



Company fact sheet

On October 31, 2016, the companies announced that **Xenios** becomes part of **Fresenius Medical Care (FME)**.

It was noted in the companies' announcements that there is great synergy in the future collaboration between Xenios and FME, and thus the combination of the companies' competences would build a significantly positive force in critical care within the intensive care unit (ICU) of hospitals across the world.

Xenios, located in Heilbronn, Germany, was formed in 2013 by combining **Novalung** and **Medos** under the Xenios moniker: Novalung was founded to replace Invasive Mechanical Ventilation (IMV), a method to assist or to replace spontaneous breathing. IMV is indicated when the patient's spontaneous ventilation (breathing) is inadequate to maintain life. Mechanical ventilation is termed "invasive" if it involves any instrument penetrating through the mouth (such as an endotracheal tube), through which air (or another gas mix) is pushed into the trachea with positive pressure. This act is unnatural because the diaphragm normally draws air into the lungs with negative pressure.

Medos was acquired because of its innovative pump technology. With this technology Medos was one of the leading German companies in this field since 1987, for the benefit of cardiac surgeons and perfusionists, but first of all for patients.

Upon acquisition by Novalung the Medos blood pump technology made possible the creation of both iLA active and i-cor synchronized cardiac assist for Xenios' state-of-the-art minimally invasive therapy portfolio. Xenios was founded to combine Novalung's lung and Medos' heart therapies into innovative systems for minimally invasive lung and cardiac assistance on one platform.

End of 2016 Xenios has become part of the FME family, the worldwide market leader in renal support. With joined forces both companies want to establish worldwide leadership in renal, lung and heart assist therapies led by a globally active sales team often serving the same target customers at the Intensive Care Unit (ICU).

Xenios brings complementary product families to FME

Xenios, a therapy leader driving innovation in lung and heart assist, offers a full product range for these contiguous organ systems that runs on one common platform. In addition the heart and the lungs are linked anatomically: the right ventricle perfuses the lungs, while the left ventricle perfuses the body. The Xenios minimally invasive common platform provides fundamental advantages to patients: they can be kept awake, mobile and active, which facilitates improved outcomes.

Thus, the combination of therapies of Xenios and FME empowers clinicians with the armamentarium required to practice true interdisciplinary care in the ICU for the benefit of seriously ill patients. Many are additionally requiring renal therapy prior or during to the need for heart and lung assistance.

Consequently, by entering the treatment of cardiac and pulmonary diseases via Xenios, FME is expanding and strengthening its position in the area of extracorporeal organ support. Treating lung and heart diseases with extracorporeal therapy systems is closely tied, of course, to dialysis—both in technological terms and in the clinical process.

Xenios is a strategic opportunity for FME to intensify its position in a highly profitable and underserved market: extracorporeal organ support.

“Our union with FME provides a unique opportunity to build a broad offering of extra-corporeal organ support therapies by joining Fresenius Medical Care expertise in acute renal replacement therapies and Xenios’ expertise in lung and heart assist. Together we are providing an unrivalled product range for organ assist and Fresenius Medical Care enables XENIOS to establish our innovative therapies worldwide.,” says **Dr. Jürgen Böhm, CEO of Xenios**. “Synergy is the foundation of an extremely bright future for Xenios and FME.”

Xenios is comprised of two stellar brands: Novalung and i-cor

Extrapulmonary gas exchange has successfully established itself in recent years, alongside highly invasive and 60-years-old invasive mechanical ventilation, and is now a clinically accepted, lung-protective procedure. A complete spectrum of new extrapulmonary therapeutic strategies is available from Novalung that can either support IMV to reduce the invasiveness of IMV or aid in weaning from IMV, or replace IMV for the treatment of acute and chronic lung failure to prevent IMV-induced pneumonia. Xenios Novalung offers the full gamut of minimally invasive, extrapulmonary lung support for a broad panorama of patients and indications.

Xenios Novalung is focused on lung failure therapies, offering a minimally invasive alternative treatment platform to immobilizing mechanical ventilation and competitors with limited-product offerings. Xenios Novalung products can replace or reduce mechanical ventilation tailored to individual needs of each patient, performing any level of CO₂ removal and oxygenation.

There are critical issues with conventional lung and heart support. Standard therapies (1) require an immobile, passive patient, which increases risk of morbidity and mortality; (2) cause ventilator-induced lung injury and pneumonia; (3) produce ‘tap-water’-like flow instead of desired pulsatile flow from their pumps; and (4) cause long-term complications related to sedation, immobilization and ventilation.

For example, one indication for Xenios Novalung is COPD (Chronic Obstructive Pulmonary Disease). About 50% of COPD patients also have concomitant heart disease and about four million COPD patients undergo mechanical ventilation. They must often be sedated to endure an endotracheal tube.

The Xenios Novalung therapies offer an alternative to immobilizing mechanical ventilation. The benefits of Novalung’s minimally invasive therapies include (1) an awake, mobile, self-actuated patient that supports improved outcomes; (2) no ventilator-associated lung injury or pneumonia; (3) a physiologic natural pulse to protect the heart; and (4) cost savings via shorter ICU stays.

Xenios Novalung products enable therapies for lung failure that are adapted to specific indications and patients. The duration and intensity of extrapulmonary lung support can be selected and adapted based on individual needs. CO₂ removal requires lower blood flows compared to oxygenation. Xenios Novalung products provide extrapulmonary blood flow as high as necessary and as low as possible.

Xenios Novalung has continuously advanced its technologies to develop iLA (interventional Lung Assist) as an alternative to invasive mechanical ventilation, and as such has spawned a paradigm shift in the treatment of acute and chronic lung failure

Xenios i-cor is focused on heart failure therapies, offering a minimally invasive cardiac assist therapy that is synchronized with a patient's own heart rate as a treatment for Cardiogenic Shock and Decompensated Heart Failure. Using a physiologic natural pulse to protect a patient's heart, Xenios i-cor products are designed to improve coronary blood flow, improve myocardial protection, and enhance organ perfusion. Patients with cardiogenic shock have a very high mortality rate. Cardiogenic shock is a medical emergency. Cardiogenic shock results from an inadequate circulation of blood due to primary failure of the heart ventricles to function effectively. As this is a type of circulatory shock, there is insufficient perfusion of tissue to meet the demands for oxygen and nutrients. The condition involves increasingly more pervasive cell death from oxygen starvation (hypoxia) and nutrient starvation (e.g. low blood sugar). This innovation not only opens up new therapy options for patients who are suffering from cardiogenic shock, but is also designed to bridge patients across high-risk interventions in the cardiac cath lab.

Pulsatile perfusion is natural and essential to endothelial function, which ensures adequate tissue perfusion of organs. Maintaining organ function serves to prevent multiorgan failure and to improve clinical outcomes. i-cor Synchronized Cardiac Assist is the world's first circulatory support system to pump in synchrony with the heart and is designed to: (1) improve coronary blood flow; (2) improve myocardial protection; (3) enhance organ perfusion. The i-cor Synchronized Cardiac Assist System makes possible a whole new chapter in circulatory support.