EveryMask - Instructions For Use

These instructions for use correspond to Revision B of the EveryMask. The revision of the corresponding mask is the last letter in the model numbers found on the 3D-printed surfaces, as seen in Figure 1.

Appropriate Use Criteria

This supplementary face mask 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 it has gone through a special verification process expedited strictly for the response to the COVID-19 pandemic.

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). 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 EveryMask was designed to be a surgical mask intended to provide liquid barrier protection, as defined in the “FDA Guidance Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)”: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health

This mask should be used within the CDC guidelines for “Strategies for Optimizing the Supply of N95 Respirators”, specifically the sections on “Personal Protective Equipment: Respiratory Protection” and “Crisis Capacity Strategies (during known shortages)”: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

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

As seen in Figure 1, the EveryMask is composed of three 3D-printed parts (Shell, Square, and Retainer), FDA-approved foam, elastic strapping, and a filter square. The concept of the EveryMask is a reusable 3D-printed mask that accepts a square piece of almost every type of filter material and can be printed with almost every plastic on every 3D printer while forming a seal with almost every type of face.

Reasons that the EveryMask could receive FDA approval for clinical use as part of the response to COVID-19 include:

- Only foam that is already FDA-approved is touching the skin for long-term use; the 3D-printed parts do not touch the user’s face.
- The FDA-approved foam conforms to the face with little force, making the mask comfortable for long-term use.
- The FDA-approved mask forms a proper seal to faces of various shapes and sizes; the mask is a true respirator.
- No adhesives or permanent bonds are used, so the mask can be disassembled, sanitized, and then reassembled for reuse, including the FDA-approved closed-cell foam.
- The mask accepts filter material up to 0.035” in thickness.
- The mask accepts filter material with a nominal size of 2.25” x 2.25” but also as small as 2.12” x 2.12”; the 0.13” tolerance is useful for hand-cut filter materials.
- Because the filter material is square and smaller in area than typical FDA-approved masks, for emergency situations, typical masks can be cut into two or more squares for use within the EveryMask.
- Strapping materials can be knotted or adjusted for tension without knots, for ease of use.
- Strapping materials are up to the user to be thermoplastic elastomers (e.g., medical-grade tourniquets) or other FDA-approved elastic strapping.

3D-printing advantages of the EveryMask for widespread dissemination include:

- 3D-printable on most common 3D printers with many plastic materials, including ABS and PLA.
- 3D-printable without supports, rafts, or brims.
- 3D-printable at normal to low quality settings.
Figure 1: (a) Front isometric view of mask assembly with FDA-approved foam and (b) back isometric view of mask assembly without FDA-approved foam. Elastic strapping is not shown.

The *EveryMask* is composed of three main plastic components (the Shell, the Square, and the Retainer), accepts a square patch of filter material, contains four Ears for attaching two elastic straps (see Figure 1), and conforms and seals to the face with FDA-approved closed-cell foam, neoprene, or silicone. Figure 2 shows an exploded view of the mask assembly. Besides the two FDA-approved elastic straps, the FDA-approved closed-cell foam is the only material that touches the skin. It is recommended that the FDA-approved foam be cut from a 14.5”-long, 3”-wide piece of 1/8”-thick FDA-listed polyethylene super-cushioning closed-cell foam, similar to this material (McMaster-Carr, Part # 8722K7):

https://www.mcmaster.com/8722k7-8722K722

See Appendix C for additional information about the materials of this supplementary face mask that are in direct contact with skin.
Figure 2: Exploded view of face mask assembly. Elastic strapping is not shown.

As shown in Figure 2, the FDA-approved foam is placed into the Groove in the Shell and then the Retainer clamps the FDA-approved foam to the Shell. Finally, the Filter is placed into the Shell and the Square clamps the Filter to the Shell. The Filter is nominally a 2.25” × 2.25” square section of filter material.

The FDA-approved foam deflects, compresses, and conforms to the human face, even with the variations of human face shapes and sizes. Hence, the *EveryMask* comes in two sizes: Small and Large. This supplementary face mask fits in a certain manner, as shown in Figure 3. Figure 3(a) shows that the user’s nose and chin fit into corresponding locations of the face mask, while Figure 3(b) and Figure 3(c) show that the Small and Large sizes of the face mask are able to fit the five headforms (small, medium, large, long/narrow, and short/wide) identified by the National Institute for Occupational Safety and Health (NIOSH):

[https://www.cdc.gov/niosh/npptl/topics/respirators/headforms/default.html](https://www.cdc.gov/niosh/npptl/topics/respirators/headforms/default.html)

Figure 3(b) shows that the Small-sized face mask fits small, medium, and short/wide NIOSH headforms, and Figure 3(c) shows that the Large-sized face mask fits large and long/narrow medium NIOSH headforms.

