

ORGANOGENESIS  
PuraPly<sup>®</sup>AM  
Antimicrobial Wound Matrix



ORGANOGENESIS  
PuraPly<sup>®</sup>XT  
Extra Fenestrated, Five-layer  
Antimicrobial Wound Matrix

# THE POWER OF PLUS

WITH PURAPLY<sup>®</sup> AM & PURAPLY<sup>®</sup> XT

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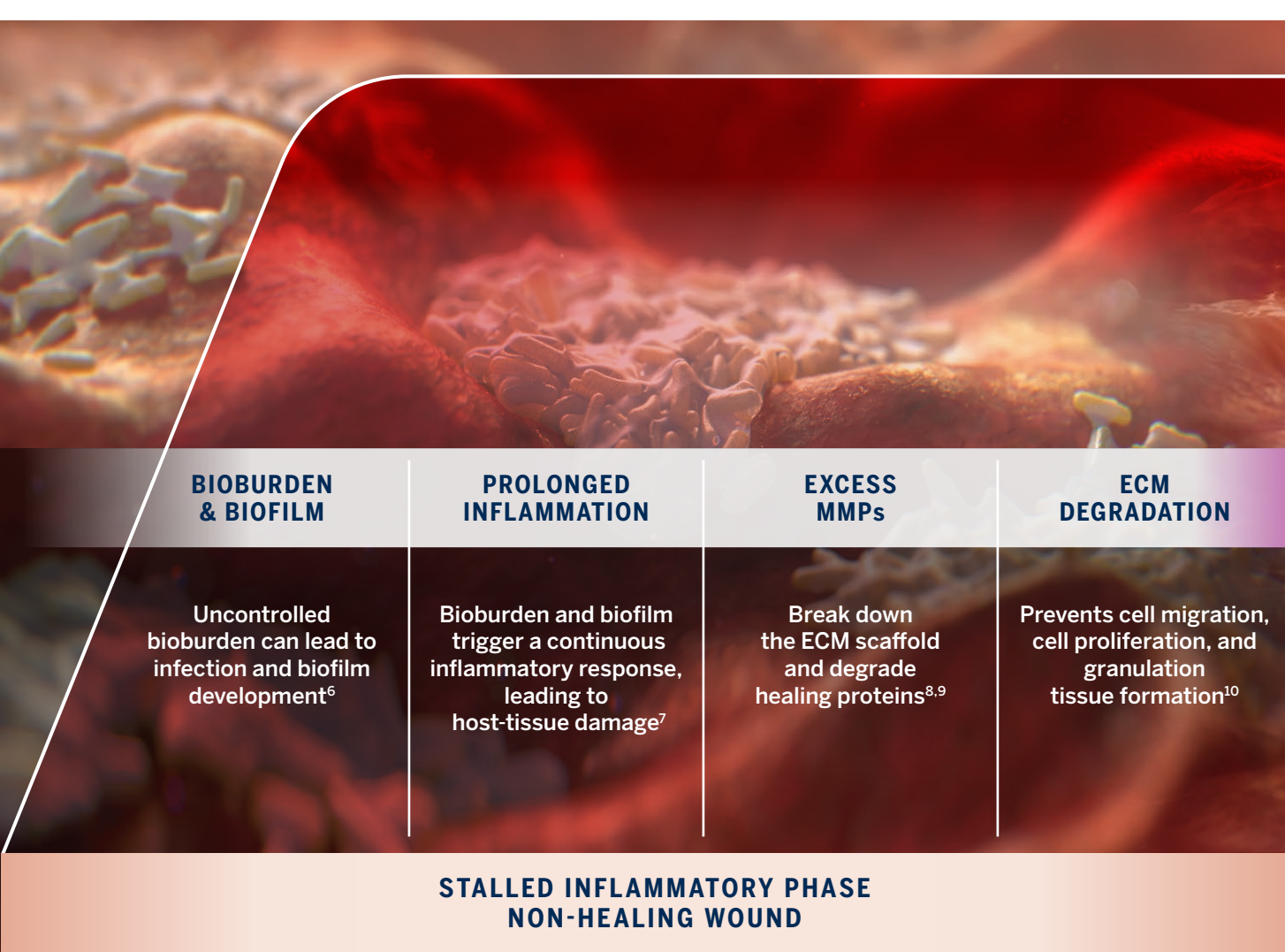
Native ECM scaffold + broad-spectrum PHMB antimicrobial  
for next-level wound healing support<sup>1-5</sup>

