Don't let your patients be sidelined by an injury



**Amnio**Fixe

## **Amnio**Fix

### **Growth Factors**

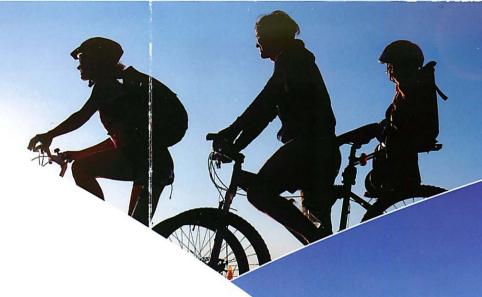
There have been 226 different growth factors, specialized cytokines, and enzyme inhibitors identified in AmnioFix®, including the following which are some of the most notable regulatory factors that help modulate inflammation and enhance healing:<sup>4-6,8</sup>

- Transforming Growth Factor Beta (TGF-B1) -Promotes normal soft tissue healing and reduced scar formation
- Fibroblast Growth Factor (FGF) Promotes cellular proliferation and important for collagen matrix formation
- Platelet Derived Growth Factors (PDGF AA & BB) -Promote cell proliferation in connective tissue and enhance soft tissue healing

Native Growth Factors Present	Relative Amount Determined by ELISA Assay (n=5)	Release Profile (n=5)  24 hr incubation period at Remaining in tissue	4°C
PDGF-AA	+++++	13% 87%	
PDGF-BB	+	4% 96%	
bFGF	++	44% 56%	
TGF-ß1	++	24% 76%	
EGF	+	63% 37%	

Growth Factors contained in PURION® Processed dehydrated amnion/chorion membrane, relative amounts and release profile. Measured by ELISA testing unlysed and lysed tissue in suspension





# AmnioFix is a bioactive tissue matrix composed of human amnion/chorion membrane for homologous use to:

- Modulate inflammation
- Reduce scar tissue formation
- Enhance healing

Conservative treatments of oral or topical anti-inflammatories and rest usually will help heal inflammation resulting from injury. If additional treatment is needed, AmnioFix might be an option for your patient.

### Is AmnioFix right for my patient?

You may consider AmnioFix as an option for your patient if:

- · Your patient has been diagnosed with an injury resulting in inflammation
- Conservative treatment such as anti-inflammatories, physical therapy, and bracing have not provided symptomatic relief of inflammation
- Your patient wants a non-steroidal option or has reached the limit of steroid injections

### How can AmnioFix help the injury?

AmnioFix contains 226 different growth factors, cytokines, and chemokines including interleukins (IL-1ra, IL-4, and IL-10) to modulate inflammation. AmnioFix contains these natural growth factors and collagens, which are core building blocks to help enhance healing.

### **Healing Properties**

*In vivo* and *in vitro* studies have shown that the properties of amniotic membrane help to modulate inflammation and enhance healing.<sup>1-4</sup>

### **Immunologically Privileged**

Human amniotic membrane is considered immunoprivileged and has not been shown to elicit an immune response from recipients.<sup>7</sup>

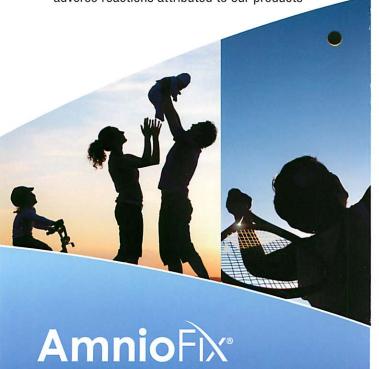
### **Proprietary PURION Process**

AmnioFix is processed using the PURION® Process, a unique approach that provides an effective and easy to use allograft.

