PREVENA RESTOR™
INCISION MANAGEMENT SYSTEM

Value Analysis Committee
Product Information Kit

PREVENA RESTOR BELLA•FORM™ Incision Management System

3M + KCI™

Value Analysis Committee - Product Information Kit

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STANDARD OF CARE FOR SURGICAL INCISIONS

Current State and Challenges

- Traditionally, incisions have been closed by primary intention, using sutures, tissue adhesives, paper tape, or a combination of these methods.
- These methods are associated with a number of limitations:
  - Tissue adhesive may interfere with healing since it can act as a barrier to epithelialization[2]
  - Complications such as surgical site infections, surgical wound dehiscence, necrosis, seromas and hematomas, and edema and pain can occur, leading to costly medical interventions and subpar patient experiences.

These post-surgical complications can be minimized or prevented with technology such as negative pressure wound therapy, which works in conjunction with existing closure methods.

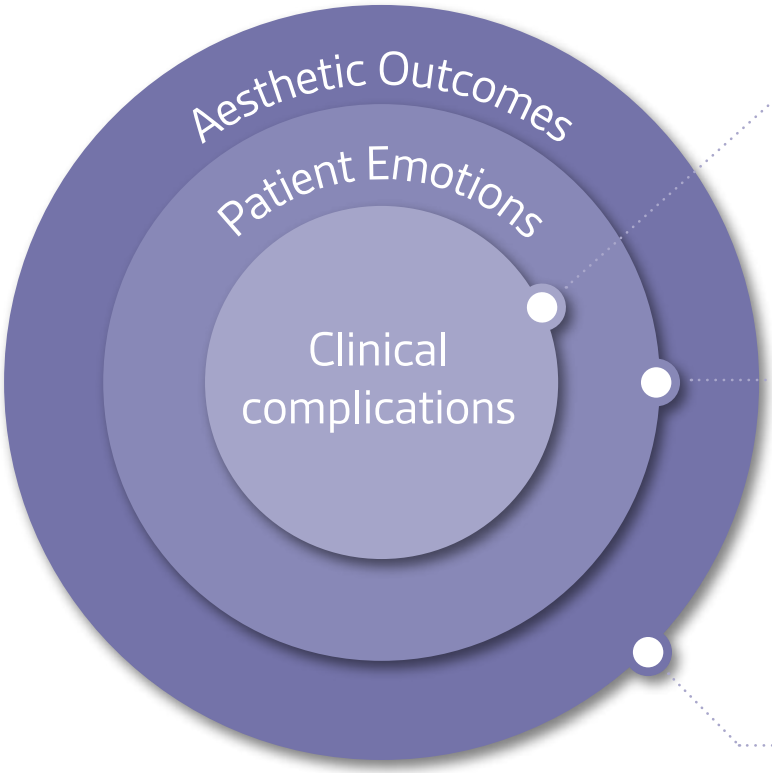
Common Post-Surgical Complications	
Surgical Site Infection (SSI)	• 8 million people are at risk for healthcare-associated infections (HAIs) like SSI[3] • SSIs are the second most common HAI in surgical patients and comprise up to 22% of all HAIs[4] • SSIs increase the average length of a hospital stay by 9.58 days[5] - An additional 9.58-day hospital stay costs $38,656[5] • 20.5% of patients who receive immediate implant-based reconstruction after a mastectomy experience infections, according to a database analysis of 3,007 patients[6]
Surgical Wound Dehiscence (SWD)	• The rate at which SWD occurs after surgical procedures has been reported as high as 9.3%[7]
Necrosis	• Mastectomy skin necrosis has been observed in 8% of breasts after reconstruction[8]
Hematomas & Seromas	• Hematomas or seromas have been reported in 10% to 45% of patients who have had abdominoplasty procedures[9] • Hematomas and/or seromas increase pressure, and compress nerves and blood vessels, which causes wound ischemia and, if untreated, may cause tissue necrosis[10]
Edema & Pain	• Edema is a normal part of the healing process, but can cause pain and discomfort for patients

CURRENT LANDSCAPE

- **33% of breast reconstruction patients will experience complications**[1], including surgical site infections, surgical wound dehiscence, necrosis, seromas, hematomas, and edema with accompanying pain. These complications can lead to costly medical intervention.
- **19% of breast reconstruction patients will need reoperations due to complications.**[1] Complications can also negatively impact aesthetic outcomes and patient satisfaction.
- Better management of surgical sites and the surrounding soft tissue envelope using negative pressure wound therapy (NPWT) can help reduce post-operative complications and improve the patient experience.

