinses are used to kill bacteria and to varying degrees adversely impact the health of gingival cells, potentially slowing wound closure. At one week the patient may begin using an oral rinse for plaque control.

For additional information on use of BioXclude in dental, endodontic, maxillofacial, oral, and periodontal surgery including use-specific guidance contact Snoasis Medical.

Adverse Effects & Reporting

- As with any surgical procedure, the possibility of infection exists.
- Proprietary processing and validated sterilization methods are used to terminally sterilize the product. However, as with all biological implants, the possibility of rejection exists.
- Any adverse reactions, including the suspected transmission of disease attributable to this allograft, should be reported immediately to Snoasis Medical.

Acceptable Storage

BioXclude should be stored in a clean, dry environment at ambient conditions. BioXclude has a 5 year shelf life. Check the label for the expiration date.

Recovery & Quality Control

All tissue recovered meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. BioXclude allografts are procured and processed in the United States according to standards and/or regulations established by the American Association of Tissue Banks (AATB) and the United States Food & Drug Administration (FDA). All tissues are recovered under full informed consent of the donors (mothers of the newborn children). The donors have consented to the transfer of the allografts to third parties. A thorough medical and social history of the donor is also obtained.

The donor is screened for:

HIV-1&2 Plus 0 Antibody	Syphilis (Serologic Test)	Hepatitis B Surface Antigen
HIV Type 1 (Nucleic Acid Test (NAT))	Hepatitis B Core Antibody	Hepatitis C Antibody
HTLV-1&2 Antibody	Hepatitis C Virus (NAT)	Hepatitis B Virus (NAT)
West Nile Virus (WNV (NAT))*		

** WNV NAT screening conducted on donors based on exposure risk per FDA Guidance for Industry.*

All tests produced negative results and were reviewed prior to the release of the tissue. Only tissue from donors with acceptable test results, according to the standards of MiMedx Tissue Services, LLC, as well as the standards and/or regulations of all state and federal regulatory bodies, are released.

The listed communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

Donated human tissue. This allograft has been determined to be suitable for transplantation.

Allograft Processing/Preservation/Sterilization

BioXclude allografts are processed based upon strict, quality-controlled protocols that have demonstrated bioburden control. An additional assurance of safety is achieved by terminally sterilizing each allograft. Based upon validations, each graft has been effectively sterilized using e-beam irradiation. BioXclude allografts are processed with aminoglycoside antibiotics.

Recipient Tracking

The FDA requires that recipient records be maintained for the purpose of tracking the allograft following surgical transplantation. The authorized dental / medical professional must complete the enclosed Tissue Utilization Record, attach a peel-off, allograft-tracking label provided, and mail to Snoasis Medical (postage-paid). Please use the remaining peel-off, allograft-tracking labels for patient and hospital records.

Caution: This product must be administered by an authorized medical/dental professional.

Snoasis Medical and its affiliates supply the allograft without any express or implied warranties. All statements or description are informational only and not made or given as a warranty of BioXclude in any way. Snoasis Medical and its affiliates make no guarantee whatsoever concerning the biological or biomechanical properties of BioXclude. The user shall be solely responsible for determining the adequacy and appropriateness of BioXclude for any and all uses to which the user shall apply BioXclude.

For customer service or questions regarding this product, please contact Snoasis Medical: 866.521.8247.

Processed with:

Purion®

Processing and donor suitability performed by MiMedx Tissue Services, LLC
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SNOASIS MEDICAL -BORN TO SMILE-

Tel: 866-521-8247 • Fax: 720-259-1405
info@snoasismedical.com
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