

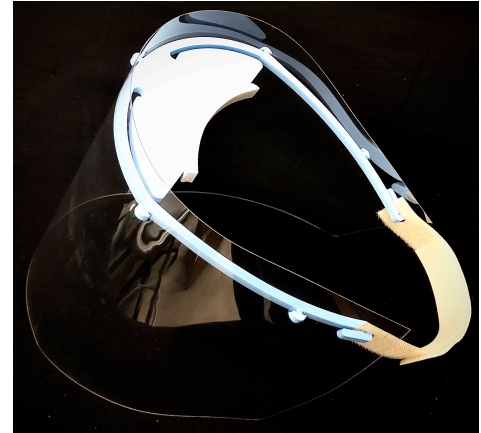
Instructions for Use – Rigid Face Shield Kits

Device Description

The Rigid Face Shield is intended to create a physical barrier separating the eyes, ears, nose, and mouth from the immediate surroundings. This device prevents liquids or droplet splash from contacting the user.

The Rigid Face Shield uses a Sheet connected to a Band. The Band has two Straps to secure the device to the back of the head. This device is intended to be used in conjunction with additional personal protective equipment (such as respirators and safety goggles).

The Rigid Face Shield is intended for single use.



Indications for Use

Face Shields are personal protective equipment intended for protection of the facial area and associated mucous membranes (eyes, nose, mouth, ears) from splashes, sprays, and spatter of body fluids.

Warnings

- **Do not sterilize** (i.e., autoclave).
- **DO NOT USE** if the components show any sign of damage.
- Do not expose components to temperature greater than listed on package labeling.
- Dispose of the product as biohazardous waste per institutional protocol.
- **Face Shields have not been validated for performance or cleaning for re-use.**
- **Face Shields are intended to support COVID-19 response.**
- This product has not been FDA cleared or approved.
- This product has been authorized by FDA under an emergency use authorization for use by healthcare providers as personal protective equipment.
- This product is only authorized for the duration of the declaration that circumstances justifying the authorization of emergency use under Section 564(b)(1) of the Act, 21 USC 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

Precautions

- **DO NOT** exert excessive force when handling the device components. Failure to do so may lead to device damage.
- Avoid creating sharp corners if trimming the Sheet.

Storage and Cleaning

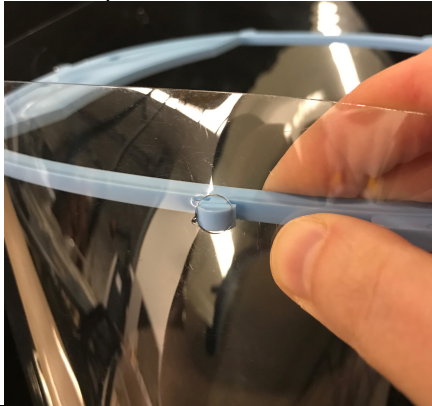
- Compatible with common non-abrasive disinfectants.
- Store in a cool, dry place.

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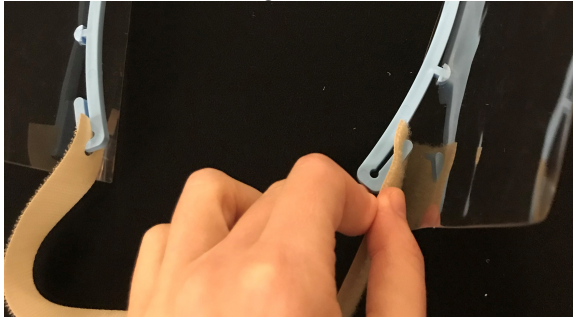
Assembly and Use Instructions

- 1) Sanitize hands prior to handling components.
- 2) Select the following components for each Face Shield to be assembled: **1 Sheet, 1 Band, 2 Straps, 1 Foam Tape**

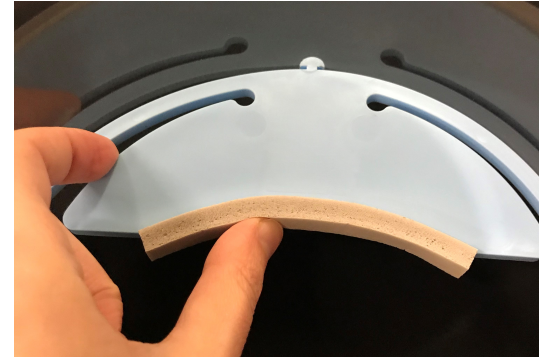
3) Snap the Band tabs into their respective holes on the Sheet



4) Attach the Straps to the Band by looping the Strap slot over the hooks on either side of the Band. Ensure that Straps are oriented to fasten together.

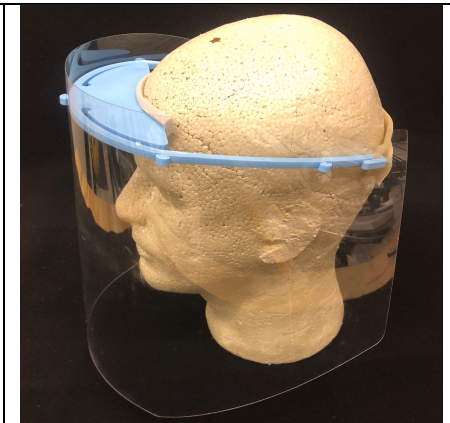


5) Remove paper backing from the Foam Tape. Apply Foam Tape to the brow-line of the Band.



CAUTION: Ensure that the Sheet, Straps and Foam Tape are secured to the Band.
CAUTION: Do not use the Face Shield if not assembled per these instructions.

- 6) Place the Face Shield around the head to cover eyes, nose, ears, and mouth.
- 7) Secure the Face Shield to the back of the head using the Straps. Apply pressure to secure the Straps.
- 8) If needed, trim the Sheet with scissors. Ensure the Sheet can still protect the eyes, ears, and mouth.
- 9) Components are compatible with common non-abrasive disinfectants.
- 10) Dispose of the Face Shield according to institutional protocol.



CAUTION: Avoid creating sharp corners when trimming. Sharp corners may catch on skin or other PPE.