AmnioCore
AMNIOTIC MEMBRANE ALLOGRAFT

STABILITY® BIOLOGICS

Clinical Overview of Amniotic Tissue and AmnioCore Amniotic Membrane Allograft

Introduction: Amniotic membrane has been used clinically for over 100 years with more than 100 publications to date.[1] The first applications were in wound care, followed by a large variety of other applications, including the use in musculoskeletal conditions.[2] Amniotic membrane is the innermost layer of the placenta consisting of epithelium, a thick basement membrane and an avascular stromal matrix. Amniotic membrane provides an extracellular matrix of structural matrix protein fibers and glycosaminoglycans, it promotes cellular migration and proliferation by providing a 3D scaffold which acts as a physical support structure while regulating cellular activity.[3]

Publications report that dehydrated human amniotic membrane has been found to have a number of characteristics that make it uniquely suited to act as natural, biologic covering to provide protection of wounds from the surrounding environment. Amniotic membrane's unique properties include anti-adhesive effects and bacteriostatic wound protection..[5] These biological processes are further regulated by extracellular signaling pathways involving cytokines, growth factors and membrane receptors.[6]

AmnioCore: AmnioCore is a dual-layer amniotic tissue allograft, which provides a safe, natural, biologic barrier. AmnioCore delivers essential growth factors on a structural protein matrix, with superior handling properties. Stability Biologics utilizes a robust, proprietary processing method in the production of AmnioCore to fully disinfect and decellularize the amniotic tissue while retaining the beneficial growth factors, yielding the largest grafts, maintaining sufficient supply and ensuring the highest quality, safe and effective grafts.

AmnioCore is stored at room temperature eliminating the need for cryopreservation, resulting in easier shipping and storage. Their repositionable design reverts to its original shape when placed in water or saline. AmnioCore provides a reliable and versatile biologic covering option within a multitude of procedures including Spine & Orthopedics, Extremity, Vascular, Urological and General Surgery.

AmnioCore membrane characterization study demonstrates the presence of angiostatin, FGF-4, ANG-2, MMP-1 as well as a myriad of other growth factors and proteins found in amniotic membrane that has direct effect on angiogenesis and wound healing.

A partial list of regulatory proteins, cytokines and chemokines in AmnioCore	
Acronym	**Name**
ANG-2	Angiopoietin-2
ANGPTL4	Angiopoietin Like 4
FGF-4	Gibco FGF-4
G-CSF	Granulocyte Colony-Stimulating Factor
GM-CSF	Granulocyte-Macrophage Colony Stimulating Factor
HB-EGF	Heparin-binding EGF-Like Growth Factor
HGF	Hepatocyte growth factor
I-309	I-309 (a CC chemokine)
IL-12p40	Inherently Agonistic Cytokine
IL-1b	Interleukin 1 beta
IL-4	Interleukin-4
I-TAC	Interferon–inducible T Cell Alpha Chemoattractant
MMP-1	Matrix metalloproteinase-1
TIE2	Angiopoietin-1 receptor
TIMP-1	TIMP Metallopeptidase Inhibitor 1
TNFa	Tumor Necrosis Factor Alpha
TNFb	Tumor Necrosis Factor Beta
VEGF	Vascular Endothelial Growth Factor
VEGF R2	Vascular Endothelial Growth Factor Receptor 2
VEGF R3	Vascular Endothelial Growth Factor Receptor 3
VEGF-D	Vascular Endothelial Growth Factor D

Appendix 1: Representative Photomicrographs of Samples and Controls

The image below shows the VEGF-A growth factor concentrated on the top and bottom surfaces of the membrane. Double layer of membrane (folded on itself) provides a layer in the middle of the graft.

