
3M
Prevena™
Incision Therapy
Protecting.
Beyond.
Spine surgery and more

In the modern era where advanced tools and implants are prevalent, surgical site complications continue to be a real issue after spine surgery

"SSI following spine surgery causes major morbidity and greatly impedes functional recovery. In the modern era of advanced operative techniques and improved perioperative care, SSI remains a problematic complication."[1]

SSIs after spine surgery pose a significant burden on the health care system

It is estimated that in 2005, SSIs extended hospital lengths of stay on average by 9.7 days and incurred an additional cost of $20,842 per admission.[2]

A total of 90 patients were identified that resulted in 110 readmissions, and these patients cumulatively underwent 138 irrigation and debridement (I&D) procedures for the management of postoperative spine SSI.

The average length of stay for the index operation and secondary

readmissions were 6.9 and 9.6 days, respectively.[2]

The mean direct cost of the treatment for SSI was

$16,242.[2]

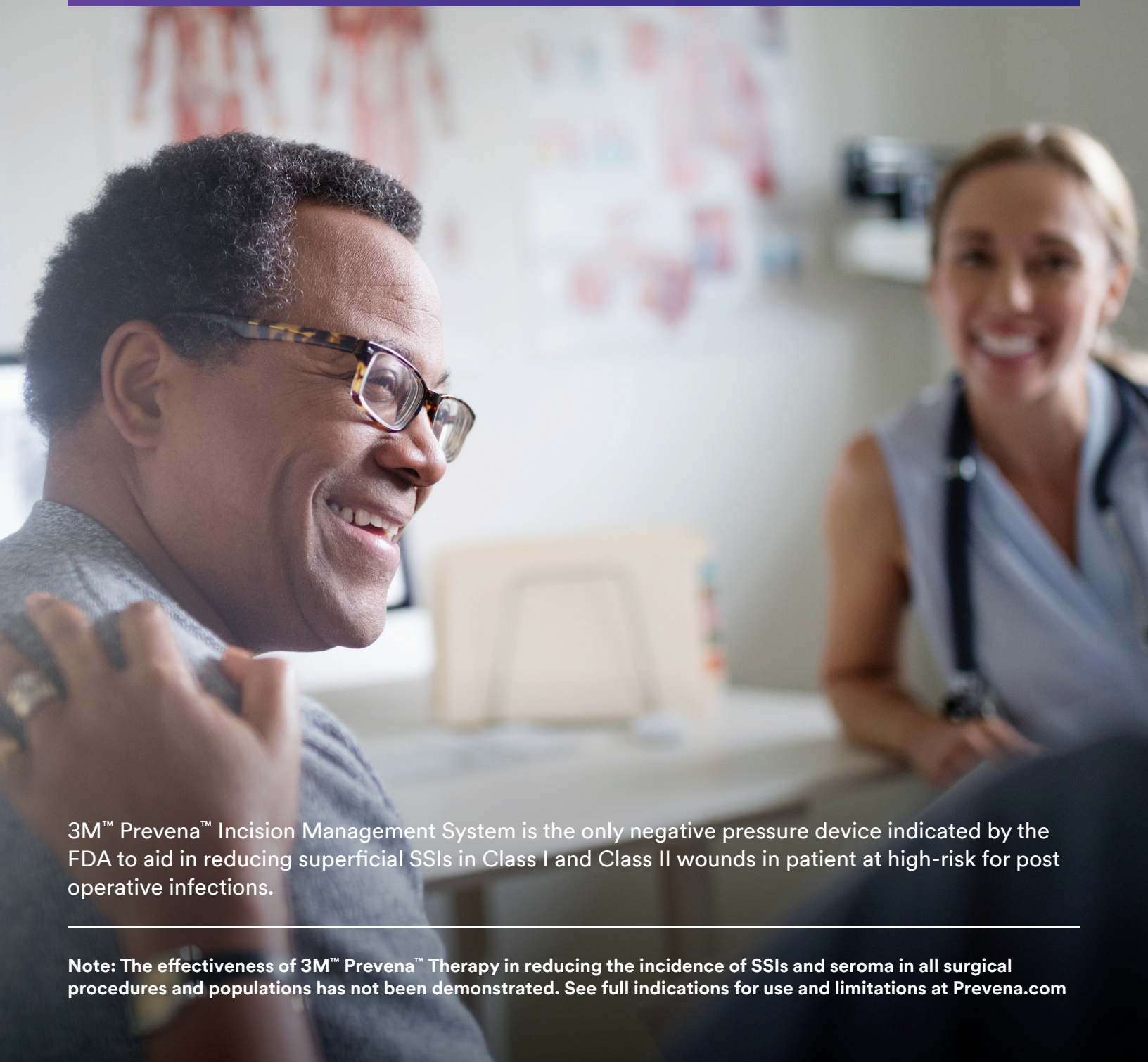
The length of stay, the number of levels fused, methicillin-resistant Staphylococcus aureus (MRSA), decreased serum albumin on readmission, and the number of I&D procedures required were significantly associated with

