# CYGNUS®

## >> AMNIOTIC ALLOGRAFTS

IMMUNE PRIVILEGED soft tissue barriers and wound coverings that provide PROTECTION for traumatized tissue while RETAINING an array of preserved endogenous growth factors, cytokines, and extracellular matrix proteins.



**CYGNUS®** is a family of amniotic tissue allografts processed to retain the inherent mechanical properties of amniotic tissue and rich supply of extracellular matrix analysis. rich supply of extracellular matrix, growth factors, and cytokines.<sup>1,2</sup>

### CYGNUS AMNIOTIC ALLOGRAFT FEATURES AND BENEFITS

Amniotic-derived tissues may be used as a soft tissue barrier and wound covering that retains endogenous extracellular matrix (ECM), growth factors, and cytokines<sup>2-5</sup> essential for signaling. The properties of amniotic tissue help provide protection to damaged tissue while maintaining nutrient-rich growth factors.<sup>6,7</sup>

### WHY CYGNUS AMNIOTIC ALLOGRAFTS

CYGNUS Matrix: Multi-layer membrane allograft maintaining the amnion layer, the intermediate/spongy layer, and the chorion layer of the amniotic sac.

- Amniotic layers are never delaminated
- ~400µm (0.4mm) thick
- 4X thicker than the single amnion layer
- Available in rectangular and circular shapes in a variety of sizes to meet clinical needs

CYGNUS Dual: Dual-layer membrane allograft featuring the amnion layer of the amniotic sac

• ~200µm (0.2mm) thick

- 2X thicker than single amnion layer
- · Double-sided membrane features 2 layers of amniotic tissue, oriented with the epithelial layer facing outward, allowing for omnidirectional application of the allograft

CYGNUS Solo: Single-layer membrane allograft featuring the amnion laver of the amniotic sac

• Thin amniotic membrane allograft, ~100µm (0.1mm) thick

### WHY CYGNUS MAX AMNIOTIC MEMBRANE ALLOGRAFTS DERIVED FROM THE UMBILICAL CORD

CYGNUS Max: Amniotic membrane allograft derived from the umbilical cord that is up to 4X thicker than the single amnion layer

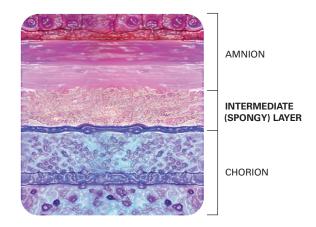
CYGNUS Max XL: Amniotic membrane allograft derived from the umbilical cord, fenestrated to allow for wound drainage and increases the size of the available allograft

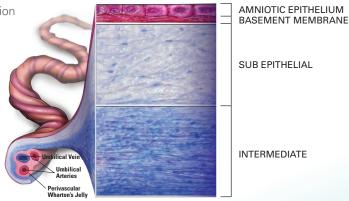
- Thickest dehydrated amniotic membrane allograft, ~400µm (0.4mm)
- Robust enough to be sutured in place

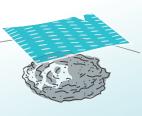
### POTENTIAL CLINICAL APPLICATIONS

In general wound care, such as diabetic foot ulcers, venous leg ulcers, pressure wounds, hard-to-heal wounds, and surgical wound dehiscence, CYGNUS has been used as a protective barrier to provide essential protection for wounds. Other potential clinical applications include general orthopedics, arthroplasty, hand and wrist, and foot and ankle procedures.

- Wounds
- Burns
- Diabetic Foot Ulcers
- Venous Leg Ulcers
- Pressure Wounds
- Hard-to-Heal Wounds
- Surgical Wound Dehiscence







WOUND







## CYGNUS



CYGNUS



**CYGNUS**<sup>®</sup>







CYGNUS

### VIVEX'S PROPRIETARY INTEGRITY PROCESSING<sup>™</sup> PRESERVES UP TO 600+ SIGNALING PROTEINS IN CYGNUS MATRIX, DUAL, SOLO, AND MAX<sup>®</sup>

VIVEX's Integrity Processing<sup>™</sup> is a gentle process that removes blood remnants, while preserving the allograft composition without compromising structural integrity.

### KNOWN GROWTH FACTORS AND EXTRACELLULAR MATRIX (ECM) PROTEINS IN AMNIOTIC ALLOGRAFTS AND THEIR CORRESPONDING ROLE<sup>3,10</sup>

