

Supplemental COVID-19 Face Shield – Instructions for Use

These instructions for use correspond to Model ID 3DPX-013375, named Faceshield 1. The design is a remix of “Easy 3D printed Face Shield” by HanochH” Thingiverse thing: 4233193 to include a post for attaching elastic buttonhole strap.

Appropriate Use Criteria

This supplementary face shield 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 used 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 as well as recommended assembly steps and cleaning instructions for reuse.

***For additional guidance on appropriate use of supplemental face shields, please defer to the CDC “Strategies for Optimizing the Supply of Facemasks” (2020) in healthcare settings when there is limited supply:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html>

Device Overview

This supplementary face shield consists of three (3) parts: the 3D printed forehead visor, the clear plastic shield, and an adjustable buttonhole elastic strap. A diagram of the components is shown below in Fig. 1.

This forehead visor is designed to receive a 9" x 11.5" thermal laminating sheet, 3 mil (or standard 8.5" x 11" transparency sheet, medium weight). The clear plastic shield is inserted into the brim of the forehead visor. Therefore, this minimal assembly design uses friction to hold the shield in place (i.e., does not require penetrations in shield material to install). Finally, an adjustable elastic strap is cut to the desired length of the end user to support snug fit.

The forehead visor and clear plastic face shield can be disinfected using common disinfecting solutions and reused. See Appendix A for disinfecting solutions recommended for this device. See Appendix B for guidelines on recommended material selection.

Components to be disinfected and reused if proper disinfectant protocol is followed and there is no visible damage to parts:

- Forehead Visor
- Clear plastic shield

Components to be disposed of after potential contamination by bodily fluids:

- Elastic Buttonhole Strap (extra straps available)

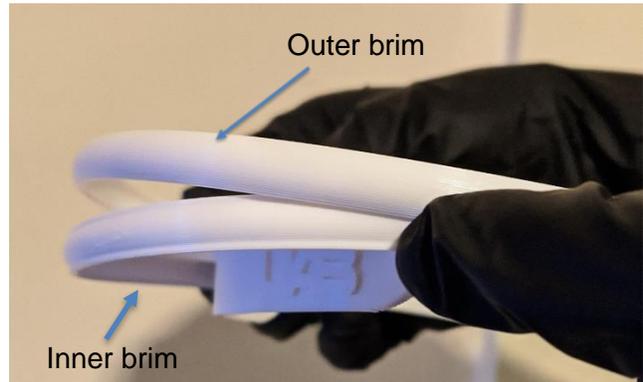
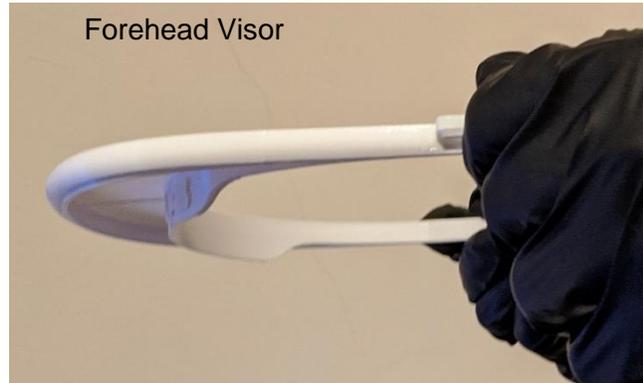
Fig 1.



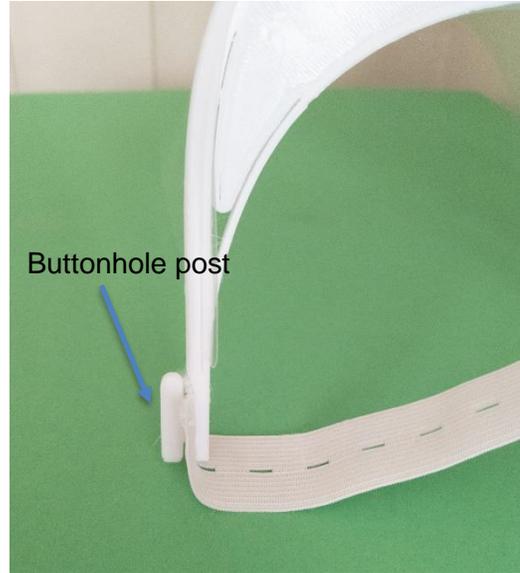
Assembly Steps

For proper assembly of the supplemental face shield, please refer to the instructions and pictures to the right and below.

