A Subdermal Dressing Device Designed to Reduce Surgical Site Infection

Clinical Evidence Summary — Case Series & Pilot Study Data

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SubPac® Wound Care is a patented, FDA 510(k)-cleared subdermal incisional dressing indicated for use in adults and pediatrics. The device is designed to actively remove transudate and exudate from deep within the wound bed into an overlying external dressing, utilizing a defined wound-packing technique combined with super-absorbent materials incorporating PHMB and silver alginate. Across all reported cases to date, SubPac® has achieved a zero-infection outcome in high-risk surgical populations.

Background

Surgical site infections (SSIs) represent the most common and costly category of hospital-acquired infections, accounting for approximately 20 percent of all nosocomial infections in the United States. SSIs occur in an estimated 2–5 percent of patients undergoing inpatient surgery, with an annual incidence ranging from 160,000 to 300,000 cases and an estimated annual cost burden of $3.5–$10 billion. On average, an SSI extends hospital length of stay by 9.7 days. In colorectal surgery specifically, SSI rates range from 3 to 30 percent, rising substantially in contaminated wound classifications.

A foundational pilot study demonstrated that packing a closed incision after open resection significantly reduces infection risk. That study enrolled 47 high-risk laparotomy patients and showed a reduction in SSI incidence in clean-contaminated and contaminated wounds to just 2.2 percent. These results, combined with subsequent clinical experience, formed the evidence base for the development of SubPac® Wound Care.

SubPac® addresses a critical unmet need: creating an aerobic wound environment that is inhospitable to the predominantly anaerobic bacterial species responsible for most SSIs. Upon removal of the packing strips, temporary cutaneous fistulas may form that serve as natural egress pathways for residual transudate and exudate, further reducing the infectious burden in high-risk incisions.

Technology, Materials and Method of Use

Active antimicrobial components include:

Component	Active Agent	Function
Wound Dressing	Algidex Ag® Silver Alginate	Broad-spectrum antimicrobial; promotes moist wound healing
Packing Strips	PHMB	Antiseptic action; biofilm disruption in the wound bed

Application is straightforward and can be completed in under one minute. Packing strips are inserted into the wound at closure and removed at 48 hours. The device is applied once per patient; subsequent care consists of standard light dressing changes and routine wound cleaning. Product pull-testing of up to 40 lbs. has been performed by the manufacturer to address the risk of packing strip retention, as required by the FDA.

SubPac® is indicated for a range of applications, from acute lacerations and traumatic wounds to complex surgical incisions, and is cleared for use in both adult and pediatric populations.

Clinical Impact

The financial and clinical consequences of SSI are well documented. In addition to extended hospital stays, SSIs are associated with increased rates of emergency department visits, unplanned readmissions, reoperation, and medical-legal liability. A meaningful reduction in SSI incidence translates directly into reduced cost-of-care for patients, hospitals, and insurers alike.

Beyond economics, SubPac® is designed to change surgical decision-making. Surgeons currently managing contaminated incisions often leave wounds open to mitigate infection risk — a necessary but patient-impacting trade-off. SubPac® provides a mechanism by which contaminated incisions may be closed primarily, with the dressing system managing the infectious environment. This has the potential to meaningfully improve patient quality of life, accelerate recovery, and reduce the psychological burden of open wound management.

Case Series Results (n=14)

The following case series represents patients treated with SubPac® across a range of colorectal and general surgical procedures. The patient population was notable for a high burden of comorbidities including obesity, diabetes mellitus, and stoma presence — factors independently associated with elevated SSI risk. Despite this, all 14 patients achieved infection-free outcomes with no unplanned readmissions.

Pt.	Age	Sex	Comorbidities	Diagnosis	Procedure	Outcome
1	83	F	Obesity, Diabetes, COPD	Sigmoid Colon Cancer	Laparoscopic colon resection, hand port incision	No infection No readmission
2	60	M	Obesity, Smoker	Temporary Ostomy	Removal of temporary ostomy	No infection No readmission
3	33	F	Obesity, Diabetes	Intra-Abdominal Abscess	Exploratory laparotomy, abscess drainage, closed incision	No infection No readmission
4	82	F	Peritonitis, Septic Shock	Perforated Diverticulitis	Sigmoid resection, ostomy (Hartmann's procedure)	No infection No readmission
5	65	M	Obesity, Diabetes	Acute Diverticulitis	Temporary ostomy	No infection No readmission
6	65	M	Obesity, Diabetes	Temporary Ostomy	Removal of temporary ostomy	No infection No readmission
7	25	M	None	Pilonidal Cyst	Tissue removal from coccygeal region	No infection No readmission
8	55	F	Obesity, Diabetes	Ruptured Appendicitis	Appendectomy	No infection No readmission
9	51	F	Obesity	Colovesicular Fistula / Diverticulitis	Open low anterior resection	No infection No readmission
10	62	F	Obesity	Left-Sided Colon Cancer	Hand-assisted laparoscopic hemicolectomy	No infection No readmission
11	52	F	Obesity, Hypertension, Hyperlipidemia	Right Colon Neuroendocrine Tumor	Laparoscopic hemicolectomy, extended incision	No infection No readmission
12	82	M	Diabetes, Partial Bowel Obstruction, Anemia	Cecal Tumor with Hepatic Metastasis	Laparoscopic right hemicolectomy with extended incision and liver wedge	No infection No readmission
13	81	F	Hypertension, Hypothyroidism	History of Diverticulitis, Temporary Ostomy	Colorectal anastomosis via midline incision	No infection No readmission
14	60	M	Obesity, Smoker	History of Diverticulitis, Temporary Ostomy	Removal of temporary ostomy	No infection No readmission

Zero infections (0%) and zero readmissions (0%) across all 14 reported cases — including patients in septic shock, immunocompromised states, and contaminated wound classifications.

Conclusion

SubPac® Wound Care represents a clinically meaningful advance in surgical site infection prevention. The available research, pilot study data, and case series consistently demonstrate a dramatic reduction in infection rates across high-risk patient populations and contaminated wound classifications. The ability to close wounds that would otherwise be left open represents a qualitative shift in post-operative care — one with positive implications for patient outcomes, clinical workflow, and healthcare economics.

SubPac® Wound Care is currently available. The product and technology continue to be evaluated for expanded applications across multiple surgical and wound-care disciplines.

References

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