



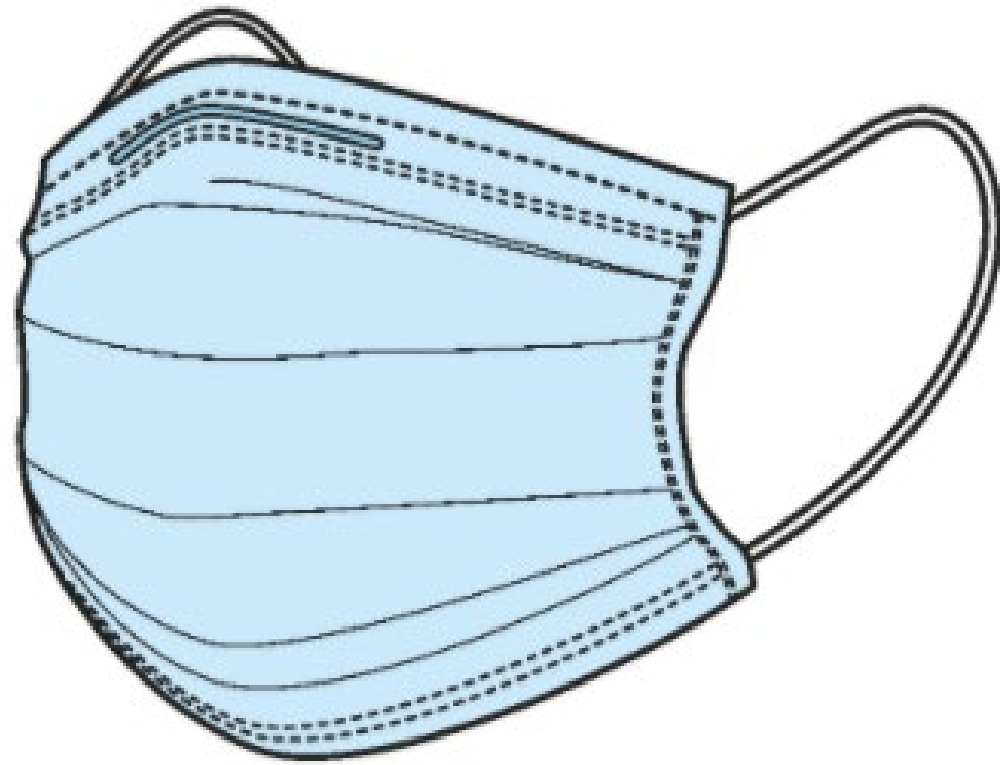
Mask Types

HOW DO THEY RATE?

What is a face mask?

- Surgical Masks
- Dental Masks
- Medical Procedure Masks
- Isolation Masks
- Laser Masks

Surgical vs. Procedure Mask



- Have ear loops for quick donning
- Used when performing patient procedures
- Used when patients are in isolation
- Protects patients and staff
- Used to prevent the spreading of germs while talking, coughing, sneezing, etc.



- Tied over surgical cap or bouffant cap
- Used in sterile environments
- Protect the environment from contamination
- Protects clinician from contaminated fluid or debris during the procedure

ASTM International

The American Society for Testing and Materials

[ASTM International](#) is a global organization that develops and publishes technical standards for products, materials, systems and services.

[ASTM F2100-11](#) is the standard for medical face masks since 2012.

In developing ASTM F2100-11, the organization tested material used to make medical face masks on **five performance metrics**.

- Fluid Resistance
- Breathability
- Bacterial Filtration
- Particulate Filtration
- Flammability

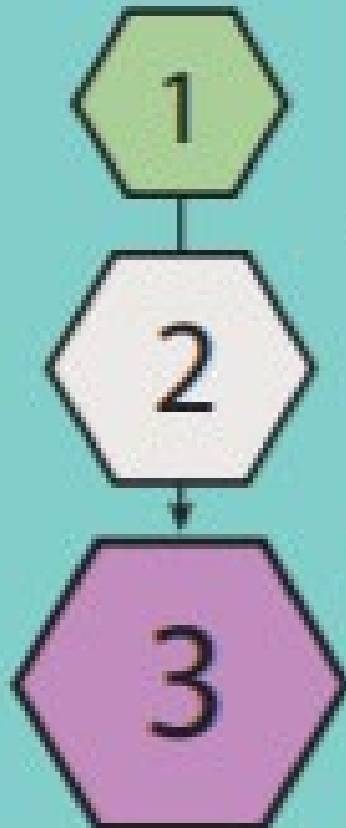
Five Performance Metrics


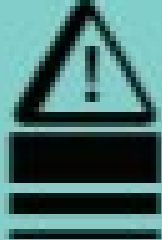
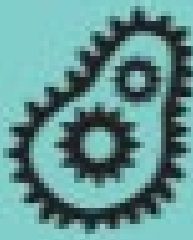
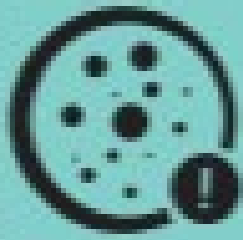

