

# CrossBay Medical, Inc. announces FDA, Health Canada, and CE mark marketing authorizations for SonoSure SonoHystero-graphy and Endometrial Sampling Device

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**CrossBay Medical, Inc.** →  
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SAN RAFAEL, Calif., April 25, 2014 /PRNewswire/ -- CrossBay Medical, Inc., today announced the United States Food and Drug Administration (FDA) clearance of its product, the SonoSure™ Sonohystero-graphy and Endometrial Sampling Device. The device has also received Health Canada clearance and the CE mark. The SonoSure™ is indicated for use to access the uterine cavity for saline infusion sonohystero-graphy and to obtain endometrial biopsy, if indicated, utilizing the same device.



CrossBay Medical Inc.'s SonoSure(TM) Sonohysterography and Endometrial Sampling Device is indicated for use to access the uterine cavity for saline infusion sonohysterography and to obtain endometrial biopsy, if indicated, utilizing the same device. (PRNewsFoto/CrossBay Medical, Inc.)



Abnormal Uterine Bleeding (AUB) occurs in 20 percent of women between the ages of 19 to 55. Saline Infusion Sonohysterography (SIS) and Endometrial Biopsy (EMB) are routinely used in the workup for AUB. Many providers perform these procedures at the same setting, using separate instrumentation for each procedure. This requires cannulation of the cervix at least twice. Other providers may require patients to have separate visits for the procedures. The SonoSure™ device combines Saline Infusion Sonohysterography and Endometrial Biopsy in the same device.

"We are excited about receiving the clearance for SonoSure™ as we can now provide our affiliate partners in the US, Canada and Europe with a truly affordable and effective product," said Piush Vidyarthi, CEO of CrossBay Medical Inc. "CrossBay's goal is to continue to develop innovative devices for women and children for the global market. We have numerous products in development that we plan to bring to market in the near future."

In the US, CrossBay has entered into an exclusive agreement to commercialize the product. "At Norgenix, it is our goal to offer quality products that provide solutions to the unmet needs within women's health," stated Michael Rackley, COO & Senior Vice President of Norgenix. "We

immediately recognized the value that CrossBay Medical's devices may have for Gynecology. With the exclusive rights to market, sell, and distribute the SonoSure™ in the U.S., we look forward to providing such innovations to the healthcare marketplace."

CrossBay Medical, Inc. was founded in 2009 with the goal of providing affordable healthcare products for women and children. The strategic partners in the company have developed, manufactured, registered and commercialized products for a combined 60 years. CrossBay Medical's products are designed in the United States, manufactured in China, and distributed by an existing network of affiliates.

ABOUT CROSSBAY MEDICAL, INC. | [www.crossbaymedicalinc.com](http://www.crossbaymedicalinc.com)

ABOUT NORGENIX | [www.norgenixpharma.com](http://www.norgenixpharma.com)

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