



WOUND CARE

ANTIMICROBIAL POLYURETHANE FOAMS PROVIDE ADVANCED, EFFECTIVE WOUND CARE

Innovative Foams in Wound Dressings
Offer Quick Kill and Long-Term Efficacy
for Infection Prevention

NANOSILVER-MODIFIED HYDROPHILIC FLEXIBLE POLYURETHANE
FOAMS FOR ANTIMICROBIAL WOUND DRESSING APPLICATIONS

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Caring for wounds effectively is a top concern for hospitals, particularly in today's climate of lifestyle-related chronic diseases, such as diabetes, and rising geriatric population. Wound dressing OEMs and contract manufacturers require the ability to produce wound care dressings that prevent infection and are durable, conformable as well as comfortable for the patient. They often turn to silver as an antimicrobial agent, but that doesn't come without problems.

How can wound dressing OEMs and contract manufacturers include the right antimicrobial materials in their wound dressings, and how can they ensure that the silver they choose meets medical standards as well as creates patient satisfaction? Fortunately, advanced polyurethane foams incorporated with nanosilver exist to ensure hospitals can reduce infection rates while meeting the demands of the increasing need for wound care. The result is a nanosilver-modified hydrophilic flexible polyurethane foam ideal for antimicrobial dressings, with a quick kill and long-term efficacy.

This white paper will review the current wound care landscape and examine the benefits of including nanosilver-modified antimicrobial foam in wound care dressings. It will also address findings from the latest research.

The Need for Advanced Wound Care Is Growing

One of the biggest challenges that hospitals and medical providers face is caring for the increasing number of patients. The need for advanced wound care has grown exponentially due to the prevalence of lifestyle-related chronic diseases such as diabetes, which require extreme caution when caring for wounds. The rising geriatric population, increased rates of severe anemia, radiation tissue damage, a higher demand for elective surgical procedures, burns, severe bacterial infections, and gangrene have all increased the demand for advanced wound care solutions.



Meanwhile, according to the U.S. Centers for Disease Control and Prevention, an estimated 648,000 people in the U.S. develop infections during hospital stays. Annually, 75,000 of them die¹. Additionally, hospitals are under pressure to reduce the rate of re-admission, which can result in financial penalties at the State and Federal level. Because of the need to effectively manage wound exudates and prevent infection, antimicrobial dressings are gaining more acceptance to prevent healthcare associated infections. Wound dressings need to adequately absorb and retain exudates, or the moisture may cause skin maceration.

Hydrophilic polyurethane foam dressings absorb exudates and lock fluid within the core of the dressing. Foam dressings may take on a broad range of physical and absorbent characteristics based on the synthetic route selected to produce the foam which, in turn, can affect its ability to retain and release desired therapeutic agents, such as anti-microbial and/or anti-fungal agents, which are gaining popularity. The idea is to create wound dressings that can adequately absorb wound exudates and maintain antimicrobial efficacy at the wound site for a desired period of time to promote new cell growth and healing.

To combat infection and provide durable, effective antimicrobial wound care dressings, many wound dressing OEMs and contract manufacturers are offering antimicrobial dressings with silver. While not new, silver's infection-fighting properties have been in use for over 2,000 years medicinally and as a preservative.

Silver's long healing history dates back to the ancient Greeks and Romans, who used silver vessels to preserve drinking water. In the 17th century, Angelus Sola used silver nitrate to treat epilepsy, tabes, and chorea². The tradition of adding silver coins to containers of drinking water has continued into today's space age, with NASA selecting a silver-based water purification system to maintain water purity and a bacteria free environment on the Space Shuttle³. Under new Federal and State legislation, hospitals are now penalized financially because of re-admission of patient's due to infections acquired by an in-hospital procedure or stay. Hospitals have financial incentives to make sure infections do not occur, forcing the demand for infection control to rise. This has driven advances in antimicrobial technologies in recent years, including the use of silver in wound dressings.



What's Missing from Current Wound Care Products

Many OEMs and manufacturers struggle to find the right polyurethane foam and silver combination. Not all silver products are the same due to the size and volume of silver used.

For example, some silver-infused dressings use silver salt, which does not uniformly distribute the silver to the wound site. This can result in skin discoloration, a cosmetic problem that nevertheless does not lead to patient satisfaction. Additionally, due to the high volume of silver needed when using silver salt, the dressings tend to be costlier.

The simple truth is, most current methods of infusing silver into wound care dressings do not have a good way to disperse small amounts of silver evenly throughout the foam in the dressings. As more patients require wound dressings that absorb and retain exudates, as well as prevent infection, hospitals will look to new polyurethane foams that contain silver to reduce infection rates and improve healing.



