Organogenesis
Empowering Healing

Organogenesis: Advanced Technologies Across Wound Care, Surgical and Sports Medicine

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Organogenesis

History
- Organogenesis was founded as a spin out of MIT in 1985
- Proven leader in regenerative medicine space

Experience
- In 1998, Organogenesis received the 1st FDA approval for a living, manufactured cell-based product
- In 2012, Organogenesis received one of the few BLA approvals that have been granted by CBER for an allogeneic living cell product
- Product portfolio consisting of PMA, BLA, 510K and 361 HCT/P products

Market Leader
- Organogenesis is a recognized innovator and a well-established leader in the Wound Care space
- In 2017, Organogenesis entered the surgical and sports medicine markets, acquiring 4 existing amniotic products, with a strong focus on osteoarthritis (OA).

Science
- Deep body of scientific, clinical and real-world outcomes data consisting of over 200 publications that review both the technical and clinical attributes of our products
- Organogenesis is grounded in research and scientific development and has a proven track record of supporting robust clinical research programs and advanced product development

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The acute wound healing process consists of four overlapping phases[1,2]

Normal wound healing is an orderly, sequential process[1,2]

1. Kane D, Krasner D, eds. *Chronic Wound Care: A Clinical Source Book for Healthcare Professionals.* 2nd ed. Wayne, PA: Health Management Publications Inc.; 1997:1-4. 2. Broughton G, et al. *Plast Reconstr Surg.* 2006;117:12S-34S.

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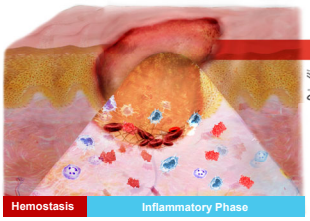
Chronic wounds occur when the normal wound healing process becomes disrupted

Chronic wounds are characterized by a prolonged period of inflammation[1-3]



Sustained Inflammation

- Excessive bacterial bioburden triggers chronic inflammation[4]
- Excess MMPs break down ECM[5,6]
- ECM degradation prevents formation of granulation tissue[7]

MMPs=matrix metalloproteinases; ECM=extracellular matrix.
1. Kane D, Krasner D, eds. *Chronic Wound Care: A Clinical Source Book for Healthcare Professionals.* 2nd ed. Wayne, PA: Health Management Publications Inc.; 1997:1-4. 2. Broughton G, Janis JE, Attinger CE. *Plast Reconstr Surg.* 2006;117:12S-34S. 3. Eming SA, et al. *J Invest Dermatol.* 2007;127:514-525. 4. Frykberg RG, et al. *Adv Wound Care.* 2015;4(9):560-582. 5. Carpenter S, et al. *Wounds.* 2016;28(6 suppl):S1-S20. 6. Gibson D, et al. *Wounds Int.* 2009;1(1):1-6. 7. Brett D. *Wounds.* 2008;20(12):347-356.

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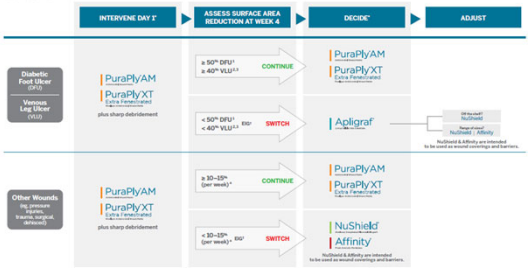
Using the Organogenesis solutions guided by the predictive indicators



*Please refer to your local coverage determination (LCD) guidelines for specific coverage.
†E=**Exudate** well-controlled; I=No signs of clinical **Infection**; G=Healthy **Granulation** tissue present.
1. Sheehan P, et al. *Diabetes Care.* 2003;26(6):1879-1882. 2. Phillips TJ, et al. *J Am Acad Dermatol.* 2000;43(4):627-630. 3. Gelfand JM, et al. *J Invest Dermatol.* 2002;119(6):1420-1425. 4. Attinger CE, et al. *Plast Reconstr Surg.* 2006;117(Suppl):72S-109S.

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Organogenesis
PuraPly AM
Antimicrobial Wound Matrix

Combination of Native Collagen and PHMB Manages Bioburden/Biofilm to Support Healing

PHMB binds and disrupts negatively charged cell membranes[1]

Intact native collagen inhibits a wide range of proteases[2]

Benefits
- **BBWM™:** sharp debridement with PuraPly AM to prevent biofilm reformation[3]
- **PHMB** is a broad spectrum antimicrobial that inhibits biofilm reformation[1]
- **Native collagen matrix** allows for a sustained antimicrobial barrier effect[4,5]

Uses
- Indicated for a wide variety of acute and chronic wounds[5]

PHMB, polyhexamethylene biguanide; PPAM, PuraPly Antimicrobial.
1. Hübner NO, Kramer A. Skin Pharmacol Physiol. 2010;23(suppl):17-27. 2. Negron L et al. Int Wound J. 2014;11:392-397. 3. Wolcott RD et al. J Wound Care. 2010;19(8):320-328. 4. Brantley J et al. Wounds Int. 2016;7(3):1-5. 5. PuraPly antimicrobial [package insert]. Canton, MA: Organogenesis, Inc; 2015.

