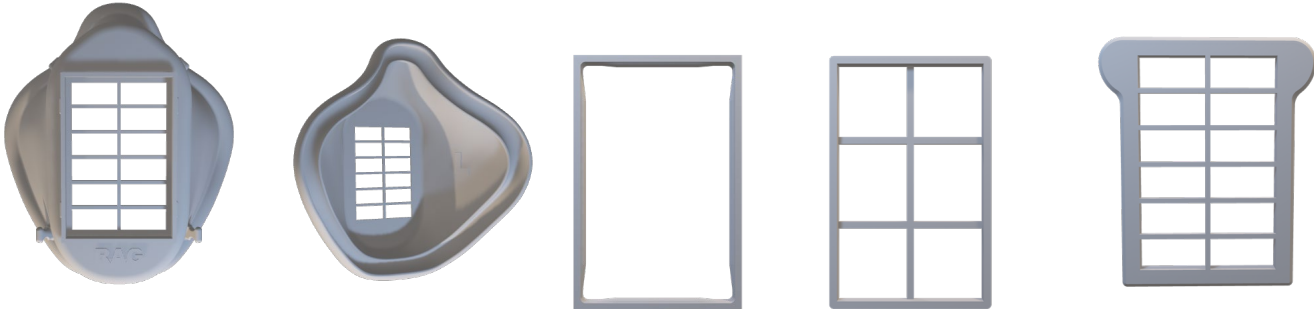


Replaceable Filter Mask (RFM)

Instructions



RAG Replaceable Filter Mask (RFM)

The RAG Replaceable Filter Mask (RFM) is a Rapid Application Group design that uses initial design language of the NIH approved stop gap surgical face mask. Our design allows a user to source all materials in the United States that are readily available! The RFM improves comfort for long term use and issues deriving from prolonged plastic-to-skin contact. The implemented comfort seal allows for a complete seal around the face to pass fit check and extended use comfort. The RFM has completed multiple independent fit check tests and clinical evaluations to determine suitability. Rapid Application Group is a proud America Makes member.

The optional buttonhole elastic distributes the force across the head providing comfort after multiple hours of use. The filter cartridge gives the user optional uses for filter media (nano filter, cut down N95 mask, cut down surgical mask, HEPPA filter, etc) and allows for an exact fit into the RFM. The quick-change filter cartridge allows the user to 3D print multiple exchangeable frames and preload with filter media. This reduces time between changes and reduces the opportunity of the filter media not seating correctly and compromising the integrity of the RFM.

This design has been optimized for Selective Laser Sintering (SLS) or MJP. The replaceable filter mask can also be manufactured with Fused Deposition Modeling (FDM) technology. This design will allow those with Selective Laser Sintering, multi jet printing or fused deposition model assets to have a clinical tested design for production.

The RFM was manufactured using the FDA's technical consideration for Additive Manufactured medical devices. The RFM was designed with a local consortium that Rapid Application Group lead with local healthcare professionals in the state of Oklahoma. This mask was developed to rapidly bridge the gap of a crippled PPE supply chain. The RFM has not been evaluated, tested or approved by NIOSH as per the requirements in 42 CFR Part 84 as a true N95 respirator, but has passed multiple independent fit test evaluations along with clinical testing for comfort and ease of use.

This design was a collaboration of multiple players:

- Chase Wichert – Design / Rapid Application Group
- Terry Hill – Rapid Application Group
- Jason Dickman – Rapid Application Group
- Tony Manuel – Rapid Application Group
- Melissa Riley – Rapid Application Group
- Kelsey Southerland – Medical Professional
- Dr. Hunter Southerland – Medical Professional
- Dr. Ed Rylander – Medical Professional
- Dr. Mitchell Duininck – Medical Professional
- Spring Morrow – Medical Professional
- Brad Petty – Multiple Fit checks at National Occupational Health Services

Disclaimer:

The RAG RFM shall only be used as an Alternative when FDA cleared or NIOSH approved N95 Respirators are not available. The CDC published on its website Strategies for optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies, which, as part of a set of crisis management recommendations, identifies alternatives to FDA-cleared or NIOSH-approved N95 respirators approved under standards used in other countries, some of which were evaluated under methods that are similar to NIOSH-approved N95 respirators. For the duration of the public health emergency, when FDA-cleared or NIOSH-approved N95 respirators are not available, FDA does not intend to object to the distribution and use of respirators identified in the CDC recommendations without compliance.

*This device is **not** suitable protection against airborne exposures and should **not** be used as a replacement for a N95 mask, PAPR device, or any other respirator device.* The RFM mask should not be used:

- 1) in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected.
- 2) in a clinical setting where the infection risk level through inhalation exposure is high.
- 3) or in the presence of a high-intensity heat source or flammable gas.

