

## 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 the right treatment for you.



# **Patient Information**





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# **Patient Information**



#### What is BioXclude?

BioXclude is a membrane sourced from 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 inner most 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.

### **Procurement & Processing**

All placental tissue is recovered, processed, stored and distributed according to the regulations of the United States Food and Drug Administration and the standards of the American Association of Tissue Banking. Prior to donation, which is done under full informed consent, blood tests are performed and a thorough medical and social history of the mother is obtained, including detailed family history. All recovered tissue meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. Following procurement, the tissue is prepared for commercialization using a proprietary process called Purion®, which cleanses and preserves the amnion and chorion tissue. For further safety, all products are terminally sterilized prior to distribution.

#### **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, eliminating the need to be secured with sutures. The membrane is also fully resorbable, unlike some other products.

## **A History of Safety**

Placental tissue has a long history of medical 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>. Amnion and amnion chorion tissue-based products have been used in ophthalmic surgery for the last decade and more recently in spine and orthopedic surgery and the treatment of chronic wounds. Throughout this long history, there have been no reported incidents of any type of adverse event associated with the use of placental tissue.

### **Dental Applications**

BioXclude can be used as a wound covering in a variety of dental applications. 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. It can also be used to treat some forms of gingival recession and in tissue augmentation. Since 2007, Snoasis Medical products have been successfully used in numerous dental procedures.

### **Our Pledge to You**

"Snoasis Medical is committed to developing products which are safe and are supported by good science and clinical outcomes. I have personally undergone several procedures with our products and can tell you first hand that the benefits are truly amazing. To experience BioXclude for yourself, consult with your dental health provider today."

- Robert Tofe, President

<sup>1.</sup> Chen E, Tofe A. A literature review of the safety and biocompatibility of amnion tissue. *JournI 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. *JADR* 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.