



Press release
June 25, 2018
Gothenburg

Perfadex Plus approved by the FDA

XVIVO Perfusion has received marketing approval (510k) in the United States from the FDA for the company's 'ready-to-use' product Perfadex Plus for cold preservation of lungs. It is already launched in European countries and will be launched in August on the important US market. About 40 percent of all lung transplants are performed in the United States.

As XVIVO Perfusion has reported earlier, the company has developed a new, ready-to-use version of its cold preservation product for lungs. Patent applications have been submitted for the new formulation called Perfadex Plus. It is currently being launched in European countries, will be launched in the US market during August, and is expected to be available on all major markets within 12 months. XVIVO Perfusion has upgraded the product through development of the formulation so that it can now be used without manual addition of buffer and electrolyte.

Perfadex is the market gold standard and has been marketed by XVIVO Perfusion since 1999. It is used for cold preservation of lungs i.e. flushing away donor blood and preserving the donated lungs before transplantation. It is being used in an overwhelming majority of all lung transplantations performed in the world and is estimated to have a worldwide market share of around 90 percent.

“It is positive that the company now offers clinics in the United States a new, safer and more easy-to-use product for cold preservation of lungs. The new version of XVIVO's 'Gold Standard' product, Perfadex Plus, will save time, reduce the risk of mistakes during preparation and thus facilitate the retrieval process for the transplant teams” says XVIVO Perfusion CEO Magnus Nilsson.

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Magnus Nilsson, CEO
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XVIVO Perfusion AB is a medical technology company which develops solutions and systems for assessing and preserving organs outside the body and for selecting usable organs and maintaining them in optimal condition pending transplantation. The company is headquartered in Gothenburg, Sweden, and has one office in Lund, Sweden and one office in the USA. The Xvivo share is listed on Nasdaq Stockholm and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com.

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This is a translation of the Swedish version of the press release. When in doubt, the Swedish wording prevails.