agion®

Trusted Antimicrobial Solutions For Medical Devices

The Growing Need for Antimicrobial Protection

According to the U.S. Centers for Disease Control and Prevention (CDC), more than two million people become ill with antibiotic-resistant infections each year. Healthcare-associated infections (HAIs), many of which are caused by antibiotic-resistant bacteria, impact 1 in 25 patients and claim the lives of 75,000 people in the U.S. each year. They also cost the healthcare industry between $36-$45 billion annually. The spread of these infections occurs through skin-to-skin or skin-to-surface contact and, in the healthcare setting, medical devices are some of the most common sources.

On top of these startling statistics, the Affordable Care Act (ACA) has provisions that financially penalize facilities with high infection rates, and increasingly informed, connected healthcare consumers are using tools like Medicare's "Hospital Compare" to make decisions about where to go for quality care.

All of these factors are forcing healthcare providers to put more pressure on medical-device manufacturers and other suppliers to share in the responsibility to improve patient care while simultaneously reducing costs. These shifts in healthcare will essentially change the suppliers' role in the industry – especially when it comes to infection prevention.

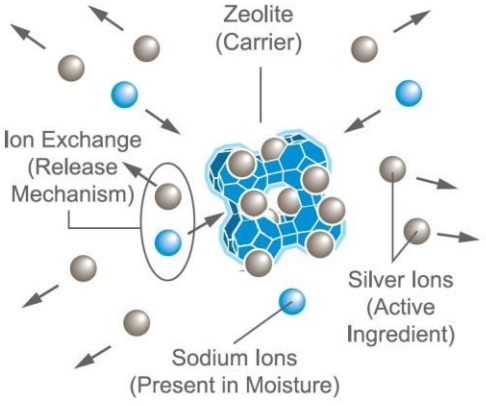
For medical-device companies, their role is clear: protect the surface to better protect the patient.

Agion® Antimicrobial Solutions

Agion Antimicrobial technology inhibits the growth and colonization of microorganisms on the surfaces of medical devices and equipment by adding an important layer of protection to these critical products. Unlike common disinfectants and antibacterial products, Agion Antimicrobial protection can be designed to meet your unique product requirements for antimicrobial performance and lifetime. With several medical grade formulations and a controlled release mechanism of action, a customized solution can be developed to meet your needs.

How Agion® Antimicrobial Works

When moisture or other fluids are present, the conditions for microbial growth become ideal. This is when the Agion Antimicrobial goes to work.



The silver ions exchange with ions in the moisture or fluid, typically sodium and potassium, resulting in controlled delivery of silver ions.

Agion® Antimicrobial Performs Against Clinically Relevant Organisms

Microbe Type	Name	Associated HAIs	Log Reduction Performance
Gram +	*Staphylococcus aureus*	Bloodstream infections, Surgical site infection, Pneumonia	6
	Methicillin-resistant *Staphylococcus aureus* (MRSA)	Bloodstream infections, Surgical site infection, Pneumonia	7
	Vancomycin-resistant Enterococci (VRE)	Bloodstream infections, Surgical site infection, Urinary tract infections	6
Gram -	*Pseudomonas*	Bloodstream infections, Surgical site infection, Pneumonia	6
	Klebsiella pneumoniae	Pneumonia, Bloodstream infections, Surgical site infection	6
	E. coli	Urinary tract infections, Pneumonia, Bloodstream infections, Surgical site infections	6
	Acinetobacter	Pneumonia, Bloodstream infections, Surgical site infection	6
	Carbapenem-resistant Enterobacteriaceae	Bloodstream infections, Urinary tract infections, Pneumonia	7
Fungi	*Candida*	Bloodstream infections, Surgical site infection	6
Virus	H1N1	Influenza	99.99% inactivation
	H3N2		
	H2N2		
	Avian Influenza A (H5N1)		
	Avian Influenza A (H9N2)		
	Swine Influenza (H1N1)		
	Equine Influenza (H3N8)		
	Influenza B		

Your Trusted Antimicrobial Partner

Agion Antimicrobial is a trusted solution for various applications within the healthcare industry. With an experienced staff and proven product, we have become a leading supplier of antimicrobials in the healthcare industry. Beyond our experience and reliability, our technology is backed by:

- A recommendation by the Society for Healthcare Epidemiology of America for use of Agion-treated catheters for the prevention central-line associated bloodstream infections
- Clinical data supporting the use of Agion antimicrobial in medical devices
- FDA Master Files on our medical grade formulations
- An Active Substance Master File with an EU Competent Authority

MedMAP® - Medical Device Market Acceleration Program

Accelerating time to market for devices incorporating antimicrobial technology

Strategy & Planning
- Design Input
- Regulatory Strategy
- Risk Management
- Predicate Device Analysis

Product Design
- Application
- Efficacy
- Lifetime
- Cost

Product Development
- Formulation Development
- Experimental Design

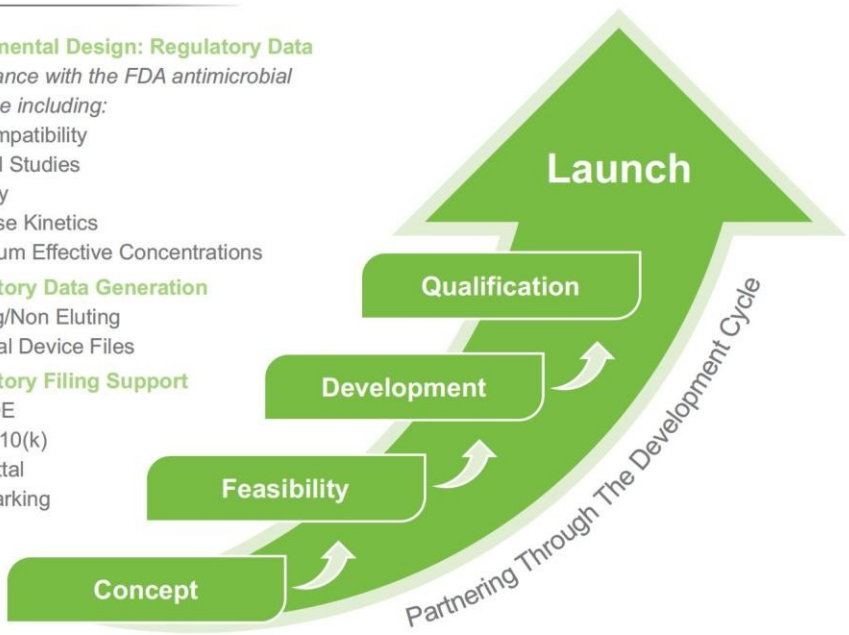
Performance Evaluation
- Verification/Validation
- Toxicity

Experimental Design: Regulatory Data

Compliance with the FDA antimicrobial guideline including:
- Biocompatibility
- Animal Studies
- Toxicity
- Release Kinetics
- Minimum Effective Concentrations

Regulatory Data Generation
- Eluting/Non Eluting
- Medical Device Files

Regulatory Filing Support
- Pre-IDE
- FDA 510(k) submittal
- CE Marking



Our Expertise and Capabilities

At Sciessent, our products are only as good as the experts behind them. With in-house microbiology and analytical laboratories, we provide the support and testing needed to quickly and efficiently design the optimal antimicrobial performance for your product. Whether you know the exact solution you need, or require a partner to help you customize the solution that is best for your application, Sciessent has you covered.

Lab Testing Capabilities

Analytical Testing
- GFAA Analysis for Metal Ions
- Ash Test
- Moisture Content Analysis
- Scanning Electron Microscopy

Antimicrobial Testing
- ASTM-E2149-01
- ASTM E2180-01
- AATCC100
- JIS L 1902 : 2008
- JIS Z 2801 : 2000
- ISO 20743 : 2013
- ISO 22196 : 2007

Custom testing can be performed based on customer requirement

Examples of Applications Where Agion® Antimicrobial Can Add Value:

- Implantable Devices
- Bio Connectors & Adaptors
- Medical Monitoring Devices
- Medical Tubing
- Drug Delivery Devices
- Reusable Medical Devices
- Wound Care Devices