GROWTH FACTORS		ROLE	
MCP-1 <sup>11</sup> , IL1-RA <sup>12</sup> , TGF-β1&2 <sup>13</sup> , IL6 <sup>12</sup>		Immune Modulation / Anti-Inflammatory	
TNF-α <sup>14</sup> , GRO-α <sup>15</sup> , HGF <sup>7</sup> , IGF1&2 <sup>16,17</sup> , VEGF <sup>18</sup> , βFGF <sup>19</sup> , PDGFα&β <sup>20</sup> , Ang <sup>21</sup>		Angiogenesis	
EGF <sup>22</sup> , FGF <sup>19</sup> , TGFβ <sup>13</sup> , TIMP(1-4) <sup>23</sup> , HGF <sup>24</sup>		Cell Growth	
PDGFa&β <sup>20</sup> , EGF <sup>22</sup> , TIMP-2&-3 <sup>23</sup> , HGF <sup>24</sup> , Ang <sup>21</sup> , KGF <sup>25</sup>		Cell Migration	
PDGFa&β <sup>20</sup> , EGF <sup>22</sup> , FGF <sup>1</sup> , TGF-β1&2 <sup>13</sup> , IGF1&2 <sup>16,17</sup> , Ang <sup>21</sup> , KGF <sup>25</sup>		Cell Proliferation	
PDGFa&β <sup>20</sup> , EGF <sup>22</sup> , TIMP-2& -3 <sup>23</sup> , TGF-β1&2 <sup>13</sup>		Cell Differentiation	
ECM PROTEINS	ROLE		
Collagen, type I-VII	Main structural protein component in the body		

Collagen, type I-VII	Main structural protein component in the body
Fibronectin	Binding protein agent, supports initial cell attachment
Hyaluronic Acid	Lubricating hydrophilic protein that coats cells and aids in hydrodynamic movements
Laminin	High molecular weight protein to which cells easily bind and migrate across
Proteoglycans	Connective proteins that fill the spaces between cells in tissue and affect the stability of the proteins and growth factors

## **>>** SAFE AND TRUSTED PARTNER



Our portfolio of allografts and other signature VIVEX solutions include viable bone matrices; demineralized bone matrices, such as cortical and cancellous bone in strips, sponges, fibers, and putties; amnion; dermis; and intervertebral disc tissue allografts. During the more than 50 years of safe and effective operations, VIVEX has delivered over 2 million allografts with no disease transmission throughout the US and eighteen countries worldwide.

- Amniotic tissue is recovered from healthy mothers at live births.
- Amniotic tissue is handled and processed in accordance with both FDA regulations and AATB standards.
- VIVEX maintains the trend of safely delivering over 2 million allografts with no disease transmission.

### **CYGNUS® MATRIX**

Amniotic Allograft

Product HCPCS Code: Q4199 (CYGNUS Matrix) per sq cm

ITEM NUMBER	SIZE	SQ. CM
CAP020200S	2x2cm	4
CAP020300S	2x3cm	6
CAP030300S	3x3cm	9
CAP040400S	4x4cm	16
CAP040600S	4x6cm	24
CAP101100S	10x11cm	110

### **CYGNUS® MATRIX DISK**

Amniotic Allograft Product HCPCS Code: Q4199 (CYGNUS Matrix) per sq cm

ITEM NUMBER	SIZE	SQ. CM
CAP015000S	15mm Disk	2
CAP025000S	25mm Disk	5
CAP035000S	35mm Disk	10

### **CYGNUS® DUAL**

Amniotic Allograft Product HCPCS Code: Q4282, CYGNUS Dual per sq cm

ITEM NUMBER	SIZE	SQ. CM
CAD020300S	2x3cm	6
CAD040400S	4x4cm	16
CAD040600S	4x6cm	24
CAD071500S	7x15cm	105

### **CYGNUS® MAX**

Amniotic Membrane Derived from Umbilical Cord Product HCPCS Code: Q4170 (CYGNUS) per sq cm

ITEM NUMBER	SIZE	SQ. CM
CAM020300S	2x3cm	6
CAM020400S	2x4cm	8
CAM030300S	3x3cm	9

### **CYGNUS® MAX XL**

Fenestrated Amniotic Membrane Derived from Umbilical Cord Product HCPCS Code: Q4170 (CYGNUS) per sq cm

ITEM NUMBER	SIZE	SQ. CM
CAX020300S	2x3cm	6
CAX040400S	4x4cm	16

### **CYGNUS® SOLO**

Amniotic Allograft

Product HCPCS Code: Q4170 (CYGNUS) per sq cm

ITEM NUMBER	SIZE	SQ. CM
CAS020300S	2x3cm	6
CAS030300S	3x3cm	9
CAS040400S	4x4cm	16
CAS040600S	4x6cm	24
CAS040800S	4x8cm	32



Ready-to-use, ambient temperature storage (2°C to 30°C)

