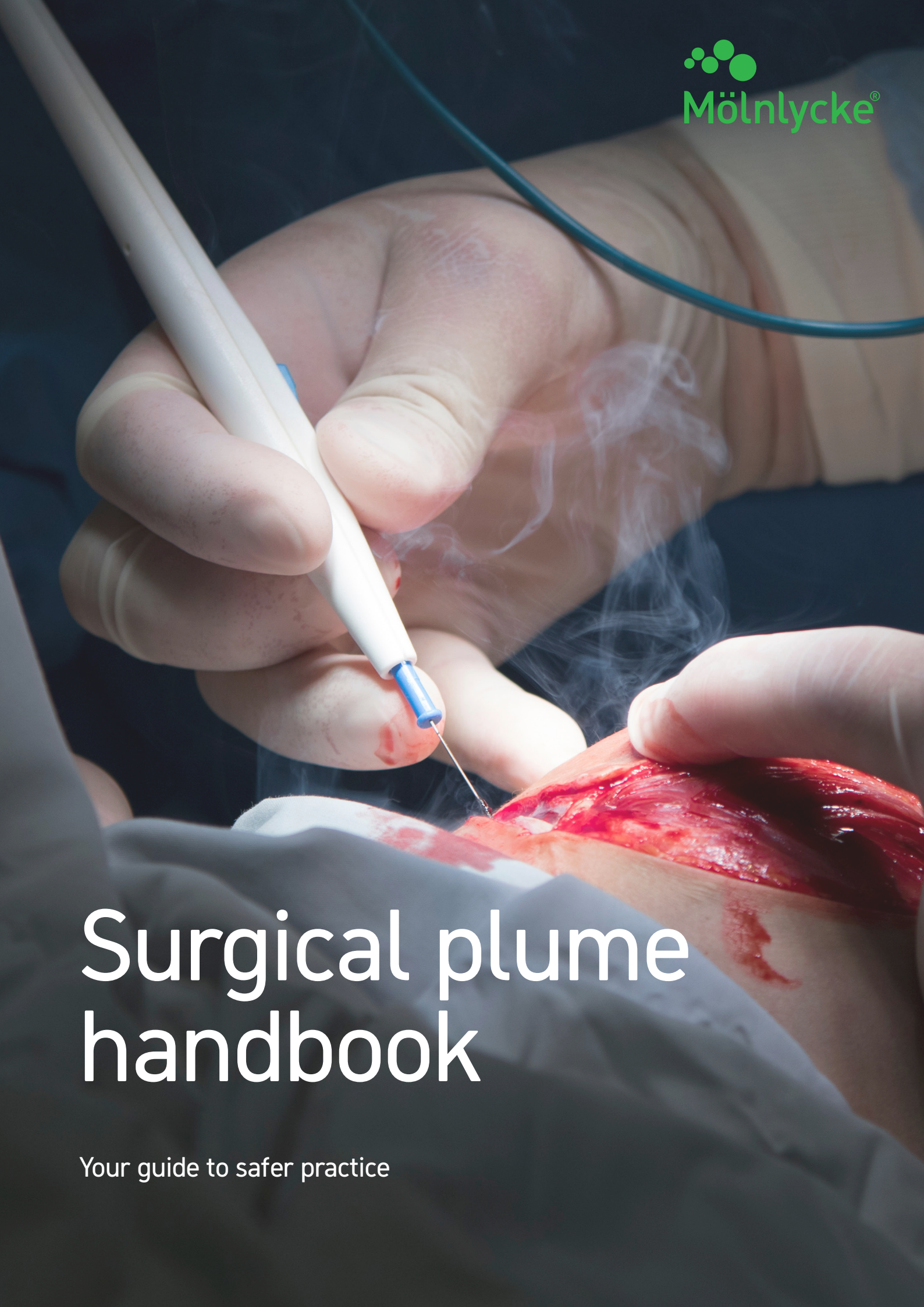

Mölnlycke®

Surgical plume handbook

Your guide to safer practice

About the author

Steve Veck
M.B.S.C.C.P, M.Acad.M.Ed, M.Inst.L.M, PG Dip Clin Ed
Electro Surgery Consultant/Clinical Educator is an Independent working alongside Hospitals, Universities and various other Academic and Medical Institutes. He is a Member of The Academy of Medical Educators, also a member of N.A.M.D.E.T (National Association of Medical Device Trainers & Educators).

With over 30 years knowledge and experience in Electrosurgery and related modalities. 'Electrosurgery is said to be the most common thermal device for surgical intervention, to provide cutting and coagulation of tissue'. Not surprisingly, electrosurgery figures in the top 10 medical devices for patient injury claims. Most of these injuries, could have been avoided, had the users been aappropriately educated and trained. The training/lectures he provides, will offer the necessary understanding of electrosurgery. This will ensure that a safer working environment is established, therefore reducing injury.

