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Dear CDRH-COVID19-Surgical Masks Team,

We are writing to receive guidance on an Emergency Use Authorization application for our rapidly deployable mask (RDM) to be used in lieu of cloth or fabric masks (non-medical use). This mask has been developed at the Fischell Institute for Biomedical Devices at the University of Maryland College Park.

The COVID-19 pandemic has forced many to quickly engineer solutions to a rapid onset of resource austerity. With the recent CDC recommendation of the use of cloth face coverings, the Fischell Institute looked to develop a rapidly deployable mask that could provide a greater level of protection than a simple fabric mask while being made from readily available materials.

Detailed in this letter are a description of the rapidly deployable mask, materials used, the production steps, and the test that has been executed to date on the mask. Also attached for reference is the OSHA 1910.134 App A – Fit Testing Procedures, Section 3.

We would greatly appreciate any guidance on submitting an EUA for this proposed RDM as a fabric mask replacement.

Sincerely,

Martha Wang

Description of Rapidly Deployable Mask (RDM)

The Rapidly Deployable Mask (RDM) described here seeks to provide greater protection than simple fabric mask for non-medical usage.

RDM Material

The RDM is fabricated from sterilization wrap or surgical drape, typically used to wrap surgical instruments or to define the sterile field during surgical procedures. This material is not sterile but is readily available in hospitals, ambulatory surgical locations, and other facilities that use sterile processing (e.g. biotech companies). The material can be sourced in 9" by 9" squares or can be cut to size.

Testing Performed on RDM:

In laboratory testing, this mask passed the (OSHA 1910.143) saccharin fit test indicating it was effective for 5 μ m particles. No testing was performed to observe effectiveness for 0.3 μ m particles – N95 masks can filter at least 95% of 0.3 μ m particles. *This mask is not a sufficient replacement for a N95 mask, but may be a better alternative to a fabric mask depending on the fit of the user.*

RDM Assembly Instructions:

Step 1: Wash Hands

Maintain hygiene. It is essential that you wash your hands before handling the material and ensure all surfaces that will be used are clean and sanitized.

Step 2: Fold fabric square along diagonal to form a triangle



Step 3: Heat seal to close the open sides of the triangle

There are two options for heat sealing, 1) Using an impulse heater seal both open ends of the triangle, the seals will be a darker line in the material and will cross at the corner of the folded fabric.



2) Using a home clothes iron on the highest setting, allow the iron to heat up for two minutes, and then apply iron to seal the edge using firm pressure for 30 seconds. If heat is applied on top of a parchment paper then paper will turn more transparent during the 30 seconds.



Step 4: Visually inspect seals for holes.

Inspect the sealed mask, look for areas of incomplete sealing, see if there are any holes around the area where the material was heat sealed. The seal will tolerate gentle pulling, but be careful not to rip the material.



Step 5: Cut triangle on folded edge.

Cut triangle along folded edge of fabric (not heat sealed sides). This will allow the triangle to be opened into a pocket.



Step 6: Attach Straps

Attach straps to sides of pocket. In the visual below, rubber bands were cut, and stapled to the edges of the pocket. These rubber bands were then tied together to provide a continuous strap from one corner of the pocket to the other.



Step 7: Attach Nose Piece

Unfold a vinyl coated paper clip (1.2mm or 0.05" in diameter). Form the clip to one's own nose. Compress the clip approximately another 30% to ensure that when the mask is positioned onto the face the fit is sufficiently tight. Tape clip to mask using strong tape (e.g. duct tape).



Step 8: Test Mask Fit

Test the ability of the mask to seal to your face. Put the mask on placing pocket side of mask over nose and mouth, secure the mask by in placing rubber band around the back of the head. Try breathing deeply and exhaling. The mask should inflate (get larger) when exhaling (breathing out) and deflate (get smaller) when inhaling (breathing in). If the mask does not inflate and deflate as expected then the seal may not be tight. Try to tighten nose clip, tighten rubber band, and evaluate if there is an area around the nose/mouth that is allowing for air to enter or leave the mask. This mask is not a replacement for a N95 respiratory-style mask but is expected to provide greater filtration compared to a fabric (sewn) mask.



Comments:

Please note that biocompatibility studies have not been conducted for this material but directions for use will advise end-users to discontinue wearing the mask in the event of skin rash or irritation.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a 3/4 -inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a sweet taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure. The nozzle is directed away from the nose and mouth of the person. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution is prepared by dissolving 0.83 gram of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted. If the test subject reports tasting the sweet taste during the ten squeezes, the screening test is

completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject is unable to taste saccharin and may not perform the saccharin fit test.

Note to paragraph 3(a): If the test subject eats or drinks something sweet before the screening test, he/she may be unable to taste the weak saccharin solution.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in 3. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I. A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended, and report if he/she tastes the sweet taste of saccharin.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of saccharin fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the original number of squeezes used initially (e.g., 5, 10 or 15).

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected. If the test subject does not report tasting the saccharin, the test is passed.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

(12) Since the nebulizer has a tendency to clog during use, the test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.