HealthCap
RISK MANAGEMENT SERVICES

FDA Update - Facemasks FAQ

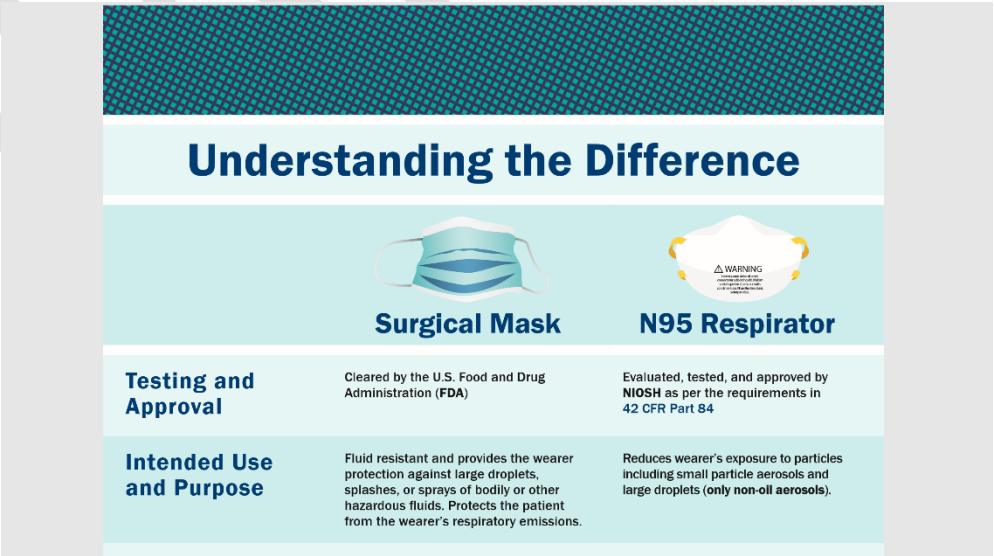
The Basics on Face Masks, Surgical Masks, and Respirators

Q: Is there a difference between a face mask, a surgical mask and a respirator?

A: Face masks, surgical masks, and respirators all cover a wearer's nose and mouth, but they differ in several aspects:

- **Face masks:** A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks that are not intended for a medical purpose are not considered medical devices. Face masks may be used by the general public and health care personnel as source control in accordance with CDC recommendations on Interim Infection Prevention and Control.
- **Surgical masks:** A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks intended for medical purposes are considered medical devices. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests. Surgical masks are also tested for biocompatibility and are considered personal protective equipment (PPE). While a surgical mask may be effective in blocking splashes and large-particle droplets, they do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the mask and your face. Surgical masks are not respiratory protective devices such as respirators.
- **Respirators, known as filtering facepiece respirators (FFRs),** including N95s and surgical N95s, filter at least 95 percent of airborne particles. They are PPE that tightly fit the face and provide certain filtration efficiency levels to help reduce wearer exposure to pathogenic airborne particles in a health care setting. They provide a higher level of protection against viruses and bacteria when properly fit-tested.

Understanding the difference:
https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf



This policy and procedure is not intended to replace the informed judgment of individual physicians, nurses or other clinicians nor is it intended as a statement of prevailing community standards or minimum standards of practice. It is a suggested method and technique for achieving optimal health care, not a minimum standard below which residents necessarily would be placed at risk.

https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-andsurgical-masks-face-masks#§4
March 16, 2020
https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Finfection-control%2Fcontrol-recommendations.html
November 4, 2020

https://blogs.cdc.gov/niosh-science-blog/2020/03/16/n95-preparedness/
March 16, 2020

Q: Which face masks and surgical masks are medical devices regulated by the FDA?

A: The FDA regulates face masks, including cloth face coverings, and surgical masks as medical devices when they are marketed for medical purposes. Medical purposes include uses related to COVID-19, such as face masks to help stop the spread of disease, surgical masks and surgical masks with antimicrobial/antiviral agents. Face masks marketed to the general public for general, non-medical purposes, such as for use in construction and other industrial applications, are not medical devices.

Using Face Masks, Surgical Masks and Respirators

Q: Do face masks provide protection from coronavirus?

A: Masks may help prevent people who have COVID-19 from spreading the virus to others. The CDC recommends people wear face masks in public settings, especially when other social distancing measures are difficult to maintain. Wearing a face mask may limit exposure to respiratory droplets and large particles and may help prevent people who have COVID-19 from spreading the virus.

