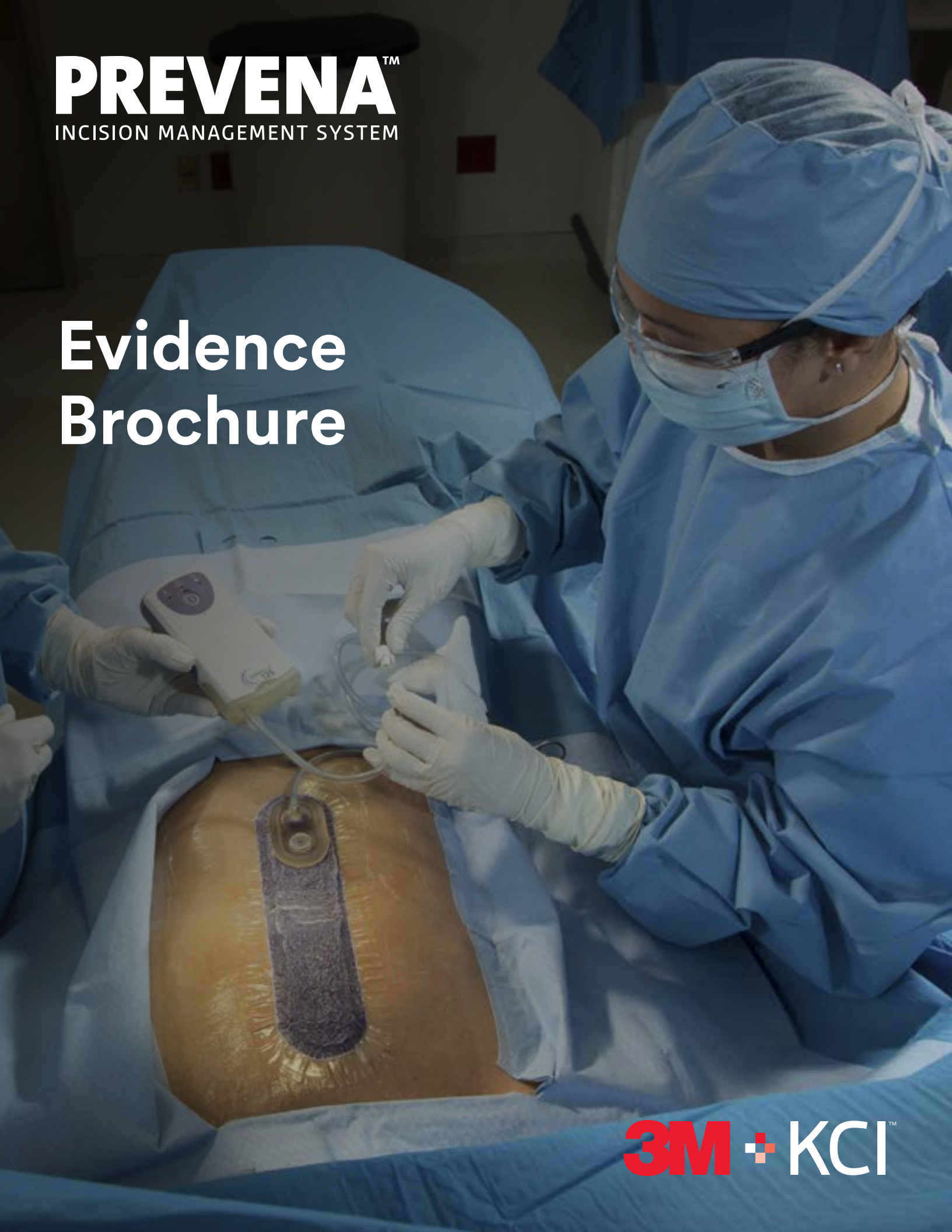
PREVENA™
INCISION MANAGEMENT SYSTEM

Evidence Brochure



3M + KCI™

Incisions can be complicated

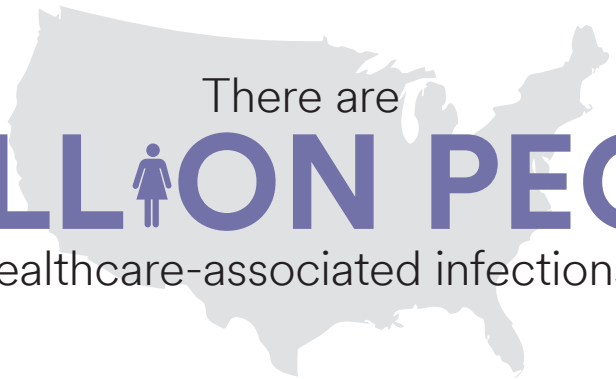
Certain surgical procedures and patient conditions can make healing difficult

Surgical procedures that most commonly lead to complications include sternotomies, C-sections, open hysterectomies, hip and knee arthroplasties, open reduction fractures, lower extremity bypasses, femoropopliteal bypasses, renal transplants, and breast reconstruction.[1]

Risk Factors that may compromise healing [2-4]

- Obesity
- Nicotine use
- Diabetes—poor control
- Radiation therapy
- Age >65
- Wound infection
- Pulmonary disease
- Peripheral vascular disease
- Hemodynamic instability
- Ostomies
- Hypoalbuminemia
- Systemic infection
- Uremia
- Hyperalimentation
- Ascites
- Malignancy
- Hypertension
- Length and depth of incision
- Anemia
- Jaundice
- Type of injury
- Steroid use
- Malnutrition

