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an alternative in the fight against mask shortages due to COVID-19**

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Sterilization of disposable face masks by means of standardized dry and steam sterilization processes; an alternative in the fight against mask shortages due to COVID-19

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Introduction/background The Covid-19 pandemic does cause imminent local shortages of personal protective equipment such as face masks, in hospitals and other healthcare facilities.

Sterilization In preparation for that scarcity we performed a study to investigate the possibility of reprocessing disposable FFP2 face masks in order to verify their re-usability with a method that could be applied in practice using already available equipment. Therefore single use FFP2 masks (type 1862+ 3M™) were sterilized with a 15-minute procedure at 121 °C, using a dry sterilization process as well as with a regular steam process with the masks in impermeable sterilization/laminate bag. The effectiveness of these processes are sufficient to inactivate the coronavirus based on knowledge of inactivation of such viruses^{1,2}. A blind comparison of unused, and once, twice and three times sterilized masks was performed by two individuals with respect to visual inspection, consistency, face fit and breathing resistance. The result of this comparison was that both investigators were unable to distinguish unused new (slightly curved and folded) masks from reprocessed sterilized masks.

We then tested the functionality of the unused and sterilized masks in several ways. First of all permeability properties for bacteria were tested by spraying a bacteria solution of *Staphylococcus epidermidis* (ATCC 12228) on the masks while air was being drawn through the masks. Unused and multiple sterilized masks showed no differences in the amount of passed bacteria (data not shown). In these experiments it was also observed that the reprocessing procedures of the masks did not appear to affect the water-repellent mask properties.

Pressure/flow and Particle tests Before sterilization, the batches were individually packed in laminate bags and sterilized with steam sterilization by means of 121 °C in Getinge autoclaves and in combination with permeable laminate bags, Halyard type CLFP150X300WI-S20. The autoclaves were activated on a 121 °C program and validated accordingly. After sterilization, the samples were tested at Delft University of Technology and at Reinier de Graaf Hospital, and benchmarked with new mouth masks. A custom test set-up was built to measure the pressure drop over the maskers and outflow with regard to the permeability of the masks. A direct comparison between new and sterilized mask did not show substantial differences between the different masks tested. Finally, the filtration capacity of the masks was evaluated using a calibrated Lighthouse Solair 3200 particle counter (Lighthouse, San Francisco, www.golighthouse.com). It was shown that the mask permeability of small particles did not change after multiple heat sterilization procedures (table 1).

We openly shared our positive experiences with the steam sterilization process with other hospitals in the Netherlands that were also preparing for the outbreak. We were informed that their attempts

to steam sterilize mouth masks at 134°C gave poor results as masks started to deform and became sticky while the elastics lost its resilience.

In addition, we tested Gamma radiated masks this process did hamper the filter capacity (table 1).

The results of our experiences and experiments indicate that our sterilization process did not influence the functionality of the masks tested. In case of an acute shortage of FFP2 masks, steam sterilization (e.g. in laminate sterilization wrappings) of used masks at 121 °C in laminated bags, is a simple, useful, cost effective and quick procedure that can be used to make used masks available for safety reuse. Therefore, the sterilization process of available standard autoclaves in all hospitals have to be adjusted in order to use this sterilization method We performed these experiments with 3M masks.

Table 1

	New FFP2	1x Heat 121 (n=2)	3x Heat 121 (n=4)	5xHeat 121 (n=2)	10kGy (n=1)	25kGy (n=2)
Filter Efficiency %						
0.3 µm	99.4	96,9	97.4	96.8	55.4	-
0.5 µm	99.8	98,0	98.4	98.7	79.1	57.5
5.0 µm	99.8	95.2	95.5	94.3	98.1	98.7

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