## Solventum

Best Practices for Reducing the Risk of SSI's Using an Infection Prevention Bundle

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#### Important Information

Prior to the use of any Solventum and/or 3M Therapy System, it is important for the provider to consult the treating physician and read and understand all Instructions for Use, including Safety Information, Dressing Application Instructions, and Therapy Device Instructions.

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

To the extent this presentation contains case studies and clinical reports, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

This information is intended for healthcare professionals only. Solventum recommends that clinicians participate in device inservice and training prior to use.

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Follow local institutional protocols for infection control and waste disposal procedures. Local protocols should be based on the applicable federal, state and/or local government environmental regulations.



### Objectives

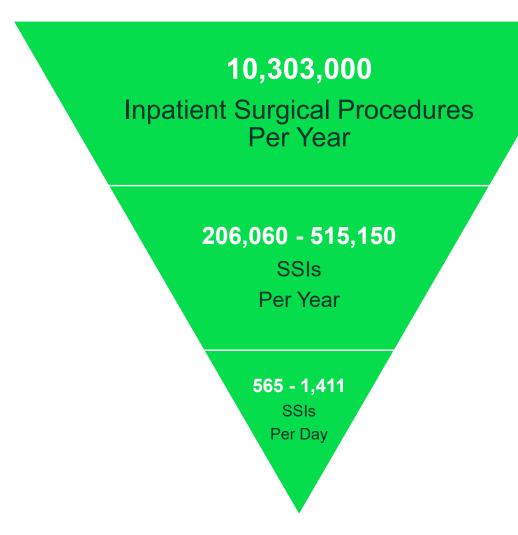
Explain the SSI Risk Equation.

Discuss Solventum solutions as part of a bundle to help reduce the dose of bacteria on a surgical patient.

Discuss a Solventum solution in the bundle that can help improve the resistance of the patient.



## Surgical Site Infections (SSIs)



Inpatient surgical procedures ~10 million in U.S.<sup>1</sup>

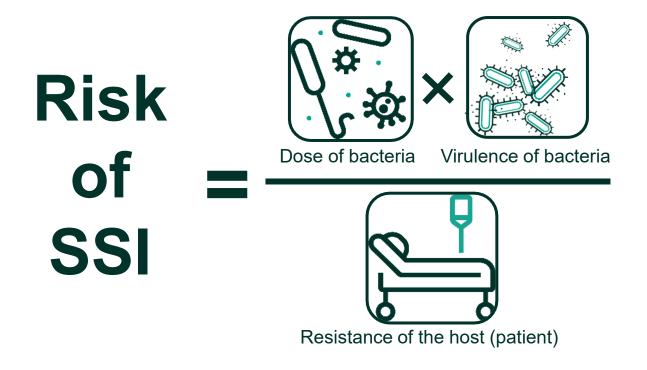
SSIs occur in 2 to 5% of patients undergoing inpatient surgery<sup>2-4</sup>

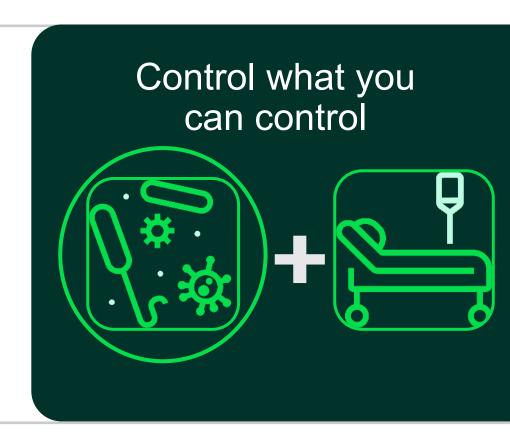
Majority of SSIs are considered preventable with evidence-based guidelines<sup>2-4</sup>

- Surgeries in Hospital-Based Ambulatory Surgery and Hospital Inpatient Settings, 2014 #223. Hcup-us.ahrq.gov. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb223-Ambulatory-Inpatient-Surgeries-2014.jsp. Revised July 2020. Accessed January 20, 2023.
- 2. Surgical Site Infections. Psnet.ahrq.gov. <a href="https://psnet.ahrq.gov/primer/surgical-site-infections">https://psnet.ahrq.gov/primer/surgical-site-infections</a>. Published 2019. Accessed January 20, 2023.
- 3. Anderson DJ, Podgorny K, Berríos-Torres SI, et al. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. *Infect Control Hosp Epidemiol*. 2014;35(6):605-627.
- 4. Fields AC, Pradarelli JC, Itani KMF. Preventing Surgical Site Infections: Looking Beyond the Current Guidelines. *JAMA*. 2020;323(11):1087–1088



## The SSI risk equation





Mangram AJ, Horan TC, Pearson ML, Silver LC, and Jarvis WR. Guideline for prevention of surgical site infection. Infect Control Hosp Epidemiol. 1999;4:247-278. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/24799638.

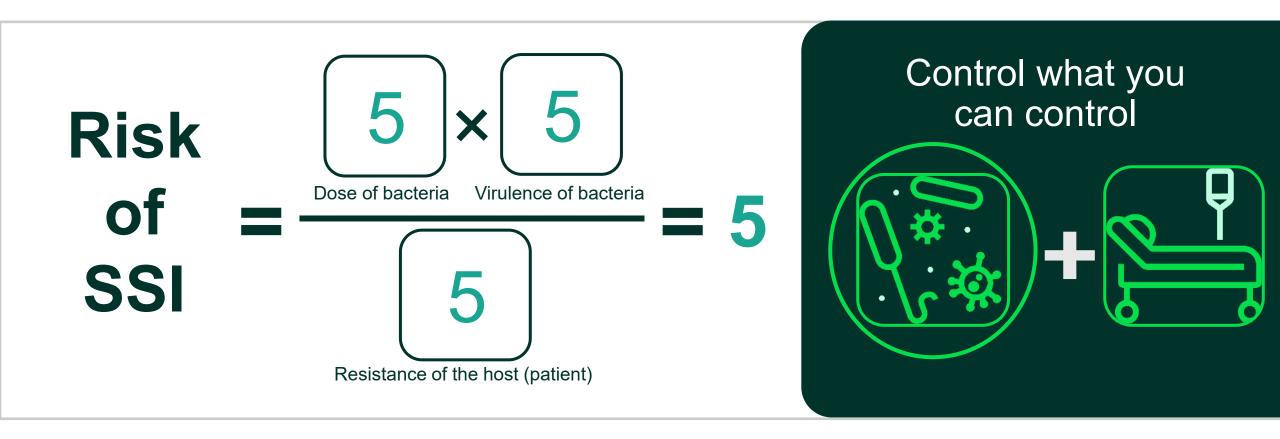


# Reducing the load of bacteria





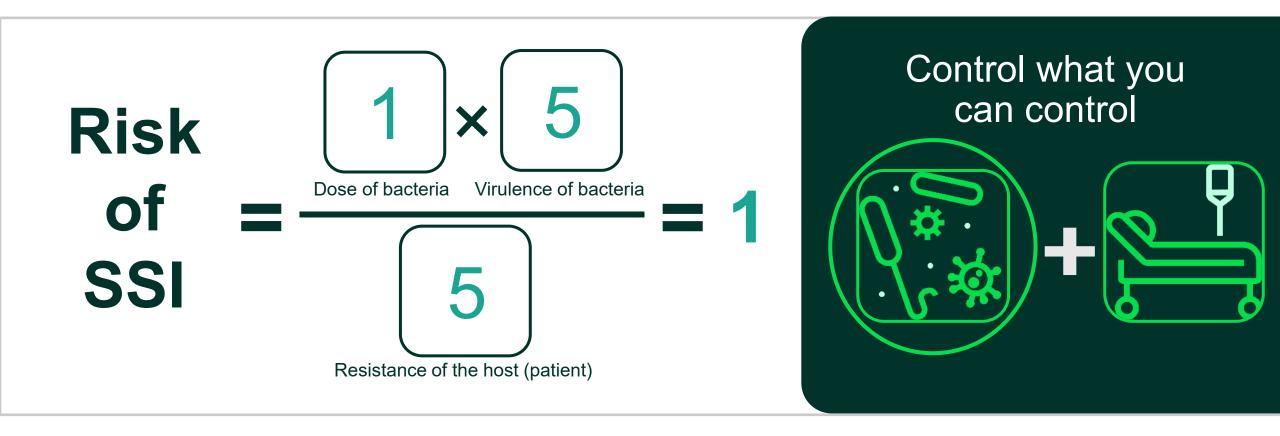
## The SSI risk equation



Mangram AJ, Horan TC, Pearson ML, Silver LC, and Jarvis WR. Guideline for prevention of surgical site infection. Infect Control Hosp Epidemiol. 1999;4:247-278. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/24799638.



## The SSI risk equation



Mangram AJ, Horan TC, Pearson ML, Silver LC, and Jarvis WR. Guideline for prevention of surgical site infection. Infect Control Hosp Epidemiol. 1999;4:247-278. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/24799638.



