



PleatMask™

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Why PleatMask

- ★ PleatMask is an American made, single-use disposable ASTM level 3 Surgical Mask that provides the highest level of protection.
- ★ As an American product, PleatMask is made with the highest level of care and quality.
*More than 60% of foreign-made masks, nearly all Chinese made, have failed basic U.S. government quality tests.
WSJ - 'FDA's shifting Standards for Chinese Face Masks Fuel Confusion' - August 3, 2020
- ★ PleatMask is customizable, allowing companies to print any design or logo and providing great branding and marketing opportunities.
- ★ Available in multiple sizes to fit a wide range of faces. The 15 pleat ergonomic design of PleatMask provides a superior fit for all.
- ★ PleatMask is made from environmentally friendly materials that are recyclable.

PleatMask

- Made in USA
- Level 3 ASTM Mask
- Customizable
- Available in various sizes
- Made from recyclable materials
- Ships from manufacturer in USA

Other Masks

- Foreign made - mostly China
- Unreliable protection and quality, most are defective and unsafe
- No customization options
- Available in just one size
- Unknown manufacturer



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As a health care worker, protecting myself from potentially infected patients is a top priority. I feel much safer wearing a surgical mask with an impenetrable barrier, as provided by the PleatMask. Not only do I wear it in the clinic and during surgery, but I also wear it to the grocery store!

”

- Dr. Scott Gledhill

SPECIFICATION - DATA SHEET

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PleatMask is a single use disposable Surgical Mask, proudly made at our facility in South Carolina, using all American materials and labor.

PleatMask is a Medical Device Class 2, Level 3 - *ASTM, F1862, ISO 22609, Passing at 160mmHg (Highest Level of Fluid Resistance).

PleatMask material is impermeable to air, bacteria and particles. Ideal for procedures where heavy to moderate amounts of fluid, spray and/or aerosols are produced.

***ASTM F1862:** Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity).

Per FDA updated guidelines and PleatMask testing conducted by Nelson Labs (<http://www.nelsonlabs.com>) in April 2020, the polyethylene barrier of the PleatMask reduces the spread of viruses and bacteria.

PleatMask should be worn in all situations where protection is required and social distancing cannot be practiced.



"Surgical Masks Intended to Provide Liquid Barrier Protection"
Per updated FDA guidelines (excerpts)

"A surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. Surgical masks are not to be shared and may be labeled as surgical, isolation, dental, or medical procedure masks. They may come with or without a face shield. These are often referred to as face masks, although not all face masks are regulated as surgical masks."

"If worn properly, a surgical mask is meant to help block large-particle droplets, splashes, sprays, or splatter that may contain germs (viruses and bacteria), keeping it from reaching your mouth and nose. Surgical masks may also help reduce exposure of your saliva and respiratory secretions to others".

"Surgical masks are not intended to be used more than once.
If your mask is damaged or soiled, or if breathing through the mask becomes difficult, you should remove the face mask, discard it safely, and replace it with a new one. To safely discard your mask, place it in a plastic bag and put it in the trash. Wash your hands after handling the used mask."

***Source:**

<https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks>



SPECIFICATIONS & INSTRUCTIONS

PleatMask is made from lightweight paper extruded with low-density polyethylene and using latex free elastics for ear loops

PleatMask is intended to be worn loosely with pleats directed downward. For optimal use, when wearing the PleatMask it is recommended to expand the pleats by pulling gently to achieve full coverage of the nose, mouth and chin and for improved breathability.

FDA "Recommendation against use in the presence of high intensity heat source or flammable gas."

