



**Prevena Restor™**  
Postoperative Recovery

# Value Analysis Committee

Product Information Kit









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# Value-based care and postop protocols

Meeting the benchmarks of value-based care has become increasingly difficult across all surgical specialties. Additionally, patient experience has become more important than ever, as online reviews and referrals can impact volume.

When previously standard postop protocols can no longer be counted on, and with recovery so dependent on factors out of your control, is there a better way to help your patients heal?

**To provide the outcomes and recovery you and your patients seek, you need new tools to support your surgical techniques and postop rehab protocols.**

## Challenges to patient outcomes, resources and spending

### Complications remain frustratingly common

Despite the best efforts to optimize outcomes in today's surgical environment, costly post-surgical complications are common across all surgical specialties:

Common post-surgical complications	
Surgical site infection (SSI)	<ul style="list-style-type: none"><li>• <b>2% to 5% occurrence</b> of SSIs in all surgeries<sup>1</sup></li><li>• <b>9.58 days increase</b> in the average length of a hospital stay caused by SSIs<sup>2</sup></li><li>• <b>\$38,656</b> for an additional 9.58-day hospital stay<sup>2</sup></li><li>• <b>5X risk</b> of readmission in patients with SSIs<sup>3</sup></li></ul>
Surgical wound dehiscence (SWD)	<ul style="list-style-type: none"><li>• <b>Up to 9.3%</b> SWD rate after surgical procedures<sup>4</sup></li><li>• <b>4 to 14 days</b> is when most SWDs occur, when collagen fibers are not strong enough to hold the incision together without sutures or staples<sup>5</sup></li></ul>
Hematomas and seromas	<ul style="list-style-type: none"><li>• <b>10% to 45% of patients</b> have had hematomas or seromas after abdominoplasty procedures<sup>6</sup></li><li>• <b>8% to 13% of patients</b> have had hematomas or seromas after rhytidectomies<sup>6</sup></li></ul>

# Orthopedic-related complications

**Orthopedic facilities are under pressure to deliver optimal outcomes under increasingly challenging circumstances:**

- A growing emphasis on **same-day discharges**
- **Bundled reimbursements** that force health systems to assume risk for the entire episode of care
- **Declining reimbursements**, which may force organizations to take on more, and sometimes higher-risk, patients

These demands can make the challenges posed by edema and swelling even more problematic: To achieve optimal outcomes, patients who've had orthopedic surgery need to ambulate and/or perform physical therapy and range-of-motion exercises. But swelling-induced pain not only creates an uncomfortable recovery experience, it can delay rehab, and often leads to emergency room visits. Prescription opioids are one answer, but they are tightly regulated and well-known to be associated with significant risks.

## The **BIG** PICTURE in orthopedics:

12%

Orthopedic surgeries that result in complications, with nearly 3% being major complications<sup>7</sup>

5.4%

30-day readmission rate across all orthopedic specialties<sup>8</sup>

# The challenges of plastic surgery

## Breast reconstruction — an expensive undertaking

Two-stage tissue expander/implant with acellular dermal matrix (TE/I+ADM) is the most common implant-based method of breast reconstruction in the United States.

**But complications persist:**

**20.5%**<sup>9</sup>

Infection rate of patients who receive immediate implant-based reconstruction after a mastectomy, according to a database analysis of 3,007 patients

**10%**<sup>10</sup>

The rate at which SSIs occur in post-mastectomy breast reconstruction patients

**8%**<sup>11</sup>

The rate at which mastectomy skin necrosis has been observed in breasts after reconstruction



**Dehiscence, seromas, hematomas, edema and pain can lead to costly interventions and subpar patient experiences**

**Plastic specialists also face a complex set of challenges. In addition to dealing with potential clinical complications:**

- They're judged according to aesthetic outcomes that can be marred by seromas, hematomas and other infections
- They must carefully navigate the stress, anxiety and expectations that their patients have

Ultimately, success is largely in the eyes of the patient, which fuels, or hinders, word-of-mouth referrals.

## Abdominal surgical wounds — high vulnerability

Perfusion-related complications like infection, seroma, hematoma and necrosis are also common in the abdomen:

**10-45%**<sup>6</sup>

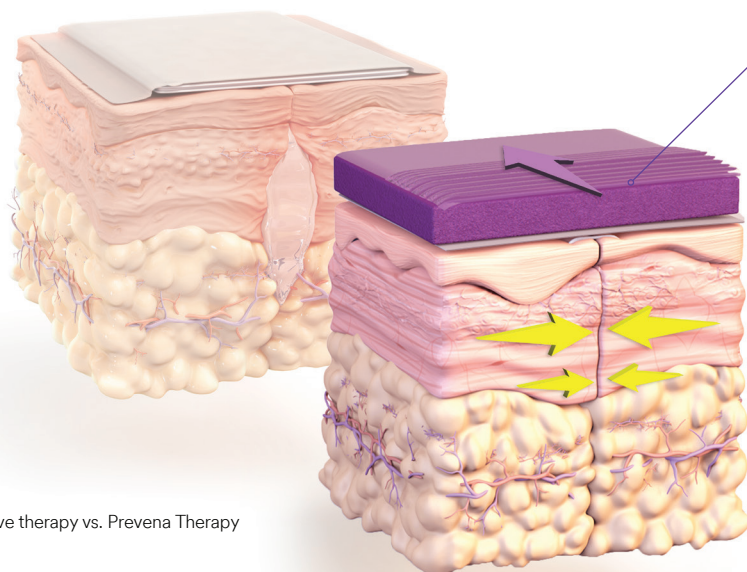
Complication rates in abdominoplasty procedures

**24.7%**<sup>12</sup>

Complication rate with deep inferior epigastric perforators (DIEP) flap surgery

# The 3M™ Prevena Restor™ Incision Management System

The next generation of incision + surrounding soft tissue management



Passive therapy vs. Prevena Therapy

## 3M™ Prevena™ Therapy science and mechanism of action

- Delivers continuous negative pressure therapy (-125mmHg) to the incision site (up to seven days)
- Helps hold incision edges together<sup>13</sup>
- Removes fluid and infectious materials<sup>14</sup>
- Creates a barrier to external contaminants<sup>15</sup>
- Reduces edema<sup>16</sup>

## With features to optimize care:



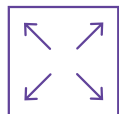
### Extended therapy time:

Up to 14 days of therapy, with a dressing change required at seven days



### Precision designed:

Dressing seamlessly conforms to the patient and allows for articulation and ambulation



### Expanded coverage area:

Larger dressing delivers therapy to the incision and surrounding soft tissue envelope



### Easy to apply:

Simply peel and place the form-fitting dressing

## Prevena Restor Incision Management System indication statement

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.

