Surgical N95 vs. Standard N95 – Which to Consider?

Description

This is a general document that is not specific to any particular airborne contaminant, including viruses and bacteria, and that is intended for a sophisticated occupational audience.

The following discussion is intended to help you differentiate standard versions and surgical versions of N95 particulate filtering facepiece respirators.

NIOSH-Approved N95 Respirators

Particulate respirators are designed to help reduce the wearer’s exposure to airborne particulate hazards. In the U.S., respirators are tested and certified by the U.S. National Institute of Occupational Safety and Health (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.

FDA-Cleared Surgical Masks

Surgical masks, in contrast, are designed to be worn by healthcare professionals during surgery and other medical tasks, to help prevent contamination of the surgical field and/or the patient by capturing liquid droplets that are expelled by the wearer. Surgical masks are cleared for use as medical devices by the U.S. Food and Drug Administration (FDA), or equivalent agencies outside the U.S. 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” for 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, such as those that might result from a human artery being punctured during surgery.1

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.

Surgical N95 Respirators

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.

Comparing Standard N95s to Surgical N95s

Putting this all together will help you differentiate between a standard NIOSH-approved N95 respirator and a surgical N95 respirator. While similar in appearance, the key difference is the fluid resistance and the resulting FDA clearance of surgical N95s. But when is that fluid resistance necessary?
Many tasks performed by healthcare workers – such as patient intake and non-emergency patient evaluation – pose little risk of generating high-pressure streams of liquid and are not conducted in a sterile field. For workers performing such tasks, a primary potential hazard to consider is airborne droplet containing viruses and bacteria, such as those generated by coughs and sneezes, which can be effectively filtered by a properly selected and worn N95 respirator.

Therefore, if a healthcare facility is prioritizing respirator use – due to limited supply during a health emergency – they may want to consider prioritizing use of surgical N95 respirators for those healthcare workers requiring respiratory protection while performing surgery or other tasks that may expose them to high pressure streams of bodily fluid or conducting work in a sterile field. 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.”\(^2\) For other workers who will not be performing such surgical procedures or do not need to maintain a sterile field, a standard non-surgical N95 (or equivalent) respirator can be worn to help reduce those workers' exposure to patient-generated airborne viruses and bacteria.

<table>
<thead>
<tr>
<th>Function</th>
<th>Help reduce particles inhaled by wearer</th>
<th>Help reduce particles both inhaled and expelled by wearer (plus fluid resistance)</th>
<th>Help reduce particles expelled by wearer into environment (plus fluid resistance)</th>
</tr>
</thead>
</table>
| 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:  
  - 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 |

NIOSH Approved  
Surgical N95 Respirators  
Surgical Masks  
FDA Cleared  
N95 Respirators
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.

<table>
<thead>
<tr>
<th></th>
<th>Standard N95 Respirator 3M Model 8210</th>
<th>Surgical N95 Respirator 3M Model 1860</th>
<th>Surgical N95 Respirator 3M Model 1870+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designed to help protect the wearer from exposure to airborne particles (e.g. dust, mist, fumes, fibers, and bioaerosols, such as viruses and bacteria)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Designed to fit tightly to the face and create a seal between the user’s face and the respirator</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Meets NIOSH 42 CFR 84 N95 requirements for a minimum 95% filtration efficiency against solid and liquid aerosols that do not contain oil</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cleared by the U.S. FDA as a surgical mask</td>
<td>❌</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Not made with natural rubber latex</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>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</td>
<td>❌</td>
<td>✓ 120 mm Hg</td>
<td>✓ 160 mm Hg</td>
</tr>
</tbody>
</table>

For a list of 3M medical facemasks and surgical respirators, see this 3M Masks and Respirators Brochure.

Notes

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.