3M | Prevena Restor™
Incision Management System

Rethink recovery

Prevena Restor™ Axio•Form™
Incision Management System

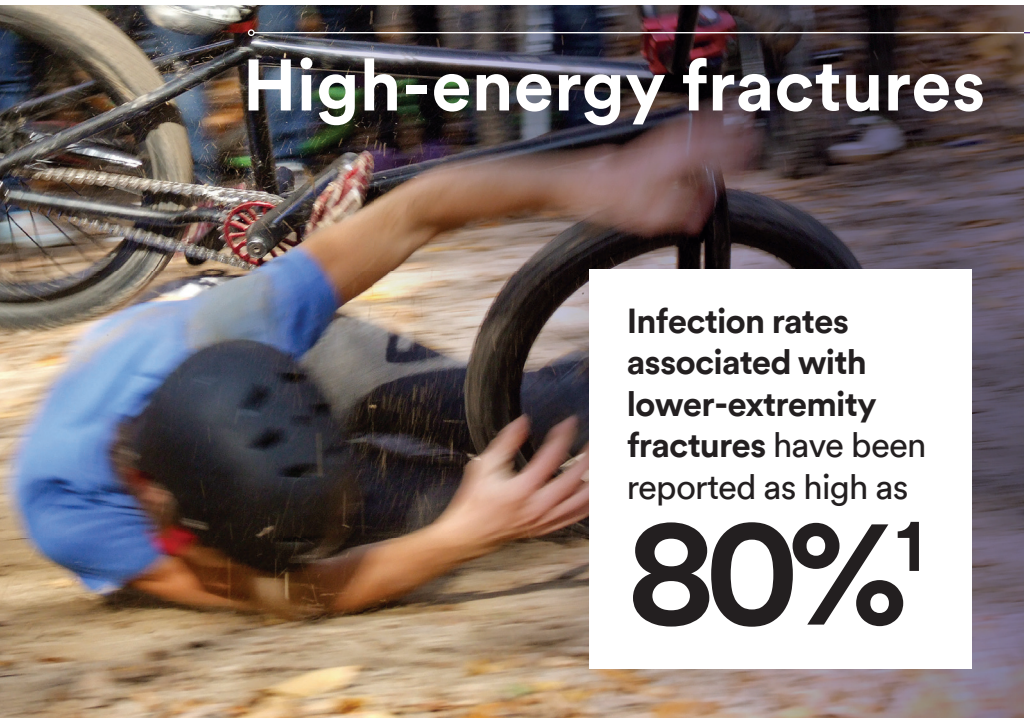
Lower extremity internal fixations are accompanied by a unique set of post-op challenges

Even after successful surgery, **recovery can be a difficult journey:**

- Significant **swelling** is inevitable.
- Swelling creates **tension around the wound**, which can lead to dehiscence.
- If **dehiscence** occurs, **infections** and other complications may result.
- Complications can **delay suture removal** or lead to a reoperation.
- If complications delay patient mobilization, **long-term functional outcomes may be jeopardized.**

> “Swelling can lead to problems with wound healing, and problems with wound healing can lead to disaster.”
>
> — Dr Julius Bishop
> Orthopaedic Trauma Surgeon
> Stanford Healthcare, CA

Early mobilization is key to healing, but swelling can increase the likelihood of complications and delay healing



High-energy fractures

Infection rates associated with lower-extremity fractures have been reported as high as

80%[1]

High-energy fractures, such as pilon fractures, are inherently high-risk due to the traumatic nature of the injury. The challenges of recovery are amplified because of:

- Significant joint damage and soft-tissue injury.
- Increased risk of infection and other wound-related issues.
- Substantially longer recovery timeframes.

