Clean Air in the Operating Room

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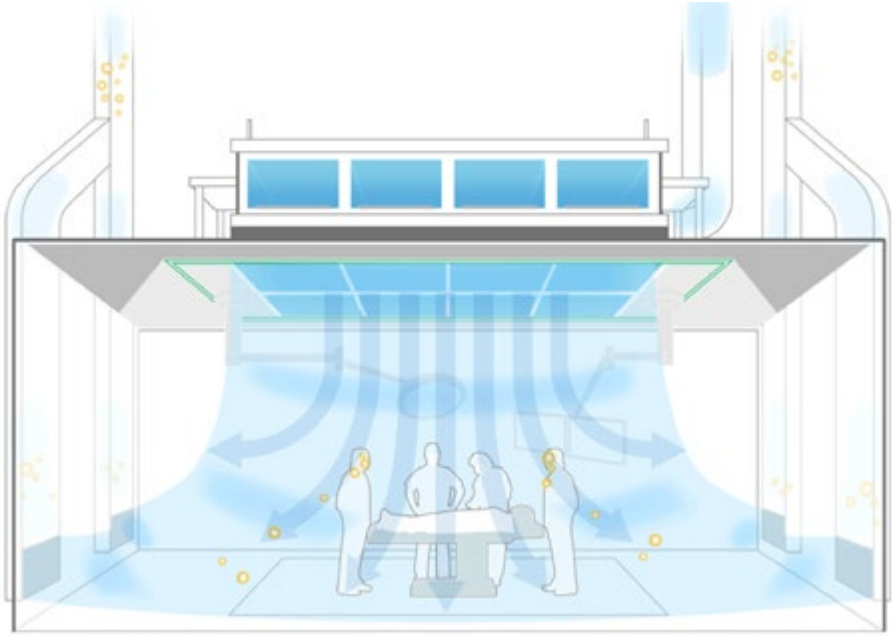
Over 16 million operative procedures occur each year in the United States. Prevalence studies show that surgical site infections (SSIs) are one of the most common healthcare associated infections (HAIs) with estimations of greater than 157,000 SSIs occurring yearly (Magill). Surgical site infections prolong hospitalization, cause 13,000 deaths annually and can cost up to $29,000 per infection according to the Centers for Disease Control and Prevention (CDC).



Driving Forces in Healthcare

The focus of health care has shifted towards monitoring and improving clinical outcomes as Medicare and Medicaid have developed guidelines that deny reimbursement for preventable complications, including surgical site infections. Hospitals are required to report patient outcomes and provide measurable, evidenced-based, quality improvement initiatives designed to improve clinical outcomes. Surgical site infections are largely preventable. The current focus on the prevention of surgical site infections is driven primarily by patient outcome improvement and secondarily by the way hospitals are reimbursed from CMS, and the focus of the Accountable Care Act on the value-based quality of care provided to the surgical patient.

Sources of Contamination

There are many ways in which pathogens may contaminate the surgical field, potentially resulting in a surgical site infection. Contamination sources in the operating room are numerous and may include equipment, instruments, the surgical team, operating room traffic, and air quality in the operating room. Published clinical studies and professional organizations such as AORN agree that airborne squames, or skin scale particles, shed from the patient and personnel in the operating room are the primary source of bacteria that cause infections in the surgical suite.(Woods et al, Knobben 2006). Squames are skin particles shed from exposed regions of skin from both the patient and personnel in the operating room.

Optimizing the Quality of Air in the OR

Airflow control is one way to decrease the number of potential pathogens introduced into the surgical site. Clinical studies have demonstrated a strong linear relationship between the level of bacteria in the air and the prevalence of a deep SSI (Andersson et al. 2012). Airborne bacteria levels are measured as colony-forming units per cubic meter (CFU/m3), and each CFU will contain between 1 and 1,000 particles of bacteria. Studies have shown a significant correlation between increased personnel in the operating room and increased bacterial counts or CFU/m3 at the surgical site, indicating that CFUs may also be originating from peripheral personnel in the OR (Stock 2010). Laminar airflow systems are designed to provide highly filtered air with continuous air exchanges to reduce airborne particles. Laminar airflow ventilation systems greatly reduce the levels of airborne contamination with a reduction of 89% in CFUs over displacement systems (Andersson et. al 2014). Literature reviewed by Howard and Hansseen determined that vertical laminar airflow is more effective than horizontal airflow. People or equipment passing or standing between horizontal airflow wall units and the patient disrupt the air flow, decreasing the effectiveness of the system. In contrast, vertical laminar airflow, coming from the ceiling, shows a significant reduction in the number of microorganisms on the instrument table and the surgical field (Hansseen, 2007). The CLEANSUITE® System is a vertical ceiling laminar airflow system that directs airborne particles away from the surgical field and the patient on the operating room table, preventing entrapment of airborne particles around the surgical site.

