

Sandstone Diagnostics Announces FDA 510(k) Clearance and Commercial Launch of Trak® Volume Cup

Now Available in the Trak® Male Fertility Testing System, the Specially-designed Volume Cup Allows Men to Measure Semen Volume and Diagnose Hypospermia at Home

LIVERMORE, CALIFORNIA, US, April 24, 2018 /EINPresswire.com/ --<u>Sandstone Diagnostics</u>, a medical device company focused on a data-driven approach to men's reproductive health, proudly announces the FDA 510(k) clearance and commercial launch of the Trak® Volume Cup. The patent-pending Volume Cup is the first FDA-cleared device that allows men to measure semen volume and diagnose hypospermia, or low semen volume, at home.



According to the World Health

Organization (WHO), men who regularly produce less than 1.5 milliliters of semen may be at risk for infertility as low volume can inhibit the ability of sperm to reach the female reproductive tract. Low semen volume can also be associated with reduced sexual function and pleasure, low testosterone, and an increased risk of other urological conditions and chronic diseases.

The <u>Trak Volume Cup</u> is coated with a liquefaction enzyme that breaks down sample viscosity, and includes specially designed features to funnel the sample into a graduated measurement compartment for a simple and accurate visual reading of semen volume. Conventional semen volume measurement requires either weighing the sample or transferring the sample from the collection cup to a separate graduated measurement device. The Trak Volume Cup is the only FDA-cleared device that integrates volume measurement directly into the collection cup itself.

"We're thrilled to expand our male reproductive health product line with the new Trak Volume Cup," said Sandstone CEO Karen Drexler. "Low semen volume is an important but often overlooked health and fertility parameter. This innovative device further improves the semen testing experience and allows our customers to measure and track an additional parameter for their reproductive health and chances of conception."

The Trak Volume Cup is now available in the <u>Trak Male Fertility Testing System</u>. Launched in 2017, the Trak System allows men to measure, track, and try to improve their sperm count in the comfort

and privacy of home. In accordance with American Urological Association (AUA) and American Society for Reproductive Medicine (ASRM) clinical guidelines, men with optimal semen parameters are unlikely to face fertility issues while men who test low in sperm count and/or semen volume are advised to see a reproductive urologist for medical evaluation.

About Sandstone Diagnostics

Founded in 2012 in part by government scientists from Sandia National Laboratories, Sandstone's mission is to provide innovative, data-driven tools to help men assess, manage, and improve their reproductive health. We are a team of scientists, developers, health and business professionals. We are also proud members of the Startup Health and Stanford StartX accelerator programs. But most importantly we are fathers, mothers, brothers, sisters, and friends who care deeply about improving men's reproductive health and helping people start their families. For more information, visit trakfertility.com, and follow us on Facebook and Twitter @TrakFertility.

Frank Tortorici Marketing Maven PR 9088758908 email us here

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