3M | Prevena™
Incision Therapy

PRM | Proactive Risk Management (PRM) with 3M™ Prevena™ Therapy

Abdominal Surgery

Advancing the standard of care

Helping to protect abdominal surgery incisions beyond the OR

Abdominal surgery patient care doesn't end in the OR

In an increasingly overwhelmed healthcare system, surgeons are asked to do more with fewer resources than ever before, creating complications for patients that extend beyond the operating room. Postoperative concerns include swelling, infection and improper tissue integration in and around the surgical site.

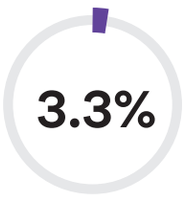
These complications can create a ripple effect of consequences, like disrupted healing, extended hospital stays and poor patient outcomes, which inevitably cause further disruption that impacts quality and cost of care. Today's complex care environment makes protecting against the ripple effect of these complications a high priority.

The implications of postoperative complications

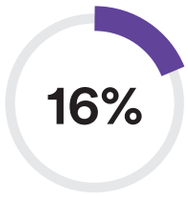
Emergency abdominal surgery presents surgeons with unique challenges for wound healing, considering unoptimised patient risk factors, poor physiological reserves, and a greater risk of wound contamination.

Rates of surgical site infections (SSIs) are much higher with abdominal surgery than with other types of surgery, depending on the level of contamination.

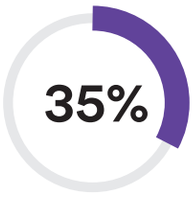
Surgical site infections complicate:



3.3% estimate across all surgical procedures in Australian public hospitals[1]



16% of major abdominal procedures had complications, 9% had deep SSIs[2]



35% of open abdominal procedures[2]

SSIs complicate up to:

- 32% of pancreaticoduodenectomies[3]
- 9.4% - 14% of gastrointestinal surgery in high-middle income countries[4]
- 10-30% of colorectal procedures[5]

Gastrointestinal surgery patients, with postoperative SSI, are associated with:

9-10 days

average additional hospital length of stay vs. patients with SSI 3 x longer than those without SSI[4]

Indirect and direct costs

$3.3 Billion AUD

total annual national cost associated with SSI – direct and indirect costs[1]

$18,800

average additional direct cost to hospital[1]

Managing the ripple effect

Given the ever-increasing challenges of abdominal surgery, clinicians and surgeons need support to safeguard their work and improve the patient's healing journey. In their efforts to effectively manage the ripple effect of surgical complications they are often motivated to favor low-touch care, including solutions that promote:

- Efficiency and cost-effectiveness
- Minimal hospital stays
- Minimal complications
- Low re-admits
- Portability of care
- Home-based recovery
- Telehealth consultations

Consider how minimising these ripple effects would affect your caseload and budgets, particularly readmissions and prolonged lengths of stay.

The power to help protect outcomes beyond the OR

3M™ Prevena™ Therapy has shown to help reduce the incidence of seromas and superficial surgical site infection. It helps protect the incision site after surgery up to 7 days – extending your control over postoperative healing and helping patients at risk of developing complications.

Prevena Therapy offers surgeons the confidence to help protect patients beyond the OR.

Acting as a barrier to external contamination[6]

Delivering continuous -125 mmHg up to 7 days[7]

Helping to hold incision edges together[8]

Decreasing lateral tension of sutured/stapled incisions[8]

Removing fluids and infectious materials**

Reducing oedema[9]

*The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at HCBGRegulatory.3M.com