Low-energy fractures

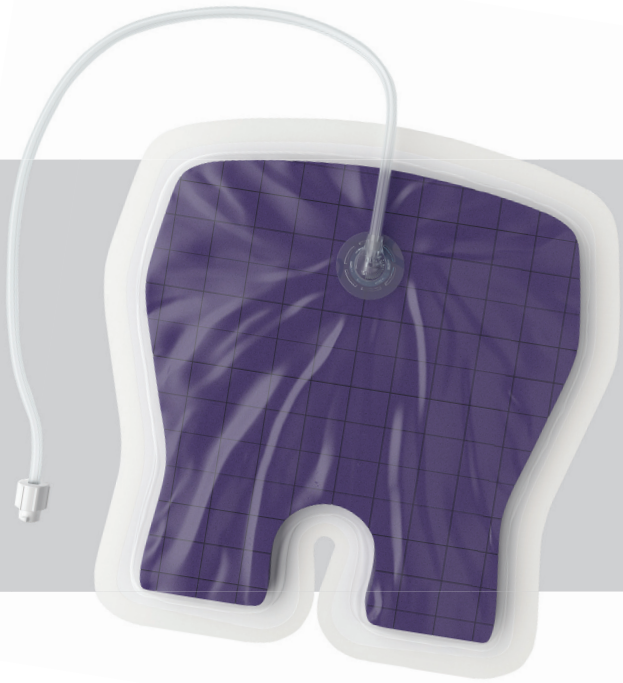
Even low-energy fractures can present profound post-op challenges — particularly when high-risk patients are involved.

Frail and/or comorbid patients can't be optimized before emergent surgery, heightening the related risks and often resulting in a recovery that can be:

- Longer
- More painful
- Less complete

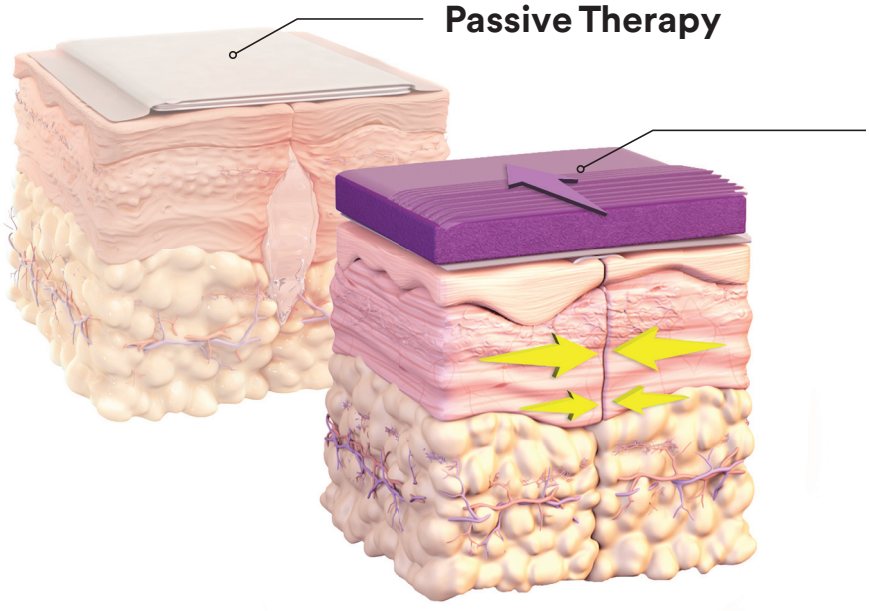
With recovery so dependent on factors out of your control, is there a better way to help your patients heal?

Introducing the 3M™ Prevena Restor™ Incision Management System with Axio•Form™ Dressing



The first and only system designed to manage the incision and surrounding soft tissue with **14 days* of negative pressure therapy**

*Therapy should be continuous for a maximum of 7 days per dressing. Dressing change required after 7 days.



3M™ Prevena™ Therapy

- Delivers continuous -125mmHg to the incision site.
- Helps hold incision edges together.[2]
- Removes fluid and infectious materials.[3]
- Creates a barrier to external contaminants.[4]
- Reduces edema.[5]

Built on the same proven technology as the original 3M™ Prevena™ Therapy

Studies have shown Prevena Therapy can result in:

Fewer overall wound complications (2/30) vs. antimicrobial dressings (29/108),
in a retrospective study on hip and knee revision patients.[6]

Fewer reoperations (2/79) vs. antimicrobial dressings (10/80),
in a randomized controlled trial on total hip and knee arthroplasty revision patients.[7]

Scientifically proven benefits of the original Prevena Therapy

Manages the incision and surrounding soft tissue with negative pressure.