System components



**3M™ Prevena™ Plus 125 Therapy Unit - 14 day with the 3M™ Prevena™ Plus 150ml Canister**  
Single-use, disposable unit used to administer -125 mmHg negative pressure and store exudate fluid.



**3M™ Prevena Restor™  
Arthro•Form™ Dressing**



**3M™ Prevena Restor™  
Axio•Form™ Dressing**



**3M™ Prevena Restor™  
Bella•Form™ Dressing**



**3M™ Prevena Restor™  
Roto•Form™ Dressing**

Applied over the incision and the surrounding soft tissue, the form-fitting dressing bolsters the incision and surrounding soft tissue envelope.

- **3M™ Prevena™ Plus 125 Therapy Unit Power Supply with Power Cord**
- **3M™ Prevena™ Patch Strips**
- **3M™ Prevena™ Plus Therapy Carry Case**

FDA 510K clearance:	Product labeling:
K181507	<ul style="list-style-type: none"><li>• 3M™ Prevena Restor™ Dressings Clinician Guide</li><li>• 3M™ Prevena™ Plus 125 Therapy Unit - 14 day Clinician Guide</li><li>• 3M™ Prevena™ Plus 125 Therapy Unit - 14 day Patient Guide</li></ul>

System features

Reticulated Open-Cell Foam (ROCF) Dressing and Interface Layer.

The Reticulated Open-Cell Foam (ROCF) used for Prevena Therapy features a skin-friendly interface layer that wicks fluid from the skin surface and foam bolster, allowing for the continuous delivery of negative pressure wound therapy.

Automatic pressure feedback

The 3M™ Prevena Restor™ Incision Management System is designed with proprietary 3M™ SensaT.R.A.C.™ Pad/Technology, which maintains and adjusts to deliver consistent negative pressure at the incision site.

3M™ SensaT.R.A.C.™ Technology	3M™ SensaT.R.A.C.™ Pad	3M™ Easyclear Purge™ Technology
Draws exudate away from the incision site and independently monitors target pressure	In conjunction with specialized software, enables monitoring and maintenance of pressure at the incision site	Multi-lumen tubing forces air into the system to help reduce blockages



# The 3M™ Prevena Restor™ Therapy — key differentiators

Only the 3M™ Prevena Restor™ Incision Management System delivers -125mmHg negative pressure therapy and accommodates the widest variety of incision sizes, exudate storage capabilities and mobility needs of patients.

## Key differentiators vs. competitors

- Incision and surrounding soft tissue management
- -125mmHg negative pressure that automatically maintains and adjusts
- 14 days of continuous therapy (with a dressing change required after seven days)
- Reticulated open-cell foam dressings
- Replaceable fluid-collection canister
- Audible alarms

System features	Prevena Restor Incision Management System	3M™ Prevena™ Therapy	Other disposable NPWT systems*	Silver impregnated/ antimicrobial dressings	Compression wrap
Unit device classification/ type	Closed-Incision Negative-Pressure Therapy (ciNPT)	Closed-Incision Negative-Pressure Therapy (ciNPT)	Disposable Negative Pressure Wound Therapy	Wound Dressing	Dressing
Pressure setting	-125 mmHg	-125 mmHg	-80 mmHg	—	—
Interface	Reticulated Open-Cell Foam (ROCF)	Reticulated Open-Cell Foam (ROCF)	Multilayer absorbent dressings	Multilayer absorbent dressings	Liquid topical skin adhesive
Replaceable canister	✓ (150 ml)	✓ (150 ml)	—	—	—
Purchase dressings without device	✓	✓	✓	—	—
Linear incisions	≤30 cm	≤90 cm	<35 cm	<27 cm	<20 cm
Portable	✓	✓	✓	✓	✓
Audible alarms	✓	✓	—	—	—
Shower friendly	✓	✓	✓	✓	✓

\*Comparison with Smith & Nephew PICO Single Use Negative Pressure Wound Therapy System based on information available on <https://www.possiblewithpico.com/pico-documentation>. Accessed July 23, 2021. Comparison with Avelle™ NPWT System based on information from <https://www.convatec.com/advanced-wound-care/avelle-negative-pressure-wound-therapy-system/>. Accessed July 23, 2021.



# The 3M™ Prevena™ Therapy family

For the results you demand, choose demonstrated technology

Backed by clinical evidence.



## 1,000+

published clinical studies using  
3M negative pressure therapy



## 70+

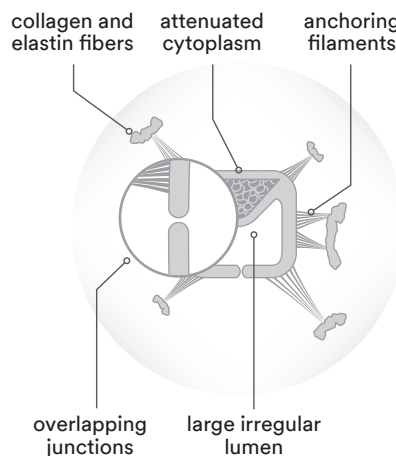
published clinical studies  
on Prevena Therapy

### How Prevena Therapy reduces edema<sup>17</sup>

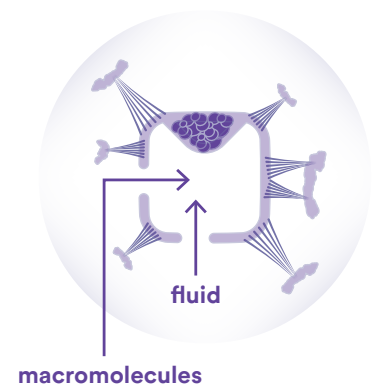
The effects of negative pressure applied to intact skin via Prevena Therapy were evaluated using finite elemental analysis (FEA). Based on the analysis, it is hypothesized that volumetric expansion may help:

- Expand the tissue beneath the dressing, pulling the tissue open
- Increase pore volume
- Lower local interstitial fluid pressure
- Open lymphatics to allow fluid clearance

#### Closed terminal lymphatic pore<sup>18</sup> (overlapping endothelial cells)



#### Open terminal lymphatic pore<sup>18</sup> (Separated endothelial cells)



# Clinical value of 3M™ Prevena™ Therapy

## Prevena Therapy in revision total knee arthroplasty (rTKA) procedures<sup>19</sup>

The PROMISES (Post-market, Randomized, Open-Label, Multicenter Study to evaluate Effectiveness; Higuera-Rueda 2021) study was a Level I multicenter randomized controlled trial with 294 patients at high-risk for wound complications, undergoing elective revision knee arthroplasty. Patients were stratified by revision type (aseptic vs. septic) and matched by demographics, comorbidities, causes of revision and duration of treatment.

