

# State-of-the-Art Mobile Infection Control Technology Aiming to Make Air Quality Safer for Immunocompromised Patients

By Ronald C. Trahan



"Fungal spores are a major source of nosocomial aspergillosis. We have significantly reduced fungal contamination in our adult and pediatric units since introducing Plasmair."

— Denis Caillot, MD, chief of service, Department of Hematology, Dijon Hospital, Dijon, France.

"The healthcare industry is making a full-fledged assault upon combating infections in acute care hospitals. AirInSpace has put a high-tech tool into the hands of hospitals for effectively and safely managing their air quality to help protect patients from airborne pathogens."

— Wade Tetsuka, president of U.S. operations for AirInSpace



PlasmairT2006 is the only system cleared by the FDA as a "medical device," differentiating it substantially from mere "air cleaning" products marketed to hospitals. Plasmair is designed to inactivate airborne particles from the air without frequent filter changes.

**A**spergillus is a genus of some 200 highly airborne molds, some of which can be deadly, especially to immunocompromised patients. Consider that incidence rates of invasive aspergillosis have been reported as high as 26 percent in allogeneic bone marrow transplant patients and 25 percent in acute leukemia patients. And in these immunocompromised patients who are infected by airborne aspergillosis spores, the scientific literature reports that death occurs in as many as 9 out of 10 of these patients.<sup>1</sup>

"In a hospital setting, construction work that liberates large amounts of Aspergillus spores is the major source of nosocomial aspergillosis," says Ludwig Aho-Glélé, MD, who heads the Hospital Hygiene and Epidemiology Unit at Dijon (France) Hospital. "Given that we were about to commence a major long-term construction project right next door to high-risk clinical units such as our adult and pediatric hematology wards, we needed to be extra diligent in preventing liberation of these spores that are the source of potentially lethal nosocomial aspergillosis."

Traditional mechanical high efficiency particulate arrestance (HEPA) air filtration, with or without laminar airflow ventilation, does reduce airborne fungal contamination and the incidence of invasive aspergillosis in a hospital setting. But the cost often precludes large-scale utilization.

Denis Caillot, MD, head of clinical hematology, turned to AirInSpace, which owns a patented core technology, HEPA-MD™ — the next generation of its initial Plasmer™ platform — that is designed to inactivate lethal airborne microorganisms. Developed initially for use in Russia's MIR space station, the AirInSpace technology is in routine

"Hospital-acquired infections affect 1 in 10 patients. New regulations to control airborne contamination require hospitals to undertake massive renovations to upgrade their ventilation systems. Alternatively hospitals are finding unprecedented success with deployment of PlasmairT2006 mobile units."

— Vance Bergeron, PhD, chief scientific officer of AirInSpace



now being used to combat hospital-acquired infections (HAIs) in high-risk areas of more than 100 hospitals and clinics throughout France, including hematology wards, intensive care units (ICUs), and operating theaters.

Traditional mechanical High Efficiency Particulate Air (HEPA) filters are the most common airborne decontamination method used in hospitals, but they don't inactivate the pathogens they trap and can serve as a reservoir that promotes their growth, leading to more pathogens released into the air to pose a lethal risk to patients, staff and maintenance personnel. New regulations are being imposed to control airborne contamination levels, requiring hospitals to undertake massive renovations to upgrade their ventilation systems. Alternatively, hospitals are finding unprecedented success with deployment of Plasmair units.

A second clinical study ("Evaluation of a new mobile system for protecting immune-suppressed patients against airborne contamination") published in the *American Journal of Infection Control* concluded that "...the (AirInSpace) unit can be used to

quickly convert standard hospital rooms into areas that can host immune-suppressed patients without the need for major building renovations. Furthermore, destruction of the microorganisms within the (AirInSpace) unit also eliminates the risk posed by mechanical HEPA filter systems concerning the growth and release of airborne microorganisms."<sup>3</sup> The study's investigation sites included two Paris sites, Hôpital Saint-Antoine and Hôpital Necker; and Centre Hospitalier Universitaire de Rennes, (France).

