Medtronic
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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.[1,2]

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 Goulart Silva Peron

Carla Peron, MD
Chief Medical Officer, Surgical Innovations

Pierre Gherardi
Vice President, Surgical Energy & Safety

Enclosure: Frequently Asked Questions

References

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Frequently Asked Questions

1: Does Medtronic have a solution to help evacuate and filter surgical smoke created during open and/or laparoscopic surgical procedures?

Open and Laparoscopic: The RapidVac™ smoke evacuator (SE3690/SE3695) is equipped with ultra-low particulate air (ULPA) filtration technology. It is used in combination with an ULPA filter (SEA3700) and handheld smoke removal pencils/tubing (see product table below).

Laparoscopic: The Valleylab™ laparoscopic smoke evacuation system (SEL7000A) with in-line ULPA filtration is a standalone device that connects directly to suction and effectively and efficiently removes surgical smoke from laparoscopic procedures.[1]

2: Should I dispose of the ULPA filter on my smoke evacuator after each procedure?

In all surgical procedures, including those involving a patient with suspected or confirmed COVID-19, Medtronic recommends the continued use of these products in accordance with its labeling. The viability of virus particles once captured in Medtronic ULPA filters is unknown; therefore, filter disposal techniques should always assume contamination and hospital staff should follow hospital safe disposal protocols.

For the RapidVac™ smoke evacuator: The design of this device prevents airflow in the incorrect direction (equipment to patient) and therefore reduces the risk of cross-contamination. As a result, the filter may be used until it has reached the end of its life as indicated on the device, at which point it should be replaced.

For the Valleylab™ laparoscopic smoke evacuation system: This device is single patient use and should be discarded after each procedure or replaced after 4 hours of continuous use.

3: Are particles captured by the smoke evacuation filter re-circulated into the operating room?

For the RapidVac™ smoke evacuator: After passing through the four stage ULPA system, filtered air is returned to the room.

For the Valleylab™ laparoscopic smoke evacuation system: This system is connected to suction, and filtered air is not returned into the operating room.

4: What sized particles do the filters in the Valleylab™ laparoscopic smoke evacuation system and RapidVac™ smoke evacuation system capture?

A common misconception in evaluating filter adequacy is that the particle size rating for high-efficiency particulate air (HEPA) filters (0.3µm / 300nm) and ULPA filters (0.12µm / 120nm) represents a 'smallest particle that can be captured' specification. In fact, this rating is better explained as the 'most difficult particle to capture'. 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 at equal or greater efficiency.[2]

5: Do ULPA filters capture COVID-19 virus particles?

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. 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.

6: Do the Sonicision™ (ultrasonic dissection) or LigaSure™ (bipolar electrosurgical vessel sealer) devices produce surgical smoke that should be evacuated?

The Sonicision™ device, like other ultrasonic dissection devices, produces surgical plume (mist) caused by the mechanical oscillation of the active blade against tissue. LigaSure™ devices produce steam caused by the heating of molecules between the jaws of the instrument.

In laparoscopic surgery, this plume/steam can be removed through laparoscopic smoke evacuation either with the Valleylab™ laparoscopic smoke evacuation system or the RapidVac™ smoke evacuator with smoke lap tubing. In open surgery, this plume/steam can be removed using the RapidVac™ smoke evacuator and RapidVac™ smoke tubing by holding this tubing near the surgical site.

7: Are Medtronic smoke evacuation products effective at removing 100% of surgical smoke?

No, and for that reason, proper Personal Protective Equipment (PPE) techniques should always be employed even when using surgical smoke evacuation.

Open Surgery: Smoke evacuation pencils and open smoke tubing only filter particulate that is captured by the device, meaning that some particulate will dissipate into the operating room even though the vast majority is captured and filtered.

Laparoscopic Surgery: While smoke capture in laparoscopic surgery is more efficient due to the closed nature of the system, some leakage will still occur. For example, trocars may leak CO_2 and particulate into the operating room during instrument exchanges or trocar insertion/removal/venting.

8: Which Medtronic smoke evacuation products are available for my facility?

Medtronic recognizes that this is a sensitive time for customers around the world. In response to society recommendations, hospitals have asked for information about which products may be used to reduce hazards in the operating room, and the following table provides basic information for smoke evacuation products. For more information, please contact your local sales representative as product availability may vary from one country to another based on regional regulatory approval.

