

[High Priority] - H0621 : [COVID-19] 3-D Printed Test Swabs Manufactured without Proper Validation Procedures Can Harm Health Care Providers and Patients [ECRI Exclusive Hazard Report] Medical Device Hazard Report

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UMDNS Terms:

- Swabs, Specimen Collection [13914]
- Swabs, Specimen Collection/Transportation [18606]

Geographic Regions: Worldwide

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

Problem:

1. Swabs that were 3-D printed and manufactured without following proper validation procedures may not perform as intended.
 1. Materials or contaminants from manufacturing and handling may affect test results or expose patients to pathogens.
 2. Swabs may be overly stiff, potentially causing patient discomfort or epistaxis or preventing access to area to be sampled.
 3. Swabs may be flimsy or too weak to collect a sample, or may buckle if pushed against an obstruction.
 4. Swabs may be brittle or prone to breakage through shipping or handling, causing unintended sharp edges.
 5. Swabs may not be able to effectively collect, retain, and elute specimen for downstream analysis.
 6. Swabs may not break cleanly when inserted into transport containers.
 7. Dimensions or specimen capture geometries may limit effectiveness.
 8. Swab materials may not be biocompatible.
 9. Swabs may not be able to be effectively sterilized, or sterilization may adversely affect product performance.
2. Defective or damaged swabs may result in false-positive or false-negative results, potentially causing errors in treatment plans and putting patients and staff at unnecessary risk.

ECRI Recommendations:

1. Consult the following resources for manufacturing and using 3-D printed swabs:
 1. [FDA Emergency Situations \(Medical Devices\) FAQs on Testing for SARS-CoV-2](#) for answers to questions relating to regulatory requirements, evaluation considerations, quality system requirements, and labeling for 3-D printed swabs.
 2. [NIH 3D Print Exchange COVID-19 Supply Chain Response: 3D-Printed Nasal Swabs](#) for the most recent summary of considerations for 3-D printed swabs with the sole purpose of collecting upper respiratory clinical specimens (e.g., nasopharyngeal, anterior nares) during the COVID-19 pandemic (in response to shortages of traditional swabs).
2. To identify and order from FDA-registered manufacturers that are 3-D printing COVID-19 nasopharyngeal test swabs using clinically tested designs, refer to <https://printedswabs.org> .
3. When considering ready-to-use 3-D printed swabs, confirm the following:
 1. The manufacturer is FDA-registered, following Current Good Manufacturing Practices (CGMPs) and using designs that have been clinically validated for the intended use. FDA [Establishment Registration & Device Listing](#) is a database that includes all medical device manufacturers registered with FDA and all medical devices listed with FDA. FDA does not certify registration and listing information. Documentation of CGMPs and clinical validation efforts should be provided by the manufacturer.
 2. Swabs have undergone adequate testing post-sterilization, including:
 1. Biocompatibility testing for cytotoxicity, irritation, and sensitization (per ISO 10993-1). Biocompatibility studies should demonstrate that the swab is safe for limited contact. This may include a history of safe use, including any prior verification that a material is non-cytotoxic, non-irritating, and non-sensitizing.
 2. Mechanical testing to demonstrate equivalent flexibility and durability to traditionally manufactured swabs that are currently on the market and previously determined to be safe and effective for collection from the same specific target (e.g., nasal, nasopharyngeal, oropharyngeal) site.
 3. Clinical testing to demonstrate equivalent performance to traditionally manufactured swabs that are currently on the market for collection from the target sample site (e.g. nasal, nasopharynx) using a comparative downstream assay (e.g., molecular (PCR) or antigen detection). Clinical assessments should include:
 1. A minimum of 30 positive samples and a minimum of 30 negative samples.

