



# Safety first: significant risk of air embolism in laparoscopic gasketless insufflation systems

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## Abstract

**Background** Gasketless laparoscopic insufflator systems are marketed for the ability to prevent desufflation of pneumoperitoneum during laparoscopy. However, surgeons raised concern for possible introduction of non-absorbable room air, including oxygen (O<sub>2</sub>), with these systems. A community-university collaborative was created to test this hypothesis.

**Methods** An artificial abdomen, calibrated to equivalent compliance and volume of an average abdomen, was connected to a flow meter, oxygen concentration sensor, and commercially available laparoscopic gasketless cannula system. A commercially available gasketed cannula system was utilized as a control. Intra-abdominal concentration of oxygen was measured at 0–60 L per minute (L/min) of insufflated carbon dioxide (CO<sub>2</sub>) aspiration, as would occur during laparoscopic suctioning. For reference, a 5-mm laparoscopic suction device has an aspiration rate of approx. 42 L per minute. At the test facility, room air was 20.5% O<sub>2</sub> at 50% humidity. Descriptive and univariate statistics were calculated with  $p < 0.05$  considered significant.

**Results** At 0 L/min CO<sub>2</sub> aspiration, there was minimal (<0.5%) oxygen detected intra-abdominally. However, with increasing rates of aspiration of pneumoperitoneum, increasing amounts of room air were detected intraabdominally in the gasketless versus gasketed cannula systems (mean ± standard deviation): 14.7 ± 1.2% versus 1.2 ± 0.5%,  $p < 0.0001$  at 5 L/min aspiration, 18.1 ± 0.69% versus 1.1 ± 0.02%,  $p < 0.0001$  at 10 L/min, 50.4 ± 2.19% vs 1.01 ± 0.003%,  $p < 0.0001$  at 20 L/min. Above 25 L/min aspiration, the standard gasketed cannula systems experienced desufflation, but the gasketless system continued to entrain air to maintain insufflation: 64% room air at 30 L/min aspiration, 71% at 40 L/min aspiration, 77% at 50 L/min aspiration, and 84% at 60 L/min aspiration.

**Conclusions** Gasketless cannula insufflation systems maintain abdominal insufflation by entraining non-medical room air. Especially at high aspiration rates, the majority of absorbable CO<sub>2</sub> was replaced by non-medical room air, increasing potential for gas embolism with poorly absorbed oxygen and nitrogen. Authors have reported these experimental findings to the FDA and companies marketing these devices.

**Keywords** Gasketless cannula · Insufflation · Venous embolism · Gas embolism · AirSeal InteliFlow · Laparoscopic surgery · Air embolism · Pneumoperitoneum

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Gasketless insufflation systems are currently marketed for use in the United States and advertise the ability to prevent abdominal collapse and desufflation during laparoscopy. These systems maintain pneumoperitoneum, even when loss of carbon dioxide (CO<sub>2</sub>) insufflation occurs, such as during intraoperative suctioning. However, without the presence of a gasket, community surgeons raised concern for potential entrainment of room air into the abdomen during laparoscopy and increased risk of non-absorbable air embolism with these systems.

While carbon dioxide (CO<sub>2</sub>) embolism may be as high as 17% in certain laparoscopic procedures [1], these emboli

are rarely clinically significant due to the rapid absorption of CO<sub>2</sub> into the body. Clinically detectable intraoperative air embolism is rare, occurring in 0.06–0.15% of routine laparoscopic cases, but has a reported mortality rate up to 30% [2–5]. The insufflation gas of choice, CO<sub>2</sub>, is rapidly absorbed in the circulatory system, while room air consists of predominantly nitrogen and oxygen. These gases are slowly absorbed from the bloodstream, compounding the effects of embolism when it occurs [6]. However, as little as 200 mL of embolized slowly absorbable gas can be lethal [4, 5]. Risk of gas embolism increases in operative situations such as venous bleeding from hepatic parenchyma or retroperic venous plexus [3, 7, 8]. During these operative scenarios, laparoscopic suctioning is frequently utilized. Especially in these situations, a gasketless system would hypothetically pull in room air via the cannulas in order to maintain insufflation pressures, and therefore raise the risk of significant non-absorbable gas embolism. Given this theoretical safety concern, a community-university collaborative was created to design a model and test this hypothesis.