Patients were randomized to receive either Prevena Therapy or an antimicrobial silver-impregnated dressing standard of care (SOC); 242 patients completed follow-up: 124 treated with Prevena Therapy and 118 treated with SOC.

**The evidence supporting the efficacy of Prevena Therapy was so strong that the study was terminated before its planned completion.\***

### Complication

### Study outcomes at 90 days

#### Surgical site complications (SSC)

**4x**

#### reduction in SSCs vs. SOC

3.4% (5/147) Prevena Therapy vs. 14.3% (21/147) SOC ( $P=0.0013$ )

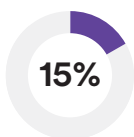
#### Readmission rates

**3x**

#### reduction in readmission rates vs. SOC

3.4% (5/147) Prevena Therapy vs. 10.2% (15/147) SOC ( $P=0.0208$ )

#### Mean dressing changes



#### fewer mean dressing changes

1.1±0.3 Prevena Therapy vs. 1.3±1.0 SOC ( $P=0.0003$ )

The above percentage calculations were derived based on relative data reported in the studies.

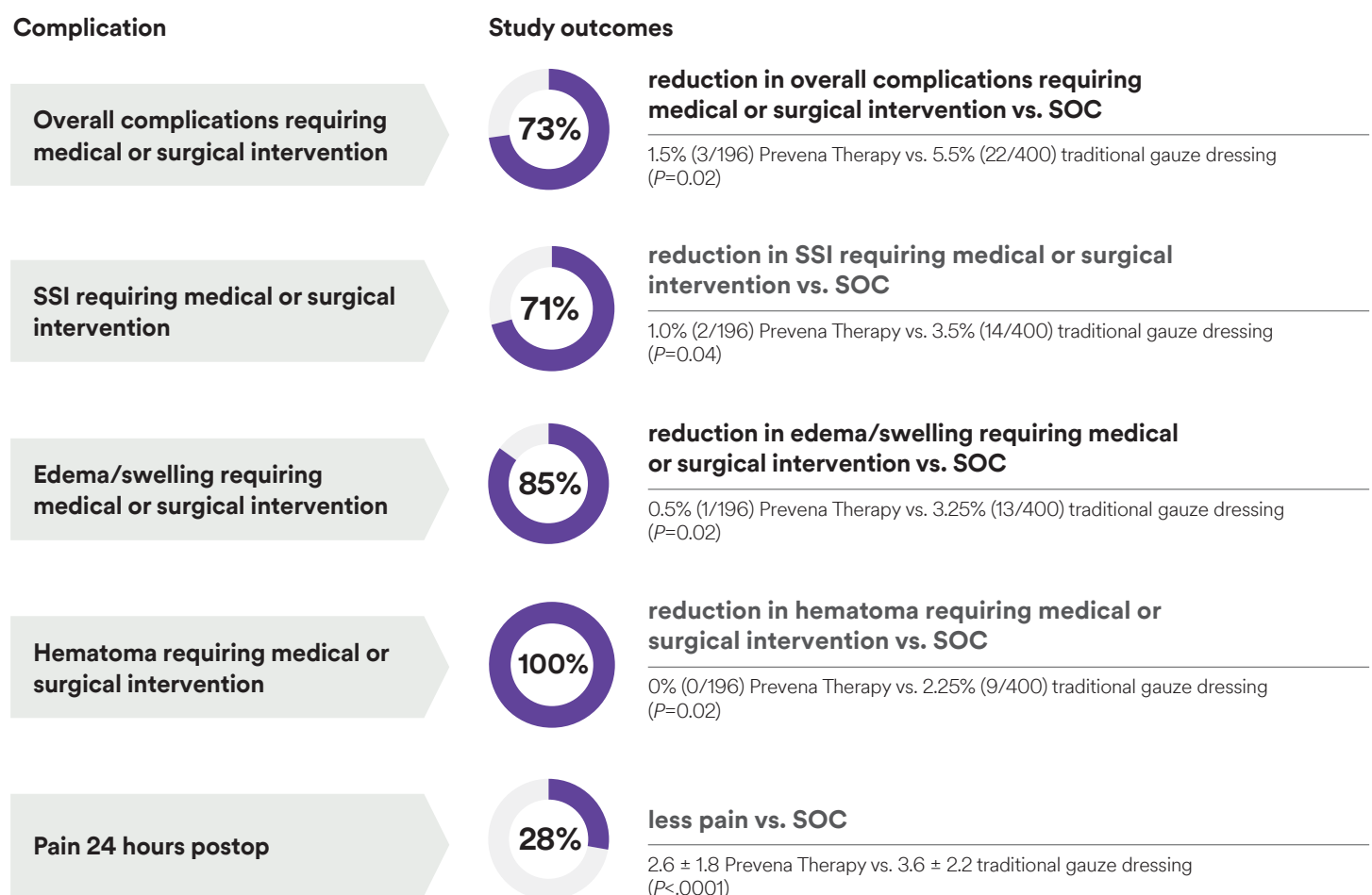
\*Statistically significant ( $p<0.05$ ).

### 3M™ Prevena™ Therapy in primary TKA and total hip arthroplasty (THA) procedures<sup>20</sup>

A single-center, open-label study (Closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty; Redfern 2017) with a prospective cohort of patients undergoing primary TKA or THA compared 196 incisions treated with Prevena Therapy to a historical control group of 400 patients treated with traditional gauze dressing to determine whether negative pressure wound therapy reduced the incidence of wound complications, surgical site infection, hematoma and seroma requiring medical or surgical intervention after total joint replacement.

In the experimental group, follow-up assessment occurred at one week postoperatively in order to remove the wound vacuum and assess the surgical site; standard two-week follow-up occurred in the control group. All patients were also reassessed at six weeks postoperatively.

The incisions treated with Prevena Therapy had significantly better outcomes than those treated with standard gauze.



The above percentage calculations were derived based on relative data reported in the studies.



