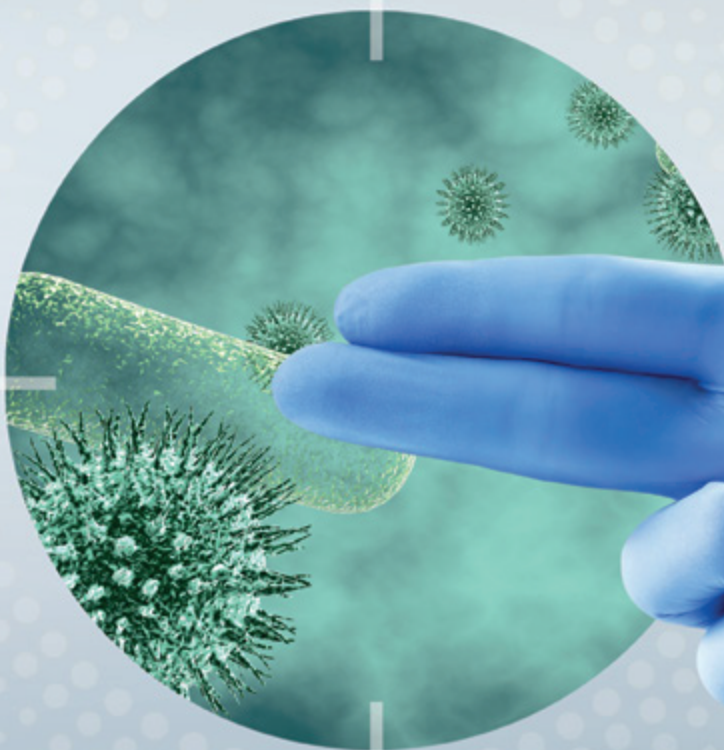


KILLS UP TO **99.999%** MICROBES

to help prevent healthcare-associated Infections



- World's 1st non-leaching antimicrobial gloves
- Kills up to 99.999% microbes
- Provides active protection against HAIs
- Tested non-sensitising on skin

WHAT ARE HEALTHCARE-ASSOCIATED INFECTIONS (HAIs)?

Healthcare-associated infections are infections that develop as a result of medical care in a hospital or other healthcare facilities, which were neither present nor incubating at the time of transmission. It includes infections acquired by patients in the medical facility but emerging after discharge, as well as occupational infections among staff.

WHAT ARE THE ADVERSE EFFECTS OF HAIs?

Every year HAIs cause unnecessary suffering and higher medical cost for hundreds of millions of patients and their families around the world. These infections prolong hospital stay, increase the risk of post-operative complications and disabilities, increase resistance to antimicrobials and even result in unnecessary deaths and massive financial losses to the healthcare system.





USA

Affected Patients 1.7 million

Deaths 99,000

Cost approx. USD 6.5 billion

EU

Affected Patients 4.1 million

Deaths 37,000

Cost approx. EUR 7 billion

Figure 1. Annual Impact of HAIs in the USA and Europe

Source : Adapted from World Health Organization, Healthcare-Associated Infections Fact Sheet¹.

HOW DO HAIs OCCUR?

Infections occur when microbes enter the body, breed and cause a reaction to the body.

3 things lead to an infection:

i. **Source**

A source is one within which an infectious agent, such as a virus, bacteria or other microbe thrive and reproduce. In healthcare settings, people such as patients, healthcare workers, visitors and family members can be a source of infection. Other source includes the healthcare environment where microbes can live and breed such as on dry and wet surfaces, dust or decaying debris, moist areas and indwelling medical devices.

ii. **Susceptible Person**

A susceptible person is someone who is not vaccinated or otherwise immune, or person with a weakened immune system of which once exposed, provides a way for the microbe to enter the body. For an infection to take place, the microbe must first enter a susceptible person's body and attack the tissues, multiply and cause a reaction.

iii. **Transmission**

Transmission refers to the route or method by which microbes are transferred from the source to the susceptible person. In healthcare settings, microbes travel via several ways - physical contact (touching), sprays and splashes, inhalation, and sharps injuries, i.e. when a needle, scalpel or other medical instruments penetrate the skin. Among these routes, physical contact is the main mode of transmission in the healthcare setting.²

