3M™ Skin and Nasal Antiseptic

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

Safety & Efficacy Information

Reduce bacteria in the nares in one hour.[1]

3M Infection Prevention Solutions

Innovation On A Mission

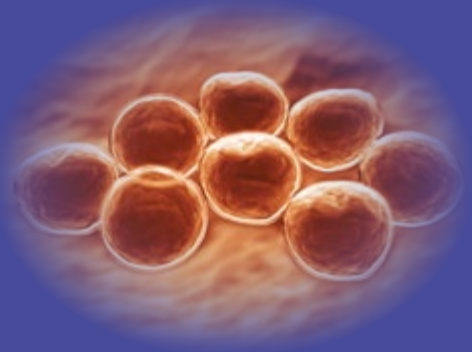
3M

Staphylococcus aureus is the leading cause of surgical site infections (SSIs).[2]

Approximately 30% of the population are colonized with *S. aureus* in the nares.[3]

80% of *S. aureus* infections are caused by the patient's own (clonal) nasal flora.[4]

Nasal carriage of *S. aureus* is a significant risk factor for developing SSI with *S. aureus*.[5,6]



Preventing a single case of SSI due to MRSA can save hospitals as much as $60,000.[7]

3M™ Skin and Nasal Antiseptic reduces bacterial counts in the nares in one hour, including *S. aureus* by 99.5%, and maintains this reduction for at least 12 hours.[1]

No increase in resistance to 3M™ Skin and Nasal Antiseptic has been shown in antibiotic-resistant strains of *S. aureus*.[8]

3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation was specifically developed by 3M to address the rising concern of surgical site infections caused by bacteria in the nares.

Assurance	Reduces bacteria in the nares[1] so you know you're helping address another variable in the fight against surgical site infections[2]
Control	Works within one hour and easily fits within your facility preoperative process, so you can ensure compliance
Science	Strong research and development created an effective, patented formula to compensate for the unique physiology of the nose
Safety	Active ingredient has been used for over 100 years, and has not been shown to lead to resistance,[3] so it won't impact your antibiotic stewardship
Easy	Antiseptic that does not require special handling and storage
Comfort	Formula is pH balanced to be non-irritating to the nares
Clean	Special formula designed not to drip

Safety

Safety Assessment of Active Ingredient

Based on *in vitro* and *in vivo* work with povidone-iodine (PVP-I) in human nares, the maximum concentration that has been used in clinical studies without adverse health effect was at a maximum dosage concentration of 5% PVP-I.

Iodine is a trace element essential to life and present throughout the body. True allergy to iodine does not exist. A very small number of patients who are extremely predisposed to allergy may exhibit sensitivity to various skin preparations.

Safety Testing — Clinical study[9] (Expert Grader Safety Assessment)

Purpose: The objective of the study (completed in 2009) was to assess the safety (irritation) of 3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation compared to a control after two applications in each nostril.

Method: Using a light scope, both nostrils of 30 subjects were assessed by an Expert Grader of skin irritation who was blinded to the study design. The level of erythema and edema were assessed using the Draize scale. Each subject was randomized to either 3M™ Skin and Nasal Antiseptic (n = 20) or 0.9% saline control (n = 10). The subject's nostrils were prepped for 30 seconds each, two times each, using four separate foam-tipped applicators saturated with the pre-determined solution. After 60 minutes, the same blinded Expert Grader, using a light scope, assessed both nostrils of the 30 subjects for the level of erythema and edema.

Results: The mean primary irritation scores obtained were 0.0 and –0.2 for the 3M™ Skin and Nasal Antiseptic and saline control groups, respectively. The primary irritation index (PII) is the difference in mean primary irritation score between the 3M™ Skin and Nasal Antiseptic and control groups. Therefore the estimated PII value is 0.0 – (–0.2) = 0.2. This value falls in the category of nonirritating. 3M™ Skin and Nasal Antiseptic was found to be nonirritating after two applications in each nostril.

Efficacy

Log Reduction Overview

The number of bacteria represented by log reduction is dependent upon the number of bacteria present initially (baseline). For example, if the baseline is 4 logs and the reduction is 3 logs, only 1 log of bacteria remains which is equal to 10 colony forming units (CFU). However, if the baseline is 6 logs and the reduction is 3 logs, 3 logs of bacteria remain which is 1000 CFUs.

