P020014/R28 C1 V1



Conceptus.



December 11, 2012

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: **ESSURE-NOVASURE Post-Approval Study**
**ESS-NSPAS: 6-month interim report**
PMA P020014
Essure® System for Permanent Birth Control ESS305

To Whom It May Concern:

In accordance with 21 CFR 822, Conceptus is submitting three copies of the 6-month interim report on the Essure-NovaSure Post-Approval Study.

The information contained in this 6-month interim report on the Essure-NovaSure Post-Approval Study is considered confidential and Conceptus therefore requests protection of this information in accordance with 18 USC 1905, 21 USC 331(I), 5 USC 552.

Please let me know if you have any questions or need additional information. I can be reached by phone at (650) 962-4078, by fax at (650) 962-5194, or by email at rachelle_acuna-narvaez@conceptus.com.

Sincerely,

Rachelle Acuña-Narvaez

Rachelle Acuña-Narvaez
Director of Regulatory and Clinical Affairs

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# Post-Approval Study Status Report
# 6-Month Interim Report

A Study to Evaluate the Effectiveness of Essure Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure Confirmation Test

Essure-NovaSure PAS

Study# ESS-NSPAS

Date of Report December 11, 2012

Data Current to November 30, 2012

# Data current to November 30, 2012

## ESS-NSPAS - 6-month Interim Report


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# 1. GENERAL INFORMATION

## 1.1 Sponsor Information

Name: Conceptus, Inc.
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Establishment Registration Number: 2951250

Contact Person: Rachelle Acuña-Narvaez, Director of Regulatory and Clinical Affairs
Telephone: 650-962-4078
Fax: 650-962-5194
Email address: rachelle_acuna-narvaez@conceptus.com

## 1.2 Product Information

Product Name: Essure Permanent Birth Control System
Model Number: ESS305
Application Number: P020014 - S017

Date of Post-Approval Study Protocol and Supplement Approval: 02/24/2012

## 2. SUBMISSION INFORMATION

Date of Submission: November 2012

Data Included in this submission: Clinical Study Data

Type of Submission: *Six Month Interim Status Report for Post-Approval Study to Evaluate the Effectiveness of Essure Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure Confirmation Test*

Additional Information: Supplement to change previously approved Post-Approval Study Protocol was submitted to FDA as P020014/S039, received by CDRH Document Control Center 11/26/2012.

# 3. STUDY INFORMATION

## 3.1 Study Purpose

### 3.1.1 Goals

This Post-Approval Study is a prospective, multi-center, single-arm observational study to monitor and evaluate the effectiveness and safety of Essure when NovaSure is performed following a successful Essure Confirmation Test.

### 3.1.2 Objectives

- Evaluate the contraceptive failure rate of Essure when NovaSure is performed following a successful Essure Confirmation Test, and
- Monitor the incidence of adverse events and/or complications associated with the performance of NovaSure in the presence of Essure inserts.

### 3.1.3 Post-Approval Study Endpoints

- Occurrence of confirmed pregnancy at 1 year and 3 years among subjects relying on Essure micro-inserts for permanent birth control when NovaSure is performed following a successful Essure Confirmation Test
- Adverse event data

## 3.2 Subject Population

Post-Approval Study subjects who have been identified as candidates for NovaSure EA and have been/will be relying on Essure micro-inserts for permanent contraception (following a successful Essure Confirmation Test) will be considered. A minimum of (b)(4) female subjects seeking treatment for menorrhagia (i.e. NovaSure), whether wearing or not currently wearing Essure micro-inserts for permanent birth control, and satisfying the eligibility requirements will be enrolled in the Post-Approval Study.

### 3.2.1 Subject Follow-up Schedule

Subjects will be followed for a total of three years post-NovaSure Endometrial Ablation with evaluations to occur at the 1 week, 12 month, 24 month and 36 month follow-up time points.

## 3.3 Report Dates

The period covered by this report is June 2012 through November 2012.
The date of database closure for this report is November 30, 2012.

## 3.4 Summary of Study Progress

### 3.4.1 Approval Dates

- The date of Essure-NovaSure Post-Approval Study approval was February 24, 2012.

- Conceptus central IRB Study Sponsor Approval was obtained May 1, 2012. Approval for study Site 01 was obtained October 23, 2012.

3.4.2 Site Enrollment

| Number of Sites Enrolled | Number of Sites with IRB Approval | Number of Sites Initiated | Estimated Completion Date for Site Enrollment |
|---|---|---|---|
| 1 | 1 | 1 | April 2013 |

3.4.3 Subject Enrollment

Subject Accrual Start Date: October 24, 2012

Subject Accrual Completion Date: To be determined

3.4.4 Study Targets: Percentage of subjects reaching each designated study visit

| Essure Placement | 3-Month Confirmation Test | NovaSure EA Procedure | One Week Post-EA Office Visit | One Year Post-EA Phone Call | Two Years Post-EA Phone Call | Three Years Post-EA Phone Call |
|---|---|---|---|---|---|---|
| (b)(4) | | | | | | |

3.4.5 Comparison of Target vs. Actual Enrollment

(b)(4)

The actual enrollment is behind the projected enrollment due to a postponed study start as discussed in the following section.

Anticipated Study Completion Date: April 2017

## 3.5 Rationale for Study Delay

(b)(4)

In order to communicate the delay and additional protocol changes to FDA, Conceptus submitted P020014-S039. In the supplement, Conceptus has requested approval to amend

- Post-Approval Study Milestones to show our current timelines
- Enrollment criteria and the schedule of procedures to streamline the study
- Minor administrative clarification changes.

The original and revised study milestones are included below.

**Original Study Milestones**

| | |
|---|---|
| Expected date of study initiation | (b)(4) |
| Expected rate per month of PAS sites with IRB approval | |
| Expected date of initiation of subject enrollment | |
| Expected rate per month per site of subjects enrolled | |
| Expected date for subject enrollment completion | |
| Expected date of final subject follow-up | |
| Expected date complete final PAS report | |

**Revised Study Milestones (Submitted in Supplement 039)**

| | |
|---|---|
| Expected date of study initiation | (b)(4) |
| Expected rate per month of PAS sites with IRB approval | |
| Expected date of initiation of subject enrollment | |
| Expected rate per month per site of subjects enrolled | |
| Expected date for subject enrollment completion | |
| Expected date of final subject follow-up | |
| Expected date complete final PAS report | |

(b)(4)

## 3.6 Subject Tree & Subject Accountability

(b)(4)

## 3.7 Summary of Safety and Effectiveness Data

### 3.7.1 Effectiveness Data

The effectiveness of the intervention is evaluated by the occurrence of confirmed pregnancy at 1 year and 3 years among subjects relying on Essure micro-inserts for permanent birth control when NovaSure is performed following a successful Essure Confirmation Test. At this time, no subjects have reached the 1 or 3 year follow-up time point.

### 3.7.2 Adverse Event Data

Unanticipated Device Effects: None

Adverse Events: None

### 3.7.3 Protocol Deviations

There have been no protocol deviations that have affected the evaluation of study results.

| Number of Deviations | Deviation | Deviation Explanation |
|---|---|---|
| (b)(4) | | |

**Post-Approval Study Status Report**
**6-Month Interim Report**

# Report Approval Signatures

Document Originator:

(b)(6)

Rachelle Acuna-Narvaez
Director of Regulatory and Clinical Affairs

Rachelle Acuna-Narvaez 12/11/12
Signature/Date