CHALLENGES IN PLASTIC SURGERY

Today's healthcare environment requires all providers to continually refine their practices. In plastic surgery, there are multiple layers of complexity to manage.



Clinical complications
- Swelling
- Seroma
- Edema
- Infection

Patient Emotions
- Nervousness
- Uncertainty
- Stress
- Expectations

Aesthetic Outcomes
- Success is largely in the eyes of the patient

Meeting the benchmarks of value-based care while catering to patient needs is more difficult than ever. Healthcare organizations need new tools to support surgeons and improve the patient's healing journey.

THE HIGH STAKES OF BREAST SURGERY

Breast reconstruction is an expensive undertaking

A cost analysis of the most common reconstruction methods

- A cost analysis of the most common postmastectomy reconstruction methods found that successful procedures range from $10,000 to $13,000 in average cost[11]

No matter the method, complications threaten clinical and financial success

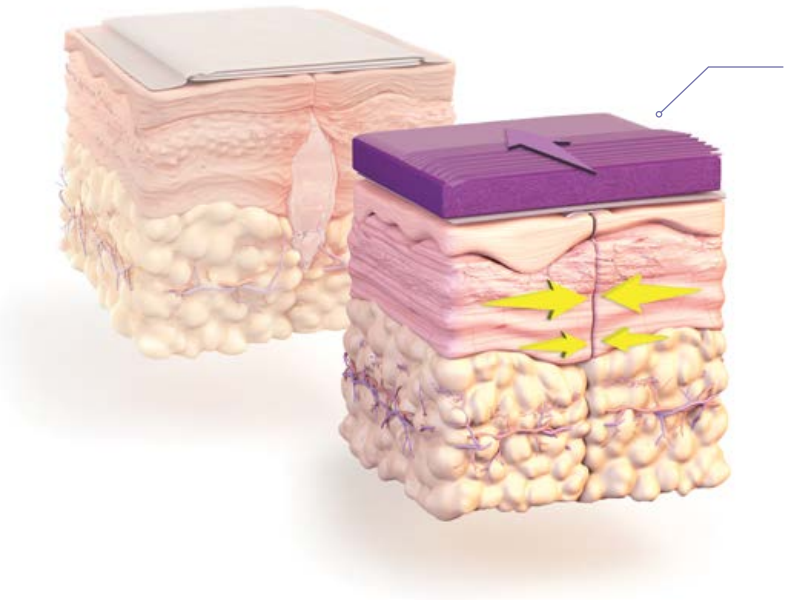
- 33% overall complication rate[1]
- 19% of breast reconstruction patients need reoperations[1]

Breast reconstruction patients are worried and stressed, but also knowledgeable and empowered

- Women who have had mastectomies:
  - Are largely unsatisfied with the aesthetic results (pre-reconstruction)[14]
  - Often experience anxiety[14]
  - May suffer from depression[14]
- These women are looking for a surgeon they can trust — a partner to help them on their healing journey. They do plenty of research and read reviews on websites like RealSelf.com
  - After reconstructions, many patients post online reviews
    - » From 2011 to 2016, the number of online reviews for breast surgery increased by 43%[15]
  - Patient experience ultimately impacts your institution's future revenue

THE PREVENA RESTOR™ INCISION MANAGEMENT SYSTEM

The next generation of incision + surrounding soft tissue management



Standard of Care vs. PREVENA™ Therapy

Built on the proven technology of the original PREVENA™ Therapy...

- Delivers continuous negative pressure therapy (-125mmHg) to the incision site
- Helps hold incision edges together[16]
- Removes fluid and infectious materials[17]
- Creates a barrier to external contaminants[18]
- Reduces edema[19]

...with new features to optimize care

Extended therapy time:

Up to **14** days, with a dressing change required at 7 days

Expanded coverage area:

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

Precision designed:

Dressing seamlessly conforms to the patient to bolster and stabilize the incision and surrounding soft tissue envelope

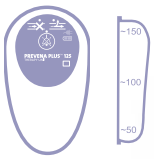
Easy to apply:

Simply peel and place the form-fitting dressing

PREVENA RESTOR™ System indication statement

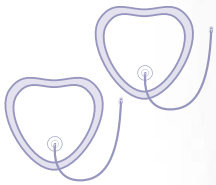
The PREVENA RESTOR™ Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