### **Ease of Use**

- Dehydrated for ease of use and application
- 5 year shelf life at ambient conditions; no special storage required

 Over 500,000 allografts distributed with no adverse reactions attributed to our products<sup>†</sup>



Since 2006, as the **premier leader** in regenerative medicine, **MiMedx**® has been dedicated to advancing healing through innovative biomaterial products and bioimplants. To date, over **25** clinical and scientific papers have been **published** in peer-reviewed journals on our PURION Processed amniotic membrane allografts. The company's **proprietary PURION Process** and its multi-layer grafts are covered by over **20 issued patents**, with more than 80 patents pending. PURION Processed allografts are **clinically effective** and more than **500,000 allografts** have been distributed to date with **no adverse reactions** attributed to our products.†

### **Product Offering**

Item Number	Size
AI-5020	20 mg
AI-5050	40 mg
AI-5125	100 mg
Al-5200	160 mg

### **Ordering Information**

Customer Service: 866.477.4219
Email: customerservice@mimedx.com

- 1. Tao H, Fan H. Implantation of amniotic membrane to reduce postlaminectomy epidural adhesions. Eur Spine J. 2009 Aug;18(8):1202-12.
- Tseng SC, Li DQ, Ma X. Suppression of transforming growth factor-beta isoforms, TFG-beta receptor type II, and myobroblast differentiation in cultured human corneal and limbal fibroblasts by amniotic membrane matrix. J Cell Physiol. 1999 Jun;179(3):325-35.
- 3. Hao Y, Ma DH, Hwang DG, Kim WS, Zhang F. Identification of antiangiogenic and anti-inflammatory proteins in human amniotic tissue. Cornea. 2000 May:19(3):348-52.
- 4. Koob TJ, Rennert R, Zabek N, Massee M, Lim JJ, Temenoff JS, Li WW, Gurtner G. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. Int Wound J. 2013Oct;10(5):493-500.
- Koob TJ, Lim JJ, Massee M, Zabek N, Denozière G. Properties of dehydrated human amnion/chorion composite grafts: implications for wound repair and soft tissue regeneration. J Biomed Mater Res B Appl Biomater. 2014 Aug;102(6):1353-62.
- 6. Koob TJ, Lim JJ, Massee M, Zabek N, Rennert R, Gurtner G, Li WW. Angiogenic properties of dehydrated human amnion/chorion allografts: therapeutic potential for soft tissue repair and regeneration. Vasc Cell. 2014 May 1;6:10.
- 7. Sherwood, Lauralee. Human Physiology, From Cells to Systems, 7th ed. Belmont, CA: Cengage Learning, 2010.
- Koob TJ, et al. A Primer on Amniotic Membrane Regenerative Healing. 1st ed. Grand Rapids, MI: MiMedx/Color House Graphics. 2015.

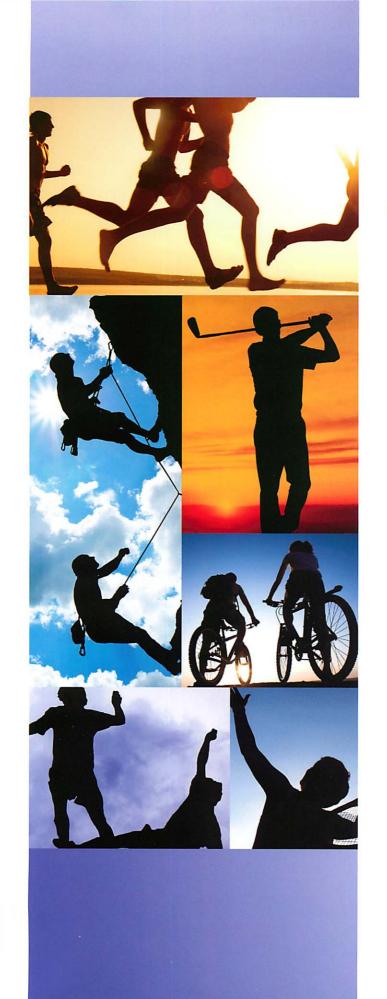
† As of January 1, 2016

### www.amniofix.com





Patents and patents pending see: www.mimedx.com/patents
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## AmnioFix®

## An Amnion/Chorion Membrane Allograft

AmnioFix® is a bioactive tissue matrix composed of human amnion/chorion membrane for homologous use to modulate inflammation, reduce scar tissue formation, and enhance healing.







