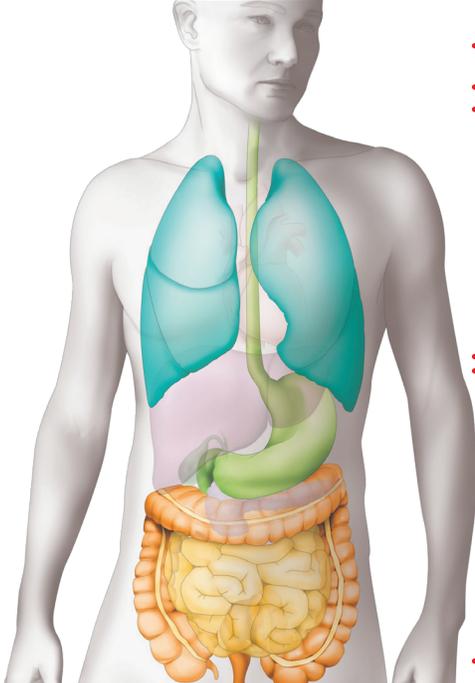


The use of ENERGY in surgical procedures during the SARS-CoV-2 pandemic

Evidence summary of viral transmission from surgical smoke and guidance on energy usage

Areas SARS-CoV-2 has been detected¹

	<p>Nasopharynx</p>	<p>+ Detected in:</p> <ul style="list-style-type: none"> • Saliva, sputum & throat swabs • Nasal swabs • Cells lining respiratory tract • Cells lining gastrointestinal tract • Blood • Bile • Feces
	<p>Upper & lower respiratory tract</p>	
	<p>Entire gastrointestinal tract</p>	<p>- Not detected (negative evaluations)</p> <ul style="list-style-type: none"> • Urine

Evidence of surgical smoke containing SARS-CoV-2²

<p>To date, there is no data on the transmission of SARS-CoV-2 in surgical smoke during MIS or open procedures</p>	<p>However, there is no indication or proof that SARS-CoV-2 is not transmissible through surgical smoke</p>
<p>Even though SARS-CoV-2 is a novel disease, evidence from similar respiratory viruses, such as influenza and other coronaviruses—Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS-CoV)—have not shown evidence of disease transmission through surgical plume or MIS CO₂ gas during prior viral epidemics or annual flu seasons.³</p>	

Evidence of surgical smoke containing any type of virus

Numerous studies have detected viral particles, viral DNA and other infectious material (e.g., bacteria) in surgical smoke from monopolar, bipolar, ultrasonic and laser.^{3,4} **To date, there is no conclusive evidence to indicate that use of electro-surgical or ultrasonic devices during open and MIS procedures increases the risk of disease transmission via the surgical plume or the CO₂ from the pneumoperitoneum.**³

Summary of relevant evidence

- **The only documented *viral transmission* from surgical smoke was human papillomavirus (HPV) to the gynecologic OR staff that used a *laser* to excise tissue in open procedures.**^{5,6,7,8,9}
- Sood, et al. (1994) detected HPV DNA in the plume generated by **loop electrosurgical** excision procedure (LEEP) from patients undergoing cervical procedures but did not report viral transmission to the perioperative staff¹⁰
- Kwak, et al. (1994) reported viral DNA of hepatitis B virus (HBV) and human immunodeficiency virus (HIV) were found in surgical plume after the use of surgical energy (e.g., **electrosurgery, laser and ultrasonic**).⁴
- According to Limchantra, et al. (2019), the surgical smoke from **laser** has been found to contain several potentially infectious components, such as viable bacteriophages, viable cells and virus particles, and is believed to have a higher infectious potential than electrocautery smoke.⁶
- In addition, Limchantra also reported that the particles created by the **ultrasonic** devices are composed of tissue, blood and blood byproducts.⁶ However, in a separate study Okoshi, et al. (2014), reported that although large numbers of cellular particles are released after ablation with **ultrasonic** devices, *very few were morphologically intact, and there were no viable cells*.¹¹
- In a preclinical study by Dr. In, et al. (2015), it was shown that smoke generated from an **ultrasonic** device activated on cancer cells in a petri dish contained viable cancer cells. In turn, the team implanted the cells found in the smoke in mice. Of the 40 injection sites, 16 (40%) grew cancer cells identical to those on the petri dish.¹²
- Lastly, as mentioned previously, **evidence from similar respiratory viruses** (e.g., influenza, other coronaviruses [Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS-CoV)]) **have not shown evidence of disease transmission through surgical smoke** during prior viral epidemics or annual flu seasons.³

Does the surgical smoke from ultrasonic devices have a higher risk of viral transmission?