Professional affiliations

- Royal College of Obstetricians & Gynaecologists - Member/Accredited Lecturer
- Member of Academy of Medical Educators
- Member of OrcID https://orcid.org/0000-0002-5406-3862
- Member of I.C.S.P (International Council for Surgical Plume) UK Council Member
- Member of NAMDET (National Association of Medical Device Educator and Trainers)
- Member Ulster Society of Obstetricians & Gynaecologists (Hon Member)
- Committee Member British Standards Institute (ISO)

Publications

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Foreword

This book has been written to provide an understanding of Surgical Plume. Several words are used to describe this potentially noxious substance. In order to be as accurate as possible, we use the phrase ‘surgical plume’ as this describes the vaporous escape during surgery. The words Smoke, Plume and even Aerosol have been used to discuss the subject. To a certain extent the words are semantics and as such both Smoke and Plume are reasonable terms to use. However, smoke generally can be visualized, whereas plume which contains almost invisible particulate matter, is less visible. For this article which seeks to provide information on the subject, we will refer to it as ‘surgical plume’.

There appears to have been a rapid rise in interest concerning surgical plume. This may be due to SARS COV-2 virus and how its precipitation has drawn people to understand how such vaporous plume behaves.

In addition, there has been an exponential increase in the number of publications regarding the subject of surgical plume.

No doubt this increased knowledge, has given an improved awareness and desire, to establish safer practices in the workplace.

We hope this book will provide you with an informed explanation concerning surgical plume, as well as how surgical plume can be safely evacuated, to maintain a safe environment.

Index

01

Introduction

From historic times, we have been using heat to provide a means to achieve haemostasis and of course to brandish lesions. The old adage 'There is no smoke without fire' is most certainly true. Oddly, that is how things have remained for many years.

In the last few decades, there has been a quantum leap in the use of thermal energy devices, including Laser, Electrosurgery (Diathermy), Ultrasonics, Cautery and several more besides.

Within Electrosurgery, there have been numerous technical developments, seeing many of todays generators providing automatic functions, ensuring a much safer approach to surgery. The modes available within an Electrosurgical Unit (ESU) have also advanced, with huge developments in the Bipolar Mode, with advanced tissue sensing modes, to ensure high quality haemostasis. Bipolar and Microwave technology appears to be the next up and coming technology, utilizing lower power than traditional ESU's.

It is fair to suggest then, that thermo-energy devices are used much more frequently than in the past. As a direct result of this, vaporous plume is produced, which has resulted in further complications. This has given rise to serious concerns, where healthcare staff are exposed to plume on an almost daily basis.

This handbook will explore a wider understanding of the risks associated with surgical plume.

02

What is surgical plume?

Surgical plume is the vaporous plume resulting from surgical intervention with tissue. This noxious and odorous by-product contains both organic and inorganic matter. Plume can also obscure visualisation of the tissue, which could conceivably give rise to some risk to patient safety.

The plume falls into two categories, those being chemical and bacteriological, of which both have their own health risks.

Chemical matter is more likely to be smaller particles, whereas Biological matter of larger size particles, however both are potential hazards to health.

Surgical plume can contain carbons, hydrocarbons, viral particles, additionally toxic gases, cellular debris, blood borne products, carcinogens and numerous noxious substances, like Benzene, Toluene and Formaldehyde.

03

How is surgical plume produced?

Essentially, any medical device, used in surgery for example Laser, Electrosurgery (Diathermy), Electrocautery, Ultrasonic Systems, Surgical Aspirators and even Surgical Drills/Burrs can produce a surgical plume.

The human body is made up of a high percentage of water, eg brain and heart around 73%, whilst the lungs are around 83% water.

When a medical device is used, it disrupts the tissue and therefore the water contained within the cell structures. This results in a vaporous plume, sometimes referred to as 'smoke'.

In principle, medical devices generate varying degrees of heat, some more than others. If we take for example electrosurgery, as this is the most frequently used energy source, when the blade/spatula electrode is applied to the tissue, during a cutting modality, small high frequency sparks are generated. The sparks strike the cells, causing intra and extracellular pressure.

The cells are effectively, super-heated and this results in cellular disruption, as the cells are no longer able to retain their structure. The liquid from the cells, produces the vaporous plume and contained within this, is the undesirable elements described earlier, the chemical and bacteriological matter.

