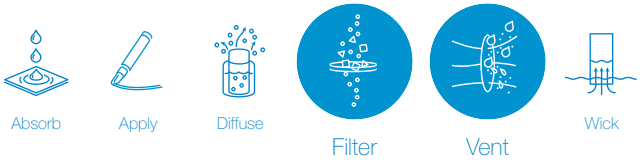
technical brief



Viral Filtration Efficiency (VFE) Testing in Medical Devices: Innovative Material Components that Protect Against HAIs

Challenge

Medical devices that are poorly designed or equipped with suboptimal filtration media can potentially spread viral particles in critical healthcare environments.

At Stake

Filtration media that is ineffective in preventing the spread of healthcare-associated infections (HAI) or other viral agents can result in an increased burden on the healthcare system due to an increased number of days hospitalized and resulting costs. Patient and healthcare workers' lives can be put at risk due to insufficient protection against blood-borne and aerosolized viruses.

Solution

Porex's high-efficiency venting and filtration media tested for Viral Filtration Efficiency (VFE)—and consistently delivering 99.99-99.9999% VFE – enable medical devices to perform their core functions, including protecting medical professional and patients from dangerous blood-borne and aerosolized viruses.

Raising the stakes of HAI spread

Long before "COVID-19" became a common term for the general population, healthcare workers in hospitals, outpatient clinics and other facilities faced daily risks of infection spread. Medical procedures, by nature, place patients and medical professionals in a vulnerable state and present opportunity for exposure to blood-borne and aerosolized viruses. Often, patients are connected to medical devices that either administer drugs or are used to provide vital functionality during a treatment. While these devices are crucial to the procedure, when designed poorly, they can inadvertently be responsible for the transfer of viruses through blood-borne, mucus and aerosol particles to the patient as well as the medical professional.

How common could this particle transfer be? While it would seem like a rarity, on any given day, about one in 31 hospital patients acquires a healthcare-associated infection (HAI)[1]. What's more, these infections account for an estimated 99,000 annual deaths In American hospitals alone, according to the Centers for Disease Control and Prevention (CDC)[2].

Key Facts about HAIs

- One in 31 hospital patients acquires a healthcare-associated infection (HAI)[1]
- HAIs account for an estimated 99,000 annual deaths in American hospitals alone, according to the Centers for Disease Control and Prevention (CDC)[2]
- Reports from the Pan American Health Organization (PAHO) confirm more than a half-million cases of healthcare workers in the Americas contracting HAIs — 2,500 of which have resulted in death[3]
- HAIs have threatened healthcare worker safety long before COVID-19, including both aerosolized and blood-borne viruses.

[1]https://www.cdc.gov/hai/data/index.html
[2]https://patientcarelink.org/improving-patient-care/healthcare-acquired-infections-hais/
[3]https://www.paho.org/en/news/2-9-2020-covid-19-has-infected-some-570000-health-workers-and-killed-2500-americas-paho

POREX Filtration Group®

These startling numbers present enough risk on their own, but with the arrival of an international pandemic transmitted via aerosols containing viral particles, concerns over infectious spread continue to mount. The COVID-19 pandemic has not only placed tremendous pressure on healthcare facility staff to treat patients for the virus itself, but it has amplified unease and heightened the stakes of infectious spread in any medical procedure.

For the medical professional, the ongoing public health crisis has magnified existing fears of HAI contraction. Reports from the Pan American Health Organization (PAHO) underscore the validity of these concerns, confirming more than a half-million cases of healthcare workers in the Americas contracting the virus—2,500 of which have resulted in death. Yet, these staggering statistics only account for infections of the coronavirus, which lives within aerosol particles. In reality, healthcare workers are also exposed to—and have fallen ill or died from—other dangerous viral infections, including blood-borne viruses. These infections threatened worker safety long before the COVID-19 outbreak but have garnered greater attention in the wake of the pandemic.

Amid these active threats, questions are arising around whether medical devices that interact with bodily fluids are harboring contaminants or contributing to new infections. In this new situation, any treatment or care requiring sterility is now under a more critical microscope, making the performance and reliability of medical devices more important than ever before.