Rapid Application Group makes no warranties, either express or implied, that the mask prevents infection or the transmission of viruses or diseases.

Health care providers should:

- 1) Check the 3D-printed mask's seal for leaks.
- 2) Confirm that they can breathe through any makeshift filter materials.
- 3) Exercise caution in surgical environments where the need for liquid barrier protection and flammability is a concern.
- 4) Recognize that the mask may not provide air filtration enough to prevent transmission of infectious agents.
- 5) Safely dispose of infectious materials and disinfect any part they intend to reuse.

Replaceable filter Mask (RFM) Overview

The replaceable filter mask consists of three components. (the mask body, the interchangeable filter frame, and the filter cover). Additional resources may need to be sourced locally including a 3/8" outside diameter 1/4" inside diameter FDA approved food grade tubing that is 30-50 durometer. To ensure a good seal, the user will need to source 1/4" outside diameter tubing. This tubing is inserted inside the 3/8" comfort tubing at the seam to ensure a good connection point. The RFM design accepts buttonhole elastic as the preferred method of securing the mask but is not limited to any specific style of attachment methods. Tubing can be sourced at <https://www.mcmaster.com/5229K58>

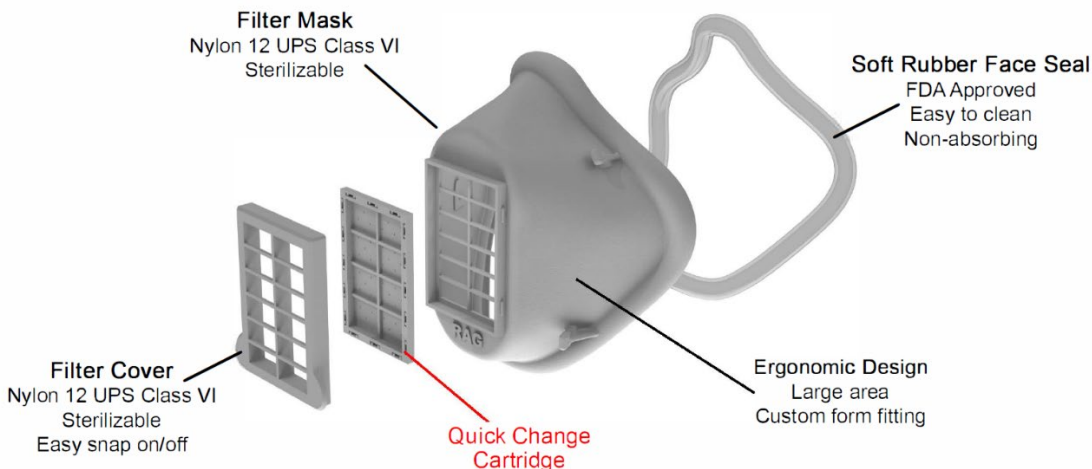
The RFM was designed to be used with different filter media. Our fit testing was completed with sacrificial N95 mask squares, surgical mask and our Polypropylene/nanofiber/Polyester composite filter media. The RFM has not been tested with other filtration media to determine fit test compatibility. The RFM was designed to accept the optional quick-change filter cartridge or a trimmed down surgical or N95 masks. Our medical team suggest that the straps and filter media be replaced after each use. Supplemental documents in the extra tab will provide detailed instructions for replacing the RFM consumable items.

After each use, the following consumables should be discarded as suggested:

- a) Filtration Media
- b) Top and Bottom buttonhole elastic straps

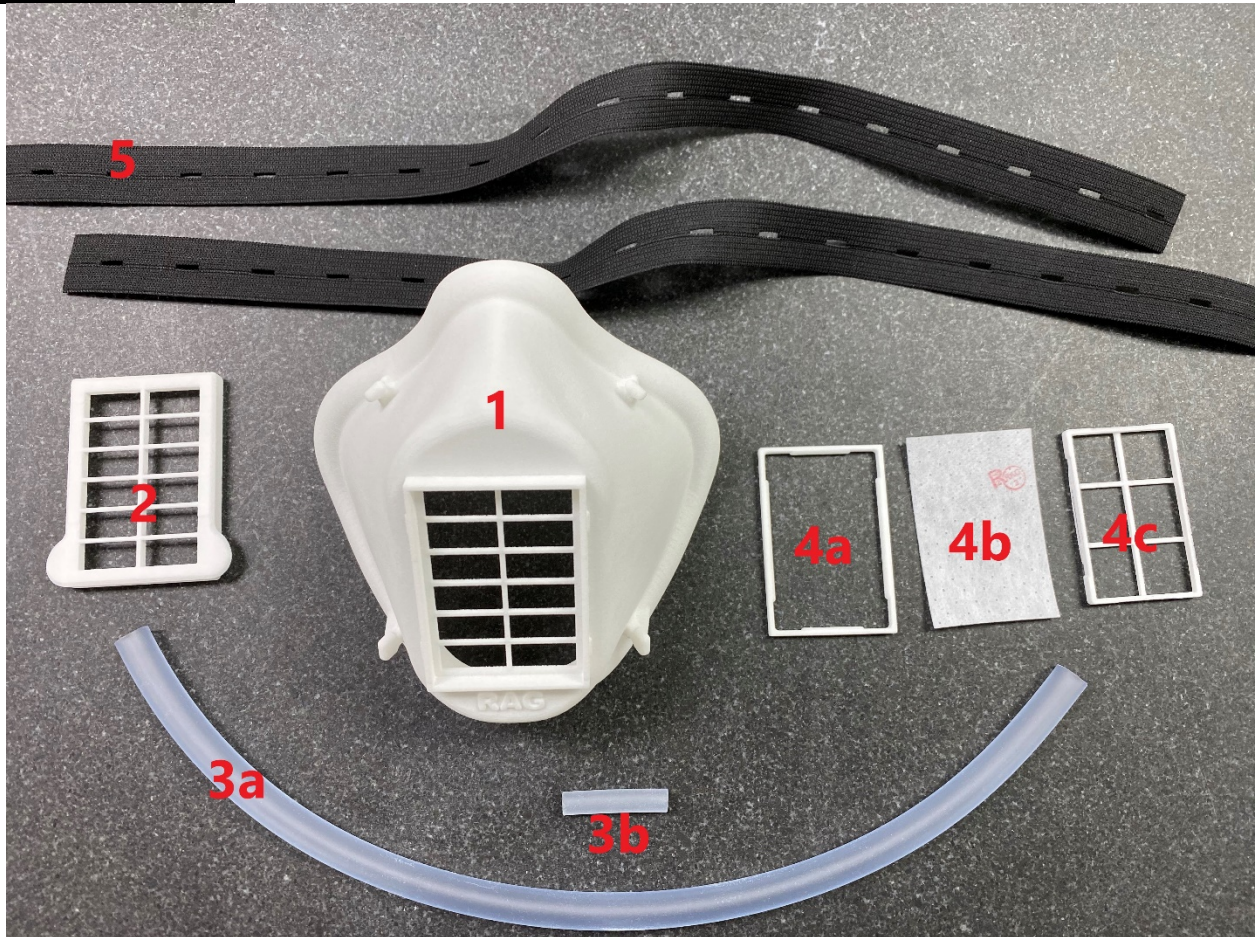
Reusable components after sanitization:

- a) RFM Frame
- b) RFM optional quick-change frame
- c) Comfort tubing



Assembly and Cleaning Instructions

Build of Materials



1. RAG RFM Filter Mask x 1
2. RAG RFM Filter Cover x 1
3. Soft Rubber Face Seal x 1 sourced at <https://www.mcmaster.com/5229K58>
 - a. 1/4" outside diameter tube
 - b. 3/8" outside diameter Tube
4. Quick Change Changeable Frame
 - a. Front of quick-change frame
 - b. Optional MERV 16+ Directional flow filter, surgical mask, N95 mask
 - c. Back of quick-change frame
5. Optional Elastic Button-hole Bands x 2, or any elastic that will provide sufficient pressure against the face to pass all fit check requirements

Assembly Instructions

Please note that Rapid Application Group will upload a 'how to' video of product assembly and operation at <https://rapidapplicationgroup.com/covid-ppe-production/>

- 1) Take the RAG Replaceable Filter Mask (RFM) and identify the nose, this is the top of the mask.
- 2) Take one elastic strap (16"), put the slot nearest one end of the strap over one of the strap attachments point so it hooks over the attachment point.
- 3) Take the free end of the same elastic strap and put the slot nearest the opposite end of the strap over the other upper most attachment point, like you did the first time.
- 4) Take another elastic strap (16"), and follow steps 5-6, but attaching the elastic strap to the two bottom most attachment points.
- 5) The RAG RFM can utilize two different styles of filters, a cartridge or self-cut filter media. If using your own filter media and cutting it to size, follow steps 9-11. If using a replaceable cartridge from Rapid Application Group, follow steps 12-14
- 6) The dimensions of the filter area are 2.32 x 1.54 inches. It will need to be cut larger to make sure there is a good seal. If the filter can be seen on the outside of the mask once the filter cover is seated in place the filter should be large enough.
- 7) Center the cut filter media over the filter opening on the mask.
- 8) Align the filter cover over the filter opening and securely press the filter cover in place, until it is fully seated.
- 9) Remove filter from sealed package.
- 10) Place filter into the filter opening. The side of the cartridge with the exposed filter **MUST** face toward the inside of the mask. Align the filter cover over the filter opening and securely press the filter cover in place, until it is fully seated.
- 11) Take the soft tubing and firmly push the tube into the groove on the RFM. Orient the pvc tubing as shown in Figure 01. (Around the nose the tubing might need to "massaged" into place to prevent kinking). Try not to stretch the tubing while inserting it into the groove. Pay special attention to where the two ends of the tubing meet. There should not be a gap between the two faces.
- 12) Turn the mask so the front is facing the ground and let it dangle by its straps. The filter cap should be snug enough so it doesn't fall off when you turn the mask over and the straps shouldn't pull through the attachment points.
- 13) Perform a final inspection of the mask after assembling all components to ensure nothing is damaged or dirty and the RFM is assembled correctly. Do not use the mask if it is damaged or visually compromised. Ensure the filter opening is completely covered by filter media. Make sure the filter cover is securely seated and a snug fit.
- 14) After final inspection, the mask is ready for operation.

