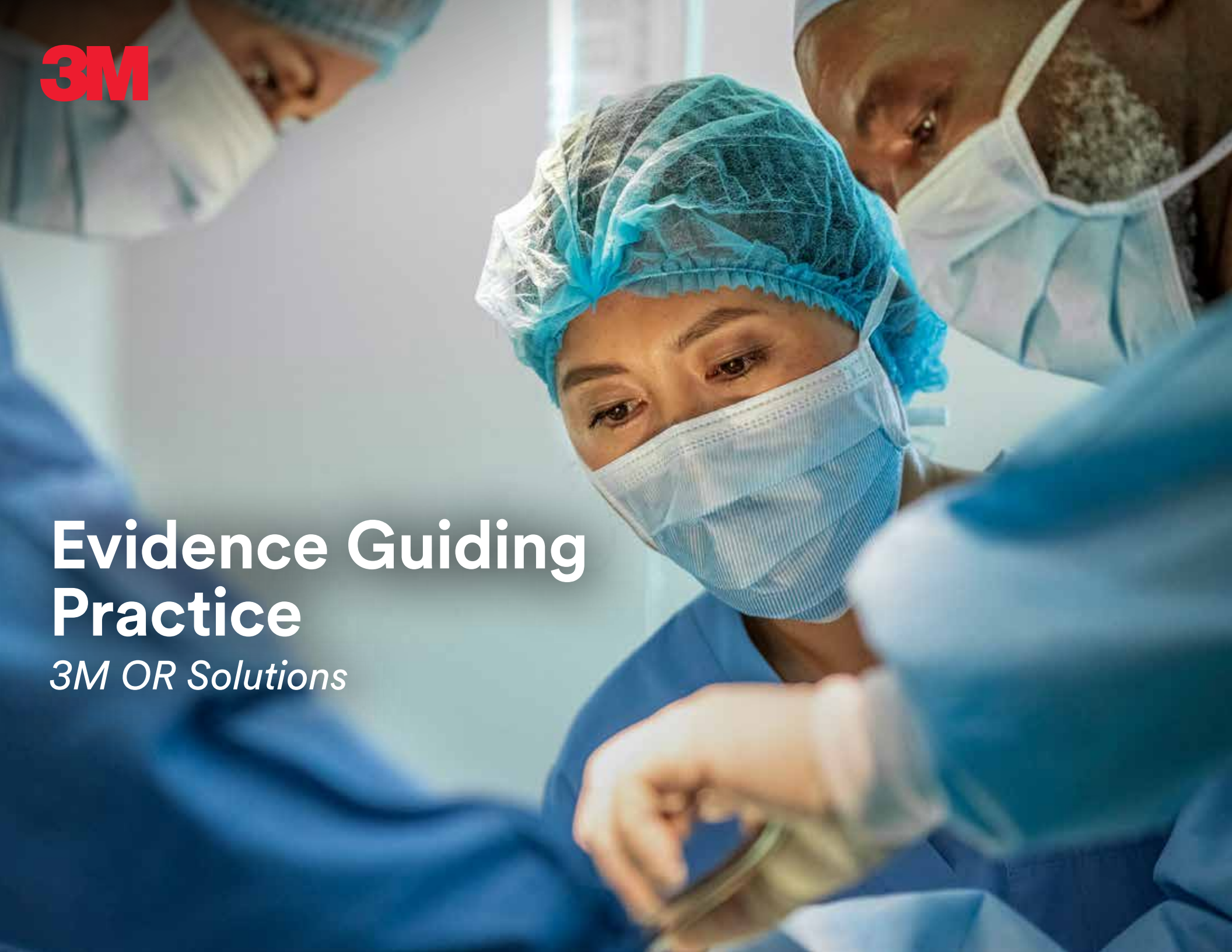

Evidence Guiding Practice

3M OR Solutions

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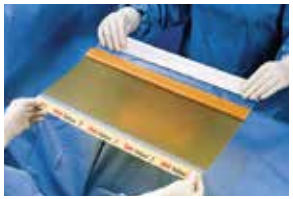
3M OR SOLUTIONS		FIRST AUTHOR (YEAR)	RECOMMENDED GUIDANCE
Bair Hugger™ Temperature Management Solutions		Balki (2020) >	MAINTAINING NORMOTHERMIA >
		Zheng (2020) >	
		Morettini (2020) >	
		Schell-Chaple (2018) >	
Ioban™ Antimicrobial Incise Drape		Rezapoor (2018) >	INCISE DRAPES >
		Hesselvig (2020) >	
		Bejko (2015) >	
Prevena™ Therapy		Higuera-Rueda (2021) >	CLOSED INCISION MANAGEMENT >
		Antoniou (2019) >	
		Kwon (2018) >	
		Newman (2019) >	
Veraflo™ Therapy		Gabriel (2021) >	WOUND MANAGEMENT >