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html
December 7, 2020

Q: Are face masks, surgical masks, and respirators safe to wear?

A: If worn properly, face masks, surgical masks, or respirators may reduce the chance of spreading a COVID-19 infection between you and those around you. The CDC provides information on Using PPE and Considerations for Wearing Masks.

FDA-cleared, surgical masks and respirators have been used by health care personnel for years and have been worn in health care facilities during extended procedures without harm to the wearer. Health care personnel with medical conditions should discuss concerns they may have with wearing respirators with their own health care providers. Health care personnel should follow the manufacturer's instructions and their facility's policies for use of all PPE.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html
August 19, 2020

https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html
August 19, 2020

Q: What does wearing a face mask for "source control" mean?

A: Source control refers to use of cloth face coverings or face masks to cover a person's mouth and nose when they are talking, sneezing, or coughing to reduce the likelihood of transmission of infection by preventing the spread of respiratory secretions. COVID-19 may be spread by individuals who may or may not have symptoms of COVID-19.

The general public's use of cloth face coverings made from common, easily accessible materials are an additional voluntary public health approach to help slow the spread of COVID-19. The CDC has information on the Use of Masks to Help Slow the Spread of COVID-19 for the general public

Face masks intended for a medical purpose, such as prevention of infectious disease transmission, are subject to FDA regulation. The FDA has issued an emergency use authorization (EUA) as well as guidance on regulatory flexibility for such products. For more information, see "I'm interested in manufacturing face masks or surgical masks for the COVID-19 pandemic. What do I need to do?

For more information on source control, see the CDC's Interim Infection Prevention and Control Recommendations for HealthCare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic.

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html
November 27, 2020

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fprevent-getting-sick%2Fcloth-face-cover-faq.html
November 12, 2020

https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
November 4, 2020

Q: During the COVID-19 public health emergency, when should health care personnel wear face masks or respirators?

A: During the COVID-19 public health emergency, the CDC recommends health care personnel wear face masks at all times while they are in the health care facility, including in breakrooms or common areas where they might encounter co-workers or visitors.

When available, surgical masks (a specific type of face mask) are preferred over cloth face coverings for health care personnel as surgical masks offer both source control and protection for the wearer against exposure to splashes and sprays of infectious material from others.

- Cloth face coverings should NOT be worn instead of a respirator or surgical mask if more than source control is needed.
- Wear an N95 or equivalent or higher-level respirator, instead of a face mask for:
    - Aerosol generating procedures, refer to "Which procedures are considered aerosol generating procedures in healthcare settings"? on the CDC's clinical questions about COVID-19: Questions and Answers.
    - Surgical procedures that might pose a higher risk for transmission if the patient has COVID-19 (for example, that generate potentially infectious aerosols or involve anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, or respiratory tract. Refer to "During the COVID-19 pandemic, are there special considerations for surgical and other procedural care setting, including performance of aerosol-generating procedures (AGPs)?" on the CDC's Clinical Questions about COVID-19: Questions and Answers page.
    - Health care personnel should consult their institutional policies for further guidance on what type of face mask or respirator to use.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
November 4, 2020

https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html
December 4, 2020

Shortages of Face Masks, Surgical Masks and Respirators During the COVID-19 Pandemic

Q: How can health care facilities know if there may be a shortage of face masks, surgical masks, or respirators so they can prepare?

A: The FDA provides information on medical device shortages during the COVID-19 public health emergency and maintains a list of devices that it has determined to be either in shortage or permanently discontinued. Health care facilities may review the list of device types to determine which devices may be included in the shortage or discontinuation lists.

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency
September 24, 2020

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-types-help-determine-section-506j-notification-obligations
November 25, 2020

Q: My supply of surgical masks is running low. What are the best strategies to conserve surgical masks during COVID-19?

A: The FDA issued a Letter to Health Care Providers on Surgical Mask and Gown Conservation Strategies that describes three recommended strategies:

- Conventional capacity strategies
- Contingency capacity strategies
- Crisis or alternate strategies if surgical masks are running low or not available

https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers
April 27, 2020

Q: Can we use expired face masks or surgical masks? Do they offer the protection needed?