increased treatment costs.[2]

How 3M™ Prevena™ Therapy can help

The FDA granted the following Indications for Use:

3M™ Prevena™ 125 and 3M™ Prevena™ Plus 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena 125 and Prevena Plus 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.



3M™ Prevena™ Incision Management System is the only negative pressure device indicated by the FDA to aid in reducing superficial SSIs in Class I and Class II wounds in patient at high-risk for post operative infections.

Note: The effectiveness of 3M™ 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 Prevena.com

Clinical evidence supporting this indication

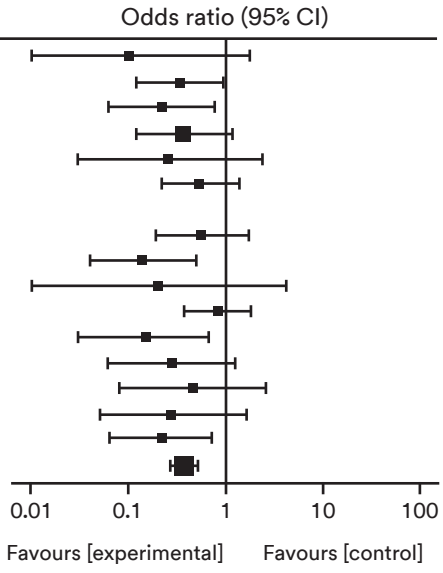
A systematic literature review and associated meta-analysis were used to support the safety and effectiveness of 3M™ Prevena™ Therapy over closed incisions in reducing the incidence of SSIs and seromas versus conventional wound dressings to support the clearance of this indication.

- Out of 426 studies in the initial search, ultimately, sixteen (16) prospective studies were included in this meta-analysis for SSI characterization.
- A total of up to 6,187 evaluable patients were included in this meta-analysis for SSI with 1,264 in the Prevena Therapy (treatment) group and 4,923 in the conventional wound dressing (control) group.
- 9 randomized controlled trials (RCTs) were included in a subgroup analysis for SSI in high risk patients.

Prevena Therapy demonstrated the greatest benefit in aiding in the reduction of the incidence of superficial SSIs in Class I and II wounds.

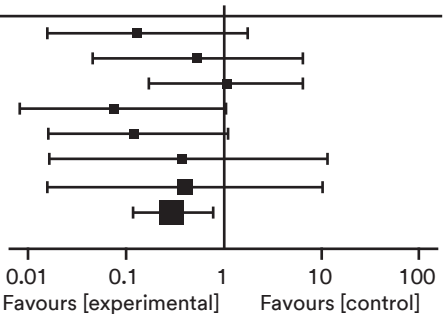
Forest plot of meta-analysis on surgical site infection

