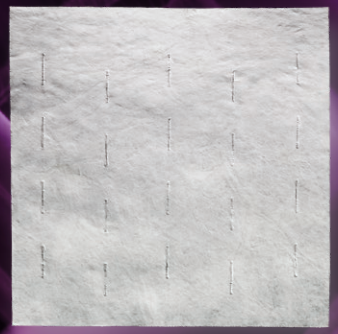


ORGANOGENESIS
PuraPly® AM
Antimicrobial Wound Matrix

ORGANOGENESIS
PuraPly® XT
Extra Fenestrated, Five-layer
Antimicrobial Wound Matrix

THE POWER OF PLUS

WITH PURAPLY® AM & PURAPLY® XT

Native ECM scaffold + broad-spectrum PHMB antimicrobial for next-level wound healing support[1-5]

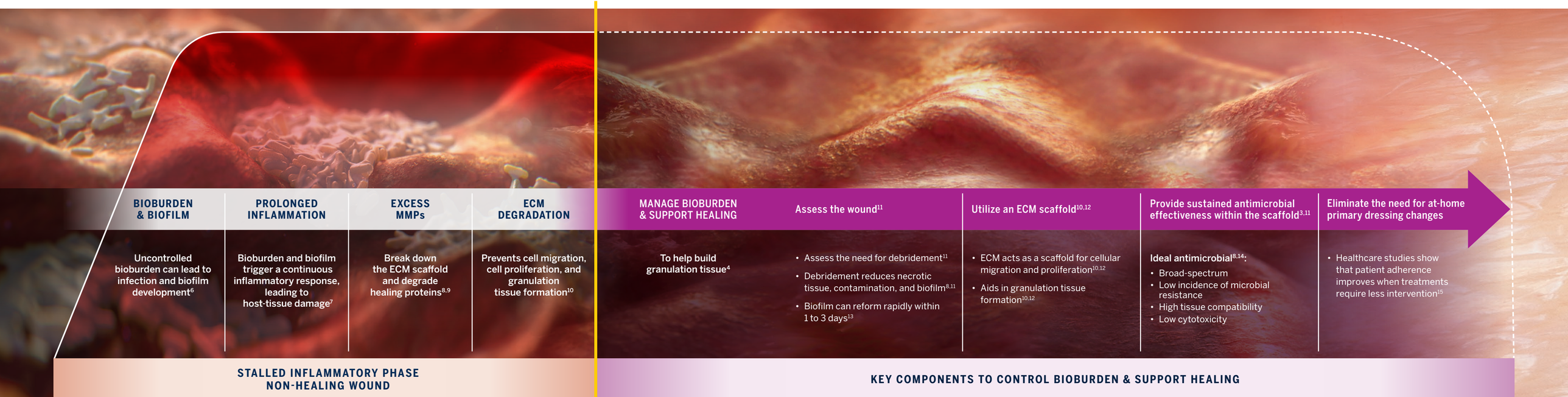
ORGANOGENESIS

IDENTIFYING KEY BARRIERS TO HEALING TO IMPROVE OUTCOMES

In acute and chronic wounds, uncontrolled bioburden can lead to biofilm resulting in excess MMPs and a continuous inflammatory response, which can break down the ECM scaffold and contribute to stalled, non-healing wounds[6-10]

SUPPORT HEALING WITH OPTIMAL WOUND CONTROL

For optimal bioburden control and wound healing support, combine standard of care with an ECM scaffold that provides sustained antimicrobial effectiveness within the product[3,10-12]



BIOBURDEN & BIOFILM

Uncontrolled bioburden can lead to infection and biofilm development[6]

PROLONGED INFLAMMATION

Bioburden and biofilm trigger a continuous inflammatory response, leading to host-tissue damage[7]

EXCESS MMPs

Break down the ECM scaffold and degrade healing proteins[8,9]

ECM DEGRADATION

Prevents cell migration, cell proliferation, and granulation tissue formation[10]

STALLED INFLAMMATORY PHASE NON-HEALING WOUND

MANAGE BIOBURDEN & SUPPORT HEALING

To help build granulation tissue[4]

Assess the wound[11]

- Assess the need for debridement[11]
- Debridement reduces necrotic tissue, contamination, and biofilm[8,11]
- Biofilm can reform rapidly within 1 to 3 days[13]

Utilize an ECM scaffold[10,12]