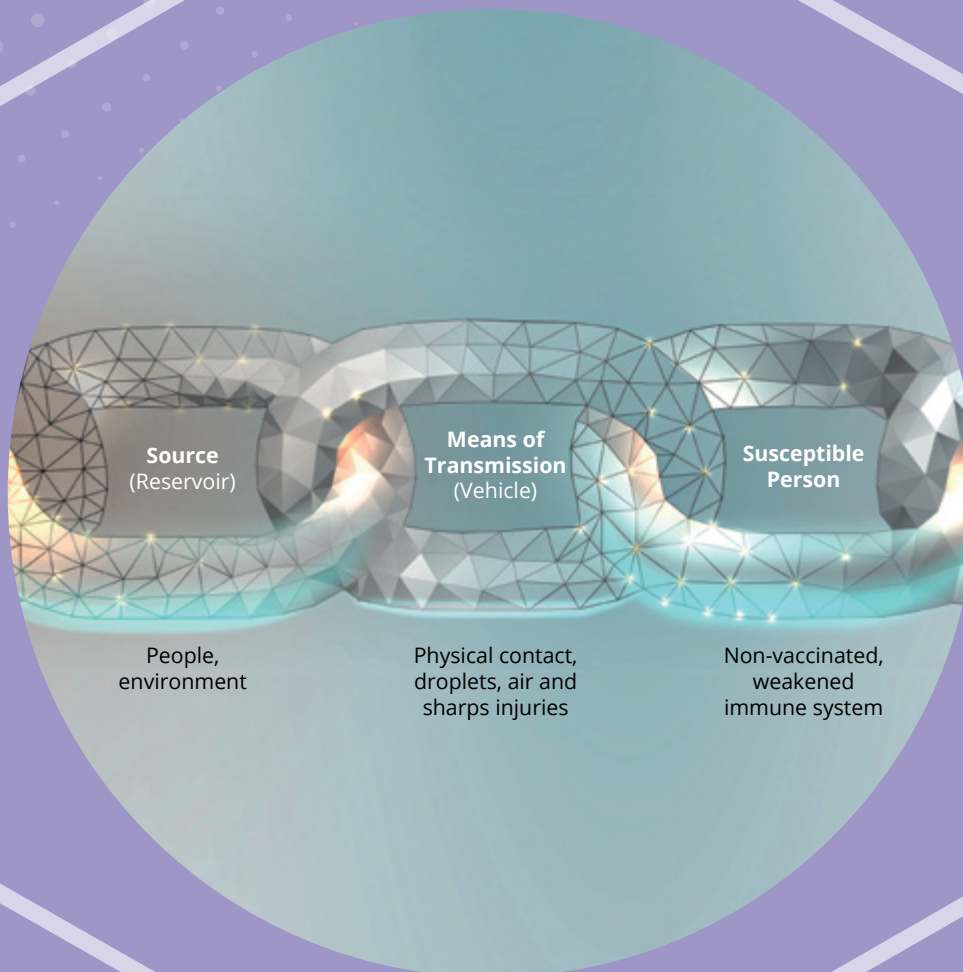


Figure 2. Chain of Infection



THE ROLE OF MEDICAL GLOVES

The World Health Organization (WHO) recommends wearing medical gloves to reduce the risk of:

- i. Blood and body fluid contamination of healthcare workers' hands.
- ii. Microbial dissemination in the environment, microbial transmission from healthcare workers to the patients and vice versa, as well as among patients.

Several clinical studies have confirmed the role of medical gloves in preventing contamination, dissemination and transmission of pathogens in healthcare settings. Thus, gloves should be worn as precautions throughout patient care activities that may involve exposure to blood and body fluids and during outbreak situations.

Nonetheless, inappropriate glove storage, and inappropriate techniques for glove donning and removing, may result in microbial transmission. Once contaminated, gloves can become a source for spreading infectious agents to healthcare workers, patients and environmental surfaces.



ANTIMICROBIAL GLOVE: AN ACTIVE APPROACH IN PREVENTING HAIs

Contrary to conventional medical gloves that serve only as a passive barrier between microbes and your hands, AMG antimicrobial gloves can play an active role in reducing the spread of infections by using its killing mechanism.

The AMG glove is designed to kill microorganisms on the external side of the glove quickly upon contact. The active ingredient on the glove is a photosensitizer which generates singlet oxygen when exposed to light. This singlet oxygen oxidizes the bacteria's protein and lipid, thus leading to the death of microbes. [Figure 3]

Ultimately, AMG antimicrobial glove helps reduce the risk of transmission from an infection source to a susceptible patient.