	Treatment			Control			
Study or subgroup	Events	Total	%	Events	Total	%	Odds ratio (95% CI)
Cantero 2016	0	17	(0.0)	9	43	(20.9)	0.10 (0.01, 1.89)
Dimuzio P 2017	6	59	(10.2)	15	60	(25.0)	0.34 (0.12, 0.95)
Grauhan O 2013	3	75	(4.0)	12	75	(16.0)	0.22 (0.06, 0.81)
Grauhan O 2014	3	237	(1.3)	119	3508	(3.4)	0.37 (0.12, 1.16)
Gunatiliake RP 2017	1	39	(2.6)	4	43	(9.3)	0.26 (0.03, 2.40)
Lavryk O 2016	7	55	(12.7)	21	101	(20.8)	0.56 (0.22, 1.40)
Lee AJ 2016	0	27	(0.0)	0	17	(0.0)	Not estimable
Lee K 2017	6	53	(11.3)	9	49	(18.4)	0.57 (0.19, 1.73)
Matatov T 2013	3	52	(5.8)	19	63	(30.2)	0.14 (0.04, 0.51)
NCT01341444	0	28	(0.0)	2	30	(6.7)	0.20 (0.01, 4.35)
NCT02196310	13	145	(9.0)	16	154	(10.4)	0.85 (0.39, 1.83)
NEWMAN JM 2017	2	80	(2.5)	12	80	(15.0)	0.15 (0.03, 0.67)
Redfern RE 2017	2	196	(1.0)	14	400	(3.5)	0.28 (0.06, 1.26)
Ruhstaller K 2017	2	61	(3.3)	4	58	(6.9)	0.46 (0.08, 2.60)
Sabat J 2016	2	3D	(6.7)	7	33	(21.2)	0.27 (0.05, 1.39)
Swift SH 2015	3	110	(2.7)	24	209	(11.5)	0.22 (0.06, 0.73)
Total		1264			4923		0.37 (0.27, 0.52)



Forest plot of meta-analysis on seroma

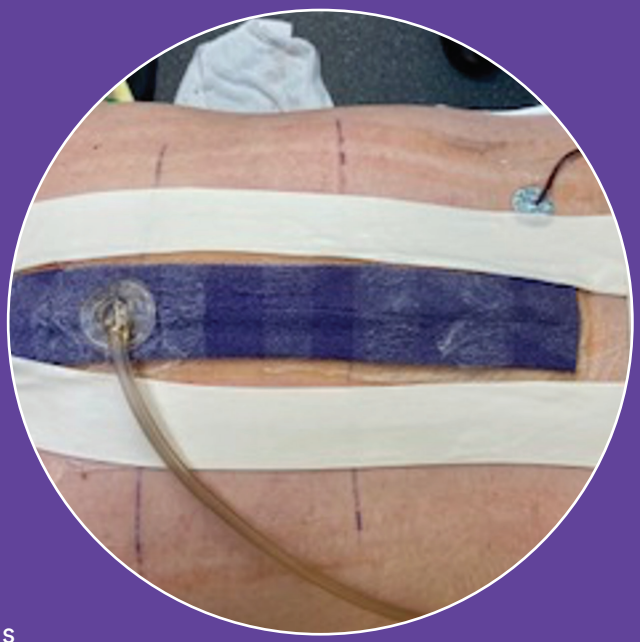
	Treatment			Control			
Study or subgroup	Events	Total	%	Events	Total	%	Odds ratio (95% CI)
Ferrando PM 2017	1	25	(4.0)	5	22	(22.7))	0.14 (0.02, 1.32)
Gunatiliake RP 2017	1	39	(2.6)	2	43	(4.7)	0.54 (0.05, 6.19)
NCT01341444	3	28	(10.7)	3	30	(10.0)	1.08 (0.20, 5.85)
Pachowsky M 2012	4	9	(44.4)	9	10	(90.0)	0.09 (0.01, 1.03)
Pauser J 2014	4	11	(36.4)	8	10	(80.0)	0.14 (0.02, 1.03)
Pleger SP 2017	0	58	(0.0)	1	71	(1.4)	0.40 (0.02, 10.05)
Refern RE 2017	0	196	(0.0)	2	400	(0.5)	0.41 (0.02, 8.49)
Total		366			586		0.31 (0.13, 0.75)