## Evidence-based prevention strategies to reduce the risk of SSIs

#### Hospital Environment

- ✓OR ventilation
- ✓ OR surfaces
- ✓OR traffic flow
- ✓ Microbiological sampling
- ✓ Reprocessing of surgical instruments
- ✓ Sterile field management

#### **Patient Preparation**

- ✓ Antiseptic showering (bathing)
- ✓ Nasal decolonization
- √ Hair removal
- ✓ Antimicrobial prophylaxis
- ✓ Preoperative patient warming
- √Glucose monitoring

#### Surgical Intervention

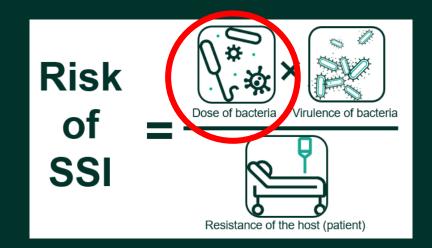
- ✓ Sterilization assurance
- √ Vascular access
- √ Hand hygiene
- √ Temperature monitoring
- ✓Intraoperative patient warming
- ✓ Surgical skin antisepsis
- ✓ Antimicrobial incise draping

#### Post Operative

- ✓ Post operative incision management
- ✓ Negative pressure
- ✓ Post operative patient warming



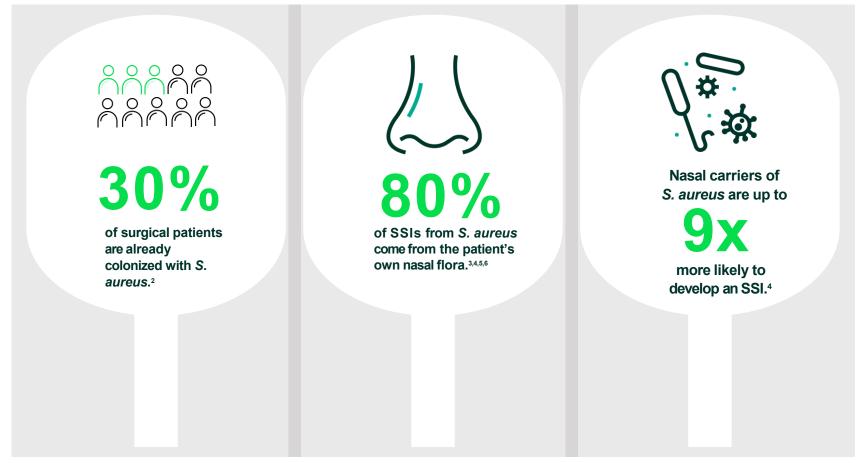
## **Nasal Decolonization**





#### Nasal colonization can increase the risk of infection

Staphylococcus aureus causes more health care associated infections (HAIs) than any other pathogen.<sup>1</sup>



<sup>1.</sup>Weiner LM, Webb AK, Limbago B, et al. Antimicrobial-Resistant Pathogens Associated with Healthcare-Associated Infections: Summary of Data Reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2011-2014. Infect Control Hosp Epidemiol. 2016;37(11):1288-1301.

<sup>2.</sup> Kuehnert MJ, Kruszon-Moran D, Hill HA, et al. Prevalence of Staphylococcus aureus nasal colonization in the United States, 2001-2002. J Infect Dis. 2006;193(2):172-179.

<sup>3.</sup> Perl TM, Cullen JJ, Wenzel RP, et al. Intranasal mupirocin to prevent postoperative Staphylococcus aureus infections. N Engl J Med. 2002;346(24):1871-1877.

<sup>4.</sup> Kalmeijer MD, van Nieuwland-Bollen E, Bogaers-Hofman D, de Baere GA. Nasal carriage of Staphylococcus aureus is a major risk factor for surgical-site infections in orthopedic surgery. Infect Control Hosp Epidemiol. 2000;21(5):319-323.

<sup>5.</sup> Kluytmans JA, Mouton JW, Ijzerman EP, et al. Nasal carriage of Staphylococcus aureus as a major risk factor for wound infections after cardiac surgery. J Infect Dis. 1995;171(1):216-219.

<sup>6.</sup> Wertheim HF, Vos MC, Ott Å, et al. Risk and outcome of nosocomial Staphylococcus aureus bacteraemia in nasal carriers versus non-carriers. Lancet. 2004;364(9435):703-705. doi:10.1016/ S0140-6736(04)16897-9

<sup>7.</sup>Anderson DJ, Kaye KS, Chen LF, et al. Clinical and financial outcomes due to methicillin resistant *Staphylococcus aureus* surgical site infection: a multi-center matched outcomes study. *PLoS ONE*. 2009;4(12):e8305.

#### Decolonization product selection

#### Challenges of the nasal environment:

- Dark
- Moist
- High levels of microorganisms<sup>1,2</sup>
- Anatomical challenges tip of the nose, nasal orifices<sup>1,2</sup>
- Cilia and mucociliary clearance<sup>3</sup>
- pH range 5.5-6.5<sup>4</sup>

The goal – select an effective formulation that can address challenges

<sup>4.</sup> England RJ, Homer JJ, Knight LC, Ell SR. Nasal pH measurement: a reliable and repeatable parameter. Clin Otolaryngol Allied Sci. 1999;24(1):67-68. doi:10.1046/j.1365-2273.1999.00223.x



<sup>1.</sup> Sakr A, Brégeon F, Mège JL, Rolain JM, Blin O. Staphylococcus aureus Nasal Colonization: An Update on Mechanisms, Epidemiology, Risk Factors, and Subsequent Infections. Front Microbiol. 2018;9:2419. Published 2018 Oct 8. doi:10.3389/fmicb.2018.02419

<sup>2.</sup> Kumpitsch C, Koskinen K, Schöpf V, Moissl-Eichinger C. The microbiome of the upper respiratory tract in health and disease. BMC Biol. 2019;17(1):87. Published 2019 Nov 7. doi:10.1186/s12915-019-0703-z

<sup>3.</sup> Bustamante-Marin XM, Ostrowski LE. Cilia and Mucociliary Clearance. Cold Spring Harb Perspect Biol. 2017;9(4):a028241. Published 2017 Apr 3. doi:10.1101/cshperspect.a028241

### Product options for nasal decolonization

Mupirocin

• 5% Povidone Iodine

• 10% Povidone Iodine

Alcohol



### Antiseptic versus antibiotic comparison

Antiseptic	Antibiotic
Biocides - destroy or inhibit the growth of microorganisms <sup>1</sup>	Can either induce cell death (bactericidal drugs) or merely inhibit cell growth (bacteriostatic drugs) <sup>4</sup>
Help reduce risk of infection <sup>1</sup>	Treat or prevent infection <sup>3</sup>
Broad spectrum <sup>1</sup>	Often narrower spectrum <sup>1,3</sup>
Kill bacteria by attacking multiple cell processes <sup>1,2</sup>	Kills or inhibits growth of bacteria by inactivation of a single target <sup>2</sup>
Nontoxic at relatively high concentrations <sup>2</sup>	Can cause toxicity at higher concentrations, especially systemically
Resistance usually does not form <sup>1</sup>	Resistance can form³

<sup>1.</sup> McDonnell G. Block's Disinfection, Sterilization, and Preservation. In: Lippincott Williams & Wilkins; 2020.

<sup>4.</sup> Overview of Antibiotics - Infections - Merck Manuals Consumer Version. https://www.merckmanuals.com/en-ca/home/infections/antibiotics/overview-of-antibiotics.



<sup>2.</sup> McDonnell G, Russell AD. Antiseptics and disinfectants: activity, action, and resistance [published correction appears in Clin Microbiol Rev 2001 Jan;14(1):227]. Clin Microbiol Rev. 1999;12(1):147-179.

<sup>3.</sup> Kohanski MA, Dwyer DJ, Collins JJ. How antibiotics kill bacteria: from targets to networks. Nat Rev Microbiol. 2010;8(6):423-435. doi:10.1038/nrmicro2333

## 3M™ Skin and Nasal Antiseptic

(Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation







### Foam applicator delivery to the nares

#### Allows application with gentle scrubbing

- Increases antimicrobial efficacy
- Dual-action (antiseptic + scrubbing)

#### Foam tipped applicators

- Absorbs and delivers effective amount of solution
- Optimized tip size for application to the nares
- Gentle feel





## Unique chemistry of 3M™ Skin and Nasal Antiseptic

Active: Povidone-Iodine Solution 5% w/w<sup>1</sup>

Formulated with:

**Unique film forming polymer:** High viscosity gel- stays in contact with the anterior nares longer for sustained activity <u>at the site</u> of colonization and prevents formulation from dripping during application

#### **Unique Buffer System:**

- Maintains optimal pH
- Optimal antimicrobial activity: lodine is rapidly reduced to inactive iodide at pH > 4.5 and hence product is buffered to help protect the reduction from happening to maintain the active iodine<sup>1</sup>
- Product safety (minimal irritation)
- Formulation stability (shelf-life)

**Combination of Surfactants:** Allows for maintaining physical and chemical stability of composition and for improved spreading to completely cover the anterior nares



#### 3M<sup>™</sup> Skin and Nasal Antiseptic



Reduces bacterial counts in the nares in 1 hour, including *Staphylococcus* aureus by 99.5% and maintains this reduction for at least 12 hours.\*1



Reduces bacteria on the groin and abdomen in 10 minutes\*2



3M Skin and Nasal Antiseptic can be used on children as young as 2 months of age<sup>‡3</sup>



Supports antibiotic stewardship



<sup>\*</sup> As demonstrated through testing; mean values

See label

<sup>.</sup> Solventum data on file: Study-05-011100

<sup>2.</sup> Solventum data on file: Study-05-010945

<sup>3.</sup> Solventum data on file: EM-05-159073.