Logs	No. of bacteria
1	10
2	100
3	1,000
4	10,000
5	100,000
6	1,000,000

Log reduction	% reduction of bacteria
1	90
2	99
3	99.9
4	99.99
5	99.999
6	99.9999

Efficacy
In Vivo Microbiology

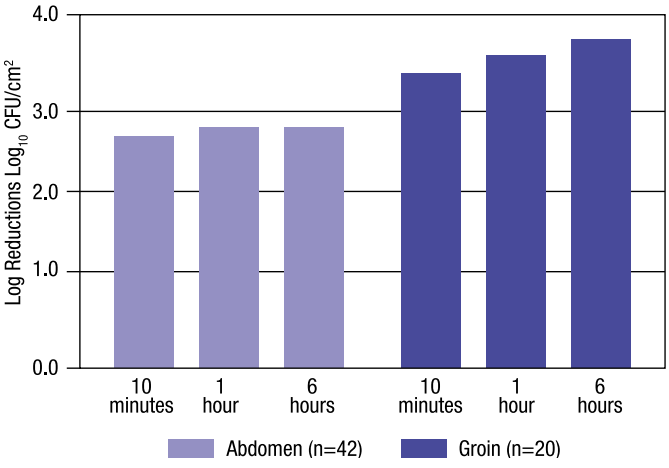
Antimicrobial Effectiveness Against Resident Human Skin Flora on Abdomen and Groin Sites[10]

Purpose: The primary objective of this study (completed in 2009) was to assess the bactericidal effect of 3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation on the abdomen and groin. The study was conducted using the methodology described in the Tentative Final Monograph for Health-Care Antiseptic Drug Products[11] to show efficacy on the skin of healthy volunteers.

Method: Baseline samples were taken before the application of the prep. One at a time, the foam-tipped applicators were saturated with the appropriate solution using a vigorous stirring motion in the bottle for at least 10 seconds. 3M™ Skin and Nasal Antiseptic was applied to the abdomen (n = 42) and groin (n = 20) test sites for two minutes with one applicator followed by a second applicator for an additional two minutes (total prep time = 4 minutes). Post-prep samples were taken at 10 minutes, one hour, and six hours from the abdomen and the groin.

Results: 3M™ Skin and Nasal Antiseptic meets the TFM requirements of producing a 2 log reduction in bacteria on the abdomen and a 3 log reduction on the groin at ten minutes post-prep, and maintains these log reductions for at least six hours post-prep.

Figure 1: Reduction of Resident Flora on Abdominal and Groin Sites



Antimicrobial Effectiveness Against Resident Human Nasal Flora, Mainly *Staphylococcus aureus,* vs. a Saline Control[1]

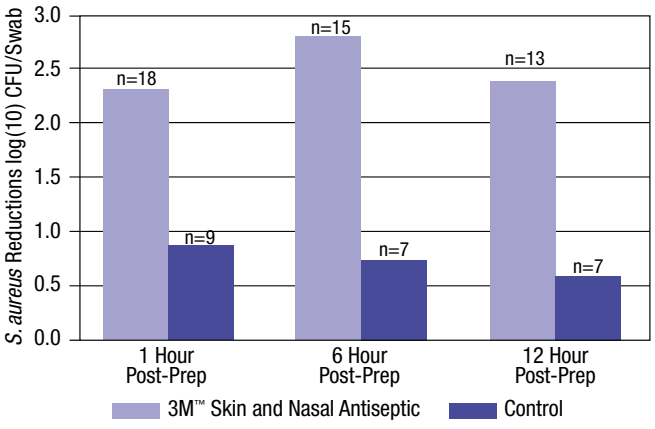
Purpose: The purpose of this study (completed in 2009) was to assess the antimicrobial efficacy of 3M™ Skin and Nasal Antiseptic on the nasal flora of healthy volunteers versus a saline control. The study measured the reduction of *S. aureus* at 1, 6, and 12-hours post treatment application. The reduction of total bacteria was also measured at these time points. Product acceptability data was collected from the subjects using a questionnaire.

