

Memphasys secures first Felix™ System commercial sale for clinical IVF use

Key Points

- **Womens Center in Coimbatore, India, has placed an initial order for a Felix™ System to use in their IVF centre.**
- **This sale comprises a Felix™ console plus an initial supply of single-use cartridges. The Felix revenue model is based on the subsequent recurring sales of the cartridges, with one cartridge used per semen sample processed.**
- **The Felix™ System will be used in routine clinical IVF practice for producing embryos, leading to embryo implantation and pregnancies.**
- **The Womens Centre determined that the Felix-produced embryos were of equal or better quality to the embryos produced by their current methods for sperm separation.**
- **The Womens Centre will initially use Felix™ for males with sperm quality issues, which is typically ~ 40% of their case load.**
- **The Coimbatore center performs up to 30 fresh IVF cycles per month, with volume fluctuating with regional Covid infection prevalence.**
- **Further sales are expected as use of the Felix™ System becomes increasingly established in the Centre and the number of cycles becomes more predictable.**

Australian-based bio-separations and reproductive biotechnology company Memphasys Limited (ASX: MEM) (“Memphasys” or “the Company”) is pleased to advise it has reached an important milestone, with the first commercial sales of its Felix™ System - a novel automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures - for clinical IVF use to the Womens Centre in Coimbatore, India.

The Womens Centre has been a participant in the Felix™ System Key Opinion Leader (“KOL”) *in vitro* study, which is being conducted across 13 leading IVF centres in 8 countries.

It was established more than 30 years ago and has a chain of fertility centres located in four (4) regional Southern Indian cities. It is a holistic facility providing high quality health care catering to a wide range of womens’ health needs including IVF treatments, other fertility and maternal, fetal and neonatal care needs and gynecological services and it also operates a regional andrology reference centre, which has conducted the KOL testing.

This first sale consists of a desk top console, which provides the power to operate the system, and a batch of single-use cartridges. The cartridge processes the semen sample to select sperm with the least DNA damage. One cartridge is used for each semen sample processed, providing separated sperm ready for use in IVF procedures after 6 minutes’ processing.

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The clinic has indicated that orders of further cartridges are likely to be ordered after determining future patient caseloads and how the device will be adopted in its clinical practice.

The Womens Centre will initially utilise the Felix™ system for IVF cases where the male has demonstrated potential signs of below average sperm quality (low sperm concentration, poor motility, high DNA damage or poor morphology), which according to the Centre represents almost half of male semen samples they deal with.

India – a Key ‘Early Market’ for the Felix™ System

India is one of the four ‘early markets’ for the Felix™ system. It accounts for approximately 10% of the global demand for fresh IVF cycles¹. It classes the Felix™ System as a laboratory device, permitting early access for sales. In 2017, approximately 190,000 IVF cycles were performed in the country. This number is anticipated to rise to 587,570 by 2025. One Felix cartridge is used for each semen sample processed, which is required for each cycle.

Commenting on the sale, Memphasys Executive Chairman Alison Coutts said:

“This is very exciting. It is the first time the Felix™ System will be put to routine clinical use, to produce embryos for implantation and pregnancies. Whilst it is a small cartridge volume order to begin with, the Felix revenue model is based on the subsequent recurring sales of the cartridges.

The Womens Centre have been a great KOL trial partner. They do meticulous work and are deeply interested in assessing the performance of the Felix device. This sale represents a further strengthening of this relationship.

This sale will provide really useful clinical performance data and should also assist to establish a reference centre in the Indian market for other clinics to observe and potentially become customers themselves.”

Memphasys has advanced commercial discussions with other IVF clinics in the ‘early markets’, including other sites in India, and is confident of securing further clinical sales to other IVF clinics in Q1 2022.

This announcement has been approved for release by the board of Memphasys Limited.

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¹ Allied Market Research Report, 2019



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About Memphasys:

Memphasys Limited (**ASX: MEM**) specialises in biological separations and reproductive biotechnology for high value commercial applications.

Reproductive biotechnology products in development include medical devices, in vitro diagnostics, and new proprietary media.

The Company's patented bio-separation technology, utilised by the Company's most advanced product, the Felix™ device, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.

Website: www.memphasys.com

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