Releases

Health Canada Approves Conceptus' Third Generation Essure(R) Permanent Birth Control System

Improvements designed to increase ease of use especially in the office setting

PRNewswire-FirstCall MOUNTAIN VIEW, Calif.

Conceptus, Inc. today announced the approval of its third generation Essure(R) permanent birth control system by Health Canada. System modifications include changes to the delivery system that reduce the number of steps a physician is required to perform during a placement procedure.

In addition to the enhanced ease-of-use, hysteroscopic visualization of the implant and placement markers was significantly improved. A new DryFlow(TM) Introducer, which alleviates distension fluid loss, a major safety concern of hysteroscopists, is packaged with the product.

"These modifications, which were made in response to physician recommendations, were approved by the U.S. Food and Drug Administration this past summer allows them to more easily add the Essure procedure to their practice services," said Mark Sieczkarek, president and chief executive officer of Conceptus, Inc., developer of the Essure procedure. "We anticipate that the physician response in Canada will be similar and will foster wider physician adoption, giving more women opportunity to select permanent birth control without the need to undergo tubal ligation and the risks associated with surgery."

"Canadian women who have decided that their family is complete, now have an even more advanced method of permanent birth control without surgery," Robert Sabbah, MD, chief of gynecology at Sacre Coeur hospital in Montreal and assistant professor of obstetrics and gynecology at the University of Montreal. "We are looking forward to offering this non-incisional procedure to our patients seeking permanent birth control."

The Essure procedure remains the first and only female sterilization procedure to have zero pregnancies in the clinical trials. It is approved for sale in Canada, the United States, Mexico, Central and South America, New Zealand, Australia and Europe. To date, more than 150,000 Essure procedures have been performed worldwide.

In previous clinical studies, Essure patients experienced little discomfort, returned to normal activity sooner and expressed a greater level of overall satisfaction when compared to tubal ligation. Because the Essure procedure does not require incisions, it can be performed in the comfort of a physician's office in less than 15 minutes with a local anesthetic. Most women who get the Essure procedure are able to return to work or other activities the following day. It is also the only female birth control method that uses a test to confirm protection from pregnancy, providing women with peace of mind.

About the Essure Procedure

The Essure procedure, initially approved by Health Canada in 2001 and by the U.S. FDA in 2002, is a permanent birth control procedure that replaces tubal ligation for women. In the comfort of a physician's office and in less then 15 minutes, the soft micro-inserts are placed into the Fallopian tubes through the cervix eliminating the need for incisions. Once in place, the device is designed to elicit tissue growth in and around the micro-insert to form an occlusion or blockage in the Fallopian tubes.

The Essure confirmation test is performed three months after the procedure to confirm that the micro-inserts are in the correct location, the tubes are blocked and that the woman can discontinue temporary birth control. The Essure procedure is 99.80% effective with four years of data and is the first and only FDA approved female sterilization procedure to have zero pregnancies in clinical trials.

About Conceptus

Conceptus, Inc. manufactures and markets the Essure Permanent Birth Control system, an innovative medical device and procedure designed to provide a non-incisional alternative to tubal ligation, which is currently the leading form of birth control worldwide. The availability of the Essure procedure in the U.S. is expected to open up a market currently occupied by incisional tubal ligation and vasectomy, which combined account for over 1 million procedures annually.

Additional information about the Essure procedure is available at <u>http://www.essure.com/</u> or by calling the Essure Information Center at 1-877-ESSURE1. Additional information about Conceptus is

available at http://www.conceptus.com/ or by calling 1-877-ESSURE2.

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