

Press Release 03/10

March, 19th 2010

By Users for Users: Worldwide iLA Registry is launched

With the help of the clinical experience of its customers Novalung GmbH is working on the future of intensive-care medicine: using the iLA Membrane Ventilator[®] to avoid the damage caused by mechanical ventilation.

The new expanded User Registry for the iLA Membrane Ventilator[®] has officially been launched. The Registry is an ongoing, worldwide collection of clinical data in which any hospital that uses the iLA Membrane Ventilator[®] can participate. In contrast to randomized studies with fixed study protocols, the iLA Registry enables an accurate representation of daily clinical reality, since all patients are included. Every participating hospital will receive an objective analysis of their own data in regular intervals. The worldwide scope of the Registry promotes the exchange of experiences between large and small hospitals, both domestically and internationally.

The redesigned iLA Registry was presented in Bremen, Germany, at one of the most important German intensive-care meetings, the 20th Symposium for Intensive-Care Medicine and Nursing. Clinical data from users for users will now be systematically collected under the guidance of Dr. Rolf Dembinski (Aachen University Hospital, Germany) and Prof. Dr. Thomas Bein (Regensburg University Hospital, Germany). The chairs of the iLA Study Group see this as a great opportunity to obtain a clear picture of the clinical status of the procedure and to more accurately describe its effect on clinically relevant outcome parameters such as time on ventilation, length of stay in the ICU and mortality.

The iLA Registry was introduced in 2007 by Novalung's Clinical Support group and currently includes over 400 patients. Preliminary analyses in 2008 and 2009 already pointed to clear, interesting trends in the use of the iLA Membrane Ventilator[®]. While it initially consisted primarily of patients with severe lung failure (e.g., ARDS) in an artificial coma, nearly two-thirds of the patients registered in 2009 suffered from an acute exacerbation of chronic lung failure (such as COPD) requiring in-hospital treatment. These patients in particular might benefit from treatment with the iLA Membrane Ventilator[®], since it provides the possibility of avoiding mechanical ventilation entirely.

Novalung's Mission is the creation of new solutions for lung failure using innovative artificial lungs that breathe outside the patient's body. Its pioneering task is to work with leading physicians globally to create new treatments that can replace the damaging procedure of mechanical ventilation.

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You can download high-resolution pictures as well as the literature compendium on www.novalung.com or it will be sent on request via email.

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Background information

iLA Membranventilator[®]

The iLA Membrane Ventilator[®] is the world's first pumpless artificial lung that breathes outside the patient and has been used to support patients' lungs in about 5,000 cases of acute lung failure due to various causes such as bacterial and viral pneumonia (including H1N1), exacerbated COPD, trauma, thoracic surgery and lung transplantation. It removes carbon dioxide effectively and reliably outside the human lung and is perfused by the heart like a natural organ, relieving the patient's lung and supporting its gas exchange capacity. The patient's natural lung is given „Time to Heal[®]“.

A hollow fibre membrane in the small artificial lung, which measures only 14 x 14 cm, takes over the gas exchange function from the lungs and supplements or replaces mechanical ventilation. The iLA Membrane Ventilator[®] is connected non-surgically to a femoral (groin) artery and vein using two specially designed NovaPort[®] vascular access devices. Without the need for an external blood pump inflammatory reactions are minimized.

Evidence:

The iLA procedure has been widely used now, its application and effectiveness is well documented by a number of case series for numerous indications. A randomized, controlled multi center trial (“Xtravent”) is running. Besides, by implementing the iLA Registry, this prospective data collection is an essential source of information as it enables an accurate representation of daily clinical reality, since all patients are included.

In the scientific literature the iLA Membrane Ventilator[®] is also known as “pecla” (pumpless extracorporeal lung assist) or „AVCO2R“ (arterio-venous CO2 removal).

Novalung – Driver of a paradigm shift

Founded in 2003, the German company Novalung GmbH operates on a highly international level in order to establish new solutions for lung failure. These advanced technologies from Germany and the U.S. were brought into the company and developed further. The goal is to replace the damaging invasive ventilation. The overall objective is to replace damaging invasive mechanical ventilation.

The privately funded Novalung GmbH is a fast growing medical technology company based in the area of Heilbronn/Germany and a subsidiary on the campus of the University of Michigan at Ann Arbor, USA.