3M™ Prevena™ Therapy is uniquely designed to manage and protect surgical incisions by:

Helping to hold incision

Reducing edema



Acting as a barrier to external contamination

Delivering continuous -125mmHg up to 7 days

Decreasing lateral tension of sutured/ stapled incisions†,3

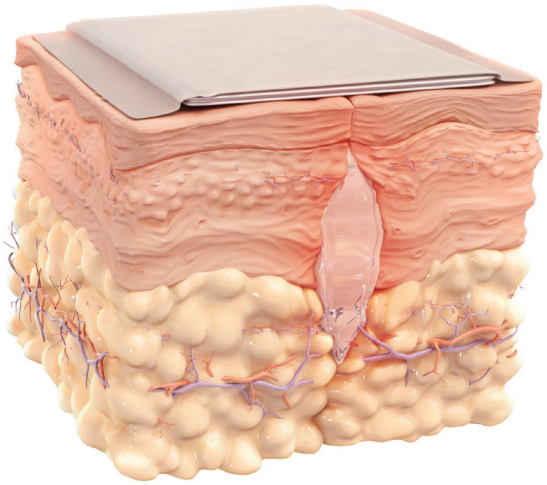
Removing fluids and infectious materials*

Designed to be flexible
3M™ Prevena™ Incision Dressings are designed to allow for movement, enhancing the post-operative rehabilitation process.

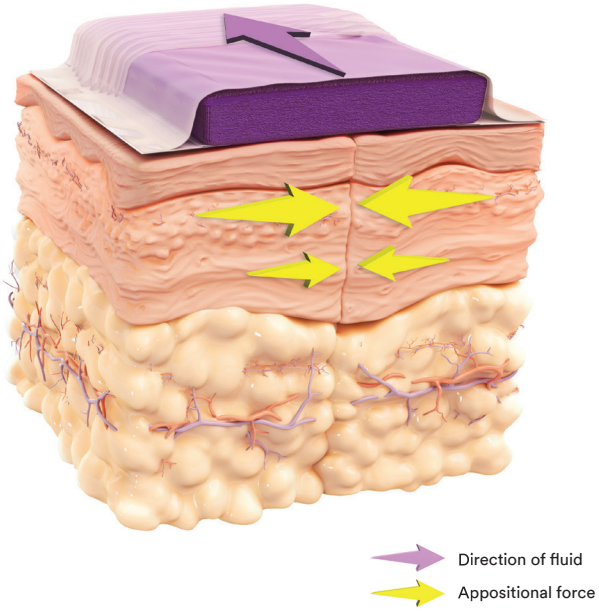
*In a canister †In computer and bench models

3M™ Prevena™ Incision Dressing utilizes reticulated open cell foam technology and -125mmHg pressure

Passive Therapy



3M™ Prevena™ Therapy



Under -125mmHg of negative pressure, the reticulated open cell foam dressing collapses to its geometric center. This brings the incision edges together, reduces lateral tension, and also allows for improved fluid management.[3,4,5]

- Contours in 3M™ Prevena™ Incision Dressing allow for even distribution of negative pressure.
- Adhesive film creates a barrier to external contaminants.
- Designed to conform to articulating joints to allow movement.
- Skin interface layer contains 0.019% ionic silver, which reduces bacterial colonization in the fabric.
- Multiple sizes and configurations.
- 3M™ Prevena™ Therapy Units and 3M™ Prevena™ Incision Dressing are shower friendly.*

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

Potential clinical value of 3M™ Prevena™ Therapy

Post-operative surgical site infection (SSI) is a common complication of spinal surgery. Negative pressure wound therapy (NPWT) has been well elucidated in surgical specialties to promote wound healing and reduce the risk of SSIs.

A retrospective chart review on patients who underwent posterior spinal fusions was completed separating groups into two cohorts[6]:

- Those who received NPWT (n=42) and those who received a traditional wound dressing (SoC; n=42).
- Cohorts were matched by type of posterior spinal fusion SPSS and regression analysis were completed on the collected data.

