3M | PREVENA™
Incision Management System

The power to protect in plastic surgery.

Enabling low-touch post-operative care to protect patients, clinicians and hospitals from the consequences of surgical site complications.

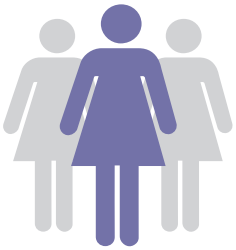
We understand things have changed recently.

The COVID-19 pandemic has resulted in consequences which have rippled across the health care setting and beyond.

As we resume elective surgery, clinicians are redefining post-operative care and adopting their approaches to achieve.

- Early discharge
- Home-based recovery
- Virtual clinics
- Low-touch care
- Minimal complications
- Low readmissions

Surgical Site Infection in plastic surgery can give a suboptimal aesthetic outcome, but it can also impair psychosocial well-being, delay hospital discharge, and lead to readmission and further surgery.[1]



Postmastectomy breast reconstruction is on the rise, and more patients are requesting and qualifying for immediate reconstruction, which has a higher complication rate.[2–4]

SSI rates are twice as high in mastectomies with immediate reconstruction than mastectomy alone.[5]

5.0%
In mastectomy without reconstruction.

10.3%
In mastectomy with implant reconstruction.

10.7%
In mastectomy with flap reconstruction.

Although breast surgery is considered to be clean surgery, infection rates are well above average.

33%
Overall surgical complication rate in breast reconstruction surgery.[6]

19%
Breast reconstruction patients need reoperations.[6]

€8,800*
Mean cost of surgical complications in breast reconstruction surgery.[7]

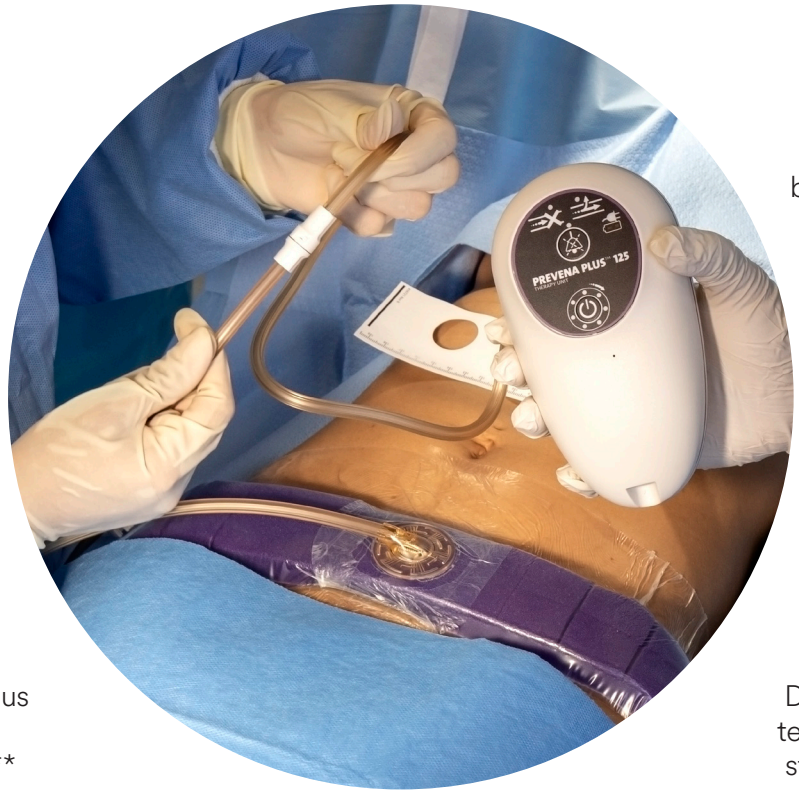
By working to protect incisions from postoperative complications, PREVENA™ Therapy works to help stop the ripple effect before it begins, protecting patients, surgeons, staff, practices, and hospitals from potential consequences through low touch care.

*Based on mean cost of $10,402. Exchange rate from USD to EUR correct as of Jul 2020.

PREVENA™ Therapy manages and protects surgical incisions by:

Helping to hold incision edges together

Reducing edema



Acting as a barrier to external contamination

Delivering continuous -125mmHg up to 7 or 14 days**

Decreasing lateral tension of sutured/ stapled incisions†[8]

Removing fluids and infectious materials*

“NICE advice”

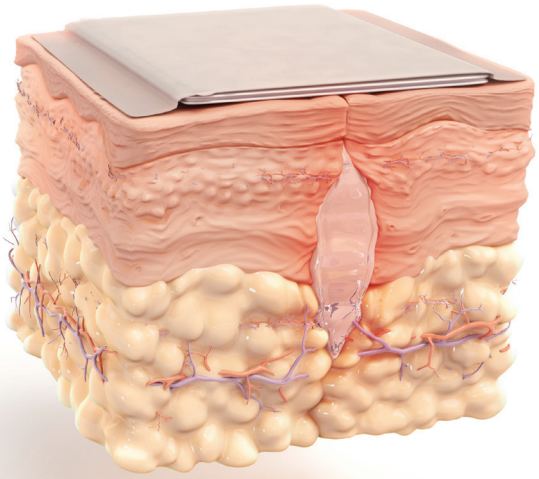
Did you know?

NICE have published a medical innovation briefing on the use of “Prevena Incision Management for Closed Surgical Incisions”. Access the full document at **https://www.nice.org.uk/advice/mib173**

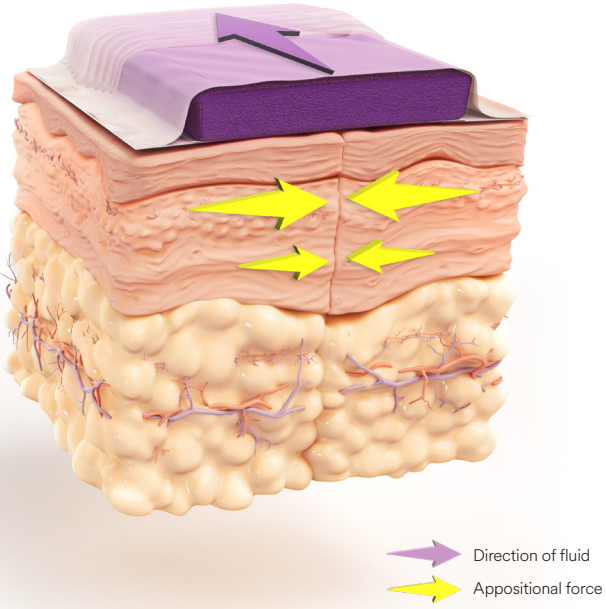
*In a canister
**Standard length of therapy is 7 days. PREVENA Plus (TM) 125 Therapy Unit (14 days) can be purchased separately.
† In computer and bench models

PREVENA™ Therapy utilizes reticulated open cell foam technology and -125mmHg negative pressure.

