



Bringing expertise in novel antimicrobials, biomaterials and drug delivery to prevent and manage wound infection.

Gatekeeper™

Antimicrobial Wound Management

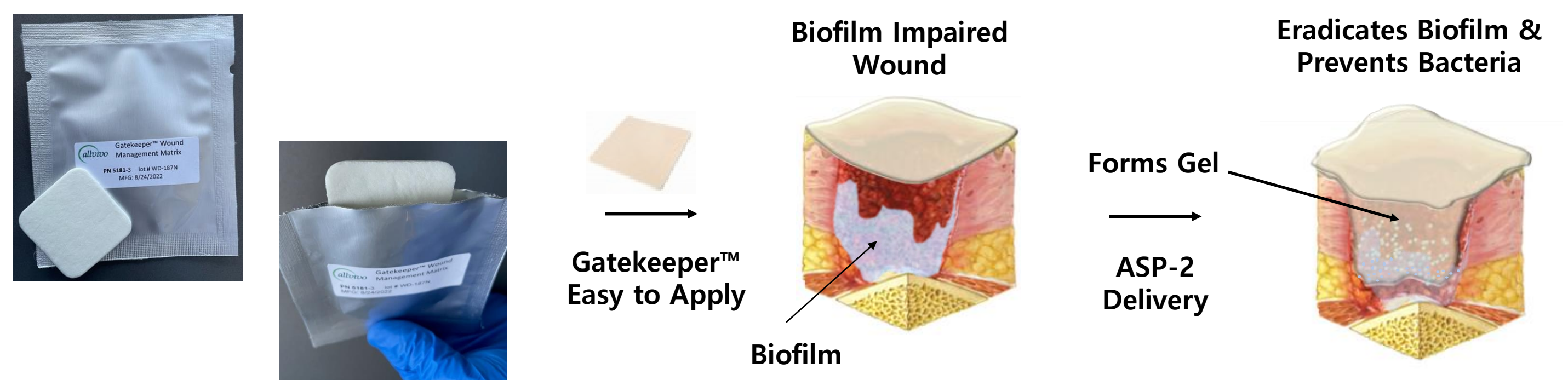
Broad Spectrum, Anti-Biofilm, Biocompatible & Biodegradable

Gatekeeper™ provides a solution to unmet civilian and military wound management needs

Our simple to use Gatekeeper™ Wound Management Matrix delivers a novel engineered antimicrobial peptide (ASP-2) that prevents biofilms from establishing in wounds and on foreign body surfaces while eradicating existing biofilms.

- Broad spectrum, biocompatible, biodegradable
- Effective against drug resistant biofilms
- Lightweight, stable, easy to apply, multipurpose
- Easy to remove by saline flush
- Improved efficacy and biocompatibility relative to silver
- Rapidly biocidal, less prone to resistance development
- Moisture retention, comfort, wound protection

Gatekeeper™ gelling, mucoadhesive matrix conforms to wound surfaces. Intimate contact ensures ASP-2 delivery and eliminates pockets of unchecked bacterial growth.



