

# Respiratory protection solutions for the surgical setting.

## **3M Respirators and Masks**

3M is on a mission to transform surgical outcomes. Surgical teams are focused on providing the highest level of care for all patients. Our mission is to benefit surgical teams and patients across the surgical continuum to protect skin, reduce complications and restore lives. Every patient, every time.

3M's Resource Guide is designed to provide information on health care professional (HCP) respiratory protection. Please continue to check the U.S. Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), U.S. Occupational Safety and Health Administration (OSHA) and state guidelines to ensure your facility is following the appropriate guidelines.

### What respiratory protection should we consider using in our facility?

### Respirators

A filtering facepiece respirator is a personal protective device that is worn on the face and covers the nose and mouth. A respirator is used to help reduce the wearers, risk of inhaling hazardous airborne particles (including infectious agents).

#### N95 Filtering Facepiece Respirators (FFR)

An N95 filtering facepiece respirator (FFR) is a type of respirator which contains filter media and forms a seal to the face, and when used properly, filters particles from the air that are breathed through it. These respirators may filter out at least 95% of non-oily particles. N95 FFRs can help reduce wearers' exposures to airborne particulate hazards, including both bioaerosols and nonbiological aerosols.

### **N95 Surgical Respirator**

An N95 Surgical Respirator (also referred as a surgical medical respirator) is recommended only for use by HCP who need protection from both airborne and fluid hazards (e.g., splashes, sprays). N95 Surgical Respirators both are approved by NIOSH as an N95 respirator and also cleared by the FDA as a surgical mask. CDC guidelines recommend prioritization of these respirators for use by HCPs who are working in a sterile field or who may be exposed to high velocity splashes, sprays, or splatters of blood or body fluids, such as in operative or procedural settings.<sup>2</sup>

### What if an N95 Surgical Respirator is not available?

If an N95 Surgical Respirator is not available for use in operative or procedural settings, then an unvalved N95 respirator may be used with a faceshield to help block high velocity streams of blood and body fluids.\*

#### What if COVID-19 testing or test results are not available?

For all patients undergoing treatment in a healthcare setting where testing or test results are not available and in regions experiencing high incidence of COVID-19 in the community, the CDC recommends that facilities consider using precautions specific to COVID-19 for all patients. This includes the prioritization of N95 respirators, for aerosol generating procedures.<sup>2</sup>

Learn more about COVID-19 Infection Prevention Guidelines View Web Page

### 3M N95 Respirators

### How do I determine if a respirator is fitting properly?

The US Occupational Safety and Health Administration (OSHA) requires that respirators be fit tested before the first use, and annually thereafter. During the COVID-19 outbreak, OSHA has issued enforcement memos to provide expanded guidance on annual fit testing requirements. For more information go to the Fit Testing Resources on the 3M website: 3M.com/coronavirus. Click on the links for more information on fit testing and to view the pdfs.

**U.S. OSHA Position on Fit Testing during COVID-19** 

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**Fit Testing during Urgent Use** of New Respirator Models

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### **Decontamination and Reuse of Filtering** Facepiece Respirators.

During the COVID-19 public health emergency, many healthcare institutions are experiencing severe shortages of N95 respirators. The U.S. Centers for Disease Control and Prevention (CDC) has issued Strategies for Optimizing the Supply of N95 Respirators. In this document the CDC recommends conventional capacity strategies, contingency capacity strategies (during expected shortages) and crisis strategies (during known shortages). 3M has been collaborating with a number of sterilization companies and institutions that are investigating ways for healthcare facilities to safely decontaminate N95 filtering facepiece respirators (FFRs).

Learn more about optimizing supply and decontamination

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Learn more about decontamination methods for 3M N95 Respirators

The U.S. Food and Drug Administration (FDA) has published a list of decontamination systems it has authorized under Emergency Use Authorizations (EUAs) for use during the COVID-19 outbreak.<sup>4</sup> Please see the current information on these decontamination systems and a summary of testing on the effects of each system on the filtration efficiency and integrity of 3M respiratory protection products. It is important to note 3M evaluation of these systems of select 3M N95 respirators, are only in the context of impact on fit and filtration performance and not their efficacy with regards to deactivation of the virus that causes COVID-19.

