3M™ Skin and Nasal Antiseptic is the only product designed for pre-surgical reduction of *Staphylococcus aureus* in the nares.

<table>
<thead>
<tr>
<th>Effective</th>
<th>Reduces 99.5% of <em>S. aureus</em> in the nares</th>
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</thead>
<tbody>
<tr>
<td>Fast Acting</td>
<td>Effective in as little as 1 hour</td>
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<tr>
<td>Persistent</td>
<td>Maintains this reduction for at least 12 hours</td>
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<tr>
<td>Safe</td>
<td>Active ingredient is an antiseptic, and has not been shown to lead to resistance.</td>
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<td>Assurance</td>
<td>Easily fits into facility’s preoperative process, so you know it has been applied and colonization of <em>S. aureus</em> in the nares has been reduced.</td>
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 Does 3M have any clinical studies to support the use of this product?

3M currently has 2 *in-vivo* studies completed for this product:

1. Reduction of Resident Flora on Abdominal and Groin Sites. In a clinical study, 3M Skin and Nasal Antiseptic meets the FDA Tentative Final Monograph (TFM criteria) for Health-Care Antiseptic Drug Products of a 2 log reduction in bacteria on the abdomen and a 3 log reduction on the groin at ten minutes post-prep and exceeds the TFM requirements by maintaining these log reductions for at least six hours.

2. Reduction of *S. aureus* in the Nares. After the 3M Skin and Nasal Antiseptic was applied to the nares, a 99.5% or 2.3 log reduction is shown at 1 hour and is maintained for at least 12 hours.

The details of these *in-vivo* efficacy studies, as well as the safety and *in-vitro* studies are provided in the 3M Safety and Efficacy Brochure.

Literature and current practice supports the market’s need for an easy, fast-acting product to preoperatively reduce *S. aureus* from the nares. Further clinical studies in selected surgical patient populations are under consideration.

How does *S. aureus* from the nose cause surgical site infections?

At this time it is unknown how *S. aureus* from the nares causes surgical site infections.

However, CDC 1999 Guideline for Prevention of Surgical Site Infections states:

“It has been known for years that the development of SSI involving *S. aureus* is definitely associated with preoperative nares carriage of the organism in surgical patients. A recent multivariate analysis demonstrated that such carriage was the most powerful independent risk factor for SSI following cardiothoracic operations.”

Aren't patients at risk for longer than 12 hours?

The most critical time to reduce nasal flora would be during the operation.

According to the CDC’s 1999 Guideline for Prevention of Surgical Site Infections:

“Microbial contamination of the surgical site is a necessary precursor of SSI. For most SSIs, the source of pathogens is the endogenous flora of the patient’s skin, mucous membranes, or hollow viscera. When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora.”

3M Skin and Nasal Antiseptic reduces S. aureus in the nose 99.5% in one hour and maintains that log reduction for at least 12 hours.

Can 3M Skin and Nasal Antiseptic be used in conjunction with my mupirocin regimen?

Yes, 3M Skin and Nasal Antiseptic can be used in conjunction with your mupirocin regimen.

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*

When your practice is for a partial course of mupirocin prior to hospital admission or you are concerned about patient compliance, 3M Skin and Nasal Antiseptic can be used with assurance in the hospital setting the day of surgery to achieve a 99.5% reduction of S. aureus one hour prior to surgery. This reduction is maintained for at least 12 hours. Your mupirocin regimen could be resumed after surgery.

* Data on file at 3M.

Why can 3M Skin and Nasal Antiseptic only be used for a pre-surgical application?

3M Skin and Nasal Antiseptic is a patient preoperative skin prep regulated as a drug by the FDA.

Skin and Nasal Antiseptic meets the FDA Tentative Final Monograph (TFM) for Patient Preoperative Skin Preparations. The leading cause of SSIs is Staphylococcus aureus, typically found both on the skin and in the nares. Since the majority of S. aureus infections are caused by the patient’s own nasal flora, it makes sense to extend the prep to the nares to reduce S. aureus prior to surgery.

Other uses of this product would not fall under the TFM and therefore would be considered off-label use.

Won’t bacteria become resistant to this antiseptic just like they have with mupirocin?

Unlike mupirocin, which is an antibiotic, 3M Skin and Nasal Antiseptic is a topical antiseptic.

Bacterial resistance has not been shown for the active ingredient, PVP-I. Iodine has been used safely for more than 50 years.
What about patients who are allergic to iodine?

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. Anaphylaxis to povidone-iodine is extremely rare and has not been proven to be from the iodine. There is no correlation between reactions to povidone-iodine and allergy to seafood or contrast media.

(Refer to 3M Fact Sheet regarding Iodine and Iodophor)

Why did 3M choose to use an iodine-based antiseptic instead of chlorhexidine gluconate (CHG)?

According to the CDC SSI guideline, both iodine and CHG have excellent activity against gram positive bacteria and good activity against gram negative bacteria. Both are considered broad spectrum.

CHG is a neurotoxin, and 3M’s toxicology assessment is that it should not be used in the nose.

Can this product be used on children?

3M Skin and Nasal Antiseptic can be used on children 2 months of age or older. The Drug Facts box clearly states: Do not use on infants less than 2 months old due to the risk of increased blood iodine levels.