- ECM acts as a scaffold for cellular migration and proliferation[10,12]
- Aids in granulation tissue formation[10,12]

Provide sustained antimicrobial effectiveness within the scaffold[3,11]

Ideal antimicrobial[8,14]:

- Broad-spectrum
- Low incidence of microbial resistance
- High tissue compatibility
- Low cytotoxicity

Eliminate the need for at-home primary dressing changes

- Healthcare studies show that patient adherence improves when treatments require less intervention[15]

KEY COMPONENTS TO CONTROL BIOBURDEN & SUPPORT HEALING

MMPs=matrix metalloproteinases; ECM=extracellular matrix

ECM=extracellular matrix

IMPROVING PATIENT LIVES STARTS WITH CHOOSING A SOLUTION THAT MEETS THEIR NEEDS

Nonhealing wounds significantly impact

PATIENT QUALITY OF LIFE[16,17]

At-home primary dressing changes can expose the wound to bacteria and

LEAD TO CONTAMINATION

Many patients with lower-extremity chronic wounds are

UNABLE TO CHANGE THEIR OWN DRESSINGS[18]

Many patients fear touching their wounds and

PREFER A DOCTOR OR A NURSE

exclusively to control their care[19]

Supports healing and controls bioburden
in a wide variety of acute and chronic wounds[1-5]

THE POWER OF PLUS

NATIVE, CROSS-LINKED ECM SCAFFOLD[1,2] + BROAD-SPECTRUM PHMB ANTIMICROBIAL[1,2,20]

ECM=extracellular matrix; PHMB=polyhexamethylene biguanide

NATIVE, CROSS-LINKED ECM SUPPORTS HEALING[5,10]

Provides a scaffold for cellular migration and proliferation to aid in granulation tissue formation[21]

