

ORIGIN

EDOC-10019-000 IFU, FS-104, FACE SHIELD ASSEMBLY, ORIGIN REV A

Origin Open-source Face Shield



Document Revision Table

REV	DESCRIPTION	AUTHOR	DATE
A	INITIAL RELEASE FOR DISTRIBUTION	JOHN PATON	4/13/20

Github repository:

<https://github.com/originlabs/origin-opensource-faceshield>

1. Description

The following document outlines the fabrication, assembly, use, and treatment of a 3D-printable face shield designed by Origin for use in medical applications, notably for Covid-19 emergency response and healthcare worker safety. The designs discussed in this document assume the part is printed using DLP, SLA, or SLS with materials approved for medical use.

In addition to meeting the requirements outlined in ANSI/ISEA Z87.1-2015 for face shields (section 9.17.2), we followed additional design constraints and considerations to address user comfort, manufacturability, and user safety:

Design Goals:

- prevents (to best ability) splash ingress over the top of visor and plastic shield
- allows user to comfortably wear n95 mask under
- prevents (to best ability) front, top, and side splash exposure to underlying PPE (masks, glasses, etc)
- headband to be reusable / sanitizable, face shield either discardable or reusable
- simple to assemble and install, comfortable for the user for all-day wear
- breathable design to prevent fogging / heat fatigue / sweat buildup
- allows immediately scalable design for face shields and headband, both in large scale manufacturing and in at-hospital "panic mode"
- accommodates variety of headband options (prefab elastic bands, OTS rubber bands, etc)
- Design(s) accommodate fits for a wide range of head sizes with equivalent protection
- If printed in sanitizable materials, must be able to withstand many sanitization cycles and damage from general use that would infringe on any of the stated design goals above

2. Scope

This open-source design is intended for general use with attribution to Origin as originators of this design. This design has not been officially reviewed by any governing or certifying body, and thus is intended as a best-effort design following all regulations

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and requirements for equivalent PPE in use already. We cannot guarantee that any modifications made to this design will maintain compliance with the aforementioned design requirements and clinical regulations, but we are able and willing to advise on any of these matters to the best of our ability and knowledge of said subjects!

3. Materials and Fabrication

The assembly consists of a visor (FS-104), a face shield (FS-105), a headband (FS-106), and an optional visor brow cushion (FS-107) for user comfort.

FS-104 Face Shield Visor:

The github repo listed at the beginning of this document contains 4 variants of FS-104 that correspond to different methods of production (DLP/SLA vs SLS) and material choice (Sterilizable vs non-sterilizable).

The primary difference between FS-104-00 / FS-104-07 (both DLP / SLA optimized) and FS-104-05 / FS-104-06 (SLS optimized) is the text on the visor's top splash cover; FS-104-07 and FS-104-06 make it clear that the parts have been printed in non-sterilizable materials, and therefore should not be reused.

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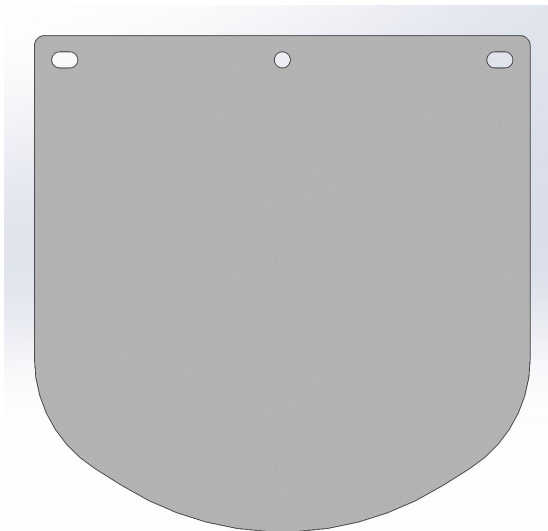
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For FS-104-00 and FS-104-05, print using medically approved and appropriate materials that are sanitizable by standard safety protocols available to hospitals and field services, including but not limited to bleaching, autoclaving, and solvent treatment.

FS-105, Face Shield Plastic:

A DXF is provided for cutting stock PET, PETG, APET or similar transparent, flexible plastics for use in medical environments. This assembly was designed with 0.02 inch thick stock PETG in mind, and can accommodate sheet stock up to 0.04 inch of PETG or similar.



