

Open Source COVID19 Medical Supplies: 3D **OSCMS** Printing - Getting Started, Safety, and Designs

Thank you for your interest in assisting in the COVID19 response. This guide will cover the information you need to get started, how to sanitize materials, and a link to designs vetted by our medical review team.

Getting Started

While some large scale manufacturers may be able to send supplies regionally, nationally, or even globally, it will be more efficient and practical for most, especially small scale manufacturers and hobbyists, to first address local needs.

To do this, please take some time to contact local or regional hospitals and medical clinics and let them know that you have the capabilities to help meet some supply needs. Ask them if they have or anticipate any supply shortages and how you can help. Also, ask them about the level of sanitization required for each item and how they will likely sanitize it as this will inform your material choice. Please make sure beforehand that what you are making aligns with their needs.

It may be helpful to contact others in your area that are able to help meet these needs or even create a space, such as a Facebook group, to share these needs with them -- the more people you share these needs with not only help fulfill the medical community's needs but also help lower the number of calls to facilities which will make it quicker for patient's to reach the hospital and easier for staff to focus on other needs.

Whenever you deliver products, please provide the facility with the type of material you used to make the item and how the item may be sanitized. This will help them use the supplies you provide in a safe and efficient manner. You should also provide credit to the source of the material. If you are supplying a large amount of items, please include multiple copies of this information so it is more widely available, keeping in mind that if a provider is using our items,

they likely are extremely busy and may not have time to make and distribute extra copies. **Note:** an example of what should be provided can be found at the end of this document.

Safety

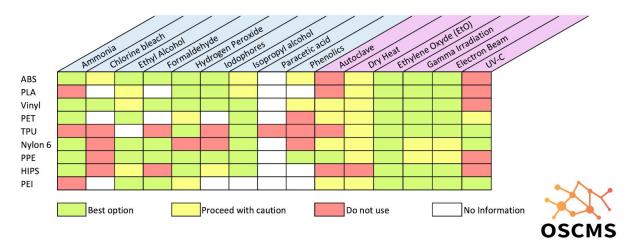
It is essential that all materials can be safely sterilized to reduce the risk of transmitting any potential pathogens. Please ensure that all items can be cleaned with at least one of the following disinfectants or sterilization methods.

Commonly used medical sanitization products can be found here.
Common sterilization methods can be found here.

In addition to 3D Printing a functioning model, you may choose to print a mold with which you can cast or vacuum-form a final product from any number of materials. **No matter how you choose to make your final product, remember to provide the medical facility with an item description that includes the material used to print and how to best sanitize the items.**

The following chart provides examples of materials for FDM printed items and how to best sanitize them, and should be used to choose a material suitable for the item and the facility's resources, as they may not have access to certain disinfectant chemicals or other sanitization methods. If you must use more than one material, try to use materials that can be sanitized the same way to prevent damage to the item; if the materials cannot be sanitized with the same chemicals or methods, be sure to highlight that on the documentation you provide with the material.





After an item is finished printing and has cooled, wash it with cool water and a gentle detergent to clean off any residues left behind from printing and, if possible, sanitize the item appropriately. If you are unable to sanitize the item appropriately, be sure to note this on the documentation provided to the facility so that they know to sanitize the item before use.

A Note About Safety and Liability (United States)

There are engineering and manufacturing risks around medical devices. Though the US FDA has issued Emergency Use Authorizations (EUA) (<u>Coronavirus Disease 2019 (COVID-19</u>) <u>Emergency Use Authorizations for Medical Devices</u>, FDA), to avoid doing more harm than good, it is recommended to attempt to the best of your ability and circumstances to follow regulations, which may seem cumbersome, but exist for good reason.

Regulatory standards that apply to the supplies and devices in question **in the United States**: eCFR: QUALITY SYSTEM REGULATION (especially Identification and Traceability, Production and Process Controls, and Labeling)

eCFR: GENERAL HOSPITAL AND PERSONAL USE DEVICES

Good Samaritan Laws in the United States

In the United States, Good Samaritan laws offer legal protection from civil lawsuits to people who voluntarily provide reasonable aid to those who are injured, ill, in danger, or otherwise incapacitated. A claim of negligent care can also be raised if the injuries or illness were made worse by the volunteer's negligence. Laws generally do not exempt a Good Samaritan who acts in a willful, wanton or reckless manner in providing care, advice, or assistance.

We are providing you with the specifications you will need to manufacture items which are much-needed during this pandemic; however, you are responsible for your creations, so please practice due diligence (the care that a reasonable person exercises to avoid harm to other persons or their property). We want your contributions to help, not harm!

If you are familiar with similar laws in other countries, please reach out to us with relevant references via this form.

To view references and the most up to date version of this note, click here.

To view references for our material sanitization charts, click here.

Designs

A list of devices has been vetted by our medical review team can be found here. To get a design, go to that link and then scroll until you find the link to the type of item you need. After you've found that item and open that link, scroll to the bottom of the document to find the vetted designs. It is important to use items approved by medical professionals to ensure the safety of medical staff, patients, and everyone they interact with.

Product Information

When you deliver an item, please provide an information sheet like the example below. <u>You can download a template of this document by clicking here.</u>

Face Shield

This item was provided by:
Open Source COVID19 Medical Supplies

This item was made with safety in mind and the materials were chosen so that the item can be easily disinfected or sterilized.

Materials: ABS, clear PVC

To disinfect this item, products with the following ingredients can be used: Ammonia, Formaldehyde, Hydrogen Peroxide, or Iodophores.

This item can be cleaned with the following sterilization methods: Ethylene Oxyde (EtO), Gamma Irradiation, or Electron Beam.

Do not use products with these ingredients as they may damage the item: Chlorine bleach, isopropyl alcohol, Paracetic acid, Phenolics. Sterilization with an autoclave or UV-C device is strongly discouraged.

Note: If the ingredients of a sanitizing product are not listed above, test it on a small portion of the item and wait 1-2 minutes before proceeding to clean the rest of the item. If damage begins to occur, rinse the area with water immediately.





Photos and design courtesy of Thingiverse.com user uLca https://www.thingiverse.com/thing:4222407



Disclaimer: This item is provided in good faith as an emergency supply for use during a product shortage. This item has not been evaluated or authorized for use by any regulatory agency. Please use discretion when using this item and only use it if no authorized solution is available.

Feedback

Our mission is to provide transparent, accurate, medically-reviewed content that will help communities around the world develop open source medical supplies. At the same time, recent

cyberattacks on American health institutions and disinformation campaigns have shown that there are state-level actors who do not want accurate information shared. Thus, for the sake of information security, we have locked all of our public-facing content to read-only.

We welcome your feedback on the factual information presented here, and especially welcome links to new projects that we can share to the global community. If you have feedback you would like to share, or have an addition to make to our content (whether more information, or projects that should be added), **PLEASE USE THIS FORM TO SUBMIT THAT FEEDBACK.** This will allow our medical team to vet incoming supply design suggestions, and let us process feedback in a centralized way that is not prone to being taken down by malicious actors.