

Society of Robotic Surgery Review: Recommendations Regarding the Risk of COVID-19 Transmission During Minimally Invasive Surgery

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Abstract

The COVID-19 pandemic has created uncertainty regarding the safety and appropriate utilization of minimally invasive surgery (MIS) during this current outbreak. Surgical governing bodies such as Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Royal Colleges of Surgery of Great Britain and Ireland have made statements regarding the possibility of COVID-19 release into CO₂ insufflant during MIS. The basis for this concern is prior evidence in the literature of other viral pathogen release during laparoscopic surgery. The recommendations are correctly based on caution given the lack of understanding of how COVID-19 compares to other viruses with regard to transmission and presence in CO₂ during MIS. In this review we have investigated the available literature on COVID-19 transmission during MIS, address the implications of current and previously published recommendations and discuss steps to mitigate COVID-19 transmission during MIS for staff and patient safety.

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Introduction

Surgical governing bodies such as Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Royal College of Surgeons (RCS) have recently made statements regarding the possibility of COVID-19 release into CO₂ during minimally invasive surgery (MIS) and the potential risk to the patient and health care team (1, 2). This release of CO₂ is one of many potential aerosol generating procedures (AGPs) that occur in the operating room. The basis for this concern is prior evidence in the literature of virus release during laparoscopic surgery. The recommendations by these organizations have erred on the side of caution given the lack of understanding of how COVID-19 compares to other viruses with regard to transmission and presence in CO₂ during MIS. The statements by these groups have created uncertainty and

confusion regarding the safety of performing MIS during the COVID-19 pandemic and surgeons and other health care workers are requesting clarity on the topic.

Society Statements on COVID-19 and Minimally Invasive Surgery

Several surgical societies have addressed the potential risk of COVID-19 transmission during MIS, most notable SAGES and The Royal College of Surgeons. The statements formulated by these groups focus on the CO₂ insufflation that is established during MIS procedures such as laparoscopic, video-assisted thoracoscopic (VATS), and robotic surgery. The concern raised is that CO₂ could theoretically contain COVID-19 particles and that aerosolization could expose health care workers to infectious virus if there is unrestricted release of CO₂ into the operating room. Coupled with the fact that CO₂ is under pressure during MIS procedures, the potential theoretically exists for viral exposure to health care workers in proximity to the surgical field.

The basis for the society statements are prior published reports of viral particles contained within CO₂ aerosol as well as surgical plume created by laser vaporization procedures and electrocautery. One of the studies referenced by the society statements concerned patients with Hepatitis B undergoing MIS procedures where viral RNA was detected in 10 of 11 patients when surgical smoke was tested (3). Another study evaluating laser vaporization found positive cultures for bacteria (*Coryne bacterium*) from the laser plume, but no virus was detected by culture (4). There were also case reports mentioned of exposed surgeons infected with Human Papilloma Virus (HPV) in patients undergoing laser ablation of HPV tumors (5). Based on these reports with other viruses and limited knowledge of COVID-19 in tissue and blood, the Surgical Societies raised concerns about the potential for COVID-19 in CO₂ aerosol created during MIS procedures. While the connection from prior studies to COVID-19 represents an extrapolation, the Societies do acknowledge “there is no current data demonstrating an aerosol presence of the COVID-19 virus released during abdominal surgery. The data referenced was on the detection of other viruses in surgical smoke” (6).

One study that has gained attention and referenced in the Society statements was recently fast-tracked published in *Annals of Surgery* (7). This is a report by surgeons from China and Italy on their perspective on surgical care during the COVID-19 crisis. This is essentially an opinion

paper of what the authors feel constitutes safe surgical practice in a time of overwhelming patient demand and limited resources. Many of their recommendations are well meaning and based on common sense, however the concerns raised about COVID-19 in CO₂ during MIS procedures and the risk to health care workers are not based on evidence. The authors state “the risk (aerosol exposure) is definitely higher in laparoscopic than in traditional open surgery.” This statement on risk is based on the assumption that COVID-19 is present in CO₂, and to date, that has not been established. The information presented in this report is best characterized as expert opinion (Level 5 evidence).

