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Respirators and Surgical Masks: A Comparison

Background

Since certain disposable filtering facepiece particulate respirators are similar in appearance to many surgical (also known as medical) masks, their differences are not always well understood. However, respirators and surgical masks are very different in intended use, fit against the face, wear time, testing and approval. The purpose of this document is to highlight some of these differences, particularly for healthcare workers. Surgical masks may be provided to patients to help protect healthcare workers and other patients from particles being introduced into the room as a patient talks, sneezes or coughs.

Intended purpose

When breathing, speaking, coughing, sneezing smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose are released. In a sterile environment, such as an operating theatre, these secretions may subsequently spread through the air and contaminate the environment. The primary purpose of a surgical mask is to help prevent biological particles from being expelled by the wearer into the immediate environment. Surgical masks are also typically designed to be fluid resistant to splash and splatter of blood and other infectious materials and not necessarily for filtration efficiency. There are three types of surgical masks - Type I surgical face masks are used to help reduce the risk of the spread of infections via the droplet route (either worn by patients and healthcare workers). Type II and Types IIR surgical masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.

Surgical masks are not necessarily designed to seal tightly to the face, and therefore the potential of air leakage around the edges exists. Even some surgical masks that appear similar to respirators may have not been designed to help protect the wearer from airborne hazards; therefore, they should not be considered an equivalent substitute to government-approved respirators. When the primary intention is to help reduce the wearer's exposure to airborne particles, then government-approved respirators should be used.

Respirators are designed to help reduce the wearer's exposure to airborne particles. They are designed to offer high levels of particle filtration and to seal tightly to the wearer's face therefore reducing the potential of air leaking into the wearer's breathing zone from around the edges of the respirator. Respirators are available offering different levels of filtration efficiency and face seal leakage.

Some government-approved respirators are designed to have the characteristics of both an approved respirator and a surgical mask. In Europe, these products are both tested to both EN 149:2001+A1:2009 (filtering facepieces) and EN 14683:2019 (surgical mask) standards and approved to both the Personal Protective Equipment (PPE) Regulations and Medical Device Directive.[1,2,3,4] The fit of surgical masks varies considerably from those which are held in place by ear loops fastened behind the wearer's ears to those with tie bands around the head and a nose clip that can be shaped to the wearer's nose. Different classes of surgical masks are based on their filtration efficiency, their breathability and their resistance to liquid splash.

For additional information, please refer to 3M Technical Data Bulletin #231.

Summary of the differences

Respirators	Surgical masks
Designed to help protect the wearer from exposure to airborne particles	Designed to help protect the sterile environment from wearer generated particles
Designed to seal tightly to the wearer's face	Not necessarily designed to seal tightly to the face and so air leakage around the edges is likely
Different classes offer different level of protection	Some types offer fluid resistance to liquid splash
Some respirators are certified as both respirators and surgical masks	Surgical masks are not Personal Protective Equipment as defined in the PPE regulations
Require face fit testing and wearer to be clean shaven	
Respirators are Personal Protective Equipment (PPE)	

Wear Time

Respirators must be properly selected and carefully donned (put on) and doffed (taken off) in a clean area and worn the entire time in the contaminated area to have a significant effect on reducing exposure. Having the respirator off even 10% of the time in a contaminated area significantly reduces the protective effect of the respirator.

For infection control purposes, both respirators and surgical masks are typically disposed of after each procedure/patient activity. Refer to your local infection control procedures for removal and redonning of respirators and surgical masks and other PPE that may be required.

Testing

Respirators

The European Personal Protective Equipment (PPE) Regulations requires that PPE placed on the market in Europe fulfil the essential health and safety requirements, as laid out in the PPE Regulations.[3] For respiratory protective equipment, conformity with the relevant European harmonized standard is the route to demonstrate compliance with the corresponding requirements set out in the PPE Regulation.