The Solution: Nanosilver-Modified Hydrophilic Flexible Polyurethane Foams

To overcome the challenges inherent with wound care, including preventing healthcare associated infections, and providing hospitals with the type of wound care dressings that improve patient care, wound dressing OEMs and contract manufacturers are turning to nanosilver-modified hydrophilic flexible polyurethane foams. These foams, which are manufactured using a catalyst-free clean prepolymer technology that stabilizes silver nanoparticles and other synergistic additives, exhibit highly efficacious antimicrobial activity.

The antimicrobial efficacy of wound care dressings can be enhanced synergistically by the inclusion of one or a combination of Polyhexamethylene biguanide (PHMB) and chlorhexidine gluconate (CHG). Regarding the antibacterial mechanism of the PHMB, the literature shows conflicting interpretations, for example, binding of PHMB to the bacterial cell membrane, causing complex reactions to alter the integrity of the cell membrane wall thus reducing wall strength and hence, death of bacterium⁴ or entering the cells and selectively condensing bacterial chromosomes⁵. CHG is an anti-septic and anti-bacterial agent. It is positively charged and reacts with the negatively charged microbial cell surface, thereby destroying the integrity of the cell membrane. Subsequently, CHG penetrates into the cell and cause leakage of intracellular components leading to cell death. Since Gram-positive bacteria are more negatively charged, they are more sensitive to this agent⁶.

With nanosilver-modified hydrophilic flexible polyurethane foams, the absorbent foam is incorporated with nanocrystals of silver and PHMB. The silver and PHMB are uniformly dispersed throughout the foam during the proprietary manufacturing process, and the foam absorbs exudates effectively. The small amount of silver used is not only highly effective at killing bacteria, but also is less costly to include in wound care dressings.

The result is a new, innovative polyurethane foam material ideal for advanced wound care, featuring quick kill and long-term efficacy through the slow release of silver ions over time to effectively control infection as well as absorb and retain exudate under compression. Meanwhile, its fast wicking properties maintain the appropriate moisture balance in the wound bed for faster healing and soft feel characteristics improve patient comfort. The nanosilver does not leach into the wound bed, minimizing discoloration on the patient's skin.

FEATURES OF NANOSILVER/PHMB-INCORPORATED POLYURETHANE FOAM

- **Highly efficacious antimicrobial activity with >99.99% for Gram-positive and Gram-negative bacteria species**
- **Quick kill and long-term efficacy through slow-release of silver ions**
- **High free swell absorptive capacity**
- **High exudate retention under compression**
- **Fast wicking and maintaining moisture balance in wound bed for faster healing**
- **Super soft velvety feel for patient comfort**
- **Ideal for medium to high exudating wounds**
- **Non-adherent**

Benefits of Nanosilver-Incorporated Polyurethane Foam

A number of significant benefits emerge when wound dressing OEMs and contract manufacturers use nanosilver-modified hydrophilic flexible polyurethane foams in wound care dressings, and when hospitals choose products including these foams, such as:

Stronger defense against infection

The quick kill of PHMB and CHG and long-term efficacy of slow release nanosilver ions create a combination that helps prevent wounds from becoming infected while healing and provide more effective infection management.

Dressings that last longer

Due to the durability of the polyurethane foam and the slow release of silver ions, the dressing maintains >99.99% efficacy for a longer period of time, for example, up to 7 days. It can be removed and replaced to clean the wound.

Patient comfort

Because the nanosilver-modified polyurethane foam is non-adherent due to fine cell structure, removal of the dressing does not cause trauma to the patient. Additionally, the reduced amount of silver in the dressing means no skin discoloration.

Compliance and low toxicity rating

Because the dressings contain less silver due to the unique nanosilver incorporation process, they have shown compliance to ISO 10993 biocompatibility guidelines, such as, cytotoxicity, Guinea pig maximization sensitization, and intracutaneous irritation.

Research Supports Efficacy of Nanosilver-Modified Hydrophilic Flexible Polyurethane Foams

In a recent study, the objective was to design and develop a biocompatible, super soft, high absorbent/retention wound dressing material consisting of polymer stabilized nanosilver and one or a combination of PHMB and CHG for exudate management, while at the same time maintaining antimicrobial efficacy of greater than 4-log reduction (>99.99%) against Gram-positive and Gram-negative bacteria species for an immediate and extended period of time.