Brain and heart around

73%

water

Lungs around

83%

water

04

What is contained within surgical plume

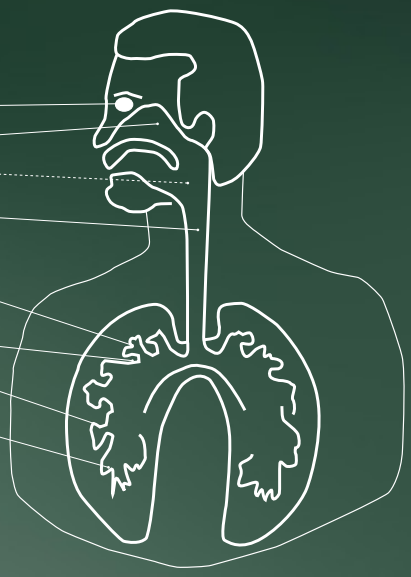
As previously stated, surgical plume contains both chemical and bacteriological matter. It can contain Carbon, Cellular Debris, Blood Products, Faecal Matter, Bacteria, Viral and Viable DNA, as well as HPV (Human Papilloma Virus) and HIV and Hep B, amongst many others.

More than 41 gases are present in plume, including some of the carbon and hydrocarbons, Benzene, Toluene, Cyanide as well as gaseous substances such as Carbon Monoxide and the highly toxic Formaldehyde.

Benzene is a known carcinogen and can even diffuse across the placenta during pregnancy, giving rise to a fetotoxic placenta. Toluene is a neurotoxin which may cause developmental and functional deficits.

Therefore, you can begin to appreciate that this is not just a bit of smoke.
It does indeed have mutagenic potential, with several examples of this mutagenic process occurring, especially amongst surgeons.

Particle size	Fate
9–30µm	visual pollution
5.5–9µm	settle in nose/throat
3.3–5.5µm	lodge in main breathing passages
2–3.3µm	lodge in small breathing passages
1–2µm	lodge in bronchi
0.3–1µm	penetrate to bronchioles and alveoli
0.1–0.3µm	penetrate to bronchioles and alveoli



05

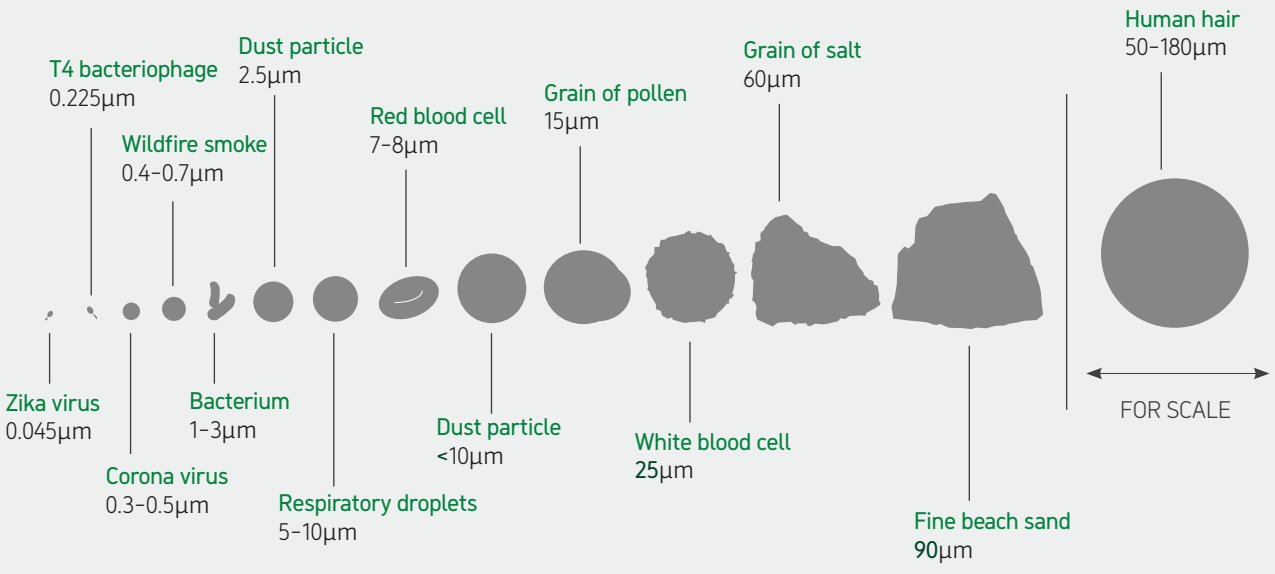
What size are the particles?

Having established the nature and hazard of the particulate matter, it may be interesting to view the sizes and put this into perspective.

The size range of particulate matter is huge, particles of around 10µm to around 40µm becoming visible to the human eye. This leaves a wide range of much smaller micro particulate matter, that is unseen.

