# Is BioXclude Right for Me?

Every patient is different, and patient outcomes may vary. Only a trained dental specialist should determine the best treatment plan.

Ask your treatment provider to determine if

BioXclude is right for you.



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**Patient Information** 



### What is BioXclude?

BioXclude is a membrane sourced from human placental tissue that is used in dental surgical procedures aimed at restoring the esthetics and/or function of a patient's teeth. The placenta is an organ that connects the developing fetus to the womb and serves as its life support system. The amniotic sac is the innermost lining of the placenta which encloses and protects the developing fetus through term. This sac consists of an inner amnion layer and an outer chorion layer. BioXclude is composed of a layer of processed amnion and chorion tissue. All tissue is donated by consenting mothers who undergo elective caesarian section delivery; this tissue would otherwise be discarded.

### The Benefits

BioXclude offers several unique benefits not offered by other available dental membrane products. The tissue used in BioXclude is considered immunoprivileged<sup>1</sup>. This is one of the reasons why the mother's immune system does not attack the placenta as a foreign body during pregnancy. BioXclude has been shown to retain key proteins known to aid in the healing process<sup>2</sup>. BioXclude comes dehydrated and, upon placement, quickly hydrates and conforms to the surgical area. The membrane is also fully resorbable, unlike some other products.

# **Dental Applications**

BioXclude is a minimally manipulated dehydrated human amnion chorion membrane serving as a barrier, conduit, connector or cushion in a variety of dental, endodontic, oral maxillofacial and periodontal regenerative procedures. It can be used to cover bone graft material in the treatment of bony defects around teeth, in conjunction with the placement or repair of dental implants, or other bone reconstruction procedures. Since 2007, BioXclude has been used successfully in hundreds of thousands of dental surgical procedures.

# **Over a Century of Safety**

The medical use of placental tissue dates back over one hundred years in a variety of applications, and during that time, there has never been a report of disease transmission, graft rejection, or an immune response associated with its use. As early as the 1900's, amnion tissue was used for skin transplantation to treat burn victims and those with ulcerated skin conditions<sup>3</sup>. Since the 1990s, amnion tissue-based products have been used in ophthalmic surgery. More recently in the 2010s, amnion and amnion chorion tissue-based products have been used in the treatment of chronic wounds, spine and orthopedic surgery, plastic surgery, along with dental applications.

### **Procurement & Processing**

All placental tissue used in BioXclude is sourced in the United States with informed consent from pre-screened mothers who choose to donate their placenta following elective caesarian section deliveries. The tissue is procured, processed, and distributed according to standards and regulations established by the American Association of Tissue Banks (AATB) and the United States Food & Drug Administration (FDA). All tissue must meet stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. All screening tests must produce negative results and are reviewed before release of the tissue. Only tissue from donors with acceptable test results, according to the standards of Snoasis Medical, as well as the standards and regulations of all state and federal regulatory bodies, are released. Following procurement, the tissue is prepared for commercialization using Snoasis Medical's proprietary process which cleanses and preserves the amnion and chorion tissue. For further safety, all products are terminally sterilized prior to distribution.

# **FAQ**

### How is BioXclude sourced?

BioXclude is comprised of the amnion and chorion layers of the placental membrane. All placental tissue is sourced in the United States with informed consent from pre-screened mothers who choose to donate their placenta following elective caesarian section deliveries.

### How are donors screened?

All tissue must meet stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. Donors are screened for all diseases that the FDA requires testing, including HIV, Hepatitis, Syphilis, West Nile Virus and more. A thorough medical and social history of the donor is also obtained. Only tissue from donors with acceptable test results, according to the standards of Snoasis Medical, as well as the standards and regulations of all state and federal regulatory bodies, are released.

### Is placental tissue safe?

The medical use of placental tissue dates back over one hundred years in a variety of applications, and during that time, there has never been a report of disease transmission, graft rejection, or an immune response associated with its use. Since 2007, BioXclude has been used successfully in hundreds of thousands of dental surgical procedures.



<sup>1.</sup> Chen E, Tofe A. A literature review of the safety and biocompatibility of amnion tissue. *Journ Impl & Adv Clin Dent* 2010; 2(3):67-75. 2. Xenoudi P, Lucas M. Comparison of porcine and amnion chorion resorbable collagen membranes using immunohistochemistry. *IADR* 2011, San Diego, CA March 16-19; Abstract #146797. 3. Davis J. Skin transplantation of 550 cases at Johns Hopkins Hospital. *Johns Hopkins Med. J.* 1910; 15:307.