New Product Category

SUBPAC®

SUBDERMAL WOUND DRESSING

NEW BREAKTHROUGH TECHNOLOGY

In Advanced Wound Care

DISRUPTIVE DEVICE:

Addressing Wound Infection at its Source

✓ Strong Executive Team ✓ Scalable ✓ High Growth Potential

Biomed Labs

SUBPAC® WOUND CARE

Introduction

Everyday thousands of people become permanently disabled, and many others die from largely preventable complications of wound infection following routine and emergency procedures and accidents.

People like Krysten Pacheco, 29, who gave birth through Cesarean section and developed a potentially deadly bacterial blood infection, consequently resulting in hand and foot amputations.[1]

Or Susan Murray Messina, who developed a severe infection after undergoing a routine procedure to remove her ovaries. Susan stated: “I went into cardiac arrest three times, needed eight blood transfusions, and experienced kidney and respiratory failure. I spent 43 days in the hospital, followed by five weeks in long-term rehab where I had to learn to walk and talk again.” [2]

And Rory Staunton, 12, who cut his arm during a gym class which quickly became infected. Rory died from infection complications less than a week after his injury.[3]

Krysten, Susan, and Rory did not have to suffer catastrophic outcomes from infectious disease. These deadly bacteria could have been neutralized within the wounds and healed without complication. Biomed Labs was founded and SUBPAC® invented to address these all-too-often horrific patient outcomes regarding deep tissue wound infection.

SUBPAC® utilizes modern materials and technologies in conjunction with wound wicking (packing) methodologies proven effective over thousands of years - dating to ancient Egyptian practices as documented in the Edwin Smith Surgical Papyrus (circa 1650 BCE) and the Ebers Papyrus (circa 1550 BCE), which describe using wicking lint, animal fat, and honey as antiseptics combined with wine and herbal medicines to pack wounds as infection preventatives as early as 3150 BCE.

Patients, medical practitioners, and medical facilities are all negatively impacted through aggressive, poorly controlled pathogens. Patients and families face increased medical expenses, suffering, disability and death. Medical staff suffer added stress and burnout. Hospitals, physicians, and trauma centers face degraded facility rankings, unreimbursed medical expenses, increased insurance premiums, federal government fines, and malpractice lawsuits.

“Globally, a staggering 310 million major surgeries are performed each year; around 40 to 50 million in the USA and 20 million in Europe. It is estimated that 1–4% of these patients will die, up to 15% will have serious postoperative morbidity, and 5–15% will be readmitted within 30 days. An annual global mortality of around 8 million patients places major surgery comparable with the leading causes of death from cardiovascular disease and stroke, cancer, and injury.” [4]

Current Practice:

Current approaches to wound infection prevention and treatment often require the patient's wound to be left open for one to three weeks when the surgeon believes the risk of closure is too high. Open wounds must be cleaned daily to reduce infection risk, and many require additional wound closure procedures. Patients face restricted lifestyles and require heightened wound care vigilance. Another common approach is installing plastic drain tubes to drain the wound of excess fluids and debris; these drains often clog and must later be removed, requiring additional procedures.

Antibiotics are routinely used and are generally effective in preventing and treating infection; however, some antibiotics are ineffective against certain pathogens. Pathogens can develop resistance — especially with overuse — posing an increased risk of infection with more virulent strains. This leaves surgeons and trauma physicians with few options in fighting infectious wound pathogens.

Our Advanced Alternative: SUBPAC®

SUBPAC® Technology *utilizes a direct attachment of PHMB-treated surgical wicking strips and a multi-layered PHMB-treated Advanced Wound Dressing designed to multi-channel exudate from deep within the wound into the attached absorbent dressing — the only dressing in the world of its kind.*

SUBPAC® represents an entirely new product category. The subdermal SUBPAC® is a complete, single-use, standalone product. It is twice patented with additional patents pending, beta tested, and trade named SUBPAC®. SUBPAC® and deep tissue wicks demonstrate remarkable clinical results: the direct drainage methodology alone achieved 84% infection reduction (Lehigh Valley Study)[9].