It is recommended that the filter material, elastic straps, and FDA-approved foam be disposed of after every use. The remaining three plastic parts (Shell, Square, and Retainer) can be disinfected using common disinfecting solutions and then sterilized for reuse. Alternatively, the FDA-approved foam (having closed cells and being impervious to air and fluids) can be disinfected in the same manner as the plastic parts and reused.
Figure 3: (a) Isometric view of the face mask, (b) side view of the Small-sized face mask on three NIOSH headforms (small, medium, and short/wide), and (c) side view of the Large-sized face mask on two NIOSH headforms (large and long/narrow).

Components to be disposed of after every use or immediately after potential contamination by bodily fluids:

- Filter material
- Top elastic strap
- Bottom elastic strap
- FDA-approved closed-cell foam

Components to be disinfected and reused:

- Shell
- Square
- Retainer
- FDA-approved closed-cell foam (Optional, following sufficient disinfecting and sterilization)

See Appendix A for recommended disinfecting solutions and sterilization methods for this device. See Appendix B for guidelines on material selection. See the “Recommended Cleaning” subsection of the “Point of Care Assembly and Cleaning Instructions” section for implementation of the recommended disinfecting and sterilization procedures for reuse of the EveryMask.
Recommendations for Manufacturing

This section contains recommendations for manufacturing certain components of the EveryMask.

Recommendations for 3D Printing

The plastic face mask parts can be printed with fused deposition modeling (FDM) because those face mask components were designed with flat bottoms and overhang angles of typically 45 degrees. For details of recommended printing parameters, please see the corresponding document titled “EveryMask – America Makes Submission Details”.

Recommendations for Cutting the FDA-Approved Foam

The FDA-approved foam is recommended to have a thickness of 0.125 in (3.18 mm), being cut from a 1/8”-thick sheet of FDA-listed polyethylene super-cushioning closed-cell foam. See Appendix B and Appendix C for additional details about the recommended materials for the FDA-approved foam.

Figure 4(a) shows how the FDA-approved foam, when cut into its final shape and secured by the Retainer in a groove of the Shell (see Figure 2), should protrude beyond the Shell by about 0.375” to 0.75”. Figure 4(b) shows a not-to-scale template that can be used to cut the foam and achieve the desired protrusion of the foam beyond the Shell. The purpose of the extra foam is for comfort and sealing of the mask to the user’s face. Whenever the foam is correctly secured, the colored dots of Figure 4(b) match the locations seen in Figure 4(a).

Figure 4: (a) Side view of the Small-sized face mask and its (b) foam cutting pattern (not to scale here, but see the last pages of this document for a 1:1 scaled printable pattern).
It is recommended to cut the FDA-approved foam to its final shape by using the patterns given in this document. The foam cutting pattern for the Small-sized face mask is shown in a shrunken version in Figure 4(b). **SEE THE LAST PAGES OF THIS DOCUMENT FOR THE 1:1 SCALED PRINTABLE FOAM CUTTING PATTERNS FOR THE SMALL- AND LARGE-SIZED FACE MASKS.** Special attention should be given to cutting the long straight edge as straight as possible, since that edge sits in the flat groove of the Shell.

An alternative method to cut the FDA-approved foam to its final shape is to start with a rectangular piece of foam that is 13" long (for the Small-sized face mask) or 14.25" long (for the Large-sized face mask) and 3" wide (for any size of the face mask), use the Retainer to clamp the foam into the Shell, and then cut the foam in situ to have a protrusion of approximately 0.375” to 0.75” beyond the Shell, as seen in Figure 4(a).

Finally, to form the best seal of the foam within the mask and to the user's face, the two small straight edges of the foam should be cut at an angle of approximately 45°. Figure 5 shows how these cut edges appears in the completed mask assembly.

![Figure 5: Back view of the completed mask assembly with the foam edges cut at an angle of approximately 45°.](image-url)
Point of Care Assembly and Cleaning Instructions

For instructions to properly assemble, clean, and reassemble for reuse of the EveryMask, please refer to the steps outlined below.

**Assembly Steps**

1. Find a clean disinfection environment in which to work.
2. Don a pair of clean gloves.
3. Take the Shell and identify the nose feature (see Figure 3), which indicates the top part of the mask.
4. Follow the procedure in Figure 6 to use the Retainer to secure the FDA-approved foam against the Shell: (a) Place in the foam such that it is nominally within the U-shaped groove of the Shell; (b) Make sure that one end of the foam overlaps by about 1” with the other end of the foam, which is in the U-shaped groove, at the bottom part of the mask; (c) Push down the foam such that you can see the foam in the U-shaped groove through the rectangular cutouts in the groove wall; (d) Hold down the two ends of the foam, as needed, while pushing down the Retainer; (e) “Snap” the Retainer into place and check to make sure the foam is secured by pulling on it slightly and inspecting to make sure you still see foam through the rectangular cutouts.

