Clinical Study

Nosefrida was developed by Ear, Nose and Throat Specialists at the University Hospital MAS in Malmo, Sweden. To evaluate Nosefrida, a clinical study of 43 children, 17 girls and 26 boys ages 0 - 2 1/2 was conducted at three different hospitals. In the study, 42 of the children suffered from severe nasal congestion. The majority of the children, 34, was suctioned with Nosefrida more than 3 times in a 24 hour period, specifically before meals and before bedtimes. 37 of the 40 parents reported positive results and found the Nosefrida very helpful. There were no complications noted. The study concluded that the nasal aspiration device Nosefrida effectively reduces the accumulation of mucous in the nose, improves feeding and reduces sleeping problems in children suffering from upper respiratory infection.

Bacteriological evaluation of NoseFrida a nose-suction device intended for use in young children with common cold.

The study was conducted between January 1997 and July 1998 in collaboration with the Department of Pediatric and the Department of Microbiology, University Hospital MAS, Malmo Sweden.

A: The study was designed to semi-quantitatively measure the transfer of bactrial pathogens and commensales from the affected child's nose through the Nosefrida suction device to the user. The study was conducted in a scientifically correct manner.

B: Evaluation of the bacteriological samples was done in accordance with standard procedures used atthe Clinical Microbiology Laboratory, University Hospital MAS.

Results: Twelve children with nasal congestion were tested. In six cases the NoseFrida device was used with the hygiene filter mounted and in six cases tested without the filter. In 10/12 children bacterial growth was detected in the distal tube of the device but in no case there was a contamination through the device. In 2/12 cases no bacterial growth were detected at the distal tube.

Statement: The investigation clearly demonstrates that the Nosefrida device if used as intended by the manufacturer is safe regarding the risk of bacterial transfer from the infected child to the nurse.

Malmo November 11th, 1998
Martin H. Laurell M.D.,Ph.D.
Infection Control Officer
Head, Clinical Microbiology Laboratory / University Hospital MAS / Malmo, Sweden

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Certificate concerning the Nosefrida nasal aspirator

Small children cannot blow their noses and the stagnation of secretion following e.g. upper airway infections leads to difficulties for the child to breate through the nose. An unimpeded passage of air in the nose is a prerequisite for, among other things, troublefree breastfeeding. The stagnation of secretion also leads to sleep disturbance. The nose aspirator can in most cases alleviate the trouble, and clinical trials that have been performed in a ten-year period show that the nose aspirator is harmless, and in a majority of cases relieves the patient's acute problems. The design of the nose aspirator precludes irritation of the susceptible nasal mucosa, and there is no indication in the clinical studies that points to a further increase of nasal secretion when using the aspirator. From a hygienic point of view nothing prevents the usage of the aspirator within the family, as experience tells us that the bacteriology is the same for all family members. The nose aspirator Nosefrida has also been tested from a bacteriological viewpoint in the Microbiology laboratory at Malmo University Hospital. The microbiological test concluded that there is no risk of a spreading of the infection from child to user. The nose aspirator,

which has been developed at The Ear, Nose and Throat Clinic in Malmo to remove secretion from the nose in small children, functions in a harmless manner. Based on the clinical tests that have been carried out nothing has been found to speak against the employment of the aspirator from a scientific or proven experience point of view.

Malmo, March 11, 1999
Lars Malm / Professor of Otohinolaryngology, specialist in Rhinology

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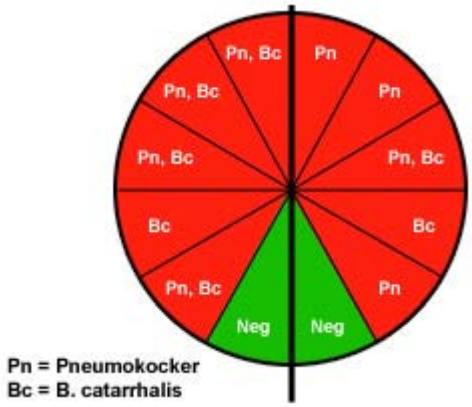
Bacteriological Evaluation

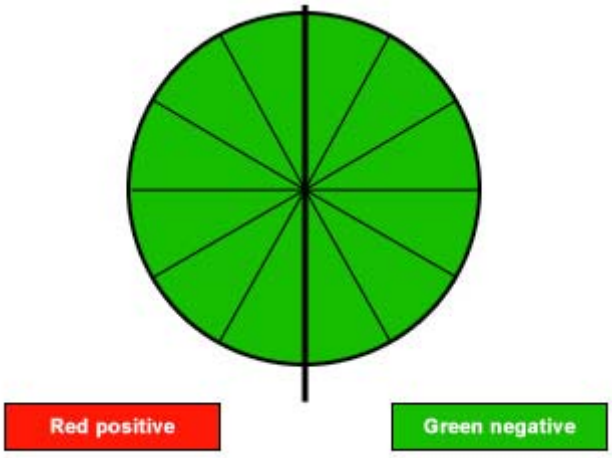
The nasal aspirator NoseFrida™ was evaluated regarding the risk of bacterial transfer from the child to the user. NoseFrida was tested in 12 children with URI and nasal congestion. None of the children was on antibiotics at the time of the test. The study was conducted at the Dept. of Paediatrics and the Dept. of Microbiology, Malmo University Hospital, Sweden.

Bacteriological evaluation, tip of the tube, in 12 patients



The study was designed to semi quantiative measure the transfer of bacterial pathogens and commensals from the affected children to the user, conducted in a scientifically correct manner.

Bacteriological evaluation, sterilefilter placed below the mouthpiece



Conclusion
The investigation demonstrates that the use of the nasal aspiration device NoseFrida constitutes no risk of bacterial transfer from the child to the user.