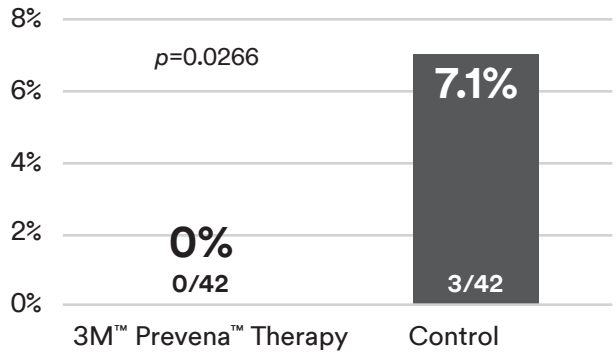
Results:

Patients treated with Prevena Therapy developed no surgical infections vs. patients treated with standard post-operative dressings (0/42 [0%] vs 3/42 [7.1%], *p*=0.034).

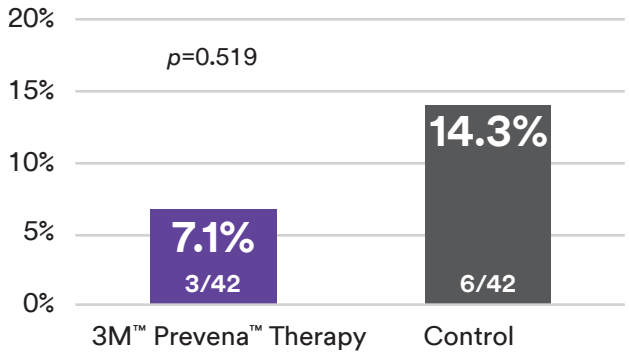
The Prevena Therapy cohort reported lower endpoints vs. traditional post-operative dressings:

- **Number of wound complications** (3 [7.1%] vs 6 [14.3%], *p*=0.519)
- **Number of superficial dehiscence** (1 [2.4%] vs 3 [7.1%], *p*=0.276)
- **Number of seromas** (1 [2.4%] vs. 2 [4.8%], *p*=0.519)
- **Number of operative revisions** (1 [2.4%] vs 3 [7.1%] , *p*=0.276)
- **Need for outpatient care** (6 [14.3%] vs 3 [7.1%], *p*=0.145)

Surgical infections



Wound complications



3M™ Prevena™ Therapy demonstrated a statistically significant difference for post-operative SSI for patients who received NPWT versus those who received traditional wound care.

45-year-old male presenting with debilitating mid-back pain, subjective leg weakness and difficulty walking. His condition had worsened over the last several months but he had been severe over the last 2 weeks.

Patient medical history: Hepatitis C with compensated cirrhosis, psoriasis, malnutrition (albumin 2.3), diabetes that was controlled with medication.

Patient surgical history: He had a history of multilevel thoracic osteomyelitis with epidural abscess that was treated with a decompressive laminectomy (T7-8 ~6 months prior) followed by long-term intravenous antibiotics.

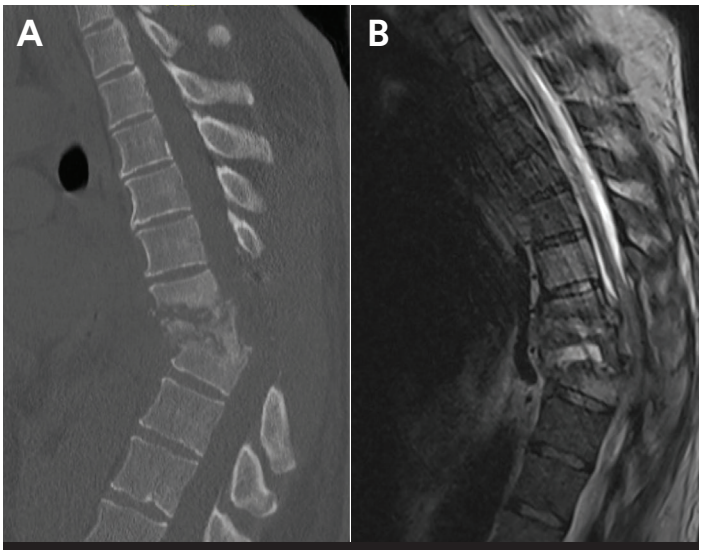


Figure 1. Left lateral view of the kyphotic deformity, shown in a CT scan (A) and MRI (B).