Incisions can be costly†



There are

8 MILLION PEOPLE

at risk for healthcare-associated infections annually.[5]

Post-surgical complications lead to significant costs

Surgical site infections (SSIs) are

21.8%

of all healthcare-associated infections[6]

Of the top 5 Healthcare Acquired Infections (HAIs), SSI is

33.7%

of the **$9.8 Billion** cost to the US healthcare system*[5]

SSIs increase average length of hospital stay by

9.58 days

at an additional cost of **$38,656**[7]

Other common complications include **dehiscence**, **hematoma** and **seroma** formation[2-4]

Consequences extend beyond discharge

Patients with an SSI are **6 times** more likely to have a

30-DAY readmission

than patients without an SSI[7]

Patients with SSIs have an ICU length of stay that is

2.2 times greater

than patients without SSIs[7]

Postoperative dehiscence increases average length of hospital stays by

9.42 days

and average costs by

$40,323[12]

The Centers for Medicare & Medicaid Services emphasize the need to decrease costs and improve care by identifying hospital-acquired conditions that will not be reimbursed, including 3 SSIs[11]:

1. Mediastinitis following coronary artery bypass graft (CABG)
2. SSIs following certain orthopedic procedures
3. SSIs following bariatric surgery for obesity

*Top five HAIs are cental line-associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), Clostridium difficile infection (C diff), Surgical Site Infections (SSI) and catheter-associated urinary tract infection (CAUTI).

† Healthcare costs are in US dollars and prevalence data are based on the US market. Actual savings will vary based on country-specific healthcare systems and on individual facility costs, protocol and patients.

How PREVENA™ Therapy can help

PREVENA™ Therapy manages and protects surgical incisions utilizing unique PREVENA™ PEEL & PLACE™ Dressings through:

- Delivering continuous negative pressure (-125mmHg) for up to 7 days
- Helping hold incision edges together
- Removing fluids and infectious materials
- Protecting the incision from external infectious sources

Indications for Use:*

The Prevena™ Incision Management System is intended to manage the environment of closed surgical incisions and surrounding intact skin in patients at risk for developing post-operative complications, such as infection, by maintaining a closed environment via the application of a negative pressure wound therapy system to the incision. The Prevena™ Incision Dressing skin interface layer with silver reduces microbial colonization in the fabric.

Contraindication:

Sensitivity to Silver.

Optimum Use:†

For maximum benefit, the PREVENA™ Incision Management System should be applied immediately post surgery to surgically closed incisions. It is to be continuously applied for a minimum of 2 days up to a maximum of 7 days. It can transition home with the patient.

Design of PREVENA™ Incision Dressings

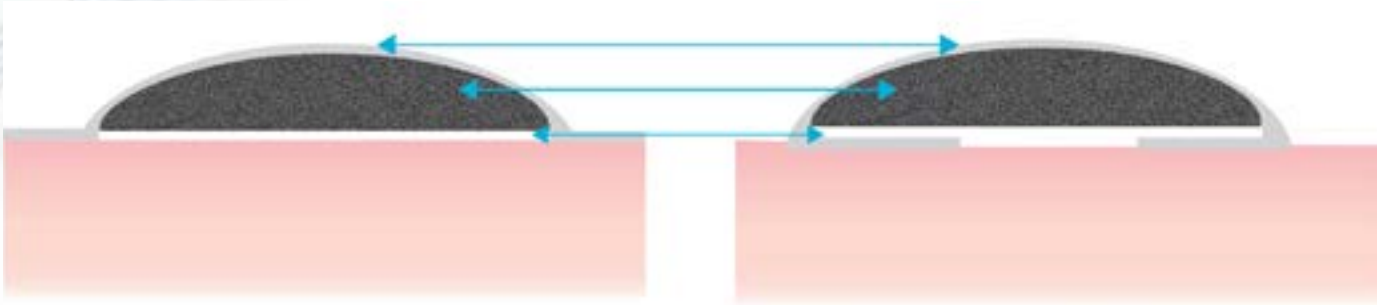
The design of the PREVENA™ Incision Dressings was derived from the NPWT dressing system described by a number of clinicians in their reported clinical studies of incisional NPWT.9-14 The dressing utilized in these clinical studies was constructed from commercially available materials:

- A skin interface layer (typically, a non-adhering dressing)
- V.A.C.® GRANUFOAM™ Dressing
- V.A.C.® Drape

The dressing was configured as shown in **Figure 1** (Incisional NPWT Dressing) and was manually prepared by the surgeon using costly OR time to construct.

Figure 1 Illustrates the configuration of these same elements in the PREVENA™ Incision Dressings, which are provided in a pre-constructed configuration that facilitates more efficient dressing application.

Figure 1. Cross-Section of Dressings Systems (as applied to patient)



Incisional NPWT Dressing **PREVENA™ Incision Dressings**

These dressing systems differ primarily only in the type of skin interface material that is used. The purpose of the non-adhering dressing was to protect the skin from direct contact with the V.A.C.® GRANUFOAM™ Dressing while allowing uninhibited delivery of negative pressure to the wound site and fluid removal from the wound site. The equivalent PREVENA™ Incision Dressing skin interface layer is a polyester knit fabric that performs the same functions as the non-adhering dressing in that it protects the skin from contact with the foam bolster, while allowing delivery of negative pressure and fluid removal.