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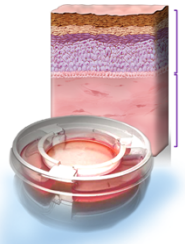
Organogenesis
Apligraf®
Living Cellular Skin Substitute

Designed With Living Keratinocytes and Fibroblasts to Heal VLUs[1,2]



Living keratinocytes and **stem cells** that provide potent healing signals (growth factors/ cytokines)[1-4]

Living fibroblasts that proliferate and produce human collagen and other ECM proteins as well as growth factors/ cytokines[1-3]

Benefits

- Only product that transforms the wound environment from a chronic to acute state[5]
- Proven to heal more VLUs, faster in a RCT and in the real-world setting, with a favorable safety profile[1,2,6-8]

Uses

- Only product FDA-approved to heal VLUs[2]

VLU = Venous Leg Ulcer
Apligraf is also FDA-approved to heal diabetic foot ulcers.

1. Data on File, Organogenesis Inc. 2. Apligraf Prescribing Information. Canton, MA: Organogenesis Inc; 2015. 3. Schmid P et al. Wounds 2000;12(5 Suppl A):4A-11A. 4. Carlson M et al. Tissue Eng Part A. 2011;17(3-4):487-493. 5. Stone RC et al. Sci Transl Med. 2017;9(371). Pii: eaaf8611. 6. Falanga V et al. Arch Dermatol. 1998;134:293-300. 7. Marston WA et al. Wound Repair Regen. 2014;22(3):334-340. 8. Treadwell T et al. Adv Wound Care. 2017;7(3);1-8.

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Organogenesis
NuShield®
Sterilized, Dehydrated Placental Allograft

The Most Complete and Versatile Dehydrated Placental Allograft Solution

TGF-ß1 = Transforming Growth Factor Beta 1
HGF = Hepatocyte Growth Factor

Benefits

- The proprietary process yields a sterilized, more complete dehydrated placental allograft with all native layers, including spongy/intermediate layer[1-3]
- **Spongy/intermediate layer:** high levels of specific growth factors, hydrated proteoglycans, Type III collagen, TGF-ß1, HGF, and hyaluronic acid[4-7]
- Analytical testing has shown NuShield retains 640 components (growth factors, cytokines, and chemokines)[1]

Uses

- As a wound covering for a wide range of acute and chronic wounds, including exposed bone and tendon[8]

1. Data on file. Organogenesis Inc. 2. Mowry KC et al. Poster presented at SAWC, Fall 2015. 3. Koob TJ et al. J Biomed Mater Res. 2014;102(6):1353-1362. 4. Hopkinson A et al. Invest Ophthalmol Vis Sci. 2006;47(10):4316-4322. 5. Koizumi NJ et al. Curr Eye Res. 2000;20(3):173-177. 6. Niknejad H et al. Eur Cells Mater. 2008;15:88-99. 7. Parolini O et al. Stem Cells. 2008;26(2):300-311. 8. NuShield Instructions for Use, 2017.

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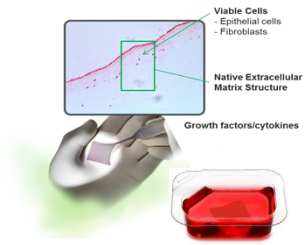
Organogenesis
Affinity®
Fresh Amniotic Membrane

The Only Fresh, Amniotic Membrane Wound Covering



Benefits

- Undergoes proprietary Allofresh™ process[1]
- Affinity is not dehydrated or frozen and is closest to native unprocessed amniotic tissue[1-4]
- Retains native tissue characteristics, including viable cells, growth factors/cytokines, and native extracellular matrix structure[1-2]

Uses

- As a wound covering for a wide range of acute and chronic wounds, including exposed bone and tendon[5]

1. Data on File. Organogenesis Inc. 2. McQuilling JP et al. *Int Wound J.* 2017;14(6):993-1005. 3. Niknejad H et al. *Eur Cells Materials* 2008;15:88-99. 4. Ghatak S et al. *Int J Cell Biol.* 2015;834893. 5. Affinity Instructions for Use, 2017.

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