New Data from PROMISES Study Shows PREVENA™ Incision Management System Significantly Reduces Major Complications and Readmissions Compared to Standard of Care

Research presented at the 30th American Association of Hip and Knee Surgeons Annual Meeting (AAHKS) builds on existing evidence that PREVENA™ Therapy lowers surgical site complications and readmission rates

ST. PAUL, Minn.--(BUSINESS WIRE)-- 3M today announced new data demonstrating the PREVENA™ Incision Management System significantly mitigated 90-day surgical site complications (SSCs) and readmission rates in patients undergoing revision total knee arthroplasty (TKAs) compared to standard of care (SOC). Patients treated with PREVENA™ Therapy were four times less likely to experience a post-operative 90-day SSC and three times less likely to be readmitted compared to the SOC group.

The data was a featured podium presentation at the 30th American Association of Hip and Knee Surgeons (AAHKS) Annual Meeting, which was held November 5-8.

“This data supports the use of the PREVENA™ Incision Management System to reduce surgical site infections and complications, which are common during total knee revision procedures, and many times the reason for extended hospital stays or need for readmission.” said Dr. Carlos Higuera-Rueda, M.D., Center Director of Orthopaedics and Rheumatology Chairman, Department of Orthopedic Surgery, Cleveland Clinic and primary investigator on the study.

Patients undergoing revision TKAs tend to have higher unplanned readmission rates than patients undergoing primary TKAs and the most common readmission reasons are related to infection and procedure-related complications.[i,ii] Specifically, data show patients requiring early surgical treatment for wound healing problems after total joint replacement are 7.5 times more likely to develop further complications, such as major subsequent surgery. These complications in arthroplasty procedures represent a severe burden to the healthcare system and substantially increased economic cost for patients.[iii,iv,v,vi]

“Minimizing the length of hospital stays is critical, now more than ever, because of the resource and financial burden they place on hospitals that are already strained from our global pandemic,” said Ronald Silverman, M.D., FACS, Chief Medical Officer, 3M. “PREVENA™ Therapy can potentially alleviate this burden by sending patients with elective surgeries home sooner, with fewer complications, and minimizing the chances they will require readmission, which can be costly.”

In 2019, the PREVENA™ Incision Management System became the first and only negative pressure medical device to be indicated by the U.S. Food and Drug Administration (FDA) to aid in the reduction of superficial surgical site infections (SSIs) for patients at high-risk for post-operative infections and aid in the reduction of seromas. This data from the PROMISES study further support the updated indication for PREVENA™ Therapy.

PROMISES Study Overview

A post-market, randomized, open-label, multicenter study with 294 patients undergoing total knee arthroplasty revision to evaluate the effectiveness of closed incision negative pressure therapy (ciNPT) [PREVENA™ Therapy] versus standard of care dressings in reducing surgical site complications (SSCs). A total of 242 patients completed follow-up; 124 patients had incisions treated with ciNPT compared to 118 patients with incisions treated with an antimicrobial silver-impregnated dressing (SOC).

Results demonstrate that the PREVENA™ Incision Management System is associated with:

Significantly decreased rates of surgical site complications (ciNPT 3.4% vs. SOC 14.3%, p=0.0013)
Significantly lower readmission rate (ciNPT 3.4% vs. SOC 10.2%, p=0.0208)
Significantly reduced the number of dressing changes (ciNPT 1.1 +0.29 vs. SOC 1.3 +0.96, p=0.0003)

About PREVENA™ Therapy

The PREVENA™ Incision Management System, launched in 2010, is the first disposable negative pressure system designed specifically for the management of closed surgical incisions. The PREVENA™ System removes fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, PREVENA™ 125 Therapy Unit and PREVENA PLUS™ 125 Therapy Units are intended to aid in reducing the incidence of seroma; and in patients at a high-risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

Please refer to the instructions for use with PREVENA™ Therapy products for important limitations and safety information.

About 3M

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[i] Schairer W, Vail T, Bozic K. What are the rates and causes of hospital readmission after total knee arthroplasty? Clin Orthop Relat Res. 2013 472(1): 181-187
[ii] Saucedo J, Marecek G, Wanke T, Lee J, Stulberg D, Puri L. Understanding readmission after primary total hip and knee arthroplasty: Who's at risk? Jour of Arthro. 2014 2(2) 256-260.
[iii] Burns AW, Bourne RB, Chesworth BM, MacDonald SJ, Rorabeck CH. Cost effectiveness of revision total knee arthroplasty. Clin Orthop Relat Res. 2006;446:29-33.
[iv] Oduwole KO, Molony DC, Walls RJ, Bashir SP, Mulhall KJ. Increasing financial burden of revision total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2010;18:945-8.
[v] Ong KL, Mowat FS, Chan N, Lau E, Halpern MT, Kurtz SM. Economic burden of revision hip and knee arthroplasty in Medicare enrollees. Clin Orthop Relat Res. 2006;446:22-8.
[vi] Galat DD, McGovern SC, Larson DR, Harrington JR, Hanssen AD, Clarke HD. Surgical treatment of early wound complications following primary total knee arthroplasty. J Bone Joint Surg Am 2009;91:48-54.

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Emilie Petersen
epetersen2@mmm.com

Lindsey Bailys
Lindsey.Bailys@gcihealth.com

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