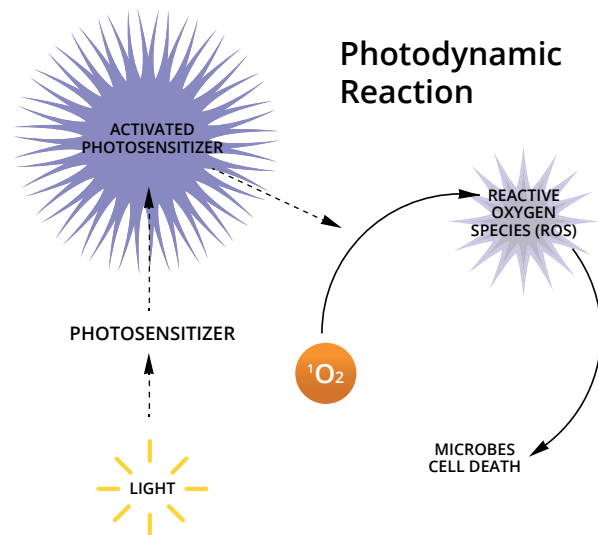
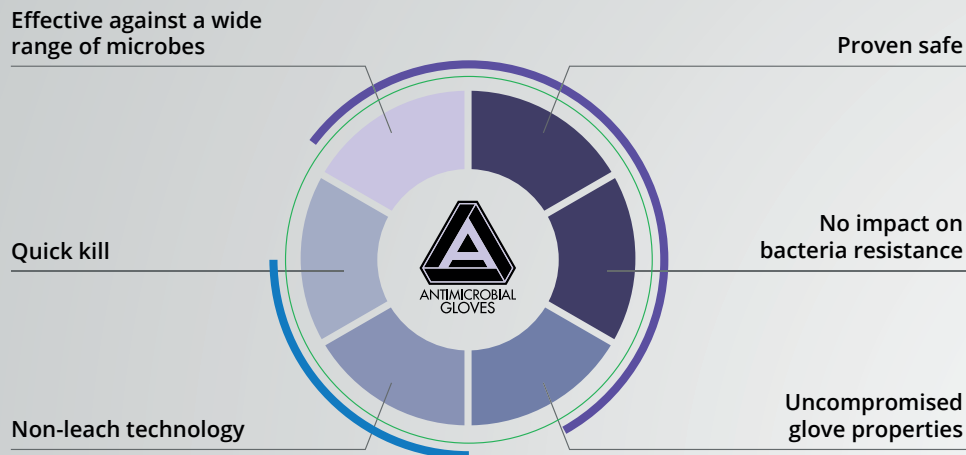


Figure 3. Photodynamic Reaction Leading to Cell Death

THE BENEFITS OF AMG



EFFECTIVE AGAINST A WIDE RANGE OF MICROBES

AMG antimicrobial glove is proven effective against the microbes in *Table 1* which have caused significant healthcare-associated infections.

No.	Microbe	Type	Impact
1	<i>Enterococcus faecalis</i> / Vancomycin-resistant enterococci (VRE)	Gram-positive Bacteria	According to the Centers for Disease Control and Prevention (CDC), <i>Enterococcus faecalis</i> is responsible for approximately 80% of human infections. ³ It is one of the bacteria that is becoming resistant to vancomycin, an antibiotic, and sometimes other standard therapies. Vancomycin-resistant enterococci (VRE) are leading causes of nosocomial bacteraemia, surgical wound and urinary tract infections.
2	<i>Enterococcus faecium</i>	Gram-positive Bacteria	<i>Enterococcus faecium</i> has been a leading cause of multi-drug resistant enterococcal infections over <i>Enterococcus faecalis</i> in the U.S. Approximately 40% of medical intensive care units reportedly found that the majority of device-associated infections were due to vancomycin-and ampicillin-resistant <i>E. faecium</i> . ⁴ The rapid increase of VRE has made it difficult for physicians to fight infections caused by <i>E. faecium</i> since not many antimicrobial solutions are available. ⁵

