A Summary of Clinical Evidence

3M™ Skin and Nasal Antiseptic
(Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP)
Patient Preoperative Skin Preparation

An innovative approach to help reduce the risk of surgical site infection (SSI)
Contents

Introduction ................................................................. 3


Rezapoore M, Nicholson T, Patel R, Mostafavi R, Chen AF, Parvizi J. Do iodine-based solutions differ in their effectiveness for decolonizing intranasal *Staphylococcus aureus*? Presented at the MSIS Annual Meeting, Cleveland, OH, August 2015. ................................. 7


Rivera K, Smith R, Hardenstine H, Rose L, Snedeker L, Wolfgang J. Implementation of a total joint replacement pre-operative skin and nasal decolonization process for the reduction of *Staphylococcus aureus* (SA) and methicillin resistant *Staphylococcus aureus* (MRSA) infection. Presented at the APIC National Conference, Charlotte, NC, June 2016. ................................. 9


Waibel ML. Revisiting process improvement for total joint arthroplasty SSI. Presented at the APIC National Conference, Fort Lauderdale, FL, June 2013 ........... 11


Osborn N, Reynolds L. Embedding an Infection Preventionist (IP) in the OR. Presented at the AORN Surgical Conference and Expo, Denver, CO, March 2015 ................................. 13
An innovative yet simple solution to a complex problem.

Surgical site infection (SSI) is associated with increased mortality and health care costs. Colonization with *S. aureus* is a modifiable risk factor for infection; however, addressing nasal carriage of bacteria may sometimes be overlooked.

**3M™ Skin and Nasal Antiseptic** is an innovative solution for reducing bacteria in the nares. The proprietary formula has broad spectrum antibacterial activity and no resistance has been shown in vitro. Applied just one hour before surgery, it works quickly to reduce bacteria in the nares, including *S. aureus* by 99.5% and maintains this reduction for at least 12 hours. One-time directly observed preoperative application ensures patient compliance and provider control over a well-documented, modifiable risk factor for infection.

Reducing *S. aureus* in the nares can help reduce the risk of SSI. 3M Skin and Nasal Antiseptic provides a simple solution to address nasal carriage of *S. aureus* and the clinical evidence is mounting for this safe and effective approach. This review provides a summary of clinical evidence that demonstrates that 3M Skin and Nasal Antiseptic helps reduce the risk of SSI when part of a comprehensive preoperative protocol.

* Clinical significance of in vitro data is unknown.

References

2. 3M Study-05-011017
3. 3M Study-05-010945
4. 3M Study-05-011322
5. 3M Study-05-01100
Background: Decolonization with mupirocin presented barriers including poor patient compliance and concerns about antibiotic resistance that led to a search for an alternative.

Design: Investigator initiated, prospective randomized controlled open-label trial comparing deep SSI within 90 days after surgery.

Surgeries: Arthroplasty or spine fusion

Methods: All patients were provided 2% CHG cloths for use the evening prior to and the morning of surgery

- Randomized to either:  
  - 3MTM Skin and Nasal Antiseptic (PI group), 1 dose given in the pre-operative hold area within 2 hours of incision,  
  - Bactroban Nasal® (antibiotic group), twice daily for the 5 days prior to surgery

Results: 1697 patients were included in the intent-to-treat analysis and 1,539 in the per-protocol. Efficacy results in the intent to treat and per protocol groups are provided in the graphs below. Patients in the 3MTM Skin and Nasal Antiseptic group reported significantly fewer treatment-related adverse events (1.8% vs 8.9%, p < 0.05) than the mupirocin group.