Passive therapy



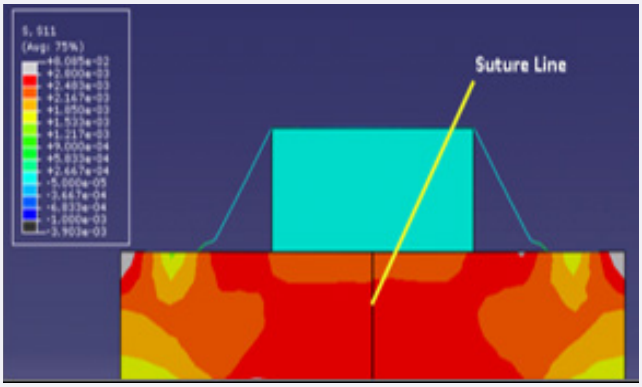
PREVENA™ Therapy



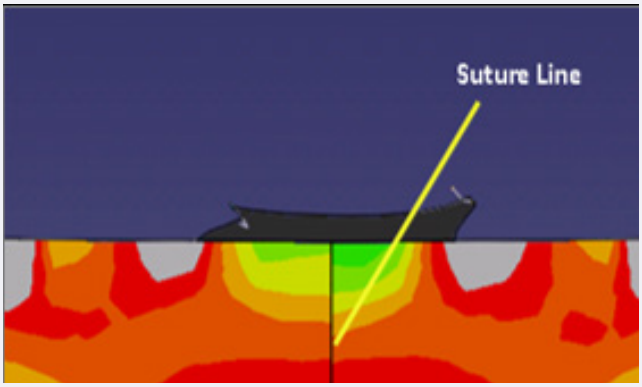
Under -125mmHg of negative pressure, the reticulated open cell foam dressing collapses to it's geometric center. This brings the incision edges together, reduces lateral tension, and also allows for improved fluid management.[8–10]

Delivering a 50% reduction in lateral tension.[8]

Reducing lateral strain is important to maintain the integrity of closed surgical incision. Using a finite computer model on a simulated incision, PREVENA™ has been shown to reduce lateral strain by approximately 50% (0.9 to 1.2kPa) along the incision.



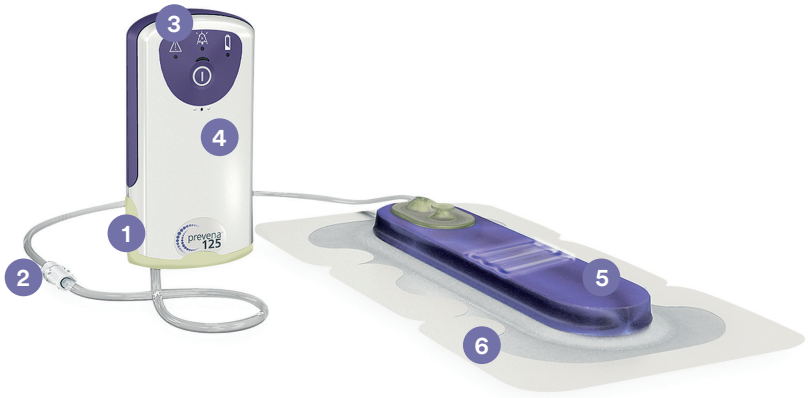
A Lateral strain on simulated incision without application of PREVENA™ therapy. Orange and red colours indicate high lateral strain.



B Lateral strain on simulated incision with application of PREVENA™ therapy. Yellow and green colours indicate low lateral strain.

The power of PREVENA™ Therapy.

PREVENA™ Therapy is packed with features specifically designed to help reduce the risk of surgical site complications.



1. **Replaceable canister**
   Store exudate and infectious fluids away from the surgical incision.
2. **V.A.C.® connector**
   Connect to other V.A.C. devices within the hospital setting for greater flexibility.
3. **Audible and visual alarms**
   Rectify therapy issues at an early stage.
4. **-125mmHg**
   To hold incision edges together and remove fluids.
5. **Foam bolster**
   Channels uniform negative pressure to the incision area, reducing lateral tension.
6. **Skin friendly interface layer**
   Wicks fluid away from the surface, with 0.019% ionic silver to help reduce bacterial colonisation.

Both the PREVENA™ and PREVENA PLUS™ Therapy units can support clinicians with early discharge into a home setting:

- Portable, singe use therapy
- No additional dressing changes for up to 7 days
- Shower friendly

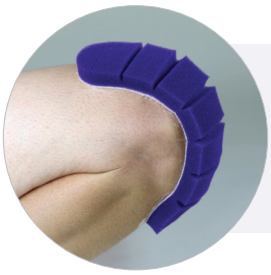
PREVENA™ 125 Therapy Unit (7 days)

Included with: PREVENA™ 13cm, PREVENA™ 20cm and PREVENA DUO™ System Kits.

PREVENA PLUS™ 125 Therapy Unit (7 days)

Included with: PREVENA™ 35cm and PREVENA CUSTOMIZABLE™ System Kits. PREVENA PLUS™ 125 Therapy Unit (14 days) can be purchased separately.

Multiple dressing sizes and configurations. With easy to use PEEL & PLACE™ dressings for linear incisions up to 35cm and CUSTOMIZABLE™ dressings for non-linear and intersecting incisions up to 90cm in length.



Designed to be flexible.

PREVENA™ Dressings are designed to allow for movement, enhancing the post-operative rehabilitation process.