With the Sars-Cov 2 Corona Virus plunging the earth into a global pandemic, there has been a much greater focus on the safety of those in the surgical workplace. Could viable Cov-2 particulate be vaporised within surgical plume? The answer is most probably yes, however there does not appear to be any specific research in this area at this time.

The very fact that Cov-2 is secreted out in surgical plume must leave questions and would suggest appropriate action be taken to protect healthcare professionals. Given the size range of 0.05-0.14 microns, it is conceivable therefore that the virus can penetrate the deepest parts of the respiratory system.



06

HEPA vs ULPA

Some manufactures suggest in their Instructions for Use (IFU) that the use of a Pre-Filter (HEPA) is recommended. The assumption perhaps, is that a lower cost Pre-Filter, will act as a buffer for certain size particulate matter. It will help to prevent particles, small amounts of liquid and tissue from reaching the often more costly ULPA Filter housed within the Plume Evacuator System.

What is meant by HEPA/ULPA?

HEPA
(High Efficiency Particulate Air)

Must trap up to 99.995%* of particulates 0.3 microns and larger.

ULPA
(Ultra Low Penetration Air)

Must trap 99.999%** of particulates 0.12 microns.

So how do filters both HEPA and ULPA work to remove particulate matter?

They both have different filtering properties, with regards to particle size, but are also complementary to each other.

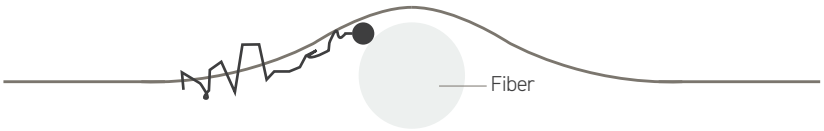
* According to ISO Class 5 HEPA Filter
** According to ISO Class 3 ULPA Filter

07

How do filters work?

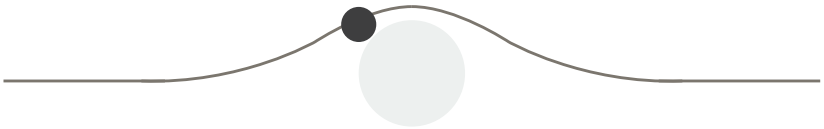
Diffusion

Collide with the filter fibres in the Brownian Motion.
(Describes the random movement of particles through a medium).



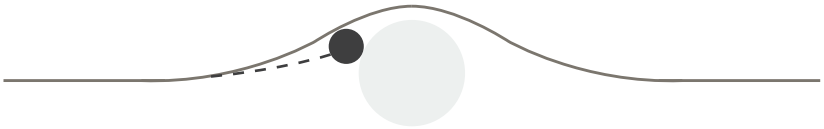
Interception

This occurs when the particle is close enough to adhere to the filter fibres.



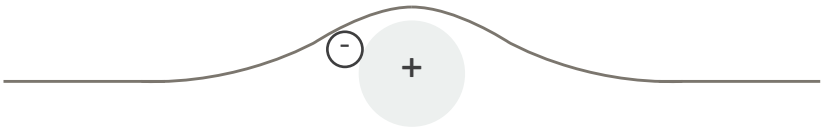
Inertial impaction

Due to heavy particles that can no longer remain in the airstream.



Electrostatic attraction

Positively charged fibres attract negatively charged particulate matter.



08

How are healthcare professionals exposed? What is the risk?

Healthcare professionals may be unwittingly exposed to the equivalent of 20-30 cigarettes per day

Earlier, we mentioned that when thermal energy devices are used, cellular disruption occurs. As a result, this produces a vaporous plume, which rises into the surrounding area and spreads throughout the entire room.

The staff are exposed to significant risk levels, which have been likened to cigarette smoking.

Some suggest only 1 gram of surgical plume is equivalent in toxicity terms to smoking between 3 to 6 cigarettes[1]. Therefore, it would be reasonable to suggest that several grams or more of surgical plume are produced during the average surgical procedure.

Based on the assumption during the average working day of 5 operative procedures involving thermal energy, healthcare professionals may be unwittingly exposed to the equivalent of smoking 20-30 cigarettes per day.

Of course, the choice to smoke cigarettes is a life-style choice, whereas healthcare professionals would not necessarily choose to be exposed in this manner.

09

What are the common symptoms to plume exposure?

Collective thinking, as well as numerous scientific publications, suggest that measures should be taken to avoid such exposure. Some of those studies are being referenced on page 25 of this booklet.

Many countries have now adopted a mandatory policy on surgical plume, including Denmark, Sweden, Norway and indeed several states in the USA and New South Wales in Australia recently confirmed a zero tolerance.

The procedure will dictate the levels of plume, as will the medical device being used. Also of consideration would be, the duration of use and clearly the tissue being disrupted.