Based on the limited evidence from prior studies focusing on virus in CO₂ and the rapidly changing scientific environment, the initial statements from societies like SAGES and the RCS have evolved. SAGES has provided 4 updates of their statement to date and their most recent version includes, “There is very little evidence regarding the relative risks of Minimally Invasive Surgery (MIS) versus the conventional open approach, specific to COVID-19” (1). The RCS initial report contained, “Laparoscopy should generally not be used as it risks aerosol formation and infection. Chinese and Italian experience reflects this” (referencing the Annals of Surgery report). Two days later the RCS revised their position, “Laparoscopy is considered to carry some risks of aerosol-type formation and infection and considerable caution is advised. The level of risk has not been clearly defined...” (2).

A statement presented by the American Association of Gynecologic Laparoscopists (AAGL) regarding MIS during COVID-19 represents a combined statement of 6 societies dedicated to gynecologic surgery (8). The AAGL statement recognizes the limitations of the available literature on the presence of COVID-19 in CO₂ and states, “There is no available evidence from the COVID-19 pandemic, or from prior global influenza epidemics, to suggest definitively that respiratory viruses are transmitted through an abdominal route from patients to health care providers in the operating room.”

Most recently, the European Association of Urology Section (ERUS) released guidelines specific to urologic procedures, further supporting the need for maximal protection of healthcare

professionals, minimizing aerosol dispersal during laparoscopic procedures, and prioritizing urgent urologic procedures while postponing those at lower risk (9).

Key Points from Society Statements and Published Literature

- There is no current evidence to demonstrate COVID-19 in the CO₂ plume created during MIS.
- There is no clear evidence that active virus is in the blood stream in COVID-19 infected patients (10). In the same report, COVID-19 RNA was found in feces, but there was no viable virus.
- There remains uncertainty regarding the presence of active COVID-19 outside of the respiratory tract.
- Viral exposure and transmission has been documented in limited prior studies in laparoscopy and laser procedures.
- The concerns regarding COVID-19 and MIS made by surgical societies such as SAGES and RCS are cautionary and based on a low level of evidence. These recommendations have evolved and now acknowledge the lack of supporting evidence. The authors are unaware of any reports of COVID-19 related fatality of health care workers directly attributed to MIS.
- The concerns put forth by statements from SAGES and RCS may discourage surgeons from performing MIS surgery without adequate evidence.
- The alternative to MIS, open surgery, is not without viral transmission risk to the health care team and increases the burden on the health care system by increasing hospital bed occupancy with a longer length of stay.

- MIS is superior to open surgery with regard to several patient outcomes across many disease states and conversion to open surgery represents a deviation from standard of care.
- Because of the uncertainty surrounding COVID-19 in the CO2 plume, measures to decrease viral exposure to the surgical team should be performed.

Mitigating COVID-19 Exposure During Minimally Invasive Surgery

Despite the limited number of evidence-based studies addressing the aerosolization of viral particles, there remains concern for the potential presence of COVID-19 in CO2 during MIS. Van Doremalen et al. has provided direct in vitro evidence that *SARS-Cov-2* is similar to *SARS-Cov-1* in that there is plausible transmission of the virus via aerosol or fomite routes (11). The study demonstrates that COVID-19 can remain viable and infectious for hours in aerosolized materials and for days on surfaces. Therefore, efforts should be made to limit cautery plume creation during MIS and CO2 release into the operating room. These efforts to reduce aerosolization and exposure of surgical personnel have been taken from Society recommendations and include:

Patient testing:

It has been recommended that patients undergoing surgery be tested for COVID-19 prior to the procedure. Patients with symptoms consistent with COVID-19 should undergo testing prior to surgery if the clinical situation allows for delay. With accumulating data on patients undergoing surgery in the setting of active COVID-19 infection, it is now more important than ever to clarify the COVID-19 status of patients undergoing any procedure. Lei et al recently reported on 34 patients undergoing elective surgery in the setting of positive testing. Alarming, 44% of these surgical patients required ICU care following surgery and 7 patients died after ICU admission (12). Although this small case series should be taken seriously, the true effect of COVID-19 in the post-operative period remains unknown as it is unclear how many patients underwent elective surgery in the study who were potentially COVID-19 positive while being asymptomatic.