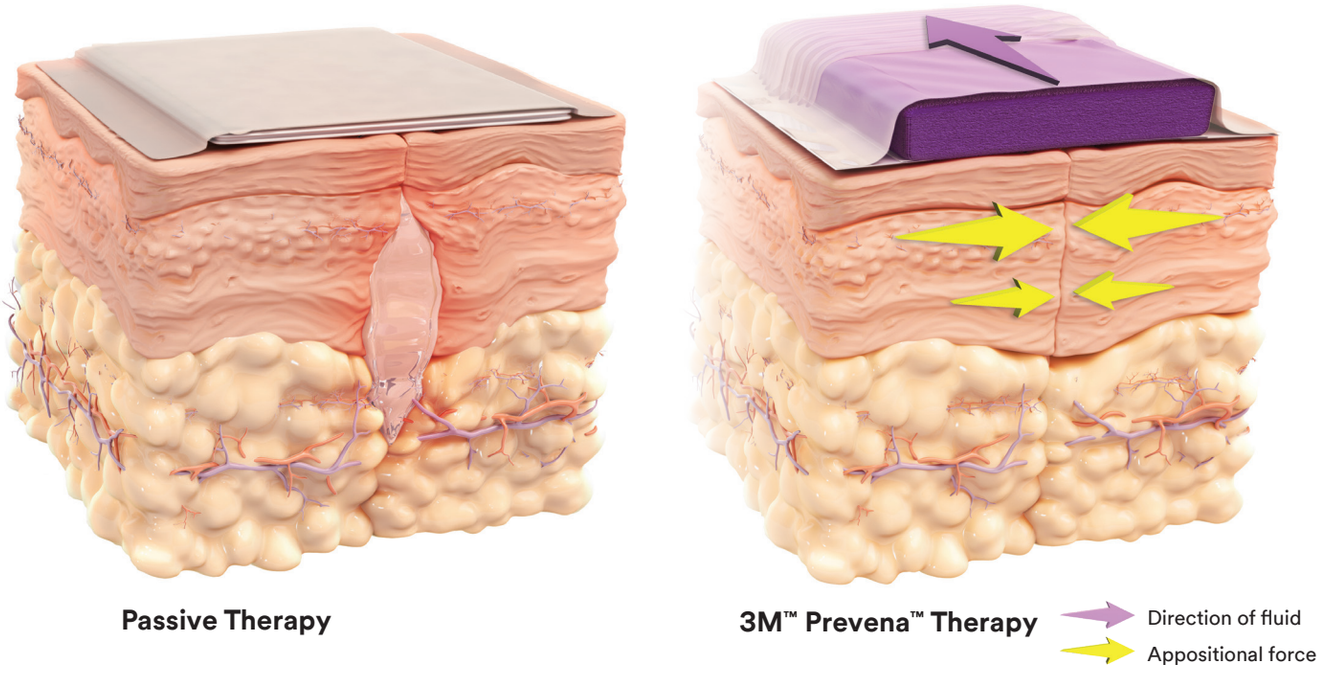
**In a canister.

Prevena™ Dressings and Prevena Restor™ Dressings can be applied to various procedures and anatomical locations.

The advanced science of 3M™ Prevena™ Therapy

Prevena Therapy utilises continuous -125 mmHg negative pressure therapy, reticulated open cell foam (ROCF) dressing technology, and optimised exudate management (replaceable canister) to help enhance healing. Visible and audible safety alarms automatically notify clinicians and patients of system alerts.

Prevena Therapy brings the incision edges together, reduces lateral tension, and allows for improved fluid management.[8-10]



Additional features to help optimise postoperative care

- Contours in Prevena Dressings allow for even distribution of negative pressure
- Adhesive film creates a barrier to external contaminants
- Designed to conform to allow movement
- Multiple sizes and configurations
- Prevena Dressings are shower friendly*

*See Prevena Therapy Patient and Clinician Guides for additional details.

Patients and procedures that may benefit from 3M™ Prevena™ Therapy

A multidisciplinary group of surgical and infectious disease experts developed an algorithm to guide when to consider using closed-incision negative pressure therapy (ciNPT).[8] They recommend that surgeons consider using ciNPT for patients at high risk for developing surgical site occurrences (SSOs) or who are undergoing a high-risk procedure or a procedure that would have highly morbid consequences if a surgical site infection (SSI) occurred.