85% reduction in edema (1/196) vs. standard surgical dressings (13/400),
in a prospective study on total hip and knee arthroplasty patients.[8]

- Improvements in wound healing[9]*
- Increased tissue perfusion[9]*

Creates a barrier to external contaminants while actively removing fluid and infectious materials.

47% fewer infections (14/141) compared with standard surgical dressings (23/122),
in a clinical study of high-risk lower extremity trauma patients.[1]

Mechanically stabilizes the incision site to help facilitate closure.

Up To **61%** greater closure than competitors.[10†]

48% less dehiscence (12/141) compared with standard surgical dressings (20/122),
in a clinical study of high-risk lower extremity trauma patients.[1]

- Reduces lateral tension on the epidermis[2]
- Holds incision edges together[2]

The data referenced in this brochure was derived from studies using the 3M family of negative pressure technology, but not specifically the 3M™ Prevena Restor™ Therapy System.

*In an animal model compared to gauze, as measured by VEGF and Factor VIII expression.

†In a comparative bench study under controlled conditions.

Your strategy for an enhanced recovery

Reduce the burden on your resources and increase patient satisfaction

$3,128
Savings Per Patient[1]

An economic model based on the clinical assessment of ortho trauma patients showed ciNPT* may reduce overall cost per patient by $3,128** compared with standard of care dressing.

In addition to saving money on complications, an optimized healing experience can lead to improved quality of life for patients.[11]

*Data on file has shown that the 3M™ Prevena Restor™ Therapy System is functionally equivalent to the incisional NPWT reported in this study, and the reported clinical outcomes may be applied to Prevena Therapy.

**Per patient cost savings was calculated based on relative patient group incidence rate reported in this study. Results are based on a prospective randomized multicenter clinical trial of 249 patients with 263 blunt-trauma, high-risk, lower-extremity fractures. 122 fractures were randomized to a control group and provided with standard postoperative dressings; 141 were treated with negative pressure wound therapy (NPWT).

Streamline post-op incision management

A simple, efficient process for you and your patient

Surgeon

- Simple to assemble and apply.
- Reduces downtime spent teaching patients how to care for their incision.
- Less worry about rehab compliance.
- May save on overall costs.
- Easy to remove after therapy.

Patient

- Lightweight, portable, and easy to use.
- Provides 14 days of therapy, with minimal dressing changes (dressing change required at 7 days).
- Allows patients to mobilize joints as soon as possible.
- Helps reduce edema that may inhibit recovery protocol compliance.
- Limited maintenance required.

Reduces swelling during the peak swelling period.

Protects and stabilizes the surgical site to allow for proper healing.

Sets the stage for the best possible recovery.

Product specs

3M™ Prevena Restor™ Axio•Form™ Dressing

- Available in 29cm x 28cm.
- Dressing change required after 7 days.

3M™ Prevena™ Plus 125 Therapy Unit

Rechargeable therapy unit lasts for up to 14 days and automatically shuts off at the end of therapy.

- The Prevena Plus Therapy canister easily attaches to the therapy unit to store exudate.

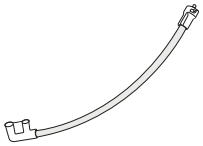
3M™ Prevena™ Plus Connector

Used to connect the 3M™ Prevena Restor™ Axio•Form™ Dressing tubing to the Prevena Plus 125 Therapy Unit.

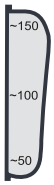
3M™ Prevena™ Plus 125 Therapy Unit Components

The 3M™ Prevena Restor™ Incision Management System contains the following single-use, disposable components:

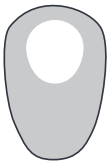
3M™ Prevena™ Plus 125 Therapy Unit (14 Day)



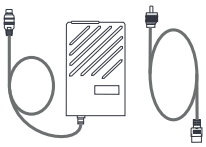
3M™ Prevena™ Plus Connector



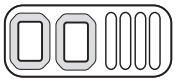
3M™ Prevena™ Plus 150ml Canister



3M™ Prevena™ Plus Therapy Unit Carry Case



3M™ Prevena™ Plus 125 Therapy Unit Power Supply with Power Cord



3M™ Prevena™ Therapy Patch Strips

The Prevena Restor Incision Management System is also compatible with the Prevena 125 Therapy Unit (7 day).