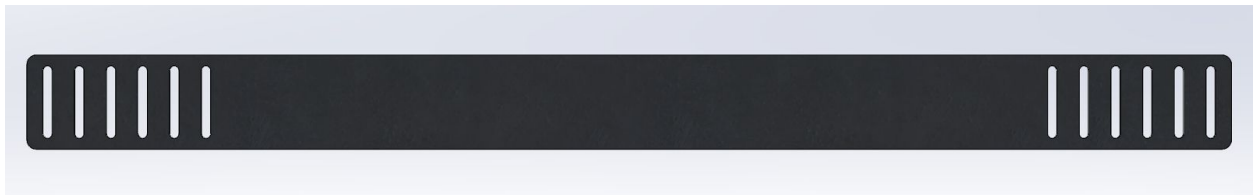
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The hole pattern used for this design is the same as that of a standard US hole-punch. Therefore, in times of crisis or material shortage, off-the-shelf transparency material or binder sleeves may be used when appropriate as a means of last-ditch protective measures without modification to the rest of the design.

FS-106, Elastic Band:

A DXF is provided for cutting stock silicone, EPDM, or similar elastomers for use in medical environments. This assembly was designed with 1/16 inch 40A shore hardness silicone in mind, and can accommodate a wide range of materials depending on stock availability and user needs.



The retention method used in this design is configured such that, in times of crisis or material shortage, off-the-shelf rubber bands, hair ties, and similarly available staples may be used to retain the assembly on the users head with similar comfort.

FS-107, Visor Brow Cushion (optional):

We recommend, where available and appropriate given sanitization capabilities, the use of a cushioning strip on the brow of the face shield assembly to improve user comfort. Material choices for this cushion include, but are not limited to, silicone closed-cell foam, hollow silicone D-ring stock, solid silicone rubber, and others.

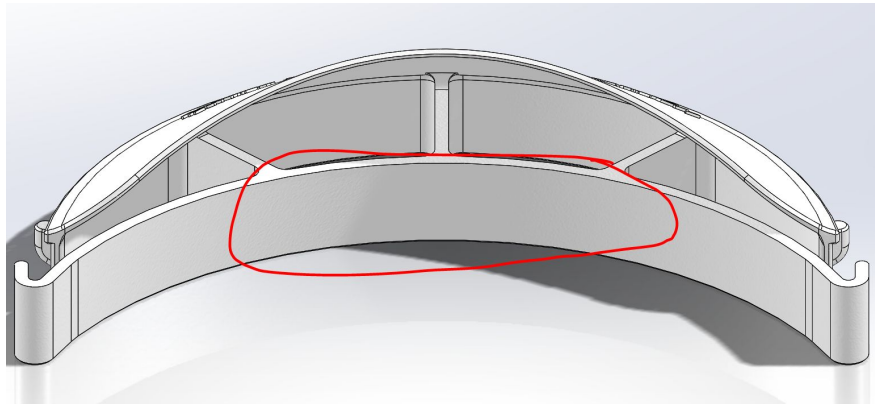
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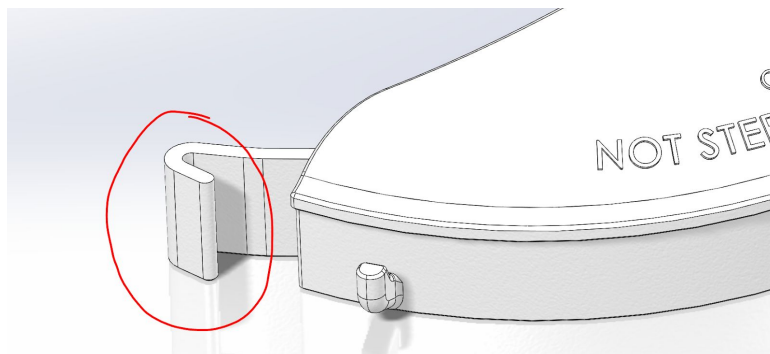
4. Assembly and Usage

Product assembly is as follows:

- Acquire FS-104 (variant depending on method of production), FS-105, FS-106, and FS-107 (if applicable)
- Check all parts for damage (cracks, holes, tears, print failures, hazards for use such as sharp corners or support remnants, etc)
- (If applicable) install FS-107 to visor's brow contact feature (see image below)



- Attach FS-105 face shield plastic to visor one hole at a time. We recommend attaching holes from left to right / right to left, rather than middle out.
- Attach FS-106 elastic band to the visor's band retention features (see image below) using the pre-cut holes in the elastic



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- Put face shield on and adjust elastic band for comfort
- When finished with use, sanitize (or dispose of) all assembled components per standard safety protocols



5. Recommendations

Regardless of material choices, sanitizable or otherwise, we always recommend inspecting each assembly component before use to check for damage and other hindrances to use or safety.

Origin is available for feedback, requests, and suggestions on a limited basis. This design is intended to be an improvement over existing open-source face shield designs that are largely for FDM printing.

6. Acknowledgements

Designed by John Paton, with help and/or feedback from Finbarr Watterson, Joel Ong, Chris Prucha, Stuart Steinbock, Brandyn Nishida, Tim Downing, Ryan Ayler, Zoli Kauker, Matt Miyamoto, and Marshall Ling!