

# Bundled-Care Program for the Prevention of Surgical-Site Infections Following Lower Extremity Total Joint Arthroplasty

HYTHAM S. SALEM, MD <sup>1,2</sup>  
RESIDENT PHYSICIAN

MITCHELL K. NG, MD <sup>3</sup>  
RESIDENT PHYSICIAN

GILES R. SCUDERI, MD <sup>1</sup>  
VICE PRESIDENT, ORTHOPAEDIC SERVICE LINE

ZHONGMING CHEN, MD <sup>1,2</sup>  
RESEARCH FELLOW

MICHAEL A. MONT, MD <sup>1,2</sup>  
DIRECTOR OF CLINICAL TRIALS

<sup>1</sup> NORTHWELL HEALTH ORTHOPAEDICS, LENOX HILL HOSPITAL, NEW YORK, NEW YORK

<sup>2</sup> RUBIN INSTITUTE FOR ADVANCED ORTHOPEDICS, CENTER FOR JOINT PRESERVATION AND REPLACEMENT, SINAI HOSPITAL OF BALTIMORE, BALTIMORE, MARYLAND

<sup>3</sup> DEPARTMENT OF ORTHOPAEDIC SURGERY, MAIMONIDES MEDICAL CENTER, BROOKLYN, NEW YORK

## ABSTRACT

**S**urgical-site infections (SSIs) are among the most difficult-to-manage complications after lower extremity total joint arthroplasty (TJA). While the rates of most implant-related complications have decreased over time due to improvements in prosthetic materials and surgical techniques, the incidence of periprosthetic joint infections (PJIs) continues to increase. They place a tremendous economic burden on healthcare systems that is projected to reach \$1.8 billion by the year 2030. A number of perioperative infection mitigation strategies exist that are often implemented concurrently to minimize the risk of these complications. A multicenter randomized controlled trial is underway to evaluate the efficacy of a bundled care program for the prevention of PJIs in lower extremity TJA. This bundle includes five infection-reduction strategies that are used pre-, peri-, and postoperatively, including: (1) povidone-iodine skin preparation and nasal decolonization; (2) iodine-alcohol surgical prepping solution; (3) iodophor-impregnated incise drapes; (4) forced-air warming blankets; and (5) negative pressure wound therapy for select patients. The aim of this review is to describe these products and their appropriate usage, review the available literature evaluating their use, and

compare them with other commercially available products. Based on the available literature, each of these strategies appear to be important components for SSI-prevention protocols. We believe that implementing all five of these mitigation strategies concurrently will lead to a synergistic effect for infection control following lower extremity TJA.

## INTRODUCTION

Recently, Northwell Health, New York's largest healthcare provider and private employer, and Maimonides Medical Center in Brooklyn, New York have endeavored to conduct a multicenter trial evaluating the implementation of a bundled care program with five products for the prevention of surgical-site infections (SSIs) after lower extremity arthroplasty procedures. Among these products are pre-, peri-, and postoperative SSI-reduction strategies including the use of: (1) povidone-iodine skin preparation and nasal decolonization (3M™ Skin and Nasal Antiseptic, 3M Company, St. Paul, Minnesota); (2) iodine-alcohol surgical prepping solution (3M™ DuraPrep™ Surgical Solution, 3M company, St. Paul, Minnesota); (3) iodophor-impregnated incise drapes (3M™ Ioban™ 2 Antimicrobial Incise Drape, 3M Company, St. Paul, Minnesota); (4) forced-air warming blankets (3M™ Bair Hugger™ Warming Blankets, 3M Company, St. Paul, Minnesota); and (5) negative pressure wound therapy (3M™ Prevena™ Duo Incision Management System, 3M Company, St. Paul, Minnesota) for selected high-risk patients. The aim of this review is to describe these products and their appropriate usage, review the available literature evaluating their use, and compare them with other commercially available products.

### Background and significance

A surgical-site infection (SSI) is defined by the Centers for Disease Control and Prevention (CDC) as microbial contamination of a surgical wound within 30 days of an operation or within 90 days of surgery if an implant is placed. Superficial SSIs occur in an estimated 1 to 3% of lower extremity total joint arthroplasty (TJA) patients and can lead to prolonged hospitalizations, higher readmission rates, and increased costs for healthcare systems.<sup>1,2</sup> However, the most devastating SSIs are periprosthetic joint infections (PJIs), which occur after an

estimated 2 to 2.4% of primary TJAs and 4% or higher of revision knee or hip arthroplasty procedures.<sup>3,4</sup>

While advancements in surgical technologies and techniques have mitigated the risks of many implant-related complications, PJIs have emerged as the leading cause of revision surgeries after TJAs.<sup>5,6</sup> Although a substantial amount of work has focused on this problem, the incidence of PJIs continues to increase.<sup>7</sup> Springer et al.<sup>7</sup> evaluated data from six arthroplasty registries including: (1) the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR); (2) the New Zealand Joint Registry; (3) the Swedish Hip Arthroplasty Register; (4) the Swedish Knee Arthroplasty Register; (4) the National Joint Registry of England, Wales, Northern Ireland, and the Isle of Man; and (5) the American Joint Replacement Registry (AJRR). The authors reported that the rate of revision surgeries performed following infection diagnoses increased in these registries from 2010 to 2015. In a study by Premkumar et al.,<sup>8</sup> it was projected that by the year 2030, the incidence of PJIs will reach 7% and result in an additional \$1.85 billion annually for the care of lower extremity TJA patients.

### Infection mitigation strategies

Various strategies exist for the prevention of SSIs following TJA procedures. Generally, they can be divided into pre-, peri-, and postoperative measures. Preoperative strategies include medical optimization of patients who have modifiable risk factors such as obesity, diabetes mellitus, tobacco abuse, immunodeficiency, or nutritional deficits.<sup>9,10</sup> In addition, preoperative decolonization of methicillin-sensitive *Staphylococcus aureus* (MSSA) and methicillin-resistant *Staphylococcus aureus* (MRSA) has been shown to decrease the risk of PJIs. Perioperatively, intravenous administration of antibiotics within 30 to 60 minutes of incision is among the most important infection prevention strategies. Adequate surgical-site preparation is also of tremendous importance, as endogenous skin flora (e.g., *Staphylococcus aureus*,

*Staphylococcus epidermidis*) are the primary source of bacteria implicated in SSIs.<sup>11</sup> Other perioperative measures include maintaining core body temperature intraoperatively and the use of surgical incise drapes. Postoperatively, a variety of wound dressings are used to promote infection-free wound healing. For selected patients who are at an increased risk of SSIs, negative pressure wound therapy has been shown to provide benefits.<sup>12,13</sup> The upcoming sections will be an in-depth overview of certain products in the bundled care program study that address some of these pre-, peri-, and postoperative measures.

## BUNDLED CARE FOR SSI PREVENTION

### Nasal decontamination

Methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-sensitive *Staphylococcus aureus* (MSSA) are among the most commonly implicated bacteria in lower extremity PJIs.<sup>14–19</sup> It is estimated that 20 to 30% of the general population carry these organisms, and the nares are the most common site of colonization by *S. aureus* species.<sup>17,19,20</sup> In fact, 80% of *S. aureus*-related SSIs come from the patient's own nasal flora.<sup>15,21,22</sup> Thus, nasal decolonization is a promising method to reduce the risk of PJIs. Intranasal mupirocin is commonly used, but because it requires twice-daily application for five days preoperatively, patient non-compliance is a concern. In addition, the emergence of resistant *S. aureus* strains may lead to reduced effectiveness if it continues to be used indiscriminately.<sup>23</sup>

### Povidone-iodine skin preparation—3M™ Skin and Nasal Antiseptic

The 3M Skin and Nasal Antiseptic (SNA) is a 5% povidone-iodine solution (0.5% available iodine) with rapid, broad-spectrum antimicrobial activity. It can be applied to the nares in two minutes during the preoperative process, thus, the issue of patient noncompliance is ameliorated. After the solution is

applied, it forms a unique polymeric film that increases its persistence in eradicating bacterial colonies. Nasal decolonization with a povidone-iodine product can significantly decrease the rate of positive cultures ( $p=0.003$ ).<sup>24</sup> When resistant strains of *S. aureus* were exposed to this product, no increases in resistance were demonstrated. Thus, it appears that 3M™ Skin and Nasal Antiseptic is not subject to the limitations observed with other currently used products. The available evidence on this product will be described in the upcoming paragraphs.