Method: Thirteen to eighteen subjects (depending on time point) applied 3M™ Skin and Nasal Antiseptic following the instructions for nasal application. Seven to nine subjects (depending on time point) applied the 0.9% saline control.

One at a time, the foam-tipped applicators were saturated with the appropriate solution using a vigorous stirring motion for at least 10 seconds. The subject's nostrils were prepped for 30 seconds each using separate applicators. This process was then repeated using two additional applicators for a total application time of 1 minute per nare (2 minutes total). Post-prep samples were taken at 1-hour, 6-hours, and 12-hours from the nares. Baseline samples were taken before the application of the prep or control.

Results: 3M™ Skin and Nasal Antiseptic killed 99.5% of *S. aureus* within 1-hour and maintained the 99.5% kill for at least 12-hours post-prep (figure 2). 3M™ Skin and Nasal Antiseptic killed 99.2% of the total bacteria within 1-hour and maintained a 98.8% kill for at least 12-hours post-prep. The *S. aureus* count and the total bacterial count for 3M™ Skin and Nasal Antiseptic were significantly different from baseline using a paired t-test (*P*-value ≤ 0.0004). 3M™ Skin and Nasal Antiseptic showed significantly more *S. aureus* reduction as well as more total bacterial reduction than control using a 2-sample t-test (*P*-value ≤ 0.02).

Figure 2: 3M™ Skin and Nasal Antiseptic *S. aureus* Reduction in the Nares Post-prep for Subjects with Baseline Counts of at least 3.7 Log_{10}



Efficacy
In vitro† Microbiology

In vitro Time-Kill Assay of 3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation[12]

Purpose: The objective of this study (completed in 2009) was to assess how rapidly 3M™ Skin and Nasal Antiseptic produces its effect on a wide variety of organisms.

Method: Known populations of the microorganisms were applied to the surface of duplicate membrane filters for each contact time. 3M™ Skin and Nasal Antiseptic (0.5 mL) in a 1:10 dilution was applied to the filters for one minute, three minutes, and five minutes. The activity of the prep was stopped (neutralized) at each time point. Surviving bacteria were enumerated and the $\log_{10}$ reduction from the initial population was calculated.

Results: 3M™ Skin and Nasal Antiseptic demonstrated rapid bactericidal activity against a broad range of microorganisms. It demonstrated bactericidal activity against aerobic gram-positive and gram-negative bacteria including antibiotic-resistant strains such as methicillin-resistant *Staphylococcus aureus* (including CA-MRSA and HA-MRSA), methicillin-resistant *Staphylococcus epidermidis* (MRSE) and vancomycin-resistant *Enterococcus faecium* and *Enterococcus faecalis* (VRE) and yeast. See Table 1 for complete results.

Table 1: Time Kill Study

Microorganism	1 Minute	3 Minutes	5 Minutes
Candida albicans (ATCC 10231)	99.999	99.999	99.999
Enterococcus faecalis (ATCC 29212)	99.953	99.999	99.999
Enterococcus faecalis (VRE) (ATCC 51299)	99.979	99.999	99.999
Enterococcus faecium (MDR) (ATCC 51559)	83.571	99.999	99.999
Escherichia coli (ATCC 11229)	99.999	99.999	99.999
Escherichia coli (ATCC 25922)	99.999	99.999	99.999
Klebsiella pneumoniae (ATCC 11296)	99.999	99.999	99.999
Micrococcus luteus (ATCC 7468)	99.999	99.999	99.999
Pseudomonas aeruginosa (ATCC 15442)	99.999	99.999	99.999
Pseudomonas aeruginosa (ATCC 27853)	99.999	99.999	99.999
Serratia marcescens (ATCC 14756)	99.999	99.999	99.999
Staphylococcus aureus (ATCC 6538)	99.999	99.999	99.999
Staphylococcus aureus (ATCC 29213)	99.999	99.999	99.999
Staphylococcus aureus (MRSA) (ATCC 33592)	99.999	99.999	99.999
Staphylococcus aureus (MRSA) (ATCC 43300)	99.999	99.999	99.999
Staphylococcus aureus (MRSA) (BAA-811)	99.999	99.999	99.999
Staphylococcus aureus (CA-MRSA USA300) (BAA-1556)	99.999	99.999	99.999
Staphylococcus aureus (HA-MRSA USA100) (NRS 382)	99.999	99.999	99.999
Staphylococcus epidermidis (ATCC 12228)	99.999	99.999	99.999
Staphylococcus epidermidis (MRSE) (ATCC 51625)	99.999	99.999	99.999
Streptococcus pyogenes (ATCC 19615)	99.999	99.999	99.999

