

PRESS RELEASE

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NovaSterilis Receives Emergency Use Authorization for the First Supercritical Carbon Dioxide Decontamination System for Select N95 Respirators

- *Proven in regenerative medicine use, system was adapted for emergency use in COVID-19*
 - *System's speed and scale enable healthcare workers to retain their own masks*
 - *Research continues for potential use in other PPE, expanded applications*

Ithaca, N.Y., -- September 1, 2020 – NovaSterilis today announced that the U.S. Food and Drug Administration has granted an Emergency Use Authorization (EUA) to NovaSterilis for the Nova2200™ system in decontaminating select N95 respirators. This authorization will help provide access to a critical piece of personal protective equipment (PPE) for use by healthcare workers during the COVID-19 pandemic.

The Nova2200 platform runs the NovaClean™ process, which decontaminates N95 respirators for single-user reuse based on the proven science of supercritical carbon dioxide (scCO₂). The technology is non-toxic, has a low environmental impact, and has broad material compatibility. The process penetrates deep within materials, is minimally reactive, and completely inactivates multiple types of bacteria, fungi, and viruses.

“With the onset of the COVID-19 global pandemic, NovaSterilis recognized the potential for the Nova2200 to help address the extreme shortage of PPE for medical personnel by using our process to decontaminate N95 masks,” said Tony Eisenhut, President and CEO of NovaSterilis. “Words cannot adequately describe the courage and devotion of healthcare workers caring for people with COVID-19. They deserve the best safety support we can offer. The NovaClean process effectively kills the coronavirus, and provides added comfort for healthcare personnel who receive their own N95 respirators back after decontamination, rather than someone else’s.”

Working with multiple collaborators, NovaSterilis demonstrated that the NovaClean process rapidly and completely inactivates human coronavirus strains from N95 respirators, including SARS-CoV-2, the virus that causes COVID-19. The Nova2200 is deployed and operated at the point of use in the hospital setting, resulting in decreased turnaround time and increased respirator availability to healthcare personnel. The throughput of 50 respirators per 90-minute run will help address the needs of hospitals as hotspots of infectivity emerge, whether in urban settings such as New York City, or in rural areas where alternative reprocessing options are limited. Importantly, the workflow allows healthcare personnel to receive their own respirators for reuse after decontamination through labeling and a chain of custody.

The rapid research to demonstrate the effectiveness of the Nova2200 in the fight against SARS-CoV-2 was made possible by multiple collaborators:

- Cayuga Health Systems supplied respirators after NovaSterilis completed proof of concept testing, in addition to guidance and access to equipment that was used to determine the performance of N95 respirators in the workplace and shorten central sterile processing turnaround time.
- ZeptoMetrix Corporation tested the efficacy of the Nova2200 on viral samples, including SARS-CoV-2, in an urgent manner within their biosafety level 3 laboratory. This work led to the understanding that NovaSterilis' technology was effective against the novel coronavirus.
- Cornell University supplied respirators and completed a preliminary coronavirus model study.
- iFyber, LLC, a contract research organization, led the regulatory submission process, designed the necessary microbiology and material compatibility testing, and performed sample preparation and decontamination testing.

NovaSterilis is also committed to exploring the use of the NovaClean process on an ongoing basis to support frontline health-care worker safety, as well as in emergency situations where PPE supply interruptions can place staff at risk.

About NovaSterilis

For almost 20 years, NovaSterilis has developed and commercialized medical products based on the application of supercritical carbon dioxide (scCO₂) with proprietary additives designed for specific use scenarios. The company's scCO₂ equipment platforms are currently being utilized for a variety of functions from sterilization on multiple biomaterials products, including allograft tissues used in orthopedic surgeries to impregnation of bioactives into drug delivery devices and to industrial fiber cleaning. NovaSterilis is committed to developing new scCO₂ applications through a deeper understanding of the chemical properties of scCO₂, the biological effects of scCO₂, and the novel engineering platforms necessary to deliver on this new understanding.

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