### Summary of available literature

There are a number of studies supporting the use of SNA for nasal antiseptic care (Table I). Rezapoor et al.<sup>24</sup> performed a randomized, placebo-controlled study comparing the efficacy of SNA to that of an off-the-shelf 10% povidone-iodine solution for nasal

decontamination prior to hip, knee, and shoulder arthroplasties, as well as femoro-acetabular osteoplasties, and pelvic osteotomies. A total of 429 patients were included and randomized into three groups: SNA ( $n=143$ ); off-the-shelf povidone iodine ( $n=143$ ); and saline ( $n=143$ ). After obtaining pre-treatment nasal culture swabs, the nostrils of each patient were treated with saline, SNA, or the 10% povidone-iodine solution. Pre-treatment cultures revealed that 95 of the 429 patients (22.1%) had nasal *S. aureus* colonization including 29 (20%) in the off-the-shelf povidone-iodine group, 34 (24%) in the SNA group, and 32 (22%) in the saline group. Among patients who had baseline *S. aureus* colonization, cultures were positive in 15 of 29 (52%) patients in the off-the-shelf povidone-iodine group, seven of 34 patients (21%) in the SNA group, and 19 of 32 (59%) patients in the saline group

at the four-hour post-treatment interval ( $p=0.003$ ). The results of this study demonstrated that 3M™ SNA had significantly greater efficacy than an off-the-shelf povidone-iodine solution for nasal decolonization of *S. aureus* preoperatively.

Bebko et al.<sup>25</sup> performed a randomized controlled trial evaluating the use of a methicillin-resistant *S. aureus* decontamination protocol (including the use of a nasal povidone-iodine solution) for patients undergoing elective orthopaedic surgery with hardware implantation. Thirty-day SSI rates were compared between patients who underwent the decontamination protocol ( $n=365$ ) and matched controls ( $n=344$ ). It was reported that the SSI rate in the study group (4 of 365; 1.1%) was significantly lower ( $p=0.02$ ) than that in the control group (13 of 344; 3.8%). In addition, multivariate regression analysis determined that implementation of the MRSA

**Table I**  
**Summary of studies on nasal povidone-iodine solutions**

Type	Study	Subjects/Patients	Interventions	Results
Basic Science	Anderson et al. <sup>26</sup> (2015)	Porcine mucosal and human skin (explant models)	Explants washed with 2% mupirocin, povidone-iodine skin and nasal antiseptic, or left untreated	Demonstrated >2.0 log colony forming unit reduction in MRSA regardless of mupirocin sensitivity
Basic Science	Peterson et al. <sup>27</sup> (2016)	Explants of porcine mucosal tissue	Explants infected with MRSA, treated with Betadine, 3M™ SNA, Clorox Healthcare Nasal Antiseptic, or untreated	Demonstrated 4.6 +/- 1.9 log <sub>10</sub> 4.8 reduction in MRSA relative to untreated control, persistence at 6 and 24 hours relative to both betadine solution and Clorox™ Nasal Antiseptic Swabs
Clinical	Neelakanta et al. <sup>28</sup> (2014)	All patients receiving hip/knee arthroplasty (2013 to 2014) at single hospital	Nasal decontamination with nasal iodine (3M™ SNA)	Demonstrated 28.3% reduction in hip/knee infection rates
Clinical	Phillips et al. <sup>29</sup> (2014)	A total of 855 patients undergoing arthroplasty or spine fusion	Patients randomized to receive mupirocin 2% ointment or povidone-iodine solution (3M™ SNA)	Similar SSI incidence, deep SSI in 14/855 surgeries in mupirocin group and 6/842 surgeries in povidone-iodine group
Clinical	Rezapoor et al. <sup>24</sup> (2017)	A total of 429 patients undergoing primary or revision total joint arthroplasty, femoro-acetabular osteoplasty, pelvic osteotomy, and total shoulder arthroplasty	Patients randomized to receive 3M™ SNA, off-the-shelf povidone-iodine solution, or saline (placebo)	At 4 hours, <i>S. aureus</i> positive in 21% of 3M™ SNA patients, positive in 52% of patients receiving off-the-shelf PVP-I and 59% of patients receiving saline
Clinical	Urias et al. <sup>30</sup> (2018)	A total of 1,892 trauma patients undergoing orthopaedic surgery for repair of lower extremity fractures	Pre-intervention group received chlorhexidine washcloth bath or solution shower and intervention group was further supplemented with 3M™ SNA	Decreased infection rate from 1.1 to 0.2% with addition of 3M™ SNA

SNA=3M™ Skin and Nasal Antiseptic; SSI=surgical-site infection; MRSA=methicillin-resistant *Staphylococcus aureus*

decontamination protocol was an independent predictor of not developing an SSI (odds ratio, 0.24;  $p=0.02$ ). Although this study did not evaluate the efficacy of povidone-iodine nasal decontamination independently, it showed that including it in a bundled program reduced SSI rates after surgical placement of orthopaedic implants.

### 3M Skin and Nasal Antiseptic compared to other products

There are other available products similar in purpose to 3M™ SNA. Mupirocin decolonization involves twice-daily intranasal application for five days prior to surgery. However, this regimen has demonstrated barriers including patient non-adherence and a growing incidence of resistance due to its widespread use.<sup>23</sup> In addition, nasal mupirocin application has been shown to have suboptimal efficacy in decreasing SSI rates.<sup>22,31</sup> Similarly, although Betadine™ (Purdue Pharma LLP, Stamford, Connecticut) and Clorox™ Nasal Antiseptic Swabs (Clorox Healthcare®, Oakland, California) have been found to reduce

rates of MRSA colonization, these products have shown suboptimal efficacy in maintaining duration of antimicrobial efficacy for 24 hours.<sup>32</sup>

Phillips et al.<sup>29</sup> performed a randomized controlled trial to compare the efficacy of mupirocin ( $n=763$ ) to SNA ( $n=776$ ) for the prevention of deep SSIs following hip, knee, and shoulder arthroplasty procedures. Patients in the mupirocin group applied the ointment twice daily for the five days leading up to surgery, while those in the povidone-iodine group had two 30-second applications in each nostril two hours postoperatively. All patients were followed for three months postoperatively to determine if a deep SSI occurred. At final follow up, it was found that *S. aureus* deep SSIs developed in five of 763 (0.6%) surgeries in the mupirocin group and 0 of 776 (0%) surgeries in the povidone iodine group ( $p=0.06$ ). It was also reported that patients who had positive *S. aureus* nasal cultures preoperatively were more likely to have an *S. aureus* deep SSI (odds ratio [OR] 6.79;  $p=0.02$ ). The results of this study demonstrated that