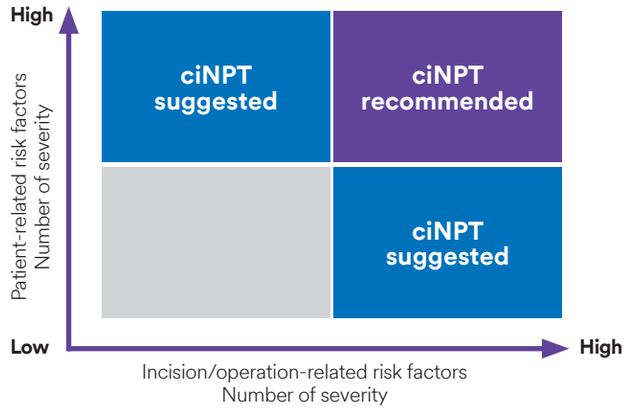
Consensus recommendations based on:

- Literature review
- ciNPT experiences
- Known risk factors for SSOs

Findings:

- Numerous publications reported SSI risk factors, with the most common including obesity (body mass index ≥30 kg/m^2); diabetes mellitus; tobacco use; or prolonged surgical time
- It is recommended that the surgeon assess the individual patient's risk factors and surgical risks

Risk factor assessment for ciNPT



Additional factors to consider:

Patient-related risk factors		General incision-related factors	
• Diabetes mellitus	• Active alcoholism	• High tension incision	• Prolonged operation time
• American Society of Anesthesiologist score ≥3	• Male sex	• Repeated incisions	• Post-surgical radiation
• Advanced age	• Hematoma	• Extensive undermining	• Mechanically unfavorable site
• Obesity	• Chronic renal insufficiency	• Traumatised soft tissue	
• Active tobacco use	• Chronic obstructive pulmonary disease	• Oedema	
• Hypoalbuminemia		• Contamination	
• Corticosteroid usage		• Emergency procedure	

Procedure/operation-related risk factors:

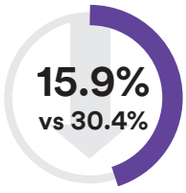
General	Plastic	Orthopedic	Vascular	Cardiovascular
• Open general	• Post-bariatric abdominoplasty	• Open reduction and internal fixation of fractures	• Above/below knee amputation	• Sternotomy
• Open colorectal	• Breast reconstruction	• Fasciotomy	• Synthetic graft implantations	
• Open urology	• Big soft tissue defects	• Above/below knee amputation		
• Open obstetrics/ gynaecology	• Soilage risk			
• Incisional hernia repair				

Clinically demonstrated to help safeguard abdominal surgery incisions while minimising risk

Clinical evidence helps support the safety and effectiveness of 3M™ Prevena™ Therapy versus conventional wound dressings for abdominal surgery.

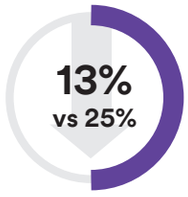
A meta-analysis of 7 peer-reviewed studies[10] in emergency laparotomies demonstrated Prevena Therapy and negative pressure -125 mmHg helped significantly reduce the risk of various surgical site complications (SSCs) while helping to improve health economic outcomes.

Clinical complications



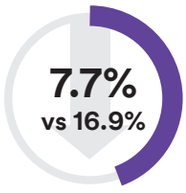
Overall surgical wound complication

7 studies; (*p*= .001)



Surgical site infection

7 studies; (*p*<0.001)*



Dehiscence**

3 studies; (*p*= .003)

*Statistically significant (*p*<0.05).
Calculation(s) are derived based on relative patient group incidence rate reported in this study.
**The use of Prevena Therapy for reduction in the incidence of deep SSI and dehiscence has not been reviewed by the U.S. FDA.

3M™ Prevena™ Therapy for high-risk pancreaticoduodenectomies

In a single-center randomized controlled trial, Prevena Therapy was shown to help reduce the rate of surgical site infections and inpatient cost for high-risk patients undergoing open pancreaticoduodenectomy surgery.