System components



PREVENA PLUS™ 125 Therapy Unit (14 Day) with the PREVENA PLUS™ 150ml Canister

- A single-use, disposable unit is used to administer -125mmHg negative pressure and store exudate fluid



PREVENA RESTOR BELLA•FORM™ Dressings x2

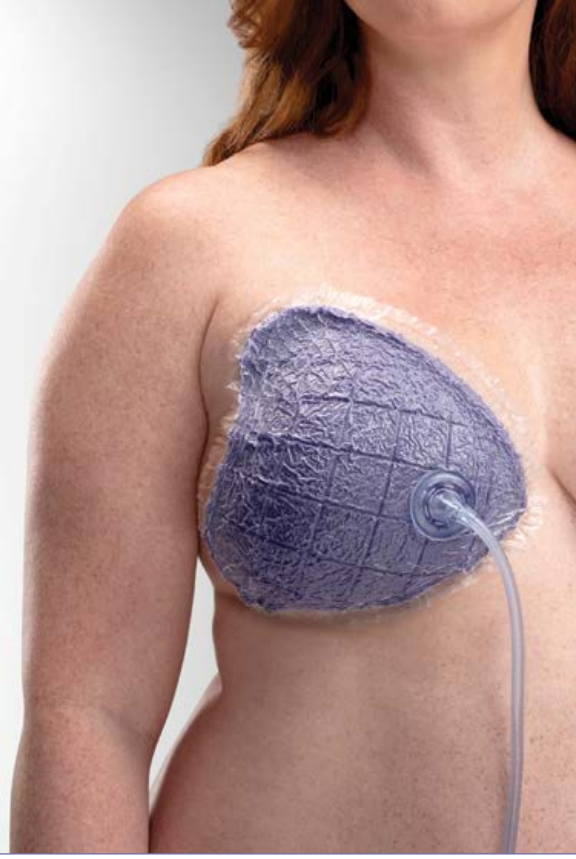
- Applied over the incision and the surrounding soft tissue, the form-fitting dressing bolsters the incision and surrounding soft tissue envelope

PREVENA PLUS™ 125 Therapy Unit Power Supply with Power Cord

PREVENA™ Patch Strips

V.A.C.® Y-Connector

PREVENA PLUS™ Therapy Carry Case



FDA 510K Clearance:	**K181507**
Product Labeling:	• **PREVENA RESTOR™ Dressings Clinician Guide** • **PREVENA PLUS™ 125 Therapy Unit (14 Day) Clinician Guide**

System features

Reticulated Open-Cell Foam (ROCF) Dressing & 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 PREVENA RESTOR™ Incision Management System is designed with proprietary SENSAT.R.A.C.™ Technology, which maintains and adjusts to deliver consistent negative pressure at the incision site

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

PREVENA RESTOR™ THERAPY – KEY DIFFERENTIATORS

Only the 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 7 days)
- Audible alarms
- Replaceable fluid-collection canister
- Reticulated open-cell foam dressings
- Dressings can be purchased separately

System Features	PREVENA RESTOR™ Incision Management System	Standard NPWT Systems	Silver Impregnated/ Antimicrobial Dressings	Compression Therapy
Unit Device Classification/Type	Closed-Incision Negative-Pressure Therapy (ciNPT)	Disposable NPWT	Dressing	Dressing
Pressure Setting	-125mmHg	-80mmHg	—	—
Interface	Reticulated Open-Cell Foam (ROCF)	Multilayer Absorbent Dressings	Multilayer Absorbent Dressings	Liquid topical Skin Adhesive
Replaceable Canister	✓ (150ml)	—	—	—
Length of Therapy	14 days	7 days	7-14 days	7-14 days
Purchase Dressings without Device	✓	✓	—	—
Linear Incisions	≤29cm	<35cm	<27cm	<20cm
Non-Linear Incisions	✓	✓	—	✓
Portable	✓	✓	✓	✓
Audible Alarms	✓	—	—	—
Shower Friendly	✓	✓	✓	✓