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Due to the relatively long incubation period of COVID-19 (3-14 days) (13), and the now recognized cohort of virus-positive asymptomatic patients in the community setting, we recommend that all patients be tested prior to surgery as permitted by the availability of testing supplies by the institution. Real-Time PCR assays detecting viral RNA have been the mainstay of testing in the United States thus far. These tests have demonstrated efficacious, though variable results with regards to sensitivity and false negative rates (14). PCR assay performance may also rely on sample type, skill of collection, and varying stages of infection in the patient (15). Given this information, we recommend the most comprehensive testing techniques available.

As of April 1st, 2020, the Food and Drug Administration has emergently approved new rapid testing based on IgM and IgG antibodies in the blood and serum (*qSARS-CoV-2 IgG/IgM Rapid Test, Cellex Inc.*). (16) This rapid test takes 15-20 minutes to result and has been approved as adjunct to PCR testing at this time with a 93.8% sensitivity. Although recent data supports serological conversion of COVID-19 can take over 7 days for IgM and greater than 10 days for IgG since onset of symptoms (14), this rapid test may prove beneficial in the surgical setting for multiple reasons:

- 1) to increase the sensitivity and capture of positive patients
- 2) to determine asymptomatic carriers
- 3) as an option where RT-PCR is not available and delay in surgery is not appropriate.

Although this test could theoretically test for immunity (IgG positive, IgM negative), given the unclear period of viral shedding we should not declare an IgG-only positive patient as non-infectious. Dual testing, with both RT-PCR and IgM/IgG antibodies may be useful for all patients undergoing elective surgical procedures in order to amplify the sensitivity of detecting positive patients, although there is not worldwide approval for antibody testing at this time.

Imaging studies, such as CT chest, have also been utilized as a potential rapid and reliable testing platform for COVID-19. Ai et al. demonstrated a 97% sensitivity when utilized in COVID-19 positive patients based on RT-PCR testing (17). Although CT chest imaging may be sensitive for

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detecting COVID-19, it lacks specificity. Furthermore, CT manifestations of COVID-19 tend to occur later in the disease process and may miss patients with earlier sequelae of the virus (18). At this time, we do not recommend widespread utilization of CT imaging as a diagnostic tool prior to elective surgery.

If a patient were to test positive, the AAGL statement recommends delaying surgery until the patient has recovered from COVID-19 if it does not put the patient at risk. If a patient were to test negative, with or without symptoms, consideration for a false negative test should be made and patients treated as “positive until proven otherwise”. Therefore, patients without COVID-19 testing and those testing negative should be treated as potentially positive and further steps to mitigate exposure should be performed during the surgical procedure.

Personal Protection:

All operating room personnel involved with MIS procedures should ideally be provided personal protection equipment (PPE) to include N-95 masks or CAPRs (Controlled Air Purifying Respirators) given the unknown risk of virus in the CO₂ plume. Some studies suggest that standard surgical masks provide protection on par with N-95 masks (19). In a randomized study involving over 2,300 health care workers comparing those who wore N-95 masks to those with standard medical masks, there was no difference in influenza acute respiratory illness or infections between the two groups. This experience is potentially transferrable to COVID-19 as the size of Influenza A is between 80-120 nm (0.08 - 0.12 microns) (20) and COVID-19 is recognized to be between 60-140 nm (0.06 – 0.14 microns). In addition to masks, full PPE to include shoe covers, impermeable gowns, protective head covering, gloves and eye protection should be utilized by all members the operative team.

Operating Room Management:

The minimum number of health care workers should be in the operating room during MIS procedures and only essential personnel should be present to limit traffic and exposure. Breaks in and out of the room should be limited to decrease personnel exposure and limit the amount of necessary PPE. Due to potential limitations in communication while wearing full PPE, conversations in the operating room should be limited to essential surgical-related topics.

Surgical training should be altered to decrease exposure to non-essential personnel, reduce operative times, and conserve limited PPE resources.