Intraop: Skin and dressing closure

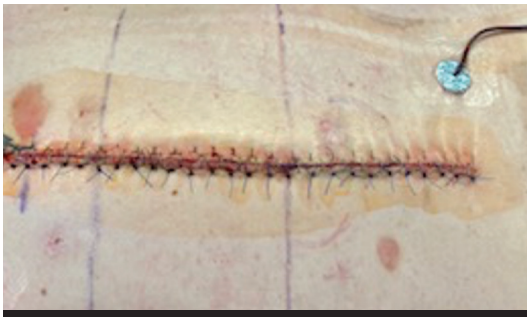


Figure 2. Intraoperative closure of the incision with sutures and staples.

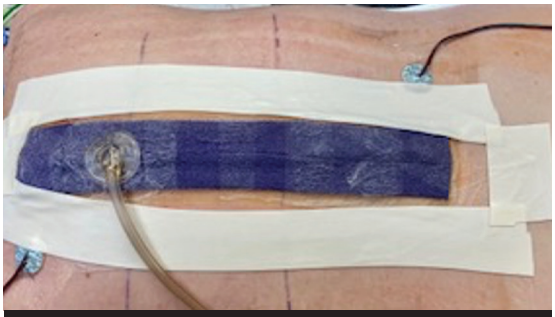


Figure 3. Placement of the 3M™ Prevena™ Customizable Dressing and application of negative pressure.

2 weeks: Staple removal

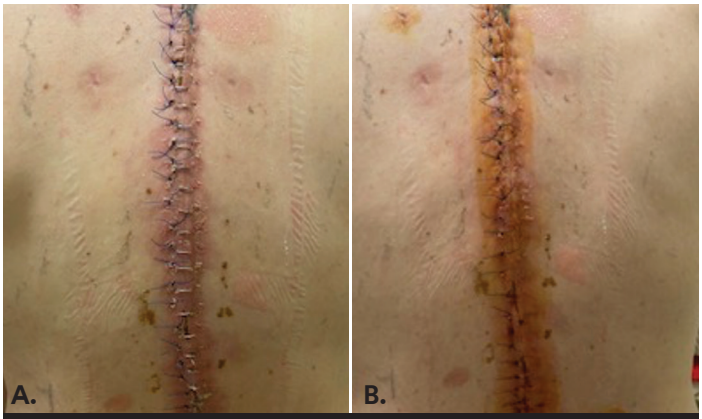


Figure 4. Incision appearance after 2 weeks, before **(A)** and after **(B)** staple removal.

3 weeks: Suture removal and skin adhesive

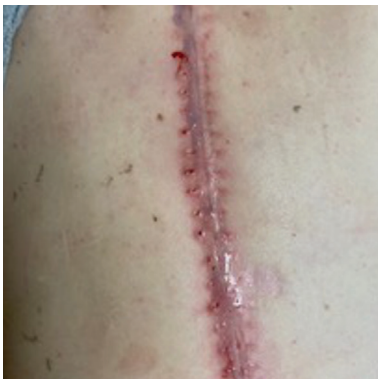


Figure 5. Incision appearance 3 weeks after surgery, upon removal of sutures and application of a topical adhesive film.

Patient data and photos courtesy of Kyle Mueller, M.D., Complex Spine Fellow, Brown University

Note: As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

A new post-op healing strategy

3M™ Prevena™ Therapy sets the stage for helping to reduce complications and optimizing outcomes for high-risk spine patients & procedures

In days after surgery

Prevena Therapy:

- Is a growing option for post-op incision management in high-risk patients and procedures.
- Helps to protect and stabilize the incision site the surgical site.
- Optimizes the healing process and helps reduce the risk of surgical site complications.
- Allows patients to mobilize as soon as possible to start recovery journey.

