

Supplemental COVID Face Shield - Instructions for Use

These instructions for use correspond to V1 of the **Central Virginia VA Health Care System (CVHCS) COVID-19 Face Shield**. The revision of the corresponding shield can be found on the inside edge of the shield.

Appropriate Use Criteria

This supplementary face shield was created as an emergency action in an 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.

Device Overview

This supplementary face shield consists of three (3) components: the shield, the frame, and an adjustable strap. A diagram of the components is shown below in **Fig. 1**.

This Face Shield is designed to receive a custom cut sheet of PETG plastic (9x11"). The clear plastic face shield and frame can be disinfected using common disinfecting solutions and reused. See **Appendix A** for disinfecting solutions recommended for this device. This device can utilize various shield materials to accommodate for variation in supply chain access. See **Appendix B** for guidelines on recommended material selection.

The frame could be 3D printed with PLA or Nylon, or even injection molded (in 3 separate parts). The tested design was laser cut from 3/16" polypropylene (copoly). This material is used in orthotics and prosthetics extensively and is widely available. It is not porous as are most 3D printed parts and is very flexible. It is not an ideal plastic for laser cutting, but performs reasonably well in this application. It does however require some sanding and cleaning to remove excess melted material.

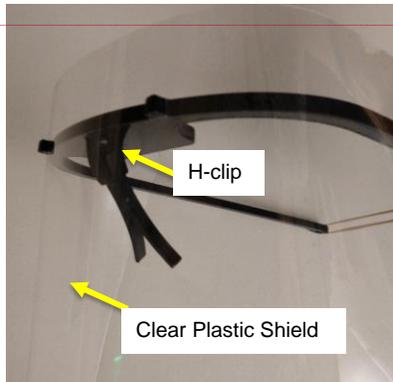
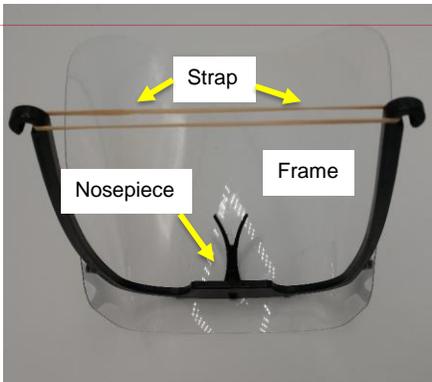
Components disposed of after daily use or potential Blood Borne Pathogens (BBP) exposure (follow your facility guidelines):

- Strap

Components to be disinfected and reused:

- Laser cut Frame (and attached nose pieces)
- Clear plastic shield

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Point of Care Assembly, Packaging, and Cleaning Instructions

For proper assembly of the face shield, please refer to the instructions outlined below.

Assembly Steps

Station 1

1. Frame pieces- (off the laser cutter): place in a wash tub with soap and water, scrub down, then rinse in clean water and place in a wash tub with 10% Bleach solution for disinfection/sterilization, then place on a clean drying rack.
2. Plastic shields- off the laser cutter: remove protective film without touching the clean plastic shield, hand plastic shield to a teammate with clean gloved hands.

Station 2

1. Find a clean disinfected environment to work in.
2. Perform hand hygiene and don clean gloves.
3. Take a single frame and firmly fold it into a closed glasses frame orientation (Figure 1). Allow to unfold.
4. Take a single folded frame, H-clip, and nosepiece. Snap the nosepiece into the H-clip, then secure the other end of the H-clip in the center of the frame.
5. Take one strap and slide it through the two attachment holes on either side of the frame and tie a knot on the ends of the strap to keep it from slipping out of the frame.
6. Holding the frame in your non-dominant hand, secure one of the outer holes in the Shield to one of the outermost frame pegs (label "c" in Fig. 2). Pull the Shield across the Frame so that the middle and remaining edge holes line up with the pegs on the Frame. Snap the frame over one peg at a time beginning from the first. The shield should securely snap into place.
7. (Optional) Place a piece of tape over the mounting holes/pegs in the face shield to fully seal any remaining gaps.
8. Gently shake the face shield to ensure that the shield is securely fastened and will not fall off during use.
9. Fold the assembly like you would a pair of glasses and clip the arms of the frame together using the provided clip.
10. Do a final inspection of the shield with all components assembled to ensure nothing is damaged and everything has been assembled properly as shown in Fig. 1 above.

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Point of Care Assembly, Packaging, and Cleaning Instructions

Packaging Instructions

For packaging in bulk (5+ units at a time)

1. Insert folded Face Shields into bag tube
2. Heat seal end
3. Seal distal most Face Shield from roll to separate it from the remaining Face Shields and cut off.
4. Repeat step 3 until all Face Shields are sealed independently.

For packaging one at a time

1. Insert folded Face Shield into bag tube
2. Heat seal end
3. Seal Face Shield off from remainder of the roll.

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 and the user has followed 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 strap if exposed.
3. Remove the shield plastic from the frame.
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 (frame and shield).
5. Wipe down and disinfect all the faces and features on the Frame.
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.

Appendix A: Recommended Disinfectants

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>), it is recommended to use the following four solutions for the disinfecting procedures of the face shield. Note: the following list is in preferential order and have been tested with this device.

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

Appendix B: Recommended Shield Materials

The level of protection provided by the supplementary face shield will be determined in part by the shield material used. The following list is in preferential order and only the first two have been tested with this device. Other readily available materials may be suitable as a replacement but have not been tested and should be used as a last resort.

1. Custom cut PETG (up to .016" thickness)
2. Apollo InkJet Printer Transparency Film

The following are also acceptable and have been tested by other Users:

3. GBC ClearView Presentation Covers (P/n: GBC 2000041)
 - a. Avery (P/n: 16741)
3. Highland Transparency Film 901 (P/n: 78-6969-8594-0)
4. Corporate Express Transparency Film (P/n: CEB00560)

Appendix C: Materials in Direct Contact with Skin

Two components will be in direct contact with the provider's skin; the Frame, and the Elastic Strap.

Frame Material(s): Material selection will be subject to availability at each printing location. Co-Polymer Polypropylene is acceptable for the frame portion and is available through most local Plastic and Prosthetic Suppliers.

Strap Material(s):

- Polyester/Nylon blend
- Shock Cord (polypropylene coated latex band)
- Rubber Bands

Other strap materials may be suitable, however due to limited availability have not been tested.