Anesthetic Concerns:

Both intubation and extubation of the patient are powerful aerosol generating procedures and pose a high risk to operating room personnel. Potential AGPs in the operating room aside from surgical smoke include tracheal intubation, manual ventilation, cardiopulmonary resuscitation and suctioning (21). The American Society of Anesthesiologists (ASA) has put forth recommendations in the setting of COVID-19 including limiting fiberoptic intubation and considering rapid sequence intubation (RSI) in order to avoid manual ventilation (22). Although negative-pressure operating rooms have been recommended to reduce potential viral contamination (23), these are not readily available at many institutions. Therefore, only core anesthetic staff should be present during intubation and extubation. According to the Association for Professionals in Infection Control and Epidemiology (APIC), “the established standard for operating rooms requires 20 air changes per hour” (24). With this information, along with the CDC guidelines on time required for airborne contaminant removal (25), a minimum of 20 minutes should be observed prior to entering the operating room after intubation.

Surgical Technique:

To decrease the risk of virus release into the CO₂ plume, steps can be taken to improve tissue dissection and division. These include reducing the electrocautery settings, decreasing application time, improving tissue moisture to reduce tissue charring and smoke formation. Recommendations state to use the lowest setting possible and to avoid techniques that create unnecessary plume in the abdomen. Ultrasonic devices such as harmonic scalpel create significant aerosol without desiccation of tissue, and potentially viral release, and should be used judiciously. It is important to recognize that open surgical procedures can generate plume with similar devices.

The uncontrolled release of CO₂ from the abdomen should also be avoided. Steps include decreasing the insufflation pressure to the lowest level possible and still permit good visualization. This will decrease the amount of CO₂ under pressure and reduce inadvertent

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release. Ports should be placed with the intent of reducing leakage around the ports and port valves should be functional or replaced. Tissue extraction should be performed after elimination of the CO₂ pressure and controlled evacuation of the CO₂ plume. Open incisions where CO₂ can readily escape, such as an open vaginal cuff, should be planned for in advance and steps taken to reduce CO₂ leakage. Finally, if a laparoscopic suction device is being used, this would ideally be connected to a filtered device with an ultra-low particulate air (ULPA) or high-efficiency particulate air (HEPA) filter and not to an in-room canister connected to wall suction.

CO₂ Plume Management:

There is no way to completely prevent CO₂ escape during a MIS procedure as the “closed” ports with a valve will leak with instrument insertion. However, there are technologies available to filter the CO₂ and plume created during MIS procedures. This would reduce the amount of potential untreated aerosol released into the operating room.

COVID-19 particles are estimated to be between 0.06 and 0.14 microns (60 to 140 nm, Table 1). To reduce virus in CO₂ aerosol, the filtration system should ideally be smaller than the diameter of the virus. There are several filtration systems available to address surgical plume and eliminate virus as well as other products created during plume formation (26), but these options may vary depending on hospital location and local industry partners.

A technology currently available for MIS is the Airseal insufflation/smoke evacuation system by Conmed (USA) and Surgiquest (UK). Airseal mode is a high flow insufflation system with concurrent smoke evacuation in a low evacuation mode (3 liters/min) and high evacuation mode (8 liters/min). The Airseal mode uses a valve-less port with a virtual valve created by an airflow “shield” (Figure 1). The Airseal mode provides smoke evacuation through a 0.01-micron filter which is smaller than the recognized diameter of COVID-19.

This technology allows for pressure release which is beneficial during increases in pressure during the procedure (patient bucking), however, it allows CO₂ escape due to the open port configuration and is not ideal when there is concern for plume containing virus. The Society

statements have recommended a “closed” insufflation system to reduce CO₂ leakage in distinction to Airseal mode which is “open”.

Perhaps unknown to some surgeons the same Airseal insufflation box offers another mode known as smoke evacuation mode (SEM) which is a closed circulation of CO₂ with the CO₂ filtered through a 0.01-micron ULPA filter (Figure 2). This allows filtration at a smaller particle size than the recognized diameter of COVID-19. The SEM uses standard laparoscopic ports with one line of the dual lumen tube as the CO₂ “in” side and the other end of the tube as the “out” which passes through the ULPA filter (Figure 3). The SEM is a closed system and provides CO₂ flow at standard inflow rates (20 or 40 liters/min).