The long-term result

With potential reduction in surgical site complications and helping to minimize delays in recovery, surgeon and patients can work toward improved immediate and long-term outcomes (clinical, functional).

Identifying risk in spine surgery

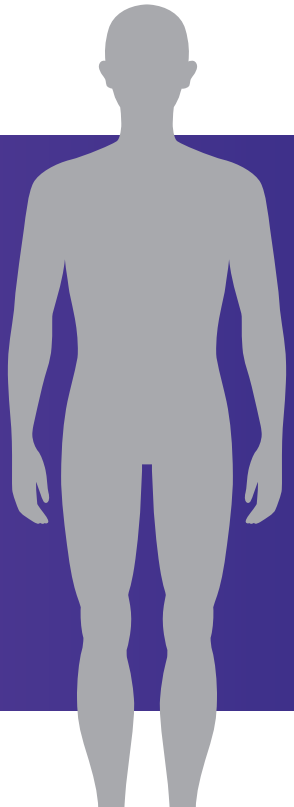
Elements that contribute to an increased risk of SSIs following spine surgery

Most surgeons assess risk based upon health attributes of the surgical patient. Secondary to the surgical patient in spine surgery are various types of surgeries, in particular revision, complex, long and posterior-based surgeries.[7]

High-Risk patients

SSI risk is primarily categorized by patient comorbidities including:

- Obesity
- Diabetes
- Smoking
- Cancer (radiation)
- Gastric bypass
- Rheumatoid medicine