Although many studies have been carried out on the surgical smoke generated by electrocautery and lasers, far fewer have focused on that generated by ultrasonic devices. As noted in the previous section, **no agreement yet exists about exact composition or viability of the particles contained in surgical smoke generated from ultrasonic devices**.¹¹ To date, **there is no evidence that shows the smoke generated from ultrasonic devices has a greater risk of transmitting any infectious disease than the surgical smoke from other electrosurgical devices**. In fact, Morris, et al. (2020), pointed out how surgery in patients with HIV, HBV and hepatitis C (HCV) has been ongoing for decades, without documented increased risk of transmission to the perioperative staff from surgical smoke or the CO₂ in the pneumoperitoneum.³

Regardless, clinical studies from past and most recent present have stated there is a higher risk of infectious disease transmission from ultrasonic plume due to the "low temperature aerosol...which cannot effectively deactivate the cellular components of virus in patients."¹³ This statement by Zheng, et al. (2020), does not include a reference to a source, though. Upon some investigation, there are several other studies that make similar statements which all seem to eventually point to a preclinical porcine study by Amaral (1994).¹⁴ In this study, Amaral tested an experimental pre-market hook-spatula ultrasonic scalpel in a porcine cholecystectomy model. In the discussion he describes the thermal profile of the device as minimal and does not exceed 80°C, which was based on a personal communication and not data.¹⁴ It is important to note the devices Amaral used in this 26-year-old study are based on the same foundational technology but are very different from the contemporary advanced ultrasonic devices available today. His devices were simple blades without a clamp arm. They lacked any intelligent communication and feedback mechanisms between the device and the generator and were composed of different materials.

To date, there is no evidence that conclusively defines the temperature of the surgical smoke generated from ultrasonic devices. In a recent preclinical porcine analysis by Hayami, et al. (2019), they compared ultrasonic to advanced bipolar under varying wet conditions.¹⁵ While they concluded the temperatures of steam from advanced bipolar were significantly higher than that from ultrasonic, high-temperature steam was still observed from ultrasonic under wet conditions. This study did not assess either the composition of the steam or the viability of the debris in the steam.

Worth knowing: The differences in energy delivery of ultrasonic devices versus electrosurgical devices

Ultrasonic devices deliver energy to the targeted tissue differently than other electrosurgical devices. Monopolar and bipolar devices use high-frequency electrical current to heat up the fluid in the tissue, causing tissue desiccation, coagulation, charring and thermal damage. Ultrasonic devices convert electrical energy to mechanical energy along the length of the blade, producing friction between the tissue and the blade. The ultrasonic blade also produces cavitation within the cells, causing cellular vaporization. These two mechanisms enable these devices to simultaneously seal and cut tissue, with minimal thermal damage. This unique process produces more vapor than smoke as the tissue does not desiccate or burn from the loss of moisture as it can with monopolar and bipolar devices.¹¹

Relative smoke volumes, particle sizes and filtration effectiveness

Table 1 provides size ranges of particles found in the surgical smoke of different energy instruments, **as compared to a single SARS-CoV-2 virion**. Table 2 provides a description of the most commonly used masks and filters by the perioperative team. Table 3 illustrates the findings from Weld, et al. (2007) on the volumes of surgical smoke produced from various devices on porcine psoas muscle.¹⁶ As shown in the table, both ultrasonic and bipolar devices have a far lower concentration of particles when compared to basic electro-surgical devices like monopolar and the floating ball.