ORGANOGENESIS



# IDENTIFYING KEY BARRIERS TO HEALING TO IMPROVE OUTCOMES

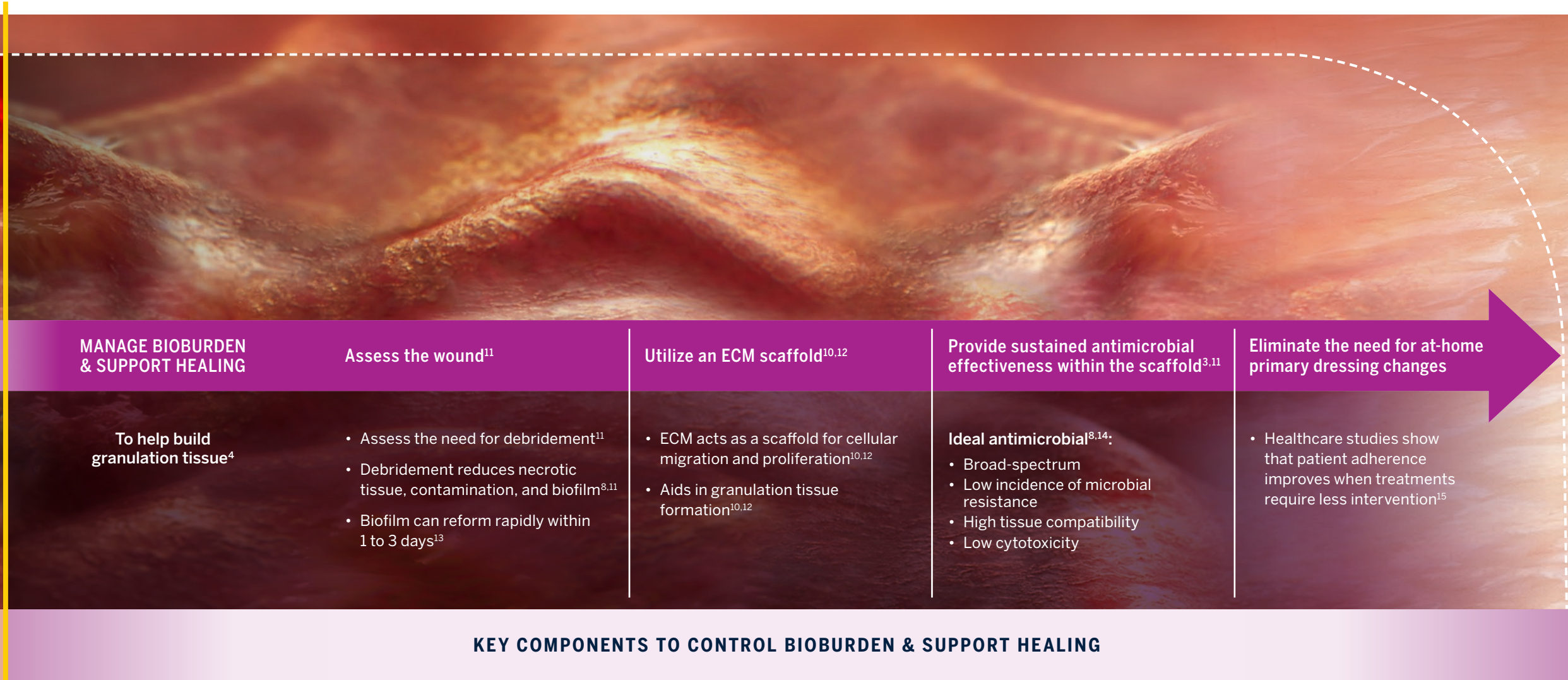
In acute and chronic wounds, uncontrolled bioburden can lead to biofilm resulting in excess MMPs and a continuous inflammatory response, which can break down the ECM scaffold and contribute to stalled, non-healing wounds<sup>6-10</sup>