- [Fluid Resistance](#) – Test ASTM F1862, evaluates the resistance of a medical face mask to penetration by a small volume (~2 mL) of synthetic blood at a high velocity (80 mmHg, 120 mmHg, or 160 mmHg). (Pass/Fail)
- [Breathability](#) – Test MIL-M-36954 C: ΔP , determines the face mask's resistance to airflow. A controlled flow of air is driven through the mask, and the pressure before and after is measured. The difference in pressure is divided by the surface (in cm²) of the sample. A lower breathing resistance indicates a better comfort level for the user.
- [Bacterial Filtration](#) (BFE) – Test ASTM F2101, measures the percentage of bacteria larger than 3 microns filtered out by the mask. The challenge material used is Staphylococcus aureus.
- [Particulate Filtration](#) (PFE) – Test ASTM F2299, measures the percentage of particles larger than 1 micron filtered out by the mask. The challenge material used consists of latex aerosol concentrations in a controlled airflow chamber.
- [Flammability](#) – Test 16 CFR Part 1610: Flame Spread, exposes the face mask material to a flame and measures the time required for the flame to proceed up the material a distance of 127 mm (5 inches). Class 1 means the material exhibits normal flammability and is acceptable for use in clothing.

ASTM Ratings

Understanding
ASTM levels of
protection is Key

ASTM F2100-11 Levels



	Characteristics	 Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	 Differential pressure, mm H₂O/cm² (Breathability)	 Bacterial filtration efficiency	 Sub-micron particulates filtration efficient at 0.1 micron	 Flame spread
Level 1: low barrier protection General use for short procedures and exams that don't involve aerosols, spray or fluids		80 mm Hg	<4.0	≥95%	≥95%	Class1
Level 2: moderate barrier protection For low to moderate levels of aerosols, spray and/or fluids		120 mm Hg	<5.0	≥98%	≥98%	Class1
Level 3: maximum barrier protection For heavy levels of aerosols, spray and/or fluids		160 mm Hg	<5.0	≥98%	≥98%	Class1

How Much Protection does each ASTM rating provide?

TEST	LEVEL 1 BARRIER	LEVEL 2 BARRIER	LEVEL 3 BARRIER
ASTM F1862 (Fluid Resistance)	80 mmHg	120 mmHg	160 mmHg
MIL-M-36954 C: ΔP (Breathability)	< 4 mm H ₂ O	< 5 mm H ₂ O	< 5 mm H ₂ O
ASTM F2101: BFE (Filtration 3 μ m)	$\geq 95\%$	$\geq 98\%$	$\geq 98\%$
ASTM F2299: PFE (Filtration 1 μ m)	$\geq 95\%$ @ 0.1 micron	$\geq 98\%$ @ 0.1 micron	$\geq 98\%$ @ 0.1 micron
16 CFR Part 1610: Flame Spread (Flammability)	Class 1	Class 1	Class 1

It protects your nose and mouth against splashes and sprays of blood and other bodily fluids, as well as bacteria and particulate matter of the sizes indicated in the above table; however, face masks do not provide respiratory protection against airborne diseases. For that purpose, a respirator is required.

3 tips for choosing the right face mask. (n.d.).
 Halyard Health. <https://www.halyardhealth.com/industry-news/2019/july/choosing-the-right-face-mask-3-things-to-know.aspx>