Currently, it is assumed SARS-CoV-2 is transmitted as it attaches to larger respiratory water droplets that are in excess of 20,000nm in diameter.³ Additionally, **when SARS-CoV-2 is aerosolized in a CO₂ gas suspension the droplet size is assumed to be less than 10,000nm in size.**³ As mentioned previously, it is unknown if SARS-CoV-2 is contained in surgical smoke and thus the actual particle size, if it exists, is unknown. But, **if intact viable virus is attached to a water droplet found in surgical smoke it is reasonable to assume that it will be captured and filtered by an N95 mask, as well as both HEPA and ULPA filters, as shown in Figure 1.**

Table 1 – Size ranges of particles (in nanometers) found in the surgical smoke of different energy instruments relative to SARS-CoV-2

SARS-CoV-2 ¹⁷	Monopolar ⁷	Laser ⁷	Basic bipolar ^{*18}	Ultrasonic ⁷
60 - 140	7 - 420	100 - 800	220 - 476	350 - 6500

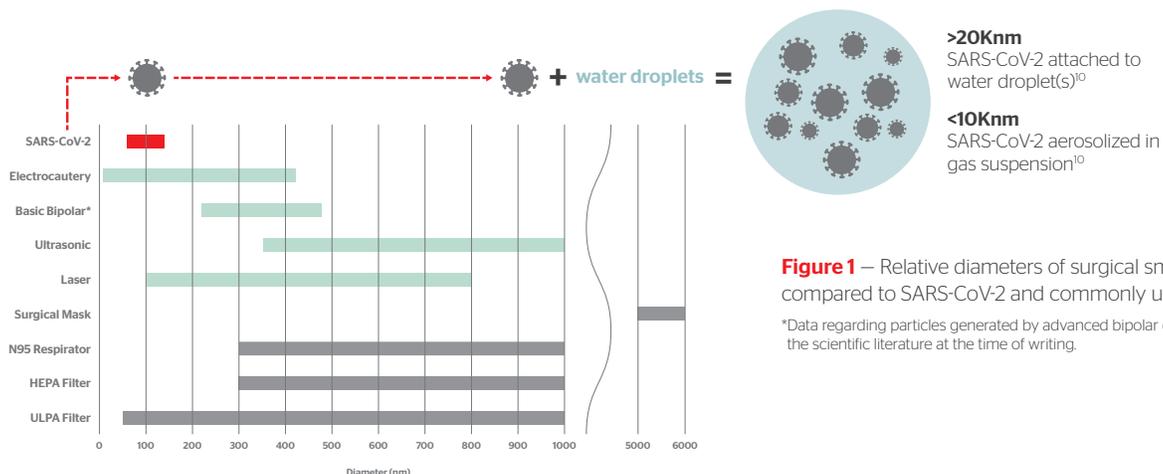
*Data regarding particles generated by advanced bipolar devices was not available in the scientific literature at the time of writing.

Table 2 – Filtering capabilities (in nanometers) of commonly used masks and filters

Standard surgical mask¹¹	≥ 5,000 Intended to provide a barrier to splashes and droplets impacting on the wearer's nose, mouth and respiratory tract. They do not provide protection against airborne (aerosol) particles.
N95 respirator mask¹⁹	> 300 Designed to filter 95% of particles >300nm.
High-Efficiency Particulate Air (HEPA) filter²⁰	≥ 300 HEPA filters have a minimum 99.97% efficiency rating for removing particles greater than or equal to 300nm.
Ultra-Low Particulate Air (ULPA) filter¹	≥ 50 to 120* ULPA filters can remove from a minimum of 99.999% of airborne particles with a maximum particle penetration size of 50 - 120nm. <small>*Different sources state ULPA can remove 50nm particles, while others state slightly larger and up to 120nm.</small>

Table 3 – Concentration of surgical smoke from several different energy devices¹⁶

	Concentration (per cm ³)		
	Particles < 500nm	Particles > 500nm	Total particles
Bipolar	5.35 x 10 ⁵	869	5.36 x 10 ⁵
Ultrasonic	6.10 x 10 ⁵	1.48 x 10 ³	6.11 x 10 ⁵
Floating Ball	1.65 x 10 ⁷	6.61 x 10 ³	1.65 x 10 ⁷
Monopolar	4.40 x 10 ⁷	8.13 x 10 ³	4.40 x 10 ⁷
Background control	3.86 x 10 ³	17	3.88 x 10 ³