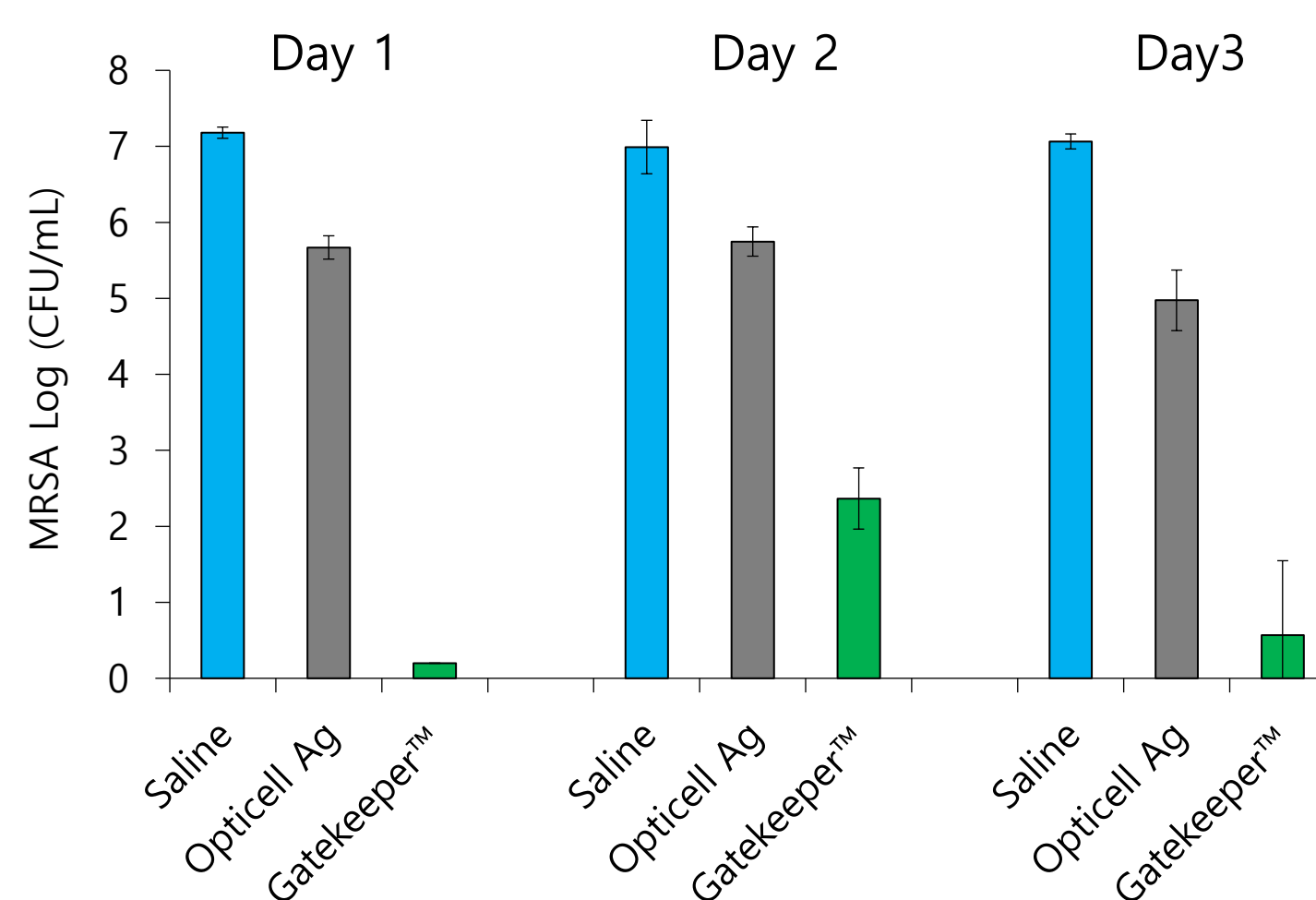
Accomplishments

- Prototypes developed
- Preclinical efficacy
 - > 99.99% kill in mature biofilms of MRSA, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii*
 - Outperforms leading silver-based dressing
 - > 99% kill in porcine infected wounds, 100% wound epithelialization at day 14
- Preclinical safety: biocompatible, no sensitization, no irritation, good therapeutic index
- Sterilization and 2-year stability established
- Regulatory strategy: 510K, FRO category
- IP Protection - Issued & pending patents