Generally, healthcare professionals will be exposed daily to surgical plume, some will even be able to tell you what procedure is being performed, just by the odour pervading into the theatre corridors.

Common symptoms include:

- Airway inflammation
- Hypoxia /Dizziness
- Coughing
- Headaches
- Tearing
- Nausea/Vomiting
- HEPAtitis
- Asthma
- Pulmonary Congestion
- Chronic Bronchitis
- Carcinoma
- Emphysema
- HIV/AIDS

10

What are considered safe working levels?

Environmental Agencies will have similar guidelines of what is considered safe working levels. They suggest a baseline of 60,000 particles per $1m^3$. However surgical plume can release 1,000,000 particles per $1m^3$ without adequate plume evacuation[1,2,3,4,5].

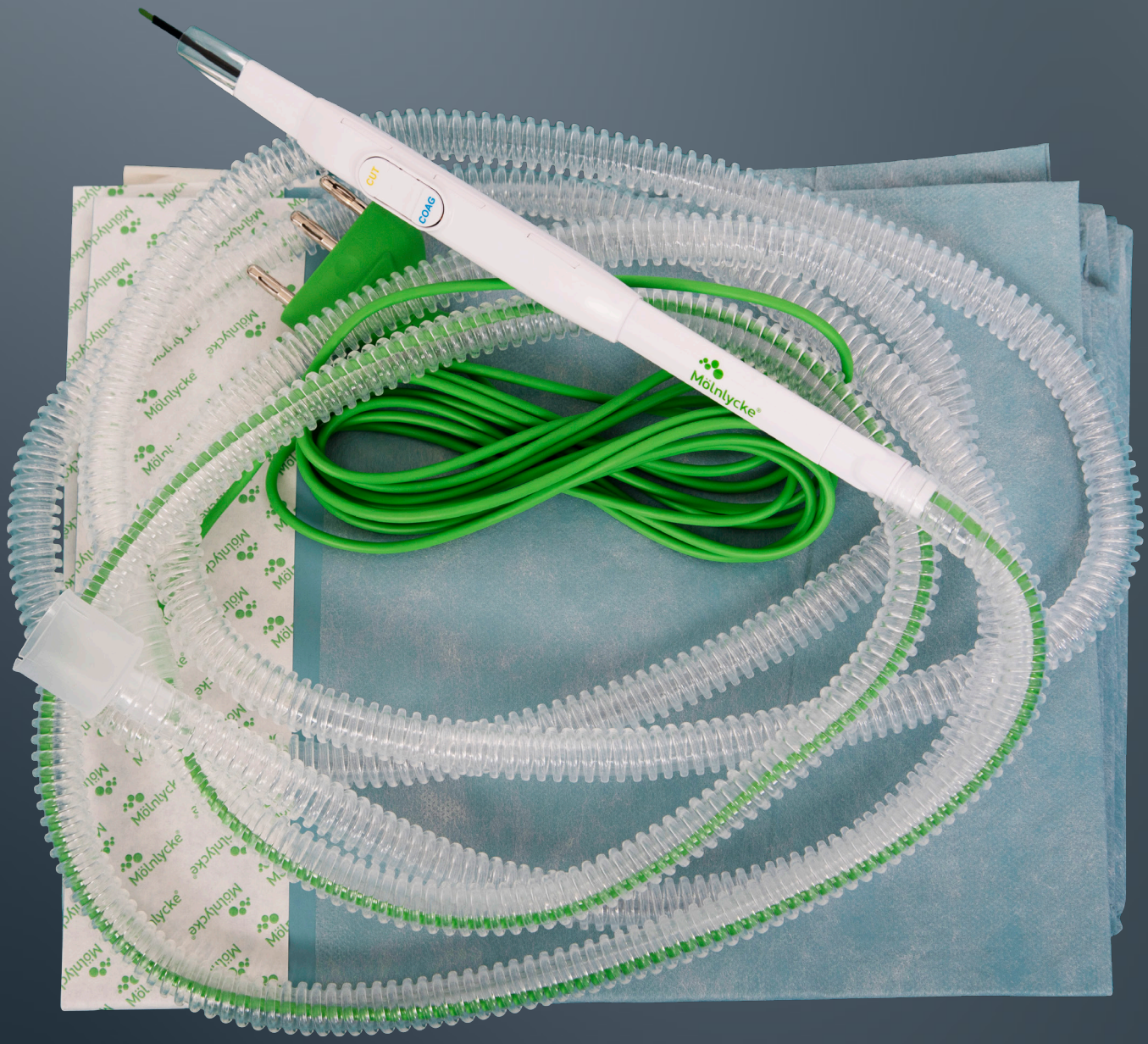
Indeed, a level of 1,000,000 particles per $1m^3$ during a Laparoscopic Cholecystectomy has been muted. This suggests that levels are exceeding Environmental Safety Standards, on a daily basis.