Recommended guidance for maintaining normothermia

ORGANIZATION	KEY GUIDANCE/RECOMMENDATIONS		
	TEMPERATURE MONITORING	**PREWARMING**	**INTRAOPERATIVE**
NICE (2016, 2013)[1,2]	• Should be direct measurement of core temperature (may be zero-heat-flux), measured and documented before surgery and every 30 minutes to end of surgery • Do not use indirect estimates of core temperature in adults having surgery[2]	• Pre-warm a minimum of 30 minutes • Pre-warm for any procedure if patient is at high risk for inadvertent intraoperative hypothermia	• Maintain active warming throughout intraoperative phase • Active warming for procedures greater than 30 minutes
ASPAN (2022)[3]	• Frequent intraoperative monitoring of core temperature in all cases • Use same method of measurement through perianesthesia	• Actively warm patients who are hypothermic • Prewarm to reduce the risk of intra/postop hypothermia • Prewarm minimum of 30 minutes	• Forced-air warming initiated in the preoperative/preprocedure and continuing throughout the surgery/ procedure to the postanesthesia care unit (PACU) is the best method for maintaining normothermia
ERAS (2020)[4]	• Reliable core temperature monitoring is recommended for all patients undergoing major surgery or surgery expected to be in excess of 30 minutes, to ensure the patient's body temperature is maintained above 36°C	• Preoperative methods to actively warm patients, such as forced air, to prevent hypothermia, should be instituted	• Intraoperative methods to actively warm patients, such as forced air, to prevent hypothermia, should be instituted
AORN (2022)[5]	• Measure and monitor the patient's temperature during all phases of care • Use the same site and method of temperature measurement throughout the perioperative phases when clinically feasible	• When active warming is indicated, prewarm the patient with the selected method • Moderate-quality evidence supports prewarming the patient for a minimum of 10 minutes • When hypothermia is identified before surgery, initiate interventions to normalize the patient's core body temperature before the patient's transfer to the operating room (OR), if possible	• When indicated, warm the patient with one or more of the following active warming methods during all phases of preoperative care, forced air warming (FAW) blanket gown. FAW systems may be used • Several clinical practice guidelines recommend use of FAW for procedures longer than 30 minutes
ORNAC (2021)[6]	• The same method of temperature monitoring should be used throughout the surgical journey • Core body temperature monitoring is considered the most accurate • Patient temperature should be taken within 1 hour preoperatively and documented	• Prewarming for procedures 30 min or longer using FAW. 30–60 min of prewarming is effective in reducing hypothermia • Warmed cotton blankets are not as effective as FAW. Patient-controlled FAW gowns reduce surgical risks.	• Active warming should be used for all procedures 30 minutes or more using FAW

REFERENCES: 1. National Institute of Health and Care Excellence (NICE). Surgical site infection. (QS49). Published October 31, 2013. Accessed May 3, 2022. **2.** National Institute of Health and Care Excellence (NICE). Hypothermia: prevention and management in adults having surgery. (CG65) Published December 14, 2016. Accessed May 3, 2022.. **3.** ASPAN's 2021-2022 Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements. **4.** Cowperthwaite L. AORN Guidelines for Perioperative Practice 2022. Denver, CO: Association for periOperative Registered Nurses, 2022. **5.** Cowperthwaite L. AORN Guidelines for Perioperative Practice 2022. Denver, CO: Association for periOperative Registered Nurses, 2022. **6.** Operating Room Nurses Association of Canada (ORNAC). The ORNAC Standards, Guidelines, and Position Statements for Perioperative Registered Nurse, 14th edition, 2019.

Level of evidence 1

Effect of perioperative active body surface warming systems on analgesic and clinical outcomes: A systematic review and meta-analysis of randomized controlled trials

Balki I, Khan JS, Staibano P, *et al.* Effect of Perioperative Active Body Surface Warming Systems on Analgesic and Clinical Outcomes: A Systematic Review and Meta-analysis of Randomized Controlled Trials. *Anesth Analg.* 2020;131(5):1430-1443. doi:10.1213/ANE.0000000000005145.

STUDY DESIGN

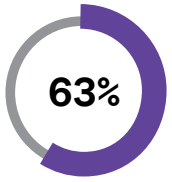
A systematic review was conducted using Ovid MEDLINE daily, Ovid MEDLINE, EMBASE, CINHAL, Cochrane CENTRAL, and Web of Science from inception to June 2019. Randomized controlled trials evaluating active body surface warming (ABSW) systems compared to nonactive warming controls in noncardiac surgeries were chosen. 54 articles (3976 patients) were included.

STUDY PURPOSE

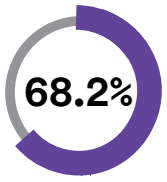
The purpose of this study was to provide a systematic review of the effects of ABSWs on perioperative outcomes in noncardiac surgeries. A detailed cost analysis was also completed.

RESULTS

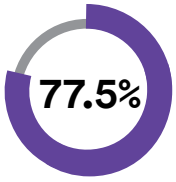
REDUCED COMPLICATIONS



reduction in postoperative wound infections (OR = 0.34; 95% CI, 0.16–0.7)*



reduction in postoperative shivering: (OR = 0.2; 95% CI, 0.11–0.36)*



reduction in 24 hour major cardiac events (OR = 0.21; 95% CI, 0.05–0.98)*

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study

SURGICAL BODY TEMPERATURE

- 58% Bair Hugger studies constributed to evidence generation in this meta-analysis
- **0.38°C** higher mean Body Core Temperature 60 min after induction with active body surface warming devices (95% CI, 0.27–0.49)
- **1.07°C** higher mean Body Core Temperature at the end of surgery with active body surface warming devices (95% CI, 0.86–1.28)

KEY POINTS

SUMMARY

ABSW is effective in maintaining physiological normothermia; decreasing wound infections, shivering, and blood transfusions; and increasing patient satisfaction, but does not appear to affect postoperative pain and opioid use.

METHODS

Outcomes studied included postoperative pain scores and opioid consumption (primary outcomes) and other perioperative clinical variables, such as temperature changes, blood loss, and wound infection (secondary outcomes). Subgroup analysis sought to determine the effect of preoperative and intraoperative warming versus intraoperative warming alone. Meta-regression evaluated the effect of year of publication, use of neuromuscular blockers, anesthesia, and surgery type on outcomes.