"Invasive aspergillosis is an extremely deadly nosocomial infection for immune-suppressed hospital patients," says Laurent Fullana, chief executive officer of AirInSpace. "The Centers for Disease Control and Prevention (CDC) reports a mortality rate of 95 percent in immune-suppressed patients who receive allogeneic bone marrow transplants and patients with aplastic anemia. These patients need a highly protective environment. The Dijon study demonstrates that our mobile system can effectively contribute to protect these patients. It's important to note that the PlasmairT2006 has been cleared as a

use today on the International Space Station (ISS). AirInSpace owns exclusive rights to this one-of-a-kind technology, which shows up to 99.999 percent single-pass inactivation of airborne microorganisms.

Under the guidance of Caillot and Aho-Glélé, Dijon Hospital conducted a 13-month pre-construction study to determine if the AirInSpace Plasmair mobile unit could indeed reduce the incidence of indoor fungal contamination in high-risk hospital rooms. Results of the study, "The use of Plasmair air-decontamination units for the prevention of invasive pulmonary aspergillosis in neutropenic patients," were published in the *Journal of Hospital Infection*.<sup>2</sup>

"Our study found that the mobile Plasmair units may provide a new approach to air-treatment in the hospital setting," explains Aho-Glélé. "Plasmair units were effective in reducing fungal contamination in both the adult and pediatric hematology units over a long period of time." Aho-Glélé continues, "My job, of course, is to prevent nosocomial infection in the hospital. We found that Plasmair is an effective device that reduced contamination by aspergillosis. Therefore we can now say that our hospital is safer as a direct result of using the AirInSpace Plasmair device. It is effective, and it is mobile, so we can place it wherever we want in the hospital. In fact we have 40 units here throughout Dijon Hospital."

AirInSpace's flagship product is the mobile air-decontamination called unit Plasmair. Its performance has been clinically proven to rapidly lower airborne biological loads and is



"Our data show that the Plasmair mobile units are providing an efficient method of reducing indoor fungal contamination, which can be lethal to immunocompromised patients."

— Ludwig Aho-Glélé, MD, chief of service, Hospital Hygiene and Epidemiology Unit, Dijon Hospital, Dijon, France.

"The cost of one Plasmair unit is less than the total cost to the hospital of a single nosocomial infection, taking into account additional days in the hospital, antifungal treatment, and potential litigation costs."

— Laurent Fullana,  
CEO of AirInSpace  
S.A.S.



Class II medical device. This means assurance of effectiveness and safety based on a thorough risk analysis in the design phase, good manufacturing practices, validated labeling and claims filed with the FDA, and post-market surveillance — all of which are not required and therefore typically not done for most appliances used as air purifiers."

"Providing immunocompromised patients with protection against airborne contamination used to require expensive and high-maintenance facilities," says Vance Bergeron, PhD, chief scientific officer of AirInSpace. "The Dijon study demonstrates that we can offer hospitals a self-contained mobile unit as a cost-effective alternative for establishing an unthreatened environment."

"I am always very concerned about nosocomial infection," Aho-Glélé comments.

"Under rigorous testing, Plasmair has proven to me that we are doing everything we can by incorporating Plasmair into our standard infection control protocol." U.S. hospitals will have the opportunity to rent the PlasmairT2006 by AirInSpace mobile unit with HEPA-MD through Hill-Rom. Hill-Rom will also provide local field technical service for the product, according to AirInSpace officials. **ICT**

#### References

1. The use of Plasmair air-decontamination units for the prevention of invasive pulmonary aspergillosis in neutropenic patients, *J Hosp Infection*. 2007;65:156-162.
2. Ibid
3. Poirot JL, et al. Evaluation of a new mobile system for protecting immune-suppressed patients against airborne contamination. *Am J Infect Control*. Sept. 2007. 35:460-6

