An Evaluation of Safety and Efficacy of the Procedural Face Mask treated with Goldshield® Anti-Microbial Agent.

Introduction

Procedural and surgical masks are considered integral personal protective equipment (PPE) designed to reduce infection in a wide variety of clinical and other settings. They provide a defensive barrier against pathogenic microorganisms. Masks are designed to filter varying sizes of organisms, thereby trapping them and not allowing them to pass through the mask. Once captured, microorganisms can continue to live within the fibers of the mask. This technical paper discusses the effect of a new antimicrobial technology upon microorganisms trapped on the filter media of a procedural mask.

Materials & Methods

Goldshield® is an environmentally benign antimicrobial agent that covalently bonds to a wide variety of surfaces, including textiles used in the fabrication of protective face masks. Through a proprietary application process, once bound to the surface of a mask, Goldshield produces a non- leaching, non-migrating, and long term residual protective coating. The Goldshield agent was uniformly applied to procedural masks to determine safety characteristics as well as the bacteriocidal efficacy of those masks when introduced to various potentially harmful microorganisms.

Test methods are described as follows:

Safety Testing of Goldshield®Treated Masks

The following tests have been performed by an independent laboratory to demonstrate the safety of the Goldshield treated masks:

IS0 Skin Irritation Study

Method

The test article, Goldshield treated face mask, Batch: Test I1 9-21-07, was evaluated for primary skin irritation in accordance with the guidelines of the International Organization for Standardization 10993. Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application.

Under the conditions of this study, very slight erythema and no edema were observed on the skin of the rabbits. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Cytotoxicity Study Using the IS0 Agarose Overlay

Method

An in vitro biocompatibility study, based on the requirements of the International Organization for Standardization (IS0 10993-5), was conducted on the test article, Goldshield™ treated face mask, Batch: Test I1 9-21-07, to determine the potential for cytotoxicity. Triplicate wells were dosed with a 1 cm x 1 cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex, as a positive control. Each was placed on an agarose surface directly overlaying a confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37OC in 5% C02 for 24 hours, the cell culture was examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any).
The culture was then examined microscopically (100X) to verify any decolorized zones and to determine cell morphology in proximity to the articles. Under the conditions of this study, the test article showed evidence of causing slight cell lysis or toxicity.

The test article met the requirements of the IS0 since the grade was less than a grade 2 (mild reactivity). The negative control and the positive control performed as anticipated.

IS0 Closed Patch Sensitization Study

Method

A study was conducted in the guinea pig to evaluate the potential for delayed dermal contact sensitization of Goldshield treated face mask, Batch: Test I1 9-21-07. The study was conducted based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity.

The test article was occlusively patched for 6 to 8 hours to the intact skin of ten guinea pigs, three times a week, for a total of nine induction treatments over a 3-week period. The control article was similarly patched to five guinea pigs. Following a recovery period, the ten test and five control animals received a challenge patch of the test article and the control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal.

Under the conditions of this study, the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

Inhalation Toxicity Testing

Test in progress, preliminary results show no adverse effects.

Antibacterial Efficacy Testing of Goldshield™ Treated Masks

Method

The efficacy of Goldshield treated face masks has been tested following the AATCC method for Antibacterial Finishes on Textile Materials: Assessment of (Test Method 100-2004). The test organisms were Staphylococcus aureus, Methicillin Resistant Staphylococcus aureus (MRSA), Vancomycin-Resistant enterococcus (VRE), and Candida albicans.

The materials used in AATCC 100-2004 are:

1. Neutralizer (Letheen Broth, 100 ml per bottle)
2. masks (Non-treated and Treated)
3. Sterile scissors, forceps, and hockey sticks
4. Sterile wide mouth jars
5. TSA plates
6. Sterile Saline Solution (0.85% NaCl)
7. Sterile test tubes
8. Flame for sterilization
9. 100-1,000 µl pipettes and pipette tips

The Test method was as follows:

1. Using Goldshield® treated face masks and not treated face masks, cut circles from masks that measure to be about 7.5 cm. Autoclave masks (optional, we decided not to autoclave the masks).
2. Inoculate circles with 100 µl of test organism (10^4 CFU/ml dilute final dilution in slurry inoculum carrier) and spread with sterile hockey stick. Start timer as soon as spread.
3. Transfer circle into sterile jar.
4. Add 100 ml. neutralizer (letheen broth) to jars at allotted time of 0, 5 and 10 min.
5. Sonicate neutralizer/mask jars for 1 minute.
6. Make serial dilutions if necessary. For all masks, take 1 ml from bottle and filter with 25 ml saline solution. Filter onto TSA (Tryptic Soy Agar) plates.
7. Allow to incubate in 37 +/- 2 ºC for 24 hrs.

As described within this document the masks are shown to be safe and, in lab testing, Goldshield treated procedural masks have proven effective against:

- Staphylococcus aureus
- Methicillin Resistant Staphylococcus aureus
- Vancomycin-Resistant enterococcus
- Candida albicans

Results:

Safety:

The Goldshield masks passed all of the safety tests.

Antibacterial Efficacy:

Table 1 shows the percent reductions of Staphylococcus aureus, Methicillin Resistant Staphylococcus aureus, Vancomycin-Resistant enterococcus and Candida albicans on Goldshield treated masks at 5 and 10 minutes.

Table1: Percent Reductions of Microorganisms on Goldshield™ Treated Masks

Time	Staphylococcus aureus	Methicillin-Resistant Staphylococcus aureus (MRSA)	Vancomycin-Resistant enterococcus (VRE)	Candida albicans
5 minutes	99%	99.99%	99%	99.9%
10 minutes	99.9%	99.999%	99.99%	99.9999%

Discussion

According to the Centers for Disease Control and Prevention (CDC), as many as 2 million patients nationwide contract bacterial infections in hospitals each year – resulting in 103,000 deaths. Clinical Infections Diseases has reported that each infection cost $15,275 or $30.5 billion annually [This figure does not include doctors' bills, home nursing care, lost time at work, and other non-hospital costs]. Additionally, Infection Control Today estimates that hospital-acquired infections produce an additional $4.5 billion in annual liability claims.

Surgical and procedure masks are commonly and widely used Personal Protective Equipment (PPE) to help reduce infection in clinical and other settings. They reduce the risk of contamination in several ways:

1. Physical barriers to protect the wearer from hazards such as splashes or droplets of blood, body fluids, and airborne pathogens and aerosols.

2. To prevent contamination by trapping particles of body fluids or airborne pathogens that may contain bacteria or viruses when they are expelled by the wearer.
3. Protect others against infection from the person wearing the mask.
4. Prevent (potentially infected) hands from touching the face.

OSHA (Occupational Safety & Health Administration) recommends that people who currently wear surgical or procedural masks should follow specific steps for donning, removing and discarding their mask in order to minimize cross-infection to the mask from contaminated hands or from the mask to the hands or other surfaces. These steps include thoroughly washing or decontaminating hands before and after removal of the mask, and to avoid touching the outside of the mask. If adherence to these protocols is not followed, cross contamination is more likely to occur. This paper shows that the Goldshield™ treated mask kills harmful bacteria that are on the mask.

(http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html#masks)

V) Conclusions

1. The results of biocompatibility and cytotoxicity studies at an independent laboratory indicated that Goldshield® treated masks are safe to use.

2. The results of the microbiology testing indicate that Goldshield® treated masks kill at least 99% of the harmful bacteria tested within 5 minutes of contact with the mask