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Level of evidence 1

Effects of preoperative warming on the occurrence of surgical site infection: A systematic review and meta-analysis

Zheng XQ, Huang JF, Lin JL, Chen D, Wu AM. Effects of preoperative warming on the occurrence of surgical site infection: A systematic review and meta-analysis. *Int J Surg*. 2020;77:40-47. doi:10.1016/j.ijsu.2020.03.016.

STUDY DESIGN

A systematic review was conducted using Medline, EMBASE, and the Cochrane Library to identify randomized controlled trials (RCTs) that evaluated the risk of surgical site infection (SSI) after surgery with and without the use of a preoperative warming protocol. Of the 249 studies identified, seven RCTs representing 1086 patients were included in the present meta-analysis.

STUDY PURPOSE

To determine whether preoperative warming can reduce the risk of SSI after surgery.

RESULTS

REDUCED COMPLICATIONS

reduction in SSI. The use of preoperative warming was associated with a significant decrease (OR = 0.60; 95% CI, 0.42–0.87; *P* = 0.072)*

- 71% Bair Hugger studies contributed to evidence generation in this meta-analysis*
- Patients who used MIX methods (temperature set <43°C and 30-min prewarming) before surgery benefited more from prewarming

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study

METHODS

The primary outcome measure was the diagnosis of SSI within 10–90 days of surgery. The pooled risk ratio was estimated with a fixed-effect meta-analysis. Sensitivity analyses were performed to examine the impact of the structural design of preoperative warming on the pooled risk of SSI.

We defined patients who used forced-air warming (FAW) and integrated measures such as liquid heating and warming blankets as the MIX group and patients who used only FAW as the FAW group.

KEY POINTS

SUMMARY

The results of this study suggest that preoperative warming can reduce rates of SSI after surgery.

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Intraoperative core temperature monitoring: Accuracy and precision of zero-heat flux heated controlled servo sensor compared with esophageal temperature during major surgery; the ESOSPOT study

Morettini E, Turchini F, Tofani L, Villa G, Ricci Z, Romagnoli S. Intraoperative core temperature monitoring: accuracy and precision of zero-heat flux heated controlled servo sensor compared with esophageal temperature during major surgery; the ESOSPOT study. *J Clin Monit Comput.* 2020;34(5):1111-1119. doi:10.1007/s10877-019-00410-z.

STUDY DESIGN

This prospective clinical study was conducted at the Careggi University Hospital (Florence, Italy) from March to August 2018. 99 adults (over 18 years of age) undergoing major general and urological surgery (greater than 30 min) with general anesethetic were included. In all the enrolled patients, a zero-heat flux (ZHF) sensor was placed on the forehead.

STUDY PURPOSE

To compare core temperature accuracy and precision of the ZHF sensor to the esophageal probe (ESO) during abdominal and urologic elective major surgery.

METHODS

A ZHF sensor was placed on the patient's forehead. After induction of general anesthesia, an esophageal probe (GE Healthcare Finland Oy) was inserted through a nostril, under laryngoscopic vision, for approximately 45 cm.

RESULTS

TEMPERATURE BIAS

- **0.005°C bias between TZHF and TESO,** with a 95% confidence interval of −0.49°C to 0.50°C*
- The percentage of measurements within 0.5°C of the reference value was 97.98% (95% CI, 92.89–99.75%)*

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study

KEY POINTS

SUMMARY

Data analysis has shown that ZHF could reliably replace the esophageal probe for core temperature measurement in patients undergoing elective abdominal and urologic major surgery.

CLICK HERE TO VIEW FULL CLINICAL STUDY

Rectal and bladder temperatures vs. forehead core temperatures measured with SpotOn™ Temperature Monitoring System*

Schell-Chaple HM, Liu KD, Matthay MA, Puntillo KA. Rectal and Bladder Temperatures vs. Forehead Core Temperatures Measured With SpotOn Monitoring System. *Am J Crit Care.* 2018;27(1):43-50. doi:10.4037/ajcc2018865.

STUDY DESIGN

Prospective comparison of zero-heat-flux (ZHF) versusrectal and urinary bladder thermometry in eligible patients enrolled in a randomized clinical trial on the effect of acetaminophen on core body temperature and hemodynamic status.

STUDY PURPOSE

To evaluate agreement between and precision of a ZHF thermometry system and continuous rectal and urinary bladder thermometry during fever and defervescence in adult patients in intensive care units.

METHODS

A total of 748 paired temperature measurements from 38 patients who had both ZHF monitoring and either continuous rectal (n=29) or continuous bladder (n=9) thermometry were analyzed.

RESULTS

TEMPERATURE MEAN DIFFERENCE

- Temperatures during the study were from 36.6°C to 39.9°C

  -0.07°C mean difference for ZHF compared with bladder thermometry (SD, 0.24°C; 95% limits of agreement, ±0.47°C [-0.54°C, 0.40°C])

  0.24°C mean difference for ZHF compared with rectal thermometry (SD, 0.29°C; 95% limits of agreement, ±0.57°C [-0.81°C, 0.33°C])

- Most differences in temperature between methods were within ±0.5°C in both groups (96% bladder and 85% rectal)

KEY POINTS

SUMMARY

The ZHF thermometry system has excellent agreement and good precision and is a potential alternative for noninvasive continuous monitoring of core temperature in critical care patients, especially when alternative methods are contraindicated or not available.

*The Bair Hugger™ Temperature Monitoring System and SpotOn™ Temperature Monitoring System are both comparable 3M™ temperature monitoring systems.

