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Rethink Type I Reusable Surgical Filter Reuse Test Report

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1. Abstract

A study was conducted by SNC to validate the disinfection and reuse of the Rethink Reusable Surgical Masks™ up to ten times by testing the filtration efficiency of the filters over a number of disinfection cycles as per the instructions for use. The results showed that the masks retained Type I particle filtration efficiency of ≥ 95% for up to 12 disinfection cycles.

2. Introduction

Unlike traditional single-use masks, nanofiber filters rely primarily on mechanical filtration mechanisms rather than electrostatic filtration, and therefore are not impacted by wetting. This allows them to be disinfected with boiling water and reused multiple times.

Filtration efficiency testing is separated into "Bacterial Filtration Efficiency" (BFE) and "Particulate Filtration Efficiency" (PFE). The requirement for BFE is ≥ 95% for Type I surgical face masks, as defined by EN 14683:2019. A study comparing the results for BFE and PFE found no significant difference in filtration efficiency measured with the two methods.[1] Previously, samples submitted by SNC for testing for both methods were compliant with the filtration efficiency required for Type II surgical masks (≥ 98%), and were within the variance between test methods noted by the study.[1] This data supports the use of PFE as a substitute for BFE testing for these filter materials, and therefore PFE testing with NaCl was used throughout the reusability study.

3. Test Method Outline

Two filter types were tested according to an internal test method: a nanofiber layer between a knitted substrate (knit/NF/knit) and a non-woven (SB/NF/SB). Briefly, each cycle consisted of placing a filter inside a compatible cloth mask, handling (bending) for five minutes, and then removing the filter and following the instructions for use in disinfection with boiling hot water. Twenty filters were each subjected to 10 and 12 cycles and sent for PFE and breathing resistance testing at Protechnik Laboratories.

4. Results and Discussion

Handling during testing was an approximation of the handling required to insert and remove the filter from the mask, as well as a limited amount of wear from movement on the face. The results are

[1] Rengasamy, S., Shaffer, R., Williams, B., Smit, S., 2017. J. Occup. Environ. Hyg. 14, 92–103.

plotted in Figure 1 and show that all of the samples retained particle filtration efficiencies above 95% as required by the Type I surgical mask requirements. Figure 1 also shows the use of two types of filters, with knitted and non-woven materials as protective layers on either side of the nanofiber layer. The comparison showed very little difference in the average drop of filtration efficiency after ten disinfection cycles with the two materials, with a decrease of 1.3% after 10 cycles for both.

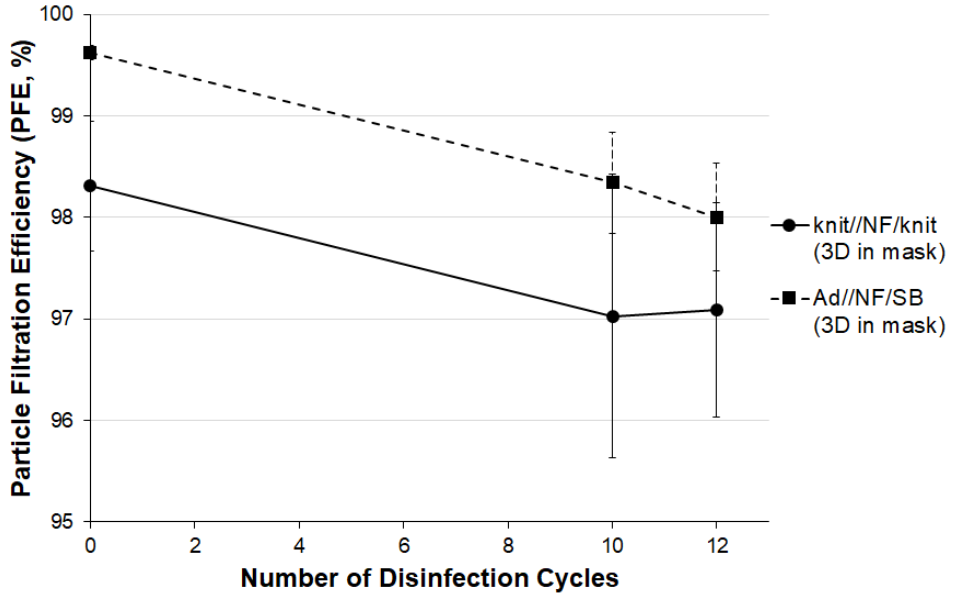

Figure 1. Results of the Particle Filtration Efficiency (PFE) testing, shown as percent filtration efficiency (PFE, %) after 0, 10 and 12 cycles of disinfection.

5. Conclusion

The nanofiber filters showed good filtration efficiency regardless of the substrate material used. The results confirmed that the nanofiber filters could be safely disinfected with boiling water while retaining their filtration efficiency and remained within the requirements needed to comply with Type I surgical masks. The reusability of the filters for up to 12 disinfection cycles, as well as the applicable instructions for use were successfully validated.

Approved by:

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