Javed A, Teinor J, Wright M, et al. Negative pressure wound therapy for surgical-site infections: A randomized trial. Annals of Surgery. 2019; 269(6):1034-1040.

Study Design:
This single-center randomized control trial evaluated the efficacy of closed-incision negative pressure therapy (ciNPT) (Prevena Therapy) to decrease surgical site infections (SSI) after open pancreaticoduodenectomy.

- Patients undergoing pancreaticoduodenectomy procedures were eligible if considered to be high-risk for SSI
- Surgeries included: open pancreaticoduoduodenectomy with preoperative billiary stenting, adjuvant chemotherapy, or both
- A total of 123 patients analyzed: Prevena Therapy (n=62) v. standard of care (SOC) (n=61)
- Preoperative and operative characteristics were not significantly different between the two groups
- The primary outcome was 30-day SSI (superficial or deep)

Summary

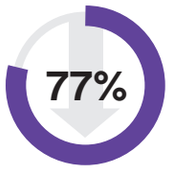
This randomised controlled trial from Johns Hopkins Hospital demonstrated significantly lower SSI rates in high-risk patients receiving Prevena Therapy after pancreaticoduodenectomy (31.1% vs. 9.7%; p=0.003)*. SSIs resulted in an increased hospitalization cost of $9,778 USD per patient. Implementing Prevena Therapy into surgical practice can help reduce the risk of potential complications and associated costs to patient health and care.

Surgical site infection

9.7% (6/62) Prevena Therapy vs.
31.1% (19/61) SOC

(p=0.003)*

Superficial surgical site infection



6.5% (4/62) Prevena Therapy vs.
27.9% (17/61) SOC

(p=0.002)*

Inpatient costs due to surgical site infection

Increase of cost for patient with SSI

Median inpatient cost per non-SSI patient

Additional inpatient cost due to SSI

*Statistically significant (p<0.05).
Calculation(s) are derived based on relative patient group incidence rate reported in this study.

3M™ Prevena™ Therapy for high-risk laparotomies

Patients undergoing laparotomy surgery experienced reduced rates of wound complications when using Prevena Therapy versus standard of care.

Zaidi A, El-Masry S. Closed incision negative pressure therapy in high-risk general surgery patients following laparotomy: a 3M™ Prevena™ study. Colorectal Disease 2016; 19(3):283-287.

Study Design:

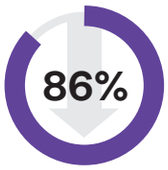
This retrospective observational study compared the rate of wound complications requiring intervention in high-risk surgical patients who received closed-incision negative pressure therapy (ciNPT) (Prevena Therapy) or standard of care (SOC) following laparotomy.

- Charts were retrospectively reviewed for 181 high-risk patients who presented for elective or emergency laparotomy; Prevena Therapy (n=69); SOC (n=112)
- High-risk inclusion criteria were obesity (BMI ≥ 35 kg/m2), or ≥ 2 of the following risk factors: malignancy, smoking, immunosuppression, malnutrition, emergency surgery, diffuse atherosclerotic disease
- Prevena Therapy (n=69) was applied over the closed incision in the operating room immediately after skin closure and remained in place for 7 days
- All patients were followed until postoperative day 30

Summary

Prevena Therapy demonstrated to be an effective method of postsurgical management in general surgery patients considered to have risk of developing wound complications following emergency or elective laparotomy. The study concluded that Prevena Therapy was associated with a positive clinical outcome.

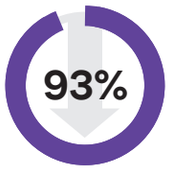
Surgical site complications



2.9% (2/69) Prevena Therapy vs. 20.5% (23/112) SOC

(p<0.0009)*

Deep surgical site infection



1.4% (1/69) Prevena Therapy vs. 20.5% (23/112) SOC

(p<0.0002)*

*Statistically significant (p<0.05).
Calculation(s) are derived based on relative patient group incidence rate reported in this study.