Filtering Out Contaminants

High efficiency particulate air (HEPA) filters are designed to filter out airborne particles. Multiple studies conclude that operating rooms with HEPA filtration systems have lower levels of microbial and Aspergillus contamination (Crimi 2009), and reduced levels of particulate matter in the air (Wan 2011). A comparative study measuring airborne microbial concentrations found fungal concentration levels to be lower in operating rooms with HEPA filters (Perdelli 2006). HEPA-filtered air minimizes the recirculation of contaminants in the surgical suite, reducing air microbial loads (Aydin 2013). The CLEANSUITE System uses HEPA filters to significantly reduce levels of particulate matter in the air, bathing the patient and surgical area with lower levels of contaminants.

Minimize Turbulence

Ventilation systems with the greatest efficiency at preventing particle emission into the sterile field are systems that provide low-turbulence displacement airflow with flow stabilizers (Hirsch 2012). The CLEANSUITE System has equalizers that stabilize and balance the airflow that can be adjusted with filters in place. This laminar air flow system maximizes the surface area of the ceiling space, ultimately forming a single large diffuser over the surgical area. The CleanScreen™ laminar flow diffuser optimizes laminar airflow to the operating table by providing unidirectional airflow that minimizes turbulence, provides optimized airflow particle containment, and produces predictable movement of particles away from the sterile field.

CLEANSUITE System Offers Wall to Wall Laminar Air

A study compared no laminar flow systems to use of laminar airflow in 80 orthopedic surgical procedures completed by Diab-Elschahawi found a significant reduction in the number of microorganisms on the instrument table and an insignificant reduction of microorganisms on other locations measured in the room, such as the back tables and implant tables. The CLEANSUITE System is modular, with the ability to custom build each surgical suite. The CLEANSUITE System can be built to cover back tables and implant tables, with the ability to offer wall to wall coverage, directing airborne particles away from all sterile surfaces, blanketing your back and implant tables with HEPA-filtered air.

CLEANSUITE System Bringing Advanced Technology to the Operating Room

Current regulations govern temperature, humidity, air pressure, and the rate of air exchanges in operating rooms. There are no regulations on airborne contamination levels; however, a widely accepted level of airborne microbes is < 10 CFU/m3 (Stocks, 2010). Clinical studies show clinical benefits can be expected when reducing contamination levels to 1 CFU/m3 (Andersson et al 2012). The CLEANSUITE System was developed to meet ISO Class 1 standards and maintains extremely well-controlled, defined ranges of airborne contamination.

Implementing Technology

Companies that manufacture pharmaceuticals, semiconductors and other sensitive products must adhere to strict industry and federal standards on airflow requirements that limits the level of particle contaminants. These industries, by complying with ISO 14644 cleanroom standards, decreased product lost as a result of a failure to meet air quality standards in sensitive environments. In general, bacterial particles are ≥ 1µm in size and tend to bunch together, forming larger clusters of airborne bacteria containing between 1 and 1000 microorganisms. The CLEANSUITE System complies with ISO cleanroom standards to decrease airborne contamination, filtering out particles that are significantly smaller measuring ≥ 0.1 µm.

The CLEANSUITE System has taken the technology that was established for these clean room environments and has moved it into the operating room, an area that contains multiple airborne contaminants, including bacteria and fungi. The CLEANSUITE System directs airborne particles away from the surgical site, by providing uniform directional HEPA-filtered airflow that moves the particles away from the surgical field and contains them via filtered return ducts. The CLEANSUITE laminar airflow system provides an added benefit of contamination control with the CleanScreen™ diffuser that optimizes airflow to a unidirectional movement with minimal turbulence creating a cleanroom environment for the operating room.