SARS-CoV-2
approx. 0.1 microns



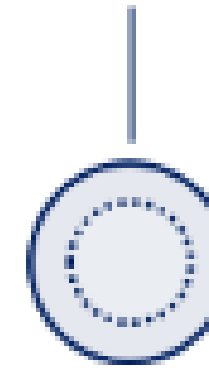
1 micron particle



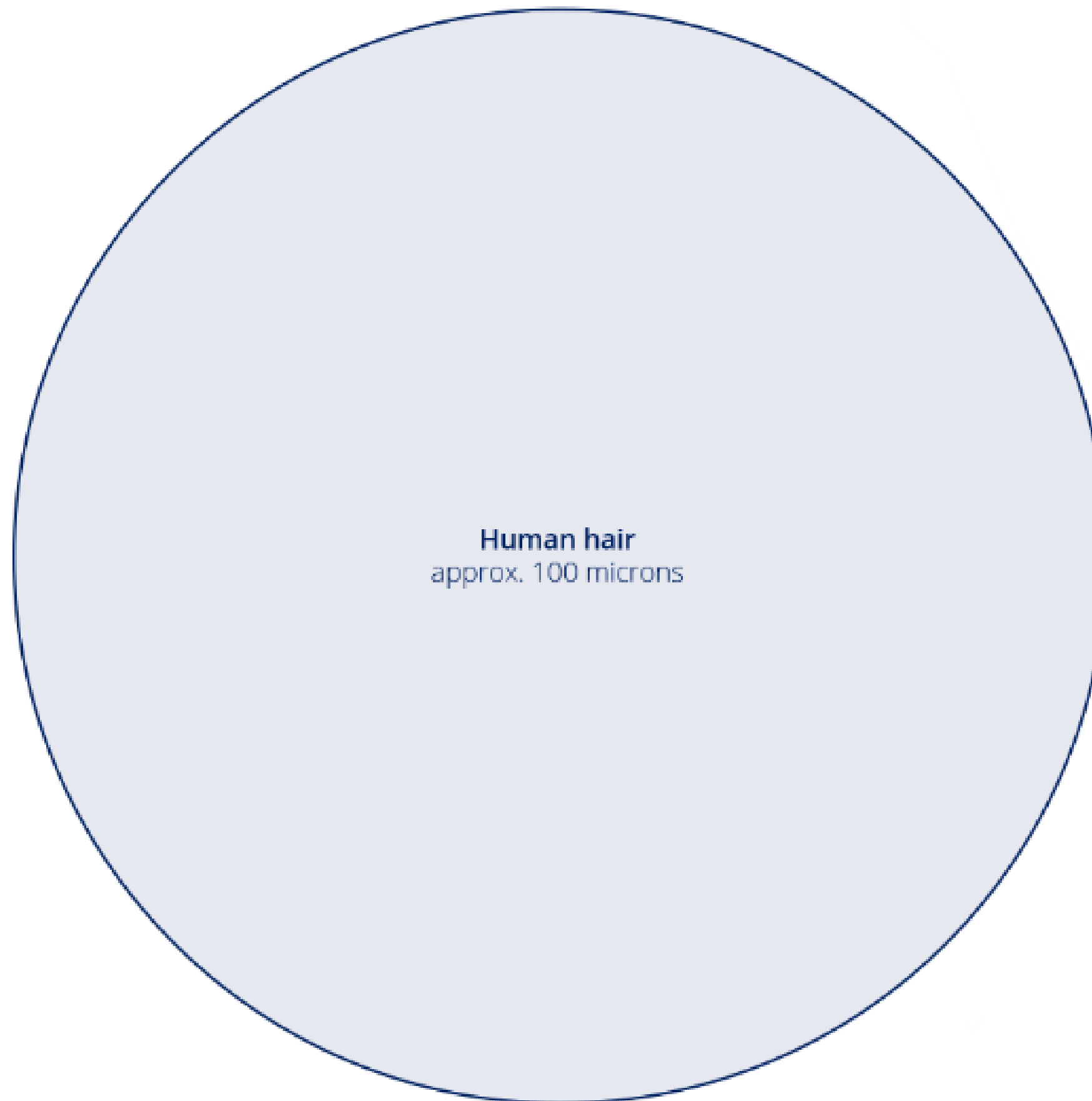
Bacterium
approx. 2 microns



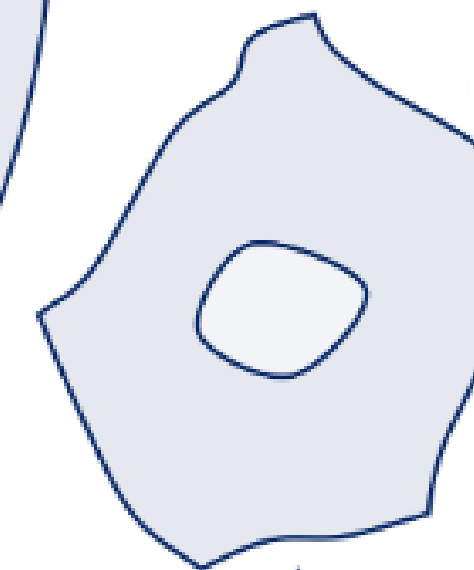
Red blood cell
approx. 8 microns



10 microns particle

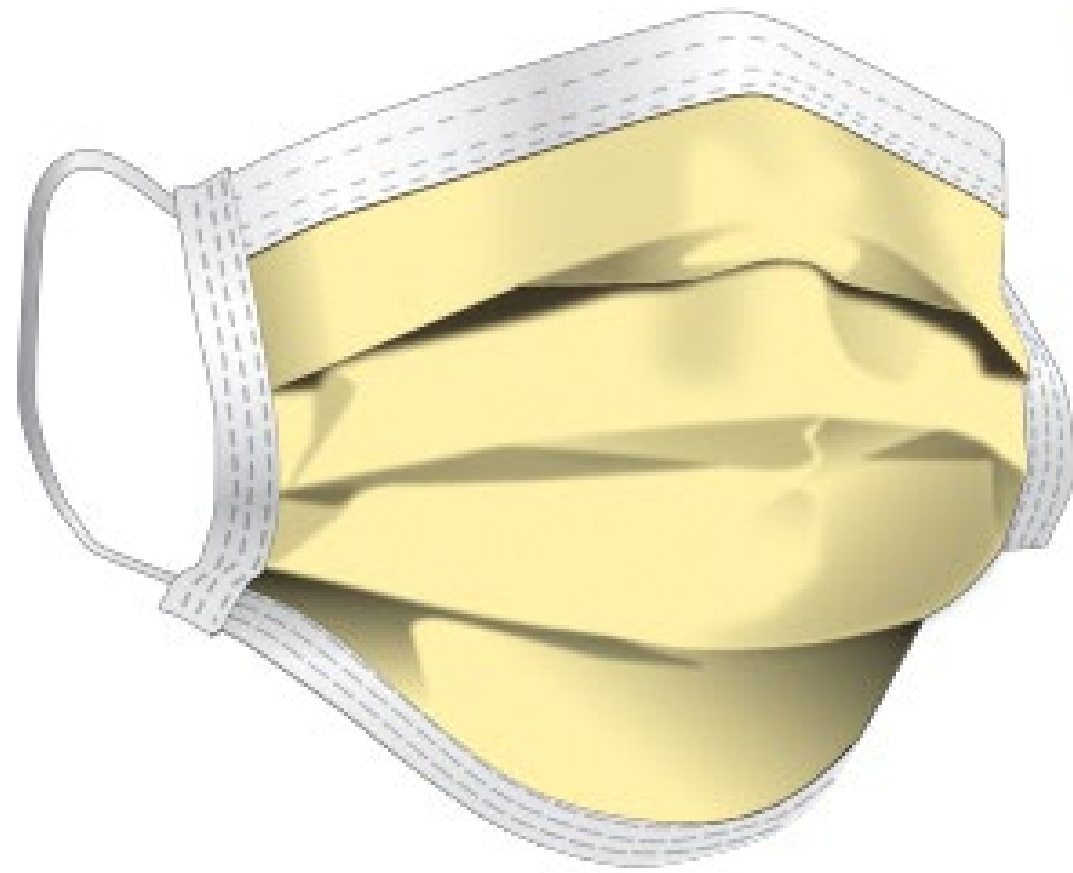


Human hair
approx. 100 microns



Skin cell
approx. 30 microns

Particle Diameter [microns]	Primary PPE	Engineering controls	Transmission characteristics
0.1 – 2	N95 respirator, Level II surgical mask, powered air purifying respirator	Building ventilation with MERV 14 filters, HEPA filters, UV sterilization	Indoor exposure over many hours, spatially uniform, multi rooms
2-8	Well-fitted mask with decent filtration efficiency	Building ventilation, MERV 12-13	Transmission uniform within rooms; exposure ~hour?
8-15	Any mask as long as it fits well	Local air extraction/filtration	Transmission <hour, non-uniform within room
15-30	Any mask if it fits; possibly some protection from face shields	Important to avoid strong drafts from fans and HVAC	Transmission follows air pathway in room; exposure of minutes; close range outdoor contact starts to become a risk
30- 100	Face shields and distance	Avoid strong drafts and install partitions	Transmission with a few meters of subject or direct air current; exposure of <min. Indoor or outdoor transmission probably equally likely
> 100	Face shields and distance	Barriers and physical distancing	Indoor or outdoor transmission with very brief contacts within 2 meters