3M™ Prevena™ Therapy for high-risk colorectal surgeries

High-risk patients undergoing colorectal surgery experienced a significantly reduced rate of wound complications when using Prevena Therapy versus standard of care.

Curran T, Alvarez D, Pastrana Del Valle J, et al. Prophylactic closed incision negative pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds. Colorectal Disease. 2019; 21(1):110-118.

Study Design:

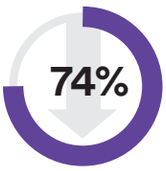
This retrospective comparative cohort study compared the incidence of surgical site infection (SSI) in high-risk open colorectal surgery patients who received closed-incision negative pressure therapy (ciNPT) (Prevena Therapy) or standard of care (SOC).

- National Surgical Quality Improvement Program (NSQIP) reviewed patients at high-risk for SSI underdoing open abdominal colorectal surgery were selected
- NSQIP facilitated the standardized assignment of SSI status with uniform 30-day follow-up
- High-risk defined patients defined as having ≥ 1 of the following risk factors: pre or postoperative stoma, diabetes, obesity, preoperative steroid or immunosuppressant use, and contaminated or dirty wound
- Validated SSI risk score used to create matched cohort subset; Prevena Therapy (n=77) & SOC (n=79)
- The primary outcome was SSIs defined as superficial SSI, deep SSI, or dehiscence at 30 days per NSQIP

Summary

The study concluded that Prevena Therapy was associated with a significant reduction in overall wound complications as defined by NSQIP. (25.3% vs. 6.5%; $p<0.01$*). The study also found a significant decrease in superficial SSI ($p<0.01$)*.

Wound complication



6.5% (5/77) Prevena Therapy vs. 25.3% (20/79) SOC

($p<0.01$)*

Readmission

8% (6/77) Prevena Therapy vs. 24% (19/79) SOC

($p<0.01$)*

*Statistically significant ($p<0.05$).
Calculation(s) are derived based on relative patient group incidence rate reported in this study.

Clinical evidence supporting 3M™ Prevena™ Therapy in abdominal surgery

Level of clinical evidence rating[11]

- **Level 1:** Evidence obtained from at least one properly designed randomised controlled trial
- **Level 1b:** Systematic reviews (with homogeneity) of randomised controlled trials
- **Level 2:** Evidence obtained from well-designed controlled trials without randomisation
- **Level 2b:** Individual cohort study or low quality randomised controlled trials (e.g., <80% follow-up)
- **Level 3:** Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- **Level 4:** Case series (and poor quality cohort and case-control studies)
- **Level 5:** Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Wound/ Surgery Type	Level of Evidence	Citation
Abdominal wall reconstruction	3	Ayuso SA, Elhage SA, Okorji LM, et al. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. *Ann Plast Surg*. 2022; 88(4):429-433.
Colorectal surgery	1	Arellano ML, Serrano CB, Guedea M, et al. Surgical Wound Complications After Colorectal Surgery with Single-Use Negative-Pressure Wound Therapy Versus Surgical Dressing Over Closed Incisions: A Randomized Controlled Trial.*Advances in Skin and Wound Care.* 2021 Jun 26.
	1	Murphy P, Knowles S, Chadi S. Negative pressure wound therapy use to decrease surgical nosocomial events in colorectal resections. *Ann Surg.* 2019; 270(1):38-42.
	3	Curran T, Alvarez D, Pastrana Del Valle J, et al. Prophylactic closed incision negative pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds. *Colorectal Disease.* 2019; 21(1):110-118.
Emergency laparotomy	3	Chung J, Ali O, Hawthornthwaite E, et al. Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis. *Surgery.* 2021; 170(5):1568-1573.
	3	Liu D, Cheng C, Islam R, et al. Prophylactic Negative-pressure Dressings Reduce Wound Complications and Resource Burden After Emergency Laparotomies. *J Surg Res.* 2021 Jan;257:22-31.
Ileostomy	2	Poehnert D, Hadeler N, Schrem H, et al. Decreased superficial surgical site infections, shortened hospital stay and improved quality of life due to incisional negative pressure wound therapy after reversal of double loop ileostomy. *Wound Repair and Regeneration.* 2017;25(6):994-1001.
Laparotomy	1	Di Re AM, Wright D, Toh JWT, et al. Surgical wound infection prevention using topical negative pressure therapy on closed abdominal incisions - the 'SWIPE IT' randomized clinical trial. *J Hosp Infect.* 2021 Apr;110:76-83.
	1	Leitao MM Jr, Zhou QC, Schiavone MB, et al. Prophylactic Negative Pressure Wound Therapy After Laparotomy for Gynecologic Surgery: A Randomized Controlled Trial. *Obstet Gynecol.* 2021 Feb 1;137(2):334-341.
	3	Zaidi A, El-Masry S. Closed incision negative pressure therapy in high-risk general surgery patients following laparotomy: 3M™ Prevena™ Therapy retrospective study. *Colorectal Disease.* 2016; 19(3):283-287.
Open abdominal surgery	1	Gök MA, Kafadar MT, Yeğen SF. Comparison of negative-pressure incision management system in wound dehiscence: A prospective, randomized, observational study. *J Med Life.* 2019;12(3):276-283.
Open hernia repair	3	Licari L, Campanella S, Carolla C, et al. Closed incision negative pressure therapy achieves better outcome than standard wound care: clinical outcome and cost-effectiveness analysis in open ventral hernia repair with synthetic mesh positioning. *Cureus.* 2020. 12(5):e8283.
Open pancreatic-oduodenectomy	1	Javed A, Teinor J, Wright M, et al. Negative pressure wound therapy for surgical-site infections: A randomized trial. *Annals of Surgery.* 2019; 269(6):1034-1040.