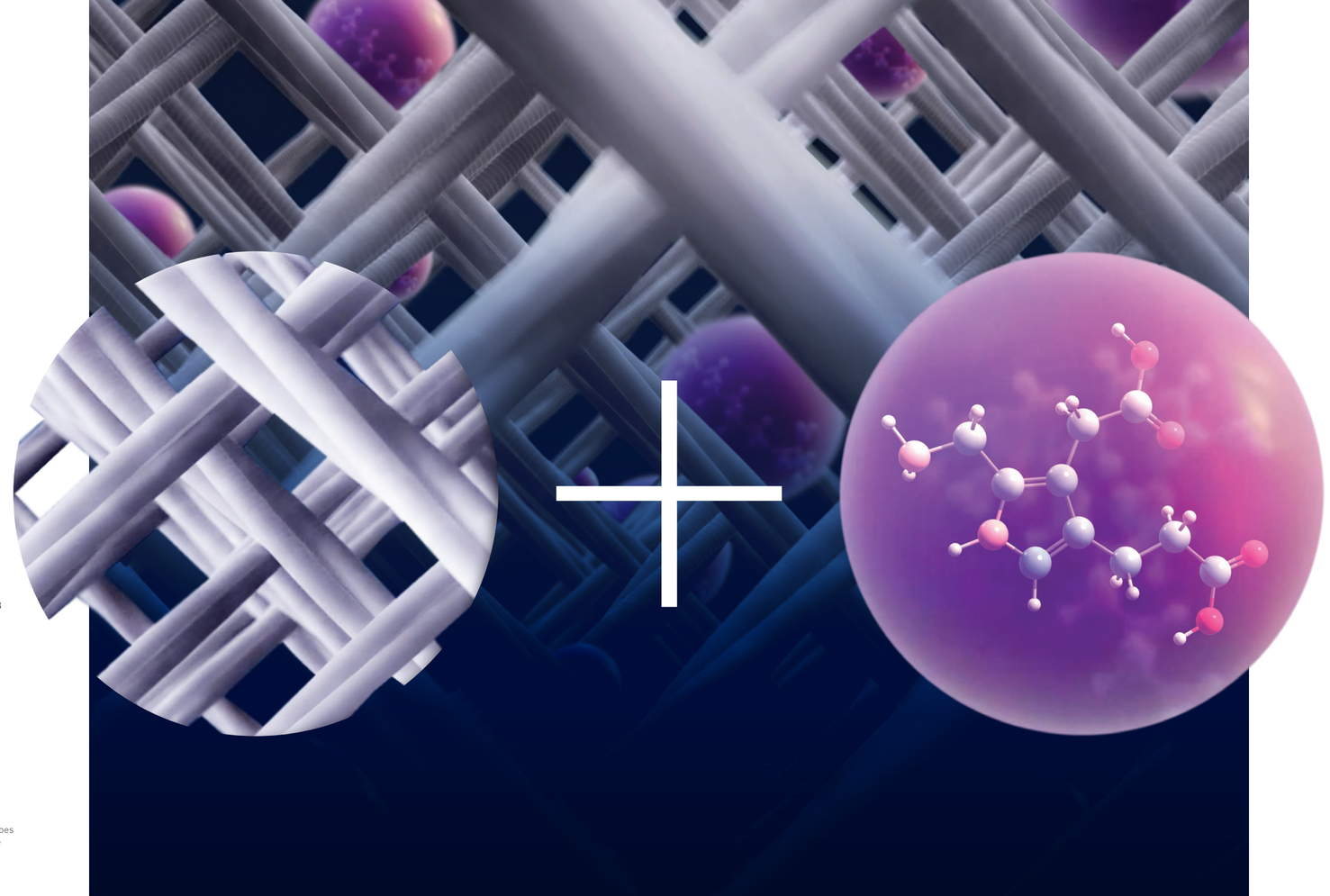
EXTRACELLULAR MATRIX SCAFFOLD OF PURAPLY® AM AND PURAPLY® XT

Maintains native collagen structure[8,22]

- Inhibits a wide range of MMPs and controls excess proteases[4,8,23]
- Ensures strength and compatibility[8,22]

Cross-linked collagen layers[4,8,22]

- Strengthens matrix bonds to resist protease degradation[24,25]
- Reinforces persistence between patient treatment visits[24,25]
- Maximizes surface area for PHMB saturation[4,8,23]



BROAD-SPECTRUM PHMB CONTROLS BIOBURDEN[3,4]

Proactively disrupts bioburden to help prevent biofilm reformation[4,26]

PHMB IS ONE OF THE BEST-INVESTIGATED ANTIMICROBIAL SUBSTANCES[20]

Positively-charged PHMB[20]

- Demonstrates high tissue compatibility and low cytotoxicity[3,20,26,27]
- Will not damage key cells (eg, fibroblasts) involved in wound healing[4]
- Exhibits no known bacterial resistance to date[4,20,26]

Covers a broad antimicrobial spectrum[20]

- Provides sustained antimicrobial effectiveness within the product[3]
- Effective against gram-positive and gram-negative bacteria (eg, MRSA, *Pseudomonas aeruginosa*) and spore-forming bacteria and fungi[20]
- Efficacy is not impaired in wound fluid, blood, or tissue[20]

ECM=extracellular matrix; MMP=matrix metalloproteinase; PHMB=polyhexamethylene biguanide

Note: PuraPly AM and PuraPly XT resist microbial colonization within the product and reduce microbes penetrating through it. PuraPly AM and PuraPly XT will naturally be resorbed into the wound and are not intended to be removed.

PHMB=polyhexamethylene biguanide; MRSA=methicillin-resistant *Staphylococcus aureus*

Note: PuraPly AM and PuraPly XT resist microbial colonization within the product and reduce microbes penetrating through it. PuraPly AM and PuraPly XT will naturally be resorbed into the wound and are not intended to be removed.

CONFIRMATION OF CONTROL: THE PURAPLY® PORTFOLIO IS BACKED BY AN EXPANDING EVIDENCE BASE

DAVIS STUDY

ANTIMICROBIAL EFFECTIVENESS STUDY

Davis SC, et al. *Int Wound J*. 2022;19(1): 86-99.

RESPOND STUDY

REAL-WORLD CLINICAL EFFECTIVENESS STUDY

Bain MA, et al. *J Comp Eff Res*. 2020; 9(10):691-703.

OROPALLO STUDY

PROSPECTIVE CASE SERIES IN DIFFICULT-TO-HEAL WOUNDS

Oropallo AR. *Plast Reconstr Surg Glob Open*. 2019;7:e2047.