Procedure Masks

ASTM Level 1

Patient & Staff isolation:
Clean environments, sterile cores,
processing departments, ER and
ICU for bedside procedures



Surgical Masks

ASTM Level 3

OR Staff in sterile environments:
closeness of fit protects against
fluid transmission or –Intended for
a high-risk of fluid exposure



Who should NOT wear a Mask:

- Children younger than 2 years old
- Anyone who has trouble breathing
- Anyone who is unconscious, incapacitated or otherwise unable to remove the mask without assistance

NOTE:

- Wearing masks may be difficult for some people with sensory, cognitive, or behavioral issues. If they are unable to wear a mask properly or cannot tolerate a mask, they should not wear one, and [adaptations and alternatives](#) should be considered

<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html>

Recommended for Outside of Healthcare Settings:



Non-medical disposable masks

<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html>

Disposable 3-Ply Face Masks (Civil-Grade)

Our **3 ply surgical masks** are for **Civilian Use and not for use in a medical or surgical setting**. The masks are made from a non-woven material with soft elastic ear loops making them easy and comfortable to wear. Personal Protective Equipment (PPE) such as **blue 3 ply face masks** could be an effective method of protection for COVID 19 (Coronavirus). These are **the best 3 ply masks** have up to 96% filtration efficiency and are ideal for everyday, civilian use. We suggest you do not attempt to re-use the masks, simply dispose of them after each use and wear a new disposable mask each time you need to.



We do not recommend these 3 ply civilian masks for medical or surgical use. Instead try ID&C's FDA approved 3 ply disposable [medical 3 ply face masks](#).

<https://www.idcband.com/en-us/3ply-mask-civilian/>

Buy surgical face masks 3Ply (civil-grade) - [IN STOCK] online | ID&C. (n.d.). Buy Custom Wristbands - Personalized Wristbands | Fast Shipping with ID&C Band. <https://www.idcband.com/en-us/3ply-mask-civilian>

ASTM F2100-11 Level 1

- Lightweight, non-woven polypropylene material
- Elastic loops fit comfortably around ears
- Nose clip molds mask securely to face
- Fluid resistant and disposable
- FDA Certified Facility
- MADE IN NY, USA
- 50 Per Box
- [PFE@0.1](#) micron >95%
- BFE>95%

**Intended For
General, Non-Medical Use**



Effectiveness

The most effective fabrics for cloth masks are

- Tightly woven fabrics, such as cotton and cotton blends
- Breathable
- Two or three layers

Less effective fabrics for cloth masks are

- Loosely woven fabrics, such as loose knit fabrics
- Difficult to breathe through (like plastic or leather)
- Single layer

The 4 F's of Mask Selection

- 1. Filtration:** When in doubt “Filter it out” use an N95
 - Airborne Communicable Disease Positive or PUI
 - 2. Fluid resistance:** In matters of Splatter, choose Fluid Resistance.
 - ASTM level 3 surgical masks are recommended.
 - 3. Features:** Bells and Whistles, Ties and Loops
 - Always use a level 3 surgical mask with ties in surgical settings.
 - Anti-fog film, foam and tapes reduce fogging issue distractions, and shields and protective eyewear keep eyes clear of blood and splash.
 - 4. Fit:** Even the correct mask could put clinicians at risk if it is not worn correctly.
 - The nose and mouth must be completely covered and create a seal around the face to prevent gaps that increase the risk of inhalation exposure.
- Bonus is “Feel” for Comfort and Breathability

Cardinal Health: Healthcare Solutions, Logistics & Supplies.

2020/Dec/18 <https://www.cardinalhealth.com/content/dam/corp/web/documents/whitepaper/Face%20Mask%20Selection%20Guide.pdf>

Masks with Exhalation Valves



CDC **does not recommend** using masks with exhalation valves or vents because this type of mask may ***not prevent you*** from spreading COVID-19 to others (Source Control).

NOTE: **The holes in the filters** may allow your respiratory droplets to escape and reach others.