Clinically proven. Across specialities.[11*]

A systematic literature review and associated meta-analysis supports the safety and effectiveness of PREVENA™ Therapy over closed incisions in reducing the incidence of surgical site infections (SSIs) and seromas versus conventional wound dressings.

Study overview

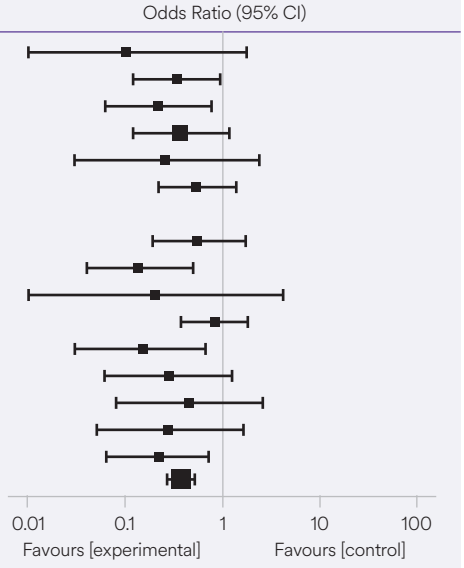
- Out of 426 studies in the initial search, ultimately, sixteen (16) prospective studies were included in this meta-analysis for SSI characterisation
- A total of up to 6,187 evaluable patients were included in this meta-analysis for SSI with 1,264 in the PREVENA™ Therapy (treatment) group and 4,923 in the conventional wound dressing (control) group
- A total of up to 952 evaluable patients were included in this meta-analysis for seroma with 366 in the PREVENA™ Therapy (treatment) group and 586 in the conventional wound dressing (control) group

Findings

- PREVENA™ Therapy aids in reducing the incidence of seroma and surgical site infections in Class I and Class II wounds.
- PREVENA™ Therapy demonstrated the greatest benefit in reducing SSIs in high risk patients

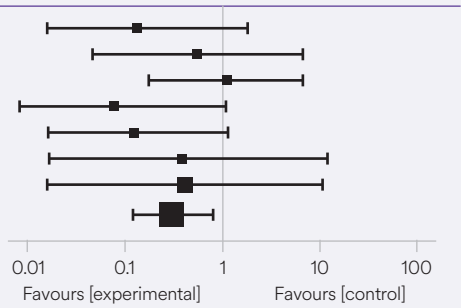
Forest plot of meta-analysis on surgical site infection

	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)



*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 myKCI.com.

Closed incision negative pressure therapy in oncological breast surgery: comparison with standard care dressings.[12]

Ferrando PM, Ala A, Bussone R, Bergamasco L. . *Plast Reconstr Surg Glob Open.* 2018 Jun;6(6):e1732.

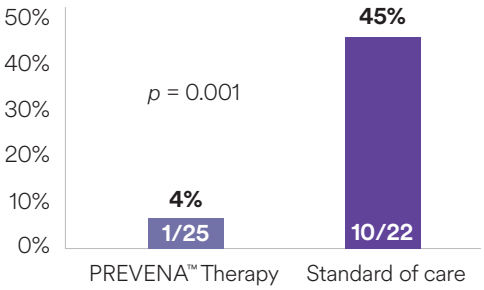
Study overview

- Prospective, single-centre comparative study to assess the efficacy of PREVENA™ Therapy vs. Standard of Care (Nexcare™ Steri-Strip™) in high risk onocological breast surgery patients
- Selected a total of 37 patients undergoing oncological breast surgery with a minimum of 4 risk factors. 17 patients (25 surgeries) voluntarily selected PREVENA™ Therapy, whereas the remaining 20 (22 surgeries) chose a conventional post-opeative dressing (standard of care)
- Follow-up controls to evaluate postsurgical complications were performed on days 7, 14, 30, and 90. At 12 months, the quality of life, scar, and overall aesthetic outcomes were evaluated with specific questionnaires filled in by surgeon and patient

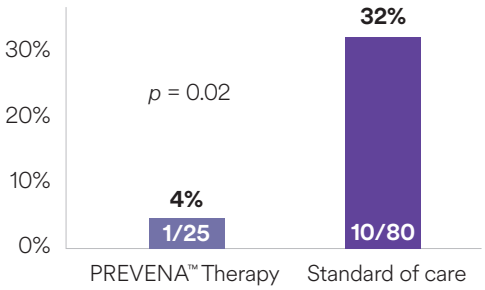
Findings

- The PREVENA™ Therapy sample showed a significant prevalence of high risk factors, especially extensive undermining and bilateral surgeries, and a predominance of women under 65 years; only 1/25 (4%) surgical procedures was followed by complications
- In the Standard Care sample, 10 of 22 surgeries (45%) were followed by complications. The difference in complication rate between the two samples was significant
- The BIS (Body Image Scale) scores suggested that most patients were satisfied with their body image regardless of the type of dressing. All other questionnaire scores clearly vouched for a significant superiority of PREVENA™ Therapy
- PREVENA™ Therapy was shown to be well-tolerated, adaptable and reliable in oncological breast surgery

Surgical site complications at 30 days



Skin necrosis at 30 days



Level of satisfaction

For all tests, the higher the scores, the lower the level of satisfaction. With the exception of the Body Image Scale (BIS), all other scores clearly vouched for a significant superiority of the PREVENA™ Therapy post-surgery approach.

Questionnaire	PREVENA™ Therapy	Standard of care	*P*
Body Image Scale *(BIS) (max 30)*	6 (1–14)	6 (3–14.5)	0.58
Patients Scar Assessment Scale *(PSAS) (max 50)*	11 (6–18)	20 (14–34)	0.002
Observer Scar Assessment Scale *(OSAS) (max 50)*	7 (6–13)	24 (17–29)	0.01
Manchester Scare Scale *(MSS) (max 18†)*	7 (5–12)	12 (19–15)	0.001

Economic analysis based on the use of closed-incision negative-pressure therapy after postoperative breast reconstruction.[7]

Gabriel A, Maxwell GP. *Plast Reconstr Surg*. 2019; 143: 36S-40S.