Product SKUs

SKU	Description	UOM
PRE5501	3M™ Prevena Restor™ Axio•Form™ System Kit - 29cm x 28cm	1
PRE4010	3M™ Prevena™ 125 Therapy Unit - 14 Day	1
PRE5555	3M™ Prevena Restor™ Axio•Form™ Dressing - 29cm x 28cm	5

Applying the 3M™ Prevena Restor™ Incision Management System is quick and easy—simply peel and place

Preparing the site

1

Prior to surgery, shave or clip the surgical area where the dressing will be applied, following institutional policy.

2

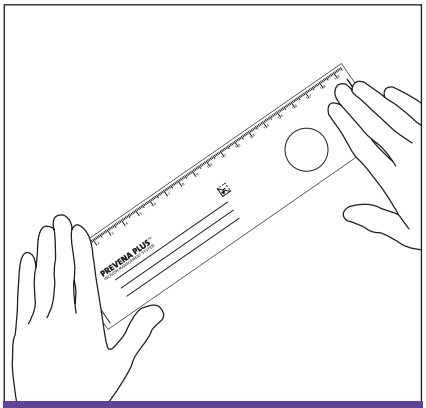
Gather all items needed for application:

- Sterile wound cleaning solution, e.g., water, saline or alcohol.
- Sterile gauze or other material to clean the application site.
- All components of the Prevena Restor Incision Management System (dressing and therapy unit).

3

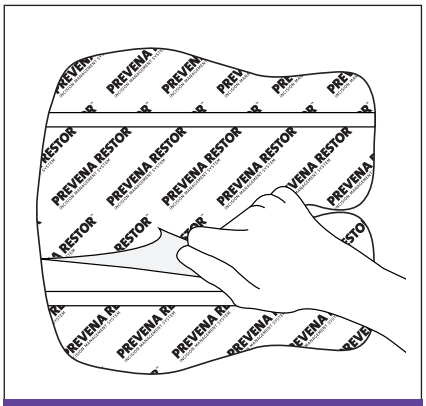
After surgery, cleanse the application site with sterile gauze and sterile wound cleaning solution and pat dry with sterile gauze.

Applying the dressing



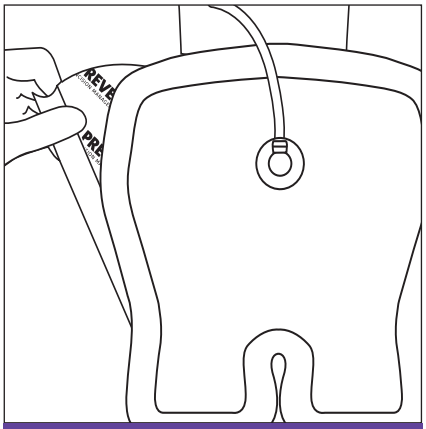
1

Measure the incision and choose the appropriate 3M™ Prevena Restor™ System Kit.



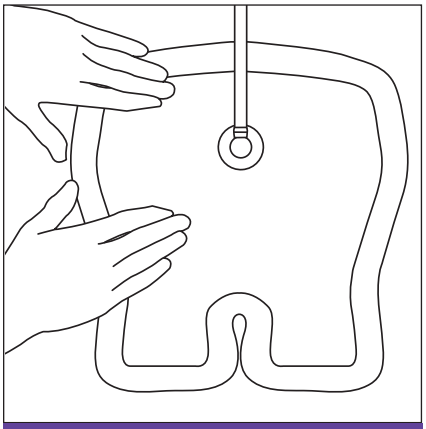
2

Gently peel back one release liner on the back of the dressing to expose the adhesive.



