TEMED Gas Diffuser

The TEMED Gas Diffuser "is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage."

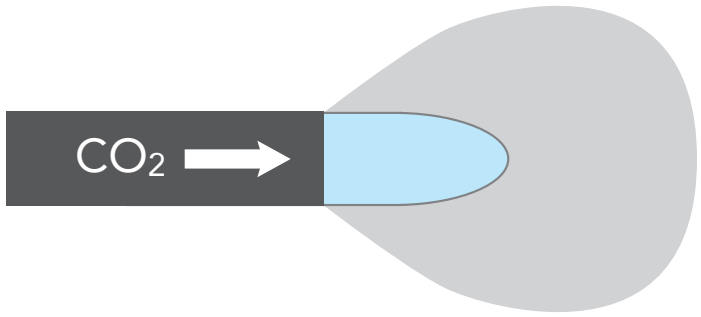
0.2 µm
Microbial
Gas Filter

Clear,
Malleable
Tubing

Hydrophobic,
Diffusing Tip

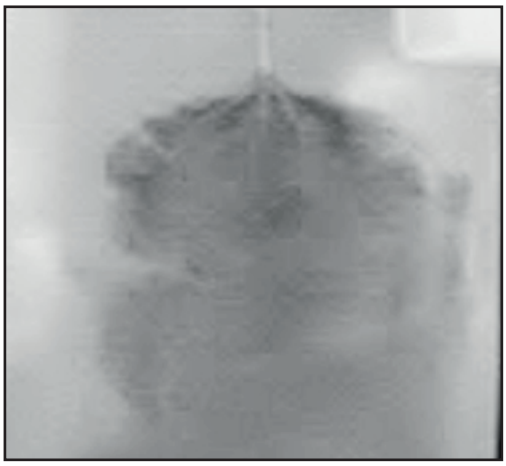
1/4" Gas
Line Tubing

Principle of Operation

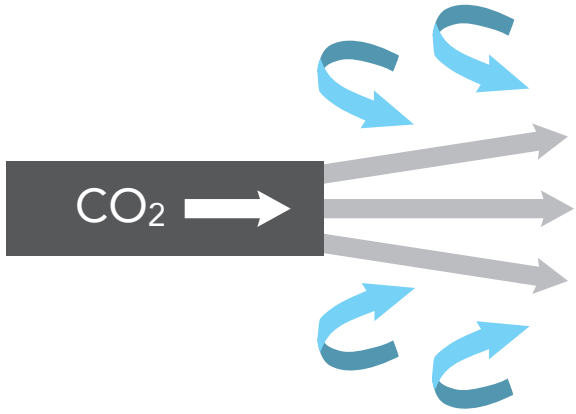


TEMED Gas Diffuser

Smooth, hydrophobic, atraumatic tip allowing precise placement in the surgical field creating a consistent CO_2 atmosphere, a stable barrier against air embolism and bacteriological contamination.

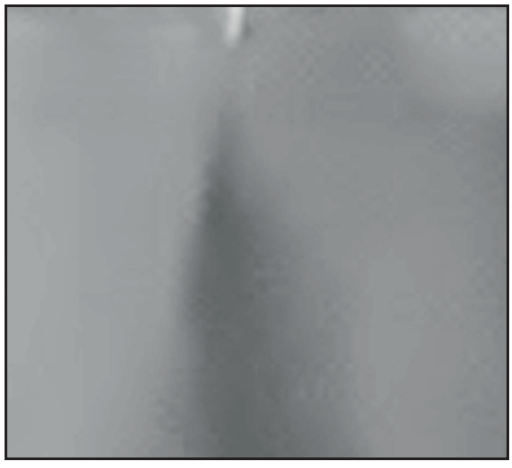


The **TEMED** Gas Diffuser is a single patient use disposable surgical device for effective insufflation of carbon dioxide (CO_2) into an open surgical wound. It aims to reduce the risk of air embolism by increasing the level of CO_2 in the local atmosphere. Air will enter the heart and great vessels during conventional open-heart surgery and can be difficult to evacuate with current de-airing techniques. Trapped air will be mobilized to the brain and other organs. Since CO_2 is 25 times more soluble than air in blood and tissue arterial CO_2 emboli will be fewer and also dissolve more quickly; decreasing the risk of organ injury if CO_2 is delivered to the surgical field. The density of CO_2 is 50% higher than air so it will naturally sink to the lowest point. Delivering CO_2 to the surgical field makes it possible to create, and maintain, an atmosphere of 100% CO_2 within the chest cavity.



