June 1st, 2020

Reuse of Respirator Masks

During COVID-19 Public Health Emergency

[Canada]

Purpose of this Document

We recognise that during a public health emergency there may be limited available options for healthcare providers facing high risk to patient wellbeing due to limited supply.

Getinge Steam Sterilizers are not intended for use with single-use instruments. However based on various studies and guidance (not conducted or validated by Getinge) on FFP2 / N95 (or equivalent) type respirator masks (including respirators and single use filters for reusable respirators), the usefulness of steam sterilization [1] has been demonstrated as an effective reprocessing method during global-supply shortages in the COVID-19 publich health emergency.

The guidelines enclosed in this document are intended to support hospitals in making their decision regarding this issue. At this moment, Health Canada authorization is not required if [2]:

- Hospitals are decontaminating N95 respirators within their institutions for their own re-use
- Hospitals are decontaminating N95 respirators from an external institution and sending the respirators back to the same institution

Note!

- The following guidelines are only applicable to COVID-19 related cases during the ongoing public health emergency.
- The following guidelines should be used together with instruction for use for respective equipment, and does not in any way replace the normal instructions for use.
- “Respirator Masks” includes respirators and single use filters for reusable respirators.
- Users should always check and comply with intended use of medical equipment (such as sterilizers and disinfectors), and medical devices (e.g. items to be processed).
- The following guidance is based on evidence from studies not conducted or validated by Getinge.
- The decision to reprocess a single-use respirator is purely up to the discretion of the user’s medical judgement regarding risks vs benefits. Risks of reprocessing cited in the studies included compromised effectiveness secondary to fit and usability.
- This information should be understood as guidance only and should not replace the recommendations of local authorities.

Guidelines in addition to sterilization procedure

Review and document the entire handling procedure including at least the following parts:

- Safe handling and transport of contaminated masks.
- Controls to ensure that only validated masks are subject of re-use.
- Marking and inspection of masks to ensure that re-use is limited to the number of cycles that has been validated to be safe and that no damaged masks could be re-used.
- Separation of contaminated and sterilized masks to avoid cross-contamination.

Getinge Steam Sterilization of Respirator Masks

COVID-19 and Steam Sterilization

Steam sterilization is a well-recognized sterilization method with broad spectrum efficacy.

A recent study conducted by Dutch National Institute of Public Health and the Environment (RIVM) [1], concluded that form and fit was acceptable with exposure of a FFP2 respirator mask to steam sterilization process including 121^{O}C, of up to two sterilization cycles.

Note!

- RIVM evaulated re-processing with two sterilization cycles (i.e. three respirator mask uses). We recommend that you follow these guidelines as a maximum re-processing limit (including any abort cycles due to operator errors), or validate maximum number of applicable re-processing cycles at your own facility.
- Do not reprocess respirators masks that have entered a particle rich environment, or that are visibly soiled.
- Conduct thorough visual inspection before and after reprocessing for any signs of physical damage.

Preparing	Respirator masks should not be reprocessed more times than maximum limitation. Please ensure that you have sufficient documentation methods to ensure traceability of re-use.
Packing	Items should be packed in in Getinge Pack Sterilization Rolls / Pouches, or other compatibile packaging as per normal instructions. Place one item per Pouch.
Placing	Please load the sterilization chamber as per normal instructions; paying attention to ensure individually packaged items are not stacked above each other. Ensure that one Chemical Indicator is placed with each individually packaged item.
Selecting Cycle	Please sterilize using the 121ºC steam cycle. Duration of Steam exposure may impact efficacy of respirator masks. Sterilization with 15-minute procedure at 121ºC has been shown to be effective at maintaining respirator mask efficacy [3].
Unloading	Following a successful sterilization cycle please conduct a visual inspection for damage of the respirator masks, and appropriately mark and discard any that appear physically damaged. Further, please ensure to document the total number of re-use cycles for each item in the load.

References

1) RIVM, "Reuse of FFP2 masks (121C steam)," 2020. [Online]. Available: https://www.rivm.nl/documenten/hergebruik-ffp2-mondmaskers.
2) Important Regulatory Considerations for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response: Notice. [Online]. Available: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/covid19-notice-reprocessing-n95-respirators.html
3) T. Delft, 2020. [Online]. Available: https://repository.tudelft.nl/islandora/object/uuid%3Af048c853-7e1d-4715-b73d-3b506b274a30.