

Press release
January 18, 2006
Kungsbacka, Sweden

Steen Solution™ approved for sales in Europe – new transplantation opportunity for more patients with very severe lung disease

Vitrolife has obtained CE approval for Steen Solution™, a solution for functional testing and reconditioning of lungs outside the body before transplantation, which means that sales in Europe can begin.

“The new method that has been developed means that the doctor can assess the suitability of the organ for donation after it has been taken from the donor in a way that was not possible previously. This in its turn means that the potential availability of organs that can be transplanted increases considerably,” says Magnus Nilsson, CEO of Vitrolife.

Vitrolife's product Steen Solution™ is part of a new method for functional testing, reconditioning and preservation of lungs outside the body. The technology enables heart-dead donors' lungs, or lungs from brain-dead patients which are initially assessed as doubtful, to be tested outside the body for possible use. The number of potential organs that can be transplanted thus increases considerably. The method has been developed by Professor Stig Steen at the University Hospital in Lund in collaboration with Vitrolife. In May 2005, Steen's transplantation team successfully carried out the second lung transplantation in man using this new technology.

“For people with severe lung disease, a group of patients that suffers greatly today, Steen Solution™ means a greater opportunity of receiving effective therapy,” says Professor Stig Steen.

Vitrolife is today the market leader within the area of lung preservation solutions with its product Perfadex® and more than 80 percent of all lung transplantations in the world are performed using this product. Together with Steen Solution™, Perfadex® is also part of the new method for functional testing and preservation of lungs outside the body. This medical breakthrough can in time lead to a fivefold to tenfold increase in the number of lung transplantations carried out, as the need for donated organs using today's methods considerably exceeds supply.

The application for marketing approval for Steen Solution™ in Europe, so-called CE marking, was submitted in October 2004. The product has been scrutinized by Europe's central pharmaceuticals authority, EMEA. Preparations to start clinical studies in the USA are ongoing.

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Magnus Nilsson
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Vitrolife is a global biotechnology/medical device Group that works with developing, manufacturing and selling advanced products and systems for the preparation, cultivation and storage of human cells, tissue and organs. The company has business activities within three product areas: Fertility, Transplantation and Cell therapy. The Fertility product area works with nutrient solutions (media) for the treatment of human infertility. The Transplantation product area works with solutions and systems to maintain tissue in optimal condition outside the body for the required time while waiting for transplantation. The Cell therapy product area works with media to enable the use of stem cells for therapeutic purposes.

Vitrolife today has approximately 80 employees and the company's products are sold in more than 80 markets. The head office is in Kungsbacka, Sweden, and there is a subsidiary in Denver, USA. The Vitrolife share is listed on the O-list of the Stockholm Stock Exchange.

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