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Recommended guidance for incise drapes

ORGANIZATION	KEY GUIDANCE/RECOMMENDATIONS
KRINKO (2018)[1]	• Increase of SSI due to the non-antiseptically impregnated incision drape is reversed with using an antimicrobial incise drape
APSIC (2019)[2]	• When using adhesive drapes, do not use non-iodophor-impregnated incise drapes routinely for surgery, as they may increase the risk of surgical site infection • In orthopaedic and cardiac surgical procedures where adhesive drapes are using, consider using an iodophor-impregnated drape, unless the patient has an iodine allergy or other contraindication
NICE (2019)[3]	• Do not use non-iodophor-impregnated incise drapes routinely for surgery, as they may increase the risk of surgical site infection • If an incise drape is required, use an iodophor-impregnated drape unless the patient has an iodine allergy
AORN (2022)[4]	• Do not use adhesive incise drapes without antimicrobial properties. Iodophor-impregnated adhesive incise drapes may be used in accordance with the manufacturer's IFU, unless contraindicated by a patient's allergy to iodine

ORGANIZATION	CONSENSUS STATEMENT FOR INCISE DRAPES
ICM (2018)[5]	• Evidence indicates antimicrobial-impregnated incise drapes result in reduction in bacterial colonization of the surgical site. "While bacterial colonization of the incision may predispose to subsequent SSIs/PJIs, there is no literature to demonstrate that the use of incise drapes results in clinical differences in the rates of subsequent PJIs. Many surgeons prefer to utilize draping for physical isolation of sterile from nonsterile regions and to prevent migration of drapes during the procedure."

REFERENCES: 1. KRINKO Surgical Site Infection Prevention Guidelines, 2018. **2.** Asia Pacific Society of Infection Control Guidelines for the Prevention of Surgical Site Infections, 2019. **3.** 3. National Institute of Health and Care Excellence (NICE). Surgical site infections: prevention and treatment. (NG125) Published April 11, 2019. Accessed May 3, 2022. **4.** Cowperthwaite L. AORN Guidelines for Perioperative Practice 2022. Denver, CO: Association for periOperative Registered Nurses, 2022. **5.** Atkins GJ, Alberdi MT, Beswick A, *et al. J Arthroplasty.* 2019;34(2S):S85-S92. doi:10.1016/j.arth.2018.09.057.

Incise draping reduces the rate of contamination of the surgical site during hip surgery: A prospective, randomized trial

Rezapoor M, Tan TL, Maltenfort MG, Parvizi J. Incise Draping Reduces the Rate of Contamination of the Surgical Site During Hip Surgery: A Prospective, Randomized Trial. *J Arthroplasty.* 2018;33(6):1891-1895. doi:10.1016/j.arth.2018.01.013.

STUDY DESIGN

Prospective, randomized clinical trial, studying 101 patients undergoing open joint preservation procedure of the hip.

STUDY PURPOSE

To evaluate the efficacy of iodophor-impregnated adhesive drapes for reducing bacterial count at the incision site.

RESULTS

BACTERIAL CONTAMINATION

reduction of risk of bacterial colonization of incision site. 12% of incisions with iodophor-impregnated adhesive drape and 27% without adhesive drapes were positive for bacterial colonization at closure of surgery (OR = 2.38; 95% CI, 1.05–5.26; p = .031)*

- Patients without an iodophor-impregnated drape were more likely to demonstrate a positive culture (adjusted OR 2.38; 95% CI, 1.053–5.263; p = .031)*
- Patients without adhesive drapes were significantly more likely to have bacterial present at the time of skin closure, and at all time points when swab cultures were taken
- Patients with no drape have increased odds (adjusted OR 5.89; 95% CI, 1.19–33.33; p = .030) of bacterial contamination compared to those with drapes that demonstrated no lift off, whereas odds (adjusted OR 2.94; 95% CI, 0.24–33.33; p = 0.397) seem to be reduced for patients with drape lift*

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study

METHODS

Patients without adhesive drapes were significantly more likely to have bacteria present at the time of skin closure, and at all time points when swab cultures were taken

- Half the patients had the adhesive drape applied to the skin prior to incision, while the remainder underwent the same surgery without a drape
- Culture swabs were taken from the surgical site at 5 points (pre-skin preparation, after skin preparation, post-incision, before subcutaneous closure, prior to dressing application) and sent for culture and colony counts
- Mixed-effects logistic regressions were used to estimate effects of time and drape application on contamination rate

KEY POINTS

SUMMARY

- Iodophor-impregnated adhesive draping significantly reduces bacterial colonization of the incision, specifically hip surgery
- Bacterial count at the skin was extremely high in some patients in whom adhesive drapes were not used, raising the possibility that a subsequent SSI or peri-prosthetic joint infection could arise had an implant been utilized
- This study found that baseline bacterial colonization predisposes the patient to an increased likelihood of colonization at later time periods. However, the use of iodophor-impregnated drapes appears to mitigate this risk of colonization. Furthermore, this study found that operative time was independently associated with culture positivity

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Does an antimicrobial incision drape prevent intraoperative contamination? A randomized controlled trial of 1187 patients

Hesselvig AB, Arpi M, Madsen F, Bjarnsholt T, Odgaard A; ICON Study Group. Does an Antimicrobial Incision Drape Prevent Intraoperative Contamination? A Randomized Controlled Trial of 1187" Patients. *Clin Orthop Relat Res.* 2020;478(5):1007-1015. doi:10.1097/CORR.0000000000001142.