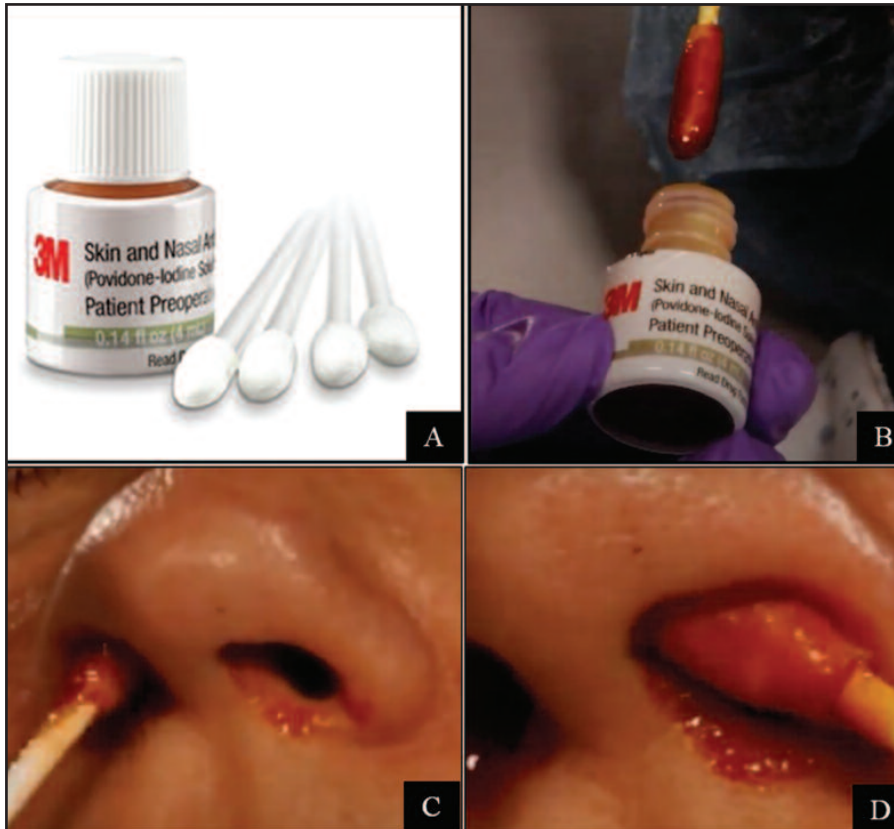
nasal carriage of *S. aureus* predisposes patients to a higher risk of PJIs and that in addition to the simple application protocol and lack of resistance found with povidone-iodine, it is more efficacious than mupirocin in preventing PJIs after arthroplasty procedures.

In addition to the demonstrated clinical benefits of 3M SNA compared to other commercially available products, the economic impact of its use has also been shown.<sup>33</sup> Rieser and Moskal<sup>33,34</sup> developed a cost-analysis model to evaluate cost-related implications of SNA utilization. At their institution, THA and TKA patients who had positive screening tests for methicillin-resistant *Staphylococcus aureus* (MRSA) would undergo a five-day course of twice daily nasal mupirocin treatment. They compared the total costs incurred with this protocol ( $n=1,360$ ) to associated SNA treatment for all patients with no screening protocol ( $n=1,360$ ). They found that the implementation of global SNA treatment resulted in an annual savings of more than \$100,000, equating to approximately \$75 per patient. Thus, in addition to the clinical advantages that have been reported with the use of SNA, its widespread implementation could potentially lead to substantial economic benefits.

In summary, 3M Skin and Nasal antiseptic appears to provide advantages over other commercially available products including: (1) an easier one-step application protocol that does not rely on patient compliance; (2) decreased risk of SSIs; (3) decreased costs of care; and (4) no evidence of bacterial resistance. Based on the available literature, we have been using 3M™ SNA for preoperative SSI prophylaxis.

### Instructions for use

Using an aseptic technique, the sterile package is opened revealing a 2mm bottle of solution and four swabs (Fig. 1A). The patient is instructed to clean the inside of both nostrils using a tissue. Next, one swab is dipped into the solution and it is stirred vigorously for 10 seconds. The swab is then withdrawn from the solution and slowly inserted into one nostril while rotating it for 15 seconds to cover all surfaces (Figs. 1B and 1C). After this, the practitioner should focus on the inside tip of the nostril for an additional 15 seconds while continuing to rotate the swab (Fig. 1D). The steps are then repeated in the other nostril using a second swab. Finally, the



**Figure 1. Application of:** (A) 3M Skin and Nasal Antiseptic for *S. aureus* decolonization of the nares. After dipping one swab into the solution and stirring it vigorously for 10 seconds; (B) withdraw the swab from the solution; and (C) slowly insert it into one nostril while rotating it for 15 seconds to cover all surfaces. Next, (D) focus on the inside tip of the nostril for an additional 15 seconds while continuing to rotate the swab. Repeat these steps in the other nostril before repeating the entire process in both nostrils, using a fresh swab each time.

entire process is repeated in both nostrils using a fresh swab each time, resulting in a total application time of approximately two minutes.

## TEMPERATURE MANAGEMENT

### The effects of hypothermia on surgical wound healing and infections

Under normal conditions, the body typically maintains a temperature between 36 and 38°C through homeostatic mechanisms of heat loss and production. During surgery, the body's thermoregulatory mechanisms are disrupted by anesthesia and can result in hypothermia (core body temperature <36°C). In fact, adults under general anesthesia lose approximately 1 to 2°C of body temperature, with a majority of heat loss occurring during the first hour of surgery.<sup>34</sup> Although this may seem inconsequential, it has been shown that even mild hypothermia can lead to a myriad of harmful complications including impairments of drug metabolism, cardiovascular abnormalities, coagulopathies, increased blood losses, wound infections, and prolonged recoveries.<sup>34</sup> The increased risk for SSIs in hypothermic patients is due, in part, to peripheral vasoconstriction and thus, decreased oxygen delivery to the wound site.<sup>35-37</sup> This results in impaired microbial killing that is typically accomplished by oxygen-dependent production of free radicals.

The consequences of perioperative hypothermia have been demonstrated in orthopaedic patients. Frisch et al.<sup>38</sup> performed a study to evaluate the effect of hypothermia on patients undergoing surgical fixation of hip fractures. A total of 1,525 consecutive surgical hip fracture patients were divided into two groups: (1) those who had mean intraoperative temperatures less than 36°C (n=260; 17%); and (2) those who had mean intraoperative temperatures of at least 36°C (n=1,265; 83%). The rate of superficial SSIs was higher in hypothermic patients (7 of 260; 3%) compared to normothermic patients (16 of 1,265; 1%). In addition, deep SSIs occurred at a higher rate in hypothermic patients (6 of 260; 2%) compared to normothermic patients (13 of 1,265; 1%). Multivariate analysis demonstrated that hypothermia was independently associated with an increased rate of deep SSIs (OR 3.30; 95% confidence interval, 1.19 to 9.14; p=0.022). Based on their results, the

authors concluded that hypothermia is associated with an increased risk of infections in patients undergoing surgical fixation of hip fractures.

### Forced-air patient warming – 3M™ Bair Hugger™

Perioperative interventions for maintaining normothermia generally include passive and active warming techniques. Passive warming includes methods to promote heat retention, such as cotton and reflective blankets. However, it has been shown that these techniques do not maintain normothermia and thus, they should only be used for patient comfort and are not acceptable interventions to prevent perioperative hypothermia.<sup>39</sup> In contrast, active warming techniques refer to the application of an external heat source to the skin and peripheral tissues via methods including forced-air warming (FAW), underbody conductive heat mats, circulating water mattresses, and radiant warmers.

The 3M™ Bair Hugger™ and 3M™ Bair Hugger Temperature Monitoring System™ are a forced-air warming system that was developed to help keep patients within the normothermic tem-

perature range by proactively monitoring and maintaining core body temperature. This system consists of a temperature control system, a heat generator, and a fan to circulate heat. It is connected to an inflatable blanket or a gown by a rubber air tube (Fig. 2A–C), and it is intended to maintain normothermia (36.0 to 37.5°C) for the duration of surgical cases. In doing so, it can streamline patient warming and core body temperature monitoring from the preoperative through the post-anesthesia time periods. Therefore, this device may aid in minimizing the risks of SSIs, cardiovascular complications, and the need for transfusions that have been associated with perioperative hypothermia. For these reasons, the Bair Hugger™ system is one of the most commonly used forced air warming devices, and it has been used for more than 30 years in up to 80% of hospitals nationally.