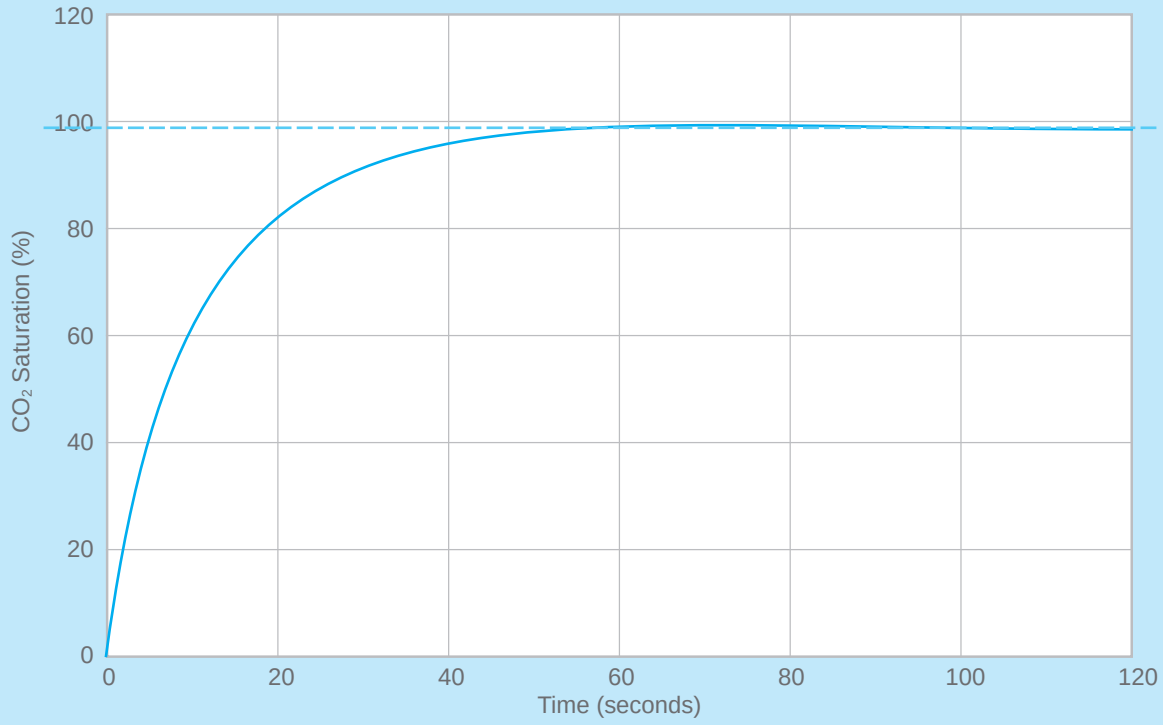
Standard open tube

Uncontrolled jet of gas with the risk of turbulence, no stable barrier. *"When an open ended tube is used as a disperser of CO_2, the gas is introduced as a jet".*
- Selman et al. 1966

