[High Priority] - H0603 : [COVID-19] 3-D Printed Objects Manufactured without Following Proper Validation Procedures Can Harm Healthcare Providers and Patients [ECRI Exclusive Hazard Report]

Medical Device Hazard Report

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Geographic Regions: U.S.

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Infection Control, Nursing, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Home Care, Internal Medicine, Staff Education, EMS/Transport, Materials Management

Problem:

1. During the COVID-19 pandemic, healthcare facilities may be using 3-D printed products that are not validated to be safe and effective.
2. Untested product designs and failure to adhere to current good manufacturing practices (CGMPs) can harm healthcare providers and patients.

ECRI Recommendations:

1. Only consider nontraditional sources of supplies if you are unable to obtain supplies through conventional channels.
2. When considering purchasing supplies from 3-D printing manufacturers:
    1. Look to 3-D printing only for the following types of objects:
        1. Personal protective equipment (PPE)
        2. Diagnostic and testing supplies
        3. Ventilator connectors and accessories
        4. Uncomplicated medical device replacement parts when original components are not available
    2. Utilize resources provided by FDA to address 3-D printing of medical devices during COVID-19, including:
        1. America Makes COVID-19 site: Connecting Manufacturers and Health Care entities
        2. Department of Veterans Affairs Innovation Ecosystem Connector Site
        3. FAQs on 3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic
    3. Evaluate and prioritize potential manufacturers by requesting the following information:
        1. Registration with FDA as a manufacturer
        2. Proof of good manufacturing practices and process controls
        3. Validation that the device has been clinically reviewed and tested to be safe and effective
    4. Upon receipt of 3-D printed devices, inspect and test all incoming products as practicable.
    5. When considering in-house manufacturing of 3-D printed devices:
        1. Recognize that FDA defines a medical device manufacturer as any establishment that manufactures a finished device.
        2. To expedite manufacturing, consider using open-source designs that have been clinically reviewed and tested:
            1. NIH 3D Print Exchange COVID-19 Response is a collaborationbetween NIH/NIAID, FDA, VHA, and America Makes to evaluate 3D printable partsand other improvised designs for their effectiveness and identify designs thatare likely to be the most useful for health care providers and patients inshortage situations.
            2. Manufacturers and vendors of 3-D printers, software, and materials have initiatives to address COVID-19 supply chain shortages, including validated open-source print files and manufacturing guidance. Your current suppliers may have print files or other resources to assist with in-house manufacturing.
        3. Follow FDA guidance, Technical Considerations for Additive Manufactured Medical Devices for design and manufacturing Considerations (Section V) and Device Testing Considerations (Section VI).
        4. Follow FDA Design Control Guidance for Medical Device Manufacturers .

Discussion:

1. Potential problems resulting from inadequate 3-D printing include the following:
    1. Failure to clinically evaluate and conduct user testing can result in ineffective and potentially dangerous device designs.
    2. Unsuitable printing materials may cause products to become unstable in certain situations.
        1. Material may be inappropriate for the environment in which the product will be used (e.g. lack necessary fluid barrier or fire resistance properties).

2. Material may lack necessary physical properties.
3. Material may not be safe to contact skin.
4. Material may not withstand disinfection or sterilization.

3. Inadequate printer technology and processing specifications can present safety risks.
    1. Inadequate printing methods can result in dimensional inaccuracies.
    2. Incorrect processing specifications can cause microscopic pores or surface imperfections which can harbor bacteria.
4. Lack of environmental controls can result in particulates and debris from the 3-D printing process becoming embedded into the finished product.
5. Failure to establish and maintain validated process controls can affect the quality and reliability of the finished device.

2. Potential problems of specific types of PPE include the following:
    1. Unconventional face masks may give a false sense of security.
        1. The filter may not provide sufficient filtration efficiencies for removal of particulate, bacterial, and viral contaminants, or may impair breathing.
        2. Components may not be cleanable, or they may be prone to harboring bacteria.
        3. The mask may not secure tightly over the face, may muffle verbal communications, or may cause bruising if worn for extended periods of time.
    2. Unvalidated face shields may not be designed to accommodate all sizes:
        1. The shield may not provide adequate coverage around the sides of the face and below the chin.
        2. The strap may not secure tightly around the head.
        3. The coverage along the forehead may not provide adequate protection against airborne droplets.
    3. Third-party ventilator accessories may have design flaws or manufacturing inconsistencies that introduce safety risks. Splitters, flow restrictors, check valves, and filter housings may have areas prone to cross-contamination.
    4. 3-D printed replacement parts may result in unexpected device operation.
        1. Replacement parts may not fit correctly and can affect overall functionality of the device.
        2. Replacement parts may not be as durable as original parts, which can result in unexpected device failures.
3. When manufacturing objects using 3-D printing, there is a trade-off between design quality and speed.
    1. More robust designs require more time to develop.
    2. Objects using greater amounts of material take longer to print.
4. 3-D printed products of higher quality often require more expensive materials.

Background:

- FDA has formed a public-private partnership with the Department of Veterans Affairs (VA) Innovation Ecosystem, National Institutes of Health (NIH) 3D Print Exchange, and America Makes.
    - VA Innovation Ecosystem includes hospitals and clinics in the VA health care network that have 3D Printing design and engineering expertise. It has created a website to help connect health care organizations with 3D printing service providers.
    - NIH 3D Print Exchange is a collaborative effort led by the National Institute of Allergy and Infectious Diseases in collaboration with the Eunice Kennedy Shriver National Institute for Child Health and Human Development and the National Library of Medicine. It is an interactive website for searching, browsing, downloading, and sharing biomedical 3D print files, modeling tutorials, and educational material.
    - America Makes is the Department of Defense's Manufacturing Innovation Institute (DoD MII) for additive manufacturing. It is comprised of member organizations from industry, academia, government, non-government agencies, and workforce and economic development resources.
- To address urgent shortages of medical devices, accessories, replacement parts, and PPE, FDA has revised enforcement policies that are intended to remain in effect only for the duration of the public health emergency.
    - FDA guidance documents related to COVID-19 can be accessed at Recent Final Medical Device Guidance Documents .
    - Changes to normal standards include:
        - FDA encourages participation of manufacturers who have not previously engaged in medical device manufacturing.
        - FDA does not intend to object to distribution and use of some PPE intended for a medical purpose without 510(k) premarket notification, registration and listing requirements, quality system regulations, reports or corrections and removals, and unique identification requirements.
- FDA is issuing Emergency Use Authorizations (EAUs) of medical devices, including alternative products used as medical devices.

Following FDA COVID-19 Response policies and recommendations for 3-D printed objects is not sufficient for confirming that the finished product is safe and effective.

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 May 7. ECRI