PURAPLY AM PROVIDES SUSTAINED ANTIMICROBIAL EFFECTIVENESS WITHIN THE PRODUCT AGAINST A BROAD SPECTRUM OF MICROBES[28]

*Candida albicans** | *Escherichia coli** | *Staphylococcus aureus** MRSA† | *Aspergillus niger** | *Pseudomonas aeruginosa**

In the US Pharmacopeia Antimicrobial Effectiveness Test, PuraPly AM reduced concentrations of these microbes on days 7, 14, and 28 within the product

* United States Pharmacopeia Antimicrobial Effectiveness Test showed reduced concentrations at days 7, 14, and 28

† Zone of inhibition test demonstrated efficacy *in vitro*

MRSA=methicillin-resistant *Staphylococcus aureus*

SUBSTANTIAL MRSA REDUCTION WITHOUT COMPROMISING WOUND HEALING CELLS[3]

DAVIS STUDY

STUDY BACKGROUND

In vivo microbiology*

Compared MRSA colonies in each wound, using a porcine deep reticular dermal wound model

KEY STUDY FINDINGS

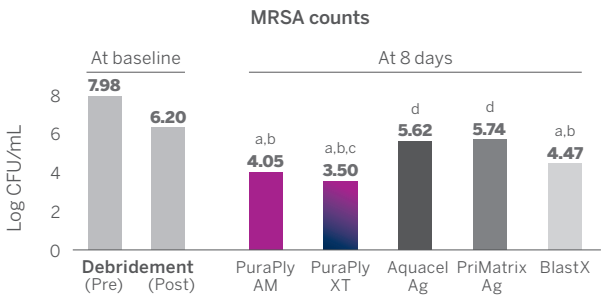
PuraPly® AM & PuraPly® XT provided a persistent and significantly greater antimicrobial effectiveness within the products

ANTIMICROBIAL EFFECTIVENESS WITHIN PURAPLY AM & PURAPLY XT†

>99%

MRSA reduction from post-debridement baseline

In vivo: **Superior MRSA reduction**



[a]*P*<0.05 vs pre- and post-debridement baseline; [b]*P*<0.05 vs Aquacel Ag and PriMatrix Ag; [c]*P*<0.05 vs BlastX; [d]*P*<0.05 vs pre-debridement baseline

Data shown compared MRSA colonies in each wound, using a porcine deep reticular dermal wound model

STUDY BACKGROUND

In vitro cytotoxicity

Measured cell proliferation and cell viability using human dermal fibroblasts in media conditioned with test materials

KEY STUDY FINDINGS

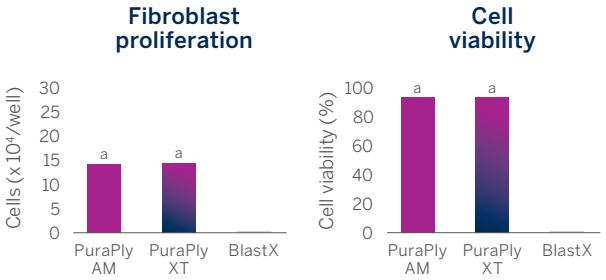
PuraPly AM & PuraPly XT did not prohibit cell proliferation and were non-cytotoxic to wound healing cells, unlike topical treatments

PURAPLY AM & PURAPLY XT LOW CYTOTOXICITY

>94%

Fibroblast viability at 48 hours

In vitro: **Low cytotoxicity**



[a]*P*<0.001 vs Blast X

Data shown measured cell proliferation and cell viability using human dermal fibroblasts in media conditioned with test materials

* Wounds were inoculated with MRSA and were allowed to form biofilm for 72 hours; the wounds were then debrided before the application of testing agent

† In a study evaluating the antimicrobial effectiveness within PuraPly AM and PuraPly XT versus a variety of other wound products

MRSA=methicillin-resistant *Staphylococcus aureus*

PROVEN REAL-WORLD EFFECTIVENESS: MULTI-CENTER STUDY

PuraPly® AM supported healing and aided in granulation tissue formation[5]

RESPOND STUDY

N=307
28 Sites

Prospective, multicenter cohort study

Large Difficult-to-Heal Wounds

12.9 cm^2 mean wound area

86% of wounds demonstrated improvement in wound bed conditions†:

Increased granulation tissue

Reduced exudate

Readiness for other advanced skin substitutes

85% of wounds achieved >75% reduction in volume†

41.5% of wounds achieved complete closure at 12 weeks

RESPOND=Real-World Effectiveness Study of PuraPly AM on Wounds

* PuraPly AM was applied post-debridement for up to 32 weeks; mean number of applications was 5.2