## SUMMARY OF AVAILABLE LITERATURE

Several well-designed studies have demonstrated that forced-air warming devices are efficacious in maintaining intraoperative normothermia. In a



Figure 2. (A) Bair Hugger™ system with (B) gown and (C) blanket.

double-blind randomized study, Kurz et al.<sup>40</sup> hypothesized that mild perioperative hypothermia increases the risk of surgical wound infections and lengthens postoperative hospitalizations. A total of 200 patients undergoing major colorectal surgery were randomly assigned to two groups: (1) the normothermia group (n=104), in which the patients' core temperatures were maintained near 36.5°C using a forced-air warming device; and (2) the hypothermia group (n=96), in which the core temperature was allowed to decrease to approximately 34.5°C. The subjects' surgical wounds were evaluated daily during hospitalization, and again at two weeks postoperatively by a physician who was unaware of the group allocations. It was reported that SSIs occurred in 18 of 96 patients in the hypothermia group (19%) and six of 104 patients in the normothermia group (6%, p=0.009). In addition, sutures were removed one day later in patients assigned to hypothermia (10.9 ± 1.9) compared to normothermia (9.8 ± 2.9; p=0.002), and the mean hospital stay in the hypothermia group (13.5 ± 4.5 days) was significantly longer than that in the normothermia group (11.8 ± 4.1; p=0.01). The authors of this landmark study concluded that perioperative hypothermia delays wound healing and increases the risk of SSIs and that maintaining normothermia decreases the risk of infectious complications in surgical patients.

Shortly after publication of the above-mentioned study that linked patient-warming during colorectal surgery to a reduction in infection rates,<sup>40</sup> Melling et al.<sup>41</sup> aimed to determine if it had the same effect on patients undergoing short-duration, clean surgeries. A total of 421 patients who underwent clean (i.e., breast, varicose vein, hernia) surgery were randomly allocated to non-warmed (n=139) and warmed groups (n=277). Patients in the warmed group received a minimum 30-minute preoperative warming to the whole body using a forced-air warming blanket. After two- and six-week follow ups, a blinded assessment of the surgical wound healing was performed. Outcomes of interest included wound infections, hematomas, seromas, wound aspirations, postoperative antibiotics, and ASEPSIS scores<sup>42</sup> (i.e., Additional treatment, the presence of Serous discharge, Erythema, Purulent exudate, Separation of the deep tissues, Isolation

of bacteria, and duration of inpatient Stay). The authors identified wound infections in 19 of 139 patients (14%) in the non-warmed group but only 13 of 277 patients (5%) who received preoperative warming (p=0.002). Patients in the non-warmed group also had higher rates of hematomas (4 vs. 2%; p=0.26), seromas (6 vs. 4%; p=0.41), and aspirated wounds (7 vs. 4%; p=0.27); however, these differences did not reach statistical significance. ASEPSIS wound scores were significantly better in the warmed group, with satisfactory healing reported in 259 of 277 (94%) of warmed patients compared to 115 of 139 (83%) of non-warmed patients (p=0.007). Moreover, the rate of postoperative antibiotic prescriptions was significantly lower for warmed (18 of 277; 7%) versus non-warmed (22 of 115; 16%) patients (p=0.002). The authors concluded that warming patients prior to clean surgeries aids in the prevention of postoperative wound infections.

A recent randomized trial aimed to determine the effects of ambient operating room temperature and patient-warming technique on the intraoperative core body temperatures of patients undergoing three major surgeries including revision or bilateral total hip arthroplasties.<sup>43</sup> A total of 292 patients were randomized in a 1:1:1 format to ambient operating room temperature of 19 (n=98), 21 (n=99), or 23°C (n=95). Each group was then further randomized in a 1:1 format to passive insulation (n=144) or forced-air warming (Bair Hugger™ 63500, 3M, St. Paul, Minnesota; n=148). Ambient temperature affected core temperature changes more with passive insulation compared to forced-air warming. Specifically, for patients who had passive insulation, there was an estimated  $0.03^{\circ}\text{C}_{\text{core}} / [\text{hour} \cdot ^{\circ}\text{C}_{\text{ambient}}]$  increase in the slope of temperature change for each 1°C increase in ambient temperature (p<0.001). In contrast, for patients who had forced-air warming, there was no association between ambient temperature and the change in slope ( $-0.01^{\circ}\text{C}_{\text{core}} / [\text{hour} \cdot ^{\circ}\text{C}_{\text{ambient}}]$ ) for each 1°C increase in ambient temperature; p=0.398). Based on their results, the authors concluded that operating room ambient temperatures can be set to comfortable levels for staff and for patients who receive forced-air warming.

In summary, various studies have demonstrated that the Bair Hugger™ successfully maintains perioperative nor-

mothermia for patients undergoing surgical procedures under anesthesia, and by doing so, it reduces the rates of surgical-site infections.

### Forced-air warming compared to other active warming modalities

Other active warming devices exist for maintaining normothermia in patients undergoing surgical procedures including underbody conductive heat mats and circulating water mattresses. The upcoming paragraphs will summarize the studies comparing forced-air warming to other active patient warming techniques.

Forced-air warming devices have demonstrated better efficacy than conductive heat mats in maintaining perioperative normothermia. A prospective randomized controlled trial was conducted by Ralte et al.<sup>44</sup> to determine if there are clinically significant differences in the core body temperatures of patients undergoing arthroscopic shoulder surgery with the use of forced-air warming (Bair Hugger™) compared to a resistive heating system that generates heat by passage of a low-voltage electrical current through a carbon-based conductive polymer resistor packaged into a mattress (Inditherm™, Inspiration Healthcare™, Crawley, United Kingdom). A total of 91 shoulder arthroscopy patients received preoperative warming with either Bair Hugger™ (n=47) or Inditherm™ (n=44) warming devices. The authors reported a steady decline in core body temperature for all patients up to 30 minutes after induction of anesthesia. After 30 minutes, patients in the Bair Hugger™ group demonstrated gradual increases in body temperature, while those in the Inditherm™ group exhibited continuing decreases. From 60 minutes onward, there was a statistically significant difference in core body temperature between patients in each group (p=0.025) that continued to increase until 90 minutes post-anesthesia induction (p<0.01). The core body temperature did not increase at any point in the Inditherm™ group. After conclusion of the study, 13 of 47 patients (27.7%) in the Bair Hugger™ group and 32 of 44 patients (72.7%) in the Inditherm™ group had hypothermia (p=0.0002). The authors of this Level I study concluded that the Bair Hugger™ is superior to the underbody conductive heat mattress in maintaining perioperative normothermia for surgical patients.

Compared to circulating water mattresses, forced-air warming systems have been shown to decrease the incidence of post-anesthesia shivering in elderly patients undergoing total knee arthroplasty (TKA) under spinal anesthesia.<sup>45</sup> A total of 46 patients aged 65 years or greater had American Society of Anesthesiologists (ASA) physical status I to III and were scheduled for elective TKA under spinal anesthesia. They were enrolled in a prospective randomized trial and randomly assigned to forced-air warming (Bair Hugger™ warming unit-Model 505, 3M Company, St. Paul, Minnesota; n=23) or circulating-water mattress (Blanketrol® II, Cincinnati Sub-Zero, Cincinnati, Ohio; n=23) groups. Perioperative temperature was monitored in all patients using an infrared tympanic thermometer until spinal anesthesia was administered, and then a rectal temperature probe was inserted and monitored continuously until the end of anesthesia. Shivering was graded using a validated scale,<sup>46</sup> and a verbal analogue score (VAS) for thermal comfort (0, extremely cold; 5, thermally neutral; and 10, extremely hot) was recorded prior to anesthesia, at 30-minute intervals intraoperatively, and in the recovery room. Although changes in core body temperatures were similar between groups, the incidence of post-anesthesia shivering was significantly lower in the forced-air warming group (13%) compared to the circulating-water group (43.5%; p<0.05). In addition, the mean final VAS score for thermal comfort was significantly better in the forced-air warming group (5.0 ± 0.5 points) compared to the circulating-water group (4.0 ± 0.7 points; p<0.05). Based on these results, it appears that compared to circulating-water mattresses, forced-air warming provides a more comfortable perioperative experience for surgical patients.

In summary, it appears that the Bair Hugger™ device compares favorably to underbody conductive heat mats and circulating water mattresses in maintaining perioperative normothermia and reducing the risk of post-anesthesia shivering. In addition, it has been shown to be more cost-effective than other commercially available products. For these reasons, forced-air warming with the Bair Hugger™ system is the senior author's preferred method for maintaining intraoperative normothermia during lower extremity total joint arthroplasty procedures.