A: Face masks and surgical masks are designed to serve as protective barriers and may still offer some protection even if they are used beyond the manufacturer's designated shelf life or expiration date. If there is no date available on the face mask label or packaging, facilities should contact the manufacturer. The user should inspect all masks prior to use and, if there are concerns such as degraded materials (such as elastic) or visible tears, the product should be discarded. For additional information please refer to the CDC's Strategies for Optimizing the Supply of Facemasks.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html
November 23, 2020

Q: How do I know what the manufacturer-designated shelf life is?
A: The manufacturer-designated shelf life or expiration date may be found on the product labeling or packaging or you can contact the manufacturer directly.

Q: Can we reuse disposable surgical masks during COVID-19?
A: The CDC does not recommend the reuse of disposable surgical masks that are intended to be used once. The FDA recognizes that there may be availability concerns with surgical masks during the COVID-19 public health emergency, but there are strategies to conserve surgical masks.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/emergency-considerations-ppe.html
November 19, 2020

https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers
April 27, 2020

Q: Can reusable facemasks be cleaned during COVID-19:

A: The CDC recommends reusable face masks be washed after each use and provides information on the cleaning of cloth face masks.

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wash-cloth-face-coverings.html
October 28, 2020

Q: Can filtering facepiece respirators (FFRs) such as N95s be reused during COVID-19?

A: The CDC considers N95-type FFRs a one-time-use product and recommends that cleaning, decontamination and subsequent reuse of FFRs should only be used when there is a critical shortage of FFRs and should only be performed on NIOSH-approved FFRs without exhalation valves. For additional details, see the CDC's Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings and the CDC's recommendations on Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators.

The FDA has issued Emergency Use Authorization (EUAs) for devices that decontaminate certain respirators. Health care facilities should check the Decontamination Systems for Personal protective Equipment EUAs for the most up-to-date information.

FFR decontamination may be an effective method of reducing the pathogen burden. The process used by EUA-authorized decontamination devices should not harm the fit or filtration performance of the FFR and should present no residual chemical hazard to the FFR user. For additional details, see the FDA's Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During the Coronavirus Disease 1029 (COVID-19) Public Health Emergency.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html#:~:text=Decontamination%20is%20a%20process%20to,practiced%20where%20FFR%20shortages%20exist
October 19, 2020

https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html
March 27, 2020

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks
May 2020

Emergency Use Authorizations for Face Masks, Surgical Masks and Respirators

Q: Why does the FDA Issue Emergency Use Authorizations (EUAs)?

A: EUAs authorize the use of medical devices that are not FDA-cleared or approved. The EUA authority allows the FDA to help strengthen the nation's public health protections against emerging infectious disease threats by facilitating the availability and use of medical devices needed during public health emergencies.

Under the Federal Food, Drug and Cosmetic Act, the FDA Commissioner may authorize the emergency use of an unapproved or uncleared medical product or an unapproved/uncleared use of an approved/cleared medical product for certain emergency circumstances after the HHS Secretary has made a declaration of emergency or threat justifying emergency use. The FDA Commissioner may issue an EUA to authorize a medical product for use in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions when there are no adequate, approved or available

alternatives. The Emergency Use Authorizations (EUAs) for diagnostic, non-diagnostic and therapeutic medical devices that the FDA has issued related to COVID-19 may be revised, terminated or revoked as needed.

For details on the Emergency Use Authorizations for these devices, see Personal Protective Equipment EUAs and Face Mask EUA.

There are currently no FDA-approved face masks, surgical masks or respirators. To identify FDA-cleared face masks, surgical masks and respirators, search the 510(k) Premarket Notification database.

https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act
March 29, 2018

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic
August 18, 2020

https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices
August 3, 2020

Q: What is a pre-EUA?

A: To help prepare for potential and current emergencies, the FDA works with medical device developers to prepare pre-EUA packages when appropriate. A pre-EUA package contains data and information about the safety, quality and effectiveness of the product, its intended use, and information about the emergency or potential emergency situation. The pre-EUA process allows the FDA's scientific and technical subject matter experts to begin a review of information and consideration of the EUA statutory criteria, assist in the development of conditions of authorization, fact sheets, and other documentation that would be needed for an EUA, and also helps to facilitate completion of EUA requests during a current emergency declaration.

For additional information, refer to Emergency Use Authorization of Medical products and Related Authorities.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities
October 17, 2018

Q: What is an Umbrella EUA?

A: Many EUAs apply only to a specific medical device. Generally, an umbrella EUA authorizes many categories of devices that meet specific criteria, helping to facilitate access to those devices by streamlining the process associated with EUAs (for example, EUA request submission and FDA authorization) for any medical devices that meet the requirements within the EUA.