Predicate Devices Using Agion® Antimicrobial

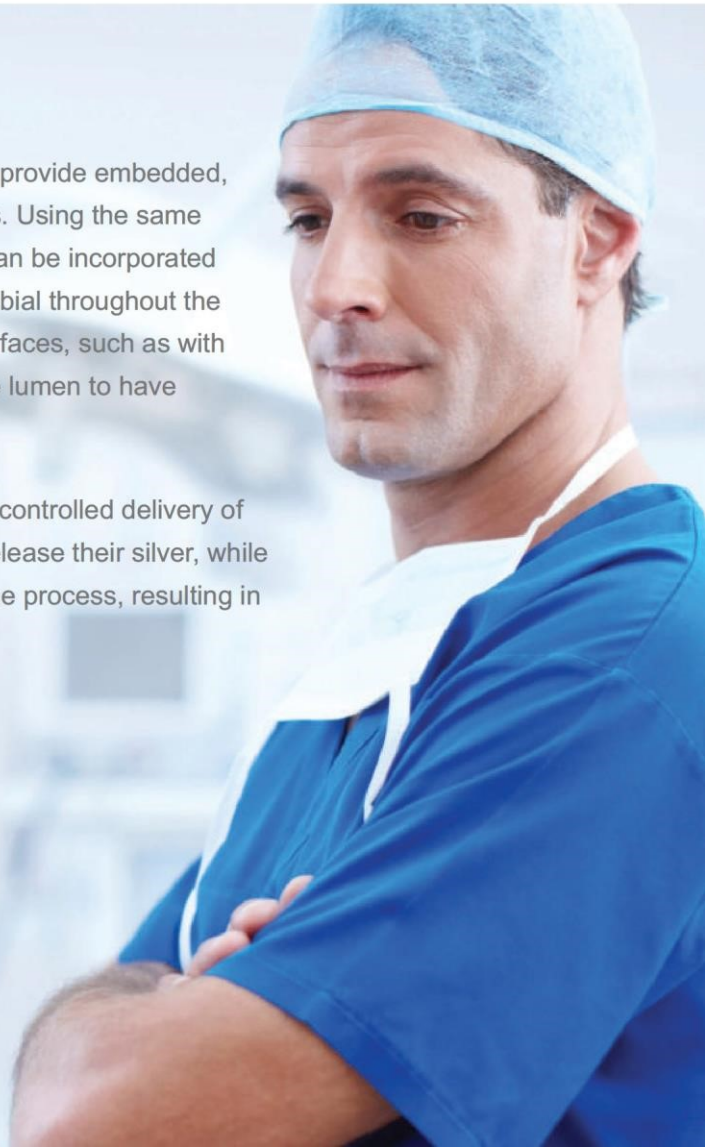
- Central Venous Catheters *(Vygon – K061250)*
- Pain Management Catheters *(Stryker – K072702)*
- Luer-activated Needless Connectors *(Medegen/CareFusion – K083765)*
- Balloon-style Gastronomy Tube *(Novartis – K001916)*
- Respirator Face Mask *(Nexera – K090414)*
- Stethoscope Diaphragm *(DRG – K002047)*
- Introduction/Drainage Catheter *(HealthShield – K991117)*

Compatible with the Full Range of Medical Polymers

Agion® Antimicrobial is easily compounded into plastics to provide embedded, durable antimicrobial surfaces to molded or extruded parts. Using the same processing techniques as adding a color pigment, Agion can be incorporated into essentially all polymers. Incorporating Agion Antimicrobial throughout the polymer is particularly valuable for intricate or complex surfaces, such as with catheters where it is desirable for both the exterior and the lumen to have antimicrobial properties.

In addition to ease of processing, Agion has the benefit of controlled delivery of silver ions. Other silver antimicrobials simply dissolve to release their silver, while Agion delivers silver ions through a controlled ion exchange process, resulting in longer use life and greater durability.

- TPU
- Silicone
- PEEK
- UHMWPE
- ABS
- PP
- PC
- PMMA
- PTFE
- PET



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The Agion® Antimicrobial is presently registered by the United States Environmental Protection Agency as a preservative and bacteriostatic agent for use in treated articles under 40 CFR 152.25a. The information presented herein is not intended to support or endorse public health claims for treated articles. The Agion Antimicrobial is also used in medical devices under the Food and Drug Administration in the US; those medical device claims are based on safety and efficacy testing and are limited to those approved by FDA. In the EU, the Agion Antimicrobial is used in medical devices under the Medical Device Directive: those medical device claims are based on safety and efficacy testing and are limited to those approved by the designated Competent Authorities and/or Notified Bodies

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