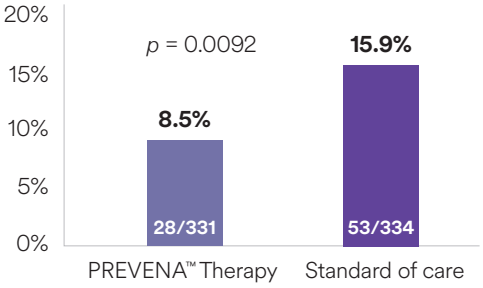
Study overview

- Single site, retrospective review of adult female patients who underwent breast reconstruction postmastectomy
- The study included data on 356 female patients (PREVENA™ Therapy = 177, SOC = 179) and 665 breasts (PREVENA™ Therapy = 331, SOC = 334)
- A hypothetical cost model was applied to clinical results of the study (costs calculated in $USD and presented in this summary as €EUR*)

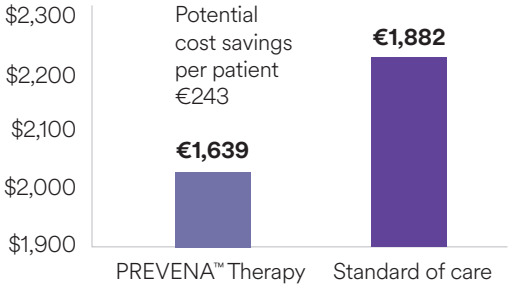
Findings

- The complication rate for the PREVENA™ Therapy breast group was 8.5% (28/331) versus 15.9% (53/334) for the SOC group (P = 0.0092)
- Based on the adjusted estimated mean complication cost of €8,800 (converted from $10,402 in the study), the total complication cost for the PREVENA™ Therapy group was approximately €211,834 versus €333,942 for the SOC group
- Taking into account the cost of each therapy, the calculation showed a per-patient cost savings of €243

Complications rates



Total per patient cost



Cost model

A hypothetical cost model applied to the clinical results of this study shows a potential cost savings of €243 per patient with the use of PREVENA™ Therapy.

Questionnaire	PREVENA™ Therapy	Standard of care
Number of patients	177	179
Percent of complications	13.6%	21.2%
Mean cost per complication	€8,800	€8,800
Total complication cost	€211,834	€333,942
Cost of complication per patient	€1,197	€1,866
Cost of therapy per patient†	€442	€16
Total cost per patient	**€1,639**	**€1,882**

†Estimate based on price of PREVENA™ PEEL & PLACE™ Dressing System and standard of care (gauze) changed once per day at €16 a week.
Exchange rate from USD to EUR correct as of Jul 2020.

Closed-incision negative-pressure therapy decreases complications in ventral hernia repair with concurrent panniculectomy.[13]

Diaconu SC, McNichols CHL, Ngaage LM, et al. *Hernia*. 2018 (24): 49-55.

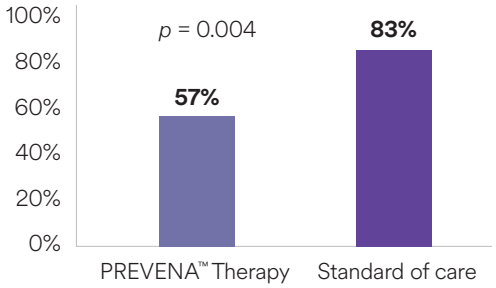
Study overview

- An 8-year, retrospective cohort study was conducted on 104 patients undergoing ventral hernia repair with concurrent panniculectomy (VHR-PAN) to evaluate the rate of post-operative complications
- 62 patients were treated with PREVENA™ Therapy and 42 patients were treated with standard sterile dressings/standard of care
- PREVENA™ Therapy cohort was older (p = 0.029), had a larger hernia size (p=0.031), higher rate of prior hernia repair (p = 0.009), higher rate required mesh use (p = 0.013) and higher rate with a component separation (p = 0.002)

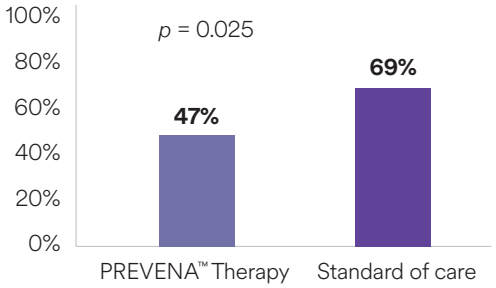
Findings

- Patients in the PREVENA™ Therapy group had fewer total complications (57% vs 83%, p = 0.004) and fewer surgical site occurrences† (SSO) (47% vs 69%, p = 0.025)
- After adjusting for potential confounding variables through logistic regression analysis, the use of PREVENA™ Therapy was shown to significantly decrease surgical site occurrence procedure intervention by nearly fourfold (OR = 0.28, p = 0.027) compared to standard surgical dressings

Total complications



Surgical site occurrences



Summary of complication outcomes

	PREVENA™ Therapy	Standard of care	*P*
n	62	42	
Surgical site occurrences (SSO)	29 (47%)	29 (69%)	0.025
Infection	23 (37%)	16 (38%)	0.918
Wound dehiscence	12 (19%)	12 (29%)	0.274
Skin necrosis	4 (7%)	7 (17%)	0.114
Chronic wound	21 (34%)	12 (29%)	0.569
Seroma	13 (21%)	8 (19%)	0.811
Hematoma	0 (0%)	3 (7%)	0.03
SSO-procedure intervention	21 (34%)	21 (50%)	0.027*

*Logistic regression used to determine effect of PREVENA™ Therapy while adjusting for potential confunders.

†Surgical site occurrence (SSO) included surgical site infection (SSI), wound dehiscence, skin necrosis, non-healing incisional wound, seroma, and hematoma.

Closed incision negative pressure therapy over incisions following hernia repair and panniculectomy.

Melanie Budd RN

Patient information

The patient was a 63-year-old female who underwent a hernia repair and panniculectomy. Previous medical history included Multiple Sclerosis and paraplegia with wheelchair use.

Diagnosis

A panniculectomy with complex abdominal wall hernia repair and placement of mesh was performed.