## Case study:

### 3M™ Prevena™ Therapy in a lower extremity wound<sup>21</sup>



**Figure 1.** Initial presentation of the infected medial left leg wound.

A 25-year-old female patient presented with an actively draining Morel-Lavallée lesion of the left lateral thigh, sustained as a pedestrian, when struck by a motor vehicle (Closure of a complex lower extremity wound with the use of multiple negative pressure therapy modalities; Eldenburg 2020).

She was then managed operatively by plastic surgery. Her care included three rounds of tissue advancement, followed by a seven-day course of negative pressure wound therapy with installation and dwell time.

After a final round of reconstruction with tissue advancement, a 3M™ Prevena Restor™ Bella●Form™ Dressing was applied to manage the incisions and bolster the graft.



**Figure 2.** Application of closed incision negative pressure.



**After one week,** the Prevena Restor™ Bella●Form™ Dressing was removed. Upon removal, the skin graft appeared viable and the wound edges appeared well-approximated, dry, and intact. Non-adherent silicone dressings (3M™ Adaptic™ Non-Adhering Dressing) were placed over the skin graft recipient site, followed by abdominal pads. This was followed by simple dressing changes several times weekly for four weeks.



**At four weeks postoperatively,** the wound appeared well approximated with normal scabbing, so staples were removed.



**Figure 3.** Wound at four weeks postoperatively.



**At six weeks,** the wound remained well-healed, with minimal scabbing.



**Figure 4.** Wound at six weeks postoperatively.

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.

### 3M™ Prevena™ Therapy in lower-extremity fracture patients<sup>22</sup>

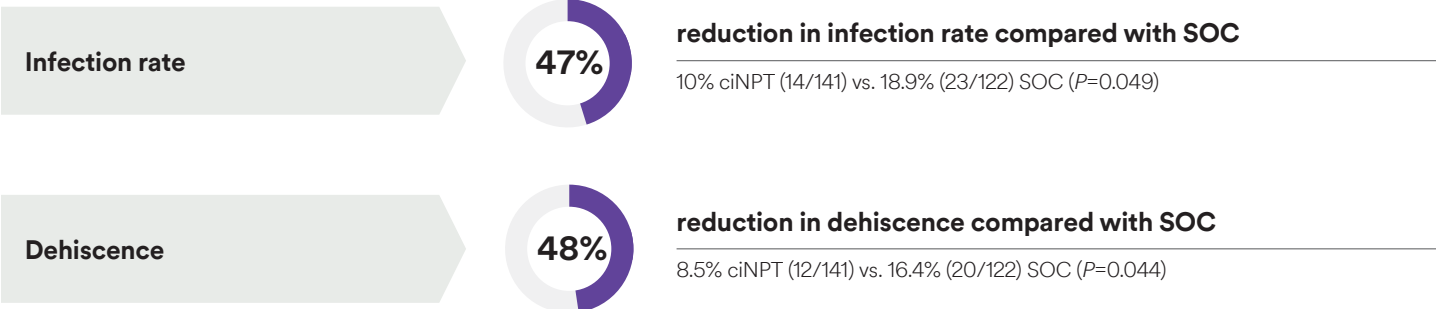
In a prospective randomized multicenter clinical trial of 249 patients with 263 blunt-trauma, high-risk, lower-extremity fractures (Incisional negative pressure wound therapy after high-risk lower extremity fractures; Stannard 2012) conducted at four Level I trauma centers, 122 fractures were randomized to a control group and provided with standard postoperative gauze dressings, and 141 fractures were treated with Prevena Therapy.

Outcome data included the development of acute infections (defined as occurring during the initial hospitalization), late infections, and wound dehiscence (defined as any separation of the surgical incision that required either local wound care or surgical treatment).

The study found that closed incision negative pressure therapy (ciNPT) demonstrated significantly better outcomes than standard postoperative dressings.

#### Complication

#### Study outcomes



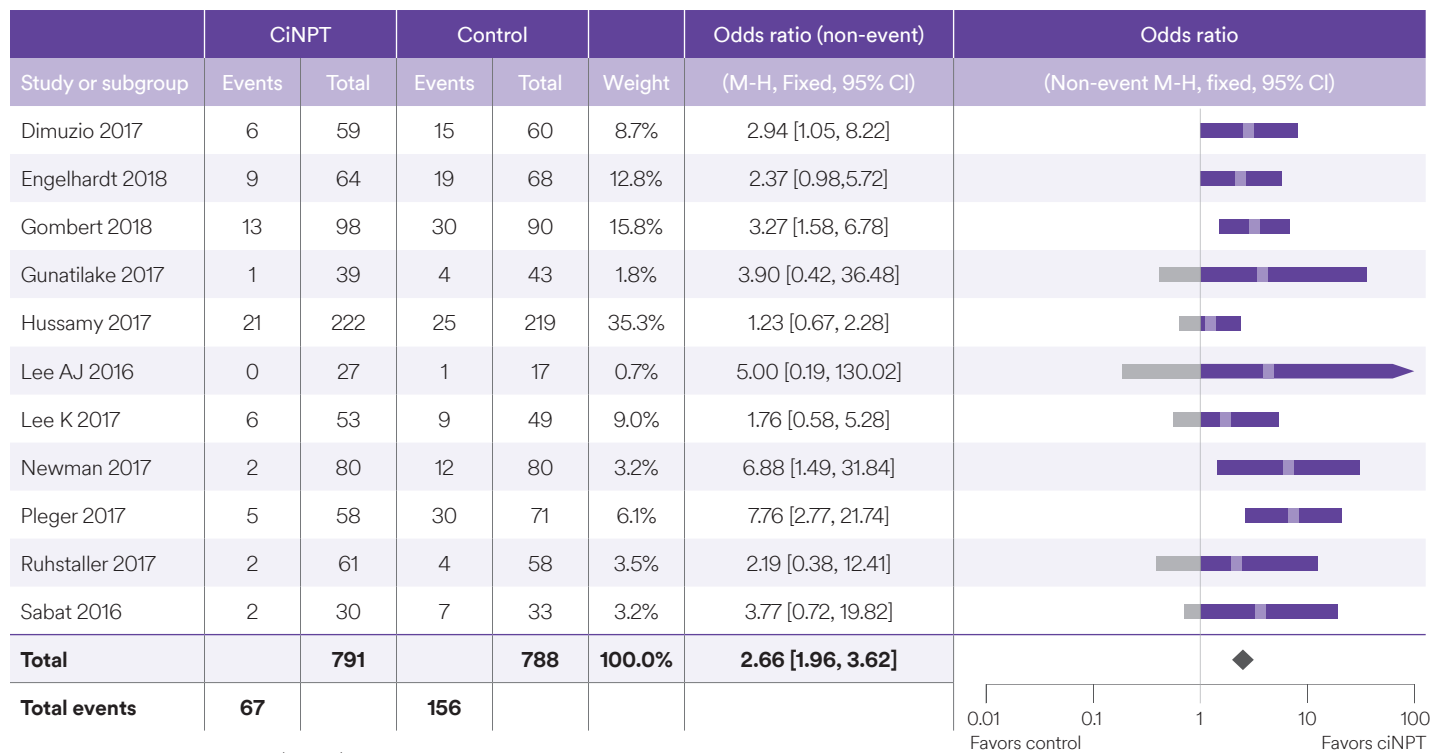
The above percentage calculations were derived based on relative data reported in the studies.

