PDI's Profend®

Nasal Decolonization Kit: an introduction





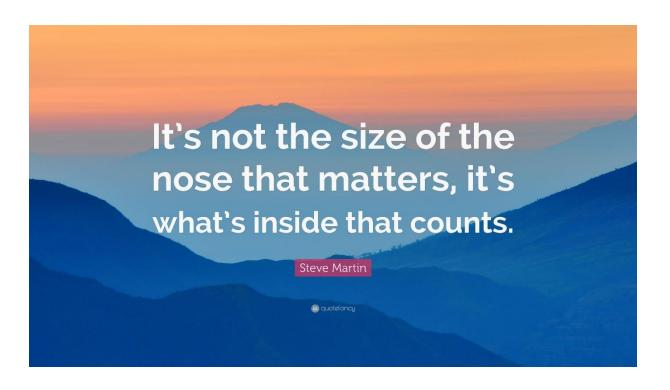




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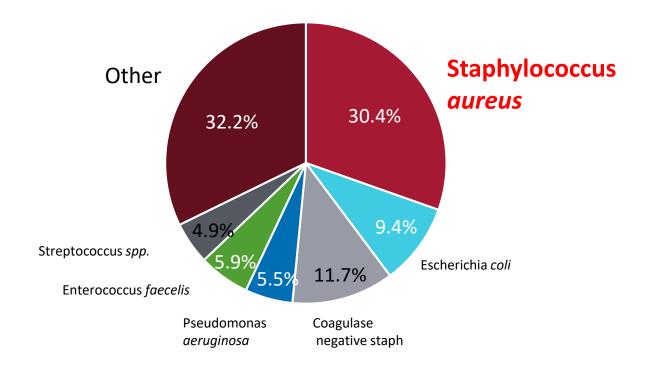
Natural Reservoirs: the Nose

- Humans are natural reservoirs for S. aureus.
- Part of the normal skin flora but most commonly carried nasally.
- 20-60% of healthy adults are colonized with *S. aureus*, and 10-20% are persistent carriers.



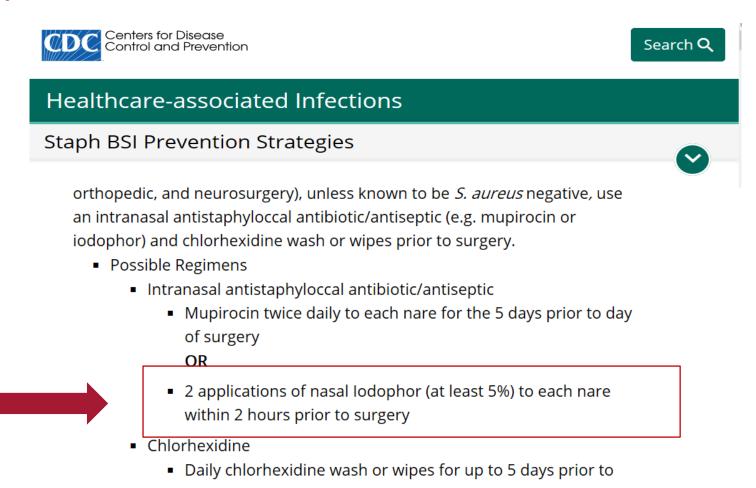


Common HAI Causing Pathogens



- For surgical site infections (SSIs) 85% S. aureus had the same DNA as the organism found in the nares (N. Engl. J. Med. 346 1871–1877.)
- For *S. aureus* bloodstream infections (BSIs), the relatedness between nares and blood was 82.2% (N Engl J Med. 344(1):11-6)
- For S. aureus pneumonia, the correlation has been reported as high as 94% (J Clin Microbiol. 43(7): 3491–3493)

Profend™ Nasal Decolonization – CDC recommendations prior to surgery



surgery

Profend™ Nasal Decolonization – CDC Recommendations for ICU patients



Core Strategy:

- Pursue a strategy to reduce carriage of *S. aureus* among all patients admitted to intensive care units (ICUs) (see table for summary of source control strategies) including:
 - Apply intranasal mupirocin twice a day to each nare for 5 days in conjunction with daily chlorhexidine bathing for duration of ICU admission
 - Intranasal iodophor could be considered as an alternative to intranasal mupirocin
 - For more information see: Universal ICU Decolonization: An Enhanced Protocol. <u>Agency for Healthcare Research and Quality (AHRQ)</u> .

SOURCE: https://www.cdc.gov/hai/prevent/staph-prevention-strategies.html

Research: Mupirocin Limitations

- Nearly a third of patients were unable to be screened or decolonized because their procedures were emergent.
- Under the ideal conditions of ZERO mupirocin resistance, decolonization failed more than a quarter of the time.
- Nearly half the patients who self-described as being compliant with the decolonization protocol were found to have **no mupirocin** in their nares when assessed using a highly sensitive methodology.
- Ten percent of patients who failed decolonization developed mediastinitis and patients colonized on the day
 of surgery were more than 9 times more likely to develop an infection.
- There is evidence of rising mupirocin resistant strains, with up to 10% of strains showing resistance in the US.
- + Patients who screen negative in the days leading up to surgery can still be positive (transiently colonized) before going to the operating room

⁺ Nicolas, Roxane, et al. "Evaluation of effectiveness and compliance with the mupirocin nasal ointment part of Staphylococcus aureus decolonization in real life using UPLC-MS/MS mupirocin quantification." *Journal of Antimicrobial Chemotherapy* 75.6 (2020): 1623-1630.