3

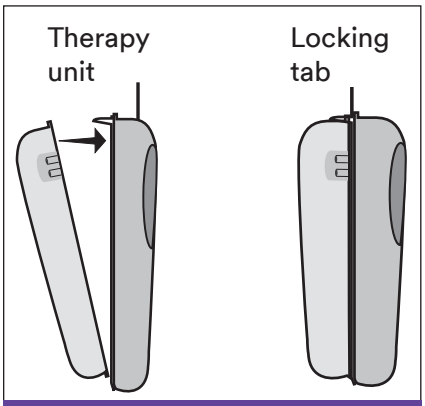
Center and apply the dressing over the closed wound or incision. Remove the remaining release liner by grasping the tab and gently pulling.



4

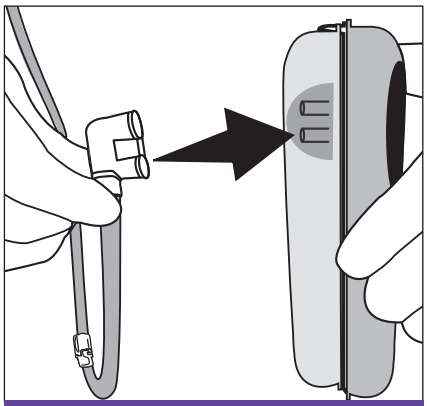
Firmly press around the dressing to ensure a good seal where the adhesive contacts the skin. Then remove the top stabilization layers.

Connecting the dressing to a 3M™ Prevena™ Plus 125 Therapy Unit (14 Day)*



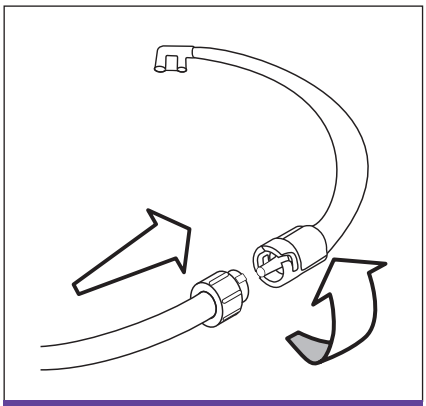
1

Insert the canister into the therapy unit.



2

Connect the 3M™ Prevena™ Plus Connector to the canister by plugging the connector onto the tubing ports on the side of the canister.

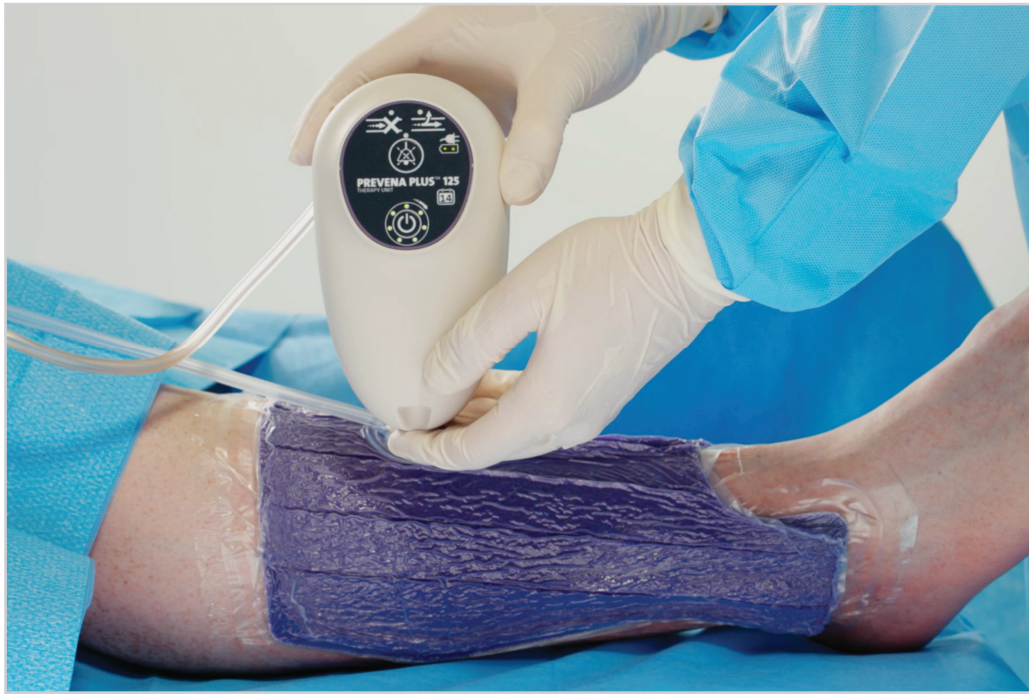


3

Connect the dressing tubing to the Prevena Plus Connector by pushing and twisting the connectors to lock. Ensure that the clamp on the canister tubing is open.