### Instructions for use

After positioning the patient appropriately, apply the garment to their upper body according to the manufacturer's instructions for the specific model being used (i.e., gown, blanket). The small holes on the underside of the garment should be in contact with the patient's skin. Connect the hose to the blanket using the desired port, taking care not to over-insert the hose into the port. Next, select the desired temperature and turn on the warming unit to inflate the garment.

### SURGICAL SKIN ANTISEPSIS

Preoperative skin preparation is an essential component of SSI prevention. The Centers for Disease Control and Prevention (CDC) attributes the occurrence of SSIs to microbes that contaminate an incision during surgery.<sup>47</sup> While these microbes can be derived from various sources or hosts, the primary source for these contaminants is typically the patient's own skin.<sup>11,48,49</sup> In fact, it has been shown that human skin can be colonized by up to 2 million bacterial cells per square centimeter, and that SSIs can result from as few as 100 microbes per gram of tissue.<sup>11,50</sup> Thus, adequate decontamination of the incision site is an imperative step of SSI prevention.

The most commonly used antiseptic solutions for skin preparation includes iodophor- and chlorhexidine gluconate-containing agents.<sup>51</sup> Iodine exhibits antiseptic properties by destroying microbial proteins and DNA. In contrast, chlorhexidine-containing products act by disrupting microbial cell membranes. Iodine- and chlorhexidine-containing agents can be further classified as water or alcohol based. Aqueous products typically require two-step applications with a scrub-and-paint technique and are limited by their relatively short-lasting properties—approximately two and six hours for aqueous iodophor- and chlorhexidine-containing agents, respectively.<sup>52,53</sup> On the other hand, alcohol-based antiseptics are applied in a one-step application. This is possible because the alcohol evaporates almost immediately after contact with skin, leaving behind a durable film with sustained antimicrobial activity.<sup>54</sup>

### DuraPrep™ Surgical Solution

DuraPrep™ is a skin disinfectant consisting of iodine povacrylex in isopropyl alcohol (0.7% available iodine, 74% iso-

propyl alcohol) that is applied in a one-step process. After a drying time of approximately three minutes, it leaves behind a water-insoluble film that maintains antimicrobial activity for up to 48 hours and is resistant to removal by saline or bodily fluids. It was formulated to protect the incision site from removal throughout the course of surgical procedures and to provide long-lasting antiseptics.<sup>55</sup> The following paragraphs will summarize the available evidence related to this product.

DuraPrep™ has demonstrated *in vitro* efficacy against a multitude of microorganisms including *Staphylococcus*, *Enterococcus*, gram-negative rods, and multi-drug resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and methicillin-resistant *Staphylococcus epidermidis* (MRSE).<sup>56</sup> Within one minute of contact, DuraPrep™ has been shown to result in a six-fold bacterial log reduction with a larger percentage release of free iodine relative to aqueous iodophors.

### Summary of available literature

Alcohol-based skin preparation solutions are known to provide more sustained and durable antimicrobial protection than their aqueous counterparts. DuraPrep™ has been shown to be more resistant to removal by saline than a commonly used alcohol-based chlorhexidine solution.<sup>57</sup> In a blinded randomized controlled trial, Stahl et al.<sup>57</sup> aimed to compare the antimicrobial persistence of DuraPrep™ to that of an alcohol-based chlorhexidine solution (ChloraPrep™, Becton, Dickinson and Company, Franklin Lakes, New Jersey) when exposed to saline. Each agent was applied to the volar surface of 36 subjects' forearms according to the manufacturer's instructions and allowed to dry. Next, the sites were exposed to either a saline rinse or a saline-saturated gauze to simulate the conditions that these preparations would face during surgical procedures. After doing so, two evaluations were performed: (1) each site was inoculated with 10<sup>8</sup> colony-forming units (CFU)/milliliter of tetracycline-resistant *Staphylococcus aureus*, allowed to reside for 30 minutes, then sampled for bacterial survival and (2) each saline-saturated gauze was chemically analyzed to evaluate for the presence of iodine or chlorhexidine. It was found that the log reductions of seeded

organisms were significantly higher in the DuraPrep™ group ( $3.67 \pm 0.86$ ) compared with the ChlorPrep™ group ( $3.20 \pm 0.65$ ) for the saline-soak condition ( $p=0.006$ ). In addition, chemical testing results revealed that DuraPrep™ was more resistant to removal by saline-soaked gauze than ChlorPrep™. Chlorhexidine from the ChlorPrep™ solution was removed from the application site in 35 of 36 subjects (97%), while the iodine from the DuraPrep™ film was removed in 0 of 36 subjects (0%;  $p<0.0001$ ). The results of this study demonstrated that when exposed to saline-soaked gauze, DuraPrep™ compares favorably to ChlorPrep™ in durability and antimicrobial activity against *S. aureus*.

Another feature of DuraPrep™ is that it acts as a primer to enhance the adhesion of incise drapes to the skin. Because incise drapes are one of the products in the bundled-care program, they will be discussed thoroughly later in this review. However, due to the unique synergistic properties between DuraPrep™ and incise drapes, they are worthy of brief mention in this section. Incise-drape lifting at the edge of an incision can expose the surgical wound to pathogens. In fact, Alexander et al.<sup>58</sup> performed a randomized controlled trial including 1,324 patients to compare the efficacy of various skin preparation protocols. They showed that separation of incise drapes from the skin during surgery was associated with a six-fold increase in SSIs when compared to operations in which the incise drape did not lift. Skin preparation with DuraPrep™ has been shown to facilitate better skin-to-drape adhesion than that with aqueous povidone-iodine solutions. In a randomized trial by Jacobson et al.,<sup>59</sup> the skin of 176 total joint arthroplasty patients was treated with DuraPrep™ or povidone iodine prior to application of the same incise drapes (3M™ Ioban™ 2 Antimicrobial Incise Drape). Postoperatively, it was reported that the mean drape lift was significantly lower in the DuraPrep™ group (1.5cm) compared to that in the povidone-iodine group (9.9cm;  $p<0.0001$ ).

Several studies have compared the efficacy of various skin preparation solutions. In a recent prospective randomized trial,<sup>60</sup> a total of 240 patients undergoing clean, soft-tissue hand surgery were randomized to one of three groups: (1) 10% povidone-iodine (Betadine™ solution;  $n=81$ ); 2% chlorhexi-

dine gluconate, and 70% isopropyl alcohol (ChlorPrep™;  $n=80$ ); or 0.7% available iodine and 74% isopropyl alcohol (DuraPrep™;  $n=79$ ). The surgical sites were prepared according to the manufacturers' instructions and allowed to dry completely. Bacterial cultures were taken from the surgical site before skin antiseptics and immediately after the solutions had dried completely. Cultures taken before skin antiseptics were positive in 35 of 81 (43.2%) Betadine™ patients, 32 of 80 (40.0%) ChlorPrep™ patients, and 24 of 79 (30.4%) DuraPrep™ patients ( $p=0.20$ ). After skin preparation, cultures were positive in one of 81 (1.2%) Betadine™ patients, 21 of 80 (26.3%) ChlorPrep™ patients, and three of 79 (3.8%) DuraPrep™ patients. Although there was no difference in culture rates between the Betadine™ and DuraPrep™ groups, ( $p=1.0$ ), DuraPrep™ was shown to be significantly superior to ChlorPrep™ in eradicating surgical-site bacteria ( $p<0.001$ ). The results of this study indicate that iodophor-based solutions perform better than their chlorhexidine-based counterparts in decontaminating incision sites prior to hand surgeries. While the aqueous and alcohol-based iodophor products performed similarly, the improved durability of alcohol-based solutions when exposed to saline and blood products that has been demonstrated in other studies gives reason to believe that DuraPrep™ is the optimal skin antiseptics prior to hand surgeries.