CA: community associated
HA: healthcare associated
MRSA: methicillin-resistant *Staphylococcus aureus*
MRSE: methicillin-resistant *Staphylococcus epidermidis*
MDR: multiple drug resistant (ampicillin, ciprofloxacin, gentamicin, rifampin, teicoplanin, vancomycin)

In vitro Minimum Bactericidal Concentration Study of 3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation[13]

Purpose: The purpose of this study (completed in 2009) was to determine the minimal concentration (in micrograms per milliliter) of 3M™ Skin and Nasal Antiseptic resulting in complete kill of microorganisms after a 30 minute contact time.

Method: The method used in this study incorporated the National Committee for Clinical Laboratory Standards "Methods for Dilution Antimicrobial Susceptibility Test for Bacteria that Grow Aerobically".[14] 3M™ Skin and Nasal Antiseptic was tested at twofold serial dilutions and the lowest concentration that resulted in complete kill of the organism was recorded as the Minimum Bactericidal Concentration (MBC) for iodine.

Results: Fifty-seven ATCC and clinical isolates (including strains of CA-MRSA, HA-MRSA, MRSE and VRE) were tested.

Table 2: Organisms Tested with MBC range (µg/mL)

Microorganism	ATCC Strain	MBC (µg/mL)	Clinical Isolate ID	MBC (µg/mL)
Acinetobacter baumannii (MDR)	BAA-1605*	0.25 – 0.5	032107Ab7*	0.25 – 1
Bacteroides fragilis	25285	0.25	042006Bf11	>64
Burkholderia cepacia	35254	0.5	051707Bc6	1
Haemophilus influenzae	33391	≤0.063 – 0.125	071906Hi8	0.125
Enterobacter cloacae	13047	0.25	111705Ecl13	0.5
Escherichia coli	11229	0.5	111705Ec22	0.5
Escherichia coli	25922	0.125 – 0.5	NA	NA
Klebsiella oxytoca	15764*	0.25 – 0.5	111705Ko19	0.25 – 0.5
Klebsiella pneumoniae	11296	1	111705Kpn8	0.25
Pseudomonas aeruginosa	15442	0.5 – 1	112905Pa7	0.5 – 1
Pseudomonas aeruginosa	27853	0.25 – 0.5	NA	NA
Proteus mirabilis	29906	0.25 – 0.5	112905Pm23	0.5
Serratia marcescens	14756	0.5	112905Sm26	0.5
Staphylococcus aureus	6538	0.25 – 0.5	NA	NA
Staphylococcus aureus	29213	0.25 – 1	NA	NA
Staphylococcus aureus (MRSA)	33592*	0.125 – 0.25	120607MRSa47*	0.125
Staphylococcus aureus (MRSA)	43300*	0.5	NA	NA
Staphylococcus aureus (CA-MRSA or HA-MRSA)	BAA-1556* USA300	0.25	042508NRSa382* USA100	0.5
Staphylococcus aureus (MRSA)	BAA-811*	0.25 – 0.5	NA	NA
Staphylococcus epidermidis	12228	0.25	112905Se25	0.125 – 0.25
Staphylococcus epidermidis (MRSE)	51625*	0.125	NA	NA
Staphylococcus hominis	27844	0.25 – 1	010606Sho39	0.5 – 1
Staphylococcus haemolyticus	29970	0.125 – 0.25	122305Sha44	0.25 – 0.5
Staphylococcus saprophyticus	15305	≤0.063 – 0.25	122305Ss46	0.125 – 0.5
Micrococcus luteus	7468	1	071906Ms11	0. 25
Streptococcus pyogenes	12344	0.5	071906Spy4	0.5 – 1
Enterococcus faecalis	29212	0.5 – 1	071906Efs7	0.5
Enterococcus faecalis (VRE)	51299*	0.5 – 1	NA	NA
Enterococcus faecium	19434	0.5 – 1	071906Efm5	1
Enterococcus faecium (MDR)	51559*	0.25	NA	NA
Streptococcus pneumoniae	33400	64	011706Spn17	0.5
Candida albicans	18804	2	011706Ca26	2
Candida tropicalis	42678	2	011706Ct2	2