Turning to effective materials and testing methodologies

As a result, the industry is facing greater demand for medical devices to perform safely and at a higher level than ever before. Medical professionals and patients are seeking reliability and reassurance that undergoing a treatment or procedure will not open the door to an HAI of any kind—especially COVID-19. This demand means manufacturers of suction canisters, catheters, syringes and other medical devices utilized in aerosol-generating medical procedures must be able to deliver dependable functionality and efficacy in their technologies, helping end users feel confident that viral particles will remain contained.

Material components, although small in size, play a critical role in facilitating this patient and professional reassurance. Medical devices typically contain filtration media to stop the spread of particles while carrying out their primary function (i.e. delivering drugs intravenously, removing harmful fluids from the body, etc.). If this filtration media is faulty or its design is not suitable for the device, aerosols containing blood-borne viral particles can spread during the procedure. When equipped with the right material technologies, medical devices can be used with the confidence that all parties are protected from infectious spread—saving countless lives, significant time and cost.

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How does the manufacturer determine the materials that will best protect against unwanted contamination? Enter: **viral filtration efficiency (VFE)** testing, an increasingly important method for analyzing material efficacy in infection prevention. The test scrutinizes performance standards for various media formulations and designs, providing important guidance for medical device manufacturers selecting product components. Equipped with VFE statistics, these manufacturers can offer safer devices that mitigate the risk of HAIs.

Turning the microscope on medical device material components

Potential infection spread can occur in a range of medical devices. In a surgical setting, suction canisters may be used to clear bodily fluids from a specific site on the body, creating more visibility for the surgeon. In other settings, suction may be used to remove fluid from the airways and prevent blockages in the lungs. Catheters and syringes are used throughout treatments where fluid delivery or release is critical—whether administering saline or blood transfusions or allowing proper flow within the urinary tract or sample collection for diagnostics (ex. like checking O2 levels). While some of these devices may not be used for or during

Manufacturers of suction canisters, catheters, and syringes must be confident in their ability to keep viral particles contained.

treatment of a COVID-infected patient, all of these devices present risks of blood-borne or aerosol particle spread due to their interaction with bodily fluids and critical organs.

These devices, and a range of others that generate blood-borne and aerosol particles, rely on components within the equipment housing to protect against viral particle spread while the device is in use (both in active and inactive states). The filtration media serves as a necessary safeguard while the device provides the fluid transfer or other primary function.

If the filtration media is designed poorly or ineffectively, consequences may be grim. Medical professionals could unknowingly be facilitating cross-contamination, exposing their patients or themselves to the dangerous COVID-19 virus, or another virus that can not only cause illness but can in some cases lead to fatalities. The effects are devastating for any individuals involved, and also on a larger level, threatening the livelihood of both the healthcare facility and medical device manufacturer. Should any legal issues, health code violations or other challenges arise, reputations are at stake.

VFE testing: the ultimate reassurance

For years, the industry relied on bacterial filtration efficiency (BFE) testing as a standard to prevent contamination of medical devices as well as to protect healthcare workers and patients who are potentially exposed to harmful bacteria in their environment. This test is performed on filtration materials and devices that are designed to provide protection against blood-borne or aerosolized bacterial transmission, such as face masks, surgical gowns, caps, air filters including suction canisters, catheters, syringes and other medical devices utilized in aerosol-generating medical procedures

With viral infections being top of mind and the mounting pressure from medical professionals to curb infectious outbreaks in a hospital environment, VFE can help revolutionize the way medical devices and equipment play a role in preventing the spread of viral particles. VFE testing takes BFE a step further by measuring virus-containing aerosol particles of specific sizes to determine efficiency of filtration media in capturing those aerosols. Since different types of viruses and bacteria have specific particle sizes, VFE is able to identify and screen out the threats encountered in these settings. Similar to BFE testing, VFE is tested at a certain air flow rate. Downstream sample is collected from the airstream to determine how many viral colonies are found in the effluent. A VFE test that receives a score of 99.99% filtration efficiency demonstrates that the material is effective in protecting healthcare workers and patients from pathogens.

