Surgical N95 vs. Standard N95 – Which to Consider?

Description

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

NIOSH-Certified 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 of all sizes with at least 95% efficiency.

FDA-Cleared Surgical Masks

Surgical masks, in contrast, are designed to be worn by healthcare professionals during surgery and nursing, 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, which the FDA evaluates and then “clears” for those products that meet the 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

Surgical N95 Respirators

Surgical respirators are both certified 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-certified 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?

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.
Many tasks performed by healthcare workers – such as patient intake and non-emergency patient evaluation – pose little to no 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 viruses and bacteria, such as those generated by coughs and sneezes, which are effectively filtered by an N95 respirator.

Therefore, if a healthcare facility is prioritizing respirator use – due to, for example, 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. 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.

The following chart demonstrates some key similarities and differences between three respirator models. The 8210 is an N95 respirator, while the 1860 and 1870+ are both surgical N95 respirators.
<table>
<thead>
<tr>
<th></th>
<th>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 for sale by the U.S. FDA as a surgical mask</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.a</td>
<td>✗</td>
<td>120 mm Hg</td>
<td>160 mm Hg</td>
</tr>
</tbody>
</table>

a. 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.

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