STUDY DESIGN

Prospective, multicentre, randomized clinical trial, of 1187 patients undergoing primary knee arthroplasty between March 1, 2016 and April 13, 2018.

STUDY PURPOSE

- To evaluate the effectiveness of antimicrobial surgical drapes reducing the risk of intraoperative microbial contamination in patients undergoing primary knee arthroplasty
- To determine if other factors, such as sex, season, age and type of arthroplasty are associated with an increased risk of contamination
- To determine if antimicrobial drape lift increases risk of contamination
- A detailed cost analysis was also completed

RESULTS

CONTAMINATION RATES

contamination detected when iodinated drapes were used vs. 15% when they were not used. (OR 0.61; 95% CI, 0.43–0.87, p = 0.005)*

BACTERIAL CONTAMINATION

reduction of risk of bacterial colonisation of incision site*

DRAPE LIFT

- Antimicrobial drape lift of more than 10-mm separation from the skin had higher odds of contamination (OR 3.54; 95% CI, 1.64–11.05; p = 0.0013)*

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study

KEY POINTS

SUMMARY

The use of antimicrobial drape resulted in lower contamination risk than operating without an antimicrobial drape.

Procedures in females (OR = 0.55; 95% CI, 0.39–0.80; p = 0.002) and those performed in the central region were less likely to show contamination (OR = 0.45; 95% CI, 0.25–0.78; p = 0.006). No other factors were associated with the risk of contamination.*

METHODS

- Participants were patients older than 18 years undergoing primary knee arthroplasty
- Patients were randomly assigned to operation with an antimicrobial drape (intervention group) or operation without (control group)

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Comparison of efficacy and cost of iodine impregnated drape vs. standard drape in cardiac surgery: Study in 5100 patients

Bejko J, Tarzia V, Carrozzini M, *et al.* Comparison of Efficacy and Cost of Iodine Impregnated Drape vs. Standard Drape in Cardiac Surgery: Study in 5100 Patients. *J Cardiovasc Transl Res.* 2015;8(7):431-437. doi:10.1007/s12265-015-9653-1.

STUDY DESIGN

Retrospective study considered prospectively collected data from 5,100 cardiac surgery patients between January 2008 and March 2015.

STUDY PURPOSE

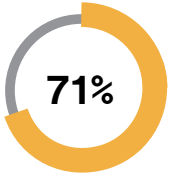
- To evaluate the impact of the use of 2 incise drapes (iodine-impregnated and not iodine-impregnated) on incidence of SSI in cardiac surgery
- A detailed cost analysis was also completed

METHODS

Using a propensity-matched analysis, 808 patients from each group were matched for available risk factors.

RESULTS

SSI INCIDENCE



SSI reduction. 1.9% SSI rate (15/808) for patients receiving Ioban 2 Antimicrobial Incise Drape vs. 6.5% (53/808) for the non-iodine impregnated incise drape, (p = 0.001)*

COST REDUCTION

€773,495

the reason for this difference is the cost related to the treatment of the complications, as negative pressure wound therapy, hospitalization days, sternal wound revision, antibiotic therapy and antiseptics

*Percentage calculation(s) is/are derived based on relative patient group incident rate reported in this study

KEY POINTS

SUMMARY

- Ioban 2 Antimicrobial Incise Drape is a cost-effective intervention associated with a significantly lower incidence of SSI

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Recommended guidance for negative pressure wound therapy

ORGANIZATION	KEY GUIDANCE/RECOMMENDATIONS
WHO (2016)[1]	• Taking resources into account, use of prophylactic negative pressure wound therapy in adult patients on primarily closed surgical incisions in high-risk wounds, for the purpose of the prevention of surgical site infection.
ERAS (2020)[2] BREAST RECONSTRUCTION	• Complex wounds following skin necrosis are treatable with debridement and negative-pressure wound therapy.
ERAS (2020)[2] MAJOR HEAD AND NECK CANCER SURGERY WITH FREE FLAP RECONSTRUCTION	• Vacuum-assisted closure is recommended for complex cervical wounds. Vacuum-assisted closure may be considered for free flap donor sites.

REFERENCE: 1. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia. *Can J Anesth.* (2018) 65:698–708 https://doi.org/10.1007/s12630-018-1111-5. **2.** Enhanced Recovery After Surgery: A Complete Guide to Optimizing Outcomes. Ljungvist, O. *et al.* Springer. Switzerland. 2020.

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

Higuera-Rueda CA, 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;36(7S):S295-S302.e14. doi:10.1016/j.arth.2021.02.076.

STUDY DESIGN

Post-market, randomized, open-label, multicenter study.

STUDY PURPOSE

Evaluate the effectiveness of closed incision negative pressure therapy (ciNPT) versus standard of care (SOC) dressings in reducing surgical site complications (SSCs).

METHODS

- A total of 294 revision total knee arthroplasty (rTKA) patients (15 centers) at high-risk for wound complications were randomized to ciNPT or SOC (n=146) and stratified by revision type (aseptic vs. septic). Demographics, comorbidities, causes of revision and duration of treatment were similar between cohorts ($P > 0.05$)
- 242 patients with incisions completed follow-up, including 124 patients treated with 3M™ Prevena™ Therapy (ciNPT) and 118 patients treated with an antimicrobial silver-impregnated dressing (SOC)
- Primary outcome was the 90-day incidence of SSCs with stratification in accordance with revision type. 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

RESULTS

WOUND COMPLICATIONS

4x

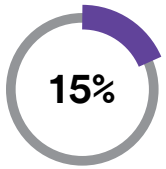
Reduction in SSCs*
3.4% (5/147) Prevena Therapy vs.
14.3% (21/47) SOC (p = 0.0013)*

READMISSIONS

3x

Reduction in readmission rates*
3.4% (5/147) Prevena Therapy vs.
10.2% (15/47) SOC (p = 0.0208)*

DRESSING CHANGES



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

Calculation(s) is/are derived based on relative patient group incidence rates reported in this study.