Procedure Type	Medtronic Product Code	Product Description	Required Complementary Products
Laparoscopic Surgery	SEL7000A	Valleylab™ laparoscopic smoke evacuation system (single patient use, ULPA filter)	None
	SEA3720	RapidVac™ smoke lap tubing with valve (single patient use)	SE3690 (110V) or SE3695 (220V)
Open Surgery	SEP5000 or SEP5015	Valleylab™ smoke evacuation rocker switch pencil (single patient use)	SE3690 (110V) or SE3695 (220V)
	SEP6000 or SEP6015	Valleylab™ telescoping smoke evacuation rocker switch pencil (single patient use)	
	CVPLP2000	Valleylab™ smoke evacuation pencil (single patient use)	
	SEA3710	RapidVac™ smoke tubing (single patient use)	
	SEA3715	RapidVac™ smoke sponge guard (single patient use)	
	SEA3700	RapidVac™ ULPA filter (25-hour activation time lifespan)	
	SE3690	RapidVac™ smoke evacuator (110V) (Reusable hardware)	Must be used with open smoke evacuation pencils or open/laparoscopic tubing
	SE3695	RapidVac™ smoke evacuator (220V) (Reusable hardware)	

9: How can I place an order for Medtronic recommended smoke evacuation products?

Please speak with your Sales Representative or call your local customer service for information on how to place an order. Local contact information is available on our website: https://www.medtronic.com/covidien/en-gb/products/smoke-evacuation.html

10: How quickly can I get smoke evacuation products shipped to my facility?

Depending on our inventory level, we usually receive, process and ship your order within a period of five days. Given the critical nature of the COVID-19 situation, we will do everything possible to expedite shipment of these products. Shipping times may vary, especially internationally, given the many border restrictions in place.

11: Is Medtronic willing to donate equipment to help customers during this critical time?

Medtronic and the Medtronic Foundation have committed product and monetary donations to COVID-19 relief efforts across the globe. The Medtronic Foundation is working closely with other nonprofits to help fund the health needs of communities through grant-making initiatives and will be announcing additional financial contributions as well as volunteerism efforts soon.

12: Is Medtronic able to support additional customer demand for smoke evacuation products during this pandemic?

Medtronic is doing everything possible to increase product availability throughout our supply chain.

13: Is Medtronic increasing prices as a result of surging demand for smoke evacuation products?

No. Our Mission to contribute to human welfare guides our business decisions and we would not take this kind of action.

14: If I decide to implement Medtronic smoke evacuation technologies, how can I receive training knowing that sales representatives are not being allowed into some operating rooms?

Medtronic has online resources that will allow clinicians to learn how our solutions work without needing a sales representative physically present in the operating room. For more information or to gain access to these resources, please reach out to your local Sales Representative.

15: What tools are available to help clinicians become more educated on smoke evacuation?

Medtronic has partnered with Pfiedler Education to develop an online study guide on Surgical Smoke. This course is accredited and offers 2.0 contact hours (US). Follow this link for access to this course: https://www.medtronic.com/covidien/en-us/clinical-education/catalog/surgical-smoke-self-study-guide.html

16: Have surgical societies issued any recommendations on implementation of smoke evacuation technologies in the operating room?

Many societies and government regulations recommend or mandate surgical smoke evacuation in all procedures. For COVID-19 specifically, some societies have released recommendations on surgical practices involving confirmed or suspected COVID-19 patients:

SAGES (US): https://www.sages.org/recommendations-surgical-response-covid-19/
ACS (US): https://www.facs.org/covid-19/faqs
AORN (US): https://www.aorn.org/guidelines/aorn-support/covid19-faqs
Intercollegiate General Surgery (UK): https://www.augis.org/wp-content/uploads/2020/03/intercollegiate-surg-guidance-COVID-19-infographic2.pdf

References:

1. Based on internal test report #RE00139506 rev A: Valleylab™ laparoscopic smoke evacuation system nurses and surgeons claims report. March 12, 2018.
2. Based on engineering report #RE0025744, Particle capture performance of ULPA filters vs. particle size.