One Way Valve - Scrutinized



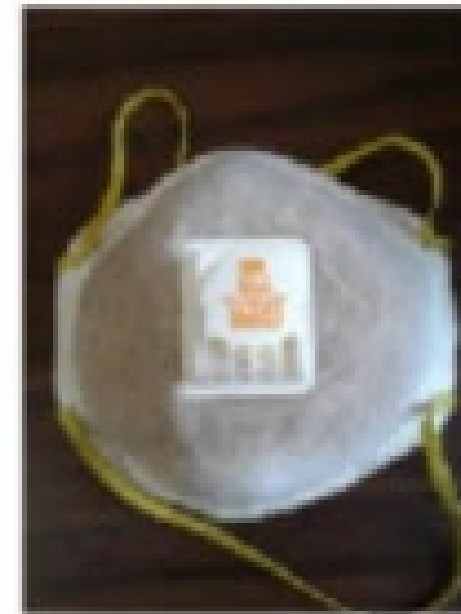
Is acceptable form of source control due to the N95 filter all the way through the mask. The exhalation valve is on the outside of the mask and **does not cause a hole to be placed through the N95 filter.**

Comparing Valve Masks

[As stated by the CDC,](#)

"Respirators with exhalation valves protect the wearer from SARS-CoV-2, the virus that causes COVID-19," and if "source control is needed, cover the exhalation valve with a surgical mask, procedure mask, or a cloth face covering that does not interfere with the respirator fit."

Valve Mask with Hole Directly from the Outside to the Inside
Not considered a Form of Source Control



Outside



Inside

Valve Mask with Built-in Face Covering Barrier Inside the Mask
Can be considered an Acceptable Form of Source Control

Outside



Inside



Valve Mask With a Surgical Mask, Procedure Mask, Or a Cloth Face Worn Over the Valve
Can be considered an Acceptable Form of Source Control

<https://www.prnewswire.com/news-releases/cdc-guides-valve-masks-worn-in-conjunction-with-cloth-face-coverings-can-protect-and-prevent-covid-19-301115086.html>

What is a respirator?

A [respirator](#) is a personal protective device that is worn on your face, covers at least your nose and mouth, requires fit-testing, and is used to reduce your risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases or vapors.

One of the most commonly used respirators is a NIOSH-approved N95 Respirator mask, which has been tested to filter out at least 95% of airborne particles.

A [Surgical N95 Respirator](#) is a NIOSH-approved N95 Respirator that has been cleared by the FDA for use as a surgical mask. Unlike other masks, N95 respirators must be fit-tested for each individual to ensure proper protection.

3 tips for choosing the right face mask. (n.d.).
Halyard
Health. <https://www.halyardhealth.com/industry-news/2019/july/choosing-the-right-face-mask-3-things-to-know.aspx>

Valved N95

A respirator with an exhalation valve provides the same level of protection to the wearer as one that does not have a valve. The presence of an exhalation valve reduces exhalation resistance, which makes it easier to breathe (exhale).

However, respirators with exhalation valves are generally **not be used in situations when a sterile field must be maintained**, such as during an invasive procedure in a surgical or procedural setting, because the exhalation valve **allows unfiltered air exhaled by the wearer**, potentially contaminated with microbes, to escape and possibly contaminate the sterile field.

There may be other healthcare activities where respirators with exhalation valves are appropriate.

If you are using this mask, and source control is required, cover the mask with a medical grade procedure mask while in use.



What is a surgical N95 respirator?

Surgical N95 Respirators **are both approved by NIOSH as an N95 respirator and also cleared by the FDA as a surgical mask**. These products are frequently referred to as medical respirators, healthcare respirators, or surgical N95s.

The **surgical N95 respirator** should be worn during higher-risk aerosol-generating procedures on patients with known or suspected aerosol-transmissible diseases, or during procedures which pose a risk of exposure to blood or bodily fluid.

Standard surgical masks with ties should **not** be used during these procedures.

