

Insufflation Recommendations

CONMED Corporation

Dear Partners in Healthcare,

In this time of heightened concern, it is important that you have factual information to help guide you in the decisions you make regarding the insufflation of patients in minimally invasive surgical procedures. This communication is designed to give you general recommendations related to insufflation as well as specific recommendations when using the AirSeal® iFS in each of its operating modes (AirSeal® Mode, Smoke Evacuation Mode, and Standard Insufflation Mode).

Recommendations with Any Insufflation System

- Because gas can leak from trocars during the insertion, manipulation, and withdrawal of laparoscopic instruments, the use of a suction-assisted smoke evacuation device (such as CONMED's PlumePort® ActiV® Laparoscopic Smoke Filtration Device, Medtronic's Valleylab™ Laparoscopic Smoke Evacuation System, or Stryker's PureView™ Active Laparoscopic Plume Filtration Device) in addition to insufflation may reduce the risk of gas leakage through trocars.
- Ensure that trocar stopcocks or luer connectors are closed prior to insertion to prevent unnecessary gas leakage. Skin incisions should be as small as possible to minimize the potential for gas leakage around the trocar.
- Once all the trocars have been placed, reduce the pressure as low as possible without compromising surgical exposure or patient safety. Reduced pressure may reduce the potential for gas leaks around trocars.
- During Minimally Invasive Hysterectomy, care should be taken to reduce exposure to cavity gas after colpotomy. The use of some method of vaginal occlusion may reduce this risk. Similar precautions should be used in similar clinical situations where a large leak is created or expected.
- During desufflation, use a suction / irrigation system or a suction-assisted smoke evacuation device to remove the gas from the cavity. This should be done under direct endoscopic vision and/or with a blunt-tipped instrument placed in the trocar where evacuation is occurring to prevent tissue from being drawn into the trocar during cavity gas evacuation.
- If specimen removal is indicated, it may best be delayed until desufflation is complete. The use of a locking grasper to secure the specimen prior to desufflation may be helpful. Specimen retrieval bags may also limit the release of fluids during extraction.

Recommendations with the AirSeal® iFS

As you know, the AirSeal® iFS offers 3 different modes of insufflation including AirSeal® Mode, Smoke Evacuation Mode, and Standard Insufflation Mode. The first two modes (AirSeal Mode and Smoke Evacuation Mode) utilize a tube set that contains a 0.01 micron ULPA filter. While this filtration level is below the published diameters of most known bacteria and viruses, you should be aware that NO product from ANY company can eliminate the potential for cavity gas loss as instrument insertion, manipulation, and withdrawal through trocars and other situations where leaks arise.

Below are considerations for the use of both AirSeal® Mode and Smoke Evacuation Mode.

AirSeal Mode

AirSeal Mode requires the valve-less AirSeal Access Port which can vent cavity gas into the OR during normal operation, similar to the way standard trocars leak cavity gas during instrument insertion, manipulation, and withdrawal. Although the ASM-EVAC1 tube set contains a 0.01 µm ULPA filter, only the gas that returns to the iFS is filtered. If AirSeal Mode is indicated for patients, we recommend augmenting AirSeal Mode with a suction-assisted smoke evacuation system (such as CONMED's PlumePort® ActiV® Laparoscopic Smoke Filtration Device, Medtronic's Valleylab™ Laparoscopic Smoke Evacuation System, or Stryker's PureView™ Active Laparoscopic Plume Filtration Device). This should enhance cavity gas evacuation and activate AirSeal Mode's entrainment feature which will reduce the likelihood of cavity gas escaping through the AirSeal Access Port. If using a suction-assisted smoke evacuation system, we recommend setting Smoke Evacuation to LOW on the AirSeal System's graphical user interface to avoid competition between the systems. *Note: Secondary smoke evacuation is not recommended for pediatric patients.*

To prevent gas leakage during desufflation, place the AirSeal Access Port's Obturator back in the AirSeal Access Port Cannula OR plug the hole at the top of the Access Port or the Sound Cap with a gloved thumb, press STOP, and utilize either a suction / irrigation device to remove the remaining gas from the cavity or use the aforementioned suction-assisted smoke evacuation system taking care to avoid tissue from being drawn into the trocar that is evacuating cavity gas.

Smoke Evacuation Mode

Smoke Evacuation Mode works with standard trocars and provides a "closed loop" of insufflation with constant smoke

evacuation through a 0.01µm ULPA filter. While cavity gas still may escape standard trocars during instrument insertion, manipulation, and withdrawal, we believe that using such a "closed loop" insufflation system may provide a more effective solution than standard insufflation and venting cavity gas through a stopcock. Augmentation with suction-assisted smoke evacuation devices, such as those mentioned above, may further reduce risk though intraabdominal pressure may be reduced depending on the rate of suction.

Standard Insufflation Mode

See "**Recommendations with Any Insufflation System**"

We recognize that you need to make informed decisions and we hope that these recommendations will help you navigate the challenges of providing excellent clinical outcomes while protecting the safety of your surgical teams.

Stay Safe,

CONMED Corporation