

Surgical Masks, Standard N95s, Surgical N95s: A Comparison

Description

The purpose of this document is to assist professionals in healthcare workplaces to differentiate between surgical masks, standard N95 and surgical N95 particulate filtering facepiece respirators.

Some disposable filtering facepiece particulate respirators (FFRs), such as N95s, are similar in appearance to certain surgical or procedure masks. This includes standard and surgical versions of N95 FFRs. While they may look similar, standard or surgical respirators on the one hand and surgical or procedure masks on the other hand are very different in intended use, fit against the face, testing and approval.

Surgical or Procedure Masks

Surgical or procedure masks are intended to help put a barrier between the wearer and the work environment or sterile field. They may help keep saliva 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. Where applicable, they are also cleared as medical devices by the U.S. Food and Drug Administration (FDA) and can therefore be used in surgery in the U.S.

Surgical or procedure masks may also 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.

FDA-Clearance

Surgical masks are cleared for use as medical devices by the FDA, or equivalent agencies outside the U.S., and are designed to be worn by healthcare professionals during surgical procedures. That clearance is based on data and proposed claims provided by the manufacturer to the FDA for review, in which the FDA evaluates and then "clears" those products that meet their requirements. Because surgical masks are meant for use during surgeries, a key performance requirement is fluid resistance – the ability of masks to resist penetration by high-pressure streams of liquid. Other performance requirements may include: Particle and bacterial filtration efficiency, differential pressure (Delta-P) test, and/or flammability testing.

The fluid resistance test in the U.S. is typically conducted based on the ASTM Test Method F 1862, "Resistance to Penetration by Synthetic Blood," which determines the mask's resistance to synthetic blood squirted at it under varying pressures.¹

1. [ASTM F1862](#) is a standard test method for resistance of medical facemasks to penetration by synthetic blood. This test is required because during certain medical procedures, a blood vessel may occasionally be punctured, resulting in a high-velocity stream of blood impacting a protective medical facemask. The test procedure specifies that a mask or respirator is conditioned in a high-humidity environment to simulate human use and is placed on a test holder. Synthetic blood (2cc) is shot horizontally at the mask at a distance of 30 cm (12 inches). Surgical masks and respirators are tested on a pass/fail basis at three velocities corresponding to the range of human blood pressure (80, 120, and 160 mmHg). The inside of the mask is then inspected to see if any synthetic blood has penetrated to the inside of the facemask. Fluid resistance according to this test method is when the device passes at any level.

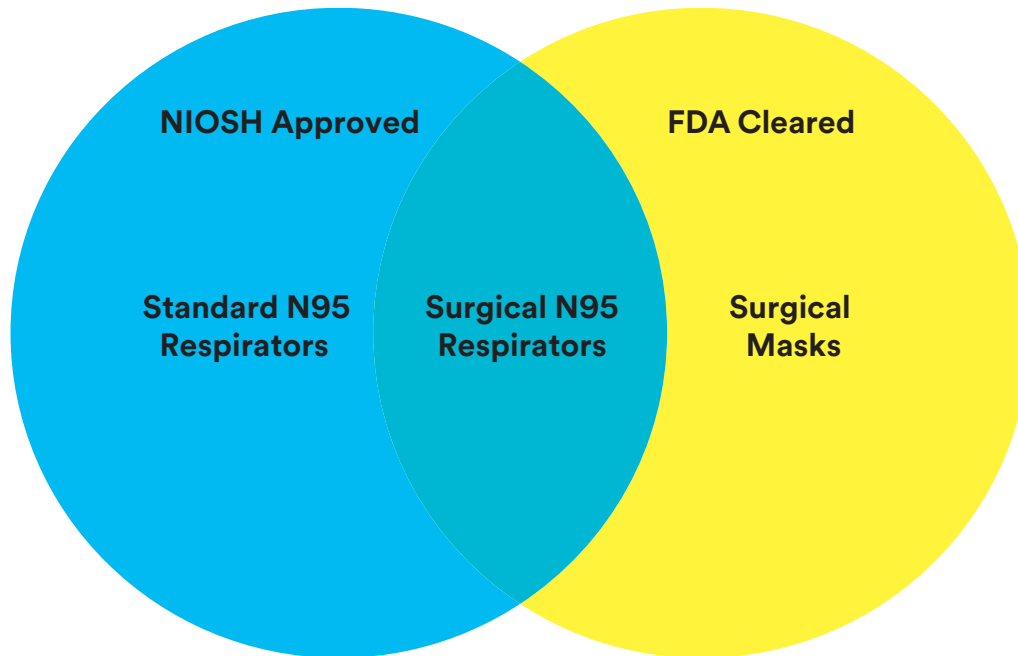
NIOSH-Approved Standard N95 Respirators

In addition to acting as a barrier, if a wearer also wants to reduce inhalation of smaller particles, they need to obtain and properly use a government-certified respirator, such as an N95 filtering facepiece particulate respirator approved by the U.S. National Institute for Occupational Safety and Health (NIOSH).

Particulate respirators are designed to help reduce the wearer's exposure to airborne particulate hazards, including virus and bacteria particles. In the U.S., respirators are tested and certified by NIOSH. NIOSH tests and certifies respirators based on their physical and performance characteristics, including filtration efficiency. For example, N95-rated filtering facepiece respirators have a filtration efficiency of at least 95% against non-oily particles when tested using the NIOSH criteria. The particles used to test the filtration are in a size range that is considered the most penetrating. Therefore, the test methods ensure that the filter media can filter particles with at least 95% efficiency.

NIOSH Approved and FDA Cleared Surgical N95 Respirators

Surgical N95 respirators are both approved by NIOSH as an N95 respirator and cleared by the FDA as a surgical mask as they are also designed and tested for fluid resistance. These products are frequently referred to as medical respirators, healthcare respirators, or surgical N95s.



Function	Help reduce particles both inhaled and expelled by wearer	Help reduce particles both inhaled and expelled by wearer and provide fluid resistance	Helps reduce particles expelled by wearer and provide fluid resistance
Application	Can be used for respiratory protection against certain particulate hazards	Can be used for respiratory protection against certain particulate hazards when fluid resistance is also required	Can be used during surgery and other procedures to help protect others from particles expelled by the wearer and/or when fluid resistance may be required

Additional information about the differences between surgical masks and N95 respirators can be found in the NIOSH infographic [Understanding the Difference Between Surgical Masks and N95 Respirators](#).