1. Find a clean disinfected environment.
2. Don a pair of clean gloves.
3. We recommend following a standard disinfecting protocol as outlined in Recommended Cleaning prior to first assembly (see recommended disinfectants below).
4. Take a single forehead visor and identify the flat top.
5. Lift the outer brim.
6. Refer to pictures for inserting the clear plastic shield into forehead visor. Insert one end in-between the outer and inner brim. Loading the shield in place is easier if you insert the first corner near the middle area and tug up until the shield wraps around the brim evenly from side to side.
7. Slide the outer brim back up into the original position.



8. Attach the elastic strap to the forehead visor using the buttonhole posts.
9. Do a final inspection prior to delivery of the faceshield with all 3 parts assembled to ensure nothing is damaged and everything has been assembled properly as shown in the pictures.
10. (Optional) Place a strip of surgical tape on the inside edge of the forehead visor to increase comfort while wearing the face shield.



Donning the Supplementary Face Shield

Follow CDC guidelines for how to don a face shield.

https://www.cdc.gov/vhf/ebola/hcp/ppetraining/n95respirator_gown/donning_13.html

Doffing the Supplementary Face Shield

Follow CDC guidelines for how to remove a contaminated face shield.

https://www.cdc.gov/vhf/ebola/hcp/ppe-training/n95respirator_coveralls/doffing_08.html

Cleaning Instructions

Recommended Cleaning

These cleaning steps are performed after each user is finished needing the PPE or device has become obviously contaminated. If device is obviously contaminated remove immediately and replace with a new device while following procedure to disinfect the contaminated one. Follow the proper procedures for doffing the device.

1. Perform hand hygiene procedures and don a pair of clean gloves.
2. Remove and properly dispose of the elastic strap and shield if exposed.
3. Remove the Shield from the forehead visor.
4. Using one of the recommended disinfecting products from the list outlined in Appendix A, prepare to perform steps 5-9 to disinfect the face shield.
5. Wipe down and disinfect all faces and features on the forehead visor.
6. Wipe down and disinfect both sides of the clear plastic Shield.
7. Doff gloves, perform hand hygiene procedures, and don a new pair of gloves.
8. Wipe down the entire face shield again making sure to cover all surfaces of the face shield (inside and outside) one more time.

9. 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-CoV2 ([EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](#)).
10. Wipe any excess disinfectant and dry the face shield using a clean paper towel.

Preparing the Supplementary Face Shield for Reuse.

1. Once the face shield is dry, follow the assembly steps listed above for assembly of a new face shield.

Recommended Disinfectants

Appendix A.

From FDA guidelines on [Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#) released March 2020 it is recommended that “this policy is intended to remain in effect 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 policy recommends to use an approved disinfection agent as it should “minimize the viability of SARS-CoV-2” on the surface of the forehead visor and face shield.

From the EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2 (<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>) and American Chemistry list of Novel Coronavirus (COVID-19)—Fighting Products the (<https://www.americanchemistry.com/Novel-Coronavirus-Fighting-Products-List.pdf>), based on the informal testing done, it is recommended to use the following four solutions for the disinfecting procedures of the face shield. Other disinfectants may work as well but have not been evaluated.

1. Super Sani-Cloth 2.
2. 10% chlorine bleach solution (*Replace shield if clouding occurs)
3. CaviWipes
4. Soap and water

Recommended Materials

Appendix B.

The Faceshield 1 is made of 3 simple parts:

1. Forehead Visor/shield frame: Amazon Basics, 3D Printer Filament – PETG, 1.75mm
2. Face shield: Fellowes Thermal laminating sheets, 11.5” x 9”, 3 mil Thickness.
 - Transparency film, 11” x 8.5”, medium weight will fit into the frame, but may be brittle or less preferred.
3. Elastic strap: Daystart, 1” buttonhole knit stretch elastic

*Optional: 3M Micropore Surgical Paper Tape https://www.3m.com/3M/en_US/company-us/all-3m-products/~3M-Micropore-Surgical-Tape/?N=5002385+3293321960&rt=rud

Materials in Direct Contact with Skin

Two components will be in direct contact with the user's skin: the Forehead Visor, and the Elastic Strap.

1. Forehead Visor Material: PETG (Polyethylene Terephthalate Glycol-modified).
2. Elastic Strap Material: Polyester and natural latex rubber

*The device also allows for a strip of hypoallergenic surgical tape to be placed on the inside of the forehead visor to increase the level of comfort provided to the user.

Additional Device and User Photos