## Meta-analysis shows significant reduction in SSIs with 3M™ Prevena™ Therapy<sup>23</sup>

A systematic literature search of 540 publications and a subsequent meta-analysis of 30 studies comparing Prevena Therapy with traditional dressings was conducted (Meta-analysis of comparative trials evaluating a single-use closed-incision negative-pressure therapy system; Singh 2019). Surgical subgroups analyzed included colorectal/abdominal, obstetrics, groin/vascular, cardiac, and lower extremity. For all meta-analyses performed using the fixed-effects approach, Prevena Therapy demonstrated a reduction in SSIs, compared with traditional dressings.

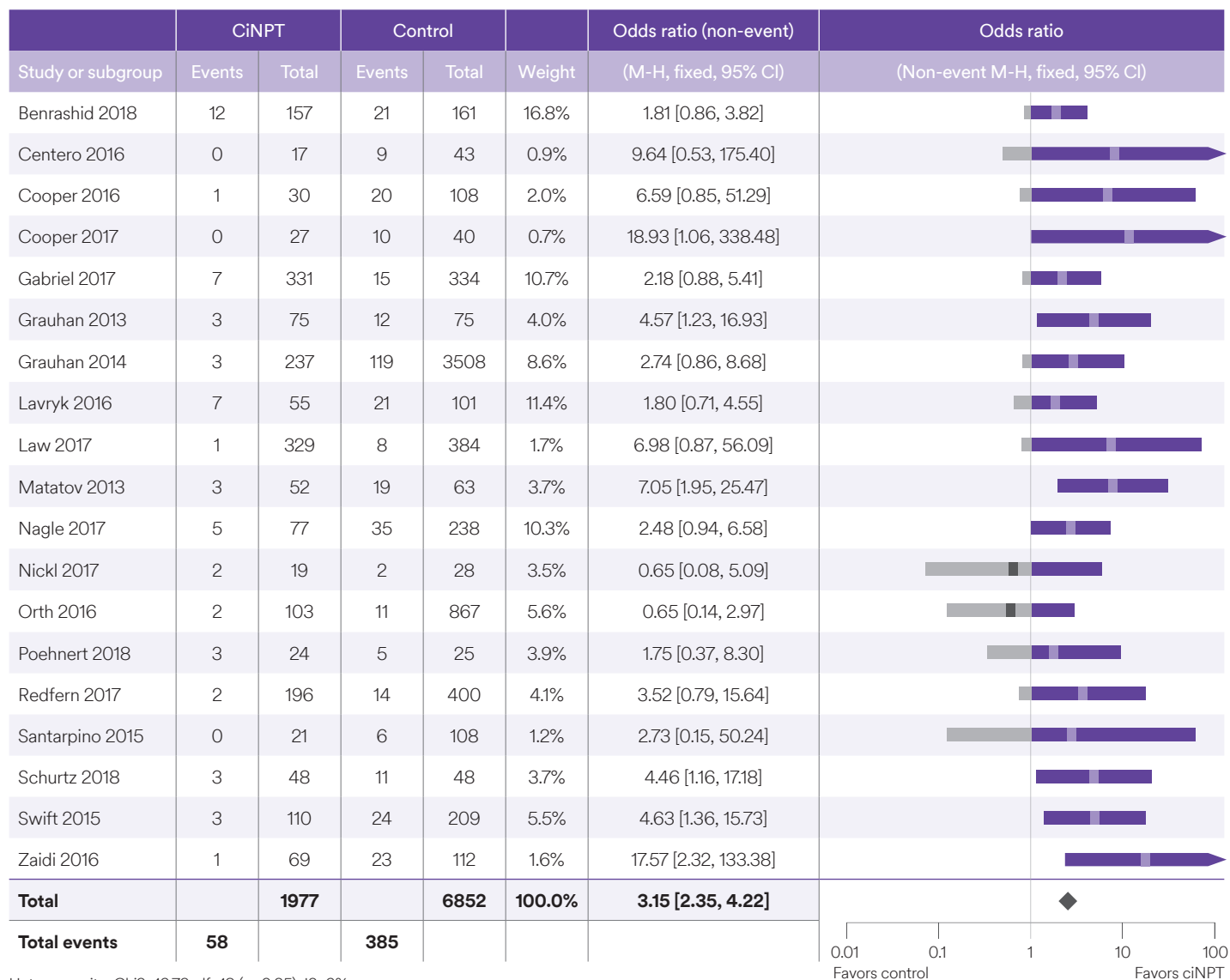
An additional lower extremity subgroup analysis was performed on five studies of total hip arthroplasty, total knee arthroplasty, and hip and knee periprosthetic fracture surgery. The results demonstrated a reduction in SSI in favor of Prevena Therapy use (OR = 6.4; 95% CI, 2.8–14.8).

