

# FACE THE FACTS:



## WHAT YOU NEED TO KNOW ABOUT MEDICAL FACE MASKS IN HEALTHCARE SETTINGS.

**Q&A with Dr. Laurent Dreyfuss, Director, Global Medical & Clinical Affairs, Owens & Minor Global Products**

### What is a surgical mask?

In the United States, surgical masks are cleared for marketing by the U.S. Food and Drug Administration (FDA). According to the FDA, surgical masks may be labeled as surgical, laser, isolation, dental or medical procedure masks.<sup>1</sup>

### What are the primary purposes for wearing splash resistant masks in the healthcare setting?

Masks have 3 primary purposes<sup>2</sup>. They are:

1. Worn by healthcare personnel to protect them from contact with splashes and sprays.
2. Worn by healthcare personnel to protect patients from exposure to infectious agents carried in a healthcare worker's mouth or nose; and
3. Worn by patients to limit potential dissemination of infectious respiratory secretions from the patient to others (protect others).



### What is ASTM?

ASTM International is one of the world's largest organizations for developing consensus standards.

### What facemask performance characteristics are tested using criteria specified by ASTM F2100. Why are these characteristics important?

#### • BFE and PFE:

Bacterial Filtration Efficiency (BFE) is a measure of the masks ability to filter out bacterial laden aerosols in the 3 micron size range. Particulate Filtration Efficiency (PFE) assesses the ability to filter out submicron particles in the 0.1 micron range. The higher the percentage, the more the mask prevents the passage of bacteria or particles.<sup>3</sup>

#### • Fluid Resistance:

Face masks are challenged with synthetic blood to simulate being splashed at low, normal or high blood pressure (80, 120, 160mm Hg) ranges. The higher the pressure, the greater the resistance to penetration by fluid splashes.

#### • Differential Pressure / Delta P (Breathability):

Measures the effort it takes to force air through the mask material. The lower the Delta P, the more breathable and comfortable the mask.

#### • Flammability:

The mask material is subjected to flame. The rate at which the material burns determines the level of flammability.

Test	ASTM F2100			
	Level 1	Level 2	Level 3	Method
Bacterial Filtration Efficiency, %	≥95	≥98	≥98	ASTM F2101
Differential Pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	<5.0	<6.0	<6.0	EN14683:2019 Appendix C
Particulate Filtration Efficiency, %	≥95	≥98	≥98	ASTM F2299
Splash Resistance to Synthetic blood, mm Hg pressure, pass result	80	120	160	ASTM F1862
Resistance to Flame Spread	Class 1	Class 1	Class 1	16 CFR 1610

### Why do I need a fluid-resistant mask?

If your mask is not fluid resistant, you are not adequately protected when performing procedures such as endotracheal intubation, bronchoscopy, and invasive surgeries which generate splashes or sprays of blood, body fluids, secretions, or excretions. Wearing a fluid-resistant mask helps to protect the wearer from mucosal contact and inhalation of these potentially infectious splashes and sprays.<sup>2</sup>

### Is there a meaningful difference between a mask that offers a 95% BFE versus 98% BFE?

A higher percentage indicates higher filtration efficiency; e.g., 95% BFE indicates that no more than 5% of the aerosolized bacteria used in testing passed through the mask material, while 98% BFE indicates no more than 2% passes through.

### How do I know if my current face mask is providing adequate protection?

Look at the package! The ASTM F2100 standard requires a graphic display on the packaging stating the mask performance level. The standard changed mask classifications from performance class (low, medium, high) to levels (1,2,3). This rating level is determined based on the test results of the material performance categories listed above.<sup>3</sup>

#### Sources/References:

1. Center for Devices and Radiological Health. Guidance for Industry and FDA Staff. Surgical Masks - Premarket notification [510(k)] submissions 2004.
2. Siegel JD, Rhinehart E, Jackson M, Chiarello L. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. Am. J. Infect. Control. Dec 2007;35(10 Suppl 2):S65-164.
3. ASTM International, Standard Specification for Performance of Materials Used in Medical Face Masks. West Conshohocken, PA

For more information for clinicians and product code ordering information, please visit:

[www.halyardhealth.com](http://www.halyardhealth.com)

Call 1-844-HALYARD (1-844-425-9273) in the United States and Canada.

