

<b>To:</b>	Valued Customer
<b>From:</b>	Stryker Endoscopy
<b>Subject:</b>	PneumoClear and PneumoSure Filtration
<b>Date:</b>	March 25, 2020

Valued Customer:

On March 19<sup>th</sup>, SAGES released guidance entitled “**SAGES RECOMMENDATIONS REGARDING SURGICAL RESPONSE TO COVID-19 CRISIS**”<sup>1</sup> that recommended healthcare providers strongly consider the possibility of viral contamination during laparoscopic surgery. SAGES further recommended that healthcare providers use smoke evacuation devices to help filter released particles during essential laparoscopic procedures.

Stryker Endoscopy offers the **PneumoClear Plus CO2 Conditioning Insufflator** which is designed to filter aerosolized particles during laparoscopic surgery.

The **PneumoClear Plus CO2 Conditioning Insufflator** contains the following pertinent safety features:

- **PneumoClear Smoke Evacuation Tube Sets** are comprised of a series of filters: 1 absorbent layer, 1 ULPA filter, 1 PVDF filter, and 2 charcoal layers. These tube sets filter particles as small as .051 microns with up to 99.999993% efficiency for outflow.<sup>2</sup>
- **Desufflate function** – The Desufflation function allows for the remaining CO2 in the cavity to be removed to a pressure of approximately 3 mmHg after insufflation has been stopped. During Desufflation gas is removed by suction through the smoke evacuation line, which passes through the ULPA filter<sup>3</sup>
- **Overpressure Venting in PneumoSure and PneumoClear** – In case of overpressure, the insufflator will vent the excess pressure. In this process, gas flows through the inflow line and out through a venting valve inside the console. Before the gas enters the console, it passes through a HEPA filter that is located in the cassette of the disposable tube set for PneumoSure and PneumoClear Tube Sets (part numbers: 0620-040-660, 0620-040-680, 0620-040-690, 0620-050-100, 0620-050-200, 0620-050-250, 0620-050-300, and 0620-050-350). This HEPA filter is capable of filtering particles as small as 0.1 microns at an efficiency of at least 99.95%. The filtration efficiency for virus contaminated droplets and aerosols as small as 2.9 µm is at least >99.99998%.<sup>4</sup>

Controlling and closing leakages e.g. at port sides or leaky trocars is an important additional measure to reduce escaping and potentially contaminated particles from the cavity. Studies have suggested that the current best practice for mitigating an infection transmission during a laparoscopic procedure is to use a multi-layered approach, which includes proper ventilation, appropriate PPE and *smoke evacuation devices with a suction and filtration system* (among other things)<sup>5</sup>. However, please note that there is no proven method to entirely reduce such exposure.

Please contact your local representative if you have questions about with regards to the above-referenced laparoscopic devices.

<sup>1</sup> <https://www.sages.org/recommendations-surgical-response-covid-19/>

<sup>2</sup> Testing located in DHFD15109

<sup>3</sup> PneumoClear User Manual, P31693 Rev. H

<sup>4</sup> Testing located in DHFD15112

<sup>5</sup> R S Parsa, N J Dirig, I N Eck, W K Payne III. Surgical Smoke and the Orthopedic Implications. The Internet Journal of Orthopedic Surgery. 2015 Volume 24 Number 1.