### lodine allergies

- There is no correlation between shellfish allergies and iodine. 1,2
- Iodine is a trace element essential to life and present throughout the body. A true allergy to the trace element iodine does not exist.
- An anaphylactic reaction to topical iodine antiseptic solutions is exceedingly rare and not proven to be related to iodine.
- Contact dermatitis related to topically applied iodine antiseptics is not an indication of an iodine allergy; rather, it is indicative of a reaction to chemicals in the product.<sup>3,4</sup>
- Today, topically applied iodine antiseptics contain a carrier complex (e.g. povidone, povacrylex). In very rare cases, these antiseptics may have an allergic potential.
- Stated iodine allergy warrants further conversations and education

Sicherer SH. Risk of severe allergic reactions from the use of potassium iodide for radiation emergencies. J Allergy Clin Immunol. 2004;114(6):1395-1397. doi:10.1016/j.jaci.2004.09.026



<sup>1.</sup> lodine "allergy" and fish allergy. February 24, 2020. American Academy of Allergy Asthma and Immunology. https://www.aaaai.org/allergist-resources/ask-the-expert/answers/old-ask-the-experts/iodine-allergy-fish.

<sup>2.</sup> Shellfish allergy is not a shell game. January 10, 2024. American Academy of Allergy Asthma and Immunology. <a href="https://www.aaaai.org/tools-for-the-public/conditions-library/allergies/shellfish-allergy-can-be-dangerous">https://www.aaaai.org/tools-for-the-public/conditions-library/allergies/shellfish-allergy-can-be-dangerous</a>.

Quatresooz P, Xhauflaire-Uhoda E, Piérard-Franchimont C, Piérard GE. Regional variability in stratum corneum reactivity to antiseptic formulations. Contact Dermatitis. 2007;56(5):271-273. doi:10.1111/j.1600-0536.2007.01097.x

## CDC Strategies to Prevent Hospital-onset *Staphylococcus aureus* Bloodstream Infections in Acute Care Facilities and SSI Prevention

Patient Type	Intensive Care Unit	Non-Intensive Care Unit	
Central venous catheter (CVC) or Midline Catheter Present	Topical chlorhexidine gluconate (at least 2%) + Intranasal antistaphylococcal antibiotic/antiseptic (e.g. mupirocin or iodophor) (core strategy)	Topical chlorhexidine gluconate (at least 2%) + Intranasal antistaphylococcal antibiotic/antiseptic (e.g. mupirocin or iodophor) (supplemental strategy)	
No CVC or Midline Catheter present	Topical chlorhexidine gluconate (at least 2%) + Intranasal antistaphylococcal antibiotic/antiseptic (i.e. mupirocin or iodophor) (core strategy)	None (note that decolonization or pathogen reduction strategies may apply to pre-operative surgical patients outside the intensive care unit)	
Surgical site infection (SSI) prevention practices	For patients undergoing high risk surgeries (e.g. cardiothoracic, orthopedic, and neurosurgery), use an intranasal antistaphylococcal antibiotic/antiseptic (e.g. mupirocin or iodophor) and chlorhexidine wash or wipes prior to surgery (core strategy)*  * Facilities can choose to apply the selected pre-operative decolonization or pathogen reduction regimen universally to all patients or can screen patients undergoing a high-risk surgery with a test that detects both MSSA and MRSA and provide the decolonization regimen only to those from whom S. aureus is identified.		



Centers for Disease Control (CDC). Strategies to Prevent Hospital-onset Staphylococcus aureus Bloodstream Infections in Acute Care Facilities Website. <a href="https://www.cdc.gov/staphylococcus-aureus/hcp/prevent-in-acute-care-facilities/index.html">https://www.cdc.gov/staphylococcus-aureus/hcp/prevent-in-acute-care-facilities/index.html</a>. Reviewed April 15, 2024.

#### SHEA/IDSA/APIC Strategies to prevent surgical site infections in acute-care hospitals: 2022 update

Risk Factor	Recommendation	Quality of Evidence
S. Aureus nasal colonization	Decolonize patients with nasal mupirocin or povidone-iodine prior to surgery	Moderate

Decolonization of surgical patients with an antistaphylococcal agent for cardiothoracic and orthopedic procedures was reclassified from an "additional approach" to an "essential practice"

Calderwood MS, Anderson DJ, Bratzler DW, et al. Strategies to prevent surgical site infections in acute-care hospitals: 2022 Update. Infect Control Hosp Epidemiol. 2023;44(5):695-720. doi:10.1017/ice.2023.67.



#### **ERAS Cardiac Society**

Turnkey Order Set for Surgical-Site Infection Prevention: Proceedings from the American Association for Thoracic Surgery ERAS Conclave 2023

Preoperative recommendations include screening for and treating Staphylococcus aureus nasal carriage.

#### **Preoperative**

- Obtain nasal swab,
  - If time permitting to get results:
    - If positive for *S. aureus*, Mupirocin 2% nasal ointment 2x/day for 5 days
  - If time not permitting to get results:
    - Empirically treat: Mupirocin 2% nasal ointment 2x/day for 5 days, discontinue if results come back negative

Or

• Administer povidone-iodine solution 5%(0.5% available iodine) USP nasal antiseptic single application in each naris on morning of surgery



## Association of periOperative Nurses (AORN)

- Use a risk-based approach to determine S. aureus decolonization strategies
- Evaluate resources and plan for expansion of services for the strategy
- Select horizontal, vertical, or blended strategy for decolonization
- Determine screening method
- Determine decolonization protocol
- Implement the decolonization protocol
- Monitor the regimen

#### Nasal Decolonization Options Listed

- Mupirocin (22 studies)
- Povidone Iodine (7 studies)
- Octenidine (1 study)
- Alcohol based (2 studies)



## Skin Prep







## Goals of Antiseptic Skin Prep Solutions<sup>1</sup>



Significantly decrease the number of bacteria colonizing on the skin, thereby reducing the risk of contamination of the incisional wound.



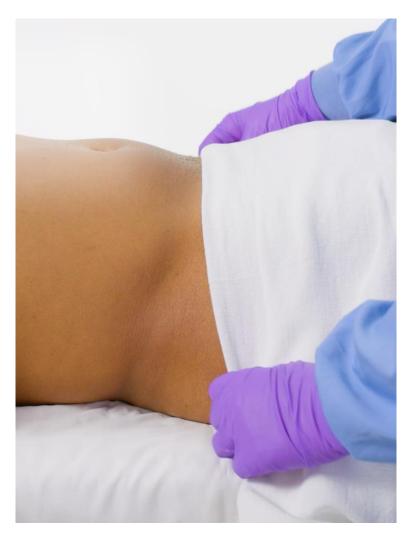
Antiseptics mechanically remove and chemically kill contaminating and colonizing flora.



Must provide broad-spectrum coverage.







#### Global Clinical Guidelines

#### Surgical Skin Preparation



Clinical guidelines recommend to use a skin prep that contains **both** alcohol and a second active ingredient unless contraindicated

- Alcohol should not be used on mucous membranes or open wounds
- Chlorhexidine Gluconate (CHG) should not be used on mucous membranes, meninges, eyes, ears
- Allergy to CHG or Iodine

WHO	World Heath Organization, 2018
AORN	Association of periOperative Registered Nurses, 2023
SHEA/IDSA	The Society for Healthcare Epidemiology of America/The Infectious Diseases Society of America, 2022
NICE	The National Institute for Health and Care Excellence, 2019
KRINKO	The Commission for Hospital Hygiene and Infection Prevention at Robert Koch Institute (2018)
CDC	Centers for Disease Control and Prevention, 2017
ACOG	American College of Obstetricians and Gynecologists, 2018
ACS/SIS	American College of Surgeons and Surgical Infection Society, 2016



#### Global Clinical Guidelines

Single-Use Container vs Multi-Use Bottle



Clinical guidelines recommend use of a single-use container to reduce potential contamination of skin antiseptic solutions.