#### Instructions for use

Prior to application of DuraPrep™, it is important to carefully assess the skin to ensure that it is clean, dry, and intact. The prepped area should be large enough to accommodate extension of the incision, the need for additional incisions, and all potential drain sites. It should also be large enough to avoid wound contamination by inadvertent drape movement during the procedure. DuraPrep™ is available in two sizes; 8630 and 8635. The 8630 product contains 26ml of solution which covers a 15- by 30-inch area. For procedures with small preparation areas (8 by 10 inches or less), the 8635 product is ideal as it only contains 6ml of solution. To activate the 8630 product, the sponge end is held parallel to the floor and the back end of the handle is firmly pressed with the opposite hand (Fig. 3A). The applicator is then held in that position so that the solution flows uniformly into the sponge. When the

solution level reaches the indicator line on the applicator (Fig. 3B), skin preparation can begin. To activate the 8635 applicator, the sponge is held in a similar parallel position (Fig. 4A) prior to snapping the lever (Fig. 4B and C). In contrast to the larger model, all of the fluid should flow into the sponge before beginning skin preparation. This preparation should begin from the incision outward, and from "clean" to "dirty." Starting at the incision site, the sponge is applied to the skin with light and overlapping strokes moving outward toward the periphery. During application, it is important to remember to paint with uniform pressure and not to scrub. The site should be allowed to dry completely (i.e., at least three minutes on hairless skin and up to one hour on hair). Once the prepared area begins to look dull, it is dry and draping can commence. DuraPrep™ should not be used on patients with known allergies to iodine or any of its other ingredients.

#### ANTIMICROBIAL SURGICAL INCISE DRAPES

As previously stated, SSI-causing pathogens are typically derived from the patient's own skin.<sup>11,48,49</sup> While preoperative skin antiseptics reduces the number of bacteria on the skin's surface, pathogens from the deeper skin layers can recolonize the wound edge during surgery.<sup>61</sup> Thus, following skin preparation, many lower extremity joint arthroplasty surgeons apply a surgical incise drape to the surgical site.

Surgical incise draping involves the application of an adhesive film to the skin around the incision site that immobilizes bacteria beneath it and provides a sterile surface prior to incision. Furthermore, some incise drapes contain iodophor-impregnated adhesives to provide both antimicrobial and physical barriers to skin recolonization. Because several studies have demonstrated that iodophor-impregnated incised drapes reduce bacterial colonization around the incision site, most SSI-prevention guidelines recommend their use. The available data from these studies will be described in the upcoming paragraphs.

#### Summary of available literature

The use of iodophor-impregnated adhesive draping has been shown to significantly reduce bacterial colonization of surgical incision sites. Rezapoor et al.<sup>62</sup>



conducted a prospective randomized trial to evaluate their efficacy in reducing bacterial counts at the incision site during hip surgery. A total of 101 patients undergoing open joint preservation procedures of the hip were enrolled. Among these, 50 patients had an iodophor-impregnated drape (3M™ Ioban™ 2 Antimicrobial Incise Drape) applied to the skin prior to the incision and the remaining 51 patients underwent the procedures without a drape. Culture swabs were taken from the incision site of each patient at five timepoints: (1) prior to skin preparation; (2) after skin preparation; (3) after incision; (4) before sub-cutaneous closure; and (5) prior to applying the wound dressing. After surgery, six of the 50 (12%) incisions with Ioban™ 2 Antimicrobial Incise Drape and 14 of the 51 (27.5%) incisions without adhesive drapes were positive for bacteria ( $p < 0.05$ ). In addition, patients who had positive swabs prior to preparation demonstrated increased post-surgical colonization (odds ratio 2.89,  $p = 0.017$ ), indicating that the source of bacteria at the incision sites was most likely from patients' own skin. The authors concluded that iodophor-impregnated adhesive drapes significantly reduce bacterial colonization of incisions and that failing to use them could lead to subsequent SSIs or PJIs.

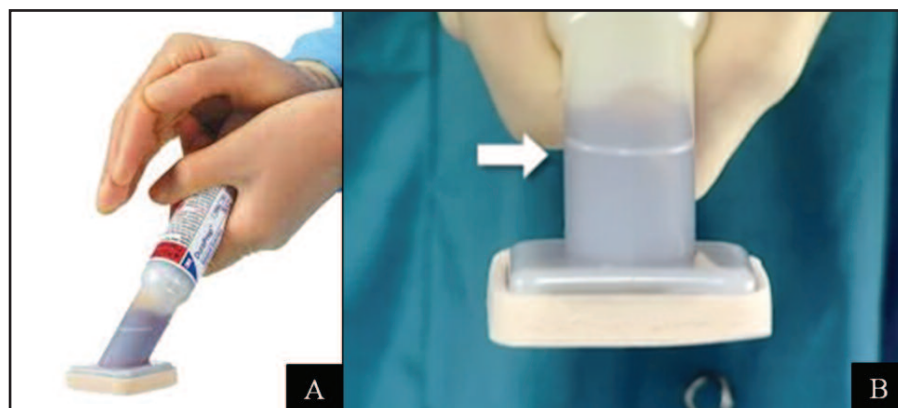
The antimicrobial effect of iodophor-impregnated incise drapes alone has also been demonstrated. In a prospective study of 122 patients undergoing surgery for hip fractures, Fairclough et al.<sup>63</sup> compared bacterial cultures before and after iodophor-impregnated plastic adhesive drapes (3M™ Ioban™ 2 Antimicrobial Incise Drape, 3M) were applied to the operation site 24 hours prior to surgery. It was reported that wound contamination decreased from 15 to 1.6% when the Ioban™ 2 Antimicrobial Incise Drape was applied to the operative site 24 hours prior to surgery ( $p < 0.05$ ). The results of this study demonstrated that iodophor-impregnated incise drapes protect surgical wound contamination by skin organisms and can also be a valuable tool for SSI and PJI prevention.

Hesseltig et al.<sup>64</sup> performed a randomized controlled trial to determine if antimicrobial incise drapes prevent intraoperative wound contamination for patients undergoing primary total knee arthroplasty (TKA). A total of 1,187 TKA patients were enrolled and randomly assigned to intervention ( $n = 603$ )

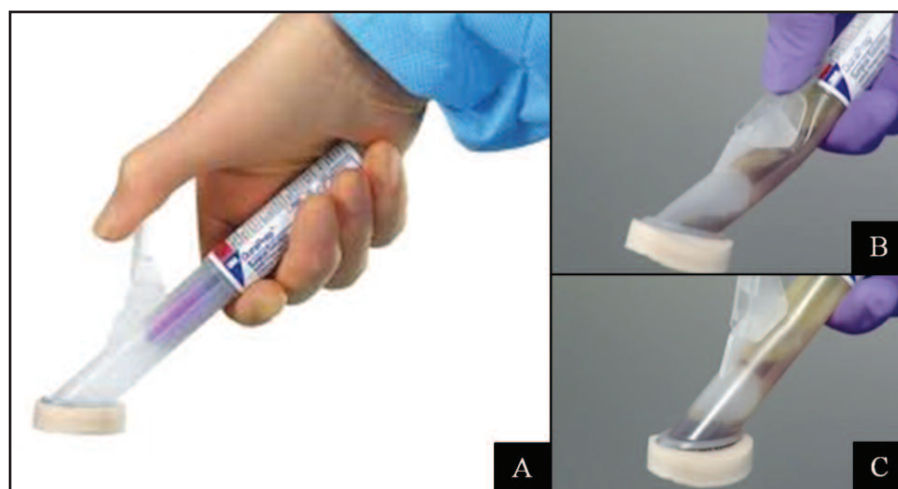
or control ( $n = 584$ ) groups. Patients in the intervention group had an iodophor-impregnated Ioban™ 2 Antimicrobial Incise Drape placed at the surgical site prior to incision, while those in the control group did not. Intraoperatively, culture swabs were taken from each surgical site and all samples that had at least one colony-forming unit were deemed contaminated. Contamination was detected in 60 of 603 (10%) procedures in which iodinated drapes were used compared to 90 of 584 (15%) in which they were not (OR 0.61 [95% confidence interval [CI] 0.43 to 0.87];  $p = 0.005$ ). It was shown that patients who had more than 10mm of separation of the drape from the skin were at increased risk of wound contamination (OR 0.6 [95% CI 0.43 to 0.86];  $p = 0.005$ ). The authors concluded that the use of antimicrobial drapes resulted in a decreased risk of wound contamination, proving usefulness as an infection-mitigation strategy for patients undergoing TKA.