For a complete understanding of all the test criteria, the reader will need to review the PPE Regulations and the relevant harmonized European standards for the type of PPE. For example, the European standard EN149 contains the performance, testing and marking requirements for filtering facepiece particulate respirators.[1]

There are three types and classes of surgical masks depending on their performance to the three tests covered below:

Performance test *	FFP1	FFP2	FFP3
Total inward leakage (%)	≤ 22	≤ 8	≤ 2
Particulate filtration efficiency (%)	≥ 80	≥ 94	≥ 99
Breathing resistance (mbar)	Inh. 2.1 @95lpm Exh. 3.0 @160lpm	Inh. 2.4 @95lpm Exh. 3.0 @160lpm	Inh. 3.0 @95lpm Exh. 3.0 @160lpm

* Please refer to EN149 for the full performance criteria.

Three main performance criteria in EN149 include:

Total inward leakage

This test consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. Ten test subjects wearing the respiratory conduct a series of exercises inside a test chamber containing an aerosol of Sodium chloride and the amount of the test aerosol inside the respiratory is measured.

Particulate filtration efficiency

The test challenges the filter material against aerosol of Sodium chloride under the following conditions:

- Sodium chloride test aerosol with a mass median aerodynamic diameter (MMAD) particle of about 0.6 μm;
- Airflow rate of 95 liters per minute (lpm); and
- Preconditioning at 70°C (dry atmosphere) and -30°C for 24 hours before testing.

Breathing resistance

This test consists of measuring the resistance to air flow through the whole respirator at various flow rates designed to represent the peak inhalation and exhalation rates of a wearer during work of low to moderate intensity (including peak flow rates of 95lpm, minute volume of 30lpm and 160lpm, minute volume of 50lpm). The maximum permitted breathing resistance is 3.0mbar.

Surgical masks

The European Medical Devices Directive (MDD) outlines the minimum requirements for ensuring the safety and performance characteristics for Medical Devices in the European market.[4] Surgical masks are testing for conformance to a harmonized standard that covers the essential requirement of the MDD; the applicable harmonized European standard is EN 14683:2019 Medical face masks - Requirements and test methods.[2]

There are three types of surgical masks depending on their performance to the three tests covered below:

Performance test*	Type I	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0

* Please refer to EN 14683 for the full performance criteria.

Three main performance criteria in EN 14683 include:

Bacterial Filtration Efficiency (BFE)

This test assesses the ability of a surgical mask to provide a barrier to large droplets expelled by the wearer. It is not a filtration efficiency test, and it does not evaluate the surgical mask's ability to provide any protection to the wearer. Only a specimen of the mask material is tested, unlike the case of a respirator where the full respirator filter body is tested. In the test a specimen of the mask is tested against an aerosol of Staphylococcus aureus. The BFE of the mask is given by the number of colony forming units passing through the medical face mask material. The mean diameter of the aerosol is about 3.0 μm.

Breathability

This test consists of measuring the resistance to air flow through specimens of the mask material. The airflow rate employed in the test is a total flow rate of 8.0lpm over an area of sample of 4.9 cm^2.

Liquid splash resistance

This test assessed the ability of a surgical mask to withstand penetration of synthetic blood projected at a given pressure. The test method challenges surgical masks with a fixed volume of synthetic blood directed at high velocity at the center of the mask. The test is defined in ISO 22609 Clothing for protection against infectious agents -- Medical face masks -- Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected).[5]

Conclusion

In conclusion, surgical masks are intended to help put a barrier between the wearer and the work environment or sterile field. They may help keep spit and mucous generated by the wearer from reaching a patient or medical equipment. They can also be used as a fluid barrier to help keep blood splatter from reaching the wearer's mouth and nose.

However, surgical masks cannot provide certified respiratory protection unless they are also designed, tested, and government-certified as a respirator. If a wearer wants to reduce inhalation of airborne particles, they need to obtain and properly use a government-certified respirator, such as a FFP2 or FFP3 filtering facepiece particulate respirator. If the wearer needs a combination surgical mask and a particulate respirator, they should use a product approved to both the Personal Protective Equipment Regulations and Medical Device Directives. Such products are sometimes called a "surgical respirator", "medical respirator" or "healthcare respirator".

References

1. EN 149:2001 +A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, Marking. European Committee for Standardization, Brussels
2. EN 14683:2019 Medical face masks - Requirements and test methods. European Committee for Standardization, Brussels
3. Personal Protective Equipment Regulations. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425
4. Medical device Directive. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042
5. ISO 22609:2004 - Clothing for protection against infectious agents -- Medical face masks -- Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

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