Publication Title	Key Findings	Relevance to CLEANSUITE System
Howard J. L., Hanseen A. D. (2007). Principles of a clean operating room environment. *Journal of Arthroplasty.* 22, 6-11.	Vertical laminar airflow is more effective than horizontal	Vertical laminar airflow significantly reduces the number of microorganisms around the surgical field.
Stocks, G. W., Self, S. D., Thompson, B., Adame, X. A., O'Connor, D. P. (2010). Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery. *Association for Professionals in Infection Control and Epidemiology, Inc, 38, 199-204.*	Airborne bacteria in the Operating Room demonstrated a correlation with postoperative infection at the surgical site and deep within the wound. Airborne bacteria cluster together forming particles measuring 4 µm – 20 µm.	CLEANSUITE System satisfies ISO Class 1 standards and filters bacteria measuring ≥ 0.1 µm with extremely controlled well defined ranges for airborne contamination numbers.
Knobben, B. A., Van Horn, J. R., Van Der Mei H. C., Brusscher, H. J., Evaluation of measures to decrease intra-operative bacterial contamination in orthopedic implant surgery. *Journal Hospital Infection* 2006;62:174-80.	Potential source of contamination is the air in the operating room with airborne bacteria deposition in surgical wounds.	CLEANSUITE System is a laminar airflow system that provides uniform directional airflow that filters out contaminants
Der Tavitian, J., Ong, S. M, Taub, N.A., Taylor, G. J. (2003). Body-exhaust suite versus occlusive clothing: A randomized, prospective trial using air and wound bacterial counts. *Journal of Bone and Joint Surgery.* 85, 490-494.	Bacteria generally are larger than ≥ 1 µm and cluster together forming particles that measure 4µm – 20 µm	CLEANSUITE System satisfies ISO Class 1 standards and filters bacteria measuring ≥ 0.1 µm with extremely controlled well defined ranges for airborne contamination numbers.
Andersson, A. E., Bergh, I, Karlsson, J., Eriksson, B. I. Nilsson, K. (2012). Traffic flow in the operating room: An explorative and descriptive study on air quality during orthopedic trauma implant surgery. *American Journal of Infection Control*. 40, 750-755.	Clinical benefits can be expected when reducing airborne contamination levels to 1 CFU/m^3 with strong linear relationship between the level of bacteria in the air and the prevalence of a deep SSI.	CLEANSUITE System satisfies ISO Class 1 standards and filters bacteria measuring ≥ 0.1 µm with extremely controlled well defined ranges for airborne contamination numbers.
Wan G. H., Chung, F. F.,Tang, C. S. (2011). Long-term surveillance of air quality in medical center operating rooms. *American Journal of Infection Control.* 39(4), 302-308.	Air quality of ORs having significantly reduced levels of contamination CFU/m^3 were rooms with HEPA filtration systems	CLEANSUITE System is a laminar air system with HEPA filters.
Anderson, A., E., Petzold, M., Bergh, I., Karlsson, J., Eriksson, B. I., Nilsson, K. (2014). Comparison between mixed and laminar airflow systems in operating rooms and the influence of human factors: Experiences from a Swedish orthopedic center. *American Journal of Infection Control.* 42, 665-669.	Laminar airflow-ventilation systems have a reduction of 89% in CFUs in comparison with displacement systems.	CLEANSUITE® System is a laminar airflow system that provides uniform directional airflow that filters out contaminates.
Crimi, P., Valgiusti, M. Macrine, G. *e al*. (2009). Evaluation of microbial contamination of air in two hematology departments equipped with ventilation systems with different filtration devices. *Journal of Preventative Medicine Hygiene.* 50,33-36	Incoming air filtered with HEPA filters had lower amounts of bacterial and Aspergillus contamination.	CLEANSUITE System uses HEPA filtration to optimize the air quality in the operating room.
Perdelli, F., Cristina, M.L., Sartine, M. et al. (2006). Fungal contamination in hospital environments. *Infection Control Hospital Epidemiology.* 27, 44-47	Operating rooms with HEPA filters had lower levels of fungal recovery than areas without HEPA filters.	CLEANSUITE System uses HEPA filtration to optimize the air quality in the operating room.
Aydin, C. N., Ucar, F. B., Haliki Uztan, A., Corbaci, C., Akpinar, O. (2013). Determination and comparison of microbial loads in atmospheres of two hospitals in Izmir, Turkey. *Ann Agric Environment Medicine.* 20, 106-110.	Filtered air minimizes the recirculation of contaminants within the perioperative area, HEPA filtration systems reduce the air microbial load.	CLEANSUITE System uses HEPA filtration to optimize the air quality in the operating room.
Hirsch, T., Hubert, H., Fischer, S., et al. (2012). Bacterial burden in the operating room: Impact of airflow systems. *American Journal of Infection Control.* 40, 228-232.	Low -turbulence displacement airflow with flow stabilizers systems were found to be the most efficient in preventing bacterial emission into the sterile field.	CLEANSUITE System has equalizers that stabilize and balance the airflow.
Diab-Elschahawi M., Berger J., Blacky A., (2011). Impact of different-sized laminar air flow verses no laminar air flow on bacterial counts in the operating room during orthopedic surgery. *American Journal Infection Control.* 39(7), 25-29.	Laminar flow system provided a significant reduction in the number of viable microorganism on the instrument table, and an insignificant reduction of microorganisms on other locations, including the area around the patient's head, the instrument table and the back table	CLEANSUITE System is a customizable modular system with the ability to provide laminar air-flow over the back tables and instrument tables. As well as the ability to offer wall to wall coverage of laminar air.

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