

Stopgap Face Mask (SFM) - Instructions for Use

These instructions for use must be provided with the Stopgap Face Mask (SFM) when it is being delivered for use and correspond to **Revision B** of the Mask Body and **Revision G** of the Filter Cover of this face mask. The revision of the corresponding mask body and filter cover can be found on the front side of the mask as shown in Fig 1.

Appropriate Use Criteria

The Stopgap Face Mask is designed to be a suitable replacement for a surgical mask and is not a suitable replacement for a respirator (N95) face mask. As a supplemental surgical mask, this device is intended to provide liquid barrier protection for medical purposes as defined in the [FDA Guidance Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency](#). This mask should be used within the CDC guidelines for [Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies](#), specifically the section on “*Healthcare Provider Use of non-NIOSH Approved Masks or Homemade Masks*”.

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. This supplementary face mask **DOES NOT MEET REQUIREMENTS FOR AIRBORNE PRECAUTIONS** and **SHOULD NOT BE USED DURING ANY AEROSOL GENERATING PROCEDURES**. The supplementary mask should not be used in a clinical setting where the infection risk level through inhalation exposure is high.

This supplementary face mask was created as an emergency action in effort to provide protection as a backup Personal Protective Equipment (PPE) option if the traditional PPE devices have become unavailable. This device has not gone through the same regulatory approval process as traditional PPE, but has gone through a special verification process expedited strictly for the response to the COVID-19 pandemic.

This device is intended to be use only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act).The decision to implement this device should be made with careful consideration and under the consultation of the corresponding institution’s occupational health and infection control departments.

The information included in this document provides device description and feature overview, recommended assembly steps, and cleaning instructions for reuse.

Device Overview

The Stopgap Face Mask consists of two main components (the mask body and the filter cover) which include features for attaching two elastic straps and receiving a patch of filter material. The mask body is offered in three different sizes (Small, Medium, & Large) and all other components are consistent across all three sizes. A diagram of the components is shown below in Fig. 1.

This mask is designed to receive a square patch of filter material that can be inserted into the filter box and secured by the filter cover for use. It is recommended that the square filter patch, foam nose piece, and elastic straps are disposed of after every use of this device. The remaining parts of the plastic mask can be decontaminated using common disinfecting solutions and have the ability to be sterilized for reuse. See Appendix A for recommended decontamination methods for this device. Filter material to be used with this supplemental mask should be cut to a 3 in x 3 in patch. See Appendix B for guidelines on filter material selection.

Components to be disposed of after every use or immediately after potential contamination by bodily fluids:

- Square filter patch
- Top elastic strap
- Bottom elastic strap
- Foam nose piece

Components to be decontaminated and reused:

