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.

Recommended Disinfectants
Disassemble to clean each component. The following list of disinfectants are in preferential order and have been tested with this device. Other disinfectants may work as well but have not been evaluated.

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

For More Information
https://3dprint.nih.gov/discover/3dpx-013887