ICU
MANAGEMENT & PRACTICE

# Novalung System Receives US FDA Clearance

**The US FDA (Food and Drug Administration) has granted 510(k) approval to Fresenius Medical Care North America and Xenios, a Fresenius Medical Care company, for long-term use of its Novalung system for patients with acute lung failure or acute cardiopulmonary failure. The FDA announced this on Friday evening.**

With class II approval, the Novalung system is the first complete system approved for ECMO therapy (ECMO = extracorporeal membrane oxygenation) and long-term use for a duration of more than six hours. This enables physicians to provide their patients suffering from acute lung failure or acute cardiopulmonary failure with ECMO therapy over a longer period of time using a single device. In addition, the Novalung system can be used to apply extracorporeal CO2 removal (ECCO2R) for severe lung diseases.
The whole system consists of the Novalung console and the XLung kit. The market launch in the US is planned for the middle of this year.

“The approval is an acknowledgement of the high quality standard of our products to which we are committed as part of Fresenius Medical Care,” Andreas Terpin explains, CEO of Xenios, and adds: “A particular success for us is the wide range of the approval from ECMO to ECCO2R.”

The clearance of the Novalung system was strengthened by clinical data from a retrospective analysis of approximately 150 patients who had received ECMO treatment. According to the FDA, the results showed that the Novalung system’s clinical efficacy and safety supports a long-term ECMO treatment and that the system is suitable for the entire spectrum of venovenous and venoarterial support.

Fresenius Medical Care North America Website
https://fmcna.com/products/critical-care/heart-and-lung/novalung/

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