There are many assumptions in regard to removal of smoke plume in the workplace, with comments such as, 'We use Laminar Flow' or 'We have a Central Plume Evacuation System'.

Some evidence suggests that when Laminar Flow is in operation the plume has a tendency to be pushed in the downward direction, however in practical terms, when several healthcare professionals surround the operating table, the plume tends to be trapped and therefore exposes those individuals[3].

With PES (Pipeline Evacuation System) whilst it will undoubtably reduce the overall levels of surgical plume, the point of collection is not close enough to the source, to ensure total protection.

Ideally, the plume should be collected from the source, eg the tip of the pencil, blade, spatula etc.


CUT
COAG
Mölnlycke®

11

Do surgical masks provide adequate and safe protection?

This booklet does not seek to assess the appropriate values of wearing or not wearing a surgical mask, this is for national organisations/ associations and indeed local policy to dictate.

However, the question of whether wearing a surgical mask is affording protection from surgical plume, is certainly worthy of some consideration. Surgical masks comes in different qualities and materials and even if the material is with a good particular filtration the safety challenge is due to the design of the surgical masks.

When you think about the particulate matter contained within surgical plume, which can be as small as 0.01 microns, or perhaps of more serious concern the SARS/COV-2 virus at 0.1–0.5 microns it shows very clearly that wearing a standard style surgical mask, affords little if any protection from surgical plume. Indeed, only a full FFP3 mask would provide adequate protection from respiratory borne pathogens.

Most healthcare professionals will agree, that wearing a full FFP3 mask is most uncomfortable. Even with this mask in place, the eyes and lachrimal ducts are fully exposed and present possible absorption risks from surgical plume unless goggles and or face shields are also worn.

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Is laparoscopy a lower level of risk with regards to surgical plume?

Laparoscopy offered a whole new approach to surgery, affording minimal access, therefore minimal scarring and with that no necessity to divide muscles or produce a sizeable incision.

It may initially look as though surgical plume exposure is greatly reduced and to a certain extent, that is the case. Again, some evidence exists to show that cannulas used for abdominal access, can leak and frequently expel surgical plume during introduction/ removal of surgical instruments eg Hook Electrodes, Laparoscopes etc. There is also the issue of abdominal gases being vented to the atmosphere at the end of the procedure.

A laparoscopic cholecystectomy has been shown to produce 1,000,000 particles per 1 cubic metre, far in excess of environmental guidelines.

Quite apart from producing visualisation problems for the surgeon, there are increased risks associated with the production of Methemoglobin and Carboxyhaemoglobin levels rising during the procedure, which results in reduced oxygen levels to the tissue. This may go on to produce complications such as dehydration and hypothermia. It can also affect pulse oximetry for up to 6 hours, post op.

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Why has there not been more widespread adoption of surgical plume evacuation devices to date?

Perhaps, in part, the answer to this question is a previous lack of awareness of the dangers present in surgical plume.

Also many of these exposure elements may not present until later in life, perhaps beyond the ability to collate data from individuals. Any suggestions therefore of morbidity or mortality due to surgical plume exposure remain subjective.

It is once again interesting that SARS/COV-2 has raised several questions and concern about the risk of exposure. Given that Covid virus, is small, it is amongst many other small particles that have existed in surgical plume, prior to the Covid Pandemic.

In addition there have been some limitations in the solutions previously offered. Surgeons have complained that of solutions being 'too noisy' causing un-neccessary distractions or that the 'hand switch plume pencils are far too bulky and cumbersome'.

Finally, a new solution, that addresses these concerns, is in your hands.

14

The solution is now in your hands

Mölnlycke® Plume Evacuation Pencil

With an integrated telescopic function providing an immediate, on demand, solution for both deep and shallow incisions

Surgical staff are at risk every time surgical plume is created in the operating room. The solution is in your hands with the new, unique Mölnlycke® Plume Evacuation Pencil, a superior solution that ensures minimised plume exposure and clear visualisation of the operative site. Putting the safety of you and your patients first.