* Antibiotic resistant organism
NA = Not applicable
CA: community associated
HA: healthcare associated
MDR: multi-drug resistant
MRSA: Methicillin-resistant *Staphylococcus aureus*
MRSE: Methicillin-resistant *Staphylococcus epidermidis*
VRE: Vancomycin-resistant *Enterococcus*

Acceptability

Acceptability as Rated by Study Subjects[1,9]

Purpose: The objective of two clinical studies (completed in 2009) was to assess the subject acceptability of 3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation and the nasal prepping procedures after two applications in each nostril.

Method: Subjects applied 3M™ Skin and Nasal Antiseptic with foam-tipped applicators saturated with the prep solution using the following procedures: Each nostril was prepped two times for 30 seconds each time, using a separate foam-tipped applicator for each application. Subjects were then asked to fill out a questionnaire answering questions about their experience after each dose (76 questionnaires completed).

Results: 96% of the subjects rated the overall acceptability of 3M™ Skin and Nasal Antiseptic as acceptable or very acceptable when used for nasal prepping (Figure 4).

Figure 3: Application Questionnaire Response of Subjects Prepped with 3M™ Skin and Nasal Antiseptic

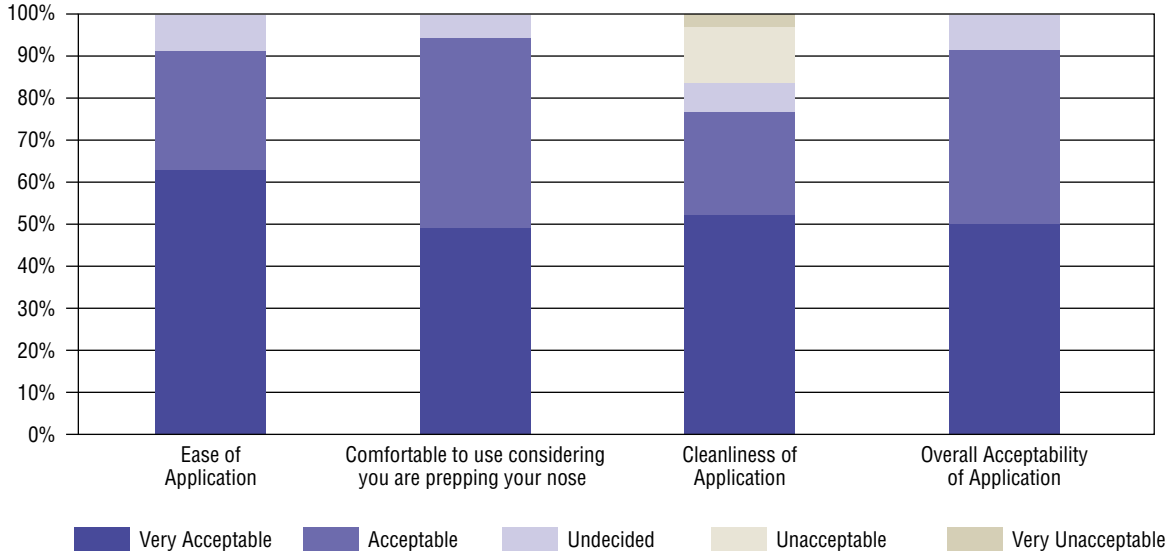
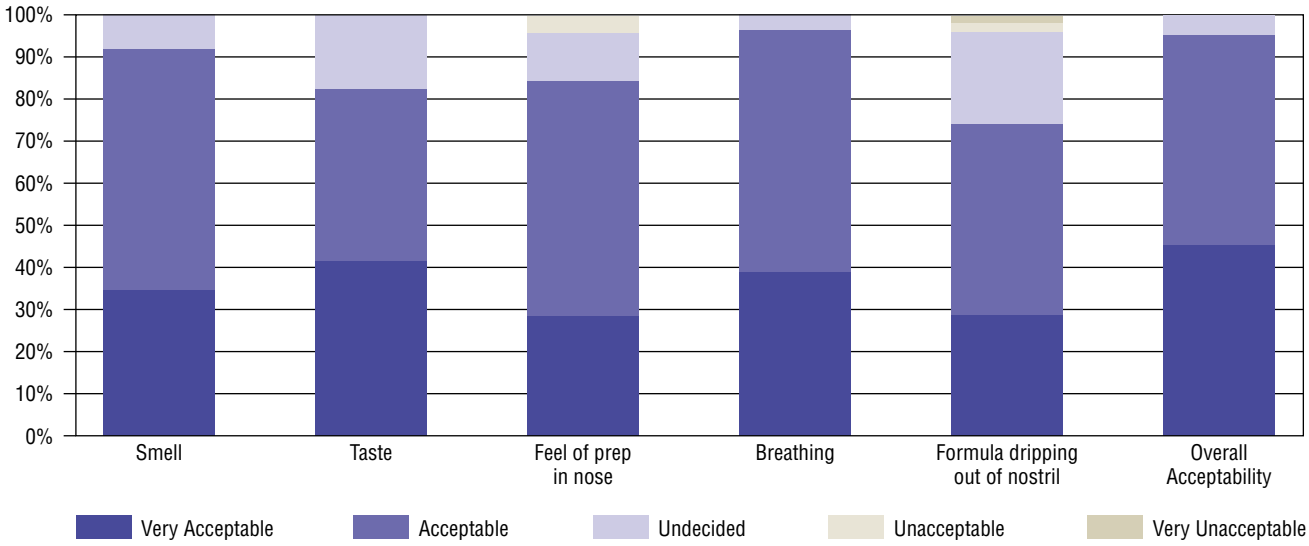