- Plastic mask body
- Plastic filter cover

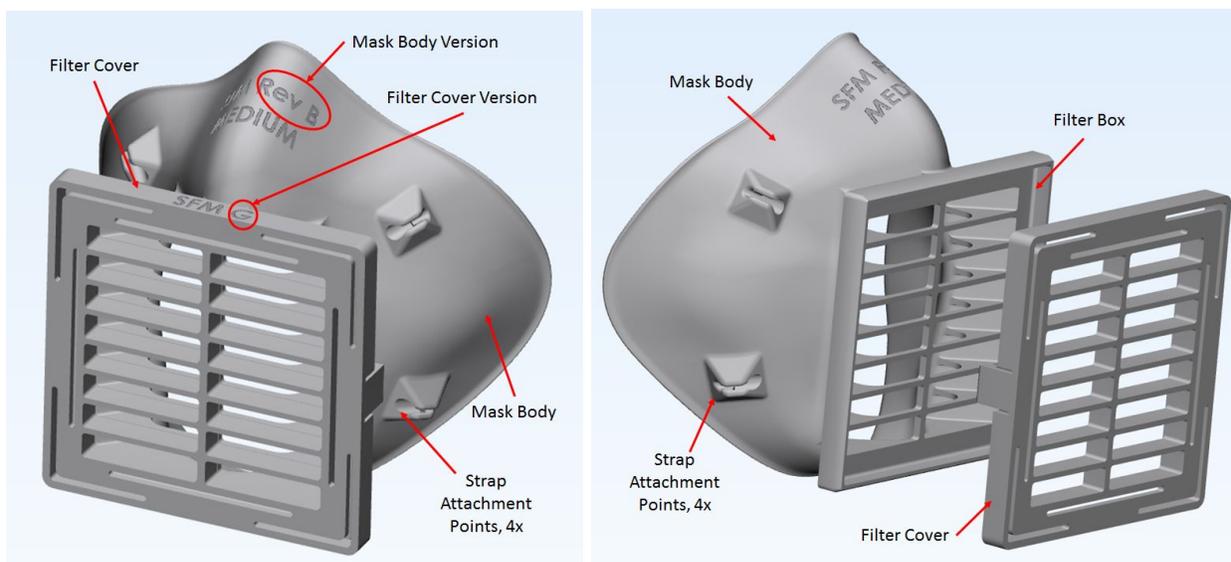


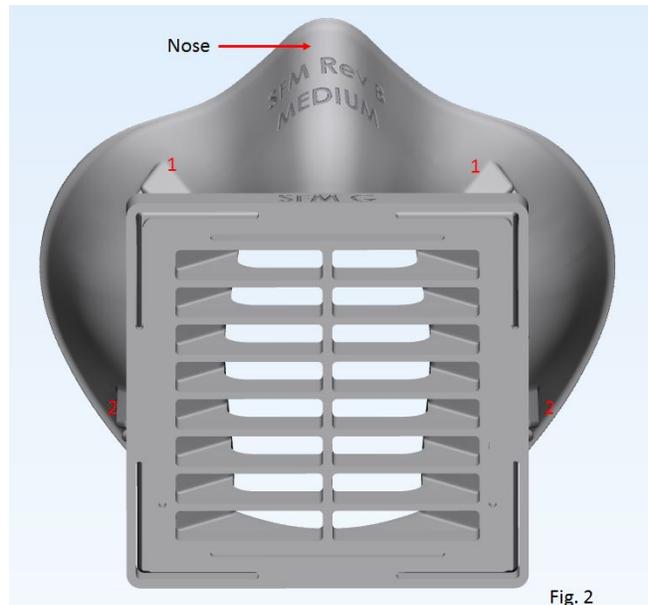
Fig. 1

Point of Care Assembly and Cleaning Instructions

Refer to the steps outlined below for instructions on how to properly assemble, clean, and reassemble for reuse of the supplemental face mask.

Assembly Steps

1. Find a clean disinfected environment to work in.
2. Don a pair of clean gloves and don a face mask for the assembly process.
3. Take a single mask body component and identify the nose feature, this will indicate the top part of the mask
4. Take one elastic strap (18”), create an overhand knot at each end of the strap, slide the end of the strap through the first set of attachment points (both marked #1 in Fig. 2), and make sure the knots are seated securely.
5. Take another elastic strap (18”), create an overhand knot at each end of the strap, slide the end of the strap through the second set of attachment points (both marked #2 in Fig. 2), and make sure the knots are seated securely.
6. Cut a patch from the filter material that is slightly smaller than the size of the filter box, 3 in x 3 in.
7. Once the square filter patch is cut, center it within the square feature (the filter box) on the front of the mask.
8. With the filter patch centered, attach the filter cover by pressing it all the way down onto the filter box until it snaps into place and is secure. Once seated, squeeze together the two connection clips on either side of the cover to ensure engagement with the mask body. Then press on all 4 corners of the cover to ensure it is fully seated. The filter patch should be sitting flat underneath the filter cover and completely covering all holes located in the front of the mask.
9. Take one strip, approximately 4 in long, of the adhesive backed foam and remove the protective sheet on the back to reveal the adhesive. Stick the foam strip to the inside of the nose feature of the mask, making sure that it is aligned with the inside of the edge of the mask as shown in Fig 3.



10. Turn the mask so the front is facing the ground and let it dangle by its straps. The filter cover 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.
11. Do a final inspection of the mask with all components assembled to ensure nothing is damaged or dirty and everything has been assembled properly as shown in Fig 3 below. Take special note to ensure the filter patch completely covers all the filter grill holes. **DO NOT USE THE MASK OR ANY COMPONENTS IF THERE IS ANY VISIBLE DAMAGE.** If any components are visibly damaged, properly dispose of the component and get a replacement.
12. Once final inspection is complete, this mask is ready to be used.