### Comparison of iodophor-impregnated incise drapes to clear plastic alternatives

The 3M™ Ioban™ 2 Antimicrobial Incise Drape is perhaps the most well-known and widely used adhesive surgical incise draping in orthopaedics. Other options such as plastic (i.e., polyethylene, polyurethane, or polyvinyl) adhesive drapes (e.g., OPSITE, Smith & Nephew plc, Hull United Kingdom) and non-impregnated steri-drapes also exist. In a prospective study of 5,100 consecutive cardiac surgery cases, overall incidence of SSIs was significantly higher in the group receiving a standard non-iodine-impregnated steri-drape (6.5 vs. 1.9%,  $p = 0.001$ ), and the Ioban™ 2 Antimicrobial Incise Drape offered a cost savings benefit of 773,495 euros (€) relative to standard steri-drape.<sup>65</sup> In an *ex vivo* study of the Ioban™ 2 Antimicrobial Incise Drape versus a non-antimicrobial incise drape (Steri-Drape, 3M Company, St. Paul, Minnesota), the Ioban™ 2 Antimicrobial Incise Drape demonstrated



**Figure 3.** Activation of the 26mm DuraPrep™ product. (A) The sponge end is held parallel to the floor and the back end of the handle is firmly pressed with the opposite hand. (B) When the solution level reaches the indicator line on the applicator, skin preparation can begin.



**Figure 4.** Activation of the 6mm DuraPrep™ product. (A) the sponge is held parallel to the floor prior to (B) snapping the lever. (C) All of the fluid should flow into the sponge before beginning skin preparation.

antimicrobial activity relative to no draping with increased inoculation of donor skin and activity against a high inoculum of MRSA ( $p < 0.001$ ) attained to 1,500 microns below the skin surface.<sup>66</sup> Given its rapid onset, antimicrobial activity, straightforward application, and lack of adverse effects, we use and recommend 3M™ Ioban™ 2 Antimicrobial Incise Drape for surgical incise drapes during orthopaedic cases.

### Instructions for use

After disinfecting the incision site and allowing the surgical skin preparation agent to dry completely, the incise drape should be applied as follows. Using an aseptic technique, peel open the package to remove the drape from its pouch (Fig. 5A) and discard the paper overwrap. Holding the drape with the printed side of the handle facing upward, separate the printed handle from the white handle (Fig. 5B). While holding the printed side of the handle upward, an assistant standing on the opposite side of the patient pulls the white-edged liner evenly away (Fig. 5C). Position the drape over the intended incision site and adhere it to the patient. Using a sterile towel or gloved hand, press down firmly on the film, first contacting the skin along the intended incision line to ensure good adherence to the skin while working away from the incision site to achieve wrinkle-free

adhesion (Fig. 5D). When applying the drape to a knee, it is recommended to do so at 30° of flexion. After applying the drape, remove the liner and printed handle from the Ioban™ 2 Antimicrobial Incise Drape film.

## INCISION MANAGEMENT

### Negative-pressure wound therapy

Persistent wound drainage after hip or knee arthroplasty is known to increase the risk of PJIs.<sup>67-70</sup> Closed incisional negative pressure wound therapy (ciNPWT) applies sub-atmospheric pressure to a wound site to help reduce the amount of drainage around the incision. In addition, it has been shown to aid in wound healing by reapproximating the wound edges, increasing tissue perfusion, reducing local edema, and stimulating the formation of granulation tissue. Originally designed for the treatment of open wounds, the success of ciNPWT has led orthopaedic surgeons to use them over closed incisions (initially off-label) in patients who were at a high risk for postoperative wound complications.

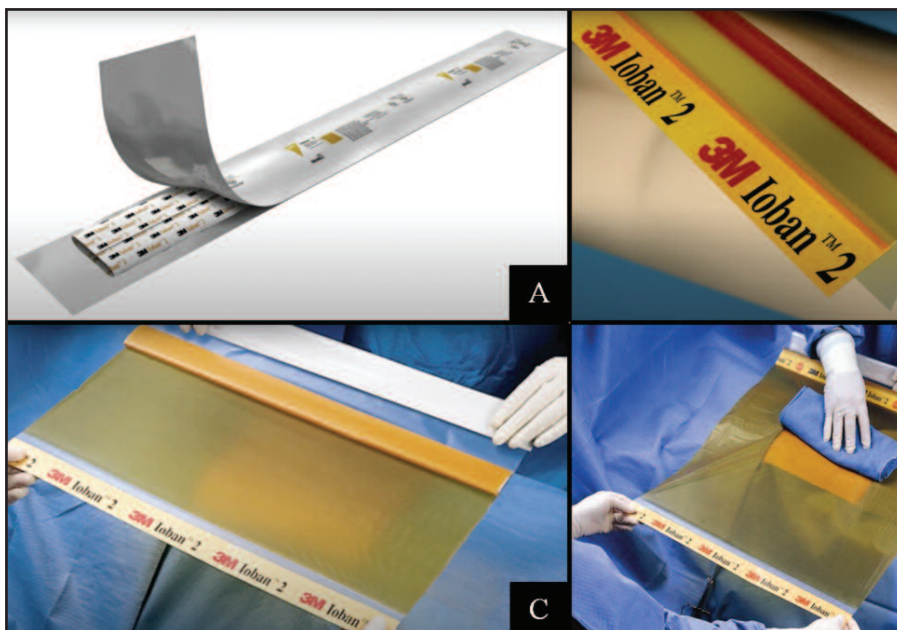
The Prevena™ Incision Management System is one of the most clinically validated ciNPWT systems with over 80 peer-reviewed publications of studies evaluating its use. In addition, it is the first and only medical device approved by the United States Food and Drug Administration (FDA) to reduce SSIs in

high-risk patients who have Class I and II wounds. Like most ciNPWT devices, the Prevena™ system consists of five basic components: foam, tubes, adhesive drapes, pump, and canister. It involves application of a reticulated open cell foam dressing, surrounded by adhesive drapes containing the foam to ensure an airtight seal. The foam collapses to its geometric center, allowing for even distribution of negative pressure. Several studies have evaluated the use of ciNPWT for hip and knee arthroplasty patients. In the following section, we will summarize some of the literature pertaining to its use.

### Summary of available literature

The use of ciNPWT after revision total hip and knee arthroplasty has demonstrated efficacy for patients who are at high risk for infection. In a prospective, randomized clinical trial by Newman et al.,<sup>12</sup> 160 patients were allocated to incision management with ciNPWT (Prevena™) or a silver-impregnated occlusive dressing (Aquacel®; ConvaTec, Greensboro, North Carolina). The outcomes of interest were wound complications, readmissions, or reoperations within 12 weeks of surgery. It was found that patients in the Prevena™ group had a lower incidence of postoperative wound complications ( $n=19$ ; 23.8 vs.  $n=8$ ; 10.1%;  $p=0.022$ ) and reoperation rates ( $n=2$ ; 2.5 vs.  $n=10$  12.5%;  $p=0.017$ ) compared to patients who received the silver-impregnated occlusive. The authors concluded that ciNPWT decreases the rate of postoperative wound complications in high-risk revision arthroplasty patients.