MMPs=matrix metalloproteinases; ECM=extracellular matrix

# 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<sup>3,10-12</sup>



ECM=extracellular matrix



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



Nonhealing wounds  
significantly impact  
**PATIENT QUALITY  
OF LIFE**<sup>16,17</sup>

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

**LEAD TO  
CONTAMINATION**

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Many patients with lower-extremity  
chronic wounds are

**UNABLE TO CHANGE  
THEIR OWN DRESSINGS**<sup>18</sup>

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Many patients fear touching  
their wounds and

**PREFER A DOCTOR  
OR A NURSE**

exclusively to control  
their care<sup>19</sup>



Supports healing and controls bioburden  
in a wide variety of acute and chronic wounds<sup>1-5</sup>

# THE POWER OF PLUS

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NATIVE,  
CROSS-LINKED  
ECM SCAFFOLD<sup>1,2</sup>

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+

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BROAD-SPECTRUM  
PHMB  
ANTIMICROBIAL<sup>1,2,20</sup>

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# NATIVE, CROSS-LINKED ECM SUPPORTS HEALING<sup>5,10</sup>

Provides a scaffold for cellular migration and proliferation to aid in granulation tissue formation<sup>21</sup>

## EXTRACELLULAR MATRIX SCAFFOLD OF PURAPLY® AM AND PURAPLY® XT

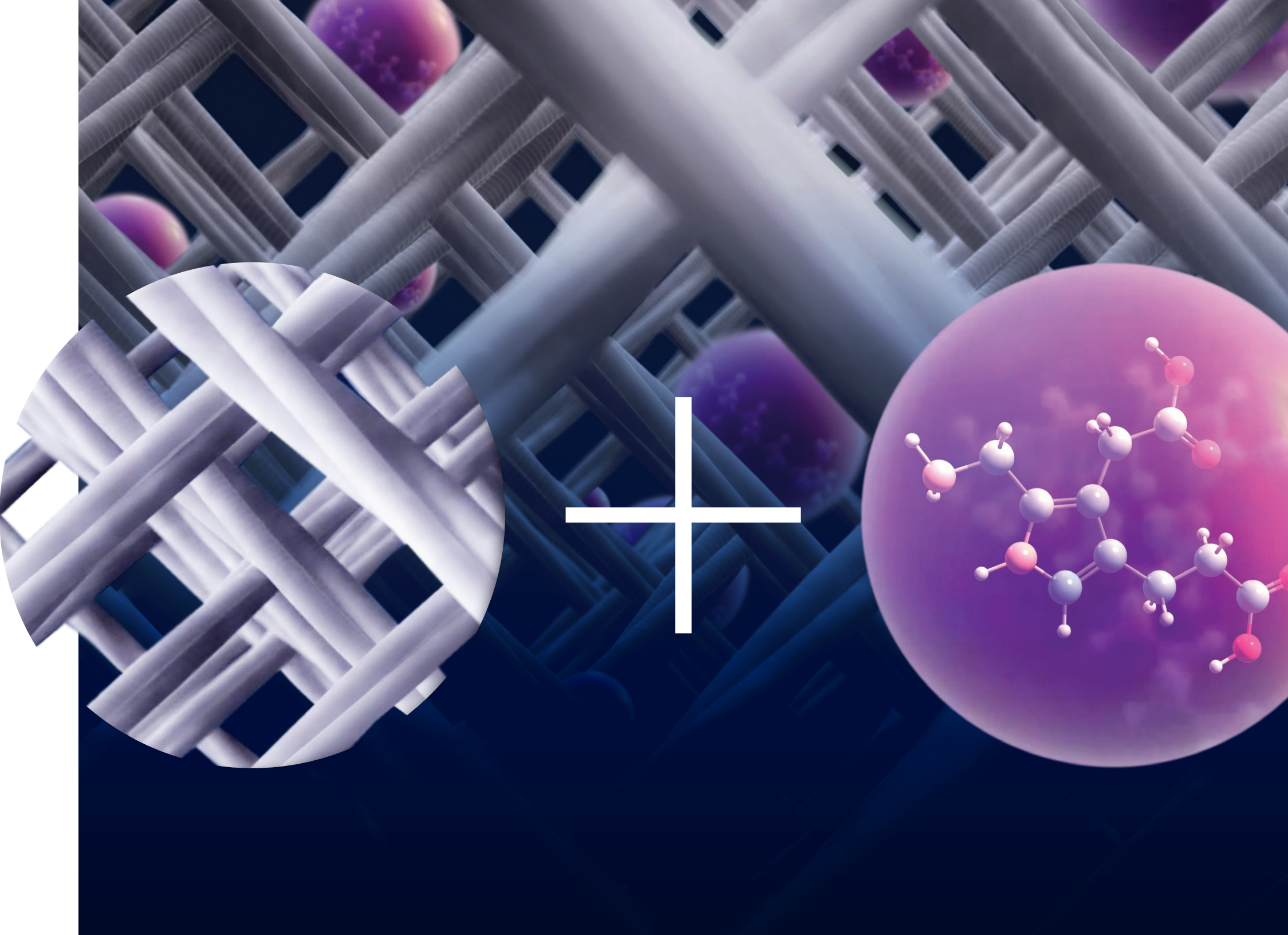
### Maintains native collagen structure<sup>8,22</sup>

