



WPT ASTM F2100-19 Level 3 EARLOOP SURGICAL FACE MASK SMS2020-50

50 Each/ Box

Disposable
Single Use
Non-sterile

INTENDED USE

The WPT ASTM F2100-19 Level 3 earloop Surgical Face Mask has been authorized by FDA under an EUA for use in healthcare settings by healthcare personnel (HCP) as personal protective equipment (PPE) to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from COVID-19 pandemic.

Mask Materials

Body Contact Materials: 100% Polypropylene
Ear loops: 100% Polyurethane elastic
Nose Piece and Ear loops not made with Rubber Latex

Warning

- Surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for aerosol generating procedures and any clinical conditions where there is a significant risk of infection through inhalation exposure.

Note

- The WPT ASTM 2100-19 Level 3 earloop surgical face mask SMS2020-50 has not been FDA cleared or approved.
- This product is authorized 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 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. They are intended to be used when FDA- cleared surgical masks or FDA cleared or authorized respirators are not available. The WPT Surgical mask is a loose-fitting device worn over the users' nose and mouth. Surgical masks may be effective in blocking respiratory droplets and large particle droplets; however, because of the loose fit between the surface of the surgical mask and the user's face, leakage can occur around the edge of the mask when the user inhales. Therefore, a surgical mask may not provide the user the reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection. For this reason, surgical masks are not recommended for use in aerosol generating procedures and any clinical conditions, where there is significant risk of infection through inhalation exposure, a filtering face piece respirator (such as an N95 respirator) with a tight fit is recommended to provide a more reliable level of respiratory protection against pathogenic biologic airborne particulates.



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How to Don a mask

- Secure on head with earloop
- Place over nose, mouth and chin
- Fix the flexible nose piece over the bridge
- Adjust fit snug to face and below chin

How to remove a mask

- Remove mask by handling earloop
- Remove the mask from your face in a downward direction
- Properly dispose of the mask by only touching the earloop

Test	Purpose	Acceptance Criteria per ASTM F2100-19 Level 3 (AQL=4.0%)	Test Results
			Test Results ASTM F2100-11 Level 3
ASTM F1862 Synthetic Blood	Determine synthetic blood penetration resistance	29 out of 32 pass at 160 mmHg	Pass (30/32)
Particulate Filtration Efficiency ASTM F2299	Determine sub micron particulate filtration efficiency	≥98%	Pass
ASTM F2101 BFE	Determine bacterial filtration efficiency	≥98%	Pass
MIL-M-36954C Delta P	Determine breathing resistance or differential pressure	< 6.0 mm H ₂ O/cm ²	Pass
CPSC 1610 Flammability	Determine flammability or flame spread	Class 1	Pass

All results of testing met ASTM F2100-19 Level 3 acceptance criteria

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