Organization	Details
AORN, 2023	Skin antiseptics should be single-use containers (Page 651, 4.4.2) <sup>1</sup>
APIC	"APIC believes that preoperative skin preparations should be manufactured and marketed in single-use containers we do not support use of multiple-use containers. Single-use containers should be designed in such a way that multiple-use is not possible." <sup>2</sup>
ORNAC, 2019	Single use containers of skin antiseptic shall be used for each patient. Single use containers decreases the risk of cross-contamination. (Page 2-41, 2.17.22) <sup>3</sup>
FDA Drug Safety Communication, 2013	Recommends antiseptics for preoperative or pre-injection skin preparation be packaged in singleuse containers. Applicators and any unused solution should be discarded after the single application.
INS, 2021	Use a single-use sterile applicator containing sterile solution, not a multiple use product (eg, bottle of antiseptic solution). (IV) Standard 33 $^{\rm 5}$



### Solventum Surgical Skin Antisepsis Options

#### 3M<sup>™</sup> DuraPrep<sup>™</sup> Surgical Solution

(Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation

#### 3M™ SoluPrep™ S Sterile Antiseptic Solution

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)
Patient Preoperative Skin Preparation







## 3M<sup>™</sup> DuraPrep<sup>™</sup> Surgical Solution Patient Preoperative Skin Preparation

- -Dries to a water-insoluble film<sup>1</sup>
- -Resists removal by blood and irrigating solutions<sup>2</sup>
- -Immobilizes bacteria remaining on the skin after prepping<sup>3</sup>
- -Keep resident bacteria counts low for at least 48 hours\*
   after blood and saline challenge<sup>4</sup>
- Applied in a single painted coat
- Provides statistically significant better drape adhesion for incise drapes than ChloraPrep™ preoperative skin preparation<sup>5</sup>

\*under simulated surgical conditions

- 1. Solventum data on file (LIMS 8198)
- Solventum data on file(05-010565 and LIMS 8198)
- 3. Solventum data on file(05-004891)
- 4. Solventum data on file(05-010565)
- 5. Solventum data on file(05-010262)





### **Application Method**

Beginning at the incision line and working your way out toward the periphery, paint a single uniform coat of solution on the skin.



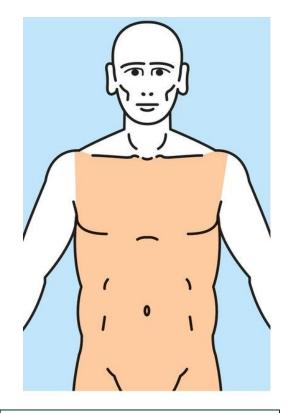


One application method for dry and moist surgical sites

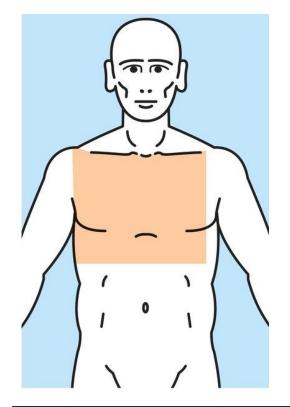




## Coverage Area



3M™ DuraPrep™ Surgical Solution 26 mL Covers 15" x 30" area (450 sq inches)



BD ChloraPrep™ Patient
Preoperative Skin Preparation\*
26 mL
Covers 13.2" x 13.2" area
(174 sq inches)



#### 3M™ SoluPrep™ S Sterile Antiseptic Solution

chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v) Patient Preoperative Skin Preparation



Provides rapid, broad-spectrum antimicrobial activity\* that persists for at least 96 hours\*\*1



FDA-approved sterile solution and sterile applicator<sup>2,3</sup>



Visible on a variety of skin tones<sup>4</sup>



Contains an ingredient that can improve incise drape adherence<sup>†5</sup>



Greater coverage area<sup>‡6</sup>



Designed with workflow efficiency and convenience in mind<sup>7</sup>

- Solventum Data on File. EM-05-013953. EM-05-014624.
- Solventum Data on File. SV-EO-05-679401.
- Solventum Data on File. SV-HEAT-05-764865.
- Solventum Data on File. TECH-REPORT-05-943704, EM-05-014753, EM-05-014733.
- 5. Olson LK, Morse DJ, Paulson JE, Bernatchez SF. Evaluation of Incise Drape Lift Using 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol Preoperative Skin Preparations in a Human Volunteer Knee Model. *Arthroplasty Today*. 2022 Mar 27;15:24-28.
- 6. Solventum Data on File. EM-05-014815.
- Solventum Data on File. DC-VER-05-726184, TECH-REPORT-05-742505, TECH-REPORT-05-757564.



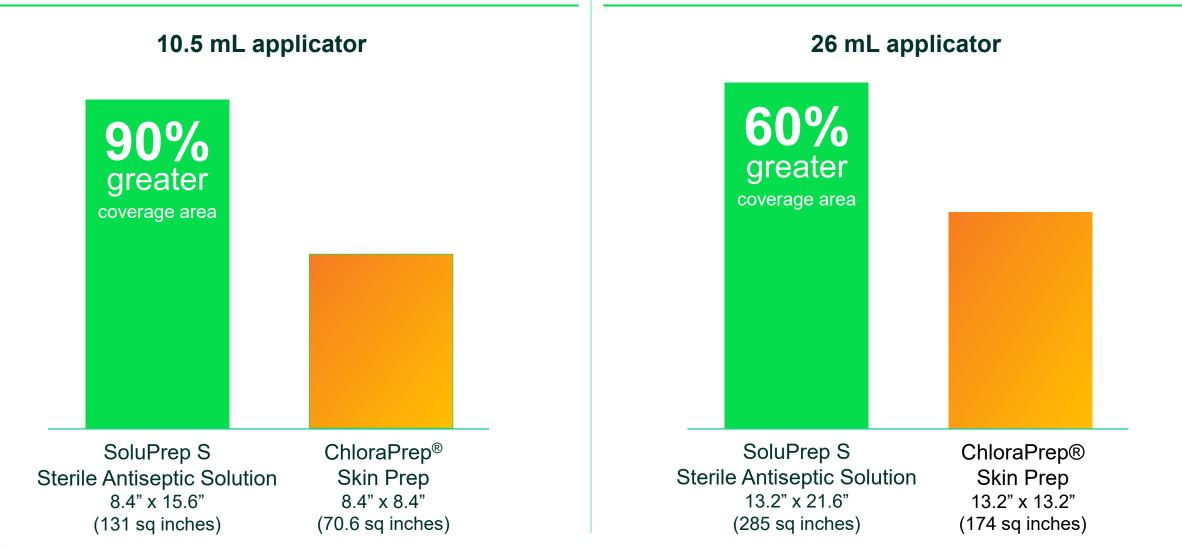


<sup>\*</sup>The clinical significance of in vitro data is unknown

†Compared to skin prepped with ChloraPrep® with 3M™ Ioban™ 2 Antimicrobial Incise Drapes in a simulated knee surgery model, 2019 ‡Compared to ChloraPrep®, 26 mL and 10.5 mL, 2021.

<sup>\*\*</sup>Study was performed on healthy volunteers under simulated surgical conditions

