Frequently Asked Questions for Medical Applications of Additive Manufacturing/3D Printing

COVID-19 RESPONSE

What resources are available from the FDA for those wanting to support healthcare during the COVID-19 pandemic?

The FDA has set up a page to answer many questions: https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

This includes:

- How to help
- FAQ: Can 3D Printing be used to make PPE?
- List of devices receiving Emergency Use Authorization (EUA)

How do I know which PPE items I can safely 3D print?

If you have a PPE device that you have had cleared by the FDA or other regulatory body, using 3D printing, you should be able to 3D print now. If you are an experienced medical device manufacturer with a GMP facility, your quality, regulatory, and 3D printing teams should be familiar with requirements and assess what you can print. If none of these apply, please check the FDA webinar: Enforcement Policy for Personal Protective Equipment (PPE) During COVID-19: Immediately in Effect Guidance

Is there a place I can sign up to print needed items?

A collaboration between the FDA, NIH, VA, and America Makes with support from ASME, has set up a repository for organizations willing to manufacture needed items. To add your organization, go to: https://covid19-response.americamakes.us/Home/ManufacturerForm

How do I find a hospital or organization that needs items?

First submit your capabilities to the manufacturers repository linked above. The America Makes team will then match you with a facility that needs items.

For hospitals or other organization, how can I indicate what we need to possibly receive 3D-printed items?

The collaboration between the FDA, NIH, VA, and America Makes also provides a form to submit requests for equipment. America Makes will match you with a manufacturer.

How do I connect to the appropriate distribution channels?

At the moment the collaborative effort with FDA, NIH, VA, and America Makes is the way to connect with the distribution channels.

Where do I find print files that have been reviewed or cleared?

The NIH 3D Print Exchange has set up a page to find designed that have been cleared for emergency use and/or reviewed clinically. https://3dprint.nih.gov/collections/covid-19-response You can also use this site to submit a design for review.

GENERAL

What are the critical medical considerations when 3D printing medical applications?

Intended use is the primary driver of all medical application considerations. These include:

- What kind of skin contact will the piece have? Temporary, permanent, or implanted? Mucus or non-mucus contact?
- Has the bicompatability of the material as printed been tested?
- Will the piece need to be sterilized?
- Will the piece be used for:
    - education? (low risk)
    - treatment planning?
    - diagnosis?
    - treatment?
- Will the piece need to be clean and sterile?
- Has the design been cleared for use and clinically reviewed?
- Has your 3D printing quality management system been verified and/or validated?
- Does the risk level class of the device require Good Manufacturing Practices (GMP)?
- What FDA class device is it? I, II, or III?

What does Class I, II, and III mean?

According to the FDA website, medical devices are categorized into "one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. The classes are designated according to the level of control necessary to ensure the safety and effectiveness of the device." Class I devices pose the lowest risk, and Class III devices present the greatest risk.

For further information, visit:
https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

If I've never 3D printed a medical application, what might I be able to print?

Because the requirements for medical applications can be very complex, the things you should print without experience are limited to very low risk items including prototypes and some assistive devices like attachments for door handles that can be used with your arm. During the COVID-19 pandemic, the FDA has also indicated a very limited number of low risk Personal Protection Equipment can be 3D printed without GMP. Primarily, this covers head bands for face shields.

What applications can I 3D print?

Experienced medical manufacturers and experienced point-of-care manufacturers (hospitals) have successfully 3D printed a broad range of applications. These fall into one or more of the following categories:

- Prototypes, Development, and non-patient interaction tools
- Anatomic models for education
- External prosthetics and assistive devices
- Dental applications
- Surgical planning (anatomic models, surgical guides)
- Production (serialized) implants
- Patient-matched implants
- Active devices

- 3D printing-enabled tissue fabrication

More information on this application groups can be found here. In general, the further down this list the application, the higher the risk and greater the risk and 3D printing consideration are. Before 3D printing, consider whether you are familiar with all of the considerations, understand the regulatory requirements, have a GMP facility, and access to any needed testing. If not, consider whether just because you can, should you 3D print the device.

Where can I find "FDA-cleared materials?"

Stand-alone materials are not cleared by the FDA. The term, "FDA-cleared material" is a misnomer. Instead, when assessing a 3D-printed material's suitability for a medical application, many variables must be considered, including the specific extrusion temperature, specific heated bed temperature, initial forms of a material (resin, powder, filament), and post processing techniques.

How do I know if a material is biocompatible?

A material by itself cannot be classified as biocompatible. Rather, biocompatibility must be assessed in the broader context of such factors as the location of a device in or on a patient, how manufacturing processes---including 3D printing and post-processing---have impacted the chemistry of a material, and how degradation products of that initial material can affect the patient.

The US Food and Drug Administration (FDA) provides guidances according to whether the device will be placed on intact skin surfaces or implanted in a patient. A separate guidance focusing exclusively on devices designed to be resorbed by the body also is available. For risk assessment, variables including duration of contact with mucous and non-mucous surfaces and the likelihood of debris forming are taken into account are addressed. MORE INFORMATION

How do I sterilize 3D printed guides, models, etc.?

Sterilization methods can vary. Your 3D printing material supplier may be your first stop to review the mechanical properties as printed of your material. This will help determine if there is a sterilization process that can be used. You will still need to do testing to ensure the process works. If working within a hospital, this may include approval from the hospital's Surgical Services and/or Regulatory and Compliance office.

FDA-recognized consensus standards

For testing, FDA-recognized consensus standards provide some guidance. A list of these can be found HERE.