† At 32 weeks

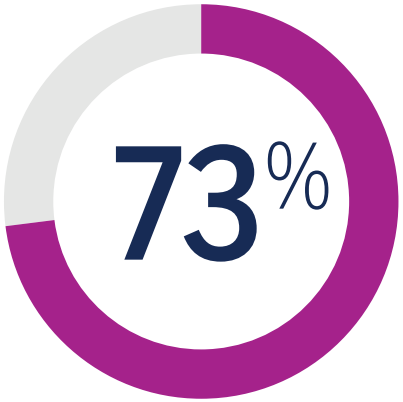
PROVEN REAL-WORLD EFFECTIVENESS: PROSPECTIVE CASE SERIES

PuraPly® AM demonstrated significant improvement in wounds that had been stalled for two years[29]

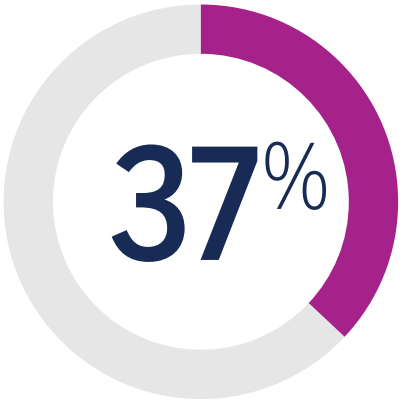
OROPALLO STUDY

Stalled, Non-Healing Wounds
103 weeks
~ 2 years mean wound duration
Prospective case series

Large Wounds
18.0 cm^2
Baseline wound area
Failed Multiple Therapies



of wounds had a **reduction in wound area**



of wounds **closed**

6.7 weeks mean time to complete closure

Prospective case series, N=41

* PuraPly AM was applied post-debridement for up to 12 weeks; mean number of applications was 8; treating physician determined the frequency and type of assessments performed for each patient, according to standard of care for their target wound

A PORTFOLIO DESIGNED FOR A VARIETY OF ACUTE AND CHRONIC WOUNDS[1]

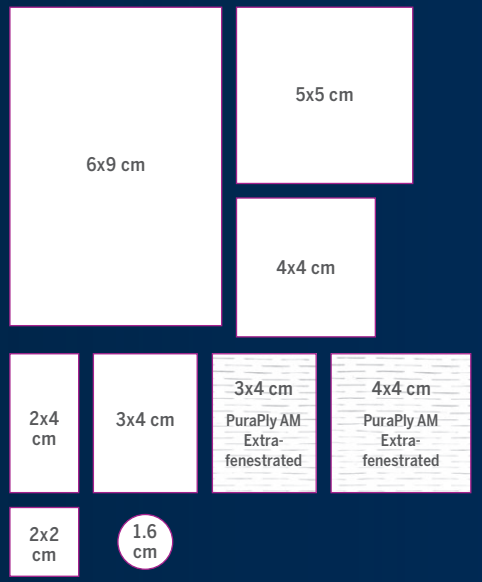
PuraPly® AM

- 2 layers
- Cross-linked ECM scaffold
- PHMB
- Fenestrated

PuraPly® AM
Extra Fenestrated

- 2 layers
- Cross-linked ECM scaffold
- PHMB
- Extra fenestrated for conforming to irregularly-shaped wounds

Product Number	Description/Dimensions	Total Size (cm^2)	Billable Units	HCPCS Code	UPC Number
515-032	PURAPLYAM-COM 1.6 DISC	1.6	2	Q4196	618474000190
515-014	PURAPLYAM-COM 2X2	4	4	Q4196	618474000084
515-016	PURAPLYAM-COM 2X4	8	8	Q4196	618474000091
515-065	PURAPLYAM-COM 3X4	12	12	Q4196	618474000435
515-048	PURAPLYAM-COM 4X4	16	16	Q4196	618474000312
515-008	PURAPLYAM-COM 5X5	25	25	Q4196	618474000107
515-018	PURAPLYAM-COM 6X9	54	54	Q4196	618474000114
515-067	PURAPLYAM-COM 3X4 EXTRA FENESTRATED	12	12	Q4196	618474000442
515-069	PURAPLYAM-COM 4X4 EXTRA FENESTRATED	16	16	Q4196	618474000459



ECM=extracellular matrix; PHMB=polyhexamethylene biguanide

THE PURAPLY® PORTFOLIO HELPS TO CONTROL BIOBURDEN AND SUPPORT HEALING FOR A WIDE RANGE OF ACUTE AND CHRONIC WOUNDS[1-5]