In addition, the PREVENA™ 125 Therapy Unit delivers negative pressure wound therapy at -125mmHg equivalent to the V.A.C.® Therapy Units, which have been described in the referenced clinical studies of incisional NPWT.

The equivalency of PREVENA™ Therapy to the Incisional NPWT reported in the medical literature is thus established, and the clinical outcomes reported in those studies are also applicable to PREVENA™ Therapy.

†Refer to the PREVENA™ Incision Management System Clinician Guide for additional information relating to Optimum Use, Indications and Contraindications, Warnings and Precautions, and Important Safety Information.

Prevention of poststernotomy wound infections in obese patients by negative pressure wound therapy[17]

Grauhan O, Navasardyan A, Hofmann M, et al. J Thorac Cardiovasc Surg 2013; 145: 1387 - 92

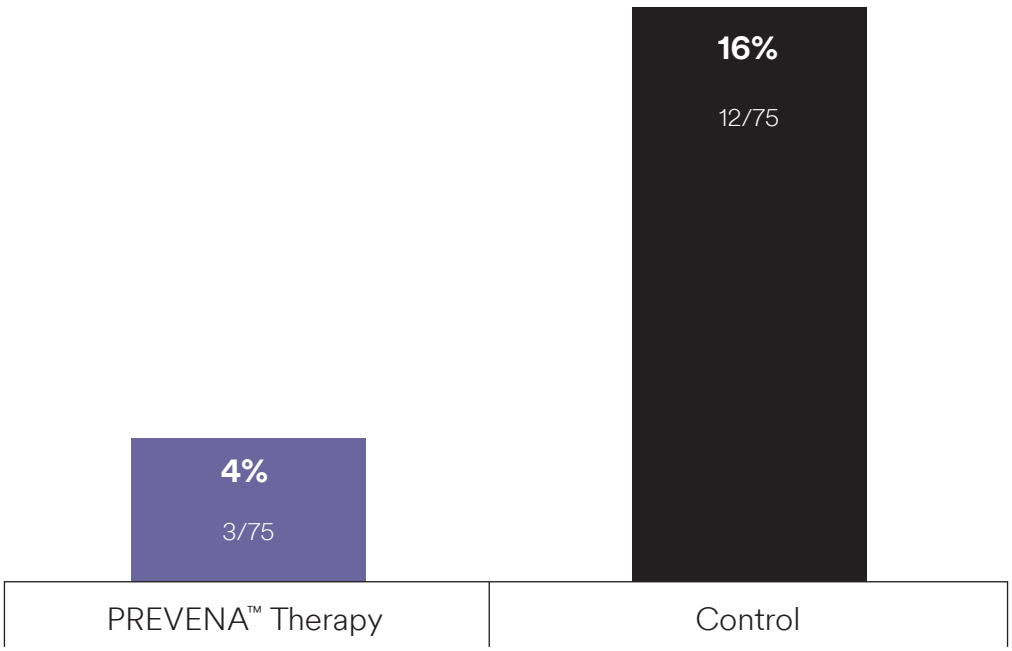
Clinical summary of Grauhan study

Study Purpose	The majority of wound infections after median sternotomy in obese patients are triggered by the breakdown of skin sutures and subsequent seepage of skin flora. The purpose of this study was to evaluate negative pressure wound dressing treatment for the prevention of infection. We hypothesized that negative pressure wound dressing treatment for 6 to 7 days applied immediately after skin closure reduces the numbers of wound infections.
Study Design	Prospective, single center clinical trial
Subjects	150 patients with a BMI of 30kg/m^2 with cardiac surgery via median sternotomy
Treatment	• PREVENA™ Therapy: 75 patients • Standard post-operative dressings: 75 patients
Outcome measures	Infection within 90 days
Results	

	PREVENA™ Therapy	Control	
Patients	75	75	
Total Infections	3	12	p=0.0266
% Infection	4%	16%	

Infection Rate[17]