*Statistically significant (p = <0.05).

KEY POINTS

SUMMARY

- Prevena Therapy significantly mitigated 90-day surgical site complications and readmission rates, and reduced frequency of dressing changes, compared with the standard of care among high-risk rTKA patients
- Treatment-related adverse effects were similar between cohorts
- The benefit of ciNPT on specific SSCs and post-rTKA patient-reported outcomes (PRO) was not established and further studies are warranted

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery

Antoniou G, Onwuka C, Antoniou S, *et al*. Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery. *J Vasc Surg* 2019; 70(5):1700-1710.

STUDY DESIGN

Meta-analysis and trial sequential analysis.

STUDY PURPOSE

To compare the efficacy of ciNPT with standard of care (SOC) in closed surgical wound incisions in vascular surgery.

METHODS

- Systematic review of literature to identify RCTs comparing prophylactic ciNPT with SOC in closed groin incisions in vascular surgery
- Fixed-effect model was used to calculate pooled odds ratio or risk difference and 95% confidence intervals
- All studies identified compared 3M™ Prevena™ Therapy to SOC
- Primary outcome: Surgical site infection
- Secondary outcomes: revision surgery, in-hospital mortality, hospital length of stay, and readmission
- Identified 6 RCTs on a total of 733 groin surgical wounds: ciNPT (n=362) vs. SOC (n=371) (all published between 2016–2018)

RESULTS

SURGICAL SITE INFECTIONS

- **ciNPT patients had a reduced risk for surgical site infections** (OR 0.36; 95% CI, 0.24–0.54; p < 0.001)*

REVISION SURGERY

- **ciNPT patients had a reduced risk for revision surgeries** (OR 0.44; 95% CI, 0.22–0.88; p = .02)*

HOSPITAL LENGTH OF STAY

2 days

Shorter hospital length of stay*
-2.14 days (95% CI, -3.78 to -0.49)
(p = 0.01)*

Calculation(s) are derived based on relative patient group incidence rates reported in this study.
*Statistically significant (p = <0.05)

SUMMARY

- Prophylactic use of negative pressure wound therapy (NPWT) helps improve over SOC through reduction in the risk of SSI in vascular surgical groin patients
- “All studies included in our analysis were published recently (2016–2019) representing contemporary clinical practice in the Western world.”
- “Evidence can be considered to be conclusive and … no more trials are required to investigate the primary outcome.”

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications

Kwon J, Staley C, McCullough M, *et al.* A Randomized Clinical Trial Evaluating Negative Pressure Therapy to Decrease Vascular Groin Incision Complications. *Journal of Vascular Surgery*. 2018; 68(6):1744-1752.

STUDY DESIGN

Prospective, single-center, randomized controlled trial (RCT).

STUDY PURPOSE

This prospective RCT evaluated negative pressure therapy (3M™ Prevena™ Therapy) to decrease wound complications and associated health care costs.

METHODS

The study included 119 femoral incisions closed primarily after elective vascular surgery procedures.

- High-risk inclusion criteria: BMI > 30, pannus, reoperative surgery, prosthetic graft, poor nutrition, immunosuppression, or HbA1c>8
- 1:1 Randomized to standard gauze (n=60) vs. Prevena Therapy (n=59)
- Outcomes evaluated at postoperative day 30: Wound complications, SSI, length of stay (LOS), reoperation, readmission

RESULTS

SURGICAL SITE COMPLICATIONS

reduction in SSC*
11.9% (7/59) Prevena Therapy vs. 26.7% (16/60) SOC (p = 0.001)*

SURGICAL SITE INFECTIONS

reduction in SSI*
10.1% (6/59) Prevena Therapy vs. 21.6% (12/60) SOC (p = 0.001)*

RETURN TO OR

2x

reduction in return to the operating room*
8.5% (5/59) Prevena Therapy vs. 18.3% (11/60) SOC (p < 0.05)*

READMISSIONS

reduction in readmissions*
6.8% (4/59) Prevena Therapy vs. 16.7% (10/60) SOC (p < 0.04)*

Calculation(s) is/are derived based on relative patient group incidence rates reported in this study.
*Statistically significant (p < 0.05).

COST SAVINGS

$6,045

reduction in per-patient cost
$30,492 Prevena Therapy vs. $36,537 SOC

Cost assessment includes variable hospital costs (for both the index hospitalization and all readmission days within 30 days related to any wound complication). Hospital variable costs (not charges) for each admission were obtained from hospital administration.

KEY POINTS

SUMMARY

- Study suggests that negative pressure therapy for patients at high risk for groin wound complications:
  - Significantly reduces major wound complications
  - Significantly reduces reoperation and readmission rates
  - May lead to a reduction in hospital costs
- ciNPT is recommended for all groin incisions considered at high risk for wound complications

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

ORTHOPEDIC
Level of evidence 1a

Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: A prospective, randomized clinical trial

Newman JM, Siqueira MBP, Klika AK, Molloy RM, Barsoum WK, Higuera CA. Use of Closed Incisional Negative Pressure Wound Therapy After Revision Total Hip and Knee Arthroplasty in Patients at High Risk for Infection: A Prospective, Randomized Clinical Trial. *J Arthroplasty.* 2019;34(3):554-559.e1. doi:10.1016/j.arth.2018.11.017.

