Honeywell

ASTM LEVEL 2
ASTM F2100 Fluid resistance

50
Pcs / Box

559250M

PROCEDURE MASK WITH EARLOOPS

Manufacture Date:
Lot Number:

8839403988677

For Fact Sheet for Healthcare personnel visit:
https://www.fda.gov/media/140895/download

PROCEDURE MASK
WITH EARLOOPS

50
Pcs / Box

Honeywell

Box Part Number: 501736662-001 REV A

PROCEDURE MASK
WITH EARLOOPS

559250M

ASTM F2100 Fluid resistance **ASTM LEVEL 2**

Honeywell

50
Pcs / Box

Read the entire label

Single-Use Disposable

Not made with natural rubber latex

Store in dry conditions

DONNING

1. Clean your hands with soap and water or hand sanitizer before touching the mask.
2. Hold mask by the ear loops. Place a loop around each ear.
3. Adjust the mask to fully cover the mouth and nose.
4. Form the nose wire around nose and cheek to close any gaps.

DOFFING

1. Grasp mask by the earloops only and remove mask Do not touch front or inside of mask.
2. Pull mask away and deposit in waste container.
3. Wash your hands or use hand sanitizer.

Single-Use Disposable

WARNINGS

ASTM Level 2

1. This mask does not eliminate the risk of contracting infection, illness or disease.
2. If, for any reason, you cannot achieve a proper fit, use an alternative mask.

This product is a SURGICAL MASK for SINGLE-USE ONLY and is NON-STERILE.

This product has not been FDA cleared or approved.
This product has been authorized by FDA under an Emergency Use Authorization (EUA) for use in healthcare settings by healthcare professionals as personal protective equipment (PPE) to provide a physical barrier to fluids and particulate materials to prevent healthcare professionals' exposure to respiratory droplets and large particles during surgical mask shortages resulting from COVID-19 pandemic. This product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators.

ASTM F2100: Level 2
ASTM F1862: 120 mm/Hg
EN 14683 ΔP: <6.0 mm H_2O/cm^2
ASTM F2101: BFE ≥ 98%
ASTM F2299: PFE ≥ 98% @0.1 micron
16 CFR Part 1610 Flammability: Class 1

Surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol-generating procedures or any clinical conditions where there is significant risk of infection through inhalation exposure. Body contacting materials may include the following: Polypropylene, Polyester, Polyethylene, Lycra, and Spandex. The mask includes a nose clip composed of carbon steel wire coated with polyethylene, embedded between the three layers.

MADE IN THE USA
Made in U.S.A.

Honeywell International Inc.
300 S. Tryon Street, Suit 500
Charlotte, NC 28202-1040

Scan for Technical Information
or visit www.honeywellsafety.com

FACT SHEET FOR HEALTHCARE PERSONNEL

Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic
August 5, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of authorized disposable, single-use surgical masks (hereafter referred to as "authorized surgical masks") during the COVID-19 pandemic.

Certain surgical masks are authorized for emergency use by healthcare personnel (HCP) in healthcare settings 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 the COVID-19 pandemic. This a Fact Sheet is specific to surgical masks that were authorized by the United States Food and Drug Administration (FDA) under an emergency use authorization (EUA).

Healthcare personnel should adhere to Standard and Transmission-based Precautions when caring for patients with SARS-CoV-2 infection per CDC guidelines.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the Centers for Disease Control and Prevention (CDC) webpage for the most up to date information.

What do I need to know about the emergency use of authorized surgical masks?

- Authorized surgical masks meet the fluid barrier, flammability, and particulate filtration efficiency performance requirements set forth in the EUA and do not pose significant risks concerning breathability and biocompatibility.
- Authorized surgical masks may be effective in blocking respiratory droplets and large particles.
- Authorized surgical masks do not include drugs, biologics, nanoparticles or antimicrobial/antiviral agents and are not FDA-cleared.
- HCP should review the authorized surgical mask labeling prior to use and follow the instructions for use.

Use appropriate PPE when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings or on the CDC webpage on Infection Control.*

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

When is it not appropriate to use an authorized surgical mask?

- Authorized surgical masks are not intended to replace the need for FDA-cleared surgical masks.
- Surgical masks may not provide the user a reliable level of protection from inhaling smaller airborne particles and are not personal respiratory protective devices. They are not intended to replace the need for FDA-cleared or authorized respirators.
- Because of the loose fit between the surface of the surgical mask and the user's face, surgical masks used by HCP are not considered respiratory protection against pathogenic biological airborne particulates.
- 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. Under those conditions, a filtering facepiece respirator (such as an N95 respirator) with a tight fit should be used to provide a more reliable level of respiratory protection.