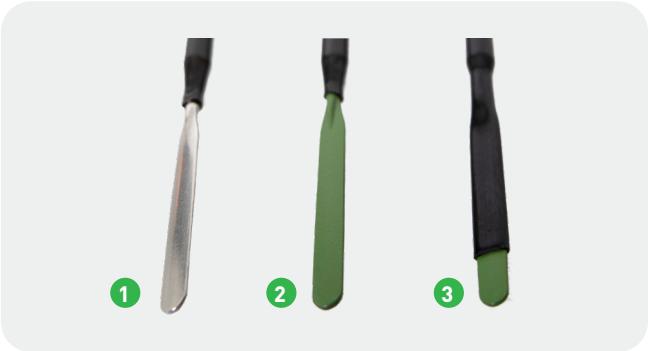
- A unique all in one light-weight, slim design with an integrated telescopic function providing an immediate, on demand, solution for both deep and shallow incisions.
- Mölnlycke Plume Evacuation Pencil offers a sustainable solution, DEPH and PVC free.
- Very high suction capacity (95 l/min) minimising plume exposure and providing rapid visualisation of the operative site.
- Available both in your customised surgical trays as well as single packed.

Technical data

Choice of electrodes:
Stainless steel ❶ for quick, simple cases.

Coated PTFE ❷ for reduced interruption of surgery due to eschar build up.

Insulated PTFE ❸ for reduced risk of inadvertent tissue damage when operating in tight spaces.



360° swivel handle enables freedom of movement reducing the risk of wrist fatigue

Universal 22mm connector to fit all plume evacuation machines

Narrow diameter ensures precise control and greater visualisation, especially in restricted spaces

Convinient 4 metre cable

Ordering information (for single packed)

Ref. No.	Product name and description
420100-00	Plume Evacuation Pencil, PTFE electrode
420101-00	Plume Evacuation Pencil, PTFE Insulated electrode
420102-00	Plume Evacuation Pencil, SS electrode

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Who are the key stakeholders?

The Control of Substances Hazardous to Health Regulations (COSHH, NIOSH, OSHA) require employers to carry out an assessment of the risks from hazardous substances and to always try to prevent exposure at source. If exposure to diathermy emissions can't be prevented, then it should be adequately controlled.

This is usually achieved by effective local exhaust ventilation (LEV). Typically, this takes the form of extraction incorporated into the electrosurgery system to remove emissions at source, known as 'on-tip' extraction.

To a certain extent, we are all stakeholders, as we all have concerns for our health, as well as that of the patient. The current standard ISO16571:2014 Systems for Evacuating Plume Generated by Medical Devices. (2019-Under Revision) is a robust document though it currently does not have any mandatory indicators!

It is through your own understanding and the support of your professional associations/ memberships that perhaps we should be asking the question;

'when will we be free of the risks of surgical plume?'

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Conclusion

Surgical plume is a complex subject matter, which is not possible to complete in a relatively small handbook. There is no doubt, with the growing number of publications, that surgical plume is harmful. It is also interesting to note that people have an increased awareness in this subject, perhaps as a direct result of Covid Virus discussion.

This leaves you, the reader with, hopefully an informative overview concerning surgical plume and perhaps an enquiring mind to learn more.

Ultimately, the objective should be to eliminate surgical plume in the workplace and to respect the healthcare professionals' own health.

For further product related support, please contact your local Mölnlycke® representative.

17

References

Key published articles

https://www.hse.gov.uk/research/rrhtm/rr922.htm
RR922 - Evidence for exposure and harmful effects of diathermy plumes (surgical smoke) - Evidence based literature review
The methods used to dissect tissue and stem blood flow during surgery have changed as technology has developed. Lasers and electro-surgery have become commonplace, so that medical staff in the operating theatre are (potentially) increasingly exposed to the thermal decomposition products of tissues. Variations in ventilation systems and the presence or absence of local exhaust ventilation are likely to influence the extent to which this occurs. A systematic review was carried out to identify existing evidence about surgical smoke (known as diathermy plume) and the potential harm to health care workers exposed in operating theatres. Limited published data were identified, but indicated that dedicated smoke evacuation/extraction devices are effective at reducing the levels of surgical smoke during various surgical procedures, and that correct (close) positioning of smoke evacuation devices to source emissions is likely to be important to the efficiency of surgical smoke removal. The data were insufficient to allow conclusions to be drawn on reported respiratory ill health symptoms linked with surgical smoke exposure.

https://www.mercyhospital.org.nz/assets/Policies/ElectrosurgcialSmokeEvacuation.pdf
Surgical smoke generated during surgical cases is potentially hazardous and must be captured and filtered through the use of smoke evacuators or in-line filters positioned on suction lines. Surgical smoke (plume) can contain toxic gases and vapours such as benzene, hydrogen cyanide, and formaldehyde along with bio aerosols, dead and live cellular material (including blood fragments), and viruses. At high concentrations, surgical smoke can cause ocular and upper respiratory tract irritation in healthcare workers and can create obstructive visual problems for the surgeon. Surgical smoke has unpleasant odours and has been shown to have mutagenic potential.

www.clinicalservicesjournal.com
Surgical Staff Safety: Going Up in smoke. July 2020
A reader survey has shown that over two-thirds of respondents working in operating theatres are concerned about the effects of surgical smoke on their health, yet only 21% said that their theatres 'always' used smoke evacuation devices when performing electrosurgery or laser treatments. Should their use now become mandatory? Louise Frampton reports.