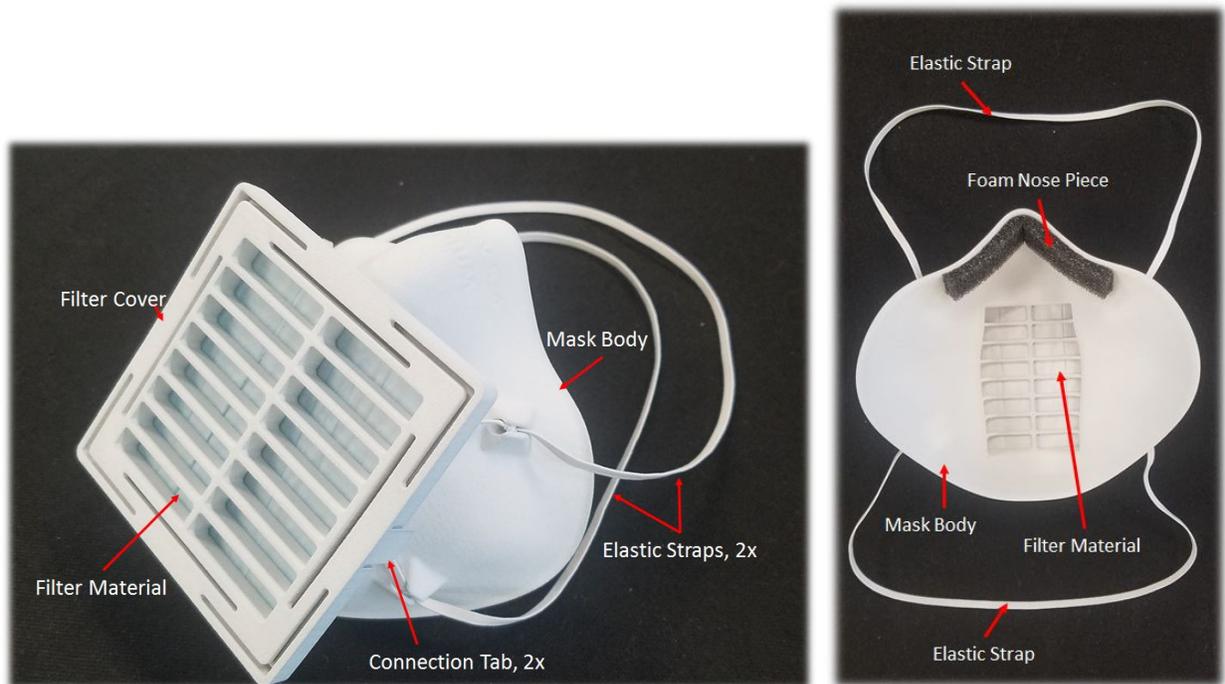


Fig. 3

Putting on the Stopgap Face Mask

1. [Follow CDC guidelines for how to don PPE gear](#)
2. There are three different sizes of the Stopgap Face Mask (Small, Medium, & Large). The proper size should be selected by determining which of the three sizes provides the closest and most comfortable fit to the user's face.
3. If the elastic is too loose, knots can be added to the elastic straps shortening them to a length that creates enough tension to keep the face mask snug to the user's face.
4. The foam nose piece can also be removed if the face mask fits better and more comfortably without it.

Taking off the Stopgap Face Mask

5. [Follow CDC guidelines for how to doff PPE gear](#)

Recommended Cleaning

The recommended materials selected for making the reusable components of this supplemental face mask have a proven track record for remaining stable during and after the use of the list of disinfectants and sterilization process outlined in Appendix A. However, the formal testing is ongoing and has not been completed yet. Leveraging existing data and recommendations from the CDC and EPA, the following decontamination procedures outlined are provided only as recommendations to be considered by local hospital administration considering the use of the Stopgap Face Mask.

Consultation from the local occupational health and infection control departments are necessary to determine if these recommended decontamination procedures are appropriate at each corresponding institution.

It is recommended that the following decontamination steps are performed after each use of the supplemental mask and the user has followed the proper procedures for doffing the device.

