

April 3, 2020

Dear Valued Customer,

Recently, SAGES in conjunction with EAES, came out with several surgical response recommendations to the COVID-19 pandemic.<sup>1</sup> One of the recommendations was that consideration be given to the possibility of viral contamination during open and laparoscopic surgery.

When surgery is performed and an energy device is used, that energy device can create surgical smoke regardless of whether the procedure is open or laparoscopic. Surgical smoke is made up of 95% water or steam and 5% cellular debris in the form of particulate material, which is composed of chemicals, blood and tissue particles, viruses and bacteria.<sup>2</sup> In a benchtop experiment, Schultz (2015)<sup>3</sup> determined that live bacteria can exist in surgical smoke produced with a blended electrosurgical current, but not with a CO<sub>2</sub> laser or with pure coagulation electrosurgery. The use of a smoke evacuation device may help to mitigate this risk.<sup>4</sup> Aerosolization of bacteria was effectively prevented using a commercially available smoke evacuation system.<sup>3</sup> In addition, to help minimize the production of smoke, electrosurgery units should be set to the lowest possible settings that still allow the surgeon to achieve the desired clinical results.<sup>5</sup>

In particular, there are concerns with laparoscopic surgery due to the carbon dioxide insufflation process. Because a virus can be aerosolized in CO<sub>2</sub>, the use of devices to filter particles should be strongly considered. Ethicon supports this position and recommends the use of a smoke evacuator, such as the MEGADYNE™ Mega Vac PLUS Smoke Evacuator, while performing laparoscopy.

Laparoscopic surgery involves insufflation of CO<sub>2</sub> gas into the peritoneal cavity producing a pneumoperitoneum. The carbon dioxide is typically insufflated into the peritoneal cavity at a rate of 4 LPM (liters per minute) to a pressure of 10-20mmHg. The pneumoperitoneum is maintained by a constant gas flow of 0.2-0.4 LPM.<sup>6</sup>

During insufflation and surgery, aerosol particles can be produced.<sup>7</sup> While the aerosols are primarily contained during laparoscopy, trocars and other minimally-invasive devices can leak CO<sub>2</sub>. With the release of pneumoperitoneum, surgical personnel may be at risk of exposure to aerosolized particles.<sup>3,7</sup> The MEGADYNE™ Smoke Evacuator can remove 4 to 18 LPM in laparoscopic mode which should cover CO<sub>2</sub> flow in laparoscopic cases and can aid with pneumoperitoneum release.<sup>11</sup>

During open surgery it is recommended that a suction device, such as the MEGADYNE™ ULTRA VAC™ Smoke Evacuation Pencil, be kept within 5cm of the surgical site for efficient removal of aerosolized particles.<sup>8</sup> The suction device should remain activated until the surgical smoke is cleared.


Currently there is no data that suggests that COVID-19 virus is released during laparoscopy, or open surgery. Given the potential risk with COVID-19, Ethicon supports the recommendation from SAGES to use a smoke evacuation system or other filter. The diligent use of a smoke evacuation system with a high efficiency filter has been identified as a feasible and potentially useful way for surgical smoke to be reduced. Smoke evacuation can capture the smoke generated at the surgical site and remove it to an area away from the surgical team. Coronavirus particles range from 60-140nm in diameter,<sup>9,10</sup> and their dispersal is generally in the form of much larger water droplets.<sup>10</sup> Smoke evacuators that use an ULPA filter, such as the MEGADYNE™ Smoke Evacuators, capture and filter 99.999954% of particulates and microorganisms greater than 0.1 micron.<sup>11</sup>

In order to ensure the safest environment for our patients, physicians, nurses and all hospital staff Ethicon supports SAGES's position and recommends that a smoke evacuator is used in laparoscopic and open cases, in addition to the strict use of appropriate personal protective equipment.

Please refer to the attached MEGADYNE™ Mega Vac and MINI VAC™ systems brochure or contact your local Ethicon representative with any further questions.