As such, when manufacturers are designing devices that require VFE filtration, they must ensure that the materials being utilized are effective. Manufacturers can leverage VFE test findings and apply them in their device designs to reassure healthcare professionals and ultimately patients, that their medical devices are not contributing to an infectious viral spread.

Pioneering new material standards: Porex leads the market

Paving the way for the material industry and supporting the medical device industry is Porex, a global leader in porous polymer solutions. Hearing the concerns of its customers in the medical device arena and anticipating the continued effects of COVID-19, Porex took on the challenge of VFE testing, using its experience with BFE testing as a foundation from which to extend the understanding of how Porex media performs against stringent viral filtration efficiency standards. With the desire to provide reassurance to customers asking questions and to give tangible, concrete evidence of material efficacy and safety, Porex initiated VFE testing and became the first in the industry to run the new analysis method on filtration media for medical devices.

In fact, Porex's medical VFE materials have received a 99.9987% viral filtration efficiency (VFE) score while its medical Bacterial Filtration

What is Viral Filtration Efficiency Testing?

Objective:
The test scrutinizes performance standards for various media formulations and designs, providing important guidance for medical device manufacturers selecting product components.

How it works:
VFE testing takes BFE a step further by measuring virus-containing aerosol particles of specific sizes to determine efficiency of filtration media in capturing those aerosols. Since different types of viruses and bacteria have specific particle sizes, VFE testing is able to identify and screen out the threats encountered in these settings. Similar to BFE testing, VFE is tested at a certain air flow rate. Downstream sample is collected from the airstream to determine how many viral colonies are found in the effluent. A VFE test that receives a score of 99.99% filtration efficiency demonstrates that the material is effective in protecting healthcare workers and patients from pathogens.

Efficiency (BFE) materials received a 99.96% score, meaning they are proven effective in preventing healthcare workers and patients from bacterial and viral pathogens. These scores reached the limits of the sensitivity of both the VFE & BFE tests, meaning no viral-containing or bacterial -containing colonies were detected after filtration.

One of the key products where VFE testing is critical is in self-sealing vents used in both Safety IV Catheters and Arterial Blood Syringes. POREX® self-sealing vents effectively "shut off" when in contact with blood or liquid/drug and prevent blood and aerosol bypass. The high BFE and VFE scores protect healthcare workers and patients from exposure to dangerous blood-borne and aerosolized bacterial and viral pathogens.

Due to their high marks in prevention of particle transfer, Porex's high-efficiency materials enable medical devices to perform as they should, carrying out their core functions and requirements while assuaging the fears of patients and professionals that a procedure may increase risk of infection. Ultimately, the capabilities of these materials to provide a reliable barrier to infection yields invaluable results: Medical device manufacturers, facility managers and medical professionals can maintain operations with confidence and security, while patients can seek and receive care with greater trust.

Eye on the future: fostering continued material efficacy

Far beyond the immediate effects of COVID-19, medical device manufacturers will be challenged with upholding equipment efficacy and maintaining end-user confidence. Preserving the conditions of a sterile healthcare environment will be of paramount concern as the industry and the world as a whole return to equilibrium following the pandemic. Even as the virus subsides, the questions and uncertainties it has created will linger for both patients and professionals.

> By partnering with Porex, manufacturers can seek out materials that not only perform to desired VFE testing standards but are also optimized for their unique devices.

With this in mind, medical device manufacturers will need to leverage the appropriate, effective filtration media within their products. By partnering with Porex, manufacturers can seek out materials that not only perform to desired VFE testing standards but are also optimized for their unique devices. A collaborative innovation process that analyzes product goals, functional requirements and the behaviors of various materials ensures devices are equipped with components that best suit their needs. Combined with a proven depth of material expertise and custom engineering capabilities that prioritize designing for more efficient manufacture, medical device suppliers can create a product that is highly specified and effective.

Long term, this emphasis on material efficacy and optimization will allow manufacturers to strengthen their positioning as reliable organizations that have taken every measure to enable safe, thoughtful healthcare—the most critical element of a successful, trusted brand.

To learn more about filtration media for medical devices and Porex's VFE testing methods, visit us at porex.com.

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