- Inhibits a wide range of MMPs and controls excess proteases<sup>4,8,23</sup>
- Ensures strength and compatibility<sup>8,22</sup>

### Cross-linked collagen layers<sup>4,8,22</sup>

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

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.



# BROAD-SPECTRUM PHMB CONTROLS BIOBURDEN<sup>3,4</sup>

Proactively disrupts bioburden to help prevent biofilm reformation<sup>4,26</sup>

## PHMB IS ONE OF THE BEST-INVESTIGATED ANTIMICROBIAL SUBSTANCES<sup>20</sup>

### Positively-charged PHMB<sup>20</sup>

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

### Covers a broad antimicrobial spectrum<sup>20</sup>

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

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

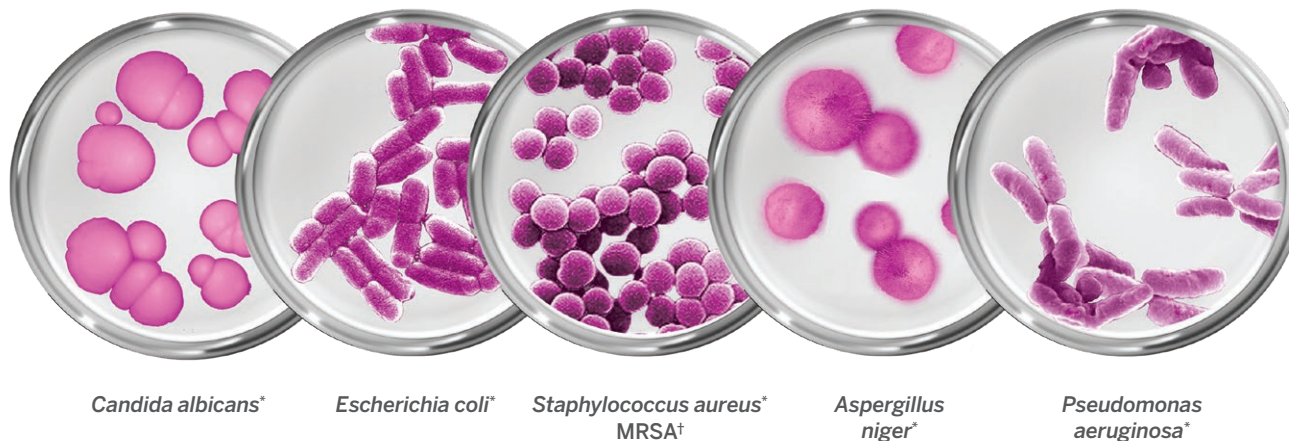
Bain MA, et al. *J Comp Eff Res*. 2020;9(10):691-703.

