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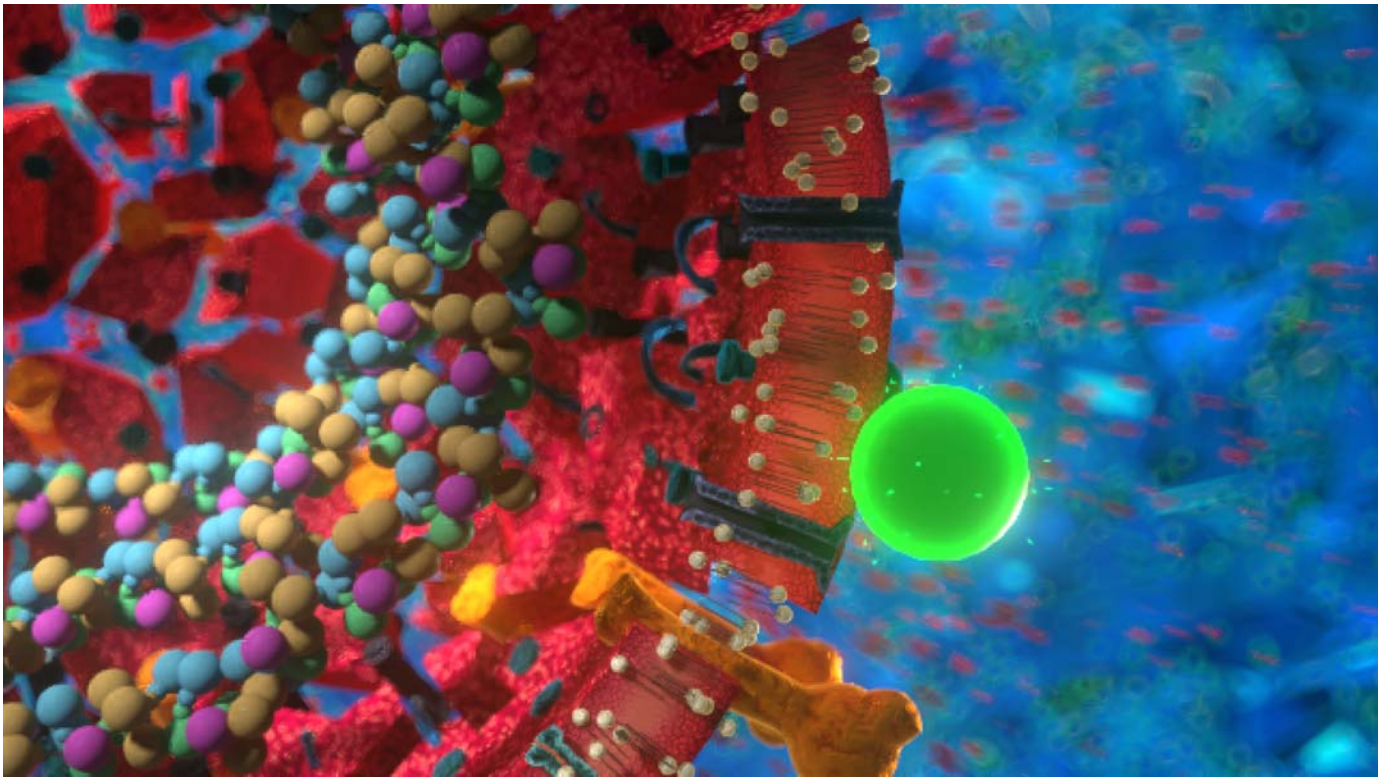
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SURGICAL MASK IN DEVELOPMENT WITH ACTEEV™ TECHNOLOGY SHOWS EFFICACY AGAINST SARS-COV-2 PLUS LEVEL III FILTRATION PROPERTIES

Surgical mask in development with Acteev™ technology shows efficacy against SARS-CoV-2 plus Level III filtration properties

July 12, 2020

Ascend's latest FDA 510(k) submission covers nanofiber and microfiber designs



Ascend Performance Materials announced today it has submitted to the U.S. Food and Drug Administration a 510(k) premarket notification for clearance to market its Acteev™ technology in a pair of high-efficacy surgical masks to protect against SARS-CoV-2, the cause of COVID-19.

The masks, a nanofiber and a microfiber nonwoven version each branded under the Acteev Biodefend™ line for medical devices, deliver a one-two punch of antiviral properties plus top-level barrier protection against microbes, harmful airborne particles and fluid splatter.

Acteev technology has been shown in laboratory tests to deactivate SARS-CoV-2, the coronavirus that causes COVID-19, and other pathogens including H1N1, betacoronavirus OC43, human coronavirus 229E and Gram-positive and Gram-negative bacteria such as staphylococcus and E. coli, according to Vikram Gopal, Ph.D., Ascend's chief technology officer. The testing was conducted following the protocols of ISO, ASTM or other international standards organizations.

The proposed masks also meet the requirements to qualify as Level III under ASTM F2100-19 standards, as tested by independent laboratories as well as Ascend scientists. Level III is the highest tier for physical barrier and safety properties, according to the common international testing standard.

Dr. Gopal said the combination of superior physical properties and antiviral protection is a breakthrough in medical device technology, as many masks succeed either at antiviral protection or at filtration and barrier effectiveness but not at both.

"Previous technologies rely on the materials within a mask to retain an electrical charge to achieve filtration efficiency," Dr. Gopal said. "But when antimicrobial agents are added, those materials lose their charge and begin to fail as barriers."

Acteev masks, however, achieve antiviral effectiveness through active zinc ions embedded within the polymer structure of polyamide 66, a hygroscopic nylon material whose equilibrium moisture keeps the zinc ions active.

"With Acteev, we have cracked the code of balancing top physical performance with antiviral protection," Dr. Gopal said.

The technology, covered by more than 15 patent families, has been tested in multiple end forms, including knit and woven fabrics; engineered plastics; and nanofiber meltblown, microfiber meltblown and spunbond nonwoven materials.

Ascend submitted its **first 510(k)** (<https://www.ascendmaterials.com/news/ascend-files-first-fda-510k-submission-based-on-acteev-technology/>) to the FDA last month. That submittal requests clearance to market a Level I surgical mask that is effective against SARS-CoV-2.

Also last month, Ascend launched **Acteev Protect** (<https://www.ascendmaterials.com/acteevprotect>)™, an antimicrobial line of protection specially formulated to guard against the growth of fungi, bacteria and other microbes to keep textiles and nonwoven fabrics fresher for longer. Acteev Protect, available for sale today in the United States and select other jurisdictions, can be used to make face coverings, filtration devices, and textiles for upholstery and apparel such as activewear.

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