No.	Microbe	Type	Impact
3	Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)	Gram-positive Bacteria	Commonly transmitted through direct contact, open wounds and contaminated hands, MRSA is a type of staph bacteria resistant to many antibiotics. Due to this, it is sometimes also called a “superbug”. MRSA can cause severe problems such as bloodstream infections, pneumonia and surgical site infection in healthcare settings such as hospitals and nursing homes. Every year, MRSA infects about 72,444 people with 9,194 related deaths in the U.S. ⁶
4	<i>Staphylococcus aureus</i>	Gram-positive Bacteria	According to CDC, about 30% of people carry this microbe in their noses. ⁷ Usually staph does not cause any harm; however in healthcare settings, it can sometimes cause infections that are serious or fatal. These infections include bacteraemia or sepsis, pneumonia, endocarditis (infection of the heart valves) and osteomyelitis (bone infection).
5	<i>Streptococcus pyogenes</i>	Gram-positive Bacteria	It is estimated that 5 - 15% of healthy individuals carry it on the skin or in the respiratory tract without showing symptoms of illness ⁸ . It can rapidly colonise and multiply within a host, causing mild infections like “strep throat” or impetigo. When it becomes invasive, it can destroy fat, skin and muscle tissues, leading to necrotising fasciitis (flesh-eating disease).
6	<i>Enterobacter cloacae</i>	Gram-negative Bacteria	<i>E. cloacae</i> has been reported as a multidrug-resistant opportunistic pathogen infecting people in hospital wards for the last three decades. These Gram-negative bacteria have been responsible for several outbreaks of HAIs in Europe, particularly in France. ⁹
7	<i>Escherichia coli</i>	Gram-negative Bacteria	<i>E. coli</i> can cause diarrhoea, urinary tract infections, respiratory illness, bloodstream infections, and other illnesses. The types of <i>E. coli</i> that can cause illness can be transmitted through contaminated water or food, or through contact with animals or people.
8	<i>Klebsiella pneumoniae</i>	Gram-negative Bacteria	These bacteria have become resistant to the class of antibiotics called carbapenems. Unfortunately, carbapenem antibiotics often are the last line of defence against Gram-negative infections that are resistant to other antibiotics. ¹⁰ The bacteria are not spread through the air, but through physical contact. It can cause pneumonia, bloodstream infections, wound or surgical site infections, and meningitis.
9	<i>Pseudomonas aeruginosa</i>	Gram-negative Bacteria	In the U.S., about 51,000 healthcare-associated infections by <i>Pseudomonas aeruginosa</i> are reported every year. Over 6,000 (13%) of these are multidrug-resistant, attributing to about 400 deaths annually. ¹¹ It can cause blood infection and pneumonia in people with a weakened immune system or after surgery, leading to severe illness and death.

Table 1. List of Microbes that AMG Antimicrobial Gloves Have Been Tested Effective Against

BACTERICIDAL EFFICACY OF AMG

Based on ASTM D7907 Standard Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves, AMG is effective in killing prevalent and antibiotic resistant microbes such as MRSA and VRE. Test data has shown that AMG can kill 99.999% of some microbes in as quickly as 5 minutes.

For the test data, please refer to *Table 2* of the addendum at the end of this booklet.



NON-LEACH TECHNOLOGY

AMG is the world's first non-leaching antimicrobial examination glove. The active has been tested for non-migration with the following medium:

- i. Water
- ii. Hot Water (45 degrees Celcius)
- iii. Sweat
- iv. Saliva
- v. Ethanol

All extracts were analysed at Intertek using validated analytical techniques to detect the active. Results conclude that no active could be found in any of the extracts from either the inner or outer glove surface. Although the active is proven safe, AMG has been designed to further ensure that it does not leach and transfer to the patients.



NO IMPACT ON BACTERIA RESISTANCE

The potential for development of bacterial resistance to the active has been assessed as 'low'. This is attributed to the non-specific nature of the glove's bacteria-killing mechanism.

Generally, oxidative antimicrobials such as the AMG technology has been viewed as low probability for development of resistance by the EU Scientific committee.¹⁰

PROVEN SAFE

AMG glove is suitable for different applications as it has been tested safe for use against various contacts such as skin, oral and food. Some of these tests confirm that the AMG glove is:

- **Non-irritating**
It does not cause primary skin irritation like redness (erythema) or slight swelling (edema).
- **Non-sensitising**
It does not contain any substance that will induce skin allergy.
- **Non-toxic**
No toxic effects occurring following oral administration.
- **Non-cytotoxic**
It does not display destructive action on cells.
- **Non-sensitising and no dermatitis potential**
Modified Draize Test shows the gloves do not cause allergic reaction in normal tissue after exposure.

Refer *Table 3* for the full list of tests.



UNCOMPROMISED GLOVE PROPERTIES

Apart from medical settings, AMG glove has been proven safe for use in different applications and industries. Its safety and effectiveness are proven to ensure it befits its intended use.

i. Medical

Tested for impermeability and glove strength, AMG glove is effective in preventing contamination between patient and healthcare practitioner, as well as for handling various chemotherapy drugs. All tests conducted are in accordance to recognised international standards such as ASTM D6319, EN 455 and ISO 11193 part 1.

ii. Personal Protective Equipment (PPE)

The glove is tested to protect users from substances and mixtures that are hazardous to health, and harmful biological agents that may cause very serious consequences or damage to health. Tests conducted are in accordance to the harmonized standard [*refer Table 3.*] which complies with PPE Regulation.

iii. Food Handling

The glove is tested safe for food contact according to the standards of US FDA, BfR XXI German Recommendation and Japan Food Sanitation. It is tested in various types of simulants representing different types of food that are acidic, alcoholic and fatty in content.