### Modulates Inflammation Reduces Scar Tissue Formation **Enhances Healing**

### **Growth Factors Present in AmnioFix**

There have been 226 different growth factors, specialized cytokines. and enzyme inhibitors identified in AmnioFix, including the following which are some of the most notable regulatory factors that help enhance healing:1-4

- Transforming Growth Factor Beta (TGF-B1) Promotes normal soft tissue healing and reduced scar formation
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### Extracellular Components in AmnioFix

The Extracellular Matrix of amniotic membrane is composed of three major classes of biomolecules:

- Structural proteins: collagen types I, III, IV, V and VII, and elastin
- Specialized proteins: fibronectin, TIMPs<sup>†</sup>, and laminins
- Proteoglycans: formed when GAGS are linked to core proteins

In addition to the properties of the growth factors present which modulate inflammation. AmnioFix can also stimulate native cells to upregulate their production of immunomodulatory factors.5

PURION® Processed dehydrated human amnion/chorion membrane (dHACM) contains extracellular matrix, stimulates multiple cell types to migrate and proliferate, and acts as a Stem Cell Magnet™ drawing mesenchymal stem cells and hematopoietic stem cells from tissues to the site of injury.6

Recruited stem cells modulate the body's inflammatory response releasing their own growth factors, cytokines, and paracrine factors to begin the healing process.7

### **PURION Process**

AmnioFix is processed using the proprietary PURION Process, a unique approach that provides an effective and easy to use allograft.

### Immunologically Privileged

Human amniotic membrane is considered immunoprivileged and has not been shown to elicit an immune response from recipients.8

### Ease of Use

- Dehydrated for ease of use and application
- Five year shelf life at ambient conditions; no special storage required
- Over 500,000 allografts distributed with no adverse reactions attributed to our products<sup>††</sup>

### Application

AmnioFix may be mixed with sterile saline. Refer to "Instructions for Use" included with product for full application instructions and recommendations.

### **Product Offering**

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<sup>7.</sup> Maxson S, Lopez EA, Yoo D, Danilkovitch-Miagkova A, Leroux MA. Concise review: role of mesenchymal stem cells in wound repair. Stem Cells Transl Med. 2012 Feb; 1(2):142-9







<sup>†</sup> Tissue Inhibitors of Metalloproteinases

<sup>† †</sup> As of January 1, 2016

<sup>1.</sup> Koob TJ, Rennert R, Zabek N, Massee M, Lim JJ, Temenoff JS, Li WW, Gurtner G. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. Int Wound J. 2013 Oct;10(5):493-500.

<sup>2.</sup> Koob TJ, Lim JJ, Massee M, Zabek N, Denozière G. Properties of dehydrated human amnion/chorion composite grafts: implications for wound repair and soft tissue regeneration. J Biomed Mater Res B Appl Biomater. 2014 Aug;102(6):1353-62.

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<sup>4.</sup> Koob TJ, et al. A Primer on Amniotic Membrane Regenerative Healing. 1st ed. Grand Rapids, MI: MiMedx/Color House Graphics. 2015.

<sup>5.</sup> Massee M, Chinn K, Lei J, Lim JJ, Young CS, Koob TJ. Dehydrated human amnion/chorion membrane regulates stem cell activity in vitro. J Biomed Mater Res B Appl Biomater. 2015 Jul 14. doi:10.1002/jbm.b.33478. [Epub ahead of print] 6. Maan ZN, Rennert RC, Koob TJ, Januszyk M, Li WW, Gurtner GC. Cell recruitment by amnion chorion grafts promotes neovascularization. J Surg Res. 2015 Feb;193(2):953-62.