Compatible with 3M negative pressure therapy devices

3M™ Prevena™ Plus 125 Therapy Unit

One single-use negative pressure therapy unit compatible with all 3M™ Prevena™ Dressings.

Negative pressure options:

- Pre-set, continuous negative pressure therapy at -125 mmHg for up to 7 or 14 days
- Disposable, single patient use
- Rechargeable battery

Specifications:

- Dimensions: Approx 8.9 × 16.3 × 5.49cm
- Weight with empty canister: 0.29kg

Prevena Dressings are also compatible with 3M traditional negative pressure therapy devices:

3M™ V.A.C.® Ulta Therapy Unit

3M™ ActiV.A.C.® Therapy Unit

The same proven technology as the original 3M™ Prevena™ Incision Management System with new features to help optimise postoperative care.

Extended therapy time
Up to 14 days

Precision designed
Dressings seamlessly conform to the patient

Expanded coverage area
Large dressings deliver therapy to the incision and surrounding soft tissue envelope

Easy to use
A variety of peel-and-place dressings are available, plus a customisable option

Additional customer resources:

- Live clinical training and product support 3M educates thousands of healthcare professionals annually
- Free product evaluation program
- Clinical and technical support hotlines
- On demand clinical and technical support

Ordering Information

SKU	Description	UOM
Therapy Devices		
PRE4010.S	3M™ Prevena™ Plus 125 Therapy Unit – 14 day	Each
Dressings		
PRE1055.S	3M™ Prevena™ Peel and Place Dressing – 20 cm	Case of 5
PRE1155.S	3M™ Prevena™ Peel and Place Dressing – 13 cm	Case of 5
PRE3255.S	3M™ Prevena™ Plus Peel and Place Dressing – 35 cm	Case of 5
PRE4055.S	3M™ Prevena™ Plus Customizable Dressing	Case of 5
PRE5055.S	3M™ Prevena Restor™ Arthro●Form™ Dressing – 33 cm x 30 cm	Case of 5
PRE5155.S	3M™ Prevena Restor™ Arthro●Form™ Dressing – 46 cm x 30 cm	Case of 5
PRE5255.S	3M™ Prevena Restor™ Bella●Form™ Dressing – 21 cm x 19 cm	Case of 5
PRE5355.S	3M™ Prevena Restor™ Bella●Form™ Dressing – 24 cm x 22 cm	Case of 5
PRE5455.S	3M™ Prevena Restor™ Bella●Form™ Dressing – 29 cm x 27 cm	Case of 5
Accessories		
PRE1095.S	3M™ Prevena™ 45 ml Canister	Case of 5
PRE4095.S	3M™ Prevena™ Plus 150 ml Canister	Case of 5
PRE9090.S	3M™ Prevena™ Therapy V.A.C.® Connector	Case of 10
Kits		
PRE1001.S	3M™ Prevena™ Incision Management System – 20 cm	Each
PRE1101.S	3M™ Prevena™ Incision Management System – 13 cm	Each
PRE3201.S	3M™ Prevena™ Plus Incision Management System – 35 cm	Each
PRE4001.S	3M™ Prevena™ Plus Customizable Incision Management System	Each
PRE5001.S	3M™ Prevena Restor™ Arthro●Form™ Incision Management System – 33 cm x 30 cm	Each
PRE5101.S	3M™ Prevena Restor™ Arthro●Form™ Incision Management System – 46 cm x 30 cm	Each
