

Felix™ technology provides clear benefits over widely used sperm preparation methods in a Japanese clinical trial

Highlights:

- **MEM's Felix™ System has outperformed a sperm preparation method comprising two of the most widely used processes, Density Gradient Centrifugation and Swim-Up (DGC+ SU), in findings from a recently completed Japanese clinical trial.**
- **The clinical performance of Felix™ System was generally better on most clinical measures, including embryo utilisation rate.**
- **The trial highlighted laboratory operations and workflow would be greatly improved through the adoption of the Felix™ System.**
- **The paper about the trial and its findings has been accepted for presentation at the European Society of Human Reproduction and Embryology (ESHRE) conference in June.**

Australian-based reproductive biotechnology company, Memphasys Limited (ASX: MEM), is pleased to announce its flagship Felix™ System has outperformed a sperm preparation method comprising two widely used technologies, a combination of Density Gradient Centrifugation followed by Swim-Up (DGC+SU), in findings from a recently completed Japanese clinical trial at the Reproduction Clinic Osaka, Japan, a Key Opinion Leader and an early adopter of the technology.

Trial findings showed clear benefits from using the Felix™ System across most clinical measures over the alternative sperm preparation methods (See Figure 1).

The DGC+SU process requires complicated procedures including centrifugation and incubation and takes around an hour to process, whereas the Felix™ System is a simple easy-to-use console and cartridge with processing time taking a mere six to seven minutes.

The clinical trial findings document results from 45 infertile couples with 401 eggs collected and then split between the Felix™ and the DGC+SU sperm preparation methods to produce embryos by Intra Cytoplasmic Sperm Injection (ICSI) for subsequent implantation.

The reported Felix™ System results were numerically better on most clinical measures, including most importantly embryo utilisation rate (Figure 1). However, the results did not reach statistical significance between the DGC+SU and Felix™ groups, given the limited scale of the clinical trial.

	DGC+SU	Felix™ System
Processing time	~1 hour	~7 minutes
Fertilisation rate	81.0%	80.6%
Blastocyst development rate	52.9%	58.4%
Good-quality blastocyst development rate	26.1%	35.7%
Embryo utilisation rate	54.3%	58.0%

Figure 1: The results of the Japanese trial comparing DGC+SU vs. the Felix System

The study has concluded the Felix™ System is a viable option for sperm isolation to alternative methods with clinical adoption of Felix™ System expected to improve laboratory operations and



workflow, as it achieves a statistically similar result in a fraction of the time compared to its competitors.

A paper about the trial and its findings has been accepted for presentation at the European Society of Human Reproduction and Embryology (ESHRE) conference to be held in June 2024.¹

CEO and Owner of the Reproduction clinic Osaka and senior research clinician, Dr Tomomoto Ishikawa said: *“I have been testing the Felix™ System in my clinic for the past few years along its development journey. I am excited to see that it has now passed that development stage and is performing well clinically. Not only does the system select high quality sperm for ICSI, but it does so very quickly, in a single, easy, and automated process. Implementation of use of the Felix device in my clinic will make a major positive difference to my clinic’s efficiency and workflow”.*

Memphasys Managing Director and CEO (Acting) Dr David Ali said: *“The positive findings from this trial further highlights the significant benefits of the Felix™ System compared to the most widely used methods. While we acknowledge it was a small sample size, the results in favour of Felix were numerically generally better on most clinical measures including most importantly embryo utilisation rate. In addition, the fact Felix is simpler to use and takes a significantly shorter time frame to use would improve lab operations and workflow. This is a huge plus for process flow in IVF laboratories which are always seeking efficiency and cost savings.”*

MEM looks forward to releasing the results of a larger randomised double-blinded study currently being conducted at Monash IVF towards the end of this year. MEM has recently enrolled a recently acquired Monash clinic (Fertility North) to accelerate patient recruitment and the full completion of the trial.

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

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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, 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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¹ “A novel electrophoretic sperm isolation system achieves equivalent ICSI outcomes to the combined density gradient centrifugation and swim-up method in a shorter processing time” S Sayaka Kitahara, Shimpei Mizuta, Yuka Iwamoto, Kazutaka Doi, Yasuhiro Ohara, Hidehiko Matsubayashi, Tomomoto Ishikawa / Reproduction clinic Osaka; Hassan W. Bakos, R. John Aitken / University of Newcastle and Memphasys