What are the known and potential benefits and risks of authorized surgical masks

Potential benefits of authorized surgical masks:

- Decreases risk of transmitting the SARS-CoV-2 virus to the wearer, other HCP, or patients
- Helps prevent HCP exposure to the spread of infection or illness

Potential risks of authorized surgical masks:

- Inadequate barrier protection leading to spread of infection or illness
- Loose-fitting contributing to inadequate respiratory protection against pathogenic biological airborne particulates
- Adverse reaction to device materials
- Flammable in the presence of high intensity heat sources or flammable gas
- Difficulty breathing

What is an EUA?

The FDA has made surgical masks available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Services (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

This product has been authorized by FDA under an EUA for use by HCP as PPE in healthcare settings 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 the COVID-19 pandemic. An authorized surgical mask made available under an EUA has not undergone the same type of review as an FDA-approved or cleared device. This product has not been FDA-cleared or approved. However, in the absence of an FDA-approvedor cleared alternative and based on the totality of scientific evidence, it is reasonable to believe the authorized surgical mask may be effective for the authorized use. 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, unless the authorization is terminated or revoked sooner.

An FDA approved or cleared device should be used instead of the authorized surgical mask under EUA, when available.

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

FACT SHEET FOR HEALTHCARE PERSONNEL
Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic
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Coronavirus Disease 2019 (COVID-19)
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50174008-001 Rev. A

Description

The Procedure Mask with Earloop is a 3-ply, pleat-style utilizing earloops attachments.
This product is a SURGICAL MASK for SINGLE-USE ONLY and is NON-STERILE.

ASTM F2100: Level 2
ASTM F1862: 120 mm/Hg
EN 14683 ΔP: <6.0 mm H20/cm2
ASTM F2101: BFE ≥ 98%
ASTM F2299: PFE ≥ 98% @0.1 micron
16 CFR Part 1610 Flammability: Class 1

Warnings

1. This mask does not eliminate the risk of contracting infection, illness or disease.
2. If, for any reason, you cannot achieve a proper fit use an alternative mask.

This product has not been FDA cleared or approved.
This product has been authorized by FDA under an Emergency Use Authorization (EUA) for use in healthcare settings by healthcare professionals (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.
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.

This product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators.
Surgical masks may be effective in blocking splashes 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 with a 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. In such clinical conditions, a filtering facepiece 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.

Storage

Temperature Range: -20 °F to 122 °F (-20 °C to 50 °C)
Humidity: Do not store above 80% Rh

Honeywell International Inc.
300 S. Tryon Street, Suite 500
Charlotte, NC, 28202-1040

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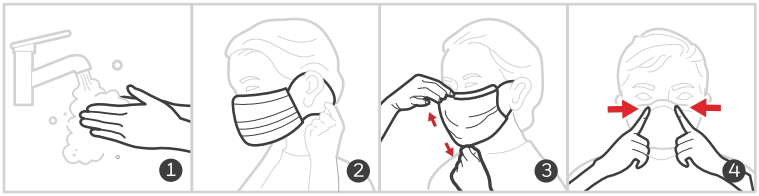
Materials and Composition

Procedure Mask with Earloop is constructed of three layers of nonwoven material.

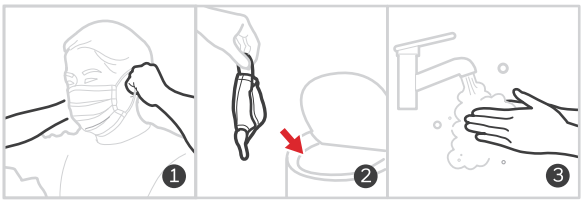
Body contacting materials may include the following:
Polypropylene, Polyester, Polyethylene, Lycra and Spandex.
The mask includes a nose clip composed of carbon steel wire coated with polyethylene, embedded between the three layers.

Donning



1. Clean your hands with soap and water or hand sanitizer before touching the mask.
2. Hold mask by the earloops. Place a loop around each ear.
3. Adjust the mask to fully cover the mouth and nose.
4. Form the nose wire around nose and cheek to close any gaps.

Doffing



1. Grasp mask by the earloops only and remove mask.
   Do not touch front or inside of mask.
2. Pull mask away and deposit in waste container.
3. Wash your hands or use hand sanitizer.

MADE IN THE USA

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