## Applicator Sizes and Coverage Area<sup>1</sup>





## Surgical Skin Preps and Incise Drape Adherence



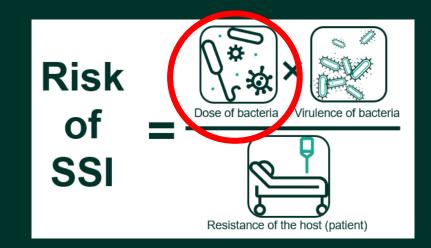






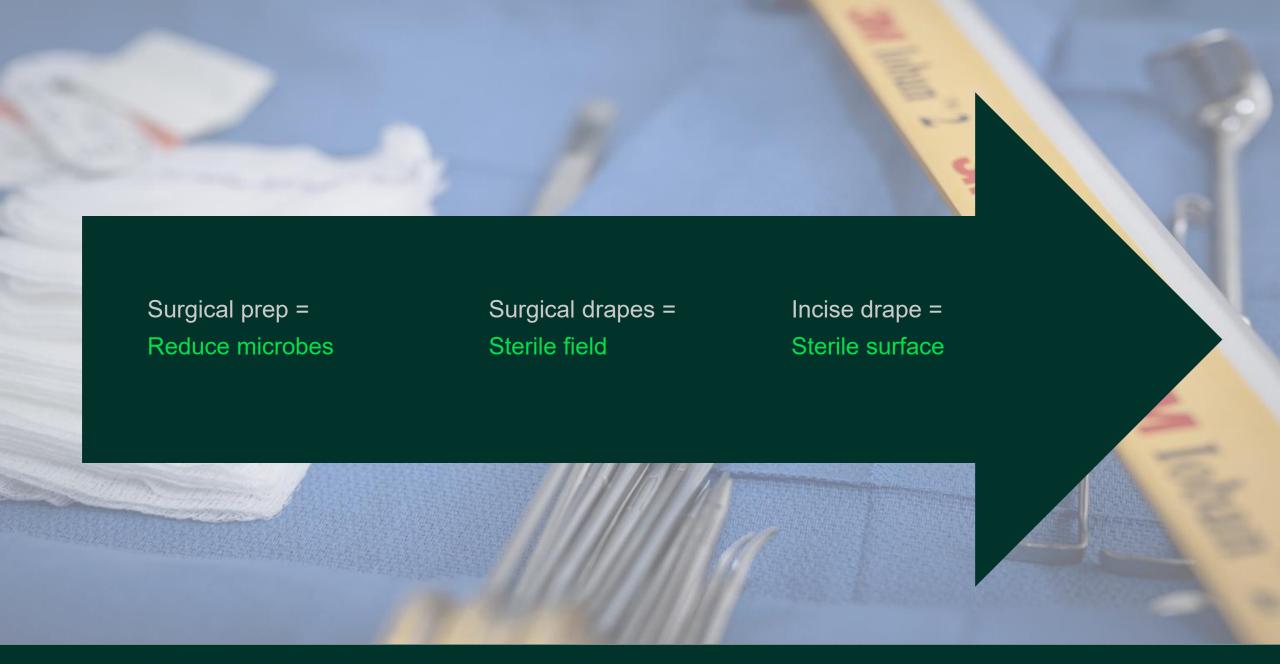


## **Incise Drapes**











# 3M™ Ioban™ 2 Antimicrobial Incise Drape







# 3M™ Ioban™ 2 Antimicrobial Incise Drape features



 Creates a sterile surface at the beginning of surgery



 Eliminates the need for towel clips and clamps to hold drapes in place



 Has 2% iodine that cannot be washed off it's in the adhesive



 Provides a barrier to liquids that can seep under the drape edges



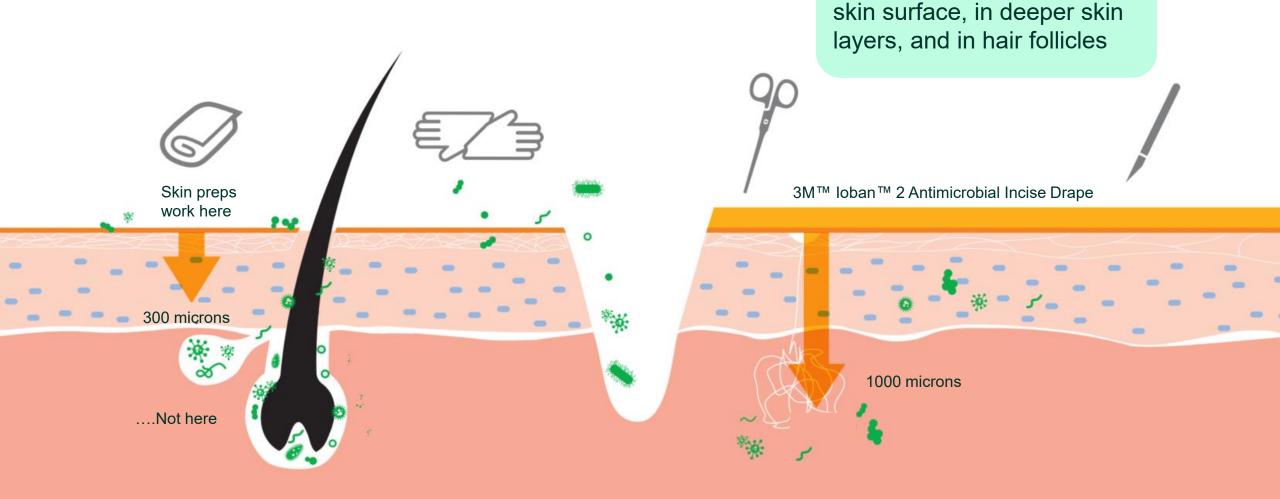
Film is breathable



 Helps prevent surgical skin preps from being washed away



# Risk of contamination





There are <u>always</u> residual

microbes that survive on the

<sup>1.</sup> Karpanen TJ, Worthington T, Conway BR, Hilton AC, Elliott TSJ, Lambert PA.Penetration of chlorhexidine into human skin.Antimicrob Agents Chemother.2008;52:3633-6.

Casey AL, Karpanen TJ, Nightingale P, Conway BR, Elliot TSJ. Antimicrobial activityand skin permeation of iodine present in an iodine-impregnated surgical incise drape. J Antimicrob Chemother. 2015;70:2255-60.

# 3M<sup>TM</sup> Ioban<sup>TM</sup> CHG Chlorhexidine Gluconate Incise Drape







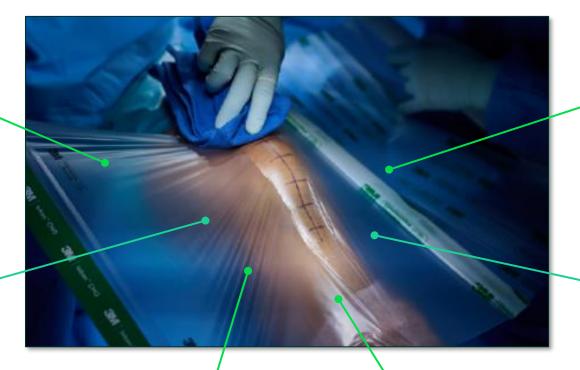
## Features & Benefits

#### CHG adhesive film\*1

Provides continuous, broadspectrum antibacterial protection

# Conformable and easy to use<sup>1</sup>

Adheres to a variety of body contours and allows for limb manipulation.<sup>1</sup> It is easy to apply and remove



#### Breathable<sup>1</sup>

Helps release moisture to encourage strong adherence

# Withstands surgical challenges<sup>1\*\*</sup>

Such as irrigation fluid, limb manipulation, retraction, and in the presence of blood and fatty tissue. Protects against skin prep wash-off

#### **Trusted adherence**

Provides adherence to skin comparable to loban 2 Antimicrobial Incise Drape<sup>1</sup>

#### Visibly transparent<sup>1</sup>

Clear incise drape allows for easy viewing of the surgical site

- 1. Solventum Data on File, LAB-SUPPORT-05-867032
- Solventum Data on File. SV-EO-05-867332, TECH-REPORT-05-889166

\*In vitro data, clinical significance is unknown.
\*\* In simulated surgery



# Global guidelines: surgical incise drapes

#### ORNAC<sup>4</sup>

- "The use of adhesive surgical incise drapes without antimicrobial properties is not recommended to prevent SSIs".
- "lodophor impregnated adhesive drapes may be used in accordance with the manufacturer's IFU to decrease SSIs, unless contraindicated by a patient's allergy".

#### KRINKO<sup>5</sup>

Evidence indicates antimicrobialimpregnated incise drapes result in reduction in bacterial colonization of the surgical site.

While bacterial colonization of the incision may predispose to subsequent SSI/PJIs, there is no literature to demonstrate that the use of incise drapes results in clinical differences in the rates of subsequent PJIs.

#### • APSIC<sup>6</sup>

"When using adhesive incise drapes, do not use non-iodophor-impregnated drapes for surgery as they may increase the risk of surgical site infection."

"In orthopedic and cardiac surgical procedures where adhesive incise drapes are used, consider using an iodophor-impregnated incise drape, unless the patient has an iodine allergy or other contraindication."

 Operating Room Nurses Association of Canada. (2025, April). Guidelines for perioperative Practice in Canada (17<sup>th</sup> ed.).http://www.ornac.ca/guidelines.phtml  KRINKO Surgical Site Infection Prevention Guidelines, 2018. 6. APSIC Asia Pacific Society of Infection Control for The Prevention of Surgical Site Infections 2019.



# Global guidelines: surgical incise drapes

#### NICE1

"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."

#### NHMRC<sup>2</sup>

"If an incise drape is required, use an iodophor-impregnated drape unless the patient has an iodine allergy."

"Do not use non-iodophor-impregnated incise drapes routinely for surgery as they may increase the risk of surgical-site-infection."

#### ACORN<sup>3</sup>

"Adhesive drapes with antimicrobial properties can be used in the critical aseptic field unless contraindicated (i.e. patient allergy)."

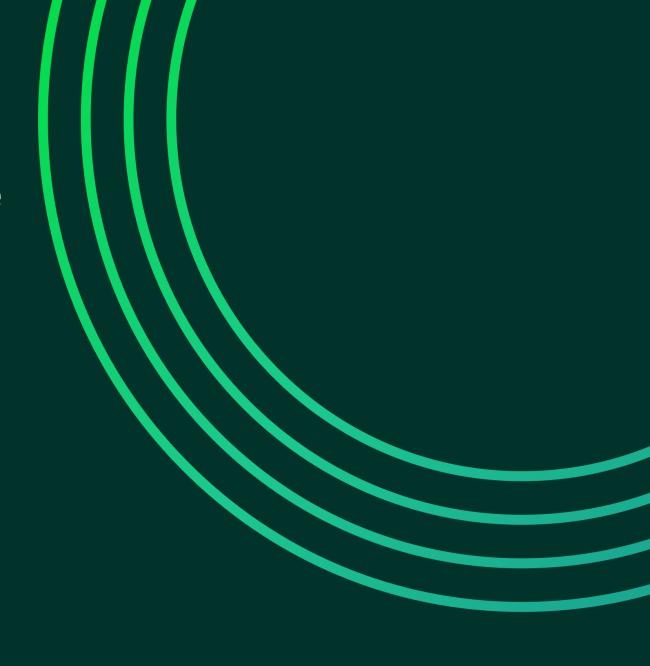
"These include but are not limited to iodophor-impregnated adhesive drapes."