This study seeks to quantify non-medical air entrainment by a commercially available laparoscopic gasketless cannula system to understand the risk of intraoperative air embolism. The authors hypothesize that gasketless insufflation system will result in marked air entrainment into the abdomen and will increase the risk of clinically significant non-absorbable gas embolism, especially when laparoscopic suction is utilized.

## Methods

### Funding and support

No human subjects or health records were utilized in this study, so institutional review board approval was not required. Equipment and support for this project was provided out of the Boise State University Chemistry Department research budget. Additional project supplies were purchased at the authors' expense. AirSeal IntelliFlow and Stryker PneumoSure insufflation pumps were supplied by Stryker Corporation and Lexion Medical as a donation. These companies did not have access to study design, data analysis, experimental results, conclusions, or decision to publish.

### Study design

During standard laparoscopy, the concentration of oxygen within the peritoneum should be nominal. With use of an artificial abdomen calibrated to approximate the volume and elasticity of the human abdomen, oxygen concentration was measured during insufflation with both gasketed and

gasketless systems. A controlled aspiration of gas was then applied to simulate standard loss of pneumoperitoneum such as during laparoscopic suctioning and introduction of 5 mm and 10 mm laparoscopic instruments. This controlled gas leakage/suctioning in the artificial abdomen is referred to as the “gas aspiration rate” for the study. The concentration of oxygen was measured within the artificial abdomen during controlled gas aspiration to demonstrate the presence of room air entrainment by the gasketless and gasketed (control) cannula systems.

### Model development

A novel artificial abdomen was created utilizing a latex weather balloon stretched to simulate the volume and elasticity of the human abdomen (i.e., 2.0 L at 5 mmHg, 2.2 L at 10 mmHg, 2.5 L at 15 mmHg). The artificial abdomen was inflated via a Surgi-Quest gasketless cannula using the Surgi-Quest AirSeal insufflation system (Milford, Connecticut). Insufflation pump and cannula were set up per manufacturer specifications using a standard CO<sub>2</sub> tank supply.

The artificial abdomen was allowed to equilibrate at standard 15 mmHg intraabdominal pressure for simulated laparoscopy. To simulate standard intraoperative CO<sub>2</sub> loss (such as by laparoscopic suctioning), aspiration rates ranging from 0 to 65 L/min were utilized. Gas aspiration rates were measured directly (Dwyer flowmeter, Michigan City, IN), and resultant O<sub>2</sub> concentrations within the abdomen were measured at each aspiration rate. This was repeated with no instrument, a 5-mm laparoscopic instrument, and 10-mm instrument inside a single gasketed or gasketless cannula; measurements were taken before, during, and after the 5-mm and 10-mm instruments were placed inside the artificial abdomen.

Consumption of CO<sub>2</sub> was measured by direct readout from the insufflator and confirmed by measuring flow over time.

An experimental control was performed in the same fashion utilizing the same artificial abdomen with a standard insufflation pump (PneumoSure High Flow Insufflator, Stryker, Kalamazoo, MI) and gasketed cannula (Endopath trocar, Ethicon, Cincinnati, OH).

### Oxygen concentration

Oxygen was the surrogate measure for room air entrainment, as it makes up a reliable percentage of the room air and is easily and consistently measured. Oxygen concentrations were determined by placing a standard O<sub>2</sub> sensor (Vernier Software and Technology, Beaverton, OR) within the artificial abdomen. It was calibrated according to manufacturer's instructions. Room air concentrations of O<sub>2</sub> were consistently 20.5% at 50% humidity; final room air concentration

was therefore equal to 4.9 times the O<sub>2</sub> concentration measured.