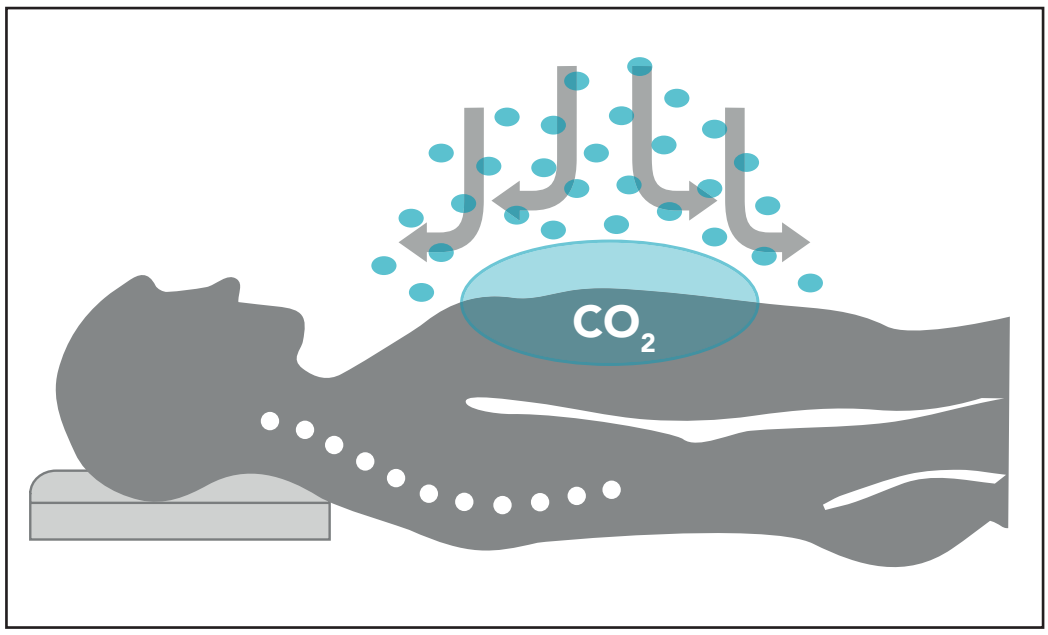


Why use the TEMED Gas Diffuser

The Time Taken for a Model Chest Cavity to Reach a level of 100% CO_2 Saturation
When CO_2 is Delivered at 2.5 lpm via the TEMED Gas Diffuser.



The tested bottled CO_2 had a 98% CO_2 saturation, therefore indicating a 100% CO_2 atmosphere at 98%



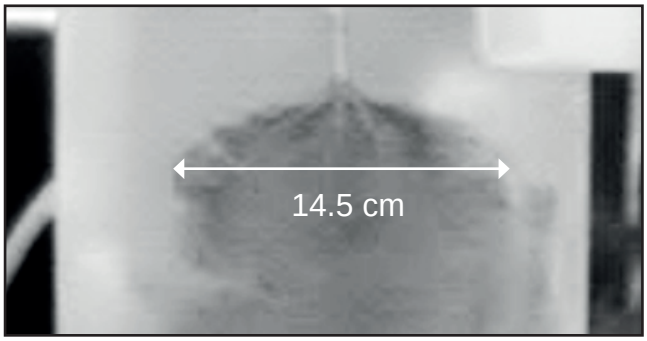
Using the TEMED Gas Diffuser:

CO_2 saturation of a model chest cavity is achieved within 60 seconds of initiating the flow at only 2.5 lpm. This is a saving of 7.5 litres of CO_2 every minute, when compared to other marketed devices.

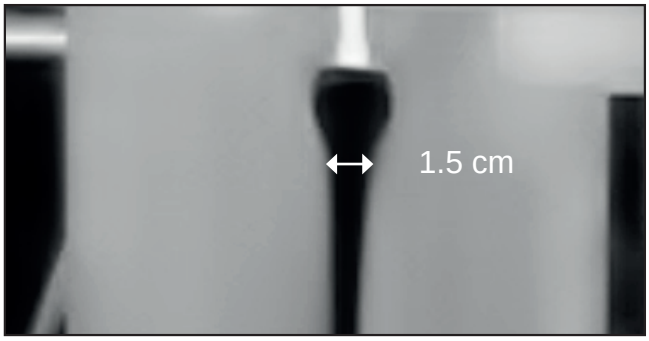
Helps to prevent air embolism during surgery

How have CO_2 delivery methods changed through time?

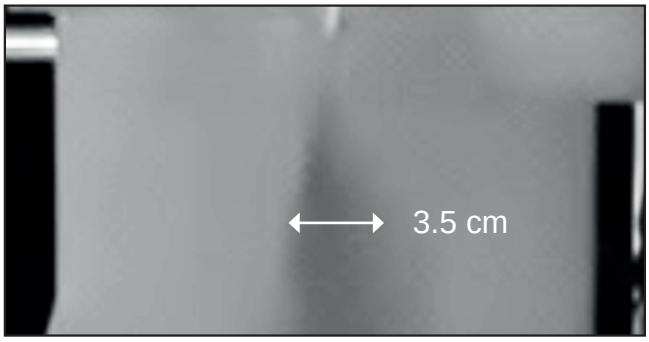
The **TEMED** Gas diffuser has a microporous hydrophobic tip which ensures that carbon dioxide is diffused over the majority of its surface, therefore reducing turbulence and creating a 100% CO2 atmosphere.



If the pores are too large, no Diffusion takes place.



Jetting occurs with an open ended tube which can draw more air in.



Images obtained using a CO2 camera which visualises CO2 between 4.2 and 4.4 Micron.

Why use Carbon Dioxide?