## 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<sup>28</sup>



*Candida albicans*\*

*Escherichia coli*\*

*Staphylococcus aureus*\*  
MRSA<sup>†</sup>

*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

<sup>†</sup> Zone of inhibition test demonstrated efficacy *in vitro*

MRSA=methicillin-resistant *Staphylococcus aureus*



# SUBSTANTIAL MRSA REDUCTION WITHOUT COMPROMISING WOUND HEALING CELLS<sup>3</sup>

## DAVIS STUDY

### STUDY BACKGROUND

#### *In vivo* microbiology\*

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

### KEY STUDY FINDINGS

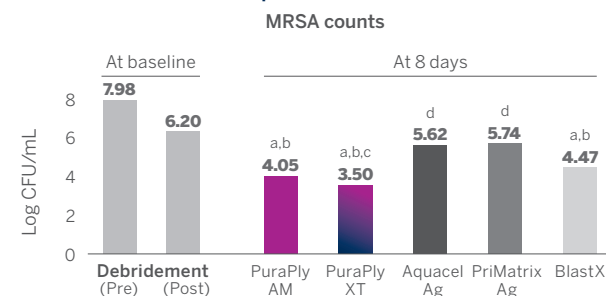
PuraPly® AM & PuraPly® XT provided a persistent and significantly greater antimicrobial effectiveness within the products

#### ANTIMICROBIAL EFFECTIVENESS WITHIN PURAPLY AM & PURAPLY XT†

>99%

MRSA reduction from  
post-debridement baseline

#### *In vivo*: Superior MRSA reduction



\*P<0.05 vs pre- and post-debridement baseline; †P<0.05 vs Aquacel Ag and PriMatrix Ag; ‡P<0.05 vs BlastX; §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

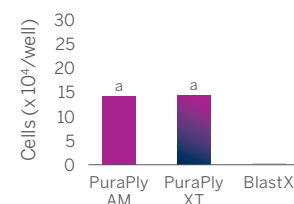
#### PURAPLY AM & PURAPLY XT LOW CYTOTOXICITY

>94%

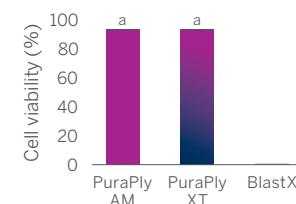
Fibroblast viability  
at 48 hours

#### *In vitro*: Low cytotoxicity

##### Fibroblast proliferation



##### Cell viability



\*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<sup>5</sup>

## RESPOND STUDY

**N=307**  
**28 Sites**

Prospective, multicenter  
cohort study

**Large**  
**Difficult-to-Heal**  
**Wounds**

12.9 cm<sup>2</sup> mean wound area

**86%** of wounds demonstrated improvement  
in wound bed conditions<sup>†</sup>:



Increased  
granulation  
tissue



Reduced  
exudate



Readiness for  
other advanced  
skin substitutes

**85%** of wounds achieved >75% reduction  
in volume<sup>†</sup>

**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

<sup>†</sup> At 32 weeks



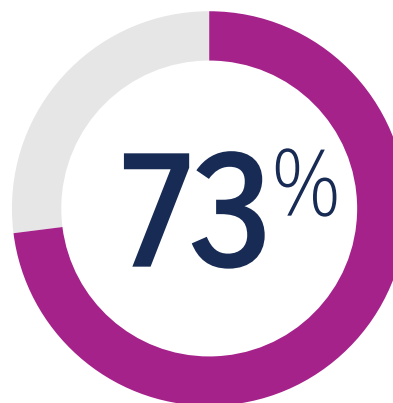
# PROVEN REAL-WORLD EFFECTIVENESS: PROSPECTIVE CASE SERIES

PuraPly® AM demonstrated significant improvement in wounds that had been stalled for two years<sup>29</sup>