p=0.0266

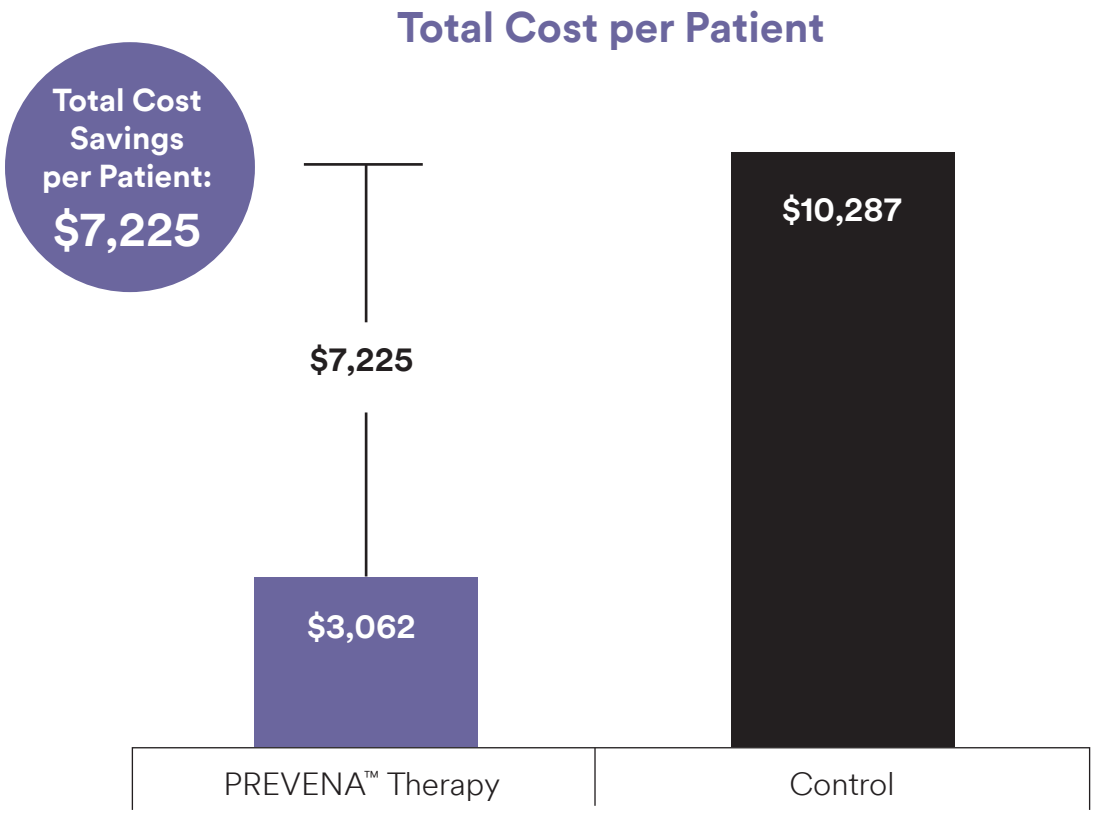


Economic analysis of the Grauhan clinical study results, using Thompson Cost Data[18]

Sternomoty Incisions	PREVENA™ Therapy	Control
Patients	75	75
Number of Infections	3 (4.0%)	12 (16.0%)
Total Infection Cost (Incremental cost of infection = $64,183 per patient)	$192,549	$770,196
Per Patient Infection Cost (Total Infection Cost / number of patients)	$2,567	$10,269
Per Patient Cost of Therapy*	$495	$18
Total Cost Per Patient	$3,062	$10,287

* KCI estimate based on price of PREVENA™ PEEL & PLACE™ Dressing System and Control therapy (gauze) changed once a day at $18 a week.

The model uses select study data to provide an illustration of estimates of costs for use of PREVENA™ Therapy or Standard of Care (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.



Healthcare costs are in US dollars and are based on the US market. Actual savings will vary based on country-specific healthcare systems and on individual facility costs, protocol and patients.

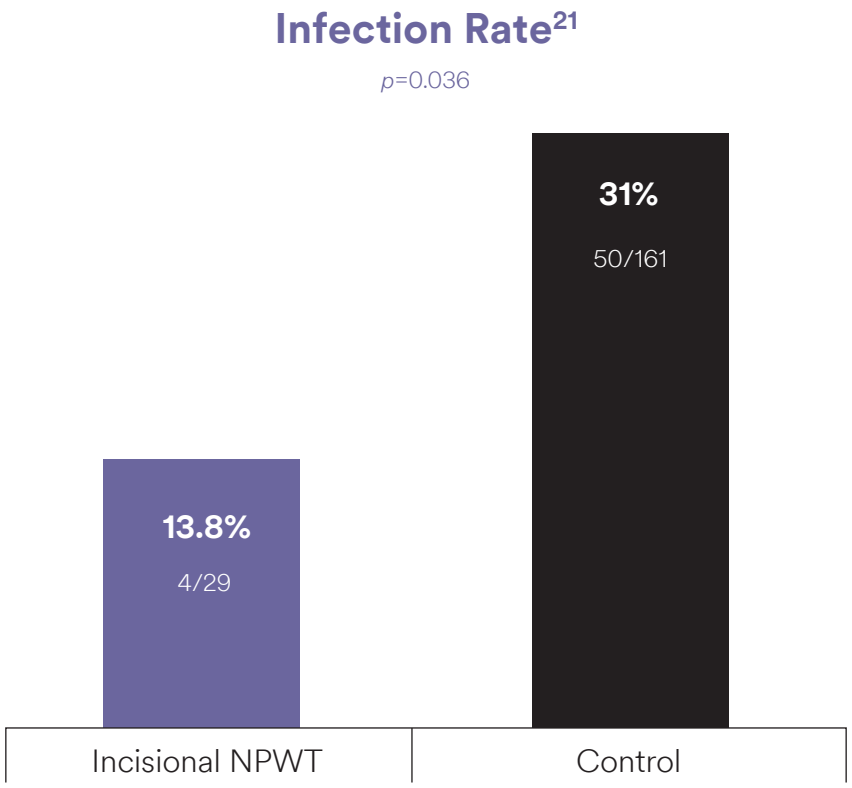
Incisional negative pressure wound therapy significantly reduces surgical site infection in open colorectal surgery[21]

Bonds AM, Novick TK, Dietert JB, et al. Dis Colon Rectum. 2013;56(12):1403-1408. Note: see sub set data page 1406

Clinical summary of Bonds study

Study Purpose	Surgical site infections in colorectal surgery remain a common problem and are associated with an increase in cost of care and length of stay. This study aims to evaluate the effect of known risk factors and the use of incisional negative pressure wound therapy on surgical site infection rates.
Study Design	Retrospective chart review at two main hospitals in a single tertiary academic medical center.
Subjects	190 non-emergent patients undergoing open colectomy from 2009 and 2011 were studied.
Treatment	• Incisional NPWT at -75mmHg, applied equivalently to PREVENA™ Therapy: 29 • Occlusive dressings: 161
Outcome measures	Presence or absence of surgical site infection
Results	Patients: Incisional NPWT* 29, Control 161 Total Infections: 4, 50, p =0.036 % Infection: 13.8%, 31%

*PREVENA™ Therapy is functionally equivalent to the incisional NPWT reported in this study, and the reported clinical outcomes can be applied to PREVENA™ Therapy.