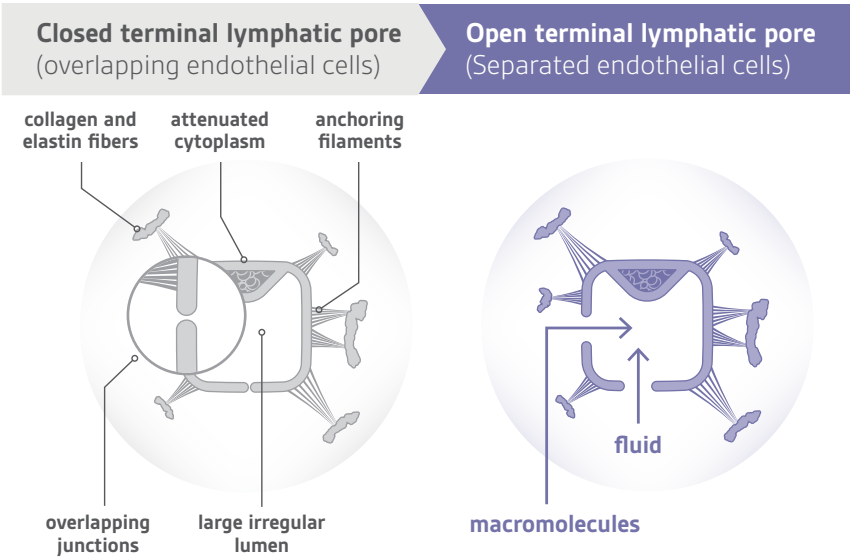
THE PREVENA™ THERAPY FAMILY

For the results you demand, choose proven gold standard technology

How PREVENA™ Therapy reduces edema[20]

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 overpressure
- Open lymphatics to allow fluid clearance



Unparalleled, Proven Clinical Value

1,000+
published clinical studies KCI Negative Pressure Therapy

70+
published clinical studies on KCI PREVENA™ Therapy

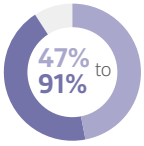
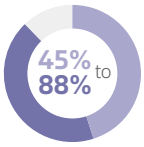
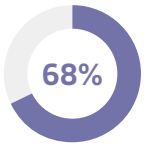
CLINICAL VALUE OF PREVENA™ THERAPY

Clinical data is based on a 7-day PREVENA™ System

The clinical benefits of PREVENA™ Therapy in breast reconstruction and oncological breast surgery[22,23]

A single-site, retrospective cohort study compared postoperative outcomes of 331 patients who used PREVENA™ Therapy with 334 patients who used standard of care (SOC). Patients were noted to have a complication if at least one of the following occurred: surgical site infection, dehiscence, necrosis, seroma, hematoma, tissue expander exposure, tissue expander replacement, or return to the operating room. All patients were discharged home after 1 midnight stay and instructed to return for follow-up on postoperative days 3 and 7. Patients were followed for 90 days after surgery.[22]

A single-center, prospective, comparative study compared patients treated with PREVENA™ Therapy (17 patients/25 breasts) with patients treated with SOC (20 patients/22 breasts). Follow-up controls to evaluate postsurgical complications were performed on days 7, 14, 30, and 90. The postsurgical complications evaluated were infection, hematoma, seroma, and skin necrosis. The PREVENA™ Therapy group had significantly better outcomes despite having a higher prevalence of high-risk factors.[23]

Complication	Proven Clinical Outcome
Overall recovery complications	 **reduction in overall complications vs. SOC** Gabriel 2018: 8.5% (28/331) PREVENA™ Therapy vs. 15.9% (53/334) Nexcare™ Steri-Strip™ (*p*=0.0092) Ferrando 2018: 4% (1/25) PREVENA™ Therapy vs. 45% (10/22) Nexcare™ Steri-Strip™ (*p*=0.001)
Surgical site infection (SSI)	 **reduction in SSI vs. SOC** Gabriel 2018: 2.1% (7/331) PREVENA™ Therapy vs. 4.5% (15/334) Nexcare™ Steri-Strip™ (*p*=0.0225)
Surgical wound dehiscence (SWD)	 **reduction in SWD vs. SOC** Gabriel 2018: 2.4% (8/331) PREVENA™ Therapy vs. 5.4% (18/334) Nexcare™ Steri-Strip™ (*p*=0.0178)
Necrosis	 **reduction in necrosis vs. SOC** Gabriel 2018: 5.1% (17/331) PREVENA™ Therapy vs. 9.3% (31/334) Nexcare™ Steri-Strip™ (*p*=0.0070) Ferrando 2018: 4% (1/25) PREVENA™ Therapy vs. 32% (7/22) Nexcare™ Steri-Strip™ (*p*=0.02)
Seroma	 **reduction in seroma vs. SOC** Gabriel 2018: 1.8% (6/331) PREVENA™ Therapy vs. 5.7% (19/334) Nexcare™ Steri-Strip™ (p=0.0106)
Returns to the operating room due to complications	 **fewer returns to the OR vs. SOC** Gabriel 2018: 2.4% (8/331) PREVENA™ Therapy vs. 5.4% (18/334) Nexcare™ Steri-Strip™ (*p*=0.0178)

*The above percentage calculations were derived based on relative patient group incidence rate reported in this study.