Another option is the PneumoClear device made by Stryker (Figure 4). This is a closed circulating insufflation system with CO₂ passed through a 0.08-micron ULPA filter. This system also offers a “desufflation” mode which removes the CO₂ contents and passes them through the ULPA filter. The PneumoClear device requires the updated version of the Stryker insufflator.

There are also inline filters available to remove small particles from CO₂ aerosol and these options do not require additional insufflators or tube sets. The Plume Port Active (Buffalo Filter) made by Conmed (Figure 5) and the Pureview filter made by Stryker (Figure 6). Both are inline filters that are connected to the side port of laparoscopic port and then to suction tubing. The amount of suction will need to be regulated to keep up with CO₂ inflow to maintain working space and visibility. Both filters contain a 0.1-micron filter which is larger than reported COVID-19 particles.

Another source of CO₂ aerosol that may impact surgical staff is the laparoscopic suction device used by the surgeon during laparoscopic and VATS procedures and the bedside assistant during robotic surgery. This suction device is usually connected to a suction canister connected to wall suction and goes unfiltered. There is a substantial volume of CO₂ removed with this device and this should ideally be filtered. Most laparoscopic suction devices have a standard suction connection and filtration options for this type of connection are limited.

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One option to address CO₂ plume from the suction device is to connect the suction tubing to a Neptune Waste Management System (Stryker, Figure 7). The Neptune possesses both a ULPA filter on the side of the unit (Figure 8) as well as a HEPA filter on the front of the device. The front ports readily accept standard suction tubing from a laparoscopic suction device. The side filter containing the ULPA filter requires a separate adaptor to filter CO₂ plume. The specifications for the ULPA and HEPA filters on the Neptune 3 device are 0.1 micron and 0.3 microns respectively. It is important to note that because of associated fluid and blood in suction irrigation device, the laparoscopic suction device should only be connected to the front manifold connections of the Neptune 3. The front manifold contains the HEPA filter and is connected to 4-liter and 20-liter canisters which are designed for fluid collection. The laparoscopic suction should not be connected to the ULPA manifold which does not have collection capability and should be used for CO₂ aerosol filtration only. There are also options for controlling the force of suction located on the back of the Neptune device and this may need to be adjusted depending on the impact of suction on maintaining adequate vision during the MIS procedure.

Recommendations

Based on the available evidence, review of the literature and practical considerations, the authors recommend the following:

Indication for Surgery:

- MIS procedures should be limited to planned urgent or emergency procedures

Testing:

- Pre-operative testing of surgical patients prior to MIS procedures if feasible
- Avoid surgery in COVID-19 positive patients and allow recovery or intervene after viral shedding is complete if clinical course permits
- If patients are not tested, or test negative, they should be managed as positive due to uncertainty around testing

Operating Room Management:

- Limit healthcare workers in the room to essential personnel
- Limit through traffic and breaks to reduce the number of staff in the room
- Surgical training should be avoided to reduce exposure and OR time

Protecting Operating Room Staff:

- Personal protective equipment, including N-95 masks, should be made available to healthcare workers in the OR especially those at the bedside during MIS procedures.
- Staff should remain remote from the surgical field if their job allows.

Optimize Surgical Technique:

- Efforts should be made to reduce surgical plume creation by reducing electrocautery settings, application time, and tissue desiccation.
- CO₂ working pressure should be reduced to the lowest acceptable level to allow a safe operating space and maintain visibility
- Uncontrolled release of CO₂ from the abdomen should be avoided during instrument placement, tissue extraction, or release of CO₂ at the end of the case. Efforts should be made to suction the residual CO₂ from the patient into a filtration system.

Filtration of CO₂ Plume:

- Efforts should be made to use a closed insufflation system to reduce escape of CO₂ into the OR environment.
- CO₂ from the working space should be filtered through a closed filtration system using the smallest filter available.
- CO₂ from the suction devices should also be filtered through a filtration system using the smallest filter available.

