

## **ASX Release**

## START OF IN-VITRO CLINICAL TRIAL AT MONASH IVF

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NuSep Holdings Limited (ASX:NSP) advises that it has started an *in-vitro* clinical trial of its SpermSep device at "Monash IVF" in Melbourne.

"Monash IVF" was chosen because it is a leading centre in Australia for the management of severe of male factor infertility. The "Monash IVF" team, led by Professor Rob McLachlan, Head of Andrology at "Monash IVF", will test the SpermSep device to determine how well it can isolate sperm from three challenging sources where viable sperm recovery is difficult: -

- From a biopsy from the testes and epididymis\*;
- From cryo-stored (frozen) ejaculates;
- From seriously compromised samples with very low sperm count.

The "Monash IVF" team will compare sperm number and motility against conventional sperm preparation methods. The collaborators at University of Newcastle, led by Professor John Aitken, Pro Vice-Chancellor of the Faculty of Health and Medicine, have oversight of the program and will perform DNA damage analysis on snap frozen material.

The separation method by SpermSep uses gentle electrical forces and a porous polymer membrane that enables contaminants to be readily separated and the best sperm, which is negatively charged, to be harvested. The University of Newcastle researchers have previously shown that the SpermSep device imparts far less oxidative damage to the sperm than current processing methods and it efficiently selects viable sperm.

The SpermSep device's ability to handle multiple samples in a busy IVF clinical setting will be assessed against present methods. Typically a large IVF clinic will handle around 20 samples a day. Obtaining substantial processing improvements is becoming increasingly important in the highly competitive IVF industry. The present methods require time consuming laboratory steps including multiple washings and centrifuging. Previous tests have shown that the SpermSep device can separate viable sperm from a sample in less than five minutes against the current methods of around 30 minutes.

Professor Rob McLachlan stated that he is excited that "Monash IVF" is the first clinic to take part in this trial. He has heard for some time about the NuSep device and is keen to test it out to determine what it can do, especially with really difficult cases.

Professor John Aitken stated that he is keen to test the device in the "Monash IVF" centre as it is only in a real clinical setting, processing very difficult samples, that the device's true potential can be established.

\*The epididymis is a structure at the back of the testicle in which sperm matures and is stored

Other leading IVF centres in Australia are to follow shortly with further *in-vitro* testing of the SpermSep device.

The trial is expected to take around six months to complete. The results will be important for determining how the SpermSep device compares against current methods and what potential it has to be applied to various types of male infertility.

Commenting on the trial, NuSep Executive Chairman Alison Coutts said, "The trial is the culmination of six months of hard work repositioning the company in line with its strategy to focus on its SpermSep product. We are pleased that the clinical trials have begun and we are looking forward to working with staff at "Monash IVF" in conducting these trials."

## For further information please contact:

Alison Coutts
Executive Chairman
+61 2 8415 7300
alison.coutts@nusep.com