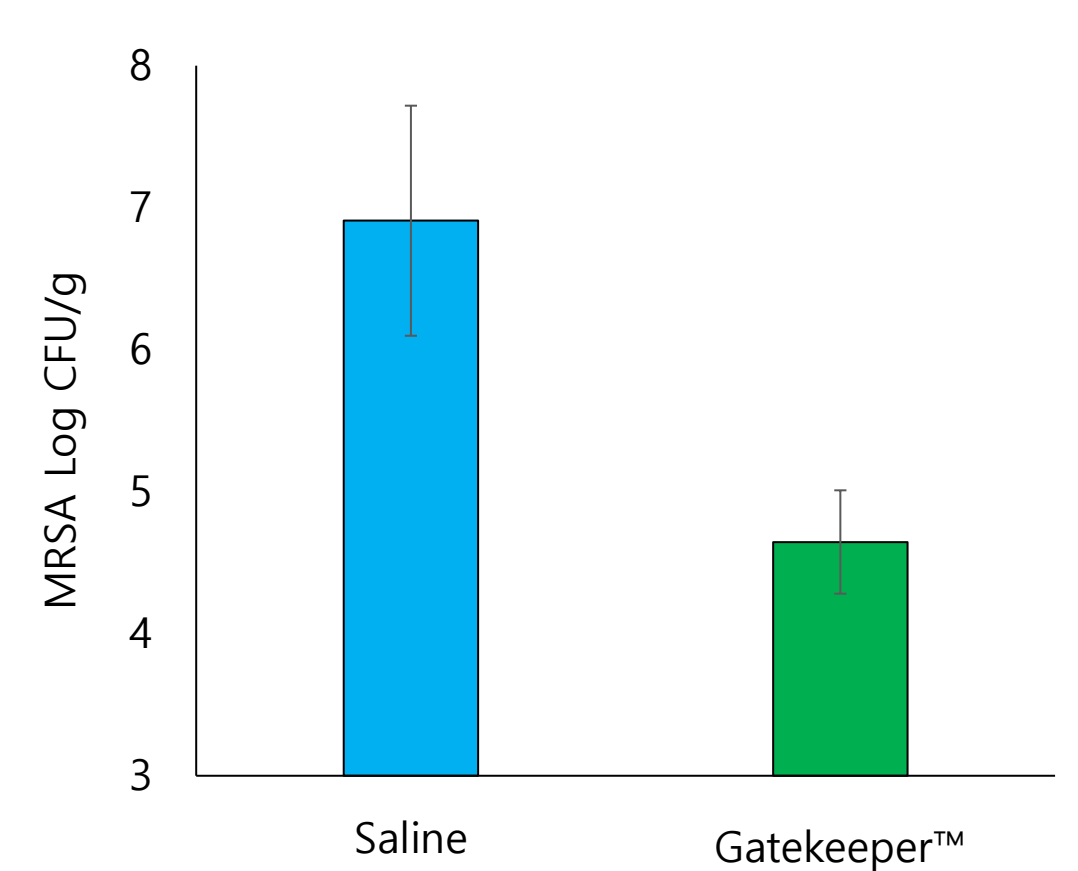
Next steps

- QMS, design controls
- Pilot GMP production
- V&V testing and GLP nonclinical studies

Preclinical Efficacy



Ex vivo efficacy of Gatekeeper™ against MRSA grown on pig skin for 3 days. Treatments were applied one time and left in place for 1- 3 days. N=3.



Log MRSA in porcine excisional wound biopsies at day 3 with saline control or Gatekeeper™. N=3.

Gatekeeper™ promises superior safety and tolerability

	Gatekeeper™	Iodine (PVP-I)	Silver (SSD, AgNO ₃)	Chlorhexidine
Biodegradable	Yes	No	No	No
Biocompatibility Index*	2.46	0.68	Not Calculable <0.006	0.98
Systemic toxicity	Low**	High (denuded skin tissue penetration)	High (large wounds, parenteral entry)	High (large wounds, parenteral entry)
Skin tolerability	Not an irritant (Rabbit) Not a sensitizer (Guinea pig) No adverse effects (Porcine wounds)	Side effects: blistering, crusting, irritation, itching	Side effects: burning feeling, argyria (skin discoloration)	Side effects: burning, itching, swelling, blistering Life-threatening allergic reaction (rare)

1. * BI > 1 indicates favorable biocompatibility BI = ratio of IC50 for fibroblasts to the minimum bactericidal concentration for *S. aureus*. G Muller, A Kramer, J Antimicrob Chemother, 61 (2008) 1281-1287.
 2. ** Gatekeeper™ ASP-2 systemic toxicity: 7-day subcutaneous daily injections in rats. NOAEL is 21X higher than the clinical human product dose. ASP-2 NOAEL : ~1000X the EFSA Tolerable Upper Intake Level for IODINE and ~3600X the US EPA Daily Intake Limit for SILVER.
 Dermal toxicity testing of Gatekeeper™ showed no local or systemic adverse effects when applied to (1) full thickness wounds over 2.5% body surface area (BSA) or (2) to abraded skin over 10% BSA daily for 7 days.

Gatekeeper™ formats



Resources

Private investment