### **Skin Protection**

Extended use of PPE, particularly devices like respirators and face shields, may impact skin and may be associated with various levels of skin breakdown. We are committed to helping you protect yourself. Explore some simple ways you can help minimize the risk of breakdown.

For more information on skin protection, visit 3M.com/PPESkin





### Reduce pressure on your skin.

- Ensure proper fit. Don't over-tighten the respirator.
- Confirm proper positioning of headbands.
- Avoid wearing a mask over the respirator. An increase in tightness can occur.
- If possible, remove the respirator at regular intervals.5 in noncontaminated areas.



### **Protect Skin from** friction and moisture.

- Apply a liquid barrier film or skin protectant.\*
- Cushion skin, or cover an abrasion, under PPE that does not require a seal to skin\*



### **Prevent interference** with the seal.

- Do not use thick creams, ointments, petroleum jelly, polyurethane foams or hydrocolloids and other products that could interfere with the fit and seal of PPF.
- If using a dressing, select the lowest profile dressing available. Conduct a fit test.



### 3M™ Cavilon™ Product Use for PPE Skin Protection.

Certain 3M skin health products may help protect the skin and not interfere with the fit of the respirator including:

3M<sup>™</sup> Cavilon<sup>™</sup> No Sting Barrier Film

3M™ Cavilon™ Advanced Skin Protectant\*\*

Learn more about skin protectants and how to use Cavilon solutions for PPE skin protection.

View PDF (lacksquare)

<sup>\*</sup>Certain products may not be appropriate due to their potential to interfere with the fit/functionality of the PPE. Respirator wearers should always follow the model-specific User Instructions, including completion of a user seal check each time a respirator is put on.

<sup>\*\*</sup>Federal Law (U.S.A.) restricts the device to sale by or on the order of a licensed health care professional.

### **Frequently Asked Questions**

# What makes N95 Surgical Respirators different from surgical masks?

Respirators and Surgical Masks: A Comparison

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	N95 Surgical Respirator	Surgical Masks		
Who should use?	Recommended for use by healthcare personnel (HCP).	Patients with confirmed or suspected COVID-19 should wear a surgical mask until they are isolated. <sup>6</sup>		
Intended use and purpose	Helps reduce wearer's exposure to airborne particles and high velocity sprays of body fluid. Helps prevent contamination of the surrounding area when a person coughs or sneezes.	Helps prevent contamination of the surrounding area when a person coughs or sneezes.		
Filtration	Filters out at least 95% of non-oily particles in the air, from small particle aerosols to large droplets.	DOES NOT protect wearer from inhaling smaller airborne particles.		
Fit	Tight-fitting.	Loose-fitting.		
Fit test required	Yes, prior to initial use and at least annually.	No.		
Seal check required?	Each time the respirator is used.	Not necessary.		

### What is an N95 Surgical Respirator and who needs to wear it?

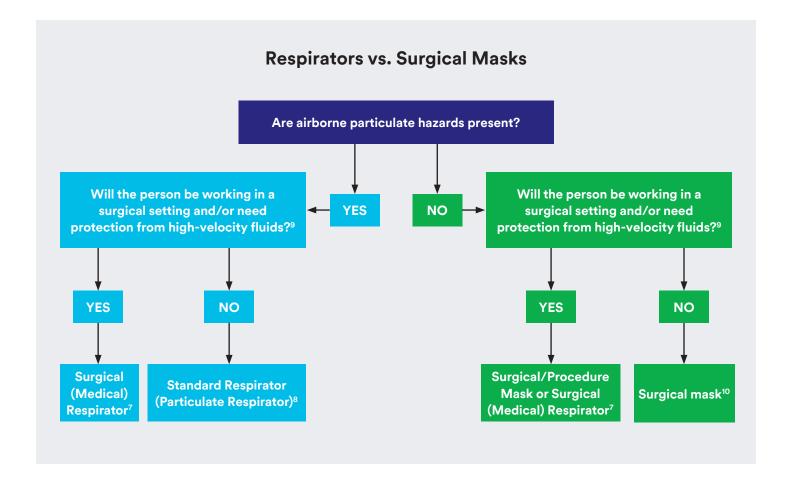
An N95 Surgical Respirator is recommended for use by HCP who need protection from both airborne particles and high velocity sprays of body fluid. These respirators are likely not used or needed outside of healthcare settings. CDC guidelines recommend prioritization of these respirators for use by HCPs who are working in a sterile field or who may be exposed to high velocity splashes, sprays, or splatters of blood or body fluids, such as in operative or procedural settings.<sup>2</sup>