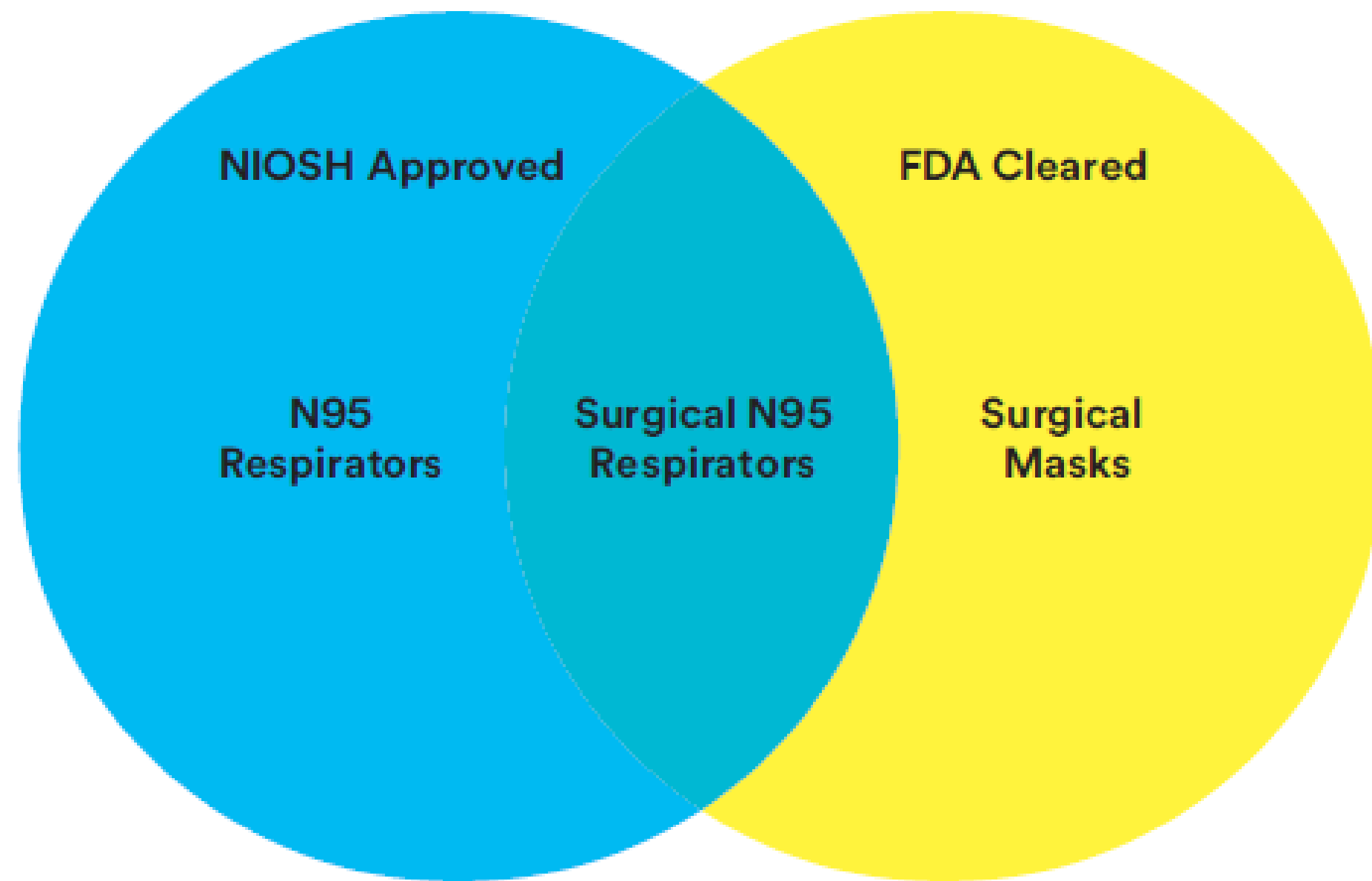


Korol, S. (n.d.). *The '4 Fs' of medical mask selection*. Becker's Hospital Review - Healthcare News. <https://www.beckershospitalreview.com/quality/the-4-fs-of-medical-mask-selection.html>

Surgical vs. Standard N95




The US Centers for Disease Control and Prevention (CDC), in their webpage Frequently Asked Questions about Personal Protective Equipment, says, “In times of shortage, **only healthcare professionals who are working in a sterile field or who may be exposed to high velocity splashes, sprays, or splatters of blood or body fluids should wear these [surgical N95] respirators, such as in operative or procedural settings.**

For other workers who will not be performing such surgical procedures and do not require protection from high-pressure streams of liquid, a **standard non-surgical N95** (or similar) respirator can be worn to help reduce those workers’ exposure to patient-generated airborne viruses and bacteria.



Function	Help reduce particles inhaled by wearer	Help reduce particles both inhaled and expelled by wearer (plus fluid resistance)	Help reduce particles expelled by wearer into environment (plus fluid resistance)
Application	Can be used for respiratory protection when wearer might be exposed to particulate hazards	Meant to be used during surgery and other tasks during which both of these are true: <ul style="list-style-type: none"> • Wearer requires respiratory protection ...and... • Expelled particulates must be contained or fluid resistance is required 	Can be used during surgery and other tasks to help protect patient, and/or when fluid resistance may be required

The following chart demonstrates some key similarities and differences between three respirator models. The 8210 is a standard N95 respirator, while the 1860 and 1870+ are both surgical N95 respirators.