Instructions with pictures are attached in the extras tab.

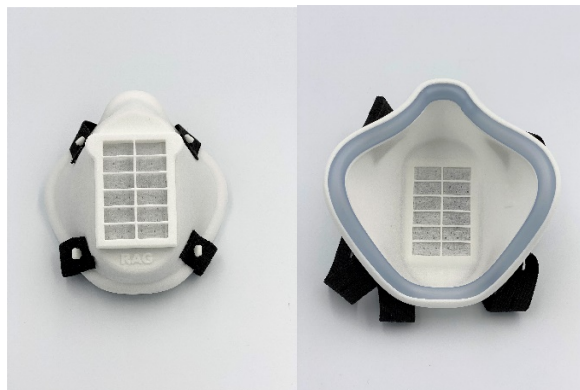
Recommended Cleaning procedures:

Please note that Rapid Application Group will upload a 'how to' video of cleaning procedures and operation at <https://rapidapplicationgroup.com/covid-ppe-production/>

The ORS_2018_Influence of sterilization on laser sintered polyamide materials in the extra tabs gives quantitative analysis of three different scenarios of sterilization of PA2200 or PA1101. This document provides a recommended method of sterilization but does not include all methods. 3D Systems Duraform PA, EOS PA2200 or PA 1101 are the recommended media for printing in medical applications as they remain stable through the disinfectant process.

We recommend that due diligence is taken to ensure that the RFM is sanitized and disinfected using the following procedures before each use.

- 1) Perform hand hygiene procedures IAW [The Center for Disease Control Hand Hygiene procedures](#)
- 2) Don a pair of clean medical grade gloves.
- 3) Remove and properly discard both the bottom and top buttonhole elastic straps.
- 4) Remove the filter cover and dispose of the optional quick-change filter and frame. If not using the filter frame, remove the filter cover and dispose of the filter media.
- 5) Ensure any dirt and debris have been removed during a hot water and soap scrub.
- 6) Remove the tubing that is in contact with the face
- 7) Using one of the recommended disinfecting products from the list outlined in the [EPA guidelines Disinfectants](#)
- 8) Wipe down and disinfect the entire front side of the mask.
- 9) Wipe down and disinfect all areas inside the mask and in the channel that holds the comfort tubing.
- 10) Wipe down and disinfect the entire filter cover.
- 11) Remove gloves, perform hand hygiene procedures, and replace gloves.
- 12) Wipe down the entire mask again making sure to get all surfaces of the mask (inside and outside surfaces) one more time.
- 13) The EPA guidelines recommends that all surfaces are visibly wet with disinfectant.
- 14) Allow mask to dry completely
- 15) If available, use a medical autoclave to sterilize as applicable.
- 16) Reassemble the mask as directed in the assembling instructions.



Recommended Disinfecting Products:

According to the [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](#) , it is recommended that this device is disinfected by using Super Sani-Cloth(s), CaviWipes, 10% Chlorine bleach solutions, Hydrogen peroxide, or soap and water.

Recommended Sterilization Procedure:

It is recommended that the RFM body to be sterilized by an autoclave sterilization process. The parameters that the autoclave should be set at are for this material: Temperature 132 celsius with a minimum exposure time of 5 minutes, and a drying time of 30 minutes.

Filter Media

The filter material used will in part determine the level of protection provided by the supplementary mask. It is recommended to use materials that meet the requirements of ASTM level 1, 2 or 3 barrier medical face mask materials. The RFM accepts trimmed N95, surgical masks, or other filtration media depending on your specific filtration needs.

Materials in Contact with Skin

Only two components will come into direct contact with the user's skin.

1. Tubing for comfort and to create a seal.
2. Buttonhole or other elastic.

Recommended Strap Material

1. Elastic or other material that will provide enough tension to maintain a seal. This will be tested during the fit test procedure.