5. Mark a square that is 2.25” x 2.25” in size on the filter material. A ruler could be used, but the Square may also be used as a template to mark out the 2.25”-sized square.
6. Cut out the marked patch that is 2.25” x 2.25” in size from the filter material.
7. Follow the procedure in Figure 7 to properly secure a filter patch into the face mask: (a) Empty the Shell; (b) Place filter patch in corresponding location in Shell, making sure to

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**Figure 6:** Steps to use the Retainer to secure the FDA-approved foam against the Shell.

**Figure 7:** Steps to properly secure a filter patch into the face mask.
push down the filter underneath the triangular overhangs on all sides; (c) Place in Square; (d) Push square down until it snaps against the long triangular overhangs; (e) Check to make sure that there is some filter material protruding along the top edge of the Square.

Figure 7: Steps for properly securing a filter patch into the face mask.

8. Take an 18"-long elastic strap and attach it to the first set of Ears (both marked #1 in Figure 3). The type of attachment depends on the type of elastic strapping, as seen in Figure 8: (a) 0.25"-wide braided elastic strap or (b) 0.5"-wide medical-grade tourniquet material. If braided elastic strapping is used, then the strap is attached to the Ears by weaving and pulling the strap through the two elliptical holes in each Ear, as seen in Figure 8(a). Use of the elliptical holes allows for tension adjustment for comfort of the face mask for the user. Alternatively, if the tourniquet material (thermoplastic elastomer) is used, then create an overhand knot at each end of the strap, slide the end of the strap through the Ears, and pull the strap so the knot is secured in the cylindrical groove of the Ears, as seen in Figure 8(b). Finally, additional unused strapping that hangs beyond the wraparound (see Figure 8(a)) or knot (see Figure 8(b)) may be cut off with scissors.

9. Take another 18"-long elastic strap and attach it to the second set of Ears (both marked #2 in Figure 3), following the same general procedure described in Step 8.

10. Do final inspection of our device prior to delivery or use. Ensure that everything has been assembled properly as described in the previous steps and that nothing is damaged or dirty. **DO NOT USE THE MASK OR ANY COMPONENTS IF THERE IS ANY VISIBLE DAMAGE.** If any components are visibly damaged, properly dispose of the component and get a replacement.

11. The mask is now ready to be used, as seen in Figure 9. In order to adjust the force of the face mask against the user's face, the strap lengths may be adjusted by changing the location of the wraparound (see Figure 8(a)) or by adding and using a new knot along the strap (see Figure 8(b)).
Figure 8: Examples of elastic strapping in Ears of Shells: (a) 0.25”-wide braided elastic strap in the two elliptical holes of an Ear for tension adjustment and (b) 0.5”-wide medical-grade tourniquet material with its knot in the circular groove of an Ear.

Figure 9: Completed mask assembly.
Donning and Doffing the Face Mask

We recommend following the guidelines from the Centers for Disease Control and Prevention (CDC) for how to safely put on a clean face mask and for how to safely remove a contaminated face mask:

https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf

Recommended Cleaning

The recommended materials selected for making the reusable components of the EveryMask 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 COVID-19 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 the EveryMask and the user has followed the proper procedures for doffing the device:

1. Perform hand hygiene procedures and don a pair of clean gloves.
2. Remove and properly dispose of both of the elastic straps.
3. Remove the Square and properly dispose of the filter patch.
4. Wash the Shell, Square, and Retainer (and optionally, the FDA-approved foam) with soap and water to remove any obvious remains of soiling on these components.
5. Using one of the recommended disinfecting products from the list outlined in Appendix A, prepare to perform Step 6 to disinfect the mask.
6. Wipe down and disinfect all surfaces of the Shell, Square, and Retainer (and optionally, the FDA-approved foam), making sure to wipe underneath some small triangular shaped protrusions in the cavity of the Shell in which the Square typically resides.
7. Doff gloves, perform hand hygiene procedures, and don a new pair of gloves.
8. Repeat Steps 6 and 7.
9. Ensure the surface is visibly wet with the disinfectant product for the duration of the contact time as defined by the Environmental Protection Agency (EPA) in “List N: Disinfectants for Use Against SARS-CoV-2” (see Appendix A).
10. Set the reusable mask components in a clean environment to dry completely.
11. Run the Shell, Square, and Retainer (and optionally, the FDA-approved foam) through a standard autoclave cycle, as prescribed in Appendix A, to ensure that complete sterilization has occurred.

Preparing the Supplementary Face Mask for Reuse

Once the mask components are clean and dry, follow the assembly steps listed in the “Assembly Steps” subsection to properly assemble the mask components together again for reuse.
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 the EveryMask.

