ICU MANAGEMENT & PRACTICE

FDA Grants ExThera's Seraph-100 Blood Filter Emergency Use Authorization for COVID-19

After promising COVID-19 treatments in Germany, France, Italy, Spain and the USA, ExThera Medical's *Seraph®100 Microbind® Affinity Blood Filter* (Seraph 100) has been granted Emergency Use Authorization by the Food and Drug Administration (FDA). This approval comes soon after first use of the device to treat COVID-19 patients in Europe and in the United States and will facilitate Seraph 100 use in U.S. hospitals.

Seraph 100 earned its CE Mark in Q3 2019 and is widely available in Europe. **Emergency Use Authorization (EUA)** by the USFDA offers a pathway for immediate use of promising healthcare technologies – devices, diagnostics, and drugs – during times of health emergencies like the COVID-19 pandemic. Seraph 100 is now available for COVID-19 treatments in the USA. At this time there is no other blood purification therapy known to bind and remove SARS-CoV-2 virus/RNA while also improving vital signs and laboratory parameters associated with inflammation and tissue damage.

Several critically-ill COVID-19 patients, including those with pre-existing medical conditions, have been treated with Seraph 100 after showing serious symptoms of the virus. Initial clinician reports indicate Seraph 100 stabilizes blood pressure and inflammatory biomarkers that correlate with poor 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 source of inflammation and potentially preventing further damage by reducing virus in the bloodstream.

"We have been in close contact with the centers treating COVID-19 and we're pleased to see general improvement in the health of COVID-19 patients during and after treatment with Seraph 100," says Professor Jan T. Kielstein, Director of Nephrology | Rheumatology | Blood Purification at Academic Teaching Hospital Braunschweig, Germany. "Treatment with this device has immediate and sustained effects on vital signs and laboratory parameters. Critically ill patients tolerate it very well in terms of cardiovascular stability. Aside from reducing pathogens in the blood, Seraph 100 has other features that that could benefit COVID-19 patients." These are currently being investigated by documenting COVID-19 patients treated with the Seraph. In addition, two multi-center clinical trials of Seraph 100 treatment of COVID-19 will start soon: one in the EU and another DOD-funded study in the USA.

In the treatment of *bacterial* infections Seraph 100 has quickly reduced drug-resistant bloodstream pathogens and consistently improved patients' oxygen saturation. The binding of SARS-CoV-2 virus together with the ability to treat secondary bacterial infections makes Seraph 100 therapy unique in the treatment of COVID-19. Our hope is that under the EUA Seraph 100 will quickly make its way into the hands of US clinicians." remarked Robert Ward NAE, President and CEO of ExThera Medical.

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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