

RE: Recommendations Regarding Surgical Response to COVID-19 Crisis

March 30, 2020

Dear Customer,

We thank you and your staff for your service during these uncertain times. We appreciate all that you are doing to keep our community safe.

This letter is to provide clarification regarding laparoscopic procedures and the COVID-19 virus.

On March 19th SAGES sent an email with recommendations regarding surgical response to COVID-19 Crisis

"For procedures deemed urgent and necessary, it is strongly recommended that consideration be given to the possibility of viral contamination during laparoscopy. Such risk should be individually weighted against the benefit of laparoscopy for a patient's health and recovery. While it is unknown whether coronavirus shares these properties, it has been established that other viruses can be released during laparoscopy with carbon dioxide. Erring on the side of safety would warrant treating the coronavirus as exhibiting a similar property. For laparoscopic procedures, use of devices to filter released CO_2 for aerosolized particles should be strongly considered."

Intelligent Pneumo Management

LEXION Medical's AP 50/30 Insufflator is a constant-flow real-time intelligent pneumo delivery system that is unique. The AP 50/30 system continuously delivers 100% CO₂ to the abdomen at your set nominal pressure to constantly maintain pneumoperitoneum. This real-time pressure-sensing technology partners with the high performing PneuView® Smoke Eliminator to evacuate smoke effectively. Traditional insufflators use intermittent flow, limiting their ability to maintain pneumo and remove all smoke and aerosolized particles from the CO₂ sufficiently or effectively.

Removal of Viral Particles

PneuView® is an active smoke evacuator that removes 100% of combustion by-products and surgical smoke when paired with standard wall suction or a suction canister. PneuView® when partnered with the InsuflowPort® provides surgical confidence of pneumo-stability coupled with safe removal of all CO₂, hazardous smoke and aerosolized particles from the abdominal cavity. PneuView® provides greater than ULPA level filtration from the operating room at 0.01 microns.

Protection from Abdominal Air

InsuflowPort®, like other standard trocars, has multiple seals preventing CO₂ gas from escaping the abdomen into the operating room. These seals also maintain pressure when instruments or scopes are used. Valveless trocars, without seals, can intermittently leak potentially unfiltered CO₂, smoke, blood



and infectious aerosols into the operating room. This puts the healthcare providers potentially at dangerous risk.

De-Insufflation & Patient Safety

In addition to actively removing plume and combustion by-products, PneuView® is equipped with a patented safety relief valve which ensures patients never reach high vacuum levels within the abdominal cavity.

To effectively and safely de-insufflate the abdomen, shut the insufflation gas off and leave the PneuView® running until abdomen has returned to normal state. Once again, the patented safety relief valve will ensure the patient does not reach a dangerous vacuum level during the de-insufflation process.

Annals of Surgery on March 15th, also released new recommendations related to laparoscopic surgery, as follows:

"Prevention and management of aerosol dispersal: During operations, whether laparoscopic or via laparotomy, instruments should be kept clean of blood and other body fluids. Special attention should be paid to the establishment of pneumoperitoneum, hemostasis and cleaning at trocar sites or incisions to prevent any gush of body fluid caused by air leakage or uncontained laparotomy incisions. Liberal use of suction devices to remove smoke and aerosol during operations, and especially, before converting from laparoscopy to open surgery or any extra-peritoneal maneuver. Avoid using two-way pneumoperitoneum insufflators to prevent pathogens colonization of circulating aerosol in pneumoperitoneum circuit or the insufflator.

One Way Insufflation

The LEXION system - AP 50/30 Insufflator, InsuflowPort® and PneuView® is the only continuous flowing, one-way insufflation system available to remove all harmful smoke, aerosolized gas and contaminants, including viruses being introduced into the operating room. Using the LEXION system enables active smoke elimination protecting your OR staff during laparoscopic surgery.

While eliminating all risk is impossible, our goal is always to provide the best and safest solutions for laparoscopic surgery.

Thank you for your continued support.

LEXION Medical