#### MEGADYNE™ Mega Vac PLUS Smoke Evacuator in lap

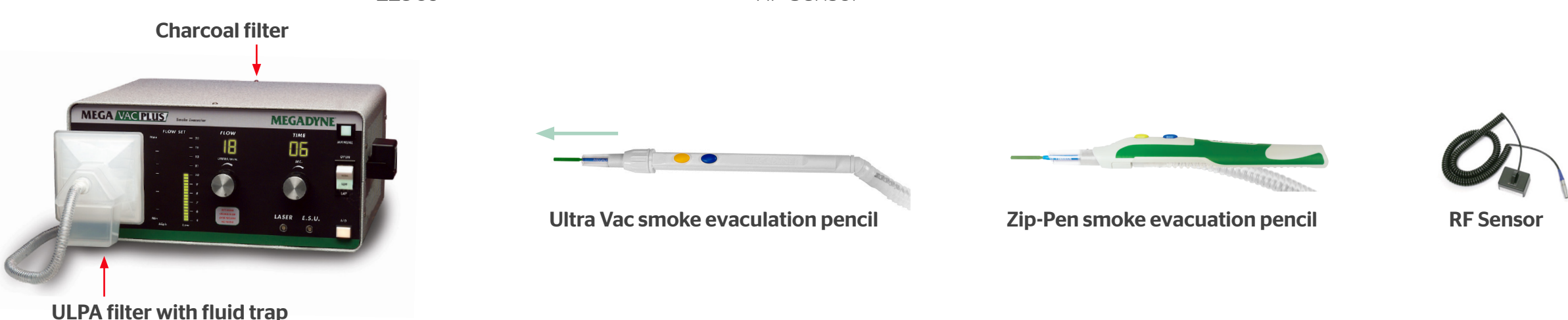
Category	Code	Name
Capital	2200J	MEGADYNE™ Mega Vac PLUS Smoke Evacuator
Disposable	2190J	Lap tubing
Accessories	2210J & 2211J	ULPA Filter, w/Fluid Trap
	2220J	Charcoal Filter
	2250J	RF Sensor



The image shows the MEGADYNE Mega Vac PLUS Smoke Evacuator unit with a charcoal filter on top and a ULPA filter with fluid trap on the front. To the right, there is a coil of blue lap tubing and an RF sensor cable.

#### MEGADYNE™ Mega Vac PLUS Smoke Evacuator in open

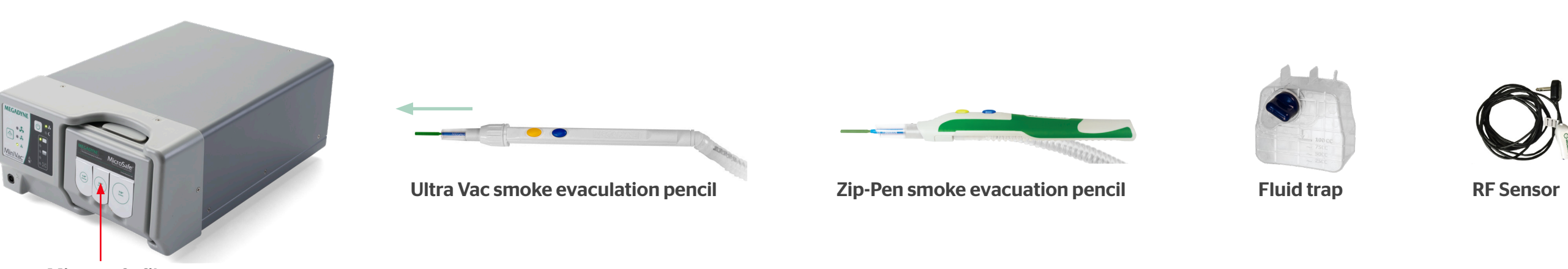
Category	Code	Name
Capital	2200J	MEGADYNE™ Mega Vac PLUS Smoke Evacuator
Disposable	211010J	MEGADYNE™ ULTRA VAC™ Smoke Evacuation Pencil, J connector
	252510	MEGADYNE™ ZIP-PEN™ Smoke Evacuation Pencil, C connector
Accessories	2210J & 2211J	ULPA Filter, w/Fluid Trap
	2220J	Charcoal Filter
	2250J	RF Sensor