General recommendations when performing surgery¹

- Educate the perioperative staff on the potential hazards of surgical smoke and possible transmission of SARS-CoV-2, arising from the generation of SARS-CoV-2-contaminated aerosols.
- Operating rooms for presumed, suspected or confirmed SARS-CoV-2-positive patients should be appropriately filtered and ventilated and, if possible, should be different than rooms used for other emergent surgical patients. The diligent use of a smoke evacuation system with a high-efficiency filter has been identified as a feasible and potentially useful way to reduce exposure to surgical smoke.
- Surgical staff should wear full personal protective equipment including an N95 mask or powered, air-purifying respirator designed for operating room use and droplet-protective PPE.
- During the surgical procedure, only essential staff should be in the operating room and if possible, there should be no exchange of room staff.
- **When using monopolar electrosurgery, laser, ultrasonic dissectors and advanced bipolar devices, minimize the creation of surgical smoke** (see below). If available, energized devices with attached smoke evacuators should be used.
 - Minimize activating any energy devices in a fluid environment.
 - Minimize the length of time for a given activation of an energy device and allow the device to cool down between activations.
 - For devices with jaws, avoid forcing too much tissue into the jaws.
 - Energy devices should be set to the lowest possible power setting for the desired tissue effect.
- Aerosol-generating procedures such as intubation and extubation may put operating room staff at risk for viral transmission. If possible, intubation and extubation should take place within a negative-pressure room. Healthcare providers who are not involved with intubation should leave the operating room. Use regional anesthesia if it is an option instead of aerosol-generating procedures of intubation and extubation.
- Surgical equipment used during procedures with SARS-CoV-2-positive patients should be cleaned separately from other surgical equipment.
- If you are using a smoke evacuator, use new tubing before each procedure and replace the smoke evacuator filter as recommended by the manufacturer.
- Consider all tubing, filters and absorbers on smoke evacuators as infectious waste and dispose of them appropriately.

Open vs. MIS procedures¹

Since the SARS-CoV-2 pandemic emerged, there have been varying opinions from surgical societies on whether it is safer for the perioperative staff to perform surgery with an open or MIS approach. Initially, and related to the potential aerosolization of viral particles during insufflation with CO₂, some societies suggested an open approach would be considered safer to the OR staff. The below recommendations from SAGES is the most current and takes a more balanced approach.

SAGES recommends that, although previous research has shown that MIS procedures can lead to aerosolization of blood-borne viruses, there is no evidence to indicate that this effect is seen with SARS-CoV-2, nor that it would be isolated to MIS procedures.²¹ Nevertheless, erring on the side of safety would warrant treating the coronavirus as exhibiting similar aerosolization properties. For MIS procedures, the use of devices to filter released CO₂ for aerosolized particles should be strongly considered. Proven benefits of the MIS approach, including reduced length of stay and complications, should be strongly considered in these patients, in addition to the potential for ultrafiltration of the majority or all aerosolized particles. Filtration of aerosolized particles may be more difficult during open surgery.²¹

Recommendations when performing minimally invasive surgery¹

- Given the potential risk with SARS-CoV-2 being present in surgical smoke, a smoke evacuation system should be used. The diligent use of a smoke evacuation system with a high-efficiency filter has been identified as a feasible and potentially useful way for surgical smoke to be reduced.
- The pressure in the pneumoperitoneum should be as low as possible for the desired effect to minimize CO₂ leakage from the trocar.
- It is recommended to reduce the amount of times instruments are removed from the trocar to minimize leakage of CO₂ from the pneumoperitoneum. The multifunctional nature of an advanced energy device can reduce leakage of CO₂ due to reduced instrument exchanges.
- If needed and possible, intubation and extubation should take place within a negative-pressure room.

- All pneumoperitoneum should be safely evacuated via a filtration system before closure, trocar removal, specimen extraction or conversion to open.
- Incisions for ports should be as small as possible to allow for the insertion of ports but not allow for leakage around ports.
 - A common best practice is to press the trocar sleeve to the skin at the desired insertion point, prior to incision, to create a temporary marking on the skin; the surgeon can then use that marking as the boundaries for incision.
 - Consider using bladeless trocars, which separate, rather than cut, along tissue fibers, pushing tissue and vessels away.
- The smoke evacuator should be ON (activated) at all times when airborne particles are produced during all surgical or other procedures.

Recommendations when performing open surgery¹

- Surgery should be performed in a negative-pressure room, especially if no smoke evacuation system is available.
- The smoke evacuator or room suction hose nozzle inlet must be kept within 2 inches (5cm) of the surgical site to effectively capture airborne contaminants generated by these surgical devices.
- When using an energy device, it is preferable that the smoke evacuation be integral to the device itself (i.e., a smoke evacuation pencil).
- The smoke evacuator should be ON (activated) at all times when airborne particles are produced during all surgical or other procedures.

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For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.
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