

Supplemental COVID Face Shield - Instructions for Use

These instructions for use correspond to the **MADE COVID-19 Face Shield**.

Appropriate Use Criteria

This supplementary face shield was created as an emergency action in effort to protect people by providing backup Personal Protective Equipment (PPE) options if the standard PPE has become unavailable. This device has not gone through the same regulatory approval process as standard PPE but has gone through a special verification process expedited strictly for the response to the COVID-19 pandemic.

The use of this supplementary face shield should always come secondary to existing PPE equipment, standards, and protocol options if available. 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.

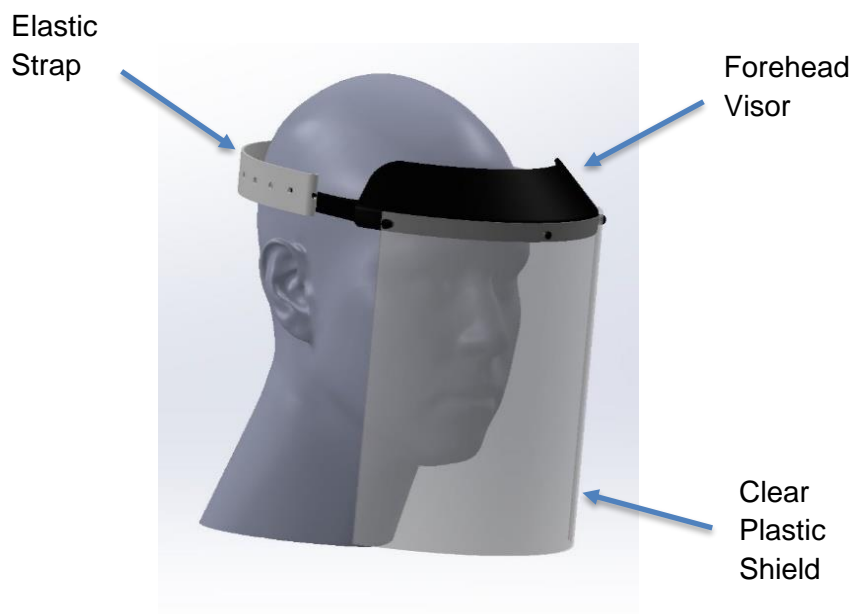
Description

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 disposed after potential Blood Borne Pathogens (BBP) exposure:

- Elastic Strap (extra straps available)



Assembly

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

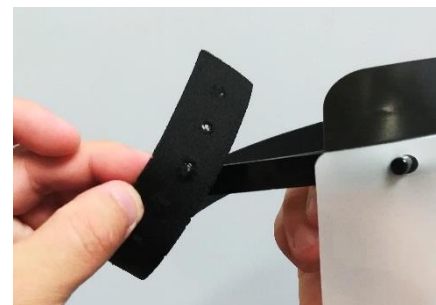
1. Find a clean disinfected environment.
2. Disinfect parts prior to assembly (see recommended disinfectants below).
3. Refer to pictures for connecting clear plastic shield to forehead visor. Connect one end and wrap around.
4. Attach the elastic strap to the forehead visor using the posts on both sides of the forehead visor.
5. Inspect the mask with all components assembled to ensure nothing is damaged and everything has been assembled properly as shown in the pictures.
6. (Optional) Place a strip of micro-foam 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/ppe-training/n95respirator_gown/donning_13.html)
(https://www.cdc.gov/vhf/ebola/hcp/ppe-training/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)
(https://www.cdc.gov/vhf/ebola/hcp/ppe-training/n95respirator_coveralls/doffing_08.html)



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 below, prepare to perform steps 5-9 to disinfect the face shield.
5. Wipe down and disinfect the all faces and features on the 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-CoV-2 \(https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2\)](https://www.epa.gov/pesticide-registration/list-n-disinfectants-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

From FDA guidelines on [Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease?utm_campaign=2020-03-29%20FDA%20Issues%20New%20Enforcement%20Policy%20for%20Sterilizers&utm_medium=email&utm_source=Eloqua) released March 2020 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease?utm_campaign=2020-03-29%20FDA%20Issues%20New%20Enforcement%20Policy%20for%20Sterilizers&utm_medium=email&utm_source=Eloqua) 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 a Forehead Visor and 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) (<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](https://www.americanchemistry.com/Novel-Coronavirus-Fighting-Products-List.pdf) 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. Note: the following list is in preferential order and have been tested with this device.

1. Super Sani-Cloth
2. 10% chlorine bleach solution (*May fog Shield over time)
3. CaviWipes
4. Soap and water

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

Forehead Visor Material: Bayblend FR110 PC/ABS blend.

Elastic Strap Material: Polyester cover over elastomeric core