Summary

Concern has been raised regarding the risk of exposure to healthcare workers in the operating room from CO₂ created during MIS procedures in patients potentially harboring COVID-19. The risk remains unclear at this time based on the lack of definitive data demonstrating active

COVID-19 virus present in CO₂ aerosol. Despite this uncertainty, efforts to protect operating room staff should be implemented to decrease exposure to surgical smoke created during MIS procedures. These efforts include pre-operative testing in all patients scheduled for MIS surgery, comprehensive personal protective equipment for staff, and reducing the production of surgical plume and filtration of CO₂ through approved filters. Although there remains no definitive evidence of COVID-19 transmission during open or minimally invasive abdominal surgery, these recommendations serve as an expert opinion, putting forth maximal precautions in the management of an unknown threat. Converting MIS procedures to open surgical procedures without clear justification may put another burden on our already stressed health care system.

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Acronym	Name	Size (microns)
HAV	Hepatitis A Virus	0.02
HEV	Hepatitis E Virus	0.03
HBV	Hepatitis B Virus	0.04
HPV	Human Papilloma Virus	0.05
HCV	Hepatitis C Virus	0.06
COVID-19	Novel Coronavirus	0.06-0.14
HIV	Human Immunodeficiency Virus	0.12
BAC	Bacteria	0.30

Table 1: Size Comparison of Virus Particles

CO2 Filtration System	Mode	Micron Filter
Airseal Smoke Evac Mode SEM (Conmed)	Insufflation/ Smoke Evacuation	ULPA 0.01
Plume Port Active (Conmed)	Inline filter	ULPA 0.1
Pneumoclear (Stryker)	Insufflation/Smoke Evacuation	ULPA 0.08
Pureview (Stryker)	Inline filter	ULPA 0.1
Neptune 3 (Stryker)	Inline filter	HEPA* 0.3 ULPA** 0.1

