



SILVERLON™ FACE MASK INSTRUCTIONS FOR USE

Available As:

<i>Code</i>	<i>Description</i>
SFM-1	Silverlon Face Mask - Pack of 1
SFM-5	Silverlon Face Mask - Pack of 5

Intended Use

The Silverlon™ Face Mask is intended for use by healthcare providers and the general public to cover their nose and mouth to help prevent the spread of infection or illness from the SARS-CoV-2 virus during the COVID-19 public health emergency.

Contraindications

Do not use the Silverlon® Face Mask if you have sensitivity to silver or nylon.

Warnings and Precautions

The Silverlon™ Face Mask is not intended as personal protective equipment (PPE) for healthcare providers in clinical settings where the infection risk level is high (e.g., high inhalation exposure or during aerosol-generating procedures), does not provide liquid barrier protection, and is not a substitute for Filtering Facepiece Respirators (FFRs) or for surgical face masks.

The Silverlon™ Face Mask may be washed and dried per cleaning instructions. Failure to follow the cleaning instructions may result in reduced antimicrobial or antiviral activity.

Some clinical studies have reported finding silver-resistant microbial strains when using silver based antimicrobial products. As of April, 2014 no adverse event or reports of Silverlon-resistant microbial strains have been received by Argentum Medical.

Adverse Reactions - N/A

Device Description

The Silverlon™ Face Mask is made from Silverlon™ which is nylon plated with 99% pure silver and 1% silver oxide. The device is provided in one size for use by adults and children. The mask is designed to fit over the wearer's nose and mouth and secure around the ears. The mask is reusable and may be machine washed and dried.

Silverlon™

Silverlon™ has been cleared by the FDA as an antimicrobial wound dressing used by millions of patients around the world and by the military for surgery, burn, wound, and trauma care for over 20 years. This same material is now being used as a face mask. Previous testing has shown that Silverlon™ is effective at killing multiple pathogens that come into contact with the material as listed below. While the Silverlon™ material has antimicrobial properties, Argentum Medical makes no representation that the Face Mask offers infection reduction or prevention against the COVID-19 virus. No clinical studies have been conducted comparing the ability of a general source control face mask and the Silverlon™ Face Mask to protect the wearer from infection, and the Silverlon™ Face Mask cannot affect pathogens inhaled around the edges of the mask.

Silverlon has been shown effective against the following pathogens*:

- Acinetobacter calcoaceticus
- Aspergillus niger
- Candida albicans
- Candida Auris
- Enterobacter cloacae
- Enterococcus sp.
- Escherichia Coli (E. coli)
- Group B Streptococcus
- Listeria monocytogenes
- Mycobacterium
- Propionibacterium Acnes
- Pseudomonas aeruginosa
- Pseudomonas cepacia
- Pseudomonas maltophilia
- Salmonella typhi
- Salmonella typhimurium
- Serratia marcescens
- Shigella sonnei
- Staphylococcus aureus (MRSA)
- Staphylococcus epidermidis
- Vancomycin Resistant Enterococcus (VRE)

*Correlation between in vitro (laboratory) testing results and infection reduction or prevention has not been established.

How to Use

1. Recommend washing prior to first use and daily thereafter, or between users, whichever comes first. Can be washed up to 30 times and will retain its antimicrobial property when washed per the cleaning process below.
2. Put loops over ears and adjust to comfort. Ensure coverage of the nose and mouth.
3. To remove contaminated mask, avoid touching outer layer of mask or your face. Remove from ears, only touching loops, and immediately put into washer or safe storage.

Washing Instructions:

- Do not exceed 50°C (122°F).
- Machine wash in cold or warm water.
- Machine dry on low heat or air dry.
- Do not use chlorine bleach.
- Do not dry clean.
- Do not use fabric softeners or dryer sheets.

Storage

- Keep dry. Avoid excessive heat or humidity.

Made in the USA.

DISCLAIMER

The Silverlon™ Face Mask has been authorized by FDA under an Emergency Use Authorization (EUA). This face mask is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 pandemic. Other face masks are on the market and their benefits vary based on design, material properties, fit, filtration, and fluid resistance performance. The design and features of a face mask should be considered relative to the intended use environment.

The Silverlon™ Face Masks are not intended as personal protective equipment (PPE) for healthcare providers in clinical settings where the infection risk level is high (e.g., high inhalation exposure or during aerosol-generating procedures), do not provide liquid barrier protection, and are not substitutes for Filtering Facepiece Respirators (FFRs) or surgical face masks. Previous testing has shown that Silverlon™ is effective at killing multiple pathogens that come into contact with the material as listed in these Instructions for Use. While the Silverlon™ material has antimicrobial properties, Argentum Medical makes no representation that the Face Mask offers infection reduction or prevention against the COVID-19 virus. No clinical studies have been conducted comparing the ability of a general source control face mask and the Silverlon™ Face Mask to protect the wearer from infection, and the Silverlon™ Face Mask cannot affect pathogens inhaled around the edges of the mask.

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