Carbon dioxide field flooding reduces neurologic impairment after open heart surgery.
Martens S, Neumann K, Sodemann C, Deschka H, Wimmer-Greinecker G, Moritz A.
Ann Thorac Surg. 2008 Feb;85(2):543-7:
"Shorter P300 peak latencies after surgery indicate less brain damage in patients who underwent heart valve operations with CO_2 flooding of the thoracic cavity."

Wound ventilation with carbon dioxide: a simple method to prevent direct airborne contamination during cardiac surgery?
Persson M, van der Linden J., J Hosp Infect. 2004 Feb;56(2):131-6:
"Intraoperative wound ventilation with CO_2 using a gas-diffuser may not only prevent air embolism, but may also significantly reduce the risk of airborne contamination and postoperative wound infection in cardiac surgery."

Effect of CO_2 insufflation on the number and behavior of air microemboli in open-heart surgery: a randomized clinical trial.
Svenarud P, Persson M, van der Linden J., Circulation. 2004 Mar 9;109(9):1127-32:
"Insufflation of CO_2 into the thoracic wound markedly decreases the incidence of microemboli."

Carbon dioxide in the prevention of air embolism during open-heart surgery
W. SHANG NG AND MICHAEL ROSEN. Thorax (1968), 23, 194.
"During any open-heart operation there is a danger of embolism from air trapped in the heart. One of the ways of reducing this is to displace the air in the wound by carbon dioxide (Myerly, Throckmorton, and Gustafson, 1957; Nichols, Morse, and Hirose, 1958; Ogawa, Kai, Seno, Taguchi, Kurihara, Fujimara, Kato, Hirano, and Adachi, 1962; Eguchi, Sakurai, and Yamaguchi, 1963; Effler, Groves, and Gulati, 1964; Burbank, Ferguson, and Burford, 1965). The solubility of carbon dioxide in blood is greater than that of air, in which nitrogen is the important relatively insoluble component (Table I). The serious effects that follow air trapped in the arterial system should be diminished by replacing this air with an equal quantity of carbon dioxide."

J Extra Corpor Technol. 2006 Jun;38(2):123-7.
Skidmore KL1, Jones C, DeWet C.
Flooding the surgical field with carbon dioxide during open heart surgery improves segmental wall motion.
"We recommend administration of carbon dioxide"

Physical features of the TEMED Gas Diffuser

0.2 µm MICROBIAL GAS FILTER

- The 0.2 micron microbial gas filter is an important element of the TEMED Gas Diffuser.
  - The filter is used to sterilise the carbon dioxide passing from the gas bottle or wall gas source to the diffusing tip.
  - Larger filter sizes such as 0.4 micron can let the Brevundimonas Dimiuta bacteria through.

CLEAR MALLEABLE DUAL LUMEN TUBING WITH ANNEALED STEEL REINFORCEMENT

- The clear malleable dual lumen tubing is the section which is visualised in the surgical field. The tubing is clear for a number of reasons:
  - The surgical field can be a cluttered environment. By utilising clear tubing to deliver the gas we are ensuring that there is minimal visual obstruction caused by using the TEMED Gas Diffuser.
  - The clear tubing allows the surgeon to see the pathway that the Carbon Dioxide gas is travelling through before it exits the Gas Diffuser. The surgeon will therefore be able to identify any potential issues which might arise due to the obstruction of the gas delivery line.
  - The clear tubed section is reinforced with annealed steel. The surgeon can therefore bend the malleable section into the shape that is required for efficient placement.

GREEN GAS LINE TUBING

- The gas line tubing which delivers the CO_2 to the surgical field is tinted green and transparent:
  - The green colour is used to identify that it is a gas line.
  - By being transparent it allows the Surgeon, Anaesthetist, Perfusionist or Nurse to identify if there is condensation within the delivery line which may impede the delivery of gas to the surgical field.
- The ¼ inch internal diameter of the gas line allows a push-fit connection to the regulator.

HYDROPHOBIC DIFFUSING TIP

- The distal section of the TEMED Gas Diffuser is manufactured from a hydrophobic material which is firm to the touch.
  - Being hydrophobic, the tip is able to diffuse gas over the majority of its surface despite any accidental submersion in fluid by the user.
  - The design enables the surgeons to have confidence that the product will not wet out.
- The diffusing tip is manufactured using the two contrasting colours of black and white.
  - The two colours easily identify the distal section of the TEMED Gas Diffuser in the potentially cluttered environment of the surgical field.

