

ExThera's Affinity Blood Filter Is Used to Treat COVID-19 Patients



Treatment of COVID-19 with ExThera's Seraph®100 Microbind® Affinity Blood Filter (Seraph 100) has begun in hospitals in Germany and Italy. Seraph 100 treatments of COVID-19 are also expected to begin soon in France and the USA.

<u>Seraph 100</u> is the only 'hemoperfusion device' approved for the reduction of pathogens in blood. In recent EU clinical cases improved lung function and rapid reduction of drug-resistant *bacterial* pathogens occurred with Seraph 100 treatment. Stabilization of blood pressure has also been observed, including during COVID-19 treatment. Another potential benefit of Seraph 100 treatment of COVID-19 is reduction in bloodborne virus/RNA, and the simultaneous treatment of bacterial and fungal 'secondary infections'.

Clinical results and virus binding studies suggested that Seraph 100 treatment should help in the treatment of COVID-19, and in future epidemics, before vaccines are available. More clinical results are needed to confirm patient benefit in COVID-19, but lab studies with cytokines and other pathogens have accurately predicted Seraph 100 clinical results in other bloodstream infections.

One consideration is whether SARS-CoV-2 is present in the bloodstream of infected patients in measurable concentrations, and if so, at what stage of the infection. Very recent publications and clinician feedback confirm the presence of the virus (RNA) in the blood of critically ill COVID-19 patients. The measured binding capacity of a single Seraph 100 filter (about the size of a 12-ounce soda can) is huge in comparison to the amount of virus present in the bloodstream of critically-ill patients.

Lakhmir S. Chawla, MD, Chair of ExThera's Scientific Advisory Board added, "In respiratory diseases caused by viruses, the onset of viremia (virus in the bloodstream) typically heralds severe disease. Reducing viral levels of COVID-19 may allow the body's immune system to combat the deadly pathogen."

President and CEO of ExThera Medical, Robert Ward NAE stated, "We are very pleased to confirm the feasibility of Seraph 100 treatment of COVID-19. Since Seraph 100 treatments have also consistently produced improved oxygenation/lung function, we believe that this feature together with virus reduction may be a useful combination for treating COVID-19, while simultaneously treating the dangerous secondary infections that can occur in COVID-19 patients."

Seraph 100 has CE Mark approval in the European Union but is not currently approved by the FDA for use in the United States. ExThera has received clinician interest in individual emergency use of Seraph 100 in the USA and we expect COVID-19 treatments to begin here soon, when they meet the criteria outlined in the FDA Guidance. ExThera will report on ongoing EU COVID-19 cases and related case studies as soon as they are available, while adhering to HIPAA and GDPR requirements for patient confidentiality. Related peer-reviewed publications are in preparation or in press.

"We are excited about adding SARS-CoV-2 to the long list of bloodborne pathogens that Seraph 100 can target," commented Keith McCrea, PhD. and Chief Science Officer of ExThera Medical. "This can open up a new treatment modality for this and future emerging diseases for which there are few if any treatments." Seraph 100's very broad-spectrum capability is based on its large biomimetic blood-contacting surface that imitates the binding sites disease-causing pathogens target once they find their way into the bloodstream.

The Seraph 100 blood filter provides a needed option for treating life-threatening bloodstream infections using new technology. Whereas first-generation hemoperfusion devices remove *only* molecules, Seraph 100 also quickly lowers the concentration of bacteria, viruses, and fungi in

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whole blood. Seraph 100 is able to significantly reduce the bloodstream concentration of both drug-susceptible and drug-resistant pathogens, providing a long-awaited adjunctive therapy that addresses the severe problem of drug-resistance, and new and future bacterial, fungal *and* viral threats like COVID-19.

Professor Jan Kielstein, Director of Medical Clinic V, Academic Teaching Hospital Braunschweig, Germany who has performed many Seraph 100 treatments recently said, "When a pathogen like SARS-CoV-2 comes out of Pandora's Box we have to think outside of the box for a countermeasure. Seraph 100 is a disruptive technology that had been shown to eliminate infectious agents from the blood without side effects. Extracorporeal treatment with the Seraph 100 could offer an added benefit to critically ill patients with severe COVID-19."

Seraph 100 received CE Mark approval for the broad indication of pathogen reduction during bloodstream infections in adjunction with antibiotic therapy. Seraph 100 distributors in the EU include Heinz Meise GmbH in Germany, Burke & Burke in Italy, and TOP Medical in the Benelux countries. Distributors have recently been named in several other regions. Working with Gorta, Ireland's oldest NGO, ExThera has also entered a public-private partnership designed to strengthen public health systems in developing countries by making world-class medical devices available at affordable prices.

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