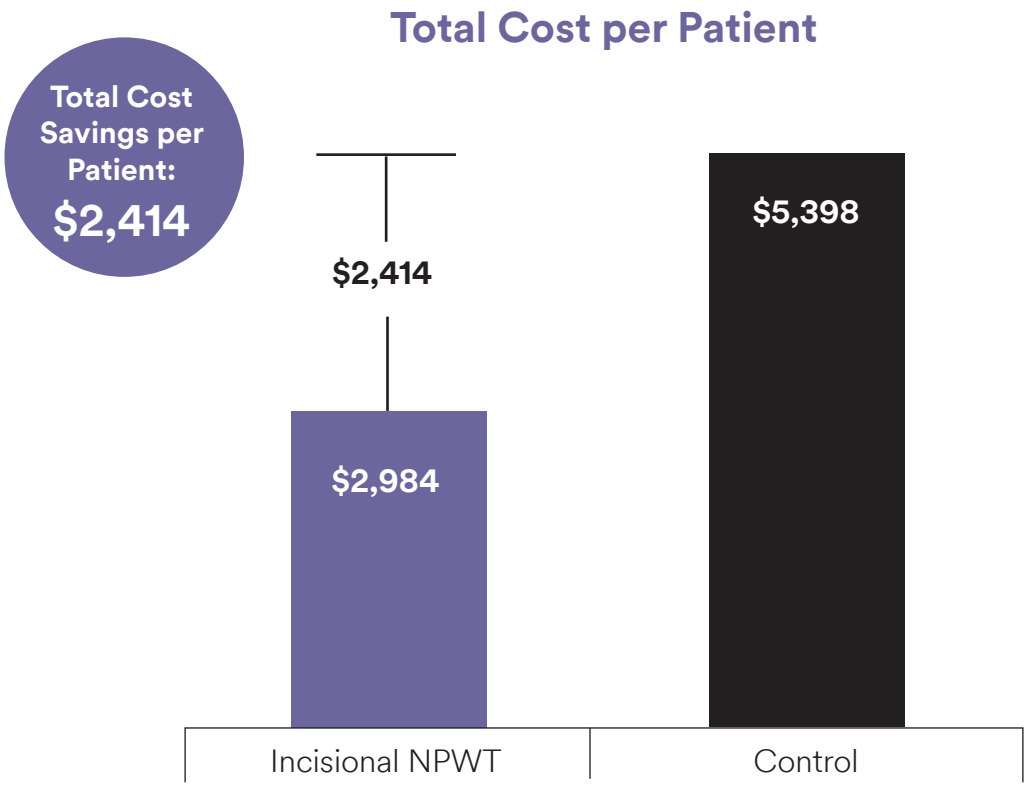


Economic analysis of the Bonds clinical study results, using Thompson Cost Data[22]

Colorectal Incisions	Incisional NPWT	Control
Patients	29	161
Number of Infections	4	50
Total Infection Cost (Incremental cost of infection = $17,324 per patient)	$69,296	$866,200
Per Patient Infection Cost (Total Infection Cost / number of patients)	$2,389	$5,380
Per Patient Cost of Therapy*	$595	$18
Total Cost Per Patient	$2,984	$5,398

* KCI estimate based on the price of PREVENA™ Customizable™ Dressing System to Control therapy (gauze) changed once a day at $18 a week.

The model uses select study data to provide an illustration of estimates of costs for use of PREVENA™ Therapy or Dermabond™ (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.



Healthcare costs are in US dollars and are based on the US market. Actual savings will vary based on country-specific healthcare systems and on individual facility costs, protocol and patients.

Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients[19]

Matatov T, Reddy KN, Doucet LD, et al. J Vasc Surg 2013 January 9.