DOUBLE BAGGED

- The TEMED Gas Diffuser is double bagged.
  - This method of packing means that the product can easily be presented to the surgical field.
  - The outer bag can be opened with an aseptic technique and the inner bag containing the product can be placed onto a sterile trolley if required.
  - The double bagging of the product also ensures that the label is tamper proof as the label is fixed to the inner bag and viewed through the transparent section of the outer bag.

Why use the TEMED Hydrophobic CO_2 Gas Diffuser

- ***"Introduction of CO_2 through open-ended tubes is an unsatisfactory method of displacing the air"*** Selman et al. Journal of Thoracic and Cardiovascular Surgery. 1966.

- ***"When an open ended tube is used as a disperser of CO_2, the gas is introduced as a jet. When the gas stream strikes the bottom of the cavity, the change in momentum promotes turbulence. Convection currents are established with air sweeping in over the sides".*** Selman et al. Journal of Thoracic and Cardiovascular Surgery. 1966.

- ***"The air content was below 1% 4 cm below the surface of the open wound model during continuous carbon dioxide inflow of 2–10 L/min with the mini diffuser. In comparison, carbon dioxide insufflation via the open ended tube resulted in a mean air content between 10 and 75%. The mean air content of the wound model remained below 1% at a carbon dioxide flow rate of 3–5 L/min during intermittent application of a suction device"*** Nyman et al. Journal of Cardiothoracic Surgery (2019) 14:12.

- **For efficient de airing, CO_2 has to be delivered from within the wound cavity. The gas-diffuser was the most efficient device. In contrast to a gas-diffuser, a multi perforated catheter or a gauze sponge is unsuitable for CO_2 de airing because they will stop functioning when they get wet in the wound.** (Persson M, Svenarud P, van der Linden J.Department of Cadiothoracic Surgery and Anesthesiology, Huddinge University Hospital, Karolinska Institute, Stockholm, Sweden. m.persson@labmed.ki.se).

- **Gauze sponge and the multi perforated catheter immediately became inefficient (70% and 96% air, respectively), whereas the gas-diffuser remained efficient (0.4% air). During surgery, the gas-diffuser provided a median air content of 1.0%.** (J Cardiothorac Vasc Anesth. 2004 Apr;18(2):180-4.

- **With the tube the median air content in the wound model was 19.5% to 51.7% at the studied carbon dioxide flows, whereas with the gas diffuser the median air content was no greater than 1.2% at 5 L/min and no greater than 0.31% at 10 L/min (P <.001).** (J Thorac Cardiovasc Surg. 2003 May;125(5):1043-9.).

- ***"The use of CO_2 in minimal invasive cardiac surgery is probably more important compared with open cardiac surgery, as minimal invasive cardiac surgery does not permit normal de-airing maneuvers."*** Nyman et al. Journal of Cardiothoracic Surgery (2019) 14:12.

- **More than fifty years ago it was recognised that having a single tube did not provide effective de-airing of the chest cavity. They found that the most effective way of de-airing was to have four tubes that were all pointing at the area requiring de-airing. They also found that de-airing was more effective when the tubes were outside of the cavity.** Thorax (1968), 23, 194. Carbon dioxide in the prevention of air embolism during open-heart surgery. W. SHANG NG AND MICHAEL ROSEN.

- **Using a Gas Diffuser it has been shown that the time taken for there to be detectable micro emboli fell from 19 minutes to 7 minutes. Therefore a 12 minute reduction in de-airing time.** Circulation. Volume 109, Issue 9, 9 March 2004, Pages 1127-1132).

Background reading

- ***"The adjusted average incremental cost due to major infection was nearly $50,000, with the additional ICU stay increasing the index hospitalization cost by $1094/day during the first 2 weeks after surgery. Patients with major index HAIs were nearly twice as likely to be readmitted as those without. Overall, there were 855 readmissions; 19 % due to HAIs, costing on average nearly twice as much as non-HAI related readmissions."*** The Economic Impact of Healthcare Associated Infections in Cardiac Surgery. Mar 2018 Circulation. 2013;128:A18267.

- ***"In an era that emphasizes early discharge and the need to avert preventable readmissions, this study shows that both are heavily influenced by infection rates and that the costs of HAIs in cardiac surgery are substantial. These data provide critical insights about the potential economic impact of infection prevention programs."*** The Economic Impact of Healthcare Associated Infections in Cardiac Surgery. Mar 2018Circulation. 2013;128:A18267.

- ***"Data from the American Society of Anesthesiologists Closed Claims Project showed 100% of claims for VAE resulted in a median payment of $325,000".*** Vascular air embolism: A silent hazard to patient safety. Brull SJ, Prielipp RC. J Crit Care. 2017 Dec;42:255-263.

