

Nitril LIOX[®] Our first germicidal

examination glove

Active protection against a variety of hospital infections Efficacy of up to 99.999% on selected microorganisms Skin compatibility confirmed by numerous tests



The challenges of infection prevention today

Each year millions of patients worldwide suffer from nosocomial infections. These infections do not only cause unnecessary suffering for patients and relatives, but also high costs, which put additional pressure on the healthcare system: Hospitalisation is extended, the risks of postoperative complications and antibiotic resistance increase.

In the worst case, treatment-associated infections lead to deaths that could have been prevented by adhering to appropriate hygiene measures. Therefore, all actors in the healthcare system are required to respond to these challenges on a daily basis by means of appropriate measures.

5 Moments of hand hygiene analogous to the WHO:

- 1 | Before patient contact
- 2 | Before aseptic activities
- 3 | After contact with potentially infectious material
- 4 | After patient contact
- 5 | After contact with the immediate patient environment

Active protection against a variety of treatment-associated infections in the health care sector

Antibacterial gloves -An active approach to control treatment-associated infections

In addition to many other measures, such as adherence to hand hygiene according to the 5 moments of the WHO to prevent such infections, the antimicrobial examination gloves from Meditrade with the innovative AMG technology represent a further step in the direction of infection protection for users and patients.

The Nitril LIOX[®] antimicrobial glove kills up to 99.999% of selected microorganisms and provides active protection against a wide range of treatment-associated infections. Skin compatibility has been confirmed by tests.

Annual effects of infections in the healthcare system

EU

Patients affected with nosocomial infections (NI)

3,000,000* Deaths (DGKH estimates)

100,000*

Annual costs approx.
7 billion Euro

DE

Patients affected (estimate) approx. 600,000*

Deaths approx. up to 30,000*

Annual additional costs for the healthcare system **1.26 billion Euro***

Nosocomial infections

Up to **90%** of nosocomial infections are transmitted via the hands. One third of this could be avoided. **

* Cost of nosocomial infections (NI), retrieved from: https://www.meduplus.de/blog/kosten-von-nosokomialen-infektionen-ni/, retrieval date: 09/05/2019

** Kramer. Hand hygiene - patient and personnel protection. GMS Hospital Hyg Interdiscip. 2006;1(1):Doc14.

Mode of action:

The Nitril LIOX[®] antimicrobial examination glove provides active protection for users in various healthcare facilities by rapidly killing microorganisms on the outside of the glove upon contact.

- An **active dye** incorporated into the glove material on the outside converts conventional oxygen into so-called singlet-oxygen ¹O₂ as soon as the glove material comes into contact with light and oxygen.
- The **singlet-oxygen** attacks the cell membrane of grampositive bacteria (among others MRSA, VRE, etc.), which leads to the death of the microorganisms affected.
- The efficacy is up to 99.999% of the affected microorganisms (germs, bacteria).

Characteristics:

 The skin compatibility of the glove material has been confirmed by numerous tests: Biocompatibility has been tested and it has been confirmed that the gloves are non-sensitising, non-irritating, non-toxic (oral) and noncytotoxic.

Personal Protective Equipment (PPE):

In addition to its suitability as a medical examination glove, the Nitril LIOX[®] with AMG technology is certified as Personal Protective Equipment (PPE) Category III / Type C.

Advantages:

- In addition to the passive barrier of an examination glove between the user and the patient, the Nitril LIOX[®] also offers an **active protective function** for both.
- Singlet-oxygen is a non-selective system that can rapidly act against many microbial components. Unlike antibiotics, there is no protective mechanism in the bacteria that can protect them from singlet-oxygen.
- Since singlet-oxygen is not used up, the mode of action is provided at all times. On the other hand, it is volatile and therefore no permanent biocides are released.