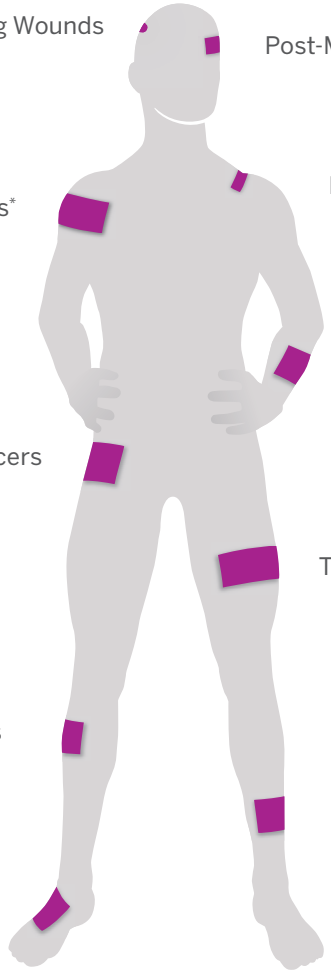
Draining Wounds

Trauma Wounds*

Pressure Ulcers

Chronic Vascular Ulcers

Diabetic Ulcers

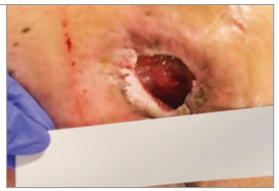


Post-Mohs Surgery Wounds

Partial-and-Full-thickness Wounds

Surgical Wounds†

Tunneling/Undermined Wounds



Venous Ulcers

* Abrasions, lacerations, second-degree burns, skin tears
† Donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence

Note: PuraPly AM and PuraPly XT are contraindicated for third-degree burns

PURAPLY® AM & PURAPLY® XT APPLICATION STEPS[1,2]

1 Prepare wound to ensure it is free of debris and necrotic tissue

2 Cut the dry sheet to the appropriate size and place in contact with the wound bed

3 Hydrate with sterile saline, do not soak

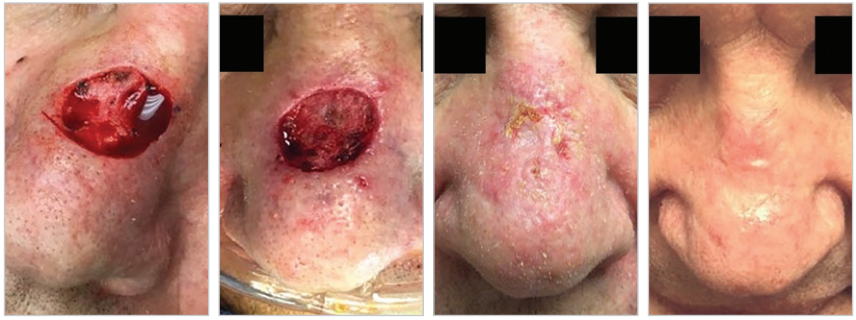
4 Anchor PuraPly AM or PuraPly XT using preferred fixation method, such as sutures, adhesive strips, or dermal adhesive and thoroughly cover with a non-adherent dressing

5 Cover and wrap with secondary dressings. Reassess at next patient treatment visit. PuraPly AM or PuraPly XT will naturally be resorbed into the wound and is not intended to be removed. Subsequent application is at the discretion of the healthcare practitioner.

ACUTE CASE STUDY

FACIAL POST-MOHS Courtesy of Jeffery L. Walding, MD, FACS

PuraPly® AM, native ECM scaffold + broad-spectrum PHMB antimicrobial, was used to control bioburden and support granulation tissue formation in preparation for a full-thickness skin graft (FTSG)



PuraPly AM application | **Prior to FTSG** | **3 weeks post-FTSG** | **3 months post-FTSG**

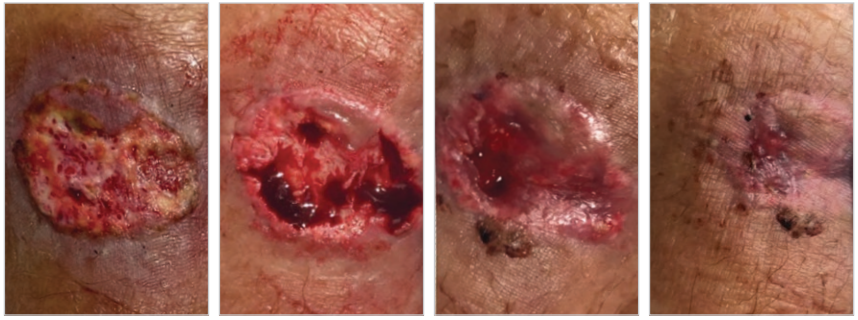
FTSG healed well with a good cosmetic outcome

