



For more information or to order Diagnostic Guardian Mask™
Contact ALK at 800-325-7354



Diagnostic Guardian™ Mask

ALK understands the needs of your Otolaryngology practice. The Diagnostic Guardian™ Mask from MaskIT is a single use, disposable face mask source control device, intended for use on a patient's face with instrument opening.

The Diagnostic Guardian™ is manufactured from a filtering face piece (materials include silicone, polypropylene, cotton, PET and elastomer strap) mounted with a clear polycarbonate housing adapter to hold a flexible medical grade silicone seal with an instrument opening. It contains no Natural Rubber Latex material.

The Diagnostic Guardian™ has been authorized by the FDA under an EUA for use as a source control by the general public as well as by health care providers in healthcare settings as to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.

The Diagnostic Guardian™ has not been FDA cleared or approved, and is authorized by the FDA under the EUA only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as used as medical devices, during the COVID -19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. & 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

Providing options for your practice.

The Diagnostic Guardian Mask™ is one more way ALK is committed to supporting your Otolaryngology practice.

WARNINGS:

Diagnostic Guardian™ is NOT an N95 Mask or intended for use as a surgical mask or a respirator and does not protect wearer from infection. The Diagnostic Guardian™ is not intended to be used by health care providers as personal protective equipment ("PPE"), is not a replacement for PPE, should not be worn by a health care provider in high risk aerosol generating procedures, and is not intended to provide liquid barrier protection. The Diagnostic Guardian™ should not be worn in a clinical setting where infection risk level through inhalation exposure is high. This product should not be used in patients with sensitivity to its materials.