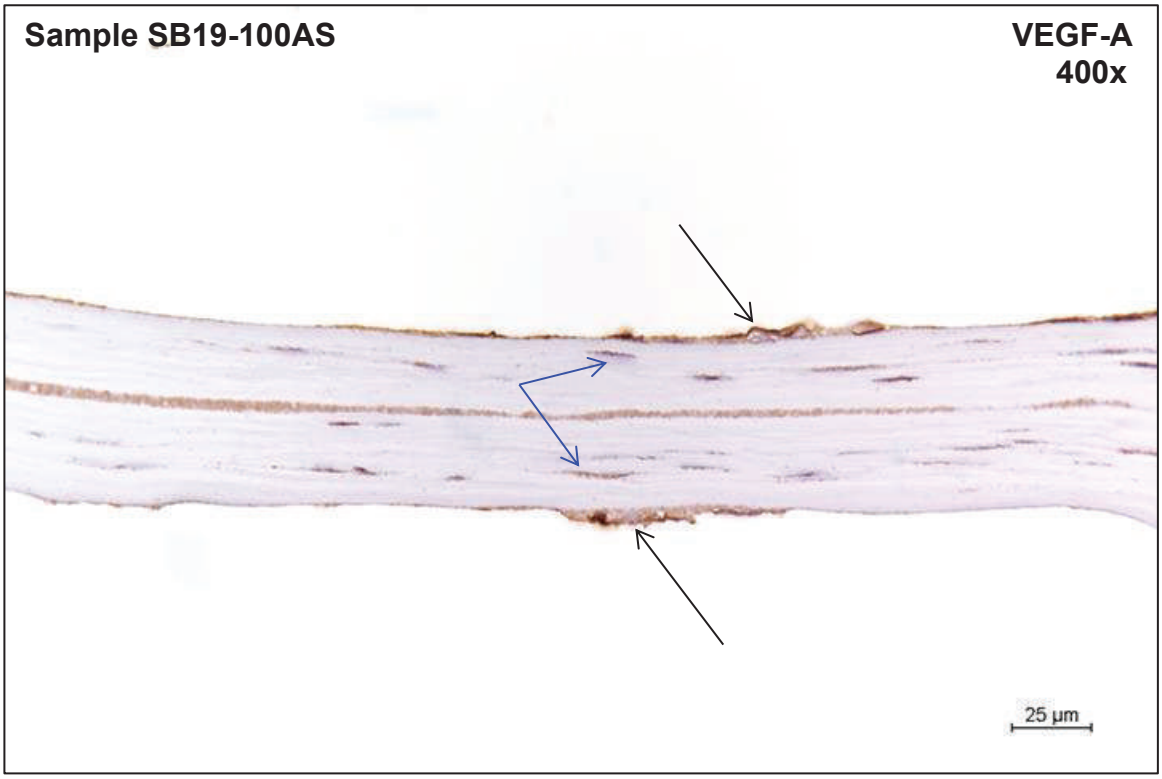


Figure 1: Representative photomicrographs of histological sections of sample SB19-100AS stained with VEGF-A immunohistochemistry. The cells of the epithelial layer (black arrows) are VEGF-A positive as are occasional cells in the fibroblast layer (blue arrows).