## OROPALLO STUDY

**Stalled,  
Non-Healing Wounds  
103 weeks**

~ 2 years mean wound duration  
Prospective case series

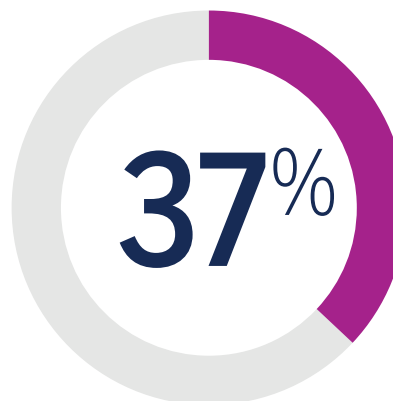


of wounds had a  
**reduction in wound area**

**Large Wounds  
18.0 cm<sup>2</sup>**

Baseline wound area

**Failed Multiple  
Therapies**



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<sup>1,2</sup>



## PuraPly<sup>®</sup>AM

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



## PuraPly<sup>®</sup>XT

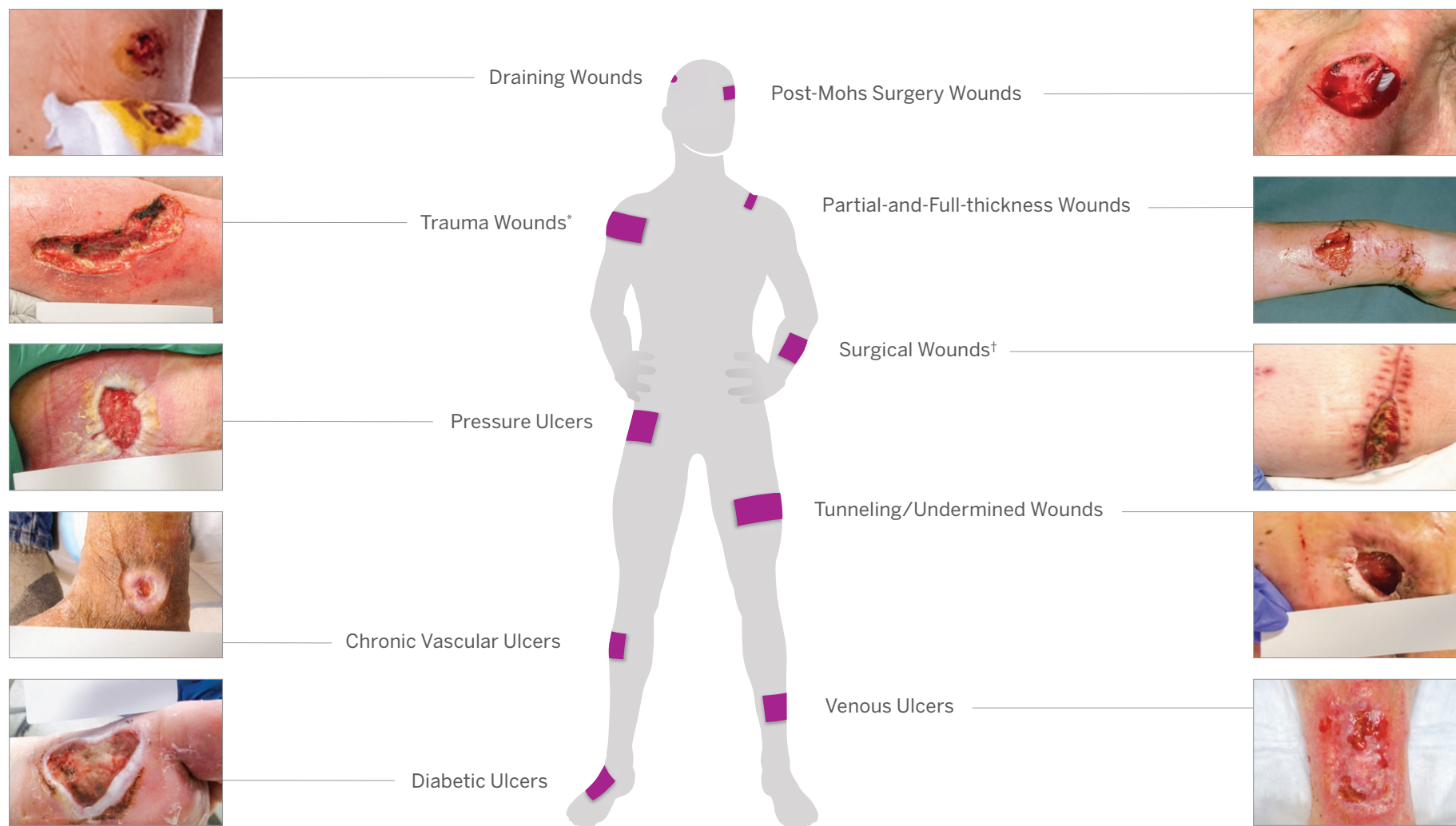
- 5 layers
- Cross-linked ECM scaffold
- PHMB
- Extra fenestrated for conforming to irregularly-shaped wounds