- **In the USA the CABG infection rate is 3.2 % with the valve rate being 3.8 % (5,158 patients).** J Am Coll Cardiol. 2014 July 29. Management practices and major infections after cardiac surgery.

- **In the UK where the TEMED Gas Diffuser is used for the majority of valve cases the CABG SSI rate is 2.12 % and the valve SSI rate is 0.87 % (46,041 patients).** Public Health England, December 2018: Surveillance of surgical site infections in NHS hospitals in England, 2013 to 2018.

- ***"Clinical strokes were detected in 17%, Transient Ischemic Attack in 2%, and in-hospital mortality was 5%. The frequency of stroke in the Society for Thoracic Surgery(STS) database in this cohort was 7%".*** Stroke after Aortic Valve Surgery: Results from a Prospective Cohort. Circulation. 2014 June 3; 129(22). Steven R. Messé et al. Hospital of the University of Pennsylvania, Philadelphia.

- ***"Clinical stroke was associated with increased length of stay, median 12 vs 10 days".*** Stroke after Aortic Valve Surgery: Results from a Prospective Cohort .Circulation. 2014 June 3; 129(22). Steven R. Messé et al. Hospital of the University of Pennsylvania, Philadelphia.

- ***"Moderate or severe stroke (NIHSS ≥10) occurred in 8 (4%) and was strongly associated with in-hospital mortality, 38% vs 4%".*** Stroke after Aortic Valve Surgery: Results from a Prospective Cohort. Circulation. 2014 June 3; 129(22). Steven R. Messé et al. Hospital of the University of Pennsylvania, Philadelphia.

- **A recent study showed that clinical strokes were detected in 17 % of patients after Aortic Valve Surgery. The frequency of stroke in the STS database in this cohort was 7 %. Many of the strokes were mild, yet overall they were associated with increased length of stay. Moderate to severe stroke was associated with a 9 fold increased mortality risk.** Stroke after Aortic Valve Surgery: Results from a Prospective Cohort .Circulation. 2014 June 3; 129(22). Steven R. Messé et al. Hospital of the University of Pennsylvania, Philadelphia.

- ***"The cost to the NHS for each patient who suffers a stroke is roughly £29,000".*** Interactive CardioVascular and Thoracic Surgery 15 (2012) 155-157.

- ***"VAEs were detected in 14 (70%) patients."***

- ***"The peak number of emboli appeared approximately 5 seconds after sternotomy and returned to baseline at the end of the procedure."*** Venous emobolization during sternotomy in children undergoing corrective heart surgery. Ilan Keidan et al. The Journal of Thoracic and Cardiovascular Surgery. 2004.

- ***"It was repeatedly noted, however, that the disappearance of visible air did not always indicate restoration of normal myocardial capillary blood flow."*** THE SIGNIFICANCE OF AIR EMBOLISM DURING CARDIOPULMONARY BYPASS. F.C.Spencer, M.D., N.P. Rossi, M.D., Shao-Chi Yu, M.D., and J.A.Koepke, M.D., Lexington, Ky.

- ***"With visible air bubbles in a failing heart, the injury was obvious. By contrast, though, was the occasional persistence of a feebly contracting cyanotic heart after all visible air had disappeared."*** THE SIGNIFICANCE OF AIR EMBOLISM DURING CARDIOPULMONARY BYPASS. F.C.Spencer, M.D., N.P. Rossi, M.D., Shao-Chi Yu, M.D., and J.A.Koepke, M.D., Lexington, Ky.

- ***"Neurologic injury after cardiac surgery is principally associated with emboli"*** Embolic Activity During In Vivo Cardiopulmonary Bypass. Gordon R. DeFoe et al. The Journal of ExtraCorporeal Technology 2014;46:150-156.

- ***"Neurologic injury us a leading cause of morbidity subsequent to cardiac surgery and is thought to be principally the result of embolization"*** Embolic Activity During In Vivo Cardiopulmonary Bypass. Gordon R. DeFoe et al. The Journal of ExtraCorporeal Technology 2014;46:150-156.

- ***"In conclusion, we have demonstrated that even with the advances in circuit design, emboli may still be detected in large numbers on CPB and may be associated with discrete processes of the perfusionist's care."*** Embolic Activity During In Vivo Cardiopulmonary Bypass. Gordon R. DeFoe et al. The Journal of ExtraCorporeal Technology 2014;46:150-156.