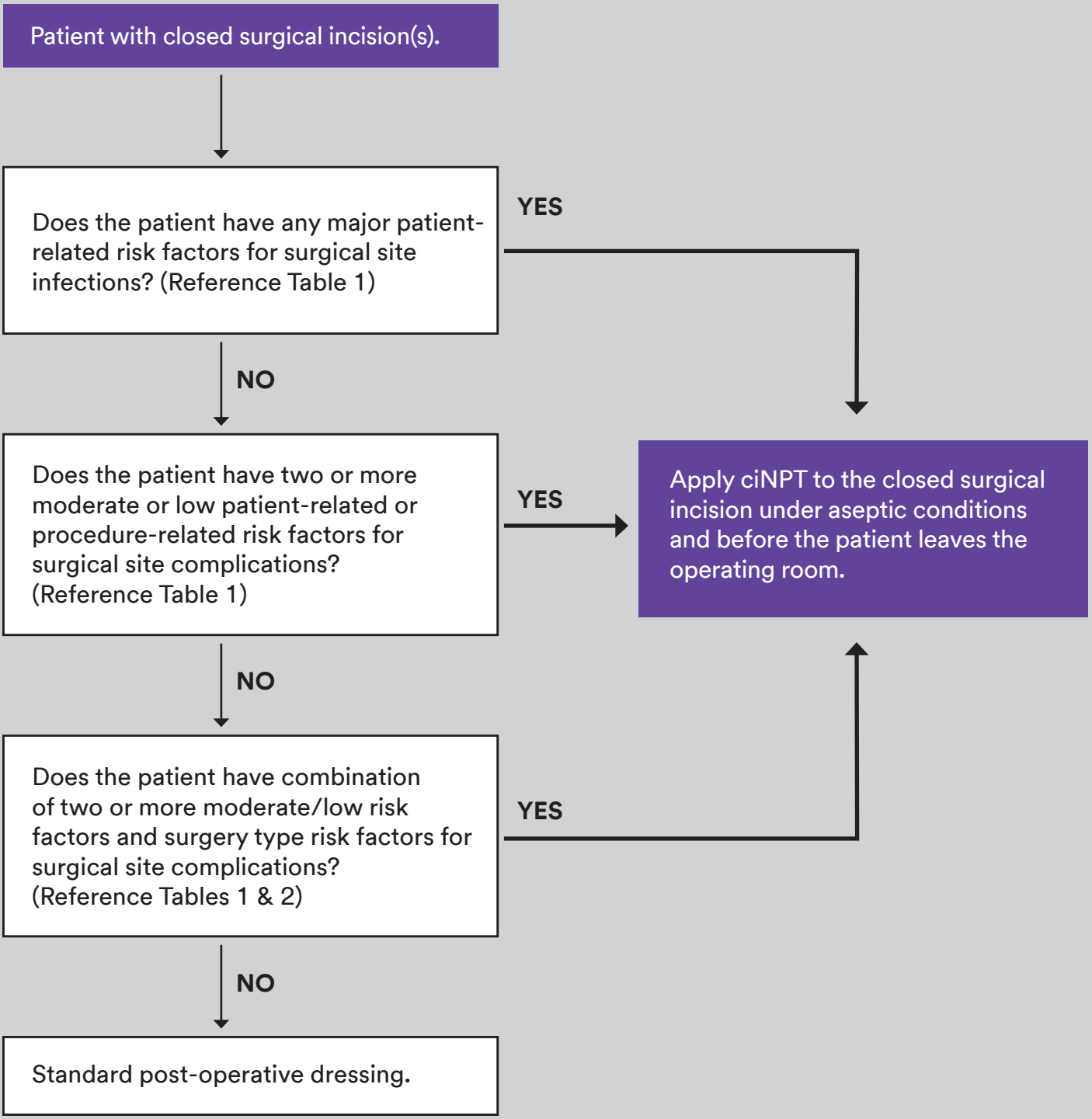


High-Risk procedures

SSI risk is less likely to be attached to a particular surgical type, but it is a concern with:

- Revision surgeries
- Complex surgeries
- Long surgeries
- Posterior approach surgeries

The World Union of Wound Healing Societies (WUWHS) consensus panel proposed the following clinical guideline for the use of closed incision negative pressure therapy (ciNPT)[8]



Note: Adapted from: 27-29

Ordering information

Item #	Product Name	Unit of Measure
PRE1101US	3M™ Prevena™ Peel and Place Incision Management System – 13cm	Each
PRE1155US	3M™ Prevena™ Peel and Place Dressing – 13cm	Case of 5
PRE1001US	3M™ Prevena™ Peel and Place Incision Management System – 20cm	Each
PRE1055US	3M™ Prevena™ Peel and Place Dressing – 20cm	Case of 5
PRE3201US	3M™ Prevena™ Plus Peel and Place Incision Management System – 35cm	Each
PRE3255US	3M™ Prevena™ Plus Peel and Place Dressing – 35cm	Case of 5
PRE4001US	3M™ Prevena™ Plus Customizable Incision Management System	Each
PRE4055US	3M™ Prevena™ Plus Customizable™ Dressing	Case of 5
PRE1121US	3M™ Prevena™ Duo Incision Management System – 13cm Peel and Place Dressings (2)	Each
PRE3321US	3M™ Prevena™ Plus Duo Incision Management System – 13 & 20cm Peel and Place Dressings	Each
PRE3021US	3M™ Prevena™ Plus Duo Incision Management System - 20cm Peel and Place Dressings (2)	Each
PRE4000US	3M™ Prevena™ Plus 125 Therapy Unit – 7 Day	Each
PRE4010	3M™ Prevena™ Plus 125 Therapy Unit – 14 Day	Each
PRE1095	3M™ Prevena™ 45ml Canister	Case of 5
PRE4095	3M™ Prevena™ Plus 150ml Canister	Case of 5

3M™ Prevena™ Therapy is easy to integrate into your practice and easy to order and use with your surgical patients. For more information, contact your local account representative or visit prevena.com

References:

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8. World Union of Wound Healing Societies (WUWHS) Consensus Document. Closed surgical incision management: understanding the role of NPWT. *Wounds International*. 2016.

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Web 3M.com/medical

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. Rx only.

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