2. Demonstration of adequate collection of specimens without damaging tissue to an extent comparable to traditionally manufactured swabs used on the same anatomic site.
 3. 95% positive and negative agreements of assay results (e.g., PCR).
 4. Packaging has been tested to ensure adequate seal strength and integrity for shipping.
 5. Sterilization processes have been validated using swabs from different production lots and using maximum parameters to ensure adequate sterilization.
 6. Labeling describes what the swab is designed for and the site it is intended to sample (e.g., nasal [NS] or nasopharyngeal [NPS] specimens). Labeling should:
 1. Specify that the swab is an absorbent tipped applicator, sterile, individually packed for single-use only and for use during the COVID-19 public health emergency. It should provide a description of the material and its characteristics.
 2. Make clear recommendations to sufficiently reduce any potential risks for use. Examples include, but are not limited to, a caution against use of non-sterile product and recommendations for healthcare providers to visually inspect products for physical integrity before use.
 3. Include a clear description of the available validation data for the device. Validation information should include the facility(s) that conducted the validation testing, and specific information about the types of tests performed. Testing should demonstrate that the 3-D printed swabs performed as good as or better than traditional swabs in biocompatibility, mechanical, and clinical tests.
4. When considering purchasing 3-D printed swabs in bulk packages:
 1. Confirm that the designs have undergone all post-sterilization testing shown above, including biocompatibility testing, mechanical testing, and clinical testing.
 2. Validate the packaging to ensure adequate seal strength and necessary integrity.
 3. For swabs that require sterilization before use, follow sterilization and packaging processes that have been validated by the manufacturer.
 4. Follow ready-to-use labeling guidelines outlined above to prepare swabs for use.
5. When considering in-house manufacturing of 3-D printed medical devices:
 1. Follow FDA guidance, [Technical Considerations for Additive Manufactured Medical Devices](#) for design and manufacturing Considerations (Section V) and Device Testing Considerations (Section VI).
 2. Follow [FDA Design Control Guidance for Medical Device Manufacturers](#). These practices and procedures provide a system of checks and balances to identify any design deficiencies and production problems that may adversely affect the overall safety and performance of the finished product.
 3. For specimen collection swabs, follow the CDC specimen collection guidelines outlined in the following documents:
 1. CDC [Specimen Collection Guidelines](#) provides general specimen collection guidelines for healthcare providers and public health staff during an unknown respiratory disease outbreak.
 2. CDC [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 \(COVID-19\)](#) provides recent revisions to CDC guidelines for clinical specimens in response to the COVID-19 pandemic.
6. For 3-D printing medical supplies and equipment in response to the COVID-19 pandemic, consider using designs that have been clinically reviewed and tested for use during the pandemic.
 1. [National Institutes of Health 3D Print Exchange COVID Collection](#) is a collaboration between NIH/NIAID, FDA, VHA, and America Makes to evaluate 3D printable parts and other improvised designs for their effectiveness and identify designs that are likely to be the most useful for healthcare providers and patients in shortage situations.
 2. Manufacturers and vendors of 3-D printers, software, and materials have initiatives addressing 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.
7. When developing a medical device design, include clinical input to verify the finished product will perform as intended.
8. During manufacturing, establish and maintain environmental controls to minimize contaminants on the finished product.
9. Evaluate all product designs for both physical features and performance requirements. Key considerations for testing swabs include:
 1. Material biocompatibility requirements for cytotoxicity, irritation, and sensitization (per ISO 10993-1).
 2. Length, diameter, and swab geometry for effective specimen collection.
 3. Location of the break point at which the tip is snapped off before insertion into the transport container.
 4. Breaking force necessary to detach the tip from the shaft.
 5. Torsional strength required to withstand twisting forces during sampling.
 6. Flexural modulus to ensure swab can bend around anatomy without breaking.
 7. Post-processing steps, including detachment from print platforms, surface preparations, cleaning and sterilization, and packaging.
10. Follow comprehensive quality assurance procedures to validate that the finished device performs as intended. Adequate processes for validating swabs are outlined above. All validation testing must be conducted on finished product that has been sterilized and packaged

for clinical use.