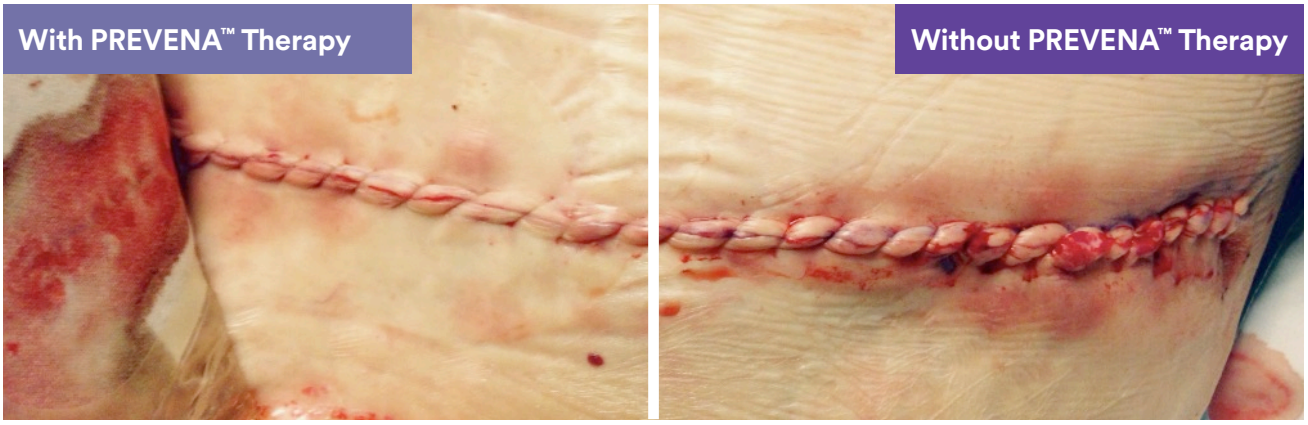


Figure A: Incision 4-hours post-surgery.

Initial incision treatment/application of PREVENA™ Therapy

Following completion of the hernia repair and panniculectomy, a PREVENA™ Incision Management System was applied using a PREVENA PEEL & PLACE™ Dressing (20cm) over the middle 1/3 of the incision area at -125mmHg continuous pressure. At 3–4 hours post-surgery, the dressing was replaced with the PREVENA CUSTOMIZABLE™ Dressing (Figure B).

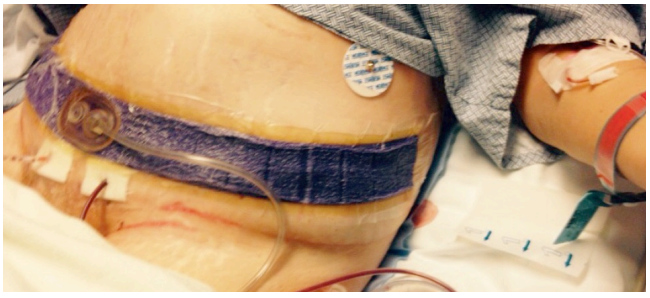


Figure B: Application of PREVENA CUSTOMIZABLE™ Dressing.

Discharge and follow-up

The PREVENA CUSTOMIZABLE™ Dressing was removed on postoperative day 4 and the patient was discharged home with standard dressings. The patient returned for follow-up 7 days post discharge. At 14 weeks post-surgery, the incisions were healed without complications. The incision remained healed without complications 12 months post surgery (Figure C).

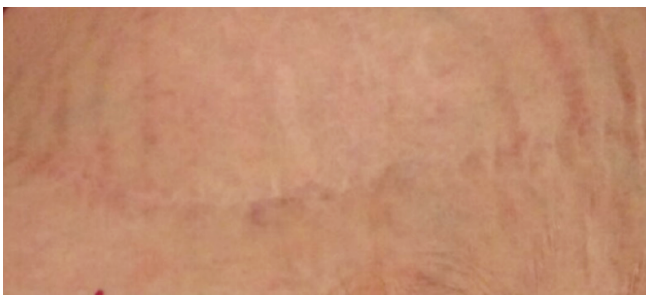


Figure C: Incision site 12 months post-surgery.

Photos and patient information courtesy of Melanie Budd RN. 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.

Mastectomy of the right breast for breast cancer and second stage reconstruction of the left breast.

Pietro M. Ferrando, MD, PhD, Plastic Surgery Department, Città della Salute e della Scienza, C.T.O. Hospital, Turin, Italy

Patient information

A 41-year-old female patient presented with breast cancer of the right breast. She had undergone a skin-sparing mastectomy for breast cancer and skin expander insertion in her left breast one year prior. A hypertrophic scar was observed in the middle of the upper quadrants of the left breast corresponding to the skin projection of the expander filling port (Figure A). The patient's comorbidities and risk factors included chemotherapy, steroid use, and smoking.

Diagnosis

The patient required nipple-sparing mastectomy on the right breast. An implant was inserted, and an acellular dermal matrix was used to support the implant. On the left breast, the skin expander was removed with a modified skin incision in order to remove the hypertrophic scar in the middle of the upper quadrants of the left breast, and an implant was inserted to complete the two-stage reconstruction.

Initial incision treatment/application of PREVENA™ Therapy

The patient was administered prophylactic cefoxitin to lower risk of infection. The PREVENA™ Incision Management System with the PREVENA™ CUSTOMIZABLE™ Dressing was applied over the closed incisions with -125mmHg negative pressure. The goals of therapy were to manage the surgical incision and hold the edges of the closed incision together. After 7 days these goals had been achieved (Figures B, C).

Diagnosis

The patient was discharged home with PREVENA™ Therapy on the incision site, and the PREVENA™ System was removed after 7 days during an outpatient clinic visit. Some skin erythema was noted where film adhesive was attached to the edges of the breasts. Thirty days post-surgery, the incisions were healed without complication (Figures D, E). Upon follow-up 12 months later, the incisions remained completely healed (Figures F, G).