Figure 4: 3M™ Skin and Nasal Antiseptic Questionnaire Response of Subjects Prepped



Bacterial Resistance†

Assessment of the Potential for Development of Bacterial Resistance to 3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation[8]

Purpose: Antiseptics are extensively used in hospitals and other health care settings for a variety of topical applications. Antibiotics are also used in healthcare and have been shown to induce antibiotic resistance in many organisms. The widespread use of antiseptics has prompted some speculation on the development of microbial resistance similar to what is seen with antibiotics. The purpose of this study was to screen 3M™ Skin and Nasal Antiseptic against various strains of methicillin-resistant *Staphylococcus aureus* (MRSA) to assess the development of resistance of the organisms to the antiseptic.

Method: This study tested 11 strains of MRSA versus 3M™ Skin and Nasal Antiseptic in an agar-dilution procedure to determine the Minimum Inhibitory Concentration (MIC) of the test product, and subsequently, to screen for the development of resistance. The challenge strains were 10 NARSA (Network on the Antimicrobial Resistance in *Staphylococcus aureus* [Herndon, VA]) clinical isolates and 1 ATCC (American Type Culture Collection) strain. Testing was performed using a modification of the agar-dilution procedure outlined in CLSI Document M7-A7, *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically*, Seventh Edition. The MIC of the test product versus each challenge strain was reported as the lowest concentration of test product (i.e., highest dilution) that completely inhibited growth. This MIC determination procedure was repeated over the course of a 2.5-week period (five complete test cycles) to determine if any increase in microbial resistance was inducible by repeated exposure to the test product.

Results: Under the conditions of this evaluation, the Minimum Inhibitory Concentrations (MIC) of the test product, expressed as product dilutions, at Test Cycle #1 and Test Cycle #2, ranged from 1:16 (v/v) to 1:32 (v/v) versus each of the test strains and continued at 1:16 (v/v) versus all challenge strains (Test and Control) during Test Cycle #3, Test Cycle #4, and Test Cycle #5. An increase in microbial resistance was not detected in any of the 11 strains of MRSA when tested against 3M™ Skin and Nasal Antiseptic.