### Randomized controlled trial forest plot





## Observational study forest plot



## In addition to reducing complications, 3M™ Prevena™ Therapy helps to demonstrate quality-of-life improvements

- **24% increase in quality of life vs. SOC**, in a single-center, single-blind, randomized controlled trial, with 64 patients, that measured quality of life (at discharge and at six weeks) as a secondary endpoint<sup>24</sup> (EQ-5D-3L score of 73 with Prevena Therapy vs. EQ-5D-3L score of 59 with standard gauze;  $P=0.039$ )
- **25% decrease in time to complete drain removal vs. SOC**, in a single-site, retrospective cohort study that compared postoperative outcomes of 331 patients who used 3M™ Prevena Therapy with 334 patients who used SOC<sup>25</sup> (9.9 days with Prevena Therapy vs. 13.1 days with SOC;  $P<0.0001$ )
- **Significant improvements in surgeon and patient satisfaction with scarring**, in a single-center, prospective, comparative study that compared patients treated with Prevena Therapy (17 patients/25 breasts) with patients treated with SOC (20 patients/22 breasts)<sup>26</sup>

## Finite/bench models

Bench and animal studies show numerous potential benefits of Prevena Therapy:

- **50% reduction in simulated lateral strain** (0.9 to 1.2kPa) along the incision in a finite model, which helped relieve the tension created by the sutures<sup>13</sup>
- **45% decrease in lateral tensile stress at superficial sutures**, and 50% decrease in lateral tensile stress at deep sutures in a finite model, closing the gap in the simulated incision and eliminating the vertical compression in the sides of the incision<sup>13</sup>
- **61% reduced incisional width vs. competitors** in a comparative bench study under controlled conditions, when measured after one hour of negative pressure application. This calculation was derived based on relative patient group incidence rate reported in this study<sup>27</sup>
- **51% stronger approximation, with 43% stronger approximation at staple lines**, in a benchtop model<sup>13</sup>

The above percentage calculations were derived based on relative data reported in the studies.

# 3M™ Prevena™ Therapy economic models

## THA and TKA surgery

	Prevena Therapy (n=30)	AQUACEL® Ag (n=108)
Number of SSIs (a)	1	20
Percentage of SSIs	3.3%	18.5%
Cost per SSI <sup>28</sup> (b)	\$15,129	\$15,129
Cost of SSI per patient (aXb)/n	\$504	\$2,802
Cost of therapy per patient*	\$695	\$31
Total cost per patient	\$1,199	\$2,833

Based on a retrospective quality improvement analysis of 138 consecutive revision hip and knee operations performed by a single surgeon over a 34-month period.

**\$1,634<sup>29</sup>**  
in potential cost  
savings per patient

## Mastectomy and breast reconstruction

	Prevena Therapy (n=25 breasts)	Standard of care (n=22 breasts)
Post-surgical complications	1 (4%)	10 (45%)
Potential additional cost <sup>30,31</sup>	≈\$10,000	≥\$100,000
Cost of therapy per breast*	\$695	\$31
Total cost per patient	\$1,610 (n=17)	\$5,034 (n=20)

In a single-center, prospective, comparative study involving oncological breast surgery, patients treated with Prevena Therapy (17 patients/25 breasts) were compared with patients treated with SOC (20 patients/22 breasts). Postsurgical complications (infection, hematoma, seroma, and skin necrosis) were evaluated on days 7, 14, 30, and 90.

**\$3,424<sup>26</sup>**  
in potential cost  
savings per patient

➤ **The Prevena Therapy group had significantly better outcomes, despite a higher prevalence of high-risk factors.**

\*Based on hypothetical economic models. Estimates based on price of 3M™ Prevena Restor™ Incision Management System and AQUACEL® Ag; individual prices may vary.



# 3M clinical education programs

## Medical education opportunities are available through the 3M Global Education Alliance

- 3M is committed to educating healthcare professionals (HCPs) on the safe and effective use of our products with a focus on optimizing patient outcomes and demonstrating value for practitioners and their facilities
- Recognizing the importance of education to quality care, 3M offers a comprehensive portfolio of evidence-based learning opportunities designed and led by expert faculty
- 3M Global Education Alliance also offers a wide range of educational forums at the local, regional and national level

Program	Program Detail
Inside 3M	<ul style="list-style-type: none"><li>• Provides HCPs globally the opportunity to learn more in our 3M offices about the development, science and clinical use of our products</li><li>• Clinical and research faculty, along with 3M leadership, facilitate a robust program with clinical discussions, scientific data and research conversation, and safety information</li><li>• Participants can tour our state-of-the-art research and development, manufacturing and simulation facilities</li></ul>
ACES programs	<ul style="list-style-type: none"><li>• Peer-to-peer events designed to educate clinicians on the scientific evidence and clinical uses of the 3M portfolio</li><li>• Didactic and interactive group discussions combine hands-on training with education on therapy options for complicated wounds, incision management and epidermal grafting</li></ul>
Bio-skills labs	<ul style="list-style-type: none"><li>• Interactive programs allow HCPs to enhance their technical skills through evidence-based didactic sessions, case-based discussions and practice in a cadaver lab with expert faculty</li><li>• Course instructors share their strategies for optimal patient management and demonstrate surgical techniques</li><li>• Through interactive group discussions with faculty and peers, attendees gain a better understanding of advanced therapies to help improve patient outcomes</li></ul>
Webinar programs	<ul style="list-style-type: none"><li>• Live or on-demand webinars</li><li>• Allow participants to view online presentations and/or video demonstrations and have open dialogue with presenters during live question-and-answer sessions</li></ul>
Medical conferences & symposiums	<ul style="list-style-type: none"><li>• 3M typically offers ancillary educational opportunities in conjunction with conferences, society meetings, or congresses that 3M attends</li><li>• At supported conferences, participants are invited to attend 3M symposiums led by expert panels that focus on advanced technologies, surgical techniques and case-based experience</li></ul>

Learn on your schedule at [www.3M.com/Medical](http://www.3M.com/Medical).

# 3M partnership programs

## Committed to a successful partnership

- Healthcare economics and new policies have changed the way you do business
- You need a partner who understands your challenges, and who delivers both value and devices that support best-in-class patient care
- 3M partners benefit from highly personalized and valuable services when they take advantage of our full line of advanced therapy products

Program	Detail
3M™ Express Program	Allows users to order, track orders, track assets and manage outcomes in one easy-to-use online portal
Customer Support (in-person and virtual)	<b>Providing:</b> <ul style="list-style-type: none"><li>• Clinician support and consultation in the acute setting</li><li>• Discharge and transition support to transition patients from the acute to the post-acute setting</li><li>• Patient and caregiver support in the post-acute setting</li></ul>
Customer Support (remote) The 3M Advantage Center	<b>Your first call for every aspect of care:</b> <ul style="list-style-type: none"><li>• Ordering, delivery, reimbursement</li><li>• Virtual Therapy Specialist consultation</li><li>• Technical support</li></ul>
3M Reimbursement Hotline	<b>A team of reimbursement professionals helps you through every step of the process:</b> <ul style="list-style-type: none"><li>• Payor requirements</li><li>• Insurance coding</li><li>• Submitting payor documentation</li></ul>
Free product evaluation	Allows healthcare providers or accounts to trial/evaluate 3M products
Digital health programs	<ul style="list-style-type: none"><li>• iOn HEALING™ Mobile App: Flexibility to instantly place orders on the go and receive status updates</li><li>• E-Prescription: An easy and secure way to submit a complete and accurate prescription directly to 3M</li><li>• ALLSCRIPTS®: 3M is integrated with pre-loaded information from your hospital EMR system</li></ul>

Contact your local 3M Representative for more information.