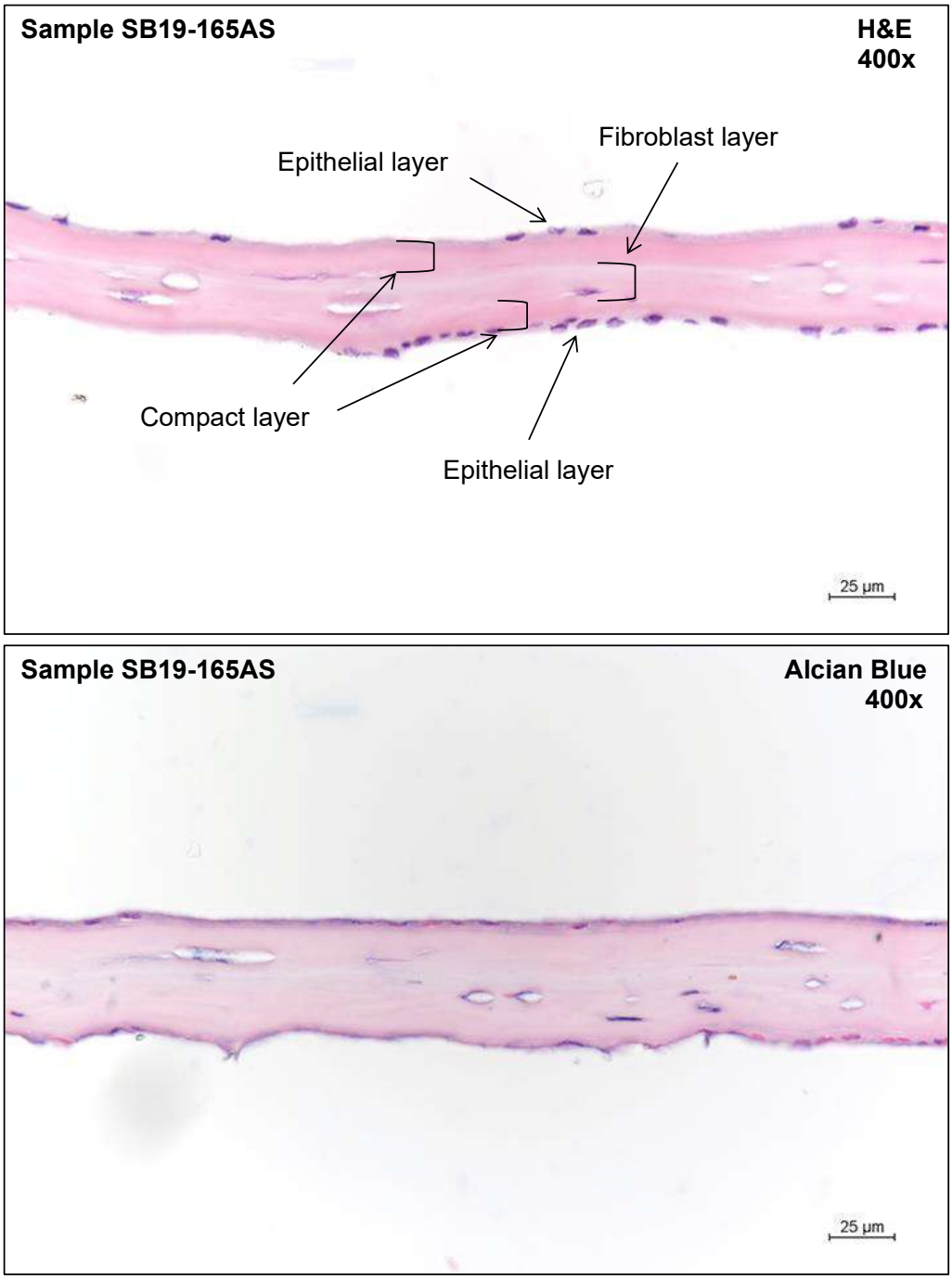


Figure 2: Representative photomicrographs of histological sections of sample SB19-165AS stained with H&E (top) and Alcian Blue (bottom). No Alcian blue positivity is present.

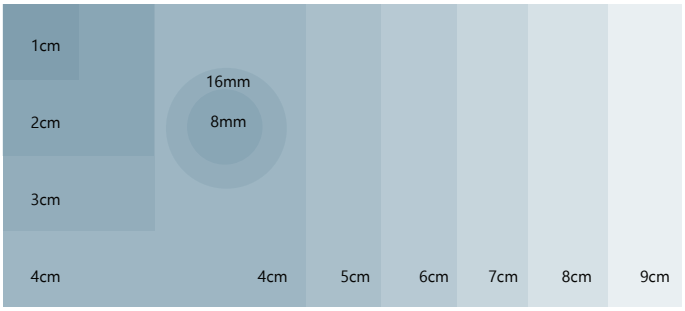
AmnioCore Application

- In its dry state and prior to hydration, the allograft may be cut with sharp scissors to the appropriate and approximate size required.
- The allograft should then be placed on the site.
- The allograft can then be hydrated while on the site with sterile saline solution.
- Suture material (absorbable, non-absorbable) and/or tissue adhesives can be used to fixate AmnioCore allografts to the site of application or itself, if desired.
- Use graft within 1 hour of reconstitution.

Product Offering

Type	Item Number	Size
Sheet	AMW-5230	2x3cm
	AMW-5330	3x3cm
	AMW-5340	3x4cm
	AMW-5440	4x4cm
	AMW-5460	4x6cm
	AMW-5480	4x8cm
	AMW-5660	6x6cm
	AMW-5690	6x9cm
	AMW-5616	6x16cm
	AMW-5920	9x20cm
Disc	AMW-5160	16mm

Sizing Reference



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The Stability Biologics® AmnioCore Product Line is regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps). AmnioCore is processed by and donor eligibility determined by Stability Biologics®. Stability Biologics® is registered with the FDA for tissue processing and accredited by the American Association of Tissue Banks (AATB).

1077 Central Parkway South Suite 500 San Antonio, TX 78232