Recommended Disinfecting Agents

It is recommended to follow the guidelines for disinfecting agents from the EPA in “List N: Disinfectants for Use Against SARS-CoV-2”:

https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

Accordingly, we recommend using the following active ingredients or products for disinfecting components of this device:

- Sodium Hypochlorite
- Super Sani-Cloth Germicidal Disposable Wipes
- Caviwipes 1
- Hydrogen Peroxide

Recommended Sterilization Method

It is recommended to follow the guidelines for sterilization from the CDC in “Steam Sterilization: Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)”:  

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/steam.html

Accordingly, we recommend using the following sterilization parameters for steam sterilization, as accomplished in an autoclave, to expose each item to direct steam contact at the required temperature and pressure for the specified time:

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>Minimum Exposure Time (min)</th>
<th>Drying Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>135</td>
<td>4</td>
<td>30</td>
</tr>
</tbody>
</table>
Appendix B: Recommended Materials

Materials for the Filter

The level of protection provided by the *EveryMask* will be determined in part by the filter material used. It is recommended to use filter materials that meet the requirements of ASTM Level 1 barrier, ASTM Level 2 barrier, or ASTM Level 3 barrier, as specified in “ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks”:

https://webstore.ansi.org/Standards/ASTM/ASTMF210019

The *EveryMask* only accepts filter materials with a thickness up to 0.035 in (0.89 mm). Any thicker filter material will prevent the Square from mating properly with the Shell. One option is to cut an existing surgical face mask into approximately four filter patches.

If permission is granted and the decision is made to use non-N95 filter material, then one possibility is to use near-N95 material, specifically filter material rated to MERV 14 @ 2000 cfm (95 percent down to 1 \(\mu\)m), which is precut to 2.25" x 2.25" filter patches:

https://www.flowmarkhightech.com/3d-face-mask-filters

Materials for the FDA-Approved Foam

Since the foam material of the *EveryMask* is in direct contact with the user’s skin, it is recommended that only materials and processes with existing examples of FDA-cleared skin contacting applications should be used. It is recommended that the FDA-approved foam be cut from a 14.5"-long, 3"-wide piece of 1/8"-thick FDA-listed polyethylene super-cushioning closed-cell foam, similar to this material (McMaster-Carr, Part # 8722K7):

https://www.mcmaster.com/8722k7-8722K722

Materials for the Elastic Straps

It is recommended that the two elastic straps be made from 1/4"-wide braided elastic strap material (Amazon, ASIN # B06XH4HGC9), so that the strapping tension can be easily adjusted by the user of the *EveryMask*:


Alternatives include FDA-approved thermoplastic elastomer material, such as that used in latex-free medical-grade tourniquets. One 1"-wide, 18"-long tourniquet can be cut into two 0.5"-wide, 18"-long elastic straps (Amazon, ASIN # B07H8QNRZL):

https://www.amazon.com/gp/product/B07H8QNRZL/ref=ppx_od_dt_b_asin_title_s00?ie=UTF8&psc=1
Materials for the Shell, Square, and Retainer

Since the plastic material of the EveryMask is not in direct contact with the user’s skin, the plastic material for the Square, the Retainer, and in particular, the Shell, can be common plastics, such as polylactic acid (PLA) and acrylonitrile butadiene styrene (ABS), which are found in common 3D printers. The plastic material of the EveryMask can be any common plastic with an acceptable level of outgassing at standard temperature and pressure (STP) as well as sufficient abrasive, thermal, and chemical resistance to changes of state during use, disinfecting, and sterilization.
Appendix C: Materials in Direct Contact with Skin

Only two components of the EveryMask will come into direct contact with the user’s skin: the FDA-approved foam and the elastic straps.

**Materials for the FDA-Approved Foam**

The FDA-approved foam (or neoprene or silicone) should be closed-cell but not adhesive-backed, both of which enable the foam to be removed, cleaned, and placed back into the EveryMask for reuse. The foam’s main purposes are to provide comfort to the user for long periods of use as well as to create a seal with the user’s face, thus enabling the face mask to function as a respirator. Nonetheless, this component is disposable and therefore it is recommended to be disposed of after use.

**Materials for the Elastic Straps**

The elastic straps’ main purpose is to provide enough force to both keep the mask on the face during use and enable a seal of the foam against the user’s face for any orientation of the head, whether tilted forwards or backwards or side to side. The elastic straps are disposable and therefore they are recommended to be disposed of after use.
EveryMask
FOAM CUTTING PATTERN
Size: Small
Revision: B

Align edge A of the foam with the corresponding location at the bottom of the mask (see inset picture below)

Align edge B of the foam with the corresponding location at the bottom of the mask (see inset picture below)

Align and tape ends B and C together here

Align edge D of the foam with the corresponding location at the bottom of the mask (see inset picture below)

Cut along dotted lines and overlap end B to align with end C below

This line should be 10 inches long

Nose Area
EveryMask

FOAM CUTTING PATTERN

Size: Large
Revision: B