A master roll of silver antimicrobial foam with a carrier paper
4.5mm thickness x 381mm width x 45.72m length

Materials and Methods

The antimicrobial flexible hydrophilic polyurethane foam was manufactured utilizing a catalyst free clean prepolymer technology, in which an isocyanate terminated polyurethane prepolymer was activated using an aqueous component containing polymer stabilized silver nanoparticles and further comprising one or a combination of other synergistic additives, for example, PHMB and CHG. During the foaming reaction, active ingredients were incorporated into the polyurethane matrix. Foam was then subjected to a drying process to obtain the silver antimicrobial foam.

Antimicrobial properties of the foam were evaluated in accordance with the Modified AATCC Test Method 100 against Gram-positive and Gram-negative bacteria species. Specified layers of sample were inoculated evenly with the challenge organism. After inoculation, samples were incubated at specified temperature for 24 hours. Immediately after inoculation, zero contact time samples were neutralized with D/E Broth (Dey-Engley Neutralizing Broth). Serial dilutions (10^{-2} , 10^{-3} , 10^{-4} , 10^{-5}) were prepared and plated in duplicate using 0.85% saline. All plates were incubated at 37 °C for 24 hours, 3-days, and 7-days. The number of bacteria per specimen was reported and the percent reduction and log reduction of bacteria was calculated.

Absorbent characteristics of the foam were measured in accordance with BS EN 13726-1:2002, test methods for primary wound dressings, Section 3.2. The physical properties were measured as per ASTM D3574 test standard. The silver and PHMB analyses were performed on production materials representing start to end of the production and specimens selected across the roll width. Silver analysis was performed with a Perkin Elmer Optima 8300 inductively coupled plasma optical emission spectroscopy (ICP-OES), while PHMB analysis of the foam was performed using liquid chromatography-mass spectrometry (LC-MS) and hydrophilic interaction liquid chromatography (HILIC).

ISO 10993 testing was performed in accordance with ISO guidelines to determine biocompatibility of the foam.

Table 1: The efficacy of silver antimicrobial foam against Gram-positive, Gram-negative bacteria and fungal species.

Contact Time	<i>S. aureus</i> (Percent/log)	<i>S. epidermidis</i> (Percent/log)	<i>E. faecalis (VRE)</i> (Percent/log)	<i>K. pneumoniae</i> (Percent/log)	<i>P. aeruginosa</i> (Percent/log)	<i>E. coli</i> (Percent/log)	<i>Candida albicans</i> (Percent/log)
24 Hours	>99.99 >4.03	>99.99 >5.47	>99.99 >4.11	>99.99 >4.07	>99.99 >4.05	>99.99 >4.99	>99.99 >4.03
3 Days	>99.99 >4.03	N/A	>99.99 >4.11	>99.99 >4.07	>99.99 >4.05	N/A	>99.99 >4.03
7 Days	>99.99 >4.03	>99.99 >5.12	>99.99 >4.11	>99.99 >4.07	>99.99 >4.05	>99.99 >4.90	>99.99 >4.03

- **Sample Size:** 48mm
- **Number of layers:** One (1)
- **Neutralizer:** D/E Broth (Dey-Engley Neutralizing Broth)
- **Neutralizer Volume:** 100 mL
- **Target Inoculum level per sample:** (1-5) x 10^{-6} CFU
- **Inoculum Volume:** 1.0mL
- **Inoculum Population:** 1.0×10^{-6} CFU/mL
- **Inoculum Carrier:** 0.85% Saline,
- **Dilution Media:** 0.85% Saline,
- **Incubation Temperature:** 35-39°C/27-29°C

The results indicate that the foam dressings were highly efficacious against Gram-positive and Gram-negative bacteria species and fungal species (*Candida albicans*), with >99.99% efficacy (>4 log reduction) exhibiting both short-term and long-term antimicrobial activities.