There was also a nominal reduction in:

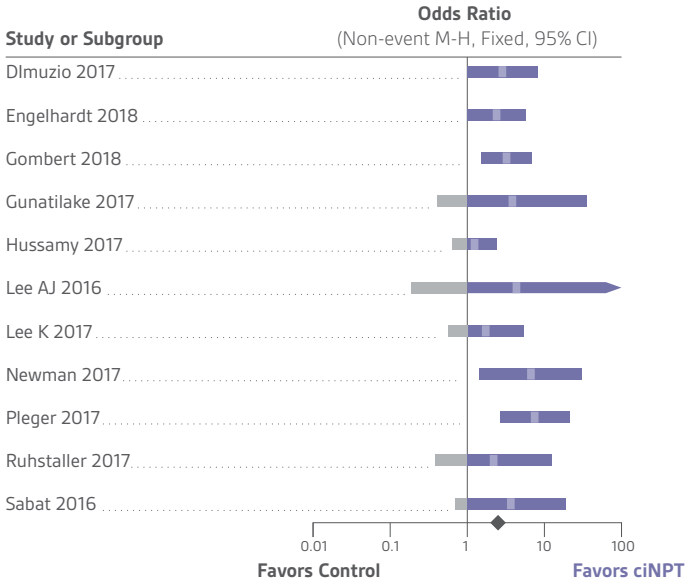
Hematoma

Ferrando 2018: 0% (0/25) PREVENA™ Therapy vs. 9% (2/22) Nexcare™ Steri-Strip™

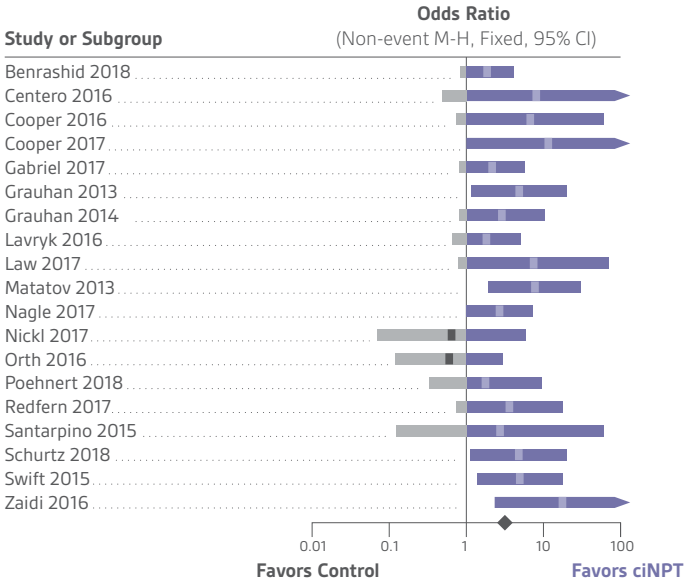
Meta-analysis shows reduction in SSIs with PREVENA™ Therapy[19]

A systematic literature search of 540 publications and a subsequent meta-analysis of 30 studies comparing PREVENA™ Therapy to traditional dressings was conducted. 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.

Randomized controlled trial forest plot



Observational study forest plot



In addition to reducing complications, PREVENA™ Therapy brings clinically proven 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 6 weeks) as a secondary endpoint [21]
  (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 PREVENA™ Therapy with 334 patients who used SOC[22] (9.9 days with PREVENA™ Therapy vs. 13.1 days with Nexcare™ Steri-Strip™; 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)[23]

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[16]
- **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[16]
- **61% reduced incisional width vs. competitors** in a comparative bench study under controlled conditions, when measured after 1 hour of negative pressure application. This calculation was derived based on relative patient group incidence rate reported in this study
- **51% stronger approximation, with 43% stronger approximation at staple lines**, in a benchtop model[16]