STUDY DESIGN

Prospective, single-center, randomized control trial (Level I).

STUDY PURPOSE

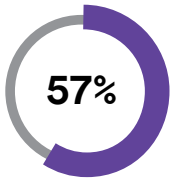
The purpose of this study was to compare the use of Prevena Therapy to a sterile antimicrobial dressing (AQUACEL® Ag SURGICAL cover dressing) in revision arthroplasty (rTHA, rTKA) patients at high risk to develop wound complications.

METHODS

- 160 patients undergoing elective rTHA and rTKA were prospectively randomized to receive Prevena Therapy or AQUACEL® Ag at a single institution
- Patients had at least one risk factor for developing a wound complication.
- All patients received perioperative treatment and antibiotics
- Study endpoints included wound complications (such as SSIs, drainage and cellulitis), readmission and reoperation rates
- Data collected at 2, 4 and 12 weeks postoperatively

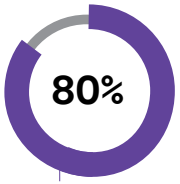
RESULTS

WOUND COMPLICATIONS



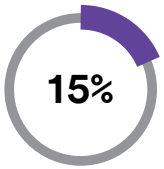
reduction in wound complications*
10.1% (8/79) Prevena Therapy vs.
23.8% (19/80) Control (p = 0.022)*

REOPERATIONS



fewer returns to the OR*
2.5% (2/79) Prevena Therapy vs. 12.5%
(10/80) Control (p = 0.017)*

READMISSIONS



fewer readmissions
20.3% (16/79) Prevena Therapy vs. 23.8%
(19/80) Control (p = 0.595)

Calculation(s) is/are derived based on relative patient group incidence rates reported in this study.
*Statistically significant (p < 0.05).

KEY POINTS

SUMMARY

- High-risk patients could benefit from closed incision negative pressure therapy (ciNPT) to help reduce the risk of wound complications and reoperations after rTHA and rTKA
- The authors suggest future multicenter clinical trials to further strengthen the results, as well as a cost-benefit analysis

Although the authors reported use of Prevena Therapy for a mean of 3.6 days (ranging from 2 to 15 days), this mean time of application is outside the recommendations for Optimum Use as stated in the Prevena Incision Management System Clinician Guide Instructions for Use: The Prevena Incision Management System is to be continuously applied for a minimum of two days up to a maximum of seven days." Use for greater than 7 days is not recommended or promoted by 3M.

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Consensus statements for negative pressure wound therapy with instillation[1]

Consensus Statement 1:

In conjunction with appropriate wound care, such as debridement and systemic antibiotics, NPWTi-d may be used as an adjunct therapy in the following acute, chronic, and/or infected wound types: (a) traumatic wounds; (b) surgical, including dehisced, wounds; (c) diabetic wounds; (d) venous leg ulcers; (e) pressure injuries/ulcers; (f) wounds with exposed intact bone; (g) wounds with treated, underlying osteomyelitis; (h) infected or contaminated wounds in the presence of orthopaedic fixation hardware; (i) full-thickness burns after excision; (j) wounds resulting from evacuation of a haematoma and when haemostasis is achieved; and (k) wounds that are a bridge between staged/delayed amputation.

Consensus Statement 2:

Compatible solutions that may be used with NPWTi-d with ROCF-V or ROCF-CC dressings include: (a) normal saline; (b) hypochlorous acid solution; (c) sodium hypochlorite solution (dilute Dakin's solution 0.125% or quarter strength); (d) acetic acid solution (0.25% to 1.0%); and (e) polyhexamethylene biguanide (0.1%) + betaine (0.1%).

Consensus Statement 3:

NPWTi-d is not recommended: (a) in wounds with presence of exposed, unprotected organs and vessels; (b) in wounds with presence of undrained abscess(es); (c) over split-thickness skin grafts; (d) over dermal substitutes; and (e) in acutely ischaemic wounds.

Consensus Statement 4:

NPWTi-d may be used with caution in: (a) wounds that contain appropriately protected vessels or organs; (b) wounds that contain appropriately protected tendons, ligaments, and nerves; (c) wounds with explored tunnels; and (d) wounds with explored areas of undermining.

Consensus Statement 5:

NPWTi-d, regardless of dressing, may be discontinued when (a) clinical goals are met; (b) wound is deemed ready for surgical closure or coverage; (c) wound is clinically stable for standard NPWT or other advanced therapy to be applied; or (d) wound has decompensated.

Consensus Statement 6:

In conjunction with appropriate wound care, such as debridement and systemic antibiotics, NPWTi-d with ROCF-V may be considered for use in wounds with the following characteristics: (a) adequately cleansed and debrided wounds; (b) clean wounds; (c) contaminated wounds; (d) wounds with heavy bioburden; (e) chronically infected wounds; and (f) wounds that are difficult to granulate.

REFERENCE: 1. Kim PJ, Attinger CE, Constantine T, *et al.* Negative pressure wound therapy with instillation: International consensus guidelines update. *Int Wound J.* 2020;17:174–186.

CLICK HERE TO VIEW ALL 11 CONSENSUS STATEMENTS

Level of evidence 2

Effects of negative-pressure wound therapy with instillation versus standard of care in multiple wound types: Systematic literature review and meta-analysis

Gabriel A, Camardo M, O'Rorke E, Gold R, Kim PJ. Effects of Negative-Pressure Wound Therapy With Instillation versus Standard of Care in Multiple Wound Types: Systematic Literature Review and Meta-Analysis. *Plast Reconstr Surg*. 2021;147(1S-1):68S-76S. doi:10.1097/PRS.0000000000007614.