If an N95 Surgical Respirator is not available for use in operative or procedural settings, the CDC advises that an unvalved N95 standard respirator may be used with a faceshield to help block high velocity streams of blood and body fluids.<sup>3</sup>

Healthcare Infection Prevention and Control FAQs for COVID-19



### **Frequently Asked Questions**



# What is the difference between an N95 Surgical and an N95 standard respirator?

For more information on N95 Surgical vs. N95 Standard Respirators, view:

Tech Bulletin N95 Surgical vs. N95 Standard Respirators View PDF

### How can I detect fraud and avoid counterfeit respirators?

3M recommends purchasing 3M products only from 3M authorized distributors or dealers, which will increase the likelihood that you will receive authentic 3M products. Here are some tips to help avoid or identify counterfeit products:

- 3M respirators will be sold in 3M packaging, with model-specific user instructions accompanying the product.
- 3M respirators should not be sold individually or without packaging (including User Instructions).
- 3M has strict quality standards, and therefore products that have missing straps, strange odors, blocked valves, misspelled words, etc. are likely not authentic 3M respirators.

Learn more how to identify fraud or counterfeit respirators

View PDF

For further assistance in determining whether a 3M product you have purchased is authentic, we encourage you to contact your **3M Technical Service team at 1-800-441-1922**. Please be prepared to share your proof of purchase information (invoice, receipt, etc.) in order to help with this process.

### **Frequently Asked Questions**

### Can your facility use reusable respirators?

Reusable respirators can be used in compliance by your staff based on your facility's protocols. These respirators can help reduce inhalation exposure to airborne biological particles, they have not been FDA cleared as surgical masks. There are two types of reusable respirators:

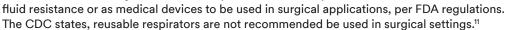
### Reusable (Elastomeric) Respirators

Elastomeric respirators are full- or half-facepiece, tight-fitting respirators that are made of synthetic or rubber material permitting them to be repeatedly disinfected, cleaned, and reused. They are equipped with replaceable filter cartridges. Similar to N95 respirators, elastomeric respirators require annual fit testing. Reusable (elastomeric) respirators are r

respirators require annual fit testing. Reusable (elastomeric) respirators are not surgical masks as they are not cleared by FDA for fluid resistance or as medical devices to be used in surgical applications, per FDA regulations. The CDC states, reusable respirators should not be used in surgical settings.<sup>11</sup>

### **Powered Air Purifying Respirators (PAPRs)**

PAPRs are reusable respirators that are typically loose-fitting hoods or helmets. These respirators are battery-powered with blower that pulls air through attached filters or cartridges. The filter is typically a high-efficiency particulate air (HEPA) filter. Loose-fitting PAPRs do not require fit-testing and can be worn by people with some facial hair. PAPRs are not surgical masks as they are not cleared by FDA for



Additional respiratory options

View Web Page

Capacity strategies from the CDC





Ford Limited-Use Public Health Emergency PAPR was created with consulting support from 3M and is a PAPR for use in reducing exposure to airborne particles. This PAPR is designed to quickly aid healthcare workers during the COVID-19 pandemic by providing constant filtered airflow.

### How is 3M distributing their respirators and masks?

Even with 3M's accelerated production combined with capacity from other manufacturers, the current reality of product availability remains a prevalent issue that we are actively working to address. 3M is working to increase output of N95 respirators and is helping to get products to those who need it most, healthcare workers. Our goal is eventually to return to our traditional order fulfillment and service levels. We appreciate your understanding during this unprecedented global crisis.

3M recommends communicating and establishing your PPE needs, including respirators, directly with your 3M authorized distributor. We will continue to rely on the healthcare supply chain distribution channel as this infrastructure is best suited to reach our customers.

