

## **Felix™ System successfully records 10 new live births in India**

### **Highlights**

- **India records ten new live births using the Felix™ System following the previously reported live birth in India earlier this year<sup>1</sup>**
- **Results show the positive impact of the Felix™ System on sperm selection in a highly challenging patient cohort - all treated couples had at least one previous failed IVF cycle and all males had high levels of sperm DNA damage**
- **Study findings were presented at the 12th Congress of the Asia Pacific Initiative on Reproduction (ASPIRE 2023) in Adelaide on 9 September 2023.**

Australian-based reproductive biotechnology company, Memphasys Limited (ASX: MEM), is pleased to report ten new live, healthy births in India from using the Felix™ System. This brings total live births to date using the Felix™ System in India to eleven.

High sperm DNA fragmentation is commonly associated with poor pregnancy outcomes. The Felix™ System has unequivocally demonstrated that it can effectively deal with high sperm DNA fragmentation levels.

MEM's Indian KOL (Key Opinion Leader) partner, Coimbatore Womens Hospital Centre, has predominantly utilised the Felix™ System for males suffering from high sperm DNA fragmentation to achieve positive pregnancy outcomes.

At the Coimbatore Womens Hospital Centre, thirty-three couples were enrolled in a study which utilised the Felix™ System. The study resulted in forty frozen embryo transfers, with a clinical pregnancy rate of 47.5%. From these pregnancies there was a total of eleven live births, equating to a live birth rate of 27.5%. The first live birth of a healthy baby boy from a patient with an extremely high DNA fragmentation level was publicly reported earlier this year.<sup>1</sup> Notably, the overall live birth result is comparable with the current Australia and NZ benchmark of 31.3% live birth rate across all patients undertaking IVF from frozen embryo transfers<sup>2</sup>. The distinguishing feature of the study is that the outcome was achieved in a demanding patient demographic, where patients had undergone at least one previously unsuccessful IVF cycle and all males had high levels of sperm DNA fragmentation (average of 34%).

Dr Ramaya Jayram from Coimbatore Womens Hospital Centre, the clinician responsible for the study, said "the use of the Felix Device enabled the patients to undertake this gentle treatment without needing to resort to invasive procedures such as surgical sperm retrieval."

The study, entitled "*First Recorded Normal Live Birth after ICSI with Electrophoretically Isolated Spermatozoa Using the Felix™ System*", was presented by Dr Jayram at the Congress of the Asia Pacific Initiative on Reproduction (ASPIRE 2023) in Adelaide on 9<sup>th</sup> September.

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<sup>1</sup> Refer to ASX announcement dated 3<sup>rd</sup> April 2023

<sup>2</sup> Report titled "Assisted Reproduction in Australia and New Zealand", published by National Perinatal Epidemiology and Statistics Unit (NPESU), UNSW, in October 2022. Live birth rate calculated across all frozen embryo transfers from all IVF cycles in Aust & NZ.

[https://npesu.unsw.edu.au/sites/default/files/npesu/data\\_collection/Assisted%20Reproductive%20Technology%20in%20Australia%20and%20New%20Zealand%202020.pdf](https://npesu.unsw.edu.au/sites/default/files/npesu/data_collection/Assisted%20Reproductive%20Technology%20in%20Australia%20and%20New%20Zealand%202020.pdf)



India represents one of the top five addressable markets globally for the Felix™ System. MEM has temporarily suspended sales of Felix™ System in India following changes introduced on 9 August 2022 by the Indian regulator, the Central Drugs Standard Control Organisation (CDSCO), which oversees the regulation of all medical devices sold in India including human assisted reproduction clinical processes.

MEM has already acted to address these changes by submitting a voluntary product registration with CDSCO as an initial strategy to sell non-commercial quantities in India. MEM is also seeking regulatory advice on importing the Felix™ System into India for special test purposes until it achieves in-country (TGA) registration which would enable unrestricted importation of the device.

Felix™ is the premium, automated device comprising a console with single-use cartridges for sperm preparation in human IVF procedures. The device gently separates sperm from a semen sample in six minutes, using electrophoresis and size exclusion membranes without causing damage to sperm DNA. Felix™ is MEM's first commercial product.

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

**ENDS**

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**About Memphasys**

Memphasys Limited (ASX: MEM) specialises in 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™ System device, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.

**Website:** [www.memphasys.com](http://www.memphasys.com)

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