Journal of Cancer 2019; 10(12):2788-2799
Awareness of surgical smoke hazards and enhancement of surgical smoke prevention among the gynecologists
Yi Liu, Yizuo Song, Xiaoli Hu, Linzhi Yan, and Xueqiong Zhuμ
Author information Article notes Copyright and License information Disclaimer
Abstract
Surgical smoke is the gaseous by-product produced by heat generating devices in various surgical operations including laser conization and loop electrosurgical procedures that often are performed by gynecologists. Surgical smoke contains chemicals, blood and tissue particles, bacteria, and viruses, which has been shown to exhibit potential risks for surgeons, nurses, anesthesiologists, and technicians in the operation room due to long term exposure of smoke. In this review, we describe the detailed information of the components of surgical smoke. Moreover, we highlight the effects of surgical smoke on carcinogenesis, mutagenesis, and infection in gynecologists.
Furthermore, we discussed how to prevent the surgical smoke via using high-filtration masks and smoke evacuation systems as well as legal guidelines for protection measures among the gynecologists.
Keywords: Cervical cancer, Cervical intraepithelial neoplasia, Electrosurgery, Smoke, Gynecologist.

References

Key published articles

Journal of Aerosol Science. 142 (2020) 105512

Morphological Characterization of Particles Emitted from Monopolar Electro Surgical Pencils.

Monopolar electrosurgical pencils are used extensively in surgical operations. With such pencils, electric current passes to the tissue, and as such, electrosurgical pencil operation generates a significant amount of thermal energy, which in turn leads to the generation of electrosurgical smoke (ES). The health risks of ES are dependent on the size distributions as well as the morphologies of the produced particles. To better characterize such particles, in this study we utilized (1) differential mobility analysis with a condensation particle counter (DMA-CPC), (2) an aerodynamic particle spectrometer (APS), (3) DMA-transmission electron microscopy analysis (DMA-TEM), and (4) DMA-aerosol particle mass analysis (DMA-APM) to examine the size distribution and morphologies of particles produced during simulated operation of an electrosurgical pencil (Neptune E-SEP, Stryker Corporation) on bovine, porcine, and ovine tissue. We find that under a variety of operating conditions, ES particles are broadly distributed, with a mode mobility diameter in the 150–200 nm size range, and concentrations well above background levels in the 50nm–5μm size range. We also find that the 'cut' mode of monopolar electrosurgical pencil operation generates higher particle concentrations than the 'coagulate' mode, and that increasing the maximum applied power from 20W to 50W also increases ES particle concentrations. TEM images of mobility selected particles reveal both spherical particles and fractal-like agglomerates in ES; these different particle types are produced under the same operation conditions leading to an externally-mixed, morphologically-complex aerosol. Quantitative analysis of the agglomerate images revealed that agglomerates have an average fractal dimension near 1.93 and that they are structurally similar to agglomerates expected from a diffusion limited cluster aggregation growth mechanism. Despite the presence of both spheres and agglomerates, DMA-APM analysis reveals that all particles have effective densities in the 1000–2000kg m^{-3} range, suggesting that they likely contain inorganic components. Finally, we determined that the collection efficiency of the ES capture suction unit attached to the electrosurgical pencil was >95% for particles in the 50–400nm mobility diameter range.

British Journal of Surgery. BJS May 2020;107:1406-1413

Safe management of surgical smoke in the age of COVID-19

Background: The COVID-19 global pandemic has resulted in a plethora of guidance and opinion from surgical societies. A controversial area concerns the safety of surgically created smoke and the perceived potential higher risk in laparoscopic surgery. Methods: The limited published evidence was analysed in combination with expert opinion. A review was undertaken of the novel coronavirus with regards to its hazards within surgical smoke and the procedures that could mitigate the potential risks to healthcare staff. Results: Using existing knowledge of surgical smoke, a theoretical risk of virus transmission exists. Best practice should consider the operating room set-up, patient movement and operating theatre equipment when producing a COVID-19 operating protocol. The choice of energy device can affect the smoke produced, and surgeons should manage the pneumoperitoneum meticulously during laparoscopic surgery.
Devices to remove surgical smoke, including extractors, filters and non-filter devices, are discussed in detail. Conclusion: There is not enough evidence to quantify the risks of COVID-19 transmission in surgical smoke. However, steps can be undertaken to manage the potential hazards. The advantages of minimally invasive surgery may not need to be sacrificed in the current crisis.

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