Bactericidal effect of the innovative AMG technology



Bactericidal effect of Nitril LIOX® with AMG technology*

Microorganism	Туре	1 minute	2 minutes	5 minutes
Enterococcus faecalis (AER)	gram-positive	99.999%	99.999%	99.999%
MRSA	gram-positive	97.766%	97.447%	99.745%
Staphylococcus aureaus	gram-positive	99.989%	99.998%	99.999%
Streptococcus pyogenes	gram-positive	99.998%	99.998%	99.998%

Further test results:

Klebsiella pneumonia (gram-negative type): 96.471% in 10 minutes Escherichia coli (gram-negative type): 99.030% in 15 minutes

*All test data are available on request. The results are based on the standard test methods for the determination of bactericidal efficacy on medical examination gloves (ASTM D9707). The test data have shown that the antimicrobial gloves are effective in killing common and antibiotic-resistant microorganisms (such as MRSA and VRE). Revision: May 2019

1. What is special about the Nitril LIOX®?

The Nitril LIOX[®] antimicrobial examination glove provides active protection for users in various healthcare facilities by rapidly killing microorganisms on the outside of the glove upon contact.

2. What is the purpose of antimicrobial gloves?

While traditional medical examination gloves are only a passive barrier between microorganisms and the hands of users, the Nitril LIOX[®] antimicrobial glove also plays an active role in reducing the spread of treatment-associated infections. It has been proven that up to 99.999% of the microorganisms affected (germs, bacteria) are killed.

3. How does the antimicrobial Nitril LIOX® glove work?

An active dye, which is incorporated on the outside of the glovematerial converts conventional oxygen (which is usually present as a stable triplet oxygen ${}^{3}O_{2}$) into so-called singlet-oxygen ${}^{1}O_{2}$, as soon as the glovematerial comes into contact with light and oxygen. The reactive singlet oxygen in turn attacks the cell membrane of Gram-positive bacteria (including MRSA, VRE etc.), which subsequently leads to the death of the microorganisms affected.

4. Is this technology safe for the user?

The Nitril LIOX[®] antimicrobial glove is designed in such a way that the active ingredient will not be spread to the user or the patient. The gloves have been tested for biocompatibility. The following tests were carried out:

- Examination at Intertek UK: Parts of the gloves were exposed to water, artificial saliva, sweat and alcohol at room temperature and at body temperature. The extracts were analysed using established laboratory procedures to detect the active ingredient. Extracted active ingredient could not be detected from either the inner surface or the outer surface of the gloves.
- An ISO 10993 biocompatibility test was performed on the inside and outside surfaces of the gloves. The results confirmed that the gloves are non-sensitising, non-irritating, non-toxic (oral) and not cytotoxic.
- The modified Draize 95 test was also performed, testing the inside and outside surfaces of the gloves on human skin. There was no clinical evidence that the gloves cause allergic reactions. Based on these test results, the US FDA has awarded the gloves "Low dermatitis potential".

5. What materials are in contact with the skin when wearing antimicrobial gloves with AMG technology?

AMG technology is used on the outside of the gloves. The user of the gloves is exposed to the inside of the glove which is similar to that of a conventional examination glove. The skin of the user is therefore not directly exposed to this technology.

6. Does the use of antimicrobial gloves replace the need for hand hygiene?

Although antimicrobial gloves have proven to be effective against a wide range of microbes, they do not replace the need for hand hygiene. The use of gloves with AMG technology serves as an additional precaution to help reduce the spread of treatmentassociated infections. Accordingly, the proven practices for disinfecting or washing the hands before putting on and removing the gloves should continue.

7. How exactly does singlet-oxygen work?

This technology uses a special dye. The dye absorbs the visible light. The dye is thereby raised from a basic state to an excited quantum state in which there is an increase in energy. The energy is then transferred to a nearby oxygen molecule in the air, causing the oxygen molecule also to enter an excited quantum state. The basic state of oxygen present in the air is a triplet electron configuration, represented as ${}^{3}O_{2}$. Upon sensitisation by means of the dye molecule, the electron configuration changes and changes to the singlet state ${}^{1}O_{2}$. This singlet state is reactive and more oxidative compared to basic state oxygen. Therefore, it can kill microbes, such as bacteria, by oxidising the protein and lipid of the cells. By using the dye as a catalyst, singlet-oxygen can be continuously generated since light and air are absorbed.

