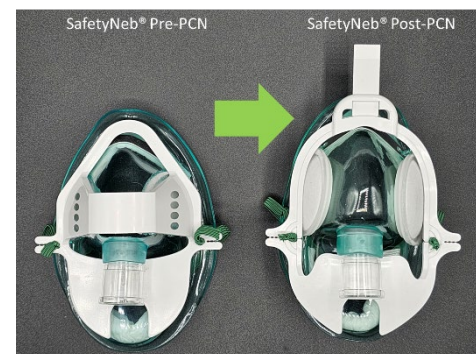


Change Description

- Upgrading the SafetyNeb™ mask filtration attachment to SafetyFilta™ device technology.
- Upgrading SafetyNeb™ mask faceplate to the SafetyFit™ device technology.
- **Summary**
 - The SafetyNeb™ and SafetyO2™ filtered masks product line is being upgraded to benefit from improved technology of the SafetyFilta™ and SafetyFit™ devices developed by Groman Inc.
 - There are no changes to the SafetyNeb and/or SafetyO2 device indications or instructions-for-use (DFU). Changes are only in product appearance and improved functionality.
 - Groman will transition to shipping product with these enhancements as older materials are depleted and new production processes are ramped up. During the transition the original filter media mounting style with the new SafetyFit™ device may be encountered.
- **Background Information**
 - We decided to develop our award winning SafetyNeb and SafetyO2 devices during the onset of COVID-19. At the time, we utilized whatever worldclass material suppliers were able to provide us to urgently address the clear and present hazard. We succeeded in many ways, but several shortcomings in process and supply chain remained. This PCN allows for product upgrades that address these shortcomings and improve the product even further.
 - The SafetyFilta™ and SafetyFit™ devices were developed by Groman Inc. to improve the functionality, flexibility, and ease-of-use of the SafetyNeb device. Details of the improvements the SafetyFilta™ and SafetyFit™ devices offer can be reviewed in the documents referenced below.
 - The SafetyFilta™ design utilized for the SafetyNeb™ device provides for a rigid air-tight attachment to the mask.
- **Reason for Change**
 - Transition to the SafetyFilta™ device technology provides the following benefits:
 - An added stage of aerosol filtration
 - A more rugged filter-to-mask interface
 - A 12.5% increase in filter media surface area
 - Increased product expiration period
 - Ability to accommodate all mask sizes and enable continuous-neb procedures --including pediatric masks (refer to Further Implications section for more details)
 - Transition to the SafetyFit™ device technology provides the following benefits:
 - More rigid light-weight design
 - Better visibility of patient during nebulization procedure
 - Ability to accommodate all mask sizes and larger filter sizes to enable continuous-neb procedures --including pediatric masks (refer to Further Implications section for more details)



- **Product Affected**
 - SafetyNeb™ filtered nebulizer masks
 - SafetyO₂ filtered oxygen masks.

- **End-User Notification**
 - A note will be provided within each packaged item informing the user that the product performance and usage remains the same although cosmetically and visibly may appear different.
 - The note will include a QR code that enables online view of this document.
 - This note will be included with every device shipped through 2023.

- **Further Implications**
 - The SafetyNeb and SafetyO₂ filtered masks with this PCN improvements will be rebranded with a PLUS proceeding the SafetyNeb+ and SafetyO₂+ to distinguish these improvements.
 - No ordering changes are required as all orders placed for standard SafetyNeb and SafetyO₂ will be shipped as SafetyNeb+ and SafetyO₂+
 - The standard SafetyNeb and SafetyO₂ devices are fabricated from Adult XL mask sizes and will remain the same. In the third quarter of this year the SafetyNeb filtered masks will be offered in smaller mask sizes to better accommodate smaller faces and pediatric patients and larger filter sizes to accommodate longer duration nebulizer procedures.
 - New items will be offered as follows:
 - Aerosoless®+ Filtered masks with same indication (15min/6cc):
 - SafetyNeb+ Adult
 - SafetyNeb+ Pediatric
 - Aerosoless® Ultra filtered masks with larger filters for Continuous Neb:
 - SafetyNeb Ultra
 - SafetyNeb Ultra Adult
 - SafetyNeb Ultra Pediatric

- **References**
 - Original SafetyNeb Information <https://aerosoless.com/>
 - SafetyFilta Benefits White Paper https://gromaninc.com/safetyfilta/safetyfilta_white_paper_rev_1026b.pdf
 - SafetyFilta Flyer https://gromaninc.com/safetyfilta/safetyfilta_flyer.pdf
 - SafetyFit Flyer https://gromaninc.com/safetyfilta/safetyfit_flyer.pdf
 - SafetyFilta Video - <https://www.youtube.com/watch?v=gjajNqExZg8>
 - SafetyFilta PPE Education Video - <https://www.youtube.com/watch?v=valISXTTk2w>

- **Key Contact**
 - Barry Groman – Inventor, Owner, and Quality Manager
 - Office – 800-906-9298 Ext. 709
 - Mobile – 954-649-8008
 - Email: BGroman@GromanInc.com