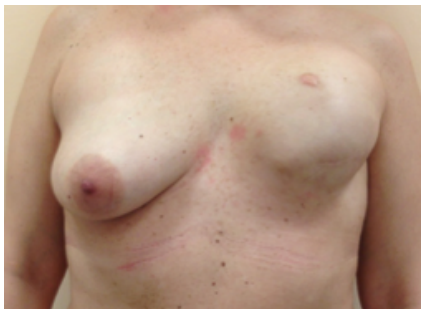


Figure A. Breasts prior to nipple-sparing mastectomy (prior skin-sparing mastectomy on the left).

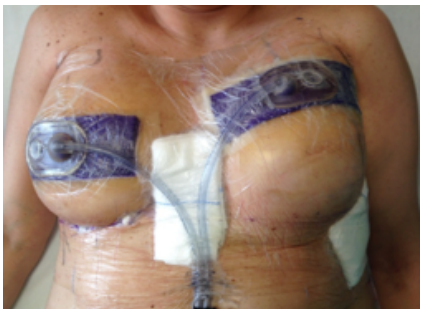


Figure B. Postoperative day 7. PREVENA™ CUSTOMIZABLE™ Dressing over the closed incisions.

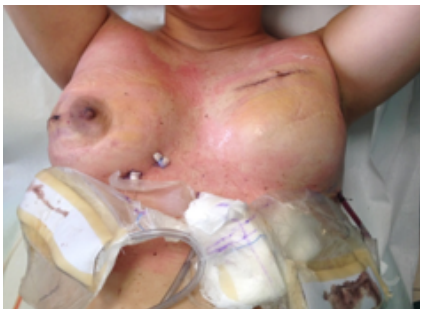


Figure C. Postoperative day 7. Removal of PREVENA™ CUSTOMIZABLE™ Dressings.

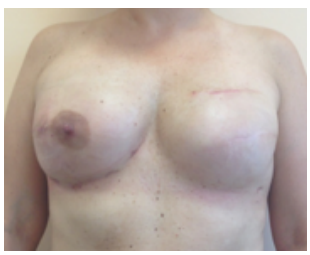


Figure D. Incisions closed at 30 days after mastectomy.

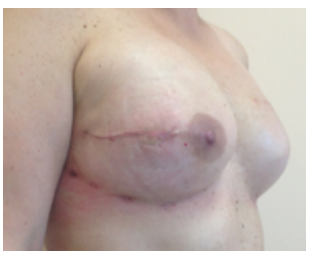


Figure E. Incisions closed at 30 days after mastectomy.

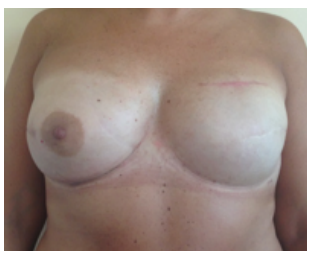


Figure F. Incisions remained healed at 12 months after mastectomy.

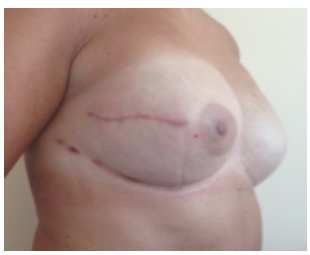


Figure G. Incision remained healed at 12 months after mastectomy.

Patient data and photos courtesy of Pietro M. Ferrando, MD, PhD; Plastic Surgery Department, Città della Salute e della Scienza, C.T.O. Hospital, Turin, Italy.

Closed-incision negative-pressure therapy: international multidisciplinary consensus reccomendations.[14]

Willy C, Agarwal A, Andersen CA et al. *Int Wound J*, 14: 385–398.

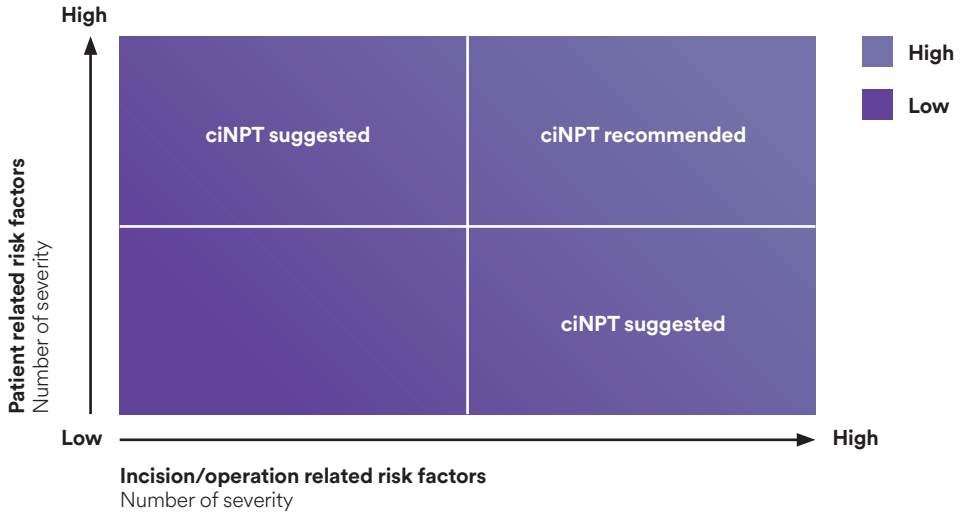
Study overview

- An extensive literature search for studies describing ciNPT use was conducted
- During a multidisciplinary consensus meeting, the 12 experts reviewed the literature, presented their own ciNPT experiences, identified risk factors for surgical site occurrences (SSOs) and developed comprehensive consensus recommendations

Findings

- Numerous publications reported SSI risk factors, with the most common including obesity (body mass index ≥30 kg/m2); diabetes mellitus; tobacco use; or prolonged surgical time
- It is recommended that the surgeon assess the individual patient's risk factors and surgical risks
- Surgeons should consider using ciNPT for patients at high risk for developing SSOs or who are undergoing a high-risk procedure or a procedure that would have highly morbid consequences if an SSI occurred