Background:

1. VA, NIH, and FDA have entered into [Memorandum of Understanding: Rapid Response to Covid-19 Using 3d Printing \(MOU 225-20-008\)](#) to create a way for legally marketed products to be presented to the community and then to ultimately connect manufacturers with those with clinical needs. Under the MOU:
 1. FDA provides engineering and support in evaluating and developing tests for 3D printed products, and provides insight into the regulatory framework and requirements for the range of products being looked at under the MOU.
 2. NIH, through the 3D Print Exchange, hosts the repository of products to be printed during the COVID-19 response. Information on regulatory requirements and best practices for manufacturing is available through the 3D Print Exchange.
 3. VA provides clinical and engineering expertise in the product evaluation process, coordinates with groups for clinical and materials testing, and provides communication and feedback back to designers about potential improvements. Significant efforts include clinical evaluation of designs for facemasks and face shields. VA intent for 3-D printed swabs is to develop the testing protocol to demonstrate equivalents to the standard of care. This protocol will then be shared publicly under the MOU.
2. The FDA guidance document, [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency](#) outlines FDA's policy for diagnostic tests for coronavirus disease to help accelerate the availability of novel coronavirus tests developed by laboratories and commercial manufacturers for the duration of the public health emergency.
3. [FDA FAQs on Testing for SARS-CoV-2](#) provides answers to frequently asked questions relating to the development and performance of tests for SARS-CoV-2. Questions and answers provided in this document are intended to provide additional clarity on existing policies and do not introduce any new policies or modify any existing policies.
4. While there are no current test standards for swabs, existing test standards such as ASTM D638 (tensile testing), ASTM D1043 (torsional testing), and ASTM D6272/D790 (flexural testing) could be used as inspiration to assess the swab's mechanical properties compared to traditionally manufactured swabs.
5. Recognize that FDA defines a manufacturer as any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development.
6. For more information about 3-D printing medical devices, see ECRI guidance article, [3-D Printing in Medicine: An Introduction](#) .
7. For more information about design and production factors affecting sterility of 3-D printed medical devices, see ECRI guidance article, [Ensuring the Sterility of 3-D Printed Objects](#).

References & Source Documents:

1. Food and Drug Administration, Technical Considerations for Additive Manufactured Medical Devices: Guidance for Industry and Food and Drug Administration Staff [online]. 2017 Dec 5, <https://www.fda.gov/media/97633/download> .
2. Food and Drug Administration, Design Control Guidance for Medical Device Manufacturers [online]. 1997 Mar 11, <https://www.fda.gov/media/116573/download> .
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4. Center for Disease Control and Prevention, Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) [online]. 2020 May 22, <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html> .
5. Food and Drug Administration, MOU 225-20-008 Memorandum of Understanding: Rapid Response to Covid-19 Using 3d Printing between National Institutes of Health within U.S. Department of Health and Human Services and Food and Drug Administration, U.S. Department of Health and Human Services and Veterans Health Administration within the U.S. Department of Veterans Affairs [online]. 2020 Mar 25, <https://www.fda.gov/about-fda/domestic-mous/mou-225-20-008> .
6. Food and Drug Administration, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) [online]. 2020 May 11, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised> .
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8. ECRI Evaluations & Guidance – Guidance, 3-D Printing in Medicine: An Introduction, Published 4/4/2018, <https://www.ecri.org/components/HDJournal/Pages/3D-Printing-in-Medicine-an-introduction.aspx?tab=1> .
9. ECRI Evaluations & Guidance – Guidance, Ensuring the Sterility of 3-D Printed Objects, Published 1/15/2020, <https://www.ecri.org/components/HDJournal/Pages/Ensuring-the-Sterility-of-3-D-Printed-Objects.aspx?tab=1> .
10. [COVID-19] 3-D Printed Objects Manufactured without Following Proper Validation Procedures Can Harm Healthcare Providers and Patients [ECRI Exclusive Hazard Report], Accession Number H0603, High Priority, Published 2020 May 07, <https://www.ecri.orgwww.ecri.org/Components/Alerts/Pages/TrackingUser/AlertDisplay.aspx?AId=1643113> .

Comments:

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

Source(s):

- 2020 Jun 8. ECRI researched report