Q: What type of mask does the umbrella EUA for surgical masks authorize?

A: The FDA issued an umbrella EUA in response to insufficient availability of disposable, single-use surgical masks. This EUA established performance criteria for the surgical mask to be authorized for use in health care settings by health care personnel as PPE.

Performance criteria that must be met include liquid barrier performance, particulate filtration efficiency, air flow resistance, and use of biocompatible, non-cytotoxic, non-irritating and non-sensitizing materials. Surgical masks that have been confirmed by the FDA to meet the criteria are listed in Appendix A of the EUA as authorized surgical masks.

To be added to Appendix A, test reports must be submitted to the FDA demonstrating that the surgical mask meets the performance criteria. Requests can be submitted to the FDA with the subject line "Surgical Masks EUA" at the link below. The Surgical Masks EUA Template for Addition to Appendix A can be used to provide the required information.

Manufacturers, importers and distributors must also comply with the conditions of authorization found in Section IV of the EUA Letter of Authorization.

The following surgical masks are not covered in the scope of this EUA:

- Surgical masks that are FDA-cleared
- Surgical masks that are manufactured in China
- Surgical masks that include drugs, biologics, nanoparticles or antimicrobial/antiviral agents

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#surgicalmasks
December 4, 2020

Q: What type of respirators does the umbrella EUA for NIOSH-Approved Air Purifying respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency authorize?

A: Respirators authorized by this EUA include:

1. Non-powered, air purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH.
2. Other powered air purifying respirators (PAPRs) approved by NIOSH.
3. FFRs that were NIOSH-approved but have since passed the manufacturer's recommended shelf life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles (referred to as expired FFRs).
4. Any authorized respirator under (1) or (3) above that has been decontaminated pursuant to the terms and conditions of an authorized decontamination system.

For more information, see CDC/NIOSH recommendations in Considerations for Release of Stockpiled N95 Beyond the Manufacturer-Designated Shelf Life.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/release-stockpiled-N95.html
July 20, 2020

Q: What type of respirator does the umbrella EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFR) authorize?

A: This EUA authorizes the emergency use of the following Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs):

- Disposable FFRs that have been designed, evaluated and validated to meet a given performance standard and have corresponding acceptable product classifications as identified in Table 1 of the EUA.
- Disposable FFRs that conform to Personal Protective Equipment (PPE) Directives as evidenced by a European Conformity (CE) mark, and the CE mark has been authenticated and verified by the FDA.
- Disposable FFRs that are manufactured by entities that hold NIOSH approval, that have been verified by the FDA and that are produced by the NIOSH approval holder under the authorization standards of another country.
- Non-valved, authorized FFRs (authorized respirators without exhalation valves) that are decontaminated using an authorized or cleared decontamination system.

Authorized Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

https://www.fda.gov/media/136403/download
June 6, 2020

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#exhibit1
December 4, 2020

Purchasing or Donating Face Masks, Surgical Masks, and Respirators During the COVID-19 Pandemic

Q: How can I tell if the face masks, surgical masks, or respirators I want to purchase are counterfeit or fraudulent?

A: The FDA does not have a list of all counterfeit or fraudulent products. To report fraudulent COVID-19 products to the FDA, email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov. The CDC provides information on identifying counterfeit respirators at Counterfeit Respirators/Misrepresentation of NOSH-Approval.

https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html
December 4, 2020

Reporting Shortages of or Problems with Face Masks, Surgical Masks or Respirators

Q: How do I report a shortage of face masks, surgical masks, or respirators?

A: The FDA encourages health care facilities which anticipate a potential shortage or are experiencing an actual shortage to notify the FDA. For potential or actual supply issues, e-mail information to the FDA at deviceshortages@fda.hhs.gov .

Q: How do I report a problem with face masks, surgical masks or respirators?

A: The FDA encourages reporting of any adverse events or suspected adverse events experienced with face masks, surgical masks or respirators.

- In general, device manufacturers, importers and device user facilities (health care facilities) must comply with the applicable medical device Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities.
- Voluntary reports from health care personnel and users can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program.
- Health care personnel employed by organizations that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their organizations.

https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities
May 22, 2020

https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda
May 22, 2018

https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-including-surgical-masks-and-respirators-covid-19
November 24, 2020