PPE: Ordinary or surgical mask, is it safe to make them?

As the days go by, health institutions, even the most prepared from the point of view of stock management, start to worry about the supply of personal protective equipment (PPE), especially regarding the respiratory protection of professionals who work on the front line, assisting patients with suspected or confirmed pathologies that can be transmitted through droplets of saliva or nasopharyngeal secretion.

On 03/31/2020, ANVISA updated technical note 04/2020, which provides guidelines for health services: prevention and control measures that must be adopted when assisting suspected or confirmed cases of infection by the new coronavirus (SARS-CoV-2). It describes that when treating patients with suspected or confirmed COVID-19 there is a distance of less than 1 meter, the professional must use to protect nose and mouth, a common mask and if the assistance produces aerosols, it is recommended to use mask N95 or equivalent.

This technical note also specifies that the common mask must be made of non-woven fabric (TNT) - the recommended weight for this material is 20-40g / m2, have at least one inner layer and one outer layer and a filter element is mandatory. The outer layer and the filter element must be resistant to the penetration of airborne fluids (fluid repellency). In addition, it must be made in such a way as to adequately cover the area of the user's nose and mouth, and have a nasal clip made of malleable material that allows the proper adjustment of the contour of the nose and cheeks. And the filter element must have particle filtering efficiency (EFP)> 98% and bacteriological filtering efficiency (BFE)> 95% (1).

The efficiency tests can be performed based on what is guided by ABNT NBR 15052 (5).

ANVISA also allowed the manufacture of common masks, according to RDC 356/2020 of ANVISA, it specifies the material allowed for the factory, namely: Surgical masks are commonly composed of 3 independent non-woven layers. The outer layers are made with non-woven spunbond, which provides structure to the product, whereas the middle layer (or filter) is a non-woven meltblown type that guarantees efficiency in filtration. As such, the ideal covering material, according to ABNT NBR 15052 (5), is a non-woven fabric that has at least three layers: the filter, an external layer and an internal layer, ideally used for purposes of dental-medical-hospital application. Thus, it is not any type of nonwoven that meets these criteria (2).

According to an ABNT note (5), the spunbond popularly known as TNT does not have the filtration capacity for this type of application (2).

In the absence of the capacity to supply meltblown nonwovens, ABNT recommends the adoption of SMS type nonwovens, since these materials have the same spunbond–meltblown-spunbond structure as a traditional surgical mask, but with layers consolidated (and not independent) and produced continuously. For surgical masks, the SMS must achieve bacteriological filtration results with particle filtering efficiency (EFP) ≥98% and bacteriological filtering efficiency (BFE) ≥95% (2). There is a need to prove this efficiency through some recognized validation method, according to the ABNT standard (5).

According to § 4 of art. 5 of the RDC nº 356/2020, it is forbidden to make surgical masks with cotton fabric, tricoline, TNT or other textiles that are not of the type “Non-woven for articles for dental-medical-hospital use” for use by them professionals in health services (2).

Attention:

NEVER attempt to clean the surgical mask already used with any type of product. Surgical masks are disposable and cannot be cleaned or disinfected for later use and when wet, they lose their filtration capacity (1).

Fabric masks are not recommended in health services, under any circumstances (1).

The health professional should NOT use the surgical mask overlaid on the N95 mask or equivalent, as in addition to not guaranteeing protection from filtration or contamination, it can also lead to the waste of another PPE, which can be very harmful in a scarcity scenario (1).

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