## PlasmairT2006: Mobile Airborne Infection Control with HEPA-MD™ (HEPA with Microbial Destruction)



- ✓ Evidence Based Clinical Efficacy<sup>1</sup>
- ✓ Safety (Class II medical device – FDA 510(k) cleared)<sup>2</sup>
- ✓ Patient Comfort<sup>3</sup>

<sup>1</sup> Jean-Louis Poirot, MD, Jean-Pierre Gangneux, MD, Alain Fischer, MD, PhD, Mireille Malbernard, RN, Svetlana Challier, MD, Nicolas Laudinet, BSc, and Vance Bergeron, PhD. Evaluation of a new mobile system for protecting immune-suppressed patients against airborne contamination, *American Journal of Infection Control*, September 2007, (2007;35:460-6)

<sup>2</sup> N. Sixt, F. Dalle, I. Lafon, S. Aho, G. Couillault, S. Valot, C. Calinon, V. Danaire, O. Vagner, B. Cuisenier, M. Sautour, J.P. Besancenot, C. L'Ollivier, D. Caillot, A. Bonnin. Reduced fungal contamination of the indoor environment with the PlasmairT system (AirInSpace), *Journal of Hospital Infection*, 2007 (2007;65: 156-162)

<sup>3</sup> V. Bergeron, PhD; G. Reboux, PhD; J. L. Poirot, MD; N. Laudinet, BS. Decreasing Airborne Contamination Levels in High-Risk Hospital Areas Using a Novel Mobile Air-Treatment Unit, *Infection Control and Hospital Epidemiology*, October 2007, (2007;28:1181-1186)

<sup>4</sup> M. Sautour, N. Sixt, F. Dalle, C.L'Ollivier, C. Calinon, V. Fourquet, C. Thaibaut, H. Jury, I. Lafon, S. Aho, G. Couillault, O. Vagner, B. Cuisenier, J.-P. Besancenot, D. Caillot, A. Bonnin, Prospective survey of indoor fungal contamination in hospital during a period of building construction. *Journal of Hospital Infection*, 2007 (2007;67: 367-373)

<sup>2</sup> 510(k) #K070722, December 2007

<sup>3</sup> Low noise (47 dB) with high air treatment recycle rate of 600 CFM (cubic feet per minute) in standard patient room size.



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# Air/Room Sterilization is the Newest Way to Eliminate Contaminants

Indoor air in a healthcare environment is a veritable invisible cloud of particulate matter, microorganisms (including spores, viruses and bacteria) and volatile organic compounds (emitted by cleaning products and furniture) dust, lint from hospital linens and fabrics, surgical smoke, and even pollen and animal dander brought in on the clothes of staff, patients and visitors. Traces of chemicals, gases and fumes can also be present. Surfaces can become contaminated with fallen particulate matter that can then be picked up and transferred on the hands of healthcare workers.

One new way of battling these contaminants is air/room sterilization, with several technology options available currently:

- STERIS Corporation offers advanced room sterilization with the VaproSure Sterilizer, featuring Vaprox® Sterilant, when used as part of a room's terminal cleaning program. The VaproSure Sterilizer is a low-temperature dry vapor designed to destroy a full spectrum of biological contaminants, including spores, bacteria, viruses and fungi, leaving no residue and no lingering odor.
- The PlasmairT2006 with HEPA-MD technology from AirInSpace is a Food and Drug Administration (FDA)-cleared mobile air decontamination unit which multi-year clinical study data suggests can contribute to reducing the incidence of airborne aspergillosis infection. The AirInSpace technology is designed to demonstrate up to 99.999 percent single-pass inactivation of airborne microorganisms.
- Xenex Technologies, Inc. offers two portable xenon pulse UV sterilization devices that produce brief pulse of intense UV light that penetrates the cell walls of viruses, bacterium, fungi and mold to fuse the strands of DNA (creating thymine dimers), resulting in cell death. The devices are portable, can be operated by one person with minimal training and can sterilize the air and visible surfaces in a room in minutes. These devices are able to kill bacterial spores at a distance of 2 meters from the lamp in 8 minutes without the use of any chemicals.
- Advanced Vapor Technologies' TANCS steam vapor disinfection system is designed to disinfect surfaces colonized by the *Acinetobacter baumannii*, which can cause a variety of diseases, ranging from pneumonia to serious blood or wound infections.