No.	Test	Method	Purpose of Testing	Result Summary
1	Primary Skin Irritation	ISO 10993-10	To determine whether exposure to gloves may produce skin irritation	Non-irritating
2	Dermal Sensitisation Study	ISO 10993-10	To assess potential of gloves to cause delayed hypersensitivity (Type IV) or allergic reaction stimulated by the immune system.	Non-sensitising
3	Acute Toxicity Oral	ISO 10993-11	To evaluate toxic potential of substance that leaches out of gloves by determining adverse effect occurring within short term exposure via oral route.	No toxic effects
4	Cytotoxicity Test	ISO 10993-5	To determine if gloves contain significant quantities of harmful extractables and their effect on cellular components.	Non-cytotoxic at 10% extract
5	Viral Penetration Test	ASTM F1671	To measure resistance of gloves against penetration by blood-borne pathogens.	No penetration < 1 PFU/ml
6	Accelerator Extraction Test	Malaysian Rubber Board (MRB) In – House Method	To quantify the amount of extractable accelerators in gloves.	Non-detectable for accelerators
7	Particulate Residue Test	EN 455-3 ASTM D6124-06	To determine the amount of residual powder (or filtered-mass) found on medical gloves.	Pass. Less than 2mg/glove

No.	Test	Method	Purpose of Testing	Result Summary
8	Food Contact	21 CFR 177.2600	To evaluate if gloves release their constituents into food at level harmful to human health.	Pass
9	Watertight Test	EN 455-1 ASTM D5151	To detect holes in gloves.	Pass
10	Physical Property Test	EN 455-2 ASTM D6319	To determine the tensile strength and elongation at break of gloves.	Pass
11	Food Contact	Japan Sanitation Law	To evaluate if gloves release their constituents into food at a level harmful to human health.	Pass
12	Food Contact	EC 1935/2004 EU 10/2011	To evaluate if gloves release their constituents into food at a level harmful to human health.	Pass according to German Recommendation BfR XXI
13	Modified Draize-95 Test	FDA	To determine whether gloves contain residual chemical additives at a level that may induce Type IV allergy.	No sensitizer detected
14	Chemical Permeation Test (Chemotherapy Drugs)	ASTM D6978	To assess resistance of gloves to permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	All selected drugs meet breakthrough time of more than 240 minutes
15	PPE Certification	PPE (EU) 2016/425 EN ISO 374-1	There are several testing methods under PPE certification as shown below:	-
	Chemical Permeation Test	ISO 16523-1	To evaluate the resistance to permeation by chemicals.	Pass
	Penetration (Air & Water Leak) Test	EN 374-2	To determine penetration resistance of gloves that protect against dangerous chemicals and/or organisms.	Pass
	Degradation Test	EN 374-4	To determine resistance of protective glove materials to degradation caused by dangerous chemicals with continuous contact.	Pass
	Protective Gloves (pH & PAH) Test	EN 420	Design and Construction: To evaluate if gloves can perform hazard related activity normally while enjoying appropriate protection at the highest possible level. Testings include sizing and measurement of hands (hand circumference and hand length) and sizing and measurement of glove (length).	Pass
			pH Value : To determine the pH value of glove.	Pass
			Dexterity : To evaluate the ability to perform its task	Pass
	Viral Penetration Test	EN ISO 374-5	To measure resistance of gloves used against penetration by blood-borne pathogens.	No penetration < 1 PFU/ml

Table 3. List of Tests AMG Gloves have been Tested for



BACTERICIDAL EFFICACY OF AMG

Microbe	Type	Average % Bacteria Killed			
		5 mins	10 mins	15 mins	20 mins
<i>Enterococcus faecalis</i> (VRE)	Gram-positive	99.982	99.996	-	99.968
<i>Enterococcus faecium</i>	Gram-positive	99.991	99.991	99.996	-
MRSA	Gram-positive	99.988	99.998	99.999	99.997
<i>Staphylococcus aureus</i>	Gram-positive	99.996	99.993	-	99.994
<i>Streptococcus pyogenes</i>	Gram-positive	99.946	99.970	99.988	99.996
<i>Escherichia coli</i>	Gram-negative	-	-	99.030	-
<i>Klebsiella pneumoniae</i>	Gram-negative	-	96.471	-	97.747

Table 2. AMG Antimicrobial Glove Test Results for Microbe Kill

End Notes:

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