ALESI SURGICAL Ultravision™

Ultravision™ is an FDA-cleared device to eliminate smoke during laparoscopic procedures through "electrostatic precipitation," which is unique in that the smoke that is created during surgery is eliminated from the operative field by rapidly suppressing its aerosolization. The smoke is precipitated out of the aerosolized form and sediments on to the peritoneal and viscera surface. This is a naturally occurring phenomenon, but this technology allows it to occur faster and more efficiently. Electrostatic precipitation is a highly characterized process used in multiple industrial and research applications, and has been shown by others to precipitate virus particles[1,2].

The use of Ultravision precipitates out the particulate matter faster and more effectively than using an active smoke evacuator alone as shown on FIGURE 1. The no-smoke control is the rate at which the precipitation occurs at normal rate in the body.

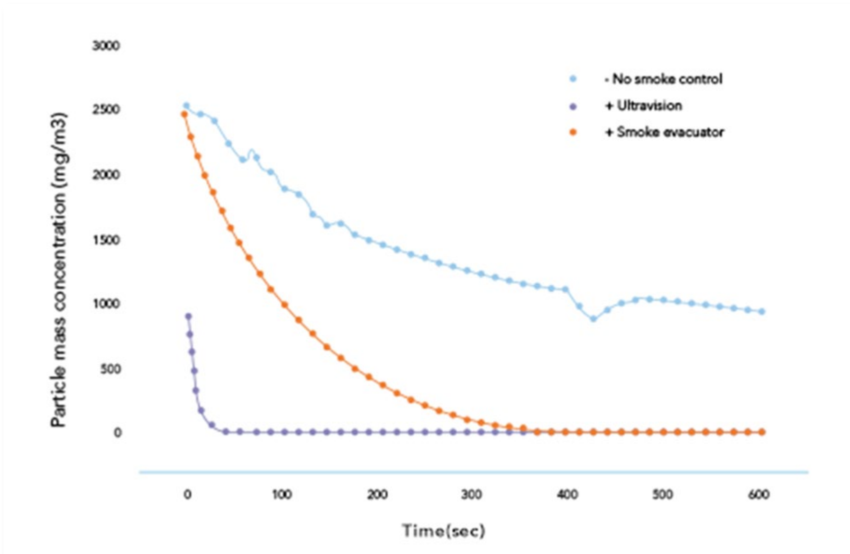

FIGURE 1: Density of particulate matter over time with Ultravision, Active Smoke Evacuator, and Control

Smoke plume particulates have a mean size of ~300 nm (range 70 – 6500 nm). Viruses typically measure between 20 – 260 nm. **The COVID-19 virus belongs the betaCoV category and their diameter is approximately 60-140 nm[3].**

Given (a) the performance of Ultravision™ relative to smoke evacuators; and (b) the literature reporting the ability of electrostatic precipitation to remove viruses from the atmosphere, we have engaged the manufacturer (Alesi Surgical), and asked for any data relating to the ability of Ultravision to precipitate particles of different sizes. **Alesi Surgical has advised that there is no data specific to viruses and makes no claims relative to this.** However, it has provided the following information on the ability of Ultravision™ to precipitate particles of different sizes. These data were generated independently by a university. Although part of previous regulatory submissions, these data are not (yet) in the public domain.

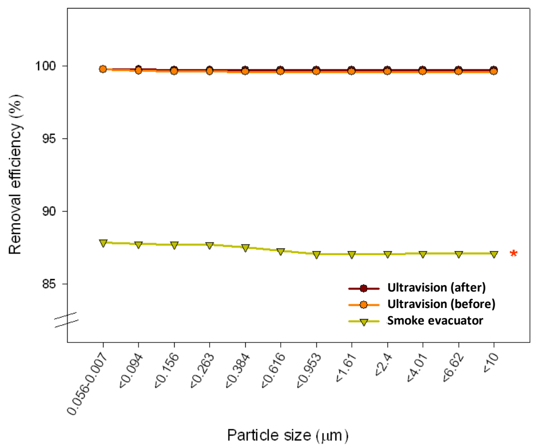

Figure 2: Ultravision performance across particle sizes

The ability to eliminate particles of different sizes, across the relevant size range of 7nm to 10um (i.e. 0.007um to 0.01um) was assessed (FIGURE 2). This size range includes all known viruses. A comparator smoke evacuator removed 87.9% of the number of particles in the size range between 7nm-56nm after 10 minutes of operation following smoke creation with a diathermy. In comparison to the smoke evacuator, Ultravision^{TM} precipitated 99.7% of particles, when switched on either before or after smoke creation. This was independent of particle size from 7nm to 10µm.