Orientation

CORRECT

CYGNUS Matrix/Solo/Max



No prep required, hydrates in site

**CYGNUS Max XL Orientation** 



E-Beam sterilized for sterility assurance level (SAL) of 10-6



5-year shelf life

CYGNUS Matrix Circular-Shaped Graft Orientation



- Rowlatt, Ursula. "Intrauterine Wound Healing in a 20 Week Human Fetus." Virchows Arch. A Path. Anat. and 1.
- 2
- 3.
- Rowlatt, Ursula. "Intratuetine Wound Healing in a 20 Week Human Fetus." VIICNOWS ARCH. A Paul. Anal. and Histol, 1979, vol. 381, pp. 353-361. Coolen, Neeltje A., et. al. "Comparison Between Human Fetal and Adult Skin." Archives of Dermatological Research, 2010, vol. 302, pp. 47-55. Coolen Neeltje A., et. al. "Cownarison Between Human Fetal and Adult Skin." Archives of Dermatological Research, 2010, vol. 302, pp. 47-55. Coolen Neeltje A., et. al. "Wound Healing in a Fetal, Adult, and Scar Tissue Model: A Comparative Study." Wound Repair and Regeneration, 2010, vol. 18, pp. 291-301. Tseng Scheiffer, et. al. "How Does Ammidic Membrane Work?" The Ocular Surface, 2004, vol. 2, pp. 177-187. Riordan, Neil H., et. al. "Case Report of Non-Healing Surgical Wound Treated with Dehydrated Human Amniotic Membrane." Journal of Translational Medicine, 2015, vol. 13, pp. 242. Delcroix Gaetta J. R., et. al. "Preserving the Natural Regenerative Potential of Amniotic Membrane." VIVEX Rinloaics. 2017. 6
- Biologics, 2017. 7
- Koob, Thomas J., et. al. "Properties of Dehydrated Human Amnion/Chorion Composite Grafts: Implications for Wound Repair and Soft Tissue Regeneration." Journal of Biomedical Materials Research B: Applied Biomaterials, 2014, vol. 102B, pp. 1353-1362.
- Data on file at Vivex Biologics, Inc.
  Meisenberg, Gerhard, et. al. "The Extracellular Matrix." Principals of Medical Biochemistry, 2016, pp. 218-234.
  Yanagishita, M. "Function of Proteoglycans in the Extracellular Matrix." Acta Pathologica Japonica, June 1993,
- Yanagishita, M. Function of Proteoglycans in the Extracellular Matrix. Acta Pathologica Japonica, June 1993, vol. 43, pp. 283-93.
  Deshmane, Satish L, et.al. "Review of Monocyte Chemoattractand Protein-1 (MCP-1): An Overview." Journal of Interferon & Cytokine Research, 2009, vol. 29, pp. 313-326.
  Srinivasan, Lakshmi, et.al. "Cytokines and Inflammatory Response in the Fetus and Neonate." Fetal and Neonatal Physiology. 2017, pp. 1241.
- 13. Link, Hans, et. al. "Transforming Growth Factor Beta." Encyclopedia of Immunology, 2nd edition, 1998,
- pp. 2392-2399

- 14. Parameswaran, Narayanan, et. al. "Tumor Necrosis Factor-alpha Signaling in Macrophages." Crit Rev Framesware (and ware) and the second s

- 2003, pp. 77-171.
  Brill, Alexander, et. al. "Angiogenesis." Platelets, 2007, pp. 757-768.
  Duffy, Angela M., et. al. "Vascular Endothelial Growth Factor (VEGF) and Its Role in Non-Endothelial Cells: Autocrine Signaling by VEGF" Landes Bioscience, 2013.
  Yun, Ye-Rang, et.al. "Fibroblast Growth Factors: Biology, Function, and Application for Tissue Regeneration." Journal of Tissue Engineering, vol. 2010.
  Klement, Giannoula Lakka, et. al. "The Role of Platelets in Angiogenesis." Platelets, 2013, pp. 487,502

- Gao, Xiangwei, et. al. "Mechanisms of Action of Angiogenin." Acta Biochim Biophys Sin, 2008, vol. 40,
- Gab, Xiangwen, et. al. Mechanisms of Action of Angrogenin. Acta biochim Biophys Sin, 2006, 901–902, pp. 619–624.
  Bodhar, Richard J. "Epidermal Growth Factor and Epidermal Growth Factor Receptor: The Yin and Yang in the Treatment of Cutaneous Wounds and Cancer." Advanced in Wound Care, 2013, vol. 2, pp. 24-29.
  Cui, Ning, et. al., "Biochemical and Biological Attributes of Matrix Metalloproteinases." Matrix Metalloproteinases and Tissue Remodeling in Health and Disease: Cardiovascular Remodeling, 2017, rev 16-70. pp. 16-20.
- Deng, Yinan, et. al. "Umbilical Cord-Derived Mesenchymal Stem Cells Instruct Monocytes Towards an IL10-Producing Phenotype by Secreting IL6 and HGF." Scientific Reports, 2016, vol. 6.
- 25. Rubin, Jeffrey S., et. al. "Keratinocyte Growth Factor." Cell Biology International, 1995, vol. 19, рр. 399-411.

VIVEX has used reasonable efforts to provide accurate and complete information herein, but this information should not be construed as providing clinical advice, dictating reimbursement policy, or as a substitute for the judgment of a health care provider. It is the health care provider's responsibility to determine the appropriate treatment, codes, charges for services, and use of modifiers for services rendered and to submit coverage or reimbursement-related documentation.



2430 NW 116th Street, Miami, FL 33167 (888) 684-7783 | vivex.com | customercare@vivex.com rrademarks <sup>™</sup> and Registered Trademarks ® of 2023 Vivex Biologics Copyright © 2023 Vivex Biologics, Inc. All rights reserved.