The image shows the MEGADYNE Mega Vac PLUS Smoke Evacuator unit with a charcoal filter on top and a ULPA filter with fluid trap on the front. To the right, there are two smoke evacuation pencils: the Ultra Vac smoke evacuation pencil (J connector) and the Zip-Pen smoke evacuation pencil (C connector), along with an RF sensor cable.

#### MEGADYNE™ MINI VAC™ Smoke Evacuator in open

Category	Code	Name
Capital	ECVV220	MEGADYNE™ MINI VAC™ Smoke Evacuator, 220V
Disposable	211010EC	MEGADYNE™ ULTRA VAC™ Smoke Evacuation Pencil, EC connector
	252510EC	MEGADYNE™ ZIP-PEN™ Smoke Evacuation Pencil, EC connector
Accessories	MGVS353	MEGADYNE™ Micro Safe Filter
	MGVSFT10	MEGADYNE™ Fluid Trap
	MGEZLINK01	MEGADYNE™ RF Sensor



The image shows the MEGADYNE MINI VAC Smoke Evacuator unit with a micro safe filter on the front. To the right, there are two smoke evacuation pencils: the Ultra Vac smoke evacuation pencil (EC connector) and the Zip-Pen smoke evacuation pencil (EC connector), a fluid trap, and an RF sensor cable.

1. SAGES RECOMMENDATIONS REGARDING SURGICAL RESPONSE TO COVID-19 CRISIS [https://www.sages.org/recommendations-surgical-response-covid-19/]. Accessed 3/30/2020. 2. Romano F, Gustén J, De Antonellis S, Joppolo CM. Electrosurgical Smoke: Ultrafine Particle Measurements and Work Environment Quality in Different Operating Theatres. Int J Environ Res Public Health. 2017;14(2):137. doi:10.3390/ijerph14020137. 3. Schultz L. Can efficient smoke evacuation limit aerosolization of bacteria? AORN Journal. 2015;102(1):7-14. 4. Ball K. Compliance with surgical smoke evacuation guidelines: implications for practice. ORNAC J. 2012;30(4-6):18-9. 5. AST Standards of Practice for Use of Electrosurgery https://www.ast.org/uploadedFiles/Main\_Site/Content/About\_US/Standard%20Electrosurgery.pdf Accessed 4.4.2020. 6. Mandy Perrin, FRCA, Anthony Fletcher, FRCA. Laparoscopic abdominal surgery. Continuing Education in Anaesthesia Critical Care & Pain. Volume 4, Issue 4, August 2004, Pages 107-110. 7. Liu Y, Song Y, Hu X, et al. Awareness of surgical smoke hazards and enhancement of surgical smoke prevention among the gynecologists. J Cancer. 2019;10:2788-2799. 8. National Institute for Occupational Safety and Health. Control of smoke from laser/electric surgical procedures. Appl Occup Environ Hyg. 1999;14(2):71. 9. Zhu, Na, et al. A novel coronavirus from patients with pneumonia in China, 2019. New England Journal of Medicine (2020). 10. Kim, S.W., Ramakrishnan, M.A., Raynor, P.C., et al. Effects of humidity and other factors on the generation and sampling of a coronavirus aerosol. Aerobiologia 23, 239-248 (2007). 11. Ethicon, 470-9024 MEGA Vac Plus Users Manual, Rev G August, 2013.

SAGES page accessed March 30, 2020. Given the developing situation in relation to Covid-19, SAGES guidance may be subject to update and change. We recommend that healthcare professionals review and follow the latest version of SAGES guidance.

**Please refer to the instructions for use / Package insert that come with the device for the most current and complete instructions**

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