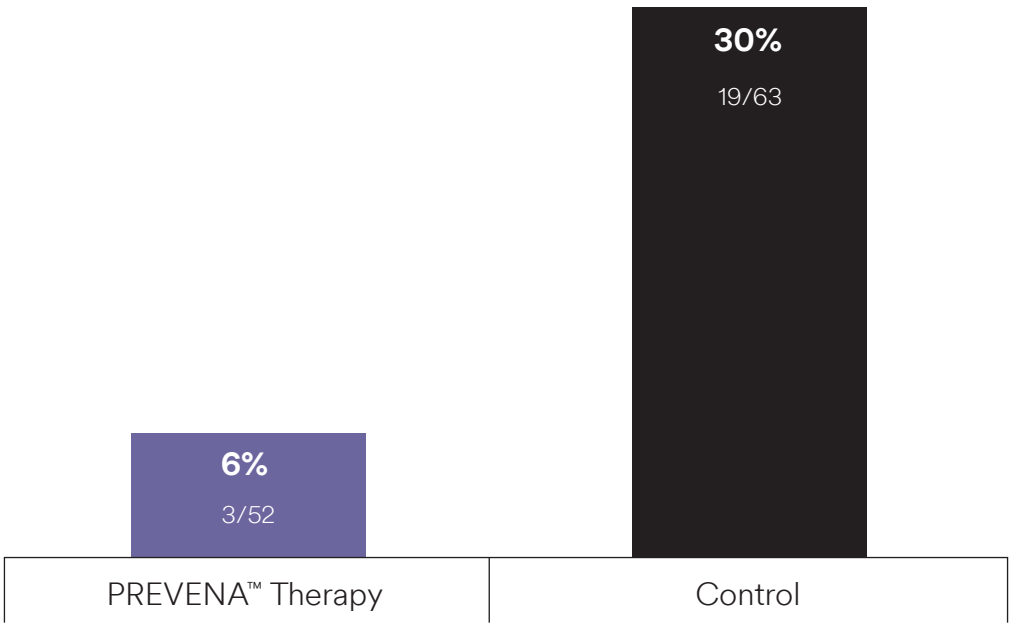
Clinical summary of Matatov study

Study Purpose	Groin wound infection is an important cause of postoperative morbidity in vascular surgery patients, especially when prosthetic grafts are involved. The objective of this study was to investigate if PREVENA™ Therapy, a negative pressure incision management system, could reduce the risk of groin wound infection in patients after vascular surgery.
Study Design	Retrospective chart review of consecutive patients at a single center
Subjects	90 patients with 115 groin incisions who underwent femoral cutdown for vascular procedures.
Treatment	• PREVENA™ Therapy: 41 patients • Skin adhesive or absorbent dressing: 49 patients
Outcome measures	Groin wound infection, graded based on Szilzgyi classifications.
Results	

	PREVENA™ Therapy	Control
Patients	41	49
Incisions	52	63
Total Infections	3 (all grade I)	19 (10 grade I; 7 grade II and 2 grade III)
p=0.0011		
% Infection	6%	30%

Infection Rate[19]

p=0.0011

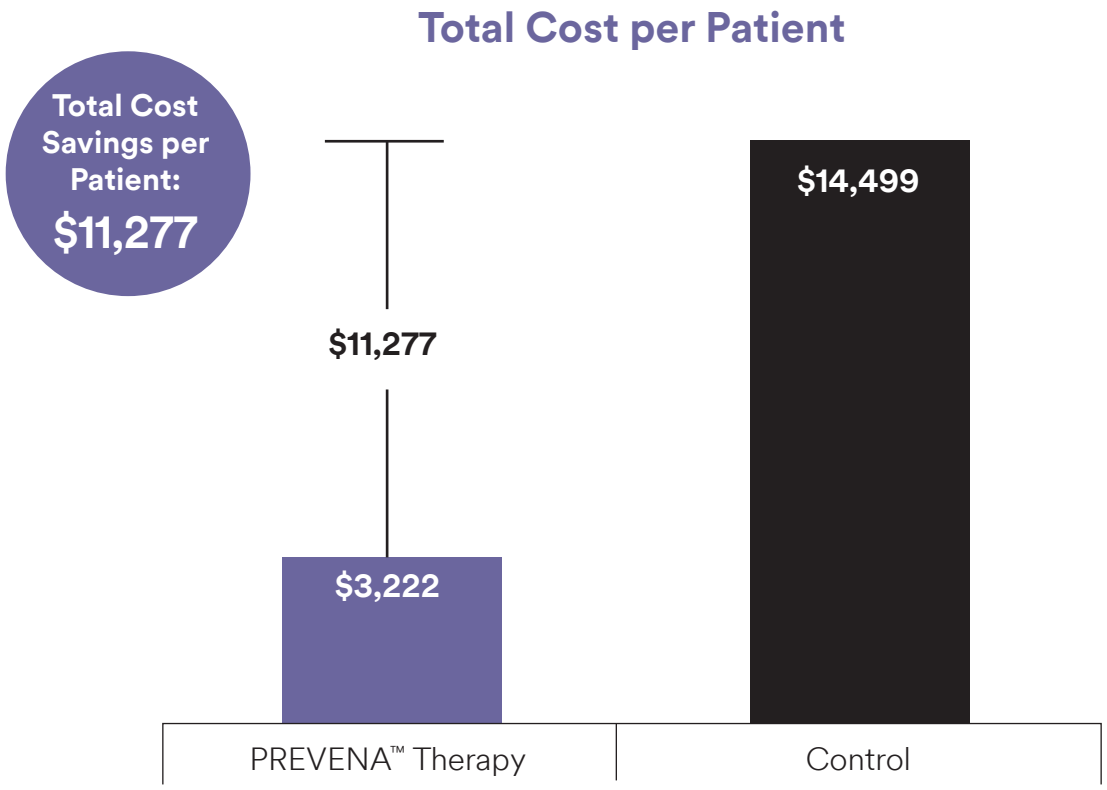


Economic analysis of the Matatov clinical study results, using Thompson Cost Data[20]

Groin Incisions	PREVENA™ Therapy	Control
Patients	41	49
Incisions	52	63
Number of Infections*	3	19
Total Infection Cost (Incremental cost of infection = $37,274 per patient)	$111,822	$708,206
Per Patient Infection Cost (Total Infection Cost / number of patients)	$2,727	$14,453
Per Patient Cost of Therapy**	$495	$46
Total Cost Per Patient	$3,222	$14,499

* Model assumes that patients could only have 1 infection.
**KCI estimate based on PREVENA™ PEEL & PLACE™ Dressing System and Non-PREVENA™ Therapy of Dermabond™ is changed once a week at $45.83 ($275/6 for 6 vials), see: http://www.claflinequip.com/ethicon-high-viscosity-dermabond-topical-skin-adhesive.html?childid=60829#60829

The model uses select study data to provide an illustration of estimates of costs for use of PREVENA™ Therapy or Dermabond™ (Control). This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.



