Georgia Tech Face Shield - Instructions for Use

These instructions for use correspond to Revision (1) of the Georgia Tech Face Shield.

These Instructions for Use must be communicated to the End User of the Device

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 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 device is a face shield and the FDA classification code is found in classification regulation 21 CFR 878.4040 and product code LYU.

No applicable warnings exist for the device.

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

The Georgia Tech Face shield is shown in Fig. 1 and its primary components in Fig. 2. The device provides clearance away from the worker’s face to allow for other PPE including respirators and facemasks, as well as eye loupes and prescription glasses. The components of the device include reusable elements (rigid band, straps, tape) as well as disposable elements (Polyethylene Terephthalate sheet). The face shield frame can be disinfected and the clear Polyethylene Terephthalate (PET) sheet should be discarded.

See Appendix A for recommended disinfecting solutions and sterilization methods for this device. See Appendix B for guidelines on material selection.

Components to be disposed of after every use or immediately after potential contamination by bodily fluids:
- Polyethylene Terephthalate (PET) sheet

Components to be disinfected and reused:
- Rigid band
- Foam tape
- Hook and loop fastener

Fig. 1. Face Shield Images

Fig. 2. Face Shield Components
Point of Care Assembly and Cleaning Instructions

For instruction on how to properly assemble, clean, and reassemble for reuse of Georgia Tech Face Shield, please refer to the steps outlined below.

Assembly Steps (reference Figure 1):
1. Find a clean disinfection environment to work in
2. Don a pair of clean gloves
3. Slide tabs on Band into holes on Sheet.
4. Loop slot in Straps over hooks on Band.
5. Apply Foam Tape to inside brow-line on Band.
6. Attach Polyethylene Terephthalate (PET) film to Band.
7. Do final inspection of our device prior to delivery.

Consult the FDA guidance on face masks and face shields posted in April 2020: https://www.fda.gov/media/136449/download

Recommended Cleaning
The recommended materials selected for making the reusable components of this Georgia Tech Face Shield 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, there has been no formal testing completed yet to support the claim that the use of disinfectants alone is a sufficient cleaning approach against the COVID19 virus specifically on the surface of this material.

Because of this, it is recommended that the following disinfection and sterilization steps are performed after each user is finished using Georgia Tech Face Shield and the user has followed the proper procedures for doffing the device.

1. Remove Polyethylene Terephthalate (PET) sheet and discard.
2. Clean rigid band, foam tape and hook and loop strap with disinfecting agents identified in Appendix A.
3. Leave materials to dry.

Preparing for Reuse.

1. Attach new Polyethylene Terephthalate (PET) sheet to rigid band.
Appendix A: Recommended Disinfectants and Sterilization Methods

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 Georgia Tech Face Shield.

Recommended Disinfecting Agents:

From the EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2, it is recommended to use the following solutions for the disinfecting procedures of this device.

- Isopropyl alcohol
- Hydrogen peroxide
Appendix B: Recommended Materials

1. Polyethylene Terephthalate (PET) sheet – transparent shield film, 0.004”-0.007” thick
2. Low density polyethylene – primary band material
3. Polycarbonate – alternate band material
4. Hook and loop fastener – 3/4” wide
5. Open cell polyurethane foam tape – 3/16” wide, 1/4” thick
Appendix C: Materials in Direct Contact with Skin

1. Low density polyethylene – primary band material
2. Polycarbonate – alternate band material
3. Open cell polyurethane foam – foam padding located on forehead contact of rigid band
4. Nylon – hook and loop fastener on rigid band