			
	Standard N95 Respirator 3M Model 8210	Surgical N95 Respirator 3M Model 1860	Surgical N95 Respirator 3M Model 1870+
Designed to help protect the wearer from exposure to airborne particles (e.g. Dust, mist, fumes, fibers, and bioaerosols, such as viruses and bacteria)	✓	✓	✓
Designed to fit tightly to the face and create a seal between the user's face and the respirator	✓	✓	✓
Meets NIOSH 42 CFR 84 N95 requirements for a minimum 95% filtration efficiency against solid and liquid aerosols that do not contain oil	✓	✓	✓
Cleared by the U.S. FDA as a surgical mask	✗	✓	✓
Not made with natural rubber latex	✓	✓	✓
Fluid Resistant - Meets ASTM Test Method F1862 "Resistance of Medical Face Masks to Penetration by Synthetic Blood" which determines the mask's resistance to synthetic blood directed at it under varying high pressures. ¹	✗	120 mm Hg ✓	160 mm Hg ✓







N95



KN95

WHAT'S THE DIFFERENCE?

vs.

Performance Standards

Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular standard. During pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an “N95, FFP2, or similar” respirator.

This document is only intended to help clarify some key similarities between such references, specifically to the following FFR performance standards:

- N95 (United States NIOSH-42CFR84)
- FFP2 (Europe EN 149-2001)
- KN95 (China GB2626-2006)
- P2 (Australia/New Zealand AS/NZA 1716:2012)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS2 (Japan JMHLW-Notification 214, 2018)
- PFF2 (ABNT/NBR 13.698-2011 – Brazil)

Respirators certified as meeting these standards can be expected to function very similarly to one another, based on the performance requirements stated in the standards and confirmed during conformity testing.

Proper Fit

Occupational Safety and Health Administration (OSHA) (29 CFR 1910.134) requires respirator users to be fit tested to confirm the fit of any respirator that forms a tight seal on your face before using it in the workplace. Fit testing is important to ensure the expected level of protection is provided by minimizing the total amount of contaminant leakage into the facepiece through the face seal.

You should be fit tested at least annually to ensure your respirator continues to fit you properly. Because each brand, model, and size of respirators will fit slightly different, you should be fit tested every time you wear a new model, manufacturer type/brand, or size. Also, if your weight changes or facial/dental alterations occur, a fit test should be done again to ensure your respirator remains effective.

User Seal Check

A user seal check is a procedure conducted by the respirator wearer to determine if the respirator is being properly worn. The user seal check can either be a positive pressure or negative pressure check.

During a positive pressure user seal check, the respirator user exhales gently while blocking the paths for air to exit the facepiece. A successful check is when the facepiece is slightly pressurized before increased pressure causes outward leakage.

During a negative pressure user seal check, the respirator user inhales sharply while blocking the paths for air to enter the facepiece. A successful check is when the facepiece collapses slightly under the negative pressure that is created with this procedure.

A user seal check is sometimes referred to as a fit check. A user seal check should be completed each time the respirator is donned (put on). It is only applicable when a respirator has already been successfully fit tested on the individual.

Elastomeric Respirators



Replace 3M™ Particulate Filters when:

- It becomes difficult to breathe comfortably (this will vary from individual to individual).
- The filter becomes dirty or physical damage occurs.
- The filter is wet or submerged.
- Per facility's infection control policy.

Sharing Elastomeric Respirators

- If it is impossible for individual HCP to have dedicated elastomeric respirators, the same elastomeric respirator may be used by multiple HCP.
- Elastomeric respirators issued to more than one employee should be cleaned, disinfected, and inspected before being worn by different individuals.
- One option is to label the respirator, conduct surface cleaning at the point of use, and return to a central location to be disinfected by central staff before reissuing the respirator to a different user.
- Fit testing is necessary to confirm if a respirator does or does not fit; for any tight-fitting respirator, such as FFRs and elastomeric respirators, a successful user seal check must be performed with each donning.



Coronavirus disease 2019 (COVID-19). (2020, October 13). Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html>

Power Air-Purifying Respirators

3M™ Versaflo™ Healthcare PAPR Kit TR-300N+ HKL, Medium - Large 1 EA/Case

- Part Number 1334262
- 3M Product Number TR-300N+ HKL
- 3M ID 7100153841
- UPC 00076308942717



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Questions?