Post-Approval Study Status Report
18-Month 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: August 24, 2013

Data current to August 7, 2013

1. GENERAL INFORMATION

1.1 Sponsor Information

Name: Bayer Healthcare
Address: 1011 McCarthy Blvd
Milpitas, California 95035 USA

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@bayer.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: August 24 , 2013

Data Included in this submission: Clinical Study Data

Type of Submission: *18 Month Report for Post-Approval Study to Evaluate the Effectiveness of Essure Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure Confirmation Test*

3. STUDY INFORMATION

3.1 Study Purpose

3.1.1 Goals

This PAS 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 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 Endometrial Ablation and have been relying on Essure inserts for permanent contraception (following a satisfactory Essure Confirmation Test) will be considered. A minimum of 220 female subjects seeking treatment for menorrhagia (i.e. NovaSure), currently wearing Essure 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 November 2012 through August 07, 2013.
The date of database closure for this report is August 7, 2013.

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.
- Conceptus central IRB Study Sponsor Approval for (b)(4) f the Study Protocol was obtained January 3, 2013.

3.4.2 Study Milestones

Revised Study Milestones (Approved in Protocol (b)(4) P020014, 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	

3.4.3 Site Enrollment

Number of Sites Enrolled	Number of Sites with IRB Approval	Number of Sites Initiated	Estimated Completion Date for Site Enrollment
(b)(4)			

