AXIAL3D SWABS

Patient data made real
COVID-19 is pushing our healthcare resources to the limit. There is a global shortage of nasopharyngeal swabs needed to collect samples for COVID-19 testing. These swabs are typically used for testing for influenza and other respiratory infections, such as COVID-19.

3D printed swab sticks provide a rapid response to the current and impending shortages of these vital medical testing aids. Axial3D 3D printed nasopharyngeal swabs are designed to collect upper respiratory specimens from patients with signs and symptoms of respiratory infection. The swabs have passed a variety of tests at USF Health, and have received an Emergency IRB approval as well as authorization from regulatory, infectious disease, and virology.

We are ready to support your hospital in the fight against COVID-19. Please reach out to us at contact@axial3D.com for more information, or call Rob Fisher on 248-798-3291
3D Printed Nasal Swabs consist roughly of a 150 mm in total length with a 70 mm breakpoint. The swabs are being printed on Formlabs Form 2 and Form 3B using Surgical Guide Resin. The following information pertains to swabs manufactured in this manner only. As of right now, we have not conducted the testing to ensure patient safety on other 3D printers or materials.

IRB

Bench lab testing has been completed at USF Health as well as Beth Israel Deaconess Medical Center. Those results are available upon request. Clinical Trial testing is ongoing at Northwell Health and USF Health/Tampa General Hospital.

The FDA has designated the swabs as a Class 1 exempt Medical Device.

INTRODUCTION AND INDICATIONS FOR USE

Axial3D 3D Printed Nasopharyngeal Swabs are designed to collect upper respiratory specimens from patients with signs and symptoms of respiratory infection.

A. DISINFECTION AND STERILIZATION

1. The swab may be cleaned, disinfected, and sterilized according to facility protocols. Tested methods of disinfection include: soaking the finished swab in fresh 70% IPA for 5 minutes.
   Note: Do not leave the part in alcohol solution for an extended period.

2. Swabs may be steam sterilized according to CDC recommended cycles (132 °C / 270 °F for 4 minutes in a pre-vacuum steam sterilizer or 30 minutes at 121 °C / 250 °F in a gravity displacement autoclave), or according to facility/autoclave manufacturer’s protocols, as long as the cycle does not exceed 20 minutes for 134 °C / 273 °F or 30 minutes at 121 °C / 250 °F.
   a. Autoclave cycles should include a dry cycle to best maintain accuracy. For example, wrapped instruments sterilized in a prevacuum autoclave should be dried for 20-30 minutes according to CDC recommendations.* Longer or hotter autoclave cycles than those listed above may result in degradation of physical properties and accuracy.
   Note: A color shift will be observed after autoclaving, this is normal.

3. After disinfection and sterilization inspect the swab for cracks to ensure the integrity of the swab.

- Biocompatible
- Autoclavable
- 150mm length
- 70 mm breakpoint

* https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf
Legal Disclaimer

The following protocol has been developed for emergency situations arising out of the COVID-19 public health emergency only. We are sharing this protocol with you, at your request, for information purposes only.

You should review and analyze the protocol for your own specific emergency use purposes and make your own determination as to whether and when deployment of this protocol may be necessary.

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