

THE CURRENT FERTILITY TREATMENT LANDSCAPE



Barriers to infertility treatment include:



Patient Factors

Individual preferences, lifestyles, and cultural barriers preclude ART for a number of women¹⁻³



Geographical Access

ART clinics are limited to metropolitan areas, leaving 19 million women with limited access to ART⁴



Affordability

IVF cycles are expensive and not always covered by insurance¹⁻³

Current treatment options are associated with lower success rate or higher cost

Lower success rate

Oral IUI



success rate^a per cycle⁵

Injectable IUI



success rate^a per cycle⁵

Higher cost

IVF



success rate^b per cycle⁶

^aSuccess rate defined as pregnancy rates, including live births and ongoing pregnancies at ≥20 weeks' gestation at the closing date of the study.⁵

^bSuccess rate defined as live birth rate in women <35 years of age.⁶



The INVOCELL Culture Device holds the egg, sperm, and culture media while **utilizing the vagina as an incubator** to support fertilization and incubation. The accompanying INVOCELL Retention Device holds the INVOCELL Culture Device in place.⁷



In a 2015 clinical trial involving 450 cycles and 107 live births, IVC with INVOCELL had a **~24% success rate^a** per cycle.⁷



To help increase patient access, INVOCELL can be **priced between** injectable IUI and IVF.

INVOCELL may be for patients seeking an option based on:



Value



Choice



Geography



Participation



Beliefs

^aSuccess rate defined as live birth rate.⁷

INDICATIONS FOR USE

INVOCELL[®] Intravaginal Culture System consists of the INVOCELL Culture Device and the INVOCELL Retention Device. The Culture Device is indicated for use in preparing, holding, and transferring human gametes or embryos during In Vitro Fertilization/Intravaginal Culture (IVF/IVC) and Intra-Cytoplasmic Sperm Injection Fertilization/Intravaginal Culture (ICSI/IVC) procedures. The Retention Device is indicated for use during the incubation period to aid in retention of the Culture Device in the vaginal cavity. The Culture and Retention Devices are not indicated for incubation periods exceeding 72 hours.

SELECT IMPORTANT SAFETY INFORMATION

- Culture and Retention Devices should not be used in patients with the inability to tolerate placement or wearing of a device within the vaginal cavity.
- Culture and Retention Devices are single use only. Do not use if product or package appears damaged.
- Do not use Culture Device in patients with hypersensitivity to medical grade silicone or polystyrene or in patients with a severe case of vaginitis or with a history of toxic shock syndrome. Evaluate patients for any recent pelvic surgery to assure it will not affect intravaginal culture procedure.
- Proper handling is extremely important to safe and effective use of Culture Device. Do not begin clinical use of INVOCELL Intravaginal Culture System without establishing competency by reading and practicing Instructions for Use.
- It is recommended that INVOCELL Intravaginal Culture System be utilized with a mild ovarian stimulation protocol. The recommended upper limit on number of oocytes or ICSI fertilized embryos to be placed in Culture Device is seven.
- Verify Culture Device is correctly locked before placement in vaginal cavity.
- Patients should avoid any activity that may alter temperature of vaginal cavity and should avoid manipulation and removal of Culture and Retention Devices while in place.

Please see the accompanying full INVOCELL Intravaginal Culture System Instructions for Use for more detailed information.

References: **1.** American Society for Reproductive Medicine. Access to Care Summit [white paper]. Washington, DC: American Society for Reproductive Medicine; September 10-11, 2015. **2.** Quinn M, Fujimoto V. *Fertil Steril.* 2016;105(5):1119-1123. **3.** Rich CW, Domar AD. *Fertil Steril.* 2016;105(5):1124-1127. **4.** Harris JA, Menke MN, Haefner JK, Moniz MH, Perumalswami CR. *Fertil Steril.* 2017;107(4):1023-1027. **5.** Reindollar RH, Regan MM, Neumann PJ, et al. *Fertil Steril.* 2010;94(3):888-899. **6.** Society for Assisted Reproductive Therapy. 2016 Preliminary National Summary Report. https://www.sartcorsonline.com/rptCSR_PublicMultiYear.aspx?reportingYear=2016. Published April 25, 2018. Accessed January 23, 2019. **7.** INVOcell Intravaginal Culture System [instructions for use]. Medford, MA: INVO Bioscience.

To learn more about INVOCELL, please visit www.invocell.com/hcp.