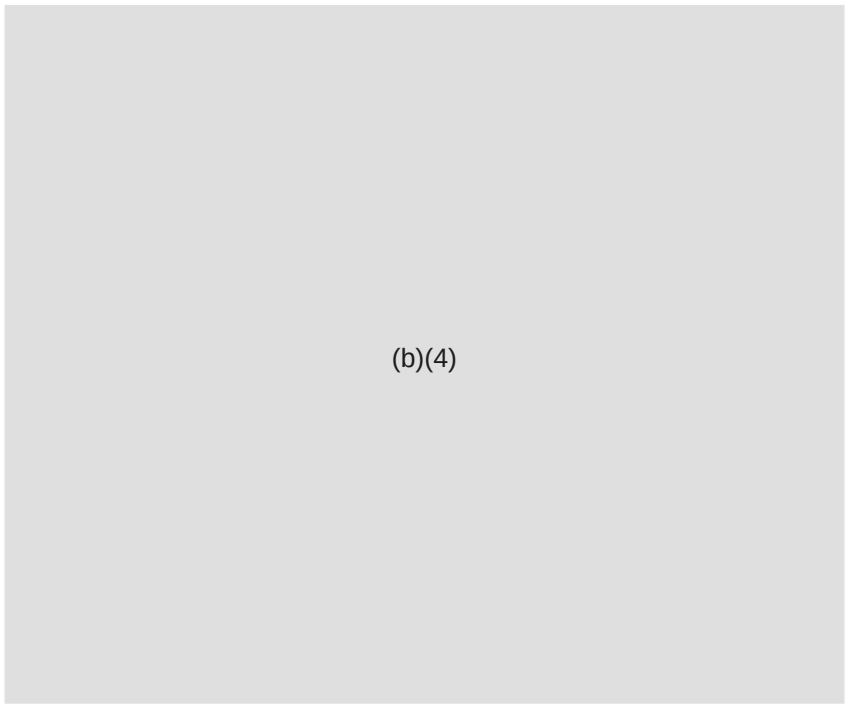
3.4.4 Subject Enrollment

Subject Accrual Start Date: October 24, 2012

Subject Accrual Completion Date: To be determined

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

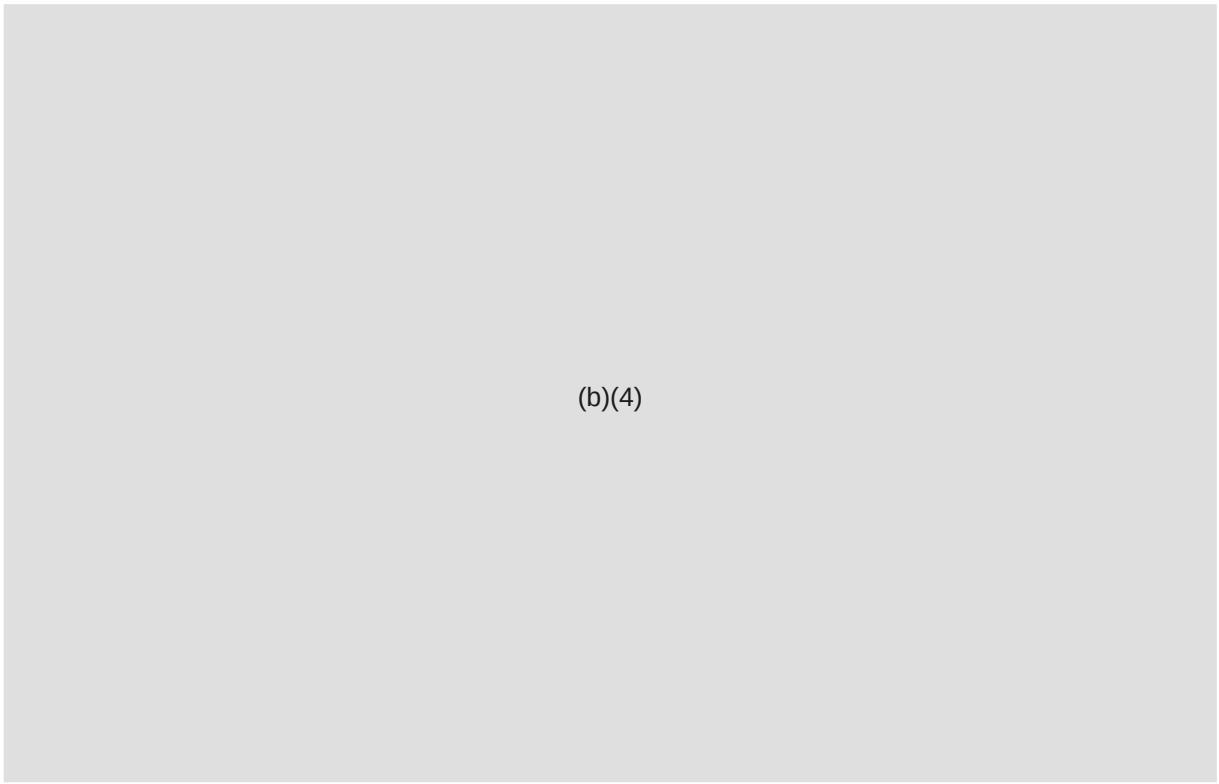
NovaSure EA Procedure	One Week Post-EA Office Visit	One Year Post-EA Phone Call	Two Years Post-EA Phone Call	Three Years Post-EA Phone Call
(b)(4)				



The actual enrollment is behind the projected enrollment as discussed in the following section.

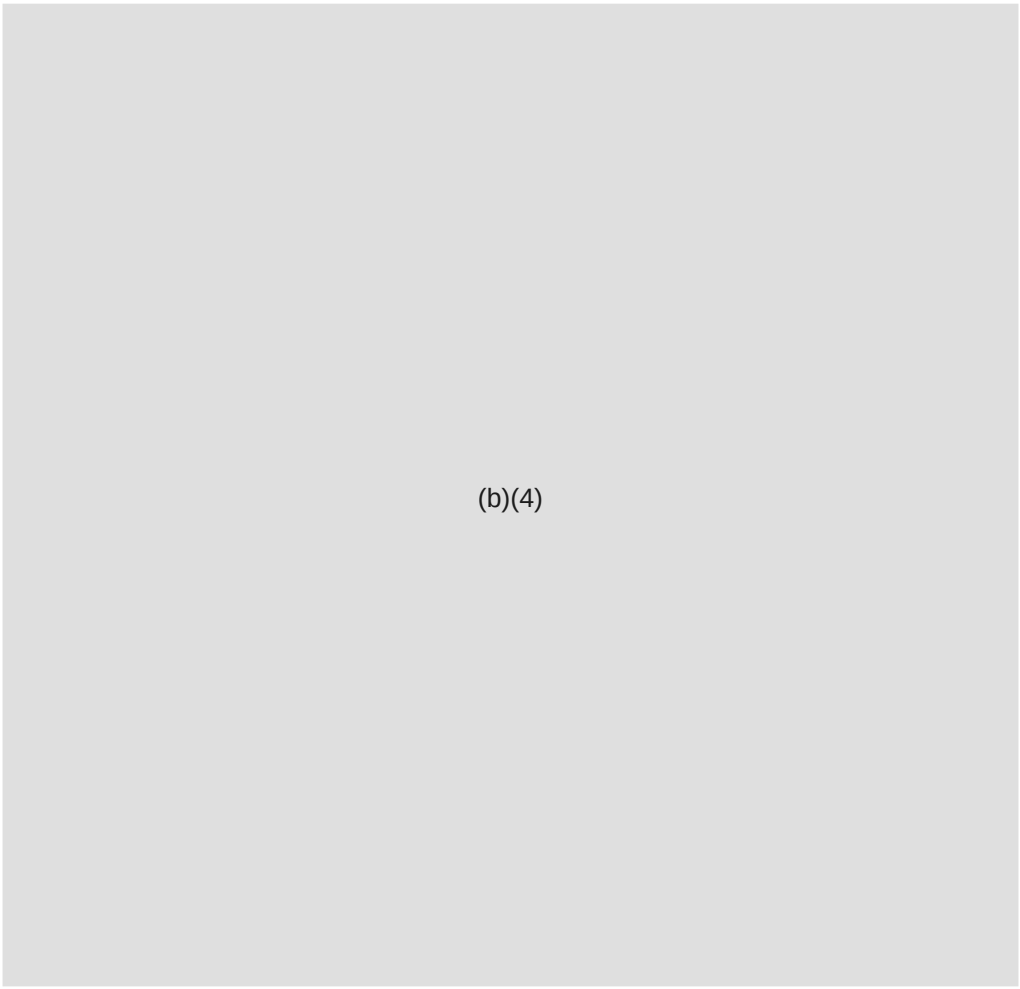
Anticipated Study Completion Date: April 2017