- 67-year-old male underwent Mohs surgery to remove a basal cell carcinoma on the nose
- Medical history included hypertension and former smoker
- PuraPly AM was applied immediately post-Mohs surgery and a FTSG was performed 1 week post-application

CHRONIC CASE STUDY

LOWER LEG WOUND Courtesy of Daniel L. Kapp, MD

PuraPly® XT, native ECM scaffold + broad-spectrum PHMB antimicrobial, was used to control bioburden and support healing in a wound that had previously failed a FTSG



1st PuraPly XT application

Pre-debridement Wound Area: 12.0 cm^2

2nd PuraPly XT application

Post-debridement Wound Area: 9.8 cm^2

5th PuraPly XT application

Post-debridement Wound Area: 1.2 cm^2

Complete wound closure

Thin layer of epithelium present

- 79-year-old female underwent surgical excision of a melanoma on the left medial leg, which was initially closed using a FTSG and subsequently failed
- Medical history included cardiac ablation
- Applications 1-5: PuraPly XT (post-debridement); wound closed at week 6

ECM=extracellular matrix; PHMB=polyhexamethylene biguanide

THE POWER OF PLUS WITH PURAPLY® AM & PURAPLY® XT

CONTROL BIOBURDEN AND SUPPORT HEALING

Bioburden and biofilm should be managed early, as they can lead to prolonged inflammation, resulting in breakdown of the ECM scaffold and delayed healing[4,6-10]

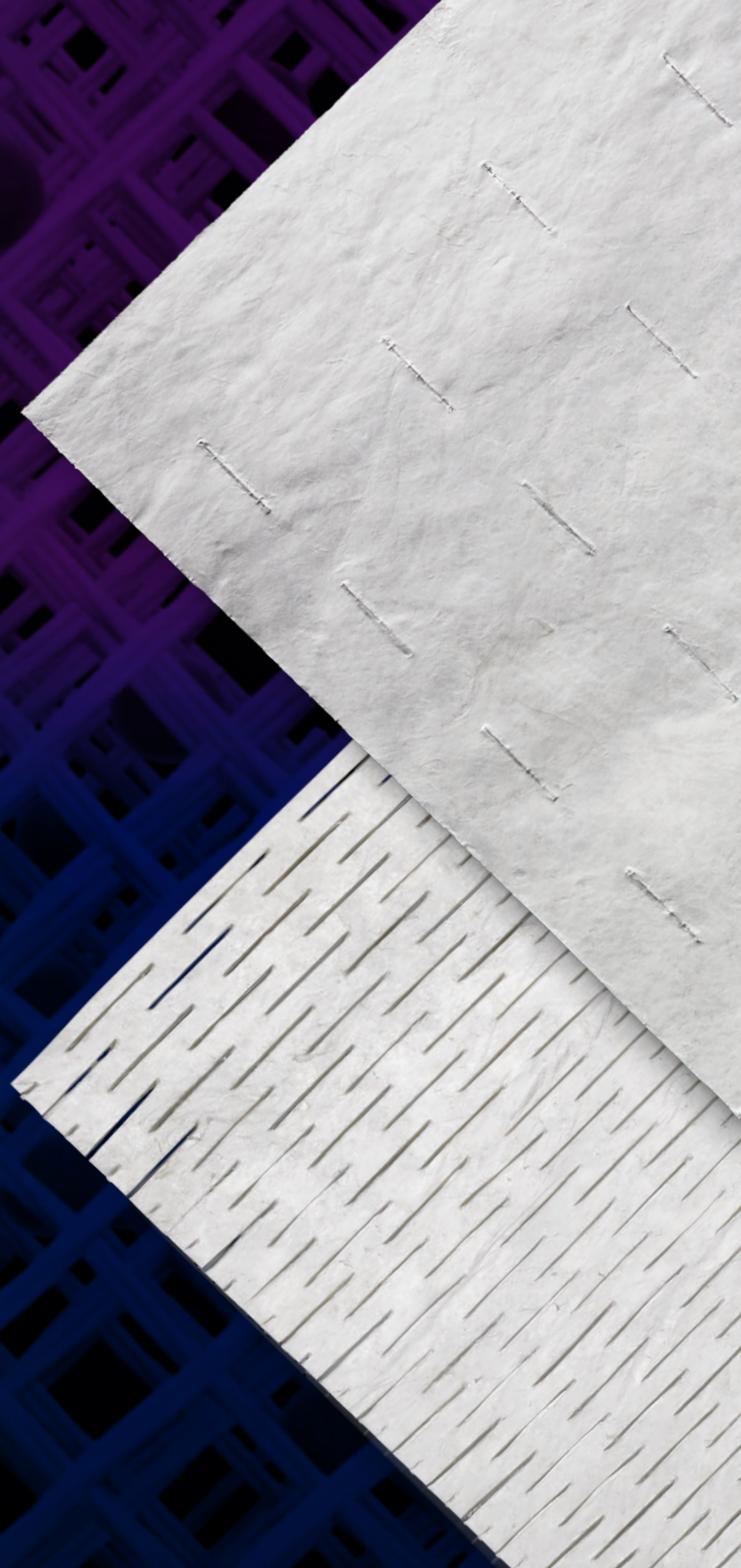
NATIVE ECM SCAFFOLD + BROAD-SPECTRUM PHMB[1,2,20,22]