Beta trials of methodology and design, as well as consistent and supportive wick packing trials, resulted in overwhelmingly successful outcomes on high-risk patients and procedures in both the prevention and treatment of wound infection. With the enhancement of modern antimicrobial technology (PHMB-treated wicking strips and anti-microbial absorbent pads), clinical trials achieved a near 100% rate of infection control.

Financial Impact for Medical Facilities

"The average hospital could save tens of millions of dollars by eliminating Surgical Site Infections (SSIs). Research indicates that hospitals could save on average $1,800 per surgery, or nearly $28 million annually, by avoiding and reducing unplanned costs associated with SSIs. This financial impact underscores the importance of infection prevention strategies in healthcare settings." [6]

The federal government's Hospital-Acquired Condition (HAC) Reduction Program mandates penalties of 1% of total Medicare payments per facility for the worst-performing 25% of US hospitals on safety metrics such as infections, blood clots, and other complications. The bottom 25% of hospitals with the highest infection rates are currently fined an average of **$328,800** (2021) annually under this program.[7]

Advantages for Surgeons and Medical Personnel

SUBPAC® is an evidence-based tool for high-risk cases. It allows complete wound closure capability, enables effective and easy wound management (including stoma patients), simplifies post-operative wound management, improves patient outcomes, and provides physician peace of mind. Surgery completed — patient healed.

Ease of Adoption & Regulatory Status

Zero workflow disruption. Simple Day 2 removal. Reduced post-operative care complexity. FDA-cleared. USA ISO manufactured.

Applicable Patient Populations

All patients, including high-risk patients (diabetes, stoma, obesity, immunocompromised), patients with infected wounds, emergency/trauma cases, adult and pediatric.

Market Opportunity

The infection control market is projected to reach USD 77.67 billion by 2030 from USD 57.31 billion in 2025, at a CAGR of 6.3%. This growth is driven by the rising prevalence of Hospital-Acquired Illnesses (HAIs), the increasing number of surgical procedures, and continuous advancements in reprocessing technologies.[5]

The SUBPAC® Device:

Clinical and Economic Value Proposition

- Easy to apply and remove
- Minimal training required
- Disposable
- Highly effective
- Works on stoma patients
- Works on infected wounds
- Inexpensive
- Compatible with all standards of care

SUBPAC® Related Case Studies

1. SUBPAC® Device — Non-Published Case Study

Fulmes M., Nalbandian H., Nakhamiyayev V. *"Subcutaneous Dressing Device Is Designed to Reduce the Risk of SSI and Justify the Closure of All Contaminated Wounds/Incisions." Surgeries performed by Mychailo Fulmes MD, PhD at New York Community Hospital (currently Maimonides Midwood Community Hospital).*[9]

Case Study Data	
Study Size:	14 patients
Surgery Type:	Various (high SSI risk category)
Results:	0 new infections — All wounds healed without complication

*SubPac applied to 22 total patients to date without complication

SUBPAC® Methodology — Related Clinical Trials

Subdermal Wound Wicking:

2. Galler et al. — Packing the Closed Incision (Pilot Study)

Fulmes M., Galler A.S., Sinnott R., Park J., Lapos L., Rakhmanine M., Bub D. *"Packing the Closed Incision after Open Colon Resection Can Decrease the Risk of Wound Infection: A Pilot Study."* [8]

Clinical Trial Data	
Study Size:	46 patients
Surgery Type:	Open colon resection (high SSI risk category)
Results:	1 superficial infection / 0 deep tissue infections

3. Gingold, Berardis & Knight Study

Gingold B.S., Berardis J., Knight P. *"Reducing the Risk of Wound Infection in Operations Upon the Colon."* Surgery, Gynecology & Obstetrics, Jan 1984, 158(1):9–12.[10]

Clinical Trial Data	
Study Size:	147 patients
Surgery Type:	Elective colonic operations (high SSI risk category)
Results:	1 superficial infection / 0 deep tissue infections