- ***"Spontaneous intraoperative VAE is a life-threatening event, and a fatal outcome was reported for 10 out of 22 humans undergoing spinal surgery (Wills et al., 2005). It is also recognised during other surgeries in human patients (Mirski et al., 2007)."*** AIR EMBOLISM DURING SPINAL SURGERY. Veronica Mortera et al.

- ***"Duke and colleagues reported a 28% incidence of VAE in the sitting position".*** The sitting position in neurosurgery-not yet obsolete! British Journal Of Anaesthesia. January 2002.

- ***"Artificial pneumothorax may induce cerebral arterial air embolism, and the application of carbon dioxide to establish artificial pneumothorax can effectively reduce the risk of air embolism"*** A Case of Massive Cerebral Arterial Air Embolism Induced by Artificial Pneumothorax and Its Analysis. Xiao-Hua Gou, Wei Yang, Yan-Li Zhang, Ya Li, Xin Wu Med Princ Pract 2019;28:297–300.

- ***"Larger quantities of air, or repeated small quantities, however, can cause enough coronary obstruction to significantly depress myocardial contractility even on bypass."*** The Harmful Effects and Treatment of Coronary Air Embolism During Open-Heart Surgery. Claire Justice, M.D., John Leach, M.D., and W. Sterling Edwards, M.D. THE ANNALS OF THORACIC SURGERY.

- ***"This is the first report in an adult human to document an exact lethal volume of air, 200 ml (albeit in a patient with congestive heart failure), rather than to estimate retrospectively the lethal volume after the incident of fatal venous air embolism. It is still unclear whether this amount, 200 ml, represents the minimum volume of air considered to be lethal to healthy adult humans."*** Volume of Air in a Lethal Venous Air Embolism.Thomas J. K. Toung, M.D., Mark I. Rossberg, M.D.,† Grover M. Hutchins, M.D. Anesthesiology 2001; 94:360–1.

- **INFECTION: CO_2 has antimicrobial properties, reducing the rate of surgical site infections.**

- Carbon dioxide has a dual physiological role in microorganisms since it can either stimulate or inhibit the cell development. *(Debs-Louka et al., 1999)* Carbon dioxide has been used as a means of preserving liquid and solid foodstuff since the 1930s, owing to its inhibitory effect. *(Dixon and Kell., 1989) (Donald et al., 1924) Haas et al., 1989) (Wei et al., 1991).*

- Before recent times, its use in the treatment of surgical site infections has been considered impractical. CO_2 is now widely used for laparoscopic colorectal surgery (LCS). When these procedures are compared to open colorectal surgery (OCS) they have been shown to develop 40% less surgical site infections (SSI). *(Aimag et al., 2011) (Richards et al., 2003).*

- Richards et al analysed results from 54,504 inpatient cholecystectomy procedures undertaken between 1992 and 1999. During this period the use of the laparoscopic technique, as opposed to open cholecystectomy, increased from 59% in 1992 to 79% in 1999. The laparoscopic technique is less invasive, requires shorter hospitalisation and is associated with faster recovery rates when compared to open cholecystectomy. The risk of surgical site infections was lower in patients undergoing the laparoscopic technique. Infecting organisms were found to be similar. Carbon dioxide is the most widely used gas during laparoscopic procedures. Inhibition of bacterial growth has been reported for the pathogen Staphylococcus Aureus. *(Persson et al., 2004)* In this study SSI data was collected for 342 patients, of which 116 had undergone laparoscopic technique with the remaining 226 undergoing an open procedure. The risk of SSI was significantly lower for laparoscopic cholecystectomy.

- A study of 122 patients (LCS 43, OCS 79), who underwent colorectal resections over a 12 month period in the UK, looked at the difference in infection rate between the laparoscopic and open procedures. The patients' demographic and operative case-mix were similar for both groups. Infection rates for LCS were 7% whilst OCS infection rates were 25%. This translates to LCS infection rates being 72% lower than OCS over that period. *(Howard et al., 2010).*

- Another study of 670 patients in Japan found that rates of surgical site infections for laparoscopic surgery for colon cancer were 4%. *(Nakamura et al., 2016).*

- It is thought that the lower rates of SSIs in LCS compared with OCS procedures may be due to the bacteriostatic effect of carbon dioxide. *(Persson et al., 2004).*

- A study into the effect of CO_2 on staphylococcus aureus at body temperature looked at the difference between having S. aureus inoculated on blood agar and then exposed to either; anaerobic gas (5% CO_2, 10% H_20 and 85% N_2), air or 100% CO_2, at 37°C and over a 24hr period. The number of S. aureus on blood agar was 100 times lower for the CO_2 plate than the anaerobic one, and 1000 times lower for CO_2 than the plate exposed to air.