Table 2: Comparison of CO2 Filtration Systems

* HEPA=High efficiency particulate air: filters at 0.3 microns @ 99.95%

** UPLA=Ultra-low particulate air: filters at 0.12 microns @ 99.99%

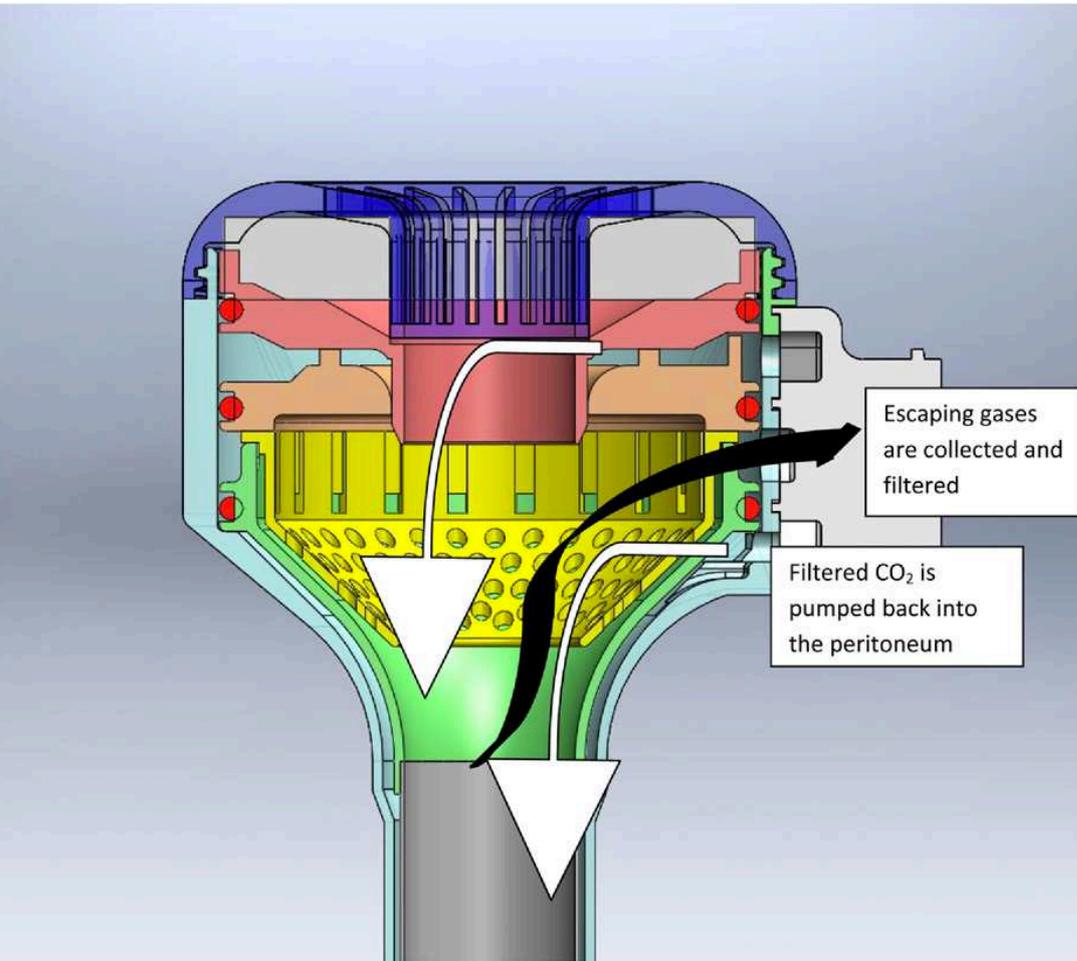


Figure 1: Airseal insufflation port. The valveless port permits CO₂ escape during increases in intra-abdominal pressure



- Smoke Evacuation Mode**
 Bifurcated, Dual-Lumen Filtered Tube Set
- Provides high flow insufflation
 - Facilitates smoke evacuation and filtration with 0.01 μ ULPA filter
 - Use with two conventional trocars



Figure 2: AirSeal Smoke Evacuation Mode (Conmed)

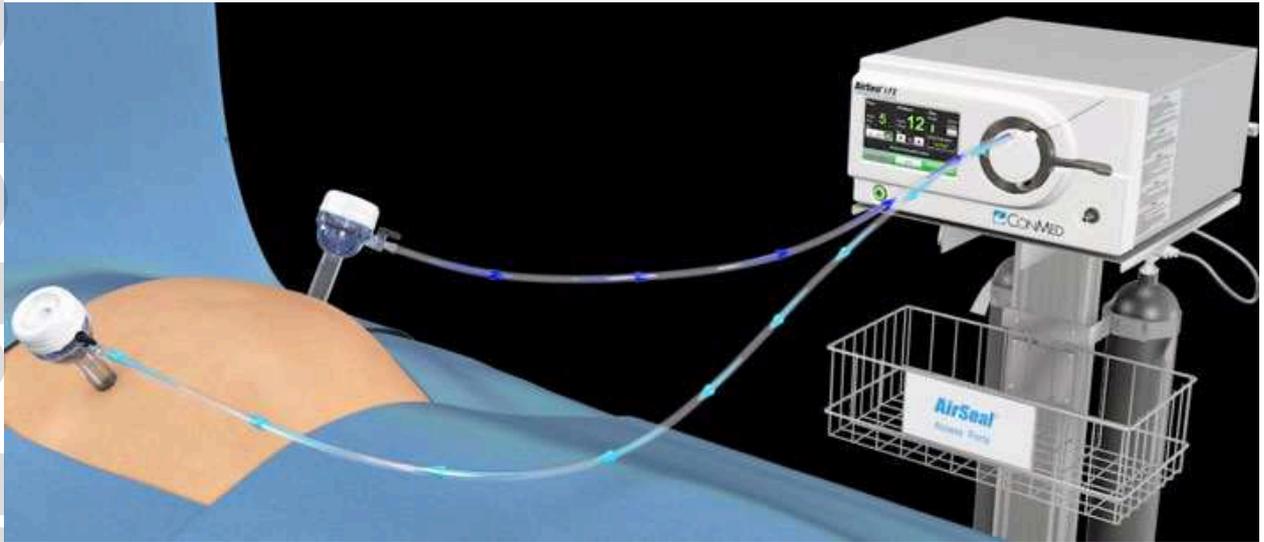


Figure 3: Smoke evacuation port set-up. CO₂ is insufflated through one port and evacuated through a second port.



Figure 4: Pneumoclear Smoke Evacuation System (Stryker)



Figure 5: Plume Port Active (Buffalo Filter, Conmed)



Figure 6: Pureview In-line Filter (Stryker)



Figure 7: Neptune 3 Waste Management System (Stryker)



Figure 8: Stryker Neptune ULPA Filter Access

Accepted Article