### 3M N95 Surgical Respirators

During surgery, or a procedure where there is a risk of encountering a high velocity stream of bodily fluids, the CDC recommends the use of an N95 Surgical Respirator. During times of shortages, the CDC recommends if an N95 Surgical Respirator is not available for use in operative or procedural settings, then an unvalved N95 standard respirator may be used with a faceshield to help block high velocity streams of blood and body fluids.<sup>3</sup>

Respirator Use FAQ View Web Page

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Product		Cat. No.	Assigned Protection Factor	Filtration Efficiency Classification	Valve	Country of Origin	Shelf Life
3M™ Health Care		1860	— 10	N95	Unvalved	Made in U.S.A. with US and imported materials	5 years from date of manufacture
Particulate Respirator and Surgical Mask		1860S (small)					
3M <sup>™</sup> VFlex <sup>™</sup> Health Care Particulate Respirator and Surgical Mask		1804*	- 10	N95	Unvalved	Made in U.S.A. with US and imported materials	5 years from date of manufacture
	*50*	1804S (small)*					

### 3M N95 Standard Respirators

The following 3M N95 standard respirators are acceptable for procedures where fluid resistance is not needed. In times of shortages, the CDC recommends that if an N95 Surgical Respirator is not available, then an unvalved N95 standard respirator may be used with a faceshield in operative or procedural settings where the health care worker may be exposed to high velocity streams of blood and body fluids.3

Respirator Use FAQ

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Product		Cat. No.	Assigned Protection Factor	Filtration Efficiency Classification	Valve	Country of Origin	Shelf Life
3M™ Particulate Respirator		8210					
		8210Plus	10	N95	Unvalved	Made in U.S.A. with US and imported materials	5 years from date of manufacture
	*	8110S	_				
	M_	9210+	10	N95	Unvalved	Made in Singapore	5 years from date of manufacture

### **3M Skin Protection**

Product		Cat. No.	Size	Items/Box	Boxes/Case	HCPCS Code
3M™ Cavilon™ No Sting Barrier Film	Carlor Cador	3343	1 mL wand	25	4	
		3344	1 mL wipe	30	4	Skin Care: A6250 Ostomy: A5120
		3345	3 mL wand	25	25	
		3346	28 mL spray bottle	12	1	Skin Care: A6250 Ostomy: A4369
3M™ Cavilon™ Advanced Skin Protectant*		5050	2.7 mL applicator	20	_	A6250
		5051	0.7 mL applicator	20	_	_

### For more information:

Visit 3M's COVID-19 **Dedicated Reference Site** (\*)

**Contact your local** 3M Account Manager

Call the 3M Health Care Helpline at 1-800-228-3957





This respirator helps reduce exposures to certain airborne contaminants. Before use, the wearer must read and understand the User Instructions provided as a part of the product packaging. Follow all local regulations. In the U.S., a written respiratory protection program must be implemented meeting all the requirements of OSHA 1910.134, including training, fit testing and medical evaluation. In Canada, CSA standard Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. Misuse may result in sickness or death. For correct use, consult supervisor and the User Instructions or call 3M PSD Technical Service in USA at 1-800-243-4630 and in Canada at 1-800-267-4414.

Always read and follow user instructions.



3M Health Care **Medical Solutions Division** 3M Center, Building 275-4E-01 St. Paul, MN 55144 USA

Phone 1-800-228-3957 Web 3M.com/medical

- \* Federal Law (U.S.A.) restricts the device to sale by or on the order of a licensed health care professional.
- 1. https://www.cdc.gov/coronavirus/2019-ncov/novel-coronavirus-2019-SupplyChecklist\_of-N95-Respirators\_COVID-19\_4\_6\_20\_num.pdf
- 2. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
- $3.\ https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html$
- 4. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-decontaminate-millions-n95 5. National Pressure Injury Advisory Panel. NPIAP POSITION STATEMENTS ON PREVENTING INJURY WITH N95 MASKS. 2020.
- 7. In the U.S., surgical/procedure masks and medical respirators must be cleared by the FDA for use in surgery. Medical respirators must be also approved by NIOSH.
- 6. https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf
  - 8. In the U.S., particulate respirators must be approved by NIOSH. 9. Patient care with potential exposure to high velocity streams of blood such as intravenous lines, surgery, emergency room, etc. Consult with your infection
  - control manager
  - 10. Comfort masks are not designed to protect lungs from airborne hazards, are not NIOSH approved, and are not FDA cleared.
- 11. https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html

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