- NICE National Institute for Health and Care Excellence. (2019, April 11). Surgical site infections: prevention and treatment. NICE National Institute for Health and Care Excellence. https://www.nice.org.uk/guidance/ng125/chapter/Recommendations#intraoperative-phase
- NHMRC National Health and Medical Research Council guidelines for the prevention and control of infection in healthcare. NHMRC. 2019.

 Australian College of Perioperative Nurses Ltd (ACORN) The New ACORN Standards. Volume-3-2023 Standards for safe and Quality Care in the Perioperative Environment (SSQCPE) for Organisations. Adelaide, South Australia: ACORN; 2023. Asepsis Standard, Critical Aseptic Field Maintenance.

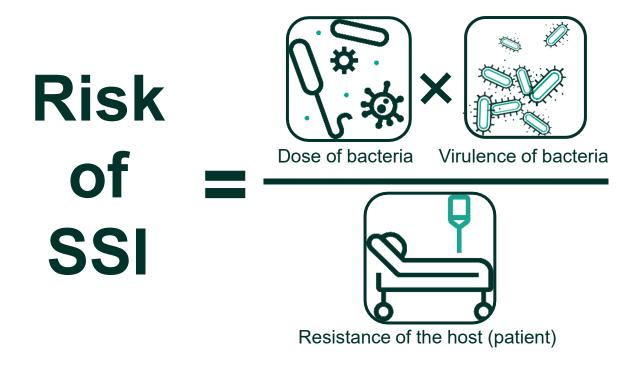


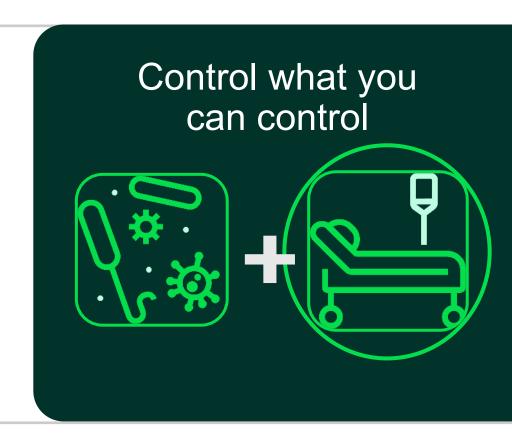
# Increasing the resistance of the patient





# The SSI risk equation

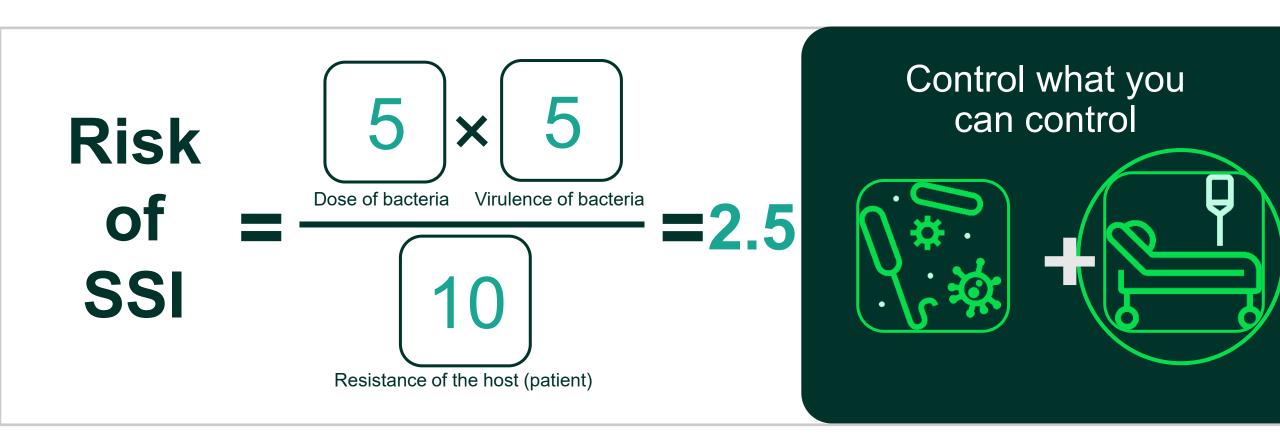




Mangram AJ, Horan TC, Pearson ML, Silver LC, and Jarvis WR. Guideline for prevention of surgical site infection. Infect Control Hosp Epidemiol. 1999;4:247-278. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/24799638.



# The SSI risk equation



Mangram AJ, Horan TC, Pearson ML, Silver LC, and Jarvis WR. Guideline for prevention of surgical site infection. Infect Control Hosp Epidemiol. 1999;4:247-278. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/24799638.



# Maintaining Normothermia







## **Guidelines:**

#### Temperature management & Surgical site infection (SSI) prevention

# World Health Organization<sup>1</sup> (WHO)

"Suggests the use of warming devices in the operating room for patient body warming with the purpose of reducing SSI."

[Conditional recommendation, moderate quality of evidence]

# Centers for Disease Control and prevention<sup>2</sup> (CDC)

"Maintain perioperative normothermia"

[Recommendation high to moderatequality evidence]

- Global guidelines for the prevention of surgical site infection, second edition. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.
- 2. Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. *JAMA Surg.* 2017;152(8):784–791. doi:10.1001/jamasurg.2017.0904.
- 3. AORN. https://aornguidelines.org/guidelines/content?sectionid=173731777&view=book. Accessed April 25, 2025.

# Association of periOperative Registered Nurses<sup>3</sup> (AORN)

"Implement preoperative warming (i.e., prewarming) as determined by the perioperative patient temperature management plan." [Recommendation]

"Implement one or more active warming methods to prevent and treat inadvertent perioperative hypothermia as determined in the perioperative patient temperature management plan for all patients during all phases of perioperative care (ie, preoperative prewarming, intraoperative, postoperative)."

[Recommendation]

"Implement intraoperative warming using methods defined in the perioperative temperature management plan."

[Recommendation]

Not a complete list of guidelines



### **Guidelines:**

#### Temperature management & Surgical site infection (SSI) prevention continued

# American College of Surgeons<sup>1</sup>

- "Studies have shown that intraoperative hypothermia is associated with increased risk of SSI, therefore, intraoperative maintenance is recommended."
- "The use of preoperative warming before short clean cases has been shown to reduce SSI and is recommended."
- "For longer cases, both preoperative warming and ongoing temperature monitoring and warming measures are recommended."

1. Ban KA, Minei JP, Laronga C, Harbrecht BG, Jensen EH, Fry DE, Itani KMF, Dellinger EP, Ko CY, Duane TM.American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. J Am Coll Surg 2017;224:59-74.

Society for Healthcare Epidemiology of America/Infectious Diseases Society of America (SHEA/IDSA)<sup>2</sup>

- "Maintain normothermia (temperature of 35.5°C or more) during perioperative period."
- "Randomized controlled trials have shown the benefits of both preoperative and intraoperative warming to reduce SSI rates and to reduce intraoperative blood loss"

[Recommendation quality of evidence grade I High]

2. Anderson DJ, Podgorny K, et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update. Infection Control and Hospital Epidemiology. 2014;35(6)

Not a complete list of guidelines

## American Society of PeriAnesthsia Nurses (ASPAN)<sup>3</sup>

- "Identify patients at increased risk for hypothermia in the perioperative period. [Recommendation]
- "Initiate preoperative/preprocedural nursing interventions to promote patient warming"
- "Patients with a temperature less than 36°C should have forced air warming initiated" [Recommendation]
- "Refer to AORN's Guideline for Prevention of Hypothermia for Intraoperative recommendations"

3. (2024). 2025-2026 Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements (1st ed.). American Society of PeriAnesthesia Nurses.

https://www.r2library.com/Resource/Title/9798895903001



# Enhanced Recovery After Surgery: Guidelines

# Association of periOperative Registered Nurses<sup>1</sup> (AORN)

- "Implement an ERAS program under the direction of the interdisciplinary team." [Recommendation]
- "Start patient warming in the preoperative period." [Recommendation]
- "Implement measures to maintain intraoperative normothermia."
- [Recommendation]

1. Implementation of ERAS (NEW). Aornguidelines.org. (n.d.). https://aornguidelines.org/guidelines/content?sectionid=246005266&view=book#246005266

# American Association of Nurse Anesthesiology<sup>2</sup> (AANA)

- Preoperative- "Maintain normothermia use warming gown"
- Intraoperative "Maintain normothermia and use active warming to decrease oxygen demand from shivering post-operatively, as well as improve healing and decrease the risk of surgical site infection."