- In broth there were fewer bacteria with CO_2 than with air. After 2h the number of bacteria had increased with the air but not with the CO_2. After 8h, the optical density measurement with air had increased from 0 to 1.2; the CO_2 saw an increase to 0.01.

- Staphylococcus Aureus accounts for 21% of SSIs detected by the Surgical Site Infection Surveillance Team in the United Kingdom *(Public Health England, 2018).*

- Public Health England have released a report by the Surgical Site Infection Surveillance team:

- The report analyses the rate of surgical site infections (SSIs) for 134,119 procedures including 105,771 from mandatory orthopaedic surveillance and 28,348 from 13 other voluntary surveillance categories. Surveillance was carried out in the UK from April 2017 to March 2018. A total of 201 hospitals reported data on varying procedures and the 1,338 surgical site infections detected during the inpatient stay or on readmission following the initial operation. It is interesting to note the difference between coronary artery bypass graft (CABG) procedures and those referred to as 'Cardiac (non-CABG)' procedures. Rates for SSIs after Coronary Artery Bypass Grafts (CABG) are more than double that of the Cardiac, non-CABG procedures (these are predominantly heart valve surgery procedures). Both of these procedures are performed in the same

theatres, by the same surgical teams. Both procedures entail patients undergoing sternotomy, therefore surgical wound sizes are very comparable. Valve surgery is typically a more complicated surgical procedure and therefore one may expect the rate of SSI to be higher than the less complicated CABG procedures.

- In the UK carbon dioxide is routinely used during heart valve surgery, however, it is rarely used during CABG procedures. The rate of infection (inpatient only) for CABG procedures was reported at 2.12% of the 29,335 operations reported on since April 2013 , compared with 0.87% of the 16,706 other cardiac procedures. For in-patient and re-admission rates we see an increase to 3.5% of CABG procedures and 1.3% for other cardiac procedures. *(Public Health England, 2018).* This report highlights that in the UK you are more than twice as likely to acquire an SSI from a CABG procedure than you are from other, typically more complicated, cardiac procedures. The main difference being that in the non CABG procedures CO_2 is usually used.

- Data taken from: Public Health England, December 2018: Surveillance of surgical site infections in NHS hospitals in England, 2017 to 2018.

Procedure	No. of procedures	2013-2018 (inpatient only) SSI Rate (%)
Cardiac (Non CABG)	16,706	0.87
Coronary Artery Bypass Graft (CABG)	29,335	2.12

HEALING: CO_2 improves micro circulation and wound healing.

- Wound healing is known to benefit from improved micro-circulation and local oxygen supply. Carbon dioxide administration to a wound has been linked with both an improvement in micro-circulation and an increase in local oxygen supply. *(Li et al., 2017).*

- Hypoxia is a common cause of chronic wounds. The administration of subcutaneous carbon dioxide has been shown to result in neoangiogenesis and increased arterial sphygmicity on cutaneous ulcers and difficult wounds such as decubitus ulcers. Tissue oxygenation values were found to have significantly increased. Lesions of wounds treated in this way benefitted from increased healing and a reduction in the injured area *(Brandi et al., 2010).*

- **Carbon dioxide is one of the molecules that triggers the Bohr Effect.**

- The Bohr effect increases the efficiency of oxygen transportation through the blood, allowing oxygen to be delivered to the tissues that require it the most. Naturally a tissue will produce more carbon dioxide as it's metabolic rate increases. The carbon dioxide causes a drop in the local pH of the blood. It is this drop in PH that promotes the oxygen dissociation from the haemoglobin, allowing the surrounding tissues to obtain enough oxygen to meets its increased demands.

Regulatory Information

TEMED Gas Diffuser Clinical History

There have not been any reported incidents in the lifetime of the product, nor have there been any concerns raised by customers, competant authority or notified body (May 2021).

- TEMED introduced its first CO_2 insufflation device to the European market in 2005
- The most recent model, the P2514, has been in production since 2010
- The TEMED Gas Diffuser attained FDA 510 (K) approval for the USA market in February 2018
- The TEMED Gas Diffuser attained TGA (Australia) approval in August 2011
- The P2514 has been used extensively throughout Europe, Australia and New Zealand.

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