And even though the use of ULPA filter attached to the port may be a reasonable option to eliminate the CO2 gas DURING and AFTER the procedure, the ULPA filters may not be enough to filter all the small particulate matters, especially viral particles. ULPA (Ultra Low Particle Air) filters are the most commonly used smoke filters in smoke evacuators and are specified to remove 99.999% of contaminants 0.12µm (120nm) or larger in diameter. The chart below shows the overlap in the performance of ULPA and the lower specification "HEPA" filters (Figure 3). The chart below shows that that, due to their size, viruses are not necessarily effectively captured by even ULPA filters.[4]

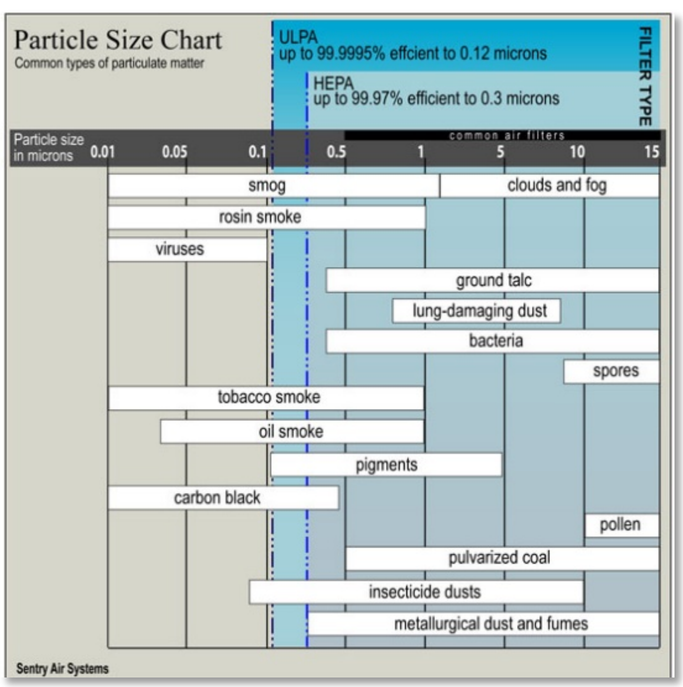

FIGURE 3: Performance of ULPA and HEPA filters (SOURCE – Sentry Air Systems)

Therefore, we recommend the following:

1) **An active smoke evacuator system should be employed during the laparoscopic/robotic surgeries. Active smoke evacuators will allow the particulate matter in the aerosolized form to be shunted in a closed, tubing system away from the patient and into a filter system. Many commercial options are available – including, but limited to Medtronic RapidVac™, Stryker PneumoClear, ConMed Airseal®. Of note, when using the Airseal® system, it must be used in the evacuation mode (connected to a non-Airseal® port) and NOT in the most commonly used insufflator mode (connected to an Airseal® port).**
2) **Ultravision™ may be used as an adjunct to significantly decrease the aerosolized particulate concentration in the CO2 gas during laparoscopic procedures.**

REFERENCES

1 Sampling and detection of airborne influenza virus towards point-of-care applications. Ladhani L et al., PLoS One. 2017 Mar 28;12(3)

2 Airborne Virus Capture and Inactivation by an Electrostatic Particle Collector, Kettleson EM et al., Environ. Sci. Technol. 2009, 43, 5940–5946

3 Features, Evaluation and Treatment Coronavirus (COVID-19). Cascella M et al.,. https://www.ncbi.nlm.nih.gov/books/NBK554776/

4 Sentry Air Systems - https://www.sentryair.com/high-efficiency-air-filter.htm