2. Enhanced Recovery After Surgery . Aana.com. (n.d.). https://www.aana.com/practice/clinical-practice/clinical-practice-resources/enhanced-recovery-after-surgery/



Not a complete list of guidelines

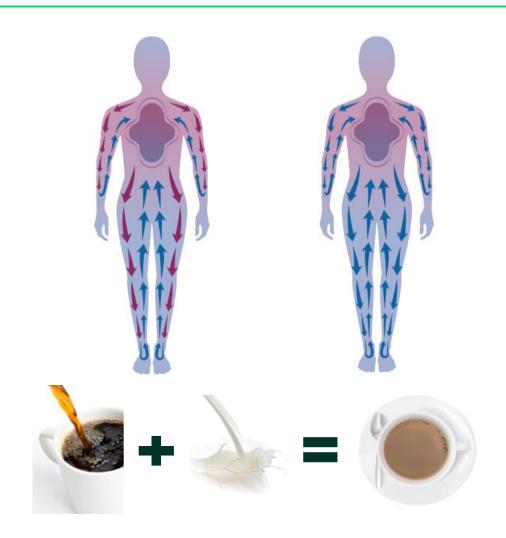
## Effects of anesthesia

Anesthesia drugs alter the hypothalamus' ability to maintain normothermia.

Anesthetic-induced vasodilation allows warmer blood from the core to flow freely and mix with the blood from the cooler periphery; cooler blood returns to the heart where it causes a drop in core temperature.<sup>1,2</sup>

This is known as **heat redistribution**, commonly referred to as **RTD** (redistribution temperature drop).

Anesthetized surgical patients cannot regulate temperature through behavioral changes and must rely on altered thermoregulation and clinical interventions to regulate temperature. <sup>1,2</sup>



<sup>2.</sup> Sessler DI. Temperature Monitoring. In: Miller RD, ed. Anesthesia. 3rd ed. New York: Churchill/Livingstone 1990



<sup>1.</sup> Sessler DI. Mild Perioperative Hypothermia. New Engl J Med. 1997;336(24):1730-1737.

# What is prewarming and why is it recommended?

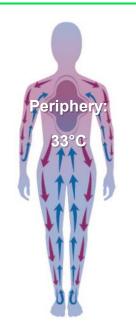
The application of heat *prior to anesthesia* for the purpose of increasing total body temperature

Prewarming = "banking heat"

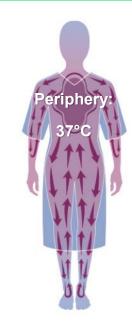
#### Why Is Prewarming Important?

It is difficult to **treat** RTD, but it can be **minimized** by prewarming.

Prewarming is the imposition of a temporary heat imbalance by active warming <u>prior</u> to anesthetic (general or neuraxial) induction to **increase the peripheral thermal compartment and mean body temperature without changing core body temperature**. <u>Effective</u> prewarming minimizes the decrease in core body temperature caused by the postinduction decrease of systemic vascular resistance (SVR) and the redistribution of body heat from the central to peripheral thermal compartment.<sup>1</sup> This is commonly referred to as Redistribution Temperature Drop (RTD).









1. Sessler DI, Schroeder M, Merrifield B, Matsukawa T, Cheng C. Optimal duration and temperature of prewarming. Anesth. 1995;82(3):674-681



# 3M<sup>TM</sup> Bair Hugger<sup>TM</sup> Warming Units

#### **Model 775**



- Hose-end temp sensing
- MERV 14 filter
- 2 fan speeds



#### Model 675





- Removable hose
- MERV 14 filter
- Filter change indicator
- Audible and visual over-temp and under-temp

#### **Model 875**



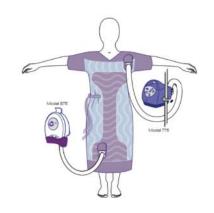
- Patient-adjustable controller
- Dust filter only
- Many mounting options

# 3M<sup>TM</sup> Bair Hugger<sup>TM</sup> Warming Gowns

#### 3 Gown Styles – globally available (used with 875 warming unit)

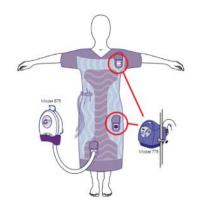


Warming gowns debuted in 2003



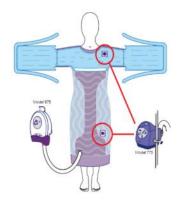
#### OR gown ('01 Gown)

- Single comfort/ prewarming port (875)
- Single OR/clinical port (675/775) – Left=Large



#### Plus gown ('02 Gown)

- Single comfort/ prewarming port (875)
- Dual OR/clinical port (675/775) Left=Large



#### Flex gown ('03 Gown)

- Single comfort/ prewarming port (875)
- 2 Bair Hugger blankets inside (675/775)
  - Upper body insert with clinical port
  - Lower body insert with clinical port
  - Left=Large



# 3M<sup>TM</sup> Bair Hugger<sup>TM</sup> Warming Gowns - Features



Hand inserts to warm hands



Easy side tie provides full coverage for modesty



Hook and Loop for easy opening at neck and shoulder



Secure hose attachment tabs on the hose end



Designed to be used through the entire perioperative journey



Patient-controlled temperature setting



Gown sides can be tucked during surgery to contain heat



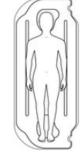
Be sure to untile back ties before positioning patient on the OR table



# 3M<sup>TM</sup> Bair Hugger<sup>TM</sup> Full Access Underbody Blanket - 63500

- Placed and secured on OR table before the patient arrives in the room.
- Accommodates patients positioned supine, prone and lateral
- Can be used in other areas of the facility as well







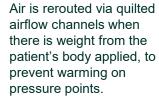
















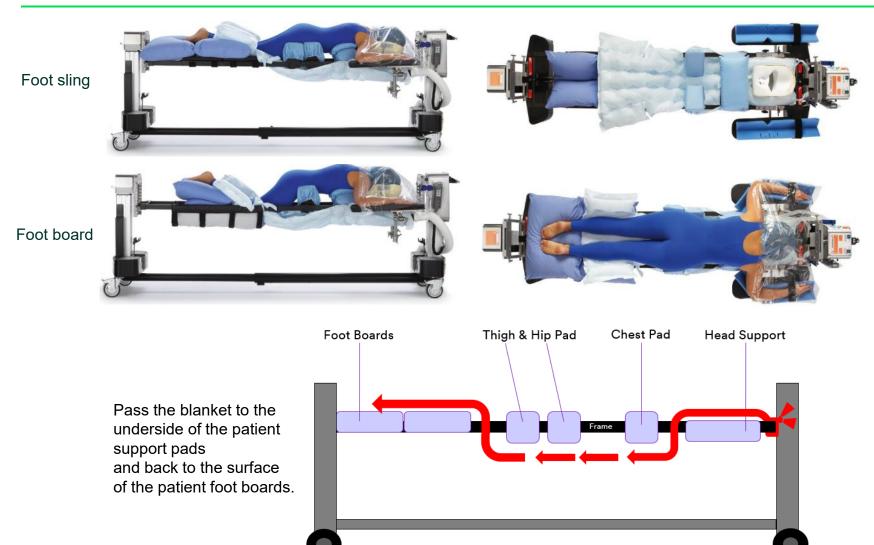
Always place a safety strap on surgical patients. Warming blankets are not designed to secure patients on OR table. Safety strap can be applied through the perforated portion on both sides of the blanket.



- Pass-through slit design allows for flexible patient positioning and drawsheet use
- Fluid outlets minimize pooling of fluids on the surface of the blanket
- Soft, radiolucent materials accommodate imaging requirements
- Perforated area at head of blanket can be removed if desired (prone position)
- Adhesive strips and tuck flaps secure the blanket to the OR/procedure table
- Resealable hose ports at either end of the blanket provide options for hose placement
- One clear plastic head drape (included) helps retain warm air around the patient's head
- Outer edges of blanket draw up next to patient, surrounding them in warmth
- Micro-perforations at the foot end are closed to prevent direct heat application to the feet



# 3M<sup>TM</sup> Bair Hugger<sup>TM</sup> Spinal Underbody Blanket - 57501







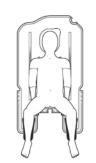


# 3M<sup>TM</sup> Bair Hugger<sup>TM</sup> Lithotomy Blanket - 58501

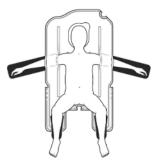
#### **Features**

- Underbody design provides full, unrestricted access to the patient and accommodate lateral, supine and lithotomy positions
- Fluid outlets minimize pooling of fluids on the surface of the blanket
- Pass-through slit design allows for flexible patient positioning and accommodates the use of a draw sheet
- Tape and tuck flaps secure the blanket to the table

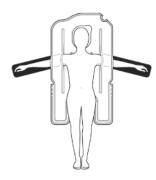
- Generously-sized perineal cut-out at the base of the blanket provides clinician unobstructed access to patient
- Integrated tie strips can be loosely secured around the stirrups/leg supports
- The blanket draws up next to patients when inflated to surround them in warmth



















