

SLUHN - FI 3D Mask Instructions for Use

Rev: 6.17.20

Appropriate Use Criteria

- The SLUHN FI 3d Mask is designed to be a suitable replacement for a respirator (N95) face mask due to the N95 filter selected. This device is intended to provide a liquid barrier protection for medical purposes as defined in the [FDA Guidance for Face Masks and Respirators During the Coronavirus Disease Public Health Emergency](#).
- This device is intended to be used 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) (42 U.S.C. 247d(a)(2)). 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. This mask was created as an emergency action to provide our hospital with Personal Protective Equipment (PPE), and has been verified to meet the standards intended to Provide Liquid Barrier Protection.
- The user must be trained and instructed in wearing the mask.
- FFP Masks do not protect against gases and vapors. The oxygen concentration of the ambient atmosphere should be at least 19, 5 % Volume. These respirators may not be used if the concentration type, and properties of contaminants in the ambient atmosphere are unknown or at dangerous levels.
- Respirators should be disposed of if damaged, if the breathing resistance becomes high due to clogging, or at the end of a shift. Never tamper with, alter or modify the respirator.

Device Overview

- Two main components, MASK BODY and GRILL COVER
- Silicone gasket
- Filter square
- Elastic
- Elastic clip

Point of Care Assembly and Cleaning Instructions

Assembly Steps

1. Assemble the Mask in a clean disinfected environment
2. Don a pair of clean gloves
3. Place a Filter Square centered on the MASK BODY, completely covering the grill openings
4. Attach the GRILL COVER by pressing it onto the MASK BODY until it snaps in place and is secure. Press on all four corners of the GRILL COVER to ensure it is fully seated. The filter square should

be visible on all sides to ensure complete coverage of all grill openings. Gently shake the assembly to ensure that it will stay together.

5. Inspect the mask with all components assembled to ensure that it is undamaged and clean.
6. DO NOT USE THE MASK IF THERE IS ANY VISIBLE DAMAGE.

Putting On the Face Mask

1. Follow CDC guidelines for how to don PPE gear
2. There are four sizes of the SLUHN-FI 3D Mask, medium, medium deep, large, and large deep. The proper size must be selected to ensure a proper FIT test, ensure a more comfortable fit, as well as ensure an unobstructed field of view.
3. A user seal check is to be performed by the wearer each time the mask is put on. It determines if the respirator is properly sealed to the face or needs to be readjusted.

Taking Off the Face Mask

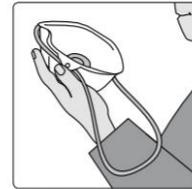
Follow CDC guidelines for how to doff PPE gear

Recommended Cleaning

The materials used for making the reusable components of this face mask remain stable when sanitized with one of the following:

- a. Super Sani-Cloth
 - b. CaviWipes
 - c. Isopropyl alcohol equal to or greater than 70%
1. Perform hand hygiene
 2. Wear gloves at all times
 3. Remove the GRILL COVER and the Filter Square. The Filter Square must be properly discarded and replaced.
 4. Wipe the MASK BODY, GRILL COVER, and ELASTIC STRAPS, completely wetting all surfaces to ensure a wet time of >3 minutes with one of the following:
 - a. Super Sani-Cloth
 - b. CaviWipes
 - c. Isopropyl alcohol equal to or greater than 70%
 5. Place the mask in a paper bag labeled with name.
 6. If required, the MASK BODY and GRILL COVER can be sterilized using UV Sterilization. These components CANNOT be run through a standard autoclave cycle

INSTRUCTIONS FOR FITTING



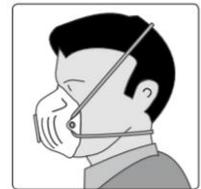
1. Pull strap to form a large loop.



3. Pull upper strap tight and then place on back of head.



2. Place respirator on chin and pull loop over head tight to the neck.



4. Ensure respirator fits secure and comfortable.

Mask Fit Testing

1. A fit test must be performed before using the SLUHN-FI 3d Mask in the workplace in accordance with the [OSHA 1910.134 App A - Fit Testing Procedures \(Mandatory\)](#). Fit testing must occur with the specific make, model, style, and size of respirator that will be used.

A “Fit test” tests the seal between the respirator's facepiece and the users face. It takes about fifteen to twenty minutes to complete and is performed at least annually. After passing a fit test with a respirator, the user must use the exact same make, model, style, and size respirator on the job.

Qualitative fit testing is a pass/fail test method that uses the sense of taste or smell, or the reaction to an irritant in order to detect leakage into the respirator facepiece. Qualitative fit testing does not measure the actual amount of leakage. Whether the respirator passes or fails the test is based simply on detecting leakage of the test substance into the facepiece. There are four qualitative fit test methods accepted by OSHA:

- Isoamyl acetate, which smells like bananas;
- Saccharin, which leaves a sweet taste in your mouth;
- Bitrex, which leaves a bitter taste in your mouth; and
- Irritant smoke, which can cause coughing.

Materials in Direct Contact with Skin

1. The Gasket material, EcoFlex 00-35 Fast
Certified Skin Safe – Gasket Materials are skin safe and certified by an independent laboratory. Liquid Ecoflex™ 00-35 FAST will cure against the skin and can be used for life casting applications. Ecoflex™ 00-35 FAST can also be used for a variety of skin safe applications including making skin safe appliances, cushioning for orthopedic and orthotic devices worn on the body.
2. Elastic strap
3. Elastic strap Clip