### Overall Infection Rate

<table>
<thead>
<tr>
<th></th>
<th>Nasal Antiseptic</th>
<th>Mupirocin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent to Treat</td>
<td>1.6% (p = 0.1)</td>
<td>0.7%</td>
</tr>
<tr>
<td>Per Protocol</td>
<td>1.7% (p = 0.06)</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

### S. aureus Infection Rate

<table>
<thead>
<tr>
<th></th>
<th>Nasal Antiseptic</th>
<th>Mupirocin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent to Treat</td>
<td>0.6% (p = 0.2)</td>
<td>0.1%</td>
</tr>
<tr>
<td>Per Protocol</td>
<td>0.7% (p = 0.03)</td>
<td>Zero S. aureus infections</td>
</tr>
</tbody>
</table>


*Approximate costs: Brand Nasal Mupirocin $55 to $130 and Nasal Antiseptic $16

©Bactroban Nasal is a registered trademark of GlaxoSmithKline.
“Universal decontamination using this low-cost protocol may be considered as an additional prevention strategy for SSIs in patients undergoing orthopedic surgery...”


**Design:** Investigator initiated, prospective before-and-after intervention cohort study comparing surgical site infection rates within 30 days of surgery

**Surgeries:** Elective orthopedic surgery with hardware implantation

**Methods:** Control and intervention groups received standard perioperative prevention measures.

**Intervention:**
- Preoperative decontamination protocol:
  - 2% chlorhexidine gluconate cloths and 0.12% chlorhexidine oral rinse the night before and morning of surgery AND
  - 3M™ Skin and Nasal Antiseptic the morning of surgery

**Results:**

**Surgical Site Infection Rate Reduction**

A total of 709 patients were included, 344 patients in control group, 365 patients in intervention group

Multivariate logistic regression identified the decontamination protocol as a significant independent protective factor against SSI (OR 0.24 [95% CI, 0.08-0.77]; \(p = 0.02\))

100% compliance to decontamination protocol in intervention group
This new protocol using 3M™ Skin and Nasal Antiseptic does not rely on patient compliance, eliminates the risk of mupirocin resistance and resulted in an average cost savings of $93.95 per patient.


**Objective:** The purpose of this study was to compare the efficacy and cost of 3M™ Skin and Nasal Antiseptic to MRSA screening and treatment with mupirocin.

**Design:** Investigator initiated, retrospective, before-and-after intervention study comparing surgical site infection rates within 90 days of surgery and cost-effectiveness of each protocol.

**Surgeries:** Primary or revision total knee arthroplasty (TKA) or total hip arthroplasty (THA)

**Methods:**

- **Control:** All patients undergoing primary or revision TKA or THA surgery from November 2011-April 2013 were screened for MRSA. Those who were culture positive were treated preoperatively with mupirocin twice daily for 5 days.

- **Intervention:** May 2013-October 2014 - All patients received 3M™ Skin and Nasal Antiseptic preoperatively.

All patients from both groups were also instructed to bathe with chlorhexidine gluconate (CHG) for 5 days before surgery and the operative leg was cleansed with a CHG wipe in preop on the day of surgery.

**Results:**

<table>
<thead>
<tr>
<th>Infection Rate and Cost</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection Rate</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Avg Cost Per Patient</td>
<td>$121.16</td>
<td>$27.21</td>
</tr>
</tbody>
</table>

1,853 patients were included; 849 in the control group, 1004 in the intervention group.

There was no difference in the SSI rate between groups (0.8% in both groups); (p=1.0).

There was a significant difference in the mean cost per case between the MRSA screening group ($121.16) and the 3M™ Skin and Nasal Antiseptic group ($27.21); (p≤ 0.01).
Off the shelf povidone iodine is not as effective as 3M™ Skin and Nasal Antiseptic for intranasal S. aureus decolonization.


Objective: The purpose of this study was to compare the efficacy of off the shelf 10% povidone iodine to 3M™ Skin and Nasal Antiseptic (5% povidone iodine).

Design: Investigator initiated, prospective randomized controlled trial comparing nasal S. aureus cultures at baseline, 4 and 24 hours after treatment.

Surgeries: Primary total joint arthroplasty

Methods: Patients were randomized to preoperatively receive one of three nasal treatments:
- Off the shelf 10% povidone iodine (10% PI)
- 3M™ Skin and Nasal Antiseptic (3M 5% PI)
- Saline (control)

All treatments were applied according to the 3M™ Skin and Nasal Antiseptic instructions for use. Nasal swabs were taken for cultures preoperatively prior to nasal treatment (baseline), and at 4 hours and 24 hours after treatment.