Closed incision negative pressure therapy risk factors assessment



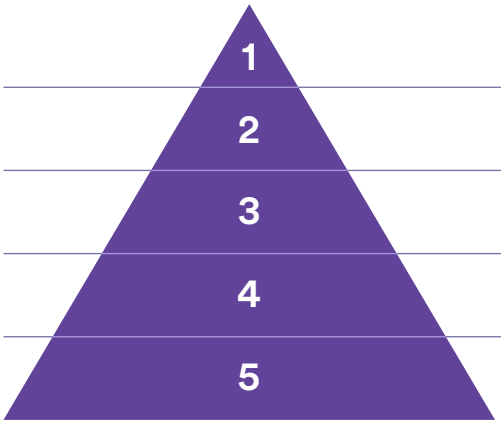
Patient related risk factors			
Diabetes mellitus	Obesity	Corticosteroid usage	Haematoma
ASA Score ≥3	Active tobacco use	Active alcoholism	Chronic renal insufficiency
Advanced age	Hypoalbuminemia	Male sex	Chronic obstructive pulmonary disease

General incision related risk factors			
High tension incision	Traumatised soft tissue	Emergency procedure	Mechanically unfavorable site
Repeated incisions	Oedema	Prolonged operation time	
Extensive undermining	Contamination	Post surgical radiation	

General incision related risk factors				
General	**Plastic**	**Orthopeadic**	**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 obgyn	Soilage risk			
Incisional hernia repair				

There are 70+ ciNPT journal publications using our products. The following publications are specific to plastic surgery.

Level of clinical evidence rating.



Level 1: Evidence obtained from at least one properly designed randomized controlled trial.
Level 1b: Systematic reviews (with homogeneity) of randomized controlled trials.

Level 2: Evidence obtained from well-designed controlled trials without randomization.
Level 2b: Individual cohort study or low quality randomized 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.'

Citation	Wound/surgery type	Level of clinical evidence*	
Muller-Sloof E, de Laat HEW, Hummelink SLM, Peters JWB, Ulrich DJO. The effect of postoperative closed incision negative pressure therapy on the incidence of donor site wound dehiscence in breast reconstruction patients: DEhiscence PREvention Study (DEPRES), pilot randomized controlled trial. *Journal of Tissue Viability*. 2018;27(4):262-266.	Breast reconstruction	1b	●
Ferrando PM, Ala A, Bussone R, Bergamasco L, Actis Perrinetti F, Malan F. Closed Incision Negative Pressure Therapy in Oncological Breast Surgery: Comparison with Standard Care Dressings. Plastic and Reconstructive Surgery - Global Open. 2018 Jun;6(6):e1732.	Breast reconstruction	2	●
Papp AA. Incisional negative pressure therapy reduces complications and costs in pressure ulcer reconstruction. *International Wound Journal*. December 2018. doi:10.1111/iwj.13045.	Pressure ulcer formation through spinal cord injury	2	●
Renno I, Boos AM, Horch RE, Ludolph I. Changes of perfusion patterns of surgical wounds under application of closed incision negative pressure wound therapy in postbariatric patients. *Clinical Hemorheology and Microcirculation*. January 2019. doi:10.3233/CH-180450.	Abdominoplasty	2	●
Swanson EW, Cheng HT, Susarla SM, Lough DM, Kumar AR. Does negative pressure wound therapy applied to closed incisions following ventral hernia repair prevent wound complications and hernia recurrence? A systematic review and meta-analysis. *Plastic Surgery*. 2016 Summer;24(2):113-8.	Ventral hernia repair	2	●
Chowdhry SA, Wilhelmi BJ. Comparing Negative Pressure Wound Therapy with Instillation and Conventional Dressings for Sternal Wound Reconstructions. Plastic and Reconstructive Surgery - Global Open. 2019;7(1). doi:10.1097/ gox.0000000000002087.	Muscle flap reconstruction of sternal wound complications	3	●
Conde-Green A, Chung TL, Holton LH 3rd, Hui-Chou HG, Zhu Y, Wang H, Zahiri H, Singh DP. Incisional negative-pressure wound therapy versus conventional dressings following abdominal wall reconstruction: a comparative study. *Annals of Plastic Surgery*. 2013 Oct;71(4):394-7.	Abdominal hernia repairs	3	●
Jorgensen MG, Toyserkani NM, Thomsen JB, Sorensen JA. Prophylactic incisional negative pressure wound therapy shows promising results in prevention of wound complications following inguinal lymph node dissection for Melanoma: A retrospective case-control series. *J Plast Reconstr Aesthet Surg*. 2019 Mar 2.	Inguinal lymph node dissection	3	●
Jorgensen MG, Toyserkani NM, Thomsen JB, Sorensen JA. Prophylactic incisional negative pressure wound therapy shows promising results in prevention of wound complications follow inguinal lymph node dissection for Melanoma: A retrospective case-control series. *Journal of Plastic, Reconstructive & Aesthetic Surgery*. 2019;000:1-6. doi:10.1016/j. bjps.2019.02.013.	Inguinal lymph node dissection	3	●
Lo Torto F, Monfrecola A, Kaciulyte J, Ciudad P, Casella D, Ribuffo D, Carlesimo B. Preliminary result with incisional negative pressure wound therapy and pectoralis major muscle flap for median sternotomy wound infection in a high-risk patient population. *Int Wound J*. 2017 Dec;14(6):1335-1339.	Pectoralis major muscle flap for sternotomy wound infections	3	●
Gabriel A, Sigalove S, Storm-Dickerson T, Rice J, Maxwell P, Griffin L. The Impact of Closed Incision Negative Pressure Therapy on Postoperative Breast Recostruction Outcomes. Plastic and Reconstructive Surgery. Global Open. 2018 Aug;6(8):e1880.	Breast reconstruction	3	●
Diaconu SC, McNichols CHL, Ngaage LM, Liang Y, Ikheloa E, Bai J, Grant MP, Nam AJ, Rasko YM. Closed-incision negative-pressure therapy decreases complications in ventral hernia repair with concurrent panniculectomy. *Hernia*. 2018 Dec 17. [Epub Ahead of Print]	Ventral hernia repairs	3	●
Abatangelo S, Saporiti E, Giatsidis G. Closed Incision Negative-Pressure Therapy (ciNPT) Reduces Minor Local Complications in Post-bariatric Abdominoplasty Body Contouring: a Retrospective Case. *Obese Surg*. 2018 Jul;28(7):2096-2104.	Abdominoplasty	3	●

● Available on request.

