

Antimicrobial Efficacy of PDI **Profend™** Nasal Decolonization Kit 10% Povidone-iodine vs. a Saline control against total bacteria and *Staphylococcus aureus* nasal colonization in Human Subjects¹

Purpose

To investigate the antimicrobial efficacy of two applications in the anterior nares of **Profend** Nasal Decolonization Kit 10% povidone-iodine (PI) vs. a saline control to measure the immediate and persistent reduction of total bacterial counts and *S. aureus*. Measurement of total bacteria and *S. aureus* reduction was performed at 10 minutes, 1-hour and 12-hours post treatment application. Safety evaluation of the product was conducted through adverse event reporting and assessment for skin and mucous membrane reactions during the study.

Methods

Healthy adult volunteers were recruited and underwent nasal screening. Participation was based on defined microbial counts of total bacteria and *S. aureus* ($3.7 \log_{10}$). Thirty-four subjects met the baseline total bacteria count criteria in the PI group and eighteen in the control group. Twenty-three subjects met the baseline *S. aureus* criteria in the PI group and twelve in the control group. Applicators containing either PI or saline were applied into each nostril for 30 seconds – 15 seconds for one applicator and 15 seconds for a second applicator – by first rotating the applicator around the circumference of the nostril and then rotating for 6 complete revolutions with slight pressure in the anterior nares. Post-treatment samples were taken at 10 minutes, 1-hour and 12-hours.

Results

Profend Nasal Decolonization Kit 10% povidone-iodine:

- Reduced 99.7% of *S. aureus* at 10 minutes and at one hour and maintained a 99.9% reduction at 12-hours post-application.
- Reduced 99.4% of the total bacteria within 1-hour and maintained a 95.9% reduction at 12-hours post-application.

No adverse events were reported and there were no clinical signs of skin irritation for any subject during the study.



¹ PDI Study Number: 0113-CTEV01