Tuck flaps



Side perforations



Perineal perforated cut-out



Integrated tie strips



# Temperature Modalities

Skin Sensor Probe (measure)

Liquid Crystal Display (measure)

Temporal Artery (predict)

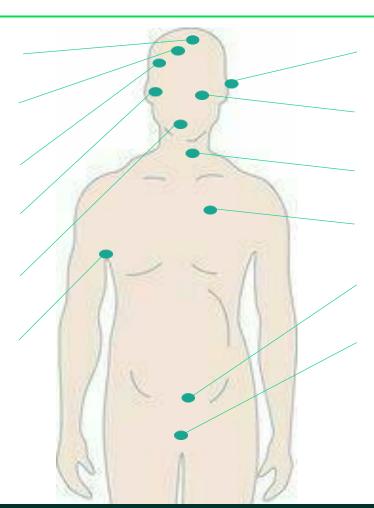
Infrared Tympanic (predict)

Oral – Sublingual (predict or measure)

Axilla (measure)

PACU & Pre-op

Less Invasive



Tympanic Membrane (measure)

Nasopharyngeal (measure)

Esophageal (measure)

Pulmonary Artery (measure)

Bladder (measure)

Rectal (predict or measure)

**Operating Room** 

More Invasive



## **AORN**

# **ASPAN**

- When possible, use the same modality throughout the surgical journey<sup>1</sup>
- Zero-heat-flux can be used to measure core temperature<sup>1</sup>
- Consider the ability to use the same modality in all phases of care<sup>2</sup>
- Zero-heat-flux (ZHF) thermometry provides an accurate reflection of the core temperature<sup>2</sup>

- 1. AORN. Recommended Practices for the Prevention of Unplanned Patient Hypothermia. AORN, Inc. 2023
- 2. ASPAN. Perianesthesia Nursing Standards, Practice Recommendations and Interpretative Statements. Practice Recommendation: Promotion of Normothermia in the Adult Patient. American Society of PeriAnesthesia Nurses. 2021-2022.



## **MHAUS**

## ACCM/IDSA

- Patients with general anesthesia >30 minutes should have core temperature monitored.<sup>1</sup>
- Most accurate and reliable method should be chosen.<sup>2</sup>

- 1. MHAUS Recommendations. MHAUS Organization. https://www.mhaus.org/healthcare-professionals/mhaus-recommendations. Accessed June 5, 2023
- 2. O'Grady NP, Barie PS, Bartlett JG, Bleck T, Carroll K, Kalil AC, Linden P, Maki DG, Nierman D, Pasculle W, Masur H; American College of Critical Care Medicine; Infectious Diseases Society of America. Guidelines for evaluation of new fever in critically ill adult patients: 2008 update from the American College of Critical Care Medicine and the Infectious Diseases Society of America. Crit Care Med. 2008 Apr;36(4):1330-49.



## **NICE**

# ASA

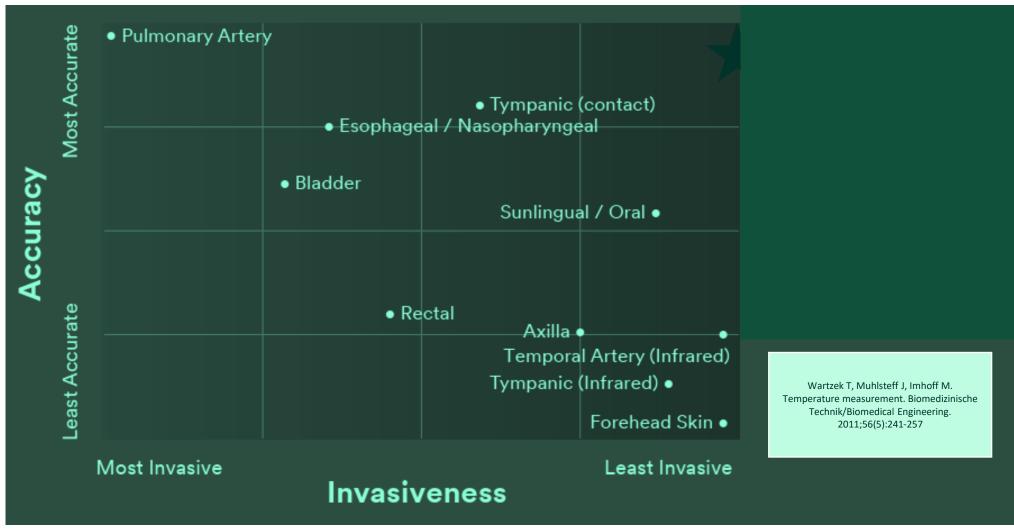
- Use a modality that is a direct measurement or direct estimate of core temperature.<sup>1</sup>
- Zero-heat-flux may be used to monitor core temperature.<sup>1</sup>

 Continually monitor temperature when giving anesthetics.<sup>2</sup>

- 1. The Management of Inadvertent Perioperative Hypothermia in Adults. NICE. https://www.nice.org.uk/guidance/cg65/chapter/Recommendations. Accessed June 5, 2023
- 2. Standards for basic anesthetic monitoring. American Society of Anesthesiologists. https://www.asahq.org/standards-and-guidelines/standards-for-basic-anesthetic-monitoring. Amended 2015. Accessed June 5, 2023



# Temperature Modality Accuracy





## Overview

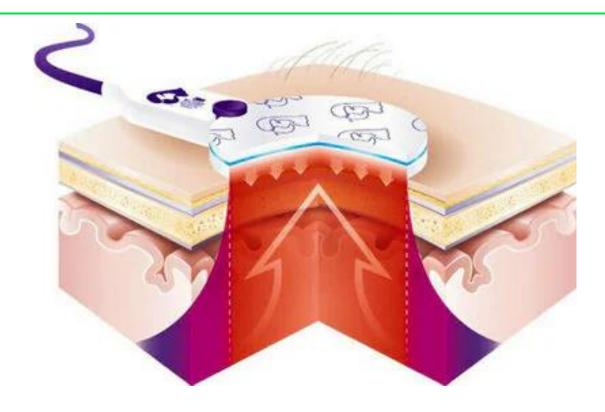


Non-invasive and accurate <u>core</u> temperature monitoring system that continuously measures temperature with a single-use sensor.





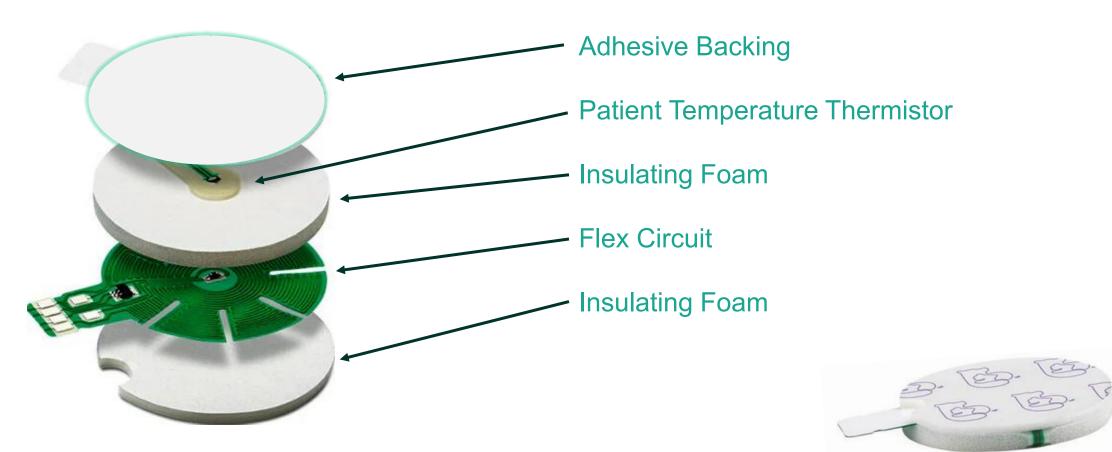
# How It Works



This image shows core temperature rising to the surface through an isothermal pathway.



## The Sensor Unveiled



Above image shows the inverse direction of how the product appears when in-use.



# **Control Unit**



Current temperature is displayed in large numbers

Previous temperature data is displayed as a trend graph

Temperature trend graph displays previous two hours of data

Temperature can be displayed in Celsius or Fahrenheit



## **Data Transfer**

Temperature data may be continuously transmitted to a compatible patient vital signs monitor and electronic medical record.



3M™ Bair Hugger™ Temperature Monitoring System

Patient Vital Signs Monitor

**EMR** 



# 3M<sup>TM</sup> Bair Hugger<sup>TM</sup> Temperature Monitoring System



Non-invasive and accurate <u>core</u> temperature monitoring system that continuously measures temperature with a single-use sensor.

Rx Only. This product is intended to be used by trained medical professionals in a clinical/surgical setting.



# Thank you!





# Solventum