

Irvine Scientific is the First Company to Receive FDA 510(k) Clearance on Vitrification Media for Use With Oocytes

Vitrification provides excellent survivability of embryos and oocytes through the freezing process

SANTA ANA, California – May 09, 2016: Irvine Scientific, a world leader in the development and manufacture of Assisted Reproductive Technologies (ART), today announced the receipt of FDA 510(k) clearance for expanded use of Vit Kit® vitrification media to include human oocytes. The company is the first, and only company to date, to obtain 510(k) clearance of vitrification media for use with oocytes within the US. Irvine Scientific's Vit Kit-Freeze and Vit Kit-Thaw are now intended for worldwide use with oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Vitrification is a cryopreservation technique that provides excellent survivability of embryos and oocytes through dehydration and ultra-rapid cooling. This process eliminates the concerns of damaging ice-crystal formation associated with traditional slow freezing. The ability to offer an FDA-cleared vitrification media for oocytes will enhance the ability of fertility clinics to preserve women's fertility through oocyte freezing. Egg freezing offers women the choice to preserve healthy eggs before undergoing cancer treatment, chemotherapy or radiation therapy which compromise ovarian function and egg viability. Age negatively impacts a woman's egg supply in both quality and quantity, so freezing eggs while young is also an option for those who wish to delay starting a family.

"We are very pleased to be the first and only company to offer vitrification media cleared by the FDA for use with oocytes in the US," said Timothy P. Mullane, Chief Operating Officer, Irvine Scientific. "It represents our commitment to supplying the best quality products to laboratories, and to support their need for an effective, regulated means to preserve fertility and help patients achieve their hopes for having healthy babies in the future."

For more information on Irvine Scientific's Vit Kit media and other ART products visit: http://www.irvinesci.com/assisted-reproductive-technology

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About Irvine Scientific

Irvine Scientific, a member of JX Group, is a worldwide leader in the innovation and manufacture of cell culture media, reagents, and medical devices for researchers and clinicians. The company provides unrivalled service and quality to scientists working in cell therapy and regenerative medicine, assisted reproductive technology and cytogenetics, and industrial cell culture for the large-scale production of biotherapeutics and vaccines. Irvine Scientific adheres to both ISO and FDA regulations and operates dual cGMP manufacturing facilities in California, USA and Tokyo, Japan. The company's consultative philosophy combined with expertise in cell culture and compliance provides customers with unique capabilities and support. For over 40 years, Irvine Scientific has remained uniquely flexible and focused on media while becoming a strategic global leader in media products and services.