References

1 Starnoni M, Pinelli M, De Santis G. Surgical Wound Infections in Plastic Surgery: Simplified, Practical, and Standardized Selection of High-risk Patients. *Plast Reconstr Surg Glob Open*. 2019 Apr; 7(4): e2202.

2 Alderman AK, Wilkins EG, Kim HM, Lowery JC. Complications in postmastectomy breast reconstruction: two-year results of the michigan breast reconstruction outcome study. *Plast Reconstr Surg.* 2002;109:2265-2274. Cited by: Gabriel A1, Maxwell GP. Economic analysis based on the use of closed-incision negative-pressure therapy after postoperative breast reconstruction. *Plast Reconstr Surg.* 2019 Jan;143(1S Management of Surgical Incisions Utilizing Closed-Incision Negative-Pressure Therapy):36S-40S.

3 Phillips BT, Bishawi M, Dagum AB, Khan SU, Bui DT. A systematic review of antibiotic use and infection in breast reconstruction: what is the evidence? *Plast Reconstr Surg.* 2013;131:1-13. Cited by: Gabriel A1, Maxwell GP. Economic analysis based on the use of closed-incision negative-pressure therapy after postoperative breast reconstruction. *Plast Reconstr Surg.* 2019 Jan;143(1S Management of Surgical Incisions Utilizing Closed-Incision Negative-Pressure Therapy):36S-40S.

4 Sullivan SR, Fletcher DR, Isom CD, Isik FF. True incidence of all complications following immediate and delayed breast reconstruction. *Plast Reconstr Surg.* 2008;122:19–28.

5 Olsen M, Nickel KB, et al. Incidence of Surgical Site Infection Following Mastectomy With and Without Immediate Reconstruction Using Private Insurer Claims Data. Inf Control & Hosp Epidemiol. 2015;36(8):907-914.

6 Bennett KG, Qi J, Kim HM, et al. Comparison of 2-year complication rates among common techniques for postmastectomy breast reconstruction. *JAMA Surg.* 2018;153(10):901-908. doi:10.1001/jamasurg.2018.1687.

7 Gabriel A, Maxwell GP. Economic analysis based on the use of closed-incision negative-pressure therapy after postoperative breast reconstruction. *Plast Reconstr Surg.* 2019 Jan;143(1S Management of Surgical Incisions Utilizing Closed-Incision Negative-Pressure Therapy):36S-40S. doi: 10.1097/PRS.0000000000005311.

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 and involvement of the lymphatic system. *Wound Repair and Regeneration.* 2011;19:588-596.

10 Glaser DA, Farnsworth CL, Varley ES, *et al.* Negative pressure therapy for closed spine incisions: a pilot study. *Wounds.* 2012;24(11):308-316.

11 Federal Drug Administration. De Novo Classification Request for PREVENA 125 and PREVENA PLUS 125 Therapy Units. De Novo Summary (DEN180013), 2019. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180013.pdf

12 Ferrando PM, Ala A, Bussone R, Bergamasco L. Closed incision negative pressure therapy in oncological breast surgery: comparison with standard care dressings. *Plast Reconstr Surg Glob Open.* 2018 Jun;6(6):e1732. doi:10.1097/GOX0000000000001732.

13 Diaconu SC, McNichols CHL, Ngaage LM, *et al.* Closed-incision negative-pressure therapy decreases complications in ventral hernia repair with concurrent panniculectomy. *Hernia*. Published online 17 December 2018. https://doi.org/10.1007/s10029-018-1865-2.

14 Willy, C., Agarwal, A., Andersen, C.A., Santis, G.D., Gabriel, A., Grauhan, O., Guerra, O.M., Lipsky, B.A., Malas, M.B., Mathiesen, L.L., Singh, D.P. and Reddy, V.S. (2017), Closed incision negative pressure therapy: international multidisciplinary consensus recommendations. *Int Wound J*, 14: 385–398. doi:10.1111/iwj.12612.

PREVENA™ Therapy System Kits

Size	Code	Contents
13cm	PRE1101	1 x PREVENA™ 125 Therapy Unit, 1 × 13cm PREVENA PEEL & PLACE™ Dressing, Patch Strips, V.A.C.® Connector
20cm	PRE1001	1 x PREVENA™ 125 Therapy Unit, 1 × 20cm PREVENA PEEL & PLACE™ Dressing, Patch Strips, V.A.C.® Connector
35cm	PRE3201	1 x PREVENA™ PLUS Therapy Unit, 1 × 35cm PREVENA PEEL & PLACE™ Dressing, Patch Strips, V.A.C.® Connector
90cm	PRE4001	1 x PREVENA™ PLUS Therapy Unit, 1 × 90cm PREVENA CUSTOMIZABLE™ Dressing with SENSAT.R.A.C.™
DUO 13cm/13cm	PRE1121	1 x PREVENA™ PLUS Therapy Unit, 2 × 13cm PREVENA PEEL & PLACE™ Dressings, 1 x V.A.C.® Y-Connector

PREVENA™ Therapy Dressing Kits

Size	Code	Contents
13cm	PRE1155	5 × 13cm PREVENA PEEL & PLACE™ Dressings
20cm	PRE1055	5 × 20cm PREVENA PEEL & PLACE™ Dressings
35cm	PRE3255	5 × 35cm PREVENA PEEL & PLACE™ Dressings
90cm	PRE4055	5 × 90cm PREVENA CUSTOMIZABLE™ Dressings with SENSAT.R.A.C™

PREVENA™ Therapy Accessories

Size	Code	Contents
14 Day Therapy Unit	PRE4010	1 x PREVENA PLUS™ Therapy Unit (14 Days)
45ml Canister	PRE1095	5 × 45ml PREVENA™ Canister
150ml Canister	PRE4095	5 × 150ml PREVENA PLUS™ Canister
V.A.C.® Connector	PRE9090	10 x PREVENA™ Therapy V.A.C.® Connector

For more information about the PREVENA™ Therapy System, contact your local representative.

Note: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. This material is intended for healthcare professionals.

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