Provides an ECM scaffold for cellular migration and proliferation[21]
plus sustained antimicrobial effectiveness within the product[3]

CONFIRMATION OF CONTROL

PuraPly AM portfolio is backed by scientific and clinical evidence demonstrating that it supports wound healing and aids in granulation tissue formation[3,5,29]

PuraPly® AM PuraPly® XT



ECM=extracellular matrix; PHMB=polyhexamethylene biguanide

References: 1. PuraPly Antimicrobial [package insert]. Canton, MA: Organogenesis Inc; 2023. **2.** PuraPly XT [package insert]. Canton, MA: Organogenesis Inc; 2023. **3.** Davis SC, et al. *Int Wound J*. 2022;19(1):86-99. **4.** Brantley J, et al. *Wounds Int*. 2016;7(3):1-5. **5.** Bain MA, et al. *J Comp Eff Res*. 2020;9(10):691-703. **6.** Percival SL, et al. *Adv Wound Care*. 2015;4(7):389-397. **7.** Frykberg RG, et al. *Adv Wound Care*. 2015;4(9):560-582. **8.** Carpenter S, et al. *Wounds*. 2016;28(6 suppl):S1-S20. **9.** Gibson D, et al. *Wounds Int*. 2009;1(1): 1-6. **10.** Brett D. *Wounds*. 2008;20(12):347-356. **11.** International Wound Infection Institute (IWII) Wound Infection in Clinical Practice. *Wounds International*. 2022. **12.** Araujo TAT, et al. *J Biomater Appl*. 2021;36(1):95-112. **13.** Wolcott RD, et al. *J Wound Care*. 2010;19(8): 320-328. **14.** Gottrup F, et al. *J Wound Care*. 2013;22(Suppl):S1-S92. **15.** Atreja A, et al. *MedGenMed*. 2005;7(1):4. **16.** Sawad A, et al. *J Comp Eff Res*. 2020;9(13):907-918. **17.** Mathias SD, et al. *Adv Skin Wound Care*. 2000;13(2):76-78. **18.** Fife C, et al. *Wounds*. 2007;19 (10):255-257. **19.** Zulec M, et al. *Int J Environ Res Public Health*. 2019;16(4):e559. **20.** Hübner NO, Kramer A. *Skin Pharmacol Physiol*. 2010;23(suppl):17-27. **21.** Data on file. PDR-0008. Organogenesis Inc. **22.** Data on file. PDR-0007. Organogenesis Inc. **23.** Data on file. PDR-0005. Organogenesis Inc. **24.** Khor E. *Biomaterials*. 1997;18(2):95-105. **25.** Billiar K, et al. *J Biomed Mater Res*. 2001;56(1):101-108. **26.** Gilbert P, et al. *J Appl Microbiol*. 2005;99(4):703-715. **27.** Sood A, et al. *Adv Wound Care*. 2014;3(8):511-529. **28.** Data on file. USP Antimicrobial Effectiveness Test. Organogenesis Inc. **29.** Oropallo AR. *Plast Reconstr Surg Glob Open*. 2019;7:e2047.

ORGANOGENESIS