Cleaning Steps

1. Perform hand hygiene procedures and don a pair of clean gloves and a face mask.
2. Remove and properly dispose both of the elastic straps and the foam nose piece.
3. Remove the filter cover by disengaging the two connection clips on either side of the filter cover, these tabs are shown in Fig 3. This will allow the filter cover to be removed from the mask body and the filter material to be accessed. Then properly dispose of the filter patch.
4. Wash the filter cover and mask body with soap and warm water to remove any large particulate on these components.
5. Using one of the recommended disinfecting products from the list outlined in Appendix A, prepare to perform steps 4-9 to disinfect the mask.
6. With one of the disinfecting products selected, wipe down the entire front side of the mask taking care to get inside the filter box.
7. Wipe down the entire inside of the mask.
8. Wipe down the entire filter cover.
9. Doff gloves, perform hand hygiene procedures, and don a new pair of gloves
10. Wipe down the entire mask again making sure to get all surfaces of the mask (inside and outside surfaces) one more time.
11. Ensure the surface is visibly wet with the disinfectant product for the duration of the contact time as defined by the [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](#).
12. Set the mask aside in a clean environment to dry completely

13. Optional Sterilization step: run both the mask body and filter cover components through a standard autoclave cycle, as outlined in Appendix A, if this has been required by the corresponding institution's occupational health and infection control departments.

Preparing the Supplementary Mask for Reuse.

1. Once the mask is dry, follow the assembly steps listed above to properly assemble the mask components for reuse.

Appendix A: Recommended Decontamination Methods

Recommended Disinfecting Agents:

The [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](#) recommend using any of the following solutions for the disinfecting procedures of this device with the contact times provided in the EPA guidelines.

1. 10% chlorine bleach solution
2. Super Sani-Cloth
3. CaviWipes
4. 3% Hydrogen peroxide

Optional Sterilization Method:

The EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2 along with preliminary results from ongoing testing support the use of common disinfection agents alone should be sufficient for normal use of this supplemental surgical face mask device. However this device has also been created to withstand the autoclaving process as well, if a sterilization process is required by the corresponding occupational health and infection control departments.

Below is a table outlining the sterilization parameters that are recommended to be used for optional autoclave sterilization processing.

Temperature (°C)	Minimum Exposure Time (min)	Drying Time (min)
132	5	30

It is recommended that all masks be visually inspected after the autoclave cycle is complete. Even though there is testing and data to support the use of steam sterilization on the materials for the mask body outline in Appendix C, there hasn't been testing completed yet to determine the maximum number of autoclave cycles that this device design can withstand. Because of this, all masks should be visually inspected after the sterilization step to ensure that no cracks or gross deformation has occurred after repeated sterilization cycles. If cracks or deformation of the mask body or filter cover are discovered, that component is no longer usable and should be disposed of.

Appendix B: Recommended Filter Materials

The level of protection provided by the supplementary mask will be determined in part by the filter material used. It is recommended to use materials that meet the requirements of ASTM level 1, 2 or 3 barrier medical face mask materials as specified in ASTM Designation: F2100–19 *Standard Specification for Performance of Materials Used in Medical Face Masks*. The design only accepts filter materials up to 0.20 in (0.5mm) thick; anything thicker will prevent the filter cover from seating fully. One option is to cut up existing traditional surgical face masks that have qualified as a level 1, 2, or 3 per ASTM F2100. A single traditional surgical face mask will make four filter patches.

Appendix C: Materials in Direct Contact with Skin

Only three components will come into direct contact with the provider's skin (the foam nose strip, the elastic straps, and the mask body).

Materials for the Foam Nose Strip

It is recommended that the nose padding be made from 1/4" thick 1/2" width polyurethane foam strips with adhesive on the back and cut to ~ 4" or similar material. This component is optional and disposable. It's main purpose is for providing comfort over long durations of use and to prevent air from escaping near the nose and into the eyes or eyewear.

Materials for the Elastic Straps

It is recommended that the straps be made from 1/8" thick braided elastic strap material or similar material. This component is disposable and its main purpose is providing enough tension to keep the mask on the face during use.

Materials for the Mask Body

Since the mask body component will be in direct contact with the user's skin for long durations of time, it is recommended that only materials and processes with existing examples of FDA cleared skin contacting applications should be used. Below are the materials that have been recommended in the manufacturing guidance document for manufacturing of the Stopgap Face Mask (SFM)

Material	Manufacturer
DuraForm ProX PA	3D Systems
HP 3D High Reusability PA 11	HP
HP 3D High Reusability PA 12	HP
HP 3D High Reusability CB PA 12 (Monochromatic)	HP
PA 1101	EOS
PA 2200	EOS