PRE5221.S	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 21 cm x 19 cm	Each
PRE5321.S	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 24 cm x 22 cm	Each
PRE5421.S	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 29 cm x 27 cm	Each

Notes

Help protect your patients beyond the OR with 3M™ Prevena™ Therapy.

For more information or to request an evaluation, contact your 3M representative

Note: Specific indications, limitations, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application.

References:

1. R Royle, B Gillespie, W Chaboyer, J Byrnes, S Nghiem. The burden of surgical site infections in Australia: a cost-of-illness study; Journal of Infection and Public Health; 2023;16(5):792-798.
2. Alkaaki A, x-Radi OO, Khoja A, et al. Surgical site infection following abdominal surgery: a prospective cohort study. Can J Surg. 2019;62(2):111-117.
3. Suragul W, Rungsakulkij N, Vassanasiri W, et al. Predictors of surgical site infection after pancreaticoduodenectomy. BMC Gastroenterology. 2020;20(1):201. Published 2020 Jun 26. 10.1186/s12876-020-01350-8.
4. Global Surgery Collaborative. Surgical site infection after gastrointestinal surgery in high-income, middle-income and low-income countries: a prospective, international, multicentre cohort study; Lancet Infectious Disease. 2018;18:516-525.
5. Falconer R, Ramsay G, Hudson J, Watson A, the Highland Colorectal SSI Group. Reducing surgical site infection rates in colorectal surgery – a quality improvement approach to implementing a comprehensive bundle. Colorectal Disease. 2021;23;2999-3007.
6. Colli A. First experience with a new negative pressure incision management system on surgical incisions after cardiac surgery in high risk patients. Journal of Cardiothoracic Surgery. 2011 December 6;6(1):160.
7. Grauhan O, Navasardyan A, Hofmann M, Muller P, Stein J, Hetzer R. Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy. J Thorac Cardiovasc Surg. 2013;145:1387-1392.
8. Wilkes RP, Kilpadi DV, Zhao Y, et al. Closed Incision Management With Negative Pressure Wound Therapy (CIM): biomechanics. Surgical Innovation. 2012;19(1):67-75.
9. Kilpadi DV, Cunningham MR. Evaluation of closed incision management with negative pressure wound therapy (CIM): hematoma/seroma andinvolvement of the lymphatic system. Wound Repair Regen. 2011;19(5):588-596.
10. Lakhani A, Jamel W, Riddiough G, Cabalag C, Stevens S, Liu D. Prophylactic negative pressure wound dressings reduces wound complications following emergency laparotomies: A systematic review and meta-analysis. Surgery, 2022. Vol 172 (3); p 949-954.
11. Sullivan D, Chung KC, Eaves FF, et al. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. PlastReconstr Surg. 2011;128(1):311-314.

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