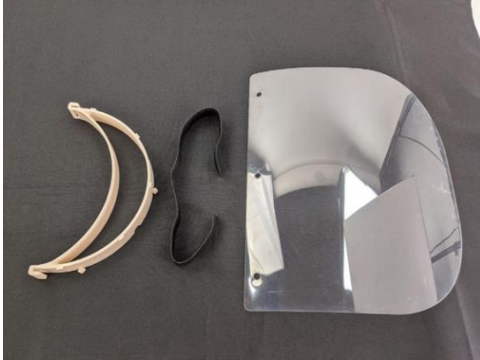


Argen Face Shield Kits

Personal Protective Equipment (PPE)

Face shields for protecting professionals.



Kit Components

Kits contain the following components. Instructions for assembly are available upon request.

- 1 - 3D Printed Headband
- 1 - Clear Plastic PET Shield
- 1 - Head Strap

Component Details

Printed Headband: The printed headband uses a tan material in a solid, open gap design.

Clear Plastic Shield: The shield is a clear, .007" thick, PET film with rounded corners. The exact material may differ due to the availability of films.

Head Strap: The head strap may or may not contain latex.



Re-Use of the Face Shield

Feedback from physicians and infection control groups suggests that the Face Shield product is suitable for reuse with appropriate cleaning in between uses (see "Cleaning the Face Shield"). Each hospital should determine appropriate use / reuse protocols based on a review of the product by the hospital's Infection Control group.

Cleaning the Face Shield

Face shields delivered to facilities should be considered non-sterile. Consult the CDC for guidance on disinfectants known to be effective against COVID-19.

The following materials are not compatible with the headband and should not be used to clean the face shield:

- Hydrogen peroxide vapor sterilization
- Autoclave
- Soaking in isopropanol or other organic solvents

Regulatory Status

In the United States, face shields are considered Class I 510(k) exempt products by the Federal Drug Administration (FDA). Based on current FDA guidance, these face shields do not require FDA clearance.

Per the FDA guidance:

- These products are not "surgical masks" or "full face respirators."
 - These products are not recommended for use: in any surgical setting or where significant exposure to liquid, bodily, or other hazardous fluids may be expected; in a clinical setting where the infection risk level through inhalation exposure is high (without the use of a primary barrier such as a N95 or surgical mask); in the presence of a high intensity heat source or flammable gas.
- The product does not make any claims of particulate filtration or possession of antibacterial or anti-viral properties.