Dadashi, Masoud, et al. "Mupirocin resistance in Staphylococcus aureus: A systematic review and meta-analysis." *Journal of Global Antimicrobial Resistance* 20 (2020): 238-247.



GUIDELINE FOR PREOPERATIVE PATIENT SKIN ANTISEPSIS **NOW INCLUDES NASAL DECOLONIZATION PROGRAM** published May 13, 2021

- Convene an interdisciplinary team
- + Determine the need to implement a pre-operative MRSA/MSSA decolonization program: perform risk-based approach, evaluate resources
- + Establish a pre-operative SA decolonization program: vertical, horizontal, or blended program
 - Determine screening method, protocol for urgent procedures
 - An alternative to nasal decolonization with mupirocin is the use of an antiseptic such as povidone iodine (5%-10%)
 - Implement the pre-operative SA decolonization program as defined by the interdisciplinary team.
 - Establish timing for initiation/completion of the decolonization protocol
 - Define a plan for procuring the decolonization agent.
 - Provide patients/HCW with education re: benefits of decolonization and the patient's role
- + Monitor the decolonization regimen as part of an overall SSI surveillance and quality improvement program.
 - Assess patients' adherence to the decolonization regimen
 - If using an antimicrobial, include surveillance for antibiotic resistance as part of the antimicrobial stewardship program.

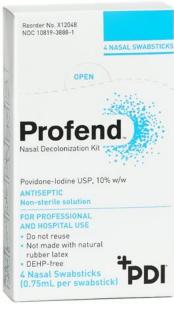
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PDI's Profend®

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Profend® Nasal Decolonization Kit

- + 10% Povidone Iodine (PVP-I) for proven efficacy and antibiotic stewardship
- Quick, 60 second total treatment time
 - 4 swabsticks per patient
 - 2 swabsticks per nostril for 15 seconds each
- Easy-to-use, pre-saturated swabstick with unique "snap & swab" design
- Neat, dry-handle with small applicator minimizes mess
- Assured treatment compliance as product is applied by clinician 1 hour prior to surgery
- Suitable for use in the OR and ICU as well as for MRSA and S. aureus-colonized patients¹
- Kills 99.7% of *S. aureus* at 10 minutes, 1 hour and 99.9% at 12 hours²





¹Sievert D. Antimicrobial-resistant pathogens associated with healthcare associated infections: summary of data reported to the NHSN at the CDC, 2009-2010. *Infect Control Hosp Epidemiol*. 2013;34(1):1–14.

²PDI in vivo Study 0113-CTEVO

Profend™ rises above the competition!

Product Parameter	Profend	Mupirocin & Bactroban	Other PVP-I Nasal products	Nozin Alcohol Popswab
Approved area of application	Anterior nares	Anterior nares	Anterior nares	Nasal vestibule (no mucous membranes)
# of applications per day	Two	Two	Two	Two
Treatment time	60 seconds	5 days	120-160 seconds	6 rotations per nostril, 2x
Visual Indication of application	Yes	Yes	Yes	No

^{*}Bactroban, as of January 2018

Profend® Nasal Decolonization of *Staphylococcus aureus*¹

99.7%

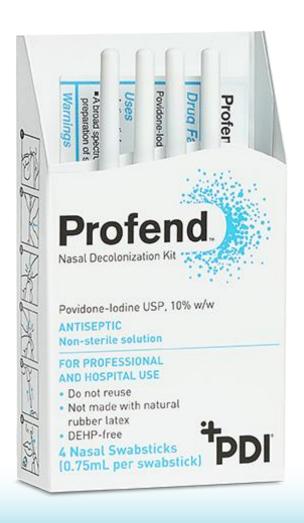




99.9% @ [12]







Profend® Nasal Decolonization Kit overview

- + 4 swabsticks per patient unit
- + 12 patient units per shelf unit
- + 4 shelf units per case (smallest orderable quantity)









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How Does **Profend®** Nasal Kit fit into the Guidelines?

- + Can be used in universal, targeted and blended decolonization programs.
- + Decolonization with **Profend®**, in coordination with ASHP surgical antibiotic prophylaxis, may make it possible to no longer require MSSA screening but MRSA screening may still be necessary
- + Treatment can efficiently be done via standing physician order.
- + Compliant with CDC and AORN Strategies (mupirocin/iodophor) and SHEA (antistaphylococcal agent)
- + Ideal for *urgent* procedures: 99.7% reduction of SA at 10 minutes (in vivo)
- + Application is simple and efficient and easily fits within the pre-operative workflow. (establish timing)
- + Applied by the pre-operative nurse to ensure compliance.
- + a 10% PVP-I, it is a broad-spectrum antiseptic with no known resistance.
- + PDI provides educational materials to explain the "why" to the patient and HCW







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