### Controlled insufflation gas leakage

Controlled aspiration of abdominal insufflation gas was designed to mimic laparoscopic suctioning and other losses of pneumoperitoneum during laparoscopic surgery. In gasketed cannula systems, laparoscopic suctioning can produce a loss of pneumoperitoneum by quick removal of insufflated CO<sub>2</sub>. Gasketless cannula systems are marketed on their ability to avoid desufflation during laparoscopic suctioning or other controlled loss of pneumoperitoneum, despite a constant CO<sub>2</sub> flow rate into the abdomen. Measured aspiration rates of standard laparoscopic suction devices were approximately 42 L/min with a 5-mm laparoscopic suction device.

### Primary outcomes, variables, and measurements

Primary study outcome was percent of oxygen (measured) and room air (calculated based on measured atmospheric oxygen concentration) contained within the artificial abdomen with standard use of the gasketed and gasketless laparoscopic cannula systems at different controlled gas aspiration rates. The aspiration rate that produced desufflation of the abdomen with each cannula system was a secondary outcome of interest.

### Data collection and statistical analysis

Experimental data were collected with Logger Pro software (Beaverton, OR). Microsoft Excel 2016 (Redmond, WA) was utilized for descriptive statistics, including percentages and means, and GraphPad software (La Jolla, CA) was also utilized to calculate univariate statistics including Student's *t* test. The experiment was repeated three times for the gasketless and gasketed cannula system at each aspiration rate; values are reported as the range, mean, and maximum of the percent room air within the artificial abdomen at each gas aspiration rate. A *p* value of <0.05 considered significant.

## Results

At a standard laparoscopic insufflation pressure of 15 mmHg but no simulated loss of pneumoperitoneum, the percent of room air concentration in the abdomen was nominal as expected, measuring around 2% for both the gasketless and gasketed cannula systems.

Room air concentration at 0 L/min aspiration was minimally elevated compared to higher aspiration rates in the gasketed (control) cannula system, 2.3% compared to 1.2–0.98%. This is likely due to the introduction of a small

amount room air during trocar placement, which is rapidly replaced in the gasketed system when aspiration is applied.

Maximum CO<sub>2</sub> delivered by the gasketless insufflator was 8.6 L/min, even at the 40 L/min setting. As hypothesized, when aspiration rates exceeded delivered CO<sub>2</sub>, room air entrainment occurred in the gasketless system. The amount of air entrained increased as the rate of controlled gas aspiration increased. The control gasketed cannula systems did not entrain significant room air, remaining around 1% or less at all aspiration rates tested, see Table 1.

Figure 1 demonstrates that increasing aspiration rates resulted in increasing room air entrainment through the gasketless insufflation system, while the gasketed system had ≤1% room air measured. At an aspiration rate of 25 L/min, the average measured room air concentration was 62% in the gasketless system but remained <1% in the gasketed system. While at a gas leak rate 40 L/min, a typical rate for a 5-mm laparoscopic suction device, room air concentration was 71% within the artificial abdomen with the gasketless system. At this high continuous aspiration rate, the gasketed cannula system experienced desufflation of the artificial abdomen.

Of note, the gasketless insufflation pneumoperitoneum did not collapse even with high aspiration rates (up to 65 L/min).

Placement of either a 5-mm or 10-mm instrument through the cannulas did not affect the room air entrainment for either system.

Univariate comparison confirmed the gasketless systems and control gasketed cannula insufflation systems had equivalent concentrations of room air without aspiration of pneumoperitoneum ( $2.3 \pm 0.81\%$  vs.  $2.4 \pm 0.87\%$ ,  $p = 0.89$ ). However, even at 5 L/min aspiration rate, the gasketless systems had a statistically significant entrainment of room air into the artificial abdomen ( $14.7 \pm 1.2\%$  vs.  $1.2 \pm 0.54\%$ ,  $p < 0.0001$ ), see Table 2. At all aspiration rates, the difference remained statistically significant. Room air concentrations within the artificial abdomen reached 85% at high aspiration rates.