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

ECONOMIC VALUE

PREVENA™ Therapy may provide a cost-avoidance opportunity

- Preventing a single complication can save over

$10,000

per patient (the average cost of complications from mastectomy and breast reconstruction)[25,26]

Patient satisfaction drives future business

- Patient reviews and word-of-mouth after breast surgery can have a significant impact on a practice's future business opportunities
- A healing experience with fewer complications and a more pleasing aesthetic result can lead to more positive reviews[27]

EXECUTIVE SUMMARY

CURRENT HEALTH CARE BURDEN & CLINICAL VALUE SUMMARY

Clinical Burden	Incidence	Key PREVENA™ Therapy Evidence
Overall recovery complications	33% of breast reconstruction patients experience complications	• **47% reduction in overall recovery complications**[22] 8.5% (28/331) PREVENA™ Therapy vs. 15.9% (53/334) Nexcare™ Steri-Strip™ (p=0.0092) • **91% reduction in overall recovery complications**[23] 4% (1/25) PREVENA™ Therapy vs. 45% (10/22) Nexcare™ Steri-Strip™ (p=0.001)
Surgical Site Infections (SSIs)	SSIs occur in nearly 10% of postmastectomy breast reconstruction patients	• **53% reduction in SSI vs. SOC**[22] 2.1% (7/331) PREVENA™ Therapy vs. 4.5% (15/334) Nexcare™ Steri-Strip™ (p=0.0225) • A meta-analysis of 30 studies that compared PREVENA™ Therapy with traditional dressings in various procedures demonstrated **a reduction in the incidence of SSIs**, in favor of PREVENA™ Therapy[19]
Surgical Wound Dehiscence (SWD)	The rate at which SWD occurs after surgical procedures has been reported as high as 9.3%	• **56% reduction in SWD vs. SOC**[22] 2.4% (8/331) PREVENA™ Therapy vs. 5.4% (18/334) Nexcare™ Steri-Strip™ (p=0.0178)
Hematoma/ Seromas	Hematomas or seromas have been reported in 10%-45% of abdominoplasty patients and 8%-13% of rhytidectomy patients	• **Reduction in hematoma vs. SOC**[23] 0% (0/25) PREVENA™ Therapy vs. 9% (2/22) Nexcare™ Steri-Strip™ • **68% reduction in seroma vs. SOC**[22] 1.8% (6/331) PREVENA™ Therapy vs. 5.7% (19/334) Nexcare™ Steri-Strip™ (p=0.0106) • **Reduction in seroma vs. SOC**[23] 0% (0/25) PREVENA™ Therapy vs. 23% (5/22) Nexcare™ Steri-Strip™
Necrosis	Mastectomy skin necrosis occurs in 8% of reconstructed breasts	• **45% reduction in necrosis vs. SOC**[22] 5.1% (17/331) PREVENA™ Therapy vs. 9.3% (31/334) Nexcare™ Steri-Strip™ (p=0.0070) • **88% reduction in necrosis vs. SOC**[23] 4% (1/25) PREVENA™ Therapy vs. 32% (7/22) Nexcare™ Steri-Strip™ (p=0.02)
Edema/Pain	Edema is a normal part of the healing process, but can cause pain and discomfort for patients	• **PREVENA™ Therapy reduces edema**[22]

ECONOMIC VALUE SUMMARY

PREVENA Therapy™ may help reduce costly complications

- Preventing complications can save over **$10,000 per patient** (the average cost of complications from mastectomy and breast reconstruction)[25,26]

PREVENA Therapy™ can enhance the recovery experience for patients, boosting online reputation

- In today's healthcare environment, social media and online reviews are powerful influences. Organizations need to find ways to stand out, and satisfied patients who've had positive experiences often post reviews that can lead to more business.

For the results you demand, choose PREVENA RESTOR™ Therapy, the only incision management system based on the proven gold standard technology of PREVENA™ Therapy.