Product Number	Description/Dimensions	Total Size (cm <sup>2</sup> )	Billable Units	HCPCS Code	UPC Number
515-044	PURAPLYAM-COM 3.02X3.02	10	10	Q4196	618474000299
515-046	PURAPLYAM-COM 3.76X3.76	15	15	Q4196	618474000305
515-008	PURAPLYAM-COM 5X5	25	25	Q4196	618474000107
515-018	PURAPLYAM-COM 6X9	54	54	Q4196	618474000114
515-071	PURAPLYAM XT-COM 4.91X4.91 EXTRA FENESTRATED	24.10	25	Q4197	618474000466





# THE PURAPLY® PORTFOLIO HELPS TO CONTROL BIOBURDEN AND SUPPORT HEALING FOR A WIDE RANGE OF ACUTE AND CHRONIC WOUNDS<sup>1-5</sup>



\* Abrasions, lacerations, second-degree burns, skin tears

† Donor sites/grfts, 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<sup>1,2</sup>



**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.

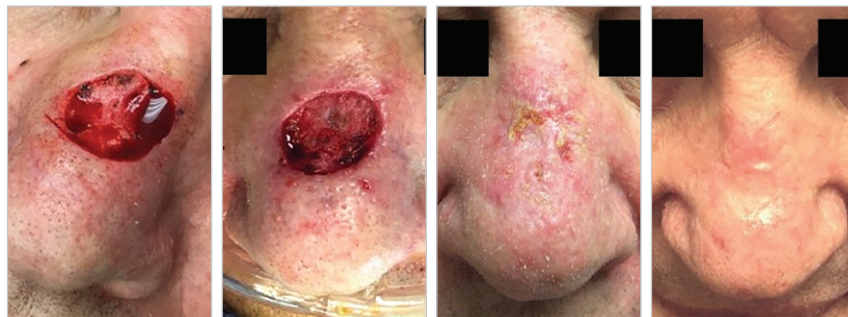


## ACUTE CASE STUDY

### 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

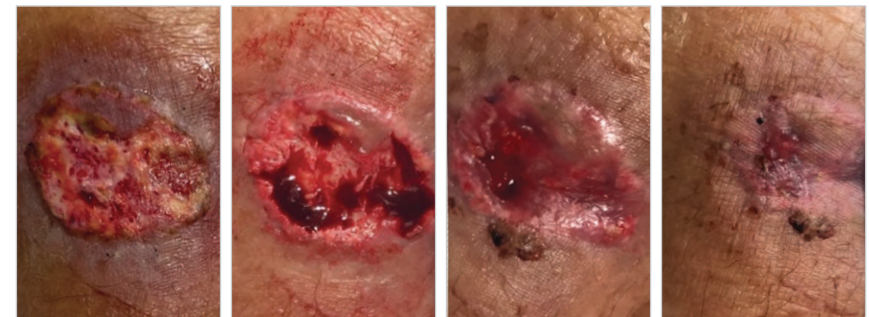
- 67-year-old male underwent Mohs surgery to remove a basal cell carcinoma on the nose
- Medical history included hypertension and former smoker
- PuraPly AM was applied immediately post-Mohs surgery and a FTSG was performed 1 week post-application

## 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



**1<sup>st</sup> PuraPly XT application**

**2<sup>nd</sup> PuraPly XT application**

**5<sup>th</sup> PuraPly XT application**

**Complete wound closure**

Pre-debridement  
Wound Area: 12.0 cm<sup>2</sup>

Post-debridement  
Wound Area: 9.8 cm<sup>2</sup>

Post-debridement  
Wound Area: 1.2 cm<sup>2</sup>

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

# 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<sup>4,6-10</sup>

## NATIVE ECM SCAFFOLD + BROAD-SPECTRUM PHMB<sup>1,2,20,22</sup>

Provides an ECM scaffold for cellular migration and proliferation<sup>21</sup>  
*plus* sustained antimicrobial effectiveness within the product<sup>3</sup>

## 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<sup>3,5,29</sup>

# | 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.** Gotttrup 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.

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 ORGANOGESIS