8. What are the benefits of singlet-oxygen?

Singlet-oxygen is a non-selective system that can rapidly act against many microbial components. There is no protective mechanism in bacteria that can protect them from singlet oxygen. This is in contrast to antibiotics, where a very specific mechanism is required to treat a patient. As singlet-oxygen is volatile, no permanent biocides are released into the environment.

9. Has singlet oxygen technology been used commercially before?

In medicine, singlet oxygen is already in use. Among other applications, it is used in the photodynamic therapy (PDT) of cancer treatment, in order to damage tumours or tissue changes. Furthermore, singlet oxygen is used in dental disinfection before a root canal treatment, whereby the dye is rinsed in the patient's mouth and a light is used to perform the disinfection quickly and safely. The most common form of use is, however, in washing powders, in which a singlet-oxygen generating dye is applied to textiles and then serves as a light bleach.

10. What is the amount of light needed to activate antimicrobial gloves with AMG technology?

The gloves were tested under general lighting conditions in hospitals at 1000 lux and at 500 lux. The results have shown no significant differences in bactericidal activity. Further tests at lower light levels are still pending.

11. Would different types of lighting affect the efficiency of antimicrobial gloves (e.g. LED, fluorescent tube, incandescent lamp)? No. The dye is activated by any white light source. In particular, light with a wavelength of 600-700 nm causes the activation. This wavelength is contained in every white light.

12. Will the dye be used up if the antimicrobial gloves are exposed to light continuously?

No, as long as there is light and oxygen, the gloves remain active. Heat-aged gloves (accelerated ageing, corresponding to 3 years of storage) showed no significant difference in bactericidal activity when compared with new gloves. The antimicrobial gloves were also exposed to "light" (equivalent to 30 days in the vicinity of an open box). Again, there was no significant difference in bactericidal activity compared to new gloves.

13. How is the efficiency of antimicrobial gloves measured?

AMG technology antimicrobial gloves begin to produce singletoxygen and kill bacteria as soon as they are exposed to light and oxygen. According to the specifications of ASTM D7907-14, the contact time during which the bacteria have been exposed to the outer surface of the gloves with antimicrobial agents should be measured at intervals of 5, 10, 20 and 30 minutes. At the end of the contact time, the glove is placed in a validated neutraliser to stop the bactericidal activity. This stops the microbicidal action of the singlet-oxygen, thereby allowing the counting of the bacteria killed. Further tests have been carried out on Staphylococcus aureus, MRSA, VRE and Streptococcus pyogenes with shorter contact times of 1 and 2 minutes and bacterial kill rates of up to 99.999%.

14. Into which different groups are bacteria divided?

Bacteria are divided into gram-positive and gram-negative bacteria. This classification is based on a colour difference, which Hans Gram observed in 1884. It was observed that some bacteria were stained with a particular dye, but not others. Later it turned out that bacteria have different cell wall structures. Gram-positive bacteria make it easier for various substances to penetrate their cell wall. The cell wall of gram-negative bacteria is multi-layered, which makes it more difficult for these substances to penetrate the cell wall.

a) Which bacteria are gram-negative?

Gram-negative bacteria include Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumoniae, Acinetobacter baumannii and others.

b) Which bacteria are gram-positive?

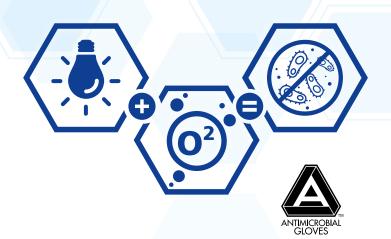
Gram-positive bacteria include MRSA, Staphylococcus aureus, Enterococcus faecium, Streptococcus pyogenes, Enterococcus faecalis (VRE) and many others.

c) Which types of bacteria survive longer on surfaces?

Based on a study that examined the survival of various types of bacteria on cotton fluff, the results showed that gram-positive bacteria survive longer on surfaces.*

This suggests that gram-positive bacteria are more easily transmitted and can cause treatment-associated infections. Gram-negative bacteria are known to die faster on surfaces, especially when the surface is dry.

* Hirai, Y. (1991). Survival of bacteria under dry conditions; from a viewpoint of nosocomial infection. Journal Of Hospital Infection, 19(3), 191-200.





The strong system partner for the future