KCI PROGRAMS: CLINICAL EDUCATION PROGRAMS

Medical Education Opportunities are available through the ACELITY Global Education

- KCI 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, KCI offers a comprehensive portfolio of evidence-based learning opportunities designed and led by expert faculty
- KCI Global Education Alliance also offers a wide range of educational forums at the local, regional and national level

Program	Program Detail
Inside KCI	• Provides HCPs globally the opportunity to learn more in our KCI offices about the development, science, and clinical use of our products • Clinical and research faculty, along with KCI leadership, facilitate a robust program with clinical discussions, scientific data & research conversation, and safety information • Participants can tour our state-of-the-art research & development, manufacturing, and simulation facilities
ACES programs	• Peer-to-peer events designed to educate clinicians on the scientific evidence and clinical uses of the KCI portfolio • Didactic and interactive group discussions combine hands-on training with education on therapy options for complicated wounds, incision management and epidermal grafting
Bio-skills labs	• 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 • Course instructors share their strategies for optimal patient management and demonstrate surgical techniques • Through interactive group discussions with faculty and peers, attendees gain a better understanding of advanced therapies to help improve patient outcomes
Webinar programs	• Live or on-demand webinars are alternatives for global participants who cannot attend KCI programs in person • Allow participants to view online presentations and/or video demonstrations and have open dialogue with presenters during live Q&A sessions
Medical conferences & symposiums	• KCI typically offers ancillary educational opportunities in conjunction with conferences, society meetings, or congresses that KCI attends • At supported conferences, participants are invited to attend KCI symposiums led by expert panels that focus on advanced technologies, surgical techniques, and case-based experience

Learn on your schedule at **www.acelity.com/education**

KCI PROGRAMS: 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
- KCI partners benefit from highly personalized and valuable services when they take advantage of our full line of advanced therapy products

Program	Detail
KCI Express® Program	Allows users to order, track orders, track assets and manage outcomes in one easy-to-use online portal
Customer Support (in-person)	**Providing:** • Clinician support & consultation in the acute setting • Discharge & transition support to transition patients from the acute to the post-acute setting • Patient & caregiver support in the post-acute setting
Customer Support (remote) The KCI Advantage Center	**Your first call for every aspect of care:** • Ordering, delivery, reimbursement • Clinical consultation • Technical support
KCI Clinical Services and Reimbursement Hotline	**A team of reimbursement professionals helps you through every step of the process:** • Payor requirements • Insurance coding • Submitting payor documentation
Free Product Evaluation	Allows healthcare providers or accounts to trial/evaluate KCI products
Digital Health Programs	• iOn HEALING™ Mobile App: Flexibility to instantly place orders on the go and receive status updates • E-Prescription: An easy and secure way to submit a complete and accurate prescription directly to KCI • ALLSCRIPTS®: KCI is integrated with pre-loaded information from your hospital EMR system

Contact your local KCI Representative for more information.

APPENDIX: CLINICAL SUPPORT

PREVENA™ THERAPY EVIDENCE TABLE BY SPECIALTY

- The body of evidence for using ciNPT has been growing steadily since 2006.
- The table listed below is based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons (ASPS)
- The types of incisions treated with ciNPT and 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	Newman (2018)	THA; TKA	SSC
		Pauser (2014)	Hip hemiarthroplasty	Seroma
		Pachowsky (2012)	THA	Seroma
	2	Redfern (2017)	THA; TKA	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)
	5	Haghshenasskashani (2011)	Popliteal-tibial bypass	
Cardiothoracic	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
Plastic & Aesthetic Surgery	2	Ferrando (2018)	Oncological breast surgery	SSCs (SSIs, hematoma, seroma, skin necrosis)
	3	Gabriel (2018)	Mastectomy & 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 & 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.

APPENDIX: ADMINISTRATIVE SUPPORT

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)[2]	Contractor-Priced[4]	Contractor-Priced[4]
Physician Fee Schedule Facility (Inpatient/ Outpatient)[2]	Contractor-Priced[4]	Contractor-Priced[4]
Hospital Inpatient* Department[2]	Included in diagnosis-related group payment (DRG)[5] – no separate payment	Included in diagnosis-related group payment (DRG)[5] – no separate payment
Hospital Outpatient Department (HOPD) i.e.[3] Fee Schedule Outpatient Observation Services** (OPPS Payment Status Indicator)[6]	$314.08 5052 (T)[6]	$314.08 5052 (T)[6]
Ambulatory Surgical Center (ASC)[3] 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 KCI Reimbursement Education Hotline at 1-800-668-6812 for assistance. Verification of benefits and coverage for PREVENA™ Incision Management System is highly recommended before services are provided.