3.5 Rationale for Study Delay



(b)(4)

3.6 Subject Tree & Subject Accountability



3.6 Summary of Safety and Effectiveness Data

3.6.1 Effectiveness Data

The effectiveness of the intervention is evaluated by the occurrence of confirmed pregnancy at 1 year, 2 year and 3 years among subjects relying on Essure inserts for permanent birth control when NovaSure is performed following a successful Essure Confirmation Test. At this time, no subjects have reached the 1, 2 or 3 year follow-up time point.

3.6.2 Adverse Event Data

Unanticipated Device Effects: None

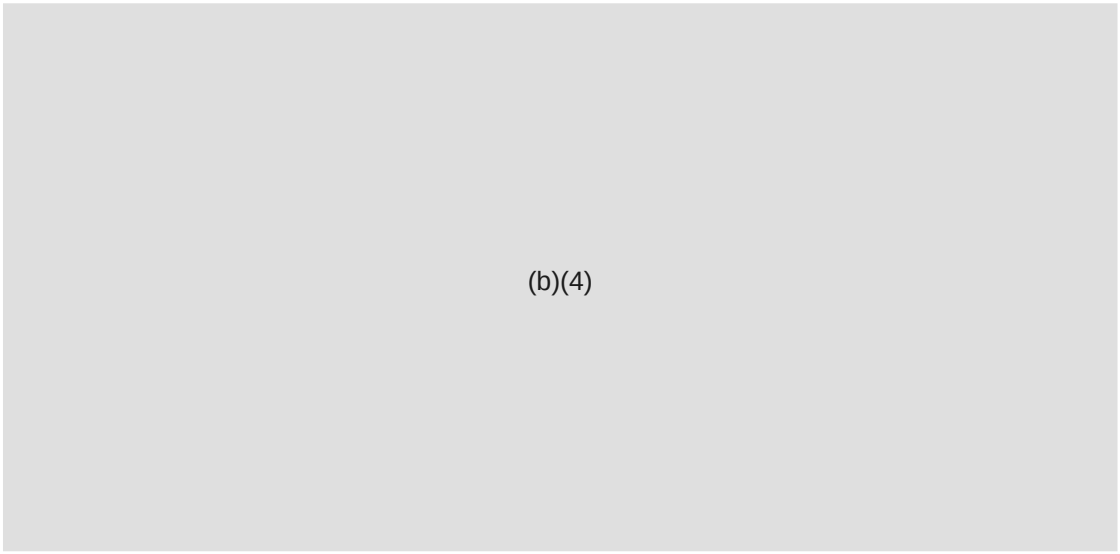
Adverse Events: 3

Subject ID	Event	Date of Onset	End Date	Duration	Severity	Related to micro insert	Outcome
(b)(6)	Cramping	27Nov2012	28Nov2012	1 day	Minor	Not related	Recovered w/out treatment
	Dysmenorrhea	18Jan2013	19Jan2013	1 day	Severe	Not related	Resolved w/out treatment
	Menorrhagia	01Dec2012	Ongoing	Intermittent w/ monthly cycles	Moderate	Not related	Subject to schedule repeat ablation in near future.

3.6.3 Protocol Deviations

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

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


(b)(4)