# Evidence table by specialty

- The body of evidence for using ciNPT has been growing steadily since 2006
- The table below is based on the Evidence Rating Scale for Therapeutic Studies by the American Society of Plastic Surgeons
- The types of incisions treated with ciNPT and 3M™ Prevena™ Therapy continue to expand and now include fractures (e.g., hip, lower extremity), abdominal wall reconstruction, laparotomy, sternal, and vascular surgical sites

Surgical specialty	Level of evidence	1st author (year)	Surgical incision type	Incision-related postoperative clinical endpoints*
Orthopedics	1	Higuera-Rueda (2021)	Revision total knee arthroplasty (rTKA)	Surgical site complications (SSC)
		Newman (2018)	Total hip arthroplasty (THA); TKA	SSC
		Pauser (2014)	Hip hemiarthroplasty	Seroma
		Pachowsky (2012)	THA	Seroma
	2	Redfern (2017)	THA; TKA	Surgical site infection (SSI); hematoma; edema; wound dehiscence
	3	Cooper (2018)	Periprosthetic fracture surgery (hip or knee)	SSC; SSI
		Anatone (2018)	THA; TKA	SSC
		Cooper (2016)	Hip revision; knee revision	SSC; SSI
Vascular	1	Engelhardt (2018)	Groin	SSI
		Gombert (2018)	Groin	SSI
		Kwon (2018)	Groin	SSCs; SSI (Szilagyi)
		Lee (2017)	Groin	SSI
		Pleger (2017)	Groin	SSI (Szilagyi Classification)
	2	Weir (2014)	Bilateral femoral incisions	SSC requiring surgical intervention
	3	Matatov (2013)	Groin incision	SSI (Szilagyi Classification)
Cardiothoracic	5	Haghshenasaskashani (2011)	Popliteal-tibial bypass	
	1	Lee (2017)	Lower leg incision - great saphenous vein harvest	
	2	Grauhan (2014)	Sternotomy	SSI
		Grauhan (2013)	Sternotomy	SSI
	3	Reddy (2016)	Sternotomy	SSC; dehiscence
	4	Colli (2011)	Sternotomy	SSI
	2	Ferrando (2018)	Oncological breast surgery	SSCs (SSIs, hematoma, seroma, skin necrosis)
Plastic and aesthetic surgery	3	Gabriel (2018)	Mastectomy and implant/reconstruction	SSCs (SSIs, dehiscence, seroma)
		Lo Torto (2017)	Sternotomy (pectoralis major muscle flap for wound infection)	Seroma; hematoma; wound dehiscence; revision
		Nickl (2017)	Sternotomy (pectoralis major muscle flap for wound infection)	SSI; hematoma; revision; wound repair disturbances
		Gabriel (2016)	Mastectomy and implant/reconstruction	Hematoma; dehiscence
Obstetrics	1	Gunatilake (2017)	Cesarean section incision	SSO; revision; pain
	2	Swift (2015)	Cesarean section incision	SSI; dehiscence
General	1	Javed (2018)	Pancreaticoduodenectomy	SSI
	2	Poehnert (2017)	Abdominal incision (ileostomy)	SSI
		Cantero (2016)	Abdominal incision (ileostomy)	SSI
	3	Schurtz (2018)	Laparotomy	SSI; dehiscence
		Zaidi (2017)	Laparotomy	SSI; dehiscence
	4	Bollero (2015)	Pathological scar revisions	

\*Clinical endpoints reflect the conditions and methods specific to each publication and should not be interpreted as general outcomes related to Prevena Therapy. Individual results for each case may vary, depending on the patient, circumstances, and conditions.



# Reimbursement information

CPT Code*	97607	97608
Description	Negative pressure wound therapy, (e.g. vacuum-assisted drainage collection) utilizing disposable, non-durable medical equipment including provision of exudate management collection system topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area less than or equal to 50 square centimeters	Negative pressure wound therapy, (e.g. vacuum-assisted drainage collection) utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area greater than 50 square centimeters
Physician fee schedule non-facility (office) <sup>†</sup>	\$351.72 <sup>‡</sup>	\$342.30 <sup>‡</sup>
Physician fee schedule facility (inpatient/outpatient) <sup>†</sup>	\$23.38 <sup>‡</sup>	\$25.82 <sup>‡</sup>
Hospital inpatient <sup>§</sup> department <sup>†</sup>	Included in diagnosis-related group payment (DRG) <sup>¶</sup> — no separate payment	Included in diagnosis-related group payment (DRG) <sup>¶</sup> — no separate payment
Hospital outpatient department (HOPD) <sup>¶</sup> Fee schedule Outpatient observation services** (OPPS payment status indicator) <sup>#</sup>	\$345.84 5052 (T) <sup>#</sup>	\$345.84 5052 (T) <sup>#</sup>
Ambulatory Surgical Center (ASC) <sup>¶</sup> Fee schedule	Not available for billing	Not available for billing

Some commercial insurers have specific HCPCS codes required when billing disposable negative pressure wound therapy (NPWT). For additional information regarding commercial insurance coverage, please call the 3M Reimbursement Education Hotline at 1-800-668-6812 for assistance. Verification of benefits and coverage for 3M™ Prevena™ Incision Management System is highly recommended before services are provided.

<sup>§</sup>An inpatient stay starts when a patient is formally admitted to a hospital with a doctor's order.

\*\*Observation services are hospital outpatient services given to help the doctor decide if the patient needs to be admitted as an inpatient.

Note: All amounts listed do not reflect adjustments for quality reporting, e-prescribing, sequestration or any other reduction. All numbers represent national averages only. The codes discussed on this coding sheet do not consider coverage; it addresses coding and payment amounts only.

\*Current Procedural Terminology (CPT) copyright 2021 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA.