Technologically advanced systems such as these can pick up where traditional environmental cleaning leaves off.

Nick Jacobs, product manager for Infection Prevention Technologies for STERIS, notes, "Recent studies suggest that environmental contamination is a likely source of infection transmission. Despite the best efforts of the environmental services department, cleaners and chemicals are limited in their effectiveness against the most virulent organisms. By adding the VaproSure™ Sterilizer to their arsenal, hospitals can now sterilize all the exposed surfaces in rooms where contamination can put patients most at risk."

In 2006, after 15 years of documented applications, STERIS obtained approval to expand the use of Vaprox Sterilant, the liquid sterilant used in combination with the VaproSure Sterilizer, for the sterilization of dry, pre-cleaned, porous and non-porous exposed surfaces within hospital rooms and emergency vehicles. The VaproSure Sterilizer sterilizes in four microprocessor-controlled phases, providing a dry sterilization process that produces only water vapor and oxygen as by-products.

Airborne pathogens can be deadly for immunocompromised individuals, so air/room sterilization systems play an important preventive role. At this year's annual meeting of the Association for Professionals in Infection Control and Epidemiology (APIC), Ludwig Aho-Glélé, MD, an epidemiologist and director of infection control at Dijon University Hospital, presented data during the AirInSpace-sponsored symposium, "Strategies for Airborne Infection Control Under Challenging Environments and Patient Conditions." Presenting with Aho-Glélé was Michael S. Phillips, MD, an epidemiologist at New York University Medical Center, and Wayne R. Thomann, PhD, director of occupational and environmental safety at Duke University Health System. "Invasive aspergillosis is a potentially deadly infection for immune-suppressed hospital patients," says Aho-Glélé. "The Centers for Disease Control and Prevention (CDC) reports a mortality rate of 95 percent in immune-suppressed patients who are recipients of allogeneic bone marrow transplants and patients who have aplastic anemia. These patients need a highly protective environment."

In July, Texas-based Antimicrobial Test Laboratories conducted two studies, each utilizing five individual test surfaces, to evaluate the capability of the TANCS system. "For each experiment, greater than 10 million viable *A. baumannii* in a 5

percent artificial soil suspension were spread over porous clay surfaces," explains Benjamin Tanner, PhD, president of Antimicrobial Test Laboratories. "At least 2 million viable *A. baumannii* cells were present on each test surface after the inoculum was dried to create a film. The surfaces were then treated briefly with the saturated steam device, for periods of 0.5, 1, 2 and 5 seconds. Immediately after treatment, test surfaces were transferred to a broth suspension for cooling and microbial enumeration by duplicate plating. Elution broth tubes were also incubated to enhance the detection limit or sensitivity for the study."

The experiment demonstrated a rapid reduction in *A. baumannii* levels with increasing treatment time, Tanner said. The destruction of pathogens on the surfaces demonstrated "roughly log-linear kinetics," with total disinfection of *A. baumannii* on the surface occurring within 5 seconds in both trials. Extraordinarily brief treatments of the surface also produced substantial reductions in the pathogen load; more than 97.5 percent of the bacteria were killed within the first 2 seconds of treatment.

TANCS® steam vapor systems offer a simple water-only cleaning and disinfection process. Heat, not pressure, does the deep cleaning and disinfecting. Contained, sustained heat breaks the bond between contaminants and a surface. "The saturated steam device tested here reduced levels of *A. baumannii* on surfaces quickly and dramatically," Tanner says. "Microbial reductions in 'real-life' usage of the device may be greater than indicated by these studies, because they were conservative in that the surface was highly porous and was cooled immediately after treatment. The similarities in performance of the device between trials suggest that it is a reliable and consistent means to disinfect a surface contaminated with *A. baumannii*." **ICT**



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