## Discussion

Our community university collaborative investigated concerns raised by surgeons regarding the potential for air embolism with laparoscopic gasketless insufflation systems and found these concerns to be justified. Clinically significant room air entrainment through the gasketless insufflation system occurred when controlled gas leakage was applied to pneumoperitoneum. Gasketless cannula insufflation systems maintain abdominal insufflation, as advertised, but especially at high aspiration rates, the majority of absorbable CO<sub>2</sub> was replaced by non-medical room air to maintain pneumoperitoneum.

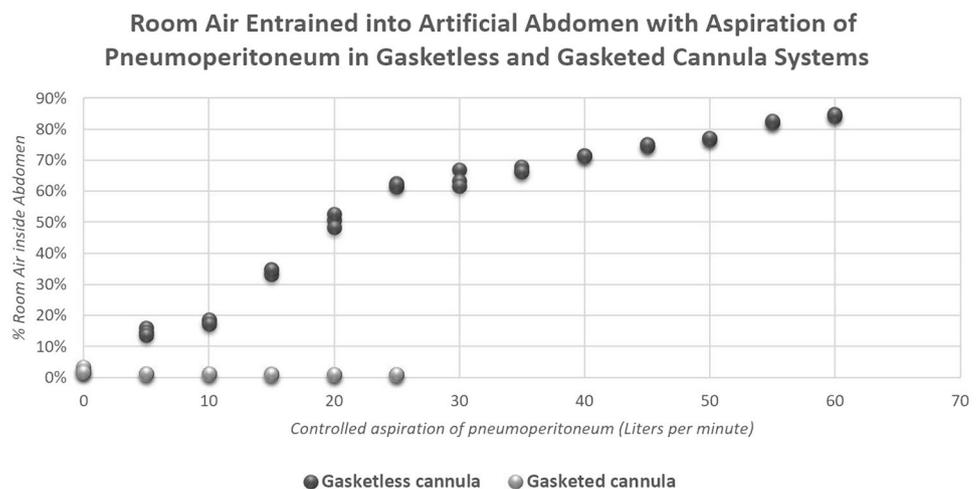
**Table 1** Concentration of room air entrained at various gas aspiration rates in laparoscopic gasketless and gasketed cannula systems

Pneumoperitoneum aspiration rate (L/min)	Gasketless cannula system				Gasketed cannula system (control)			
	Mean oxygen concentration (%)	Max oxygen concentration (%)	Mean room air entrained (%)	Max room air entrained (%)	Mean oxygen concentration (%)	Maximum oxygen concentration (%)	Mean % room air entrained	Max % room air entrained
0	0.46	0.44	2	2	0.48	0.91	2	4%
5	3.01	5.34	15	26	0.25	0.26	1.2	1.3
10	3.69	7.42	18	36	0.22	0.23	1.1	1.1
15	7.0	8.1	34	40	0.21	0.22	1.0	1.1
20	10.3	11.2	50	55	0.21	0.26	1.0	1.3
25	12.7	13.6	62	66	0.20	0.21	1.0	1.0
30	13.1	13.7	64	67	NA	NA	NA	NA
35	13.7	14.3	67	70	NA	NA	NA	NA
40	14.6	15.1	71	74	NA	NA	NA	NA
45	15.3	15.6	75	76	NA	NA	NA	NA
50	15.8	15.9	77	78	NA	NA	NA	NA
55	16.9	17.1	82	83	NA	NA	NA	NA
60	17.3	17.5	84	85	NA	NA	NA	NA

Concentrations are measured as % of total pneumoperitoneal gas within artificial abdomen. Pneumoperitoneal aspiration rate simulate laparoscopic suctioning and other sources of gas leakage during laparoscopic surgery. Oxygen comprised 20.5% room air at laboratory facility. Above gas aspiration rate of 30 L/min, the gasketed cannula systems experienced desufflation of the artificial abdomen, and no measurements could be taken. Experimental and control runs were performed 3 times at each rate, means and max represent the combined data of 3 runs to ensure precision/accuracy