<sup>†</sup>Place of Service (POS) Code for non-facility includes: Office-11, Prison/ Correctional Facility-09, Skilled Nursing Facility (SNF) Part B-32, and Independent Clinic-49. POS Code for facility includes: Off-Campus-Outpatient Hospital-19, Inpatient Hospital-21, On-Campus-Outpatient Hospital-22, Ambulatory Surgical Center (ASC)-24, and SNF Part A-31. CMS Place of Service Code Sheet

<sup>¶</sup>Medicare Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment Period (NFRM) CMS-1736-FC

<sup>‡</sup>Medicare Final Rule. CMS-1734-F- Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2021

<sup>¶</sup>Medicare IPPS Annual Proposed and Final Rules, and Relevant Correction Notices: Fiscal Year 2021

<sup>#</sup>CMS assigns an OPPS payment status indicator to every HCPCS code. The status indicator identifies whether the service described by the HCPCS code is paid under OPPS and if so, whether payment is made separately or packaged. Status Indicator T means - Procedure or Service, Multiple Procedure Reduction Applies. Paid under OPPS; Separate APC Payment. CMS Addendum D1

For more information, call the 3M Reimbursement Education Hotline at **1-800-668-6812** or email: **ReimbursementEducation@mmm.com**

**Important Note:** The information contained in this document is provided for informational purposes only and represents no statement, promise or guarantee by 3M concerning the levels of reimbursement, payment, calculations, eligibility, charges or that these policies and codes will be appropriate for specific services or products provided or that reimbursement will be made. Information is current as of the date of publication and is subject to change at any time. 3M recommends that you consult your local CMS contracted carrier, Medicaid carrier or other applicable payor organization with regard to specific reimbursement policies, coverage, documentation, payment and criteria. Individual circumstances and situations may vary.

# Company overview

## World-class care deserves world-class support partners

### About 3M:

At 3M, we apply science in collaborative ways to improve lives daily. More than 60,000 3M products are used in homes, businesses, schools, hospitals and other industries. With corporate operations in 70 countries and sales in 200, we are committed to creating the technology and products that advance every company, enhance every home and improve every life.

### About 3M Medical Solutions:

We partner with healthcare professionals globally to manage and repair skin, reduce complications and restore lives. From products designed to protect and support your patient along their surgical journey to leading innovations in negative pressure wound therapy, surgical incision management, advanced wound care and skin integrity, we are focused on addressing your challenges and meeting the needs of the people you care for every day.

- Our team of customer service representatives in the U.S. takes more than 50,000 calls a year, helping clinicians understand how to safely use our products and apply them to patients.
- 3M Health Care Academy offers multiple resources and training opportunities to help deepen expertise.
- We've invested more than \$2 billion into research and development and have over 115,000 patents in our name.
- In 2019 alone, 3M offered more than 1,000 virtual and in-person educational programs for 123,000 providers, issuing 70,000+ continuing education credits. What's more, our field services team is available to answer questions you might have, at any time.
- 3M has supported more than 2,200 peer-reviewed publications and 4,300 publications globally.

Clinical scenario	Wound therapy innovation	
Dressings to assist with chronic, stalled, or delayed healing wounds	Wound management	3M™ Promogran™ Matrix Wound Dressing 3M™ Promogran Prisma™ Matrix
Clean closed incisions following sutured or stapled closure	Incision management	3M™ Prevena™ Incision Management System
	Incision & surrounding soft tissue management	3M™ Prevena Restor™ Incision Management System
Open abdomen where primary goal is fascial closure	Active open abdomen management	3M™ AbThera™ Advance Open Abdomen Negative Pressure Therapy
Open wounds, including acute, traumatic, chronic, sub-acute and dehiscent wounds	Hospital-use wound management	3M™ V.A.C.® Ulta Therapy System 3M™ Veraflo™ Therapy
	Portable wound management — ideal for patient transition or discharge	3M™ V.A.C.® Via Therapy System 3M™ ActiV.A.C.™ Therapy System

## Your 3M team

Role	Area of focus	Our promise
Surgical Site Representative (SSR)	Perioperative support	Ensuring a seamless 3M surgical/OR experience for surgeon, hospital, staff and patient
Wound Healing Solutions Rep (WHS)	Wound healing support	Ensuring a seamless 3M wound healing experience with healthcare provider, product, program and patient/caregiver support
Associate Territory Representative	Patient transitions	Ensuring a seamless experience for transition support with discharging the patient from acute to post-acute
District Clinical Specialist	Clinical support	Ensuring clinical training and support as needed by the account
Field Service Manager	Field service	Ensuring product delivery/support as required by the customer
District Manager	Account oversight	Ensuring an overall best-in-class experience and serving as account liaison for supporting 3M account team

Through years of continuous design evolution, technological improvements, and account-dedicated personnel resources, the 3M NPWT platform has developed devices that can help to improve patient outcomes. This is what makes 3M more than a business partner.



# Product ordering information

SKU	Description	UOM
PRE5001	3M™ Prevena Restor™ Arthro●Form™ Incision Management System – 33 cm X 30 cm	1
PRE5055	3M™ Prevena Restor™ Arthro●Form™ Dressing Kits – 33 cm X 30 cm	5
PRE5101	3M™ Prevena Restor™ Arthro●Form™ Incision Management System – 46 cm X 30 cm	1
PRE5155	3M™ Prevena Restor™ Arthro●Form™ Dressing Kits – 46 cm X 30 cm	5
PRE5501	3M™ Prevena Restor™ Axio●Form™ Incision Management System – 29 cm X 28 cm	1
PRE5555	3M™ Prevena Restor™ Axio●Form™ Dressing Kits – 29 cm X 28 cm	5
PRE5221	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 21 cm X 19 cm	1
PRE5255	3M™ Prevena Restor™ Bella●Form™ Dressing Kits – 21 cm X 19 cm	5
PRE5321	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 24 cm X 22 cm	1
PRE5355	3M™ Prevena Restor™ Bella●Form™ Dressing Kits – 24 cm X 22 cm	5
PRE5421	3M™ Prevena Restor™ Bella●Form™ Incision Management System – 29 cm X 27 cm	1
PRE5455	3M™ Prevena Restor™ Bella●Form™ Dressing Kits – 29 cm X 27 cm	5
PRE5601	3M™ Prevena Restor™ Roto●Form™ Incision Management System 31 cm X 29 cm	1
PRE5655	3M™ Prevena Restor™ Roto●Form™ Dressing 31 cm X 29 cm	5

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1-800-228-3957

Web 3M.com/Medical

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

**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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