

VOIL

VOIL is a ready to use light paraffin oil for ART-procedures to overlay small volumes of tissue culture medium. VOIL prevents the evaporation of water and protects the media from changes in osmolality and pH.

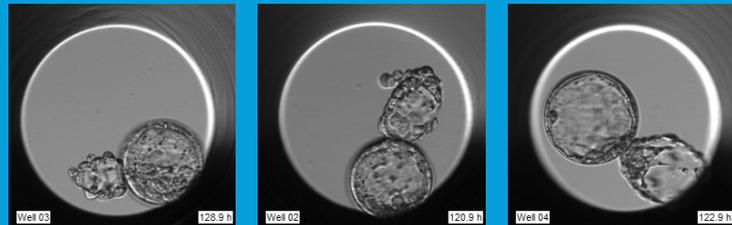
Furthermore, it enhances rates of embryonic development during embryo culture.

Highly refined for medical purpose

The quality of in vitro culture is improved by prewashing VOIL twice with ultrapure water to reduce contaminants and embryotoxicity¹. Washing the oil is a routine practice in our manufacturing process and very beneficial in minimizing adverse effects of the finished VOIL.

1-cell time lapse morphokinetics mouse embryo assay (MEA) for 120 hours to assure the best quality

A LOT-wise time lapse morphokinetics mouse embryo assay is performed with culturing the 1-cell mouse embryos for 120 hours to the expanded blastocyst stage (see figure below). The 1-cell system has proven to be the more sensitive method in order to detect minimal changes compared to the 2-cell². The MEA is recorded up to day 6 including photos of their final stages as well as video sequences of the whole development.



1-cell mouse embryos in VOIL after more than 120 hours of culture

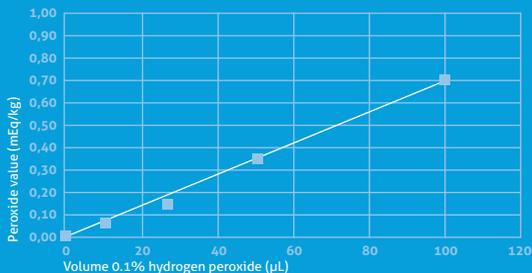


What counts is the blastocyst cell

On day 6 of mouse embryo development, embryos from the test and control group are fixed and processed for total cell counting. The average number of cells (+/- SD) in expanded blastocysts are recorded for each ^vOIL LOT of production. In addition, the embryos pass a morphological examination of the inner cell mass (ICM) and the trophectoderm (TE) cells^{3,4}.

Detection of peroxides is a must for IVF oils

^vOIL is pre-washed with ultrapure water, which reduces contaminants and embryotoxicity, resulting in a product with very low oxidative content, < 0.1 mEq/kg. ^vOIL undergoes a LOT-wise peroxide value (POV) assessment based on the EP (European Pharmacopoeia), describing an iodometric, visual method as the state of the art in the pharmaceutical industry⁵.



Linearity of the POV assay (cited by Frank Eertmans et al., 2013)

^vOIL is exposed to a more sensitive POV measurement, which has been upgraded specially for ART in 2013. The changes resulted in a much lower detection limit of 0.0356 mEq/kg, which is 56 times minor than the value of the classic method (Frank Eertmans et al. 2013).

^vOIL represents a stringent quality control with a batch-to-batch consistency of the finished product

- ✔ Sterility by sterile filtration over 0.2 micrometer filter
- ✔ Endotoxin, kinetic turbidimetric LAL assay < 0.1 EU/mL
- ✔ 120 hours 1-cell time lapse morphokinetics mouse embryo assay (MEA) ≥ 80%
- ✔ Blastocyst cell count on day 6 of mouse embryo development
- ✔ Peroxide value (POV) determination < 0.1 mEq/kg
- ✔ Solid paraffin complies with Ph. Eur.



- 1 Dean E. Morbeck, PhD. et al. (2010). Washing mineral oil reduces contaminants and embryotoxicity. *Fertility and sterility*, Vol. 94, Pages 2747-2752.
- 2 Ady Davidson M.D. et al. (1988). Mouse embryo culture as quality control for human in vitro fertilization: the one-cell versus the two-cell model, *Fertility and sterility*, Vol. 49, Pages 516-521.
- 3 Koji Matsuura PhD et al. (2010). Blastocyst Quality Scoring Based on Morphological Grading Correlates with Cell Number. *Fertility and Sterility*. Volume 94 (3), Pages 1135-1137.
- 4 Borut Kovačič and Veljko Vlasisavljević (2012) Importance of Blastocyst Morphology in Selection for Transfer. *Biochemistry, Genetics and Molecular Biology*, Chapter 11.
- 5 European Pharmacopoeia, 7th Edition, 01/2008:20505, 2011, 138.

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