STUDY DESIGN

A systematic literature review and a meta-analysis of comparative studies, published between January 1, 2004 and December 31, 2019.

STUDY PURPOSE

The purpose of this study was to determine outcomes of negative-pressure wound therapy with instillation (NPWTi-d) versus standard of care in a variety of wound types.

METHODS

Weighted standardized mean difference or odds ratios and 95% confidence intervals were calculated to pool study and control group results in each publication for analysis.

RESULTS

WOUND CLOSURE

- Wounds in the NPWTi-d group were ready for closure faster than control wounds (p = 0.03)

2.39x more likely to have wound closure in the NPWTi-d

WOUND COMPLICATIONS

- Reduction of bacterial count in NPWTi-d wounds was evident in all studies that captured that endpoint

4.4x greater odds of reducing bacterial count at baseline in the NPWTi-d group than control group wounds (p = 0.003)

LENGTH OF THERAPY

- **Significantly shorter length of therapy** in NPWTi-d patients versus control patients (p = 0.03)
- **Length of hospital stay was not significantly reduced** for NPWTi-d patients compared with that for control patients (p = 0.06)

KEY POINTS

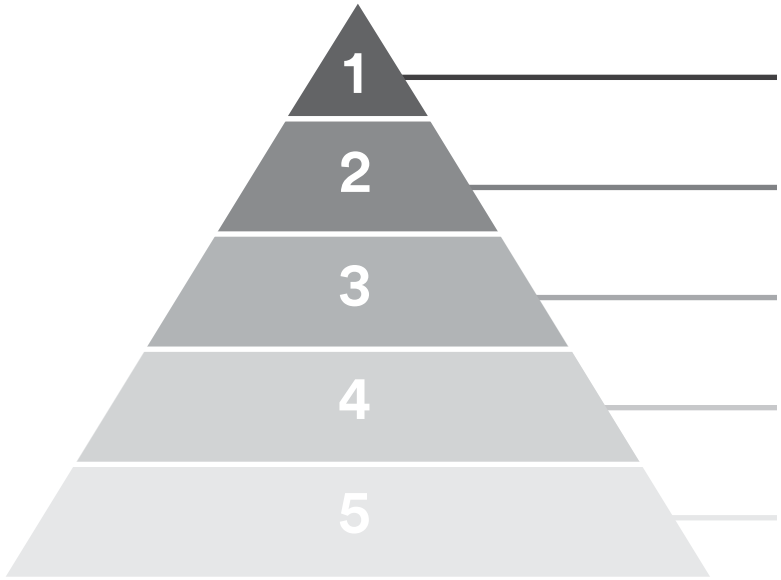
SUMMARY

NPWTi-d, when used in conjunction with good clinical practice (e.g., debridement, appropriate antibiotics), was more beneficial than the comparator with respect to number of surgical debridements during therapy, time to readiness for final wound closure, number of patients with reduced bacterial bioburden, duration of therapy, and number of wounds closed, but similar with respect to hospital length of stay. Results of this meta-analysis show a positive effect with use of NPWTi-d in various wounds.

CLICK HERE TO VIEW FULL CLINICAL STUDY
CLICK HERE TO VIEW ECONOMIC BENEFITS

Rating scale for evidence summaries

The clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale[1]



Level 1a: Evidence obtained from at least one properly designed randomized controlled trial
Level 1b: Systematic reviews (with homogeneity) of randomized controlled trials

Level 2a: Evidence obtained from well-designed controlled trials without randomization
Level 2b: Individual cohort study or low-quality randomized controlled trials (e.g., <80% follow-up)

Level 3: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

Level 4: Case series (and poor-quality cohort and case-control studies)

Level 5: Expert opinion without explicit critical appraisal; or based on physiology, bench research or "first principles"

REFERENCE: 1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. *Plast Reconstr Surg* 2011;128(1):311-314.

INDICATION STATEMENTS

3M™ Bair Hugger™ Temperature Monitoring System

The Bair Hugger family of temperature management systems are indicated for hypothermic patients or normothermic patients for whom induced hypothermia or localized temperature therapy is clinically indicated. In addition, the temperature management systems can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The temperature management systems can be used with adult and pediatric patients.

3M™ Ioban™ Antimicrobial Incise Drape

Ioban 2 Antimicrobial Incise Drape is indicated for use as an incise drape with continuous antimicrobial activity. It is intended for external use only.

3M™ Veraflo™ Therapy

The 3M™ V.A.C.® Ulta Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option. Negative Pressure Wound Therapy in the absense of instillation is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. The instillation option is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed. 3M™ V.A.C.® Ulta Negative Pressure Wound Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.

The 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit is used as part of an integrated wound management system that provides 3M™ Veraflo™ Therapy, which consists of negative pressure wound therapy (3M™ V.A.C.® Therapy) with an instillation option.

- 3M™ V.A.C.® Therapy in the absence of instillation is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material
- The instillation option is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions overthe wound bed The Veraflo Cleanse Choice Complete™ Dressing Kit with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.

3M™ Prevena™ Incision Management System

TThe 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, the 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 postoperative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.*

*The effectiveness of 3M™ 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 Prevena.com

For maximum benefit, the 3M™ Prevena™ Incision Management System should be applied immediately post-surgery to clean, surgically closed incisions for a minimum of 2 days and up to a maximum of 7 days. It can transition home with the patient.

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