4. MacFarlane & Ryan Study (1977–1983)

MacFarlane S.D., Ryan J.A. Jr. *"Prevention of Wound Infection After Elective Colorectal Resection."* NIH National Library of Medicine. Am J Surg 1987 Nov;154(5):482–6.[11]

Clinical Trial Data	
Study Size:	243 patients
Surgery Type:	Elective colonic resections (high SSI risk category)
Results:	0 superficial infections / 0 deep tissue infections — All patients healed without complication

5. Kim & Aloia Study (2011–2015)

Kim & Aloia. *"An Inexpensive Modified Primary Closure Technique for Class IV (Dirty) Wounds."* [12]

Clinical Trial Data — Wound Wicking: Class IV (Dirty) Wounds	
Study Size:	14 patients
Surgery Type:	Class IV dirty wounds
Results:	0 new superficial infections / 0 new deep tissue infections — All patients healed without complications

SUBPAC® PHMB Studies — Systematic Review

Article: *"Polyhexamethylene Biguanide and Its Antimicrobial Role in Wound Healing: A Narrative Review" (2023).* 24 independent PHMB studies. Aggregate patient count: 21,325. The review identified evidence supporting a key role for PHMB in the prevention and treatment of wound infection across many different microorganisms and wound types.[13]

AI Systematic Review Meta-Analysis of Studies

Consistent Patterns Across Studies

1.	Wound wicking effectiveness: Multiple independent studies demonstrate 0–2.2% infection rates
2.	High-risk population success: Effective even with multiple comorbidities
3.	Complete closure possible: Eliminates need for open wounds in majority of cases
4.	Cost-effectiveness: Reduces readmissions, additional procedures, extended hospital stays

Competitive Landscape

SUBPAC® Differentiators — No Direct Competitors

Other products offer only a topical dressing and often require additional procedures, products, and additional time during the wound healing process. Biomed Labs has combined and optimized historical medical practices with modern advanced materials for a synergistic, impactful solution to infection control. The cited wicking strip and PHMB studies support Biomed Labs' approach.

SUBPAC® can be applied in approximately one minute and removed two days later in under 30 seconds. No open holes in the patient's body. No plastic drains or fluid collection canisters. No additional procedures or drain removals — only standard-of-care protocols, light dressings, and routine wound cleaning after SUBPAC®.

Comparable Over Current Alternatives

Feature	SUBPAC©	Open Wound	Penrose	J-Drain	All Other Dressings
Single 48-Hr Procedure	Y	S	X	X	X
Deep Tissue Exudate Removal	Y	X	Y	Y	X
Deep Tissue Anti-Microbial	Y	X	NA	X	X
Topical Anti-Microbial	Y	S	S	S	Y
Wound Closure	Y	X	X	X	X
Infection Barrier	Y	X	X	X	X
All-in-One	Y	X	X	X	X
Institutional Cost Savings	Y	X	X	X	X

Key: *Y = Yes* *X = No* *S = Some* *NA = Not Applicable*

Biomed Labs Team & Milestones

Our team has 70 years of executive experience in advanced wound care manufacturing and global sales, along with an additional 20 years of expertise in General, Colorectal, and Cardiothoracic surgical medicine. Jim Wetrich, our CEO, has expanded annual sales in medical device sectors totaling over 2 billion dollars in his executive positions at Molnlycke and Abbott Laboratories. He and Marc Etchells, our CTO, have successfully launched many new medical device projects. Together they have been associated with some of the largest medical products companies in the world, including: Mölnlycke Health Care, Johnson & Johnson, Kendall (currently Cardinal Health), and Abbott Laboratories.

Biomed Labs has secured two broad US patent allowances and has a global PCT patent pending, as well as a new Trademark for the US and EU with our recently branded product name, SUBPAC®. Our USA based assembly and manufacturing system is fully automated and in the optimization process prior to full launch.

Conclusions & Results

SUBPAC® is designed as a standalone, single-use wound closure and multi-purpose treatment device. SUBPAC® works quickly — in only 48 hours — and is patient and medical professional friendly.

SUBPAC® is here and poised to serve as the New Standard in Infection Control

— **Biomed Labs** —

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