Healthcare costs are in US dollars and are based on the US market. Actual savings will vary based on country-specific healthcare systems and on individual facility costs, protocol and patients.

Incisional negative pressure wound therapy after high-risk lower extremity fractures[15]

Stannard JP, Volgas DA, McGwin G III, et al. J Orthop Trauma. 2012:26(1):37-42.

Clinical summary of Stannard study

Study Purpose	To investigate negative pressure wound therapy (NPWT) to prevent wound dehiscence and infection after high-risk lower extremity trauma.
Study Design	Prospective, randomized multicenter clinical trial
Subjects	249 blunt trauma patients with one of three high risk fracture types (tibial plateau, pilon, calcaneus) requiring surgical stabilization
Treatment	• Incisional NPWT at -125mmHg, applied equivalently to PREVENA™ Therapy: 130 patients • Standard post-operative dressings: 119 patients
Outcome measures	Acute and chronic wound dehiscence and infection

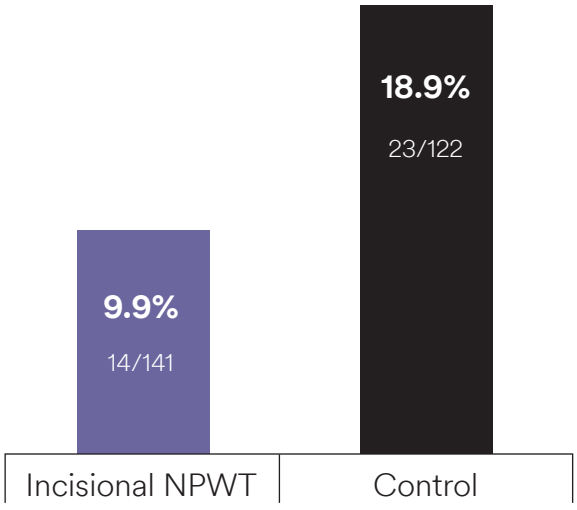
Results

	Incisional NPWT*	Control	
Patients	130	119	
Fractures	141	122	
Total Infections	14	23	
% Infection	9.9%	18.9%	p=0.049
Total Dehiscence	12	20	
% Dehiscence	8.6%	16.5%	p=0.044

*PREVENA™ Therapy is functionally equivalent to the incisional NPWT reported in this study, and the reported clinical outcomes can be applied to PREVENA™ Therapy.

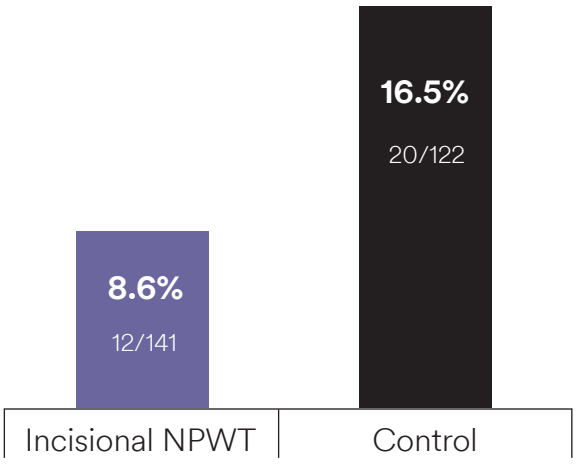
Infection Rate

p=0.049



Dehiscence Rate

p=0.044



Economic analysis of the Stannard clinical study results, using Thompson Cost Data[16]

Orthopedic Incisions	Incisional NPWT	Control
Patients	130	119
Number of Infections*	14	23
Number of Dehiscence*	12	20
Total Infection Cost (Incremental cost of infection = $64,611 per patient)	$904,554	$1,486,053
Total Dehiscence Cost (Incremental cost of dehiscence = $26,447 per patient)	$317,364	$528,940
Per Patient Infection Cost (Total Infection Cost / number of patients)	$6,958	$12,488
Per Patient Dehiscence Cost (Total Dehiscence Cost / number of patients)	$2,441	$4,445
Per Patient Cost of Therapy**	$495	$18
Total Cost Per Patient	$9,894	$16,951

* Model assumes that patients could only have 1 infection and 1 dehiscence.
** KCI estimate based on price of PREVENA™ PEEL & PLACE™ Dressing System and Control therapy (gauze) changed once a day at $18 a week.

