

# PROMISEs RCT data suggests Solventum™ Prevena™ Therapy can help advance the standard of care

Data from a multicenter (15) randomized controlled trial (RCT) and subsequent cost-effectiveness analysis demonstrated that Prevena Therapy significantly reduced the risk of 90-day surgical site complications (SSCs)<sup>1</sup>, readmissions<sup>1</sup>, and surgical site management costs<sup>2</sup> vs. silver-impregnated dressings (Standard of Care [SOC]).

## Clinical evidence summary

The PROMISEs (Post-market, Randomized, Open-Label, Multicenter Study to evaluate Effectiveness) Trial: The effectiveness of closed incision negative pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty.

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett MP, Scuderi GR, Cushner FD, Piuze NS, Silverman RP. J. Arthroplasty 2021; doi: 10.1016/j.arth.2021.02.076

## Results



**Note:** The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seromas in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at [Prevena.com](https://www.solventum.com/prevena)

**Note:** The use of Prevena Therapy for reduction in the incidence of deep SSI and dehiscence has not been reviewed by the U.S. FDA. Calculation(s) are derived based on the relative patient group incidence rate reported in this study; \*Statistically significant (p<0.05)

<p><b>Study design:</b> Post-market, multicenter (15) randomized controlled trial</p>	<p><b>Methods:</b></p> <ul style="list-style-type: none"> <li>294 high-risk revision total knee arthroplasty (rTKA) patients (15 centers) randomized to ciNPT or SOC (n=146 each) and stratified by revision type (aseptic vs. septic)</li> <li>Inclusion criteria: exhibit at least one risk factor for postoperative SSC: BMI &gt; 35kg/m<sup>2</sup> use of non-aspirin blood thinners postoperatively; current/previous diagnosis of peripheral vascular disease; current tobacco use; history of prior infection history at operative site; operative limb lymphedema; insulin-dependent diabetes; current use of immunomodulators or corticosteroids; ongoing malignancy excluding localized skin cancer; rheumatoid arthritis; renal failure or dialysis; malnutrition; liver disease; solid organ transplant recipients; or human immunodeficiency virus infection</li> <li>Primary outcome was the 90-day incidence of SSCs. Secondary outcomes were the 90-day health care utilization parameters (readmission, reoperation, dressing changes, and visits) and patient-reported outcomes (PROs). Treatment-related adverse events were compared and stratified as severe and non-severe</li> </ul>
<p><b>Study purpose:</b> Evaluate the effectiveness of closed incision negative pressure therapy (ciNPT) versus standard of care (SOC) dressings in reducing surgical site complications (SSCs)</p>	

# Cost effectiveness evidence summary

Cost-effectiveness of closed incision negative pressure therapy for surgical site management after revision total knee arthroplasty: Secondary analysis of a randomized clinical trial.

Cooper HJ, Bongards C, Silverman RP. Cost-Effectiveness of Closed Incision Negative Pressure Therapy for Surgical Site Management After Revision Total Knee Arthroplasty: Secondary Analysis of a Randomized Clinical Trial. *J Arthroplasty*. 2022;37(8S):S790-S795. doi:10.1016/j.arth.2022.03.022

## Results – all patients

**\$989** reduction in per-patient cost of care  
\$1,047 Solventum™ Prevena™ Therapy vs.  
\$2,036 SOC

**79%** reduction in SSC non-surgical  
interventions  
2.7% Prevena Therapy vs. 12.9% SOC  
( $p=0.0017$ )\*

**85%** reduction in surgical interventions  
0.7% Prevena Therapy vs. 4.8% SOC  
( $p=0.0666$ )

## Results – higher-risk patients (CCI $\geq 2$ )

**\$2318** reduction in per-patient cost  
\$894 Prevena Therapy  
vs. \$3,212 SOC

**85%** reduction in SSC non-surgical  
interventions  
1.8% Prevena Therapy vs. 11.1% SOC  
( $p=0.0604$ )

**100%** reduction in SSC surgical  
interventions  
0% Prevena Therapy vs. 5.6% SOC  
( $p=0.1182$ )

Calculation(s) are derived based on the relative patient group incidence rate reported in this study; \*Statistically significant ( $p < 0.05$ )

### Study design:

Health Economic assessment of a post-market, multicenter (15) randomized controlled trial

### Study purpose:

Determine the cost-benefit of ciNPT in revision total knee arthroplasty (rTKA) surgical site management by reducing 90-day cost for surgical site complication (SSC)-related interventions based on randomized control trial study (RCT) data

### Methods:

- Original RCT study data was used to determine the type and frequency of SSC-related interventions clustered into surgical and non-surgical groupings
- Health economic model was applied to determine the mean per-patient costs for postoperative dressings, surgical interventions, readmission, and non-surgical interventions
- Subsequent sub-analysis was also performed by dividing patients into “lower risk” (Charlson Comorbidity Index [CCI]  $< 2$ ) and “higher risk” (CCI  $\geq 2$ ) groups

**Prevena Therapy Indications for Use:** The Solventum™ Prevena™ 125 Therapy Unit and Solventum™ Prevena Plus™ 125 Therapy Unit manages the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena 125 Therapy Units and Prevena Plus 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.\*

\*The effectiveness of Prevena Therapy in reducing the incidence of SSI and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at [Prevena.com](https://www.prevena.com)

**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. Rx only.

**References:** 1. Higuera-Rueda C, Emara AK, Nieves-Malloure Y, et al. The Effectiveness of Closed Incision Negative Pressure Therapy versus Silver-Impregnated Dressings in Mitigating Surgical Site Complications in High-Risk Patients after Revision Knee Arthroplasty: The PROMISES Randomized Controlled Trial. *J Arthroplasty* (2021), doi: <https://doi.org/10.1016/j.arth.2021.02.076>. 2. Cooper HJ, Bongards C, Silverman RP. Cost-Effectiveness of Closed Incision Negative Pressure Therapy for Surgical Site Management After Revision Total Knee Arthroplasty: Secondary Analysis of a Randomized Clinical Trial. *J Arthroplasty*. 2022;37(8S):S790-S795. doi:10.1016/j.arth.2022.03.022



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