L/min liters per minute

**Fig. 1** Room air entrained into artificial abdomen with aspiration of pneumoperitoneum in gasketless and gasketed systems. Room air is 4.9 times the concentration of oxygen measured in the artificial abdomen. Without aspiration of pneumoperitoneum (0 L/min), the average percent of room air is less than 2% in both systems. Data represent the average values of multiple experimental runs at each aspiration rate. Above 25 L/min aspiration, the gasketed system experienced desufflation of the abdomen



Gasketless insufflation systems work by propelling carbon dioxide within their proprietary trocars to create a horizontal gas vortex within the cannula rather than utilizing a solid barrier. As a result, when pneumoperitoneum is lost through conditions such as suctioning or leakage, the gasketless insufflation system will introduce room air in order to maintain pressure. In standard laparoscopic insufflation systems with gasketed trocars, pneumoperitoneum is maintained in a closed system of carbon dioxide with solid gaskets that do not allow the introduction of air.

At a standard laparoscopic suction/aspiration rate of 25 L/min, intraabdominal room air concentrations reached 62% in the gasketless cannula system but were <1% in the gasketed systems. In our experimental study, the gasketless cannula system remained inflated despite the demands of continuous aspiration by drawing in room air—a majority of the medical CO<sub>2</sub> was replaced by room air at an average aspiration rate and almost completely replaced CO<sub>2</sub> at the highest aspiration rates tested. The gasketed systems

**Table 2** Comparison of room air entrained at various gas aspiration rates in laparoscopic gasketless and gasketed cannula systems

Pneumoperitoneum aspiration rate (L/min)	Gasketless % Room air entrained	Control % Room air entrained	<i>p</i> value
0	2.3 ± 0.81	2.4 ± 0.87	0.89
5	14.7 ± 1.2	1.2 ± 0.54	<0.0001
10	18.1 ± 0.69	1.1 ± 0.02	<0.0001
15	34.4 ± 0.99	1.04 ± 0.01	<0.0001
20	50.4 ± 2.19	1.01 ± 0.003	<0.0001
25	62.2 ± 0.55	0.98 ± 0.01	<0.0001

Pneumoperitoneal aspiration rate simulate laparoscopic suctioning and other sources of gas leakage during laparoscopic surgery with standard carbon dioxide insufflation. Above gas aspiration rate of 30 L/min, the control gasketed cannula systems experienced desufflation of the artificial abdomen, and no measurements could be taken. Experimental and control runs were performed 3 times at each rate; means and standard deviations presented

*L/min* liters per minute

*p* value of <0.05 considered significant

were not able to be tested above approximately 30 L/min aspiration due to pneumoperitoneum collapse.

Though undesired desufflation can sometimes be frustrating to surgeons during an operation, this event represents a safe closed system where the inflow of CO<sub>2</sub> does not match its rapid outflow, such as by rapid continuous suctioning.

The potential for air embolism is dramatically increased with gasketless insufflation systems compared to gasketed systems. Fatal air embolism has been reported to occur with volumes of 200–300 mL or in volumes ranging from 2 to 5 mL/kg [4, 5], far less than the liters of non-medical gas entrained into the artificial abdomen with the gasketless cannula system in our study. Additionally, the rate of air entrainment matters—high rates of gas entry into the venous system increase the risk of air embolism [9].

Carbon dioxide as an inert, cost-effective, and rapidly absorbed gas has been the standard for insufflation for laparoscopy, but even with the use of CO<sub>2</sub>, venous embolism remains a known risk of laparoscopy [3, 6]. In the setting of blood loss, more suctioning is applied, and the risk of venous gas embolism rises accordingly when brisk venous bleeding is encountered [1, 9–12]. High flow suctioning rates used to expose and control such bleeding will create significant air entrainment and may result in subsequent mixed air and CO<sub>2</sub> embolism. In laparoscopic liver resection, the risk of venous gas emboli is higher than in open liver resection (*p* < 0.001) and is widely known to be high-risk procedure for potential gas embolism [9]. In one animal study of laparoscopic liver resection, 100% had CO<sub>2</sub> emboli detected by 2D transesophageal echocardiogram, with an average of 7–20 episodes per operation. Laparoscopic robot-assisted retroperitoneal prostatectomy has a 17% incidence of embolism, likely from aspiration of gas through the retroperitoneal venous plexus in steep Trendelenburg position [1]. In this study, we demonstrate that rapid suctioning/insufflation gas rates can result in substantial introduction of

