SMOKE EVACUATION AND CORONAVIRUS (COVID-19)

March 30, 2020

Dear Valued Customer,

Since the outbreak of COVID-19, Medtronic continues to coordinate with our customers, employees, and relevant public health authorities to better understand any emerging issues and ensure that appropriate guidelines and best practices are being followed. Our priority is the safety and wellbeing of our employees, our customers, the patients who rely on our products and the resilience of our shared communities.

Over the past few days, societies from across the world, including the Society of American Gastrointestinal Endoscopic Surgeons (SAGES)\(^1\), the American College of Surgeons (ACS)\(^2\) and Intercollegiate General Surgery\(^3\) (UK) have published recommendations on how to operate in the Surgical Theatre with COVID-19 infected patients. These societies are recommending that healthcare providers use smoke evacuation devices in open and laparoscopic procedures in addition to ensuring that proper Personal Protective Equipment (PPE) is used.

Facts about COVID-19 and Surgery

The novel Coronavirus, COVID-19 is described as round or oval in shape, with a diameter within the range of 60-140nm and widely distributed in humans and other mammals.\(^4,5\) Infected patients are presenting with varied symptoms across several organ systems, suggesting the virus is present in tissue outside of the respiratory system.\(^6,7\) The information related to this virus changes daily as more data is being collected, analyzed and reported. Regions highly impacted by this virus are sharing surgical recommendations, which include managing exposure to droplets, bodily fluids, surgical smoke and aerosols.\(^8\) Currently, there is no research or data on the transmission of the COVID-19 virus via surgical smoke\(^9\); however, other viruses are known to transmit through surgical smoke.\(^10\)

Smoke Evacuation Filters and COVID-19

Medtronic has not conducted direct testing to evaluate the interaction of COVID-19 and surgical smoke evacuation products, and our clinical experts are not aware of external publications on this subject. Medtronic smoke evacuation products utilize ULPA filtration, which is the standard in surgical particle filtration. Filters are rated to capture a wide range of particle sizes but typically have a stated particle size rating. The ULPA filter efficiency rating of 99.9995% is based on a 0.12µm particle size, but this is not a minimum size. ULPA filters can capture smaller and larger particles.\(^11\) Despite this potential, there is no definitive evidence at this time to conclude that Medtronic smoke evacuation products are effective to prevent the transmission of the COVID-19 virus.
Recommendations for Medtronic Smoke Evacuation Products and COVID-19

If the clinician determines it appropriate to use a Medtronic smoke evacuation product or any other Medtronic product during a surgical procedure involving a patient with suspected or confirmed COVID-19, Medtronic recommends they be used in accordance with their respective labeling. The viability of virus particles once captured in Medtronic ULPA filters is unknown; therefore, proper filter disposal techniques should always assume contamination and hospital staff should follow hospital safe disposal protocols. While surgical smoke evacuation cannot capture smoke particles with 100% efficiency, this technology represents an effective tool in reducing exposure to the known hazards of surgical smoke and aerosols.¹²

Medtronic Smoke Evacuation Portfolio

Medtronic recognizes that this is a sensitive time for customers around the world. In response to society recommendations, hospitals have asked for information about what products may be used to reduce hazards in the operating room during this critical period. For more information on our smoke evacuation solutions, please contact your local sales representative. You may also find enclosed with this letter a list of Frequently Asked Questions.

At Medtronic, we believe that medical technology contributes to human welfare by alleviating pain, restoring health and extending life. We remain focused on doing our part to ensure healthcare teams have the information, tools and resources they need to treat patients around the world.

As always, we are here to help you take healthcare Further, Together.

Sincerely,

Carla Peron, MD      Pierre Gherardi
Chief Medical Officer, Surgical Innovations   Vice President, Surgical Energy & Safety

Enclosure: Frequently Asked Questions
References


11. Based on engineering report #RE0025744, Particle capture performance of ULPA filters vs. particle size.


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