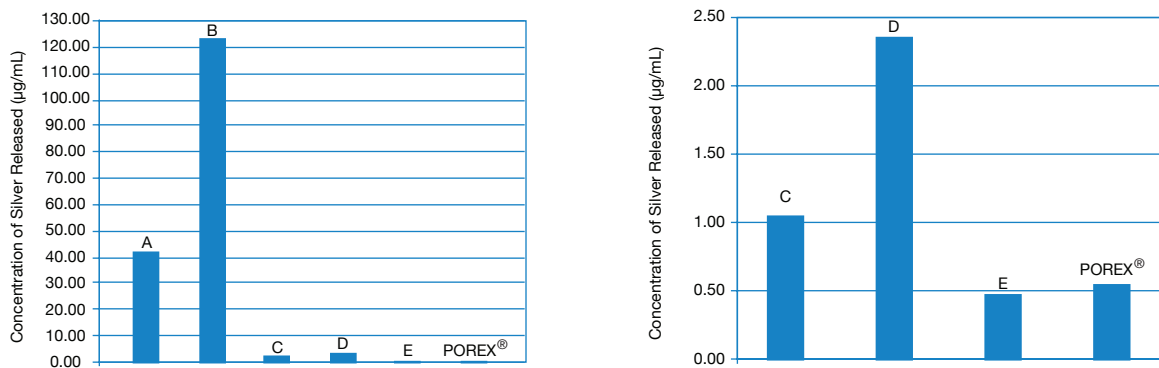


Table 2: Typical absorption and physical characteristics of silver antimicrobial foam

Property	Typical Value
Foam Thickness	4.5mm
Density	96.1-120.1 kg/m ³
Tensile Strength	160kPa
Elongation at Break	225%
Tear Strength	290 N/m
Absorption rate of a water drop	~2sec
Free swell absorptive capacity	~ 15 g/g
Fluid retention under 40mmHg	~10 g/g

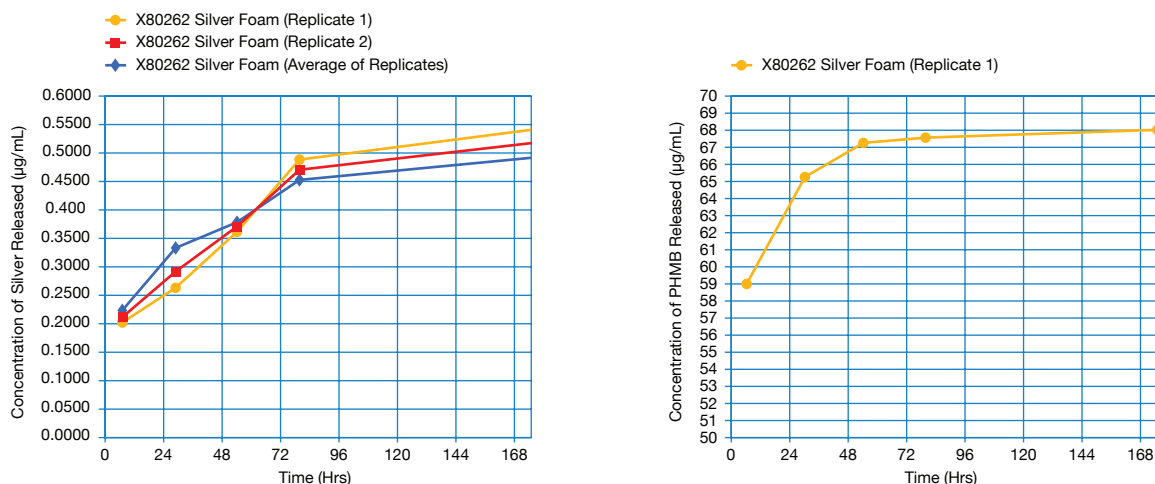
The resulting dressing material with density of 96.1-120.1 kg/m³ and excellent physical characteristics was highly absorptive and showed instantaneous absorptive characteristics together with free swell fluid absorbent capability of about 15 g/g (1500%) and fluid retention under 40mmHg compression of about 10g/g (1000%).

Figure 1: Cumulative Silver Concentration Eluted from Commercially Available Silver Containing Wound Dressings Over Multi-Day Exposure to Simulated Wound Exudate



POREX® antimicrobial foam achieves the same efficacy as competitive foams with the lowest silver elution.

Figure 2: Cumulative Silver (Left) and PHMB (Right) concentrations released from POREX® silver foam wound dressing. The silver elution profile revealed the elution rate from 0.200 to about 0.450 µg/mL during initial 5 to 77 hrs time frame and then a slow release from there to 7-day time point. The PHMB elution profile showed cumulative release of 59.0 to 67.3 µg/mL during 5-53 hrs time frame followed by a slow release of about 68 µg/mL from 53 to 7-day time point.



	5 Hour (µg/mL)	29 Hour (µg/mL)	53 Hour (µg/mL)	77 Hour (µg/mL)	173 Hour (µg/mL)
Cumulative Silver Elution (Average of Replicates)	0.199	0.263	0.361	0.488	0.544
Cumulative PHMB Elution	59.000	65.292	67.333	67.500	68.792

Kirby Bauer Zone of Inhibition (ZOI) Assay against *Staphylococcus aureus* and *Pseudomonas aeruginosa*

Neither of the samples tested exhibited any appreciable zone of inhibited bacterial growth beyond the area in direct contact with samples. Results showed silver foam inhibiting bacterial growth on the agar surface directly beneath the area that the specimens were in direct contact indicating that silver antimicrobial foam does exhibit antimicrobial activity at sample's surface, but it does not leach an appreciable quantity of active antimicrobial agent that would provide antimicrobial action outside the area in direct contact with the sample.

