

Conceptus[®]

Incorporated

October 2006

**IMPORTANT INFORMATION FOR PHYSICIANS ON MODIFICATIONS TO THE *ESSURE*[®]
PERMANENT BIRTH CONTROL SYSTEM LABELING RELATED
TO CONCOMITANT USE WITH GYNECARE THERMACHOICE*
UTERINE BALLOON THERAPY SYSTEM**

Dear Physician:

Conceptus, Inc. would like to inform you of important new information regarding the *Essure* Permanent Birth Control System. Recent discussions with the United States Food and Drug Administration (FDA) regarding the results of a clinical study titled “*Essure* System Combined with GYNECARE THERMACHOICE Uterine Balloon Therapy HSG Evaluation Study” have led to Conceptus and the FDA agreeing to certain modifications of the *Essure* product labeling.

According to certain FDA post-approval requirements for the *Essure* System, Conceptus conducted this prospective study to assess whether a concomitant THERMACHOICE endometrial ablation procedure causes intrauterine synechiae that could prevent or interfere with an effective hysterosalpingogram (HSG) at 3-months post-*Essure* placement.

Data presented in the post-approval study report submitted to FDA included cases with intrauterine synechiae that were observed in 10 of the 30 women that underwent the HSG evaluation 3-months after the combined procedure. Of these 10, there were 5 women with scarring or synechiae that prevented the study physicians from assessing tubal occlusion by hysterosalpingogram. According to the *Instructions For Use* of the *Essure* System, these five women cannot rely on the *Essure* micro-inserts for permanent birth control because they failed to fully satisfy requirements of the FDA-approved HSG protocol.

Based upon the study findings, modifications to the *Essure* System labeling will be made to reflect that the *Essure* System and THERMACHOICE should not be performed concomitantly due to the possible inability to complete the 3-month *Essure* Confirmation Test (a low-pressure HSG) that determines the *Essure* micro-insert placement and confirms tubal occlusion. Please keep in mind that hysteroscopic sterilization with the *Essure* System and global endometrial ablation with THERMACHOICE may still be appropriate treatments for the same patient. However, the THERMACHOICE treatment should not be performed until after the completion of the 3-month *Essure* Confirmation Test.

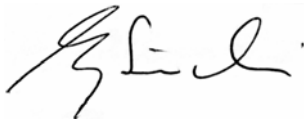
(Continued next page)

Consequently, please be advised that your patients should not be instructed to rely on the *Essure* micro-inserts for permanent birth control if they underwent a concomitant THERMACHOICE endometrial ablation procedure and were subsequently unable to complete the requirements of their 3-month *Essure* Confirmation Test. The instructions to your patient should be no different than what would be provided in any *Essure* case where satisfactory micro-insert location and evidence of bilateral occlusion could not be adequately assessed. The current warnings about use of the *Essure* system and other endometrial ablation devices remain the same as the *Instructions For Use*.

Conceptus will be revising its product literature, training materials, and *Instruction for Use* to reflect the information provided in this letter.

For further information, please contact your Conceptus Sales or Training representative.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Sinclair". The signature is fluid and cursive, with a prominent initial "E" and a trailing flourish.

Edward J. Sinclair
Vice President, Clinical Research, Regulatory Affairs and Quality Assurance
Conceptus Incorporated
331 E. Evelyn Ave.
Mountain View, CA 94041
Phone: 650-962-4000

* Trademark