

CrossBay Medical Receives FDA Clearance for CrossGlide Endometrial Tissue Sampler

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SAN FRANCISCO--(BUSINESS WIRE)--CrossBay Medical, Inc., a health technology company focused on improving the delivery of women's healthcare, today announced it has received clearance from the Food and Drug Administration (FDA) to market its CrossGlide™ ETS Endometrial Tissue Sampler.

The CrossGlide ETS, the third product to utilize the frictionless CrossGlide technology platform, enables medical providers to perform an office-based endometrial biopsy procedure gently, effortlessly and without a tenaculum. The product is designed for simpler access to the uterine cavity than currently available modalities.

Endometrial biopsy is a common tissue-sampling procedure performed in women's health offices worldwide. In today's typical practice, a medical provider will try to push a pipelle across the cervical canal to access the uterus. If they're unable to advance the pipelle by more forceful pushing, they will use a tenaculum to grasp, pull, and manipulate the cervix to assist in pushing the pipelle into the uterine cavity. This can be uncomfortable for the patient. The CrossGlide ETS is uniquely designed to require no grasping or manipulation of the cervix to allow for easy, dependable access into the uterine cavity regardless of the complexity or variability of the patient's specific anatomy.

There are approximately four million endometrial biopsies performed per year in the European Union and United States for gynecological indications, and there are an additional two million endometrial biopsies performed globally for infertility reasons.

"The FDA's approval of CrossBay ETS not only marks another step in our company's development," said Pius Vidyarthi, CrossBay Medical's CEO, "it also ushers in the next step in the movement to make women's care a comfortable experience for patients. Uterine access in the office doesn't need to be difficult and painful for the patients. It is tremendously rewarding to be able to make CrossGlide ETS available to US clinicians and their patients, and further our mission to address the all-too-common discomfort associated with biopsy performed in the diagnostic work-up of abnormal uterine bleeding disorders and infertility. We look forward to bringing this to more physicians' offices in the coming months."

In addition, Vidyarthi noted that CrossBay plans to develop products for other office-based gynecology procedures using CrossGlide wherever cervical access is required, including products for IUD insertion and hysteroscopy.

About CrossBay Medical, Inc.

CrossBay Medical, Inc. is a health technology company driven by its singular mission to modernize the delivery of women's healthcare on a global level. CrossBay also serves as a strategic innovation partner to large medical device firms interested in incorporating the company's game-changing CrossGlide technology into their suites of patient-friendly product offerings.

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