ICU
MANAGEMENT & PRACTICE

DOD to Fund a Clinical Trial of COVID-19 Treatment with ExThera's Seraph 100 Blood Filter

After encouraging preliminary results in the treatment of critically-ill COVID-19 patients at a military hospital in the United States and fourteen other hospitals in Europe, the Department of Defense has selected the *Seraph®100 Microbind® Affinity Blood Filter* (Seraph 100) as one of its main interventions in a pivotal, US-based randomized controlled trial. Financial support for the multi-center trial will be provided by the Department of Defense and run by investigators at the Uniformed Services University in Bethesda.

COVID-19 patients, including those with pre-existing medical conditions, have been treated with Seraph 100 after showing serious symptoms of the virus. Initial reports indicate Seraph 100 stabilizes blood pressure and inflammatory biomarkers that correlate with poor patient outcome: IL-6, Ferritin, D-dimers, LDH, and Nt-proBNP, all decreased during Seraph 100 treatments of COVID-19 patients. It appears that Seraph 100 helps improve patient outcomes by providing additional time for supportive care while reducing the sources of inflammation and possibly preventing further damage by reducing SARS-CoV-2 virus/RNA in the bloodstream.

Seraph 100 earned its CE Mark in Q3 2019 and is widely available in Europe where it is the subject of a large clinical trial for treatment of a variety of bloodstream infections (BSI). Prior to the COVID-19 pandemic, Seraph 100 was being used successfully to treat individual cases of sepsis and drug-resistant BSIs in the prevention of septic shock. However, over the past few months, most clinical cases have involved COVID-19.

The USFDA granted Seraph 100 Emergency Use Authorization (EUA) during the current pandemic. Under the EUA Seraph 100 is broadly available in the USA, for COVID-19 treatments. At this time there is no other blood purification therapy known to bind and remove SARS-CoV-2 virus/RNA *and* bacteria while also improving vital signs *and* laboratory parameters associated with inflammation and tissue damage.

In the treatment of bacterial infections Seraph 100 has quickly reduced drug-resistant bloodstream pathogens and consistently improved patients' oxygen saturation. The binding of the SARS-CoV-2 virus together with the ability to treat secondary bacterial infections makes Seraph 100 therapy unique in the treatment of COVID-19. "We are excited to have this opportunity and confident that this large DOD clinical trial will firmly establish the safety and efficacy of Seraph 100 as a treatment for COVID-19 treatment. A successful trial will also support the use of Seraph 100 as a broad-spectrum countermeasure against future pandemics, especially during the critical period before vaccines are available" according to Bob Ward, NAE, President and CEO of ExThera Medical Corporation.

In contrast to other blood purification technologies which only remove molecules, Seraph 100 also quickly lowers the concentration of viruses, bacteria, and fungi in whole blood. In pre-clinical testing and in clinical use, Seraph 100 has been shown to significantly reduce the bloodstream concentration of both drug-susceptible and drug-resistant pathogens, providing a long-awaited therapy that addresses the severe problem of drug-resistance, and new and future microbial threats like the COVID-19 virus.

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