Results:

Negative Nasal S. aureus Cultures Post Treatment

<table>
<thead>
<tr>
<th></th>
<th>3M 5% PI (n=34)</th>
<th>10% PI (n=34)</th>
<th>Saline (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 hours</td>
<td>79%</td>
<td>48%</td>
<td>41%</td>
</tr>
<tr>
<td>24 hours</td>
<td>41%</td>
<td>41%</td>
<td>28%</td>
</tr>
</tbody>
</table>

429 patients were randomized, of which 95/429 (22.1%) were positive at baseline for S. aureus and 13.6% of these were MRSA. 3M™ Skin and Nasal Antiseptic demonstrated significantly more effective intranasal decolonization of S. aureus over the 4 hour time interval (p=0.003).
“Pre-operative use of 3M™ Skin and Nasal Antiseptic on nasal mucosa prior to surgical intervention resulted in a statistically significant decrease in post-operative infections.”


Design: Investigator initiated, before-and-after intervention study comparing SSI rates.

Surgeries: Spine surgery

Methods:

Control: All patients undergoing spine surgery from January 2009-August 2010

Intervention: September 2010-November 2011- All patients received 3M Skin and Nasal Antiseptic at least one hour prior to surgery

Results:

9,135 patients were included; 5,154 in the control group and 3,981 in the intervention group.

The SSI rate was significantly lower in the intervention group (0.45%; 18/3,981 patients) than in the control group (1.22%; 63/5,154 patients) (p=0.0029)
“The rates of total and SA/MRSA SSI after joint replacement were significantly lower in the post-intervention timeframe when compared to baseline.”


**Results:**

**Overall Infection Rate**

(Cases per 100 Subjects)

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total SSI</strong></td>
<td>1.52%</td>
<td>1.70%</td>
</tr>
<tr>
<td><strong>p</strong></td>
<td>0.0006</td>
<td></td>
</tr>
<tr>
<td><strong>SA/MRSA SSI</strong></td>
<td>0.76%</td>
<td>0.33%</td>
</tr>
<tr>
<td><strong>p</strong></td>
<td>0.0095</td>
<td></td>
</tr>
</tbody>
</table>

8,961 patients were included; 2,507 in the control group and 6,454 in the intervention group.

The total SSI rate was significantly lower in the intervention group (0.70/100 procedures) than in the control group (1.52/100 procedures); (p=0.0006).

The SA/MRSA SSI rate was significantly lower in the intervention group (0.33/100 procedures) than in the control group (0.76/100 procedures); (p=0.0095).

**Design:** Investigator initiated, before-and-after intervention study comparing SSI rates.

**Surgeries:** Knee or hip arthroplasty

**Methods:**

**Control:** Patients undergoing hip or knee replacement from Jan 2012-Sept 2013 were encouraged to bathe with CHG or antibacterial soap for two days prior to their procedure.

**Intervention:** Oct 2013-Mar 2016- Patients were provided CHG soap and instructed to bathe with it for three days prior to surgery. 3M™ Skin and Nasal Antiseptic was applied in the preop department the day of surgery.
Background: Aspects of a bundle that included appropriate antibiotic use, appropriate hair removal, alcohol containing skin prep and 3 days of preoperative chlorhexidine gluconate bathing were already in place. Implementation of the final element of the bundle, *Staphylococcus aureus* screening and decolonization with mupirocin, was associated with barriers including increased time, increased cost and potential for mupirocin resistance.

Design: Investigator initiated, before-and-after intervention study comparing SSI rates.

Methods: Total joint arthroplasty

Intervention: 3M™ Skin and Nasal Antiseptic the morning of surgery (instead of screening and treating carriers)

Results: The overall rate of SSI decreased significantly following implementation of 3M™ Skin and Nasal Antiseptic.

