

Study data suggests 3M™ Prevena™ Therapy drives a new standard of care

Clinical evidence (level I): Orthopedics surgery, TKA & THA

Summary of findings

According to study data,¹ patients that receive Prevena Therapy experienced mitigated 90-day surgical site complications, readmission rates, and frequency of dressing changes compared with the standard of care among high-risk revision knee arthroplasty (rTKA) patients.

RESULTS



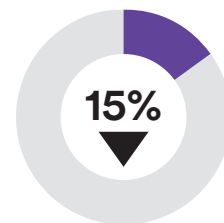
Reduction in SSCs*

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



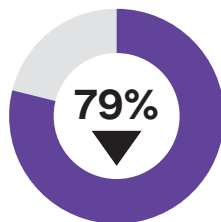
Reduction in readmission rates*

3.4% (5/147) Prevena Therapy vs. 10.3% (15/147) SOC (p=0.0208)*



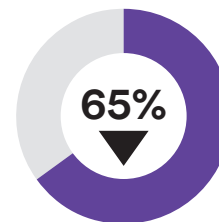
Fewer mean dressing changes*

1.1 ± 0.3 Prevena Therapy vs. 1.3 ± 1.0 SOC (p=0.0003)*



79% Reduction in dehiscence

0.7% (1/147) Prevena Therapy vs. 2.0% (5/147) SOC (p=0.2133)



65% Reduction in deep SSIs

0.7% (1/147) Prevena Therapy vs. 2.0% (3/147) SOC (p=0.6221)

Calculation(s) are derived based on relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

Study design

Multi-center randomized controlled trial (Level I)

Study purpose

Evaluate the effectiveness of closed incision negative pressure therapy (ciNPT) versus standard of care (SOC) silver-impregnated dressings in reducing surgical site complications (SSCs) in high-risk patients after revision knee arthroplasty (rTKA)

Methods

- 294 high-risk rTKA patients (15 centers) randomized to ciNPT (n=147) or SOC (n=147).
- Inclusion criteria: exhibit at least one risk factor for postoperative SSC: BMI > 35kg/m2 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.
- Primary outcome was 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 (PRO). Treatment-related adverse events were compared and stratified as severe and non-severe.

1. Higuera-Rueda C, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett M, Scuderi GR, Cushner FD, Piuze NS, Silverman RP. 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 Jul;36(7S):S295-S302.e14.

Understanding relevant risk factors for orthopedic procedures

Patient Risk Stratification

How to identify the patient as high risk for surgical site infection or complication:

Hip and knee arthroplasty

If the patient has any **one of the following** risk factors data¹ suggests that Prevena Therapy should be considered:

- BMI > 35 kg/m²
- Non-aspirin anticoagulation
- Active tobacco use
- Diabetes mellitus
- Autoimmune disease
- Chronic kidney disease
- Staphylococcus aureus nasal colonization
- Revision surgery



Scan this QR code to learn more about when to use Prevena Therapy.

1. Higuera-Rueda C, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett M, Scuderi GR, Cushner FD, Piuze NS, Silverman RP. 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 Jul;36(7S):S295-S302.e14.

Advancing the Standard of Care.



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3M™ Prevena™ 125 Therapy Unit and 3M™ Prevena™ Plus 125 Therapy Unit manage 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 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 SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at mykci.com.

NOTE: Specific indications, limitations, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

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