Table 3

Drug Resistant Strain of methicillin-resistant *Staphylococcus aureus*	Increase in Resistance detected with 3M™ Skin and Nasal Antiseptic
ATCC #33592	None detected
Clinical Isolate; NARSA Strain NRS383; USA 200	None detected
Clinical Isolate; NARSA Strain NRS384; USA 300	None detected
Clinical Isolate; NARSA Strain NRS385; USA 500	None detected
Clinical Isolate; NARSA Strain NRS386; USA 700	None detected
Clinical Isolate; NARSA Strain NRS643; CA-127	None detected
Clinical Isolate; NARSA Strain NRS654; CA-548	None detected
Clinical Isolate; NARSA Strain NRS683; GA-298	None detected
Clinical Isolate; NARSA Strain NRS694; GA-92	None detected
Clinical Isolate; NARSA Strain NRS703; MN-095	None detected
Clinical Isolate; NARSA Strain NRS739; TN-74	None detected

Ordering Information

Catalog Number	Description	Pouch Contents	Pouches/Box	Boxes/Case
192401	3M™ Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP) Patient Preoperative Skin Preparation	1 Bottle 0.14 fl oz (4mL) 4 Sterile Swabs	12	4

References

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9. 3M Study-05-011017
10. 3M Study-05-010945
11. Health-Care Antiseptic Drug Product TFM, Proposed Rule, 59 Federal Register, p. 31402–31452 (Friday, June 17, 1994).
12. 3M Study-05-010944
13. 3M Study-05-010943
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Drug Facts

Active Ingredient — ***Purpose***
Povidone-Iodine USP, 5% (0.5% Available Iodine) — Antiseptic

Uses
- For preparation of the skin prior to surgery
- Helps reduce bacteria that potentially can cause skin infections

Warnings
For external use only.

Do not use if you have a known sensitivity to iodine or any other ingredient in this product. Do not use in eyes. If product gets into eyes, flush immediately with water. Do not use on infants less than 2 months old due to the risk of increased blood iodine levels.

Stop use and ask a doctor if significant irritation, sensitization or other allergic reactions occur.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Open package and remove bottle and swabs
- Unscrew cap by turning cap counter-clockwise

Skin Application:
1. Apply to clean dry skin.
2. Dip one swab into solution and stir vigorously for 10 seconds. Withdraw the swab slowly to avoid wiping solution off during removal.
3. Scrub prep site for 2 minutes working from clean to dirty using both sides of the swab.
4. Repeat steps 2 & 3 using second swab.
5. Allow prep solution to dry. Do not blot.

Nasal Application:
1. Use a tissue to clean the inside of both nostrils including the inside tip of nostril. Discard.
2. Tilting the bottle slightly, dip one swab into solution and stir vigorously for 10 seconds. Withdraw the swab slowly to avoid wiping solution off during removal.
3. Insert swab comfortably into one nostril and rotate for 15 seconds covering all surfaces. Then focus on the inside tip of nostril and rotate for an additional 15 seconds. (swab 1)
4. Using a new swab: Repeat steps 2 & 3 with the other nostril. (swab 2)
5. Repeat the application in both nostrils using a fresh swab each time. (swabs 3 & 4)
6. Do not blow nose. If solution drips out of nose, it can be lightly dabbed with a tissue.

Other information • Store at 20-25°C (68-77°F)

Inactive Ingredients: lactic acid, lauramidopropylamine oxide, malic acid, polyquarternium-10, PPG-5-ceteth-10 phosphate, sodium hydroxide, sodium iodide, steareth-100, water, xylitol

Questions?
Call 1 800-228-3957 (Monday to Friday 7 am to 6 pm CST) www.3M.com

For more product information and to request your free product sample, visit www.3M.com/nose

The combination of 3M™ Skin and Nasal Antiseptic with Bactroban Nasal® *in vitro*†, does not result in inactivation of 3M™ Skin and Nasal Antiseptic, and also does not reduce antimicrobial efficacy compared with that of 3M™ Skin and Nasal Antiseptic alone. There is no known safety concern with the use of these products in combination.*

† The clinical significance of *in vitro* data is unknown.
* Data on file at 3M.

Infection Prevention Division
3M Health Care
3M Center, Building 275-4E-01
St. Paul, MN 55144-1000
U.S.A.
1 800 228-3957
www.3M.com/infectionprevention

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