**Arthroplasty SSI (All Pathogens)**

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hip</strong></td>
<td>1.17%</td>
<td>0.50%</td>
</tr>
<tr>
<td><strong>Knee</strong></td>
<td>0.85%</td>
<td>0.62%</td>
</tr>
<tr>
<td><strong>Hips &amp; Knees</strong></td>
<td>1.01%</td>
<td>0.53%</td>
</tr>
</tbody>
</table>

**Arthroplasty SSI (S. aureus)**

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hip</strong></td>
<td>0.61%</td>
<td>0.22%</td>
</tr>
<tr>
<td><strong>Knee</strong></td>
<td>0.27%</td>
<td>0.34%</td>
</tr>
<tr>
<td><strong>Hips &amp; Knees</strong></td>
<td>0.46%</td>
<td>0.28%</td>
</tr>
</tbody>
</table>
“The readmission cost avoidance was $62,302 based on the actual cost of MRSA SSI readmissions in the six months prior to the product trial.”

Waibel ML. Revisiting process improvement for total joint arthroplasty SSI. Presented at the APIC National Conference, Fort Lauderdale, FL, June 2013.

**Background:** A lean process improvement in 2009 was successful in reducing total hip arthroplasty (THA) infections and was then adopted for total knee arthroplasty (TKA).

By the end of 2011, the number of THA and TKA infections increased, indicating that these processes were no longer in control.

**Design:** Investigator initiated, before-and-after intervention study comparing SSI rates.

**Surgeries:** Total joint arthroplasty

**Intervention:**
- Realignment of previous lean process improvements
- 3M™ Nasal Antiseptic the morning of surgery (Feb 2012-Jan 2013)

**Results:**

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Total SSI</th>
<th>MRSA SSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/2011 - 1/2012</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>2/2012* - 7/2012</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>8/2012 - 1/2013</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Note: 3M Skin and Nasal trial began 2/2012 for all total joint patients

No MRSA infections were identified after intervention implementation.

Read the Abstract
“The number of THA/TKA SSIs was reduced to zero in the seven months following implementation of the best practice bundle.”


**Results:**

**Design:** Investigator initiated, before-and-after intervention study comparing SSI rates.

**Surgeries:** Total hip arthroplasty (THA) and Total knee arthroplasty (TKA)

**Intervention:**

**Best practice bundle:**

- 2% chlorhexidine gluconate (CHG) cloths the night before and morning of surgery
- 3M™ Skin and Nasal Antiseptic applied in preop holding
- Patient warming 30 minutes preop and during surgery using 3M™ Bair Paws™ System
- Antibiotic infusion completed 10 minutes prior to incision
- Team huddle prior to patient entry into OR to review completion of checklist and coordination of start time for opening of instruments.

---

**Read the Abstract**
“We experienced a 61% reduction in neurosurgery spinal fusion infections resulting in a cost savings of $228,635 within 12 months.”

Osborn N, Reynolds L. Embedding an Infection Preventionist (IP) in the OR. Presented at the AORN Surgical Conference and Expo, Denver, CO, March 2015.

**Design:** Investigator initiated, before-and-after intervention study comparing surgical site infection (SSI) rates.

**Surgeries:** Spine fusion

**Intervention:** Jan 2013 Infection Preventionist (IP) with OR experience was embedded in the OR

- June 2013 – in addition to IP, implemented bundle:
  - Prewarming with Bair Paws warming gown
  - CHG bathing
  - 3M™ Skin and Nasal Antiseptic

Infection rates and hypothermia rates were tracked.

**Results:**

**Spine Fusion Infection Rate**

Surgeries without intervention had 5 times the number of SSIs compared to those that received the intervention.

In random sampling of groups of 10 patients, hypothermia rates were reduced to zero with improved utilization of prewarming.

---

Read the Abstract
3M is here to help you lead

3M Infection Prevention is truly on a mission to help reduce healthcare-associated infections through innovative infection prevention solutions.

With our system of people, products and processes, 3M remains a trusted resource, committed to helping health care facilities reduce the risk of infections, improve patient outcomes, and control their bottom lines.

Designed to be used in the preoperative process, 3M™ Skin and Nasal Antiseptic replaces patient-applied nasal treatments. It’s a simple step that makes a difference in helping to reduce the risk of surgical site infections. [www.3m.com/morecontrol](http://www.3m.com/morecontrol)