***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.

For more information, call the KCI Reimbursement Education Hotline at 1-800-668-6812 or email: ReimbursementEducation@Acelity.com

1. Current Procedural Terminology (CPT®) copyright 2016 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA.
2. 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
3. Medicare Correction Notice for Hospital Outpatient Prospective PaymentcmS-1695-FC-2019 Hospital Outpatient Prospective Payment Notice
4. Medicare Final RulecmS-1693-F Revisions to Payment Policies under the Medicare Physician Fee Schedule Quality Payment Program and Other Revisions to Part B for CY 2019
5. Medicare Final Rule Inpatient Prospective Payment Systems (IPPS) 2018cmS-1694-F andcmS-1694-CN2 Final Rule and Correction Notice

6.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

Important Note:

The information contained in this document is provided for informational purposes only and represents no statement, promise or guarantee by KCI 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. KCI recommends that you consult your localcmS 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.

APPENDIX: ADMINISTRATIVE SUPPORT

COMPANY OVERVIEW

KCI®, an Acelity Company

World-Class Care Deserves World-Class Support Partners

Our Mission:

To change the practice of medicine with solutions that advance the science of healing, create economic value, and improve patients' lives

Our Vision:

Restoring People's Lives

Our Vision:

- Outcomes - Nearly 800,000 patients treated annually
- Education – Over 25,000 healthcare providers trained annually
- Support - Over 1,000 KCI field and service personnel to assist accounts, healthcare providers, and patients

MORE THAN NEGATIVE PRESSURE THERAPY (NPT); MEETING THE UNIQUE NEEDS OF ALL CLINICANS & PATIENTS

Every patient is special, and each wound is unique. KCI has a full line of products that enable clinical teams to treat multiple patient care needs across care settings.

- Recent acquisitions of global Advanced Wound Dressing (AWD) providers allows KCI to better serve our customers with a broader portfolio of advanced wound solutions
- Behind KCI's technology and products stand our vast support teams, who are committed to delivering world class care to meet the wound care needs of patients and clinicians
- KCI delivers state-of-the-art support and simplifies the overall ordering, transition and delivery process, while participating in rounding and patient troubleshooting solutions
- Unparalleled medical education and training – investing in making advanced wound and surgical the best it can be

Clinical Scenario	Wound Therapy Innovation	
Dressings to assist with chronic, stalled, or delayed healing wounds	*Wound management*	PROMOGRAN™ Matrix Wound Dressing PROMOGRAN™ PRISMA Matrix
Clean closed incisions following sutured or stapled closure	*Incision management*	PREVENA™ Incision Management System
	Incision & soft tissue management	PREVENA RESTOR™ Incision Management System
Open abdomen where primary goal is fascial closure	*Active abdomen management*	ABTHERA™ Active Abdominal Therapy
Open wounds, including acute, traumatic, chronic, sub-acute, and dehisced wounds	*Hospital-use wound management*	V.A.C.ULTA™ Therapy System V.A.C. VERAFLO™ Therapy
	Portable wound management – ideal for patient transition or discharge	V.A.C.VIA™ Therapy System ACTIV.A.C.™ Therapy System

YOUR KCI TEAM

Role	Area of Focus	Our Promise
Territory Manager	Acute support	Ensuring a seamless KCI acute-setting experience with healthcare provider product, program, and post-procedure support
Associate Territory Representative	Patient transitions	Ensuring a seamless experience with transition support for discharging the patient from acute to post-acute
Territory Sales	Post-acute support	Ensuring a seamless KCI post-acute-setting experience with healthcare-provider product, program, and patient/caregiver support
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 KCI account team

Through years of continuous design evolution, technological improvements, and account-dedicated personnel resources, the KCI NPT platform has developed market-leading devices that can clinically improve patient outcomes. This is what makes KCI more than a business partner.

APPENDIX: ADMINISTRATIVE SUPPORT

PRODUCT ORDERING INFORMATION

SKU	Description	UOM
PRE5221	PREVENA RESTOR BELLA•FORM™ SYSTEM KIT - 21cm x 19cm	1
PRE5321	PREVENA RESTOR BELLA•FORM™ SYSTEM KIT - 24cm x 22cm	1
PRE5421	PREVENA RESTOR BELLA•FORM™ SYSTEM KIT - 29cm x 27cm	1
PRE5255	PREVENA RESTOR BELLA•FORM™ Dressings - 21cm x 19cm	5
PRE5355	PREVENA RESTOR BELLA•FORM™ Dressings - 24cm x 22cm	5
PRE5455	PREVENA RESTOR BELLA•FORM™ Dressings - 29cm x 27cm	5

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

The data referenced in this brochure was derived from studies using the KCI family of negative pressure technology, but not specifically the PREVENA RESTOR™ System.

3M + KCI™