

# Catheter Ultrasound Transmission Element (CUTE) Catheter

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## Technology description

Unmet Need Approximately 48.5 million couples are infertile worldwide. In the US, more than one million couples seek infertility treatment each year, and spend more than \$3 billion in pursuit of babies. Unfortunately, current infertility treatments, including artificial insemination and embryo transfer approaches, can't offer both an effective and economic solution. Obviously, there is a clear clinical need to increase fertilization success rate in a non-invasive and easy-to-perform approach, while reducing the overall time/cost and the hormone intake. From literature and from our center's experience, the best fertilization success rate of 75% happens in in vitro assay by accumulating 10000 sperms with an egg in a 50 $\mu$ L volume. Clearly, this high success rate is attributed to both the high sperm count density (sperms per unit volume) and the targeting and delivery very close to the egg. Also, many clinical studies on the male-factor corroborate this hypothesis.

Undoubtedly, there is a strong clinical need for a precise catheter tracking technology for infertility treatment guidance that can deliver high sperm count per volume to the appropriate Fallopian tube (for artificial insemination treatment), and deposit embryos with millimeter precision away from the fundus area (for in vitro fertilization treatment), leading to potential increase in success rates and reducing time/cost and hormonal intake. To gain a wide acceptance, this "smart" catheter shouldn't interrupt current clinical workflow, has to be intuitive and easy to use, works with any ultrasound vendor, and should be low-cost disposable. Available catheter tracking technologies including electromagnetic approach come with a high-cost or an intrusive setup that prevented their acceptance in this market.

## Technology Overview

To address the clinical need described above and overcome the current technical challenges or complexities, we invented, designed and developed a new catheter tracking platform called Active Ultrasound Pattern Injection System (AUSPIS). The AUSPIS system is composed of a catheter with ultrasound tracking elements (CUTE catheter), and smart transmit/receiver circuit. The system receives the image beacon pulses, analyzes the acquired signal, and fires one or a series of active echo pulses from the same catheter element with a proper timing, frequency, duration and amplitude. Thus it enables us to inject any "virtual" pattern into the B-mode image. The encoding is based on the B-mode US image formation technique, so it doesn't require any modification to the US machine. It continuously measures the local acoustic signal amplitude, by which sub-millimeter elevation

localization accuracy can be achieved. By configuring the pattern formations, the technique can be used for tracking, tool guidance, and annotation.

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