Study Conclusion

A highly efficacious, cost effective, synergistically modified antimicrobial polyurethane absorbent wound dressing material with biocompatible compliance was developed utilizing polyurethane prepolymer technology incorporating polymer-stabilized colloidal silver nanoparticles and one or a combination of a PHMB and CHG.

The resulting dressing material with density of 6-7.5 lbs/ft³ [96.1 – 120.1 kg/m³] was highly absorptive and showed instantaneous absorptive characteristics together with free swell fluid absorptive capacity of about 15 g/g (1500%) and fluid retention under 40mmHg compression of about 10g/g (1000%) together with excellent physical foam characteristics.

When tested in accordance with AATCC Modified Test Method 100, dressing material showed short-term (24 hrs) and long-term (7 days) efficacy of >99.99% (>4.0 log reduction) against Gram-positive and

Gram-negative bacteria species and fungal species. Silver and PHMB analysis of the foam showed a uniform distribution of active ingredients throughout the foam during the entire foam production.

Silver and PHMB release kinetics of the foam showed a cumulative elution of silver from 0.200 to about 0.450 µg/mL during initial 5 to 77 hrs time frame and then a slow release until 7-day time point while PHMB elution profile exhibiting cumulative release of 59.0 to 67.3 µg/mL during the first 5-53 hrs followed by constant release of about 68 µg/mL until 7-day time point.

Kirby Bauer Zone of Inhibition (ZOI) Assay confirmed that the foam does not leach an appreciable quantity of active ingredients, but rather to react with the exudate absorbed into the foam and preventing the foam itself from bacterial colonization.



How POREX® Revolutionizes Wound Care Dressings

POREX® makes it possible to produce high-performance wound care dressings with its nanosilver-incorporated polyurethane foams. The POREX® silver antimicrobial foam is developed by combining the Medisponge® SuperSoft hydrophilic polyurethane foam technology with polymer colloidal nanosilver to deliver infection prevention foam with advanced performance and comfort characteristics. Because the silver in the antimicrobial foam is from nanocrystals, it dissolves during the process of manufacturing the foam. This results in the silver being uniformly dispersed and distributed throughout the matrix of the foam. It becomes a part of the foam, not a coating or surface spraying or impregnation that lays on top of it, and cannot be washed off nor seep into the wound. Because the silver is incorporated directly into the foam through a proprietary manufacturing process, it lasts longer with a control release rate.

Additionally, since a small amount of silver has been proven to achieve the same efficacy of foam made of silver salt, POREX® does not need to overuse silver. The nanosilver together with synergistic additives helps reduce the silver content, reducing cytotoxicity levels and achieving ISO 10993 compliance for intracutaneous irritation and Guinea pig maximization sensitization tests. POREX® combines two different materials, the Medisponge® SuperSoft foam and the polymer colloidal nanosilver, to achieve the synergistic quick kill and long-term efficacy expected from wound care dressings.

POREX® silver antimicrobial foam fights healthcare associated bacteria and fungus infections. When tested in accordance with AATCC Modified Test Method 100, the POREX® silver antimicrobial foam dressing material showed short-term (24 hours) and long-term (7 days) efficacy of >99.99% (>4.0 log reduction) against Gram-positive bacteria (*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Enterococcus faecalis*), Gram-negative bacteria (*E. coli*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*) species and fungus (e.g., *Candida albicans*).

Request more Information:
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About POREX®

POREX® is trusted by global brands for the performance excellence required in functional components. Our unmatched expertise in porous plastics, bonded fiber, and open-cell foam technologies create today's most innovative products. For over 50 years, we've delivered the optimal solutions behind innovations in biomedical, transportation, industrial, electronics, and consumer markets.

At POREX®, we go to great lengths to provide a comprehensive, collaborative engineering partnership with our customers. We offer high-value porous solutions across functions such as absorbing, applying, diffusing, filtering, venting and wicking that enable our customers to bring new ideas to life. With our unmatched experience, stringent regulatory and quality standards, extensive global footprint, and clean manufacturing practices, we partner with leading companies to create a safer, healthier, and more productive world.

¹ <https://www.consumerreports.org/cro/health/hospital-acquired-infections/index.htm> - move to reference section to be consistent

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