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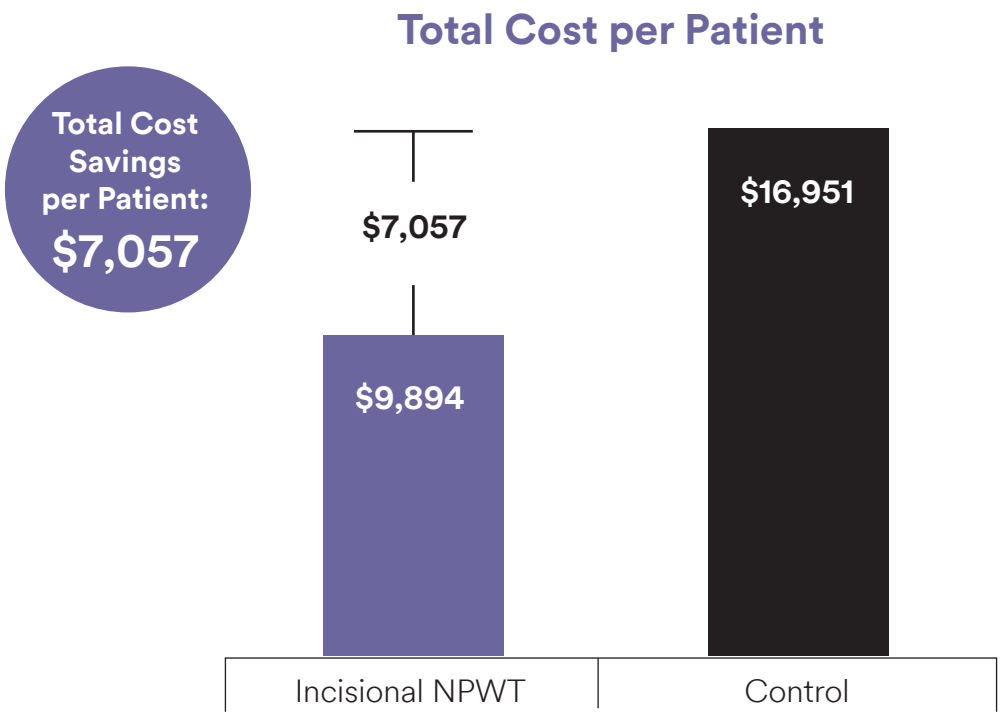

Healthcare costs are in US dollars and are based on the US market. Actual savings will vary based on country-specific healthcare systems and on individual facility costs, protocol and patients.

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19. Matatov T, Reddy KN, Doucet LD, et al. Experience with New Negative Pressure in Incision Management System in Prevention of Groin Wound Infection in Vascular Surgery Patients. J Vasc Surg 2013 January 9.

20. Market Research National Level Report. Data from the Marketscan Projected Inpatient, Hospital Drug and Medpar Databases: Calendar Year 2008. New York, NY: Thomson Reuters; 2009 Oct 1 Incremental cost of infection is based on a national average of all patients with ICD9 39.29 –other shunt and vascular bypass and a co-occurring complication of infection.

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The negative pressure incision management system with the most published clinical evidence*

PREVENA™ Therapy helps manage and protect closed surgical incisions utilizing a unique PREVENA™ PEEL & PLACE™ Dressing by:

- Protecting the incision from external infectious sources
- Delivering continuous negative pressure (-125 mmHg) for up to 7 days
- Helping to hold incision edges together
- Removing fluids and infectious materials

*Among negative pressure based incision management systems

Help manage closed surgical incisions with PREVENA™ Therapy

Item #	Product Name	Qty
PREVENA™ PEEL & PLACE™ SYSTEM		
PRE1001.S	PREVENA™ PEEL & PLACE™ System – 20cm (For use on up to 20cm linear incisions)	1
PRE1055.S	PREVENA™ PEEL & PLACE™ Dressing – 20cm (For use on up to 20cm linear incisions)	5
PRE1101.S	PREVENA™ PEEL & PLACE™ System – 13cm (For use on up to 13cm linear incisions)	1
PRE1155.S	PREVENA™ PEEL & PLACE™ Dressing – 13cm (For use on up to 13cm linear incisions)	5
PREVENA™ CUSTOMIZABLE™ SYSTEM		
PRE2001.S	PREVENA™ CUSTOMIZABLE™ System Kit (For use on non-linear or up to 90cm linear incisions)	1
PRE2055.S	PREVENA™ CUSTOMIZABLE™ Dressing (For use on non-linear or up to 90cm linear incisions)	5
PRE1095.S	PREVENA™ 45ml Canister	5
PRE9090.S	PREVENA V.A.C.® Connector	10
PREVENA PLUS™ CUSTOMIZABLE™ SYSTEM		
PRE4001.S	PREVENA PLUS™ CUSTOMIZABLE™ Incision Management System (For use on non-linear or up to 90cm linear incisions)	1
PRE4055.S	PREVENA PLUS™ CUSTOMIZABLE™ Dressing (For use on non-linear or up to 90cm linear incisions)	5
PRE4095.S	PREVENA PLUS™ 150ml Canister with PREVENA PLUS™ Connector	5

For more information, call **1300 524 822** or visit **myKCI.com**

Follow local institutional protocols for infection control and waste disposal procedures. Local protocols should be based on the applicable local government environmental regulations.

NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for PREVENA™ Therapy. Please consult the applicable PREVENA™ System Clinician Guide US instructions for use for important limitations, contraindications, warnings and precautions prior to application. Rx only.

 DSL#15-0187.PRE.EC.ANZ (Rev. 9/16)

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