

Stryker Instruments

1941 Stryker Way, Portage, MI 49002 USA
P +1 269 323 7700
F +1 800 965 6505
www.stryker.com

February 6, 2020

Both the World Health Organization¹ and the U.S. Centers for Disease Control (CDC)² have reported a novel Coronavirus (2019-nCoV) outbreak identified first in Wuhan, China. There have been reported cases in the U.S. as well, including in Washington, California, Arizona, Massachusetts, and Illinois. Please see more information the CDC has posted about the 2019-nCoV Coronavirus at <https://www.cdc.gov/coronavirus/index.html>.

The CDC released guidance titled "Prevention & Treatment." This material may be accessed directly through the following link: <https://www.cdc.gov/coronavirus/2019-ncov/about/prevention-treatment.html>.

NOTE: Always defer to the latest CDC guidance regarding protection against Coronavirus and the cleared device Instructions for Use.

The nCoV-2019 Coronavirus is a respiratory illness originally transmitted through animal-to-person contact, and now continues to spread as an airborne pathogen. As a growing number of patients reportedly have not had exposure to animals, it appears that 2019-nCoV is also spreading via person-to-person contact.

As referenced in the above hyperlinked documents, the CDC recommends that HCPs involved wear the appropriate PPE. This personal protective equipment includes disposable gloves, a gown (fluid resistant/impermeable), respiratory protection (N95 filtering respirator), and eye protection (goggles or face shield).³

Stryker has received a number of questions from our customers regarding the appropriate use of the Flyte PPE products. In an attempt to respond to our customers' questions as they prepare for any such cases in U.S. hospital facilities, we recommend that our customers follow the cleared device Instructions for Use (IFU). Specific relevant instructions from the IFU are provided below.

Stryker Flyte Personal Protection System:

- The Stryker Steri-Shield Flyte Toga/Hood is a component of the Stryker Personal Protection System and is intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material. The Steri-Shield Flyte Toga/Hood is sterile, single use only.
- For details regarding the Flyte Toga protection zones and levels please refer to the device IFU.
- **The Flyte PPE products are not cleared as respiratory protective products.** CDC guidance for respiratory protection directs the use of an N95 or higher rated mask for staff performing Aerosol Generating Procedures.

¹ "Novel Coronavirus (2019-nCoV)." World Health Organization. n.p. n.d. Web. January 30, 2020.

² "2019 Novel Coronavirus." Centers for Disease Control. n.p. January 30, 2020. Web. January 30, 2020.

³ "Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-nCoV) in a Healthcare Setting" Centers for Disease Control. n.p. Web. January 30, 2020.