4

Begin therapy by pressing and holding the On/Off button for three seconds. The green lights on the front of the unit will illuminate, indicating that therapy is active.



*Also compatible with the 3M™ Prevena™ Plus 125 Therapy Unit (7 day).

What can you do to better manage the surgical site and swelling?

- What do you do to optimize healing after a lower extremity internal fixation?
- What is your strategy to control post-op swelling?
- How well do your patients comply with post-op swelling-reduction instructions during the peak swelling period?
- How does swelling impact your ability to take out sutures at the optimal time (roughly two weeks) after surgery?
- What types of complications tend to prolong recovery for your high-energy fracture patients?
- How often do your comorbid patients experience complications that delay mobilization and rehab?

To learn more, contact your local 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. Rx only.
The Prevena Restor Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.
The data referenced in this brochure was derived from studies using the 3M family of negative pressure technology, but not specifically the 3M™ Prevena Restor™ Therapy System.

References: 1. Stannard JP, Volgas DA, McGwin G, et al. Incisional negative pressure wound therapy after high-risk lower extremity fractures. *J Orthop Trauma* 2012;26:37-42. 2. Wilkes RP, Kilpadi DV, Zhao Y, et al. Closed Incision management with negative pressure wound therapy (CIM): biomechanics. *Surg Innov*. 2012;19(1):67-75. 3. Kilpadi DV, Cunningham MR. Evaluation of closed incision management with negative pressure wound therapy (CIM): hematoma/ seroma and involvement of the lymphatic system. *Wound Repair Regen*. 2011;19(5):588-596. doi:10.1111/j.1524-475X.2011.00714.x. 4. Payne J. Evaluation of the resistance of the Prevena incision dressing top film to viral penetration. San Antonio, TX: Kinetic Concepts, Inc.; June 19, 2009. Report No.: 0000021109. 5. Glaser DA, Farnsworth CL, Varley ES, et al. Negative pressure therapy for closed spine incisions: a pilot study. *Wounds*. 2012;24(11):308-316. 6. Cooper HJ, Bas MA. Closed-incision negative-pressure therapy versus antimicrobial dressings after revision hip and knee surgery: a comparative study. *J Arthroplasty*. 2016;31(5):1047-1052. doi:https://doi.org/10.1016/j.arth.2015.11.010. 7. Newman JM, Siqueira MBP, Klika AK, et al. Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: a prospective, randomized clinical trial. *J Arthroplasty*. November 17, 2018. pii:S0883-5403(18)31144-6. doi:10.1016/j.arth.2018.11.017. 8. Redfern RE, Cameron-Ruetz C, O'Drobinak SK, et al. Closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty. *J Arthroplasty*. 2017;32:3333-3339. 9. Shah A, Sumpio BJ, Tsay C, et al. Incisional negative pressure wound therapy augments perfusion and improves wound healing in a swine model pilot study. *Ann Plast Surg*. 2019; 82(4S):S222-S227 10. Kilpadi DV, Olivie M. Impact of 2 negative pressure incisional management systems on simulated incisions in a tissue proxy at 2 time points. AWC/WHS. Atlanta, GA. 2016. 11. Lee AJ, Sheppard CE, Kent WDT, et al. Safety and efficacy of prophylactic negative pressure wound therapy following open saphenous vein harvest in cardiac surgery: a feasibility study. *Interact CardioVasc Thorac Surg*. 2016. doi:10.1093/icvts/ivw400.

3M Company
2510 Conway Ave
St. Paul, MN 55144 USA

Phone 1-800-275-4524 (NPWT products)
1-800-228-3957
Web 3M.com/medical

 70-2011-8269-1 PRA-PM-US-02545 (07/21)