room air into the abdomen with a gasketless cannula system [9]. Recently, these results were collaborated by a French study utilizing the gold standard of gas chromatography to examine the intraabdominal presence of room air with gasketless insufflation systems. The authors found significantly increased amount of intraabdominal oxygen in gasketless systems compared to standard laparoscopic insufflator systems in patients undergoing laparoscopic gynecologic and general surgical procedures [13]. In a clinical scenario where laparoscopic bleeding is being controlled with a suction device, such as when liver parenchyma is divided or venous plexus bleeding encountered in the pelvis, the risk of fatal gas embolism with the use of a gasketless cannula system becomes a potential reality.

Clinically, patients with venous gas embolism may experience dizziness, dyspnea, chest pain, and syncope and may demonstrate a mill-wheel murmur and decreased in end tidal CO<sub>2</sub> [7, 14]. Myocardial infarction, acute hypotension, pulmonary edema, cerebral hypoperfusion, and death are the common intraoperative manifestation of large venous gas emboli [7, 14]. Ultrasound, especially with transesophageal echocardiogram, is useful for prompt confirmation of the diagnosis [2, 7, 9, 11, 14]. If immediately recognized, the abdomen is desufflated, and the patient is positioned in Durant's position (Trendelenburg, left side up) [2, 7, 14]. A central line should be placed into the right atrium, and aspiration of the embolized gas from the right heart is attempted. In 30% of the general population with a patent foramen ovale, there is risk of paradoxical embolization to the brain [14, 15]. Administration of 100% oxygen and volume expansion is recommended, and hyperbaric oxygen therapy is an option for treatment of arterial gas embolism [2, 7, 14].

Even in the setting of routine surgery where hemorrhage is not encountered, micro gas emboli are commonly reported. Up to 68% of patients during laparoscopic cholecystectomy had asymptomatic bubbling of CO<sub>2</sub> detected in

their right ventricle on intraoperative echocardiogram [16]. While minor CO<sub>2</sub> emboli occur frequently in laparoscopic surgery, the clinical impact is generally trivial due to the rapidly absorbable nature of CO<sub>2</sub>. However, in oxygen or nitrogen emboli, even minor venous gas embolism could become clinically relevant. Because these gases are poorly absorbed from the circulatory system, room air embolism may result in circulatory collapse and death [14, 16].

In conclusion, gasketless cannula systems advertise the ability to maintain pneumoperitoneum despite rapid suctioning. Our study demonstrates this claim is true, but at the cost of rapid entrainment of room air into the abdomen. This technology has potential to introduce significant non-medical room air into the abdomen compared to standard systems and merits further study to determine the risk and incidence of clinically significant gas embolism. Patients could also be at risk of unintended consequences of pneumoperitoneum with oxygen and nitrogen, such as prolonged postoperative crepitus and pneumothorax.

The authors have submitted these experimental findings to the Food and Drug Administration to communicate the potential hazard of these devices. Current marketers of this technology have been approached directly with concerns for patient safety based on these findings. This experimental study confirms concerns raised by community surgeons, and the authors conclude gasketless cannula insufflation systems could theoretically increase the risk of non-absorbable air embolism. This technology should be approached with caution for any operations with potential for parenchymal or venous bleeding or anticipated use of laparoscopic suctioning. Surgeons and anesthesia providers should be aware of these potential risks prior to utilizing gasketless insufflator systems.

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### Compliance with ethical standards

**Disclosures** Dr. Ciara Huntington, Mr. Prince, Ms. Hazelbaker, Mr. Lopes, Mr. Webb, Dr LeMaster, and Dr. Thomas Huntington declare that there are no conflicts of interest or financial ties to disclose with any products or corporations relevant to this publication.

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