BioXclude®

Amnion Chorion Allograft Membrane Information / Instructions for Use

Symbol Glossary

	Consult Instructions For Use		Do Not Reuse
	Use By Date	SN	Serial Number
	Manufacturer		Do Not Use If Package Is Damaged
LOT	Batch Code	STERILE R	Sterilized Using Irradiation
REF	Catalogue Number		Do Not Resterilize

All symbols may not appear in labeling

www.maxxeusdental.com

QC-605-F-108 Ver 2

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.

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.

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 postoperative complications.
- BioXclude allografts remain suitable for transplantation in an unopened, undamaged package, under proper storage conditions.
- Do not use if package integrity has been compromised. Once the user breaks the container seal, the tissue grafts must be transplanted or discarded.
- Please inspect the integrity of the package upon receipt. If the package and contents appear defective or damaged in any way, immediately contact Solvita.
- Intended for use in one patient, on a single occasion only.
- This tissue is intended for use by qualified healthcare specialists such as physicians or dentists.
- Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- Discard all damaged, mishandled or potentially contaminated tissue.
- TISSUE MAY NOT BE STERILIZED OR RE-STERILIZED.

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. If not used, BioXclude must be immediately discarded once opened.

Surgical Use

Due to its unique physical properties, BioXclude has its own set of guidelines for sizing and placement. For detailed guidance on the use of BioXclude in dental, endodontic, maxillofacial, oral, and periodontal surgery, please visit www.maxxeusdental.com.

Adverse Effects & Reporting

- As with any surgical procedure, the possibility of infection exists.
- Proprietary processing and validated sterilization methods are used to sterilize the product. However, as with all biological implants, the possibility of rejection exists.
- Adverse outcomes potentially attributable to this tissue must be reported promptly to Solvita.

Acceptable Storage

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant. BioXclude must be stored in a clean, dry environment at ambient conditions. BioXclude has up to a 5-year shelf life. Check the label for the expiration date.

Screening & Testing

DONATED HUMAN TISSUE. Donor has been determined to be eligible by a Solvita Medical Director at 349 S Main Street, Dayton, Ohio 45402 based on the results of screening and testing. Screening includes a review of medical and social history, relevant medical records, infectious disease screening, and physical exam. All tissue is acquired, processed, stored, and distributed for use in accordance with the standards of the American Association of Tissue Banks. All tissues are acquired under the full informed consent of the donor (mother of the newborn).

The donor is tested and found negative (acceptable) for:

- HIV-1&2 Antibody
- Syphilis (Serologic Test)
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody
- Hepatitis C Antibody
- HIV Type 1 (Nucleic Acid Test (NAT))
- Hepatitis B Virus (NAT)
- Hepatitis C Virus (NAT)

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 Solvita, as well as the standards and/or regulations of all state and federal regulatory bodies, are released. FDA licensed test kits are used when available. Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. Communicable disease testing has been 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).

Insert continued on reverse side below Allograft Tissue Usage form.

BioXclude®

Allograft Tissue Usage Form

FDA Regulations and Joint Commission Standards require tissue usage systems in all facilities using allograft tissue for transplantation. In order to comply with these requirements, please complete this form.

How to return this form:	
Email	tissueusage@solvita.org
Fax	937-222-2538
Mail	Solvita Attn. Tissue Usage 2900 College Drive Kettering, Ohio 45420

Patient ID or Date of Birth: _____

Date of Surgery: _____

Surgical Procedure: _____

Practice Name: _____ **Phone Number:** _____

Comments: _____

One patient, one procedure per usage form. Place peel-off label for up to 3 allografts or write tissue ID# in the spaces provided.

Solvita does not consider the information requested on this form to be protected health information (PHI), as defined under the HIPAA regulations. Information considered to be PHI by the originator should not be released to Solvita.

Allograft Tissue ID#	**Allograft Tissue ID#**	**Allograft Tissue ID#**
Place Peel-Off Label Here	Place Peel-Off Label Here	Place Peel-Off Label Here

Tissue Insert Continued

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 irradiating each allograft. Based upon validations, each graft has been effectively sterilized using gamma irradiation.

Recipient Tracking

Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Complete the enclosed Allograft Tracking Form and return to Solvita. Federal Regulations (21 CFR 1271.290(b)) and Joint Commission Standards (TS.03.02.01, EP 7) require proper tracking of this tissue. It is the responsibility of the end-user to provide this information, which enables Solvita to maintain records for the purpose of tracing the tissue post-transplant. 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.

Solvita is accredited by the American Association of Tissue Banks. Solvita is ISO 13485 certified. Solvita makes no claims concerning the biological or biomechanical properties of the provided tissue. Solvita disclaims all liability and responsibility for any misuse of tissue provided for clinical application.

For customer service or questions regarding this product, please contact Solvita: 855-MAXXEUS.

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