The effectiveness of ciNPWT in mitigating surgical-site complications following revision TKA in high-risk patients has been shown. Higuera-Rueda et al.<sup>13</sup> performed a 15-center randomized controlled trial comparing the Prevena™ incision management system to a silver-impregnated occlusive dressing. High-risk patients were defined as those who had at least one of the following risk factors: (1) body mass index  $>35\text{kg}/\text{m}^2$ ; (2) postoperative use of blood thinners other than aspirin; (3) peripheral vascular disease; (4) current tobacco use; (5) history of prior infection at operative site; (6) operative limb lymphedema; (7) insulin-dependent diabetes; (8) current use of immune-modulators or corticosteroids; (9) ongoing malignancy; (10) rheumatoid arthritis; (11) renal failure or



**Figure 5.** 3M™ Ioban™ 2 Antimicrobial Incise Drape. After (A) peeling open the package and removing the drape from its pouch, remove the paper overwrap and (B) separate the printed handle from the white handle. Next, (C) pull the handles away from each other evenly and place over the surgical site, then (D) press down firmly on the film using a sterile towel or gloved hand to achieve a wrinkle-free application.

dialysis; (12) malnutrition supported by laboratory values of albumin <3.5g/dL, a total lymphocyte count <1,500 cells/mm<sup>3</sup>, and/or a transferrin level <200mg/dL; (13) liver disease; (14) solid organ transplant recipients; or (15) human immunodeficiency virus infection. Eligible patients undergoing full exchange and reimplantation of new prosthetic components or open reduction and internal fixation of periprosthetic fractures were randomized (n=147, each) to receive a ciNPT system (Prevena™ Plus Customizable) or a silver-impregnated (Aquacel® Ag) for a minimum of five-day duration. Outcomes of interest included surgical-site complications including superficial SSIs, PJs, as well as cases of skin dehiscence, seroma or hematoma requiring drainage, skin necrosis, or continuous drainage. Readmission rates and numbers of dressing changes were also recorded. At 90-day follow up, the rate of surgical-site complications was lower for the ciNPWT cohort (3.4%) compared to the silver-impregnated dressing group (14.3%; OR: 0.22, 95% CI [0.08, 0.59]; p=0.0013). In addition, readmission rates (3.4 vs. 10.2%, OR: 0.30; 95% CI [0.11, 0.86]; p=0.0208) and mean dressing changes (1.1 ± 0.3 vs. 1.3 ± 1.0; p=0.0003) were lower in the ciNPWT group. The authors concluded that the Prevena™ incision management system is effective in reducing the rates of postoperative surgical-site complications, readmissions, and number of dressing changes after revision TKA.

A systematic review including 44 randomized controlled trials with 5,693 surgical patients—of which included 13 trials and 1,493 were orthopaedic—found that patients treated with NPWT experienced a nearly 40% risk reduction relative to those treated with conventional dressings (pooled risk ratio 0.61, 95% CI: 0.49 to 0.74).<sup>71</sup>

In a study of 323 consecutive primary TJAs,<sup>72</sup> high-risk patients treated prophylactically with Prevena™ experienced significant improvement in superficial skin complications (SSCs) relative to those who received Aquacel® (7.3 vs. 26.2%, p<0.001), while low-risk patients demonstrated no significant improvement (8.6 vs. 6.5%, p=0.344). In a single-center, prospective study of 596 patients undergoing primary total knee or hip arthroplasty, patients receiving ciNPT experienced significantly decreased rates of infection (1.0 vs.

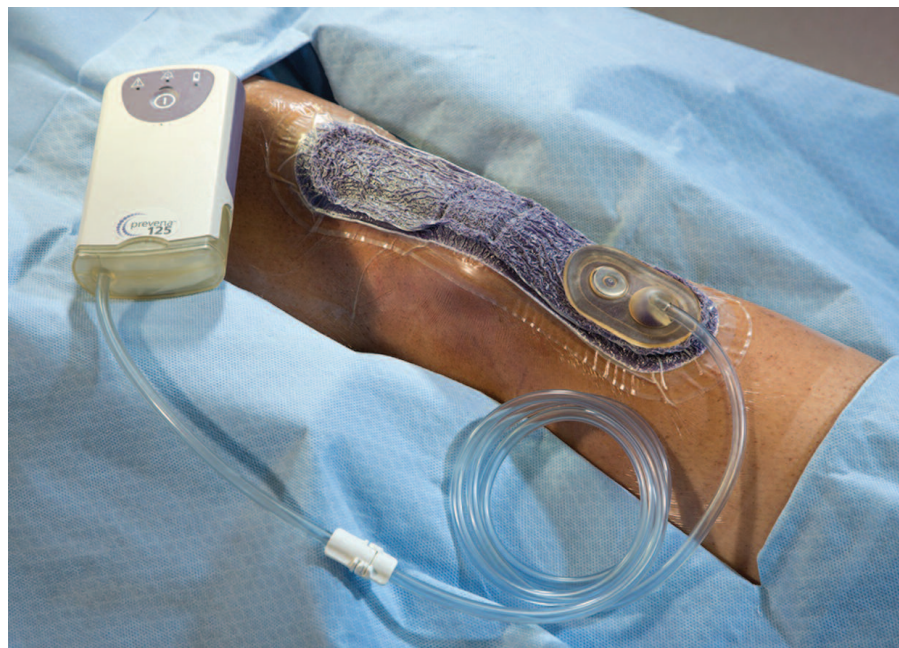


Figure 6. Prevena™ Incision Management System.

3.5%, p=0.040 and decreased overall complication rates (1.5 vs. 5.5%, p=0.02).<sup>73</sup> Apart from SSI prophylaxis, there appears to be utility in using ciNPT in both primary and revision total joint arthroplasty patients for preventing seroma formation and stopping wound drainage.<sup>74</sup>

Apart from Prevena™, the most common NPWT system is the PICO™ (Smith & Nephew plc, Hull, United Kingdom). While there is a growing amount of literature examining NPWT versus conventional non-pressure dressings such as gauze or Aquacel®, few studies exist which directly compare different types of NPWT with each other. In an *in vivo* study of porcine full-thickness excisions and incisions comparing these three NPWTs with a novel platform wound dressing, there were no significant differences between NPWTs in rate of wound healing and local inflammatory reaction (measured by histo-pathologic and immuno-histochemical examination).<sup>75</sup> Overall, we use and recommend Prevena™ for primary hip and knee arthroplasty patients who have SSI risk factors and for complex revision hip/knee arthroplasty patients (Fig. 6).

## CONCLUSION

Based on the rationale and evidence summarized in this review, Northwell Health and Maimonides Medical Center launched a bundled care program with

the five surgical products outlined above. The goals of this bundled versus standard-of-care initiative involves utilization of the aforementioned products routinely for lower extremity arthroplasty cases to reduce SSI incidence in a safe and cost-effective manner. Current literature has characterized a host of preoperative, intraoperative, and postoperative risk factors for SSIs; however, the specifics for prophylactically reducing these risks are less clear. In particular, the primary objective of our bundled care program study is aimed toward determining whether the combination of these products is effective in further reducing SSI incidence over individual usage and relative to the standard of care. **STI**

## AUTHORS' DISCLOSURES

Dr. Mont is a board or committee member for The Knee Society and The Hip Society, receives research support from National Institutes of Health, and is on the editorial board for the Journal of Arthroplasty, Journal of Knee Surgery, Surgical Technology International, and Orthopaedics. Dr. Mont also receives company support from 3M, Centrexion, Ceras Health, Flexion Therapeutics, Johnson & Johnson, Kolon TissueGene, NXSCI, Pacira, Pfizer-Lily, Skye Biologics, SOLVD Health, Smith & Nephew, CERAS Health, MirrorAR, PeerWell, US Medical Innovations, Johnson & Johnson, RegenLab, Stryker, TissueGene, Medicus Works LLC, Up-to-Date,

Wolters Kluwer Health – Lippincott Williams & Wilkins, Journal of Arthroplasty, Journal of Knee Surgery, Orthopedics, Surgical Technology International, AAHKS, Knee Society, and Hip Society.

Dr. Scuderi receives royalties and/or is a consultant for Zimmer Biomet, 3M KCI, Elsevier, Springer, Thieme, and World Scientific. He has stock options in Force Therapeutics and ROM Tech. Dr. Scuderi is also on the editorial board for the Journal of Knee Surgery and is a board member for Operation Walk USA.

All other authors have no conflicts of interest to disclose.

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Tel. +1 415 704 3160

Email: [info@surgicaltechnology.com](mailto:info@surgicaltechnology.com), Internet: [www.surgicaltechnology.com](http://www.surgicaltechnology.com)  
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