

DIAGNOSTIC GUARDIAN™ Instructions for Use



DESCRIPTION:

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 of 2.5 mm or 3.5 mm diameter. It contains No Natural Rubber Latex material.

WARNINGS:

- **Diagnostic Guardian™** is **NOT** an **N95 Mask** or intended for use as a surgical mask or a respirator and does not protect wearer.
- **Diagnostic Guardian™** is not intended to provide liquid barrier protection and is not a replacement for personal protective equipment and is not to be used in the presence of high intensity heat source or flammable gas.
- This product is disposable and is intended for single use to prevent any contamination or cross contamination.
- Diagnostic Guardian™ is meant solely as a source protection device and use of it does not remove the risk of infection or death from infection.
- This product should not be used in patients with sensitivity to its materials.

How to Use:

1. Place the mask on the patient's face with the straps behind their head. Adjust placement and then adjust tensioning clips for a tight fit. Squeeze the metal nose bridge to close any gaps around the nose.
2. Lubricate the instrument with Surgilube® or equivalent. Insert the instrument through the hole in the seal while visualizing the patient's nose through the clear plastic fitting.

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 infection or illness 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.

DG-1225-10: 2.5mm Diameter MaskIT Diagnostic Guardian

DG-1235-10: 3.5mm Diameter MaskIT Diagnostic Guardian

Manufactured for MaskIT, Inc. in the USA
with some foreign components

Surgilube® is a registered trademark of HR Pharmaceuticals Inc.

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